

ANNEX III

Food simulants

1. Food simulants

For demonstration of compliance for plastic materials and articles not yet in contact with food the food simulants listed in Table 1 below are assigned.

TABLE 1

List of food simulants

Food simulant	Abbreviation
Ethanol 10 % (v/v)	Food simulant A
Acetic acid 3 % (w/v)	Food simulant B
Ethanol 20 % (v/v)	Food simulant C
Ethanol 50 % (v/v)	Food simulant D1
Vegetable oil ^a	Food simulant D2
poly(2,6-diphenyl-p-phenylene oxide), particle size 60-80 mesh, pore size 200 nm	Food simulant E

^a This may be any vegetable oil with a fatty acid distribution of

No of carbon atoms in fatty acid chain: No of unsaturation	6-12	14	16	18:0	18:1	18:2	18:3
Range of fatty acid composition expressed % (w/w) of methyl esters by Gas chromatography	< 1	< 1	1,5-20	< 7	15-85	5-70	< 1,5

2. General assignment of food simulants to foods

Food simulants A, B and C are assigned for foods that have a hydrophilic character and are able to extract hydrophilic substances. Food simulant B shall be used for those foods which have a pH below 4.5. Food simulant C shall be used for alcoholic foods with an alcohol content of up to 20 % and those foods which contain a relevant amount of organic ingredients that render the food more lipophilic.

Food simulants D1 and D2 are assigned for foods that have a lipophilic character and are able to extract lipophilic substances. Food simulant D1 shall be used for alcoholic foods with an alcohol content of above 20 % and for oil in water emulsions. Food simulant D2 shall be used for foods which contain free fats at the surface.

Food simulant E is assigned for testing specific migration into dry foods.

3. Specific assignment of food simulants to foods for migration testing of materials and articles not yet in contact with food

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For testing migration from materials and articles not yet in contact with food the food simulants that corresponds to a certain food category shall be chosen according Table 2 below.

For testing overall migration from materials and articles intended to come into contact with different food categories or a combination of food categories the food simulant assignment in point 4 is applicable.

Table 2 contains the following information:

Column 1 (Reference number): contains the reference number of the food category.

Column 2 (Description of food): contains a description of the foods covered by the food category

Column 3 (Food simulants): contains sub-columns for each of the food simulants

The food simulant for which a cross is contained in the respective sub-column of column 3 shall be used when testing migration of materials and articles not yet in contact with food.

For food categories where in sub-column D2 the cross is followed by an oblique stroke and a figure, the migration test result shall be divided by this figure before comparing the result with the migration limit. The figure is the correction factor referred to in point 4.2 of Annex V to this Regulation.

For food category 01.04 food simulant D2 shall be replaced by 95 % ethanol.

For food categories where in sub-column B the cross is followed by (*) the testing in food simulant B can be omitted if the food has a pH of more than 4.5.

For food categories where in sub-column D2 the cross is followed by (**) the testing in food simulant D2 can be omitted if it can be demonstrated by means of an appropriate test that there is no 'fatty contact' with the plastic food contact material.

TABLE 2

food category specific assignment of food simulants

(1) Reference number	(2) Description of food	(3) Food simulants					
		A	B	C	D1	D2	E
01	Beverages						
01.01	Non-alcoholic beverages or alcoholic beverages of an alcoholic strength lower than or equal to 6 % vol.:						

	A. Clear drinks: Water, ciders, clear fruit or vegetable juices of normal strength or concentrated, fruit nectars, lemonades, syrups, bitters, infusions, coffee, tea, beers, soft drinks, energy drinks and the like, flavoured water, liquid coffee extract	X(*)	X			
	B. cloudy drinks: juices and nectars and soft drinks containing fruit pulp, musts containing fruit pulp, liquid chocolate	X(*)		X		
01.02	Alcoholic beverages of an alcoholic strength of			X		

