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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, amending Regulation (EC) No 1895/2005 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.

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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) (FCM 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 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 other materials such as printing inks, adhesives, ion-exchange resins and rubbers that form part of finished food contact articles. BPA can migrate into food from the material or article with which it 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 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

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.

children. This prohibition was introduced in addition to the prohibition on 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 in order to account for 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 reproductive and developmental effects, metabolic effects as well as adverse effects on the immune system. The Authority considered the immune system the most sensitive to effects from BPA and on that basis, 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 all age groups exceed 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 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 that 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 such very low levels. Therefore, in order to minimise its 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 in which it may be used, including plastics, varnishes and coatings, printing inks, adhesives, ion-exchange resins and rubbers should be prohibited. In addition to the rules laid down in this Regulation, Regulation (EU) No 10/2011 should be amended to remove BPA from the list of substances authorised for the use in the manufacture of plastic food contact materials and articles.
- (5) Exceptionally for certain food contact applications, it is necessary to consider their criticality in food production, whilst taking into account any potential risk.
- (6) The disodium salt of BPA (disodium 4,4'-isopropylidenediphenolate, CAS No 2444-90-8) is used with the authorised monomer 4,4'-dichlorodiphenyl sulphone (CAS No 80-07-9) in a condensation reaction to manufacture plastic polysulfone resins. These polysulfone resins are critical in the preparation of a wide range of foods, to ensure that they are safe to consume, as either a separation membrane or as a support to other plastic membranes. In addition to the purification of drinking water, polysulfone-based

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.

membranes are used for applications in dairy processing, clarification and concentration of fruit juices, reduction or removal of alcohol from wine and beer and purification of sugar. Currently no alternatives exist that are technically feasible at commercial scale and which can provide the necessary mechanical strength and chemical stability for such applications. As manufacturers can ensure that any presence of residual BPA in the polysulfone-based membrane is avoided or reduced to negligible amounts following good manufacturing practices; and that migration potential is low because of the short time that the food spends in contact with the membrane, it is estimated that the use of such applications does not lead to exposure to BPA that poses a risk to consumers. Taking this into account and in light of the necessity for these applications to ensure safety of consumers of a wide range of foodstuffs, it is appropriate to authorise the disodium salt of bisphenol A specifically for the manufacture of polysulfone resins for such plastic food contact membranes by way of amendment to Regulation (EU) No 10/2011, provided that its migration into food is not detectable.

- (7) BPA is also used as a precursor in the chemical synthesis of the substance bisphenol-A diglycidyl ether ('BADGE') (CAS No 1675-54-3) and its derivatives, which in turn are used in the manufacture of liquid epoxy-based varnishes and coatings and for which restrictions are laid down by Commission Regulation (EC) No 1895/2005⁷. BADGE and its derivatives are used in particular as monomers in the manufacture of repeat-use heavy-duty varnishes and coatings that are applied to large tanks and other vessels such as metal drums typically with a capacity above 250 litres, as well as pipes, used in the processing, storage and transport of food, including wines, beers, oils, dairy products and cereal grains. This use results in low surface area to volume ratios as regards the amount of food in contact with the material and consequently, any migration results in very low or negligible concentrations in the food. Together with the fact that business operators can also control the purity of BADGE-based heavy-duty varnishes and coatings so that the presence of residual BPA is avoided or reduced to negligible amounts following good manufacturing practices, use of BADGE-based heavy-duty varnishes and coatings is not expected to lead to exposure to BPA that poses a risk to consumers. Taking these factors into account, it is appropriate to allow for the continued synthesis of the starting substance BADGE using BPA, only for the manufacture of BADGE-based heavy-duty varnishes and coatings to be applied to materials and articles with a capacity of more than 250 litres, provided that migration of any residual BPA into food is not detected. For the purposes of checking compliance, rules laid down in Regulation (EU) No 10/2011 should apply. Regulation (EC) No 1895/2005 should also be amended to reflect the fact that BADGE can no longer be used to manufacture food contact varnishes and coatings to be applied to materials and articles with a capacity of less than 250 litres, including food packaging, as the use of BPA in the synthesis of BADGE for such food contact varnishes and coatings is no longer permitted.
- (8) The prohibition of BPA will consequently result in business operators needing to identify substances, in particular other bisphenols and their derivatives, to replace BPA in the food contact materials and articles where it is currently used, particularly for food contact varnishes and coatings, in order to continue to adequately meet the needs of the food supply chain and ensure food safety. As a consequence of

