

ANNEX V

COMPLIANCE TESTING

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 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

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		T where $70\text{ }^{\circ}\text{C} \leq T \leq 100\text{ }^{\circ}\text{C}$ 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 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.

**Textual Amendments**

**F1** Substituted by [Commission Regulation \(EU\) 2020/1245 of 2 September 2020 amending and correcting Regulation \(EU\) No 10/2011 on plastic materials and articles intended to come into contact with food \(Text with EEA relevance\).](#)

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.]

**[F2]3.2. Substitute overall migration tests for tests with food simulant D2**

[F1If 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.

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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.]

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]

#### Textual Amendments

- F2** 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 \(Text with EEA relevance\)](#).

### [<sup>F2</sup>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.

#### [<sup>F1</sup>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 of the European Parliament and of the Council<sup>(1)</sup>. 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

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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.]]

#### 3.4. Screening approaches

[<sup>F2</sup>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.

##### [<sup>F2</sup>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.]

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- (1) <sup>[F2]</sup><sup>[F1]</sup>Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation) ([OJ L 95, 7.4.2017, p. 1](#)).<sup>]]</sup>

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**Textual Amendments**

- F1** Substituted by [Commission Regulation \(EU\) 2020/1245 of 2 September 2020 amending and correcting Regulation \(EU\) No 10/2011 on plastic materials and articles intended to come into contact with food](#) (Text with EEA relevance).
- F2** 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).

**Changes to legislation:**

There are currently no known outstanding effects for the Commission Regulation (EU) No 10/2011, CHAPTER 3.