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駐歐盟兼駐比利時代表處經濟組　函

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裝

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主旨：有關歐盟正式公告將禁止與食品接觸之材料及製品使用雙酚A(Bisphenol A，BPA)事，請查照。

訂

說明：

一、相關文號：本組上(113)年6月12日比貿字1130000365號函。

二、謹查雙酚A常用於金屬食品包裝之內外表面塗層(例如罐頭、金屬罐之封蓋、用於生產食品之大型缸器等)、特定與食品接觸之塑膠包材(例如塑膠飲料瓶、飲水機之供水桶等)、印於接觸食品材料上之油墨等，其可能透過食品接觸包材之方式移轉至食品中，使消費者暴於健康風險。

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三、為提升對公民健康之保護、確保食安高標準，及在考量最新科學證據之情況下，歐盟會員國前於上年6月12日採認禁止食品包材使用雙酚A之法規。

四、歐盟嗣於上年12月31日以Commission Regulation (EU) 2024/3190公告旨揭法規(如附件)，其內容重點如

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(一)禁止使用雙酚A來製造下列與食品接觸之材料，並禁止於歐盟市場上市(第1條及第3條第1項)：

1、食品包裝黏著劑(adhesives)；

2、橡膠(rubbers)；

3、離子交換樹脂(ion-exchange resins)；

4、塑膠(plastics)；

5、印刷油墨(printing inks)；

6、矽(silicons)；及

7、上光油與塗層(varnishes and coatings)。

(二)然倘目前技術不可行且暫無安全替代原料之情況下，業者仍得例外使用雙酚A製造前述與食品接觸材料。依據該法規第3條第2項，例外得使用雙酚A之情形與其條件規定於附錄II，目前包含以下兩項：

1、上光油與塗層：業者得將雙酚A用於製造液體環氧樹脂(liquid epoxy resins)之單體(monomer)或初始物質(starting substance)，俾用於容量大於1,000公升且可自力支撐之與食品接觸材料或製品(self-supporting food contact materials or articles)。然不應檢出雙酚A移轉至食品之情形，且業者應在將與食品接觸之最終製品用來包裝食品前，予以清潔及沖洗。

2、塑膠：業者得將雙酚A用於製造聚碸過濾膜組件(polysulfone filtration membrane assemblies)之單體或初始物質。然不應檢出雙酚A移轉至食品之情形，且業者應在將與食品接觸之最終製品用來包裝食品前，予以清潔及沖洗。

(三)此外，依據附錄II規定使用雙酚A製造與食品接觸材

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料之業者，應向歐盟執委會(EU Commission)提供是否存在替代物質之資訊。然倘業者係屬微、中小型企業，前述資訊之提供則屬自願性(第7條)。

(四)倘使用其他雙酚或其衍生物製造之與食品接觸材料或製品，則不應有任何雙酚A殘留(第4條)。

(五)原則禁止業者使用其他危險雙酚或其衍生物製造與食品接觸之材料或製品，或在歐盟市場上市前述產品(第5條第1項)例外情形與條件則規定於第5條第3項。另倘業者欲使用其他危險雙酚或其衍生物製造前述產品，應依據第6條提出申請，俾獲核准。

(六)符合性聲明：

1、業者應確保受本法規範且尚未與食品接觸之材料與製品，及欲用於製造前述產品單體或初始物質之雙酚及其衍生物，在零售外之所有銷售階段，均依Regulation (EC) No 1935/2004第16(1)條規定檢附書面聲明，說明產品係符合規範。

2、前述書面聲明應涵蓋之資訊規定於本法附錄III，包含：

(1)簽發該符合性聲明之業者名稱、地址及聯繫資訊；

(2)製造或進口該與食品接觸材料或製品之業者資訊；

(3)與食品接觸之材料或製品資訊，包括中間材料及最終製品；

(4)聲明作成日期；

(5)製造與食品接觸之材料或製品所使用之雙酚或其衍生物清單；

(6)中間材料及最終製品符合本法及Regulation

(EC) No1935/2004第3、15及17條規範之聲明。

(七)檢驗：為確保與食品接觸之材料符合本法規規範，歐方將依據Regulation (EU) 2017/625第34條選擇檢驗方法(第9條)

(八)調適期：該法規將於公告在歐盟公報後20日生效(第14條)，惟其規範賦予部分產品調適期，包含：

1、使用雙酚A製造與食品接觸之最終一次性製品(第11條)：

(1)倘產品在本法生效前係符合歐盟規定，即得在歐盟上市至115年7月20日止。

(2)然倘前述產品係屬用以保存蔬果、漁產品者，得在歐盟市場上市至117年1月20日止；倘前述產品使用雙酚A製造之上光油與塗層，僅用於外部金屬表面，亦得在歐盟上市至117年1月20日止。

(3)另前述產品仍得在上述調適期結束後之12個月內用以填充食品及密封。前述包裝食品則得在歐盟市場上市之庫存耗盡。

2、使用雙酚A製造與食品接觸之最終重複利用製品(第12條)：

(1)倘產品在本法生效前係符合歐盟規定，即得在115年7月20日前初次投放至歐盟市場，並可在歐盟市場流通至118年1月20日止。

(2)倘前述產品係作為專業食品製造設備使用，且在本法生效前係符合歐盟規定，則得在117年1月20日前初次投放至歐盟市場，並可在歐盟市場上流通至118年1月20日止。

