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Feedback
[...] (2024) **XXX** draft

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

of **XXX**

amending Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food and amending Regulation (EC) No 2023/2006 on good manufacturing practice for materials and articles intended to come into contact with food as regards recycled plastic and other matters related to quality control and manufacturing of plastic materials and articles intended to come into contact with food.

(Text with EEA relevance)

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

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

of **XXX**

amending Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food and amending Regulation (EC) No 2023/2006 on good manufacturing practice for materials and articles intended to come into contact with food as regards recycled plastic and other matters related to quality control and manufacturing of plastic materials and articles intended to come into contact with food.

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

Whereas:

- (1) Commission Regulation (EU) No 10/2011² lays down specific rules as regards plastic materials and articles intended to come into contact with foods. In particular Chapter II thereof sets out compositional requirements for plastic materials and articles that are to ensure that final plastic materials intended to come into contact with food are sufficiently safe, in order to meet the requirements of Article 3 of Regulation (EC) No 1935/2004.
- (2) In its Chapter II, Regulation (EU) No 10/2011 sets out the compositional requirements for substances that can be used to manufacture plastic materials and articles, specifically referring to 'plastic layers' in plastic materials and articles. However, in many cases, plastic materials and articles do not conform to a layer structure but consist of a single homogenous material with a complex shape, leading to ambiguity. Therefore, Chapter II of Regulation (EU) No 10/2011 should refer to plastic materials and articles instead of to plastic layers. Since the new wording could raise doubts as to whether the compositional requirements laid down in Regulation (EU) No 10/2011 apply to non-plastic layers of plastic materials and articles, such as adhesives, printing inks, varnishes and coatings, it should be clarified that those layers do not fall under the scope of Regulation (EU) No 10/2011. However, the reference to 'plastic layers' in Chapter III of Regulation (EU) No 10/2011 should be maintained since it allows, in relation to multi-layer materials and articles, for some of the provisions of that Chapter to apply to some layers and not to others. In particular, the plastic layer which is separated from the food by a functional barrier in multi-layer materials may be

¹ 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, ELI: <http://data.europa.eu/eli/reg/2004/1935/oj>).

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>).

manufactured with substances not listed in the Union list. It should also remain possible to verify compliance with the migration limits in accordance with Regulation (EU) 10/2011 of materials and articles falling within its scope that are held together by adhesives or that are printed and/or covered by a coating.

- (3) According to the definition in Regulation (EU) No 10/2011 plastics consists of polymers to which additives or other substance may have been added. That Regulation authorises additives and starting substances separately. In most cases, additives do not chemically react with the polymers. However certain particles, fibres, or other solid materials that are added to the plastic to achieve a physical effect are coupled to the polymer by means of a chemical bond to ensure the overall integrity of the material. Given the definitions of plastics, additives, polymers and starting substances in Regulation (EU) No 10/2011, this chemical bond may create uncertainty over whether such a solid material is to be regarded as an additive or as a starting substance. Therefore, also uncertainty ensues over whether that solid material should be authorised as an additive or a starting substance. However, it should be considered that a solid material functions as an additive and not as a starting substance where it consists of many individual molecules or substances of which only a small number located at the surface of that material becomes bonded to the polymer, it does not participate in the polymerisation process and the physical effect achieved by that solid material is the reason for adding it. Therefore, it is appropriate to clarify the definition of additives by adding that solid materials that are chemically bonded to the polymer to which they are added should be considered additives.
- (4) Biocidal products containing active substances may be incorporated into various materials, including plastics, which may enter into contact with food. Regulation (EU) No 10/2011 provides that, in order to be used in the manufacturing of plastic food contact materials and articles, such substances must have been authorised by the Commission or, pending such authorisation, be included in the provisional list referred to in Article 7 of that Regulation. However, Regulation (EU) No 528/2012 of the European Parliament and of the Council³ lays down rules for the authorisation of the types of biocidal products listed in its Annex V, including those intended to be incorporated into food contact materials, and the placing on the market of treated articles containing such products, such as food contact materials. In accordance with that Regulation, a biocidal product containing an active substance may be incorporated into food contact materials provided that both the substance and the product containing that substance are approved and authorised respectively under Regulation (EU) No 528/2012 for that use. Therefore, Regulation (EU) No 10/2011 should refer to Regulation (EU) No 528/2012 as to the active substances and biocidal products that may be used in plastic food contact materials.
- (5) During the manufacture of plastic materials and articles, it is not possible to fully avoid the production of off-cuts, scraps and other by-products. Allowing the re-processing of these by-products for manufacturing plastic materials and articles, can contribute to reduction of the occurrence of unusable manufacturing materials. By-products are not considered waste if they can be used directly in the manufacturing of