⁷ Commission Regulation (EC) No 1895/2005 of 18 November 2005 on the restriction of use of certain epoxy derivatives in materials and articles intended to come into contact with food (OJ L 302, 19.11.2005, p. 28, ELI: <http://data.europa.eu/eli/reg/2005/1895/oj>).

similarities in the chemical structure and activity, certain other bisphenols and their derivatives may also present risks similar to BPA when they are used in food contact materials and articles and migrate into food resulting in consumer exposure. Some bisphenols have already been identified as having properties hazardous to human health due to their reproductive toxicity and their potential endocrine disrupting properties and have been subject to harmonised classification and listed as such in accordance with Regulation (EC) No 1278/2008 of the European Parliament and of the Council⁸. 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 Council⁹ and the introduction of new hazard classes for endocrine disruptors by Commission Delegated Regulation (EU) 2023/707¹⁰. It is therefore appropriate to ensure that the use of such bisphenols and their derivatives in the manufacture of food contact materials and articles is not permitted without first being risk assessed and authorised, to ensure that their use in the manufacture of food contact materials and articles does not endanger human health. Whilst for plastic food contact materials and articles, such a mechanism currently exists, as substances used in their manufacture are already subject to a risk assessment and authorisation process by way of Regulation (EU) No 10/2011 regardless of their classification under Regulation (EC) No 1278/2008, business operators should be given time to apply for specific uses in other food contact applications, either from the application of this Regulation in the case of substances with existing harmonised classification or from the date of application of the harmonised classification laid down by Regulation (EC) No 1278/2008 concerning possible future harmonised classifications.

- (9) In addition to the intentional use of BPA in the manufacture of certain food contact materials and articles, its unintentional presence in other food contact materials and articles and subsequent migration into food may also occur at levels of relevance to human health. Principally, it may be present as a contaminant in the input waste stream used to produce recycled materials including paper and board. This contamination can persist despite the application of cleaning and decontamination processes and may eventually be present in the final food contact article, including single use packaging. As business operators do not intentionally use BPA in such manufacturing processes and such contamination cannot be fully controlled; and in light of ongoing efforts in the Union to promote a circular economy, it is neither practical nor proportionate to prohibit the unintentional presence of BPA in recycled materials.
- (10) However, as there is a lack of information on levels of BPA in recycled paper and board food contact materials and articles and in order to coordinate a common

⁸ 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>).

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

approach and promote a level playing field, monitoring by business operators and reporting to Member States for the unintentional presence of BPA in recycled paper and board food contact materials and articles should be established at Union level. Such monitoring will help to identify best practices to reduce potential contamination, such as selection of the input waste stream or prevent migration, such as the use of a functional barrier to help to ensure that BPA levels in recycled paper and board food contact materials and articles are kept as low as possible. Monitoring should be undertaken by manufacturers since, should BPA be found, they are best placed to initiate follow-up investigations, to identify the source and to actively pursue ways to remedy the situation, with cooperation from other businesses in the supply chain. These activities will also provide feedback on the impact of other regulatory intervention introduced at Union level, such as the prohibition of BPA in thermal paper which has applied from 2 January 2020¹¹, which should in turn contribute to reducing levels that may be present in the input waste stream.

