

## SCHEDULE 3

Regulations 9 and 13

### Overall and Specific Migration Testing Using Food Simulants

#### **PART 1**

##### Basic Rules

1. Subject to paragraphs 2, 3 and 4 of this Part, migration tests for the determination of specific and overall migration must be carried out using the food simulants specified in Parts 2, 3 and, where appropriate 4, and under conventional migration test conditions as specified in Part 5.

2. Subject to paragraphs 3 and 4 of this Part, substitute tests which use test media under the conventional substitute test conditions as specified in Part 6 must be carried out if the migration test using the fatty food simulants specified in Part 3 is not feasible for technical reasons connected with the method of analysis.

3. Subject to paragraph 4 of this Part, alternative tests as specified in Part 7 may be used instead of the migration test with fatty food simulants specified in Part 3 but the results of such alternative tests may not be used to determine compliance with a migration limit unless the conditions specified in Part 7 are fulfilled.

4. In migration testing it is permissible to —

- (a) reduce the number of tests to be carried out to that or those which, in the specific case under examination, is or are generally recognised to be the most severe on the basis of scientific evidence;
- (b) omit the migration, the substitute or the alternative tests where —
  - (i) there is conclusive proof that the migration limits cannot be exceeded in any foreseeable conditions of use of the material or article, or
  - (ii) the conditions for non-compulsory testing set out in Article 8(2) or 8(3) of the Directive are met.

#### **PART 2**

##### Food Simulants to be used in Migration Testing

1. Subject to Parts 3, 4, 5 and 7, the simulants to be used in migration testing are specified in the Table to this paragraph (referred to in this Part as “the Table”).

| <i>I</i><br><i>Abbreviation</i> | <i>2</i><br><i>Food Simulant</i>   |
|---------------------------------|--|
| Simulant A:                     | Distilled water or water of equivalent quality   |
| Simulant B:                     | 3% Acetic acid (w/v) in aqueous solution   |
| Simulant C:                     | 10% Ethanol (v/v) in aqueous solution except that the concentration of ethanol solution shall be adjusted to the actual alcoholic strength of the food if it exceeds 10% (v/v) |
| Simulant D:                     | Rectified olive oil having the characteristics specified in paragraph 3 or, subject to   |

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| <i>I</i><br><i>Abbreviation</i> | <i>2</i><br><i>Food Simulant</i>                                      |
|---------------------------------|---|
|                                 | paragraph 5, any of the fatty food simulants specified in paragraph 4 |

2. For the purposes of this Schedule a reference to an abbreviation in column 1 of the Table means a reference to the simulant in column 1 of that Table opposite that abbreviation.

3. The characteristics of rectified olive oil referred to in the Table are —

- Iodine value (Wijs) = 80 to 88;
- Refractive index at 25°C = 1.4665 to 1.4679;
- Acidity (expressed as % of oleic acid) = 0.5% maximum;
- Peroxide number (expressed as oxygen milli-equivalents per kg of oil) = 10 maximum.

4. The fatty food simulants referred to in the Table are —

- corn oil with standardised specifications;
- sunflower oil, the characteristics of which are —
  - Iodine value (Wijs) = 120 to 145;
  - Refractive index at 20°C = 1.474 to 1.476;
  - Saponification number = 188 to 193;
  - Relative density at 20°C = 0.918 to 0.925;
  - Unsaponifiable matter = 0.5% to 1.5%;
- a synthetic mixture of triglycerides the composition of which is as set out in the following tables:

Fatty acid distribution

| No<br>of C-<br>atoms<br>in fatty<br>acid<br>residue | 6 | 8   | 10   | 12    | 14    | 16   | 18   | others |
|---|---|-----|------|-------|-------|------|------|--------|
| GLC<br>area<br>(%)                                  | 1 | 6—9 | 8—11 | 45—52 | 12—15 | 8—10 | 8—12 | 1      |

Purity

|  |       |
|--|-------|
| Content of monoglycerides<br>(enzymatically) | ≤0.2% |
| Content of diglycerides (enzymatically)      | ≤2.0% |
| Unsaponifiable matter                        | ≤0.2% |
| Iodine value<br>(Wijs)                       | ≤0.1% |

|                           |                            |
|---------------------------|----------------------------|
| Acid value                | $\leq 0.1\%$               |
| Water content (K Fischer) | $\leq 0.1\%$               |
| Melting point             | $28 \pm 2^{\circ}\text{C}$ |

Typical absorption spectrum (thickness of layer:  $d = 1 \text{ cm}$ ; Reference: water at  $35^{\circ}\text{C}$ )

|                      |     |     |     |     |     |     |     |     |     |
|----------------------|-----|-----|-----|-----|-----|-----|-----|-----|-----|
| Wavelength<br>(nm)   | 290 | 310 | 330 | 350 | 370 | 390 | 430 | 470 | 510 |
| Transmittance<br>(%) | ~2  | ~15 | ~37 | ~64 | ~80 | ~88 | ~95 | ~97 | ~98 |

At least 10% light transmittance at 310 nm

5. Where a fatty food simulant specified in paragraph 4 is used in migration testing and the result of that test shows that a plastic material or article does not comply with any migration limit specified in regulation 9 or the Annexes, verification that the plastic material or article does not comply with the specified migration must be carried out by testing that material or article using olive oil if such testing is technically feasible, and if such testing is not technically feasible the plastic material or article will be deemed not to comply with the specified migration limit.

