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EUROPEAN
COMMISSION

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

of **XXX**

**on maximum levels for certain contaminants in food and repealing Regulation (EC) No
1881/2006**

(Text with EEA relevance)

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

of **XXX**

on maximum levels for certain contaminants in food and repealing Regulation (EC) No 1881/2006

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Council Regulation (EEC) No 315/93 of 8 February 1993 laying down Community procedures for contaminants in food ⁽¹⁾, and in particular Article 2(3) thereof,

Whereas:

- (1) Commission Regulation (EC) No 1881/2006 ⁽²⁾ sets maximum levels for certain contaminants in food. That Regulation has already been amended substantially many times and since a number of new amendments are to be made to that Regulation, it should be replaced.
- (2) Maximum levels should be set at a strict level, which is reasonably achievable by following good agricultural, fishery and manufacturing practices and taking into account the risk related to the consumption of the food. In the case of a possible health risk, maximum levels for contaminants should be set at a level, which is as low as reasonably achievable (ALARA). Such an approach ensures that food business operators apply measures to prevent and reduce the contamination as much as possible in order to protect public health. It is furthermore appropriate for the protection of the health of infants and young children, a vulnerable group, to establish the lowest maximum levels, which are achievable through a strict selection of the raw materials used for the manufacturing of foods for that population, combined, where appropriate, with specific manufacturing practices. This strict selection of the raw materials is also appropriate for the production of specific food placed on the market for the final consumer, for which a strict maximum level has been set out in order to protect vulnerable populations.
- (3) To ensure an efficient protection of public health, food containing contaminants exceeding the maximum levels not only should not be placed on the market as such, but should also not be used as a food ingredient or be mixed with food.
- (4) To allow maximum levels to be applied to dried, diluted, processed and compound food, for which no specific Union maximum levels have been set out, food business operators should provide to the competent authorities the specific concentration, dilution and processing factors and, in case of compound food, the proportion of ingredients, accompanied by the appropriate experimental data justifying the factors proposed.

⁽¹⁾ OJ L 37, 13.2.1993, p. 1.

⁽²⁾ Commission Regulation (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs (OJ L 364, 20.12.2006, p. 5).

- (5) Due to the lack of toxicological data and scientific evidence of the safety of the metabolites created by chemical detoxification, it is appropriate to prohibit such treatment of food.
- (6) It is recognised that sorting or other physical treatments make it possible to reduce the content of contaminants in food. In order to minimise the effects on trade, it is appropriate to allow higher levels of contaminants for certain products, which are not placed on the market for the final consumer or as a food ingredient. In those cases, the maximum levels for contaminants should be set out taking into consideration the effectiveness of such treatments to reduce the content of contaminants in food to levels below the maximum levels set out for those products placed on the market for the final consumer or used as a food ingredient. To avoid that these higher maximum levels are abused, it is appropriate to lay down provisions for the marketing, labelling and use of the concerned products.
- (7) Certain commodities have uses other than food and for which less strict or no maximum levels for a certain contaminant are applicable. To enable effective enforcement of the maximum levels for contaminants in these foods, it is appropriate to lay down suitable labelling provisions for those foods.
- (8) Certain fish species originating from the Baltic region may contain high levels of dioxins, dioxin-like polychlorinated biphenyls ('DL-PCBs') and non dioxin-like polychlorinated biphenyls ('NDL-PCBs'). A significant proportion of those fish species from the Baltic region does not comply with the maximum levels and would therefore be excluded from the diet if the maximum levels were applied. However, the exclusion of fish from the diet may have a negative impact on the health of the population of the Baltic region.
- (9) Latvia, Finland and Sweden have systems in place to ensure that consumers are informed of the dietary recommendations for identified vulnerable groups of the population to restrict consumption of fish from the Baltic region in order to avoid health risks. Therefore, it is appropriate to maintain a derogation to Latvia, Finland and Sweden allowing them to authorise the placing on their respective market for the final consumer without time limit certain fish species originating in the Baltic region with levels of dioxins and/or DL-PCBs and/or NDL-PCBs higher than those set in this Regulation. In order to allow the Commission to monitor the situation, Latvia, Finland and Sweden should continue to report yearly to the Commission the measures they have taken to effectively inform consumers of the dietary recommendations and to ensure that fish and products thereof non-compliant with the maximum levels are not marketed in other Member States, as well as the effectiveness of those measures.
- (10) Despite the application of good smoking practices to the extent possible, the current maximum levels for polycyclic aromatic hydrocarbons ('PAHs') are not achievable in several Member States in certain traditionally smoked meats and meat products and traditionally smoked fish and fishery products, where smoking practices cannot be altered without changing significantly the organoleptic characteristics of the food. Consequently, if maximum levels were applied, such traditionally smoked products would disappear from the market resulting in the closure of many small and medium size enterprises. That is the case with certain traditionally smoked meat and smoked meat products in Ireland, Spain, Croatia, Cyprus, Latvia, Poland, Portugal, Slovakia, Finland and Sweden and certain traditionally smoked fish and smoked fishery products in Latvia, Finland and Sweden. Therefore, a derogation for local production and consumption should be maintained without a time limit for certain traditionally

smoked meat and smoked meat products and traditionally smoked fish and smoked fishery products only in those Member States.

