



EUROPEAN
COMMISSION

Brussels, XXX
PLAN/2023/1013
(POOL/E2/2023/1013/1013-EN.docx)
[...] (2024) XXX draft

COMMISSION REGULATION (EU) .../...

of XXX

**on the use of bisphenol A (BPA) and other bisphenols and their 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**

This draft has not been adopted or endorsed by the European Commission. Any views expressed are the preliminary views of the Commission services and may not in any circumstances be regarded as stating an official position of the Commission.

COMMISSION REGULATION (EU) .../...

of **XXX**

on the use of bisphenol A (BPA) and other bisphenols and their 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

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/EEC¹, and in particular Article 5(1), points (a), (d), (e), (h), (i) and (j) thereof,

Whereas:

- (1) The substance 4,4'-isopropylidenediphenol (CAS number 80-05-7) (HCM 151), commonly known as bisphenol A ('BPA'), is used in the manufacture of certain food contact materials and articles. Primarily it is used 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 in the manufacture of certain types of plastic, including polycarbonate and polysulfone food storage and processing equipment. 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 10/2011². 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) 2018/213³ on the basis of an opinion of the European Food Safety Authority ('the Authority') published in 2015⁴. The latter Regulation also introduced a prohibition on the use of BPA in polycarbonate drinking cups or 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

¹ OJ L 338, 13.11.2004, p. 4.

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 The EFSA Journal 2015;13(1):3978.

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 321/2011⁵.

- (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 2023⁶. 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 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 a level, which corresponds directly with an SML derived from the new TDI, using the normal calculation for the SML from a TDI for food contact materials and articles. Therefore, in order to minimise BPA's presence and migration into food and subsequent consumers' dietary exposure as far as possible, its use 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 specific food contact articles applications in food production and the extent to which there are currently alternatives, whilst taking into account any potential exposure from such applications and whether there is any consequent health risk.
- (6) 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

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).

⁶ The EFSA Journal 2023;21(4):6857.

membrane 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 using BPA to manufacture polysulfone, manufacturers can ensure that the presence of residual BPA in the polysulfone-based membrane 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 deploying flushing and cleaning steps before the first use to remove any remaining residual BPA. This latter step may also be achieved by the user of the membranes, 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 their repeated use 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 necessity for these specific polysulfone applications to ensure 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 plastic food contact membranes applications using polysulfone resins, together with a restriction that BPA does not migrate into food.

- (7) 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. The purity of the varnishes and coatings and therefore 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, where actual migration is not expected to lead to exposure to BPA, which would represent a risk to consumers if the containers have a capacity above 1000 litres. 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 food contact materials and articles.
- (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 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, namely BPA derivatives. Such BPA derivatives may also result from chemical reactions that do not use BPA. Therefore, while Union rules on food contact materials and articles do not regulate the stages before the formation of monomers or other starting substances, the purity of BPA derivatives as monomers or other starting substances should be assured so that

the food contact material or articles do not contain BPA, which may present a risk to consumer health.

- (9) The prohibition of BPA will consequently result in the need for business operators to identify substances – including other bisphenols and their derivatives – that can 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 their 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 identified 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 Council⁷. This includes 4,4'-sulphonyldiphenol (CAS number 80-09-4) (FCM 155), commonly known as bisphenol S ('BPS'), which is currently authorised for use in plastic food contact materials and articles. Further harmonised classification of bisphenols and their 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 European Parliament and of the Council⁸ and the introduction of new hazard classes for endocrine disruptors by Commission Delegated Regulation (EU) 2023/707⁹. It is therefore appropriate to ensure that the use of bisphenols or their derivatives with specific harmonised classification, in the manufacture of food contact materials and articles, is not permitted without an up-to-date, specific risk assessment. Such an assessment will support the decision-making process in determining whether or not to authorise such a bisphenol or bisphenol derivative for use in the manufacture of specific food contact articles or applications, in particular to limit such use and ensure that their use in the manufacture of food contact materials and articles does not endanger human health.
- (10) Where such hazardous bisphenols or their derivatives are necessary in the manufacture of food contact materials and articles, business operators should be given the possibility to provide relevant scientific data and apply for authorisation to use the respective hazardous bisphenol or derivative in the manufacture of a specific food contact article or application. The application should be prepared and submitted taking into account detailed guidelines adopted by the Authority concerning the preparation and the submission of applications for this purpose are available. In developing such guidelines, the Authority will require information on the current use of bisphenols and their derivatives and should therefore launch a call for such data. Applications for authorisation of such hazardous bisphenols or their derivatives should be submitted in

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 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>).

⁹ 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, 31.3.2022, p. 7, ELI: http://data.europa.eu/eli/reg_del/2023/707/oj).

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 the hazardous bisphenol or bisphenol derivative should be allowed to continue on the market until such time that the Authority has published its scientific opinion and the Commission has taken a decision based on that opinion, concerning the authorisation for use of the hazardous bisphenol or derivative for a specific, limited food contact article or application.

