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PROSPECTIVE

SCHEDULE 3

Regulations 9 and 11

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 shall 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.

Commencement Information

- II Sch. 3 Pt. 1 para. 1 in force at 19.11.2006, see reg. 1
- **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 shall 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.

Commencement Information

- I2 Sch. 3 Pt. 1 para. 2 in force at 19.11.2006, see reg. 1
- **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.

Commencement Information

- I3 Sch. 3 Pt. 1 para. 3 in force at 19.11.2006, see reg. 1
- **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.

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Commencement Information

I4 Sch. 3 Pt. 1 para. 4 in force at 19.11.2006, see reg. 1

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").

1	2
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 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 paragraph 5, any of the fatty food simulants specified in paragraph 4

Commencement Information

I5 Sch. 3 Pt. 2 para. 1 in force at 19.11.2006, see reg. 1

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.

Commencement Information

- I6 Sch. 3 Pt. 2 para. 2 in force at 19.11.2006, see reg. 1
- 3. The characteristics of rectified olive oil referred to in the Table are
 - (a) Iodine value (Wijs) = 80 to 88;
 - (b) Refractive index at 25° C = 1.4665 to 1.4679;
 - (c) Acidity (expressed as % of oleic acid) = 0.5% maximum;
 - (d) Peroxide number (expressed as oxygen milli-equivalents per kg of oil) = 10 maximum.

Commencement Information

I7 Sch. 3 Pt. 2 para. 3 in force at 19.11.2006, see reg. 1

- **4.** The fatty food simulants referred to in the Table are
 - (a) corn oil with standardised specifications;

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

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

Purity

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

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

Wavelength (nm)	290	310	330	350	370	390	430	470	510
Transmittance (%)	~2	~15	~37	~64	~80	~88	~95	~97	~98
At least 10% light tr									

Commencement Information

I8 Sch. 3 Pt. 2 para. 4 in force at 19.11.2006, see reg. 1

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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 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.

Commencement Information

I9 Sch. 3 Pt. 2 para. 5 in force at 19.11.2006, see reg. 1

PART 3

Selection of Food Simulants

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 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.

Commencement Information

I10 Sch. 3 Pt. 3 para. 1 in force at 19.11.2006, see reg. 1

- **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 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 of 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;
 - (c) a reduction factor shall be applied to a test result by dividing the result by that reduction factor.

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Commencement Information

III Sch. 3 Pt. 3 para. 2 in force at 19.11.2006, see reg. 1

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

Table 1: Food types

Definition	Meaning
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

Commencement Information

I12 Sch. 3 Pt. 3 para. 3 in force at 19.11.2006, see reg. 1

Commencement Information

- I10 Sch. 3 Pt. 3 para. 1 in force at 19.11.2006, see reg. 1
- III Sch. 3 Pt. 3 para. 2 in force at 19.11.2006, see reg. 1
- I12 Sch. 3 Pt. 3 para. 3 in force at 19.11.2006, see reg. 1

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.

Commencement Information

I13 Sch. 3 Pt. 3 para. 4 in force at 19.11.2006, see reg. 1

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 -

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- (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.

Commencement Information

I14 Sch. 3 Pt. 3 para. 5 in force at 19.11.2006, see reg. 1

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 (EC) No 1935/2004 of the European Parliament and of the Council on materials and articles intended to come into contact with food(1) ("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 shall 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.

Commencement Information

I15 Sch. 3 Pt. 3 para. 6 in force at 19.11.2006, see reg. 1

- 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 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 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 the simulant or simulants which, for the purposes of Part 4, is or are specified in relation to that food or group of foods.

⁽¹⁾ OJNo. L338, 13.11.2004, p.4.

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Commencement Information 116 Sch. 3 Pt. 3 para. 7 in force at 19.11.2006, see reg. 1

- **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

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	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

Commencement Information

II7 Sch. 3 Pt. 3 para. 8 in force at 19.11.2006, see reg. 1

Commencement Information

- I15 Sch. 3 Pt. 3 para. 6 in force at 19.11.2006, see reg. 1
- I16 Sch. 3 Pt. 3 para. 7 in force at 19.11.2006, see reg. 1
- I17 Sch. 3 Pt. 3 para. 8 in force at 19.11.2006, see reg. 1

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

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specific food or specific group of foods in the Table to this Part, and the Table shall be read in conjunction with the notes to it and with paragraphs 2 to 5.

Commencement Information

I18 Sch. 3 Pt. 4 para. 1 in force at 19.11.2006, see reg. 1

- 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 allowed by an oblique stroke and a reduction factor.

Commencement Information

I19 Sch. 3 Pt. 4 para. 2 in force at 19.11.2006, see reg. 1

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.

Commencement Information

I20 Sch. 3 Pt. 4 para. 3 in force at 19.11.2006, see reg. 1

- **4.** Where 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.

