STATUTORY INSTRUMENTS

2006 No. 1401

FOOD, ENGLAND

The Plastic Materials and Articles in Contact with Food (England) Regulations 2006

Made - - - - -	*23rd May 2006*
Laid before Parliament	*2nd June 2006*
Coming into force - -	*30th June 2006*

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The Secretary of State makes the following Regulations in exercise of the powers conferred by sections 16(2), 17(1) and (2), 26(1)(a) and (3), 31 and 48(1) of the Food Safety Act 1990(**a**), and now vested in her(**b**).

In accordance with section 48(4A) of that Act she has had regard to relevant advice given by the Food Standards Agency.

As required by Article 9 of Regulation (EC) No. 178/2002 of the European Parliament and of the Council laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety(**c**), there has been open and transparent public consultation during the preparation and evaluation of these Regulations.

PART 1

Preliminary

Title, application and commencement

1. These Regulations may be cited as the Plastic Materials and Articles in Contact with Food (England) Regulations 2006, apply in relation to England only and come into force on 30th June 2006.

Interpretation

2.—(1) In these Regulations —

"the Act" means the Food Safety Act 1990;

"authorised officer" means any person, whether or not an officer of the enforcement authority, who is authorised by it in writing to act in matters arising under these Regulations;

"BADGE" has the meaning given in Article 1(1)(a) of Regulation 1895/2005;

"BFDGE" has the meaning given in Article 1(1)(b) of Regulation 1895/2005;

"business" is to be construed in accordance with section 1(3) of the Act;

"capable" means capable as established under regulation 11;

"Directive 82/711" means Council Directive 82/711/EEC(**d**) laying down the basic rules necessary for testing migration of the constituents of plastic materials and articles intended to come into contact with foodstuffs, as last amended by Commission Directive 97/48/EC(**e**);

"Directive 85/572" means 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(**f**);

(**a**) 1990 c.16.

(**b**) Functions formerly exercisable by "the Ministers" (being, in relation to England and Wales and acting jointly, the Minister of Agriculture, Fisheries and Food and the Secretaries of State respectively concerned with health in England and food and health in Wales and, in relation to Scotland, the Secretary of State) are now exercisable in relation to England by the Secretary of State pursuant to paragraph 8 of Schedule 5 to the Food Standards Act 1999 (1999 c. 28). Those functions, so far as exercisable in relation to Wales, were transferred to the National Assembly for Wales by S.I. 1999/672 as read with section 40(3) of the 1999 Act. Those functions, so far as exercisable in relation to Scotland, were transferred to the Scottish Ministers by section 53 of the Scotland Act 1998 (1998 c. 46) as read with section 40(2) of the 1999 Act. Section 17(1) was amended by paragraph 12(a), section 17(2) by paragraph 12(b) and section 48 by paragraph 21, of Schedule 5 to the 1999 Act.

(**c**) OJ No. L31, 1.2.2002, p.1. That Regulation was last amended by Regulation (EC) No. 1642/2003 of the European Parliament and of the Council (OJ No. L245, 29.9.2003, p.4).

(**d**) OJ No. L297, 23.10.1982, p.26.

(**e**) OJ No. L222, 12.8.1997, p.10.

(**f**) OJ No. L372, 31.12.1985, p.14.

"Directive 88/388" means Council Directive 88/388/EEC on the approximation of the laws of the Member States relating to flavourings for use in foodstuffs and to source materials for their production(**a**);

"Directive 89/107" means Council Directive 89/107/EEC on the approximation of the laws of the Member States concerning food additives authorised in foodstuffs intended for human consumption(**b**);

"the Directive" means Commission Directive 2002/72/EC(**c**) relating to plastic materials and articles intended to come into contact with foodstuffs, as last amended by Commission Directive 2004/19/EC(**d**);

"EEA State" means a Member State (other than the United Kingdom), Norway, Iceland and Liechtenstein;

"EFSA" means the European Food Safety Authority;

"enforcement authority" means an authority having responsibility under regulation 14 for executing and enforcing these Regulations;

"food" is to be construed in accordance with section 16(5) of the Act;

"good technical quality" means good technical quality as regards the purity criteria;

"handling of food" means use in connection with the storage, preparation, packaging, sale or serving of food;

"import" means import in the course of a business;

"material or article" means a material or article falling within the definition of materials and articles in Article 1(2) of Regulation 1895/2005;

"monomer" means any substance that is included for the purposes of the Directive among monomers and other starting substances;

"NOGE" has the meaning given in Article 1(1)(c) of Regulation 1895/2005;

"the 1998 Regulations" means the Plastic Materials and Articles in Contact with Food Regulations 1998(**e**);

"the 2005 Regulations" means the Materials and Articles in Contact with Food (England) Regulations 2005(**f**);

"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;

"the Purity Directives" means Commission Directive 95/31/EC laying down specific criteria of purity concerning sweeteners for use in foodstuffs(**g**), Commission Directive 95/45/EC laying down purity criteria concerning colours for use in foodstuffs(**h**) and Commission Directive 96/77/EC laying down specific purity criteria for food additives other than colours or sweeteners(**i**);

"Regulation 1895/2005" means Commission Regulation (EC) No 1895/2005 on the restriction of use of certain epoxy derivatives in materials and articles intended to come into contact with food(**j**);

"sell" includes offer or expose for sale or have in possession for sale, and "sale" shall be construed accordingly;

(**a**) OJ No. L184, 15.7.1988, p.61.
(**b**) OJ No. L40, 11.2.1989, p. 27.
(**c**) OJ No. L220, 15.8.2002, p.18.
(**d**) OJ No. L71, 10.3.2004, p.8.
(**e**) S.I. 1998/1376, as amended in relation to England by S.I. 2000/3162, S.I. 2002/2364, S.I. 2002/3008, S.I. 2004/3113 and S.I. 2005/325.
(**f**) S.I.2005/898.
(**g**) OJ No. L178, 28.7.97, p.1, as last amended by Commission Directive 2004/46, OJ No. L114, 21.4.2004, p.15.
(**h**) OJ No. L226, 22.9.95, p.1, as last amended by Commission Directive 2004/47, OJ No. L113, 20.4.2004, p.24.
(**i**) OJ No. L339, 30.12.96, p.1, as last amended by Commission Directive 2003/95, OJ No. L283, 31.10.2003, p.71.
(**j**) OJ No. L302, 19.11.2005, p.28.

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

(3) Any other expression used in these Regulations and in the Directive, Directive 82/711, Directive 85/572 or Regulation 1895/2005 bears the same meaning in these Regulations as it bears in that Directive or Regulation.

PART 2

Requirements for Materials and Articles

Restriction on the use, sale or import of plastic materials and articles

3.—(1) No person may —

(a) use for the handling of food in the course of a business;

(b) sell for the purpose of handling of food; or

(c) import from anywhere other than an EEA State for the purpose of handling of food,

a plastic material or article which fails to meet the required standard.

(2) For the purposes of this regulation a plastic material or article fails to meet the required standard if —

(a) it has been manufactured with a prohibited monomer as described in regulation 4(2) or a prohibited additive as described in regulation 5(2); or

(b) it does not meet the required standards set out in regulation 6, 7, 8, 9 or 10.

Restriction on the use of monomers in the manufacture of plastic materials and articles

4.—(1) Subject to paragraphs (3), (4) and (5), no person may use any prohibited monomer in the manufacture of any plastic material or article.

(2) A prohibited monomer is any monomer which is not —

(a) of good technical quality;

(b) identified by PM/REF No, CAS No (if any) and name in columns 1, 2 and 3 respectively of the relevant section of Part 1 of Schedule 1; and

(c) used in accordance with any restrictions and specifications for that monomer set out or referred to in column 4 of that section.

(3) Paragraph (1) does not apply to the use of a monomer in the manufacture of any —

(a) surface coatings obtained from resinous or polymerised products in liquid, powder or dispersion form, including but not limited to varnishes, lacquers and paints;

(b) epoxy resins;

(c) adhesives and adhesion promoters; or

(d) 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 in question is a mixture which falls within paragraph 3(c) (relating to mixtures of authorised substances) of Annex II to the Directive and is of good technical quality.

(5) 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 mentioned in paragraph (2)(b) it shall be a defence for the person accused to prove that —

(a) each 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, or

(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,

and is of good technical quality.

(6) Part 2 of Schedule 1 has effect to supplement this regulation and Part 1 of that Schedule.

Restriction on the use of additives in the manufacture of plastic materials and articles

5.—(1) Subject to paragraph (3) no person may use in the manufacture of any plastic material or article any prohibited additive.

(2) A prohibited additive is —

(a) any additive identified by PM/REF No, CAS No (if any) and name in columns 1, 2 and 3 respectively of Part 1 or Part 2 of Schedule 2 which —

(i) is not of good technical quality, or

(ii) is not used in accordance with any restrictions and specifications for that additive set out in the corresponding entry in column 4 of Part 1 or Part 2 of that Schedule; or

(b) any food additive authorised by Directive 89/107 or any flavouring authorised by Directive 88/388 that migrates into food —

(i) in a quantity that has a technological function in the final food product, or

(ii) where the food is of a type for which the use of any such food additive or flavouring is so authorised, in quantities exceeding the limits provided for in Directive 89/107 or Directive 88/388 as appropriate, or in Schedule 2, whichever is the lower.

(3) 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 1 or Part 2 of Schedule 2 which is not of good technical quality, it shall be a defence for the person accused 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.

(4) Part 3 of Schedule 2 has effect to supplement this regulation and Parts 1 and 2 of that Schedule.

Required standard for non-migration of constituents of monomers

6.—(1) Subject to paragraph (2), where a migration limit expressed in mg/kg is indicated in column 4 of the relevant section of Part 1 of Schedule 1 in relation to any monomer, a plastic material or article manufactured from that monomer meets the required standard under this regulation if it is not capable of transferring constituents of that monomer to food with which the 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 in column 4 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 in column 4 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 can be filled, having a capacity of less than 500 millilitres or more than 10 litres, or

(ii) sheet, film or other plastic material or article which cannot be filled or for which it is impracticable to estimate the relationship between the surface area of the material or article in question and the quantity of food in contact with that surface area.

(2) A plastic material or article manufactured from any monomer for which a migration limit in mg/kg is expressed in column 4 of the relevant section of Part 1 of Schedule 1 is not deemed to be capable of transferring constituents of that monomer to food with which the plastic material or article may come into contact in quantities exceeding the appropriate limit in paragraph (1) if the only food with which that plastic material or article may come into contact is food to which regulation 9(3) applies.

Required standard for non-migration of constituents of additives

7.—(1) Subject to paragraph (2), where a migration limit expressed in mg/kg is indicated in column 4 of Part 1 or 2 of Schedule 2 in relation to any additive, a plastic material or article manufactured containing that additive meets the required standard under this regulation if it is not capable of transferring constituents of that additive to food with which the 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 indicated in column 4 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 in column 4 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 can be filled, having a capacity of less than 500 millilitres or more than 10 litres, or

(ii) sheet, film or other plastic material or article which cannot be filled or for which it is impracticable to estimate the relationship between the surface area of the material or article in question and the quantity of food in contact with that surface area.

(2) A plastic material or article manufactured containing an additive for which a migration limit in mg/kg is expressed in column 4 of Part 1 or Part 2 of Schedule 2 is not deemed to be capable of transferring constituents of that additive to food with which the plastic material or article may come into contact in quantities exceeding the appropriate limit in paragraph (1) if the only food with which that plastic material or article may come into contact is food to which regulation 9(3) applies.

Required standard for products obtained by bacterial fermentation

8. A product obtained by bacterial fermentation meets the required standard under this regulation if it is —

(a) of good technical quality;

(b) identified by PM/REF No, CAS No and name in columns 1, 2 and 3 respectively of Schedule 3: and

(c) in compliance with the restrictions and specifications set out in column 4 of that Schedule.

Required standards relating to overall migration limits

9.—(1) Subject to paragraph (3), a plastic material or article meets the required standard under this regulation if it is not capable of transferring its constituents to food with which it may come into contact in quantities exceeding the appropriate limit specified in paragraph (2).

(2) (a) In the case of any plastic material or article comprising —

(i) an article which is a container or comparable to a container or 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, or

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

the appropriate limit is an overall migration limit of 60 milligrams of constituents released per kilogram of food.

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

(3) For the purposes of this regulation a plastic material or article is not deemed to fail to meet the required standard under paragraph (1) if the only food with which that material or article may come into contact is food —

(a) which is specified in the table to Part 4 of Schedule 6; and

(b) where there is no "X" placed anywhere in the group of columns headed "Simulants to be used" opposite that food.

(4) In any proceedings for an offence under these Regulations where it is alleged that a plastic material or article does not comply with this regulation, the defences available in paragraph 6(2) and 7(2) of Schedule 5 shall be available as specified in those paragraphs.

Required standard for non-migration of primary aromatic amines

10.—(1) Subject to paragraph (3), a plastic material or article manufactured using isocyanates or colourants prepared by diazo-coupling meets the required standard under this regulation if it is not capable of transferring in a detectable quantity primary aromatic amines (expressed as aniline), not being primary aromatic amines listed in these Regulations, to food with which that plastic material or article may come into contact.

(2) Schedule 4 has effect for the purpose of prescribing, for certain items listed in Part 1 of Schedule 1, Part 1 or 2 of Schedule 2, or Schedule 3, the specifications for those items that are referred to in column 4 of the Part or Schedule concerned.

(3) In paragraph (1) a detectable quantity means a quantity which can be determined with an analytical method capable of achieving a detection limit of at least 0.02 milligrams per kilogram of food or food simulant (including analytical tolerance).

Method of testing the capability of plastic materials or articles to transfer constituents, and methods of analysis

11.—(1) A plastic material or article shall be treated as capable of transferring constituents to food with which it may come into contact to the extent that such capability is established —

(a) in any case other than one to which sub-paragraph (b) applies, and subject to Article 8.4 of the Directive (which may be applied on compliance with the conditions stated therein), by the verification methods specified in Schedule 5 (including the analytical tolerances referred to in paragraph 8 of that Schedule) and Schedule 6;

(b) in any case where the extent to which vinyl chloride, as identified in Part 1 of Schedule 1, is capable of such transfer falls to be established, by the method referred to in regulation 7(2) of the 2005 Regulations.

(2) In Schedules 5 and 6, references to migration or release of a substance are to 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) The specific migration of a constituent from a plastic material or article shall where applicable be determined in the manner specified in the relevant sub-paragraph of paragraph 8 of Annex II to the Directive.

(4) The quantity of a constituent in a plastic material or article shall where applicable be determined in the manner specified in the sub-paragraph of paragraph 8 of Annex II to the Directive relating to the term "QM(T)", "QMA" or "QMA(T)" as the case may be.

Labelling

12.—(1) At marketing stages other than the retail stage a person who is in possession of any plastic material or article must ensure that the plastic material or article is accompanied by a written declaration which —

(a) accords with the requirements of Article 16(1) of Regulation (EC) No. 1935/2004 of the European Parliament and of the Council(**a**); and

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(**a**) Regulation (EC) No 1935/2004 of the European Parliament and of the Council on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC (OJ No. L338, 13.11.2004, p.4).

