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STATUTORY RULES OF NORTHERN IRELAND

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**1998 No. 264**

**FOOD**

**Plastic Materials and Articles in Contact with  
Food Regulations (Northern Ireland) 1998**

*Made - - - - 27th July 1998*

*Coming into operation 14th September 1998*

The Department of Health and Social Services for Northern Ireland, in exercise of the powers conferred on it by Articles 15(2), 16(1), 25(1)(a) and (3), 32 and 47(2) of the Food Safety (Northern Ireland) Order 1991<sup>(1)</sup> and, being a designated Department<sup>(2)</sup> for the purposes of section 2(2) of the European Communities Act 1972<sup>(3)</sup> in relation to materials and articles in contact with food or drink or intended for such contact, in exercise of the powers conferred on it by the said section 2(2) and of all other powers enabling it in that behalf and after consultation in accordance with Article 47(3) of the said Order with such organisations as appear to it to be representative of interests likely to be substantially affected by these Regulations (in so far as the Regulations are made in exercise of the said Order), hereby makes the following Regulations:

**Citation and commencement**

1. These Regulations may be cited as the Plastic Materials and Articles in Contact with Food Regulations (Northern Ireland) 1998 and shall come into operation on 14th September 1998.

**Interpretation**

2.—(1) In these Regulations—

“additive” means a substance, other than one which directly influences the formation of polymers which is—

- (a) incorporated into a plastic material or article to achieve a technical effect in the finished product and is intended to be present in the finished product; or
- (b) used to provide a suitable medium in which polymerisation occurs;

“capable” means capable as established under regulation 6;

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(1) S.I.1991/762 (N.I. 7) as amended by S.I. 1996/1633 (N.I. 12). See Article 2(2) for the definitions of “the Department concerned” and “regulations”  
(2) S.I. 1976/2141  
(3) 1972 c. 68

“Council Directive 82/711” means Council Directive [82/711/EEC](#) laying down the basic rules necessary for testing migration of the constituents of plastic materials and articles intended to come into contact with foodstuffs<sup>(4)</sup>, as amended by Commission Directives [93/8/EEC](#)<sup>(5)</sup> and [97/48/EC](#)<sup>(6)</sup>;

“the Directive” means Commission Directive ([EEC](#)) No. [90/128](#) relating to plastic materials and articles intended to come into contact with foodstuffs<sup>(7)</sup> (as corrected) and as amended by Commission Directives [92/39/EEC](#), [93/9/EEC](#), [95/3/EC](#) and [96/11/EC](#)<sup>(8)</sup>;

“EEA Agreement” means the Agreement on the European Economic Area<sup>(9)</sup> signed at Oporto on 2nd May 1992 as adjusted by the Protocol<sup>(10)</sup> signed at Brussels on 17th March 1993;

“EEA State” means a State (other than the United Kingdom) which is a contracting party to the EEA Agreement;

“food” has the same meaning as it has in Article 15(5) of the Order;

“good technical quality” means good technical quality as regards the purity criteria;

“import” means import in the course of a business;

“monomer” means anything which is included for the purposes of the Directive among monomers and other starting substances;

“the Order” means the Food Safety (Northern Ireland) Order 1991;

“plastic material or article” means anything which for the purposes of the Directive is included among those plastic materials and articles and parts thereof to which the Directive applies;

“sell” includes offer or expose for sale or have in possession for sale;

“the 1987 Regulations” means the Materials and Articles in Contact with Food Regulations (Northern Ireland) 1987<sup>(11)</sup>;

“the 1993 Regulations” means the Plastic Materials and Articles in Contact with Food Regulations (Northern Ireland) 1993<sup>(12)</sup>.

(2) For the purposes of these Regulations the supply of any plastic material or article, otherwise than on sale, in the course of a business shall be deemed to be a sale of the plastic material or article.

(3) Any expression, other than one defined in paragraph (1), used both in these Regulations and in the Directive, Council Directive 82/711, or Council Directive 85/572 EEC 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<sup>(13)</sup> has the same meaning as it bears in the Directive in which it appears.

(4) The Interpretation Act (Northern Ireland) 1954<sup>(14)</sup> shall apply to these Regulations as it applies to a Measure of the Northern Ireland Assembly.

### **Restriction on the use, sale or importation of plastic materials and articles**

3.—(1) A plastic material or article which fails to meet the requisite standards shall not be—

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(4) O.J. No. L297, 23.10.82, p. 26

(5) O.J. No. L90, 14.4.93, p. 22

(6) O.J. No. L222, 12.8.97, p. 10

(7) O.J. No. L75, 21.3.90, p. 19

(8) Corrigendum in O.J. No. L349, 13.12.90, p. 26; amending Directives in O.J. No. L168, 23.6.92, p. 21, O.J. No. L90, 14.3.93, p. 26, O.J. No. L41, 23.2.95, p. 44 and O.J. No. L61, 12.3.96, p. 26

(9) O.J. No. L1, 3.1.94, p. 1

(10) O.J. No. L1, 3.1.94, p. 571

(11) [S.R. 1987 No. 432](#); the relevant amending Regulations are [S.R. 1991 Nos. 203 and 344](#) and [S.R. 1994 No. 174](#)

(12) [S.R. 1993 No. 173](#); the relevant amending regulations are [S.R. 1995 No. 107](#) and [S.R. 1996 Nos 164 and 580](#)

(13) O.J. No. L372, 30.12.85, p. 14

(14) [1954 c. 33 \(N.I.\)](#)

- (a) used by any person in the course of a business in connection with the storage, preparation, packaging, sale or serving of food for human consumption;
- (b) sold by any person for the purpose of its being used in connection with the storage, preparation, packaging, sale or serving of food for human consumption; or
- (c) imported by any person from any place other than an EEA State for the purpose of its being used in connection with the storage, preparation, packaging, sale or serving of food for human consumption.

(2) In any proceedings for an offence under these Regulations where it is alleged that a plastic material or article which fails to meet the requisite standards was used, sold or imported, it shall be a defence for the person charged to prove that the plastic material or article in respect of which the offence is alleged to have been committed was intended for export to a country, other than an EEA State, which has legislation analogous to these Regulations and that the plastic material or article complies with such legislation.

(3) In any proceedings for an offence under these Regulations where it is alleged that a plastic material or article which fails to meet the requisite standards was used, sold or imported it shall be a defence for the person charged to prove that the plastic material or article was manufactured—

- (a) before 14th September 1998; and
- (b) in accordance with regulation 4 of the 1993 Regulations as that regulation applied when the plastic material or article was manufactured.

(4) For the purposes of this regulation a plastic material or article fails to meet the requisite standards—

- (a) if—
  - (i) it has been manufactured with a prohibited monomer as described in regulation 4(1) or a prohibited additive as described in regulation 5(1) or does not comply with regulation 4(5) or 7; and
  - (ii) no defence indicated in regulation 4(7), 5(2) or 7(5) would be available in proceedings for an offence under these Regulations relating to that manufacture or want of compliance; or
- (b) if it has been manufactured outside Northern Ireland and sub-paragraph (a) would have applied to it had it been manufactured in Northern Ireland.

#### **Restriction on manufacture with monomers**

4.—(1) Subject to the following paragraphs, no plastic material or article shall be manufactured by any person with any prohibited monomer, other than a monomer which is—

- (a) of good technical quality;
- (b) identified by PM/REF No., CAS No., (if any) and name respectively in columns 1, 2 and 3 of the relevant section of Part 1 of Schedule 1; and
- (c) used in accordance with the restrictions (if any) specified in the corresponding entry in column 4 of the relevant section of that Part of that Schedule.

(2) For the purposes of this regulation the relevant section of Part I of Schedule 1 is—

- (a) in the case of a plastic material or article manufactured before 1st January 1999, Section A, B, or C;
- (b) in the case of a plastic material or article manufactured after 31st December 1998 and before 1st January 2002, Section A or B; and
- (c) in the case of a plastic material or article manufactured after 31st December 2001, Section A.

- (3) Paragraph (1) does not apply to the use of a monomer in the manufacture of any—
- (a) surface coatings obtained from resinous or polymerized products in liquid, powder or dispersion form, including, but not limited to, varnishes, lacquers and paints;
  - (b) silicones;
  - (c) epoxy resins;
  - (d) products obtained by means of bacterial fermentation;
  - (e) adhesives and adhesion promoters; or
  - (f) printing inks.

(4) Paragraph (1) shall not be taken to prohibit the manufacture of any plastic material or article with any substance if the substance is a mixture which falls within paragraph 3(c) of Annex II to the Directive and does not contravene paragraph 4 of that Annex.

(5) Subject to paragraph (6), where column 4 of the relevant section of Part I of Schedule 1 expresses a migration limit of mg/kg in relation to any monomer, no plastic material or article manufactured from that monomer shall be capable of transferring constituents of that monomer to food with which that plastic material or article may come into contact in quantities exceeding the appropriate limit, and for the purposes of this paragraph the appropriate limit is—

- (a) the number of milligrams expressed therein released per kilogram of food in the case of any plastic material or article other than one specified in sub-paragraph (b); and
- (b) one sixth of the number of milligrams expressed therein per square decimetre of surface area of the plastic material or article if the plastic material or article comprises—
  - (i) an article which is a container or is comparable to a container or which can be filled, with a capacity of less than 500 millilitres or more than 10 litres, or
  - (ii) sheet, film or other material which cannot be filled or for which it is impracticable to estimate the relationship between surface area of that material and the quantity of food in contact with that surface area.

(6) A plastic material or article manufactured from any monomer in respect of which column 4 of the relevant section of Part I of Schedule 1 expresses a migration limit of mg/kg shall not be considered capable of transferring constituents of that monomer to food with which that plastic material or article may come into contact in quantities exceeding the appropriate limit in paragraph (5) if the only food which that plastic material or article may come into contact with is food to which regulation 7(3) applies.

(7) In any proceedings for an offence under these Regulations where it is alleged that a plastic material or article does not comply with paragraph (1) because it was manufactured with any monomer (whether or not of good technical quality) other than one identified in the relevant section of Part I of Schedule 1, it shall be a defence for the person charged to prove that—

- (a) each such monomer is present in the finished plastic material as an impurity, a reaction intermediate or a decomposition product, which falls within paragraph 3(a) of Annex II to the Directive;
- (b) each such monomer is an oligomer or a natural or synthetic macromolecular substance or a mixture thereof which falls within paragraph 3(b) of that Annex; or
- (c) each such monomer falls within either sub-paragraph (a) or sub-paragraph (b)

and does not contravene paragraph 4 of that Annex

(8) Part II of Schedule 1 shall have effect to supplement this regulation and Part I of Schedule 1.

### **Restriction on manufacture with additives**

5.—(1) Subject to the following paragraphs, no person shall use in the manufacture of plastic materials or articles any prohibited additive, that is to say an additive identified by PM/REF No., CAS No. (if any) and name respectively in columns 1, 2 and 3 of Part I of Schedule 2 which is not of good technical quality.

(2) In any proceedings for an offence under these Regulations, where it is alleged that the commission of the offence is due to the manufacture of a plastic material or article with any additive identified in Part I of Schedule 2 which is not of good technical quality, it shall be a defence for the person charged to prove that each such additive is present in the finished plastic material or article as an impurity, a reaction intermediate or a decomposition product.

(3) Part II of Schedule 2 shall have effect to supplement this regulation and Part I of Schedule 2.

### **Method of testing capability of transferring constituents**

6.—(1) For the purposes of these Regulations, a plastic material or article shall be treated as being capable of transferring constituents to food with which it may come into contact to the extent that it is established for those purposes—

(a) in any case other than one to which sub-paragraph (b) relates, by the verification methods specified in Schedules 3 and 4;

(b) in any case where the extent to which vinyl chloride, as identified in Section A of Part I of Schedule 1, is capable of such transfer falls to be established, by the method referred to in regulation 14(2) of the 1987 Regulations.

(2) In Schedules 3 and 4, references to migration or release of a substance shall be construed as references to the transfer of constituents to the simulant representing the food or, as the case may be, food with which it may come into contact.

(3) In paragraph (1)(a) analytical tolerances, as referred to in paragraph 8 of Schedule 3, shall be treated as included among verification methods.

### **Transfer of constituents**

7.—(1) No plastic material or article shall be capable of transferring its constituents to food with which it may come into contact in quantities exceeding the appropriate limit.

(2) For the purposes of this regulation a plastic material or article shall not be considered capable of transferring its constituents to food with which it may come into contact, in quantities exceeding the appropriate limit, if the only food which that plastic material or article may come into contact with is food to which paragraph (3) applies.

