WORKING GROUP ON FOOD CONTACT MATERIALS

22-23 January 2024

DG SANTE
European Commission

Agenda & Objectives

Agenda

Today

- Revision
  - State-of-play (short)
- Quality amendment
  - Decision + amending act
- Recycling
  - Correcting Act
  - Amending Act
- AoB
  - peppermill grinding wheels

Tomorrow

- Recycling
  - Authorisations
  - Register
  - (Novel Technologies)
- BPA

Both days: break will be planned for best fit with on-going discussions

Acts under preparation

act	State
• 250 authorisation Decisions	• Template completed – drafting of decisions underway – written procedure
• BPA	• First draft provided, internal procedures underway – formal consultation to start in February, vote in April
• quality Amendment	• First draft provided, internal procedures underway – formal consultation to start in February, vote in April
• Decision provisional list	• First draft provided, adoption February/March
• recycling Amendment	• First draft provided, internal procedures underway – no formal consultation, vote foreseen 27 February
• recycling Correction	• First draft provided, internal procedures underway – no formal consultation, vote foreseen 27 February

Objectives

- To discuss the provided texts
- To explain our drafting
- To exchange views
- To prepare for consultation
  - note: we will consult only on the main points and principles, not on drafting detail

Revision state of play

State of play Revision

- Drafting of discussion document in progress
  - delayed because of high workload on implementation
  - it will provide the basis for discussions in dedicated expert groups
  - Organisation of expert groups being started
- On-going studies
  - EY study on pillar D and E; report on options being finalised; final report in April
  - ToR for study on sustainability finalised – procedure for the call is starting

Amendments to Regulation (EU) No 10/2011 on plastic FCM and Regulation (EC) No 2023/2006 on GMP

European Commission

Overview of amendments

- By means of a Commission Regulation:
  - Amending Articles 3, 4, 5, 6, 7, 8, 10, 14 and 17 of the Plastics Regulation (Regulation (EU) No 10/2011),
  - Adding new Article 3a to the Plastics Regulation (high degree of purity)
  - Amending Annexes III, IV and V to Plastics Regulation (Regulation (EU) No 10/2011),
  - Amending section B of the Annex to GMP Regulation (Regulation (EC) No 2023/2006)
    - introducing also a new Annex C
  - Adding new section C of the Annex GMP Regulation (Regulation (EC) No 2023/2006)
  - Transitional measures
- By means of a Commission decision updating the provisional list
  - all 11 substances included in the provisional list

Commission Decision updating provisional list

- By means of a Commission Regulation:
  - Amending Articles 3, 4, 5, 6, 7, 8, 10, 14 and 17 of the Plastics Regulation (Regulation (EU) No 10/2011),
  - Adding new Article 3a to the Plastics Regulation (high degree of purity)
  - Amending Annexes III, IV and V to Plastics Regulation (Regulation (EU) No 10/2011),
  - Amending section B of the Annex to GMP Regulation (Regulation (EC) No 2023/2006)
    - introducing also a new Annex C
  - Adding new section C of the Annex GMP Regulation (Regulation (EC) No 2023/2006)
  - Transitional measures
- By means of a Commission decision updating the provisional list
  - all 11 substances included in the provisional list

Time-line

- WG FCM January 2024
- Have your say: March 2024
- PAFF April 2024
- EP election recess until 10 July 2024
- Scrutiny EP and Council
- Adoption 2024

Article 3

Definitions

328 *Article 1*↵
329 *Amendments to Regulation (EU) No 10/2011*¶

330 (1) → Article 3 is amended as follows: ¶

331 (1) → Paragraph (7) is replaced by the following:¶

332 '(7) → additive' means a substance which is intentionally added to plastics to achieve
333 a physical or chemical effect during processing of the plastic or in the final
334 material or article; it is intended to be present in the final material or article;
335 this includes particles and fibers of which the surface of these substances is
336 covalently bound to the polymers contained in the plastic;'¶

Article 3

Definitions

Article 1

Amendments to Regulation (EU) No 10/2011

(1) → Article 3 is amended as follows:

(2) → the following new paragraph 20 is added:

'(20) 're-processing of plastic' means the return of plastic materials resulting as a by-product from an intermediate or final manufacturing stage either to that stage itself or to an earlier stage in the manufacturing chain where they are remelted, mixed, reacted or otherwise combined with material originating from earlier manufacturing stages, or used in place thereof, to use them again in the manufacture of plastic materials and articles.'

(2) → A new Article 3a is added:

'Article 3a

High degree of purity

A 'high degree of purity' shall mean that any substance used in the manufacture of plastic materials and articles in accordance with Articles 5 or 6 shall contain only contaminants, or individual impurities, decomposition, degeneration or reaction products that either:

(i) → comply with the specifications or restrictions specified in the authorisation of the substance in table 1 of Annex I, if any; or,

(ii) → have been subject to a risk assessment in accordance with Article 19 and considered compliant; or,

(iii) → have been subject to a toxicological assessment that according to which genotoxicity is ruled out, in accordance with the relevant guidance adopted by the Authority and that are present at a level in the plastic material and article that cannot give rise to an individual migration of the substance from the final plastic material or article into food exceeding 0.05 mg/kg in food, assuming their full migration into food; or,

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

(2) → A new Article 3a is added:

'Article 3a

High degree of purity

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

By derogation from points (iii) and (iv), where the plastic is used to pack:

– → dry unpeeled fruit or vegetables that must be peeled or washed, or,

– → other dry non-fatty foods, if the packaging is in contact with less than 10% of the food surface and is open to the atmosphere, or,

– → foods packed in sealed metal or glass packaging,

10% migration into food may be assumed.'

Article 4

Placing on the market of plastic materials and articles

(d) are manufactured according to good manufacturing practice as s
out in Commission Regulation (EC) No 2023/2006 ([1]); and

(e) comply with the compositional and declaration requirements set o
in Chapters II, III and IV of this Regulation.

378 (3) → In·Article·4,·point·(d)·is·replaced·by·the·following:¶

379 ‘(d)→are· manufactured· according· to· good· manufacturing· practice· as· set· out· in·
380 Commission·Regulation·(EC)·No·2023/2006[12];¶

381 (e) → comply· with· the· compositional· and· declaration· requirements· set· out· in·
382 Chapters·II,·III·and·IV·of·this·Regulation;·and¶

383 (f) → comply·with·Commission·Regulation·(EU)·2022/1616[13]··if·they·fall·within·the·
384 scope·of·that·Regulation.’¶

385 ¶

Article 5

Union list of authorised substances

(4) → In·Article·5,·paragraph·1·is·replaced·by·the·following:¶

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

Article 6

Derogations for substances not included in the Union list

(5) → Article 6 is amended as follows: ¶

(1) → in paragraphs 1 and 2, the phrase 'plastic layers in' is deleted; ¶

(2) → in paragraph 4 the phrase 'the plastic layers of' is deleted; ¶

Article 6

Derogations for substances not included in the Union list

5. By derogation from Article 5, additives not included in the Union list may continue to be used subject to national law after 1 January 2010 until a decision is taken to include or not to include them in the Union list provided they are included in the provisional list referred to in Article 7.

(5) → Article 6 is amended as follows:

(3) → the following new paragraphs 5 and 6 are added:

‘5. → By way of derogation from Article 5, biocidal products allowed to be placed or made available on the Union market in accordance with Regulation (EU) No 528/2012[14] 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. The biocidal product shall be used in compliance with the applicable terms and conditions, restrictions and specifications set out in this Regulation.

Article 6

Derogations for substances not included in the Union list

(5) → Article 6 is amended as follows:

(3) → the following new paragraphs 5 and 6 are added:

6. → By way of derogation from Article 5, any substance may be used in the manufacture of adhesives, coatings and printing inks and applied on or incorporated in plastic materials and articles, if that use complies with Article 3 of Regulation (EC) No 1935/2004 and, where applicable, with specific measures and national law applicable to adhesives, coatings and printing inks.'

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.

(7) → Article 8 is replaced by the following:

'*Article 8*

General requirements on substances

1. → A substance used in the manufacture of plastic materials and articles in accordance with Article 5 shall correspond to the identity of the substance listed in Table 1 of Annex I which is specified in the opinion of the Authority. In case of doubt over the resulting designated identity of a substance a Member State or the Commission may consult the Authority.

Article 8

General requirement on substances

(7) → Article 8 is replaced by the following:

'*Article 8*

General requirements on substances

2. → Substances used in the manufacture of plastic materials and articles shall be of a high degree of purity and shall be of a technical quality suitable for the intended and foreseeable use of the materials or articles. manufacturers of plastic materials and articles, and of products from intermediate stages of their manufacturing, shall know the composition of the substance and make it available to the competent authorities on request.

