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amending Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food, amending Regulation (EU) 2022/1616 on recycled plastic materials and articles intended to come into contact with foods, and repealing Regulation (EC) No 282/2008, 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/EEC [1], and in particular Article 5(1), points (a), (c), (d), (e), (h), (i) and (j) thereof,

Whereas:

(1) Commission Regulation (EU) No 10/2011 [2] 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, the compositional requirements for substances that can be used to manufacture plastic materials and articles are 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 the compositional requirements do not apply to those layers. 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 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) No 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 of 'plastic' in Regulation (EU) No 10/2011, 'plastic' consists of polymers to which additives or other substances may have been added, in order to achieve a physical or chemical effect in the plastic. That Regulation authorises additives and starting substances as two different categories. Therefore, an additive cannot be used as a starting substance if not authorised as such and vice versa. Typically, additives are not chemically bonded to the polymers. However certain particles, fibres, or other solid materials used in plastics to achieve a physical effect are bonded with or without the aid of a bonding agent to the polymer to ensure the overall integrity of the material. Given the definitions of plastic, additives, polymers and starting substances in Regulation (EU) No 10/2011 where this bond is a chemical bond there may be doubts as to whether such a solid material is to

[1] 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).

be regarded as an additive or as a starting substance. Therefore, uncertainty ensues over whether that solid material is to be authorised as an additive or as a starting substance. Consequently, it is appropriate to clarify the definition of additives. In particular, since the nature of starting substances makes them suitable for polymerisation, a process that involves significant chemical change, while solid materials used as additives remain substantially in the form in which they have been added, it should be considered that a solid material that is chemically bonded to the polymer to which it is added functions as an additive and not as a starting substance, even though its surface may still react with the polymers in the plastic.

(4) Certain authorised substances listed in Annex I to Regulation (EU) No 10/2011 are derived from materials of natural origin, including minerals and living organisms, which are also used as additives in plastics, as fibres or as small particles. These materials have historically been considered substances used for the manufacture of plastics and therefore as falling within the scope of that Regulation. However, the composition of those substances is complex, variable, and may not be fully known. As a result, it is difficult to define those substances' identities and this creates difficulties, since clearly defining those substances is important to distinguish each of them from other substances. These substances are referred to in Regulation (EC) No 1907/2006 of the European Parliament and the Council ([3]) as substances of unknown or variable composition, complex reaction products or biological materials ('UVCB'). To ensure better alignment of Regulation (EU) No 10/2011 with Regulation (EC) No 1907/2006 and, in particular, to facilitate the future alignment of the risk assessment and authorisation of such substances, it is therefore appropriate to apply this concept of UVCB substances also under Regulation (EU) No 10/2011.

(5) Pursuant to Article 5 of Regulation (EU) No 10/2011, the Union list of substances laid down in Annex I to that Regulation contains the substances authorised to be 'intentionally' used in the manufacture of plastic materials and articles. In certain cases Annex I also includes specifications on the impurities that may be present in the substance, provided they are relevant for the risk assessment and have the potential to affect human health. The same applies for any substance-related reaction and degradation products that can be formed during the manufacturing of the plastic material or article. However, those impurities, reaction and degradation products are not intentionally present in the plastic material or article. Therefore, it is appropriate to delete the word 'intentionally' in Article 5 of Regulation (EU) No 10/2011.

(6) Substances listed in Table 1 of Annex I to Regulation (EU) No 10/2011 are denoted by their 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 European Food Safety Authority ('the Authority'), the designated 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.

(7) 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, substances which are intended to be present in the final plastic materials or articles and having a biocidal function must have been authorised by the Commission or, pending such authorisation, be one of the substances included in the provisional list referred to in Article 7 of that

([3]) Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p. 1, ELI: http://data.europa.eu/eli/reg/2006/1907/2024-06-06).

Regulation. However, Regulation (EU) No 528/2012 of the European Parliament and of the Council ([4]) 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 articles, and the placing on the market of treated articles containing such products, such as food contact materials and articles. 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 biocidal active substances and biocidal products that may be used in the manufacturing of and intentionally present in plastic food contact materials.