(b) provides, in respect of substances that are subject to a restriction on quantities migrating into food, information obtained from experimental data or theoretical calculation concerning —

(i) the levels of migration specific to those substances;

(ii) where appropriate, purity criteria in accordance with the purity Directives.

(2) In establishing which descriptions of food a material or article may come into contact with, it is to be assumed until the contrary is proved that, for the purposes of these Regulations, if particulars are shown in relation to that material or article in accordance with paragraph (1)(a), those particulars are accurate and that unless the particulars so indicate, there are no restrictions on the intended conditions of contact.

Provisions relating to the use of certain epoxy derivatives (BADGE, BFDGE and NOGE)

13.—(1) In this regulation —

(a) any reference to a numbered Article is a reference to that Article in Regulation1895/2005;

(b) paragraphs (2) to (5) are subject to Article 1(3) (exception relating to certain storage containers and pipelines);

(c) for the purpose of Article 6(4) the competent authority is the authority identified in regulation 14.

(2) Subject to Article 6(1), (2) (transitional provisions) and (4) (labelling requirements), no person may —

(a) manufacture,

(b) use for the handling of food in the course of a business,

(c) sell for the purpose of the handling of food, or

(d) import for the purpose of the handling of food

any material or article in contravention of Article 3 or Article 4 (prohibitions relating to BFDGE and NOGE respectively).

(3) No person may manufacture any material or article in such a way as to contravene the requirements of Article 2 (controls on the migration of BADGE from materials and articles).

(4) Subject to Article 6(1), no person may —

(a) use for the handling of food in the course of a business,

(b) sell for the purpose of the handling of food, or

(c) import for the purpose of the handling of food

any material or article that has been manufactured in such a way as to contravene the requirements of Article 2.

(5) Subject to Article 6(3) (transitional provisions relating to materials and articles brought into contact with food before 1st January 2007), no person shall contravene or fail to comply with the requirements of Article 5 (obligations regarding the provision of a written statement when marketing materials or articles containing BADGE or its derivatives).

(6) No person shall without reasonable excuse fail to comply with a request made under Article 6(4) (requirement to disclose date of filling to competent authority).

PART 3

Execution and Enforcement

Enforcement

14. Each food authority in its area and each port health authority in its district shall execute and enforce —

(a) the provisions of Regulation 1895/2005 mentioned in regulation 13, and

(b) these Regulations.

Offences and Penalties

15.—(1) Any person who —

(a) contravenes or fails to comply with regulation 3(1), 4(1), 5(1), 12(1) or 13(2) to (5);

(b) intentionally obstructs any person acting in the execution of Regulation 1895/2005 or these Regulations;

(c) contravenes regulation 13(6) or, without reasonable excuse, otherwise fails to give to any person acting in the execution of Regulation 1895/2005 or these Regulations any assistance or information which that person may reasonably require; or

(d) in purported compliance with any requirement mentioned in sub-paragraph (c), knowingly or recklessly supplies information that is false or misleading in any material particular,

is guilty of an offence.

(2) Anyone convicted of an offence under these Regulations is liable —

(a) in the case of an offence under paragraph (1)(a) —

(i) on conviction on indictment to a term of imprisonment not exceeding two years or to a fine or both;

(ii) on summary conviction to a term of imprisonment not exceeding six months or to a fine not exceeding the statutory maximum or both;

(b) in the case of any other offence under these Regulations to a term of imprisonment not exceeding three months or to a fine not exceeding level five on the standard scale or both.

(3) Nothing in paragraph (1)(c) is to be construed as requiring any person to answer any question or give any information if to do so might incriminate him.

(4) Where an offence under these Regulations which has been committed by a body corporate or a Scottish partnership is proved to have been committed with the consent or connivance of or to be attributable to any neglect on the part of —

(a) any director, manager, secretary or other similar officer of the body corporate or any partner of the Scottish partnership, or

(b) any person purporting to act in such a capacity,

he as well as the body corporate or, as the case may be, the Scottish partnership shall be deemed to be guilty of that offence and liable to be proceeded against and punished accordingly.

(5) No prosecution for an offence under these Regulations shall be begun after the expiry of three years from the commission of the offence or one year from its discovery by the prosecutor, whichever is the earlier.

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

General defences

16.—(1) In any proceedings for an offence under these Regulations it shall, subject to paragraph (5), be a defence for the person accused 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.

(2) Without prejudice to the generality of paragraph (1), a person accused of an offence under these Regulations who did not —

(a) prepare the plastic material or article or, as the case may be, the material or article in respect of which the offence is alleged to have been committed; nor

(b) import it into the United Kingdom,

shall be taken to have established the defence provided by paragraph (1) if he satisfies the requirements of paragraphs (3) and (4).

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

(a) that the commission of the offence was due to the act or default of some other person who was not under his control, or to reliance on information supplied by such a person;

(b) that either —

(i) he carried out all such checks of the plastic material or article or material or article in question as were reasonable in all the circumstances, or

(ii) it was reasonable in all the circumstances for him to rely on checks carried out by the person who supplied him with the plastic material or article or the material or article in question; and

(c) that he did not know and had no reason to suspect at the time the offence was committed that his act or omission would amount to an offence under these Regulations.

(4) 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 the act or default of some other person who was not under his control, or to reasonable reliance on information supplied by such a person;

(b) that the sale of which the 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 the offence was committed that his act or omission would amount to an offence under these Regulations.

(5) If in any case the defence provided by this regulation involves the allegation that the commission of the offence was due to the act or default of another person, or to reliance on information supplied by another person, the person accused 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 the court in connection with the alleged offence, within one month of his first such appearance,

he has served on the prosecutor a written notice giving such information identifying or assisting in the identification of that other person as was then in his possession.

Transitional defences and savings

17. Not withstanding the revocations made in regulation 24, in relation to any plastic material or article —

(a) manufactured before the 1st July 1998, the defence in regulation 3(3) of the 1998 Regulations;

(b) manufactured or imported into the European Community before 1st January 2003, the defence in regulation 10(15) of the 1998 Regulations;

(c) put into free circulation in the European Community before 30th November 2002, the defence in regulation 10(16) of the 1998 Regulations;

(d) manufactured or imported into the European Community before 1st March 2004, the defence in regulation 10(21)(a) of the 1998 Regulations;

(e) manufactured or imported into the European Community before 1st March 2003, the defence in regulation 10(21)(b) of the 1998 Regulations;

(f) containing azodicarbonamide and brought into contact with food before 2nd August 2005, the defence in regulation 10(23) of the 1998 Regulations; or

(g) manufactured or imported into the European Community before 1st March 2006, the defence in regulation 10(25) of the 1998 Regulations,

shall apply in relation to offences under these Regulations in like manner as it applied to offences under the equivalent provisions in those Regulations.

Procedure where a sample is to be analysed

18.—(1) An authorised officer who has procured a sample under section 29 of the Act and who considers it should be analysed shall divide the sample into three parts.

(2) If the sample consists of sealed containers and opening them would, in the opinion of the authorised officer, impede a proper analysis, the authorised officer shall divide the sample into parts by putting the containers into three lots, and each lot shall be treated as being a part.

(3) The authorised officer shall —

(a) if necessary place each part in a suitable container and seal it;

(b) mark each part or container;

(c) as soon as reasonably practicable, give one part to the owner and notify him in writing that the sample will be analysed;

(d) submit one part for analysis in accordance with section 30 of the Act; and

(e) retain one part for future submission under regulation 19.

Secondary analysis by the Government Chemist

19.—(1) Where a sample has been retained under regulation 18 and —

(a) proceedings are intended to be or have been commenced against a person for an offence under these Regulations; and

(b) the prosecution intends to adduce as evidence the result of the analysis mentioned above,

paragraphs (2) to (7) apply.

(2) The authorised officer —

(a) may of his own volition;

(b) shall if requested by the prosecutor (if a person other than the authorised officer);

(c) shall if the court so orders; or

(d) shall (subject to paragraph (6)) if requested by the defendant,

send the retained part of the sample to the Government Chemist for analysis.

(3) The Government Chemist shall analyse the part sent to him under paragraph (2) and send to the authorised officer a certificate of analysis.

(4) Any certificate of the results of testing transmitted by the Government Chemist under this regulation shall be signed by or on behalf of him, but the testing may be carried out by any person under the direction of the person who signs the certificate.

(5) The authorised officer shall immediately on receipt supply the prosecutor (if a person other than the authorised officer) and the defendant with a copy of the Government Chemist's certificate of analysis.

(6) Where a request is made under paragraph (2)(d) the authorised officer may give notice in writing to the defendant requesting payment of a fee specified in the notice to defray some or all of the Government Chemist's charges for performing the functions under paragraph (3), and in the absence of agreement by the defendant to pay the fee specified in the notice the authorised officer may refuse to comply with the request.

(7) In this regulation "defendant" includes a prospective defendant.

PART 4

Application for Authorisation

Applications for inclusion of an additive in the Community list of authorised additives

20.—(1) This regulation applies where a person wishes to make an application for the inclusion of an eligible additive in the Community list referred to in Article 4 of the Directive.

(2) The application mentioned in paragraph (1), including supporting data, must be made to EFSA before 1st January 2007.

(3) If during examination of the data referred to in paragraph (2), EFSA calls for supplementary information, the eligible additive may, if otherwise permitted to be used under English law, continue to be so used until EFSA has issued an opinion, provided the supplementary opinion is submitted within the time limits specified by EFSA.

(4) For the purposes of this regulation, an eligible additive is one whose use is permitted in one or more Member States before 1st January 2007.

PART 5

General and Supplementary

Application of provisions of the Act

21. The following provisions of the Act shall apply for the purposes of these Regulations as they apply for the purposes of the Act —

(a) section 3 (presumption that food is intended for human consumption);

(b) section 30(8) (relating to documentary evidence);

(c) section 36 (offences by bodies corporate);

(d) section 36A (offences by Scottish partnerships);

(e) section 44 (protection of officers acting in good faith).

Amendment of the Food Safety (Sampling and Qualifications) Regulations 1990

22. In the Food Safety (Sampling and Qualifications) Regulations 1990(**a**), in Schedule 1 (provisions to which those Regulations do not apply) for the title and reference of the 1998 Regulations substitute the title and reference of these Regulations.

Amendments to the Materials and Articles in Contact with Food (England) Regulations 2005

23.—(1) The 2005 Regulations are amended in accordance with paragraphs (2) to (6).

(2) In regulation 2(1) —

(a) omit the definition of "the 1998 Regulations";

(b) after the definition of "sell" add the following definition —

""the 2006 Regulations" means the Plastic Materials and Articles in Contact with Food (England) Regulations 2006(**b**)."

(3) In regulation 8(4), for the expression "Schedules 1, 2 or 2A to the 1998 Regulations" substitute "Schedules 1, 2 or 3 to the 2006 Regulations".

(4) In regulation 9(3) —

(**a**) S.I. 1990/2463
(**b**) S.I. 2006/1401

(a) for the expression "Part I of Schedule 1 to the 1998 Regulations" substitute "Part 1 of Schedule 1 to the 2006 Regulations"; and

(b) in sub-paragraph (b) for "Part II" substitute "Part 2".

(5) In regulation 9(5), for the expression "Schedules 3 and 4 of the 1998 Regulations as read with regulation 6 of those Regulations" substitute "Schedules 5 and 6 of the 2006 Regulations as read with regulation 11 of those Regulations".

(6) In regulation 10(2), for the expression "proceedings for an offence under regulation" substitute "proceedings for an offence of contravening regulation".

Revocations

24. The following Regulations or parts thereof are revoked —

(a) the 1998 Regulations in so far as they apply in relation to England;

(b) the Plastic Materials and Articles in Contact with Food (Amendment) (England) Regulations 2000(**a**);

(c) the Plastic Materials and Articles in Contact with Food (Amendment) (England) Regulations 2002(**b**);

(d) the Plastic Materials and Articles in Contact with Food (Amendment) (England) (No.2) Regulations 2002(**c**);

(e) the Plastic Materials and Articles in Contact with Food (Amendment) (England) Regulations 2004(**d**);

(f) the Plastic Materials and Articles in Contact with Food (Amendment) (England) Regulations 2005(**e**);

(g) regulation 15 of the 2005 Regulations.

Signed by authority of the Secretary of State for Health

Caroline Flint
Minister of State,
Department of Health

23rd May 2006

(**a**) S.I. 2000/3162
(**b**) S.I. 2002/2364
(**c**) S.I. 2002/3008
(**d**) S.I. 2004/3113
(**e**) S.I. 2005/325

SCHEDULE 1

Regulations 4 and 6

Authorised Monomers

PART 1

List of Monomers with Restrictions and Specifications

	1 *PM/REF No*	*2* *CAS No*	3 *Name*	*4* *Restrictions and specifications*
1	10030	000514-10-3	Abietic acid	
2	10060	000075-07-0	Acetaldehyde	SML(T) = 6mg/kg (2)
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 12mg/kg
5	10150	000108-24-7	Acetic anhydride	
6	10210	000074-86-2	Acetylene	
6A	10599/90A	061788-89-4	Acids, fatty, unsaturated (C_{18}), dimers, distilled	QMA(T) = 0.05 mg/6 dm^2 (27)
6B	10599/91	061788-89-4	Acids, fatty, unsaturated (C_{18}), dimers, non distilled	QMA(T) = 0.05 mg/6 dm^2 (27)
6C	10599/92A	068783-41-5	Acids, fatty, unsaturated (C_{18}), dimers, hydrogenated, distilled	QMA(T) = 0.05 mg/6 dm^2 (27)
6D	10599/93	068783-41-5	Acids, fatty, unsaturated (C_{18}), dimers, hydrogenated, distilled	QMA(T) = 0.05 mg/6 dm^2 (27)
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, *n*-butyl ester	
12	10810	002998-08-5	Acrylic acid, *sec*-butyl ester	
13	10840	001663-39-4	Acrylic acid, *tert*-butyl ester	
13A	11000	050976-02-8	Acrylic acid, dicyclopentaidien-yl ester	The quantity of this substance in the finished plastic material or article shall not exceed 0.05 mg/6 m^2
13B	11245	002156-97-0	Acrylic acid, dodecyl ester	The specific migration of this substance shall

				not exceed 0.05 mg/kg (1)
14	11470	000140-88-5	Acrylic acid, ethyl ester	
15	As item 19	000818-61-1	Acrylic acid, hydroxyethyl ester	
15A	11530	000999-61-1	Acrylic acid, 2-hydroxypropyl ester	QMA = 0.05 mg/6 dm^2 for the sum of acrylic acid, 2-hydroxypropoyl ester and acrylic acid, 2-hydroxyisopropyl ester and in compliance with the specifications laid down in Schedule 4
16	11590	000106-63-8	Acrylic acid, asobutyl 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, n-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	
23A	12265	004074-90-2	Adipic acid, divinyl ester	The quantity of this substance in the finished plastic material or article shall not exceed 5 mg/kg. For use only as comonomer
24	12280	002035-75-8	Adipic anhydride	
25	12310	-	Albumin	
26	12340	-	Albumin, coagulated by formaldehyde	
27	12375	-	Alcohols, aliphatic, monohydric, saturated, linear, primary (C_4-C_{22})	
28	12670	002855-13-2	1-Amino-3-aminomethyl-3, 5, 5-trimethylcyclohexane	The specific migration of this substance shall not exceed 6 mg/kg
28A	12761	000693-57-2	12-Aminododecanoic acid	The specific migration of this substance shall not exceed 0.05 mg/kg
28B	12763	000141-43-5	2-Aminoethanol	SML = 0.05 mg/kg. Not for use in polymers contacting foods for which simulant D is laid down in Council

