Working group FCM –quality amendment

Brussels– 2 September 2024

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1

Quality amendment

This presentation is intended to facilitate discussion and understanding of the matters presented. It does not necessarily represent a final position and does not commit the European Commission. The European Commission accepts no responsibility for the accuracy of any data or information contained in this presentation, which may be under validation or preliminary assessment. Only the Court of Justice of the European Union is competent to authoritatively interpret Union law.

2

Time-line

- Have your say: deadline 15 April 2024
- SPS deadline 24 May 2024; TBT deadline 8 June 2024
- Information event 14 June 2024
- WG FCM 2 September 2024
- PAFF 20 September 2024
- Scrutiny EP and Council
- Publication 2025

Main points raised in feedback

1. High purity requirement for substances
2. Substances of natural origin
3. Lifespan
4. Migration testing for multi-material multi-layer materials
5. Surface to volume ratio small containers

Feedback in the period June-August 2024

1. ALPLA Werke
2. Flexible Packaging Europe
3. Contact Sensitive & Food Contact Plastics Regulatory Expert Panel
4. IK Industrievereinigung
5. Metal Packaging Europe
6. European Plastic Converters
7. PlasticsEurope
8. PlasticRecyclersEurope

5

The presentation shows changes from the version of the quality amendment that was given at the Information Event for stakeholders (14 June 2024)

6

High degree of purity Article 3a (1st slide)

- Article 3a: Amending the points iii) and iv): apply to substances used in the manufacturing, present in the final plastic material, considering the impact of the manufacturing process and the characteristics of the substance

(iii) they have been subject to an toxicological assessment in accordance with the relevant guidance adopted by the Authority, which concludes that genotoxicity is ruled out, and 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 are present at a level in the final plastic material that cannot give rise to a migration resulting in 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 at a level in the final plastic material that can give rise to a migration into food resulting in their individual presence in food exceeding 0.00015 mg/kg.

High degree of purity Article 3a (2nd slide)

Only editorial changes

14 June 2024 version

(iii) they have been subject to an toxicological assessment in accordance with the relevant guidance adopted by the Authority, which concludes that genotoxicity is ruled out, and 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 are present at a level in the final plastic material that cannot give rise to a migration resulting in 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 at a level in the final plastic material that can give rise to a migration into food resulting in their individual presence in food exceeding 0.00015 mg/kg.

2 September 2024 version

(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··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·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.¶

High degree of purity (3rd slide)

Recital (9)

' …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 the concentration in and migration from the final materials and articles into food such as the specificities of the manufacturing process of the plastic material or article, the characteristics of the substance and the intended use and characteristics of the final materials and articles…'

'…The level of migration into food can be determined by using experimental data on the actual migration levels of these substances or similar substances, modelling or other general accepted technical methods…'

High degree of purity Article 8 (4th slide)

- Article 8(1): revised text referring to 'final plastic material'
- Article 8(3): supporting documentation shall show compliance with high purity requirement

Current text in Plastics Regulation

Article 8

General requirement on substances

Substances used in the manufacture of plastic layers in plastic materials and articles shall be of a technical quality and a purity suitable for the intended and foreseeable use of the materials or articles. The composition shall be known to the manufacturer of the substance and made available to the competent authorities on request.

'*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 and made available to the competent authorities on request, together with any documentation regarding their degree of purity.

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.

High degree of purity Article 8 (fifth slide)

Article 8(3) is moved to Article 16(3)

14 June 2024 version

'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 and made available to the competent authorities on request, together with any documentation regarding their degree of purity.

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.

2 September 2024 version

'Article 8

General requirements on substances

.. → 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.

'Article 16

Supporting documents

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.

11

High degree of purity DoC (6th slide)

- Link to Declaration of compliance in Article 15 and Annex IV

Article 15

Declaration of compliance

(5) confirmation that the plastic materials or articles, products from intermediate stages of manufacture or the substances meet the relevant requirements laid down in this Regulation and in Article 3, 11(5), 15 and 17 of Regulation (EC) No 1935/2004;

(6) adequate information relative to the substances used or products of degradation thereof for which restrictions and/or specifications are set out in Annex I and II to the Regulation to allow the downstream business operators to ensure compliance with the Regulation.

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

— that are subject to restrictions in Annex II, or

— 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 a migration from the final material exceeding 0,00015 mg/kg food or food simulant;

ANNEX IV

Declaration of compliance

Annex IV is amended as follows:

(a) → point 6 is replaced by the following:

'6. → adequate information relative to the substances used including non-intentionally added substances that are present for which restrictions and/or specifications are set out in Annexes I and II to allow the downstream business operators to ensure compliance with the Regulation, 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 substances in the intermediate material,

– → that are subject to restrictions and/or specifications Annex II, or

– → 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 or food simulant;';

12

High degree of purity –Annex IV (7th slide)

Only editorial changes

- Link to Declaration of compliance in Article 15 and Annex IV

14 June 2024 version

Annex IV is amended as follows:

(a) → point 6 is replaced by the following:

'6. → adequate information relative to the substances used including non-intentionally added substances that are present for which restrictions and/or specifications are set out in Annexes I and II to allow the downstream business operators to ensure compliance with the Regulation, 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 substances in the intermediate material,

– → that are subject to restrictions and/or specifications Annex II, or

– → 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 or food simulant;';

2 September 2024 version

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 substances in the intermediate material,

– → that are subject to restrictions and/or specifications Annex II, or

– → 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 or food simulant;';

13

High degree of purity - amendment Recycling Regulation (8th slide)

- Amendment of Recycling Regulation: the purity requirement in Article 8(1) does not apply to input and output of decontamination process

Article 2

Amendment to Regulation (EC) No 2022/1616

Article 4, paragraph 2 of Regulation (EC) No 2022/1616 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. By derogation from Article 8(1) thereof, the quality and purity of plastic input and the output of a decontamination processes shall be in accordance with this Regulation.'

14

High degree of purity –amendment Recycling Regulation (9th slide)

It is emphasized that the substances used in the manufacturing of plastics, including those manufactured from waste, must meet the high purity requirement (see Article 8(1)).

Only editorial changes

14 June 2024 version

Article 2

Amendment to Regulation (EC) No 2022/1616

Article 4, paragraph 2 of Regulation (EC) No 2022/1616 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. By derogation from Article 8(1) thereof, the quality and purity of plastic input and the output of a decontamination processes shall be in accordance with this Regulation.'

2 September 2024 version

Article 2

Amendment to Regulation (EC) No 2022/1616

Article 4, paragraph 2 of Regulation (EC) No 2022/1616 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 a decontamination processes and the quality and purity of the input and output shall be in accordance with this Regulation.'

15

High degree of purity (10th slide)

(10) ' …Substances manufactured from waste may however contain incidental contamination. However, 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. Manufacturers and operators using these substances would consequently be able to ensure that those substances are of a high level of purity as defined in this Regulation. …'

(23) '…The high purity requirement in Regulation (EU) No 10/2011 is included in Chapter II of Regulation (EU) No 10/2011 and it applies to substances used in the manufacture of plastic materials and articles. As a result, recycled plastic and recycled plastic materials and articles, and any contaminants derived of the plastic input which entered into a decontamination process of plastic waste, are not subject to the requirement of high purity …However, the high purity requirement should apply 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. '

16

Substances of natural origin (1st slide)

- Article 8(2): addressing purity requirement for substances where the source is biological or mineral

'Article 8

General requirements on substances

2. By derogation from paragraph 1, as regards purity, for UVCB substances that are identified by a name in this Regulation that refers to a natural multi constituent material where the source is biological or mineral, that substance may be used as obtained from its natural origin, provided it does 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.

Substances of natural origin (2nd slide)

Only editorial changes

14 June 2024 version

'Article 8

General requirements on substances

2. By derogation from paragraph 1, as regards purity, for UVCB substances that are identified by a name in this Regulation that refers to a natural multi constituent material where the source is biological or mineral, that substance may be used as obtained from its natural origin, provided it does 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.

2 September 2024 version

'Article 8

General requirements on substances

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.'

Substances of natural origin (3rd slide)

Recital (11)

(11) ' …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 and/or may be 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…Based on the latest knowledge, the identity of such substances should be described as detailed as possible, including its composition, its source, the process used to obtain it, and the uncharacterized fraction should be specified 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. '

19

Lifespan

- References to lifespan are removed in Article 10(3), Article 14a(1) and point 8 of Annex IV (DoC)

No change of approach

20

Migration and multi-material multi-layer materials (1st slide)

SMLs and OML apply only to the plastic layer in direct contact with food; for other parts of MMML Articles 11 and 12 do not apply.

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.'

Current text in Plastics Regulation

Article 3

Definitions

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

(1) 'plastic materials and articles' means:

(a) materials and articles referred to in points (a), (b) and (c) of Article 2(1); and

(b) plastic layers referred to in Article 2(1)(d) and (e);

Article 11

Specific migration limits

1. Plastic materials and articles shall not transfer their constituents to foods in quantities exceeding the specific migration limits (SML) set out in Annex I. Those specific migration limits (SML) are expressed in mg of substance per kg of food (mg/kg).

Article 14

Multi-material multi-layer materials and articles

1. In a multi-material multi-layer material or article, the composition of each plastic layer shall comply with this Regulation.

4. By derogation from paragraph 1, Articles 11 and 12 of this Regulation do not apply to plastic layers in multi-material multi-layer materials and articles.

21

Migration and multi-material multi-layer materials (2nd slide)

No change of approach

14 June 2024 version

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.'

2 September 2024 version

Article 14 is amended as follows:

(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.'

22

Migration and multi-material multi-layer materials (3rd slide)

Recital (15)

(15) ' …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… '

Surface to volume ratio (1st slide)

Current text in Plastics Regulation

Article 17

Expression of migration test results

1. To check the compliance, the specific migration values shall be expressed in mg/kg applying the real surface to volume ratio in actual or foreseen use.

