



Council of the
European Union

Brussels, 12 May 2016
(OR. en)

8801/16
ADD 1

DENLEG 44
AGRI 255
SAN 179

COVER NOTE

From:	European Commission
date of receipt:	10 May 2016
To:	General Secretariat of the Council

No. Cion doc.:	D044711/03 - Annex 1
Subject:	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

Delegations will find attached document D044711/03 - Annex 1.

Encl.: D044711/03 - Annex 1



Brussels, **XXX**
SANTE/10261/2015 ANNEX
(POOL/E2/2015/10261/10261-EN
ANNEX.doc) D044711/03
[...](2016) **XXX** draft

ANNEX 1

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

(1) Annex I is amended as follows:

(a) In point 1, the paragraph referring to Column 8 of Table 1 is replaced by the following:

"Column 8 (SML [mg/kg]): the specific migration limit applicable for the substance. It is expressed in mg substance per kg food. It is marked as ND ('not-detectable') if the substance is one in respect of which no migration is permitted, to be determined in accordance with Article 11(4).";

(b) In point 1, the last paragraph before Table 1 is deleted;

(c) In point 1, in column 10 of Table 1, in the entries for the substances with FCM substance Nos 72, 642, 672, 776, 782, 923 and 974, the word "should" is replaced by the word "shall";

(d) In point 1, Table 1 is amended as follows:

(i) in column 10, in the entries for the substances with FCM substance Nos 93, 199, 262, 326, 637, 768, 803, 810, 815, 819 and 884, the words "simulant D" are replaced by the words "simulant D1 and/or D2";

(ii) the entries concerning substances with FCM substance Nos 87, 391, 641, 752, 779 and 974 are replaced by the following:

"87	86285		Silicon dioxide, silanated	yes	no	no			For synthetic amorphous silicon dioxide, silanated: primary particles of 1–100 nm which are aggregated to a size of 0,1–1 µm and may form agglomerates within the size distribution of 0,3 µm to the mm size."	
"391	22932	0001187-93-5	perfluoromethyl perfluorovinyl ether	no	yes	no	0,05		Only to be used in: - anti-stick coatings; - fluoro- and perfluoropolymers intended for repeated use applications where the contact ratio is 1 dm ² surface in contact with at least 150 kg food."	
"641	22331	0025513-64-8	mixture of (35-45% w/w) 1,6-diamino-2,2,4-trimethylhexane and	no	yes	no	0,05"			

			(55-65% w/w)1,6-diamino-2,4,4-trimethylhexane							
"752	39890	0087826-41-3 0069158-41-4 0054686-97-4 0081541-12-0	bis(methylbenzylidene)sorbitol	yes	no	no"				
"779	39815	0182121-12-6	9,9-bis(methoxymethyl)fluorene	yes	no	yes	0,05			(2)"
"974	74050	939402-02-5	phosphorous acid, mixed 2,4-bis(1,1-dimethylpropyl)phenyl and 4-(1,1-dimethylpropyl)phenyl triesters	yes	no	yes	5		SML expressed as the sum of the phosphite and phosphate forms of the substance, 4-tert-amylphenol and 2,4-di-tert-amylphenol. The migration of 2,4-di-tert-amylphenol shall not exceed 1 mg/kg food."	

(iii) the following entries are inserted in numerical order of the FCM substance numbers:

"871		0287916-86-3	dodecanoic acid, 12-amino-, polymer with ethene, 2,5-furandione, α -hydro- ω -hydroxypoly (oxy-1,2-ethanediyl) and 1-propene	yes	no	no			Only to be used in polyolefins at levels of up to 20 weight %. These polyolefins shall only be used in contact with foods for which Table 2 of Annex III assigns food simulant E, at ambient temperature or below, and when migration of the total oligomeric fraction of less than 1000 Da does not exceed 50 μ g/kg food."	(23)"
"1031		3238-40-2	furan-2,5-dicarboxylic acid	no	yes	no	5		Only to be used as a monomer in the production of polyethylene furanoate. The migration of the oligomeric fraction of less than 1000 Da shall not exceed 50 μ g/kg food (expressed as furan-2,5-dicarboxylic acid).	(22) (23)

