

SCHEDULE 1

Regulations 4 and 5

Supplementary Provisions Relating to Annexes II and III

1. In Sections A and B of Annexes II and III (in this Schedule referred to together as “the Annexes”)–

- (a) the PM/REF No of any substance is its EEC packaging material reference number;
- (b) the CAS No of any substance is its CAS (Chemical Abstracts Service) Registry Number;
- (c) the name of any substance is its chemical name, and to the extent that there is any inconsistency between the CAS number and the name, the name shall take precedence over the CAS number; and
- (d) references to specific migration are to be taken to mean specific migration as measured in accordance with Schedules 2 and 3.

2. If a substance appearing in the Annexes as an individual compound also falls within a generic term which appears therein, any restriction applying to that substance shall be that indicated for the individual compound and the entry applying to the generic term shall be treated as varied to the extent necessary.

3.—(1) The items identified in Section A or B of Annex II shall be taken to include–

- (a) substances undergoing polymerisation (including polycondensation, polyaddition or any other similar process) to manufacture macromolecules;
- (b) natural or synthetic macromolecular substances used in the manufacture of modified macromolecules, if the monomers required to synthesise them are not so identified; and
- (c) substances used to modify existing natural or synthetic macromolecular substances.

(2) Salts (including double salts and acid salts) of aluminium, ammonium, calcium, iron, magnesium, potassium and sodium of authorised acids, phenols or alcohols are not included in the lists in the Annexes even if they are authorised and intentionally used; however names containing “... ..acid(s), salts” do appear in the lists if the corresponding free acid(s) is or are not mentioned.

(3) Salts (including double salts and acid salts) of zinc of authorised acids, phenols or alcohols are not included in the lists in the Annexes even if they are authorised and intentionally used. For these salts a Group SML = 25/mg/kg (expressed as Zn) applies. The same restriction for Zn applies to–

- (a) substances whose name contains “... .. acid(s), salts” which appear in the lists, if the corresponding free acid(s) is or are not mentioned; and
- (b) substances referred to in note 38 of Annex VI.

4. In the case of substances listed in Section B of Annex III, the specific migration limits listed in column 4 shall have effect where the verification of compliance is carried out in Simulant D or in test media of substitute tests as prescribed in Directives 82/711 and 85/572.

5. Where an entry in column 4 of the Annexes (restrictions and specifications) includes a bracketed number, that entry shall be subject to a note relating to that number as set out in Annex VI.

SCHEDULE 2

Regulations 9 and 13

Provisions Applicable when Testing Compliance with the Migration Limits

General Provisions

1. When the results of the migration tests specified in this Schedule and, where appropriate Schedule 3, are analytically determined, the specific gravity of any simulants used shall be assumed to be 1, so that milligrams of any substance released per litre of simulant will correspond numerically to milligrams of that substance released per kilogram of that simulant.

2. Where any migration test specified in this Schedule and, where appropriate, Schedule 3 is carried out on any sample taken from any plastic material or article and the quantities of food or simulant placed in contact with the sample differ from those employed in the actual conditions under which the plastic material or article is used or is to be used, the results obtained should be corrected by applying the formula $M = ((m \cdot a_2 / a_1 \cdot q) \cdot 1000)$ where—

- (a) M is the migration in mg/kg;
- (b) m is the mass in the mg of substance released by the sample as determined by the migration test;
- (c) a_1 is the surface area in square decimetres of the sample in contact with the food or simulant during the migration test;
- (d) a_2 is the surface area in square decimetres of the plastic material or article in actual conditions of use; and
- (e) q is the quantity in grams of food in contact with the plastic material or article in actual conditions of use.

3.—(1) Subject to sub paragraph (2), any testing of migration from any plastic material or article shall be carried out on that plastic material or article.

(2) In any case where determination in accordance with sub paragraph (1) is impracticable, such testing shall be carried out, using either specimens taken from that plastic material or article, or where appropriate, specimens representative of that plastic material or article.

(3) Any sample used for such testing shall be placed in contact with the simulant or food, as the case may be, in a manner representing the contact conditions in actual use, and for this purpose the testing shall be carried out in such a way that only those parts of the sample intended to come into contact with food in actual use will be in contact with the simulant or food.

(4) Any migration testing of caps, gaskets, stoppers or similar devices for sealing shall be carried out on these articles by applying them to the containers for which they are intended in a manner which corresponds to the conditions of closing in normal or foreseeable use.