				Directive 85/572/EEC and for indirect food contact only, behind the PET layer
28C	12765	844354-12-8	N-(2-aminoethyl)-beta-alanine, sodium salt	SML – 0.05 mg/kg
29	12788	002432-99-7	11-Aminoundecanoic acid	The specific migration of this substance shall not exceed 5mg/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-Benzenedi-methanamine	The specific migration of this substance shall not exceed 0.05 mg/kg
33A	13060	004422-95-1	1,3,5-Benzenetricarboxylic acid trichloride	The quantity of this substance in the finished plastic material or article shall not exceed 0.05 mg/6 m^2 (measured as 1,3,5-benzenetricarboxylic acid)
33B	13075	000091-76-9	Benzoguanamine	(see "2,4-Diamino-6-Phenyl-1,3,5-Triazine")
34	13090	000065-85-0	Benzoic acid	
35	13150	000100-51-6	Benzyl alcohol	
35A	13180	000498-66-8	Bicyclo [2.2.1] hept-2-ene (= Norbornene)	The specific migration of this substance shall not exceed 0.05 mg/kg
35B	13210	001761-71-3	Bis (4-aminocyclohexyl) methane	The specific migration of this substance shall not exceed 0.05 mg/kg
36	As item 79	000111-46-6	Bis (2-hydroxyethyl) ether	As item 79
37	As item 217	000077-99-6	2,2-Bis (hydroxymethylbutan-1-ol)	As item 217
37A	13323	000102-40-9	1,3-Bis (2-hydroxyethoxy) benzene	SML = 0.05 mg/kg
38	13390	000105-08-8	1,4-Bis (hydroxymethyl) – cyclohexane	
38A	13395	004767-03-7	2,2-Bis (hydroxymethyl) propionic acid	QMA = 0.05 mg/6 dm^2
39	13480	000080-05-7	2,2-Bis (4-hydroxyphenyl) propane	SML(T) = 0.6 mg/kg (28)
40	13510	001675-54-3	2,2-Bis (4-hydroxyphenyl) propane bis (2,3-epoxypropyl) ether	Use must be in accordance with Regulation 1895/2005
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	13560	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
47A	13617	000080-09-1	Bisphenol S	As item 86A
47B	13620	010043-35-3	Boric acid	SML(T) – 6 mg/kg (22) (expressed as boron) without prejudice to the provisions of Directive 98/83/EC on water for human consumption
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 not be detectable (when measured by a method with a limit of detection of 0.02mg/kg, analytical tolerance included)
49	13690	000107-88-0	1,3-Butanediol	
49A	13720	000110-63-4	1,4-Butanediol	SML(T) = 0.05 mg/kg (23)
49B	13780	002425-79-8	1,4-Butanediol bis(2,3-epoxypropyl) ether	The quantity of this substance in the finished plastic material or article shall not exceed 1 mg/kg (expressed as epoxy group, molecular weight equal to 43)
49C	13810	000505-65-7	1,4-Butanediol formal	QMA = 0.05 mg/6 dm^2
50	13840	000071-36-3	Butan-1-ol	
51	13870	000106-98-9	But-1-ene	
52	13900	000107-01-7	But-2-ene	
52A	13932	000598-32-3	3-Buten-2-ol	QMA = ND (DL = 0.02 mg/6 dm^2). To be used only as a co-monomer for the preparation of polymeric additive
52B	14020	000098-54-4	4-tert-Butylphenol	The specific migration of this substance shall not exceed 0.05 mg/kg
53	14110	000123-72-8	Butyraldehyde	
54	14140	000107-92-6	Butyric acid	
55	14170	000106-31-0	Butyric acid anhydride	
56	14200	000105-60-2	Caprolactam	SML(T) = 15 mg/kg (5)

57	14230	002123-24-2	Caprolactam, sodium salt	SML(T) = 15 mg/kg (5) (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	Caster oil	
62	14500	009004-34-6	Cellulose	
63	14530	007782-50-5	Chlorine	
63A	14650	000079-38-9	Chlorotrifluorethylene	QMA = 0.5 mg/6 dm^2
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	*m*-Cresol	
67	14740	000095-48-7	*o*-Cresol	
68	14770	000106-44-5	*p*-Cresol	
68MA	14800	003724-65-0	Crotonic acid	QMA(T) = 0.05 mg/6 dm^2 (33)
68A	14841	000599-64-4	4-Cumylphenol	The specific migration of this substance shall not exceed 0.05 mg/kg
69	As item 38	000105-08-8	1,4-Cyclohexanedimethanol	
70	14950	003173-53-3	Cyclohexyl isocyanate	QM(T) = 1mg/kg in FP (expressed as NCO) (26)
70A	15030	000931-88-4	Cyclooctene	SML = 0.05 mg/kg. For use only in polymers contacting foods for which simulant A is laid down in Council Directive 85/572/EEC
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	
73A	15130	000872-05-9	1-Decene	The specific migration of this substance shall not exceed 0.05 mg/kg
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
76A	15310	000091-76-9	2,4-Diamino-6-phenyl-1,3,5-triazine	QMA = 5 mg/6 dm^2
77	15565	000106-46-7	1,4-Dichlorobenzene	The specific migration of this substance shall not exceed 12 mg/kg
77A	15610	000080-07-9	4,4'-Dichlorodiphenyl sulphone	SML = 0.05 mg/kg
78	15700	005124-30-1	Dicyclohexylmethane-4,4'	QM(T) = 1mg/kg

			– diisocyanate	(expressed as NCO (25)
79	15760	000111-46-6	Diethylene glycol	SML(T) = 30 mg/kg (3)
80	15790	000111-40-0	Diethylenetriamine	The specific migration of this substance shall 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 shall not exceed 2.4 mg/kg
84	15940	000123-31-9	1,4-Dihydroxybenzene	The specific migration of this shall not exceed 0.6 mg/kg
85	15970	000611-99-4	4,4'-Dihydroxybenzophenone	SML(T) = 6 mg/kg (14)
86	16000	000092-88-6	4,4'-Dihydroxybiphenyl	The specific migration of this substance shall not exceed 6 mg/kg
86A	16090	000080-09-01	4,4'-Dihydroxydiphenyl sulphone	SML = 0.05 mg/kg
87	16150	000108-01-0	Dimethylaminoethanol	The specific migration of this substance shall not exceed 18 mg/kg
87A	16210	006864-37-5	3,3'-Dimethyl-4,4'-diaminodicyclohexyl methane	SML = 0.05 mg/kg (32). To be used only in polyamides
88	16240	000091-97-4	3,3'-Dimethyl-4,4'-diisocyanatobiphenyl	QM(T) = 1 mg/kg (expressed as NCO) (25)
88A	16360	000576-26-1	2,6-Dimethylphenol	The specific migration of this substance shall not exceed 0.05 mg/kg
88B	16390	000126-30-7	2,2-Dimethyl-1,3-propanediol	SML = 0.05 mg/kg
88C	16450	000646-06-0	1,3-Dioxolane	The specific migration of this substance shall not exceed 0.05 mg/kg
89	16480	000126-58-9	Dipentaerythritol	
89A	16540	000102-09-0	Diphenyl carbonate	SML = 0.05 mg/kg
90	16570	004128-73-8	Diphenylether-4,4'-diisocyanate	QM(T) = 1mg/kg (expressed as NCO) (25)
91	16600	005873-54-1	Diphenylmethane-2,4'-diisocyanate	QM(T) = 1 mg/kg (expressed as NCO) (25)
92	16630	000101-68-8	Diphenylmethane-4,4'-diisocyanate	QM(T) – 1 mg/kg (expressed as NCO) (25)
92A	16650	000127-63-9	Diphenyl sulphone	SML(T) = 3 mg/kg (24)

93	16660	000110-98-5	Dipropyleneglycol	
93A	16690	001321-74-0	Divinylbenzene	QMA = 0.01 mg/6 dm2 or SML = ND (DL = 0.02 mg/kg, analytical tolerance included) for the sum of divinylbenzene and ethylvinylbenzene and in compliance with the specifications laid down in Schedule 4
93B	16694	013811-50-2	N,N'-Divinly-2-imidazolidinone	The quantity of this substance in the finished plastic material or article shall not exceed 5 mg/kg
93C	16697	000693-23-2	n-Dodecanedioic Acid	
93D	16704	000112-41-4	1-Dodecene	The specific migration of this substance shall not exceed 0.05 mg/kg
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	SML(T) = 30 mg/kg (3)
99	17005	000151-56-4	Ethyleneamine	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	000104-76-7	2-Ethylhexan-1-ol	The specific migration of this substance shall not exceed 30 mg/kg
101A	17110	016219-75-3	5-Ethylidenebicyclo[2,2,1] hept-2-ene	QMA = 0.05 mg/6 dm^2. The ratio surface/quantity of food shall be lower than 2 dm^2/kg
102	17160	000097-53-0	Eugenol	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)
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	SML(T) = 15mg/kg (21)
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	
111A	18220	068564-88-5	N-Heptylaminoundecanoic acid	The specific migration of this substance shall not exceed 0.05 mg/kg
112	18250	000115-28-6	Hexachloroendomethylene-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	Hexachloroendomethylene-tetrahydrophthalic anhydride	The specific migration of this substance shall not be 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 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	QM(T) = 1 mg/kg (expressed as NCO) (25)
118	18670	000100-97-0	Hexamethylenetetramine	SML(T) = 15 mg/kg (expressed as formaldehyde) (21)
118MA	18700	000629-11-8	1,6-Hexanediol	SML = 0.05 mg/kg
118A	18820	000592-41-6	1-Hexene	The specific migration of this substance shall not exceed 3 mg/kg
119	As item 84	000123-31-9	Hydroquinone	As item 84
120	18880	000099-96-7	p-Hydroxybenzoic acid	
120ZA	18896	001679-51-2	4-(Hydroxymethyl)-1-cyclohexene	SML = 0.05 mg/kg
120A	18897	016712-64-4	6-Hydroxy-2-	SML = 0.05 mg/kg

			naphthalenecarboxylic acid	
120B	18898	000103-90-2	N-(4-Hydroxyphenyl) acetamide	SML = 0.05 mg/kg
121	19000	000115-11-7	Isobutene	
121A	19060	000109-53-5	Isobutyl vinyl ether	The quantity of this substance in the finished plastic material or article shall not exceed 5 mg/kg
121B	19110	004098-71-9	1-Isocyanato-3-isocyanatomethyl-3,5,5-trimethylcyclohexane	QM(T) = 1 mg/kg (expressed as NCO) (25)
121C	19150	000121-91-5	Isophthalic acid	The specific migration of this substance shall not exceed 5 mg/kg
122	19210	001459-93-4	Isophthalic acid, dimethyl ester	The specific migration of this substance shall not exceed 0.05 mg/kg
122A	19243	000780-79-5	Isoprene	As item 145A
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	
126A	19490	000947-04-6	Laurolactam	SML = 5 mg/kg
127	19510	011132-73-3	Lignocellulose	
128	19540	000110-16-7	Maleic acid	SML(T) = 30 mg/kg (4)
129	19960	000108-31-6	Maleic anhydride	SML(T) = 30 mg/kg (4) (expressed as maleic acid)
130	As item 215	000108-78-1	Melamine	As item 215
130A	19990	000079-39-0	Methacrylamide	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)
131	20020	000079-41-4	Methacrylic acid	
131A	20050	000096-05-9	Methacrylic acid, allyl ester	The specific migration of this substance shall not exceed 0.05 mg/kg
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, *sec*-butyl ester	
135	20170	000585-07-9	Methacrylic acid, *tert*-butyl ester	
135A	20260	000101-43-9	Methacrylic acid, cyclohexyl ester	SML = 0.05 mg./kg
135B	20410	002082-81-7	Methacrylic acid, diester with 1,4-butanediol	SML = 0.05 mg/kg

135BM	20440	000097-90-5	Methacrylic acid, diester with ethyleneglycol	SML = 0.05 mg/kg
135C	20530	002867-47-2	Methacrylic acid, 2-(dimethylamino) ethyl ester	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)
135D	20590	000106-91-2	Methacrylic acid, 2,3-epoxypropyl ester	QMA = 0.02 mg/6 dm^2
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	
142A	21400	054276-35-6	Methacrylic acid, sulphopropyl ester	QMA = 0.05 mg/6 dm^2
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)
144A	21520	001561-92-8	Methallylsulphonic acid, sodium salt	SML = 5 mg/kg
145	21550	000067-56-1	Methanol	
145A	21640	000078-79-5	2-Methyl-1,3-butadiene	QM = 1 mg/kg in FP or SML = ND (DL = 0.02 mg/kg, analytical tolerance included)
145B	21730	000563-45-1	3-Methyl-1-butene	The quantity of this substance in the finished plastic material or article shall not exceed 0.006 mg/ 6 dm^2. For use only in polypropylene
145C	21765	106246-33-7	4,4'-Methylenebis (3-chloro-2,6-diethylaniline)	QMA = 0.05 mg/6 dm^2

145D	21821	000505-65-7	1,4-(Methylenedioxy) butane	As item 49C
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-Methyl-1-pentene	SML = 0.05 mg/kg
147A	22331	025513-64-8	Mixture of (35-45% w/w) 1,6-diamino-2,2,4-trimethylhexane and (55-65% w/w) 1,6-diamino-2,4,4-trimethylhexane	QMA = 5 mg/6 dm^2
147B	22332	-	Mixture of (40% w/w) 2,2,4-trimethylhexane-1, 6-diisocyanate and (60% w/w) 2,4,4-trimethylhexane-1,6-diisocyanate	QM(T) = 1 mg/kg (expressed as NCO) (26)
148	22350	000544-63-8	Myristic acid	
148A	22360	001141-38-4	2,6-Naphthalenedicarboxylic acid	SML = 5 mg/kg
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	QM(T) = 1 mg/kg (expressed as NCO) (25)
150A	22437	000126-30-7	Neopentylglycol	As item 88B
151	22450	009004-70-0	Nitrocellulose	
152	22480	000143-08-8	Nonan-1-ol	
152A	22550	000498-66-8	Norbornene	The specific migration of this substance shall not exceed 0.05 mg/kg
153	22570	000112-96-9	Octadecyl isocyanate	QM(T) = 1mg/kg (expressed as NCO) (25)
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	
156XA	22775	000144-62-7	Oxalic acid	SML(T) = 6 mg/kg (29)
156A	22778	007456-68-0	4,4'-Oxybis (benzenesulphonyl azide	QMA = 0.05 mg/6 dm^2
157	22780	000057-10-3	Palmitic acid	
158	22840	000115-77-5	Pentaerythritol	
159	22870	000071-41-0	Pentan-1-ol	
159A	22900	000109-67-1	1-Pentene	SML = 5 mg/kg
159B	22937	001623-05-8	Perfluoropropyl perfluorovinyl ether	The specific migration of this substance shall not exceed 0.05 mg/kg

