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Changes to legislation: There are currently no known outstanding effects for the Commission Regulation (EU) No 10/2011, ANNEX V. (See end of Document for details)

ANNEX V

COMPLIANCE TESTING

For testing compliance of migration from plastic food contact materials and articles the following general rules apply.

CHAPTER 1

Testing for specific migration of materials and articles already in contact with food

1.1. Sample preparation

The material or article shall be stored as indicated on the packaging label or under conditions adequate for the packaged food if no instructions are given. The food shall be removed from contact with the material or article before its expiration date or any date by which the manufacturer has indicated the product should be used for reasons of quality or safety.

1.2. Conditions of testing

The food shall be treated in accordance with the cooking instructions on the package if the food is to be cooked in the package. Parts of the food which are not intended to be eaten shall be removed and discarded. The remainder shall be homogenised and analysed for migration. The analytical results shall always be expressed on the basis of the food mass that is intended to be eaten, in contact with the food contact material.

1.3. Analysis of migrated substances

The specific migration is analysed in the food using an analytical method in accordance with the requirements of Article 11 of Regulation (EC) No 882/2004.

[^{F1}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.]

Textual Amendments

- F1** Substituted by [Commission Regulation \(EU\) 2016/1416 of 24 August 2016 amending and correcting Regulation \(EU\) No 10/2011 on plastic materials and articles intended to come into contact with food \(Text with EEA relevance\)](#).

CHAPTER 2

Testing for specific migration of materials and articles not yet in contact with food

2.1. Verification method

Verification of compliance of migration into foods with the migration limits shall be carried out under the most extreme conditions of time and temperature foreseeable in actual use taking into account paragraphs 1.4, 2.1.1, 2.1.6 and 2.1.7.

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Verification of compliance of migration into food simulants with the migration limits shall be carried out using conventional migration tests according to the rules set out in paragraphs 2.1.1 to 2.1.7.

2.1.1. Sample preparation

The material or article shall be treated as described by accompanying instructions or by provisions given in the declaration of compliance.

Migration is determined on the material or article or, if this is impractical, on a specimen taken from the material or article, or a specimen representative of this material or article. For each food simulant or food type, a new test specimen is used. Only those parts of the sample which are intended to come into contact with foods in actual use shall be placed in contact with the food simulant or the food.

2.1.2. Choice of food simulant

Materials and articles intended for contact with all types of food shall be tested with food simulant A, B and D2. However, if substances that may react with acidic food simulant or foods are not present testing in food simulant B can be omitted.

Materials and articles intended only for specific types of foods shall be tested with the food simulants indicated for the food types in Annex III.

2.1.3. Conditions of contact when using food simulants

[^{F1}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 Tables 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 isooctane. 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.]

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TABLE 1

[^{F1}Selection of test time]

Contact time in worst foreseeable use	[^{F1}Time to be selected for testing]
$t \leq 5$ min	5 min
$5 \text{ min} < t \leq 0,5$ hour	0,5 hour
$0,5 \text{ hours} < t \leq 1$ hour	1 hour
$1 \text{ hour} < t \leq 2$ hours	2 hours
$2 \text{ hours} < t \leq 6$ hours	6 hours
$6 \text{ hours} < t \leq 24$ hours	24 hours
$1 \text{ day} < t \leq 3$ days	3 days
$3 \text{ days} < t \leq 30$ days	10 days
Above 30 days	See specific conditions

[^{F1}TABLE 2

Selection of test temperature

Worst foreseeable contact temperature	Contact temperature to be selected for testing
$T \leq 5$ °C	5 °C
$5 \text{ °C} < T \leq 20$ °C	20 °C
$20 \text{ °C} < T \leq 40$ °C	40 °C
$40 \text{ °C} < T \leq 70$ °C	70 °C
$70 \text{ °C} < T \leq 100$ °C	100 °C or reflux temperature
$100 \text{ °C} < T \leq 121$ °C	121 °C ^a
$121 \text{ °C} < T \leq 130$ °C	130 °C ^a
$130 \text{ °C} < T \leq 150$ °C	150 °C ^a
$150 \text{ °C} < T < 175$ °C	175 °C ^a
$175 \text{ °C} < T \leq 200$ °C	200 °C ^a
$T > 200$ °C	225 °C ^a

a 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.]

[^{F1}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⁽¹⁾.

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- (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.]

2.1.5. Specific conditions for combinations of contact times and temperature

[^{F1}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.]