- (11) Member States are to collect and report data from official controls and from monitoring of contaminants in accordance with control plans and with the specific requirements on official controls of contaminants laid down in Commission Delegated Regulation (EU) 2022/931 ⁽³⁾ and in Commission Implementing Regulation (EU) 2022/932 ⁽⁴⁾. For certain specific contaminants, for which more occurrence data are needed, it is recommended that Member States, food business operators and other interested parties should monitor and report the occurrence data, as well as report on the progress with regard to the application of preventative measures, to allow the Commission to assess the need to modify existing measures or to adopt additional ones. For the same reasons, it is also appropriate that Member States communicate to the Commission the information they have collected as regards other contaminants.
- (12) Maximum levels as currently set out by Regulation (EC) No 1881/2006, as amended, should be maintained by this Regulation. However, in light of the experience gained with that Regulation and in order to improve the readability of the rules, it is appropriate, on the one hand, to avoid the use of numerous footnotes and, on the other hand, to increase the references to Annex I to Regulation (EC) No 396/2005 of the European Parliament and of the Council ⁽⁵⁾ for the definitions of the categories.
- (13) Also in light of the experience gained with that Regulation and in order to enable uniform enforcement of the maximum levels, it is appropriate to clarify that lower bound concentrations should be used in those cases where maximum levels are set for multiple compounds (sum of maximum levels), except when specified otherwise, and to clarify the body parts of crustaceans to which maximum levels apply.
- (14) As regards cadmium, it is appropriate to extend the current exemption for malt to all cereals used for the production of beer or distillates, provided that the remaining cereal residue is not placed on the market as food, because cadmium mainly remains in the cereal residue and therefore the content of cadmium in beer is very low.
- (15) As regards PAHs, based on the available analytical data and on the production method, which showed that negligible amount of those substances was found in instant/soluble coffee, it is appropriate to exclude instant/soluble coffee from the maximum level for powders of food of plant origin for the preparation of beverages. Furthermore, as regards maximum levels for PAHs for infant formulae, follow-on formulae and young-child formulae and for food for special medical purposes intended for infants and young children, they are currently set out for products as placed on the market without the distinction of the physical form of the product. It is therefore appropriate to clarify that these maximum levels refer to the products ready to use (placed on the market as such or after reconstitution as instructed by the manufacturer).

⁽³⁾ Commission Delegated Regulation (EU) 2022/931 of 23 March 2022 supplementing Regulation (EU) 2017/625 of the European Parliament and of the Council by laying down rules for the performance of official controls as regards contaminants in food (OJ L 162, 17.6.2022, p. 7).

⁽⁴⁾ Commission Implementing Regulation (EU) 2022/932 of 9 June 2022 on uniform practical arrangements for the performance of official controls as regards contaminants in food, on specific additional content of multi-annual national control plans and specific additional arrangements for their preparation (OJ L 162, 17.6.2022, p. 13).

⁽⁵⁾ 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).

- (16) As regards melamine, Codex Alimentarius has adopted, additionally to the powdered infant formula, a maximum level for liquid infant formula, which the Union has accepted. It is therefore appropriate to apply that maximum level for melamine in infant formula and follow-on formula accordingly.
- (17) Therefore, Regulation (EC) No 1881/2006 should be repealed.
- (18) When the Commission sets out new maximum limits for contaminants in food, it provides, where appropriate, for transitional measures in order to enable economic operators to prepare for the application of the new rules. In order to ensure a smooth transition between Regulation (EC) No 1881/2006 and this Regulation, it is appropriate to maintain the transitional measures as regards those maximum limits taken over by this Regulation, which are still relevant.
- (19) 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

Definitions

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

- (a) ‘food’ means food as defined in Article 2 of Regulation (EC) No 178/2002 of the European Parliament and of the Council ⁽⁶⁾;
- (b) ‘food business operator’ means food business operator as defined in Article 3, point 3, of Regulation (EC) No 178/2002;
- (c) ‘placing on the market’ means placing on the market as defined in Article 3, point 8, of Regulation (EC) No 178/2002;
- (d) ‘final consumer’ means final consumer as defined in Article 3, point 18, of Regulation (EC) No 178/2002;
- (e) ‘processing’ means processing as defined in Article 2(1), point (m) of Regulation (EC) No 852/2004 of the European Parliament and of the Council ⁽⁷⁾;
- (f) ‘unprocessed products’ means unprocessed products as defined in Article 2(1), point (n), of Regulation (EC) No 852/2004; and
- (g) ‘processed products’ means processed products as defined in Article 2(1), point (o), of Regulation (EC) No 852/2004.