(7) → Article 8 is replaced by the following:

'*Article 8*

General requirements on substances

3. → The following requirements shall apply to the purity of substances of a natural origin:

(i) → if the substance is identified by a chemical name in this Regulation, it shall have a high degree of purity, or,

(ii) → if the substance is identified by a name in this Regulation that refers to a natural multi constituent material, that substance may be used as obtained from its natural origin, provided it has been entirely separated from the other natural matter, or parts of the plant or other natural sources from which was obtained that are not forming part of the identity of the substance.

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

Article 8

General requirement on substances

409 (7) → Article·8·is·replaced·by·the·following:¶

410 ‘*Article·8*¶

411 **General·requirements·on·substances**[¶

436 4. → Substances·manufactured·from·waste·shall·be·of·a·high·degree·of·purity.¶

(7) → Article 8 is replaced by the following:

'*Article 8*

General requirements on substances

5. → 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 4 shall be part of the documentation referred to in Article 16.

6. → Manufacturers of plastic materials and articles, and of products from intermediate stages of their manufacturing, shall ensure that it is possible for competent authorities to verify the degree of purity and the composition of the relevant substances by taking samples thereof.'

Article 10

General restrictions on plastic materials and articles

General restrictions related to plastic materials and articles are laid down in Annex II.

(8) → 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 may contain reprocessed plastic if such reprocessed plastic meets the following conditions:

(a) → it is collected in accordance with point B and C of the Annex to Regulation (EC) No 2023/2006;

(b) → it originates only from off-cuts and scraps from plastic materials and articles referred to in Article 2(1), point (a) that meet the compositional requirements set out in chapter II of this Regulation, and which are considered to be a by-product in accordance with Article 5 of Directive 2008/98/EC of the European Parliament and of the Council[15];

(8) → 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· may· contain· reprocessed· plastic· if· such· reprocessed·plastic·meets·the·following·conditions:¶

(c) → it·does·not·contain·substances·in·an·amount·which·could,·after·using·the· reprocessed·plastics·for·the·manufacture·of·plastic·materials·and·articles:¶

(i) → exceed· migration· limits· applicable· to· the· plastic· materials· and· articles;·or,·¶

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

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

(i) → food;¶

(ii) → printing,·coating,·or·adhesives;¶

(iii)→ substances·used·for·processing·the·plastic·from·which·the·off-cuts· and·scraps·originate,·such·as·lubricants·or·cutting·fluids.¶

Article 10

General restrictions on plastic materials and articles

General restrictions related to plastic materials and articles are laid down in Annex II.

(8) → Article 10 is replaced by the following:

'*Article 10*

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

2. → The composition of plastic materials and articles shall meet the restrictions on plastic materials and articles laid down in Annex II.

Article 10

General restrictions on plastic materials and articles

General restrictions related to plastic materials and articles are laid down in Annex II.

(8) → Article 10 is replaced by the following:

'*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 plastic materials and articles shall be such, so as to guarantee that no increase in the migration of constituents of the material or article to the food would occur during their maximum life span when subjected to subsequent use cycles.

The manufacturer or seller responsible for placing on the market shall provide information about the maximum life span of the material and article 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 and that it has reached its maximum life span.

Article 10

General restrictions on plastic materials and articles

General restrictions related to plastic materials and articles are laid down in Annex II.

(8) → Article 10 is replaced by the following:

‘*Article 10*

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

4. → Plastic materials and articles shall be labelled with instructions of use directed at the final user of that material or article, where they are intended to be brought into contact with food but are not yet in contact with food, at the moment of their sale or supply to consumers, and 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,

– → specific foods or groups of foods,

– → contact time and/or temperature, and/or,

– → to heating conditions such as oven and microwave use,

(8) → Article 10 is replaced by the following:

'Article 10

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

4. →

The instructions of use shall mention the restriction and provide the user provided with adequate information to prevent using the material or article under conditions exceeding the applicable limitations.

By derogation from to Article 15(7) of Regulation (EU) No 1935/2004, if such a material or article is intended for repeated use, and such labelling shall be indelibly affixed to the material or article, unless it is not possible for technical reasons. A minimum font size of 3 mm (9 pt.) shall apply.'

Article 14

Multi-material multi-layer materials and articles

(9) → 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.'

Article 14

Multi-material multi-layer materials and articles

(10) → Article 14, paragraph 6 is replaced by the following:¶

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

Article 17

Expression of migration test results

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,

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

512 (11) → Article·17(2),·point·(a)·is·replaced·with·the·following:¶

513 ‘(a)·→containers·and·other·articles,·containing·or·intended·to·contain·more·than·10·

514 litres.’¶

Article 3

Transitional measures

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

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

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:

Table 2 contains the following information:

— Column 1 (Reference number): contains the reference number of the food category;

— Column 2 (Description of food): contains a description of the foods covered by the food category;

— Column 3 (Food simulants): contains sub-columns for each of the food simulants:

(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 relative to the substances used, including impurities in the substances used, reaction intermediates formed during the production process, decomposition or reaction products, in particular 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.

(2) → Annex IV is amended as follows:

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

At intermediate stages, this information shall include the identification and amount of the substances referred to in first subparagraph and present in the intermediate material,

– → that are subject to restrictions and/or specifications in Annex I and/or 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;';

14 (2) → Annex·IV·is·amended·as·follows:·¶

(b) → ·the·following·new·paragraph·his·added·to·point·8:··¶

‘(iv)· the· maximum· lifespan· of· the· material· or· article· based· on· a· report· evaluating· the· maximum· lifespan· of· the· material· or· article· based· on· the· elements·in·point·3·of·Article·10;’;¶

(2) → Annex IV is amended as follows:

(c) → points 10, 11 and 12 are added:

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

(a) → the confirmation that it complies with Article 10(1) of this Regulation and that it has been collected 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;

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:

Table 2 contains the following information:

— Column 1 (Reference number): contains the reference number of the food category;

— Column 2 (Description of food): contains a description of the foods covered by the food category;

— Column 3 (Food simulants): contains sub-columns for each of the food simulants:

(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· relative· to· the· substances· used,· including· impurities· in· the· substances· used,· reaction· intermediates· formed· during· the·production·process,·decomposition·or·reaction·products,·in·particular· 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.·¶

(2) → Annex IV is amended as follows:

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

At intermediate stages, this information shall include the identification and amount of the substances referred to in first subparagraph and present in the intermediate material,

– → that are subject to restrictions and/or specifications in Annex I and/or 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;';

14 (2) → Annex·IV·is·amended·as·follows:·¶

(b) → ·the·following·new·paragraph·his·added·to·point·8:··¶

‘(iv)· the· maximum· lifespan· of· the· material· or· article· based· on· a· report· evaluating· the· maximum· lifespan· of· the· material· or· article· based· on· the· elements·in·point·3·of·Article·10;’;¶

(2) → Annex IV is amended as follows:

(c) → points 10, 11 and 12 are added:

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

(a) → the confirmation that it complies with Article 10(1) of this Regulation and that it has been collected 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;

(2) → Annex IV is amended as follows:¶

(c) → points 10, 11 and 12 are added:¶

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 Regulation (EU) No 10/2011 that have been manufactured from waste materials:¶

(a) → a confirmation that the level of individual contaminants is compliant with point (4) of Article 8 of this Regulation; and,¶

(b) → an indication of the total content of substances manufactured from waste in the plastic material or article calculated as weight of substances manufactured from waste per weight of the total material or article and expressed in percent.¶

14 (2) → Annex·IV·is·amended·as·follows:·¶

37 (c) → points·10,·11·and·12·are·added:·¶

54 12.·→ In· case· a· product· from· an· intermediate· stage· of· the· manufacturing· of·
55 plastic· materials· and· articles· or· a· substance· intended· for· the·
56 manufacturing·of·such·a·product,·material·or·article·which·complies·with·
57 Regulation·(EU)·No·10/2011·as·applicable·before·the·entry·into·force·of·
58 this·Regulation·and·which·is·first·placed·on·the·market·after·*[enter·date·9·*
59 *months· after· the· date· of· entry· into· force· of· this· Regulation]*· does· not·
60 comply· with· this· Regulation,· the· declaration· of· compliance·
61 accompanying· that· substance· or· product· shall· indicate· that· it· does· not·
62 comply· with· this· Regulation· and· that· it· can· only· be· used· in· the·
63 manufacture·of·plastic·materials·and·articles·to·be·placed·on·the·market·
64 before· *[enter· date· 18· months· after· the· date· of· entry· into· force· of· this·*
65 *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[1] shall be selected, applying the following specific performance criteria:

– → The calibration range of analytical methods shall be at least R_L (relative lower calibration range threshold) * LL (legal limit) to R_U (relative upper calibration range threshold) * LL, using a minimum of 5 calibration points equally distributed in this range. Unless otherwise specified in table 1 or 2 of Annex I for the substance of which the LL is being verified, R_L shall be 0.2, and R_U shall be 2

(3) → 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 LL=SML for the verification of compliance with a SML, unless the result of the migration test shall be divided by the correction factor used in the sub-columns for D2 and E in Table 2 of Annex III, or by the FRF in accordance with point 4.1 of this Annex. In this case the calibration range shall be adjusted upwards to compensate for this division, as follows:

(3) → Annex V is amended as follows:¶

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

‘¶

COMPLIANCE TESTING¶

– → LL = FRF * SML when only the FRF is applicable;¶

– → LL = C_{T2} * SML where C_{T2} = 2, 3, 4, 5 or 10 as applicable given the figure indicated in Table 2 of Annex III, when the FRF is not applicable; or,¶

– → LL = FRF * C_{T2} * SML if the FRF applies and FRF * C_{T2} < 5, C_{T2} = 2, 3, 4, 5 or 10; or,¶

– → LL = 5 * SML if the FRF applies and FRF * C_{T2} ≥ 5, C_{T2} = 2, 3, 4, 5, or 10;¶

(3) → Annex·V·is·amended·as·follows:¶

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

¶

- → 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.·The·formulas·for·calculating·the·CV_R·are·as·follows:¶

CV_R·=·0.22· → for → m·≤·0.12·*·10^{-6}·kg·/kg;·and,¶

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

Where·m·is·the·measured·concentration·of·a·substance·that·is·to·be·evaluated·against·the·legislative·limit,·and·the·uncertainty·of·the·measured·concentration·of·a·substance,·u(m),·shall·be·determined·as·follows:·u(m)·=·CV_R·*·m.¶

(3) → Annex V is amended as follows:¶

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

‘¶

COMPLIANCE TESTING¶

– → The compliance with the specific migration level shall then be evaluated by applying the following specific performance criterium, where *m* is the measured concentration of a substance that is to be evaluated against the legislative limit:¶

IF $(m - LL)/[u(m)] > 1.64$ → → THEN $m > LL$¶

If m > LL the measured concentration of a substance shall be considered non compliant.¶

In addition, the rules in Chapter 1 - 4 of this Annex shall apply.’¶

(3) → Annex V is amended as follows:

(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(s) 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 migration found out in the course of the third test and on the basis of the stability of the material or article. The specific migration found out during the second 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 during the second test.

(3) → Annex V is amended as follows:¶

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

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

m_3 > SML, or,¶

m_1 < m_2, or,¶

m_2 < m_3, or,¶

m_1 < m_3,¶

where m_1, m_2, and m_3 are respectively the measured concentration during the first, the second and the third migration test carried out in accordance with the first subparagraph.¶

(3) → Annex·V·is·amended·as·follows:¶

(b) → In·Chapter·2·of·Annex·V,·point·2.1.6·of·is·replaced·by·the·following:¶

The·compliance·with·the·specific·migration·level·shall·be·evaluated·applying·the·following·specific·performance·criteria:¶

– → IF·(m_3·-·SML·)/[(u(m_3)]·>·1.64 → → THEN·m_3·>·SML,¶

– → IF·(m_2·-·m_1)/[(u(m_2)·+·u(m_1)]·>·1.64 → THEN·m_1·<·m_2¶

– → IF·(m_3·-·m_2)/[(u(m_3)·+·u(m_2)]·>·1.64 → THEN·m_2·<·m_3¶

– → IF·(m_3·-·m_1)/[(u(m_3)·+·u(m_1)]·>·1.64 → THEN·m_1·<·m_3¶

where·the·uncertainty·of·the·measured·concentration·of·a·substance,·u(m),·shall·be·determined·as·follows:·u(m)=·CV_R·*·m.¶

67 (3) → Annex·V·is·amended·as·follows:¶

115 (b) → In·Chapter·2·of·Annex·V,·point·2.1.6·of·is·replaced·by·the·following:¶

141 In· case· a· measured· concentration· *m*· <· R_L· (relative· lower· calibration· range·
142 threshold)·*·SML,·the·measured·concentration·*m*·shall·be·considered·equal·to·
143 R_L·*·SML.·This·concentration·shall·be·used·for·determining·the·corresponding·
144 uncertainty·of·the·measured·concentration·and·the·concentration·R_L·*·SML·and·
145 the· corresponding· determined· uncertainty· shall· be· used· for· evaluating· the·
146 compliance·with·the·performance·criteria·set·out·in·this·point.·¶

(3) → Annex V is amended as follows:

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

However, if there is scientific proof that the level of the migration decreases the course of the second and third migration tests and if the migration limit not exceeded during the first migration test, the material or article is consider compliant with the specific migration limit laid down in Regulation (EU) N 10/2011.

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

67 (3) → Annex·V·is·amended·as·follows:¶

156 (c) → In·Chapter·2·of·Annex·V,·point·2.1.7·of·is·replaced·by·the·following:¶

157 ‘At·the·end·of·the·prescribed·contact·time,·the·specific·migration·is·analysed·in·
158 the·food·or·food·simulant·using·an·analytical·method·in·accordance·with·the·
159 applicable·performance·criteria·laid·down·in·this·Annex.’.·¶

(3) → Annex V is amended as follows:¶

(d) → 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.¶

(3) → Annex V is amended as follows:¶

(d) → In Chapter 3 of Annex V, point 3.3.2 is replaced by the following:¶

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 test results shall be considered to represent the three successive overall migrations.¶

However, if there is scientific proof that the level of the migration 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 specific migration limit laid down in Regulation (EU) No 10/2011.'.

(3) → Annex·V·is·amended·as·follows:¶

(b) → In·Chapter·2·of·Annex·V,·point·2.1.6·of·is·replaced·by·the·following:¶

The·compliance·with·the·specific·migration·level·shall·be·evaluated·applying·the·following·specific·performance·criteria:¶

– → IF·(m_3·-·SML·)/[(u(m_3)]·>·1.64 → → THEN·m_3·>·SML,¶

– → IF·(m_2·-·m_1)/[(u(m_2)·+·u(m_1)]·>·1.64 → THEN·m_1·<·m_2¶

– → IF·(m_3·-·m_2)/[(u(m_3)·+·u(m_2)]·>·1.64 → THEN·m_2·<·m_3¶

– → IF·(m_3·-·m_1)/[(u(m_3)·+·u(m_1)]·>·1.64 → THEN·m_1·<·m_3¶

where·the·uncertainty·of·the·measured·concentration·of·a·substance,·u(m),·shall·be·determined·as·follows:·u(m)=·CV_R·*·m.¶

(3) → Annex V is amended as follows:¶

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

In case a measured concentration m < R_L (relative lower calibration range threshold) * SML, the measured concentration m shall be considered equal to R_L * SML. This concentration shall be used for determining the corresponding uncertainty of the measured concentration and the concentration R_L * SML and the corresponding determined uncertainty shall be used for evaluating the compliance with the performance criteria set out in this point.¶

(3) → Annex V is amended as follows:

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

However, if there is scientific proof that the level of the migration decreases the course of the second and third migration tests and if the migration limit not exceeded during the first migration test, the material or article is consider compliant with the specific migration limit laid down in Regulation (EU) N 10/2011.

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

67 (3) → Annex·V·is·amended·as·follows:¶

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158 the·food·or·food·simulant·using·an·analytical·method·in·accordance·with·the·
159 applicable·performance·criteria·laid·down·in·this·Annex.’.·¶

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(3) → Annex V is amended as follows:¶

(d) → In Chapter 3 of Annex V, point 3.3.2 is replaced by the following:¶

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 test results shall be considered to represent the three successive overall migrations.¶

However, if there is scientific proof that the level of the migration 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 specific migration limit laid down in Regulation (EU) No 10/2011.'.

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.'

183 **ANNEX·II**¶

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

193 (2) → In·section·B,·the·following·paragraph·3·is·added·after·point·2,·point·(f):·¶

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

ANNEX II

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

(2) → In section B, the following paragraph 3 is added after point 2, point (f):

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 conform 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.’

ANNEX II

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

'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(1) of Regulation (EU) No 10/2011 ('materials intended for reprocessing') shall be collected separately from waste as close as technical 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.

ANNEX·II¶

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

(3) → The·following·new·section·C·is·added:¶

‘C. → Reprocessing· of· plastics· falling· within· the· scope· of· Regulation· (EU)· No· 10/2011¶

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.·¶

ANNEX II

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

(3) → The following new section C is added:

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

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, point (20) of Regulation (EU) 2022/1616 shall apply.

