

SCHEDULE 4

Regulations 6 and 7

**Overall and Specific Migration Testing Using Food Simulants**

**Part I**

**Basic Rules**

1. Subject to paragraphs 2, 3 and 4, migration tests for the determination of specific and overall migration shall be carried out using the food simulants specified in Parts II, III and, where appropriate, IV and under conventional migration test conditions as specified in Part V.
2. Subject to paragraphs 3 and 4, substitute tests which use test media under the conventional substitute test conditions as specified in Part VI shall be carried out if the migration test using the fatty food simulants specified in Part III is not feasible for technical reasons connected with the method of analysis.
3. Subject to paragraph 4, alternative tests as specified in Part VII may be used instead of the migration test with fatty food simulants specified in Part III but the results of such alternative tests may not be used to determine compliance with a migration limit unless the conditions specified in Part VII 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 there is conclusive proof that the migration limits cannot be exceeded in any foreseeable conditions of use of the material or article.

**Part II**

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

1. Subject to Parts III, IV, V, VI and VII, the simulants to be used in migration testing are specified in the Table to this paragraph (referred to in this Part as “the Table”).

TABLE

<i>Abbreviation</i>	<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 save 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 paragraph 5, any of the fatty food simulants specified in paragraph 4.

*Status: This is the original version (as it was originally made). This item of legislation is currently only available in its original format.*

2. For the purposes of this Schedule a reference to an abbreviation in column 1 of the Table shall mean 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 as hereinafter described—

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 milliequivalents per kg of oil)	= 10 maximum

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

- (a) corn oil with standardised specifications;  
 (b) 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%; and

(c) a synthetic mixture of triglycerides the composition of which is as follows—

(i) fatty acid distribution

No. of C-atoms in fatty acid residue	6	8	10	12	14	16	18	others
GLC area (%)	~1	6-9	8-11	45-52	12-15	8-10	8-12	≤1

(ii) purity

Content of monoglycerides (enzymatically)	≤0.2%
Content of diglycerides (enzymatically)	≤2.0%
Unsaponifiable matter	≤0.2%
Iodine value (Wijs)	≤0.1%
Acid value	≤0.1%
Water content (K. Fischer)	≤0.1%
Melting point	28 ± 2°C

(iii) typical absorption spectrum (thickness of layer: d = 1cm; Reference: water at 35°C)

**Status:** This is the original version (as it was originally made). This item of legislation is currently only available in its original format.

Wavelength (nm)	290	310	330	350	370	390	430	470	510
Transmittance (%)		~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 7 or Schedule 1 verification that the plastic material or article does not comply with the specified migration limit shall 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 shall be deemed not to comply with the specified migration limit.

### Part III

#### Selection of Food Simulants

##### A.

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

1. The testing of plastic materials and articles shall be carried out under the test conditions specified in Part V 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 groups 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, shall be applied to the test result; and
- (b) the plastic material or article shall 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 7 or Schedule 1 if, following application of the 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 purposes 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 IV;
- (b) a reduction factor is specified for a food or group of foods where, in the Table to Part IV—
  - (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; and
- (c) a reduction shall be applied to a test result by dividing the result by that reduction factor.

3. Food types are defined in the Table to this paragraph (referred to in this Part as “Table 1”).

*Status: This is the original version (as it was originally made). This item of legislation is currently only available in its original format.*

**TABLE 1**

<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 IV
Acidic foods having a pH ≤ 4.5	Foods in relation to which simulant B only is specified in the Table to Part IV
Alcoholic foods	Foods in relation to which simulant C only is specified in the Table to Part IV
Fatty foods	Foods in relation to which simulant D only is specified in the Table to Part IV
Dry foods	Foods in relation to which no simulant is specified in the Table to Part IV

**B.*****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 shall be those mentioned below which, at the test conditions specified in Part V, are considered to be the more severe:

- simulant B;
- simulant C; and
- simulant D.

**C.*****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 article which is already in contact with a known food shall be—

- (a) where the known food is a specific food or is within a specific group of foods described in column 2 of the Table to Part IV and, for the purposes of Part IV, 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 the known food is neither a specific food nor within a specific group of foods described in the Table to Part IV, the simulant or simulants in column 2 of Table 2 to this Part opposite the description of food in column 1 of that Table which corresponds most closely to the known food.

**D.*****Selection of simulants for testing materials or 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 7 or 8, as appropriate, of the 1987 Regulations, 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 shall be the simulant or simulants in column 2 of Table 2 to this Part opposite the contact food in column 1

**Status:** This is the original version (as it was originally made). This item of legislation is currently only available in its original format.

of that Table which corresponds most closely to the type or type 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 7 or 8, as appropriate, of the 1987 Regulations, is accompanied by a specific indication, expressed in accordance with paragraph 8, stating any food or group of food described in the Table to Part IV with which it may or may not be used shall 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 IV, the food simulatant or food simulants which, for the purposes of Part IV, 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 the Table to Part IV, a simulatant other than the simulatant or simulants which, for the purposes of Part IV, is or are specified 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 IV 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 IV.