(3) This paragraph applies to food which is specified in the Table to Part IV of Schedule 4 where there is no “X” placed anywhere in the group of columns headed “Simulants to be used” opposite that food.

(4) For the purposes of this regulation the appropriate limit is—

(a) an overall migration limit of 60 milligrams of constituents released per kilogram of food in the case of any plastic material or article comprising—

(i) an article which is a container or is comparable to a container or which can be filled, with a capacity of not less than 500 millilitres and not more than 10 litres;

(ii) an article which can be filled and for which it is impracticable to estimate the surface area in contact with food;

(iii) a cap, gasket, stopper or similar device for sealing, and

(b) in the case of any other plastic material or article, an overall migration limit of 10 milligrams per square decimetre of the surface area of the plastic material or article.

(5) In any proceedings for an offence under these Regulations an element of which is that a plastic material or article does not comply with this regulation the defences in paragraph 6(2) and 7(2) of Schedule 3 shall be available as specified therein.

### **Labelling**

8.—(1) Subject to paragraph (2), at marketing stages other than the retail stage a person who is in possession of any plastic material or article which is intended to come into contact with food shall ensure that that plastic material or article is accompanied by a written declaration attesting that it complies with the legislation applicable to it.

(2) Paragraph (1) shall not apply to a person in possession of any plastic material or article which by its nature is clearly intended to come into contact with food.

### **Enforcement**

9. Each district council shall enforce and execute these Regulations in its own district.

### **Offences**

10.—(1) Any person who contravenes regulation 3, 4(1), 5(1) or 8 shall be guilty of an offence.

(2) Any person who—

- (a) intentionally obstructs any person acting in the execution of these Regulations, or
- (b) without reasonable cause, fails to give to any person acting in the execution of these Regulations any assistance or information which that person may reasonably require of him for the performance of his functions under these Regulations,

shall be guilty of an offence.

(3) Nothing in paragraph (2)(b) shall be construed as requiring any person to answer any question or give any information if to do so might incriminate him.

(4) Any person who, in purported compliance with any such requirement as is mentioned in paragraph (2)(b)—

- (a) furnishes information which he knows to be false or misleading in a material particular, or
- (b) recklessly furnishes information which is false or misleading in a material particular,

shall be guilty of an offence.

(5) Where the commission by any person of an offence under these Regulations is due to an act or default of some other person, that other person shall be guilty of the offence; and a person may be charged with and convicted of the offence by virtue of this paragraph whether or not proceedings are taken against the first mentioned person.

(6) In any proceedings for an offence under these Regulations it shall, subject to paragraph (10), be a defence for the person charged to prove that he took all reasonable precautions and exercised all due diligence to avoid the commission of the offence by himself or by a person under his control.

(7) Without prejudice to the generality of paragraph (6), a person charged with an offence under these Regulations who neither—

- (a) prepared the plastic material or article in respect of which the offence is alleged to have been committed, nor
- (b) imported it into Northern Ireland,

shall be taken to have established the defence provided by that paragraph if he satisfies the requirements of paragraph (8) or (9).

(8) A person satisfies the requirements of this paragraph if he proves—

- (a) that the commission of the offence was due to an act or default of another person who was not under his control, or to reliance on information supplied by such a person;
- (b) that he carried out all such checks of the plastic material or article in question as were reasonable in all the circumstances, or that it was reasonable in all the circumstances for him to rely on checks carried out by the person who supplied the plastic material or article to him; and
- (c) that he did not know and had no reason to suspect at the time of the commission of the alleged offence that his act or omission would amount to an offence under these Regulations.

(9) A person satisfies the requirements of this paragraph if the offence is one of sale and he proves—

- (a) that the commission of the offence was due to an act or default of another person who was not under his control, or to reliance on information supplied by such a person;
- (b) that the sale of which alleged offence consisted was not a sale under his name or mark; and
- (c) that he did not know, and could not reasonably have been expected to know, at the time of the commission of the alleged offence that his act or omission would amount to an offence under these Regulations.

(10) If in any case the defence provided by paragraph (6) involves the allegation that the commission of the offence was due to an act or default of another person, or to reliance on information supplied by another person, the person charged shall not, without leave of the court, be entitled to rely on that defence unless—

- (a) at least seven clear days before the hearing, and
- (b) where he has previously appeared before a court in connection with the alleged offence, within one month of his first such appearance,

he has served on the prosecutor a notice in writing giving such information identifying or assisting in the identification of that other person as was then in his possession, and in this paragraph any reference to appearing before a court shall be construed as including a reference to being brought before a court.

(11) Any person guilty of an offence under these Regulations shall be liable on summary conviction to a fine not exceeding the statutory maximum or to imprisonment for a term not exceeding three months or to both and on conviction on indictment to a fine or to imprisonment for a term not exceeding two years or both.

(12) No prosecution for an offence under these Regulations shall be begun after the expiry of—

- (a) three years from the commission of the offence; or
- (b) one year from its discovery by the prosecutor,

whichever is earlier.

### **Presumption as to food with which a plastic material or article is to come into contact**

**11.** In establishing which descriptions of food a plastic material or article may come into contact with it shall be assumed for the purposes of these Regulations, until the contrary is proved, that, if particulars are shown in relation to that plastic material or article in accordance with the 1987 Regulations, those particulars are accurate and that, unless the particulars so indicate, there are no restrictions on the intended conditions of contact.

### **Application of other provisions**

**12.**—(1) The following provisions of the 1987 Regulations shall apply in relation to plastic materials or articles as they apply to materials and articles for the purposes of those Regulations, as if those provisions formed part of these Regulations—

- (a) regulation 12 (powers of authorised officers);
- (b) regulation 13 (analysis, examination and testing);
- (c) regulation 16 (confidentiality);
- (d) regulation 19 (evidence of analysis); and
- (e) regulation 20 (analysis by Government Chemist).

(2) Article 4(d) of the Order (relating to the presumption of intention for human consumption) shall apply for the purposes of these Regulations as it applies for the purposes of the Order.

(3) Articles 29 and 30 of the Order (which deal with procurement and analysis of samples) shall, in so far as they relate to plastic materials or articles, be modified to the extent necessary to avoid restricting the scope of paragraph 1(a), (b), (d) and (e).

### **Amendment**

**13.** In the Food Safety (Sampling and Qualifications) Regulations (Northern Ireland) 1991(**15**), in Schedule 1 (provisions to which those regulations do not apply), for the title and reference of the 1993 Regulations there shall be substituted the title and reference of these Regulations.

### **Revocations**

**14.** The 1993 Regulations, the Plastic Materials and Articles in Contact with Food (Amendment) Regulations (Northern Ireland) 1995(**16**), the Plastic Materials and Articles in Contact with Food (Amendment) Regulations (Northern Ireland) 1996(**17**) and the Plastic Materials and Articles in Contact with Food (Amendment No. 2) Regulations (Northern Ireland) 1996(**18**) are hereby revoked.

Sealed with the Official Seal of the Department of Health and Social Services for Northern Ireland  
on

L.S.

27th July 1998.

*J. R. Kearney*  
Assistant Secretary

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(15) S.R. 1991 No. 198  
(16) S.R. 1995 No. 107  
(17) S.R. 1996 No. 164  
(18) S.R. 1996 No. 580



## SCHEDULE 1

Regulation 4

**Part I**  
**Authorised Monomers**

*SECTION A*

***Monomers authorised without time limit***

<i>Item</i>	1 <i>PM/REF No.</i>	2 <i>CAS No.</i>	3 <i>Name</i>	4 <i>Restrictions</i>
1.	10030	000514-10-3	Abietic acid	
2.	10060	000075-07-0	Acetaldehyde	
3.	10090	000064-19-7	Acetic acid	
4.	10120	000108-05-4	Acetic acid, vinyl ester	The specific migration of this substance shall not exceed 12 mg/kg
5.	10150	000108-24-7	Acetic anhydride	
6.	10210	000074-86-2	Acetylene	
7.	10630	000079-06-1	Acrylamide	The specific migration of this substance shall be not detectable (when measured by a method with a limit of detection of 0.01 mg/kg)
8.	10660	015214-89-8	2-Acrylamido-2-methylpropane-sulphonic acid	The specific migration of this substance shall not exceed 0.05 mg/kg
9.	10690	000079-10-7	Acrylic acid	
10.	10750	002495-35-4	Acrylic acid, benzyl ester	
11.	10780	000141-32-2	Acrylic acid, <i>n</i> -butyl ester	
12.	10810	002998-08-5	Acrylic acid, <i>sec</i> -butyl ester	
13.	10840	001663-39-4	Acrylic acid, <i>tert</i> -butyl ester	

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<i>Item</i>	<i>1 PM/REF No.</i>	<i>2 CAS No.</i>	<i>3 Name</i>	<i>4 Restrictions</i>
14.	11470	000140-88-5	Acrylic acid, ethyl ester	
15.	As item 19	000818-61-1	Acrylic acid, hydroxyethyl ester	
16.	11590	000106-63-8	Acrylic acid, isobutyl ester	
17.	11680	000689-12-3	Acrylic acid, isopropyl ester	
18.	11710	000096-33-3	Acrylic acid, methyl ester	
19.	11830	000818-61-1	Acrylic acid, monoester with ethylene glycol	
20.	11890	002499-59-4	Acrylic acid, <i>n</i> -octyl ester	
21.	11980	000925-60-0	Acrylic acid, propyl ester	
22.	12100	000104-13-1	Acrylonitrile	The specific migration of this substance shall be not detectable (when measured by a method with a limit of detection of 0.02 mg/kg analytical tolerance included)
23.	12130	000124-04-9	Adipic acid	
24.	12280	002035-75-8	Adipic anhydride	
25.	12310	—	Albumin	
26.	12340	—	Albumin, coagulated by formaldehyde	
27.	12375	—	Alcohols, aliphatic, monohydric, saturated, linear, primary (C4-C22)	
28.	12670	002855-13-2	1-Amino-3- aminomethyl-3,5,5- trimethylcyclohexane	The specific migration of this substance shall

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<i>Item</i>	<i>1 PM/REF No.</i>	<i>2 CAS No.</i>	<i>3 Name</i>	<i>4 Restrictions</i>
				not exceed 6 mg/kg
29.	12788	002432-99-7	11-Aminoundecanoic acid	The specific migration of this substance shall not exceed 5 mg/kg
30.	12789	007664-41-7	Ammonia	
31.	12820	000123-99-9	Azelaic acid	
32.	12970	004196-95-6	Azelaic anhydride	
33.	13000	001477-55-0	1,3-Benzenedimethanamine	The specific migration of this substance shall not exceed 0.05 mg/kg
34.	13090	000065-85-0	Benzoic acid	
35.	13150	000100-51-6	Benzyl alcohol	
36.	As item 79	000111-46-6	Bis(2-hydroxymethyl)ether	As item 79
37.	As item 217	000077-99-6	2,2-Bis(hydroxymethyl)butan-1-ol	As item 217
38.	13390	000105-08-8	1,4-Bis(hydroxymethyl)-cyclohexane	
39.	13480	000080-05-7	2,2-Bis(4-hydroxyphenyl)propane	The specific migration of this substance shall not exceed 3 mg/kg
40.	13510	001675-54-3	2,2-Bis(4-hydroxyphenyl)propane bis(2,3-epoxypropyl) ether	The quantity of this substance in the finished plastic material or article shall not exceed 1 mg/kg or the specific migration of this substance shall be not detectable (when measured by a method with a limit of detection of 0.02 mg/kg, analytical

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<i>Item</i>	<i>1 PM/REF No.</i>	<i>2 CAS No.</i>	<i>3 Name</i>	<i>4 Restrictions</i>
				tolerance included)
41.	13530	038103-06-9	2,2-Bis(4-hydroxyphenyl) propane bis(phthalic anhydride)	The specific migration of this substance shall not exceed 0.05 mg/kg
42.	As item 93	000110-98-5	Bis(hydroxypropyl) ether	
43.	As item 78	005124-30-1	Bis(4-isocyanatocyclohexyl) methane	As item 78
44.	13600	047465-97-4	3,3-Bis(3-methyl-4-hydroxyphenyl-indolin-2-one	The specific migration of this substance shall not exceed 1.8 mg/kg
45.	As item 39	000080-05-7	Bisphenol A	As item 39
46.	As item 40	001675-54-3	Bisphenol A bis(2,3-epoxypropyl) ether	As item 40
47.	13614	038103-06-9	Bisphenol A bis (phthalic anhydride)	As item 41
48.	13630	000106-99-0	Butadiene	The quantity of this substance in the finished plastic material or article shall not exceed 1 mg/kg or the specific migration of this substance shall be not detectable (when measured by a method with a limit of detection of 0.02 mg/kg, analytical tolerance included)
49.	13690	000107-88-0	Butan-1,3-diol	
50.	13840	000071-36-3	Butan-1-ol	
51.	13870	000106-98-9	But-1-ene	