4.—(1) Any sample of plastic material or article shall be placed in contact with the appropriate simulant or the food for a period and at a temperature which are chosen by reference to the contact conditions in actual use in accordance with the provisions of this Schedule and, where appropriate, Schedule 3.

(2) At the end of the period referred to in sub paragraph (1), analytical determination of the total quantity of substances (overall migration), each specific quantity of a substance (specific migration) or, as the case may be, both that total and that specific quantity released by the sample shall be carried out on the simulant or food, as the case may be.

(3) Verification that migration into food complies with a migration limit specified in regulation 9 or Annexes II, III or IV (for the purposes of this Schedule and Schedule 3 referred to as

“the Annexes”) shall be carried out under the most extreme conditions of time and temperature foreseeable in actual use in accordance with the provisions of this Schedule.

(4) Verification that migration into food simulants complies with a migration limit specified in regulation 9 or the Annexes shall be carried out in accordance with the provisions of this Schedule and using conventional migration tests, the basic rules for which are set out in Schedule 3.

5. Where a plastic material or article is intended to come into repeated contact with food, any migration test shall (subject to paragraph 7) be carried out three times on a single sample in accordance with the conditions laid down in this Schedule and, where appropriate, Schedule 3 using separate samples of the simulant or, as the case may be food, on each occasion, and the level of the migration found in the third test shall be treated as the level relevant to that test.

Special provisions relating to the fat reduction factor

6.—(1) Subject to paragraph 7, the results of tests for specific migration in foods containing more than 20% fat shall be corrected by the fat reduction factor (“FRF”), being a factor between 1 and 5 (expressed as M_{FRF}) by which measured migration of lipophilic substances listed in Annex IVa into a fatty food or stimulant D and its substitutes are divided before comparison with specific migration limits.

(2) The following equations shall be applied before comparison with the specific migration limit—

(a) $M_{FRF} = M/FRF$, and

(b) $FRF = (\text{g fat in food/kg of food})/200 = (\% \text{ fat} \times 5)/100$.

7.—(1) Correction by the FRF does not apply—

(a) where the plastic material or article is or is intended to be brought into contact with foods intended for infants and young children;

(b) for substances listed in the Annexes having a restriction in column (4) of SML = ND;

(c) for substances not listed in the Annexes and used behind a plastic functional barrier with a migration limit of 0.01 mg/kg;

(d) except in the circumstances specified in sub paragraph (2), for plastic materials or articles—

(i) for which it is impracticable to estimate the relationship between the surface area and the quantity of food in contact with it, due to shape, use or other factors, and

(ii) where the migration is calculated using the conventional surface area/volume conversion factor of 6 dm²/kg.

(2) For containers and other fillable articles with a capacity of less than 500 millilitres or more than 10 litres and for sheets and films in contact with foods containing more than 20% fat—

(a) the migration may be calculated as concentration (expressed as mg/kg) in the food or food simulant and corrected by the FRF; or

(b) the migration may be re calculated as mg/dm² without applying the FRF,

and, provided the value resulting from the calculation under either sub paragraph (a) or (b) is below the SML, the plastic material or article shall be considered to be in compliance.

8. If use of the FRF under paragraph 6 or 7(2) produces a result that indicates the overall migration limit has been exceeded, the material or article in question shall not be considered to be in compliance.

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Special provisions relating to the correction of specific migration in stimulant D

9. The specific migration of those lipophilic substances listed in Annex IVa into stimulant D and its substitutes shall be corrected by—

- (a) the stimulant D reduction factor (“DRF”), being the reduction factor referred to in paragraph 2(2) of Part 3 and paragraphs 2 and 3 of Part 4 of Schedule 3, provided that—
 - (i) in cases where the specific migration into stimulant D is higher than 80% of the content of the substance in the finished plastic material or article, it can be demonstrated by scientific or experimental evidence, such as testing with the most critical foods, that the DRF is appropriate, and
 - (ii) the substance is not one mentioned in paragraph 7(1)(b) or (c);
- (b) the FRF, provided that the fat content of the food to be packed is known and the requirements of paragraphs 6, 7 and 8 are fulfilled; or
- (c) the total reduction factor (“TRF”), being the factor—
 - (i) by which a measured specific migration into stimulant D or a substitute shall be divided before comparison with the specific migration limit, and
 - (ii) which is obtained by multiplying the DRF by the FRF with a maximum value of 5, when both factors are applicable.