4. → At any stage of production or reprocessing operations, operators shall ensure that the quality assurance system prevents that materials intended for reprocessing are mixed with batches of plastic of another composition, other materials, or with waste materials.'

Commission Decision updating provisional list

Article 1

In accordance with Article 6(5) of Regulation (EU) No 10/2011, the substances:

– → 2,4,4'-trichloro-2'-hydroxydiphenyl ether (reference number 93930),

– → silver sodium hydrogen zirconium phosphate (reference number 86434),

– → silver zeolite A (silver zinc sodium ammonium alumino silicate), silver content 2-5% (reference number 86437),

– → silver zinc zeolite A (silver-zinc sodium alumino silicate calcium metaphosphate), silver content 1 -1.6 % (reference number No. 86438),

– → silver zinc zeolite A (silver-zinc sodium magnesium alumino silicate calcium phosphate), silver content 0.–4 - 0.54 % (reference number No 86438/50),

– → silver-zinc- aluminium – boron – phosphate glass mixed with 5-20% barium sulphate, silver content 0,35 – 0,6 % (reference number 86437/50),

– → silver-containing glass (Silver-magnesium-calcium-phosphate-borate) (reference number 86432),

– → silver containing glass (silver-magnesium-aluminium-phosphate-silicate), silver content less than 2% (reference number 86432/20),

– → silver containing glass (silver-magnesium-aluminium-sodium-phosphate-silicate-borate), silver content less than 0.5% (reference number 86432/40),

– → silver containing glass (silver-magnesium-sodium-phosphate), silver content less than 3% (reference number 86432/60), and,

– → silver chloride (20% w/w) coated onto titanium dioxide (80% w/w) (reference number 86430)

shall not be included in Annex I to Regulation (EU) No 10/2011.

Article 2

Plastic materials and articles treated with or incorporating substances listed in Article 1 and complying with Regulation (EU) No 10/2011, containing additives in accordance with Article 6(5) thereof, used in accordance with national law and placed on the market before the entry into force of this Regulation, may continue to be placed on the market until the exhaustion of stocks.

Mineral oil hydrocarbons and substances

Mineral oils

Online FORUM on mineral oil hydrocarbons in food 18 January 2024

Planning

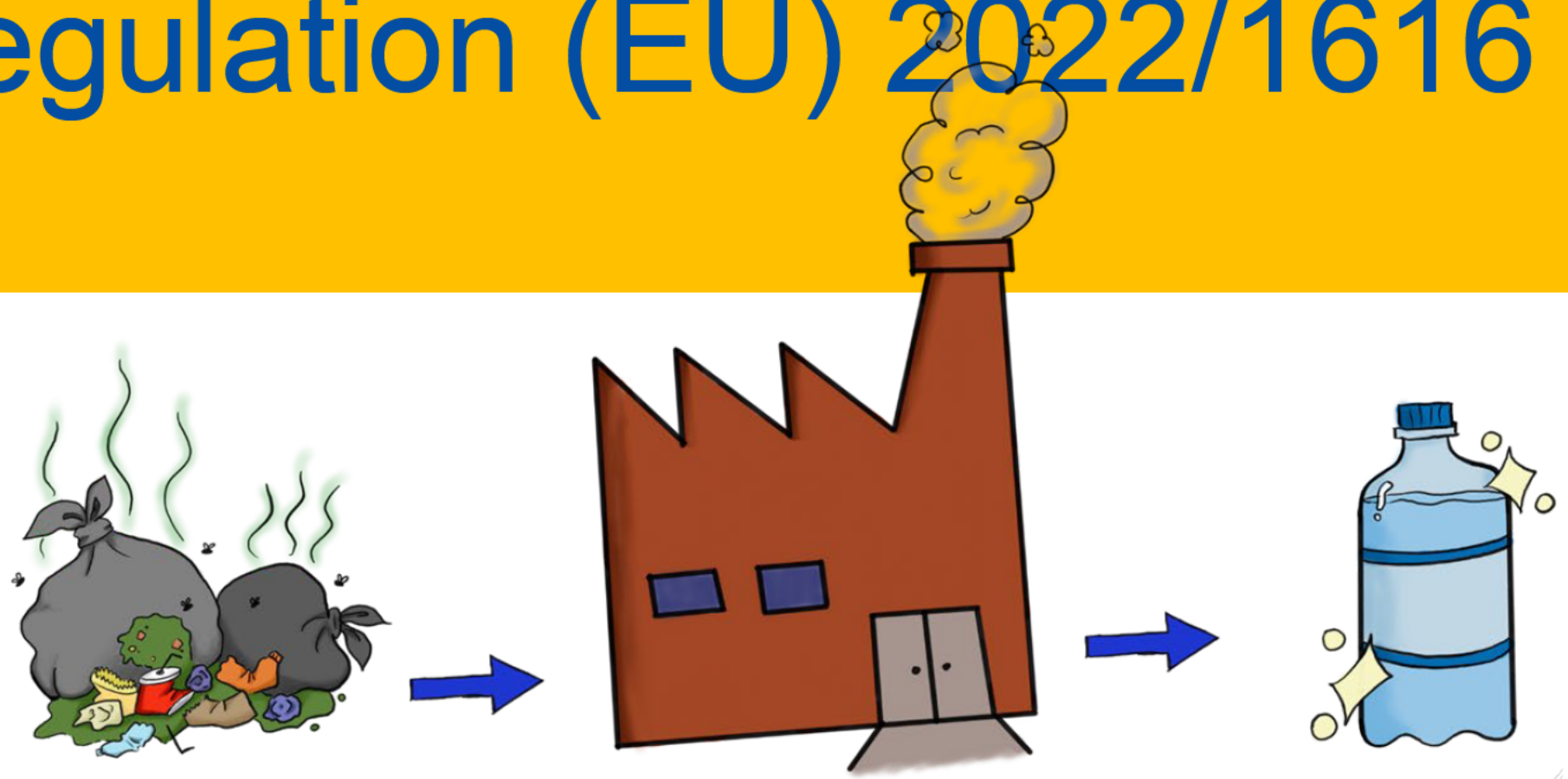
Substances

Chopped carbon fibre

Recycling

European Commission

Corrections and Amendments to Regulation (EU) 2022/1616



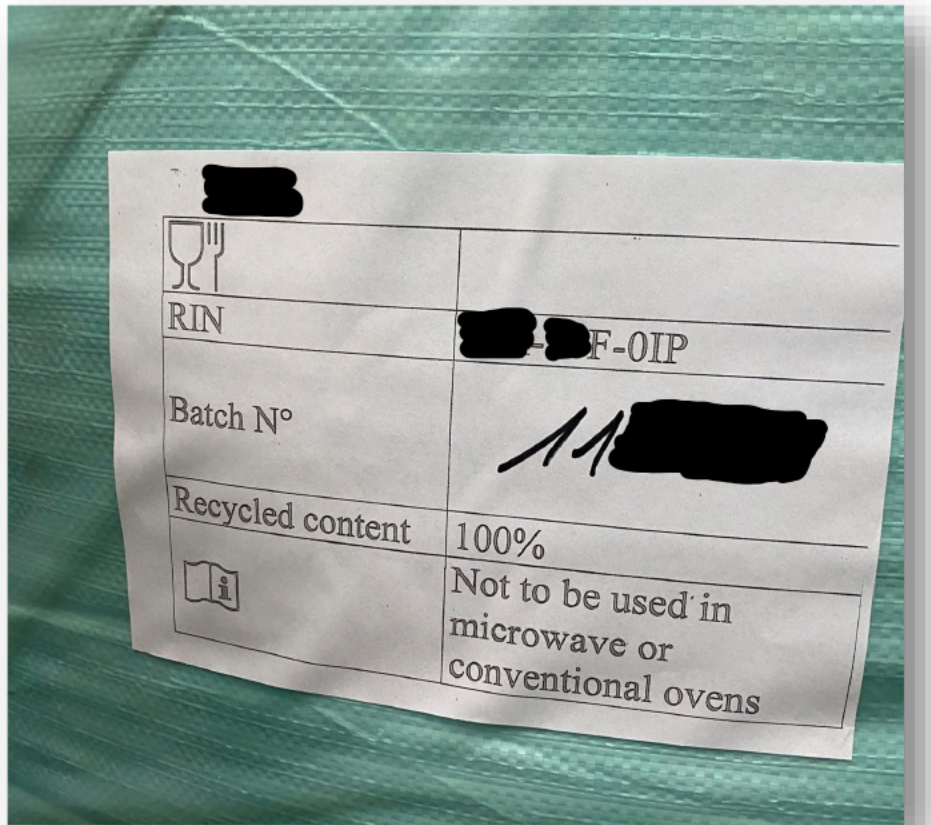
European Commission

Corrections to R 2022/1616

1. Reference in Article 4(1) does not include paragraph 8
2. Article 5(3) refers to ‘containers of’ instead of ‘containers with’
3. Article 10(4) states: ‘At the time of the notification, the **recycler** shall also publish a detailed initial report on…’; this should refer to ‘the developer’ instead of to ‘the recycler’#
4. Article 10(8) refers to itself and to paragraph 1-7 instead of 1-6
5. Article 14(6) states: ‘… the Authority [EFSA] may request the developers of the novel technologies under assessment to supplement the information available to it with information compiled in accordance with **Articles 10** and 12, ...’; the reference to Article 10 should only be to 10(3)-(5). The rest is not about information, or about information to competent authorities
6. Article 14(8) refers to Article12(1)(b) and (e); this should be to 12(1)(a) and (c)

Containers of vs. Containers with….