- (11) Mandatory monitoring and reporting to Member States should also be carried out for food contact materials and articles for which a derogation from the prohibition of the use of BPA in their manufacture is granted, namely for the synthesis of BADGE for heavy-duty varnishes and coatings and for polysulfone resins for use in filtration membranes. This will help to ensure that appropriate practices are in place and that any possible residual BPA does not migrate into food and pose a risk to consumers. In order to assist Member States' competent authorities, business operators should ensure that it is possible for competent authorities to verify the degree of purity and composition of BADGE-based heavy-duty varnishes and coatings as and when competent authorities may take samples.
- (12) In accordance with Article 16(1) of Regulation (EC) No 1935/2004, specific measures adopted by the Commission are to require that materials and articles covered by those measures are accompanied by a written declaration stating that they comply with the rules applicable to them. Therefore, such an obligation should be provided for food contact materials and articles to which the rules on BPA and other bisphenols and their derivatives laid down in this Regulation apply. That declaration should accompany the food contact materials and articles at all stages of marketing so that all business operators responsible for placing on the market intermediate materials and articles as well as final food contact articles on the market have the declaration of compliance in their possession. 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.
- (13) 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 on the Union market. 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 not manufactured using BPA needs to be organised so as to avoid disruptions in the

¹¹ Commission Regulation (EU) 2016/2235 of 12 December 2016 amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards bisphenol A (OJ L 337, 13.12.2016, p. 3, ELI: <http://data.europa.eu/eli/reg/2016/2235/oj>).

food supply within the Union and to not compromise the safety of food. 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 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.

- (14) For some specific 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. Taking this into account and in order to avoid disruption to the food supply chain, it is appropriate to provide for extra transition time to complete the reformulation of specific food contact materials and articles in order to be able to phase out the use of BPA completely.
- (15) In particular, some specific foods provide additional challenges in finding suitable alternatives to replace the current BPA-based food contact varnishes and coatings because of the high acidity of those foods. These foods are particularly aggressive to materials in which they are packaged, including fruit and vegetable products such as tomatoes. Consequently, a longer transition period is needed to complete the validation steps of the alternatives and ensure product safety. Furthermore, the seasonal nature of certain products such as fruit, vegetables and fish products, creates peaks in food production and thus in demand for packaging during certain periods that is not expected to be met 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 provide for a 36-month transition period to continue to allow final food contact articles using varnishes and coatings manufactured with BPA specifically for the packaging of processed fruit, vegetable and processed fish products.
- (16) Formulations to manufacture varnishes and coatings using alternatives to BPA applied to the external surface of metal packaging are also under development although such developments are less advanced than for the interior surface. A longer transition time is therefore also required, estimated by industry to be three years. 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 phase of coated and varnished materials and articles either through direct contact as a result of 'set-off' or via vapour phase transfer, resulting in very small levels of exposure. As this may be minimised or eliminated with good manufacturing practices which reduces the risk of such exposure and as the function of the varnishes and coatings is to ensure the integrity of the packaging and safety of the food, it is appropriate to grant a 36-month

transition time to transition to final articles using varnishes and coatings manufactured without BPA to be applied to the external surface of metal packaging.

- (17) Certain final food contact articles manufactured with BPA are used as repeat-use components in professional food production equipment, such as moulds, seals, pumps, flanges, gauges and sight glasses. Not all of these articles can easily be replaced with food contact materials and articles manufactured without BPA, whilst replacement articles also 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 36-month transition time for the 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 to eventually replace them altogether.
- (18) The manufacture of final food contact articles including metal packaging typically involves the supply of different intermediate materials and articles such as varnishes and coatings or printing inks from prior manufacturing stages by business operators who are not involved in curing the varnish or coating to the metal substrate or assembling the final food contact article. As such, it is necessary to take into account the various steps in the supply chain and anticipate the time needed to complete the manufacture of final food contact articles from intermediate materials and articles. Therefore, business operators manufacturing intermediate materials and articles with BPA should be required to communicate to their customers using those intermediate materials, from nine months before the end of the relevant transitional period that those intermediate materials and articles cannot be used to manufacture final food contact articles for placing on the market after the relevant transition period.
- (19) Business operators placing repeat-use final food contact articles on the market for use by food business operators for professional food production and processing equipment should also be required to communicate to the food business operator using those articles that they do not comply with this Regulation. This information is needed in order for food business operators to know when such articles should eventually be phased out and removed from use.
- (20) In most cases, it is appropriate to allow final food contact articles to remain on the market until exhaustion of stocks, as these will eventually be replaced once they have reached the end of their lifespan. For certain final food contact articles manufactured with BPA, it is more pertinent to set a limit on the length of time during which they may be used by business operators in order to ensure a timely phase-out of food contact materials and articles manufactured using BPA. Repeat-use final food contact articles used in professional food production equipment may be used for many years and possibly decades, whereas some will continue to contribute to consumer exposure to BPA. It is therefore appropriate to limit their use to a maximum of 10 years. Metal packaging is often used for products with a long shelf-life and may be stored and consumed for up to five years or more after the food is packaged, during which time migration and therefore exposure to BPA will continue. Such single-use final food contact articles for packaging food should therefore be used for their intended purpose and filled with food within 12 months from the end of the respective transitional periods.
- (21) 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.