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³ Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products (OJ L 167, 27.6.2012, p. 1, ELI: <http://data.europa.eu/eli/reg/2012/528/oj>).

plastics without any further processing. Therefore, Regulation (EU) No 2022/1616⁴ does not apply to these by-products and rules should be laid down to ensure the safety of their use.

- (6) In its Note for Guidance for the preparation of an application for the safety assessment of a substance to be used in plastic food contact materials⁵, the European Food Safety Authority ('the Authority') considers that in case a substance used in the manufacturing of a food contact material or article exceeds a migration level of 0.05 mg/kg into food, applicants are required to submit genotoxicity tests and additional toxicity tests to assess the potential adverse effects of chemical exposure on human health. On the other hand, no toxicity testing of the migrating substance would be needed if consumer exposure is below the threshold level of 0.00015 mg substance/kg food. It is appropriate to set out the purity specification for substances used in the manufacturing of food contact materials or articles in relation to these thresholds. The individual toxicological assessment for genotoxicity of a substance may be substituted with a group assessment of genotoxicity under specific requirements. This is also possible if the substances are obtained as a mixture representative for migration into food. However, for assessing the genotoxicity of mixtures, specific considerations are needed. The Authority developed a statement clarifying how to perform genotoxicity assessment of chemical mixtures⁶. To evaluate expected consumer exposure to the substances used in the manufacturing of food contact materials or articles, it is appropriate to assume, for safety purposes, that substances could potentially migrate up to 100% into the food with which the plastic is in contact. However, in situations where high migration levels are clearly not expected, it is appropriate to reduce the assumed level of 100% migration into food of the substances in plastics.
- (7) Substances listed in table 1 of Annex I to Regulation (EU) No 10/2011 are denoted by FCM substance number, reference number and their chemical name and, where available, by their respective Chemical Abstracts Service (CAS) registry number. However, experience shows that there may remain doubts as to the precise identity of the substances authorised. Since the application for an authorisation of a substance is to contain information on the identity of the substance, such as the chemical name, chemical composition, level of purity, molecular weight and spectroscopic data, and this information is verified by the Authority, the identity of the substances listed in table 1 of Annex I to Regulation (EU) No 10/2011 should be considered in relation to the identity of the substance specified in the opinion of the Authority. Therefore, if a level of doubt over the designation of a substance remains, the Authority should be consulted.
- (8) Regulation (EU) 2022/1616 on recycled plastic materials and articles aims, amongst others, at ensuring that incidental contamination is removed during the manufacture of recycled plastic materials intended to come into contact with food to an extent that the requirements of Article 3 of Regulation (EC) No 1935/2004 are met. Since Regulation (EU) 2022/1616 lays down that the requirements of Regulation (EU) No 10/2011

⁴ Commission Regulation (EU) 2022/1616 of 15 September 2022 on recycled plastic materials and articles intended to come into contact with foods, and repealing Regulation (EC) No 282/2008 (OJ L 243, 20.9.2022, p. 3, ELI: <http://data.europa.eu/eli/reg/2022/1616/oj>).

⁵ EFSA CEF Panel (EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids), 2008. Note for Guidance for the preparation of an application for the safety assessment of a substance to be used in plastic Food Contact Materials. EFSA Journal 2008;6(7):21r, 41 pp.; <https://doi.org/10.2903/j.efsa.2008.21r>.