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<i>Item</i>	<i>1 PM/REF No.</i>	<i>2 CAS No.</i>	<i>3 Name</i>	<i>4 Restrictions</i>
52.	13900	000107-01-7	But-2-ene	
53.	14110	000123-72-8	Butyraldehyde	
54.	14140	000107-92-6	Butyric acid	
55.	14170	000106-31-0	Butyric anhydride	
56.	14200	000105-60-2	Caprolactam	The specific migration of this substance alone or together with item 57 shall not exceed a total of 15 mg/kg
57.	14230	002123-24-2	Caprolactam, sodium salt	The specific migration of this substance alone or together with item 56 shall not exceed a total of 15 mg/kg (expressed as caprolactam)
58.	14320	000124-07-2	Caprylic acid	
59.	14350	000630-08-0	Carbon monoxide	
60.	14380	000075-44-5	Carbonyl chloride	The quantity of this substance in the finished plastic material or article shall not exceed 1 mg/kg
61.	14411	008001-79-4	Castor oil	
62.	14500	009004-34-6	Cellulose	
63.	14530	007782-50-5	Chlorine	
64.	As item 94	000106-89-8	1-Chloro-2,3-epoxypropane	As item 94
65.	14680	000077-92-9	Citric acid	
66.	14710	000108-39-4	<i>m</i> -Cresol	
67.	14740	000095-48-7	<i>o</i> -Cresol	
68.	14770	000106-44-5	<i>p</i> -Cresol	
69.	As item 38	000105-08-8	1,4-Cyclohexanedimethanol	
70.	14950	003173-53-3	Cyclohexyl isocyanate	The quantity in the finished

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<i>Item</i>	<i>1 PM/REF No.</i>	<i>2 CAS No.</i>	<i>3 Name</i>	<i>4 Restrictions</i>
				plastic material or article of any substance within, or any combination of substances within, items 70, 78, 88, 90, 91, 92, 117, 150, 153, 211, 212 and 213 shall not exceed 1 mg/kg (expressed as isocyanate moiety)
71.	15070	001647-16-1	Dec-1,9-diene	The specific migration of this substance shall not exceed 0.05 mg/kg
72.	15095	000334-48-5	Decanoic acid	
73.	15100	000112-30-1	Decan-1-ol	
74.	15250	000110-60-1	1,4-Diaminobutane	
75.	As item 97	000107-15-3	1,2-Diaminoethane	As item 97
76.	As item 116	000124-09-4	1,6-Diaminohexane	As item 116
77.	15565	000106-46-7	1,4-Dichlorobenzene	The specific migration of this substance shall not exceed 12 mg/kg
78.	15700	005124-30-1	Dicyclohexylmethane 4,4'-diisocyanate	As item 70
79.	15760	000111-46-6	Diethylene glycol	The specific migration of this substance alone or together with item 98 shall not exceed a total of 30 mg/kg
80.	15790	000111-40-0	Diethylenetriamine	The specific migration of this substance shall

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<i>Item</i>	<i>1 PM/REF No.</i>	<i>2 CAS No.</i>	<i>3 Name</i>	<i>4 Restrictions</i>
				not exceed 5 mg/kg
81.	15820	000345-92-6	4,4'-Difluorobenzophenone	The specific migration of this substance shall not exceed 0.05 mg/kg
82.	15880	000120-80-9	1,2-Dihydroxybenzene	The specific migration of this substance shall not exceed 6 mg/kg
83.	15910	000108-46-3	1,3-Dihydroxybenzene	The specific migration of this substance shall not exceed 2.4 mg/kg
84.	15940	000123-31-9	1,4-Dihydroxybenzene	The specific migration of this substance shall not exceed 0.6 mg/kg
85.	15970	000611-99-4	4,4'-Dihydroxybenzophenone	The specific migration of this substance shall not exceed 6 mg/kg
86.	16000	000092-88-6	4,4'-Dihydroxybiphenyl	The specific migration of this substance shall not exceed 6 mg/kg
87.	16150	000108-01-0	Dimethylaminoethanol	The specific migration of this substance shall not exceed 18 mg/kg
88.	16240	000091-97-4	3,3'-Dimethyl- 4,4'-diisocyanatobiphenyl	As item 70
89.	16480	000126-58-9	Dipentaerythritol	
90.	16570	004128-73-8	Diphenylether-4,4'-diisocyanate	As item 70
91.	16600	005873-54-1	Diphenylmethane-2,2'-diisocyanate	As item 70

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<i>Item</i>	<i>1 PM/REF No.</i>	<i>2 CAS No.</i>	<i>3 Name</i>	<i>4 Restrictions</i>
92.	16630	000101-68-8	Diphenylmethane-4,4'-diisocyanate	As item 70
93.	16660	000110-98-5	Dipropyleneglycol	
94.	16750	000106-89-8	Epichlorohydrin	The quantity of this substance in the finished plastic material or article shall not exceed 1 mg/kg
95.	16780	000064-17-5	Ethanol	
96.	16950	000074-85-1	Ethylene	
97.	16960	000107-15-3	Ethylenediamine	The specific migration of this substance shall not exceed 12 mg/kg
98.	16990	000107-21-1	Ethylene glycol	The specific migration of this substance alone or together with item 79 shall not exceed a total of 30 mg/kg
99.	17005	000151-56-4	Ethyleneimine	The specific migration of this substance shall be not detectable (when measured by a method with a limit of detection of 0.01 mg/kg)
100.	17020	000075-21-8	Ethylene oxide	The quantity of this substance in the finished plastic material or article shall not exceed 1 mg/kg
101.	17050	00104-76-7	2-Ethylhexan-1-ol	The specific migration of this substance shall not exceed 30 mg/kg
102.	17160	000097-53-0	Eugenol	The specific migration of this



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<i>Item</i>	<i>1 PM/REF No.</i>	<i>2 CAS No.</i>	<i>3 Name</i>	<i>4 Restrictions</i>
				substance shall not exceed 0.01 mg/kg
103.	17170	061788-47-4	Fatty acids, coco	
104.	17200	068308-53-2	Fatty acids, soya	
105.	17230	061790-12-3	Fatty acids, tall oil	
106.	17260	000050-00-0	Formaldehyde	The specific migration of this substance shall not exceed 15 mg/kg
107.	17290	000110-17-8	Fumaric acid	
108.	17530	000050-99-7	Glucose	
109.	18010	000110-94-1	Glutaric acid	
110.	18070	000108-55-4	Glutaric anhydride	
111.	18100	000056-81-5	Glycerol	
112.	18250	000115-28-6	Hexachlorendomethylene tetrahydrophthalic acid	The specific migration of this substance shall be not detectable (when measured by a method with a limit of detection of 0.01 mg/kg)
113.	18280	000115-27-5	Hexachlorendomethylene tetrahydrophthalic anhydride	The specific migration of this substance shall be not detectable (when measured by a method with a limit of detection of 0.01 mg/kg)
114.	18310	036653-82-4	Hexadecan-1-ol	
115.	18430	000116-15-4	Hexafluoropropylene	The specific migration of this substance shall be not detectable (when measured by a method with a limit of

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<i>Item</i>	<i>1 PM/REF No.</i>	<i>2 CAS No.</i>	<i>3 Name</i>	<i>4 Restrictions</i>
				detection of 0.01 mg/kg)
116.	18460	000124-09-4	Hexamethylenediamine	The specific migration of this substance shall not exceed 2.4 mg/kg
117.	18640	000822-06-0	Hexamethylene diisocyanate	As item 70
118.	18670	000100-97-0	Hexamethylenetetramine	The specific migration of this substance shall not exceed 15 mg/kg (expressed as formaldehyde)
119.	As item 84	000123-31-9	Hydroquinone	As item 84
120.	18880	000099-96-7	<i>p</i> -Hydroxybenzoic acid	
121.	19000	000115-11-7	Isobutene	
122.	19210	001459-93-4	Isophthalic acid, dimethyl ester	The specific migration of this substance shall not exceed 0.05 mg/kg
123.	19270	000097-65-4	Itaconic acid	
124.	19460	000050-21-5	Lactic acid	
125.	19470	000143-07-7	Lauric acid	
126.	19480	002146-71-6	Lauric acid, vinyl ester	
127.	19510	011132-73-3	Lignocellulose	
128.	19540	000110-16-7	Maleic acid	The specific migration of this substance alone or together with item 129 shall not exceed a total of 30 mg/kg
129.	19960	000108-31-6	Maleic anhydride	The specific migration of this substance alone or together with item 128 shall not exceed a

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<i>Item</i>	<i>1 PM/REF No.</i>	<i>2 CAS No.</i>	<i>3 Name</i>	<i>4 Restrictions</i>
				total of 30 mg/ kg (expressed as maleic acid)
130.	As item 215	000108-78-1	Melamine	As item 215
131.	20020	000079-41-4	Methacrylic acid	
132.	20080	002495-37-6	Methacrylic acid, benzyl ester	
133.	20110	000097-88-1	Methacrylic acid, butyl ester	
134.	20140	002998-18-7	Methacrylic acid, <i>sec</i> -butyl ester	
135.	20170	000585-07-9	Methacrylic acid, <i>tert</i> -butyl ester	
136.	20890	000097-63-2	Methacrylic acid, ethyl ester	
137.	21010	000097-86-9	Methacrylic acid, isobutyl ester	
138.	21100	004655-34-9	Methacrylic acid, isopropyl ester	
139.	21130	000080-62-6	Methacrylic acid, methyl ester	
140.	21190	000868-77-9	Methacrylic acid, monoester with ethyleneglycol	
141.	21280	002177-70-0	Methacrylic acid, phenyl ester	
142.	21340	002210-28-8	Methacrylic acid, propyl ester	
143.	21460	000760-93-0	Methacrylic anhydride	
144.	21490	000126-98-7	Methacrylonitrile	The specific migration of this substance shall be not detectable (when measured by a method with a limit of detection of 0.02 mg/kg, analytical tolerance included)
145.	21550	000067-56-1	Methanol	

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<i>Item</i>	<i>1 PM/REF No.</i>	<i>2 CAS No.</i>	<i>3 Name</i>	<i>4 Restrictions</i>
146.	21940	000924-42-5	N-Methylolacrylamide	The specific migration of this substance shall be not detectable (when measured by a method with a limit of detection of 0.01 mg/kg)
147.	22150	000691-37-2	4-Methypent-1-ene	The specific migration of this substance shall not exceed 0.02 mg/kg
148.	22350	000544-63-8	Myristic acid	
149.	22390	000840-65-3	2,6-Naphthalenedicarboxylic acid, dimethyl ester	The specific migration of this substance shall not exceed 0.05 mg/kg
150.	22420	003173-72-6	1,5-Naphthalene diisocyanate	As item 70
151.	22450	009004-70-0	Nitrocellulose	
152.	22480	000143-08-8	Nonan-1-ol	
153.	22570	000112-96-9	Octadecyl isocyanate	As item 70
154.	22600	000111-87-5	Octan-1-ol	
155.	22660	000111-66-0	Oct-1-ene	The specific migration of this substance shall not exceed 15 mg/kg
156.	22763	000112-80-1	Oleic acid	
157.	22780	000057-10-3	Palmitic acid	
158.	22840	000115-77-5	Pentaerythritol	
159.	22870	000071-41-0	Pentan-1-ol	
160.	22960	000108-95-2	Phenol	
161.	23050	000108-45-2	1,3-Phenylenediamine	The quantity of this substance in the finished plastic material or article shall not exceed 1 mg/kg