- (22) 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 for food contact materials and articles falling within the scope of Article 1(2) of Regulation (EC) No 1935/2004 placed on the Union market, specifically as regards:
 - (a) the use of 4,4'-isopropylidenediphenol ('BPA') (CAS No 80-05-7) in the manufacture of food contact plastics, varnishes and coatings, printing inks, adhesives, ion-exchange resins and rubbers;
 - (b) the use of other bisphenols and bisphenol derivatives listed in Annex VI, Part 3 of Regulation (EC) No 1272/2008 due to their harmonised classification as category 1A or 1B 'mutagenic', 'carcinogenic', 'toxic to reproduction' or category 1 'endocrine disrupting' for human health, in the manufacture of food contact varnishes and coatings, printing inks, adhesives, ion-exchange resins and rubbers;
 - (c) the monitoring for any presence or migration of BPA from food contact BADGE-based heavy-duty varnishes and coatings, polysulfone resins for use in filtration membranes and paper and board containing recycled material.

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 materials and articles that are in their finished state for end use, including those that are ready to be used in contact with food or are already in contact with food without undergoing further chemical, biological or physical processing or modification; in the case of articles used for single-use packaging, requiring only the processing or modification necessary for filling with food, including the sealing process;
 - (b) 'intermediate food contact materials and articles' means materials and articles that are intended to undergo further chemical, biological or physical processing or modification in order to manufacture all or part of a final food contact article of which it is to become part;
 - (c) 'BADGE' means bisphenol-A diglycidyl ether (CAS No 1675-54-3);
 - (d) 'BADGE-based heavy-duty varnishes and coatings' means non-self-supporting polymeric varnishes and coatings synthesised directly only from BADGE and its derivatives as monomers, to be applied on self-supporting materials or

articles with a capacity greater than 250 litres, as well as pipelines belonging to or connected with them;

- (e) 'bisphenol' means a substance consisting of two hydroxyphenyl functional groups linked by a bridge where there may be additional groups attached to the bridging atom(s), denoted by 'X', in accordance with structure A laid out in Annex I; derivatives are indicated by the general structure B;
- (f) 'batch' means a quantity of material of the same quality and produced using uniform production parameters at a certain manufacturing stage, stored and contained to exclude mixing with other materials, or contamination, and designated as such by a single production number.

Article 3

Prohibition of the use of BPA

1. The use of BPA at any manufacturing stage of food contact varnishes and coatings, printing inks, adhesives, ion-exchange resins and rubbers and the placing on the market of final food contact articles composed partly or wholly of these materials manufactured using BPA is prohibited.
2. By derogation from paragraph 1, the use of BPA as a precursor in the synthesis of BADGE and its derivatives to be used as monomers for the manufacture and placing on the market of BADGE-based heavy-duty varnishes and coatings is permitted subject to the following restrictions:
 - (a) liquid epoxy BADGE-based heavy-duty varnishes and coatings shall be obtained in separate identifiable batches before subsequent manufacturing steps;
 - (b) the migration of BPA from materials and articles on which BADGE-based heavy-duty varnishes and coatings is applied shall not be detectable with a limit of detection (LOD) of 0.01 mg/kg;
 - (c) the use of BADGE-based heavy-duty varnishes and coatings in the manufacture of food contact materials and articles shall not lead to its hydrolysis or any other reaction either during manufacturing or when in contact with food that results in the presence of BPA in those materials and articles or in the food.