五、本案法規亦將影響我國輸銷歐盟之食品包材產品，爰敬請協助將資訊轉請我國相關公協會及業者參考及因應。

部國際騎縫章
經濟部貿易署

正本：農業部、衛生福利部食品藥物管理署、經濟部國際貿易署
副本：行政院經貿談判辦公室、經濟部商業發展署、經濟部產業發展署、經濟部中小及新創企業署、經濟部標準檢驗局、駐歐盟兼駐比利時代表處農業組、駐歐盟兼駐比利時代表處衛生組 電子公文交換章 2025/01/05 18:47:49

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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

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to 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 ([1]), and in particular Article 5(1), points (a), (d), (e), (h), (i), (j) and (n) thereof,

Whereas:

(1) The substance 4,4'-isopropylidenediphenol (CAS number 80-05-7) (FCM 151), commonly known as bisphenol A ('BPA'), is used in the manufacture of certain food contact materials and articles. Primarily it is used as a monomer or starting substance in the manufacture of epoxy resins that form the basis of varnishes and coatings, including those applied to the internal and external surfaces of metal food packaging, such as cans, tins and jar lids, as well as large tanks and vessels used in food production. It is also used in the manufacture of certain types of plastic food contact materials and articles, including those made from polycarbonate and polysulfone. Due to its diverse chemical properties, BPA may also be used in printing inks, adhesives and other materials that form part of finished food contact articles. BPA can migrate into food from the material or article with which such food is in contact, resulting in exposure to BPA for consumers of those foods.

(2) The use of BPA as a monomer in the manufacture of plastic food contact materials and articles is authorised by Commission Regulation (EU) No 10/2011 ([2]). This use, as well as its presence in food contact varnishes and coatings, is subject to a specific migration limit (SML) of 0,05 mg of BPA per kg of food (mg/kg), set in Commission Regulation (EU) 2018/213 ([3]) on the basis of an opinion of the European Food Safety Authority ('the Authority') published in 2015 ([4]). The latter Regulation also introduced a prohibition on the use of BPA in polycarbonate drinking cups and bottles for infants and young children and migration from varnishes or coatings applied to food contact 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 infants and young children. This prohibition was introduced in addition to the prohibition of its use in the manufacture of polycarbonate infant feeding bottles and cups for young children laid down in Commission Implementing Regulation (EU) No 321/2011 ([5]).

([1]) OJ L 338, 13.11.2004, p. 4, ELI: http://data.europa.eu/eli/reg/2004/1935/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]) Commission Regulation (EU) 2018/213 of 12 February 2018 on the use of bisphenol A in varnishes and coatings intended to come into contact with food and amending Regulation (EU) No 10/2011 as regards the use of that substance in plastic food contact materials (OJ L 41, 14.2.2018, p. 6, ELI: http://data.europa.eu/eli/reg/2018/213/oj).
([4]) *EFSA Journal* 2015; 13(1):3978.
([5]) Commission Implementing Regulation (EU) No 321/2011 of 1 April 2011 amending Regulation (EU) No 10/2011 as regards the restriction of use of Bisphenol A in plastic infant feeding bottles (OJ L 87, 2.4.2011, p. 1, ELI: http://data.europa.eu/eli/reg_impl/2011/321/oj).

(3) Following a mandate by the Commission in 2016 to undertake a re-evaluation of BPA, to take account of the results of new studies and scientific data to address remaining uncertainties, including the output from a two-year chronic study from the United States' National Toxicology Program, the Authority published an updated opinion on BPA in 2023 ([6]). In this opinion, the Authority concluded that BPA exerts a number of adverse effects, including on the immune system, which it considered the most sensitive to effects from BPA. On that basis, the Authority established a tolerable daily intake (TDI) of 0,2 nanograms per kilogram (ng/kg) bodyweight, which is 20 000 times lower than the temporary TDI of 4 micrograms per kilogram (µg/kg) (or 4 000 ng/kg) bodyweight it established in its 2015 opinion. The Authority noted that a dose range similar to that which led to effects on the immune system also caused adverse metabolic effects as well as adverse effects on the reproductive and developmental systems. Comparison of the TDI of 0,2 ng/kg bodyweight with the dietary exposure estimates from the Authority's 2015 opinion indicates that the exposure for all age groups exceeds the TDI by two to three orders of magnitude. The Authority therefore concluded that there is a health concern from dietary BPA exposure for all population groups.

(4) Based on the scientific opinion of the Authority of 2023, the authorisation of BPA for use in the manufacture of plastic food contact materials and articles, as well as its use in other food contact materials and articles, should be updated. In light of the TDI established by the Authority in its 2023 opinion, even very small amounts of BPA that migrate from food contact materials and articles, several-fold below the current SML, could lead to exposure above the newly established TDI. Furthermore, whilst validated analytical methods may be needed to verify compliance or to support official controls, no such methods exist that are able to quantify the migration of BPA reliably and consistently at the level of an SML that would be derived from the new TDI. Therefore, in order to minimise BPA's presence and migration into food and subsequent consumers' dietary exposure as far as possible, its use, including that of its salts, in the manufacture of those food contact materials and articles of which it may be a component, including adhesives, rubbers, ion-exchange resins, plastics, printing inks, silicones and varnishes and coatings, should be prohibited.

(5) Exceptionally, it is necessary to consider the criticality of BPA in the manufacture of certain food contact materials and articles for specific applications in food production and the extent to which there are currently suitable alternatives, whilst taking into account any potential exposure from such applications and whether there is any consequent health risk.