- The containers may be made **of** any material
  - usually these are big bags made from PP (or PVC), not PET
- The containers contain recycled PET
  - i.e. containers **with** recycled PET
- The containers with recycled PET must be labelled
  - more or less correct example→



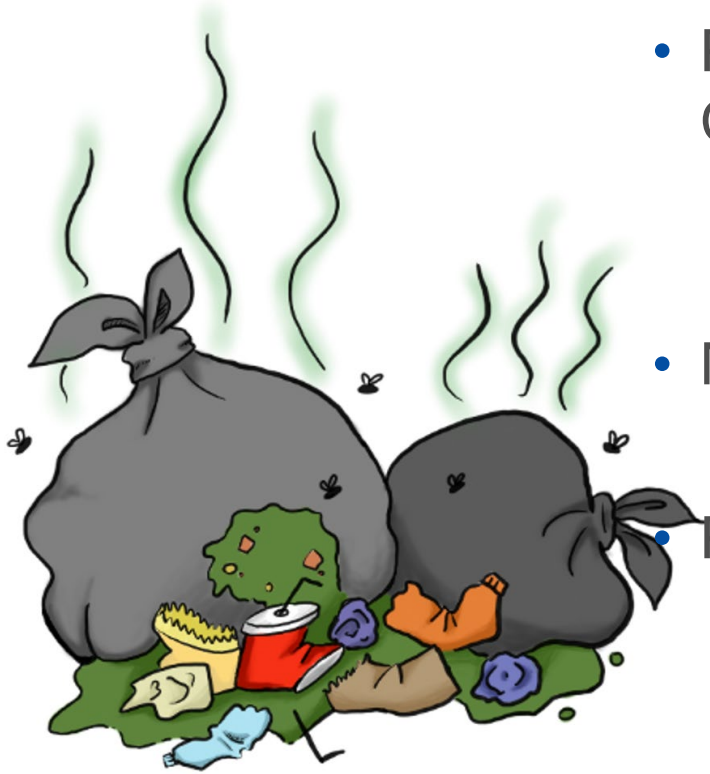
Discussion on amendment to R 2022/1616

- First internal draft was provided to you – may be subject to change
  - we welcome your views
  - vote in February still feasible
- Most matters we have seen before
- Some provisions are new; forthcoming from:
  - Discussions with Industry on possible 66% limitation
  - Preparation of authorisation decisions

Possible 66% limit on recycled PET content

- Why consider to introduce it? Two reasons:
  1. deterioration of quality of polymers that are recycled many times
  2. apparent rapid growth of import into the EU of plastic input to recycling
- Outcome discussion with industry
  - reason 2 is the most relevant issue and is largely confirmed
  - 66% limit not effective against reason 2 → for now this limit will not be considered
- Alternative solution certification of plastic input
  - Expedited work under Article 6(3)(c)
  - Certification (declaration of compliance) of plastic input

Importance of plastic input quality



- EFSA assessment assumes a fixed maximum contamination level
  - contamination in recycled PET = cleaning efficiency * contamination in input
- PET input must be compliant with Article 6 and Table 1 (Row 1 Column 5)
  - separately collected post-consumer PET, 5% non-food origin
  - Regulation (EU) No 10/2011 applies
- Mechanical recycling processes can only recycle compliant input
  - whether to be used up to 100% or less
- Poor quality, or unknown origin should be considered a health risk

Ensuring the correct input quality

- At present input quality is ensured via
  - Article 6(3): quality assurance during collection and pre-processing
  - Article 7(1): recycler to ensure specifications of input
- Limited means to control quality of the input directly
  - checks for foreign materials can be done
  - no available methods to check for contamination levels
  - which authorities are competent? Are there sufficient resources available?
- Only documentary checks can be used
  - by both recyclers as well as competent authorities

imports into the EU are particularly concerning

- Indications that there is a higher level of contamination
  - EFSA still applies the 3 mg/kg also to material from outside the EU, but there are doubts
- Compliance with Article 6 is far from ensured
  - which collection system was used? compliance with 10/2011? mis-use?
- There is no apparent control mechanism
  - No suitable TARIC codes, no Competent Authority, no documentation
- Driven potentially by cost savings, and desire to grow quickly
- (note, none of these problems are fully excluded in the EU internal market)

Meetings with the Industry

- Two meetings with the major stakeholders (recyclers, beverage producers)
- 21 December to discuss the 66% rPET content limit
  - outcome: instead of this limit, focus at documentation (not presently required!) and certification (Article 6(3)(c))
- 10 January to discuss how to achieve certification
  - the recyclers will expedite their work on a standard, the regulation to provide legal support
    - in the future we may lay down an annex referring to existing standards for this purpose
  - certification (=declaration of compliance) of the input material at batch level
    - including reporting requirements on origin and mode of collection
    - to be implemented by means of the present amending Regulation
- Other outcomes
  - There will be a questionnaire to help us better understand the situation on the market
  - The stakeholder will consider monitoring, similar as required for novel technologies

Types of certification

- Certification of the process
  - Subject: GMP procedures used in waste collection and pre-processing
  - Requirement: Article 6(3)(c)
  - Certifying body: Third party (no further requirements at present)

3. The plastic waste shall be controlled throughout collection and pre-processing by means of quality assurance systems. The quality assurance systems shall:

(a) ensure the conditions and requirements set out in paragraph 1 and 2 are met;

(b) ensure traceability of each batch up to the point of the first sorting of collected plastic waste; and,

(c) be certified by an independent third party.

- Certification of the product (i.e. the plastic input, 'declaration of compliance')
  - Subject: (at least) the PET input used in a recycling (decontamination) process
  - Requirement: No explicit requirement
  - Certifying body: Not defined, but presumably the pre-processing operator

certification under Article 6(3)(c)

3. The plastic waste shall be controlled throughout collection and pre-processing by means of quality assurance systems. The quality assurance systems shall:

(a) ensure the conditions and requirements set out in paragraph 1 and 2 are met;

(b) ensure traceability of each batch up to the point of the first sorting of collected plastic waste; and,

(c) be certified by an independent third party.

- Article 6(3)(c) is not being amended – no need
- we need to ensure that it becomes implemented as soon as possible
- application to be significantly postponed (to 01/2026 or 10/2026)
  - counter intuitive given urgency, but the present deadline won't be met
  - step 1: standard, step 2: support by Regulation, step 3: auditing and certification
  - later-on also accreditation of third parties (expected timeline is long)

delay of entry into force of Article 6(3)(c)

- Industry indicated they are not ready for third party certification
  - Step 1: establish standard for certification
  - Step 2: provide legal certainty over essential elements of that standard
    → add annex to the Regulation
  - Step 3: start certifying
- Our estimate is two years at least:

> (10) The last subparagraph of Article 33 is replaced by the following:
>
> ‘Article 13(2) shall apply from 10 October 2024 and Article 6(3)(c) shall apply from 15 January 2026.’;

- Accreditation of third parties may be needed
  - Work to continue over the next few months

Amendments: certification (DoC) of products (input)

New obligations under Article 6

- We regret using '*certificate*'; to become '*declaration of compliance*'
- Article 6(4) to ensure compliance and traceability
- Article 6(5) to provide data on the origin and mode of collection

(3) The following paragraphs 4 and 5 is added to Article 6:

'4. At marketing stages in the collection and pre-processing chain a certificate stating that the conditions and requirements set out in paragraph 1, 2 and 3 are met shall be provided with each batch of collected or pre-processed material. This certificate shall identify the operator, its address, and the number of the batch it accompanies, as well as any other data necessary to describe the quality of the material and to ensure traceability.

5. The certificate referred to in paragraph 4 shall indicate the origin of the plastic contained in the batch, which shall be the geographic origin of where the material was collected, and its mode of collection. The origin and mode of collection shall be described as follows:

(i) The origin shall be either:

– 'EU;' or,

– 'non-EU'.