Article 4

Specific requirements on the use of other bisphenols and bisphenol derivatives

1. The use of bisphenols and bisphenol derivatives listed in Annex VI, Part 3 of Regulation (EC) No 1272/2008 due to their harmonised classification as category 1A or 1B 'mutagenic', 'carcinogenic', 'toxic to reproduction' or category 1 'endocrine disrupting' for human health, in the manufacture of food contact varnishes and coatings, printing inks, adhesives, ion-exchange resins and rubbers is prohibited.
2. By derogation from paragraph 1, such bisphenols and bisphenol derivatives may be used in the manufacture of food contact varnishes and coatings, printing inks, adhesives, ion-exchange resins and rubbers provided that the following conditions are fulfilled:

- (a) an application for the authorisation of the bisphenol or the bisphenol derivative has been submitted to the competent authority in accordance with Article 9 of Regulation (EC) No 1935/2004 either
 - (i) before [insert date 9 months after the entry into force of this Regulation] for those bisphenols and bisphenol derivatives already listed in Annex VI, Part 3 of Regulation (EC) No 1272/2008 with harmonised classification due to the properties referred to in paragraph 1;
 - (ii) within nine months of the date of application of the relevant amendment to Regulation (EC) No 1272/2008 listing the bisphenol or bisphenol derivative in Annex VI, Part 3 of Regulation (EC) No 1272/2008 with harmonised classification due to the properties referred to in paragraph 1;
 - (b) the information provided to the Authority is in accordance with Article 9 of Regulation (EC) No 1935/2004 and includes a statement that the application is an application submitted in accordance with this Article;
 - (c) the Authority has not considered the application invalid and;
 - (d) the use of the bisphenol or bisphenol derivative is limited to the intended conditions of use described in the application.
3. Food contact varnishes and coatings, printing inks, adhesives, ion-exchange resins and rubbers may be placed on the market in accordance with paragraph 2 until such time when the Commission has authorised the bisphenol or its derivative or taken a decision not to authorise it.

Article 5

Monitoring and reporting of results

1. A manufacturer placing on the Union market the following food contact materials and articles shall monitor for the presence of BPA and its migration from:
 - (a) materials and articles on which BADGE-based heavy-duty varnishes and coatings is applied;
 - (b) polysulfone resins for use in filtration membranes;
 - (c) paper and board materials and articles containing recycled material.
2. The monitoring shall be carried out in accordance with rules on compliance, where applicable. For the purpose of point (c) the amount of BPA in the material may be determined using an extraction test.
3. Each business operator referred to in paragraph 1 shall carry out the monitoring on 5% of the batches of food contact materials and articles that it places on the market. The business operator shall select batches at random. When it is not possible to identify individual batches in case of continuous production, a sample shall be taken at a random time during a period of production that does not exceed 200 times the average residence time of the material in the production system.
4. If BPA is not detected in any batch or period of sampling within a 6 month period from the start of the monitoring or from the previous detection of BPA in accordance with this Article and provided that a minimum of 10 batches or periods of production was subjected to monitoring, the monitoring may be reduced to 1% of the batches or by 1000 times the average residence time, as applicable.

5. In case the results of the monitoring indicate the presence of BPA, the business operator referred to in paragraph 1 shall carry out an investigation to determine the source of the BPA with cooperation from other business operators in the supply chain and where necessary, follow-up actions to reduce or eliminate the presence of BPA in the food contact materials or articles that it places on the market, including changes to its production practices or changes to specifications of intermediate materials and articles obtained from suppliers.
6. A report of the monitoring referred to in paragraph 1 including the batch or period of sampling, the method of analysis used and result shall be submitted to the competent authority in the Member State where the food contact material or article was tested every 12 months from the date of entry into force of this Regulation. If BPA is found, its level shall be reported without delay to that competent authority and an outline of the planned remedial action shall be provided within 20 working days from the date on which a result is generated. The results of the remedial action shall also be reported once such action is implemented.