(8) Regulation (EU) No 10/2011 presently lays down that substances used in the manufacture of plastic layers in plastic materials and articles are to be of a purity suitable for the intended and foreseeable use of the materials or articles. Experience shows that in order to ensure a high level of protection of human health and help business operators to assess the compliance of materials and articles with the Regulation (EU) No 10/2011, the concept of purity of substances used to manufacture food contact materials and articles should be defined. Given the current scientific information and regulatory provisions for the authorisation of substances used in the manufacturing of food contact materials and articles, it is appropriate to define the high degree of purity for substances used in the manufacturing of food contact materials or articles in relation to their identity and, as relevant, to the specifications or restrictions laid down in Annex I to Regulation (EU) No 10/2011, to a risk assessment in accordance with Article 19 or to the relevant guidance of the Authority. In this regard, 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 materials ([5]), the Authority has established the principle that the higher the exposure of consumers through migration of substances in food contact materials or articles into food, the more toxicological data would be needed. In particular, the Authority considers that, where a substance used in the manufacturing of a food contact materials or article has a migration level into food below of 0,00015 mg substance/kg food (0,15 µg/kg), the risk of genotoxicity is unlikely and no toxicity testing of the migrating substance is needed ([6]), and that, where it has a migration level of more than 0,15 µg/kg but less than 0,05 mg/kg only data on genotoxicity tests is needed ([7]). However, at the early stages in the manufacturing process of plastic materials and articles, the next manufacturing steps and/or the final use of the materials and articles may not be sufficiently known to calculate the migration levels of a substance into food. Therefore, to evaluate whether a substance used in the manufacturing of a food contact material or article complies with these threshold levels, it is appropriate to take into account factors that affect their concentration in and migration from the final materials and articles into food. Furthermore, where the assessment of genotoxicity of an individual substance is required, it should be possible to substitute it with an assessment of genotoxicity of a group of substances, but only under specific requirements ([8]).

(9) 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. Substances manufactured from waste may however contain incidental contamination. In order to protect human health and considering that certain manufacturing processes of substances can eliminate the presence of incidental contaminants or reduce it so as to ensure that contamination in the final plastic material does not result in a risk to human health, it should be required that substances produced from waste should also be of a high level of purity.

([4]) 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).

([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 CEF Panel (EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids), 2016. Scientific opinion on recent developments in the risk assessment of chemicals in food and their potential impact on the safety assessment of substances used in food contact materials. *EFSA Journal* 2016;14(1):4357, 28 pp. https://doi.org/10.2903/j.efsa.2016.4357.

([7]) 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.

([8]) 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.

(10) Specific rules need to be laid down as regards the purity of substances of natural origin, so-called UVCB substances. In some cases, a substance originates from a portion of an organism that has not had any of its components removed, or it originates from a natural material that has only been partially purified and, consequently, its full composition may be unknown or variable. However, in other cases, where the natural substance can be extracted from the natural material and further purified, a substance with a known chemical composition may be obtained. Therefore, as regards substances of natural origin, it is appropriate to specify how their identity is to be determined in order to apply the requirement of high degree of purity. Based on the latest knowledge, the Authority describes the identity of such substances as detailed as possible, including its composition, its source, the process used to obtain it, and specifies the uncharacterized fraction as far as possible. However, where historically such a detailed designation was not provided, the name of the substance should be the determining factor for its identification.

(11) 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 reprocessing of these by-products for manufacturing plastic materials and articles can contribute to the reduction of the occurrence of unusable manufacturing materials. If by-products can be used directly in the manufacturing of plastics without any further operations than normal industrial practices such as shredding and re-granulation, they are not considered waste. As Commission Regulation (EU) 2022/1616 ([9]) does not apply to these by-products and clarity is required over which by-products can be considered safe for reprocessing, rules should be laid down to ensure the safety of their use. It is therefore appropriate to include a definition of reprocessing to have a clear delineation between the products to which Regulation (EU) No 10/2011 apply and those to which Regulation (EU) 2022/1616 applies, and to lay down rules for the safe reprocessing of these by-products.

(12) Since Directive (EU) 2019/904 of the European Parliament and of the Council ([10]) discourages the use of single use 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 deterioration of the plastic material or article, leading to an increase of migration 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 and 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, is not in principle a deterioration of the material or article. To prevent the use of deteriorated plastic articles, the manufacturer or other operator responsible for placing on the market of the final plastic food contact article should provide users of plastic food contact articles with information about how to prevent or slow down deterioration and the changes that indicate the deterioration by repeated use.

