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Delegations will find attached document D066086/02 - ANNEX.

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ANNEX

ANNEX

to the

COMMISSION REGULATION (EU) …/…

amending and correcting Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food

ANNEX

"Annexes I, II, IV, and V to Regulation (EU) No 10/2011 are amended as follows:

(1) Annex I is amended as follows:

(a) in point 1, Table 1 is amended as follows:

(i) entry 236 on 1,3-phenylenediamine is replaced by the following:

"236	23050	000010 8-45-2	1,3-phenylenediamine	no	yes	no	ND			(28) "

(ii) entry 398 on antimony trioxide is replaced by the following:

"398	35760	000130 9-64-4	antimony trioxide	yes	no	no				(6)"

(iii) the following entries are inserted in numerical order:

"1075			Montmorillonite clay modified with hexadecyltrimethyl ammonium bromide	yes	no	no			Only to be used as additive at up to 4,0% w/w in polylactic acid plastics intended for long term storage of water at ambient temperature or below. Can form platelets in the nanoform that are in one or two dimensions thinner than 100 nm. Such platelets shall be oriented parallel to the polymer surface and shall be fully embedded in the polymer.	
1076		122793 7-46-3	Phosphorous acid, triphenyl ester, polymer with alpha-hydro-omega-hydroxypoly[oxy(methyl-1,2-ethanediyl)], C10-	yes	no	no	0,05		Only to be used as an additive at up to 0,2% w/w in high impact polystyrene materials and articles intended contact with food at room	

			16 alkyl ester						temperature and below, including hot-fill and/or heating up to 100°C for up to 2 hours. It shall not be used in contact with foods for which simulant C and/or D1 is assigned in Annex III.	
1077			Titanium dioxide surface-treated with fluoride-modified alumina	yes	no	no			Only to be used at up to 25,0% w/w, including in the nanoform.	29”

(b) in point 3 of Table 3, the following entries are added:

“28	A detection limit of 0,002 mg/kg food or food simulant applies
29	In polar polymers which swell in contact with foods for which simulant B is assigned in Annex III, there is a risk that under severe contact conditions the migration limits for aluminium and fluoride are exceeded. Under contact conditions above 4 hours at 100 °C this exceedance can be high.”

(2) Annex II is replaced in its entirety by the following:

“ANNEX II

Restrictions on plastic materials and articles

The following restrictions on plastic materials and articles apply:

1. Plastic materials and articles shall not release the substances in Table 1 below in quantities exceeding the specific migration limits expressed in mg/kg food or simulant specified in column (3), and subject to the remarks in Column (4)..

   Substances listed in Table 1 shall only be used in accordance with the compositional requirements set out in Chapter II. If Chapter II does not provide a basis for the authorised use of such a substance, that substance may only be present as an impurity subject to the restrictions specified in Table 1.

Table 1

General list of migration limits for substances migrating from plastic materials and articles

(1)	(2)	(3)	(4)
Name	**Salts allowed in accordance with Article 6(3)(a)**	**SML [mg/kg food or food simulant]**	**Remark**
Aluminium	yes	1	
Ammonium	yes	-	(1)
Antimony	no	0,04	(2)
Arsenic	no	ND	
Barium	yes	1	
Cadmium	no	ND (LOD 0,002)	
Calcium	yes	-	(1)
Chromium	no	ND	(3)
Cobalt	yes	0,05	
Copper	yes	5	
Europium	yes	0,05	(4)
Gadolinium	yes	0,05	(4)
Iron	yes	48	
Lanthanum	yes	0,05	(4)
Lead	no	ND	
Lithium	yes	0,6	
Magnesium	yes	-	(1)
Manganese	yes	0,6	
Mercury	no	ND	
Nickel	no	0,02	

Potassium	yes	-	(1)
Sodium	yes	-	(1)
Terbium	yes	0,05	(4)
Zinc	yes	5	

ND: Not Detectable; detection limit assigned in accordance with second subparagraph of Article 11(4); LOD: specified Limit of Detection

Remarks

(1) The migration is subject to Article 11(3) and Article 12

(2) The note in Annex I, Table 1, FCM No 398 applies: SML might be exceeded at very high temperature

(3) To verify compliance with the Regulation, the detection limit of 0,01 mg/kg shall apply for total chromium. However if the operator that placed the material on the market can prove on the basis of pre-existing documentary evidence that the presence of hexavalent chromium in the material is excluded because it is not used or formed or during the entire production process, a limit for the total chromium of 3,6 mg/kg food shall apply.