⁶ EFSA Scientific Committee, 2018. Genotoxicity assessment of chemical mixtures. EFSA Journal 2019;17(1):5519, 11 pp. <https://doi.org/10.2903/j.efsa.2019.5519>.

apply to recycled plastic materials and articles, it is appropriate to include a reference to Regulation (EU) 2022/1616 in Regulation (EU) No 10/2011.

- (9) Experience shows, that in order to ensure a high level of protection of human health, it should be required that substances used in the manufacture of plastic materials and articles, are of high purity and this notion should be defined. However, specific rules need to be laid down as regards the purity of substances of natural origin. While a well-defined substance with a known chemical composition may be obtained if the natural material can be extracted and further purified, when a substance originates from a portion of an organism that has not had any of its components removed, or when the natural material has only been slightly refined, it has many different constituents, some of which may be unknown, and its composition can be variable or difficult to predict. Therefore, as regards substances of natural origin, it is appropriate to lay down the required level of purity in relation to the extent to which the chemical composition of those substances can be defined.
- (10) Regulation (EU) No 10/2011 does not impose restrictions on the source of substances that can be used in the manufacture of plastic materials and articles and, therefore, such substances may be manufactured from waste. However, substances manufactured from waste are likely to contain incidental contamination. To ensure a high level of protection of human health, it is appropriate to require that substances manufactured from waste are also of a high degree of purity.
- (11) Supporting documents should be kept available for the enforcement authorities at each stage of the manufacturing process. This documentation should also demonstrate compliance with the rules regarding the high level of purity introduced by this Regulation.
- (12) Since Regulation (EU) No 10/2011 sets out specifications for substances intended for the manufacturing of plastic materials and articles and for products from intermediate stages of that manufacturing, in order to ensure compliance with Regulation (EU) No 10/2011, Member States are to put in place effective control measures, including not only the sampling of plastic materials and articles, but also of those substances and products from intermediate stages. Therefore, it is appropriate to require that manufacturers facilitate inspections by ensuring that inspectors can take samples at each stage of the manufacturing process.
- (13) Since Directive (EU) 2019/904⁷ discourages the single use of plastic food contact materials due to their environmental impact, increasingly plastic materials and articles in contact with food are designed for repeated use. However, repeated use may lead to unacceptable deterioration of the plastic material or article, leading to an increase of constituents into food that may endanger human health. Such deterioration of plastic materials and articles is indicated by various signs, for example, by surface cracks (crazes), blisters, delamination, shrinkage or other deformation, and yellowing or other permanent discoloration or loss of gloss or transparency. However, usage related changes such as tainting from colorants from foods, including from lycopene and curcumin, or mechanical damage such as scratches or breakage, is not in principle a deterioration of the material or article, unless so extensive that it may result in higher migration of the constituents of the material or article. To prevent the use of unacceptable deteriorated plastic materials and articles, the manufacturer or other

⁷ Directive (EU) 2019/904 of the European Parliament and of the Council of 5 June 2019 on the reduction of the impact of certain plastic products on the environment (OJ L155, 12.6.2019, p. 1) aims to prevent and reduce the impact of certain single-use plastic products on the environment.

operator responsible for placing on the market of the plastic material or article should provide users of plastic food contact materials and articles with information about how to slow down deterioration and the changes that indicate the deterioration by a repeated use.