160	22960	000108-95-2	Phenol	
161	23050	000108-45-2	1,3-Phenylenediamine	SML = ND (DL = 0.02 mg/kg. Analytical tolerance included)
161A	23070	000102-39-6	(1,3-Phenylenedioxy) diacetic acid	QMA = 0.05 mg/6 dm^2
162	As item 60	000075-44-5	Phosgene	As item 60
163	23170	007665-38-2	Phosphoric acid	
163A	23175	000122-52-1	Phosphorous acid, triethyl ester	The quantity of this substance in the finished plastic material or article shall be not detectable (when measured by a method with a detection limit of 1 mg/kg)
164	As item 204	-	Phthalic acid	As item 204
165	23200	000088-99-3	o-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	*Alpha*-Pinene	
169	23500	000127-91-3	*Beta*-Pinene	
169A	23547	009016-00-6 063148-62-9	Polydimethylsiloxane (Mw >6800)	In compliance with the specifications laid down in Schedule 4
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	
173A	23770	000504-63-2	1,3-Propanediol	The specific migration of this substance shall not exceed 0.05 mg/kg
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	
177A	23920	000105-38-4	Propionic acid, vinyl ester	SML(T) = 6 mg/kg (2) (expressed as acetaldehyde)
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	000128-80-9	Pyrocatechol	As item 82

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
184A	24073	000101-90-6	Resorcinol diglycidyl ether	QMA = 0.005 mg/6 dm^2. Not for use in polymers contacting foods for which simulant D is laid down in Council Directive 85/572/EEC and for indirect food contact only, behind the PET layer
185	24100	008050-09-7	Rosin	
186	24130	008050-09-7	Rosin gum	
187	24160	008052-10-6	Rosin tall oil	
188	24190	065997-05-9	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	
197	24550	000057-11-4	Stearic acid	
198	24610	000100-42-5	Styrene	
198A	24760	026914-43-2	Styrenesulphonic acid	The specific migration of this substance shall not exceed 0.05 mg/kg
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 acid, monosodium salt, dimethyl ester	The specific migration of this substance shall not exceed 0.05 mg/kg
204	24910	000100-21-0	Terephthalic acid	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 along 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	
206A	25080	001120-36-1	1-Tetradecene	The specific migration of this substance shall not exceed 0.05 mg/kg
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	N,N,N'N'-Tetrakis (2-hydroxypropyl)-ethylenediamine	
211	25210	000584-84-9	2,4-Toluene diisocyanate	QM(T) = 1 mg/kg (expressed as NCO) (25)
212	25240	000091-08-7	2,6-Toluene diisocyanate	QM(T) = 1 mg/kg (expressed as NCO) (25)
213	25270	026747-90-0	2,4-Toluene diisocyanate dimer	QM(T) = 1 mg/kg (expressed as NCO) (25)
214	25360		Trialkyl (C_5-C_{15}) acetic acid, 2,3-epoxypropyl ester	The quantity of this substance in the finished plastic material or article shall not exceed 1 mg/kg (expressed as epoxy group, molecular weight = 43)
214A	25380		Trialkyl acetic acid (C_7 – C_{17}), vinyl esters (= vinyl versatate)	QMA = 0.05 mg/6 dm^2
214B	25385	000102-70-5	Triallylamine	In compliance with the specifications laid down in Schedule 4
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
215A	25450	026896-48-0	Tricyclodecanedime-thanol	SML = 0.05 mg/kg
216	25510	000112-27-6	Triethylene glycol	
217	25600	000077-99-6	1,1,1-Trimethylolpropane	The specific migration of this substance shall not exceed 6 mg/kg
217A	25840	003290-92-4	1,1,1-trimethylolpropane trimethacrylate	SML = 0.05 mg/kg
217B	25900	000110-88-3	Trioxane	SML = 0.05 mg/kg
218	25910	024800-44-0	Tripropylene glycol	
218A	25927	027955-94-8	1,1,1-Tris (4-hydroxyphenol) ethane	The quantity of this substance in the finished plastic material or article shall not exceed 0.5 mg/kg. For

				use only in polycarbonates
219	25960	000057-13-6	Urea	
220	26050	000075-01-4	Vinyl chloride	The restrictions are those in regulation 6 (1) of the 2005 Regulations when analysed by the method referred to in regulation 7 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
223	26155	001072-63-5	1-Vinylimidazole	The quantity of this substance in the finished plastic material or article shall not exceed 5 mg/kg
224	26170	003195-78-6	N-Vinyl-N-methylacetamide	The quantity of this substance in the finished plastic material or article shall not exceed 2 mg/kg
225	26320	002768-02-7	Vinyltrimethoxysilane	The quantity of this substance in the finished plastic material or article shall not exceed 5 mg/kg
226	26360	007732-18-5	Water	In compliance with Directive 98/83/EC on the quality of water intended for human consumption

PART 2

Supplementary

1. In regulation 4 and Part 1 of this Schedule—

(a) the PM/REF number. of any substance is its EEC packaging material reference number;

(b) the CAS number of any substance is its CAS (Chemical Abstracts Service) Registry Number;

(c) the name of any substance is its chemical name, and to the extent that there is any inconsistency between the CAS number and the name, the name shall take precedence over the CAS number; and

(d) references to specific migration are to be taken to mean specific migration as measured in accordance with Schedules 5 and 6.

2. If a substance appearing in Part 1 of this Schedule as an individual compound also falls within a generic term which appears therein, any restriction applying to that substance shall be that indicated for the individual compound and the entry applying to the generic term shall be treated as varied to such extent as is necessary.

3.—(1) The items identified in Part 1 of this Schedule shall be taken to include—

(a) substances undergoing polymerisation (including polycondensation, polyaddition or any other similar process) to manufacture macromolecules;

(b) natural or synthetic macromolecular substances used in the manufacture of modified macromolecules, if the monomers required to synthesise them are not so identified; and

(c) substances used to modify existing natural or synthetic macromolecular substances.

(2) If a substance identified in Part 1 of this Schedule 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 of aluminium, ammonium, calcium, iron, magnesium, potassium, sodium or zinc) then any such 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 1 of this Schedule 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.

4. Where an entry in column 4 of Part 1 of this Schedule (restrictions and specifications) includes a bracketed number, that entry shall be subject to a note relating to that number as follows, the following bracketed numbers corresponding with those appearing in that Part —

(1): Warning: there is a risk that the specific migration limit could be exceeded in fatty food simulants.

(2): SML(T) in this case means that the restriction shall not be exceeded by the sum of the migration of the substances having PM/REF Nos. 10060 and 23920.

(3): SML(T) in this case means that the restriction shall not be exceeded by the sum of the migration of the substances having PM/REF Nos. 15760, 16990, 47680, 53650 and 89440.

(4): SML(T) in this case means that the restriction shall not be exceeded by the sum of the migration of the substances having PM/REF Nos. 19540, 19960 and 64800.

(5): SML(T) in this case means that the restriction shall not be exceeded by the sum of the migration of the substances having PM/REF Nos. 14200, 14230 and 41840.

(14): SML(T) in this case means that the restriction shall not be exceeded by the sum of the migration levels of the substances of the substances having PM/REF Nos. 15970, 48640, 48720, 48880, 61280, 61360 and 61600.

(21): SML(T) in this case means that the restriction shall not be exceeded by the sum of the migration levels of the substances having PM/REF Nos. 17260, 18670, 54880 and 59280.

(22): SML(T) in this case means that the restriction shall not be exceeded by the sum of the migration levels of the substances having PM/REF/Nos. 13620, 36840, 40320 and 87040.

(23): SML(T) in this case means that the restriction shall not be exceeded by the sum of the migration levels of the substances having PM/REF/Nos. 13720 and 40580.

(24): SML(T) in this case means that the restriction shall not be exceeded by the sum of the migration levels of the substances having PM/REF/Nos. 16650 and 51570.

(25): QM(T) in this case means that the restriction shall not be exceeded by the sum of the residual quantities of the substances having PM/REF/Nos. 14950, 15700, 16240, 16570, 16600, 16630, 18640, 19110, 22332, 22420, 22570, 25210, 25240 and 25270.

(27): QMA(T) in this case means that the restriction shall not be exceeded by the sum of the residual quantities of the following substances having PM/REF Nos. 10599/90A, 10599/91, 10599/92A and 10599/93.

(28): SML(T) in this case means that the restriction shall not be exceeded by the sum of the migration levels of the following substances having PM/REF Nos. 13480 and 39680.

(29): SML(T) in this case means that the restriction shall not be exceeded by the sum of the migration levels of the following substances having PM/REF Nos. 22775 and 69920.

(32): Compliance testing when there is a fat contact should be performed using isooctane as substitute of simulant D (unstable).

(33): QMA(T) in this case means that the restriction shall not be exceeded by the sum of the residual quantities of the following substances having PM/REF Nos. 14800 and 45600.

SCHEDULE 2

Regulations 5 and 7

Authorised Additives

PART 1

Incomplete List of Additives Used in the Manufacture of Plastic Materials and Articles (not being Additives to which Paragraph 5 of Part 3 of this Schedule Applies)

Item	*1* *PM/REF No.*	*2* *CAS No.*	*3* *Name*	*4* *Restrictions and specifications*
1	30000	000064-19-7	Acetic acid	
2	30045	000123-86-4	Acetic acid, butyl ester	
2A	30080	004180-12-5	Acetic acid, copper salt	SML(T) = 30 mg/kg (7) (expressed as copper)
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	
7A	30610	-	Acids C_2-C_{24} aliphatic, linear monocarboxylic, from natural oils and fats and their mono-, di- and triglycerol esters (branched fatty acids at naturally occurring levels are included)	
7B	30612	-	Acids C_2-C_{24} aliphatic linear, monocarboxylic, synthetic and their mono-, di- and triglycerol esters	
8	30960	-	Acids, aliphatic, monocarboxylic (C_6-C_{22}), esters with polyglycerol	
9	31328	-	Acids, fatty, from animal or vegetable foods fats and oils	
9A	31530	123968-25-2	Acrylic acid, 2,4-di-tert-pentyl-6[1(3,5-di-tert-pentyl-2-hydroxyphenyl) ethyl] phenyl ester	The specific migration of this substance shall not exceed 5 mg/kg
10	31730	000124-04-9	Adipic acid	
11	33120	-	Alcohol's, aliphatic, monohydric, saturated, linear, primary (C_4-C_{24})	
12	33350	009005-32-7	Alginic acid	
12A	33801	-	n-Alkyl (C_{10}-C_{13}) benzenesulphonic acid	The specific migration of this substance shall not exceed 30 mg/kg
13	34281	-	Alkyl (C_8-C_{22}) 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	
18A	34850	143925-92-2	Amines, bis (hydrogenated tallow alkyl) oxidised	QM = For use only: (a) in polyolefines at 0.1% (w/w) not in LDPE when it is in contact with foods for which Directive 85/572/EEC establishes a reduction factor less than 3; (b) in PET at 0.25% (w/w) in contact with foods other than those for which the simulant D is laid down in Directive 85/572/EEC SML = 0.05 mg/kg
18B	34895	000088-68-6	2-Aminobenzamide	SML = 0.05 mg/kg. To be used only for PET for water and beverages
19	35120	013560-49-1	3-Aminocronic acid, diester with thiobis (2-hydroxyethyl) ether	
19A	35160	006642-31-5	6-Amino-1,3-dimethyluracil	SML = 5 mg/kg
19B	35170	000141-53-5	2-Aminoethanol	SML = 0.05 mg/kg. Not for use in polymers contacting foods for which simulant D is laid down in Council Directive 85/572/EEC and for indirect food contact only, behind the PET layer
19C	35284	000111-41-1	N-(2-aminoethyl) ethanolamine	SML = 0.05 mg/kg. Not for use in polymers contacting foods for which simulant D is laid down in Council Directive 85/572/EEC and for indirect food contact only, behind the PET layer
20	35320	007664-41-7	Ammonia	
21	35440	001214-97-9	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	
27B	36840	012007-55-5	Barium tetraborate	SML(T) = 1 mg/kg expressed as barium (11) and SML(T) = 6 mg/kg (22) (expressed as boron) without prejudice to the provisions of Directive 98/83/EC on water for human consumption
28	36880	008012-89-3	Beeswax	
29	36960	003061-75-4	Behenamide	
30	37040	000112-85-6	Behenic acid	
31	37280	001302-78-9	Bentonite	
31A	37360	000100-52-7	Benzaldehyde	(10)
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	
36A	38320	005242-49-9	4-(2-benzoxazolyl)-4'- (5-methyl-2-benzoxazolyl) stilbene	In compliance with the specifications laid down in Schedule 4
36B	38510	136504-96-6	1,2-Bis(3-aminopropyl) ethylenediamine, polymer with N-butyl-2,2,6,6-tetramethyl-4-piperidinamine and 2,4,6-trichloro-1,3,5-triazine	The specific migration of this substance shall not exceed 5 mg/kg
36C	38515	001533-45-5	4,4'-Bis(2-benzoxazolyl) stilbene	The specific migration of this substance shall not exceed 0.05 mg/kg (1)
36D	38810	080693-00-1	Bis(2,6-di-tert-butyl-4-methylphenyl) pentaerythritol diphosphite	The specific migration of this substance shall not exceed 5 mg/kg (sum of phosphite and phosphate)
36E	38840	154862-43-8	Bis(2,4-dicumylphenyl) pentaerythritoldiphosphite	SML = 5 mg/kg (as sum of the substance itself, its oxidised form bis (2,4-dicumylphenyl) pen-taerythritol-phosphate and its hydrolysis product (2,4-dicumylphenol)
36F	38879	135861-56-2	Bis (3,4-dimethylbenzylidene) sorbitol	
37	38950	079072-96-1	Bis(4-ethylbenzylidene) sorbitol	
37A	39200	006200-40-4	Bis (2-hydroxyethyl)-2-hydroxypropyl-3-(dodecyloxy) methylammonium chloride	The specific migration of this substance shall not exceed 1.8 mg/kg
37AA	39680	000080-05-7	2,2-Bis(4-hydroxyphenyl) propane	SML(T) = 0.6 mg/kg (28)
37B	39815	182121-12-6	9,9-Bis(methoxymethyl) fluorene	The quantity of this substance in the finished plastic material or article

				shall not exceed 0.05 mg/6 dm^2
38	39890	087826-41-3	Bis(methylbenzylidene) sorbitol	
		069158-41-4	Ditto	
		054686-97-4	Ditto	
		081541-12-0	Ditto	
38A	39925	129228-21-3	3,3-Bis (methoxymethyl)- 2,5-dimethyl hexane	SML = 0.05 mg./kg
38B	40120	068951-50-8	Bis(polyethyleneglycol) hydroxymethylphosphonate	SML = 0.6 mg/kg
38C	40320	010043-35-3	Boric acid	SML(T) = 6 mg/kg (22) (expressed as boron) without prejudice to the provisions of Directive 98/83/EC on water for human consumption
39	40400	010043-11-5	Boron nitride	
40	40570	000106-97-8	Butane	
40A	40580	000110-63-4	1,4,-Butanediol	SML(T) = 0.05 mg/kg (23)
41	41040	005743-36-2	Calcium butyrate	
41A	41120	010043-52-4	Calcium chloride	
42	41280	001305-62-0	Calcium hydroxide	
43	41520	001305-78-8	Calcium oxide	
44	41600	012004-14-7	Calcium sulphoaluminate	
		037293-22-4	Ditto	
44A	41680	000076-22-2	Camphor	(10)
45	41760	008006-44-8	Candelilla wax	
45A	41840	000105-60-2	Caprolactam	SML(T) = 15 mg/kg (5)
46	41960	000124-07-2	Caprylic acid	
47	42160	000124-38-9	Carbon dioxide	
47A	42320	007492-68-4	Carbonic acid, copper salt	SML(T) = 30 mg/kg (7) (expressed as copper)
48	42500	-	Carbonic acid, salts	
49	42640	009000-11-7	Carboxymethylcellulose	
50	42720	008015-86-9	Carnauba wax	
51	42800	009000-71-9	Casein	
51A	42880	008001-79-4	Castor oil	
52	42960	064147-40-6	Castor oil, dehydrated	
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	
57A	43515	-	Chlorides of choline esters of coconut oil fatty acids	The quantity of this substance in the finished plastic material or article shall not exceed 0.9 mg/ 6 dm^2
58	44160	000077-92-9	Citric acid	
59	44640	000077-93-0	Citric acid, triethyl ester	
59A	45195	007787-70-4	Copper bromide	SML(T) = 30 mg/kg (7)