1034		3710-30-3	1,7-octadiene	no	yes	no	0.05		Only to be used as a crosslinking co-monomer in the manufacture of polyolefins for contact with any type of foods for long term storage at room temperature, including when packaged under hot-fill conditions.	
1045		1190931-27-1	perfluoro{acetic acid, 2-[(5-methoxy-1,3-dioxolan-4-yl)oxy]}, ammonium salt	yes	no	no			Only to be used as a polymer production aid during the manufacture of fluoropolymers under high temperature conditions of at least 370 °C".	
"1046			zinc oxide, nanoparticles, coated with [3-(methacryloxy)propyl] trimethoxysilane (FCM No 788)	yes	no	no			Only to be used in unplasticised polymers. The restrictions and specifications specified for FCM substance No 788 shall be respected.	
1048		624-03-3	ethylene glycol dipalmitate	yes	no	no		(2)	Only to be used when produced from a fatty acid precursor that is obtained from edible fats or oils.	
1050			zinc oxide, nanoparticles, uncoated	yes	no	no			Only to be used in unplasticised polymers.	
1051		42774-15-2	N,N'-bis(2,2,6,6-tetramethyl-4-piperidiny) isophthalamide	yes	no	no	5"			
1052		1455-42-1	2,4,8,10-tetraoxaspiro[5.5]undecane-3,9-diethanol,β3,β3,β9,β9-tetramethyl- ('SPG')	no	yes	no	5		Only to be used as a monomer in the production of polyesters. The migration of oligomers of less than 1000 Da shall not exceed 50 µg/kg food (expressed as SPG).	(22) (23)
1053			fatty acids, C16–18 saturated, esters with dipentaerythritol	yes	no	no			Only to be used when produced from a fatty acid precursor that is obtained from edible fats or oils"	

- (e) In point 2, in Table 2, the entry concerning the group restriction with Group Restriction No 2 is replaced by the following:

"2	89 227 263 1048	30	expressed as ethyleneglycol";
----	--------------------------	----	-------------------------------

- (f) In point 3, in column 2 of Table 3, in the entries for Notes 4 and 5, the word "should" is replaced by the word "shall";

- (g) In point 3, in Table 3, the following entries are added:

"(22)	When used in contact with non-alcoholic foods for which Table 2 of Annex III assigns food simulant D1, food simulant C shall be used for verification of compliance instead of food simulant D1;
(23)	When a final material or article containing this substance is placed on the market, a well described method to determine whether the oligomer migration complies with the restrictions specified in column 10 of Table 1 shall form part of the supporting documentation referred to in Article 16. This method shall be suitable for use by a competent authority to verify compliance. If an adequate method is publicly available, reference shall be made to that method. If the method requires a calibration sample, a sufficient sample shall be supplied to the competent authority on its request.";

- (2) Annex II is amended as follows:

- (a) Point 1 is replaced by the following:

"1. Plastic materials and articles shall not release the following substances in quantities exceeding the specific migration limits below:

Aluminium = 1 mg/kg food or food simulant

Barium = 1 mg/kg food or food simulant

Cobalt = 0,05 mg/kg food or food simulant

Copper = 5 mg/kg food or food simulant

Iron = 48 mg/kg food or food simulant

Lithium = 0,6 mg/kg food or food simulant

Manganese = 0,6 mg/kg food or food simulant

Zinc = 5 mg/kg food or food simulant.";

- (b) Point 2 is replaced by the following:

"2. Primary aromatic amines which are not listed 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 in accordance with Article 11(4). The detection limit referred to in the second subparagraph of Article 11(4) applies to the sum of primary aromatic amines released.";

(3) Annex III is amended as follows:

(a) Table 1 'List of food simulants' is replaced in its entirety by the following:

“Table 1

List of food simulants

Food simulant	Abbreviation
Ethanol 10% (v/v)	Food simulant A
Acetic acid 3% (w/v)	Food simulant B
Ethanol 20% (v/v)	Food simulant C
Ethanol 50% (v/v)	Food simulant D1
Any vegetable oil containing less than 1% unsaponifiable matter	Food simulant D2
poly(2,6-diphenyl-p-phenylene oxide), particle size 60-80 mesh, pore size 200 nm	Food simulant E

”

(b) Point 3, excluding Table 2, is replaced by the following:

"3. Specific assignment of food simulants to foods for migration testing of materials and articles not yet in contact with food

For testing migration from materials and articles not yet in contact with food the food simulants that corresponds to a certain food category shall be chosen according to Table 2 below.

For testing migration from materials and articles intended to come into contact with foods not listed in Table 2 below, or a combination of foods, the general food simulant assignments in point 2 shall be used for specific migration testing, and for overall migration testing the food simulant assignments in point 4 shall be applicable.