- (14) Article 15 of Regulation (EC) No 1935/2004 provides that materials and articles which are not yet in contact with food when placed on the market, if necessary, are to be accompanied by special instructions to be observed for safe and appropriate use. Where Regulation (EC) No 10/2011 sets out restrictions to the use of plastic materials and articles, such special instructions should always be provided to consumers.
- (15) Article 14(4) of Regulation (EU) No 10/2011 sets out that the rules on migration limits laid down in Articles 11 and 12 do not apply to plastic layers in multi-material multi-layer materials and articles. Since final plastic multi-material multi-layer materials or articles, in which the layer in direct contact with food is a plastic layer, may raise the same potential health risks as plastic material or articles, they should comply with the provisions concerning migration set out in Regulation (EU) No 10/2011.
- (16) The real surface-to-volume ratio of the final article serves as the basis for the rules on migration testing laid down in Regulation (EU) No 10/2011. To simplify migration testing, several exceptions to these rules have been established. However, to further increase food safety, it is appropriate to remove the exception for containers and other articles containing less than 500 millilitres or grams, since experience shows that this exception often leads to an underestimation of the real migration of substances into food.
- (17) Point 07.04 of Table 2 of Annex III to Regulation (EU) No 10/2011 assigns food simulants to categories of cheese. However, the present assignments, in particular categories 07.04.B and 07.04.C, do not correspond to the common interpretation and usage of 'natural cheese' and 'processed cheese'. More concretely, melting cheese is usually considered as a processed cheese, while cheeses similar to cottage cheese are commonly considered unprocessed natural cheeses. The present assignments also do not follow the terminology used in the 'FoodEx2 classification' established by the Authority⁸, in particular regarding unripened (fresh) and ripened cheese. Therefore, it is appropriate to amend the respective categories in order to classify in a better manner natural and processed cheeses and ripened and unripened cheese, while setting out simulant assignments appropriate for these new categories of cheese on the basis of the existing assignments.
- (18) In order to ensure safety, business operators need to receive all information relevant for the safety of the plastic materials and articles they manufacture or use. However, Regulation (EU) No 10/2011 only requires that the written declaration of compliance contains information on the substances used or products of degradation thereof for which restrictions and/or specifications are set out in Annex I and II to that Regulation. Also, no information is required on the lifespan of a plastic article or material. Nevertheless, usage may result in a higher migration of the constituents of the material or article. To further increase safety, it is appropriate to require that the declaration of compliance contains information also on other substances, impurities and products present in the materials and articles or intermediate material and the maximum lifespan of the material or article.

⁸ European Food Safety Authority, 2015. The food classification and description system FoodEx2 (revision 2). EFSA supporting publication 2015: EN-804. 90pp; <https://doi.org/10.2903/sp.efsa.2015.EN-804>.

- (19) The current rules as regards the written declaration of compliance do not require specifying whether the plastic material has been manufactured with substances manufactured from waste material, despite the fact that such substances may contain contaminants derived from wasted plastic materials and articles that could endanger human health. It is therefore necessary to amend the provisions for the declaration of compliance, so that the manufacturer of the final plastic article gets adequate information that would enable it to ensure compliance with the requirement laid down in Article 3(1) of Regulation (EC) No 1935/2004 that plastic materials and articles are not to endanger human health.
- (20) To achieve results that are comparable, laboratories need to conduct compliance testing under standardised test conditions. In addition, analysis of the test results needs to be carried out consistently. It is therefore appropriate to further specify the rules on the verification of compliance testing in Annex V to Regulation (EU) No 10/2011.
- (21) Regulation (EU) 2022/1616 lays down rules regarding quality assurance systems for collection, preprocessing, decontamination and recycling of plastic waste material were introduced by and this Regulation lays down rules for the reprocessing of plastic by-products of plastic manufacturing. To further increase food safety, detailed rules on good manufacturing practices should be laid down in Regulation (EC) No 2023/2006 as regards reprocessing and recycling.
- (22) Plastic by-products intended for re-processing might be re-processed at a manufacturing location other than the one from which they originally came. However, if it is not clear for what purpose these by-products would be suitable, or if they are contaminated during transport from the production facility from which they originate, their reprocessing could pose risks. Therefore, in order to prevent any use of plastic by-products for purposes for which they are not suitable and contamination of plastic by-products from the point where they are produced until their point of reprocessing, rules should be laid down in Commission Regulation (EC) No 2023/2006⁹. In addition, when such by-products are placed on the market, the declaration of compliance referred to in Article 15 of Regulation (EU) No 10/2011 shall provide the information required for their reprocessing, in particular as regards their suitability for particular uses.
- (23) In order to allow operators to adapt to the changes provided for in this Regulation and subject to Articles 89 to 94 of Regulation (EU) No 528/2012, where relevant, it is appropriate to provide that plastic materials and articles complying with Regulation (EU) No 10/2011, as applicable before the date of the entry into force of this Regulation, are allowed to be first placed on the market for a period of 18 months after the entry into force of this Regulation and remain on the market until the exhaustion of stocks. However, the production of final plastic materials and articles typically involves the supply of several products and substances from intermediate manufacturing stages by other operators. For the sake of consumer safety, the transition to full compliance with this Regulation should be achieved as efficiently as possible, and with minimum delay. Therefore, operators placing on the market, as of nine months before expiry of the 18-months transition period, intermediate products and substances that do not yet comply with this Regulation, should be required to