(6) Firstly, BPA is used as a starting substance in the manufacture of plastic polysulfone resins. These polysulfone resins are used in the manufacture of either separation membranes for micro- and ultra-filtration, or as a microporous support of thin-film polyamide membranes for nano-filtration or reverse osmosis. These processes are critical in the production of a wide range of foods, including dairy-based foods, to ensure that they are safe to consume by filtering out pathogens, including viruses and bacteria as well as certain contaminants such as heavy metals and pesticides. However, no alternatives currently exist that are technically feasible at commercial scale, and which can provide the necessary mechanical strength and chemical stability for such applications. In addition, to avoid potential health risks from the presence of residual BPA in the polysulfone-based membrane if BPA is used to manufacture polysulfone, manufacturers can ensure that such presence is avoided or reduced to negligible amounts following good manufacturing practice (GMP). This can be achieved both in the polymer manufacturing as well as in the final manufacturing stages, by flushing and cleaning the membrane before its first use to remove any remaining residual BPA. This may be done by the user of the membrane, including a food business operator. Furthermore, if a trace amount of BPA is left in the polysulfone material, its actual migration would be very low because of the short time that the food spends in contact with the membrane. Considering this and the repeated use of the membranes over a long period of time, it is estimated that the use of such applications does not lead to exposure to BPA that poses a risk to consumers. Taking those factors into account and in light of the criticality of these specific polysulfone applications in ensuring safety of consumers of a wide range of foodstuffs, it is appropriate to allow a derogation from the prohibition of the use of BPA and authorise its use specifically in the manufacture of polysulfone filtration membrane assemblies, together with a restriction that BPA does not migrate into food.

([6]) *EFSA Journal* 2023; 21(4):6857.

(7) Secondly, BPA is also used in the manufacture of liquid epoxy-based varnishes and coatings, which are cured onto the surface of large tanks and vessels as well as large capacity piping interconnecting these containers. These articles are typically used in the processing, storage and transport of food, including wines, beers, oils, dairy products and cereal grains. Currently, challenges remain in the timely replacement of BPA-based epoxy-based varnishes and coatings for such applications, which would likely result in the removal and destruction of such large, fixed tanks and vessels with disproportionate costs. However, the presence of residual BPA can be avoided or reduced to negligible amounts following GMP and the use of flushing and cleaning before the first use to remove any remaining residual BPA. In addition, the application of such varnishes and coatings to large tanks and vessels results in low surface area to volume ratios as regards the amount of food in contact with the material, in particular if the containers have a capacity above 1 000 litres where actual migration is not expected to lead to a level of exposure to BPA that would represent a risk to consumers. Taking this into account and the repeated use of such containers over a long period of time, it is appropriate to allow a derogation from the prohibition of the use of BPA and specifically authorise its use in the manufacture of liquid epoxy-based varnishes and coatings applied to the surface of such large capacity final food contact articles, with a restriction that BPA does not migrate into food.

(8) At stages prior to the manufacture of food contact materials and articles, BPA may also be used as a precursor in the chemical synthesis of other monomers or starting substances, such as bisphenol-A diglycidyl ether ('BADGE') (CAS No 1675-54-3) and consequently form part of the chemical structure of such substances, resulting in another bisphenol or bisphenol derivative. Although other bisphenols or bisphenol derivatives are somewhat chemically different from BPA itself, their use as monomers or other starting substances in the manufacture of food contact materials and articles, may result in the presence of small amounts of BPA in food contact materials and articles. This is particularly the case for the manufacture of liquid epoxy resins, which, as varnishes or coatings are applied to a substrate in the manufacture of a final food contact article. Therefore, while Union rules on food contact materials and articles do not in principle regulate the stages before the formation of monomers or other starting substances, it should be ensured that the use of other bisphenols or bisphenol derivatives as monomers or other starting substances does not result in the presence of free BPA in the resulting food contact material or articles, including intermediate food contact materials to be used to manufacture final food contact articles.

(9) The prohibition of BPA will consequently result in the need for business operators to identify substances – including other bisphenols and bisphenol derivatives – that provide a safe alternative to replace BPA in the manufacture of food contact materials and articles, in order to continue to adequately meet the needs of the food supply chain and ensure food safety. As a consequence of similarities in their chemical structure and activity, certain other bisphenols or bisphenol derivatives may also present risks similar to BPA when they are used in food contact materials and articles and migrate into food. Some bisphenols have already been confirmed as having properties that are hazardous to human health due to their reproductive toxicity and have consequently been subject to harmonised classification and listed as such in accordance with Regulation (EC) No 1272/2008 of the European Parliament and of the Council ([7]). This includes 4,4'-sulphonyldiphenol (CAS number 80-09-1) (FCM 154), commonly known as bisphenol S ('BPS'), which is currently authorised for use in plastic food contact materials and articles. The Authority issued a Technical Report on BPS in 2020 ([8]), which did not take into consideration the full toxicological dataset available for BPS, whereas the Authority recommended collection of data on the use of BPS in plastic food contact materials and articles and on its occurrence and migration into food in the context of its possible use as an alternative to BPA. This alone supports the need to update the assessment of the use of BPS in food contact materials and articles, in particular in light of its harmonised classification as toxic to reproduction category 1B. Further harmonised classification of bisphenols and bisphenol derivatives is likely in the future, following the identification of some of them as substances of very high concern under Regulation (EC) No 1907/2006 of the

([7]) 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).