Article 2

General rules

1. The food listed in Annex I shall not be placed on the market and shall not be used as a raw material in food or as an ingredient in food where it contains a contaminant at a level which exceeds the maximum level set out in Annex I.

⁽⁶⁾ 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).

⁽⁷⁾ Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs (OJ L 139, 30.4.2004, p.1).

2. Food complying with the maximum levels set out in Annex I shall not be mixed with food which exceeds these maximum levels.
3. The maximum levels set out in Annex I, unless otherwise specified in that Annex, shall apply to food as placed on the market and to the edible part of the food concerned.
4. In systems where cereal production and processing are integrated so that all incoming lots are cleaned, sorted and processed in the same establishment, the maximum levels shall apply to unprocessed cereals in the production chain at the stage before first-stage processing.

Article 3

Dried, diluted, processed and compound food

1. Where no specific Union maximum levels are set out in Annex I for food which is dried, diluted, processed or compound food (i.e. composed of more than one ingredient), the following aspects shall be taken into account when applying the maximum levels set out in Annex I to such food:
 - (a) changes of the concentration of the contaminant caused by drying or dilution processes;
 - (b) changes of the concentration of the contaminant caused by processing;
 - (c) the relative proportions of the ingredients in the product;
 - (d) the analytical limit of quantification.
2. Where the competent authority carries out an official control, the food business operator shall provide and justify the specific concentration, dilution or processing factors for the drying, diluting or processing operations concerned or the specific concentration, dilution or processing factors for the dried, diluted, processed or compound food concerned as well as the proportion of ingredients for mixing operations concerned.

Where the food business operator does not provide the necessary concentration, dilution or processing factor or where the competent authority deems that factor inappropriate in view of the justification given, the competent authority shall itself define that factor, based on the available information and with the objective of maximum protection of human health.
3. Where no specific Union maximum levels for food for infants and young children are set out in Annex I, Member States may provide for stricter maximum levels for such food.

Article 4

Prohibition on detoxification

Food containing contaminants listed in Annex I shall not be deliberately detoxified by chemical treatments.

Article 5

Food to be subjected to sorting or other physical treatment before placing on the market for the final consumer or use as a food ingredient

1. Where a maximum level for a contaminant is set out in Annex I specifically as regards food to be subjected to sorting or other physical treatment before placing on the market for the final consumer or use as a food ingredient, such food may be placed on the market provided that:
 - (a) it is not placed on the market for the final consumer or use as a food ingredient;
 - (b) it complies with the maximum level set out in Annex I for that contaminant in that food to be subjected to sorting or other physical treatment before placing on the market for the final consumer or use as a food ingredient; and
 - (c) it is labelled and marked in accordance with paragraph 2.
2. The label of each individual package and the original accompanying document of food referred to in paragraph 1, point (c), shall clearly show its use and bear the following information: 'Product shall be subjected to sorting or other physical treatment to reduce [name contaminant(s)] contamination before placing on the market for the final consumer or use as a food ingredient'.

The consignment/batch identification code shall be indelibly marked on each individual package of the consignment and on the original accompanying document.
3. Food to be subjected to sorting or other physical treatment to reduce contamination levels shall not prior to this be mixed with food placed on the market for the final consumer or with food intended for use as a food ingredient.
4. Food which has been subjected to sorting or other physical treatment to reduce contamination levels may be placed on the market provided that the maximum levels set out in Annex I for food placed on the market for the final consumer or use as a food ingredient are not exceeded and that the treatment used has not resulted in the presence of other harmful residues.

Article 6

Labelling provisions for groundnuts (peanuts), other oilseeds, derived products thereof and cereals

1. The label of each individual package and the original accompanying document of groundnuts (peanuts), other oilseeds, derived products thereof and cereals shall clearly show its intended use.

The consignment/batch identification code shall be indelibly marked on each individual package of the consignment and on the original accompanying document. The business activity of the consignee of the consignment given on the accompanying document shall be compatible with the intended use.
2. In the absence of a clear information that their intended use is not to be placed on the market as food, the maximum levels set out in Annex I shall apply to all groundnuts (peanuts), other oilseeds and derived products thereof and cereals placed on the market.