⁹ Regulation (EC) No 2023/2006 on good manufacturing practice for materials and articles intended to come into contact with food (OJ L 384, 29.12.2006, p. 75, ELI: <http://data.europa.eu/eli/reg/2012/528/oj>).

inform the users of those products that they cannot be used to manufacture plastic materials and articles to be placed on the market after the transition period expires.

- (24) 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
Amendments to Regulation (EU) No 10/2011

- (1) Article 2, paragraph 3 is replaced by the following:
- ‘3 This Regulation shall be without prejudice to the Union or national provisions applicable to printing inks, adhesives or coating on substances that may be used in the manufacture of adhesives, coatings and printing inks and applied on or incorporated in plastic materials and articles, if that use complies with Article 3 of Regulation (EC) No 1935/2004.’
- (2) Article 3 is amended as follows:
- (1) Point (7) is replaced by the following:
- ‘(7) ‘additive’ means a substance or material which is intentionally added to the plastic to achieve a physical or chemical effect during processing of the plastic or in the final material or article and it is intended to be present in the final material or article, including substances or materials in a solid state that become bonded to the polymer that constitute the plastic.’
- (2) The following point is added:
- ‘(20) ‘reprocessing of plastic’ means remelting, mixing, reacting or otherwise combining plastic materials resulting as a by-product from an intermediate or final manufacturing stage to use them again in the manufacture of plastic materials and articles alone or combined with material originating from earlier manufacturing stages.’
- (3) A new Article 3a is added:

‘Article 3a

High degree of purity

A substance used in the manufacture of plastic materials and articles shall be considered as having a high degree of purity where all of its constituents form part of its identity, and it otherwise contains only a minor amount of contaminants and non-intentionally added substances that fulfil one of the following conditions:

- (i) they comply with the specifications or restrictions specified in the authorisation of the substance in table 1 of Annex I, if any;
- (ii) they have been subject to a risk assessment in accordance with Article 19 and considered compliant;
- (iii) they have been subject to an individual toxicological assessment which concludes that genotoxicity is ruled out, in accordance with the relevant guidance adopted by the Authority, and they are present at a level in the plastic material or article that, assuming their full migration into food, cannot give rise

to an individual migration of any of them resulting in their presence in food exceeding 0.05 mg/kg;

- (iv) they are unknown or have not been subject to an assessment specified in points (ii) or (iii), but are present at a level in the plastic material or article that, assuming their full migration into food, cannot give rise to individual migration into food of any of them resulting in their presence in food exceeding 0.00015 mg/kg.

For the purpose of point (iii), the individual assessment of genotoxicity may be substituted with a group assessment of genotoxicity, if the assessed substances are chemically related and belong to the same or similar functional groups that could give rise to toxicity, or if the substances are obtained as a mixture representative for migration into food and this mixture is assessed through appropriate methods.

By derogation from points (iii) and (iv), 10% migration into food may be assumed where the substance is only intended for the manufacture of plastic materials and articles used to pack:

- dry unpeeled fruit or vegetables that must be peeled or washed,
- other dry non-fatty foods, if the packaging is in contact with less than 10% of the food surface and is open to the atmosphere, or,
- foods packed in sealed metal or glass packaging.’