## PART 3

### Selection of Food Simulants

#### Testing, reduction factors and definition of food types

1. The testing of plastic materials and articles must be carried out under the test conditions specified in Part 5 using a simulant or simulants selected in accordance with this Part and taking a new test specimen of the plastic material or article for each simulant used.

2.—(1) Where a test is carried out on a plastic material or article intended to come into contact with more than one food or group of foods and a reduction factor is specified for one or more of those foods or groups of foods which is not equivalent to the reduction factor specified for one or more of the other foods or groups of foods with which the plastic material or article is intended to come into contact —

- (a) the reduction factor specified for each food or group of foods, as appropriate, must be applied to the test result; and
- (b) the plastic material or article must be treated as being capable of transferring its constituents to food with which it may come into contact in excess of a migration limit specified in regulation 9 or the Annexes if, following application of those specified reduction factors, one or more of the results show that the material or article does not comply with that specified migration limit.

(2) For the purpose of this paragraph —

- (a) a reduction factor is the figure which follows an “X” and oblique stroke in the group of columns headed “Simulants to be used” in the Table to Part 4;
- (b) a reduction factor is specified for a food or group of foods where, in the Table to Part 4 —
  - (i) the food or group of foods is described in the column headed “Description of food”, and

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- (ii) “X” is placed in a column headed by a specified simulant opposite that food or group of foods followed by an oblique stroke and a reduction factor;
- (c) a reduction factor will be applied to a test result by dividing the result by that reduction factor.

3. Food types are defined in Table 1 below as follows —

**Table 1:**  
**Food types**

| <i>Definition</i>               | <i>Meaning</i>   |
|---------------------------------|--|
| Aqueous foods having a pH > 4.5 | Foods in relation to which simulant A only is specified in the Table to Part 4 |
| Acidic foods having a pH ≤ 4.5  | Foods in relation to which simulant B only is specified in Table to Part 4     |
| Alcoholic foods                 | Foods in relation to which simulant C only is specified in the Table to Part 4 |
| Fatty foods                     | Foods in relation to which simulant D only is specified in the Table to Part 4 |
| Dry Foods                       | Foods in relation to which no simulant is specified in the Table to Part 4     |

**Selection of simulants for testing materials and articles intended for contact with all food types**

4. The simulants to be used in testing a plastic material or article which is intended for contact with all food types are simulant B, simulant C and simulant D which, at the test conditions specified in Part 5, are considered to be more severe.

**Selection of simulants for testing materials and articles which are already in contact with a known food**

5. The simulant or simulants to be used in testing a plastic material or article which is already in contact with a known food will be —

- (a) where —
  - (i) the known food is a specific food or is within a specific group of foods described in column 2 of the Table to Part 4 and,
  - (ii) for the purposes of that Part, a simulant is, or simulants are, specified in relation to that specific food or specific group of foods,
 the simulant or simulants so specified;
- (b) where —
  - (i) the known food is neither a specific food, nor
  - (ii) within a specific group of foods described in the Table to Part 4 of this Schedule,
 the simulant or simulants in column 2 of Table 2 opposite the description of food in column 1 of that Table which corresponds most closely to the known food.

### **Selection of simulants for testing materials and articles which are accompanied by a specific indication**

6. The simulant or simulants to be used in testing a plastic material or article which, pursuant to Regulation 1935/2004 is accompanied by a specific indication stating any type or types of food described in Table 1 with which it may or may not be used will be the simulant or simulants in column 2 of Table 2 opposite the contact food in column 1 of that Table which corresponds most closely to the type or types of food with which it may be used, as identified by the indication which accompanies the plastic material or article.

7. The simulant or simulants to be used in testing a plastic material or article which, pursuant to Regulation 1935/2004, is accompanied by a specific indication, expressed in accordance with paragraph 8, stating any food or group of foods described in the Table to Part 4 with which it may or may not be used will be —

- (a) where the indication states that the plastic material or article may be used with a food or group of foods described in column 2 of the Table to Part 4, the food simulant or food simulants which, for the purposes of Part 4, is or are specified in relation to that food or group of foods;
- (b) where the indication states that the plastic material or article should not be used with any food or group of foods described in column 2 of Table to Part 4, a simulant other than one specified, for the purposes of Part 4, in relation to that food or group of foods.

8. A specific indication referred to in paragraph 7 is expressed in accordance with this paragraph if it is expressed —

- (a) at a marketing stage other than retail, by using the reference number in column 1 of the Table to Part 4 of these Regulations or the description of food in column 2 of that Table which, in either case, corresponds to the food;
- (b) at the retail stage, by using an indication which refers to only a few foods or groups of foods described in the Table to Part 4.