Article 6

Methodologies for verification of compliance

1. In order to verify compliance concerning the migration of BPA from materials and articles on which BADGE-based heavy-duty varnishes and coatings is applied, rules laid down in Article 11(4), Article 18, in Annex III and in Chapters 1, 2 and 4 of Annex V to Regulation (EU) No 10/2011 shall apply.
2. In case the foreseeable contact occurs under continuous flow conditions, such as in pipes, the testing time shall equal the average residence time.
3. Results of monitoring obtained shall be expressed in accordance with the rules laid down in Article 17, paragraphs 1 to 3 of Article 17 of Regulation (EU) No 10/2011.
4. Business operators shall ensure that competent authorities can take samples of intermediate preparations of BADGE-based heavy-duty varnishes and coatings before they are applied to other materials to verify their degree of purity and composition.

Article 7

Written declaration of compliance and supporting documentation

1. Business operators shall ensure that materials and articles covered by this Regulation are accompanied at all stages of marketing 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 II.
3. The declaration of compliance shall permit an easy identification of the materials and articles from intermediate stages of manufacture.
4. Appropriate documentation shall be available to demonstrate such compliance. That documentation shall be made available without delay to the competent authorities on demand.

Article 8

Amendment to Regulation (EC) No 1895/2005

Article 2 to Regulation (EC) No 1895/2005, after the title 'BADGE', is replaced by the following:

- “1. The use of BADGE in the manufacture of materials and articles with a capacity of less than 250 litres is prohibited.
2. Materials and articles with a capacity between 250 litres and 10 000 litres shall not release the substances listed in Annex I in a quantity exceeding the limits laid down in that Annex.”

Article 9

Amendment to Regulation (EU) No 10/2011

Annex I to Regulation (EU) No 10/2011 is amended in accordance with Annex III to this Regulation.

Article 10

Transitional provisions

1. Final food contact articles composed of plastics, varnishes and coatings, printing inks, adhesives, ion-exchange resins and rubbers complying with the rules as applicable before the date of entry into force of this Regulation may be first placed on the market until *[insert date 18 months after the entry into force of this Regulation]* subject to the rules applicable before the date of entry into force of this Regulation.
2. By derogation from paragraph 1, the following final food contact articles referred to in parts (a) to (c) below complying with the rules as applicable before the date of entry into force of this Regulation, may be first placed on the market until *[insert date 36 months after the entry into force of this Regulation]*, subject to the rules applicable before the date of entry into force of this Regulation:
 - (a) single-use final food contact articles intended to be filled with processed fruits, vegetables and fish products;
 - (b) single-use final food contact articles on which a varnish or coating has been applied specifically to the exterior metal surface;
 - (c) repeat-use final food contact articles used as components in professional food production equipment.
3. For intermediate food contact materials and articles, which comply with the rules as applicable before the date of entry into force of this Regulation and which are first placed on the market as of nine months before the end of the applicable transitional period, the declaration of compliance shall indicate that the intermediate material or article does not comply with this Regulation, and that it can only be used in the manufacture of final articles to be placed on the market before the end of the transitional period applicable to those final articles.
4. For repeat-use final food contact articles to be used in professional food production equipment, which comply with the rules as applicable before the date of entry into force of this Regulation and which are first placed on the market before the end of

the applicable transitional period, the declaration of compliance shall indicate to the food business operator that the final food contact article does not comply with this Regulation.

5. Final food contact articles which were lawfully first placed on the market before the end of the applicable transitional period may remain on the market until exhaustion of stocks subject to the rules applicable before the date of entry into force of this Regulation.
6. By derogation from paragraph 5, single-use final food contact articles for packaging food not complying with this Regulation and not yet filled with food shall be filled with food at the latest 12 months following the expiry of the applicable transitional period.
7. By derogation from paragraph 5, repeat-use final food contact articles used in professional food production equipment not complying with this Regulation shall be removed from the market at the latest 10 years following the expiry of the applicable transitional period.

Article 11

Repeal

Regulation (EU) 2018/213 is repealed.

Article 12

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,

For the Commission

The President

Ursula VON DER LEYEN