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	between 6 %vol and 20 %.						
01.03	Alcoholic beverages of an alcoholic strength above 20 % and all cream liquors				X		
01.04	Miscellaneous: undenaturated ethyl alcohol		X(*)			Substitute 95 % ethanol	
02	Cereals, cereal products, pastry, biscuits, cakes and other bakers' wares						
02.01	Starches						X
02.02	Cereals, unprocessed, puffed, in flakes (including popcorn, corn flakes and the like)						X
02.03	Cereal flour and meal						X
02.04	Dry pasta e.g. macaroni, spaghetti and similar products and fresh pasta						X

02.05	Pastry, biscuits, cakes, bread, and other bakers' wares, dry:						
	A. With fatty substances on the surface					X/3	
	B. Other						X
02.06	Pastry, cakes, bread, dough and other bakers' wares, fresh:						
	A. With fatty substances on the surface					X/3	
	B. Other						X
03	Chocolate, sugar and products thereof Confectionery products						
03.01	Chocolate, chocolate-coated products, substitutes and products coated					X/3	

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	with substitutes						
03.02	Confectionery products:						
	A. In solid form:						
	I. With fatty substances on the surface				X/3		
	II. Other						X
	B. In paste form:						
	I. With fatty substances on the surface				X/2		
	II. Moist		X				
03.03	Sugar and sugar products						
	A. In solid form: crystal or powder						X
	B. X Molasses, sugar syrops, honey and the like						
04	Fruit, vegetables						

	and products thereof						
04.01	Whole fruit, fresh or chilled, unpeeled						
04.02	Processed fruit:						
	A. Dried or dehydrated fruits, whole, sliced, flour or powder						X
	B. Fruit in the form of purée, preserves, pastes or in its own juice or in sugar syrup (jams, compote, and similar products)	X(*)	X				
	C. Fruit preserved in a liquid medium:						

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	I.	In an oily medium				X	
	II.	In an alcoholic medium			X		
04.03		Nuts (peanuts, chestnuts, almonds, hazelnuts, walnuts, pine kernels and others):					
	A.	Shelled, dried, flaked or powdered					X
	B.	Shelled and roasted					X
	C.	X In paste or cream form				X	
04.04		Whole vegetables, fresh or chilled, unpeeled					
04.05		Processed vegetables:					
	A.	Dried or dehydrated vegetables whole, sliced or					X

		in the form of flour or powder					
	B.	X Fresh vegetables, peeled or cut					
	C.	Vegetables in the form of purée, preserves, pastes or in its own juice (including pickled and in brine)	X(*)	X			
	D.	Preserved vegetables:					
	I.	X In an oily medium				X	
	II.	In an alcoholic medium			X		
05	Fats and oils						
05.01	Animals and vegetable fats and					X	

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	oils, whether natural or treated (including cocoa butter, lard, resolidified butter)						
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. X Fresh, chilled, processed, salted or smoked including fish eggs					X/3(**)	
	B. Preserved fish:						
	I. X In an oily medium					X	
	II. In an aqueous medium	X(*)	X				
06.02	Crustaceans and molluscs (including						

	oysters, mussels, snails)						
	A.	Fresh within the shell					
	B.	Shell removed, processed, preserved or cooked with the shell					
	I.	X In an oily medium				X	
	II.	In an aqueous medium	X(*)	X			
06.03	Meat of all zoological species (including poultry and game):						
	A.	X Fresh, chilled, salted, smoked				X/4(**)	
	B.	X Processed meat products (such as ham, salami, bacon, sausages, and other)				X/4(**)	

