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

(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 points (d), (e), (h), (i) and (j) of Article 5(1) thereof,

Whereas:

(1) The substance 2,2-bis(4-hydroxyphenyl)propane (CAS 0000080-05-7), commonly known as bisphenol A (BPA) is used in the manufacture of certain materials and articles intended to come into contact with food, such as polycarbonate plastic and epoxy resins used in varnishes and coatings. 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 production of plastic materials and articles is authorised by Commission Regulation (EU) No 10/2011 ([2]). The authorisation is subject to a specific migration limit (SML) of 0,6 mg of BPA per kg of food (mg/kg) based on a previous evaluation by the Scientific Committee on Food ([3]). The European Food Safety Authority (the Authority) has reviewed scientific information and updated its opinion on BPA in 2006 ([4]), 2008 ([5]), 2010 ([6]) and 2011 ([7]). A prohibition is in place on its use in the manufacture of polycarbonate infant feeding bottles on the basis of the precautionary principle.

(3) After the publication of its scientific advice on BPA in 2011, the Authority noted that its exposure assessment which dated back to its 2006 opinion needed to be updated in light of new data and that the relevance of dietary exposure in the context of other routes of exposure should also be investigated. The Authority decided to undertake a full re-evaluation of BPA based on the most recent scientific evidence. In 2012, in accordance with Article 29(1)(b) of Regulation (EC) No 178/2002 of the European Parliament and of the Council ([8]), the Authority asked its scientific Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF) to provide a scientific opinion on the risks to public health related to the presence of BPA in foodstuffs.

(4) The Authority adopted an opinion on 11 December 2014 ([9]), having reviewed the available data and scientific studies published from 2006 to 2012 as well as some studies available in 2013. In that opinion, the Authority established changes in mean relative kidney weight in a two-generation study in mice as the critical endpoint and calculated a Benchmark Dose (Lower Confidence Limit) ($BMDL_{10}$) of 8 960 µg/kg bw per day. It was able to apply

([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).
([3]) Opinion of the Scientific Committee on Food on Bisphenol A (SCF/CS/PM/3936 Final).
([4]) The EFSA Journal (2006) 428, 1.
([5]) The EFSA Journal (2008) 759, 1.
([6]) The EFSA Journal 2010;8(9):1829.
([7]) The EFSA Journal 2011;9(12):2475.
([8]) Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1).
([9]) The EFSA Journal 2015;13(1):3978.

new toxicokinetic data to allow a more accurate substance-specific extrapolation of data from animals to humans and established a human equivalent dose (HED) of 609 μg/kg bw per day. The HED was used as a reference point for establishing a health-based guidance value for BPA.

(5) To establish this health-based guidance value, the Authority applied an uncertainty factor of 2,5 for inter-species differences and 10 for intra-species differences. It applied an additional factor of 6 to take into account uncertainties surrounding potential health effects of BPA on the mammary gland, reproductive, metabolic, neurobehavioural and immune systems. As a result, an overall uncertainty factor of 150 was applied to establish a new Tolerable Daily Intake (TDI) of 4 μg/kg bw per day. However, the Authority designated the TDI as temporary (t-TDI) pending the anticipated outcome of a long-term toxicity study on BPA in rodents being undertaken by the National Toxicology Program/Food and Drug Administration (NTP/FDA) in the United States of America (USA).

(6) The Authority noted that dietary exposure to BPA is below the t-TDI and concluded that there is no health concern at the estimated levels of exposure. In its opinion adopted on 11 December 2014, the Authority also estimated non-dietary sources of exposure as well as those from the diet. Non-dietary sources include exposure through air, ingestion of dust and uptake through the skin as a result of contact with thermal paper and cosmetics. The Panel concluded that the central estimates for aggregated exposure to BPA through dietary and non-dietary sources for the highest exposed groups including infants, children and adolescents, are below the t-TDI and that the health concern for BPA is low at the estimated levels of aggregated exposure.

(7) Following the opinion published by the Authority in 2014, the current SML for plastic materials and articles should be updated to take account of the new t-TDI. The setting of the SML uses a conventional exposure assumption that 1 kg of food is consumed daily by a person of 60 kg body weight and that all exposure comes from food contact materials. Article 5(1)(e) of Regulation (EC) No 1935/2004 establishes that specific limits on the migration of certain constituents into or onto food should take due account of other possible sources of exposure to those constituents. The Authority noted that exposure from non-dietary sources of BPA may contribute a significant proportion of overall exposure for some population groups and that in addition to these non-dietary sources, non-canned meat and meat products were found to be a major contributor to BPA exposure for several population groups. In such cases where sources other than food contact materials may contribute significantly to the potential overall exposure of a substance, it is not appropriate to allocate the full TDI to food contact materials and a lower value should be used.

(8) Taking into account conventional assumptions on the use of allocation factors for food contact materials, including that the overall exposure does not exceed the t-TDI and the uncertainty factor of 150 in the derivation of the t-TDI, as well as the data in the Authority's opinion on sources of BPA other than food contact materials, an allocation factor of 20 % is considered appropriate when setting the SML. Therefore, on the basis of the t-TDI, the allocation factor and the exposure assumption, an SML of 0,05 mg of BPA per kg of food (mg/kg) should be set for plastic materials and articles to ensure that exposure to BPA remains below the t-TDI and does not endanger human health.

