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 of this Part of this Schedule, 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 of this Schedule and under conventional migration test conditions as specified in Part V of this Schedule.
- 2. Subject to paragraphs 3 and 4 of this Part of this Schedule, substitute tests which use test media under the conventional substitute test conditions as specified in Part VI of this Schedule shall be carried out if the migration test using the fatty food simulants specified in Part III of this Schedule is not feasible for technical reasons connected with the method of analysis.
- **3.** Subject to paragraph 4 of this Part of this Schedule, alternative tests as specified in Part VII of this Schedule may be used instead of the migration test with fatty food simulants specified in Part III of this Schedule 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 of this Schedule 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 of this Schedule, the simulants to be used in migration testing are specified in the Table to this paragraph (referred to in this Part of this Schedule as "the Table").

TABLE

Abbreviation	Food Simulant
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 of this Part of this Schedule or, subject to paragraph 5 of this Part

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Abbreviation	Food Simulant
	of this Schedule, any of the fatty food simulants specified in paragraph 4 of this Part of this Schedule

- **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 $20^{\circ}\text{C} = 0.918$ 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% 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 = 1 cm; Reference: water at 35°C)

Waveleng 1910 (nm)	310	330	350	370	390	430	470	510
Transmit#Ace (%)	#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 of this Part of this Schedule 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 of this Schedule using a simulant or simulants selected in accordance with this Part of this Schedule 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, 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 of this Schedule;
 - (b) a reduction factor is specified for a food or group of foods where, in the Table to Part IV of this Schedule—
 - (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 factor 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 of this Schedule as "Table 1").

TABLE 1

Definition	Meaning
Aqueous foods having a pH> 4.5	Foods in relation to which simulant A only is specified in the Table to Part IV of this Schedule
Acidic foods having a pH<= 4.5	Foods in relation to which simulant B only is specified in the Table to Part IV of this Schedule
Alcoholic foods	Foods in relation to which simulant C only is specified in the Table to Part IV of this Schedule
Fatty foods	Foods in relation to which simulant D only is specified in the Table to Part IV of this Schedule
Dry foods	Foods in relation to which no simulant is specified in the Table to Part IV of this Schedule

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 of this Schedule, 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 or 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 of this Schedule and, for the purposes of Part IV of this Schedule, 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 of this Schedule, the simulant or simulants in column 2 of Table 2 to this Part of this Schedule 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 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 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 of this Schedule 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 7 or 8, as appropriate, of the 1987 Regulations, is accompanied by a specific indication, expressed in accordance with paragraph 8 of this Part of this Schedule, stating any food or group of foods described in the Table to Part IV of this Schedule 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 simulant or food simulants which, for the purposes of Part IV of this Schedule, 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 of this Schedule, a simulant other than the simulant or simulants which, for the purposes of Part IV of this Schedule, is or are specified in relation to that food or group of foods.
- **8.** A specific indication referred to in paragraph 7 of this Part of this Schedule 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 of these Regulations or the decription 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 of this Schedule.

TABLE 2
Simulants to be selected for testing food contact materials in special cases

Contact foods	Simulant
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	Simulants 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

Contact foods	Simulant	
All fatty, alcoholic and acidic foods	Simulants D, C and B	

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 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 of this Schedule, and the Table shall be read in conjunction with the notes thereto and the following paragraphs of this Part of this Schedule.
 - 2. For the purposes of this Part of this Schedule—
 - (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 of this Schedule;
 - (b) a reduction factor is specified in relation to a specific food or group of foods where, in the Table to this Part of this Schedule—
 - (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 allowed by an oblique stroke and a reduction factor.
- **3.** Where, in the Table to this Part of this Schedule, a reduction factor is specified 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 of this Schedule, 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 of this Schedule 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 Description A B C D Number of food 01 Beverages		Simulants	s to be used			
01 Beverages		A	В	С	D	
	Beverages					

- (*) 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.

		Simulants	s to be used		
Reference Number	Description of food	A	В	С	D
01.01	Non-alcoholic beverages or alcoholic beverages of an alcoholic strength lower than 5% vol.: Waters, ciders, fruit or vegetable juices of normal strength or concentrat musts, fruit nectars, lemonades and mineral waters, syrups, bitters, infusions, coffee, tea, liquid chocolate, beers and other		X(a)	(÷ž)	
01.02	Alcoholic beverages of an alcoholic strength equal to or exceeding 5% vol.: Beverages		X ^(*)	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.

		Simulants	to be used		
Reference Number	Description of food	A	B	C	D
	under heading 01.01 but with an alcoholic strength equal to or exceeding 5% vol.: Win spir and liqu	nes, its			
01.03	Miscellaneous: undenatured ethyl alcohol		X ^(*)	X ^(**)	
02	Cereals, cereal products, pastry, biscuits, cakes and other bakers' wares				
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				

^(*) 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.

