

*Status: Point in time view as at 31/01/2019.*

*Changes to legislation: There are currently no known outstanding effects for the Commission Regulation (EU) No 10/2011, ANNEX III. (See end of Document for details)*

## 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.

<sup>F1</sup>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
Any vegetable oil containing less than 1 % unsaponifiable matter	Food simulant D2
poly(2,6-diphenyl-p-phenylene oxide), particle size 60-80 mesh, pore size 200 nm	Food simulant E]

#### Textual Amendments

- F1** Substituted by [Commission Regulation \(EU\) 2016/1416 of 24 August 2016 amending and correcting Regulation \(EU\) No 10/2011 on plastic materials and articles intended to come into contact with food \(Text with EEA relevance\).](#)

#### 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.

#### <sup>F13</sup> **Specific assignment of food simulants to foods for migration testing of materials and articles not yet in contact with food**

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 to Table 2 below.

For testing migration from materials and articles intended to come into contact with foods not listed in Table 2 below, or a combination of foods, the general food simulant assignments in

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point 2 shall be used for specific migration testing, and for overall migration testing the food simulant assignments in point 4 shall be 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 or E the cross is followed by an oblique stroke and a figure, the migration test result shall be corrected by dividing the result by this figure. The corrected test result shall then be compared to the migration limit to establish compliance. The test results for substances that shall not migrate in detectable quantities shall not be corrected in this way.

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 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	<b>Beverages</b>						
01.01	Non-alcoholic beverages or alcoholic beverages of an alcoholic strength lower than or equal to 6 % vol.:						
	A. Water, ciders, clear	Clear drinks:	X(*)	X			

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	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						
	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 between 6 %vol and 20 %.			X			
01.03	Alcoholic beverages of an				X		

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	alcoholic strength above 20 % and all cream liquors						
01.04	Miscellaneous: undenaturated ethyl alcohol	X(*)				Substitute 95 % ethanol	
02	<b>Cereals, cereal products, pastry, biscuits, cakes and other bakers' wares</b>						
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'						

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	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	<b>Chocolate, sugar and products thereof Confectionery products</b>						
03.01	Chocolate, chocolate- coated products, substitutes and products coated with substitutes					X/3	
03.02	Confectionery products:						

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	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 syrups, honey and the like					
04		<b>Fruit, vegetables and products thereof</b>					

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I <sup>F1</sup> 04.01	Fruit, fresh or chilled:						
	A. unpeeled and uncut						X/10
	B. <input checked="" type="checkbox"/> peeled and/or cut	X (*)					I
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						

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	a liquid medium:						
	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	
[ <sup>F1</sup> 04.04	Vegetables, fresh or chilled:						
	A. unpeeled and uncut						X/10
	B. X peeled and/	X (*)					I



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	or cut					
[ <sup>F1</sup> 04.05	Processed vegetables:					X
	A. Dried or dehydrated vegetables whole, sliced or in the form of flour or powder.					
	B. ( <i>obsolete</i> )					
	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			X		I	

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		alcoholic medium					
05	<b>Fats and oils</b>						
05.01	Animals 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	<b>Animal products and eggs</b>						
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	

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	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(**)	

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	B.	X Processed meat products (such as ham, salami, bacon, sausages, and other) or in the form of paste, creams				X/4(**)	
	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

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	B.	Liquid and cooked			X		
07	<b>Milk products</b>						
07.01	Milk						
	A.	Milk and milk based drinks whole, partly dried and skimmed or partly skimmed			X		
	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					X

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		edible rind					
	B.	Natural cheese without rind or with edible rind (gouda, camembert, and the like) and melting cheese				X/3(**)	
	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	<b>Miscellaneous products</b>						
08.01	Vinegar		X				

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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					

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		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 e.g. mayonnaise, sauces derived from mayonnaise, salad creams and other oil/ water mixtures e.g. coconut based sauces	X(*)			X	
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						



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	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 on the surface				X/5	
	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	

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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 camomile, mallow, mint, tea, lime blossom and others						X
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	

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**[<sup>F2</sup>4. Food simulant assignment for testing overall migration**

For tests to demonstrate compliance with the overall migration limit food simulants shall be chosen as set out in Table 3:

TABLE 3

**Food simulant assignment for demonstrating compliance with the overall migration limit**

<b>Foods covered</b>	<b>Food simulants in which testing shall be performed</b>
all types of food	<ol style="list-style-type: none"> <li>1. distilled water or water of equivalent quality or food simulant A;</li> <li>2. food simulant B; and</li> <li>3. food simulant D2.</li> </ol>
all types of food except for acidic foods	<ol style="list-style-type: none"> <li>1. distilled water or water of equivalent quality or food simulant A; and</li> <li>2. food simulant D2.</li> </ol>
[ <sup>F3</sup> all aqueous and alcoholic foods and milk products with a pH ≥ 4,5	food simulant D1
all aqueous and alcoholic foods and milk products with a pH < 4,5	food simulant D1 and food simulant B]
all aqueous foods and alcoholic foods up to an alcohol content of 20 %	food simulant C
all aqueous and acidic foods and alcoholic foods up to an alcohol content of 20 %	<ol style="list-style-type: none"> <li>1. food simulant C; and</li> <li>2. food simulant B.]</li> </ol>

**Textual Amendments**

**F3** Substituted by [Commission Regulation \(EU\) 2019/37 of 10 January 2019 amending and correcting Regulation \(EU\) No 10/2011 on plastic materials and articles intended to come into contact with food \(Text with EEA relevance\).](#)

**Textual Amendments**

**F2** Substituted by [Commission Regulation \(EU\) 2017/752 of 28 April 2017 amending and correcting Regulation \(EU\) No 10/2011 on plastic materials and articles intended to come into contact with food \(Text with EEA relevance\).](#)

**[<sup>F4</sup>5. General derogation to the assignment of food simulants**

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By derogation from the assignments of food simulants in points 2 to 4 of this Annex, where testing with several food simulants is required, a single food simulant shall be sufficient if on the basis of evidence acquired using generally recognised scientific methods this food simulant is shown to be the most severe food simulant for the particular material or article being tested under the applicable time and temperature conditions selected in accordance with Chapters 2 and 3 of Annex V.

The scientific basis on which this derogation is used shall in such cases form part of the documentation required under Article 16 of this Regulation.]

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#### **Textual Amendments**

- F4** Inserted by [Commission Regulation \(EU\) 2016/1416 of 24 August 2016 amending and correcting Regulation \(EU\) No 10/2011 on plastic materials and articles intended to come into contact with food \(Text with EEA relevance\).](#)

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