(13) 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. It is appropriate to consider that, where Regulation (EC) No 10/2011 sets out restrictions to the use of plastic articles, it is always necessary that such special instructions are provided to consumers.

([9]) 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).

([10]) 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 L 155, 12.6.2019, p. 1, ELI: http://data.europa.eu/eli/dir/2019/904/oj) aims to prevent and reduce the impact of certain single-use plastic products on the environment.

(14) 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. However, since final 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, this layer should comply with the provisions concerning migration set out in Regulation (EU) No 10/2011. On the contrary, Articles 11 and 12 of Regulation (EU) No 10/2011 should still not apply to non-plastic layers in multi-material multi-layer materials. Other Union legislation or national rules may apply. Nonetheless, the migration limits set out in Regulation (EU) No 10/2011 continue to apply to plastic layers in materials and articles that are printed, coated or held together by adhesives.

(15) In order to further specify the obligations of business operators in relation to the information they are to supply to competent authorities, it should be required that business operators make available to competent authorities information on the composition of starting substances and supporting documents 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.

(16) In order to ensure compliance with Regulation (EU) No 10/2011, Member States are to have in place effective control measures, including the sampling of plastic materials and articles, as well as products from intermediate stages of the manufacturing process of plastic materials and articles. However, experience shows that inspectors may encounter practical challenges taking samples at certain stages of the manufacturing process on manufacturing sites. Therefore, it is appropriate to require that manufacturers facilitate inspections by ensuring that inspectors can take samples at relevant stages of the manufacturing process and they can take samples of substances and (intermediate) materials used for the manufacturing that are present on the manufacturing site.

(17) The real surface-to-volume ratio of the plastic final food contact article serves as the basis for the rules on migration testing laid down in Regulation (EU) No 10/2011. However, that Regulation establishes also that as regards certain materials and articles a fixed surface-to-volume ratio is to be applied, in order to facilitate the determination of the level of migration, in particular when testing articles not yet in contact with food, for which it is not feasible to determine the surface area that is in contact with food or to compensate for the expected level of over- or underestimation of the exposure of consumers to constituents in those materials and articles. However, in certain cases applying a fixed surface-to-volume ratio may lead to an underestimation of the exposure of consumers to constituents in those materials and articles that may endanger human health. Therefore, it is appropriate that business operators have the possibility to opt for the real surface-to-volume ratio instead of being obliged to use the fixed surface-to-volume ratio established for these exceptions.

(18) 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 the expressions 'natural cheese' and 'processed cheese'. More specifically, 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 Authority [11], 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.

(19) 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. To further increase

[11] European Food Safety Authority, 2015. The food classification and description system FoodEx2 (revision 2). *EFSA Supporting Publications* 2015: EN-804. 90pp; https://doi.org/10.2903/sp.efsa.2015.EN-804.

safety, it is appropriate to require that the declaration of compliance contains information also on non-intentionally added substances, such as impurities and reaction intermediates, decomposition, or reaction products formed during the manufacturing process of the plastic material or article and that could be present in the final food contact material or article.

(20) Even though substances manufactured from waste may contain contaminants derived from waste that could endanger human health, 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. 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.

(21) 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.

(22) Regulation (EU) 2022/1616 requires that recycled plastic materials and articles comply with Chapters II and III and Chapter V of Regulation (EU) No 10/2011. The high purity requirement laid down by this Regulation in Chapter II of Regulation (EU) No 10/2011 applies to substances used in the manufacture of plastic materials and articles. However, there is no need that the high purity requirement applies to as regards substances contained in the input and remaining in the output of the decontamination process of plastic waste since Regulation (EU) 2022/1616 ensures that incidental contamination is removed from the material 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. Therefore, concerning the manufacturing of recycled plastic materials and articles, the high purity requirement should apply only to any substance added during the recycling process and to any reaction intermediate, decomposition or reaction product resulting from that substance. It is therefore appropriate to further specify in Regulation which provisions apply of Regulation (EU) No 10/2011 to recycled plastic materials and articles.