Commencement Information

I21 Sch. 3 Pt. 4 para. 4 in force at 19.11.2006, see reg. 1

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	Description of food		Simulants to be used				
Number		Α	В	С	D		
01	Beverages						
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 concentrated, musts, fruit nectars, lemonades and mineral waters, syrups, bitters, infusions, coffee, tea, liquid chocolate, beers and other	X(a)	X(a)				
01.02	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 ⁽¹⁾	X ⁽²⁾			
01.03	Miscellaneous: undenatured ethyl alcohol		X ⁽¹⁾	X ⁽¹⁾			
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 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, biscuits, 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						

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

⁽²⁾ 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.

⁽³ If it can be demonstrated under regulation 12(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 shall not be used.

Reference	Description of food		Simulants to be used				
Number		A	В	C	D		
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						
	A In solid form						
	B Honey and the like	X					
	C Molasses and sugar syrups	X					
04	Fruit, vegetable 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 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):						
	— 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 ⁽¹⁾	X			
04.03	Nuts (peanuts, chestnuts, almonds, hazelnuts, walnuts, pine kernels and others)						
	A Shelled, dried						
	B Shelled and roasted				$X/5^{(3)}$		
	C In paste or cream form	X			$X/3^{(3)}$		

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

⁽²⁾ 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.

⁽³ If it can be demonstrated under regulation 12(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 shall not be used.

Reference	Description of food		Simulants to be used				
Number		A	В	C	D		
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						
	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 ⁽¹⁾	X			
05	Fats and oils						
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	Animal products and eggs						
06.01	Fish:						
	A Fresh, chilled, salted, smoked	X			$X/3^{(3)}$		
	B In the form of paste	X			$X/3^{(3)}$		
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		
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:						

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

⁽²⁾ 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.

⁽³ If it can be demonstrated under regulation 12(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 shall not be used.

Reference	Description of food		Simulants to be used				
Number		A	В	C	D		
	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	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 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)				
	C All others	X(a)	X(a)		X/3 ⁽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, concentrates);						

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

⁽²⁾ 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.

⁽³ If it can be demonstrated under regulation 12(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 shall not be used.

Reference	Description of food		Simula	nts to b	e used
Number		A	В	C	D
	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 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 ⁽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-frozen foods				
08.12	Concentrated extracts of an alcoholic strength equal to or exceeding 5% vol		X ⁽¹⁾	X	

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

⁽²⁾ 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.

⁽³ If it can be demonstrated under regulation 12(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 shall not be used.

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Reference	Description of food		Simulants to be used				
Number		A	В	С	D		
08.13	Cocoa:						
	A Cocoa powder				X/5 ⁽³		
	B Cocoa paste				X/3 ⁽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 and other						

- (1) Simulant B shall not be used where the pH is more than 4.5.
- (2) 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.
- (3 If it can be demonstrated under regulation 12(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 shall not be used.

Commencement Information

I22 Sch. 3 Pt. 4 para. 5 in force at 19.11.2006, see reg. 1

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 shall 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.

Commencement Information

I23 Sch. 3 Pt. 5 para. 1 in force at 19.11.2006, see reg. 1

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

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all the applicable worst foreseeable conditions appropriate to the sample, using the same portion of food simulant.

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Commencement Information

124 Sch. 3 Pt. 5 para. 2 in force at 19.11.2006, see reg. 1
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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.

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Commencement Information
125 Sch. 3 Pt. 5 para. 3 in force at 19.11.2006, see reg. 1
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Commencement Information
123 Sch. 3 Pt. 5 para. 1 in force at 19.11.2006, see reg. 1
124 Sch. 3 Pt. 5 para. 2 in force at 19.11.2006, see reg. 1
125 Sch. 3 Pt. 5 para. 3 in force at 19.11.2006, see reg. 1
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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 that recognises the loss of volatile migrants which may occur in the worst foreseeable conditions of use.

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Commencement Information
126 Sch. 3 Pt. 5 para. 4 in force at 19.11.2006, see reg. 1
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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.

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Commencement Information
127 Sch. 3 Pt. 5 para. 5 in force at 19.11.2006, see reg. 1
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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 shall be carried out in the worst foreseeable conditions of use in which such physical or other change does not occur.

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Commencement Information
128 Sch. 3 Pt. 5 para. 6 in force at 19.11.2006, see reg. 1
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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.

Commencement Information

I29 Sch. 3 Pt. 5 para. 7 in force at 19.11.2006, see reg. 1

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

Conditions of contact in worst foreseeable use	Test conditions	
Contact time:	Test time:	
less than or equal to 5 minutes	(t)	
>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	
Contact temperature:	Test temperature:	
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 to100°C	100°C or reflux temperature	
>100°C but less than or equal to 121°C	121°C (2)	
>121°C but less than or equal to 130°C	130°C (2)	
>130°C but less than 150°C	150°C (2)	
>150°C	175°C ⁽²⁾	

⁽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.