				(expressed as copper)
59B	45200	001335-23-5	Copper iodide	SML(T) = 30 mg/kg (7) (expressed as copper) and the specific migration of this substance shall not exceed 1 mg/kg (10) (expressed as iodine)
60	45280	-	Cotton fibres	
60A	45450	068610-51-5	p-Cresol-dicyclopentadiene-isobutylene, copolymer	SML = 5 mg/kg
61	45560	014464-46-1	Cristobalite	
61A	45600	003724-65-0	Crotonic acid	QMA(T) = 0.05 mg/ 6 dm^2(33)
61B	45640	005232-99-5	2-Cyano-3, 3-dipheneylacrylic acid, ethyl ester	SML = 0.05 mg/kg
62	45760	000108-91-8	Cyclohexylamine	
63	45920	009000-16-2	Dammar	
64	45940	000334-48-5	*n*-Decanoic acid	
65	46070	010016-20-3	Alpha-Dextrin	
66	46080	007585-39-9	Beta-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	
69A	46700	-	5,7-di-tert-Butyl-3- (3,4- and 2,3 –dimethylphenyl)-3H-benzofuran-2-one containing: (a) 5,7-di-tert-butyl-3-(3,4-dimethylphenyl)-3H-benzofuran-2-one (80-100% w/w); and (b) 5,7-di-tert-butyl-3-(2,3-dimethylphenyl)-3H-benzofuran-2-one (0-20% w/w)	SML = 5 mg/kg
69B	46720	004130-42-1	2,6-Di-tert-butyl-4-ethylphenol	QMA = 4.8 mg/ 6 dm^2
70	46790	004221-80-1	3,5-Di-tert-butyl-4-hydroxybenzoic acid, 2,4-di-tert-butylphenyl ester	
71	46800	067845-93-6	3,5-Di-tert-butyl-4-hydroxybenzoic acid, hexadecyl ester	
72	46870	003135-18-0	3,5-Di-tert-butyl-4-hydroxybenzylphosphonic acid, dioctadecyl ester	
72A	46880	065140-91-2	3,5-Di-tert-butyl-4-hydroxybenzyl phosphonic acid, monoethyl ester, calcium salt	The specific migration of this substance shall not exceed 6 mg/kg
72B	47210	026427-07-6	Dibutylthiostannoic acid polymer [= thiobis(butyl-tin sulphide), polymer]	In compliance with this specifications laid down in Schedule 4
73	47440	000461-58-5	Dicyanodiamide	
73A	47540	027458-90-8	Di-tert-dodecyl disulfide	SML – 0.05 mg/kg

73B	47680	000111-46-6	Diethyleneglycol	SML(T) = 30 mg/kg (3)
73C	48460	000075-37-6	1,1-Difluoroethane	
73D	48620	000123-31-9	1,4-Dihydroxybenzene	SML = 0.6 mg/kg
73E	48720	000611-99-4	4,4'Dihydroxybenzophenone	SML(T) = 6 mg/kg (14)
73F	49485	134701-20-5	2,4-Dimethyl-6-(1-methylpentadecyl) phenol	The specific migration of this substance shall not exceed 1 mg/kg
74	49540	000067-68-5	Dimethyl sulphoxide	
75	51200	000126-58-9	Dipentaerythritol	
75A	51700	147315-50-2	2-(4,6-Diphenyl-1,3,5-triazin-2-yl)-5- (hexyloxy) phenol	The specific migration of this substance shall not exceed 0.05 mg/kg
76	51760	025265-71-8	Dipropyleneglycol	
		000110-98-5	Ditto	
77	52640	016389-88-1	Dolomite	
77A	52645	010436-08-5	Cis-11-eicosenamide	
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	N,N'-Ethylenebisoleamide	
84	53440	005518-18-3	N,N'-Ethylenebispalmitamide	
85	53520	000110-30-5	N,N'-Ethylenebisstearamide	
86	53600	000060-00-4	Ethylenediaminetetraacetic acid	
86A	53610	054453-03-1	Ethylenediaminetetraacetic acid, copper salt	SML(T) = 30 mg/kg (7) (expressed as copper) (3)
86B	53650	000107-21-1	Ethyleneglycol	SML(T) = 30 mg/kg
87	54005	005136-44-7	Ethylene-N-palmitamide-N'-stearamide	
88	54260	009004-58-4	Ethylhydroxyethylcellulose	
89	54270	-	Ethylhydroxymethylcellulose	
90	54280	-	Ethylhydroxypropylcellulose	
90A	54300	118337-09-0	2,2'-Ethylidenebis (4,6-di-tert-butylphenyl) fluorophosphonite	The specific migration of this substance shall not exceed 6 mg/kg
91	54450	-	Fats and oils, from animal or vegetable food sources	
92	54480	-	Fats and oils, hydrogenated, from animal or vegetable food sources	
92A	54930	025359-91-5	Formaldehyde-1-naphthol, copolymer [= Poly (1-hydroxynaphthyl-methane)]	The specific migration of this substance shall not exceed 0.05 mg/kg
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	
103	56486	-	Glycerol, esters with acids, aliphatic, saturated, linear, with an even number of carbon atoms C_{14}-C_{18}) and with acids, aliphatic, unsaturated, linear, with even number of carbon atoms (C_{16}-C_{18})	
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	
109A	56535	-	Glycerol, esters with nonanoic acid	
110	56540	-	Glycerol, esters with oleic acid	
111	56550	-	Glycerol, esters with palmitic 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 monooctanoate	
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	52780	-	Glycerol monopalmitate, ester with citric acid	
124	57600	-	Glycerol monostearate, ester with ascorbic acid	
125	57680	-	Glycerol monostearate, ester with citric acid	
125A	57800	018641-57-1	Glycerol tribehenate	
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	
131A	59280	000100-97-0	Hexamethylenetetramine	SML(T) = 15 mg/kg (21)

				(expressed as Formaldehyde)
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	
140A	60480	003864-99-1	2-(2-Hydroxy-3,5,-di-tert-butylphenyl)-5-chlorobenzotriazole	SML(T) = 30 mg/kg (18)
141	60560	009004-62-0	Hydroxyethylcellulose	
142	60880	009032-42-2	Hydroxyethylmethylcellulose	
143	61120	009005-27-0	Hydroxyethyl starch	
144	61390	037353-59-6	Hydroxymethylcellulose	
145	61680	009004-64-2	Hydroxypropylcellulose	
146	61800	009049-76-7	Hydroxypropyl starch	
146	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	Lactic 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	
164A	64800	000110-16-7	Maleic acid	SML(T) = 30 mg/kg(4)
165	65020	006915-15-7	Malic acid	
166	65040	000141-82-2	Malonic acid	
167	65520	000087-78-5	Mannitol	
167A	65920	066822-60-4	N-methacryloyloxyethyl-N,N-dimethyl-N- carboxymethyl-ammonium chloride, sodium salt-octadecyl methacrylate-ethyl methacrylate –cyclohexyl methacrylate-N-vinyl-2-	

			pyrrolidone, copolymers	
168	66200	037206-01-2	Methylcarboxymethylcellulose	
169	66240	009004-67-5	Methylcellulose	
169A	66560	004066-02-8	2,2'-Methylenebis (4-methyl-6-cyclohexylphenol)	SML(T) = 3 mg/kg (6)
169B	66580	000077-62-3	2,2'-Methylenebis (4-methyl-6-(1-methylcyclo-hexyl) phenol)	SML(T) = 3 mg/kg (6)
170	66640	009004-59-5	Methylethylcellulose	
171	66695	-	Methylhydroxymethylcellulose	
172	66700	009004-65-3	Methylhydroxypropylcellulose	
172A	66755	002682-20-4	2-Methyl-4-isothiazolin-3-one	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
173	67120	012001-26-2	Mica	
173B	67180	-	Mixture of (50% w/w) phthalic acid n-decyl n-octyl ester, (25% w/w) phthalic acid di-n-decyl ester, and (25% w/w) phthalic acid di-n-octyl ester	The specific migration of this substance shall not exceed 5 mg/kg (1)
174	67200	001317-33-5	Molybdenum disulphide	
175	67840	-	Montanic acids and/or their esters with 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	
178A	68078	027253-31-2	Neodecanoic acid, cobalt salt	SML(T) = 0.05 mg/kg (expressed as Neodecanoic acid) and SML(T) = 0.05 mg/kg (13) (expressed as Cobalt). Not for use in polymers contacting foods for which simulant D is laid down in Directive 85/572/EEC
179	68125	037244-96-5	Nepheline syenite	
179A	68145	080410-33-9	2,2',2"-Nitrilo(triethyl tris (3,3',5,5'- tetra-tert-butyl-1-1'-bi-phenyl-2-2-diyl) phosphite)	The specific migration of this substance shall not exceed 5 mg/kg (sum of phosphite and phosphate)
180	68960	000301-02-0	Oleamide	
181	69040	000112-80-1	Oleic acid	
182	69760	000143-28-2	Oleyl alcohol	
182A	69920	000144-62-7	Oxalic acid	SML(T) = 6 mg/kg (29)
183	70000	070331-94-1	2,2'-Oxamidobis(ethyl-3-(3,5-di-tert-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	
188A	71635	025151-96-6	Pentaerythritol dioleate	The specific migration of this substance shall not exceed 0.05 mg/kg. Not for use with foods for which simulant D is laid down in Directive 85/572/EEC
188B	71670	178671-58-4	Pentaerythritol tetrakis (2-cyano-3,3-diphenylacrylate)	SML = 0.05 mg/kg
189	71680	006683-19-8	Pentaerythritol tetrakis [3-(3,5-di-tert-butyl-4- hydroxyphenyl) -propionate]	
190	71720	000109-66-0	Pentane	
191	72640	007664-38-2	Phosphoric acid	
191A	73160		Phosphoric acid, mono- and di-n-alkyl (C_{16} and C_{18}) esters	SML = 0.05 mg/kg
191B	73720	000115-96-8	Phosphoric acid, trichloroethyl ester	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
191C	74010	145650-60-8	Phosphorous acid, bis (2,4-di-tert-butyl-6- methylphenyl) ethyl ester	The specific migration of this substance shall not exceed 5 mg/kg (covering the sum of phosphite and phosphate)
192	74240	031570-04-4	Phosphorous acid, tris (2,4-di-tert-butylphenyl) ester	
193	74480	000088-99-3	*o*-Phthalic acid	
194	76320	000085-44-9	Phthalic anhydride	
195A	76721	009016-00-6 063148-62-9	Polydimethylsiloxane (Mw > 6800)	In compliance with the specifications laid down in Schedule 4
195B	76730		Polydimethylsiloxane, gamma-hydroxypropylated	SML = 6 mg/kg
195D	76865	-	Polyesters of 1, 2-propanediol and/or 1,3- and/or 1,4-butanediol and/or polypropyleneglycol with adipic acid, which may be end-capped with acetic or fatty acids C_{12}-C_{18} or n-octanol and/or n-decanol	SML = 30 mg/kg
196	76960	025322-68-3	Polyethyleneglycol	
197	77600	061788-85-0	Polyethyleneglycol ester of hydrogenated caster oil	

