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ANNEXES 1 to 2

ANNEXES

to the

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

amending Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food, amending Regulation (EU) 2022/1616 on recycled plastic materials and articles intended to come into contact with foods, and repealing Regulation (EC) No 282/2008, and amending Regulation (EC) No 2023/2006 on good manufacturing practice for materials and articles intended to come into contact with food as regards recycled plastic and other matters related to quality control and manufacturing of plastic materials and articles intended to come into contact with food.

ANNEX I

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

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

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

(2) Annex IV is amended as follows:

(a) point 6 is replaced by the following:

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

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

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

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

(b) points 10 and 11 are added:

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

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

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

11. when the plastic material has been manufactured with one or more substances included in the Union list of authorised substances in accordance with Article 5 of Regulation (EU) No 10/2011 that have been manufactured from waste, a confirmation that the substances used are compliant with point (1)-of Article 8 of this Regulation.'

(3) Annex V is amended as follows:

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

'

COMPLIANCE TESTING

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

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

– RL is the relative lower method working range threshold

– RU is the relative upper method working range threshold.

– RU shall be 2. RL shall be 0.2 unless 0.2 * SML is below the analytical limit of quantification (LOQ) of the substance then the RL * SML is set at the LOQ of the substance.

– Prior to the verification of compliance with a SML, the specific migration test result, *m*, needs to be corrected, if relevant, (1) 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.

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

$CV_R = 0.22$ for $m_c < 0.12 * 10^{-6}$ kg /kg; and,

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

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

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

IF $(m_c - SML)/[(u(m_c)] > 1.64$, then m_c exceeds the SML.

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

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

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

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

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

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

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

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

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

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

– IF $(m_{c,3}$ - SML)/[(u($m_{c,3}$)] > 1.64, then third migration is higher than the SML,

– IF $(m_{c,2} - m_{c,1})$/[(u($m_{c,2}$) + u($m_{c,1}$)] > 1.64, then the first migration is smaller than the second migration,

– IF $(m_{c,3} - m_{c,2})$/[(u($m_{c,3}$) + u($m_{c,2}$)] > 1.64, then the second migration is smaller than the third migration,

– IF $(m_{c,3} - m_{c,1})$/[(u($m_{c,3}$) + u($m_{c,1}$)] > 1.64, the first migration is smaller than the third migration.

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

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

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

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

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

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

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

standard measurement uncertainty derived on the basis of the approach as specified in the introductory part on compliance testing preceding Chapter 1.

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

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

[*] Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation) (OJ L 95, 7.4.2017, p. 1, ELI: http://data.europa.eu/eli/reg/2017/625/oj.'

ANNEX II

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

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

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

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

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

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

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

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

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

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

(3) The following section C is added:

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

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

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

containers shall be designed to prevent any contamination of the plastic material.

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

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