# RECOMMENDATIONS

## COMMISSION RECOMMENDATION (EU) 2019/794

**of 15 May 2019**

**on a coordinated control plan with a view to establishing the prevalence of certain substances migrating from materials and articles intended to come into contact with food**

*(notified under document C(2019) 3519)*

**(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 292 thereof,

Having regard to Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules ([1]), and in particular Article 53 thereof,

After consulting the Standing Committee on Plants, Animals, Food and Feed,

Whereas:

(1) Article 53 of Regulation (EC) No 882/2004 empowers the Commission to recommend coordinated control plans where considered necessary, organised on an ad hoc basis, with a view to establishing the prevalence of hazards in feed, food and animals.

(2) Regulation (EC) No 1935/2004 of the European Parliament and of the Council ([2]) lays down general requirements on the safety of materials and articles intended to come into contact with food ('food contact materials'), specifically regarding the transfer of the constituents of food contact materials into food. In addition, specific measures for groups of food contact materials have been established in accordance with Article 5(1) of that Regulation. In particular, for plastic food contact materials, a list of authorised substances has been established under Commission Regulation (EU) No 10/2011 ([3]). Some of these authorised substances are also subject to restrictions, including Specific Migration Limits (SML), which restrict their migration into or onto food.

(3) Information available from the Rapid Alert System for Food and Feed ('RASFF') reported pursuant to Article 50 of Regulation (EC) No 178/2002 of the European Parliament and of the Council ([4]) indicates various non-compliances as regards migration of certain substances from food contact materials. However, at present there is inadequate information to sufficiently determine the prevalence of these substances in food migrating from food contact materials.

(4) Primary aromatic amines ('PAA') are a family of compounds, some of which are carcinogenic, while others are suspected carcinogens. PAA may arise in food contact materials from authorised substances, from the presence of impurities or from breakdown products as well as the use of azo dyes to colour materials. Annex II of Regulation (EU) No 10/2011 sets out that such PAA shall not migrate from plastic materials and articles into food or food simulant. Work undertaken by the Joint Research Centre of the European Commission has also determined that PAA occur at concentrations in coloured paper napkins that are relevant for monitoring.

([1]) OJ L 165, 30.4.2004, p. 1.
([2]) Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC (OJ L 338, 13.11.2004, p. 4).
([3]) 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).
([4]) 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).

(5) Formaldehyde (FCM No 98) is a substance authorised at Union level for use in the manufacture of plastic food contact materials. However, it is subject to an SML of 15 mg/kg (expressed as total formaldehyde and hexamethylenetetramine).

(6) Commission Regulation (EU) No 284/2011 ([5]) lays down specific conditions and detailed procedures for the import of polyamide and melamine plastic kitchenware originating in or consigned from the People's Republic of China and Hong Kong, including mandatory physical controls of 10 % of consignments by Member States. The Regulation was introduced on the basis of elevated numbers of non-compliances due to the release of high levels of PAA from polyamide plastic food contact materials and formaldehyde from melamine plastic food contact materials.

(7) A recent analysis of data based on controls carried out at the point of import into the European Union and reported in accordance with Article 9 of Regulation (EU) No 284/2011 indicates a decrease in non-compliance of these products. Nevertheless, RASFF data shows that some of these products are still non-compliant based on results from analysis of samples taken from the market. Information also shows that the origin of such products is not restricted to China and Hong Kong. It is therefore appropriate to control levels of PAA and formaldehyde in addition to the controls carried out under Regulation (EU) No 284/2011.

(8) Melamine (FCM No 239) is a substance also authorised in the manufacture of plastic food contact materials and subject to an SML of 2,5 mg/kg. In addition to formaldehyde, migration of melamine from melamine plastic kitchenware has also been reported. It is therefore appropriate to control levels of melamine migrating from the same samples.

(9) Phenol (FCM No 241) is a substance authorised for use as a monomer to manufacture plastic food contact materials and may also be used to manufacture other types of materials that come into contact with food, including epoxy resins used in varnishes and coatings. An SML of 3 mg/kg applies to plastic food contact materials, which was introduced by Commission Regulation (EU) 2015/174 ([6]) on the basis of a re-evaluation by the European Food Safety Authority ('the Authority'). In its opinion, the Authority reduced the Tolerable Daily Intake (TDI) from 1,5 mg/kg bw to 0,5 mg/kg bodyweight (bw), noting that there are many sources of exposure to phenol in addition to food contact materials, which may contribute to levels of exposure at or above the TDI. It is therefore appropriate to control levels of phenol in light of potential exceedances of the TDI.