		Simulants	to be used		
Reference Number	Description of food	A	В	С	D
	and similar products				
02.05	Pastry, biscuits, cakes and other bakers' wares, dry:				
	A. With fatty substances on the surface				X/5
	B. Other				
02.06	Pastry, cakes and other bakers' wares, fresh:				
	A. With fatty substances on the surface				X/5
	B. Other	X			
03	Chocolate, sugar and products thereof Confectionery products				
03.01	Chocolate, chocolate- coated products, substitutes and products coated with substitutes				X/5
03.02	Confectionery products:				
	A. In solid form:				

^(*) 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.

		Simulants	to be used		
Reference Number	Description of food	A	В	С	D
	I. With fatty substances on the surface				X/5
	II. Other				
	B. In paste form				
	I. With fatty substances on the surface				X/3
	II. Moist	X			
03.03	Sugar and sugar products				
	A. In solid form				
	B. Honey and the like	X			
	C. Molasses and sugar syrups	X			
04	Fruit, vegetables and products thereof				
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	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.

		Simulants to	be used		
Reference Number	Description of food	A	В	С	D
	chunks, puree or paste				
	C. Fruit preserves (jams and similar products— whole fruit or chunks or in the form of flour or powder, preserved in a liquid medium):				
	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 ^(*)	X	
04.03	Nuts (peanuts, chestnuts, almonds, hazelnuts, walnuts, pine kernels and others)				
	A. Shelled, dried				
	B. Shelled and roasted				X/5 ^(***)
	C. In paste or cream form	X			X/3 ^(***)
04.04	Whole vegetables,				

^(*) 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.

		Simulants to b	e used		
Reference Number	Description of food	A	В	C	D
	fresh or chilled				
04.05	Processed vegetables:				
	A. Dried or dehydrated vegetables whole or in the form of flour or powder				
	B. Vegetables, cut, in the form of purées	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 ^(*)	X	
05	Fats and oils				
05.01	Animal and vegetable fats and oils, whether natural or treated (including cocoa butter, lard, resolidified butter)				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.

		Simulants to	be used		
Reference Number	Description of food	A	В	C	D
05.02	Margarine, butter and other fats and oils made from water emulsions in oil				X/2
06	Animal products and eggs				
06.01	Fish:				
	A. Fresh, chilled, salted, smoked	X			X/3 ^(***)
	B. In the form of paste	X			X/3 ^(***)
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
	B. In the form of paste, creams	X			X/4

^(*) 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.

Simulants to be used					
Reference Number	Description of food	A	В	C	D
06.04	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)		
	B. In an oily medium	X(a)	X(a)		X
06.06	Eggs not in shell:				
	A. Liquid				
	B. Other	X			
06.07			Egg yolks:		
A. Liquid	X				
B. Powdered or frozen					
06.08	Dried white of egg				
07	Milk products				
07.01	Milk:				
	A. Whole	X			
	B. Partly dried	X			
	C. Skimmed or partly skimmed	X			
	D. Dried				
07.02	Fermented milk such		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.

		Simulant	s to be used		
Reference Number	Description of food	A	В	С	D
	as yoghurt, buttermilk and such products in association with fruit and fruit products				
07.03	Cream and sour cream	X(a)	X(a)		
07.04	Cheeses:				
	A. Whole, with rind				
	B. Processed cheeses	X(a)	X(a)		
	C. All others	X(a)	X(a)		X/3 ^(***)
07.05	Rennet:				
	A. In liquid or viscous form	X(a)	X(a)		
	B. Powdered or dried				
08	Miscellaneous products				
08.01	Vinegar		X		
08.02	Fried or roasted foods:				
	A. Fried potatoes, fritters and the like				X/5
	B. Of animal origin				X/4
08.03	Preparations for soups, broths in liquid, solid or powder form (extracts,				

^(*) 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.

		Simulants			
Reference Number	Description of food	A	В	С	D
	concentrates); homogenized composite food preparations, prepared dishes:				
	A. Powdered or dried				
	I. With fatty substances on the surface				X/5
	II. Other				
	B. Liquid or paste:				
	I. 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. Mayonnaise, sauces derived from mayonnaise, salad creams and other	X(a)	X(a)		X/3

^(*) 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.

		Simulants to b	e used		
Reference Number	Description of food	A	В	С	D
	oil in water emulsions				
	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 ^(***)
08.08	Sandwiches, toasted bread and the like containing any kind of foodstuff:				
	A. With fatty substances on the surface				X/5
	B. Other				
08.09	Ice-creams	X			
08.10	Dried foods:				
	A. With fatty substances on the surface				X/5
	B. Other				
08.11	Frozen or deep-fozen foods				
08.12	Concentrated extracts of an alcoholic strength equal to or		X ^(*)	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.

		Simulants t	o be used		
Reference Number	Description of food	A	В	С	D
	exceeding 5% vol.				
08.13	Cocoa:				
	A. Cocoa powder				X/5 ^(***)
	B. Cocoa paste				X/3 ^(***)
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: Camomile mallow, mint, tea, lime blossom and others	,			
08.17	Spices and seasonings in the natural state: Cinnamon cloves, powdered mustard, pepper, vanilla, saffron	,			

^(*) 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.