(9) While the SML established, which takes into account the opinion, serves as a basis for the overall management of risks posed by BPA from food contact materials, there are still uncertainties, which are identified in that opinion. With respect to two new studies on the developmental immunotoxicity of BPA, the Authority stated in 2016 ([1]) that the new evidence presented by those studies adds to the indications of developmental immunotoxicity of BPA. Taking into account the extent of the scientific uncertainties and the nature of the potential adverse effects, in particular developmental effects, further precautionary steps should be taken as regards more vulnerable population groups, in particular infants and young children, where developmental effects could be irreversible and would last a life-time.

(10) The precautionary principle referred to in Article 7 of Regulation (EC) No 178/2002 authorises the adoption of provisional measures on the basis of available pertinent information, pending results related to continued uncertainties, to an additional assessment of risk and a review of the measure within a reasonable period of time.

([1]) EFSA Journal 2016;14(10):4580.

(11) The Commission is authorised to take preventive measures as regards the use of BPA on the basis of the precautionary principle which is applicable in a situation in which there is scientific uncertainty, even if the risk, notably to human health, has not yet been fully demonstrated. In order to do so, BPA should not be used to manufacture polycarbonate drinking cups or bottles which are intended for infants and young children as defined in Regulation (EU) No 609/2013 of the European Parliament and of the Council ([1]).

(12) In addition to its use in plastic food contact materials, BPA is used extensively in epoxy resins for varnishes and coatings, particularly for application on the interior of food cans. While specific measures provided for in Article 5 of Regulation (EC) No 1935/2004 have been adopted as regards BPA in plastic materials and articles, such measures have not been adopted as regards BPA in varnishes and coatings at the Union level. Therefore, in accordance with Article 6 of that Regulation, Member States have been able to maintain or adopt national provisions on BPA in varnishes and coatings provided those measures comply with the rules laid down in the Treaties.

(13) In light of the introduction by Member States of divergent national measures applicable to BPA in food contact materials and the resulting technical and practical burdens reported by industry, and having regard to the contribution to dietary exposure of BPA from canned food identified in the Authority's opinion of 2014 and the extensive use of BPA in epoxy resins for varnishes and coatings applied to food cans, it is also appropriate to establish restrictions for BPA used in varnishes and coatings.

(14) The same assumption concerning exposure to BPA from plastic materials and articles applies to varnishes and coatings. In order to ensure the effective functioning of the internal market and to ensure a high level of protection for human health, the SML established for BPA from plastic materials and articles should also apply to varnishes and coatings applied to materials and articles, where that varnish or coating has been produced using BPA. As BPA may be used in food packaging containing foods for infants and young children, BPA should not migrate from varnishes and coatings applied to materials or articles specifically intended to come into contact with food intended for infants and young children as referred to in Regulation (EU) No 609/2013, namely 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 young children.

(15) In conjunction with the establishment of restrictions for varnishes and coatings, it is also necessary to define rules for verification of compliance with the restrictions. In particular, rules for migration testing and rules for expression of migration testing results should be established. Therefore it is appropriate to establish such rules for checking compliance with the restrictions for varnishes and coatings applied to materials and articles where those varnishes or coatings have been produced using BPA.

(16) Regulation (EU) No 10/2011 establishes a comprehensive framework for verifying compliance of plastic food contact materials with defined restrictions, including rules on the expression of migration test results. As the varnishes and coatings applied to materials and articles do not have specific characteristics that would require the establishment of different or more specific provisions, it is appropriate to extend the application of the rules laid down in Regulation (EU) No 10/2011 to the verification of compliance of varnishes and coatings applied to materials and articles with the established restrictions.

(17) Article 16(1) of Regulation (EC) No 1935/2004 provides that materials and articles covered by specific measures be accompanied by a written declaration of compliance stating that they comply with the rules applicable to them. On production of the varnished or coated material or article, the responsible business operator should document compliance with the applicable rules in a declaration of compliance which is made available to their customers. In order to ensure that the declaration provides sufficient information to enable verification of compliance, it is appropriate to specify the information that must be included in the declaration. In addition, competent authorities should be able to verify compliance with the applicable rules. Business operators should therefore be required to make available for the competent authorities appropriate supporting documentation, substantiating the declaration of compliance.

([1]) Regulation (EU) No 609/2013 of the European Parliament and of the Council of 12 June 2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control and repealing Council Directive 92/52/EEC, Commission Directives 96/8/EC, 1999/21/EC, 2006/125/EC and 2006/141/EC, Directive 2009/39/EC of the European Parliament and of the Council and Commission Regulations (EC) No 41/2009 and (EC) No 953/2009 (OJ L 181, 29.6.2013, p. 35).