198	77702	-	Polyethyleneglycol esters of aliphatic monocarboxylic acids (C_6-C_{22}), and their ammonium and sodium sulphates	
198A	77895	068439-49-6	Polyethyleneglycol (EO = 2-6) monoalkyl (C_{16}-C_{18}) ether	SML = 0.05 mg/kg and in compliance with the specifications laid down in Schedule 4
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 (C_2-C_4) dimethylpolysiloxane	
207	80720	008017-16-1	Polyphosphoric acids	
208	80800	025322-69-4	Polypropyleneglycol	
208A	81220	192268-64-7	Poly-[[6-[N-(2,2,6,6-tetramethyl-4-piperidinyl)-n-butylamino]- 1,3,5-triazine-2,4-diyl][2,2,6,6-tetramethyl-4-piperidinyl)imino]-1,6-hexanedyl[2,2,6,6- tetramethyl-4-piperidinyl) imino]] – alpha-[N,N,N',N'''-tetrabutyl-N – (2,2,6,6-tetramethyl-4-piperidinyl)-N''-[6,(2,2,6,6-tetramethyl-4-piperidinylamino)-hexyl][1,3,5-triazine-2,4,6-triamine]-omega-N,N,N',N'-tetrabutyl-1,3,5-triazine-2,4-diamine	SML = 5 mg/kg
208B	81515	087189-25-1	Poly(zinc glycerolate)	
209	81520	007758-02-3	Potassium bromide	
210	81660	001310-58-3	Potassium hydroxide	
210A	81760	-	Powders, flakes and fibres of brass, bronze, copper, stainless steel, tin and alloys of copper, tin and iron	SML(T) = 30 mg/kg (7) (expressed as copper); the specific migration of this substance shall not exceed 48 mg/kg (expressed as iron)
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	
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	
229A	83599	068442-12-6	Reaction products of oleic acid, 2-mercaptoethyl ester, with dichlorodimethyltin, sodium sulphide and trichloromethyltin	SML(T) = 0.18 mg/kg (15) (expressed as tin)
230	83610	073138-82-6	Resin acids and rosin acids	
231	83840	008050-09-6	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	
239A	85360	000109-43-3	Sebacic acid, dibutyl ester	
240A	85610	-	Silicates, natural, silanated (with the exception of asbestos)	
240ZA	85601	-	Silicates, natural, (with the exception of asbestos)	
240B	85680	001343-98-2	Silicic acid	
240C	85840	053320-86-8	Silicic acid, lithium magnesium sodium salt	SML(T) = 0.6 mg/kg (8) (expressed as lithium)
242	86000	-	Silicic acid, silylated	
243	86160	000409-21-2	Silicon carbide	
244	86240	007631-86-9	Silicon dioxide	
244A	86285	-	Silicon dioxide, silanated	
245	86560	007647-15-6	Sodium bromide	
246	86720	001310-73-2	Sodium hydroxide	
246A	87040	001330-43-4	Sodium tetraborate	SML(T) = 6 mg/kg (22) (expressed as boron) without prejudice to the provisions of Directive 98/83/EC on water for

				human consumption
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	
259A	88640	008013-07-8	Soybean oil, epoxidized	In compliance with the specifications laid down in Schedule 4
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	
263A	89200	007617-31-4	Stearic acid, copper salt	SML(T) = 30 mg/kg (7) (expressed as copper)
263B	89440	-	Stearic acid, esters with ethyleneglycol	SML(T) = 30 mg/kg (3)
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	
270A	92030	010124-44-4	Sulphuric acid, copper salt	SML(T) = 30 mg/kg (7) (expressed as copper)
271	92080	014807-96-6	Talc	
271A	92150	001401-55-4	Tannic acids	According to the JECFA specifications
272	92160	000087-69-4	Tartaric acid	
273	92195	-	Taurine, salts	
274	92205	057569-40-1	Terephthalic acid, diester with 2,2'-methylenebis (4-methyl-6-tert-butylphenol)	
275	92350	000112-60-7	Tetraethyleneglycol	
276	92640	000102-60-3	N,N,N',N'- Tetrakis (2-hydroxypropyl) ethylenediamine	
276A	92700	078301-43-6	2,2,4,4- Tetramethyl-20-(2,3-epoxypropyl)- 7-oxa-3,20-diazadispiro-[5.1.11.2]-heneicosan-21-one, polymer	The specific migration of this substance shall not exceed 5 mg/kg
276B	92930	120218-34-0	Thiodiethanolbis (5-methoxycarbonyl-2,6-dimethyl-1,4-dihydropridine-3-	The specific migration of this substance shall not exceed 6 mg/kg

			carboxylate)	
277	93440	013463-67-7	Titanium dioxide	
278	93520	000059-02-9 010191-41-0	*alpha*-Tocopherol Ditto	
279	93680	009000-65-1	Tragacanth gum	
279A	93720	000108-78-1	2,4,6-Triamino-1,3,5-triazine	SML = 30 mg/kg
280	94320	000112-27-6	Triethyleneglycol	
280A	94960	000077-99-6	1,1,1-Trimethylolpropane	The specific migration of this substance shall not exceed 6 mg/kg
280B	95000	028931-67-1	Trimethylolpropane trimethacrylatemethyl methacrylate copolymer	
281	95200	001709-70-2	1,3,5-Trimethyl-2,4,6-tris (3,5-di-tert-butyl-4- hydroxybenzyl) benzene	
281A	95270	161717-32-4	2,4,6-Tris(tert-butyl) phenyl 2-butyl-2-ethyl-1,3-propanediol phosphite	SML = 2 mg/kg (as sum of phosphite, phosphate and the hydrolysis product = TTBP)
281B	95725	110638-71-6	Vermiculite, reaction product with citric acid, lithium salt	SML(T) = 0.6 mg/kg (8) (expressed as lithium)
281C	95855	007732-18-5	Water	In compliance with Directive 98/83/EC
281D	95859	-	Waxes, refined, derived from petroleum based or synthetic hydrocarbon feedstocks	In compliance with the specifications laid down in Schedule 4
281E	95883	-	White mineral oils, paraffinic, derived from petroleum based hydrocarbon feedstocks	In compliance with the specifications laid down in Schedule 4
282	95905	013983-17-0	Wollastonite	
283	95920	-	Wood flour and fibres, untreated	
284	95935	011138-66-2	Xanthan gum	
285	91690	020427-58-1	Zinc hydroxide	
286	96240	001314-13-2	Zinc oxide	
287	96320	001314-98-3	Zinc sulphide	

PART 2

Incomplete List of Additives Used in the Manufacture of Plastic Materials and Articles (Being Additives to which Paragraph 5 of Part 3 of this Schedule Applies)

Item	*1* *PM/REF No.*	*2* *CAS No*	*3* *Name*	*4* *Restrictions and specifications*
1	30180	002180-18-9	Acetic acid, manganese salt	SML(T) = 0.6 mg/kg (9) (expressed as manganese)
2	31520	061167-58-6	Acrylic acid, 2-tert-butyl- 6-(3-tert- butyl- 2-hydroxy-5-methylbenzyl)-4-methylphenyl ester	SML = 6 mg/kg
3	31920	000103-23-1	Adipic acid, bis (2-ethylhexyl) ester	SML = 18 mg/kg (1)

4	34230		Alkyl (C_8-C_{22}) sulphonic acids	SML = 6 mg/kg
4A	34650	151841-65-5	Aluminium hydroxybis [2,2'-methylenebis (4,6-di-tert-butylphenyl)] phospate	SML = 5 mg/kg
5	35760	001309-64-4	Antimony trioxide	SML = 0.02 mg/kg (expressed as anti-monium and analytical tolerance included)
6	36720	017194-00-2	Barium hydroxide	SML(T) = 1 mg/kg (11) (expressed as barium)
7	36800	010022-31-8	Barium nitrate	SML(T) = 1 mg/kg (11) (expressed as barium)
7A	38000	000553-54-8	Benzoic acid, lithium salt	SML(T) = 0.6 mg/kg (8) (expressed as lithium)
8	38240	000119-61-9	Benzophenone	SML = 0.6 mg/kg
9	38560	007128-64-5	2,5-Bis (5-tert-butyl-2-benzoxazolyl) thiophene	SML = 0.6 mg/kg
10	38700	063397-60-4	Bis (2-carbobutoxyethyl) tin-bis (isooctyl mercaptoacetate)	SML = 18 mg/kg
11	38800	032687-78-8	N,N'-Bis (3-(3,5-di-tert-butyl-4-hydroxyphenyl) propionyl) hydrazide	SML = 15 mg/kg
12	38820	026741-53-7	Bis (2,4-di-tert-butylphenyl) pentaery-thritol diphosphite	SML = 0.6 mg/kg
13	39060	035958-30-6	1,1-Bis (2-hydroxy-3, 5-di-tert-butylphenyl) ethane	SML = 5 mg/kg
14	39090		N,N-bis (2-hydroxyethyl) alkyl (C_8-C_{18}) amine	SML(T) = 1.2 mg/kg (12)
15	39120		N,N-bis (2-hydroxyethyl)-alkyl (C_8-C_{18}) amine hydrochlorides	SML(T) = 1.2 mg/kg (12) expressed as tertiary amine (expressed excluding HCI)
16	40000	000991-84-4	2,4-Bis (octylmercapto) – 6- (4-hydroxy- 3,5,di-tert-butylanilino) - 1,3,5-triazine	SML = 30 mg/kg
17	40020	110553-27-0	2,4-Bis (octylthiomethyl) – 6-methylphenol	SML = 6 mg/kg
18	40160	061269-61-2	N,N'-bis (2,2,6,6-tetramethyl-4-piperidyl) hexamethy-lenediamine- 1,2-dibromoethane, copolymer	SML = 2.4 mg/kg
18A	40720	025013-16-5	Tert-butyl- 4-hydroxyanisole (= BHA)	SML = 30 mg/kg
19	40800	013003-12-8	4,4' – butylidene-bis (6-tert-butyl-3-methylphenyl-ditridecyl phosphite)	SML = 6 mg/kg
20	409080	019664-95-0	Butyric acid, manganese salt	SML(T) = 0.6 mg/kg (9) (expressed as manganese)
21	42000	063438-80-2	(2-carbobutoxyethyl) tin-tris (isooctyl mercaptoacetate)	SML = 30 mg/kg
22	42400	010377-37-4	Carbonic acid, lithium salt	SML(T) = 0.6 mg/kg (8) (expressed as lithium)
23	42480	000584-09-8	Carbonic acid, rubidium salt	SML = 12 mg/kg

24	43600	004080-31-3	1- (3- Chloroallyl) – 3,5,7 – triaza-1-azoniaadamantane chloride	SML = 0.3 mg/kg
25	43680	000075-45-6	Chlorodifluoromethane	SML = 6 mg/kg and in compliance with the specifications laid down in Schedule 4
26	44960	011104-61-3	Cobalt oxide	SML(T) = 0.05 mg/kg (13) (expressed as cobalt)
27	45440	-	Cresols, butylated, styrenated	SML = 12 mg/kg
27A	45650	006197-30-4	2-Cyano-3,3-diphenylacrylic acid, 2-ethylhexyl ester	SML = 0.05 mg/kg
27B	46640	000128-37-0	2,6-di-tert-butyl-p-cresol (= BHT)	SML = 3.0 mg/kg
29	47600	084030-61-5	Di-n-dodecyltin bis (isooctyl mercaptoacetate)	SML = 12 mg/kg
30	48640	000131-56-6	2,4-Dihydroxybenzophenone	SML(T) = 6 mg/kg (14)
31	48800	000097-23-4	2,2'-Dihydroxy-5,5'-dichlorodiphenylmethane	SML = 12 mg/kg
32	48880	000131-53-3	2,2'Dihydroxy-4-methoxybenzophenone	SML(T) = 6 mg/kg (14)
33	49600	026636-01-1	Dimethyltin bis (isooctyl mercaptoaecetate)	SMT(T) 0.18 mg/kg (15) (expressed as tin)
34	49840	002500-88-1	Dioctadecyl disulphide	SMT = 3 mg/kg
35	50160		Di-n-octyltin bis(n-alkyl (C_{10}-C_{16}) mercaptoacetate)	SML(T) = 0.04 mg/kg (16) (expressed as tin)
36	50240	010039-33-5	Di-n-octyltin bis (2-ethylhexyl maleate)	SML(T) = 0.04 mg/kg (16) (expressed as tin)
37	50320	015571-58-1	Di-n-octyltin bis (2-ethylhexyl mercaptoaectate)	SML(T) = 0.04 mg/kg (16) (expressed as tin)
38	50360		Di-n-octyltin bis (ethyl maleate)	SML(T) = 0.04 mg/kg (16) (expressed as tin)
39	50400	033568-99-9	Di-n-octyltin bis (isooctyl maleate)	SML(T) = 0.04 mg/kg (16) (expressed as tin)
40	50480	026401-97-8	Di-n-octyltin bis (isooctyl mercaptoacetate)	SML(T) = 0.04 mg/kg (16) (expressed as tin)
41	50560		Di-n-octyltin 1,4-butanediol bis (mercaptoacetate)	SML(T) = 0.04 mg/kg (16) (expressed as tin)
42	50640	003648-18-8	Di-n-octyltin dilaurate	SML(T) = 0.04 mg/kg (16) (expressed as tin)
43	50720	015571-60-5	Di-n-octyltin dimaleate	SML(T) = 0.04 mg/kg (16) (expressed as tin)
44	50800	-	Di-n-octyltin dimaleate, esterified	SML(T) = 0.04 mg/kg (16) (expressed as tin)
45	50880	-	Di-n-octyltin dimaleate, polymers (n = 2-4)	SML(T) = 0.04 mg/kg (16) (expressed as tin)
46	50960	069226-44-4	Di-n-octyltin ethyleneglycol bis (mercaptoacetate)	SML(T) = 0.04 mg/kg (16) (expressed as tin)
47	51040	015535-79-2	Di-n-octyltin mercaptoacetate	SML(T) = 0.04 mg/kg (16) (expressed as tin)
48	51120		Di-n-octyltin thiobenzoate 2-ethyl-hexyl mercaptoacetate	SML(T) = 0.04 mg/kg (16) (expressed as tin)
49	51570	000127-63-9	Diphenyl sulphone	SML(T) = 3 mg/kg (24)

50	51680	000102-08-9	N,N'-diphenylthiourea	SML = 3 mg/kg
51	52000	027176-87-0	Dodecylbenzenesulphonic acid	SML = 30 mg/kg
52	52320	052047-59-3	2-(4-Dodecylphenyl) indole	SML = 0.06 mg/kg
53	52880	023676-09-7	4-Ethoxybenzoic acid, ethyl ester	SML = 3.6 mg/kg
54	53200	023949-66-8	2-Ethoxy-2'-ethyloxanilide	SML = 30 mg/kg
54A	54880	000050-00-0	Formaldehyde	SML(T) = 15 mg/kg (21)
54B	55200	001166-52-5	Gallic acid, dodecyl ester	SML(T) = 30 mg/kg (34)
54C	55280	001034-01-1	Gallic acid, octyl ester	SML(T) = 30 mg/kg (34)
54D	55360	000121-79-9	Gallic acid, propyl ester	SML(T) = 30 mg/kg (34)
55	58960	000057-09-0	Hexadecyltrimethylammonium bromide	SML = 6 mg/kg
56	59120	023128-74-7	1,6-Hexamethylene-bis (3- (3,5-di-tert-butyl-4-hydroxyphenyl) propionamide)	SML = 45 mg/kg
57	59200	035074-77-2	1,6- Hexamethylene-bis (3-(3,5-di-tert-butyl-4-hydroxyphenyl) propionate	SML = 6 mg/kg
58	60320	070321-86-7	2- (2-Hydroxy-3,5-bis (1,1-dimethylbenzyl) phenyl) benzotriazole	SML = 1.5 mg/kg
59	60400	003896-11-5	2- (2'-Hydroxy-3'-tert-butyl-5'-methylphenyl) –5-chlorobenzotriazole	SML(T) = 30 mg./kg (18)
60	60800	065447-77-0	1-(2- Hydroxyethyl) –4-hydroxy- 2,2, 6,6-tetramethyl, piperidine-succinic acid, dimethyl ester, copolymer	SML = 30 mg/kg
61	61280	003293-97-8	2-Hydroxy-4-n-hexyloxybenzophenone	SML(T) = 6 mg/kg (14)
62	61360	000131-57-7	2-Hydroxy-4-methoxybenzophenone	SML(T) = 6 mg/kg (14)
63	61440	002440-22-4	2-(2-Hydroxy-5-methylphenyl) benzotriazole	SML(T) = 30 mg/kg (18)
64	61600	001843-05-6	2-Hydroxy-4-n-octyloxybenzophenone	SML(T) = 6 mg/kg (14)
65	63200	051877-53-3	Lactic acid, manganese salt	SML(T) = 0.6 mg/kg (9) (expressed as manganese)
66	64320	010377-51-2	Lithium iodide	SML(T) = 1 mg/kg (10) (expressed as iodium) and SML(T) = 0.6 mg/kg (8) (expressed as lithium)
67	65120	007773-01-5	Manganese chloride	SML(T) = 0.6 mg/kg (9) (expressed as manganese)
68	65200	012626-88-9	Manganese hydroxide	SML(T) = 0.6 mg/kg (9) (expressed as manganese
69	65280	010043-84-2	Manganese hypophosphite	SML(T) = 0.6 mg/kg (9) (expressed as manganese
70	65360	011129-60-5	Manganese oxide	SML(T) = 0.6 mg/kg (9) (expressed as manganese
71	65440		Manganese pyrophosphite	SML(T) = 0.6 mg/kg (9) (expressed as manganese