**Table 2:**

#### **Simulants to be selected for testing food contact materials in special cases**

| <i>Contact foods</i>                   | <i>Simulant</i>      |
|--|----------------------|
| Only aqueous foods                     | Simulant A           |
| Only acidic foods                      | Simulant B           |
| Only alcoholic foods                   | Simulant C           |
| Only fatty foods                       | Simulant D           |
| All aqueous and acidic foods           | Simulant B           |
| All alcoholic and aqueous foods        | Simulant C           |
| All alcoholic and acidic foods         | Simulant C and B     |
| All fatty and aqueous foods            | Simulants D and A    |
| All fatty and acidic foods             | Simulants D and B    |
| All fatty, alcoholic and aqueous foods | Simulants D and C    |
| All fatty, alcoholic and acidic foods  | Simulants D, C and B |

## PART 4

### Simulants to be used in relation to a Specific Food or Group of Foods

1. For the purposes of this Schedule a simulant is specified in relation to a specific food or a specific group of foods where “X” is placed in the column headed by that simulant opposite that specific food or specific group of foods in the Table to this Part, and the Table will be read in conjunction with the notes to it and with paragraphs 2 to 5.

2. For the purposes of this Part —

- (a) a reduction factor is the figure which follows an “X” and oblique stroke in the group of columns headed “Simulants to be used” in the Table to this Part;
- (b) a reduction factor is specified in relation to a specific food or group of foods where, in the Table —
  - (i) the food or group of foods is described in the column headed “Description of food”; and
  - (ii) “X” is placed in a column headed by a specified simulant opposite that food or group of foods followed by an oblique stroke and a reduction factor.

3. Where a reduction factor is specified in the Table in relation to a specific food or a specific group of foods, that reduction factor shall be applied to the result of any migration test using the simulant specified in relation to that food or group of foods by dividing the result of the test by the reduction factor.

4.—(1) Where the letter “a” is shown in brackets after the “X”, only one of the two simulants specified will be used in the migration test, that is to say —

- (a) if the pH value of the food is higher than 4.5, simulant A will be used;
- (b) if the pH value of the foodstuff is 4.5 or less, simulant B will be used.

(2) Where the letter “b” is shown in brackets after the “X”, the indicated test will be carried out with ethanol 50% (v/v).

5. Where a food is listed in the Table under both a specific and a general heading, the simulant relating to the specific heading is the simulant which falls to be used for the migration test.

| Reference Number | Description of food  | Simulants to be used |      |   |   |
|------------------|--|----------------------|------|---|---|
|                  |  | A                    | B    | C | D |
| 01               | <b>Beverages</b>   |                      |      |   |   |
| 01.01            | Non-alcoholic beverages or alcoholic beverages of an alcoholic strength lower than 5% vol: | X(a)                 | X(a) |   |   |

- (1) Simulant B will not be used where the pH is more than 4.5.
  - (2) This test will be carried out in the case of liquids or beverages of an alcoholic strength exceeding 10% vol. with aqueous solutions of ethanol of a similar strength.
  - (3) If it can be demonstrated under regulation 13(2) or proved by means of an appropriate test that there is to be no fatty contact with the plastic material or article, simulant D will not be used.
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| Reference Number | Description of food  | Simulants to be used |                  |                  |   |
|------------------|--|----------------------|------------------|------------------|---|
|                  |  | A                    | B                | C                | D |
| 01.02            | — Waters, ciders, fruit or vegetable juices of normal strength or concentrated, musts, fruit nectars, lemonades and mineral waters, syrups, bitters, infusions, coffee, tea, liquid chocolate, beers and other |                      |                  |                  |   |
|                  | Alcoholic beverages of an alcoholic strength equal to or exceeding 5% vol.   |                      |                  |                  |   |
|                  | — Beverages shown under heading 01.01 but with an alcoholic strength equal to or exceeding 5% vol.   |                      |                  |                  |   |
|                  | — Wines, spirits and liqueurs  |                      | X <sup>(1)</sup> | X <sup>(2)</sup> |   |

- (1) Simulant B will not be used where the pH is more than 4.5.
- (2) This test will be carried out in the case of liquids or beverages of an alcoholic strength exceeding 10% vol. with aqueous solutions of ethanol of a similar strength.
- (3) If it can be demonstrated under regulation 13(2) or proved by means of an appropriate test that there is to be no fatty contact with the plastic material or article, simulant D will not be used.

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| Reference Number | Description of food  | Simulants to be used |                  |                  |     |
|------------------|--|----------------------|------------------|------------------|-----|
|                  |  | A                    | B                | C                | D   |
| 01.03            | Miscellaneous:<br>undenatured<br>ethyl alcohol   |                      | X <sup>(1)</sup> | X <sup>(2)</sup> |     |
| 02               | <b>Cereals,<br/>cereal<br/>products,<br/>pastry,<br/>biscuits,<br/>cakes and<br/>other bakers'<br/>wares</b>                         |                      |                  |                  |     |
| 02.01            | Starches   |                      |                  |                  |     |
| 02.02            | Cereals,<br>unprocessed,<br>puffed,<br>in flakes<br>(including<br>popcorn,<br>cornflakes and<br>the like)                            |                      |                  |                  |     |
| 02.03            | Cereal flour<br>and meal   |                      |                  |                  |     |
| 02.04            | Macaroni,<br>spaghetti<br>and similar<br>products  |                      |                  |                  |     |
| 02.05            | Pastry,<br>biscuits, cakes<br>and other<br>bakers' wares,<br>dry:<br><br>A With fatty<br>substances on<br>the surface<br><br>B Other |                      |                  |                  | X/5 |
| 02.06            | Pastry,<br>biscuits, cakes   |                      |                  |                  |     |

(1) Simulant B will not be used where the pH is more than 4.5.