Special provisions relating to overall migration

10.—(1) Subject to sub paragraph (2), any method of analytical determination may be used to prove excess of an overall migration limit in relation to a plastic material or article.

(2) In any proceedings for an offence under these Regulations where it is alleged that a plastic material or article does not comply with regulation 9 it shall be a defence for the person charged to prove that—

- (a) if an aqueous simulant specified in Schedule 3 had been used, and the analytical determination of the total quantity of substances released by a sample of the plastic material or article tested had been carried out by evaporation of the simulant and weighing of the residue; or
- (b) if rectified olive oil or any of its substitutes had been used as a simulant and—
 - (i) a sample of the plastic material or article had been weighed before and after contact with the simulant;
 - (ii) the simulant absorbed by the sample had been extracted and determined quantitatively;
 - (iii) the quantity of simulant so found had been subtracted from the weight of the sample measured after contact with the simulant; and
 - (iv) the difference between the initial and corrected final weights had been determined to represent the overall migration of the sample examined,there would have been no such excess so determined.

11.—(1) Where a plastic material or article is intended to come into repeated contact with food and it is technically impossible to carry out the test described in paragraph 5, the test shall be modified in accordance with sub paragraph (2) or in such other way so as to enable the level of migration occurring during the third such test to be determined, and such a determination may be used as evidence of the overall migration in relation to a plastic material or article.

(2) Three identical samples of the plastic material or article are to be procured, following which—

- (a) the first sample is to be subjected to the appropriate test according with paragraph 4 and the overall migration determined (M_1);
 - (b) the second and third samples are to be subjected to the same conditions of temperature as the first but the period of contact is to be two and three times respectively that specified and the overall migration determined in each case (M_2 and M_3).
- (3) Where a modified test has been carried out in accordance with sub paragraph (2), provided that either M_1 or M_3 – M_2 did not exceed the overall migration limit, the plastic material or article subjected to the test shall be deemed to be in compliance with that limit.

12.—(1) Any plastic material or article which exceeds its overall migration limit by an amount not exceeding the analytical tolerance specified in sub paragraph (2) shall be deemed for the purposes of these Regulations not to exceed its overall migration limit.

- (2) The following analytical tolerances shall be applied for limits of overall migration—
- (a) 20 mg/kg or, as the case may be, 3 milligrams per square decimetre in migration tests using as a simulant rectified olive oil or substitutes;
 - (b) 12 mg/kg or, as the case may be, 2 milligrams per square decimetre in migration tests using other simulants referred to in Schedule 3.

Special provisions relating to caps, lids, gaskets, stoppers and similar sealing articles

13.—(1) If the intended use is known, caps, lids, gaskets, stoppers and similar sealing articles shall be tested by applying them to the containers for which they are intended under conditions of closure corresponding to the normal or foreseeable use and on the assumption that such articles are in contact with a quantity of food filling the container.

(2) The results of any tests carried out under sub paragraph (1) shall be expressed in mg/kg or mg/dm^2 as appropriate in accordance with the requirements of regulation 9(2), taking into account the whole contact surface of sealing article and container that is potentially in contact with the food.

(3) If the intended use of an article of the type mentioned in sub paragraph (1) is not known, it shall be—

- (a) tested separately from the container for which it is intended, with the result being expressed in mg/article; and
- (b) the value added, if appropriate, to the quantity migrated from that container.

SCHEDULE 3

Regulations 9 and 13

Overall and Specific Migration Testing Using Food Simulants

PART 1

Basic Rules

1. Subject to paragraphs 2, 3 and 4 of this Part, migration tests for the determination of specific and overall migration 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.

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

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using the fatty food simulants specified in Part 3 is not feasible for technical reasons connected with the method of analysis.

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

4. In migration testing it is permissible to—

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

PART 2

Food Simulants to be used in Migration Testing

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

<i>1</i> <i>Abbreviation</i>	<i>2</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 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

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—

- (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

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(Wijs)	≤0.1%
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 (%)	~15	~15	~37	~64	~80	~88	~95	~97	~98

At least 10% light transmittance at 310 nm

5. Where 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

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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.

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.