(23) Regulation (EU) 2022/1616 lays down rules regarding quality assurance systems for collection, pre-processing, decontamination and recycling of plastic waste material. This Regulation introduces 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 Commission Regulation (EC) No 2023/2006 ([12]) as regards reprocessing and recycling.

(24) Plastic by-products intended for reprocessing might be reprocessed 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 storage or 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 Regulation (EC) No 2023/2006. 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 should provide the information required for their reprocessing, in particular as regards their suitability for particular uses.

(25) In order to allow operators to adapt to the changes provided for in this Regulation, 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, and any other relevant Union legislation 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

([12]) Commission Regulation (EC) No 2023/2006 of 22 December 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/2006/2023/oj).

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 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.

(26) 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 Union or national provisions applicable to substances that may be used in the manufacture of adhesives, coatings and printing inks and applied on or incorporated in plastic materials and articles.'.

2. Article 3 is amended as follows:

(1) point (7) is replaced by the following:

'(7) "additive" means a substance 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 in a solid state the surface of which becomes bonded to the polymers that constitute the plastic.';

(2) the following points are added:

'(20) "reprocessing of plastic" means the remelting, mixing, reacting or otherwise processing of plastic materials that result as a by-product from an intermediate or final manufacturing operation in the manufacture of plastic materials and articles, alone or combined with material originating from other manufacturing operations, by applying, if necessary, transfer and operations to make the use of these by-products possible again.

(21) "UVCB substance" means a substance of unknown or variable composition, complex reaction products or a material of a biological or other natural origin.'.

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 correspond to its identity, and it otherwise contains only a minor amount of non-intentionally added substances that individually 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 a toxicological assessment in accordance with the relevant guidance adopted by the Authority, which concludes that genotoxicity is ruled out, and that, on the basis of documented analysis concerning their foreseeable use, characteristics and fate during subsequent manufacturing stages, it can be reasonably assumed that none of the substances will be present in the final plastic material or article at a level that could give rise to a migration such as to their individual presence in food exceeding 0,05 mg/kg;

(iv) they have not been subject to an assessment specified in points (ii) or (iii), but to a risk assessment which concludes, on the basis of documented analysis concerning their foreseeable use, characteristics and fate during subsequent manufacturing stages, that it can be reasonably assumed that they cannot be present in the final plastic material or article at a level that could give rise to a migration into food such as to their individual 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.'.

4. In Article 4, the following point is added:

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

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(*) 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 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) paragraph 1 is replaced by the following:

'1. By way of derogation from Article 5, substances other than those included in the Union list may be used as polymer production aids in the manufacture of plastic materials and articles subject to national law.';

(2) paragraph 2 is replaced by the following:

'2. By way of derogation from Article 5, colorants and solvents may be used in the manufacture of plastic materials and articles subject to national law.';

(3) paragraph 4 is replaced by the following:

'4. The following substances not included in the Union list may be present in plastic materials or articles:

(a) non-intentionally added substances;

(b) aids to polymerisation.';

(4) paragraph 5 is replaced by the following:

'5. By way of derogation from Article 5, substances with a biocidal function used in biocidal products that may be made available on the Union market in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council (*) 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.

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(*) 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 that may be present in the final plastic material, 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.

The composition shall be known to the manufacturer of the substance.

2. By derogation from paragraph 1, as regards purity, UVCB substances that are identified by a name in this Regulation that refers to a natural multi constituent material the source of which is biological or mineral, may be used as obtained from their natural origin, provided they do not contain substances or materials that do not correspond to its identity as designated by that name. 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.'.

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. 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 a by-product in accordance with Article 5 of Directive 2008/98/EC of the European Parliament and of the Council (*);

(b) it is collected and used in accordance with section C of the Annex to Regulation (EC) No 2023/2006;

(c) it originates from one of the following off-cuts and scraps from plastic materials and articles:

(i) 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, or

(ii) off-cuts and scraps from plastic materials and articles referred to points (b) and (c) of Article 2(1), provided that such reprocessed plastic does not contain a layer which functions as a functional barrier and all of its individual constituents either meet the compositional requirements set out in Chapter II of this Regulation, or have been subject to risk assessment on the basis of Article 19 taking into account the conditions of reprocessing and their presence in the reprocessed material;

(d) it does not contain substances in an amount which could:

(i) exceed migration limits applicable for the substance as specified in this Regulation; or

(ii) cause any other non-compliance of those plastic materials and articles with Article 3 of Regulation (EC) No 1935/2004.