(18) In order to ensure that the business operators have sufficient time to adjust their manufacturing processes to comply with the restrictions and to reduce the administrative and financial burden that such adjustment may entail, it is appropriate to defer the application of this Regulation and to permit materials and articles which have been lawfully placed on the market before the date of application of this Regulation to remain on the market until the exhaustion of stocks.

(19) Regulation (EU) No 10/2011 should therefore be amended accordingly.

(20) 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

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

(1) 'specific migration limit' (SML) means the maximum permitted amount of a given substance released from a material or article into food or food simulants;

(2) 'materials and articles' means any materials or articles which fall within one of the categories laid down in Article 1(2) of Regulation (EC) No 1935/2004;

(3) 'varnishes' or 'coatings' means materials or articles composed of one or more non-self-supporting layer or layers manufactured using 2,2-bis(4-hydroxyphenyl)propane ('BPA'), applied on a material or article in order to impart special properties on it or to improve its technical performance.

Article 2

1. The migration into or onto food of 2,2-bis(4-hydroxyphenyl)propane ('BPA') (CAS No 0000080-05-7) from varnishes or coatings applied to materials and articles shall not exceed a specific migration limit of 0,05 mg of BPA per kg of food (mg/kg).

2. By derogation from paragraph 1, no migration of BPA shall be permitted 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 young children, as referred to in Regulation (EU) No 609/2013.

Article 3

1. In order to verify compliance with Article 2 of this Regulation, rules laid down in Article 11(4), in paragraphs 1, 2, 3, 6 and 7 of Article 18, in Annex III and in Chapters 1, 2 and 4 of Annex V to Regulation (EU) No 10/2011 shall apply.

2. Test results obtained as part of the verification procedure referred to in paragraph 1 shall be expressed in accordance with the rules laid down in paragraphs 1 to 3 of Article 17 of Regulation (EU) No 10/2011.

Article 4

1. In accordance with Article 16(1) of Regulation (EC) No 1935/2004, business operators shall ensure that varnished or coated materials and articles are accompanied by a written declaration of compliance containing the information laid down in Annex I to this Regulation. The declaration shall be available at all stages of manufacture, processing and distribution other than the retail stage.

2. The written declaration shall permit an easy identification of the varnished or coated materials and articles to which it applies. It shall be renewed to reflect any changes in migration levels from the varnish or coating that has been applied to materials and articles.

3. Business operators shall, upon request of a national competent authority, make available appropriate supporting documentation to demonstrate compliance with the written declaration referred to in paragraph 1. Such supporting documentation shall be provided without delay and in any event not later than 10 days following receipt of the request. The documentation shall contain the conditions and results of the testing, calculations, including modelling, other analysis and evidence on the safety or reasoning demonstrating compliance.

Article 5

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

Article 6

Varnished or coated materials and articles and plastic materials and articles that were lawfully placed on the market before 6 September 2018 may remain on the market until exhaustion of stocks.

Article 7

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

It shall apply from 6 September 2018.

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

Done at Brussels, 12 February 2018.

For the Commission
The President
Jean-Claude JUNCKER

ANNEX I

The written declaration referred to in Article 4 shall contain the following information:

(1) the identity and address of the business operator issuing the declaration of compliance;

(2) the identity and address of the business operator which manufactures or imports the coated material or article;

(3) the identity of the varnished or coated material or article;

(4) the date of the declaration;

(5) confirmation that the varnish or coating applied to the material or article meets the restrictions laid down in Article 2 of this Regulation and the requirements set out in Articles 3, 15 and 17 of Regulation (EC) No 1935/2004;

(6) specifications on the use of the coated material or article, such as:

(a) the type or types of food with which it is intended to be put into contact;

(b) the time and temperature of treatment and storage in contact with food;

(c) the highest food contact surface area to volume ratio for which compliance has been verified in accordance with Articles 17 and 18 of Regulation (EU) No 10/2011 or equivalent information.

ANNEX II

In Table 1 of Annex I to Regulation (EU) No 10/2011, the entry concerning substance No 151 is replaced by the following:

‘151	13480 13607	0000080-05-7	2,2-bis(4-hydroxyphenyl) propane	no	yes	no	0,05		Not to be used for the manufacture of polycarbonate infant [1] feeding bottles [2]. Not to be used for the manufacture of polycarbonate drinking cups or bottles which, due to their spill proof characteristics, are intended for infants [3] and young children [4].	

[1] Infant as defined in Article 2(2)(a) of Regulation (EU) No 609/2013 of the European Parliament and of the Council of 12 June 2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control and repealing Council Directive 92/52/EEC, Commission Directives 96/8/EC, 1999/21/EC, 2006/125/EC and 2006/141/EC, Directive 2009/39/EC of the European Parliament and of the Council and Commission Regulations (EC) No 41/2009 and (EC) No 953/2009 (OJ L 181, 29.6.2013, p. 35).
[2] This restriction is applicable from 1 May 2011 as regards the manufacture and from 1 June 2011 as regards the placing on the market and importation into the Union.
[3] Infant as defined in Article 2(2)(a) of Regulation (EU) No 609/2013
[4] Young children as defined in Article 2(2)(b) of Regulation (EU) No 609/2013.’