EUROPEAN
COMMISSION

Brussels, XXX
PLAN/2022/1435 CIS
(POOL/E2/2022/1435/1435-CIS
ANNEX.docx) feedback
[…](2024) XXX draft

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 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 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.

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;';

(b) in point 8, the following point is added:

'(iv) the maximum lifespan of the material or article based on a report evaluating the maximum lifespan of the material or article taking into account the elements set out in Article 10(3);';

(c) 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 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;

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.'

(3) Annex V is amended as follows:

(c) 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:

– 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.

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:

- 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;

– 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 $m \leq 0.12 * 10^{-6}$ 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.

– 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.'

(d) 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.

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.

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: $u(m) = CV_R * m$.

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.

However, if there is scientific proof that the level of the migration decreases in the course of the second and third migration tests and if the migration limit is not exceeded during the first migration test, the material or article is considered compliant with the specific migration limit laid down in Regulation (EU) No 10/2011.

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

(e) In Chapter 2 of Annex V, point 2.1.7 of 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.'.

(f) 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.

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.

[*] 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 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.'

(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(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.

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 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.’