72	66360	085209-91-2	2-2'-Methylene bis (4,6-di-tert-butylphenyl) sodium phosphate	SML = 5 mg/kg
73	66400	000088-24-4	2-2'-Methylene bis (4-ethyl-6-tert-butylphenol)	SML(T) = 1.5 mg/kg (19)
74	66480	000119-47-1	2-2'-Methylene bis (4-methyl-6-tert-butylphenol)	SML(T) = 1.5 mg/kg (19)
75	67360	067649-65-4	Mono-n-dodecyltin tris (isooctyl mercaptoacetate)	SML = 24 mg/kg
76	67520	054849-38-6	Monomethyltin tris (isooctyl mercaptoacetate)	SML(T) = 0.18 mg/kg (15) (expressed as tin)
77	67600		Mono-n-octyltin tris (alkyl (C_{10}-C_{16}) - mercaptoacetate	SML(T) = 1.2 mg/kg (17) (expressed as tin)
78	67680	027107-89-7	Mono-n-octyltin tris (2-ethylhexyl mercaptoacetate	SML(T) = 1.2 mg/kg (17) (expressed as tin)
79	67760	026401-86-5	Mono-n-octyltin tris (isooctyl mercaptoacetate)	SML(T) = 1.2 mg/kg (17) (expressed as tin)
79A	67896	020336-96-3	Myristic acid, lithium salt	SML(T) = 0.6 mg/kg (8) (expressed as lithium)
81	68320	002082-79-3	Octadecyl 3- (3,5-di-tert-butyl-4- hydroxylphenyl) propionate	SML = 6 mg/kg
82	68400	010094-45-8	Octadecylerucamide	SML = 5 mg/kg
82A	68860	004724-48-5	n-Octylphosphonic acid	SML = 0.05 mg/kg
83	69840	016260-09-6	Oleylpalmitamide	SML = 5 mg/kg
83A	71935	007601-89-0	Perchloric acid, sodium salt monohydrate	SML = 0.05 mg/kg (31)
84	72160	000948-65-2	2-Phenylindole	SML = 15 mg/kg
85	72800	001241-94-7	Phosphoric acid, diphenyl 2-ethylhexyl ester	SML = 2.4 mg/kg
86	73040	013763-32-1	Phosphoric acid, lithium salts	SML(T) = 0.6 mg/kg (8) (expressed as lithium)
87	73120	010124-54-6	Phosphoric acid, manganese salt	SML(T) = 0.6 mg/kg (9) (expressed as manganese)
88	74400		Phosphorous acid, tris (nonyl- and/or dinonylphenyl) ester	SML = 30 mg/kg
88A	76680	068132-00-3	Polycyclopentadiene, hydrogenated	SML = 5 mg/kg (1)
89	77440		Polyethyleneglycol diricinoleate	SML = 42 mg/kg
90	77520	061791-12-6	Polyethyleneglycol ester of caster oil	SML = 42 mg/kg
91	78320	009004-97-1	Polyethyleneglycol monoricinoleate	SML – 42 mg/kg
92	81200	071878-19-8	Poly [6- [1,1,3,3-tetramethylbutyl) – amino]-1,3,5-triazine-2,4-diyl]-[(2,2,6,6-tetramethyl- 4-piperidyl)-imino] hexamethylene- [2,2,6,6-tetramethyl-4-piperidyl) imino]	SML = 3 mg/kg
93	81680	007681-11-0	Potassium iodide	SML(T) = 1 mg/kg (10) (expressed as iodium)
94	82020	019019-51-3	Propionic acid, cobalt salt	SML(T) = 0.05 mg/kg (13) (expressed as cobalt)

95	83595	119345-01-6	Reaction product of di-tert-butylphosphonite with biphenyl, obtained by condensation of 2,4-di-tert-butylphenol with Friedel Craft reaction product of phosphorus trichloride and biphenyl	SML = 18 mg/kg and in compliance with the specifications in Schedule 4
96	83700	000141-22-0	Ricinoleic acid	SML = 42 mg/kg
97	84800	000087-18-3	Salicylic acid, 4-tert-butylphenyl ester	SML = 12 mg/kg
98	84880	000119-36-8	Salicylic acid, methyl ester	SML = 30 mg/kg
99	85760	012068-40-5	Silicic acid, lithium aluminium salt (2:1:1)	SML(T) = 0.6 mg/kg (8) (expressed as lithium)
100	85920	012627-14-4	Silicic acid, lithium salt	SML(T) = 0.6 mg/kg (8) (expressed as lithium)
100A	86480	007631-90-5	Sodium bisulphite	SML(T) = 10 mg/kg (30) (expressed as SO_2)
101	86800	007681-82-5	Sodium iodide	SML(T) = 1 mg/kg (10) (expressed as iodium)
102	86880		Sodium monoalkyl dialkylphenoxybenzenedi-sulphonate	SML = 9 mg/kg
102A	86920	007632-00-0	Sodium nitrite	SML = 0.6 mg/kg
102B	86960	007757-83-7	Sodium sulphite	SML(T) = 10 mg/kg (30) (expressed as SO_2)
102C	87120	007772-98-7	Sodium thiosulphate	SML(T) = 10 mg/kg (30) (expressed as SO_2)
103	89170	013586-84-0	Stearic acid, cobalt salt	SML(T) = 0.05 mg/kg (13) (expressed as cobalt)
104	92000	007727-43-7	Sulphuric acid, barium salt	SML(T) = 1 mg/kg (11) (expressed as barium)
105	92320		Tetradecyl-polyethyleneglycol (EO = 3-8) ether of glycolic acid	SML = 15 mg/kg
106	92560	038613-77-3	Tetrakis (2,4- di-tert-butyl-phenyl) – 4-4’ –biphenylylene diphosphonite	SML = 18 mg/kg
107	92800	000096-69-5	4,4’-Thiobis (6-tert-butyl- 3-methylphenol)	SML = 0.48 mg/kg
108	92880	041484-35-9	Thiodiethanol bis (3-(3-5-di-tert- butyl-4-hydroxyphenyl) propionate)	SML = 2.4 mg/kg
109	93120	000123-28-4	Thiodipropionic acid, didodecyl ester	SML(T) = 5 mg/kg (20)
110	93280	000693-36-7	Thiodipropionic acid, dioctadecyl ester	SML(T) = 5 mg/kg (20)
110A	94400	036443-68-2	Triethyleneglycol bis[3-(3-tert-butyl- 4-hydroxy- 5-methylphenyl) propionate]	SML = 9 mg/kg
111	94560	000122-20-3	Triisopropanolamine	SML = 5 mg/kg
112	95280	040601-76-1	1,3,5- Tris (4-tert-butyl-3-hydroxy –2,6- dimethylbenzyl)-1,3,5-triazine-2,4,6 (1H,	SML = 6 mg/kg

			3H,5H)- trione	
113	95360	027676-62-6	1,3,5 – Tris (3,5-di-tert-butyl-4 hydroxybenzyl)- 1,3,5-triazine – 2,4,6 (1H, 3H, 5H) - trione	SML = 5 mg/kg
114	95600	001843-03-4	1,1,3- Tris (2-methyl-4-hydroxy-5-tert-butylphenyl) butane	SML = 5 mg/kg

PART 3

Supplementary

1. In regulations 5 and 7 and Parts 1 and 2 of this Schedule—

(a) the PM/REF No of any additive is its EEC packaging material reference number,

(b) the CAS No. of any additive is its CAS (Chemical Abstracts Service) Registry Number; and

(c) 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 Parts 1 or 2 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 of aluminium, ammonium, calcium, iron, magnesium, potassium, sodium or zinc), then any such salts shall be treated as included in the specification of that substance.

3. If, as indicated in paragraph 2 of Annex III to the Directive, a substance is identified in Parts 1 or 2 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.

4. Where an entry in column 4 of Part 1 or Part 2 includes a bracketed number, that entry shall be subject to a note relating to that number as follows, the following bracketed numbers corresponding with those appearing in those Parts —

(1): Warning: there is a risk that the SML could be exceeded in fatty food simulants.

(2): SML(T) in this case means that the restriction shall not be exceeded by the sum of the migration of the substances having PM/REF Nos. 10060 and 23920.

(3): SML(T) in this case means that the restriction shall not be exceeded by the sum of the migration of the substances having PM/REF Nos. 15760, 16990, 47680, 53650 and 89440.

(4): SML(T) in this case means that the restriction shall not be exceeded by the sum of the migration of the substances having PM/REF Nos. 19540, 19960 and 64800.

(5): SML(T) in this case means that the restriction shall not be exceeded by the sum of the migration of the substances having PM/REF Nos. 14200, 14230 and 41840.

(6): SML(T) in this case means that the restriction shall not be exceeded by the sum of the migration of the substances having PM/REF Nos. 66560 and 66580.

(7): SML(T) in this case means that the restriction shall not be exceeded by the sum of the migration levels of the substances having PM/REF Nos. 30080, 42320, 45195, 45200, 53610, 81760, 89200 and 92030.

(8): SML(T) in this case means that the restriction shall not be exceeded by the sum of the migration levels of the substances having PM/REF Nos. 38000, 42400, 64320, 67896, 73040, 85760, 85840, 85920 and 95725.

(9): SML(T) in this case means that the restriction shall not be exceeded by the sum of the migration levels of the substances having PM/REF Nos. 30180, 40980, 63200, 65120, 65200, 65280, 65360, 65440 and 73120.

(10): SML(T) in this case means that the restriction shall not be exceeded by the sum of the migration levels (expressed as iodine) of the substances having PM/REF Nos. 45200, 64320, 81680 and 86800.

(11): SML(T) in this case means that the restriction shall not be exceeded by the sum of the migration levels of the substances having PM/REF Nos. 36720, 36800, 36840 and 92000.

(12): SML(T) in this case means that the restriction shall not be exceeded by the sum of the migration levels of the substances having PM/REF Nos. 39090 and 39120.

(13): SML(T) in this case means that the restriction shall not be exceeded by the sum of the migration levels of the substances having PM/REF Nos. 44960, 68078, 82020 and 89170.

(14): SML(T) in this case means that the restriction shall not be exceeded by the sum of the migration levels of the substances having PM/REF Nos. 15970, 48640, 48720, 48880, 61280, 61360 and 61600.

(15): SML(T) in this case means that the restriction shall not be exceeded by the sum of the migration levels of the substances having PM/REF Nos. 49600, 67520 and 83599.

(16): SML(T) in this case means that the restriction shall not be exceeded by the sum of the migration levels of the substances having PM/REF Nos. 50160, 50240, 50320, 50360, 50400, 50480, 50560, 50640, 50720, 50800, 50880, 50960, 51040 and 51120.

(17): SML(T) in this case means that the restriction shall not be exceeded by the sum of the migration levels of the substances having PR/REF Nos. 67600, 67680 and 67760.

(18): SML(T) in this case means that the restriction shall not be exceeded by the sum of the migration levels of the substances having PM/REF Nos. 60400, 60480 and 61440.

(19): SML(T) in this case means that the restriction shall not be exceeded by the sum of the migration levels of the substances having PM/REF Nos. 66400 and 66480.

(20): SML(T) in this case means that the restriction shall not be exceeded by the sum of the migration levels of the substances having PM/REF Nos. 93120 and 93280.

(21): SML(T) in this cases means that the restriction shall not be exceeded by the sum of the migration levels of the substances having PM/REF Nos. 17260, 18670, 54880 and 59280.

(22): SML(T) in this case means that the restriction shall not be exceeded by the sum of the migration levels of the substances having PM/REF/Nos. 13620, 36840, 40320 and 87040.

(23): SML(T) in this case means that the restriction shall not be exceeded by the sum of the migration levels of the substances having PM/REF/Nos. 13720 and 40580.

(24): SML(T) in this case means that the restriction shall not be exceeded by the sum of the migration levels of the substances having PM/REF Nos. 16650 and 51570.

(26): QMA(T) in this case means that the restriction shall not be exceeded by the sum of the residual quantities of the following substances having PM/REF Nos. 14950, 15700, 16240, 16570, 16600, 16630, 18640, 19110, 22332, 22420, 22570, 25210, 25240 and 25270.

(27): QMA(T) in this case means that the restriction shall not be exceeded by the sum of the residual quantities of the following substances having PM/REF Nos. 10599/90A, 10599/91, 10599/92A and 10599/93.

(28): SML(T) in this case means that the restriction shall not be exceeded by the sum of the migration levels of the following substances having PM/REF Nos. 13480 and 39680.

(29) SML(T) in this case means that the restriction shall not be exceeded by the sum of the migration levels of the following substances having PM/REF Nos. 22775 and 69920.

(30): SML(T) in this case means that the restriction shall not be exceeded by the sum of the migration levels of the following substances having PM/REF Nos. 86480, 86960 and 87120.

(31): Compliance testing when there is a fat contact should be performed using saturated fatty food simulants as simulant D.

(32): Compliance testing when there is a fat contact should be performed using isooctane as substitute of simulant D (unstable).

(33): QMA(T) in this case means that the restriction shall not be exceeded by the sum of the residual quantities of the following substances having PM/REF Nos. 14800 and 45600.

(34): SML(T) in this case means that the restriction shall not be exceeded by the sum of the migration levels of the following substances having PM/REF Nos. 55200, 55280 and 55360.

5. In the case of the substances listed in Part 2, the specific migration limits specified in column 4 of that Part (restrictions and specifications) shall have effect with effect from 1st July 2006 where the verification of compliance is carried out in simulant D or in test media of substitute tests as prescribed in Council Directive 82/711/EEC and Council Directive 85/572/EEC.