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 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;
- (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 Table 1 as follows—

Table 1:

Food types

<i>Definition</i>	<i>Meaning</i>
Aqueous foods having a pH > 4.5	Foods in relation to which stimulant A only is specified in the Table to Part 4
Acidic foods having a pH < 4.5	Foods in relation to which stimulant B only is specified in the Table to Part 4

<i>Definition</i>	<i>Meaning</i>
Alcoholic foods	Foods in relation to which stimulant C only is specified in the Table to Part 4
Fatty foods	Foods in relation to which stimulant D only is specified in the Table to Part 4
Dry Foods	Foods in relation to which no stimulant is specified in the Table to Part 4

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

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

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

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

(a) where—

(i) the known food is a specific food or is within a specific group of foods described in column 2 of the Table to Part 4 and,

(ii) for the purposes of that Part, a simulant is, or simulants are, specified in relation to that specific food or specific group of foods,

the simulant or simulants so specified;

(b) where—

(i) the known food is neither a specific food, nor

(ii) within a specific group of foods described in the Table to Part 4 of this Schedule,

the simulant or simulants in column 2 of Table 2 opposite the description of food in column 1 of that Table which corresponds most closely to the known food.

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

6. The simulant or simulants to be used in testing a plastic material or article which, pursuant to Regulation 1935/2004 is accompanied by a specific indication stating any type or types of food described in Table 1 with which it may or may not be used 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.

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

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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 one specified for the purposes of Part 4 in relation to that food or group of foods.

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

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

Table 2:

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

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

PART 4

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

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

2. For the purposes of this Part—

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

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- (i) the food or group of foods is described in the column headed “Description of food”; and
- (ii) “X” is placed in a column headed by a specified simulant opposite that food or group of foods followed by an oblique stroke and a reduction factor.

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

4.—(1) Where the letter “a” is shown in brackets after the “X”, only one of the two simulants specified 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.

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

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

Reference Number	Description of food	Simulants to be used			
		A	B	C	D
01	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,	X(a)	X(a)		

- (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 13(2) or proved by means of an appropriate test that there is to be no fatty contact with the plastic material or article, simulant D shall not be used.

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Reference Number	Description of food	Simulants to be used			
		A	B	C	D
01.02	coffee, tea, liquid chocolate, beers and other Alcoholic beverages of an alcoholic strength equal to or exceeding 5% vol. – Beverages shown under heading 01.01 but with an alcoholic strength equal to or exceeding 5% vol.– Wines, spirits and liqueurs		X ⁽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,				

(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 13(2) or proved by means of an appropriate test that there is to be no fatty contact with the plastic material or article, simulant D shall not be used.

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Reference Number	Description of food	Simulants to be used			
		A	B	C	D
02.03	cornflakes and the like) 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 B Other				X/5
02.06	Pastry, biscuits, cakes and other bakers' wares, fresh: A With fatty substances on the surface B Other				X/5
03	Chocolate, sugar and products thereof Confectionery products	X			
03.01	Chocolate, chocolate coated products, substitutes and products				X/5
<p>(1) Simulant B shall not be used where the pH is more than 4.5.</p> <p>(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.</p> <p>(3) If it can be demonstrated under regulation 13(2) or proved by means of an appropriate test that there is to be no fatty contact with the plastic material or article, simulant D shall not be used.</p>					

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Reference Number	Description of food	Simulants to be used			
		A	B	C	D
03.02	coated with substitutes				
	Confectionery products:				
	A in solid form:				
	– with fatty substances on the surface				X/5
03.03	– Other				
	B in paste form:				
	– with fatty substances on the surface				X/3
	– moist	X			
04	Sugar and sugar products				
	A In solid form				
	B Honey and the like	X			
04.01	C Molasses and sugar syrups	X			
	Fruit, vegetable and products thereof				
04.02	Whole fruit, fresh or chilled				
04.02	Processed fruit:				
	A Dried or dehydrated fruit, whole				

- (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 13(2) or proved by means of an appropriate test that there is to be no fatty contact with the plastic material or article, simulant D shall not be used.

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Reference Number	Description of food	Simulants to be used			
		A	B	C	D
	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⁾

- (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 13(2) or proved by means of an appropriate test that there is to be no fatty contact with the plastic material or article, simulant D shall not be used.

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Reference Number	Description of food	Simulants to be used			
		A	B	C	D
	C In paste or cream form	X			X/3 ⁽³⁾
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,				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 13(2) or proved by means of an appropriate test that there is to be no fatty contact with the plastic material or article, simulant D shall not be used.

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Reference Number	Description of food	Simulants to be used			
		A	B	C	D
05.02	resolidified butter) 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	

(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 13(2) or proved by means of an appropriate test that there is to be no fatty contact with the plastic material or article, simulant D shall not be used.