3. The exception of groundnuts (peanuts) and other oilseeds for crushing from the application of the maximum levels set out in Annex I, shall only apply to consignments, which:
- (a) are clearly labelled showing their intended use;
 - (b) bear the following information ‘Product to be subject to crushing for the production of refined vegetable oil’ on the label of each individual package and on the original accompanying document; and
 - (c) have a crushing plant as the final destination.

Article 7
Derogations from Article 2

1. By way of derogation from Article 2, Latvia, Finland and Sweden may authorise the placing on their respective market for the final consumer, within their annual quota as set in Regulation (EU) No 1380/2013 of the European Parliament and of the Council ⁽⁸⁾, of wild caught salmon (*Salmo salar*) and products thereof originating in the Baltic region with levels of dioxins and/or DL-PCBs and/or NDL-PCBs higher than those set out in point 4.1.5 of Annex I, provided that:
- (a) a system is in place to ensure that consumers, are fully informed of the national dietary recommendations with regard to the restrictions on the consumption of wild caught salmon from the Baltic region and products thereof by identified vulnerable groups of the population in order to avoid potential health risks;
 - (b) Latvia, Finland and Sweden continue to apply the necessary measures to ensure that wild caught salmon and products thereof not complying with point 4.1.5 of Annex I are not marketed in other Member States;
 - (c) Latvia, Finland and Sweden report yearly to the Commission the measures they have taken to effectively inform consumers of the dietary recommendations and to ensure that wild caught salmon and products thereof not compliant with the maximum levels are not marketed in other Member States and provide evidence of the effectiveness of those measures.
2. By way of derogation from Article 2, Finland and Sweden may authorise the placing on their respective market, within their annual quota as set in Regulation (EU) No 1380/2013, wild caught Baltic herring larger than 17 cm (*Clupea harengus membras*), of wild caught char (*Salvelinus* spp.), wild caught river lamprey (*Lampetra fluviatilis*) and wild caught trout (*Salmo trutta*) and products thereof originating in the Baltic region with levels of dioxins and/or DL-PCBs and/or NDL-PCBs higher than those set out in point 4.1.5 of Annex I, provided that:
- (a) a system is in place to ensure that consumers are fully informed of the dietary recommendations with regard to the restrictions on the consumption of wild caught Baltic herring larger than 17 cm, wild caught char, wild caught river lamprey and wild caught trout from the Baltic region and products thereof by identified vulnerable groups of the population in order to avoid potential health risks;

⁽⁸⁾ Regulation (EU) No 1380/2013 of the European Parliament and of the Council of 11 December 2013 on the Common Fisheries Policy, amending Council Regulations (EC) No 1954/2003 and (EC) No 1224/2009 and repealing Council Regulations (EC) No 2371/2002 and (EC) No 639/2004 and Council Decision 2004/585/EC (OJ L 354, 28.12.2013, p. 22).

- (b) Finland and Sweden continue to apply the necessary measures to ensure that wild caught Baltic herring larger than 17 cm, wild caught char, wild caught river lamprey and wild caught trout and products thereof not complying with point 4.1.5 of Annex I are not marketed in other Member States;
 - (c) Finland and Sweden report yearly to the Commission the measures they have taken to effectively inform the identified vulnerable sections of the population of the dietary recommendations and to ensure that fish and products thereof not compliant with the maximum levels is not marketed in other Member States and provide evidence of the effectiveness of those measures.
3. By way of derogation from Article 2, the following Member States may authorise the placing on their respective market for the final consumer of the following traditionally smoked meat and smoked meat products, smoked in their territory with levels of PAHs higher than those set out in point 5.1.6 of Annex I, provided that those products do not contain more than 5,0 µg/kg for benzo(a)pyrene and 30,0 µg/kg for the sum of benzo(a)pyrene, benz(a)anthracene, benzo(b)fluoranthene and chrysene:
- (a) Ireland, Croatia, Cyprus, Spain, Poland and Portugal: traditionally smoked meat and meat products;
 - (b) Latvia: traditionally smoked pork, hot smoked chicken meat, hot smoked sausages and hot smoked game meat;
 - (c) Slovakia: salted traditionally smoked meat, traditionally smoked bacon, traditionally smoked sausage (klobása), where 'traditionally smoked' means developing smoke by burning woods (wood logs, wood sawdust, wood chips) in a smokehouse;
 - (d) Finland: traditionally hot smoked meat and meat products;
 - (e) Sweden: meat and meat products smoked over glowing wood or other plant materials.