([8]) *EFSA Supporting Publications* 2020; 17(4):1844.

European Parliament and of the Council [9] and the introduction of new hazard classes for endocrine disruptors by Commission Delegated Regulation (EU) 2023/707 [10]. It is therefore appropriate to ensure that the use in the manufacture of food contact materials and articles, of bisphenols or bisphenol derivatives with a specific harmonised classification, including the salts of these substances, is not permitted without an up-to-date assessment by the Authority, showing that their use does not endanger human health.

(10) Since such hazardous bisphenols or hazardous bisphenol derivatives may be necessary or critical in the manufacture of food contact materials and articles for a specific application where suitable alternatives do not exist, business operators should be given the possibility to apply for authorisation to use the respective hazardous bisphenol or bisphenol derivative in the manufacture of food contact materials and articles for a specific application. Applications for authorisation of such hazardous bisphenols or hazardous bisphenol derivatives should be submitted in accordance with the procedures laid down in Regulation (EC) No 1935/2004 concerning authorisation of substances. Provided that such an application is made within a reasonable timeframe, food contact materials and articles manufactured using a hazardous bisphenol or bisphenol derivative and already on the market should be allowed to continue to be placed on the market until the Commission has taken a decision on the application.

(11) Whilst guidelines concerning the preparation and the submission of an application for the authorisation of a substance in the manufacture of food contact materials and articles exist, in particular as regards plastic food contact materials and articles, these may need to be updated or supplemented, in accordance with the latest scientific developments and requirements of the Authority, specifically for the assessment of hazardous bisphenols or hazardous bisphenol derivatives, including their use in materials other than plastic. In line with the Commission's 'one substance, one assessment' initiative, the Authority and the European Chemicals Agency should work in collaboration, since the latter is already in the process of assessing the safety of bisphenols and their derivatives. In order to support this work, business operators who rely on the use of a hazardous bisphenol or a hazardous bisphenol derivative to manufacture their food contact materials and articles should submit information to the Authority if required, on the current use of those bisphenols and bisphenol derivatives.

(12) Although the continued use of BPA to manufacture a very limited number of food contact materials and articles for specific applications is currently justified and does not present an unacceptable risk, the aim in the long term should be to replace BPA altogether, as well as other bisphenols and their derivatives with specific properties that are particularly hazardous to human health, with alternatives that do not have such properties. In order to promote this and enable the Commission to evaluate the continued need for derogations laid down by this Regulation, it is appropriate to require the producers of the relevant food contact materials and articles using BPA or another hazardous bisphenol or bisphenol derivatives to report on the status of developments of alternative solutions. However, taking into account the need to minimise regulatory burden on small and medium-sized businesses ('SMEs'), it is appropriate that this requirement applies to large businesses, disposing of greater capacity and resources to develop and introduce alternatives.

[9] Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p. 1, ELI: http://data.europa.eu/eli/reg/2006/1907/oj).

[10] Commission Delegated Regulation (EU) 2023/707 of 19 December 2022 amending Regulation (EC) No 1272/2008 as regards hazard classes and criteria for the classification, labelling and packaging of substances and mixtures (OJ L 93, 31.3.2023, p. 7, ELI: http://data.europa.eu/eli/reg_del/2023/707/oj).

(13) For reasons of consistency, the rules on checking compliance including rules on the use of food simulants and testing conditions, as well as on expression of test results should be in line with those laid down in Regulation (EU) No 10/2011 for plastic food contact materials and articles. The choice of analytical methods to confirm the absence of migration of BPA or other hazardous bisphenols or hazardous bisphenol derivatives should be in accordance with the Union requirements concerning official controls. However, methods for the determination of the absence of these substances in food contact materials and articles that can already be uniformly applied throughout the Union may not exist. Therefore, after consultation with the National Reference Laboratories and relevant stakeholders, it may be necessary to request that the European Union Reference Laboratory develop such methods within a period agreed with the Commission and the Member States.

(14) In accordance with Article 16(1) of Regulation (EC) No 1935/2004, specific measures adopted by the Commission are to require that the food contact materials and articles are accompanied by a written declaration attesting their compliance with the applicable rules ('declaration of compliance'). That declaration should accompany the food contact materials and articles at all stages of placing on the market, except during the retail stage, such as the transfer of packaged foods or sale of food contact materials and articles to consumers. All business operators responsible for placing intermediate food contact materials as well as final food contact articles on the market should therefore have the declaration of compliance in their possession. For the sake of clarity and simplicity for compliance, in particular taking into consideration the transitional provisions, the declaration should include an indication as to whether or not BPA or other relevant bisphenols or bisphenol derivatives have been used in the manufacture of the food contact material or article.

(15) In order to ensure coherence and facilitate compliance, the requirements of this Regulation should apply to all relevant food contact materials and articles, including plastics. Regulation (EU) No 10/2011 on plastic food contact materials and articles should therefore be amended accordingly.