- (11) Although the continued use of BPA to manufacture a very limited number of specific applications is currently justified and does not present an unacceptable risk, the aim in the long term should be to replace BPA, as well as other bisphenols and their derivatives with specific properties that are particularly hazardous to human health, with safer alternatives. 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 articles and applications to report on the status of developments of alternative solutions that can provide the function and level of performance required to serve the same purpose of that specific food contact article or application, without the use of BPA or another hazardous bisphenol. Taking into account the need to minimise regulatory burden on small and medium-sized businesses, it is appropriate that this requirement applies to large businesses, disposing of greater capacity and resources to develop and introduce alternatives, within a reasonable period of time.
- (12) For reasons of consistency, the rules on checking compliance including rules on the use of food simulants and testing conditions, as well as expression of test results should be in line with those laid down in Regulation (EU) No 10/2011 on plastic food contact materials and articles. The choice of analytical methods to confirm the absence of migration of BPA or other bisphenols or their derivatives above a specified limit of detection should be in accordance with the requirements of Union rules concerning official controls. For the sake of coherence and legal certainty, that limit of detection should be defined based on what is technically achievable, whilst giving sufficient time for Member States and business operators, including compliance laboratories, to ensure that their methodologies are capable of verifying compliance with the new requirements.
- (13) 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 covered by those measures are accompanied by a written declaration attesting their compliance with the applicable rules (a '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 derivatives have been used in the manufacture of the food contact material or article. In addition to the declaration of compliance, business operators should be required to make available for the competent authorities appropriate supporting documentation substantiating the declaration of

compliance, such as documentation on the substances used to manufacture the materials and articles.

- (14) 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.
- (15) The prohibition on the use of BPA presents a significant shift away from conventional chemistry, on which business operators have relied for many decades to manufacture food contact materials and articles for many different applications and that 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.
- (16) 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, requires extra transition time.
- (17) 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 food contact 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 that 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.

- (18) 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 good manufacturing practices which reduces 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.
- (19) 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 significant 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.
- (20) 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.
- (21) 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 for 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 need to be replaced.

- (22) 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.
- (23) 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 ('BPA') (CAS No 80-05-7) and other hazardous bisphenols and 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 final food contact articles, which have been manufactured using a BPA 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 article' means a product composed of one or more food contact materials and articles that fall within the scope of Article 1(2) of Regulation (EC) 1935/2004, which are in their finished state for end use, without undergoing any further chemical, biological or physical processing or modification, except in the case of processing or modification of articles to be used for single-use packaging, which is only necessary for filling with food, 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;

- (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. Additional groups may be attached to the bridging atom;
- (d) 'bisphenol derivative' means a substance containing the bisphenol structure referred to in point (c) and indicated by the general structure B laid down in Annex I;
- (e) 'hazardous bisphenol or derivative' means a bisphenol or 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;
- (f) 'BPA derivative' means a substance, for which BPA is used in the chemical synthesis of that substance, or forms part of the structure of that substance.

Article 3

Prohibition of the use of BPA

1. The use of BPA in the manufacture of food contact materials and articles referred to in Article 1(2) and the placing on the market of those food contact materials and articles, which are manufactured using BPA, is prohibited.
2. By way of derogation from paragraph 1, BPA may be used in the manufacture of food contact materials and articles for the specific food contact article or application set out in Annex II, subject to the restrictions laid down therein.

Article 4

Food contact materials and articles for which BPA derivatives are used in their manufacture

Food contact materials and articles that have been manufactured using a BPA derivative shall not contain BPA.

Article 5

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

1. The use of hazardous bisphenols or derivatives other than BPA at any manufacturing stage of food contact materials and articles referred to in Article 1(2) and the placing on the market of such food contact materials and articles is prohibited.
2. By way of derogation from paragraph 1, of hazardous bisphenols or derivatives other than BPA may be authorised in accordance with Article 6 for use in the manufacture of food contact materials and articles for the specific food contact article or application set out in Annex II, subject to the restrictions laid down therein.

Article 6

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

1. To obtain an authorisation for the use of a hazardous bisphenol or derivative referred to in Article 5(2) in the manufacture of food contact materials and articles for a specific article or application, an application shall be submitted in accordance with Article 9 of Regulation (EC) No 1935/2004.