3. Where intended for repeated use in contact with food, the composition and the design of final food contact 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 when subjected to subsequent use cycles of the articles in accordance with the instructions for intended use as described in documentation or labelling.

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(*) 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).'.

12. Article 13 is amended as follows:

(1) in point (b) of paragraph 2, the phrase 'in the provisional list' is deleted;

(2) in paragraph 4 the phrase 'or provisional list' is deleted.

13. The title of Chapter IV is replaced by the following:

'LABELLING, DECLARATION OF COMPLIANCE AND DOCUMENTATION'.

14. A new Article 14a is added:

'*Article 14a*

Labelling

1. The manufacturer or other operator responsible for placing on the market a final plastic food contact article intended for repeated use, shall provide to its users in accordance with Articles 15(7) and (8) of Regulation (EC) No 1935/2004 the following:

(a) appropriate instructions designed to slow down deterioration of the article;

(b) a description of observable changes of the article that may indicate the deterioration of the article or material;

(c) a warning in case specific damages or foreseeable misuse would cause increased migration or would cause the article to become otherwise unsuitable for further use in contact with food.

2. Plastic materials and articles intended to be brought into contact with food but which are not yet in contact with it shall be accompanied at the moment of their sale or supply to consumers at retail stage with instructions of use, in accordance with Article 15(1) of Regulation (EC) No 1935/2004, directed at the consumer of that final food contact article, 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

— heating conditions such as oven and microwave use.

The instructions of use shall mention the restrictions and provide the consumer with adequate information to avoid using the article under conditions not complying such restrictions.'.

15. Article 14 is amended as follows:

(1) in paragraphs 2 and 3, the phrase 'or the provisional list' is deleted;

(2) 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.';

(3) 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 16 is replaced with the following:

'*Article 16*

Supporting documents

1. Appropriate documentation to demonstrate that the materials and articles, products from intermediate stages of their manufacturing as well as the substances intended for the manufacturing of those materials and articles comply with the requirements of this Regulation shall be made available by the business operator to the national competent authorities on request.

For substances used in the manufacture of plastic materials and articles, documentation on the composition shall be made available to the competent authorities on request, together with any documentation regarding their degree of purity.

2. That documentation shall contain the conditions and results of testing, calculations, including modelling, other analysis, and evidence on the safety or reasoning demonstrating compliance. Rules for experimental demonstration of compliance are set out in Chapter V.

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 of Article 8 is part of the documentation referred to in paragraph 1.

4. Manufacturers of plastic materials and articles, and of products from intermediate stages of their manufacturing, shall ensure that competent authorities can take samples during the carrying out of official controls to verify their degree of purity and their composition, including that of the substances and materials used for their manufacture.'.

17. In Article 17, paragraph 2 is replaced with the following:

'2. By derogation from paragraph 1, a surface to volume ratio equal or higher than 6 dm^2 per kg of food may be applied for the following materials and articles:

(a) containers and other articles, containing or intended to contain a volume of less than 500 ml or more than 10 litres;

(b) a material or article for which, due to its form, it is impracticable to estimate the relationship between its surface area and the quantity of food in contact therewith;

(c) sheets and films that are not yet in contact with food;

(d) for sheets and films containing a volume less than 500 ml, or more than 10 litres.

This paragraph does not apply to plastic materials and articles intended to be brought into contact with or already in contact with food for infants and young children, as defined by Regulation (EU) No 609/2013 of the European Parliament and of the Council (*).

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(*) 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, ELI: http://data.europa.eu/eli/reg/2013/609/oj).'.

18. Annexes III to V are amended in accordance with Annex I to this Regulation.

Article 2

Amendment to Regulation (EU) 2022/1616

In Article 4, paragraph 2 is replaced by the following:

'2. The requirements set out in Chapters II and III and Chapter V of Regulation (EU) No 10/2011 shall apply to recycled plastic materials and articles. Article 8(1) thereof shall not apply to the contaminants in the input and the output of decontamination processes and the quality and purity of the input and output shall be in accordance with this Regulation.'.