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<i>Item</i>	<i>1 PM/REF No.</i>	<i>2 CAS No.</i>	<i>3 Name</i>	<i>4 Restrictions</i>
162.	As item 60	000075-44-5	Phosgene	As item 60
163.	23170	007664-38-2	Phosphoric acid	
164.	As item 204	—	Phthalic acid	As item 204
165.	23200	000088-99-3	<i>o</i> -Phthalic acid	
166.	23230	000131-17-9	Phthalic acid, diallyl ester	The specific migration of this substance shall be not detectable (when measured by a method with a limit of detection of 0.01 mg/kg)
167.	23380	000085-44-9	Phthalic anhydride	
168.	23470	000080-56-8	<i>alpha</i> -Pinene	
169.	23500	000127-91-3	<i>beta</i> -Pinene	
170.	23590	025322-68-3	Polyethylene glycol	
171.	23650	025322-69-4	Polypropylene glycol (molecular weight greater than 400)	
172.	23651	025322-69-4	Polypropyleneglycol	
173.	23740	000057-55-6	Propan-1,2-diol	
174.	23800	000071-23-8	Propan-1-ol	
175.	23830	000067-63-0	Propan-2-ol	
176.	23860	000123-38-6	Propionaldehyde	
177.	23890	000079-09-4	Propionic acid	
178.	23950	000123-62-6	Propionic anhydride	
179.	23980	000115-07-1	Propylene	
180.	24010	000075-56-9	Propylene oxide	The quantity of this substance in the finished plastic material or article shall not exceed 1 mg/kg
181.	As item 82	000120-80-9	Pyrocatechol	As item 82

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<i>Item</i>	<i>1 PM/REF No.</i>	<i>2 CAS No.</i>	<i>3 Name</i>	<i>4 Restrictions</i>
182.	24057	000089-32-7	Pyromellitic anhydride	The specific migration of this substance shall not exceed 0.05 mg/kg (expressed as pyromellitic acid)
183.	24070	073138-82-6	Resin acids and rosin acids	
184.	As item 83	000108-46-3	Resorcinol	As item 83
185.	24100	008050-09-7	Rosin	
186.	24130	008050-09-7	Rosin gum	
187.	24160	008052-10-6	Rosin tall oil	
188.	24190	009014-63-5	Rosin wood	
189.	24250	009006-04-6	Rubber, natural	
190.	24270	000069-72-7	Salicylic acid	
191.	24280	000111-20-6	Sebacic acid	
192.	24430	002561-88-8	Sebacic anhydride	
193.	24475	001313-82-2	Sodium sulphide	
194.	24490	000050-70-4	Sorbitol	
195.	24520	008001-22-7	Soybean oil	
196.	24540	009005-25-8	Starch, edible	The specific migration of this substance shall not exceed 0.05 mg/kg
197.	24550	000057-11-4	Stearic acid	
198.	24610	000100-42-5	Styrene	
199.	24820	000110-15-6	Succinic acid	
200.	24850	000108-30-5	Succinic anhydride	
201.	24880	000057-50-1	Sucrose	
202.	24887	006362-79-4	5-Sulphoisophthalic acid, monosodium salt	The specific migration of this substance shall not exceed 5 mg/kg
203.	24888	003965-55-7	5-Sulphoisophthalic	The specific migration of this

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<i>Item</i>	<i>1 PM/REF No.</i>	<i>2 CAS No.</i>	<i>3 Name</i>	<i>4 Restrictions</i>
204.	24910	000100-21-0	acid, monosodium salt, dimethyl ester Terephthalic acid	substance shall not exceed 0.05 mg/kg The specific migration of this substance alone or together with item 205 shall not exceed a total of 7.5 mg/kg
205.	24940	000100-20-9	Terephthalic acid dichloride	The specific migration of this substance alone or together with item 204 shall not exceed 7.5 mg/ kg (expressed as terephthalic acid)
206.	24970	000120-61-6	Terephthalic acid, dimethyl ester	
207.	25090	000112-60-7	Tetraethylene glycol	
208.	25120	000116-14-3	Tetrafluoroethylene	The specific migration of this substance shall not exceed 0.05 mg/kg
209.	25150	000109-99-9	Tetrahydrofuran	The specific migration of this substance shall not exceed 0.6 mg/kg
210.	25180	000102-60-3	<i>N, N, N', N'</i> - Tetrakis (2- hydroxypropyl)- ethylenediamine	
211.	25210	000584-84-9	2,4-Toluene diisocyanate	As item 70
212.	25240	000091-08-7	2,6-Toluene diisocyanate	As item 70
213.	25270	026747-90-0	2,4-Toluene diisocyanatedimer	As item 70
214.	25360	—	Trialkyl (C5-C15) acetic acid 2,3- epoxypropyl ester	The specific migration of this substance shall

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<i>Item</i>	<i>1 PM/REF No.</i>	<i>2 CAS No.</i>	<i>3 Name</i>	<i>4 Restrictions</i>
				not exceed 6 mg/kg
215.	25420	000108-78-1	2,4,6-Triamino-1,3,5,-triazine	The specific migration of this substance shall not exceed 30 mg/kg
216.	25510	000112-27-6	Triethylene glycol	
217.	25600	000077-99-6	1,1,1-Trimethylolpropanem	The specific migration of this substance shall not exceed 6 mg/kg
218.	25910	024800-44-0	Tripropylene glycol	
219.	25960	000057-13-6	Urea	
220.	26050	000075-01-4	Vinyl chloride	The restrictions are those in regulation 5(1) (a) and (b) of the 1987 Regulations when analysed by the method referred to in regulation 14 of those Regulations
221.	26110	000075-35-4	Vinylidene chloride	The quantity of this substance in the finished plastic material or article shall not exceed 5 mg/kg or the specific migration of this substance shall be not detectable (when measured by a method with a limit of detection of 0.05 mg/kg)
222.	26140	000075-38-7	Vinylidene fluoride	The specific migration of this substance shall not exceed 5 mg/kg



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## SECTION B

*Monomers authorised up to the end of 2001*

<i>Item</i>	<i>1 PM/REF No.</i>	<i>2 CAS No.</i>	<i>3 Name</i>	<i>4 Restrictions</i>
1.	10599/90A	061788-89-4	Acids, fatty, unsaturated (C18), dimers, distilled	
2.	10599/91	061788-89-4	Acids, fatty, unsaturated (C18), dimers, non-distilled	
3.	10599/92A	068783-41-5	Acids, fatty, unsaturated (C18), dimers, hydrogenated, distilled	
4.	10599/93	068783-41-5	Acids, fatty, unsaturated (C18), dimers, hydrogenated, non-distilled	
5.	11000	050976-02-8	Acrylic acid, dicyclopentadienyl ester	
6.	11245	002156-97-0	Acrylic acid, dodecyl ester	
7.	11500	000103-11-7	Acrylic acid, 2-ethylhexyl ester	
8.	11530	000999-61-1	Acrylic acid, 2-hydroxypropyl ester	
9.	12265	004074-90-2	Adipic acid, divinyl ester	
10.	12910	001732-10-1	Azelaic acid, dimethyl ester	
11.	As item 78	000528-44-9	1,2,4-Benzenetricarboxylic acid	As item 78
12.	13060	004422-95-1	1,3,5-Benzenetricarboxylic acid trichloride	
13.	As item 23	000091-76-9	Benzoguanamine	
14.	As item 28	000080-09-1	Bisphenol S	

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<i>Item</i>	<i>1 PM/REF No.</i>	<i>2 CAS No.</i>	<i>3 Name</i>	<i>4 Restrictions</i>
15.	13720	000110-63-4	Butan-1,4 diol	
16.	13780	002425-79-8	Butan-1,4 diol, bis(2,3-epoxypropyl) ether	The quantity in the finished plastic material or article of any substance within, or any combination of substances within, items 16 and 56 shall not exceed 5 mg/kg (expressed as epoxy)
17.	13810	000505-65-7	Butan-1,4 diol, formal	
18.	13932	000598-32-3	But-3-en-2-ol	
19.	14020	000098-54-4	4- <i>tert</i> -Butylphenol	
20.	14260	000502-44-3	Caprolactone	
21.	14800	003724-65-0	Crotonic acid	
22.	15130	000872-05-9	Dec-1-ene	
23.	15310	000091-76-9	2,4-Diamino-5-phenyl-1,3,5-triazine	
24.	15370	003236-53-1	1,6-Diamino-2,2,4-trimethylhexane	
25.	15400	003236-54-2	1,6-Diamino-2,4,4-trimethylhexane	
26.	15610	000080-07-9	4,4'Dichlorodiphenyl sulphone	
27.	15730	000077-73-6	Dicyclopentadiene	
28.	16090	000080-09-1	4,4'-Dihydroxydiphenyl sulphone	
29.	16210	006864-37-5	3,3'-Dimethyl-4,4'-diamino-dicyclohexylmethane	
30.	16360	000576-26-1	2,6-Dimethylphenol	

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<i>Item</i>	<i>1 PM/REF No.</i>	<i>2 CAS No.</i>	<i>3 Name</i>	<i>4 Restrictions</i>
31.	16390	000126-30-7	2,2-Dimethylpropan-1,3-diol	
32.	16450	000646-06-0	1,3-Dioxolane	
33.	16540	000102-09-0	Diphenyl carbonate	
34.	16690	001321-74-0	Divinylbenzene	
35.	16697	000693-23-2	Dodecanedioic acid	
36.	17110	016219-75-3	5-Ethylidenebicyclo [2.2.1]hept-2-ene	
37.	18220	068564-88-5	<i>N</i> -Heptylaminoundecanoic acid	
38.	18370	000592-45-0	Hexa-1,4-diene	
39.	18441	000085-42-7	Hexahydrophthalic anhydride	
40.	18700	000629-11-8	Hexan-1,6-diol	
41.	18820	000592-41-6	Hex-1-ene	
42.	19060	000109-53-5	Isobutyl vinyl ether	
43.	19150	000121-91-5	Isophthalic acid	
44.	19180	000099-63-8	Isophthalic acid dichloride	
45.	As item 60	000078-79-5	Isoprene	
46.	19490	000947-04-6	Lauro lactam	
47.	19570	000999-21-3	Maleic acid, diallyl ester	
48.	19600	000105-76-0	Maleic acid, dibutyl ester	
49.	19990	000079-39-0	Methacrylamide	
50.	20050	000096-05-9	Methacrylic acid, allyl ester	
51.	20260	000101-43-9	Methacrylic acid, cyclohexyl ester	
52.	20380	001189-08-8	Methacrylic acid, diester with butan-1,3-diol	

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<i>Item</i>	<i>1 PM/REF No.</i>	<i>2 CAS No.</i>	<i>3 Name</i>	<i>4 Restrictions</i>
53.	20410	002082-81-7	Methacrylic acid, diester with butan-1,4-diol	
54.	20440	000097-90-5	Methacrylic acid, diester with ethyleneglycol	
55.	20530	002867-47-2	Methacrylic acid, 2-(dimethylamino) ethyl ester	
56.	20590	000106-91-2	Methacrylic acid, 2,3- epoxypropyl ester	As item 16
57.	21370	010595-80-9	Methacrylic acid, 2-sulphoethyl ester	
58.	21400	054276-35-6	Methacrylic acid, sulphopropyl ester	
59.	21520	001561-92-8	Methallylsulphonic acid, sodium salt	The quantity of this substance in the finished plastic material or article shall not exceed 5 mg/kg
60.	21640	000078-79-5	2-Methylbut-1,3 diene	
61.	21730	000563-45-1	3-Methylbut-1-ene	
62.	As item 17	000505-65-7	1,4-(Methylenedioxy) butane	
63.	21970	000923-02-4	<i>N</i> -Methylolmethacrylamide	
64.	22210	000098-83-9	<i>alpha</i> -Methylstyrene	
65.	22360	001141-38-4	2,6-Naphthalenedicarboxylic acid	
66.	As item 31	000126-30-7	Neopentylglycol	
67.	22428	051000-52-3	Neodecanoic acid, vinyl ester	

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<i>Item</i>	<i>1 PM/REF No.</i>	<i>2 CAS No.</i>	<i>3 Name</i>	<i>4 Restrictions</i>
68.	22720	000140-66-9	4- <i>tert</i> -Octylphenol	
69.	22900	000109-67-1	Pent-1-ene	
70.	22937	001623-05-8	Perfluoropropyl perfluorovinyl ether	
71.	23770	000504-63-2	Propan-1,3-diol	
72.	23920	000105-38-4	Propionic acid, vinyl ester	
73.	24370	000106-79-6	Sebacic acid, dimethyl ester	
74.	24760	026914-43-2	Styrenesulphonic acid	
75.	25380	—	Trialkyl (C5-C15) acetic acid, vinyl ester (= vinyl versatate)	
76.	25390	000101-37-1	Triallyl cyanurate	
77.	25450	026896-48-0	Tricyclodecanedimethanol	
78.	25540	000528-44-9	Trimellitic acid	The quantity of this substance alone or together with item 79 in the finished plastic material or article shall not exceed 5 mg/kg
79.	25550	000552-30-7	Trimellitic anhydride	The quantity of this substance alone or together with item 78 in the finished plastic material or article shall not exceed 5 mg/kg (expressed as trimellitic acid)
80.	25810	015625-89-5	1,1,1-Trimethylolpropane triacrylate	
81.	25840	003290-92-4	1,1,1-Trimethylolpropane trimethacrylate	