(2) This test will be carried out in the case of liquids or beverages of an alcoholic strength exceeding 10% vol. with aqueous solutions of ethanol of a similar strength.

(3) If it can be demonstrated under regulation 13(2) or proved by means of an appropriate test that there is to be no fatty contact with the plastic material or article, simulant D will not be used.

(1)  
(1)

| Reference Number | Description of food  | Simulants to be used |   |   |     |
|------------------|--|----------------------|---|---|-----|
|                  |  | A                    | B | C | D   |
| 03               | and other bakers' wares, fresh   |                      |   |   |     |
|                  | A With fatty substances on the surface   |                      |   |   | X/5 |
|                  | B Other  | X                    |   |   |     |
|                  | <b>Chocolate, sugar and products thereof</b>   |                      |   |   |     |
|                  | <b>Confectionery products</b>  |                      |   |   |     |
| 03.01            | Chocolate, chocolate-coated products, substitutes and products coated with substitutes |                      |   |   | X/5 |
| 03.02            | Confectionery products:  |                      |   |   |     |
|                  | A in solid form  |                      |   |   |     |
|                  | — with fatty substances on the surface   |                      |   |   | X/5 |
|                  | — Other  |                      |   |   |     |
|                  | B in paste form:   |                      |   |   |     |
|                  | — with fatty substances on the surface   |                      |   |   | X/3 |
|                  | — moist  | X                    |   |   |     |
| 03.03            | Sugar and sugar products   |                      |   |   |     |

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- (1) Simulant B will not be used where the pH is more than 4.5.
  - (2) This test will be carried out in the case of liquids or beverages of an alcoholic strength exceeding 10% vol. with aqueous solutions of ethanol of a similar strength.
  - (3) If it can be demonstrated under regulation 13(2) or proved by means of an appropriate test that there is to be no fatty contact with the plastic material or article, simulant D will not be used.
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| Reference Number | Description of food   | Simulants to be used |      |   |   |
|------------------|---|----------------------|------|---|---|
|                  |   | A                    | B    | C | D |
| 04               | A In solid form   |                      |      |   |   |
|                  | B Honey and the like  | X                    |      |   |   |
|                  | C Molasses and sugar syrups   | X                    |      |   |   |
|                  | <b>Fruit, vegetable and products thereof</b>  |                      |      |   |   |
| 04.01            | Whole fruit, fresh or chilled   |                      |      |   |   |
| 04.02            | Processed fruit:  |                      |      |   |   |
|                  | A Dried or dehydrated fruit, whole or in the form of flour or powder                      |                      |      |   |   |
|                  | B Fruit in the form of chunks, puree or paste   | X(a)                 | X(a) |   |   |
|                  | C Fruit preserves (jams and similar products  |                      |      |   |   |
|                  | — whole fruit or chunks or in the form of flour or powder, preserved in a liquid medium): |                      |      |   |   |

- (1) Simulant B will not be used where the pH is more than 4.5.
- (2) This test will be carried out in the case of liquids or beverages of an alcoholic strength exceeding 10% vol. with aqueous solutions of ethanol of a similar strength.
- (3) If it can be demonstrated under regulation 13(2) or proved by means of an appropriate test that there is to be no fatty contact with the plastic material or article, simulant D will not be used.

| Reference Number | Description of food  | Simulants to be used |                  |   |  |
|------------------|--|----------------------|------------------|---|--|
|                  |  | A                    | B                | C | D  |
|                  | — i) In an aqueous medium  | X(a)                 | X(a)             |   |  |
|                  | — ii) In an oily medium  | X(a)                 | X(a)             |   | X  |
|                  | — iii) In an alcoholic medium > 5% vol   |                      | X <sup>(1)</sup> | X |  |
| 04.03            | Nuts (peanuts, chestnuts, almonds, hazelnuts, walnuts, pine kernels and others)<br>A Shelled, dried<br>B Shelled and roasted<br>C In paste or cream form | X                    |                  |   | X/5 <sup>(3)</sup><br>X/3 <sup>(3)</sup> |
| 04.04            | Whole vegetables, fresh or chilled   |                      |                  |   |  |
| 04.05            | Processed vegetables:<br>A Dried or dehydrated vegetables whole or in the form of flour or powder  |                      |                  |   |  |