Article 3

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 4

Transitional measures

1. Plastic materials and articles complying with Regulation (EU) No 10/2011 as applicable before the entry into force of this Regulation, and any other relevant Union legislation, which were first placed on the market before 16 September 2026 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 16 December 2025 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 16 September 2026.

Article 5

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, 21 February 2025.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX I

Annexes III to V to Regulation (EU) No 10/2011 are amended as follows:

(1) in Table 2 of Annex III, the descriptions and simulant assignments for cheeses with reference number 07.04 are replaced by the following:

(1)	(2)	(3)					
Reference number	Description of food	Food simulants					
		A	B	C	D1	D2	E
‘07.04	Cheeses:						
	A. Whole cheese with inedible rind						X’
	B. Unripened soft cheese (fresh cheese), e.g. cottage cheese, quark, ricotta, cream cheese, fromage frais, and similar cheeses		X (*)		X		
	C. Sliced ripened soft, firm or hard cheese or whole with edible rind, e.g. gouda, cheddar, gruyère, parmesan, stilton, tallegio, beaufort, tomino, brie, camembert, and similar cheeses					X/3	
	D. Processed cheese, e.g. wedges, spreads and slices					X/3	
	E. Brined or fresh cheese in a liquid medium e.g. feta and mozzarella:						
	I. in an oily medium					X	
	II. in an aqueous medium		X (*)		X		

(2) Annex IV is amended as follows:

(a) point 6 is replaced by the following:

‘6. adequate information allowing the downstream business operators to ensure compliance with this Regulation relative to the substances used for which restrictions and/or specifications are set out in Annexes I and II, including adequate information on the presence of non-intentionally added substances if present in an amount that could cause non-compliance of a final material with Article 3 of Regulation (EC) No 1935/2004.

At intermediate stages, this information shall include the identification and amount of the following substances contained in the intermediate material:

— substances that are subject to restrictions and/or specifications in Annex II, or

— substances for which genotoxicity has not been ruled out, and which originate from an intentional use during a manufacturing stage of that intermediate material and which could be present in an amount that foreseeably gives rise to an individual migration into food from the final plastic material or article exceeding 0,00015 mg/kg food;’;

(b) points 10 and 11 are added:

‘10. when the plastic material is a batch of material intended for reprocessing:

(a) the confirmation that it complies with Articles 10(1) and 10(2) of this Regulation and that it has been collected and used in accordance with point C of the Annex to Regulation (EC) No 2023/2006; and

(b) as appropriate, a specification of its composition and instructions for reprocessing;

11. when the plastic material has been manufactured with one or more substances included in the Union list of authorised substances in accordance with Article 5 of this Regulation that have been manufactured from waste, a confirmation that the substances used are compliant with point (1) of Article 8 of this Regulation.';

(3) Annex V is amended as follows:

(a) The introductory part on compliance testing preceding Chapter 1 is replaced by the following:

'**COMPLIANCE TESTING**

For testing compliance of migration from plastic food contact materials and articles, an analytical method in accordance with the requirements of Article 34 of Regulation (EU) 2017/625 of the European Parliament and of the Council (*) shall be selected, applying the following specific performance criteria:

(i) The analytical method working range of analytical methods shall be at least R_L × SML to R_U × SML, as described in the relevant guidance documents, where

— R_L is the relative lower method working range threshold,

— R_U is the relative upper method working range threshold,

— R_U shall be 2. R_L shall be 0,2 unless 0,2 × SML is below the analytical limit of quantification (LOQ) of the substance then the R_L × SML is set at the LOQ of the substance.

(ii) Prior to the verification of compliance with a SML, the specific migration test result, *m*, needs to be corrected, if relevant: (1) by the real surface-to-volume ratio ($(S/V)_{real}$) and the surface-to-volume ratio $(S/V)_{test}$ in accordance with Article 17; and/or (2) by the correction factor (C_{T2}) used in the sub-columns for the food simulants D2 and E in Table 2 of Annex III to Regulation (EU) No 10/2011; and/or (3) by the FRF in accordance with point 4.1 of this Annex. When the results are corrected in application of C_{T2} in combination with the FRF, in accordance with point 4.1 in Annex V, the combined correction factor shall not exceed 5, unless the correction factor laid down in Table 2 of Annex III exceeds 5.