- (4) In Article 4, the following paragraph is added:

‘(f) comply with Commission Regulation (EU) 2022/1616* if they fall within the scope of that Regulation.’

* Commission Regulation (EU) 2022/1616 of 15 September 2022 on recycled plastic materials and articles intended to come into contact with foods, and repealing Regulation (EC) No 282/2008 (OJ L 243, 20.9.2022, p. 3, ELI: <http://data.europa.eu/eli/reg/2022/1616/oj>).

- (5) In Article 5, paragraph 1 is replaced by the following:

‘1. Only the substances included in the Union list of authorised substances (hereinafter referred to as the Union list) set out in Annex I may be intentionally used in the manufacture of plastic materials and articles.’

- (6) In Article 5, the following paragraph is added:

‘4. In case of doubt over the resulting designated identity of a substance, a Member State or the Commission may consult the Authority.’

- (7) Article 6 is amended as follows:

(1) in paragraphs 1 and 2, the phrase ‘plastic layers in’ is deleted;

(2) in paragraph 4 the phrase ‘the plastic layers of’ is deleted;

(3) paragraph 5 is replaced by the following:

‘5. By way of derogation from Article 5, substances with a biocidal function used in biocidal products authorised to be made available on the Union market in accordance with Regulation (EU) No 528/2012** for product-type 4 for use that covers incorporation into plastic materials and articles which may enter into contact with food, may be used as additives in the manufacturing of plastic materials and articles.

**Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products (OJ L 167, 27.6.2012, p. 1, ELI: <http://data.europa.eu/eli/reg/2012/528/oj>).

(8) Article 7 is deleted.

(9) Article 8 is replaced by the following:

‘Article 8

General requirements on substances

1. Substances used in the manufacture of plastic materials and articles, including those manufactured from waste, shall be of a high degree of purity and shall be of a technical quality suitable for the intended and foreseeable use of the materials or articles.

Manufacturers of plastic materials and articles and of products from intermediate stages of their manufacturing shall know the composition of the substance and make it available to the competent authorities on request.

2. By derogation from paragraph 1, as regards purity, the following requirements shall apply to substances of natural origin:
 - (i) if the substance is identified by a name in this Regulation that refers to a natural multi constituent material where the source is biological, that substance may be used as obtained from its natural origin, provided it has been entirely separated from other natural materials from which the substance was obtained and that are not forming part of its identity, or,
 - (ii) if the substance is identified by a name in this Regulation that refers to a natural multi constituent material where the source is mineral, that substance may be used as obtained from its natural origin, provided it has been entirely separated from the other natural matter that is not forming part of its identity of the substance.

Any additional specifications or requirements applicable to a substance or material of natural origin set out in Table 1 of Annex I, applicable to the substance or material, shall apply.

3. Manufacturers of plastic materials and articles, and of products from intermediate stages of their manufacturing shall ensure that documentation showing compliance with paragraphs 1 to 2 is part of the documentation referred to in Article 16.
4. Manufacturers of plastic materials and articles, and of products from intermediate stages of their manufacturing shall ensure that competent authorities can take samples to verify their degree of purity and their composition, including that of the substances and materials used for their manufacture.’

(10) In Article 9, paragraph 1, the phrase ‘plastic layers in’ is deleted.

(11) Article 10 is replaced by the following:

‘Article 10

General restrictions and requirements concerning the composition of plastic materials and articles

1. The composition of plastic materials and articles shall meet the restrictions on plastic materials and articles laid down in Annex II.
2. Plastic materials and articles may contain reprocessed plastic if such reprocessed plastic meets the following conditions:
 - (a) it is collected in accordance with section B and C of the Annex to Regulation (EC) No 2023/2006;
 - (b) it originates only from off-cuts and scraps from plastic materials and articles referred to in point (a) of Article 2(1) that meet the compositional requirements set out in chapter II of this Regulation, and which are considered to be a by-product in accordance with Article 5 of Directive 2008/98/EC of the European Parliament and of the Council¹⁰;
 - (c) it does not contain substances in an amount which could:
 - (i) exceed migration limits applicable to the plastic materials and articles; or,
 - (ii) cause any other non-compliance of those plastic materials and articles with Article 3 of Regulation (EC) No 1935/2004;