(4) The lanthanide substances europium, gadolinium, lanthanum, and/or terbium can be used in accordance with Article 6(3)(a) provided that:

a) The sum of all lanthanide substances migrating to the food or food simulant does not exceed the specific migration limit of 0,05 mg/kg; and,

b) analytical evidence using a well described methodology demonstrating that the lanthanide substance(s) used are present in dissociated ionic form in the food or the food simulant, forms part of the documentation referred to in Article 16.

2. Primary aromatic amines ('PAAs') listed in entry 43 to Appendix 8 of Annex XVII to Regulation (EC) No 1907/2006[1] and for which no migration limit is specified in Table 1 of Annex I shall not migrate or shall not otherwise be released from plastic materials and articles into food or food simulant. They shall not be detectable using analytical equipment with a limit of detection of 0.002 mg/kg food or food simulant applied to each individual primary aromatic amine ('PAA'), in accordance with Article 11(4).

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

For PAAs not listed in entry 43 to Appendix 8 of Annex XVII to Regulation (EC) No 1907/2006, but for which no specific migration limit is specified in Annex I, compliance with Article 3 of Regulation (EC) 1935/2004 shall be verified in accordance with Article 19. The sum of those PAAs shall however not exceed 0.01 mg/kg in food or food simulant."

(3) In Annex IV, point 6 is replaced by the following:

"

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

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

– that are subject to restrictions in Annex II; or,

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

(4) Annex V is amended as follows:

(a) Chapter 2 is amended as follows:

(i) in the second paragraph of point 2.1.3, the following subparagraph is added:

"(iv) if the plastic material or article intended to come into contact with food of which the compliance must be verified becomes in its final application part of a food processing equipment or an appliance, or a part thereof, the migration tests may be carried out by determining the specific migration into the food or food simulant produced or processed by the whole equipment or appliance, or the part thereof, as appropriate, subject to the following conditions:

– the food or food simulant is processed during testing by the equipment or part thereof in accordance with the worst foreseeable conditions that can be achieved if the equipment or its part is operated in accordance with its operating instructions, and,

– the migration from parts used for storage such as from reservoirs, containers, or capsules or pads which are part of the equipment during the processing of the food, is determined using conditions representative for their use,

unless the applied testing conditions for the whole tested equipment or appliance are representative also of their use.

When migration testing is done under the above conditions, and the transfer of constituents from the equipment or appliance as a whole does not exceed the migration limits, the plastic parts or materials present in the equipment or appliance shall be considered to comply with Article 11(1).

The testing of the parts used for storage or supply such as reservoirs, containers, capsules or pads shall be under conditions representative of their use, and shall include the foreseeable storage conditions of the food in these parts.

The supporting documentation referred to in Article 16 shall clearly document the testing on the whole food processing and/or food producing equipment or appliance, or on parts thereof. It shall demonstrate that the testing was representative of its foreseeable use, and shall indicate for which substances migration testing was carried out and provide all testing results. The manufacturer of individual plastic parts shall ensure the absence of migration for substances for which the Regulation specifies that their migration shall not be detectable at a specified level of detection in accordance with Article 11(4).

Compliance documentation supplied in accordance with the Regulation to the producer of the final equipment or appliance, or part thereof, shall list all substances subject to migration limits that might be exceeded under the foreseeable use of the supplied part or material.

When the result is not in compliance with the Regulation it shall be determined whether the source of the non-compliance is a plastic part subject to the Regulation or a part made from another material not subject to the Regulation on the basis of documentary evidence or analytical testing. Without prejudice to Article 3 of Regulation (EU) No 1935/2004, non-compliance to the Regulation shall only be established if the migration originates from a plastic part."

(ii) point 2.1.6, is replaced in its entirety by the following:

"*2.1.6. Repeated use materials and articles*

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. The specific migration in 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 in the second test.

Compliance of the material or article shall than be verified on the basis of the level of the migration found in the third test and on the

basis of the stability of the material or article from the first to the third migration test. The stability of the material shall be considered insufficient if migration is observed above the level of detection in any of the three migration tests, and increases from the first migration test to the third migration test. In case of insufficient stability, compliance of the material shall not be established even in case the specific migration limit is not exceeded in any of the three tests.

