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SANCO/XXXX
[...] (2015) **XXX** draft

ANNEX 1

ANNEX

to the

COMMISSION REGULATION (EU) No .../..

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

ANNEX

Regulation (EU) No 10/2011 is amended as follows:

- (1) In Article 3(16) the words 'Table 2 of Annex V' are replaced by 'Table 2 of Annex III'
- (2) In Article 3 the following points (19) and (20) are added:
'(19) 'rubber' means a polymeric material, of which:
 - (a) the main structural component undergoes vulcanisation during or after its final polymerisation step; or
 - (b) at least one polymeric component is vulcanised during the last polymerisation step of a mixture that contains several polymeric components;(20) 'vulcanisation' means the crosslinking of polymeric chains with a specific type of covalent bonds, using sulphur and/or chemically equivalent curatives.'
- (3) In Article 6(3) point (a) is replaced with the following wording:
'(a) salts (including multiple salts, acid salts, and salt hydrates) of aluminium, ammonium, barium, calcium, cobalt, copper, iron, lithium, magnesium, manganese, potassium, sodium, and zinc of authorised acids, phenols or alcohols;'
- (4) In Article 9, the following paragraph 3 is added:
'3. Substances listed in Annex I for which a restriction on the migration of oligomers is laid down in that Annex shall only be used if a suitable method of analysis for determining the migration of oligomers is published by the European Union reference laboratory for material intended to come into contact with foodstuffs, established as laid down in Regulation (EC) No 882/2004, in accordance with the rules set out in Article 18a.'
- (5) In Article 13(3) the first sentence is replaced by the following:
'The migration of the substances under paragraph 2(b) into food or food simulant shall not be detectable measured by a method of analysis set out in Article 11 of Regulation (EC) No 882/2004 with a limit of detection of 0,01 mg/kg, taking into account measurement uncertainty.'
- (6) In Article 17(3)(a) the phrase 'in mg/dm²' is deleted:
- (7) In Article 18(4) the words 'A, B, C, D1, and D2 as' are deleted
- (8) The following Article 18a is inserted:
'Article 18a
Publication of methods of analysis by the European Union reference laboratory
1. When this Regulation requires the publication of one or more methods by the European Union reference laboratory for materials intended to come into contact with foodstuffs ('the reference laboratory') before a substance can be placed on the market, and not all necessary methods have been published for that substance, any business operator wishing to use the substance can submit a suitable method to the reference laboratory.'

Any calibrants required for the use of the submitted method shall be made available to that reference laboratory along with the method.

The reference laboratory shall publish the method without delay on its website, taking account of any relevant previous withdrawal notices it published.

2. The European Union reference laboratory for materials intended to come into contact with foodstuffs shall review all methods it publishes for their technical and practical suitability. It may amend or withdraw methods which it considers not suitable, replace them, or include them in other methods.

3. The European Union reference laboratory for materials intended to come into contact with foodstuffs shall only withdraw a method when an alternative method is made available or eight months after the publication of a withdrawal notice on its website. This notice shall give detailed reasons justifying the withdrawal and providing information to the improvement of the method.'

- (9) In Article 19 the first paragraph is replaced by the following:
'Compliance with Article 3 of Regulation (EC) No 1935/2004 of substances referred to in Articles 6(1), 6(2), 6(4), 6(5), 13(2)(b) and 14(2) of this Regulation which are not covered by an inclusion in Annex I to this Regulation shall be assessed in accordance with internationally recognised scientific principles on risk assessment.'
- (10) In Article 22 paragraph 4 is replaced by:
'Until 31 December 2016 constituents of glass fibre sizing agents for glass fibre reinforced plastics which are not listed in Annex I have to comply with the risk assessment provisions set out in Article 19.'
- (11) In Article 23 the fourth paragraph is replaced by:
'The provision of Article 5 as regards the use of constituents of glass fibre sizing agents for glass fibre reinforced plastics, shall apply from 31 December 2016.'
- (12) The word 'should' is replaced by 'shall' in the following locations in Annex I:
- (a) In table 1, substance 72, column 10
 - (b) In table 1, substance 642, column 10
 - (c) In table 1, substance 672, column 10
 - (d) In table 1, substance 776, column 10
 - (e) In table 1, substance 782, column 10
 - (f) In table 1, substance 923, column 10
 - (g) In table 1, substance 974, column 10
 - (h) In table 3, Note No (4), column 2
 - (i) In table 3, Note No (5), column 2
- (13) In column (10) of table 1 of Annex I the phrase 'simulant D' is replaced by 'simulant D1 and/or D2' in the entries for the substances with Nos. 93, 199, 262, 326, 637, 768, 803, 810, 815, 819, and 889.
- (14) Table 1 of Annex I is amended as follows:

(a) the entry concerning FCM substances Nos. 87, is replaced by the following:

'87	86285		Silicon dioxide, silanated	Yes	No	No			When produced from particles smaller than 100 nm, no particles of less than 100 nm shall remain in the final material	
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* Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications of food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).'

(b) 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 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	
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)
1034		3710-30-3	1,7-octadiene	no	yes	no	0.05		Only to be used as a crosslinking comonomer in the manufacture of polyolefins for contact with any type of foods for	

									long term storage at room temperature, including 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	
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	
1051		42774-15-2	N,N'-bis(2,2,6,6-tetramethyl-4-piperidinyl) 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)
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	

(c) The entry concerning FCM substance No 725 is deleted.

(15) In Table 2 of Annex I, the entries concerning group restrictions Nos. 2 and xx are replaced by the following:

'2	89 227 263 1048	30	expressed as ethyleneglycol
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- (21) In table 2 of Annex III the entry 04.05.B. ('Fresh vegetables, peeled or cut') is deleted
- (22) To Annex III the following point 5 is added:
- '5. General derogation to the assignment of food simulants
- In derogation to the assignments for food simulants in point 1 to 4 of this Annex, only a single food simulant suffices if on the basis of scientific evidence it is established that this food simulant is the most severe for the particular material being tested under the applicable time temperature conditions.
- The scientific basis on which basis this derogation is used shall in such case be part of the documentation required under Article 16 of this Regulation.'
- (23) In the beginning of Annex V the section 'compliance testing' is replaced by the following:
- Compliance Testing**
- For testing compliance of migration from plastic food contact materials and articles the general rules set out in chapter 1-4 of this Annex apply.
- When applying these rules, any specified temperature shall always be determined at the contact surface between the food contact material and the food or food simulant. If measuring at the contact surface is not practicable the test temperature shall be adjusted to ensure the real temperature at the contact surface corresponds to the specified temperatures.'
- (24) The word 'should' is replaced by 'shall' in the following locations in Annex V:
- (a) In paragraph 1.1., last sentence
 - (b) In paragraph 2.1.5, first sentence
 - (c) In paragraph 2.1.6, last sentence
 - (d) In paragraph 4.2, last sentence
- (25) In the second paragraph of point 2.1.3 the phrase 'in which these physical or other changes do not take place' at the end of the paragraph is deleted.
- (26) To point 2.1.3 the following paragraph is added at the end:
- 'If under real worst foreseeable conditions of use it is not technical feasible to perform the test 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.'
- (27) In Table 1 of Annex V the header of column 2 is replaced by the following:
- 'Contact time during testing'
- (28) Table 2 of Annex V is replaced with the following table:

Conditions of contact in worst foreseeable use	Test conditions
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Contact temperature	Test temperature
$T \leq 5\text{ °C}$	5 °C
$5\text{ °C} < T \leq 20\text{ °C}$	20 °C
$20\text{ °C} < T \leq 40\text{ °C}$	40 °C
$40\text{ °C} < T \leq 70\text{ °C}$	70 °C
$70\text{ °C} < T \leq 100\text{ °C}$	100 °C or reflux temperature
$100\text{ °C} < T \leq 121\text{ °C}$	121 °C(*)
$121\text{ °C} < T \leq 130\text{ °C}$	130 °C (*)
$130\text{ °C} < T \leq 150\text{ °C}$	150 °C (*)
$150\text{ °C} < T < 175\text{ °C}$	175 °C (**)
$175\text{ °C} < T \leq 200\text{ °C}$	200° C(**)
$T > 200\text{ °C}$	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> <p>(**) Materials and articles used at contact temperatures exceeding 175°C shall be tested using only simulant E.</p>	

(29) Point 2.1.4 of Annex V is replaced with the following point 2.1.4:

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

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

- Testing for 10 days at 20 °C shall cover all storage times at frozen condition.
- 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 100 C for up to 15 minutes.
- Testing for 10 days at 50 °C shall cover all storage times of up to 6 months at room temperature

- Testing for 10 days at 60 °C shall cover long term storage above 6 months at room temperature and below including hot-fill conditions and/or heating up to 100 °C for up to 15 minutes.