(d) it does not contain constituents originating from the following sources unless each constituent is identified and complies with the conditions referred to in point (c) demonstrated on the basis of an assessment in accordance with Article 19:

- (i) food;
- (ii) printing, coating, or adhesives;
- (iii) substances used for processing the plastic from which the off-cuts and scraps originate, such as lubricants or cutting fluids.

3. Where intended for repeated use in contact with food, the composition of plastic materials and articles shall be such, so as to guarantee that no increase in the migration of constituents of the material or article to the food would occur during their maximum life span when subjected to subsequent use cycles.’

(12) The title of Chapter IV is replaced by the following:

‘LABELLING, DECLARATION OF COMPLIANCE AND DOCUMENTATION’

(13) A new Article 14a is added:

‘Article 14a
Labelling

1. The manufacturer or other operator responsible for placing on the market a material or article intended for repeated use shall provide information about its the maximum life span to its users by means of labelling or instructions, including appropriate instructions designed to slow down deterioration of the material or article, as well as a description of observable changes of the article

¹⁰ Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives (OJ L 312, 22.11.2008, p. 3, ELI: <http://data.europa.eu/eli/dir/2008/98/oj>).

or material that may indicate the deterioration of the article or material and that it has reached its maximum life span.

2. Plastic materials and articles intended to be brought into contact with food but are not yet in contact with food shall be labelled with instructions of use directed at the final user of that material or article at the moment of their sale or supply to consumers, where they are manufactured with substances included in the Union list of authorised substances, for which column 10 of table 1 of Annex I sets out restrictions related to one or more of the following elements:
 - specific foods or groups of foods,
 - contact time and/or temperature, and/or,
 - to heating conditions such as oven and microwave use,

The instructions of use shall mention the restrictions and provide the user with adequate information to prevent using the material or article under conditions not complying with them.

If such a material or article is intended for repeated use, such labelling shall be indelibly affixed to the material or article, unless that is not possible for technical reasons. A minimum font size of 3 mm (9 pt.) shall apply.'

(14) In Article 14, paragraph 4 is replaced by the following:

'4. Articles 11 and 12 apply to multi-material multi-layer materials and articles when the surface layer that is in contact with food is made of a material falling within the scope of this Regulation.'

(15) Article 14, paragraph 6 is replaced by the following:

'6. If the surface layer that is in contact with food is made of a material falling not within the scope of this Regulation, specific and overall migration limits for plastic layers and for the final material or article may be established by national law.'

(16) Article 17(2), point (a) is replaced with the following:

'(a) containers and other articles, containing or intended to contain more than 10 litres.'

(17) Annexes III to V are amended in accordance with Annex I to this Regulation.

Article 2

Amendments to Regulation (EC) No 2023/2006

The Annex to Regulation (EC) No 2023/2006 is amended in accordance with Annex II to this Regulation.

Article 3

Transitional measures

1. Plastic materials and articles complying with Regulation (EU) No 10/2011 as applicable before the entry into force of this Regulation, which were first placed on the market before [*enter date 18 months after the date of entry into force of this Regulation*] may continue to be placed on the market until the exhaustion of stocks.

2. In case a product from an intermediate stage of the manufacturing of plastic materials and articles or a substance intended for the manufacturing of such a product, material or article, which complies with Regulation (EU) No 10/2011 as applicable before the entry into force of this Regulation and which is first placed on the market after *[enter date 9 months after the date of entry into force of this Regulation]* does not comply with this Regulation, the declaration of compliance accompanying that substance or product shall indicate that it does not comply with this Regulation, and that it can only be used in the manufacture of plastic materials and articles to be placed on the market before *[enter date 18 months after the date of entry into force of this Regulation]*.

Article 4

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