
Status: Point in time view as at 14/01/2011.

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.

1.4. Special cases

When contamination occurs from sources other than food contact materials this has to be taken into account when testing for compliance of the food contact materials, in particular for phthalates (FCM substance 157, 159, 283, 728, 729) referred to in Annex I.

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.

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.

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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

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.

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.

TABLE 1

Contact time

Contact time in worst foreseeable use	Test time
$t \leq 5$ 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

TABLE 2

Contact temperature

Conditions of contact in worst foreseeable use	Test conditions
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.

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Contact temperature	Test temperature
$T \leq 5 \text{ }^{\circ}\text{C}$	5 °C
$5 \text{ }^{\circ}\text{C} < T \leq 20 \text{ }^{\circ}\text{C}$	20 °C
$20 \text{ }^{\circ}\text{C} < T \leq 40 \text{ }^{\circ}\text{C}$	40 °C
$40 \text{ }^{\circ}\text{C} < T \leq 70 \text{ }^{\circ}\text{C}$	70 °C
$70 \text{ }^{\circ}\text{C} < T \leq 100 \text{ }^{\circ}\text{C}$	100 °C or reflux temperature
$100 \text{ }^{\circ}\text{C} < T \leq 121 \text{ }^{\circ}\text{C}$	121 °C ^a
$121 \text{ }^{\circ}\text{C} < T \leq 130 \text{ }^{\circ}\text{C}$	130 °C ^a
$130 \text{ }^{\circ}\text{C} < T \leq 150 \text{ }^{\circ}\text{C}$	150 °C ^a
$150 \text{ }^{\circ}\text{C} < T < 175 \text{ }^{\circ}\text{C}$	175 °C ^a
$T > 175 \text{ }^{\circ}\text{C}$	Adjust the temperature to the real temperature at the interface with the food ^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.

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 in an accelerated test at elevated temperature for a maximum of 10 days at 60 °C. Testing time and temperature conditions shall be based on the following formula.

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

E_a is the worst case activation energy 80kJ/mol

R is a factor 8,31 J/Kelvin/mol

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

t_1 is the contact time

t_2 is the testing time

T_1 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).

T_2 is the testing temperature in Kelvin.

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 heating up to 70 °C for up to 2 hours, or heating up to 100 °C for up to 15 minutes.

Testing for 10 days at 50 °C shall cover all storage time at refrigerated and frozen conditions including heating up to 70 °C for up to 2 hours, or heating up to 100 °C for up to 15 minutes and storage times of up to 6 months at room temperature.

Status: Point in time view as at 14/01/2011.

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Testing for 10 days at 60 °C shall cover long term storage above 6 months at room temperature and below including heating up to 70 °C for up to 2 hours, or heating up to 100 °C for up to 15 minutes.

The maximum testing temperature is governed by the phase transition temperature of the polymer. At the test temperature the test specimen should not undergo any physical changes.

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.

2.1.5. Specific conditions for combinations of contact times and temperature

If a material or article is intended for different applications covering different combinations of contact time and temperature the testing should 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.

The material or article shall respect the specific migration limit already in the first test for substances for which in Annex I Table 1 column 8 or Table 2 column 3 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.

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

Status: Point in time view as at 14/01/2011.

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)

To screen if a material or article complies with the migration limits any of the following approaches can be applied which are considered more severe than 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.

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 such as to overestimate real migration.

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 overestimate migration compared to the regulated food simulants.

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.

TABLE 3

Standardised testing conditions

Column 1	Column 2	Column 3
Test number	Contact time in days [d] or hours [h] at Contact temperature in [°C]	Intended food contact conditions

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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 heating up to 70 °C for up to 2 hours, or heating up to 100 °C for up to 15 minutes.
OM3	2 h at 70 °C	Any contact conditions that include heating up to 70 °C for up to 2 hours, or up to 100 °C for up to 15 minutes, which are not followed by long term room or refrigerated temperature storage.
OM4	1 h at 100 °C	High temperature applications for all food simulants 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 with food simulants A, B or C, at temperature exceeding 40 °C.
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 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 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 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 OM1 and OM3.

3.2. Substitute test for OM7 with food simulant D2

In case it is technically NOT feasible to perform OM7 with food simulant D2 the test can be replaced by test OM 8 or OM9. Both test conditions described under the respective test shall be performed with a new test sample.

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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

3.3. Repeated use articles

Where a material or article is intended to come into repeated contact with foods, the migration test shall be carried out three times on a single sample using another sample of the 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 overall migration limit is not exceeded on the first test, no further test is necessary.

3.4. Screening approaches

To screen if a material or article complies with the migration limits any of the following approaches can be applied which are considered more severe than 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.

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 overestimate migration compared to the regulated food simulants.

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 $FRF = (g \text{ fat in food}/kg \text{ of food})/200 = (\% \text{ fat} \times 5)/100$.

The FRF shall be applied according to the following rules.

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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.

The application of the FRF shall not lead to a specific migration exceeding the overall migration limit.

4.2. Correction of migration into food simulant D2

For the food categories where in sub-column D2 of column 3 of Table 2 of Annex III the cross is followed by a figure the migration test result into food simulant D2 shall be divided by this figure.

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 substances in the Union list in Annex I for which the specific migration limit in column 8 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.

4.3. Combination of correction factors 4.1 and 4.2.

The correction factors described in 4.1 and 4.2 can be combined for migration of substances for which the FRF is applicable when testing is performed in food simulant D2 by multiplying both factors. The applied maximum factor shall not exceed 5.

Status:

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