Those Member States and concerned food business operators shall continue to monitor the presence of PAHs in traditionally smoked meat and smoked meat products referred to in the first subparagraph and shall ensure that good smoking practices are implemented where possible, without losing typical organoleptic characteristics of those products.

4. By way of derogation from Article 2, the following Member States may authorise the placing on their respective market for the final consumer of the following traditionally smoked fish and smoked fishery products, smoked in their territory with levels of PAHs higher than those set out in point 5.1.7 of Annex I, provided that those smoked products do not contain more than 5,0 µg/kg for benzo(a)pyrene and 30,0 µg/kg for the sum of benzo(a)pyrene, benz(a)anthracene, benzo(b)fluoranthene and chrysene:
- (a) Latvia: traditionally hot smoked fish;
 - (b) Finland: traditionally hot smoked small fish and fishery products made from small fish;
 - (c) Sweden: fish and fishery products smoked over glowing wood or other plant materials.

Those Member States and concerned food business operators shall continue to

monitor the presence of PAHs in traditionally smoked fish and smoked fishery products referred to in the first subparagraph and shall ensure that good smoking practices are implemented where possible, without losing typical organoleptic characteristics of those products.

Article 8 *Monitoring and reporting*

1. By 1 July 2023, Member States and interested parties shall communicate to the Commission the results of investigations undertaken and the progress with regard to the application of prevention measures to avoid contamination by ergot sclerotia and ergot alkaloids in rye and rye milling products and ergot alkaloids in milling products of barley, wheat, spelt and oats grains.

Member States and interested parties shall report every year to the European Food Safety Authority ('Authority') the occurrence data on ergot sclerotia and ergot alkaloids in rye and rye milling products and on ergot alkaloids in milling products of barley, wheat, spelt and oats grains.
2. Member States shall communicate to the Commission, when requested, the investigations undertaken and the relevant sources identified following Commission Recommendations for monitoring of the presence of contaminants in food and the progress with regard to the application of prevention measures to avoid contamination.
3. Member States shall report to the Authority the occurrence data that they have collected on other contaminants than those referred to in paragraph 1. Food business operators and other interested parties may submit such occurrence data to the Authority.
4. Member States, food business operators and other interested parties shall provide to the Authority the occurrence data in accordance with Authority's reporting requirements.

Article 9 *Repeal*

Regulation (EC) No 1881/2006 is repealed.

References to the repealed Regulation shall be construed as references to this Regulation and shall be read in accordance with the correlation table in Annex II.

Article 10 *Transitional measures*

1. Food lawfully placed on the market prior to the dates referred to in points (a) to (k) may remain on the market until their date of minimum durability or use-by date:
 - (a) 19 September 2021 as regards the maximum levels for tropane alkaloids in baby foods and processed cereal-based foods for infants and young children, containing maize or its derived products set out in point 2.2.1 of Annex I;
 - (b) 1 January 2022 as regards the maximum levels for ergot sclerotia and ergot alkaloids set out in point 1.8 of Annex I;

- (c) 3 May 2022 as regards the maximum levels for mercury set out in point 3.3 of Annex I;
 - (d) 1 July 2022 as regards the maximum levels for opium alkaloids set out in point 2.5 of Annex I;
 - (e) 1 September 2022 as regards the maximum levels for tropane alkaloids set out in points 2.2.2 to 2.2.9 of Annex I;
 - (f) 1 January 2023 as regards the maximum levels for ochratoxin A set out in point 1.2 of Annex I;
 - (g) 1 January 2023 as regards the maximum levels for hydrocyanic acid set out in point 2.3 of Annex I;
 - (h) 1 January 2023 as regards the maximum levels for the sum of Δ^9 -THC and Δ^9 -THCA set out in point 2.6 of Annex I;
 - (i) 1 January 2023 as regards the maximum levels for the sum of dioxins and for the sum of dioxins and DL-PCBs set out in points 4.1.1, 4.1.2, 4.1.11 and 4.1.12 of Annex I;
 - (j) 1 January 2023 as regards the maximum levels for the sum of perfluoroalkyl substances set out in point 4.2 of Annex I;
 - (k) *[Publication office, please add the date of entry into force of SANTE/10384/2021]* as regards the maximum levels for arsenic set out in point 3.4 of Annex I.
2. Food lawfully placed on the market before 1 July 2022 may remain on the market until 31 December 2023 as regards the maximum levels for pyrrolizidine alkaloids set out in point 2.4 of Annex I.
3. The burden of proving the date when the products were lawfully placed on the market shall be borne by the food business operator.

Article 11

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