(10) The substance 2,2-bis(4-hydroxyphenyl)propane (FCM No 151), commonly known as bisphenol A ('BPA') is a substance authorised for use as a monomer to manufacture plastic food contact materials but is also used to manufacture other materials and articles which come into contact with food, including epoxy resins used in varnishes and coatings. Recently, a new SML of 0,05 mg/kg was introduced by Commission Regulation (EU) 2018/213 ([7]) for plastic food contact materials and in addition the SML applies to varnishes and coatings, on the basis of a re-evaluation by the Authority, who concluded on a lower temporary Tolerable Daily Intake (tTDI) compared to the previous TDI. It is therefore appropriate to control these food contact materials to determine compliance of BPA migration in light of this new SML.

(11) In addition to BPA, other bisphenols may be used in or migrate from food contact materials. In particular, 4,4′-dihydroxydiphenyl sulphone, commonly known as bisphenol S ('BPS', FCM No 154) is used as a monomer to manufacture polyethersulphone plastic and is authorised to be used for manufacturing plastic food contact materials in the Union with an SML of 0,05 mg/kg. There is no recent information available on its possible migration into food and information on its possible use or migration from varnished or coated food contact materials is incomplete. It is therefore appropriate to control materials from which BPS potentially migrates to check for the prevalence of BPS migrating into food.

(12) Phthalate esters ('phthalates') are a group of substances widely used as plasticisers and technical support agents. Five phthalates have been authorised for use in plastic food contact materials, including di-butylphthalate

([5]) Commission Regulation (EU) No 284/2011 of 22 March 2011 laying down specific conditions and detailed procedures for the import of polyamide and melamine plastic kitchenware originating in or consigned from the People's Republic of China and Hong Kong Special Administrative Region, China (OJ L 77, 23.3.2011, p. 25).

([6]) Commission Regulation (EU) 2015/174 of 5 February 2015 amending and correcting Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food (OJ L 30, 6.2.2015, p. 2).

([7]) 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).

('DBP', FCM No 157), butyl-benzyl-phthalate ('BBP', FCM No 159), bis(2-ethylhexyl)phthalate ('DEHP', FCM No 283), diisononyl phthalate ('DINP', FCM No 728) and diisodecyl phthalate ('DIDP', FCM No 729). These phthalates are included in a group restriction SML (T) of 60 mg/kg, along with a number of other substances. Individual SMLs are also applicable to DBP, BBP and DEHP, whereas a group restriction exists for DINP and DIDP of 9 mg/kg. The concentration of these five phthalates is also restricted in childcare articles for feeding, as set out in Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council ([8]). In addition to results from the RASFF indicating non-compliance with the SMLs, phthalates that are not authorised for use in plastic food contact materials may still be found in plastic food contact materials and migrate into food. It is therefore appropriate to control levels of phthalates in light of possible non-compliance.

(13) In addition to the use of phthalates, other non-phthalate substances are also used in food contact materials as plasticisers. Epoxidized soybean oil ('ESBO', FCM No 532) as well as 1,2-Cyclohexane dicarboxylic acid diisononyl ester ('DINCH', FCM No 775) and terephthalic acid, bis(2-ethylhexyl)ester ('DEHTP' or 'DOTP', FCM No 798) are authorised for use in the manufacture of plastic food contact materials and are included in the group SML (T) of 60 mg/kg. In addition, both DEHTP and ESBO have individual SMLs of 60 mg/kg, except in the case of PVC gaskets used to seal glass jars containing infant and baby foods for infants and young children where, the SML for ESBO is 30 mg/kg. Previous work carried out by Member States and Switzerland has identified compliance issues with the migration of ESBO from jar lids. As there is also an indication that DINCH and DEHTP may be used as replacements for phthalates and there is little or no available information on their migration into food, it is appropriate to check for the prevalence of these substances migrating into food.