(iii) The reproducibility coefficient of variation CV_R, which can be expressed in percentage if multiplied by 100, is used to calculate the relative standard measurement uncertainty with the purpose to evaluate compliance. The formulas for calculating the CV_R are as follows:

$CV_R = 0,22$ for $m_c < 0,12 \times 10^{-6}$ kg /kg; and,

$CV_R = 2^{(1-½\log(m_c))}/100$ for $0,12 \times 10^{-6}$ kg/kg ≤ m_c ≤ 0,138 kg/kg.

Where m_c is the specific migration test result of a substance or, if relevant, the corrected specific migration result that is to be evaluated against the SML set out in this Regulation, the standard measurement uncertainty of m_c of a substance, $u(m_c)$, shall be determined as follows: $u(m_c) = CV_R \times m_c$.

(iv) The compliance with the SML shall then be evaluated by applying the following specific performance criterion, where m_c is to be evaluated against the SML:

If $(m_c - \text{SML})/[(u(m_c)] > 1{,}64$, then m_c exceeds the SML.

If m_c is higher than the SML the m_c of a substance shall be considered non-compliant. In addition, the rules in Chapter 1-4 of this Annex shall apply.

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(*) 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, ELI: http://data.europa.eu/eli/reg/2017/625/oj).';

(b) in Chapter 2 of Annex V, point 2.1.6 of is replaced by the following:

'If the material or article is intended to come into repeated contact with foods, the migration test shall be carried out three times on a single sample using another portion of food simulant on each occasion. Compliance of the material or article shall then be verified on the basis of the level of the specific migration observed in the third migration test and on the basis of the stability of the material or article. The specific migration observed in the second migration test shall not exceed the level observed in the first test, and the specific migration in the third test shall not exceed the level observed in the second test.

For the purpose of the first paragraph, the sample shall be considered non-compliant if:

$m_{c,3} > \text{SML}$, or,

$m_{c,1} < m_{c,2}$, or,

$m_{c,2} < m_{c,3}$, or,

$m_{c,1} < m_{c,3}$,

where $m_{c,1}$, $m_{c,2}$, and $m_{c,3}$ are respectively the m_c during the first, the second and the third migration test carried out in accordance with the first subparagraph.

The compliance with the SML and the stability rule shall be evaluated applying the following criteria:

— If $(m_{c,3} - \text{SML})/[(u(m_{c,3})] > 1{,}64$, then the third migration is higher than the SML,

— If $(m_{c,2} - m_{c,1})/[(u(m_{c,2}) + u(m_{c,1})] > 1{,}64$, then the first migration is smaller than the second migration,

— If $(m_{c,3} - m_{c,2})/[(u(m_{c,3}) + u(m_{c,2})] > 1{,}64$, then the second migration is smaller than the third migration,

— If $(m_{c,3} - m_{c,1})/[(u(m_{c,3}) + u(m_{c,1})] > 1{,}64$, the first migration is smaller than the third migration.

In case m_c is smaller than $R_L \times \text{SML}$, the m_c shall be considered equal to $R_L \times \text{SML}$. This m_c shall be used for determining the corresponding standard measurement uncertainty of the m_c and for evaluating the compliance with the performance criteria set out in this point.

However, if there is scientific proof that the level of the specific migration is not increasing as described in the second paragraph above in the course of the second and third migration tests and if the SML is not exceeded during the first migration test, the material or article is considered compliant with the SML laid down in this Regulation.