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- (1) Simulant B will not be used where the pH is more than 4.5.
- (2) This test will be carried out in the case of liquids or beverages of an alcoholic strength exceeding 10% vol. with aqueous solutions of ethanol of a similar strength.
- (3) If it can be demonstrated under regulation 13(2) or proved by means of an appropriate test that there is to be no fatty contact with the plastic material or article, simulant D will not be used.
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| Reference Number | Description of food   | Simulants to be used |                  |   |     |
|------------------|---|----------------------|------------------|---|-----|
|                  |   | A                    | B                | C | D   |
|                  | B Vegetables, cut, in the form of purees  | X(a)                 | X(a)             |   |     |
|                  | C Preserved vegetables:   |                      |                  |   |     |
|                  | — i) In an aqueous medium   | X(a)                 | X(a)             |   |     |
|                  | — ii) In an oily medium   | X(a)                 | X(a)             |   | X   |
|                  | — iii) In an alcoholic medium (> 5% vol)  |                      | X <sup>(1)</sup> | X |     |
| 05               | <b>Fats and oils</b>  |                      |                  |   |     |
| 05.01            | Animal and vegetable fats and oils, whether natural or treated (including cocoa butter, lard, re-solidified butter) |                      |                  |   | X   |
| 05.02            | Margarine, butter and other fats and oils made from water emulsions in oil  |                      |                  |   | X/2 |
| 06               | <b>Animal products and eggs</b>   |                      |                  |   |     |
| 06.01            | Fish:   |                      |                  |   |     |

(1) Simulant B will not be used where the pH is more than 4.5.

(2) This test will be carried out in the case of liquids or beverages of an alcoholic strength exceeding 10% vol. with aqueous solutions of ethanol of a similar strength.

(3) If it can be demonstrated under regulation 13(2) or proved by means of an appropriate test that there is to be no fatty contact with the plastic material or article, simulant D will not be used.

| Reference Number | Description of food   | Simulants to be used |      |   |                    |
|------------------|---|----------------------|------|---|--------------------|
|                  |   | A                    | B    | C | D                  |
| 06.02            | A Fresh, chilled, salted, smoked  | X                    |      |   | X/3 <sup>(3)</sup> |
|                  | B In the form of paste  | X                    |      |   | X/3 <sup>(3)</sup> |
| 06.02            | Crustaceans and molluscs (including oysters, mussels, snails) not naturally protected by their shells | X                    |      |   |                    |
| 06.03            | Meat of all zoological species (including poultry and game):  |                      |      |   |                    |
|                  | A Fresh, chilled, salted, smoked  | X                    |      |   | X/4                |
| 06.04            | B In the form of paste, creams  | X                    |      |   | X/4                |
|                  | Processed meat products (ham, salami, bacon and other)  | X                    |      |   | X/4                |
| 06.05            | Preserved and part-preserved meat and fish:   |                      |      |   |                    |
|                  | A In an aqueous medium  | X(a)                 | X(a) |   |                    |

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- (1) Simulant B will not be used where the pH is more than 4.5.
- (2) This test will be carried out in the case of liquids or beverages of an alcoholic strength exceeding 10% vol. with aqueous solutions of ethanol of a similar strength.
- (3) If it can be demonstrated under regulation 13(2) or proved by means of an appropriate test that there is to be no fatty contact with the plastic material or article, simulant D will not be used.
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| Reference Number | Description of food   | Simulants to be used |      |   |      |
|------------------|---|----------------------|------|---|------|
|                  |   | A                    | B    | C | D    |
|                  | B In an oily medium   | X(a)                 | X(a) |   | X    |
| 06.06            | Eggs not in shell:  |                      |      |   |      |
|                  | A Powdered or dried   |                      |      |   |      |
|                  | B Other   | X                    |      |   |      |
| 06.07            | Egg yolks:  |                      |      |   |      |
|                  | A Liquid  | X                    |      |   |      |
|                  | B Powdered or frozen  |                      |      |   |      |
| 06.08            | Dried white of egg  |                      |      |   |      |
| 07               | <b>Milk products</b>  |                      |      |   |      |
| 07.01            | Milk:   |                      |      |   |      |
|                  | A Whole   |                      |      |   | X(b) |
|                  | B Partly dried  |                      |      |   | X(b) |
|                  | C Skimmed or partly skimmed   |                      |      |   | X(b) |
|                  | D Dried   |                      |      |   |      |
| 07.02            | Fermented milk such as yoghurt, buttermilk and such products in association with fruit and fruit products |                      | X    |   | X(b) |
| 07.03            | Cream and sour cream  |                      | X(a) |   | X(b) |
| 07:04            | Cheeses:  |                      |      |   |      |

- (1) Simulant B will not be used where the pH is more than 4.5.
- (2) This test will be carried out in the case of liquids or beverages of an alcoholic strength exceeding 10% vol. with aqueous solutions of ethanol of a similar strength.
- (3) If it can be demonstrated under regulation 13(2) or proved by means of an appropriate test that there is to be no fatty contact with the plastic material or article, simulant D will not be used.