**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	Simulant D and A
All fatty and acidic foods	Simulant D and B
All fatty, alcoholic and aqueous foods	Simulant D and C
All fatty, alcoholic and acidic foods	Simulant D, C and B

**Status:** This is the original version (as it was originally made). This item of legislation is currently only available in its original format.

## Part IV

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

1. For the purposes of this Part 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 shall be read in conjunction with the notes thereto and the following paragraphs of this Part.

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 to this Part—
  - (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 specific simulant opposite that food or group of foods followed by an oblique stroke and a reduction factor.

3. Where, in the Table to this Part, a reduction factor is specified 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 that reduction factor.

4. Where, in the Table to this Part, the letter “a” is shown in brackets after the “X”, only one of the two simulants specified shall 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 shall be used,
- (b) if the pH value of the foodstuff is 4·5 or less, simulant B shall be used.

5. Where a food is listed in the Table to this Part 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.

TABLE

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.: Waters, ciders,	X(a)	X(a)		

(\*) Simulant B shall not be used where the pH is more than 4·5.

(\*\*) This test shall 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

(\*\*\*) If it can be demonstrated under regulation 11 or proved by means of an appropriate test that there is to be no fatty contact with the plastic material or article, simulant D shall not be used.

*Status: This is the original version (as it was originally made). This item of legislation is currently only available in its original format.*

Reference Number	Description of food	Simulants to be used			
		A	B	C	D
	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.				
01.02	Alcoholic beverages of an alcohol strength equal to or exceeding 5% vol.: Beverages shown under heading 01.01 but with an alcoholic strength equal to or exceeding 5% vol.				

(\*) Simulant B shall not be used where the pH is more than 4.5.

(\*\*) This test shall 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

(\*\*\*) If it can be demonstrated under regulation 11 or proved by means of an appropriate test that there is to be no fatty contact with the plastic material or article, simulant D shall not be used.

**Status:** This is the original version (as it was originally made). This item of legislation is currently only available in its original format.

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

(\*) Simulant B shall not be used where the pH is more than 4.5.

(\*\*) This test shall 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

(\*\*\*) If it can be demonstrated under regulation 11 or proved by means of an appropriate test that there is to be no fatty contact with the plastic material or article, simulant D shall not be used.



**Status:** This is the original version (as it was originally made). This item of legislation is currently only available in its original format.

Reference Number	Description of food	Simulants to be used			
		A	B	C	D
	B. Other				
02.06	Pastry, cakes and other bakers' ware, fresh:				X/5
	A. With fatty substances on the surface				
	B. Other	X			
03	<b>Chocolate, sugar and products thereof Confectionery products</b>				
03.01	Chocolate, chocolate-coated products, substitutes and products coated with substitutes				X/5
03.02	Confectionery products:				X/5
	A. In solid form:				
	(I) With fatty substances on the surface				
	(II) Other				
	B. In paste form:				X/3
	(I) With fatty substances on the surface				

(\*) Simulant B shall not be used where the pH is more than 4.5.

(\*\*) This test shall 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

(\*\*\*) If it can be demonstrated under regulation 11 or proved by means of an appropriate test that there is to be no fatty contact with the plastic material or article, simulant D shall not be used.

*Status: This is the original version (as it was originally made). This item of legislation is currently only available in its original format.*

Reference Number	Description of food	Simulants to be used			
		A	B	C	D
	(II) Moist	X			
03.03	Sugar and sugar products: A. In solid form: B. Honey and the like C. Molasses and sugar syrups	X			
04	<b>Fruit, vegetables 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, purée or paste C. Fruit preserves (jams and similar products— whole fruit or chunks or in the form of flour	X(a)	X(a)		

(\*) Simulant B shall not be used where the pH is more than 4-5.

(\*\*) This test shall 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

(\*\*\*) If it can be demonstrated under regulation 11 or proved by means of an appropriate test that there is to be no fatty contact with the plastic material or article, simulant D shall not be used.

**Status:** This is the original version (as it was originally made). This item of legislation is currently only available in its original format.

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

(\*) Simulant B shall not be used where the pH is more than 4.5.

(\*\*) This test shall 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

(\*\*\*) If it can be demonstrated under regulation 11 or proved by means of an appropriate test that there is to be no fatty contact with the plastic material or article, simulant D shall not be used.

**Status:** This is the original version (as it was originally made). This item of legislation is currently only available in its original format.