If the material or article is intended for a food contact application where it is successively subject to a combination of two or more times and temperatures, the migration test shall be carried out subjecting the test specimen successively to all the applicable worst foreseeable conditions appropriate to the sample, using the same portion of food simulant.

2.1.6. Repeated use 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. Its compliance shall be checked on the basis of the level of the migration found in the third test.

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

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[^{F1}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).]

2.1.7. Analysis of migrating substances

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 requirements of Article 11 of Regulation (EC) No 882/2004.

2.1.8. Verification of compliance by residual content per food contact surface area (QMA)

For substances which are unstable in food simulant or food or for which no adequate analytical method is available it is indicated in Annex I that verification of compliance shall be undertaken by verification of residual content per 6 dm² of contact surface. For materials and articles between 500 ml and 10 l the real contact surface is applied. For materials and articles below 500 ml and above 10 l as well as for articles for which it is impractical to calculate the real contact surface the contact surface is assumed to be 6 dm² per kg food.

2.2. Screening approaches

[^{F1}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.]

2.2.1. Replacing specific migration by overall migration

To screen for specific migration of non-volatile substances, determination of overall migration under test conditions at least as severe as for specific migration can be applied.

2.2.2. Residual content

To screen for specific migration the migration potential can be calculated based on the residual content of the substance in the material or article assuming complete migration.

[^{F1}2.2.3. *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.]

[^{F1}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.]

[^{F2}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.]

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Textual Amendments

- F2** Inserted by [Commission Regulation \(EU\) 2016/1416 of 24 August 2016 amending and correcting Regulation \(EU\) No 10/2011 on plastic materials and articles intended to come into contact with food \(Text with EEA relevance\).](#)

CHAPTER 3

Testing for overall migration

Overall migration testing shall be performed under the standardised testing conditions set out in this chapter.

3.1. Standardised testing conditions

The overall migration test for materials and articles intended for the food contact conditions described in column 3 of Table 3 shall be performed for the time specified and at the temperature specified in column 2. For test OM5 the test can be performed either for 2 hours at 100 °C (food simulant D2) or at reflux (food simulant A, B, C, D1) or for 1 hour at 121 °C. The food simulant shall be chosen in accordance with Annex III.

If it is found that carrying out the tests under the contact conditions specified in Table 3 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.

^{F1}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 °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 =

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		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 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.]

[^{F1}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.]

[^{F1}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 isoctane. 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
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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]

[^{F1}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.]

3.4. Screening approaches

[^{F1}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.]

3.4.1. Residual content

To screen for overall migration the migration potential can be calculated based on the residual content of migratable substances determined in a complete extraction of the material or article.

[^{F1}3.4.2. Food simulant substitutes

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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.]

CHAPTER 4

Correction factors applied when comparing migration test results with migration limits

4.1. Correction of specific migration in foods containing more than 20 % fat by the Fat Reduction Factor (FRF)

For lipophilic substances for which in Annex I it is indicated in column 7 that the FRF is applicable the specific migration can be corrected by the FRF. The FRF is determined according to the formula $FRF = (\text{g fat in food/kg of food})/200 = (\% \text{ fat} \times 5)/100$.

The FRF shall be applied according to the following rules.

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

The correction by the FRF is not applicable in the following cases:

- (a) when the material or article is or is intended to be brought in contact with food intended for infants and young children as defined by Directives 2006/141/EC and 2006/125/EC;
- (b) for materials and articles for which it is impracticable to estimate the relationship between the surface area and the quantity of food in contact therewith, for example due to their shape or use, and the migration is calculated using the conventional surface area/volume conversion factor of 6 dm²/kg.

[^{F1}The specific migration in food or food simulant shall not exceed 60 mg/kg food before application of the FRF.]

[^{F2}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.]

^{F3}4.2. Correction of migration into food simulant D2

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Textual Amendments

- F3** Deleted by [Commission Regulation \(EU\) 2016/1416 of 24 August 2016 amending and correcting Regulation \(EU\) No 10/2011 on plastic materials and articles intended to come into contact with food \(Text with EEA relevance\)](#).

^{F3}4.3. Combination of correction factors 4.1 and 4.2.

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- (1) [^{F1}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.]

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Textual Amendments

- F1** Substituted by [Commission Regulation \(EU\) 2016/1416 of 24 August 2016 amending and correcting Regulation \(EU\) No 10/2011 on plastic materials and articles intended to come into contact with food](#) (Text with EEA relevance).

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