| Reference Number | Description of food  | Simulants to be used |      |   |                    |
|------------------|--|----------------------|------|---|--------------------|
|                  |  | A                    | B    | C | D                  |
| 07:05            | A Whole, with non-edible rind  |                      |      |   |                    |
|                  | B All others   | X(a)                 | X(a) |   | X/3 <sup>(3)</sup> |
|                  | Rennet:  |                      |      |   |                    |
| 08               | A In liquid or viscous form  | X(a)                 | X(a) |   |                    |
|                  | B Powdered or dried  |                      |      |   |                    |
|                  | <b>Miscellaneous products</b>  |                      |      |   |                    |
| 08.01            | Vinegar  |                      | X    |   |                    |
| 08.02            | Fried or roasted foods:  |                      |      |   |                    |
|                  | A Fried potatoes, fritters and the like  |                      |      |   | X/5                |
| 08.03            | B Of animal origin   |                      |      |   | X/4                |
|                  | Preparations for soups, broths in liquid, solid or powder form (extracts, concentrates); homogenized composite food preparations, prepared dishes: |                      |      |   |                    |
|                  | A Powdered or dried  |                      |      |   |                    |

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- (1) Simulant B will not be used where the pH is more than 4.5.
- (2) This test will be carried out in the case of liquids or beverages of an alcoholic strength exceeding 10% vol. with aqueous solutions of ethanol of a similar strength.
- (3) If it can be demonstrated under regulation 13(2) or proved by means of an appropriate test that there is to be no fatty contact with the plastic material or article, simulant D will not be used.
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| Reference Number | Description of food  | Simulants to be used |      |   |     |
|------------------|--|----------------------|------|---|-----|
|                  |  | A                    | B    | C | D   |
|                  | — i)<br>With fatty substances on the surface   |                      |      |   | X/5 |
|                  | — ii) Other<br>B Liquid or paste:  |                      |      |   |     |
|                  | — i)<br>With fatty substances on the surface   | X(a)                 | X(a) |   | X/3 |
|                  | — ii) Other  | X(a)                 | X(a) |   |     |
| 08.04            | Yeasts and raising agents:   |                      |      |   |     |
|                  | A In paste form  | X(a)                 | X(a) |   |     |
|                  | B Dried  |                      |      |   |     |
| 08.05            | Salt   |                      |      |   |     |
| 08.06            | Sauces:  |                      |      |   |     |
|                  | A Without fatty substances on the surface  | X(a)                 | X(a) |   |     |
|                  | B<br>Mayonnaise, sauces derived from mayonnaise, salad creams and other oil in water emulsions | X(a)                 | X(a) |   | X/3 |
|                  | C Sauce containing oil and water forming two distinct layers                                   | X(a)                 | X(a) |   | X   |

- (1) Simulant B will not be used where the pH is more than 4.5.
- (2) This test will be carried out in the case of liquids or beverages of an alcoholic strength exceeding 10% vol. with aqueous solutions of ethanol of a similar strength.
- (3) If it can be demonstrated under regulation 13(2) or proved by means of an appropriate test that there is to be no fatty contact with the plastic material or article, simulant D will not be used.

| Reference Number | Description of food   | Simulants to be used |                  |   |                    |
|------------------|---|----------------------|------------------|---|--------------------|
|                  |   | A                    | B                | C | D                  |
| 08.07            | Mustard (except powdered mustard under heading 08.17)   | X(a)                 | X(a)             |   | X/3 <sup>(3)</sup> |
| 08.08            | Sandwiches, toasted bread and the like containing any kind of foodstuff:<br><br>A With fatty substances on the surface<br><br>B Other |                      |                  |   | X/5                |
| 08.09            | Ice-creams  | X                    |                  |   |                    |
| 08.10            | Dried foods:<br><br>A With fatty substances on the surface<br><br>B Other   |                      |                  |   | X/5                |
| 08.11            | Frozen or deep-frozen foods   |                      |                  |   |                    |
| 08.12            | Concentrated extracts of an alcoholic strength equal to or exceeding 5% vol   |                      | X <sup>(1)</sup> | X |                    |
| 08.13            | Cocoa:<br><br>A Cocoa powder  |                      |                  |   | X/5 <sup>(3)</sup> |

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- (1) Simulant B will not be used where the pH is more than 4.5.
- (2) This test will be carried out in the case of liquids or beverages of an alcoholic strength exceeding 10% vol. with aqueous solutions of ethanol of a similar strength.
- (3) If it can be demonstrated under regulation 13(2) or proved by means of an appropriate test that there is to be no fatty contact with the plastic material or article, simulant D will not be used.
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| Reference Number | Description of food   | Simulants to be used |   |   |                    |
|------------------|---|----------------------|---|---|--------------------|
|                  |   | A                    | B | C | D                  |
|                  | B Cocoa paste   |                      |   |   | X/3 <sup>(3)</sup> |
| 08.14            | Coffee, whether or not roasted, decaffeinated or soluble, coffee substitutes, granulated or powdered                      |                      |   |   |                    |
| 08.15            | Liquid coffee extracts  | X                    |   |   |                    |
| 08.16            | Aromatic herbs and other herbs:<br><br>Camomile, mallow, mint, tea, lime blossom and others                               |                      |   |   |                    |
| 08.17            | Spices and seasonings in the natural state:<br><br>Cinnamon, cloves, powdered mustard, pepper, vanilla, saffron and other |                      |   |   |                    |

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- (1) Simulant B will not be used where the pH is more than 4.5.
- (2) This test will be carried out in the case of liquids or beverages of an alcoholic strength exceeding 10% vol. with aqueous solutions of ethanol of a similar strength.
- (3) If it can be demonstrated under regulation 13(2) or proved by means of an appropriate test that there is to be no fatty contact with the plastic material or article, simulant D will not be used.
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## PART 5

### Migration Test Conditions (Times and Temperatures)

#### General criteria

1. Subject to paragraphs 2, 4, 6 and 7 below and to paragraph 4.4 of Chapter II of the Annex to Directive 82/711, when carrying out migration tests the time and temperature used will be the time and temperature selected from column 2 of the Table to this Part which correspond to the worst foreseeable conditions of contact specified in column 1 of that Table for the plastic material or article being tested and to any labelling information on maximum temperature for use.

