II

(Preparatory Acts)

COMMISSION

Proposal for a Council Directive laying down the list of simulants to be used for testing migration of constituents of plastic materials and articles intended to come into contact with foodstuffs

COM(84) 152 final

(Submitted by the Commission to the Council on 2 April 1984)

(84/C 102/05)

THE COUNCIL OF THE EUROPEAN COMMUNITIES

Having regard to the Treaty establishing the European Economic Community,

Having regard to Council Directive 82/711/EEC of 18 October 1982 laying down the basic rules necessary for testing migration of the constituents of plastic materials and articles intended to come into contact with foodstufs (1), and in particular Article 2 (3) thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the European Parliament,

Having regard to the opinion of the Economic and Social Commitee,

Whereas, by virtue of Article 2 (3) of, together with the first indent of Chapter I (2) of the Annex to Directive 82/711/EEC, appropriate simulants to carry out migration tests should be indicated for plastic materials and articles intended to come into contact with a single foodstuff or a specific group of foodstuffs,

Whereas, in determining appropriate simulants, account must be taken in particular of the chemical composition of the foodstuff and its physical properties,

Whereas, for some foodstuffs containing fat, the result obtained in migration tests with the simulant is higher than that obtained in migration tests with the foodstuff itself; whereas, therefore, the result should be corrected by applying a 'reduction factor' appropriate to the particular situation;

Whereas the adaptation of this Directive to technical progress constitutes an implementing measure, the adoption of which, in order to simplify and accelerate the procedure, should in principle be the responsibility of the Commission;

Whereas in all cases in which the Council confers on the Commission authority to implement the provisions relating to plastic materials and articles intended to come into contact with foodstuffs, a procedure should be laid down establishing close cooperation between Member States and the Commission within the Standing Committee for Foodstuffs,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Pursuant to Article 2 (3) of Directive 82/711/EEC, the simulants to be used for testing migration of the constituents of plastic materials and articles intended to come into contact with a single foodstuff or specific group of foodstuffs and the concentration of these simulants shall be those indicated in the Annex.

Article 2

Adaptations to be made to the Annex to this Directive in the light of progress in scientific and technical knowledge shall be adopted in accordance with the procedure laid down in Article 10 of Council Directive 76/893/EEC (2).

Article 3

Member States shall take all measures necessary to comply with this Directive not later than such time as they take the measures to implement Directive 82/711/EEC.

Article 4

This Directive is addressed to the Member States.

(1) OJ No L 297, 23. 10. 1982, p. 26.

(2) OJ No L 340, 9. 12. 1976, p. 19.

ANNEX

LIST OF SIMULANTS

1. In the following tables the simulants to be used in migration tests with a particular foodstuff or group of foodstuffs are identified by the letters shown:

   Simulant A: distilled water or the equivalent,

   Simulant B: 3 % (w/v) acetic acid in aqueous solution,

   Simulant C: 15 % (v/v) ethanol in aqueous solution,

   Simulant D: rectified olive oil (1): if for technical reasons it proves impossible to determine migration in olive oil, the latter is replaced by sunflower oil or by a standard mixture of synthetic triglycerides (2).

2. Only the simulant(s) indicated by an 'X' is(are) to be used for each heading or subheading; a new sample should be used for each liquid. Where no 'X' appears, no migration test is required for the heading or subheading concerned.

3. When 'X' is followed by a stroke and a figure, the result of the migration tests should be divided by the number indicated. In the case of certain types of fatty foodstuffs this figure, known as the 'reduction factor', is used to take account of the greater extractive capacity of the simulating liquid for such foodstuffs.

4. Where the letter 'a' is shown in brackets after the 'X', only one of the two simulants given should be used:

   — if the pH value of the foodstuff is higher than 5, simulant A should be used,

   — if the pH value of the foodstuff is 5 or less, simulant B should be used.

5. Where a foodstuff is listed under both a specific and a general heading, only the simulant(s) indicated under the specific heading is(are) to be used.

(1) Characteristics of rectified olive oil:
— iodine number (Wijs numbers) = 80 to 88,
— refractive index at 25° C = 1,4665 to 1,4679,
— acidity (expressed as % oleic acid) = 0,5 maximum,
— number of peroxides (expressed as oxygen milli-equivalents per kilogram of oil) = 10 maximum.

(2) Characteristics of the HB 307 standard mixture of synthetic triglycerides: see K. Figge, Fd. Cosmet. Toxicol., 10, 1972, p. 815.