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<i>Item</i>	1 <i>PM/REF No.</i>	2 <i>CAS No.</i>	3 <i>Name</i>	4 <i>Restrictions</i>
82.	25900	000110-88-3	Trioxane	
83.	26170	003195-78-6	N-Vinyl-N-methylacetamide	The quantity of this substance in the finished plastic material or article shall not exceed 5 mg/kg

### SECTION C

#### *Monomers authorised up to the end of 1998*

<i>Item</i>	1 <i>PM/REF No.</i>	2 <i>CAS No.</i>	3 <i>Name</i>	4 <i>Restrictions</i>
1.	10160	002206-94-2	<i>alpha</i> -Acetoxystyrene	
2.	10162	010521-96-7	<i>beta</i> -Acetoxystyrene	
3.	10480	—	Acids, aliphatic, monocarboxylic saturated (C2-C24)	
4.	10510	—	Acids, aliphatic, monocarboxylic unsaturated (C3-C24)	
5.	10599/70	—	Acids, fatty, unsaturated (C18)	
6.	10930	003066-71-5	Acrylic acid, cyclohexyl ester	
7.	11050	001070-70-8	Acrylic acid, diester with butan- 1,4-diol	
8.	11180	017831-71-9	Acrylic acid, diester with tetraethyleneglycol	
9.	11195	068901-05-3	Acrylic acid, diester with tripropyleneglycol	
10.	11520	002918-23-2	Acrylic acid, 2-hydroxyisopropyl ester (= acrylic acid, 2-hydroxy-	

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<i>Item</i>	<i>1 PM/REF No.</i>	<i>2 CAS No.</i>	<i>3 Name</i>	<i>4 Restrictions</i>
			1-methylethyl ester)	
11.	11560	005888-33-5	Acrylic acid, isobornyl ester	
12.	11620	001330-61-6	Acrylic acid, isodecyl ester	
13.	11650	029590-42-9	Acrylic acid, isooctyl ester	
14.	11695	003121-61-7	Acrylic acid, 2-methoxyethyl ester	
15.	11740	010095-13-3	Acrylic acid, monoester with butan-1,3-diol	
16.	11770	002478-10-6	Acrylic acid, monoester with butan-1,4-diol	
17.	11800	013533-05-6	Acrylic acid, monoester with diethyleneglycol	
18.	12010	040074-09-7	Acrylic acid, 2-sulphoethyl ester	
19.	12040	039121-78-3	Acrylic acid, sulphopropyl ester	
20.	12055	094160-26-6	Acrylic acid, triester with glycerol tris(2-hydroxypropyl) ether	
21.	12062	075577-70-7	Acrylic acid, triester with 1,1,1-trimethylolpropane tris(2-hydroxyethyl) ether	
22.	12160	002998-04-1	Adipic acid, diallyl ester	
23.	12190	000105-97-5	Adipic acid, didecyl ester	
24.	12220	027178-16-1	Adipic acid, diisodecyl ester	

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<i>Item</i>	1 <i>PM/REF No.</i>	2 <i>CAS No.</i>	3 <i>Name</i>	4 <i>Restrictions</i>
25.	12250	000123-79-5	Adipic acid, dioctyl ester	
26.	12370	—	Alcohols, aliphatic, monohydric, saturated, linear, secondary or tertiary (C4-C22)	
27.	12610	000107-18-6	Allyl alcohol	
28.	12700	000150-13-0	<i>p</i> -Aminobenzoic acid	
29.	12790	000080-46-6	<i>p</i> - <i>tert</i> -Amylphenol	
30.	12850	029602-44-6	Azelaic acid, bis(2- hydroxyethyl) ester	
31.	13328	000104-38-1	Bis(2- hydroxyethyl) ether of hydroquinone	
32.	13660	000584-03-2	Butan-1,2-diol	
33.	13750	000513-85-9	Butan-2,3-diol	
34.	13960	001852-16-0	<i>N</i> - (Butoxymethyl) acrylamide	
35.	15020	002182-05-0	Cyclohexyl vinyl ether	
36.	15280	000542-02-9	2,4-Diamino-6- methyl-1,3,5- triazine	
37.	15340	000109-76-2	1,3- Diaminopropane	
38.	15490	002215-89-6	4,4'- Dicarboxydiphenyl ether	
39.	15580	001653-19-6	2,3- Dichlorobuta-1,3- diene	
40.	16270	000526-75-0	2,3- Dimethylphenol	



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<i>Item</i>	<i>1 PM/REF No.</i>	<i>2 CAS No.</i>	<i>3 Name</i>	<i>4 Restrictions</i>
41.	16300	000105-67-9	2,4-Dimethyphenol	
42.	16330	000095-87-4	2,5-Dimethyphenol	
43.	17040	000149-57-5	2-Ethylhexanoic acid	
44.	17350	000105-75-9	Fumaric acid, dibutyl ester	
45.	18400	000592-42-7	Hexa-1,5-diene	
46.	18905	002628-17-3	4-Hydroxystyrene	
47.	18970	000078-83-1	Isobutanol	
48.	19030	016669-59-3	<i>N</i> -(Isobutoxymethyl) acrylamide	
49.	19090	000078-84-2	Isobutyraldehyde	
50.	19120	025339-17-7	Isodecanol	
51.	19130	026896-18-4	Isononanoic acid	
52.	19936	007423-42-9	Maleic acid, mono(2-ethylhexyl) ester	
53.	20470	025852-47-5	Methacrylic acid, diester with polyethyleneglycol	
54.	20740	039670-09-2	Methacrylic acid, ester with ethoxytriethyleneglycol	
55.	20950	000923-26-2	Methacrylic acid, 2-hydroxypropyl ester	
56.	21115	000816-74-0	Methacrylic acid, methallyl ester	
57.	21220	032360-05-7	Methacrylic acid, octadecyl ester	
58.	21760	000694-91-7	5-Methylenebicyclo [2.2.1] hept- 2-ene	
59.	21837	001116-90-1	4-Methylhexa-1,4-diene	The specific migration of this substance shall be not detectable

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<i>Item</i>	<i>1 PM/REF No.</i>	<i>2 CAS No.</i>	<i>3 Name</i>	<i>4 Restrictions</i> (when measured by a method with a limit of detection of 0.05 mg/kg)
60.	22240	000622-97-9	<i>p</i> -Methylstyrene	
61.	22270	000107-25-5	Methyl vinyl ether	
62.	22540	000104-40-5	4-Nonylphenol	
63.	22585	003710-30-3	Octa-1,7-diene	
64.	22932	001187-93-5	Perfluoromethyl perfluorovinyl ether	
65.	23530	025190-06-1	Poly(1,4-butylene glycol) (molecular weight greater than 1000)	
66.	23650	025322-69-4	Polypropylene glycol (molecular weight greater than 400)	
67.	24560	000111-63-7	Stearic acid, vinyl ester	
68.	25030	016646-44-9	Tetra(allyloxy)ethane	
69.	25161	000085-43-8	1,2,3,6-Tetrahydrophthalic anhydride	
70.	25300	000088-19-7	<i>o</i> -Toluenesulphonamide	
71.	25480	000102-71-6	Triethanolamine	
72.	26290	025013-15-4	Vinyltoluene	
73.	26320	002768-02-7	Vinyltrimethoxysilane	The quantity of this substance in the finished plastic material or article shall not exceed 5 mg/kg

## Part II

### Supplementary

1. In regulation 4 and Part I—

- (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 CAS No. and the name, the name shall take precedence over the CAS No., and
- (d) references to specific migration are to be taken to mean specific migration as measured in accordance with Schedules 3 and 4.
2. If a substance appearing in Part I as an individual compound also falls within a generic term which appears therein, the restriction (if any) 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 such extent (if any) as is necessary therefor.
- 3.—(1) The items identified in Part I shall be taken to include—
- (a) substances undergoing polymerisation (which shall be taken to include 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) If a substance identified in Part I is an acid, a phenol or an alcohol and has salts (including double salts) of one or more of the following names (that is to say salts (including double salts) of aluminium, ammonium, calcium, iron, magnesium, potassium, sodium or zinc), then any such salts (including double salts) shall be treated as included in the specification of that substance.
- (3) If, as indicated in paragraph 2 of Annex II to the Directive, a substance is identified in Part I as an “. . . acid, salt” and has salts of one or more of the following names (that is to say salts of aluminium, ammonium, calcium, iron, magnesium, potassium, sodium or zinc), then the free acid corresponding to that substance is not treated as included in the specification of that substance.

## SCHEDULE 2

Regulation 5

**Part I**  
**Additives**

<i>Item</i>	1 <i>PM/REF No.</i>	2 <i>CAS No.</i>	3 <i>Name</i>
1.	30000	000064-19-7	Acetic acid
2.	30045	000123-86-4	Acetic acid, butyl ester
3.	30140	000141-78-6	Acetic acid, ethyl ester
4.	30280	000108-24-7	Acetic anhydride
5.	30295	000067-64-1	Acetone
6.	30370	—	Acetylacetic acid, salts
7.	30400	—	Acetylated glycerides

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<i>Item</i>	1 <i>PM/REF No.</i>	2 <i>CAS No.</i>	3 <i>Name</i>
8.	30960	—	Acids, aliphatic, monocarboxylic (C6-C22), esters with polyglycerol
9.	31328	—	Acids, fatty, from animal or vegetable food fats and oils
10.	31730	000124-04-9	Adipic acid
11.	33120	—	Alcohols, aliphatic, monohydric, saturated, linear, primary (C4-C24)
12.	33350	009005-32-7	Alginic acid
13.	34281	—	Alkyl (C8-C22) sulphuric acids, linear, primary, with an even number of carbon atoms
14.	34475	—	Aluminium calcium hydroxide phosphite, hydrate
15.	34480	—	Aluminium fibres, flakes and powders
16.	34560	021645-51-2	Aluminium hydroxide
17.	34690	011097-59-9	Aluminium magnesium carbonate hydroxide
18.	34720	001344-28-1	Aluminium oxide
19. (2-hydroxyethyl) ether	35120	013560-49-1	3-Aminocrotonic acid, diester with thiobis
20.	35320	007664-41-7	Ammonia
21.	35440	012124-97-9	Ammonium bromide
22.	35600	001336-21-6	Ammonium hydroxide
23.	35840	000506-30-9	Arachidic acid
24.	35845	007771-44-0	Arachidonic acid
25.	36000	000050-81-7	Ascorbic acid
26.	36080	000137-66-6	Ascorbyl palmitate
27.	36160	010605-09-1	Ascorbyl stearate
28.	36880	008012-89-3	Beeswax
29.	36960	003061-75-4	Behenamide

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<i>Item</i>	<i>1 PM/REF No.</i>	<i>2 CAS No.</i>	<i>3 Name</i>
30.	37040	000112-85-6	Behenic acid
31.	37280	001302-78-9	Bentonite
32.	37600	000065-85-0	Benzoic acid
33.	37680	000136-60-7	Benzoic acid, butyl ester
34.	37840	000093-89-0	Benzoic acid, ethyl ester
35.	38080	000093-58-3	Benzoic acid, methyl ester
36.	38160	002315-68-6	Benzoic acid, propyl ester
37.	38950	079072-96-1	Bis(4-ethylbenzylidene) sorbitol
38.	39890	087826-41-3	Bis(methylbenzylidene) sorbitol
		069158-41-4	Bis(methylbenzylidene) sorbitol
		054686-97-4	Bis(methylbenzylidene) sorbitol
39.	40400	010043-11-5	Boron nitride
40.	40570	000106-97-8	Butane
41.	41040	005743-36-2	Calcium butyrate
42.	41280	001305-62-0	Calcium hydroxide
43.	41520	001305-78-8	Calcium oxide
44.	41600	012004-14-7	Calcium sulphoaluminate
		037293-22-4	Calcium sulphoaluminate
45.	41760	008006-44-8	Candelilla wax
46.	41960	000124-07-2	Caprylic acid
47.	42160	000124-38-9	Carbon dioxide
48.	42500	—	Carbonic acid, salts
49.	42640	009000-11-7	Carboxymethylcellulose
50.	42720	008015-86-9	Carnauba wax
51.	42800	009000-71-9	Casien
52.	42960	064147-40-6	Castor oil, dehydrated