2. Where the plastic material or article being tested is intended for a food contact application covered by a combination of two or more times and temperatures specified in column 2 of the Table to this Part, the migration test will be carried out by subjecting the test specimen successively to all the applicable worst foreseeable conditions appropriate to the sample, using the same portion of food simulant.

3. For the purposes of this Part the worst foreseeable conditions of contact are those which are recognised to be the most severe on the basis of scientific evidence.

#### Volatile migrants

4. When carrying out a test of the specific migration of volatile substances any test using a simulant must be performed in a manner that recognises the loss of volatile migrants which may occur in the worst foreseeable conditions of use.

#### Special cases

5. When carrying out a migration test of a plastic material or article that is intended for use in a microwave oven, if the appropriate time and temperature is selected from the table to this Part, either a conventional oven or a microwave oven may be used.

6. Where the carrying out of a migration test under contact conditions specified in the Table to this Part causes any physical or other change in the test specimen that does not occur under the worst foreseeable conditions of use of the plastic material or article being tested, the migration test will be carried out in the worst foreseeable conditions of use in which such physical or other change does not occur.

7. Where, in actual use, the plastic material or article being tested is intended to be used for periods of less than 15 minutes at any temperature of not less than 70°C and not more than 100°C and such use is indicated by appropriate labelling or instructions, no test other than for 2 hours at 70°C shall be carried out on the plastic material or article unless the plastic material or article is also intended to be used for storage at room temperature, in which case no test other than for 10 days test at 40°C shall be carried out.

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*Conditions of contact in worst foreseeable use    Test conditions*

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**Contact time:**

less than or equal to 5 minutes

**Test time:**

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(1) The period of time which represents the worst foreseeable conditions of contact.

(2) This temperature will be used only for simulant D. For simulant A, B or C the test may be replaced by a test at 100°C or at reflux temperature for a duration of four times the time selected in accordance with paragraph 1 of this Part.

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| <i>Conditions of contact in worst foreseeable use</i> | <i>Test conditions</i>      |
|---|-----------------------------|
| >5 minutes but less than or equal to 0.5 hours        | 0.5 hours                   |
| >0.5 hours but less than or equal to 1 hour           | 1 hour                      |
| >1 hour but less than or equal to 2 hours             | 2 hours                     |
| >2 hours but less than or equal to 4 hours            | 4 hours                     |
| >4 hours but less than or equal to 24 hours           | 24 hours                    |
| >24 hours   | 10 days                     |
| <b>Contact temperature:</b>                           | <b>Test temperature:</b>    |
| less than or equal to 5°C                             | 5°C                         |
| >5°C but less than or equal to 20°C                   | 20°C                        |
| >20°C but less than or equal to 40°C                  | 40°C                        |
| >40°C but less than or equal to 70°C                  | 70°C                        |
| >70°C but less than or equal to 100°C                 | 100°C or reflux temperature |
| >100°C but less than or equal to 121°C                | 121°C <sup>(2)</sup>        |
| >121°C but less than or equal to 130°C                | 130°C <sup>(2)</sup>        |
| >130°C but less than 150°C                            | 150°C <sup>(2)</sup>        |
| >150°C  | 175°C <sup>(2)</sup>        |

(1) The period of time which represents the worst foreseeable conditions of contact.

(2) This temperature will be used only for simulant D. For simulant A, B or C the test may be replaced by a test at 100°C or at reflux temperature for a duration of four times the time selected in accordance with paragraph 1 of this Part.

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## PART 6

### Substitute Fat Test for Overall and Specific Migration

1. Subject to paragraphs 2, 4 and 5, all the test media specified in the Table to this Part will be used in the substitute fat test for overall or specific migration under the test conditions corresponding to the test conditions for simulant D.

2. Test conditions other than those specified in the Table to this Part may be used in the substitute fat test if the assumptions underlying the test conditions specified in that Table and, where the plastic material or article being tested is a polymer, the existing experience of that type of polymer are taken into account.

3. For each test —

- (a) a new test specimen must be used;
- (b) the rules prescribed for simulant D in Parts 3, 4 and 5 of this Schedule must be applied for each test medium;

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(c) subject to paragraph 4, compliance with a migration limit must be determined by selecting the highest value using all the test methods.

4. Where carrying out a migration test causes any physical or other change in the test specimen which does not occur under the worst foreseeable conditions of use of the plastic material or article the result of that test shall not be used to ascertain compliance with a migration limit.