(16) The prohibition on the use of BPA presents a significant shift away from the use of specifically formulated food contact materials and articles, on which business operators have relied for several decades to manufacture food contact materials and articles for many different applications, and which are currently widely used in the Union. This is particularly true for varnishes and coatings applied to metal packaging, where several hundreds of possible formulations of BPA-based epoxy resins exist, depending on the requirements of the final food contact article. Therefore, the transition to food contact materials and articles that are manufactured without the need for BPA should be organised so as to avoid compromising the safety of food and to avoid disruption to food supply chains within the Union. Many business operators, in particular those in the varnished and coated metal packaging supply chain, have been proactive in preparing for a transition away from BPA and changes have already been instigated in response to supply chain demand. In order to allow time for business operators to complete this process and comply with the rules laid down in this Regulation, final food contact articles complying with the existing rules as applicable before the date of the entry into force of this Regulation, rather than the rules applicable in this Regulation, should be allowed to be placed on the Union market for the first time for a transition period of 18 months after the entry into force of this Regulation.

(17) For some specific food contact materials and articles however, a transition period of 18 months is insufficient, since business operators require additional time to identify, and ensure the technical feasibility, of alternatives at scale for the whole of the Union market. This includes the time taken to fully develop replacement formulations and assess their functionality and performance against critical parameters, including chemical safety, protection of the food to avoid microbiological spoilage and to ensure adequate shelf life, where no accelerated methods exist to test shelf life, before eventual scaling up for availability at commercial level. The reformulation of specific food contact materials and articles and phasing out of BPA completely, whilst avoiding disruption to the food supply chain, therefore requires extra transition time.

(18) In particular, certain fruits and vegetables that are preserved inside varnished or coated tin cans or glass jars with varnished lids, create an acidic environment inside the packaging. This in turn poses additional burden in the validation steps necessary to ensure that the alternatives are safe and function as required. Furthermore, the seasonal nature of fruit and vegetable production as well as that of fishery products, creates peaks in food production and thus in demand for packaging during certain periods, which cannot be met alone with packaging manufactured without BPA, during the standard 18 months transition period. Therefore, in order to allow enough time to bring the applications for these types of packaging to commercial scale and to avoid food waste, it is appropriate to allow final food contact articles using varnishes and coatings manufactured with BPA, specifically for the packaging used to preserve fruit, vegetables and processed fish products, to be placed on the market during a period of 36 months after the entry into force of this Regulation.

(19) Formulations to manufacture varnishes and coatings using alternatives to BPA applied to the external surfaces of metal packaging are also under development although such developments are less advanced than those for the internal surfaces. A transition period longer than 18 months is therefore also required for those products, which is estimated, on the basis of information provided by industry, to be 36 months. Migration into food of BPA present in varnishes and coatings applied to the external surface of metal packaging is normally prevented by the metal substrate, which acts as a barrier layer. However, it may occasionally transfer to the interior surface of the packaging that eventually comes into contact with food during the manufacturing of varnished and coated food contact materials and articles, either through direct contact as a result of 'set-off' or via vapour phase transfer. As this may be minimised or eliminated with GMP which reduce the risk of such transfer, and as the function of the varnishes and coatings is important in ensuring the integrity of the packaging and safety of the food, it is appropriate to grant a transition period of 36 months. Such a period would enable a transition to final articles using varnishes and coatings manufactured without BPA to be applied to the external surfaces of metal packaging.

(20) Single-use final food contact articles, including metal packaging, are often used to package food with a long shelf life and may thus be stored and consumed for a number of years after the food is packaged, during which time migration and exposure to BPA will continue. In order to limit the period of time during which food packaged in single-use final food contact articles containing BPA will be consumed, such single-use final food contact articles for packaging food should be filled with food and sealed within 12 months from the end of the respective transitional periods. Thereafter, it is nonetheless appropriate to allow the placing on the market of packaged food until exhaustion of stocks, in order to avoid food waste and disruption of food supply chains.

(21) Certain final food contact articles manufactured with BPA are used as repeat-use components in professional food production equipment, such as confectionary moulds, seals, pumps, flanges, gauges and sight glasses. Not all of these repeat-use final food contact articles used as professional food production equipment can be easily manufactured with materials that do not need BPA in their manufacture. Replacement articles often need to be designed and produced taking into account their function and interaction with other components as part of an overall food production or processing system, to avoid the need to replace the entire system. Taking these factors into account, it is appropriate to allow for a transition period of 36 months for such final food contact articles, in order to ensure food supply continuity, whilst also recognising the need to direct business operators to make progress in phasing out BPA-based technologies and eventually to replace them altogether.

(22) For repeat-use final food contact articles, in order to avoid that distributors create large stocks of articles covered by the transitional measures laid down in this Regulation, it is appropriate that such articles that have been first placed on the market by their manufacturers, may continue to be placed on the market to sell and pass on to customers, including food business operators or consumers, for a maximum period of one year. In the case of repeat-use final food contact articles used as professional food production equipment, it would be neither practical nor efficient to discontinue and remove them from use as they often form part of a larger system and may necessitate an immediate replacement of that system in its entirety, with disproportionate costs and burden to food businesses, including SMEs. Food businesses may therefore continue to use that repeat-use final food contact article until such time that the article ceases to be functional and needs to be replaced.

(23) The measures provided for in this Regulation supersede the measures laid down in Regulation (EU) 2018/213. It is therefore appropriate to repeal that Regulation.

(24) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

Subject matter and scope

1. This Regulation is a specific measure within the meaning of Article 5 of Regulation (EC) No 1935/2004.

2. This Regulation establishes specific requirements concerning 4,4'-isopropylidenediphenol ('bisphenol A' or 'BPA') (CAS No 80-05-7) and its salts as well as other hazardous bisphenols and hazardous bisphenol derivatives, as regards their use in the manufacture of the following groups of food contact materials and articles falling within the scope of Article 1(2) of Regulation (EC) No 1935/2004, which are placed on the Union market:

(a) adhesives;

(b) rubbers;

(c) ion-exchange resins;

(d) plastics;

(e) printing inks;

(f) silicones; and

(g) varnishes and coatings.