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

The food simulant for which a cross is contained in the respective sub-column of column 3 shall be used when testing migration of materials and articles not yet in contact with food.

For food categories where in sub-column D2 or E the cross is followed by an oblique stroke and a figure, the migration test result shall be corrected by dividing the result by this figure. The corrected test result shall then be compared to the migration limit to establish compliance. The test results for substances that shall not migrate in detectable quantities shall not be corrected in this way.

For food category 01.04 food simulant D2 shall be replaced by 95% ethanol.

For food categories where in sub-column B the cross is followed by (*) the testing in food simulant B can be omitted if the food has a pH of more than 4.5.

For food categories where in sub-column D2 the cross is followed by (**) the testing in food simulant D2 can be omitted if it can be demonstrated that there is no 'fatty contact' with the plastic food contact material.";

(c) Table 2 is amended as follows:

(i) the entries with reference numbers 04.01 and 04.04 are replaced by the following:

"04.01	Fruit, fresh or chilled: A. unpeeled and uncut B. peeled and/or cut	X	X(*)";				X/10
"04.04	Vegetables, fresh or chilled: A. unpeeled and uncut B. peeled and/or cut	X	X(*)";				X/10

(ii) in the entry with reference number 04.05 is replaced by the following:

"04.05	Processed vegetables: A. Dried or dehydrated vegetables whole, sliced or in the form of flour or powder. B. (<i>obsolete</i>) C. Vegetables in the form of purée, preserves, pastes or in its own juice (including pickled and in brine). D. Preserved vegetables: I. In an oily	X	X(*)	X			X
--------	---	---	------	---	--	--	---

	medium						
	II. In an alcoholic medium				X”;		

(d) The following point 5 is added:

"5. General derogation to the assignment of food simulants

By derogation from the assignments of food simulants in points 2 to 4 of this Annex, where testing with several food simulants is required, a single food simulant shall be sufficient if on the basis of evidence acquired using generally recognised scientific methods this food simulant is shown to be the most severe food simulant for the particular material or article being tested under the applicable time and temperature conditions selected in accordance with Chapters 2 and 3 of Annex V.

The scientific basis on which this derogation is used shall in such cases form part of the documentation required under Article 16 of this Regulation.”;

(4) Annex IV is amended as follows:

(a) Point (5) is replaced by the following:

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

(5) Annex V is amended as follows:

(a) Section 1.4 of Chapter 1 is replaced by the following:

"1.4 Account of substances originating from other sources

In case there is evidence linked to the food sample that a substance partially or wholly originates from a source or sources other than the material or article for which the test is being carried out, the test results shall be corrected for the amount of that substance originating from the other source or sources before comparing the test results to the applicable specific migration limit"

(b) In Section 2.1.3 of Chapter 2, the text before Table 1 is replaced in its entirety by the following:

"The sample shall be placed in contact with the food simulant in a manner representing the worst of the foreseeable conditions of use as regard contact time in Table 1 and as regard contact temperature in Table 2.

By way of derogation to the conditions set out in Tables 1 and 2, the following rules apply:

- (i) If it is found that carrying out the tests under the combination of contact conditions specified in Tables 1 and 2 causes physical or other changes in the test specimen which do not occur under worst foreseeable conditions of use of the material or article under examination, the migration tests shall be carried out under the worst foreseeable conditions of use in which these physical or other changes do not take place;
- (ii) if the material or article during its intended use is subjected only to precisely controlled time and temperature conditions in food processing equipment, either as part of food packaging or as part of the processing equipment itself, testing may be done using the worst foreseeable contact conditions that can occur during the processing of the food in that equipment;
- (iii) if the material or article is intended to be employed only for hot-fill conditions, only a 2-hour test at 70°C shall be carried out. However, if the material or article is intended to be used also for storage at room temperature or below, the test conditions set out in Table 1 and 2 of this Section or in Section 2.1.4 of this Chapter apply depending on the duration of storage.