5. Any test conditions in the Table to this Part which are generally recognised on the basis of scientific evidence as not being appropriate for the material or article to be tested must not be used.

Conventional conditions for substitute tests

| <i>Test conditions with simulant D</i> | <i>Test conditions with isooctane</i> | <i>Test conditions with ethanol 95%</i> | <i>Test conditions with MPPO<sup>(1)</sup></i> |
|--|---------------------------------------|---|--|
| 10 days at 5°C                         | 0.5 days at 5°C                       | 10 days at 5°C                          |  |
| 10 days at 20°C                        | 1 day at 20°C                         | 10 days at 20°C                         |  |
| 10 days at 40°C                        | 2 days at 20°C                        | 10 days at 40°C                         |  |
| 2 hours at 70°C                        | 0.5 hours at 40°C                     | 2 hours at 60°C                         |  |
| 0.5 hours at 100°C                     | 0.5 hours at 60°C <sup>(2)</sup>      | 2.5 hours at 60°C                       | 0.5 hours at 100°C                             |
| 1 hour at 100°C                        | 1 hour at 60°C <sup>(2)</sup>         | 3 hours at 60°C <sup>(2)</sup>          | 1 hour at 100°C                                |
| 2 hours at 100°C                       | 1.5 hours at 60°C <sup>(2)</sup>      | 3.5 hours at 60°C <sup>(2)</sup>        | 2 hours at 100°C                               |
| 0.5 hours at 121°C                     | 1.5 hours at 60°C <sup>(2)</sup>      | 3.5 hours at 60°C <sup>(2)</sup>        | 0.5 hours at 121°C                             |
| 1 hour at 121°C                        | 2 hours at 60°C <sup>(2)</sup>        | 4 hours at 60°C <sup>(2)</sup>          | 1 hour at 121°C                                |
| 2 hours at 121°C                       | 2.5 hours at 60°C <sup>(2)</sup>      | 4.5 hours at 60°C <sup>(2)</sup>        | 2 hours at 121°C                               |
| 0.5 hours at 130°C                     | 2 hours at 60°C <sup>(2)</sup>        | 4 hours at 60°C <sup>(2)</sup>          | 0.5 hours at 130°C                             |
| 1 hour at 130°C                        | 2.5 hours at 60°C <sup>(2)</sup>      | 4.5 hours at 60°C <sup>(2)</sup>        | 1 hour at 130°C                                |

(1) MPPO = Modified polyphenylene oxide

(2) The volatile test media are used up to a maximum temperature of 60°C. A precondition of using these tests is that the material or article will withstand the test conditions that would otherwise be used with simulant D. Immerse a test specimen in olive oil under the appropriate conditions. If the physical properties are changed (eg melting, deformation) then the material is considered unsuitable for use at that temperature. If the physical properties are not changed then proceed with the substitute tests using new specimens.

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| <i>Test conditions with simulant D</i> | <i>Test conditions with isooctane</i> | <i>Test conditions with ethanol 95%</i> | <i>Test conditions with MPPO<sup>(1)</sup></i> |
|--|---------------------------------------|---|--|
| 2 hours at 150°C                       | 3 hours at 60°C <sup>(2)</sup>        | 5 hours at 60°C <sup>(2)</sup>          | 2 hours at 150°C                               |
| 2 hours at 175°C                       | 4 hours at 60°C <sup>(2)</sup>        | 6 hours at 60°C <sup>(2)</sup>          | 2 hours at 175°C                               |

(1) MPPO = Modified polyphenylene oxide

(2) The volatile test media are used up to a maximum temperature of 60°C. A precondition of using these tests is that the material or article will withstand the test conditions that would otherwise be used with simulant D. Immerse a test specimen in olive oil under the appropriate conditions. If the physical properties are changed (eg melting, deformation) then the material is considered unsuitable for use at that temperature. If the physical properties are not changed then proceed with the substitute tests using new specimens.

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## PART 7

### Alternative Fat Tests for Overall and Specific Migration

1. Subject to paragraph 2 of this Part the conditions which must be fulfilled to allow the result of either test specified in paragraph 3 to be used as an alternative to the result of a migration test carried out under Part 3 are that —

- (a) the result obtained in a “comparison test” shows that the values are equal to or greater than those obtained in the test with simulant D; and
- (b) the migration occurring in either test specified in paragraph 3 does not, after application of the appropriate reduction factor, exceed the appropriate migration limit.

2. The condition in sub-paragraph (a) of paragraph 1 does not have to be fulfilled if it can be shown on the basis of the result of scientific experiment that the values obtained in either of the tests specified in paragraph 3 are equal to or greater than those obtained in any of the migration tests specified in Part 3.

3. The migration tests referred to in paragraphs 2 and 3 are —

- (a) a test carried out using volatile media including isooctane, ethanol 95%, other volatile solvents or a mixture of solvents at such contact conditions as would result in values equal to or greater than those obtained in a test using simulant D;
- (b) other tests using media having a very strong extraction power under very severe test conditions where, on the basis of scientific evidence, it is generally recognised that the results using these tests are equal to or higher than those obtained in a test using simulant D.

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