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		or in the form of paste, creams					
	C.	X Marinated meat products in an oily medium				X	
06.04	Preserved meat:						
	A.	X In an fatty or oily medium				X/3	
	B.	In an aqueous medium	X(*)		X		
06.05	Whole eggs, egg yolk, egg white						
	A.	Powdered or dried or frozen					X
	B.	Liquid and cooked			X		
07	Milk products						
07.01	Milk						
	A.	Milk and			X		

		milk based drinks whole, partly dried and skimmed or partly skimmed					
	B.	Milk powder including infant formula (based on whole milk powder)					X
07.02		Fermented milk such as yoghurt, buttermilk and similar products	X(*)		X		
07.03		Cream and sour cream	X(*)		X		
07.04		Cheeses:					
	A.	Whole, with not edible rind					X
	B.	Natural cheese without rind or with edible rind (gouda, camembert,				X/3(**)	

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		and the like) and melting cheese					
	C.	Processed cheese (soft cheese, cottage cheese and similar)	X(*)		X		
	D.	Preserved cheese:					
	I.	X In an oily medium				X	
	II.	In an aqueous medium (feta, mozzarella, and similar)	X(*)		X		
08	Miscellaneous products						
08.01	Vinegar		X				
08.02	Fried or roasted foods:						
	A.	X Fried potatoes, fritters and the like				X/5	
	B.	X Of animal origin				X/4	
08.03	Preparations for soups,						

	broths, sauces, in liquid, solid or powder form (extracts, concentrates); homogenised composite food preparations, prepared dishes including yeast and raising agents						
	A. Powdered or dried:						
	I. With fatty character				X/5		
	II. Other					X	
	B. any other form than powdered or dried:						
	I. ^X With fatty character	X(*)			X/3		
	II. Other	X(*)	X				
08.04	Sauces:						
	A. With aqueous character	X(*)	X				
	B. ^X With fatty character	X(*)			X		

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		e.g. mayonnaise, sauces derived from mayonnaise, salad creams and other oil/ water mixtures e.g. coconut based sauces					
08.05	Mustard (except powdered mustard under heading 08.14)	X	X(*)			X/3(**)	
08.06	Sandwiches, toasted bread pizza and the like containing any kind of foodstuff						
	A.	X With fatty substances on the surface				X/5	
	B.	Other					X
08.07	Ice- creams			X			
08.08	Dried foods:						
	A.	With fatty substances				X/5	

		on the surface					
	B.	Other					X
08.09		Frozen or deep-frozen foods					X
08.10		Concentrated extracts of an alcoholic strength equal to or exceeding 6 % vol.	X(*)		X		
08.11		Cocoa:					
	A.	Cocoa powder, including fat-reduced and highly fat reduced					X
	B.	Cocoa paste				X/3	
08.12		Coffee, whether or not roasted, decaffeinated or soluble, coffee substitutes, granulated or powdered					X
08.13		Aromatic herbs and other herbs such as					X

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	camomile, mallow, mint, tea, lime blossom and others						
08.14	Spices and seasonings in the natural state such as cinnamon, cloves, powdered mustard, pepper, vanilla, saffron, salt and other						X
08.15	Spices and seasoning in oily medium such as pesto, curry paste					X	

4. Food simulant assignment for testing overall migration

To demonstrate compliance with the overall migration limit for all type of foods testing in distilled water or water of equivalent quality or food simulant A and food simulant B and simulant D2 shall be performed.

To demonstrate compliance with the overall migration limit for all types of food except for acidic foods testing in distilled water or water of equivalent quality or food simulant A and food simulant D2 shall be performed.

To demonstrate compliance with the overall migration limit for all aqueous and alcoholic foods and milk products testing in food simulant D1 shall be performed.

To demonstrate compliance with the overall migration limit for all aqueous, acidic and alcoholic foods and milk products testing in food simulant D1 and food simulant B shall be performed.

To demonstrate compliance with the overall migration limit for all aqueous foods and alcoholic foods up to an alcohol content of 20 % testing in food simulant C shall be performed.

To demonstrate compliance with the overall migration limit for all aqueous and acidic foods and alcoholic foods up to an alcohol content of 20 % testing in food simulant C and food simulant B shall be performed.