If the testing conditions representative for the worst foreseeable conditions of intended use of the material or article, are not technically feasible in food simulant D2, migration tests shall be done using ethanol 95% and isoctane. In addition a migration test shall be done using food simulant E if the temperature under the worst foreseeable conditions of intended use exceeds 100°C. The test that results in the highest specific migration shall be used to establish compliance with this Regulation.";

- (c) In Table 1, the title of the table is replaced by the following:

"Selection of test time";

- (d) In Table 1, the title of column 2 is replaced by the following:

"Time to be selected for testing";

- (e) Table 2 is replaced by the following:

"Table 2

Selection of test temperature

Worst foreseeable contact temperature	Contact temperature to be selected for testing
$T \leq 5^{\circ}\text{C}$	5°C
$5^{\circ}\text{C} < T \leq 20^{\circ}\text{C}$	20°C
$20^{\circ}\text{C} < T \leq 40^{\circ}\text{C}$	40°C
$40^{\circ}\text{C} < T \leq 70^{\circ}\text{C}$	70°C
$70^{\circ}\text{C} < T \leq 100^{\circ}\text{C}$	100°C or reflux temperature

100°C < T ≤ 121°C	121°C(*)
121°C < T ≤ 130°C	130°C(*)
130°C < T ≤ 150°C	150°C(*)
150°C < T < 175°C	175°C(*)
175°C < T ≤ 200°C	200°C(*)
T > 200°C	225°C(*)
<p>(*) This temperature shall be used only for food simulants D2 and E. For applications heated under pressure, migration testing under pressure at the relevant temperature may be performed. For food simulants A, B, C or D1 the test may be replaced by a test at 100°C or at reflux temperature for duration of four times the time selected according to the conditions in Table 1.";</p>	

(f) Section 2.1.4 of Chapter 2 is replaced by the following:

"2.1.4. Specific conditions for contact times above 30 days at room temperature and below

For contact times above 30 days (long term) at room temperature and below, the specimen shall be tested in accelerated test conditions at elevated temperature for a maximum of 10 days at 60°C(*).

- (a) Testing for 10 days at 20°C shall cover all storage times at frozen condition. This test can include the freezing and defrosting processes if labelling or other instructions ensure that 20°C is not exceeded and the total time above -15°C does not exceed 1 day in total during the foreseeable intended use of the material or article.
- (b) Testing for 10 days at 40°C shall cover all storage times at refrigerated and frozen conditions including hot-fill conditions and/or heating up to 70°C ≤ T ≤ 100°C for maximum $t = 120/2^{((T-70)/10)}$ minutes.
- (c) Testing for 10 days at 50°C shall cover all storage times of up to 6 months at room temperature, including hot-fill conditions and/or heating up to 70°C ≤ T ≤ 100°C for maximum $t = 120/2^{((T-70)/10)}$ minutes.
- (d) Testing for 10 days at 60°C shall cover storage above 6 months at room temperature and below, including hot-fill conditions and/or heating up to 70°C ≤ T ≤ 100°C for maximum $t = 120/2^{((T-70)/10)}$ minutes.
- (e) For storage at room temperature the testing conditions can be reduced to 10 days at 40°C if it is shown by scientific evidence that migration of the respective substance in the polymer has reached equilibration under this test condition.
- (f) For worst foreseeable conditions of intended use not covered by the test conditions set out in points (a) to (e), the testing time and temperature conditions shall be based on the following formula:

$$t_2 = t_1 * \text{Exp} (9627 * (1/T_2 - 1/T_1))$$

t1 is the contact time

t2 is the testing time

T1 is the contact temperature in Kelvin. For room temperature storage this is set at 298K (25°C). For refrigerated conditions it is set at 278K (5°C). For frozen storage it is set at 258 K (-15°C).

T2 is the testing temperature in Kelvin.

(*) When testing at these accelerated test conditions the test specimen shall not undergo any physical or other changes compared to the real conditions of use, including a phase transition of the material.";

(g) The first paragraph of Section 2.1.5 of Chapter 2 is replaced by the following:

"If a material or article is intended for different applications covering different combinations of contact time and temperature the testing shall be restricted to the test conditions which are recognised to be the most severe on the basis of scientific evidence.";

(h) In Section 2.1.6 of Chapter 2, the third paragraph is replaced by the following:

"The material or article shall respect the specific migration limit already in the first test for substances that are prohibited from migrating or from being released in detectable quantities under Article 11(4).";

(i) The first paragraph of Section 2.2 of Chapter 2 is replaced by the following:

"To screen if a material or article complies with the migration limits any of the following approaches can be applied which are considered at least as severe as the verification method described in section 2.1.";

(j) Section 2.2.3 of Chapter 2 is replaced by the following:

"Migration modelling

To screen for specific migration, the migration potential can be calculated based on the residual content of the substance in the material or article applying generally recognised diffusion models based on scientific evidence that are constructed in a way that must never underestimate real levels of migration.";

(k) Section 2.2.4 of Chapter 2 is replaced by the following:

"2.2.4. Food simulant substitutes

To screen for specific migration, food simulants can be replaced by substitute food simulants if it is based on scientific evidence that the substitute food

simulants result in migration that is at least as severe as migration that would be obtained using the food simulants specified in Section 2.1.2";

- (l) In Section 2.2 of Chapter 2, the following paragraph 2.2.5 is added:

"2.2.5 Single test for successive combinations of time and temperature

If the material or article is intended for a food contact application where it is successively subject to two or more time and temperature combinations, a single migration contact test time can be defined based on the highest contact test temperature from Section 2.1.3 and/or 2.1.4 by using the equation as described in point (f) of Section 2.1.4. The reasoning justifying that the resulting single test is at least as severe as the combined time and temperature combinations shall be documented in the supporting documentation provided for in Article 16.";

- (m) Table 3 in Chapter 3 is 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
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 $70^{\circ}\text{C} \leq T \leq 100^{\circ}\text{C}$ 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 $70^{\circ}\text{C} \leq T \leq 100^{\circ}\text{C}$ 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	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	High temperature

	1 h at 121°C	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.";

- (n) In Section 3.1 of Chapter 3, the paragraphs below Table 3 are replaced by the following:

"Test OM7 also covers food contact conditions described for OM1, OM2, OM3, OM4 and OM5. It represents the worst case conditions for food simulant D2 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 Section 3.2.

Test OM6 covers also food contact conditions described for OM1, OM2, OM3, OM4 and OM5. It represents worst case conditions for food simulants A, B, C and D1 in contact with non-polyolefins.

Test OM5 covers also food contact conditions described for OM1, OM2, OM3, and OM4. It represents the worst case conditions for all food simulants in contact with polyolefins.

Test OM2 covers also food contact conditions described for OM1 and OM3.";

- (o) Section 3.2 of Chapter 3 is replaced by the following:

"3.2. Substitute overall migration tests for tests with food simulant D2

If it is not technically feasible to perform one or more of the tests OM1 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 specific migration shall be used to establish compliance with this Regulation.

In case it is technically not feasible to perform OM7 with food simulant D2 the test can be replaced by either test OM8 or test OM9 as appropriate given the intended or foreseeable use. Both tests involve testing at two test conditions for which a new test sample shall be used for each test. The test condition that results in the highest overall migration shall be used to establish compliance with this Regulation.

Test number	Test conditions	Intended food contact conditions	Covers the intended food contact conditions described
--------------------	------------------------	---	--

			in
OM8	Food simulant E for 2 hours at 175°C and food simulant D2 for 2 hours at 100°C	High temperature applications only	OM1, OM3, OM4, OM5 and OM6
OM9	Food simulant E for 2 hours at 175°C and food simulant D2 for 10 days at 40°C	High temperature applications including long term storage at room temperature	OM1, OM2, OM3, OM4, OM5 and OM6";

(p) Section 3.3 of Chapter 3 is replaced by the following:

"3.3. Verification of compliance

3.3.1 Single use articles and materials

At the end of the prescribed contact time, to verify compliance the overall migration is analysed in the food simulant using an analytical method in accordance with the requirements of Article 11 of Regulation (EC) No 882/2004.

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 11 of Regulation (EC) No 882/2004. 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 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, it shall not be higher than the first result and 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 does not increase 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.";

(q) The first paragraph of Section 3.4 of Chapter 3 is replaced by the following:
"To screen if a material or article complies with the migration limits, any of the

following approaches can be applied which are considered at least as severe as the verification method described in sections 3.1. and 3.2.";

- (r) Section 3.4.2 of Chapter 3 is replaced by the following:

"3.4.2. Food simulant substitutes

To screen for overall migration, food simulants can be replaced if based on scientific evidence the substitute food simulants result in migration that is at least as severe as migration that would be obtained using the food simulants specified in Annex III.";

- (s) In Section 4.1 of Chapter 4, the fifth paragraph is replaced by the following:

"The specific migration in food or food simulant shall not exceed 60 mg/kg food before application of the FRF.";

- (t) In Section 4.1 of Chapter 4, the following paragraph is added:

"When testing is performed in food simulant D2 or E and when the test results are corrected in application of the correction factor laid down in Table 2 of Annex III this correction may be applied in combination with the FRF by multiplying both factors. The combined correction factor shall not exceed 5, unless the correction factor laid down in Table 2 of Annex III exceeds 5.";

- (u) Sections 4.2 and 4.3 of Chapter 4 are deleted.