Irrespective of the above rules, a material or article shall never be considered to comply with this Regulation where in any of the migration tests a substance that is prohibited from migrating or from being released in detectable quantities under Article 11(4) of this Regulation is detected.';

(c) in Chapter 2 of Annex V, text of point 2.1.7 is replaced by the following:

'At the end of the prescribed contact time, the specific migration is analysed in the food or food simulant using an analytical method in accordance with the applicable performance criteria laid down in this Annex.';

(d) in Chapter 3 of Annex V, text of point 3.3.2 is replaced by the following:

'The applicable overall migration test shall be carried out three times on a single sample using a different portion of food simulant on each occasion. The migration shall be determined using an analytical method in accordance with the requirements of Article 34 of Regulation (EU) 2017/625. Compliance with the overall migration limit shall be verified on the basis of the level of the overall migration found during the third test and on the basis of the stability of the material or article i.e. the overall migration during the second test shall not exceed the level observed in the first test, and the overall migration in the course of the third test shall not exceed the level observed during the second test. The compliance shall be evaluated in accordance with the specific performance criteria described in point 2.1.6 in Chapter 2 of Annex V. However, the standard measurement uncertainty of the analytical method as determined by the laboratory shall be used to determine u(*m*), instead of the standard measurement uncertainty derived on the basis of the approach as specified in the introductory part on compliance testing preceding Chapter 1.

If it is not technically feasible to test the same sample three times, such as when testing in vegetable oil, the overall migration test can be carried out by testing different samples for three different periods of time lasting one, two and three times the applicable contact test time. The first migration, the difference between the second and the first migration and the difference between the third and the second migration shall be considered to represent the three successive overall migrations.

However, if there is scientific proof that the level of the migration, as described in point 2.1.6 in Chapter 2 of Annex V, is not increasing during the second and third migration tests and if the migration limit is not exceeded in the course of the first migration test, the material or article is considered compliant with the overall migration limit.'.

ANNEX II

The Annex to Regulation (EC) No 2023/2006 is amended as follows:

(1) the title of section B and point 1 thereof are replaced by the following:

'B. **Minimum requirements for a quality assurance system to be operated at recycling facilities, where recycled plastic is manufactured in accordance with Regulation (EU) 2022/1616**

1. The quality assurance system implemented by the recycler must give adequate confidence in the ability of all recycling operations taking place at the facility to ensure the recycled plastic meets the requirements set out in Regulation (EU) 2022/1616.';

(2) in section B, the following paragraph is added:

'3. The quality assurance system implemented by the recycler shall include specific operations in the recycling process, "Quality Assessment Stages", at which the recycler shall assess the quality of each batch of material directly originating from a manufacturing stage.

This assessment shall check the quality of that material by verifying:

— whether the applicable critical limits referred to in point 2, point (c) have been met at each unit operation that is part of the manufacturing stage, and

— whether the quality of the resulting material meets pre-defined criteria, using the tests, protocols and evidence referred to in point 2, point (e) applicable to the manufacturing stage.

The assessment shall result in a decision on whether the quality of the batch is considered as complying with Regulation (EU) 2022/1616 and suitable for further processing, whether its quality requires correction before further processing or, whether the batch is to be discarded or used for non-food applications.';

(3) the following section C is added:

'C. **Reprocessing of plastics falling within the scope of Regulation (EU) No 10/2011**

1. Plastic offcuts, scraps, and similar by-products of plastic manufacturing processes and intended to be reprocessed in accordance with Article 10(2) of Regulation (EU) No 10/2011 ("materials intended for reprocessing") shall be collected separately from waste as close as technically achievable to the point at which they are cut, scrapped or otherwise produced from a similar plastic manufacturing operation leading to offcuts and scraps and similar by-products of plastic.

2. Materials intended for reprocessing shall be collected either using a closed piping or belt system intended for that purpose only, or in clean bins, bags, or other containers designated to this purpose and which can easily be recognised as being intended only for this purpose. Those types of containers shall be closed as soon as they are fully filled. Up to the point of reinsertion in the plastic production process the applied containers shall be designed to prevent any contamination of the plastic material.

3. Such bins, bags or containers may be transferred for reprocessing individually or be grouped in secondary packaging. The resulting unit shall be considered as a batch of material intended for reprocessing. The definition of "batch" in Article 2(3), point (20) of Regulation (EU) 2022/1616 shall apply.

4. At any stage of the reprocessing of plastic, operators shall ensure that the quality assurance system prevents it from being mixed with plastic of a different composition, other materials, or with waste. The transfer of batches of plastic by-products between operations prior to their use in the manufacturing of plastic materials and articles, including the mixing with plastic of the same composition, shall be recorded and their traceability shall be accounted for in the quality assurance system.'.