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Commencement Information 130 Sch. 3 Pt. 5 para. 8 in force at 19.11.2006, see reg. 1

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Commencement Information

127 Sch. 3 Pt. 5 para. 5 in force at 19.11.2006, see reg. 1

128 Sch. 3 Pt. 5 para. 6 in force at 19.11.2006, see reg. 1

129 Sch. 3 Pt. 5 para. 7 in force at 19.11.2006, see reg. 1

130 Sch. 3 Pt. 5 para. 8 in force at 19.11.2006, see reg. 1
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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 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.

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Commencement Information

I31 Sch. 3 Pt. 6 para. 1 in force at 19.11.2006, see reg. 1
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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.

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Commencement Information

I32 Sch. 3 Pt. 6 para. 2 in force at 19.11.2006, see reg. 1
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- 3. For each test—
 - (a) a new test specimen shall be used;
 - (b) the rules prescribed for simulant D in Parts 3, 4 and 5 of this Schedule 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.

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Commencement Information

133 Sch. 3 Pt. 6 para. 3 in force at 19.11.2006, see reg. 1
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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.

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Commencement Information

I34 Sch. 3 Pt. 6 para. 4 in force at 19.11.2006, see reg. 1

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.

Commencement Information

I35 Sch. 3 Pt. 6 para. 5 in force at 19.11.2006, see reg. 1

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

Conventional 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
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 (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.

Commencement Information

I36 Sch. 3 Pt. 6 para. 6 in force at 19.11.2006, see reg. 1

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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.

Commencement Information

I37 Sch. 3 Pt. 7 para. 1 in force at 19.11.2006, see reg. 1

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.

Commencement Information

I38 Sch. 3 Pt. 7 para. 2 in force at 19.11.2006, see reg. 1

- 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.

Commencement Information

I39 Sch. 3 Pt. 7 para. 3 in force at 19.11.2006, see reg. 1

Status:

This version of this schedule contains provisions that are prospective.

Changes to legislation:

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      Sch. 3 Pt. 1 para. 1 coming into force by S.I. 2006/2687 reg. 1
      Sch. 3 Pt. 1 para. 2 coming into force by S.I. 2006/2687 reg. 1
      Sch. 3 Pt. 1 para. 3 coming into force by S.I. 2006/2687 reg. 1
      Sch. 3 Pt. 1 para. 4 coming into force by S.I. 2006/2687 reg. 1
      Sch. 3 Pt. 2 para. 1 coming into force by S.I. 2006/2687 reg. 1
      Sch. 3 Pt. 2 para. 2 coming into force by S.I. 2006/2687 reg. 1
      Sch. 3 Pt. 2 para. 3 coming into force by S.I. 2006/2687 reg. 1
      Sch. 3 Pt. 2 para. 4 coming into force by S.I. 2006/2687 reg. 1
      Sch. 3 Pt. 2 para. 5 coming into force by S.I. 2006/2687 reg. 1
      Sch. 3 Pt. 3 para. 1 coming into force by S.I. 2006/2687 reg. 1
      Sch. 3 Pt. 3 para. 2 coming into force by S.I. 2006/2687 reg. 1
      Sch. 3 Pt. 3 para. 3 coming into force by S.I. 2006/2687 reg. 1
      Sch. 3 Pt. 3 para. 4 coming into force by S.I. 2006/2687 reg. 1
      Sch. 3 Pt. 3 para. 5 coming into force by S.I. 2006/2687 reg. 1
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      Sch. 3 Pt. 3 para. 7 coming into force by S.I. 2006/2687 reg. 1
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      Sch. 3 Pt. 4 para. 4 coming into force by S.I. 2006/2687 reg. 1
      Sch. 3 Pt. 4 para. 5 coming into force by S.I. 2006/2687 reg. 1
      Sch. 3 Pt. 5 para. 1 coming into force by S.I. 2006/2687 reg. 1
      Sch. 3 Pt. 5 para. 2 coming into force by S.I. 2006/2687 reg. 1
      Sch. 3 Pt. 5 para. 3 coming into force by S.I. 2006/2687 reg. 1
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      Sch. 3 Pt. 5 para. 8 coming into force by S.I. 2006/2687 reg. 1
      Sch. 3 Pt. 6 para. 1 coming into force by S.I. 2006/2687 reg. 1
      Sch. 3 Pt. 6 para. 2 coming into force by S.I. 2006/2687 reg. 1
      Sch. 3 Pt. 6 para. 3 coming into force by S.I. 2006/2687 reg. 1
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      Sch. 3 Pt. 6 para. 6 coming into force by S.I. 2006/2687 reg. 1
      Sch. 3 Pt. 7 para. 1 coming into force by S.I. 2006/2687 reg. 1
      Sch. 3 Pt. 7 para. 2 coming into force by S.I. 2006/2687 reg. 1
      Sch. 3 Pt. 7 para. 3 coming into force by S.I. 2006/2687 reg. 1
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