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		Simulant	s to be used			
Reference	Description	A	В	C	D	
Number	of food					
	and					
	other					

NOTES:

- (*) 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 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 shall be the time and temperature selected from column 2 of the Table to this Part of this Schedule 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 of this Schedule 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 of this Schedule 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 of this Schedule, 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 of this Schedule causes any physical or other change in the test specimen which does not occur under the worst forseeable 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 test other than for 10 days test at 40°C shall be carried out.

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

TABLE

Conditions of contact in worst foreseeable use	Test conditions
Contact time	Test time
t<=5 minutes	0
5 minutes <t<=0.5 hours<="" td=""><td>0.5 hours</td></t<=0.5>	0.5 hours
0.5 hours <t<=0.5 hours<="" td=""><td>1 hour</td></t<=0.5>	1 hour
1 hour <t<=2 hours<="" td=""><td>2 hours</td></t<=2>	2 hours
2 hours <t<=4 hours<="" td=""><td>4 hours</td></t<=4>	4 hours
4 hours <t<=24 hours<="" td=""><td>24 hours</td></t<=24>	24 hours
t>24 hours	10 days
contact temperature	Test temperature
T<=5°C	5°C

contact temperature	Test temperature
T<=5°C	5°C
5°C <t<=20°c< th=""><th>20°C</th></t<=20°c<>	20°C
20°C <t<=40°c< th=""><th>40°C</th></t<=40°c<>	40°C
40°C <t<=70°c< th=""><th>70°C</th></t<=70°c<>	70°C
70°C <t<=100°c< th=""><th>100°C or reflux temperature</th></t<=100°c<>	100°C or reflux temperature
100°C <t<=121°c< th=""><th>121°C⁽²⁾</th></t<=121°c<>	121°C ⁽²⁾
121°C <t<=130°c< th=""><th>130°C⁽²⁾</th></t<=130°c<>	130°C ⁽²⁾
130°C <t<=150°c< th=""><th>150°C⁽²⁾</th></t<=150°c<>	150°C ⁽²⁾
T>150°C	175°C ⁽²⁾

NOTES:

- (1) The period of time which represents the worst foreseeable conditions of contact.
- (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°C or at reflux temperature for a duration of four times the time selected in accordance with paragraph 1 of this Part of this Schedule.

PART VI

Substitute Fat Test for Overall and Specific Migration

1. Subject to paragraphs 2, 4 and 5 below, all the test media specified in the Table to this Part of this Schedule 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 of this Schedule 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 of this Schedule shall be applied for each test medium;
 - (c) subject to paragraph 4 below, 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 of this Schedule 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 of this Schedule shall be read with the notes to it.

TABLEConventional conditions for substitute tests

Test conditions with simulant D	Test conditions with isooctane	Test conditions with ethanol 95%	Test conditions with MPPO ⁽¹⁾
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 (2)	2.5 hours at 60°C	0.5 hours at 100°C
1 hour at 100°C	1 hour at 60° C $^{(2)}$	3 hours at 60°C (2)	1 hour at 100°C
2 hours at 100°C	1.5 hours at 60°C (2)	3.5 hours at 60°C (2)	2 hours at 100°C
0.5 hours at 121°C	1.5 hours at 60°C (2)	3.5 hours at 60°C (2)	0.5 hours at 121°C
1 hour at 121°C	2 hours at 60°C (2)	4 hours at 60°C (2)	1 hour at 121°C
2 hours at 121°C	2.5 hours at 60°C (2)	4.5 hours at 60°C (2)	2 hours at 121°C
0.5 hours at 130°C	2 hours at 60°C (2)	4 hours at 60°C (2)	0.5 hours at 130°C
1 hour at 130°C	2.5 hours at 60°C (2)	4.5 hours at 60°C (2)	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 (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.

Test conditions with simulant D	Test conditions with isooctane	Test conditions with ethanol 95%	Test conditions with MPPO ⁽¹⁾
2 hours at 150°C	3 hours at 60°C (2)	5 hours at 60°C (2)	2 hours at 150°C
2 hours at 175°C	4 hours at 60°C (2)	6 hours at 60°C (2)	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 of this Part of this Schedule the conditions which must be fulfilled to allow the result of either test specified in paragraph 3 of this Part of this Schedule to be used as an alternative to the result of a migration test carried out under Part III of this Schedule 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 of this Part of this Schedule does not, after application of the appropriate reduction factor, exceed the appropriate migration limit.
- 2. The condition in sub-paragraph (a) of paragraph 1 of this Part of this Schedule 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 of this Part of this Schedule are equal to or greater than those obtained in any of the migration tests specified in Part III of this Schedule.
 - 3. The migration tests referred to in paragraphs 2 and 3 of this Part of this Schedule 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.