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:	X(a)	X(a)		
	(I) In an aqueous medium				
	(II) In an oily medium	X(a)	X(a)		X
	(III) In an alcoholic medium (≥5% vol.)		X(*)	X	
05	<b>Fats and oils</b>				
05.01	Animal and vegetable fats and oils, whether natural or treated (including cocoa butter, lard, resolidified 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:	X			X/3 <sup>(***)</sup>

(\*) Simulant B shall not be used where the pH is more than 4.5.

(\*\*) This test shall 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

(\*\*\*) If it can be demonstrated under regulation 11 or proved by means of an appropriate test that there is to be no fatty contact with the plastic material or article, simulant D shall not be used.

**Status:** This is the original version (as it was originally made). This item of legislation is currently only available in its original format.

Reference Number	Description of food	Simulants to be used			
		A	B	C	D
	A. Fresh, chilled, salted, smoked				
	B. In the form of paste	X			X/3 <sup>(***)</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):	X			X/4
	A. Fresh, chilled, salted, smoked				
	B. In the form of paste, creams	X			X/4
06.04	Processed meat products (ham, salami, bacon and other)	X			X/4
06.05	Preserved and part-preserved meat and fish:	X(a)	X(a)		
	A. In an aqueous medium				
	B. In an oily medium	X(a)	X(a)		X

(\*) Simulant B shall not be used where the pH is more than 4-5.

(\*\*) This test shall 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

(\*\*\*) If it can be demonstrated under regulation 11 or proved by means of an appropriate test that there is to be no fatty contact with the plastic material or article, simulant D shall not be used.

**Status:** This is the original version (as it was originally made). This item of legislation is currently only available in its original format.

Reference Number	Description of food	Simulants to be used			
		A	B	C	D
06.06	Eggs not in shell: A. Liquid B. Other	X			
06.07	Egg yolks: A. Liquid B. Powdered or frozen	X			
06.08	Dried white of egg				
07	<b>Milk products</b>				
07.01	Milk: A. Whole B. Partly dried C. Skimmed or partly skimmed D. Dried	X			
07.02	Fermented milk such as yoghurt, buttermilk and such products in association with fruit and fruit products		X		
07.03	Cream and sour cream	X(a)	X(a)		
07.04	Cheeses: A. Whole, with rind B. Processed cheeses	X(a)	X(a)		

(\*) Simulant B shall not be used where the pH is more than 4.5.

(\*\*) This test shall 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

(\*\*\*) If it can be demonstrated under regulation 11 or proved by means of an appropriate test that there is to be no fatty contact with the plastic material or article, simulant D shall not be used.

**Status:** This is the original version (as it was originally made). This item of legislation is currently only available in its original format.

Reference Number	Description of food	Simulants to be used			
		A	B	C	D
	C. All others	X(a)	X(a)		X/3 <sup>(***)</sup>
07.05	Rennet:	X(a)	X(a)		
	A. In liquid or viscous form				
	B. Powdered or dried				
08	<b>Miscellaneous products</b>				
08.01	Vinegar			X	
08.02	Fried or roasted foods:				X/5
	A. Fried potatoes, fritters and the like				
	B. Of animal origin				X/4
08.03	Preparations for soups, broths in liquid, solid or powder form (extracts, concentrates); homogenized composite food preparations, prepared dishes:				X/5
	A. Powdered or dried:				
	(I) With fatty substances on the surface				

(\*) Simulant B shall not be used where the pH is more than 4.5.

(\*\*) This test shall 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

(\*\*\*) If it can be demonstrated under regulation 11 or proved by means of an appropriate test that there is to be no fatty contact with the plastic material or article, simulant D shall not be used.

**Status:** This is the original version (as it was originally made). This item of legislation is currently only available in its original format.

Reference Number	Description of food	Simulants to be used			
		A	B	C	D
	(II) Other				
	B. Liquid or paste:	X(a)	X(a)		X/3
	(I) With fatty substances on the surface				
	(II) Other	X(a)	X(a)		
08.04	Yeast and raising agents:	X(a)	X(a)		
	A. In paste form				
	B. Dried				
08.05	Salt				
08.06	Sauces:	X(a)	X(a)		
	A. Without fatty substances on the surface				
	B. 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
08.07	Mustard (except powdered mustard under heading 08.17)	X(a)	X(a)		X/3 <sup>(***)</sup>

(\*) Simulant B shall not be used where the pH is more than 4.5.

(\*\*) This test shall 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

(\*\*\*) If it can be demonstrated under regulation 11 or proved by means of an appropriate test that there is to be no fatty contact with the plastic material or article, simulant D shall not be used.



**Status:** This is the original version (as it was originally made). This item of legislation is currently only available in its original format.