2. By derogation from paragraph 1 for:

(a) containers and other articles, containing or intended to contain, less than 500 millilitres or grams or more than 10 litres,

(b) materials and articles for which, due to their form it is impracticable to estimate the relationship between the surface area of such materials or articles and the quantity of food in contact therewith,

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

(d) sheets and films containing less than 500 millilitres or grams or more than 10 litres,

the value of migration shall be expressed in mg/kg applying a surface to volume ratio of 6 dm^2 per kg of food.

Article 17(2) is replaced with the following: ¶

'2. By derogation from paragraph 1 for:¶

(a) → containers and other articles of a volume of less than 100 ml, a surface to volume ratio of 12 dm^2 per kg of food may be applied,¶

(b) → a material or article for which, due to their form it is impracticable to estimate the relationship between the surface area of such materials or articles and the quantity of food in contact therewith, a surface to volume ratio of 12 dm^2 per kg of food may be applied,¶

(c) → sheets and films that are not yet in contact with food, a surface to volume ratio of 12 dm^2 per kg of food may be applied. ¶

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 Directives 2006/141/EC and 2006/125/EC.'¶

Surface to volume ratio (2nd slide)

Change the article to 'may' provision; leave the provisions in Article 17(2) exactly as they are in the currently applicable regulation. The possibility of generating new data on food packaging uses and health risks will be explored with EFSA.

14 June 2024 version

Article 17(2) is replaced with the following: ¶

'2. By derogation from paragraph 1 for: ¶

(a) → containers and other articles of a volume of less than 100 ml, a surface to volume ratio of 12 dm^2 per kg of food may be applied, ¶

(b) → a material or article for which, due to their form it is impracticable to estimate the relationship between the surface area of such materials or articles and the quantity of food in contact therewith, a surface to volume ratio of 12 dm^2 per kg of food may be applied, ¶

(c) → sheets and films that are not yet in contact with food, a surface to volume ratio of 12 dm^2 per kg of food may be applied. ¶

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 Directives 2006/141/EC and 2006/125/EC.' ¶

2 September 2024 version

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

(b) → for 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) → for 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 Directives 2006/141/EC and 2006/125/EC.' ¶

Taking samples by authorities

Provision moved from Article 8(4) to Article 16(4); editorial changes.

14 June 2024 version

'Article 8

General requirements on substances

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.'

2 September 2024 version

Article 16 is replaced with the following: ¶

'Article 16 ↵

Supporting documents ¶

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.' ¶

¶

Reprocessed plastics

Editorial changes of Article 10(2).

14 June 2024 version

'Article 10

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

2. Plastic materials and articles may contain reprocessed plastic if such reprocessed plastic meets the following conditions:

(a) it can be considered to be a by-product in accordance with Article 5 of Directive 2008/98/EC of the European Parliament and of the Council[2];

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

(c) 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;

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

(i) exceed migration limits applicable for the substance as specified in Regulation (EU) No 10/2011; or,

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

(e) by derogation to point (c), it may originate from off-cuts and scraps from plastic materials and articles referred to points (b) and (c) of Article 2(1), and 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.

2 September 2024 version

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[2];¶

(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 following off-cuts and scraps from plastic materials and plastics:¶

(i) 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, or¶

(ii) from off-cuts and scraps from plastic materials and articles referred to points (b) and (c) of Article 2(1), and 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 Regulation (EU) No 10/2011; or,¶

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

27

Reprocessing (2nd slide)

Recital (12)

(12) ' …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.. '

European Commission

28

Repeated use

Editorial changes.

14 June 2024 version

'*Article 10*

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

3. Where intended for repeated use in contact with food, the composition of 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 materials and articles in accordance with the instructions for intended use as described in documentation or labelling. '

'*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 information 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 or material that may indicate the deterioration of the article or material. Information shall warn in case specific damage or foreseeable misuse would cause increased migration or would cause the material or article to become otherwise unsuitable for further use in contact with food.

2 September 2024 version

'*Article 10*

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

3. Where intended for repeated use in contact with food, the composition of 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 materials and articles in accordance with the instructions for intended use as described in documentation or labelling. '

'*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 by means of labelling or otherwise 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.

29

Repeated use (2nd slide)

Recital (13)

(13) ' …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…To prevent the use of unacceptably 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 ~~a~~ repeated use. '

30

Annex V, introductory part (compliance testing)

Technical changes.

2 September 2024 version

Annex V is amended as follows:

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

'

COMPLIANCE TESTING

The LL shall be the SML for the verification of compliance with a SML, unless the result of the migration test (1) needs to be corrected for 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.

→ 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 → $m \leq 0.12 * 10^{-6}$ kg/kg; and,

$CV_R = 2^{(1-½\log(m))}/100$ → for → $0.12 * 10^{-6}$ kg/kg $\leq m \leq 0.138$ kg/kg;

31

Annex V, point 3.3.2 introductory part (compliance testing)

Technical changes.

2 September 2024 version

In Chapter 3 of Annex V, 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.

32

Annex V, point 3.3.2 introductory part (compliance testing)

Technical changes.

2 September 2024 version

In Chapter 3 of Annex V, 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.

Addressing editorial error in last paragraph of point 3.3.2

However, if there is scientific proof that the level of the migration is not [non-increasing as defined above decreases] 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.