3. This Regulation also establishes specific requirements on the content of BPA in food contact materials and articles, which have been manufactured using another bisphenol or bisphenol derivative.

Article 2

Definitions

1. For the purposes of this Regulation, the definitions in Article 3 of Regulation (EU) No 10/2011 shall apply.

2. For the purposes of this Regulation, the following definitions shall also apply:

(a) 'final food contact articles' means products composed of one or more food contact materials and articles that fall within the scope of Article 1(2) of Regulation (EC) No 1935/2004, which are in their finished state for end use, without undergoing any further chemical, biological or physical processing or modification, except their further processing or modification for filling with food, in order for them to be used for single-use packaging, including the sealing process;

(b) 'intermediate food contact materials' means materials that are intended to undergo further chemical, biological or physical processing or modification in order to become all or part of a final food contact article, other than the further processing or modification for filling with food, in order for them to be used for single-use packaging, including the sealing process;

(c) 'bisphenol' means a substance consisting of two hydroxyphenyl functional groups linked by one bridging atom, in accordance with structure A laid down in Annex I and includes the salt form of the bisphenol. Additional groups may be attached to the bridging atom;

(d) 'bisphenol derivative' means a substance indicated by the general structure B laid down in Annex I, not including the salt form of a bisphenol;

(e) 'hazardous bisphenol or hazardous bisphenol derivative' means a bisphenol or a bisphenol derivative listed in Part 3 of Annex VI to Regulation (EC) No 1272/2008 due to its harmonised classification as category 1A or 1B 'mutagenic', 'carcinogenic', 'toxic to reproduction' or category 1 'endocrine disrupting' for human health'.

Article 3

Prohibition of the use of BPA

1. The use of BPA and its salts in the manufacture of food contact materials and articles referred to in Article 1(2) and the placing on the Union market of food contact materials and articles manufactured using BPA, is prohibited.

2. By way of derogation from paragraph 1, BPA and its salts may be used in the manufacture of food contact materials and articles for a specific application set out in Annex II, subject to the restrictions laid down therein.

Article 4

Prohibition on the presence of BPA in food contact materials and articles for which other bisphenols or bisphenol derivatives are used in their manufacture

Food contact materials and articles that have been manufactured using another bisphenol or bisphenol derivative shall not contain any residual BPA.

Article 5

Prohibition of the use of hazardous bisphenols other than BPA or hazardous bisphenol derivatives

1. The use of hazardous bisphenols other than BPA or hazardous bisphenol derivatives in the manufacture of food contact materials and articles referred to in Article 1(2) and the placing on the market of food contact materials and articles manufactured using hazardous bisphenols other than BPA or hazardous bisphenol derivatives is prohibited.

2. By way of derogation from paragraph 1, a hazardous bisphenol other than BPA or hazardous bisphenol derivatives may be used in the manufacture of food contact materials and articles for a specific application and those food contact materials and articles may be placed on the market if that use has been authorised in accordance with Article 6 and is set out in Annex II.

3. By way of derogation from paragraph 1, a hazardous bisphenol other than BPA or hazardous bisphenol derivative, the use of which has not been authorised in accordance with Article 6 and set out in Annex II, may be used in the manufacture of food contact materials and articles for a specific application and the placing on the market of those food contact materials and articles is allowed if the following conditions are fulfilled:

(a) it was already used in the manufacture of the same food contact materials and articles for that specific application on one of the following dates:

  (i) either the date on which the European Food Safety Authority ('the Authority') publishes the information referred to in Article 6(4) for hazardous bisphenols and bisphenol derivatives for which the harmonised classification applies on that date; or

  (ii) once the Authority has published the information referred to in Article 6(4), the date on which the harmonised classification applies to the hazardous bisphenol or hazardous bisphenol derivative listed in Part 3 of Annex VI to Regulation (EC) No 1272/2008; and

(b) the application referred to in Article 6(1) is submitted within 9 months from one of the following dates:

  (i) either the date on which the Authority publishes the information referred to Article 6(4) for hazardous bisphenols and bisphenol derivatives for which the harmonised classification applies on that date; or

(ii) once the Authority has published the information referred to in Article 6(4), the date on which the harmonised classification applies to the hazardous bisphenol or hazardous bisphenol derivative listed in Part 3 of Annex VI to Regulation (EC) No 1272/2008; and

(c) the food contact materials and articles comply with the rules as applicable before the date of entry into force of this Regulation; and

(d) the Commission has not taken a decision on the application pursuant to Article 6(3).

Article 6

Authorisation for the use of hazardous bisphenols other than BPA or hazardous bisphenol derivatives in the manufacture of food contact materials and articles for a specific application

1. To obtain an authorisation for the use of a hazardous bisphenol other than BPA or hazardous bisphenol derivative in the manufacture of a food contact material or article for a specific application, an application shall be submitted in accordance with Article 9 of Regulation (EC) No 1935/2004.