However, if there is conclusive scientific proof that the level of the migration decreases in the second and third tests and if the migration limits are not exceeded on the first test, no further test is necessary.

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

(b) Chapter 3 is amended as follows:

(i) in point 3.1, Table 3 and the four paragraphs below Table 3 are replaced by the following:

"Table 3

Standardised conditions for testing the overall migration

Column 1	Column 2	Column 3
Test number	Contact time in days [d] or hours [h] at Contact temperature in [°C] for testing	Intended food contact conditions
OM0	30 min at 40 °C	Any food contact at cold or ambient temperatures and for a short duration (≤ 30 minutes).
OM1	10 d at 20 °C	Any food contact at frozen and refrigerated conditions
OM2	10 d at 40 °C	Any long term storage at room temperature or below, including when packaged under hot-fill conditions, and/ or heating up to a temperature T where 70 °C ≤ T ≤ 100 °C for a maximum of t = 120/2^((T-70)/10) minutes.
OM3	2 h at 70 °C	Any food contact conditions that include hot-fill and/or heating up

		to a temperature T where 70 °C ≤ T ≤ 100 °C for maximum of t = 120/2^((T-70)/10) minutes, which are not followed by long term room temperature or refrigerated storage.
OM4	1 h at 100 °C or at reflux	High temperature applications for all types of food at temperature up to 100 °C.
OM5	2 h at 100 °C or at reflux or alternatively 1 h at 121 °C	High temperature applications up to 121 °C.
OM6	4 h at 100 °C or at reflux	Any food contact conditions at a temperature exceeding 40 °C, and with foods for which point 4 of Annex III assigns simulants A, B, C or D1.
OM7	2 h at 175 °C	High temperature applications with fatty foods exceeding the conditions of OM5.

Test OM 7 covers also food contact conditions described for OM0, OM1, OM2, OM3, OM4, OM5. It represents the worst case conditions for fatty food simulants in contact with non-polyolefins. In case it is technically not feasible to perform OM 7 with food simulant D2 the test can be replaced as set out in paragraph 3.2.

Test OM 6 covers also food contact conditions described for OM0, OM1, OM2, OM3, OM4 and OM5. It represents worst case conditions for food simulants A, B and C in contact with non-polyolefins.

Test OM 5 covers also food contact conditions described for OM0, OM1, OM2, OM3, OM4. It represents the worst case conditions for all food simulants in contact with polyolefins.

Test OM 2 covers also food contact conditions described for OM0, OM1 and OM3."

(ii) in point 3.2, the paragraphs before the table are replaced by the following:

"If it is not technically feasible to perform one or more of the tests OM0 to OM6 in food simulant D2, migration tests shall be done using ethanol 95 % and isooctane. In addition a test shall be done using food simulant E in case the worst foreseeable conditions of use exceed 100 °C. The test that results in the highest overall migration shall be used to establish compliance with the Regulation

In case it is technically not feasible to perform OM7 with food simulant D2, either test OM8 or test OM9 shall be selected as a replacement test by selecting the most appropriate of these two tests on the basis of the intended and the foreseeable use of the material or article that is being tested. Subsequently, a migration test shall be done at each of the two test conditions specified for the selected test, using a new test sample for each test condition. The test condition that results in the higher overall migration shall be used to establish compliance with the Regulation."

(iii) point 3.3.2, is replaced in its entirety by the following:

"*3.3.2. Repeated use articles and materials*

The applicable overall migration test shall be carried out three times on a single sample using another 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. The overall migration in the second test shall be lower than in the first test, and the overall migration in the third test shall be lower than in the second test. Compliance with the overall migration limit shall be verified on the basis of the level of the overall migration found in the third 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 difference between the third and the second test results shall be considered to represent the overall migration. Compliance shall be verified on the basis of this difference, which shall not exceed the overall migration limit. In addition, the difference between the second and the first test results shall be lower than the first test results and the difference between the third and the second test results shall be lower than the difference between the second and the first test results.

By derogation from the first paragraph, if, on the basis of scientific evidence, it is established that for the material or article being tested the overall migration decreases in the second and third tests and if the overall migration limit is not exceeded in the first test, the first test alone shall be sufficient."