Reference Number	Description of food	Simulants to be used			
		A	B	C	D
08.08	Sandwiches, toasted bread and the like containing any kind of foodstuff: A. With fatty substances on the surface B. Other				X/5
08.09	Ice creams	X			
08.10	Dried foods: A. With fatty substances on the surface 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>(*)</sup>	X	
08.13	Cocoa: A. Cocoa powder B. Cocoa paste				X/5 <sup>(***)</sup> X/3 <sup>(***)</sup>
08.14	Coffee, whether or not roasted, decaffeinated or soluble,				

(\*) Simulant B shall not be used where the pH is more than 4.5.

(\*\*) This test shall 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

(\*\*\*) If it can be demonstrated under regulation 11 or proved by means of an appropriate test that there is to be no fatty contact with the plastic material or article, simulant D shall not be used.

**Status:** This is the original version (as it was originally made). This item of legislation is currently only available in its original format.

Reference Number	Description of food	Simulants to be used			
		A	B	C	D
	coffee substitutes, granulated or powdered				
08.15	Liquid coffee extracts	X			
08.16	Aromatic herbs and other herbs: Camomile, mallow, mint, tea, lime blossom and others				
08.17	Spices and seasonings in the natural state:  Cinnamon, cloves, powdered mustard, pepper, vanilla, saffron and others				

(\*) Simulant B shall not be used where the pH is more than 4.5.

(\*\*) This test shall 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

(\*\*\*) If it can be demonstrated under regulation 11 or proved by means of an appropriate test that there is to be no fatty contact with the plastic material or article, simulant D shall not be used.

## Part V

### Migration Test Conditions (Times and Temperatures)

#### A.

##### **General criteria**

1. Subject to paragraphs 2, 4, 6 and 7 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 shall be 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.

**Status:** This is the original version (as it was originally made). This item of legislation is currently only available in its original format.

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 shall 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.

### **B.**

#### ***Volatile migrants***

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

### **C.**

#### ***Special Cases***

5. When carrying out a migration test of a plastic material or article which 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 which does not occur under the worst foreseeable conditions of use of the plastic material or article being tested the migration test shall 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 further test other than for 10 days test at 40°C shall be carried out.

8. The Table to this Part shall be read with the notes to it.

TABLE

<i>Conditions of contact in worst foreseeable use</i>	<i>Test conditions</i>
Contact time	Test time
$t \leq 5$ minutes	(1)
$5 \text{ minutes} < t \leq 0.5 \text{ hours}$	0.5 hours
$0.5 \text{ hours} < t \leq 1 \text{ hour}$	1 hour
$1 \text{ hour} < t \leq 2 \text{ hours}$	2 hours
$2 \text{ hours} < t \leq 4 \text{ hours}$	4 hours
$4 \text{ hours} < t \leq 24 \text{ hours}$	24 hours
$t > 24 \text{ hours}$	10 days

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

**Status:** This is the original version (as it was originally made). This item of legislation is currently only available in its original format.

Contact temperature	Test temperature
$T \leq 5^{\circ}\text{C}$	$5^{\circ}\text{C}$
$5^{\circ}\text{C} < T \leq 20^{\circ}\text{C}$	$20^{\circ}\text{C}$
$20^{\circ}\text{C} < T \leq 40^{\circ}\text{C}$	$40^{\circ}\text{C}$
$40^{\circ}\text{C} < T \leq 70^{\circ}\text{C}$	$70^{\circ}\text{C}$
$70^{\circ}\text{C} < T \leq 100^{\circ}\text{C}$	$100^{\circ}\text{C}$ or reflux temperature
$100^{\circ}\text{C} < T \leq 121^{\circ}\text{C}$	$121^{\circ}\text{C}^{(2)}$
$121^{\circ}\text{C} < T \leq 130^{\circ}\text{C}$	$130^{\circ}\text{C}^{(2)}$
$130^{\circ}\text{C} < T \leq 150^{\circ}\text{C}$	$150^{\circ}\text{C}^{(2)}$
$T > 150^{\circ}\text{C}$	$175^{\circ}\text{C}^{(2)}$

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

## Part VI

### 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 shall 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 shall be used;
  - (b) the rules prescribed for simulant D in Part III, IV and V shall be applied for each test medium;
  - (c) subject to paragraph 4, compliance with a migration limit shall 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 shall not be used.
6. The Table to this Part shall be read with the notes to it.

**Status:** This is the original version (as it was originally made). This item of legislation is currently only available in its original format.

TABLE

## 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
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 (e.g 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.

## Part VII

## Alternative Fat Tests for Overall and Specific Migration

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

- (a) the result obtained in a “comparison test” shows that the values are equal 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 migration tests specified in paragraph 3 are equal to or greater than those obtained in any of the migration tests specified in Part III.

3. The migration tests referred to in paragraphs 1 and 2 are—

**Status:** This is the original version (as it was originally made). This item of legislation is currently only available in its original format.

- (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 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.