2. In accordance with Article 10 of Regulation (EC) No 1935/2004, the Authority shall issue an opinion for the use of the hazardous bisphenol or hazardous bisphenol derivative in the manufacture of a food contact material or article for a specific application for which a valid application was submitted in accordance with Article 9 of Regulation (EC) No 1935/2004. In case the Authority receives several applications regarding the same hazardous bisphenol or hazardous bisphenol derivative, the Authority may publish a single opinion concerning that hazardous bisphenol or hazardous bisphenol derivative.

3. The Commission shall thereafter adopt a specific measure in accordance with Article 11 of Regulation (EC) No 1935/2004, either authorising, subject to restrictions where appropriate, or not authorising the use of the hazardous bisphenol or hazardous bisphenol derivative for the manufacture of the food contact material or article for a specific application. In case of authorisation, the hazardous bisphenol or hazardous bisphenol derivative shall be included in Annex II to this Regulation accordingly.

4. For the purpose of paragraph 1, and before 20 January 2027, the Authority shall publish scientific output detailing the information necessary for the assessment of the use of hazardous bisphenols or hazardous bisphenol derivatives, in the manufacture of a food contact materials and articles for a specific application, supplementing or updating where necessary the detailed guidelines referred to in Article 9(2) of Regulation (EC) No 1935/2004. The Authority and the European Chemicals Agency shall collaborate with each other for this purpose.

5. Upon request by the Authority, business operators using bisphenols or bisphenol derivatives in the manufacture of food contact materials and articles shall provide data on the use of the bisphenols and bisphenol derivatives in the manufacture of food contact materials and articles to inform the preparation of the information referred to in paragraph 4.

Article 7

Reporting obligations concerning alternative substances to BPA, hazardous bisphenols and hazardous bisphenol derivatives laid down in Annex II

1. Business operators using BPA, other hazardous bisphenols or hazardous bisphenol derivatives listed in Annex II, shall provide information to the Commission regarding the status of alternative substances.

By derogation, such reporting shall be voluntary for micro, small and medium-sized enterprises as defined by Commission Recommendation of 6 May 2003 ([11]).

([11]) Commission Recommendation of 6 May 2003 concerning the definition of micro, small and medium-sized enterprises (OJ L 124, 20.5.2003, p. 36, ELI: http://data.europa.eu/eli/reco/2003/361/oj).

2. The information referred to in paragraph 1 shall be made available to the Commission after 4 years and at the latest 5 years after the date from which the use of the hazardous bisphenol or hazardous bisphenol derivative is authorised for use in the manufacture of the food contact material or article for a specific application. This information shall be updated and made available to the Commission after 4 years and at the latest 5 years from the previous date of submission, if the authorisation for the use of the hazardous bisphenol or derivative for the final food contact article for a specific application remains in place.

Article 8

Declaration of compliance and supporting documentation

1. Business operators shall ensure that food contact materials and articles covered by this Regulation which are not yet in contact with food, as well as bisphenols and bisphenol derivatives intended to be used as monomers or other starting substances in the manufacture of those food contact materials and articles, are accompanied at all marketing stages other than the retail stage by a written declaration as referred to in Article 16(1) of Regulation (EC) No 1935/2004 stating that they comply with the rules applicable to them ('declaration of compliance').

2. The declaration of compliance shall contain the information laid down in Annex III.

3. Appropriate supporting documentation shall be available to demonstrate such compliance. That documentation shall be made available without delay to the competent authorities on their demand.

Article 9

Verification of compliance with the requirements of this Regulation

1. For the verification of compliance with the requirements of this Regulation, appropriate test methods shall be selected in accordance with Article 34 of Regulation (EU) 2017/625 of the European Parliament and of the Council ([12]).

2. For the selection of methods used to verify that a food contact material or article does not contain BPA, another hazardous bisphenol or a hazardous bisphenol derivative, or does not release those substances into food above the specified detection limit or specific migration limit, the following additional rules apply:

(a) where the European Union Reference Laboratory ('EURL') for food contact materials has developed or recommended a method, that method shall be used;

(b) a method shall have a detection limit of 1 µg/kg unless a different detection limit is set out in Annex II, or as part of the method recommended in accordance with point (a)

(c) to verify that a food contact material or article does not contain BPA, another hazardous bisphenol or a hazardous bisphenol derivative, an extraction method shall be used.

3. The EURL for food contact materials shall consult the national reference laboratories and relevant stakeholders to identify possible methods for the purpose of paragraph 2. In case it concludes that a suitable method does not exist at Union level for a specific verification purpose forthcoming from paragraph 2, it shall complete the development of such a method within a date agreed with the Commission.

4. The following rules shall apply for the purposes of verification with specific detection or migration limits:

(a) test results shall be expressed in accordance with the rules laid down in Article 17 of Regulation (EU) No 10/2011;

([12]) Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products (OJ L 95, 7.4.2017, p. 1, ELI: http://data.europa.eu/eli/reg/2017/625/oj).

(b) compliance with a migration limit shall be established in accordance with Article 18, Annex III and Chapters 1 and 2 of Annex V to Regulation (EU) No 10/2011;

(c) in case the foreseeable contact occurs under continuous flow conditions, such as in pipes or filtration assemblies, the testing time shall equal the average residence time of the food in that pipe or filtration assembly.