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<i>Item</i>	1 <i>PM/REF No.</i>	2 <i>CAS No.</i>	3 <i>Name</i>
53.	43200	—	Castor oil, mono- and diglycerides
54.	43280	009004-34-6	Cellulose
55.	43300	009004-36-8	Cellulose acetate butyrate
56.	43360	068442-85-3	Cellulose, regenerated
57.	43440	008001-75-0	Ceresin
58.	44160	000077-92-9	Citric acid
59.	44640	000077-93-0	Citric acid, triethyl ester
60.	45280	—	Cotton fibres
61.	45560	014464-46-1	Cristobalite
62.	45760	000108-91-8	Cyclohexylamine
63.	45920	009000-16-2	Dammar
64.	45940	000334-48-5	<i>n</i> -Decanoic acid
65.	46070	010016-20-3	<i>alpha</i> -Dextrin
66.	46080	007585-39-9	<i>beta</i> -Dextrin
67.	46375	061790-53-2	Diatomaceous earth
68.	46380	068855-54-9	Diatomaceous earth, soda ash flux-calcined
69.	46480	032647-67-9	Dibenzylidene sorbitol
70.	46790	004221-80-1	3,5-Di- <i>tert</i> -butyl-4-hydroxybenzoic acid, 2,4-di- <i>tert</i> -butylphenyl ester
71.	46800	067845-93-6	3,5-Di- <i>tert</i> -butyl-4-hydroxybenzoic acid, hexadecyl ester
72.	46870	003135-18-0	3,5-Di- <i>tert</i> -butyl-4-hydroxybenzylphosphonic acid, dioctadecyl ester
73.	47440	000461-58-5	Dicyanodiamide
74.	49540	000067-68-5	Dimethyl sulphoxide
75.	51200	000126-58-9	Dipentaerythritol
76.	51760	025265-71-8	Dipropylene glycol
		000110-98-5	Dipropylene glycol
77.	52640	016389-88-1	Dolomite

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<i>Item</i>	1 <i>PM/REF No.</i>	2 <i>CAS No.</i>	3 <i>Name</i>
78.	52720	000112-84-5	Erucamide
79.	52730	000112-86-7	Erucic acid
80.	52800	000064-17-5	Ethanol
81.	53270	037205-99-5	Ethylcarboxymethylcellulose
82.	53280	009004-57-3	Ethylcellulose
83.	53360	000110-31-6	<i>N,N'</i> - Ethylenebisoleamide
84.	53440	005518-18-3	<i>N,N'</i> - Ethylenebispalmitamide
85.	53520	000110-30-5	<i>N,N'</i> - Ethylenebistearamide
86.	53600	000060-00-4	Ethylenediaminetetracetic acid
87.	54005	005136-44-7	Ethylene- <i>N</i> - palmitamide- <i>N'</i> - stearamide
88.	54260	009004-58-4	Ethylhydroxyethylcellulose
89.	54270	—	Ethylhydroxymethylcellulose
90.	54280	—	Ethylhydroxypropylcellulose
91.	54450	—	Fats and oils, from animal or vegetable food sources
92.	54480	—	Fats and oils, hydrogenated, from animal or vegetable food sources
93.	55040	000064-18-6	Formic acid
94.	55120	000110-17-8	Fumaric acid
95.	55190	029204-02-2	Gadoleic acid
96.	55440	009000-70-8	Gelatine
97.	55520	—	Glass fibres
98.	55600	—	Glass microballs
99.	55680	000110-94-1	Glutaric acid
100.	55920	000056-81-5	Glycerol
101.	56020	099880-64-5	Glycerol dibehenate
102.	56360	—	Glycerol, esters with acetic acid

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<i>Item</i>	1 <i>PM/REF No.</i>	2 <i>CAS No.</i>	3 <i>Name</i>
103.	56486	—	Glycerol, esters with acids, aliphatic, saturated, linear, with an even number of carbon atoms (C14-C18) and with acids, aliphatic, unsaturated linear, with an even number of carbon atoms (C16-C18)
104.	56487	—	Glycerol, esters with butyric acid
105.	56490	—	Glycerol, esters with erucic acid
106.	56495	—	Glycerol, esters with 12-hydroxystearic acid
107.	56500	—	Glycerol, esters with lauric acid
108.	56510	—	Glycerol, esters with linoleic acid
109.	56520	—	Glycerol, esters with myristic acid
110.	56540	—	Glycerol, esters with oleic acid
111.	56550	—	Glycerol, esters with palmitic acid
112.	56565	—	Glycerol, esters with nonanoic acid
113.	56570	—	Glycerol, esters with propionic acid
114.	56580	—	Glycerol, esters with ricinoleic acid
115.	56585	—	Glycerol, esters with stearic acid
116.	56610	030233-64-8	Glycerol monobehenate
117.	56720	026402-23-3	Glycerol monohexanoate
118.	56800	030899-62-8	Glycerol monolaurate diacetate
119.	56880	026402-26-6	Glycerol monoctanoate



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<i>Item</i>	1 <i>PM/REF No.</i>	2 <i>CAS No.</i>	3 <i>Name</i>
120.	57040	—	Glycerol monooleate, ester with ascorbic acid
121.	57120	—	Glycerol monooleate, ester with citric acid
122.	57200	—	Glycerol monopalmitate ester with ascorbic acid
123.	57280	—	Glycerol monopalmitate, ester with citric acid
124.	57600	—	Glycerol monostearate, ester with ascorbic acid
125.	57680	—	Glycerol monostearate, ester with citric acid
126.	57920	000620-67-7	Glycerol triheptanoate
127.	58300	—	Glycine, salts
128.	58320	007782-42-5	Graphite
129.	58400	009000-30-0	Guar gum
130.	58480	009000-01-5	Gum arabic
131.	58720	000111-14-8	Heptanoic acid
132.	59360	000142-62-1	Hexanoic acid
133.	59760	019569-21-2	Huntite
134.	59990	007647-01-0	Hydrochloric acid
135.	60030	012072-90-1	Hydromagnesite
136.	60080	012304-65-3	Hydrotalcite
137.	60160	000120-47-8	4-Hydroxybenzoic acid, ethyl ester
138.	60180	004191-73-5	4-Hydroxybenzoic acid, isopropyl ester
139.	60200	000099-76-3	4-Hydroxybenzoic acid, methyl ester
140.	60240	000094-13-3	4-Hydroxybenzoic acid, propyl ester
141.	60560	009004-62-0	Hydroxyethylcellulose
142.	60880	009032-42-2	Hydroxyethylmethylcellulose
143.	61120	009005-27-0	Hydroxyethyl starch

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<i>Item</i>	1 <i>PM/REF No.</i>	2 <i>CAS No.</i>	3 <i>Name</i>
144.	61390	037353-59-6	Hydroxymethylcellulose
145.	61680	009004-64-2	Hydroxypropylcellulose
146.	61800	009049-76-7	Hydroxypropyl starch
147.	61840	000106-14-9	12-Hydroxystearic acid
148.	62140	006303-21-5	Hypophosphorous acid
149.	62240	001332-37-2	Iron oxide
150.	62450	000078-78-4	Isopentane
151.	62640	008001-39-6	Japan wax
152.	62720	001332-58-7	Kaolin
153.	62800	—	Kaolin, calcined
154.	62960	000050-21-5	Lactic acid
155.	63040	000138-22-7	Latic acid, butyl ester
156.	63280	000143-07-7	Lauric acid
157.	63760	008002-43-5	Lecithin
158.	63840	000123-76-2	Levulinic acid
159.	63920	000557-59-5	Lignoceric acid
160.	64015	000060-33-3	Linoleic acid
161.	64150	028290-79-1	Linolenic acid
162.	64500	—	Lysine, salts
163.	64640	001309-42-8	Magnesium hydroxide
164.	64720	001309-48-4	Magnesium oxide
165.	65020	006915-15-7	Malic acid
166.	65040	000141-82-2	Malonic acid
167.	65520	000087-78-5	Mannitol
168.	66200	037206-01-2	Methylcarboxymethylcellulose
169.	66240	009004-67-5	Methylcellulose
170.	66640	009004-59-5	Methylethylcellulose
171.	66695	—	Methylhydroxymethylcellulose
172.	66700	009004-65-3	Methylhydroxypropylcellulose
173.	67120	012001-26-2	Mica
174.	67200	001317-33-5	Molybdenum disulphide
175.	67840	—	Montanic acids and/or their esters with

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<i>Item</i>	<i>1 PM/REF No.</i>	<i>2 CAS No.</i>	<i>3 Name</i>
			ethyleneglycol and/ or with 1,3-butanediol and/or with glycerol
176.	67850	008002-53-7	Montan wax
177.	67891	000544-63-8	Myristic acid
178.	68040	003333-62-8	7-[2H-Naphtho-(1,2-D)triazol-2-yl]-3-phenylcoumarin
179.	68125	068187-64-4	Nepheline syenite
180.	68960	000301-02-0	Oleamide
181.	69040	000112-80-1	Oleic acid
182.	69760	000143-28-2	Oleyl alcohol
183.	70000	070331-94-1	2,2'-Oxamidobis[ethyl-3-(3,5-di- <i>tert</i> -butyl-4-hydroxyphenyl)propionate]
184.	70240	012198-93-5	Ozokerite
185.	70400	000057-10-3	Palmitic acid
186.	71020	000373-49-9	Palmitoleic acid
187.	71440	009000-69-5	Pectin
188.	71600	000115-77-5	Pentaerythritol
189.	71680	006683-19-8	Pentaerythritol tetrakis [3-(3,5-di- <i>tert</i> -butyl-4-hydroxyphenyl)propionate]
190.	71720	000109-66-0	Pentane
191.	72640	007664-38-2	Phosphoric acid
192.	74240	031570-04-4	Phosphorous acid, tris(2,4-di- <i>tert</i> -butylphenyl) ester
193.	74480	000088-99-3	<i>o</i> -Phthalic acid
194.	76320	000085-44-9	Phthalic anhydride
195.	76720	009016-00-6	Polydimethylsiloxane
		063148-62-9	Polydimethylsiloxane
196.	76960	025322-68-3	Polyethyleneglycol
197.	77600	061788-85-0	Polyethyleneglycol ester of hydrogenated castor oil

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<i>Item</i>	1 <i>PM/REF No.</i>	2 <i>CAS No.</i>	3 <i>Name</i>
198.	77702	—	Polyethyleneglycol esters of aliphatic monocarboxylic acids (C6-C22), and their ammonium and sodium sulphates
199.	79040	009005-64-5	Polyethyleneglycol sorbitan monolaurate
200.	79120	009005-65-6	Polyethyleneglycol sorbitan monooleate
201.	79200	009005-66-7	Polyethyleneglycol sorbitan monopalmitate
202.	79280	009005-67-8	Polyethyleneglycol sorbitan monostearate
203.	79360	009005-70-3	Polyethyleneglycol sorbitan trioleate
204.	79440	009005-71-4	Polyethyleneglycol sorbitan tristearate
205.	80240	029894-35-7	Polyglycerol ricinoleate
206.	80640	—	Polyoxyalkyl (C2-C4) dimethylpolysiloxane
207.	80720	008017-16-1	Polyphosphoric acids
208.	80800	025322-69-4	Polypropyleneglycol
209.	81520	007758-02-3	Potassium bromide
210.	81600	001310-58-3	Potassium hydroxide
211.	81840	000057-55-6	1,2-Propanediol
212.	81882	000067-63-0	2-Propanol
213.	82000	000079-09-4	Propionic acid
214.	82080	009005-37-2	1,2-Propyleneglycol alginate
215.	82240	022788-19-8	1,2-Propyleneglycol dilaurate
216.	82400	000105-62-4	1,2-Propyleneglycol dioleate
217.	82560	033587-20-1	1,2-Propyleneglycol dipalmitate
218.	82720	006182-11-2	1,2-Propyleneglycol distearate

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<i>Item</i>	1 <i>PM/REF No.</i>	2 <i>CAS No.</i>	3 <i>Name</i>
219.	82800	027194-74-7	1,2-Propyleneglycol monolaurate
220.	82960	001330-80-9	1,2-Propyleneglycol monooleate
221.	83120	029013-28-3	1,2-Propyleneglycol monopalmitate
222.	83300	001323-39-3	1,2-Propyleneglycol monostearate
223.	83320	—	Propylhydroxyethylcellulose
224.	83325	—	Propylhydroxymethylcellulose
225.	83330	—	Propylhydroxypropylcellulose
226.	83440	002466-09-3	Pyrophosphoric acid
227.	83455	013445-56-2	Pyrophosphorous acid
228.	83460	012269-78-2	Pyrophyllite
229.	83470	014808-60-7	Quartz
230.	83610	073138-82-6	Resin acids and rosin acids
231.	83840	008050-09-7	Rosin
232.	84000	008050-31-5	Rosin, ester with glycerol
233.	84080	008050-26-8	Rosin, ester with pentaerythritol
234.	84210	065997-06-0	Rosin, hydrogenated
235.	84240	065997-13-9	Rosin, hydrogenated, ester with glycerol
236.	84320	008050-15-5	Rosin, hydrogenated, ester with methanol
237.	84400	064365-17-9	Rosin, hydrogenated, ester with pentaerythritol
238.	84560	009006-04-6	Rubber, natural
239.	84640	000069-72-7	Salicylic acid
240.	85600	—	Silicates, natural
241.	85980	—	Silicic acid, salts
242.	86000	—	Silicic acid, silylated
243.	86160	000409-21-2	Silicon carbide
244.	86240	007631-86-9	Silicon dioxide