(14) Per- and polyfluoroalkyl substances ('PFAS') are a group of compounds that includes perfluorooctanoic acid ('PFOA') and perfluorooctane sulphonate ('PFOS'). Due to their amphiphilic properties, these fluorinated compounds are used in the production of water and fat repellent coatings such as those used on paper and board based food packaging materials. Information from some Member States indicates possible concerns on the levels of these substances in coated paper and board based packaging materials. In addition, PFOA is restricted for use in the production and placing on the market of articles, including food contact materials and articles from 4 July 2020, as laid down in Commission Regulation (EU) 2017/1000 ([9]). It is therefore appropriate to further investigate the prevalence of these substances in food contact materials.

(15) Metals and alloys are used in food contact materials and articles including kitchenware and tableware as well as food processing equipment. A number of SMLs are laid down at Union level for metals migrating from plastic food contact materials; however, information from the RASFF shows a number of non-compliances for metal kitchenware and tableware, based on risk assessments or moreover national legislation. As the hazards from certain metals such as lead and cadmium is well defined, it is appropriate to carry out controls on the migration of metals into food and to improve the understanding of the prevalence of migration of metals, including in particular from imported food contact materials and articles as well as traditional and artisanal products.

(16) In order to ensure the overall inertness and safety of plastic food contact materials, an overall migration limit (OML) is set to restrict the release of non-volatile constituents into food, including particles such as microfibres. As conventional plastic materials and articles are under pressure to be replaced due to environmental concerns, additives derived from natural sources are being used as fillers in combination with plastic in order to reduce environmental impacts. In order to verify that good manufacturing practices have been followed and that these plastic food contact materials and articles are sufficiently inert, it is appropriate to control for overall migration.

(17) To ensure uniform application of this Recommendation and in order to generate reliable and comparable results of the controls, the European Union Reference Laboratory (EU-RL) for Food Contact Materials should assist Member States in implementing this Recommendation where necessary.

([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).

([9]) Commission Regulation (EU) 2017/1000 of 13 June 2017 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 perfluorooctanoic acid (PFOA), its salts and PFOA-related substances (OJ L 150, 14.6.2017, p. 14).

(18) In order to maximise the available information on the prevalence of substances migrating from food contact materials, Member States should also be encouraged to submit relevant data that have been generated recently, prior to the application of this Recommendation. To ensure that these results are reliable and consistent with those generated as part of this control program, only those results that have been generated following relevant rules on the sampling and analysis of the food contact materials as well as legislation on official controls should be reported.

(19) The primary aim of this Recommendation is to establish the prevalence of substances migrating from food contact materials and articles into food or the prevalence of substances in the food contact material or article; it is not intended to contribute to the understanding of exposure levels. Data should therefore be submitted using a common format in order to ensure that they are coordinated and compiled in a consistent manner.

(20) Where appropriate, the competent authorities of the Member States should consider enforcement action in accordance with applicable legislation and procedures.

(21) The information generated on the prevalence of these substances resulting from this Recommendation should be used to determine whether any possible future action is necessary, in particular to secure a high level of human health protection and the interests of consumers. Such future action may include additional control measures for substances from plastic materials for which specific EU measures exist. In addition, the results may contribute towards an information base on which to consider future priorities in the context of the evaluation of food contact materials legislation, in particular for materials for which no specific EU measures exist.

(22) The implementation of this coordinated control plan is without prejudice to other official controls carried out by Member States in the framework of their national control programmes, as provided in Article 3 of Regulation (EC) No 882/2004,

HAS ADOPTED THIS RECOMMENDATION:

1. Member States should implement the coordinated control plan for materials and articles intended to come into contact with food as indicated in the Annex to this Recommendation. The minimum total number of samples recommended in the Annex should be followed as far as possible.

2. Member States should report the results of the official controls carried out in accordance with the Annex.

3. Member States should also report results generated as part of any previous controls undertaken within the five years prior to 1 January 2019. These controls should be relevant to the substances in or migrating from materials and articles intended to come into contact with food subject to this Recommendation and undertaken in accordance with relevant legislation on materials and articles intended to come into contact with food and official controls. The results should be reported in accordance with the Annex.