Article 10

Amendment to Regulation (EU) No 10/2011

Regulation (EU) No 10/2011 is amended as follows:

(1) In Article 6, the following paragraph is added:

'6. By way of derogation from Article 5, 2,2-bis(4-hydroxyphenyl)propane ("bisphenol A" or "BPA") (CAS No 80-05-7) and other hazardous bisphenols or hazardous bisphenol derivatives as defined and falling within the scope of Regulation (EU) 2024/3190 may only be used in the manufacture of plastic materials and articles in accordance with that Regulation.';

(2) in Table 1 of Annex I, the entries concerning substance No 151 (2,2-bis(4-hydroxyphenyl)propane) and substance No 154 (4,4'-dihydroxydiphenyl sulphone) are deleted.

Article 11

Transitional provisions concerning single-use final food contact articles

1. Single-use final food contact articles manufactured using BPA and complying with the rules as applicable before the date of entry into force of this Regulation, which do not comply with the rules in this Regulation, may be placed on the market until 20 July 2026.

2. By way of derogation from paragraph 1, the following single-use final food contact articles complying with the rules as applicable before the date of entry into force of this Regulation, which do not comply with the rules in this Regulation, may be placed on the market until 20 January 2028:

(a) single-use final food contact articles intended for the preservation of the following foodstuffs:

(i) fruits or vegetables, excluding products defined in Annex I to Council Directive 2001/112/EC ([13]); or

(ii) fishery products as defined by Regulation (EC) No 853/2004 of the European Parliament and of the Council ([14]);

(b) single-use final food contact articles on which a varnish or coating manufactured using BPA has only been applied to the exterior metal surface.

3. Single-use final food contact articles placed on the market in accordance with paragraphs 1 and 2 may be filled with food and sealed during the 12 months following the expiry of the applicable transitional period. The resulting packaged food may be placed on the market until exhaustion of stocks.

([13]) 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).

([14]) 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

Transitional provisions concerning repeat-use final food contact articles

1. Repeat-use final food contact articles manufactured using BPA and complying with the rules as applicable before the date of entry into force of this Regulation, which do not comply with the rules in this Regulation, may be first placed on the market until 20 July 2026.

2. By way of derogation from paragraph 1, repeat-use final food contact articles used as professional food production equipment, complying with the rules as applicable before the date of entry into force of this Regulation, which do not comply with the rules in this Regulation, may be first placed on the market until 20 January 2028.

3. Repeat-use final food contact articles that were first placed on the market in accordance with paragraphs 1 and 2 may remain on the market until 20 January 2029 at the latest.

Article 13

Repeal

Regulation (EU) 2018/213 is repealed.

Article 14

Entry into force

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

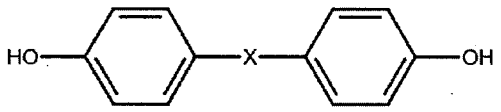
Done at Brussels, 19 December 2024.

For the Commission
The President
Ursula VON DER LEYEN

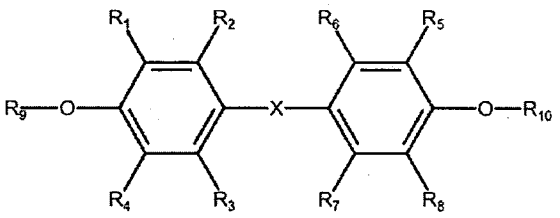
ANNEX I

The chemical structure of substances for which the definition 'bisphenol' and 'bisphenol derivative' applies is as follows:

(A) Bisphenol structure



(B) Bisphenol derivative structure



Notes. X refers to any bridging group separating the two phenyl rings by one single atom, but the atom can have any substituent(s).

R_1 to R_{10} refers to any substituent. At least one of the substituents is not a hydrogen atom (H).

ANNEX II

Union list of BPA and other hazardous bisphenols and hazardous bisphenol derivatives authorised for use in the manufacture of food contact materials and articles for specific applications

Column 1 (FCM substance No): the Food Contact Materials (FCM) substance number

Column 2 (CAS No): the Chemical Abstracts Service (CAS) registry number

Column 3 (Substance name): the IUPAC chemical name

Column 4 (Material type): the group of materials and articles which may be covered by specific measures

Column 5 (Specific application): the specific application for which the use of the substance is restricted and for which the derogation applies

Column 6 (Other restrictions): other restrictions that apply

(1)	(2)	(3)	(4)	(5)	(6)
FCM substance No	CAS No	Substance name	Material type	Specific application	Other restrictions
151	80-05-7	4,4'-isopropylidenedi-phenol (bisphenol A)	Varnishes and coatings	For use as a monomer or starting substance in the manufacture of liquid epoxy resins to be applied on self-supporting food contact materials or articles with a capacity greater than 1 000 litres	Migration into food shall not be detectable. Final food contact articles shall be cleaned and flushed prior to first being brought into contact with food
			Plastics	For use as a monomer or starting substance in the manufacture of polysulfone filtration membrane assemblies	Migration into food shall not be detectable. Final food contact articles shall be cleaned and flushed prior to first being brought into contact with food

ANNEX III

The declaration of compliance referred to in Article 8 shall contain the following information:

(1) the identity and address as well as contact details including either a current telephone number or email address of the business operator issuing the declaration of compliance;

(2) the identity and address as well as contact details including either a current telephone number or email address of the business operator which manufactures or imports the food contact material or article;

(3) the identity of the food contact material or article, including both intermediate food contact materials and final food contact articles;

(4) the date of the declaration;

(5) a list of any bisphenols or bisphenol derivatives used in the manufacture of the food contact material or article;

(6) a statement that the intermediate food contact material or article or final food contact article complies with this Regulation and the requirements set out in Articles 3, 15 and 17 of Regulation (EC) No 1935/2004.