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Reference Number	Description of food	Simulants to be used			
		A	B	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 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)
	B Partly dried				X(b)
07.01	C Skimmed or partly skimmed				X(b)
	D Dried				
07.02	Fermented milk such as yoghurt,		X		X(b)

- (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 13(2) or proved by means of an appropriate test that there is to be no fatty contact with the plastic material or article, simulant D shall not be used.

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Reference Number	Description of food	Simulants to be used			
		A	B	C	D
	buttermilk and similar products				
07.03	Cream and sour cream		X(a)		X(b)
07:04	Cheeses:				
	A Whole, with non-edible rind				
	B 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); homogenized composite food preparations,				

(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 13(2) or proved by means of an appropriate test that there is to be no fatty contact with the plastic material or article, simulant D shall not be used.

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Reference Number	Description of food	Simulants to be used			
		A	B	C	D
	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	X(a)	X(a)		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 13(2) or proved by means of an appropriate test that there is to be no fatty contact with the plastic material or article, simulant D shall not be used.

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Reference Number	Description of food	Simulants to be used			
		A	B	C	D
	forming two distinct layers				
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	
08.13	Cocoa:				
	A Cocoa powder				X/5 ⁽³⁾
	B Cocoa paste				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 13(2) or proved by means of an appropriate test that there is to be no fatty contact with the plastic material or article, simulant D shall not be used.

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Reference Number	Description of food	Simulants to be used			
		A	B	C	D
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 13(2) or proved by means of an appropriate test that there is to be no fatty contact with the plastic material or article, simulant D shall not be used.

PART 5

Migration Test Conditions (Times and Temperatures)

General criteria

1. Subject to paragraphs 2, 4, 6 and 7 and to paragraph 4.4 to this Part 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 which correspond to the worst foreseeable

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conditions of contact specified in column 1 of that Table for the plastic material or article being tested and to any labelling information on maximum temperature for use.

2. Where the plastic material or article being tested is intended for a food contact application covered by a combination of two or more times and temperatures specified in column 2 of the Table to this Part, the migration test 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.

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.

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 or 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 shall be read with the notes to it.

<i>Conditions of contact in worst foreseeable use</i>	<i>Test conditions</i>
Contact time:	Test time:
less than or equal to 5 minutes	(1)
>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

(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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<i>Conditions of contact in worst foreseeable use</i>	<i>Test conditions</i>
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 to 100°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	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.

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 stimulant 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 the 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 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.

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.

<i>CONVENTIONAL CONDITIONS FOR SUBSTITUTE TESTS</i>			
<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⁽¹⁾</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 ⁽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.

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—

- the result obtained in a “comparison test” shows that the values are equal to or greater than those obtained in the test with stimulant D; and
- 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 paragraph 1(a) does not have to be fulfilled if it can be shown on the basis of the result of scientific experiment that the values obtained in either of the tests specified in paragraph 3 are equal to or greater than those obtained in any of the migration tests specified in Part 3.

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

- a 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 stimulant D;

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- (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.

SCHEDULE 4

Regulation 14

Information to be contained in a declaration of compliance

1. The identity and address of the business operator which manufactures or imports the plastic materials or articles or the substances intended for the manufacturing of those materials or articles.
2. The identity of the materials, the articles or the substances intended for the manufacturing of those materials and articles.
3. The date of the declaration.
4. Confirmation that the plastic materials or articles meet relevant requirements laid down in the Directive and Regulation 1935/2004.
5. Adequate information relative to the substances used for which restrictions and/or specifications are in place under this Directive to allow the downstream business operators to ensure compliance with those restrictions.
6. Adequate information relative to the substances which are subject to a restriction in food, obtained by experimental data or theoretical calculation about the level of their specific migration and, where appropriate, the purity criteria to enable the user of these materials or articles to comply with the relevant Community provisions or, in their absence, with national provisions applicable to food.
7. Specifications on the use of the material or article, such as—
 - (a) type or types of food with which it is intended to be put in contact;
 - (b) time and temperature of treatment and storage in contact with the food;
 - (c) ratio of food contact surface area to volume used to establish the compliance of the material or article.
8. Confirmation that, when a plastic functional barrier is used in a plastic multi layer material or article, the material or article complies with the requirements of Article 7a(2), (3) and (4) of the Directive.