For storage at room temperature testing time can be reduced to 10 days at 40 °C if there is scientific evidence that migration of the respective substance in the polymer has reached equilibration under this test condition.

- For worst foreseeable conditions of use not covered by above test conditions, the testing time and temperature conditions shall be based on the following formula:

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

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 298 K (25 °C). For refrigerated and frozen conditions it is set at 278 K (5 °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.

- (30) In point 2.1.6 of Annex V the third paragraph is replaced by the following:

'The material or article shall respect the specific migration limit already in the first test for all substances for which the specific migration limit is set as non-detectable and for non-listed substances used behind a plastic functional barrier covered by the rules of point (b) of Articles 13(2) which should not migrate in detectable amounts.'

- (31) In points 2.2 and 3.4 of Annex V the phrase 'more severe than' is replaced with the phrase 'at least as severe as'.

- (32) In point 2.2.3 of Annex V the word 'overestimate' is replaced by 'at least as severe as'

- (33) In point 2.2.4 of Annex V the first paragraph is replaced by the following:

'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 as severe as migration that would be obtained using the food simulants specified in section 2.1.'

- (34) At the end of point 2.2 of Annex V the following point 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 temperatures 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 Arrhenius equation as described in 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.'

(35) In table 3 of Annex V the entry for OM6 is replaced by the following:

OM6	4 h at 100°C or at reflux	Any food contact conditions with food simulants A, B, C or D1, at temperature exceeding 40°C.
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and paragraph 4 of point 3.1 is replaced by the following:

' Test OM 6 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'

(36) In point 3.1 of Annex V paragraph 3 is replaced by the following:

'Test OM 7 covers also food contact conditions described for OM1, OM2, OM3, OM4, 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 paragraph 3.2.'

(37) Point 3.2 of Annex V is replaced by the following point 3.2:

'3.2 Alternative overall migration tests for tests with simulant D2'

'If under real worst foreseeable conditions of use it is not technical feasible to perform one or more of the tests OM1 to OM6 in food simulant D2, migration tests shall be done using 95% ethanol 95% and isooctane. In addition a test shall be done using 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 OM 8 or test OM9 as appropriate given the intended or foreseeable use. Both tests involve testing at two tests conditions for each of which a new test sample shall be used. 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
OM 8	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

OM 9	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
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(38) Point 3.3 of Annex V is replaced by the following point 3.3:

‘3.3 Repeated use articles

If the material or article is intended to come into repeated contact with foods, the overall migration test(s) shall be carried out three times on a single sample using another portion of food simulant on each occasion. Compliance shall be checked on the basis of the level of the overall migration found in the third test.

If it is not technically feasible to use the same sample three times, such as when testing in oil, the overall migration test described in the first paragraph can be carried out by testing different samples one, two and three times the contact test time and by calculating the overall migration of each migration as a difference of two successive test results.

In derogation to the first paragraph, if on the basis of scientific evidence it is known that for the material 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, only the first test is necessary.’

(39) In point 3.4.2 of Annex V the first paragraph is replaced by the following:

‘To screen for overall migration food simulants can be replaced if based on scientific evidence that the substitute food simulants result in migration that is as severe as migration that would be obtained using the food simulants specified in section 2.1.’

(40) In point 4.1 of Annex V the last paragraph is replaced by the following:

‘The specific migration in food shall not exceed the generic specific migration limit before application of the FRF’

(41) Point 4.2. of Annex V is replaced by the following:

‘4.2. Correction of migration into food simulant D2 or E

The migration test results shall be divided by the correction factor before comparing with the migration limits.

The correction is not applicable to the specific migration for all substances for which the specific migration limit is ‘not detectable’ and for non-listed substances used behind a plastic functional barrier covered by the rules of Article 13(2)(b) which should not migrate in detectable amounts.’

(42)