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<i>Item</i>	1 <i>PM/REF No.</i>	2 <i>CAS No.</i>	3 <i>Name</i>
245.	86560	007647-15-6	Sodium bromide
246.	86720	001310-73-2	Sodium hydroxide
247.	87200	000110-44-1	Sorbic acid
248.	87280	029116-98-1	Sorbitan dioleate
249.	87520	062568-11-0	Sorbitan monobehenate
250.	87600	001338-39-2	Sorbitan monolaurate
251.	87680	001338-43-8	Sorbitan monooleate
252.	87760	026266-57-9	Sorbitan monopalmitate
253.	87840	001338-41-6	Sorbitan monostearate
254.	87920	061752-68-9	Sorbitan tetrastearate
255.	88080	026266-58-0	Sorbitan trioleate
256.	88160	054140-20-4	Sorbitan tripalmitate
257.	88240	026658-19-5	Sorbitan tristearate
258.	88320	000050-70-4	Sorbitol
259.	88600	026836-47-5	Sorbitol monostearate
260.	88800	009005-25-8	Starch, edible
261.	88880	068412-29-3	Starch, hydrolysed
262.	88960	000124-26-5	Stearamide
263.	89040	000057-11-4	Stearic acid
264.	90720	058446-52-9	Stearoylbenzoylmethane
265.	90800	005793-94-2	Stearoyl-2-lactylic acid, calcium salt
266.	90960	000110-15-6	Succinic acid
267.	91200	000126-13-6	Sucrose acetate isobutyrate
268.	91360	000126-14-7	Sucrose octaacetate
269.	91840	007704-34-9	Sulphur
270.	91920	007664-93-9	Sulphuric acid
271.	92080	014807-96-6	Talc
272.	92160	000087-69-4	Tartaric acid
273.	92195	—	Taurine, salts
274.	92205	057569-40-1	Terephthalic acid, diester with 2,2'-methylenebis (4-

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<i>Item</i>	<i>1 PM/REF No.</i>	<i>2 CAS No.</i>	<i>3 Name</i>
			methyl-6- <i>tert</i> -butylphenol)
275.	92350	000112-60-7	Tetraethyleneglycol
276.	92640	000102-60-3	<i>N, N, N', N'</i> -Tetrakis(2-hydroxypropyl) ethylenediamine
277.	93440	013463-67-7	Titanium dioxide
278.	93520	000059-02-9	<i>alpha</i> -Tocopherol
		010191-41-0	<i>alpha</i> -Tocopherol
279.	93680	009000-65-1	Tragacanth gum
280.	94320	000112-27-6	Triethyleneglycol
281.	95200	001709-70-2	1,3,5-Trimethyl-2,4,6-tris(3,5-di- <i>tert</i> -butyl-4-hydroxybenzyl) benzene
282.	95905	013983-17-0	Wollastonite
283.	95920	—	Wood flour and fibres, untreated
284.	95935	011138-66-2	Xanthan gum
285.	96190	020427-58-1	Zinc hydroxide
286.	96240	001314-13-2	Zinc oxide
287.	96320	001314-98-3	Zinc sulphide

## Part II

### Supplementary

1. In regulation 5 and Part I—

- the PM/REF No. of any additive is its EEC packaging material reference number,
- the CAS No. of any additive is its CAS (Chemical Abstracts Service) Registry Number, and
- the name of any additive is its chemical name, and to the extent that there is any inconsistency between the CAS No. and the name, the name shall take precedence over the CAS No.

2 If a substance identified in Part I is an acid, a phenol or an alcohol and has salts (including double salts) of one or more of the following names (that is to say salts (including double salts) of aluminium, ammonium, calcium, iron, magnesium, potassium, sodium or zinc), then any such salts (including double salts) shall be treated as included in the specification of that substance.

3 If, as indicated in paragraph 2 of Annex III of the Directive, a substance is identified in Part I as an “. . . acid, salt” and has salts of one or more of the following names (that is to say, salts of

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aluminium, ammonium, calcium, iron, magnesium, potassium, sodium or zinc), then the free acid corresponding to that substance is not treated as included in the specification of that substance.

## SCHEDULE 3

Regulations 6 and 7

### Provisions Applicable when Testing Compliance with the Migration Limits

#### A.

##### *General provisions*

1. When the results of the migration tests specified in this Schedule and, where appropriate, Schedule 4 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 4 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 following formula:

$$M = \frac{m \cdot a_1}{a_2 \cdot q} \cdot 1000$$

where:

$M$  is the migration in mg/kg;

$m$  is the mass in mg of substance released by the sample as determined by the migration test;

$a_1$  is the surface area in square decimetres of the sample in contact with the food or simulant during the migration test;

$a_2$  is the surface area in square decimetres of the plastic material or article in actual conditions of use;

$q$  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 a 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 4.

(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 7 or Schedule 1 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 7 or Schedule 1 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 4.

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 4 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.

## **B.**

### ***Special provisions relating to overall migration***

6.—(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 7 it shall be a defence for the person charged to prove that—

- (a) if an aqueous simulant specified in Schedule 4 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

7.—(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 so modified as to enable the level of migration occurring during the third such test to be determined and, subject to sub-paragraph (2), such a determination may be used to prove excess of an overall migration limit in relation to a plastic material or article.

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(2) In any proceedings for an offence under these Regulations where it is alleged, following determination under sub-paragraph (1), that a plastic material or article does not comply with regulation 7 it shall be a defence for the person charged to prove that, if—

- (a) three identical shapes of the plastic material or article had been procured;
- (b) one of them had been subjected to the appropriate test according with paragraph 4 and the overall migration determined ( $M_1$ );
- (c) the second and third samples had been subjected to the same conditions of temperature but the period of contact had been two or three times that specified and overall migration had been determined in each case ( $M_1$  and  $M_2$  respectively); and
- (d) the plastic material or article had been deemed to comply with the overall migration limit relevant to it provided that either  $M_1$  or  $M_2$ — $M_3$  did not exceed the overall migration limit,

the plastic material or article would not have been deemed to exceed that limit.

8.—(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) 6 mg/kg or, as the case may be, 1 milligram per square decimetre in migration tests using other simulants referred to in Schedule 4.

## SCHEDULE 4

Regulations 6 and 7

### Overall and Specific Migration Testing Using Food Simulants

#### Part I

##### Basic Rules

1. Subject to paragraphs 2, 3 and 4, migration tests for the determination of specific and overall migration shall be carried out using the food simulants specified in Parts II, III and, where appropriate, IV and under conventional migration test conditions as specified in Part V.

2. Subject to paragraphs 3 and 4, substitute tests which use test media under the conventional substitute test conditions as specified in Part VI shall be carried out if the migration test using the fatty food simulants specified in Part III is not feasible for technical reasons connected with the method of analysis.

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

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- (b) omit the migration, the substitute or the alternative tests where there is conclusive proof that the migration limits cannot be exceeded in any foreseeable conditions of use of the material or article.

## Part II

### Food Simulants to be used in Migration Testing

1. Subject to Parts III, IV, V, VI and VII, the simulants to be used in migration testing are specified in the Table to this paragraph (referred to in this Part as “the Table”).

TABLE

<i>Abbreviation</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 save 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 as hereinafter described—

Iodine value (Wijs)	= 80 to 88
Refractive index at 25°C	= 1.4665 to 1.4679
Acidity (expressed as % of oleic acid)	= 0.5% maximum
Peroxide number (expressed as oxygen milliequivalents per kg of oil)	= 10 maximum

4. The fatty food simulants referred to in the Table are—

- (a) corn oil with standardised specifications;  
 (b) sunflower oil the characteristics of which are—

Iodine value (Wijs)	= 120 to 145
Refractive index at 20°C	= 1,474 to 1,476
Saponification number	= 188 to 193
Relative density at 20°C	= 0.918 to 0.925
Unsaponifiable matter	= 0.5% to 1.5%; and

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(c) a synthetic mixture of triglycerides the composition of which is as follows—

(i) 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

(ii) 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

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

Wavelength (nm)	290	310	330	350	370	390	430	470	510
Transmittance (%)	~12	~15	~37	~64	~80	~88	~95	~97	~98

At least 10% light transmittance at 310 nm.

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 7 or Schedule 1 verification that the plastic material or article does not comply with the specified migration limit 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 III

### Selection of Food Simulants

#### A.

#### *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 V 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 groups 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 7 or Schedule 1 if, following application of the 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 purposes 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 IV;
- (b) a reduction factor is specified for a food or group of foods where, in the Table to Part IV—
  - (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; and
- (c) a reduction shall be applied to a test result by dividing the result by that reduction factor.

3. Food types are defined in the Table to this paragraph (referred to in this Part as “Table 1”).

**TABLE 1**

<i>Definition</i>	<i>Meaning</i>
Aqueous foods having a pH > 4·5	Foods in relation to which simulant A only is specified in the Table to Part IV
Acidic foods having a pH ≤ 4·5	Foods in relation to which simulant B only is specified in the Table to Part IV
Alcoholic foods	Foods in relation to which simulant C only is specified in the Table to Part IV
Fatty foods	Foods in relation to which simulant D only is specified in the Table to Part IV

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<i>Definition</i>	<i>Meaning</i>
Dry foods	Foods in relation to which no simulant is specified in the Table to Part IV

**B.**

***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 shall be those mentioned below which, at the test conditions specified in Part V, are considered to be the more severe:

- simulant B;
- simulant C; and
- simulant D.

**C.**

***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 article which is already in contact with a known food shall be—

- (a) where the known food is a specific food or is within a specific group of foods described in column 2 of the Table to Part IV and, for the purposes of Part IV, 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 the known food is neither a specific food nor within a specific group of foods described in the Table to Part IV, the simulant or simulants in column 2 of Table 2 to this Part opposite the description of food in column 1 of that Table which corresponds most closely to the known food.

**D.**

***Selection of simulants for testing materials or 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 7 or 8, as appropriate, of the 1987 Regulations, 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 to this Part opposite the contact food in column 1 of that Table which corresponds most closely to the type or type 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 7 or 8, as appropriate, of the 1987 Regulations, is accompanied by a specific indication, expressed in accordance with paragraph 8, stating any food or group of food described in the Table to Part IV 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 IV, the food simulant or food simulants which, for the purposes of Part IV, is or are specified in relation to that food or group of foods;

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- (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 the Table to Part IV, a simulant other than the simulant or simulants which, for the purposes of Part IV, is or are specified 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 IV 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 IV.

**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	Simulant D and A
All fatty and acidic foods	Simulant D and B
All fatty, alcoholic and aqueous foods	Simulant D and C
All fatty, alcoholic and acidic foods	Simulant D, C and B

**Part IV**

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

1. For the purposes of this Part 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 thereto and the following paragraphs of this Part.
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 to this Part—
    - (i) the food or group of foods is described in the column headed “Description of food”; and

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(ii) “X” is placed in a column headed by a specific simulant opposite that food or group of foods followed by an oblique stroke and a reduction factor.

3. Where, in the Table to this Part, a reduction factor is specified 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 that reduction factor.

4. Where, in the Table to this Part, 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.

5. Where a food is listed in the Table to this Part 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.

TABLE

Reference Number	Description of food	Simulants to be used			
		A	B	C	D
01	<b>Beverages</b>				
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,	X(a)	X(a)		

(\*) Simulant B shall not be used where the pH is more than 4·5.

(\*\*) 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

(\*\*\*) If it can be demonstrated under regulation 11 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.



**Status:** This is the original version (as it was originally made). This item of legislation is currently only available in its original format.