2. For the purpose of paragraph 1, and before [enter date two years after the entry into force of this Regulation], the European Food Safety Authority ('the Authority') shall publish detailed guidelines concerning the preparation and the submission of applications for the authorisation of the use of hazardous bisphenols or derivatives referred to in Article 5(2) in the manufacture of food contact materials and articles for a specific article or application. The Authority shall launch a call for data on the use of bisphenols and bisphenol derivatives in the manufacture of food contact materials and articles to inform the preparation of its detailed guidelines.
3. Following the publication of the guidelines referred to in paragraph 2, the application referred to in paragraph 1 shall be submitted within 9 months from the date, either:
 - (a) on which the Authority publishes its detailed guidelines referred to in paragraph 2; or
 - (b) on which the hazardous bisphenol or derivative is listed in Part 3 of Annex VI to Regulation (EC) No 1272/2008 and for which the harmonised classification applies, for those substances that are only classified as such after the date on which the Authority publishes its detailed guidelines.
4. 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 derivative in the manufacture of a specific article or application for which a valid application was submitted in accordance with Article 10 of Regulation (EC) No 1935/2004. In case the Authority receives several applications regarding the same hazardous bisphenol or derivative, the Authority may publish a single opinion concerning that hazardous bisphenol or derivative.
5. The Commission shall thereafter adopt a specific measure in accordance with Article 11 of Regulation (EC) No 1935/2004, either authorising or not authorising the use of the hazardous bisphenol or derivative for the manufacture of the specific food contact article or application.
6. Specific food contact articles or applications manufactured using a hazardous bisphenol or derivative, for which a valid application for the use of the hazardous bisphenol or derivative in the manufacture of that specific article or application has been received, may be placed on the market until such time that the Commission has authorised a use of the hazardous bisphenol or derivative and it is included for use in the manufacture of a specific food contact article or application in Annex II or the Commission has taken a decision not to authorise such a use.

Article 7

Reporting obligations concerning alternative substances to manufacture food contact materials and articles for the specific articles or applications laid down in Annex II

1. Manufacturers of the specific articles or applications laid down in column 6 of the table in Annex II shall provide information to the Commission regarding the status of the development of any alternative food contact materials and articles or substances, which do not use the substance for which an authorisation for the specific article or application is necessary, and which are capable of providing the function and the level of performance required to serve the same purpose of that specific article or application. By derogation, such reporting shall be voluntary for micro, small and

medium-sized enterprises as defined by Commission Recommendation of 6 May 2003¹⁰.

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 derivative is authorised for use in the manufacture of the specific food contact article or 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 specific food contact article or application remains in place.

Article 8

Written 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 substances intended to be used 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 accordance with 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 demand.

Article 9

Verification of compliance with the requirements of this Regulation

1. For the purposes of analytical verification of compliance, the following rules apply:
 - (a) appropriate migration test methods shall be selected in accordance with Article 34 of Regulation (EU) 2017/625 of the European Parliament and of the Council¹¹, that can be used to confirm the absence of migration above the specified detection limit;
 - (b) a detection limit of 0,001 mg/kg shall apply unless a different detection limit is specified;
 - (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 in that pipe or filtration assembly.

¹⁰ Commission Recommendation of 6 May 2003 concerning the definition of micro, small and medium-sized enterprises (OJ L 124, 20.5.2003, p. 36–41. ELI: <http://data.europa.eu/eli/reco/2003/361/oj>).

¹¹ 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. 1–142. ELI: <http://data.europa.eu/eli/reg/2017/625/oj>).

2. Compliance shall be established in accordance with rules laid down in Article 18, in Annex III and in Chapters 1, 2 and 4 of Annex V to Regulation (EU) No 10/2011, including for confirmation that the substance is not present in the final food contact article or does not migrate from it.
3. Test results shall be expressed in accordance with the rules laid down in Article 17 of Regulation (EU) No 10/2011, except in the case of containers and other articles, containing or intended to contain more than 10 litres, for which the real surface area to volume ratio shall apply.

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, BPA and other hazardous bisphenols or derivatives as defined and falling within the scope of Regulation [insert this Regulation reference] 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 the use of BPA in the manufacture and the placing on the market of single-use final food contact articles

1. 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 [insert date 18 months after the entry into force of this Regulation].
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 [insert date 36 months after the entry into force of this Regulation]:
 - (a) single-use final food contact articles intended for the preservation of the following foodstuffs:
 - (i) fruits or vegetables¹² as listed in the relevant category as defined in Annex I to Regulation (EC) No 396/2005; or
 - (ii) fishery products as defined by Regulation (EC) 853/2004¹³;

¹² Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC (OJ L 70, 16.3.2005, p. 1. ELI: <http://data.europa.eu/eli/reg/2005/396/oj>).

- (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.

Article 12

Transitional provisions concerning the use of BPA in the manufacture and the placing on the market of repeat-use final food contact articles

1. Repeat-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 first placed on the market until *[insert date 18 months after the entry into force of this Regulation]*.
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 *[insert date 36 months after the entry into force of this Regulation]*.
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 *[insert date 12 months after the date of the relevant transitional provision]* at the latest.

Article 13

Transitional provisions concerning authorisation for the use of a hazardous bisphenol or derivative other than BPA in the manufacture of food contact materials and articles

Article 5(1) shall apply from 9 months after the date on which the Authority publishes the detailed guidelines referred to in Article 6(2).

Article 14

Repeal

Regulation (EU) 2018/213 is repealed.

Article 15

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.

¹³ 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, 30.04.2004, p. 55. ELI: <http://data.europa.eu/eli/reg/2004/853/oj>).

Done at Brussels,

For the Commission
The President
Ursula VON DER LEYEN

DRAFT