'non-EU' shall be used for plastic input containing more than 10% plastic that was collected outside of the European Union.

(ii) The mode of collection shall be either:

– 'PCW' if the plastic input is post-consumer waste and was collected in accordance with Article 6;

– 'DRS', if the plastic input was collected in accordance with Article 6 or 9 and using a deposit return or refund system;

– 'novel technology' if the plastic input was collected in a way specific to a novel technology being developed in accordance with Article 10; in this case the certificate shall provide the novel technology number as referred to in Article 24(3);

– 'other' if any of the previous does not apply; in this case the certificate shall describe the mode of collection by referring at least to the users of the plastic from whom it was collected, with what other waste it was collected together, and what sorting methods were used to remove that other waste.'

Amendments: certification (DoC) of products (input)

New obligations under Article 7

- Certificate is required and has to be retained for 5 years
- A sample to be retained
- Reporting to competent Authorities of quantity of input and recycled output to competent authority (to enable risk based enforcement)
- Should we require reporting from Member State to Commission?

(4) In Article 7, paragraph 1 is replaced by the following:

'1. The plastic input and the output of the applied decontamination process shall meet the specifications set out in column 3, 5, and 6 of table 1 of Annex I for the relevant recycling technology and, if applicable, the specific criteria set out in the authorisation.

Only batches of plastic input material that are accompanied by a certificate issued in accordance with Article 6(4) and (5) shall be accepted for decontamination. Where the recycler performs the last pre-processing steps itself, the recycler shall self-certify for this purpose.

The recycler shall retain the certificates accompanying the plastic input for a period of at least 5 years. A sample of at least 500 grams of the plastic contained in the batch shall be retained for a period of at least 2 years.'

(5) The following paragraph 5 is added to Article 7:

'5. For each recycling facility, the recycler shall report to the competent authority in the territory where the facility is located the total quantity of plastic input and recycled output, differentiated by the applied recycling technology, and the origin and mode of collection as referred to in Article 6(5). The reporting period shall be 6 months, starting on 1 January and on 1 July of the reporting year. The recycler shall provide the report within 1 month from the end of the reporting period to the competent authority.'

Amendment to Article 5(2)

- First considered a correction because of inconsistency with Article 29
- However, more is needed
  - Clarity over the supply chain stages at which a DoC needs to be provided
  - Simplified model for stages at which part B of Annex III is not needed
- Basis is Article 16 of Regulation (EC) No 1935/2004:

Article 16

Declaration of compliance

1. The specific measures referred to in Article 5 shall require that materials and articles covered by those measures be accompanied by a written declaration stating that they comply with the rules applicable to them.

Appropriate documentation shall be available to demonstrate such compliance. That documentation shall be made available to the competent authorities on demand.

DoC requirement in Article 5(2)

- Presently inconsistent with Article 29
- alignment with Article 16 of R 1935/2004
  - up to and including the retailer
  - explicit requirement for supporting documentation

173	(2)	In Article 5, paragraph 2 is replaced by the following:
174 175 176		'2. Recycled plastic, recycled plastic materials and articles, and other products in which those materials or articles are contained, shall be accompanied by a declaration of compliance in accordance with Article 29.
177 178 179 180 181 182		Appropriate documentation to demonstrate that the recycled plastic or the recycled plastic materials and articles as well as products containing it comply with the requirements of this Regulation shall be available. It shall be made available without delay to the national competent authorities on their request. In case of recycled plastic, this shall include all relevant records kept in accordance with Article 7(4).';

Simplified DoC after conversion stages

- FBO's and similar operators may pass on, use simplified DoC
- labelling of the product may be used alternatively
- NEW wording!

262 (a) the heading is replaced by the following:

263 '*requirements for declarations of compliance*';

264 (b) the following paragraphs 4 to 6 are added:

265 '4. When placing products on the EU market, the following operators may make
266 available a written declaration of compliance using the template provided in part C of
267 Annex III:

268 – food business operators using recycled plastic materials and articles
269 to pack food,

270 – business operators manufacturing kitchenware, appliances and
271 processing equipment that contain recycled plastic or recycled
272 plastic materials and articles, and,

273 – distributers and importers of those products

274 Alternatively, these operators may label the products they provide with the
275 information required in part C of Annex III. In this case the information in fields
276 2.1.1 and 2.1.2 of part C may be omitted, and the information in fields 2.1.3 and 2.2
277 may be combined using the following sentence: 'This product contains X% of plastic
278 recycled in accordance with Regulation (EU) 2022/1616'; in which X% shall be the
279 amount specified in field 2.1.3. The reference 'This product' may be replaced with a
280 more specific reference to that product, such as 'This bottle', 'This tray', or 'This
281 bowl'.

282 In case such labelling is not applied, and no simplified declaration of compliance
283 based on the model set out in part C of Annex III is issued, a declaration of
284 compliance based on Part B of Annex III shall be issued.

By derogation to paragraph 4 operators that do not change a material or article
ning recycled plastic, may pass on the declaration of compliance they received
heir suppliers to the next operator in the supply chain without issuing their
288 own.

289 6. Retailers may omit issuing a declaration of compliance, provided relevant
290 instructions based on information received from the supplier of the product are
291 provided to the users of the product by other means, such as labelling.'

new part C

2. The following part C is added to Annex III

'PART C

Declaration to be used by operators in accordance with Article 29(4)

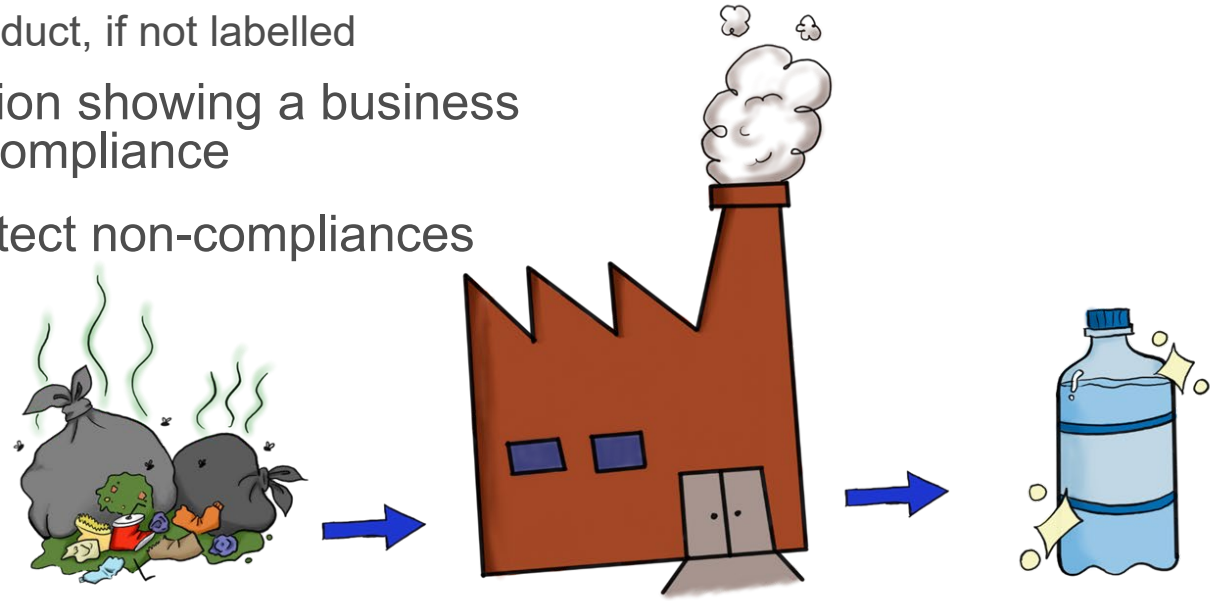
DECLARATION of COMPLIANCE in accordance with Article 29(4) of REGULATION (EU) 2022/1616		
Section 1: Identification		
1.1.1 Identity of the operator issuing the declaration		
1.1.2 Address of the operator issuing the declaration		
1.2 Identity of the product to which the declaration applies		
Section 2: Compliance		
2.1.1 Total recycled plastic content in product		gram†
2.1.2 Total plastic content in product (both recycled and new)		gram†
2.1.3 Percentage of recycled plastic content		(2.1.1 /2.1.2) x 100%†
2.2 All plastic materials and articles with recycled content in this product comply with Regulation (EU) 2022/1616	YES / NO††	
Section 3: Instructions and information to users of the product		
3.2.1 Relevant instructions to the users of the product		

† The amount in field 2.1.1 is the sum of the values obtained by the multiplication of the weight of each plastic material or article contained in the product with the percentage indicated in field 2.1.4 of the declaration of compliance supplied by the converter that manufactured that plastic material or article, for all plastic materials with recycled content contained in the product; the amount in field 2.1.2 is the combined weight of each plastic materials contained in the product to which this declaration applies. Where the amount exceeds 500 grammes, it may be expressed as kg. The value in field 2.1.3 shall be calculated by dividing the value in field 2.1.1 by the value in field 2.1.2 and shall be expressed as %.