4. In case of non-compliance, Member States should consider further enforcement action in accordance with Article 54 of Regulation (EC) No 882/2004. Without prejudice to other reporting requirements, such enforcement action should not be reported to the Commission in the context of this Recommendation.

5. This Recommendation is addressed to the Member States.

Done at Brussels, 15 May 2019.

*For the Commission*
Vytenis ANDRIUKAITIS
*Member of the Commission*

*ANNEX*

**ACTIONS AND SCOPE OF THE COORDINATED CONTROL PLAN**

1. **Objective**

The general objective of the control plan is to establish the prevalence of substances migrating from food contact materials into food or the presence of substances in the food contact material. Competent Authorities of the Member States should therefore carry out official controls in order to establish the prevalence on the European Union market as regards

— the migration of targeted substances from food contact materials,

— targeted substances in food contact materials,

— overall migration from plastic food contact materials.

2. **Sample descriptions and methodology**

The table below sets out the types of food contact materials, which should be sampled together with the substances for which migration from those food contact materials should be analysed, except in the case of fluorinated compounds for which the quantity in the material should be analysed.

Sampling should include the point of import for food contact materials from third countries, although Member States should take into account controls already being undertaken in accordance with Regulation (EU) No 284/2011. Member States should also undertake market controls, including sampling at wholesale and distribution points in order to permit access to a sufficient sample size of a given lot or batch and where necessary facilitate any follow up action.

Laboratories used for the analysis of samples should be those laboratories designated in accordance with Article 12 of Regulation (EC) No 882/2004, supported by national reference laboratories in accordance with Article 33(2)(e) of that Regulation. The EU-RL should support this Recommendation in accordance with Article 94(2)(a) of Regulation (EU) 2017/625 of the European Parliament and of the Council ([1]) if required by national reference laboratories.

If it is not practical to determine the migration using a food or food simulant, the prevalence should be determined in the material and calculation or modelling should be used to estimate the maximum migration into the food.

| Substances to be tested | Food contact material to be sampled |
|---|---|
| Primary aromatic amines (PAA) | Plastic tableware and kitchenware and printed food contact materials including paper and board |
| Formaldehyde and Melamine | Plastic tableware and kitchenware including non-conventional plastic kitchenware and tableware, such as reusable coffee cups using additives in the plastic derived from natural sources such as bamboo |
| Phenol | Plastic kitchenware and tableware; varnished or coated materials and; printed plastic and paper and board packaging materials |
| Bisphenols including BPA and BPS | Polycarbonate plastic (BPA) and polyethersulfone plastic (BPS); coated metal packaging (e.g. cans, lids) |

([1]) 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, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation) (OJ L 95, 7.4.2017, p. 1).

| Substances to be tested | Food contact material to be sampled |
|---|---|
| Phthalates and non-phthalate plasticisers | Plastic materials and articles, in particular those manufactured using polyvinylchloride (PVC) such as thermoformed sheets, flexible packaging and tubing; closures and lids |
| Fluorinated compounds | Paper and board based materials and articles, including those used to wrap fast-food, takeaway and bakery products and microwave popcorn bags |
| Metals | Ceramic, enamel, vitreous and metal kitchenware and tableware including artisanal and traditionally produced materials and articles |
| Overall migration | Non-conventional plastic kitchenware and tableware, such as reusable coffee cups using additives in the plastic derived from natural sources such as bamboo |

3. **Sample numbers**

The table below gives the indicative recommended total number of samples to be tested in each Member State, for those Member States that are participating, for the purpose of this coordinated control plan.

| Member State | Recommended minimum total number of samples |
|---|---|
| Belgium, Germany, Spain, France, Italy, United Kingdom | 100 |
| Czechia, Cyprus, Hungary, Netherlands, Poland, Romania | 75 |
| Denmark, Ireland, Greece, Croatia, Lithuania, Austria, Portugal, Sweden | 50 |
| Bulgaria, Estonia, Latvia, Luxembourg, Malta, Slovenia, Slovakia, Finland | 25 |

4. **Time frame for controls**

Controls should take place from 1 June 2019 to 31 December 2019.

5. **Reporting**

The results should be reported to the Commission using a common format by 29 February 2020.