TABLE

Reference No	Description of foodstuffs	Simulants to be used			
		A	B	C	D
01	**Beverages**				
01.01	Beverages of an alcoholic strength lower than 5 % (v/v):				
	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, camomile, beers and other	X(a)	X(a)		
01.02	Beverages of an alcoholic strength equal to or exceeding 5 % (v/v):				
	Beverages shown under heading 01.01 but with an alcoholic strength exceeding 5 %, wines, undenatured ethyl alcohol, potable spirits, concentrated extracts; liqueurs and other	X(a)	X(a)	X	
02	**Cereals, cereal products, baker's and pastrycook's wares**				
02.01	Starches				
02.02	Cereals, unprocessed, puffed, in flakes (including popcorn, corn flakes and the like)				
02.03	Cereal flours and meals				
02.04	Pasta products				
02.05	Baker's and pastrycook's wares, dry:				
	A. With fatty substances on the surface				X/5
	B. Other				
02.06	Pastrycook's 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:				
	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. Semi-solid	X			
03.03	Sugar and sugar products:				
	A. In solid form				
	B. Honey and the like	X			
	C. Molasses and sugar syrups	X			

Reference No	Description of foodstuffs	Simulants to be used			
		A	B	C	D
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 chunks, purée 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):				
	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 % (v/v) alcohol)	X(a)	X(a)	X	
04.03	Nuts (peanuts, chestnuts, almonds, hazelnuts, walnuts, pine kernels and other):				
	A. Shelled, dried				
	B. Shelled and roasted				X/5
	C. In paste or cream form	X			X/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 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 % (v/v) alcohol)	X(a)	X(a)	X	
05	**Fats and oils**				
05.01	Animal and vegetable fats and oils, whether natural or treated (including cocoa butter, lard, melted butter)				X
05.02	Margarine, butter and other fats and oils emulsified in water	X(a)	X(a)		X/2
06	**Animal products and eggs**				
06.01	Fish:				
	A. Fresh, chilled, salted, smoked	X			X/3 (1)
	B. In the form of paste	X			X/3 (1)
06.02	Crustaceans and molluscs (including oysters, mussels, snails) not naturally protected by their shells	X			

(1) The test with simulant D is to be used only for foodstuffs with fatty substances on the surface.

Reference No	Description of foodstuffs	Simulants to be used			
		A	B	C	D
06.03	Meat of all zoological species (including poultry and game):				
	A. Fresh, chilled, salted, smoked	X			X/3 (1)
	B. In the form of paste, creams	X			X/3 (1)
06.04	Processed meat products (ham, salami, bacon and other)	X			X/3 (1)
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			X/3
	B. Powdered or deep-frozen				
06.08	Dried white of egg				
07	**Grocery products**				
07.01	Vinegar		X		
07.02	Cocoa:				
	A. Cocoa powder				X/5
	B. Cocoa paste				X/3
07.03	Coffee, whether roasted or not, decaffeinated or soluble, coffee substitutes, granulated or powdered				
07.04	Liquid coffee extracts	X			
07.05	Aromatic herbs and medical herbs: Chamomile, mallow, mint, tea, lime blossom tea and other				
07.06	Yeasts and raising agents:				
	A. In paste form	X(a)	X(a)		
	B. Dried				
07.07	Edible salt				
07.08	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. Not emulsified water/oil sauces	X(a)	X(a)		X
07.09	Spices and seasonings in the natural state: Cinnamon, cloves, powdered mustard, pepper, vanilla, saffron and other				

(1) The test with simulant D is to be used only for foodstuffs with fatty substances on the surface.

Reference No	Description of foodstuffs	Simulants to be used			
		A	B	C	D
08	**Milk products**				
08.01	Milk:				
	A. Whole	X(a)	X(a)		
	B. Dried or partly dried	X(a)	X(a)		
	C. Skimmed or partly skimmed	X(a)	X(a)		
08.02	Fermented milk such as yoghourt, buttermilk and such products in association with fruit and fruit products	X(a)	X(a)		
08.03	Cream	X(a)	X(a)		
08.04	Cheeses:				
	A. Whole, with rind				
	B. Soft cheeses	X(a)	X(a)		
	C. All others	X(a)	X(a)		X/3 (1)
08.05	Rennet:				
	A. In liquid or viscous form	X(a)	X(a)		
	B. Powdered or dried				
09	**Food preparations**				
09.01	Fried or roasted foods:				
	A. Fried potatoes, fritters and the like				X/5
	B. Of animal origin				X/3
09.02	Preparations for soups, stews and broths; prepared soups, stews and broths (extracts, 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 thick:				
	I. With fatty substances on the surface	X(a)	X(a)		X/3
	II. Other	X(a)	X(a)		
09.03	Mustard (except powdered mustard under heading 07.09)	X(a)	X(a)		X/3
09.04	Spread bread, sandwiches, toasted bread and the like containing any kind of foodstuff:				
	A. With fatty substances on the surface				X/5
	B. Other				
10	**Miscellaneous products**				
10.01	Ice-creams				
10.02	Dried foods:				
	A. With fatty substances on the surface				X/5
	B. Other				
10.03	Deep-frozen or quick-frozen foods				

(1) If it can be demonstrated by means of an appropriate test that there is no 'fatty contact' with the plastic, the test with simulant D may be dispensed with.