†† cross out which does not apply

DoC Conclusion

- A DoC needs to be made available at all marketing stages
  - collection and pre-processing (‘certificate’ in the present text)
  - recycling, post-processing and further sales, DoC.
  - retailers must provide only instructions for using a product, if not labelled
- This is to ensure that there is always documentation showing a business operator has taken its responsibilities regarding compliance
- It is also because there is no analytical way to detect non-compliances
  - it helps CAs to enforce using a risk-based frequency
  - it facilitates traceability
  - it provides data
- It does come at an administrative cost
  - collection and preprocessing
  - operators using recycled plastic in their products
- It has been made urgent due rapid changes in market



deactivation of recycling installations

- Installations can be suspended if there are compliance problems
- Recyclers indicated there is a need to de-activate (not remove) registrations
- Max two years
- Timing foresees in seasonal deactivation

(1) In Article 4, paragraph 8 is replaced by the following:

'8. The status in the Register established in Article 24 of the decontamination installation used for the manufacturing is not 'suspended' or 'inactive'.'

(6) The following paragraph 5 is added to Article 25:

'5. A recycler may notify to the Commission and the competent authority in the territory where it is located that a recycling installation under its control is not used for period of at least 6 months, provided its registration status was not 'inactive' for 5 months or less immediately prior to that notification. The registration status in accordance with paragraph 2, point (g), of Article 24 shall then be 'inactive'.

At a date no sooner than 6 months after the date of notification, the recycler may take the recycling installation into active use again by using it to manufacture recycled plastic in accordance with this Regulation. The date at which the manufactured recycled plastic is first placed on the market shall be notified without delay to the Commission and to the competent authority in the territory where it is located, and this shall be the re-activation date.

After such re-activation, the registration status in accordance with paragraph 2, point (g), of Article 24 shall be either:

(i) the same as the status before the de-activation, provided the inactive period lasted for less than 20 months, or;

(ii) if the inactive period lasted for 20 months or more, the status shall become 're-activated', and the procedure in Article 26 shall apply.

If point (i) applies, and if the status prior to the status change was 'being-established' the deadline of 1 year referred to in Article 26(4) shall be extended by the duration of the inactive period; if point (ii) applies the start date of the production shall be the day of re-activation.'

(7) The following sentence is added to the end of Article 27 below point (b):

'Official controls of recycling installations shall not take place when the registration status in accordance with paragraph 2, point (g), of Article 24 is 'inactive'.'

Delay of suspension of installations

- Was discussed before
  - Register not yet fully operational
  - Competent authorities have not yet finished auditing

303	(9)	The following paragraph 7 is added to Article 31:
304 305 306		'7. By derogation to Article 26(4) the status of the registration of a decontamination installation shall not be changed to 'suspended' before 10 October 2024.';

Amendment to Annex I

- Two amendments forthcoming from establishing template on Decisions
  - 'washed and dried' is added to avoid that we have to say that in every decision
  - ISO 12418-2:2012 is oven test to approach Annex A of the EFSA opinions
    - $m1$ is the mass of label and other visible contaminants
    - $m2$ is the mass of the discoloured (black) particles (mostly PVC)
    - $m3$ is the mass of the yellowish particles (adhesive, some other plastics)
    - these oven tests are common at recyclers

Appendix A – Technical data of the washed flakes as provided by the applicant[10]

Parameter	Value
PVC content	< 200 mg/kg
Polyolefins content	< 100 mg/kg
Metal content (aluminium, ferrous, others)	< 200 mg/kg
Other Plastics	< 200 mg/kg
Dust	< 1.5%
Moisture	< 2.5%
Bulk density	200–600 kg/m^3
Amount of non-food application PET	5%

PVC: poly(vinyl chloride); PET: poly(ethylene terephthalate).

Appendix A – Technical data of the washed flakes as provided by the applicant

Parameter	Value
Moisture max.	1.0%
Bulk density	> 160 kg m^{-3}
Material temperature	10–170°C
Material temperature variation	± 10°C h^{-1}
PVC max.	100 ppm
Glue max.	500 ppm (inclusive flakes)
Polyolefins max.	100 ppm
Metals max.	20 ppm

PVC: poly(vinyl chloride).

(5)

Specification of plastic input

Only PET PCW containing maximum 5 % of materials and articles that were used in contact with non-food materials or substances.

Washed and dried PET PCW containing maximum 5 % of materials and articles that were used in contact with non-food materials or substances. The test results of a test in accordance with Annex A of ISO-12418-2:2012 shall be: m_1/m_0, ≤500 ppm, m_2/m_0≤200 ppm, and m_3/m_0≤500 ppm.

Bisphenol A (BPA) in FCM

Draft Commission Regulation

Subject matter and scope of the measure (Article 1)

a) BPA in the manufacture of plastics, varnishes and coatings, printing inks, adhesives, ion-exchange resins and rubbers

b) the use of other bisphenols classified as category 1A or 1B ‘mutagenic’, ‘carcinogenic’, ‘toxic to reproduction’ or category 1 ‘endocrine disrupting’ for human health in accordance with Union rules on harmonised classification in the manufacture of varnishes and coatings, printing inks, adhesives, ion-exchange resins and rubbers

c) the monitoring for BPA in BADGE-based heavy-duty varnishes and coatings and paper and board materials and articles containing recycled material

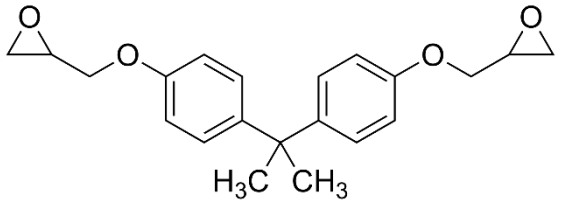
Definitions (Article 2)

- Distinction between intermediate food contact materials and final food contact articles for clarity
- BADGE-based heavy-duty varnishes and coatings → clarification of the volume of containers (250 litres or greater)
- Bisphenol definition in order to clarify which other substances would be subject to a risk assessment and authorisation in case of harmonised hazard classification
- Batch → taken from Reg 2022/1616
- Not all definitions can be addressed

Rules set out in the measure (Article 3)

- The use of BPA in the manufacture of plastic, varnishes and coatings, printing inks, adhesives, ion-exchange resins and rubber FCM is prohibited
- **Except** in the synthesis of BADGE and derivatives for the production of heavy-duty food contact coatings (for containers above 250l or pipes)
  - BADGE to be obtained in separate identifiable batches
  - Must not be present with ND (0.01 mg/kg)
  - Must not lead to reaction (e.g. hydrolysis) which liberates or generates BPA
- **Except** as disodium BPA in the manufacture of polysulfone resins for filtration membranes (ND)

BADGE (bisphenol A diglycidyl ether)