Reference Number	Description of food	Simulants to be used			
		A	B	C	D
01.02	infusions, coffee, tea, liquid chocolate, beers and other.				
	Alcoholic beverages of an alcohol 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 liquers		X <sup>(*)</sup>	X <sup>(**)</sup>	
01.03	Miscellaneous: undenaturated ethyl alcohol		X <sup>(*)</sup>	X <sup>(**)</sup>	
02	<b>Cereals, cereal products, pastry biscuits, cakes and</b>				

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

(\*\*) 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

(\*\*\*) If it can be demonstrated under regulation 11 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
	<b>other bakers' wares</b>				
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 B. Other				X/5
02.06	Pastry, cakes and other bakers' ware, fresh: A. With fatty substances on the surface B. Other				X/5
03	<b>Chocolate, sugar and products</b>		X		

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

(\*\*) 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

(\*\*\*) If it can be demonstrated under regulation 11 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
04	<b>Fruit, vegetables and products thereof</b>				
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 medium):	X(a)	X(a)		
	(I) In an aqueous medium				
	(II) In an oily medium	X(a)	X(a)		X
	(III) In an alcoholic		X(*)	X	

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

(\*\*) 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

(\*\*\*) If it can be demonstrated under regulation 11 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
04.03	medium ( $\geq 5\%$ vol.)				
	Nuts (peanuts, chestnuts, almonds, hazelnuts, walnuts, pine kernels and others):				
	A. Shelled, dried				
	B. Shelled and roasted				X/5 <sup>(***)</sup>
	C. In paste or cream form	X			X/3 <sup>(***)</sup>
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. Vegetable cut, in the form of purees	X(a)	X(a)		
	C. Preserved vegetables:	X(a)	X(a)		
	(I) In an aqueous medium				
(II) In an oily medium	X(a)	X(a)		X	

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

(\*\*) 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

(\*\*\*) If it can be demonstrated under regulation 11 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
	(III) In an alcoholic medium ( $\geq 5\%$ vol.)		X <sup>(*)</sup>	X	
05	<b>Fats and oils</b>				
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	<b>Animal products and eggs</b>				
06.01	Fish:	X			X/3 <sup>(***)</sup>
	A. Fresh, chilled, salted, smoked				
	B. In the form of paste	X			X/3 <sup>(***)</sup>
06.02	Crustaceans and molluscs (including oysters, mussels, snails) not naturally	X			

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

(\*\*) 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

(\*\*\*) If it can be demonstrated under regulation 11 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
	protected by their shells				
06.03	Meat of all zoological species (including poultry and game): A. Fresh, chilled, salted, smoked B. In the form of paste, creams	X			X/4  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 B. In an oily medium	X(a)	X(a)		  X
06.06	Eggs not in shell: A. Liquid B. Other				X
06.07	Egg yolks: A. Liquid B. Powdered or frozen	X			
06.08	Dried white of egg				

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

(\*\*) 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

(\*\*\*) If it can be demonstrated under regulation 11 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
07	<b>Milk products</b>				
07.01	Milk:	X			
	A. Whole				
	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 <sup>(***)</sup>
07.05	Rennet:	X(a)	X(a)		
	A. In liquid or viscous form				
	B. Powdered or dried				
08	<b>Miscellaneous products</b>				
08.01	Vinegar			X	

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

(\*\*) 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

(\*\*\*) If it can be demonstrated under regulation 11 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
08.02	Fried or roasted foods:				X/5
	A. Fried potatoes, fritters and the like				
	B. Of animal origin				X/4
08.03	Preparations for soups, broths in liquid, solid or powder form (extracts, concentrates); homogenized composite food preparations, prepared dishes:				X/5
	A. Powdered or dried:				
	(I) With fatty substances on the surface				
	(II) Other				
	B. Liquid or paste:	X(a)	X(a)		X/3
	(I) With fatty substances on the surface				
	(II) Other	X(a)	X(a)		
08.04	Yeast and raising agents:	X(a)	X(a)		
	A. In paste form				

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

(\*\*) 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

(\*\*\*) If it can be demonstrated under regulation 11 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
	B. Dried				
08.05	Salt				
08.06	Sauces:	X(a)	X(a)		
	A. Without fatty substances on the surface				
	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 <sup>(***)</sup>
08.08	Sandwiches, toasted bread and the like containing any kind of foodstuff:				X/5
	A. With fatty substances on the surface				
	B. Other				
08.09	Ice creams	X			
08.10	Dried foods:				X/5

(\*) Simulant B shall not be used where the pH is more than 4-5.

(\*\*) 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

(\*\*\*) If it can be demonstrated under regulation 11 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
	A. With fatty substances on the surface				
	B. Other				
08.11	Frozen or deep-frozen foods				
08.12	Concentrated extracts of an alcoholic strength equal to or exceeding 5% vol		X <sup>(*)</sup>	X	
08.13	Cocoa:				X/5 <sup>(***)</sup>
	A. Cocoa powder				
	B. Cocoa paste				X/3 <sup>(***)</sup>
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				

(\*) Simulant B shall not be used where the pH is more than 4-5.

(\*\*) 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

(\*\*\*) If it can be demonstrated under regulation 11 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
08.17	Spices and seasonings in the natural state:  Cinnamon, cloves, powdered mustard, pepper, vanilla, saffron and others				

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

(\*\*) 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

(\*\*\*) If it can be demonstrated under regulation 11 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 V

### Migration Test Conditions (Times and Temperatures)

#### A.

##### *General criteria*

1. Subject to paragraphs 2, 4, 6 and 7 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 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.

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.

#### B.

##### *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.

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### C.

#### *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 for storage at room temperature in which case no further 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.

TABLE

<i>Conditions of contact in worst foreseeable use</i>	<i>Test conditions</i>
Contact time	Test time
$t \leq 5$ minutes	(1)
5 minutes < $t \leq 0.5$ hours	0.5 hours
0.5 hours < $t \leq 1$ hour	1 hour
1 hour < $t \leq 2$ hours	2 hours
2 hours < $t \leq 4$ hours	4 hours
4 hours < $t \leq 24$ hours	24 hours
$t > 24$ hours	10 days

(1) The period of time which represents the worst foreseeable conditions of contact.

Contact temperature	Test temperature
$T \leq 5^{\circ}\text{C}$	5°C
$5^{\circ}\text{C} < T \leq 20^{\circ}\text{C}$	20°C
$20^{\circ}\text{C} < T \leq 40^{\circ}\text{C}$	40°C
$40^{\circ}\text{C} < T \leq 70^{\circ}\text{C}$	70°C
$70^{\circ}\text{C} < T \leq 100^{\circ}\text{C}$	100°C or reflux temperature
$100^{\circ}\text{C} < T \leq 121^{\circ}\text{C}$	121°C <sup>(2)</sup>
$121^{\circ}\text{C} < T \leq 130^{\circ}\text{C}$	130°C <sup>(2)</sup>
$130^{\circ}\text{C} < T \leq 150^{\circ}\text{C}$	150°C <sup>(2)</sup>

(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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Contact temperature	Test temperature
T > 150°C	175°C <sup>(2)</sup>
(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 VI

### 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.
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.
3. For each test—
  - (a) a new test specimen shall be used;
  - (b) the rules prescribed for simulant D in Part III, IV and V 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.

**TABLE**

#### Conventional conditions for substitute tests

<i>Test conditions with simulant D</i>	<i>Test conditions with iso-octane</i>	<i>Test conditions with ethanol 95%</i>	<i>Test conditions with MPPO<sup>(1)</sup></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	—

(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 (e.g 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.

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<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<sup>(1)</sup></i>
0·5 hours at 100°C	0·5 hours at 60°C <sup>(2)</sup>	2·5 hours at 60°C	0·5 hours at 100°C
1 hour at 100°C	1 hour at 60°C <sup>(2)</sup>	3 hours at 60°C <sup>(2)</sup>	1 hour at 100°C
2 hours at 100°C	1·5 hours at 60°C <sup>(2)</sup>	3·5 hours at 60°C <sup>(2)</sup>	2 hours at 100°C
0·5 hours at 121°C	1·5 hours at 60°C <sup>(2)</sup>	3·5 hours at 60°C <sup>(2)</sup>	0·5 hours at 121°C
1 hour at 121°C	2 hours at 60°C <sup>(2)</sup>	4 hours at 60°C <sup>(2)</sup>	1 hour at 121°C
2 hours at 121°C	2·5 hours at 60°C <sup>(2)</sup>	4·5 hours at 60°C <sup>(2)</sup>	2 hours at 121°C
0·5 hours at 130°C	2 hours at 60°C <sup>(2)</sup>	4 hours at 60°C <sup>(2)</sup>	0·5 hours at 130°C
1 hour at 130°C	2·5 hours at 60°C <sup>(2)</sup>	4·5 hours at 60°C <sup>(2)</sup>	1 hour at 130°C
2 hours at 150°C	3 hours at 60°C <sup>(2)</sup>	5 hours at 60°C <sup>(2)</sup>	2 hours at 150°C
2 hours at 175°C	4 hours at 60°C <sup>(2)</sup>	6 hours at 60°C <sup>(2)</sup>	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 (e.g 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 VII

### Alternative Fat Tests for Overall and Specific Migration

1. Subject to paragraph 2 the conditions which must be fulfilled to allow the result of either of the migration tests specified in paragraph 3 to be used as an alternative to the result of a migration test carried out under Part III are—

- (a) the result obtained in a “comparison test” shows that the values are equal 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.

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 migration tests specified in paragraph 3 are equal to or greater than those obtained in any of the migration tests specified in Part III.

3. The migration tests referred to in paragraphs 1 and 2 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 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.

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## EXPLANATORY NOTE

*(This note is not part of the Regulations.)*

These Regulations come into operation on 14th September 1998.

These Regulations implement—

- (a) Council Directive (EEC) 82/711 (O.J. No. L297, 23.10.82, p. 26), as amended by Commission Directives 93/8/EEC (O.J. No. L90, 14.4.93, p. 22) and 97/48/EC (O.J. No. L222, 12.8.97, p. 10), laying down the basic rules necessary for testing migration of the constituents of plastic materials and articles intended to come into contact with foodstuffs;
- (b) Council Directive (EEC) 85/572 (O.J. No. L372, 30.12.85, p. 14) 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; and
- (c) Commission Directive (EEC) 90/128 (O.J. No. L75, 21.3.90, p. 19, to be read with the corrigendum in O.J. No. L349, 13.12.90, p. 26), as amended by Commission Directives (EEC) 92/39 (O.J. No. L168, 23.6.92, p. 21), 93/9 (O.J. No. L90, 14.4.93, p. 26), 95/3/EEC (O.J. No. L41, 23.2.95, p. 44) and 96/11/EC (O.J. No. L61, 12.3.96, p. 26), relating to plastic materials and articles intended to come into contact with foodstuffs.

These Regulations—

- (a) prohibit the use, sale or importation of plastic materials and articles which do not meet specified standards and provide a defence in relation to plastic materials and articles intended for export (regulation 3(1), (2) and (4));
- (b) prohibit the manufacture of plastic materials and articles with any monomer other than one which meets specified requirements and provide a defence in relation to plastic materials and articles manufactured before 14th September 1998 and in accordance with regulation 4 of the Plastic Materials and Articles in Contact with Food Regulations (Northern Ireland) 1993 (regulations 3(3) and 4);
- (c) prohibit the use in the manufacture of plastic materials or articles of any specified additive which is not of good technical quality (regulation 5);
- (d) provide the methods for testing the capability of plastic materials or articles of transferring constituents to food (regulation 6);
- (e) stipulate the overall migration limit for plastic materials and articles (regulation 7);
- (f) require, at marketing stages other than retail, persons in possession of any plastic material or article intended to come into contact with food to ensure such material or article is accompanied by a specified declaration (regulation 8);
- (g) specify the enforcement authority (regulation 9);
- (h) provide offences and defences and specify penalties (regulation 10);
- (i) provide that specified presumptions shall arise from particulars shown in relation to a plastic material or article in accordance with the Materials and Articles in Contact with Food Regulations (Northern Ireland) 1987 (“the 1987 Regulations”) (regulation 11);
- (j) apply provisions of the 1987 Regulations and of the Food Safety (Northern Ireland) Order 1991 (regulation 12); and
- (k) amend and revoke other legislation (regulations 13 and 14).



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The materials and articles to which these Regulations relate are also subject to the 1987 Regulations. These Regulations are made under specified provisions of the Food Safety (Northern Ireland) Order 1991 and, in so far as they cannot be made under those provisions, section 2(2) of the European Communities Act 1972. The provisions included under the 1972 Act are those which key into provisions of the 1987 Regulations (save where covered by Article 47(2)(a) of the 1991 Order) and revocations of Regulations made under section 2(2) of the 1972 Act.