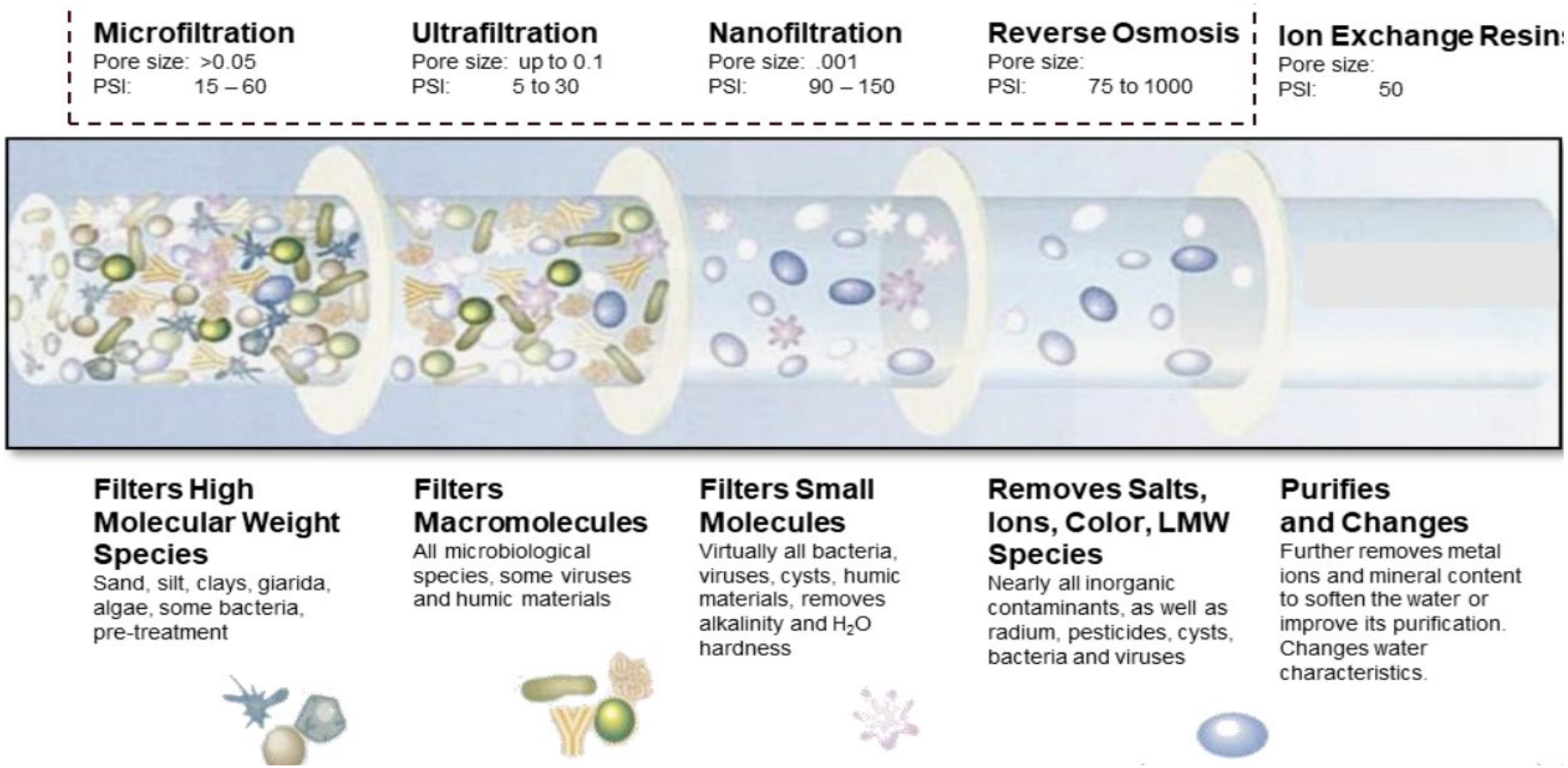


- BPA + epichlorohydrin = BADGE
- Only to be used for heavy-duty coatings (e.g. wine and beer vats, piping, cereal silos, transport tanks)
- Cannot be used in applications below 250l including packaging (smallest containers e.g. beer kegs)
- Down to 250 litres → surface area to volume ratio <1
- Liquid epoxy form should not contain any residual BPA → ND of 0.01 mg/kg should not lead to exposure above TDI
- Commission Regulation (EC) No 1895/2005 may need to be amended

Use of BPA in polysulfone resins

- Condensation reaction of the disodium salt of bisphenol A (BPA) with 4,4-dichlorodiphenyl sulfone (EC No 201-247-9, CAS No 80-07-9)
- Critical as either a separation membrane or as a microporous support of a thin-film polyamide membrane to ensure food safety:
  - purification of drinking water or sugar
  - dairy processing, clarification and concentration of fruit juices
  - reduction or removal of alcohol from wine and beer
- Currently no alternative that is technically and economically feasible at commercial scale and which can provide the necessary mechanical strength and chemical stability for such applications

Use of BPA in polysulfone resins



Use of BPA in polysulfone resins

- The application of appropriate practices in the manufacture of these polysulfone resins can ensure that any presence of residual BPA in the polysulfone-based membrane is avoided or reduced to negligible amounts
- Such applications should not lead to exposure to BPA that poses a risk to consumers
- Authorisation of disodium bisphenol A specifically for the manufacture of polysulfone resins for food contact membranes, provided that the migration into food is not detectable
- Annex I to Commission Regulation (EC) No 10/2011 is amended as such (Annex III of draft measure)

Requirements on the use of other bisphenols (Article 4)

- Bisphenols classified as category 1A or 1B ‘mutagenic’, ‘carcinogenic’, ‘**toxic to reproduction**’ or category 1 ‘endocrine disrupting’ for human health in accordance with the criteria set out in sections 3.5, 3.6, 3.7 and 3.11 respectively of Annex I to Regulation (EC) No 1272/2008 may only be used in the manufacture of materials and articles if explicitly authorised
- Bisphenol → defined and set out in Annex I
- Applications for an assessment and authorisation within 9 months of the measure or classification; thereafter may be placed on the market until decision by Commission based on EFSA opinion. None foreseen at present
- Plastic not included per se as assessment and authorisation already required for all substances subject to Article 5 of Regulation 10/2011

Monitoring and reporting (Article 5)

- Mandatory monitoring for
  - BPA in heavy-duty BADGE-based varnishes and coatings
  - presence in or migration from recycled paper and board FCM
- Frequency of 5% of batches or production run (P&B), selected at random
- Follow up when BPA detected to ascertain source, taking into account possible presence from source(s) other than FCM
- Reporting of methods and results to Member States every year including action taken to reduce levels where appropriate
  - Member States to report levels to Commission
- Discussion on
  - (need for) action level – for P&B
  - methodology

Methodology and reporting

- For BPA in heavy-duty BADGE-based varnishes and coatings
  - Standard operating procedure for BPA in uncured liquid epoxy resin by LC-MS
  - Views on LoD and determination in liquid resin as opposed to migration welcome
- For BPA in paper and board
  - CEN/TS 17497:2020 extracts BPA from 5 g of paper in 10 ml of acetonitrile at 23 °C for 24 h. Unclear whether the extraction of BPA is complete which may hamper comparability of results between different papers
  - EN 15519:2007 extracts substances from 10 g of paper in iso-octane or 95 % ethanol at temperatures and contact times depending on the intentional use of the paper article. Also unclear whether the extraction of BPA is complete
  - Weight of the paper should also be determined (EN ISO 536) to recalculate the content of BPA in the paper as a mass per paper area potentially supporting exposure estimates

Declaration of compliance (Article 6)

- Necessary to confirm that BPA has not been used in the manufacture of the relevant materials and articles
- Annex II:
  1. the identity and address of the business operator issuing the declaration of compliance;
  2. the identity and address of the business operator which manufactures or imports the material or article;
  3. the [identity of the] intermediate food contact material or final food contact article;
  4. the date of the declaration;
  5. confirmation that the material or article complies with the restrictions laid down in Articles 3 of this Regulation and the requirements set out in Articles 3, 15 and 17 of Regulation (EC) No 1935/2004.

Transitional provisions (Article 8)

- In general, 18 months after application of the draft measure for final food contact articles except for the following:
  - final food contact articles intended to be filled with processed fruits and vegetables and processed fish (36 months)
  - final articles on which a varnish or coating has been applied specifically to the exterior metal surface, applicable only to that exterior material (36 months)
  - repeat-use final articles used as fixed components in professional food production equipment (e.g. moulding equipment, hoses, tubes, pumps, valves, closures, flanges, seals, gauges and sight glasses) (48 months)
- Manufacturers of intermediate FCM to notify 9 months in advance in DoC
- Packaging to be filled within 12 months after transitional period

Transitional provisions (Article 8)

Plastic FCM

Current	Up to 18 months after coming into force	Between 18 months and 48 months	Permanently
BPA authorised except in baby bottles and sippy cups and packaging for infants and young children	Status quo	BPA banned except for repeat-use final articles used as fixed components in professional food production equipment	BPA banned except for polysulfone resin used in filtration units in professional food production equipment

FCM varnishes and coatings

Current	Up to 18 months after coming into force	Between 18 months and		Permanently
		36 months	48 months	
BPA subject to SML (allowed) except in packaging for infants and young children	Status quo	BPA banned except in: • Packaging to be filled with processed fruits & vegetables and processed fish; • Exterior of metal packaging	BPA banned except for repeat-use final articles used as fixed components in professional food production equipment and to make BADGE for heavy duty coatings	BPA banned except for use to make BADGE for heavy duty coatings

FCM adhesives, inks, rubbers, IER

Current	Up to 18 months after coming into force	Between 18 months and 48 months	Permanently
No EU rules (allowed subject to national rules and Article 3)	Status quo	BPA banned except for repeat-use final articles used as fixed components in professional food production equipment	BPA banned

Next steps

- Draft measure will be published for four-week feedback shortly
- Please wait on this draft text before providing written comments to us
- Vote foreseen PAFF 24 April 2024

AoB

AoB

- Micro plastics from peppermill grinding wheels
- Two possible approaches
  - Article 3(c) of Regulation (EC) No 1935/2004
  - Article 12 of Regulation (EU) No 10/2011
- What are your views?

END - Monday

European Commission

Thank you