SCHEDULE 3

Regulation 8

Products Obtained by Bacterial Fermentation

Item	*1* *PM/REF No*	*2* *CAS No*	*3* *Name*	*4* *Restrictions and specifications*
1	18888	080181-31-3	3-hydroxybutanoic acid- 3-hydroxypentanoic acid, copolymer	In compliance with specifications included in Schedule 4

SCHEDULE 4

Schedules 1,2 & 3

Specifications

Item	*1* *PM/REF No*	*2* *Specifications*	
1	11530	Acrylic acid, 2-hydroxypropyl ester	
		It may contain up to 25% (m/m) of acrylic acid, 2-hydroxyisopropyl ester (CAS No. 002918-23-2)	
2	16690	Divinylbenzene	
		It may contain up to 45% (m/m) of Ethylvinylbenzene	
3	18888	3-Hydroxybutanoic acid – 3-hydroxypentanoic acid, copolymer	
		Definition	The copolymers are produced by the controlled fermentation of *Alcaligenes eutrophus* using mixtures of glucose and propanoic acid as carbon sources. The organism used has not been genetically engineered and has been derived from a single wild-type organism *Alcaligenes eutrophus* strain H16 NCIMB 10442. Master stocks of the organism are stored as freeze-dried ampoules. A submaster/working stock is prepared from the master stock and stored in liquid nitrogen and used to prepare inocula for the fermenter. Fermenter samples will be examined daily both microscopically and for any changes in colonial morphology on a variety of agars at different temperatures. The copolymers are isolated from heat treatment bacteria by controlled digestion of the other cellular components, washing and drying. These copolymers are normally offered as formulated, melt formed granules containing additives such as nucleating agents, plasticisers, fillers, stabilisers and pigments which all conform to the general and individual specifications.
		Chemical name	Poly(3-D-hydroxybutanoate-co-3-D-hydroxypentanoate)

		CAS number	080181-31-3
		Structural formula	As set out in Part B of Annex V to the Directive
		Average molecular weight	Not less than 150 000 Daltons (measured by gel permeation chromatography)
		Assay	Not less than 98% poly (3-D-hydroxybutanoate -co-3-D-hydroxypentanoate) analysed after hydrolysis as a mixture of 3-D-hydroxybutanoic and 3-D-hydroxypentanoic acids
		Description	White to off-white powder after isolation
		Solubility	Soluble in chlorinated hydrocarbons such as chloroform or dichloromethane but practically insoluable in ethanol, aliphatic alkanes and water
		Restriction	QMA for crotonic acid is 0.05 mg/6 dm^2
		Purity	Prior to granulation of the raw material copolymer powder must contain:
		- nitrogen	Not more than 2,500 mg/g of plastic
		- zinc	Not more than 100 mg/kg of plastic
		- copper	Not more than 5 mg/kg of plastic
		- lead	Not more than 2 mg/kg of plastic
		- arsenic	Not more than 1 mg/kg of plastic
		- chromium	Not more than 1 mg/kg of plastic
4	23547	Polydimethylsiloxane (Mw > 6800)	
		Minimum viscosity 100 x $10^{-6} m^2/s$ (= 100 centistokes) at 25° C	
5	25385	Triallylamine	
		40 mg/kg hydrogel at a ratio of 1 kg food to a maximum of 1.5 grams of hydrogel. For use only in hydrogels intended for non-direct food contact use.	
6	38320	4-(2-Benzoxazolyl)-4'- (5-methyl-2-benzoxazolyl) stilbene	
		Not more than 0.05% w/w (quantity of substance used / quantity of the formulation)	
7	43680	Chlorodifluoromethane	
		Content of chlorofluoromethane less than 1 mg/kg of the substance	
8	47210	Dibutylthiostannoic acid polymer	
		Molecular unit = $(C_8H_{18}S_3Sn_2)$ n (n = 1.5-2)	
9	76721	Polydimethylsiloxane (Mw > 6800)	
		Minimum viscosity 100 x $10^{-6} m^2/s$ (= 100 centistokes) at 25° C	
10	77895	Polyethyleneglycol (EO = 2-6) monoalkyl (C_{16}-C_{18}) ether	
		The composition of this mixture is as follows:	
		-polyethyleneglycol (EO = 2-6) monoalkyl (C_{16}-C_{18}) ether approximately 28%)	
		-fatty alcohols (C_{16}-C_{18}) (approximately 48%)	
		-ethyleneglycol monoalkyl (C_{16}-C_{18}) ether (approximately 24%)	
11	83595	Reaction product of di-tert-butylphosphonite with biphenyl, obtained by condensation of 2,4-di-tert-butylphenol with Friedel Craft reaction product of phosphorus trichloride and bipheny[1]	
		Composition	
		-4,4'-Biphenylene-bis [0,0-bis (2,4-di-tert-butylphenyl) phosphonite] (CAS No. 38613-77-3) (36-46% w/w)[1]	

		-4,3'-Biphenylene-bis [0,0-bis (2,4-di-tert-butylphenyl) phosphonite] (CAS No. 118421-00-4) (17-23% w/w)[1]
		-3-3'-Biphenylene-bis [0,0-bis (2,4-di-tert-butylphenyl) phosphonite] CAS No. 118421-01-5) (1-5% w/w)[1]
		-4-Biphenylene-0,0-bis [0,0-bis (2,4-di-tert-butylphenyl) phosphonite] (CAS No. 91362 – 37-7 (11-19% w/w)[1]
		-Tris (2,4-di-tert-butylphenyl) phosphite (CAS No. 31570-04-4) (9-18% w/w)[1]
		-4,4'-Biphenylene-0,0-bis (2,4-di-tert-butylphenyl) phosphonate-0,0-bis (2,4-di-tert-butylphenyl) phosphonite (CAS No. 112949–97-0) (< 5% w/w)[1]
		Other specifications
		-Phosphor content of minimum 5.4% to maximum 5.9%
		-Acid value of maximum 10 mg KOH per gram
		-Melt range of 85-110°C
12	88640	Soybean oil, epoxidized
		Oxirane less than 8%, iodine number < 6
13	95859	Waxes, refined, derived from petroleum based or synthetic hydrocarbon feedstocks. The product should have the following specifications:
		-Phosphor content of minimum 5.4% to maximum 5.9%
		-Content of mineral hydrocarbons with carbon number less than 25: not more than 5% (w/w)
		-Viscosity not less than 11 x 10^{-6} m^2/s (= 11 centistokes) at 100°C
		-Average molecular weight not less than 500
14	95883	White mineral oils, paraffinic, derived from petroleum based hydrocarbon feedstocks
		The product shall have the following specifications:
		-Content of mineral hydrocarbons with carbon number less than 25: not more than 5% (w/w)
		-Viscosity not less than 8.5 x 10^{-6} m^2/s (= 8.5 centistokes) at 100°C
		-Average molecular weight not less than 480

[1] Quantity of substance used/quantity of formulation

SCHEDULE 5

Regulations 9 and 11

Applicable Provisions when Testing Compliance with the Migration Limits

General Provisions

1. When the results of the migration tests specified in this Schedule and, where appropriate Schedule 6, 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 6 is carried out on any sample taken from any plastic material or article and the quantities of food or simulant placed in contact with the sample differ from those employed in the actual conditions under which the plastic material or article is used or is to be used, the results obtained should be corrected by applying the formula $M = ((m.a_2/a_1.q).1000)$ where —

(a) M is the migration in mg/kg:

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

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

(d) a_2 is the surface area in square decimetres of the plastic material or article in actual conditions of use; and

(e) q is the quantity in grams of food in contact with the plastic material or article in actual conditions of use.

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

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

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

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

4.—(1) Any sample of plastic material or article shall be placed in contact with the appropriate simulant or the food for a period and at a temperature which are chosen by reference to the contact conditions in actual use in accordance with the provisions of this Schedule and, where appropriate, Schedule 6.

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

(3) Verification that migration into food complies with a migration limit specified in regulation 9, Schedule 1 or Schedule 2 shall be carried out under the most extreme conditions of time and temperature foreseeable in actual use in accordance with the provisions of this Schedule.

(4) Verification that migration into food simulants complies with a migration limit specified in regulation 9, Schedule 1 or Schedule 2 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 6.

5. Where a plastic material or article is intended to come into repeated contact with food, any migration test shall (subject to paragraph 7 below) be carried out three times on a single sample in accordance with the conditions laid down in this Schedule and, where appropriate, Schedule 6 using separate samples of the simulant or, as the case may be food, on each occasion, and the level of the migration found in the third test shall be treated as the level relevant to that test.

Special provisions relating to 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 9 it shall be a defence for the person charged to prove that—

(a) if an aqueous simulant specified in Schedule 6 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.

(2) In any proceedings for an offence under these Regulations where it is alleged, following determination under sub-paragraph (1) above, that a plastic material or article does not comply with regulation 9 it shall be a defence for the person charged to prove that, if—

(a) three identical samples of the plastic material or article had been procured;

(b) one of them had been subjected to the appropriate test according with paragraph 4 above 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 and three times that specified and overall migration had been determined in each case (M_2 and M_3 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 $M_3 – M_2$ did not exceed that 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) 12mg/kg or, as the case may be, 2 milligrams per square decimetre in migration tests using other simulants referred to in Schedule 6.

SCHEDULE 6

Regulations 9 and 11

Overall and Specific Migration Testing Using Food Simulants

PART 1

Basic Rules

1. Subject to paragraphs 2, 3 and 4 of this Part, migration tests for the determination of specific and overall migration shall be carried out using the food simulants specified in Parts 2, 3 and, where appropriate 4, and under conventional migration test conditions as specified in Part 5.

2. Subject to paragraphs 3 and 4 of this Part, substitute tests which use test media under the conventional substitute test conditions as specified in Part 6 shall be carried out if the migration test using the fatty food simulants specified in Part 3 is not feasible for technical reasons connected with the method of analysis.

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

4. In migration testing it is permissible to—

(a) reduce the number of tests to be carried out to that or those which, in the specific ase under examination, is or are generally recognised to be the most severe on the basis of scientific evidence;

(b) omit the migration, the substitute or the alternative tests where —

(i) there is conclusive proof that the migration limits cannot be exceeded in any foreseeable conditions of use of the material or article, or

(ii) the conditions for non-compulsory testing set out in Article 8.2 or 8.3 of the Directive are met.

PART 2

Food Simulants to be used in Migration Testing

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

1 *Abbreviation*	*2* *Food Simulant*
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 of this Part of this Schedule or, subject to paragraph 5 of this Part of this Schedule, any of the fatty food simulants specified in paragraph 4 of this Part of this Schedule

2. For the purposes of this Schedule a reference to an abbreviation in column 1 of the Table shall mean a reference to the simulant in column 1 of that Table opposite that abbreviation.

3. The characteristics of rectified olive oil referred to in the Table are —

(a) Iodine value (Wijs) = 80 to 88

(b) Refractive index at 25°C = 1.4665 to 1.4679

(c) Acidity (expressed as % of oleic acid) = 0.5% maximum

(d) Peroxide number (expressed as oxygen milli-equivalents per kg of oil) = 10 maximum

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

(a) corn oil with standardised specifications;

(b) sunflower oil, the characteristics of which are —

(i) Iodine value (Wijs) = 120 to 145

(ii) Refractive index at 20°C = 1.474 to 1.476

(iii) Saponification number = 188 to 193

(iv) Relative density at 20°C = 0.918 to 0.925

(v) Unsaponifiable matter = 0.5% to 1.5%.

(c) a synthetic mixture of triglycerides the composition of which is as set out in the following tables:

Fatty acid distribution

No of C-atoms in fatty acid residue	6	8	10	12	14	16	18	Others
GLC area (%)	~1	6-9	8-11	45-52	12-15	8-10	8-12	1

Purity

Content of monoglycerides (enzymatically)	≤0.2%
Content of diglycerides (enzymatically)	≤2.0%
Unsaponifiable matter	≤0.2%
Iodine value (Wijs)	≤0.1%
Acid value	≤0.1%
Water content (K Fischer)	≤0.1%
Melting point	28 ± 2°C

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

Wavelength (nm)	290	310	330	350	370	390	430	470	510
Transmittance (%)	~2	~15	~37	~64	~80	~88	~95	~97	~98
At least 10% light transmittance at 310 nm (cell of 1 cm, reference: water at 35°C)									

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 9 or Schedule 1, 2 or 3, verification that the plastic material or article does not comply with the specified migration shall be carried out by testing that material or article using olive oil if such testing is technically feasible, and if such testing is not technically feasible the plastic material or article shall be deemed not to comply with the specified migration limit.

PART 3

Selection of Food Simulants

Testing, reduction factors and definition of food types

1. The testing of plastic materials and articles shall be carried out under the test conditions specified in Part 5 using a simulant or simulants selected in accordance with this Part and taking a new test specimen of the plastic material or article for each simulant used.

2.—(1) Where a test is carried out on a plastic material or article intended to come into contact with more than one food or group of foods and a reduction factor is specified for one or more of those foods or groups of foods which is not equivalent to the reduction factor specified for one or more of the other foods or groups of foods with which the plastic material or article is intended to come into contact—

(a) the reduction factor specified for each food or group of foods, as appropriate, shall be applied to the test result; and

(b) the plastic material or article shall be treated as being capable of transferring its constituents to food with which it may come into contact in excess of a migration limit specified in regulation 9 or Schedule 1, 2 or 3 if, following application of those specified reduction factors, one or more of the results show that the material or article does not comply with that specified migration limit.

(2) For the purpose of this paragraph —

(a) a reduction factor is the figure which follows an "X" and oblique stroke in the group of columns headed "Simulants to be used" in the Table to Part 4;

(b) a reduction factor is specified for a food or group of foods where, in the Table to Part 4 —

(i) the food of group of foods is described in the column headed "Description of food", and

(ii) "X" is placed in a column headed by a specified simulant opposite that food or group of foods followed by an oblique stroke and a reduction factor;

(c) a reduction factor shall be applied to a test result by dividing the result by that reduction factor.

3. Food types are defined in Table 1 below as follows —

Table 1: Food types

Definition	*Meaning*
Aqueous foods having a pH > 4.5	Foods in relation to which simulant A only is specified in the Table to Part 4
Acidic foods having a pH ≤ 4.5	Foods in relation to which simulant B only is specified in Table to Part 4
Alcoholic foods	Foods in relation to which simulant C only is specified in the Table to Part 4
Fatty foods	Foods in relation to which simulant D only is specified in the Table to Part 4
Dry Foods	Foods in relation to which no simulant is specified in the Table to Part 4

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

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

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

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

(a) where —

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

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

the simulant or simulants so specified;

(b) where —

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

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

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

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

6. The simulant or simulants to be used in testing a plastic material or article which, pursuant to Regulation (EC) No 1935/2004 of the European Parliament and of the Council on materials and articles intended to come into contact with food(**a**) ("Regulation 1935/2004"), is accompanied by a specific indication stating any type or types of food described in Table 1 with which it may or may not be used shall be the simulant or simulants in column 2 of Table 2 opposite the contact food in column 1 of that Table which corresponds most closely to the type or types of food with which it may be used, as identified by the indication which accompanies the plastic material or article.

7. The simulant or simulants to be used in testing a plastic material or article which, pursuant to Regulation 1935/2004, is accompanied by a specific indication, expressed in accordance with paragraph 8, stating any food or group of foods described in the Table to Part 4 with which it may or may not be used shall be—

(a) where the indication states that the plastic material or article may be used with a food or group of foods described in column 2 of the Table to Part 4, the food simulant or food simulants which, for the purposes of Part 4, is or are specified in relation to that food or group of foods;

(b) where the indication states that the plastic material or article should not be used with any food or group of foods described in column 2 of Table to Part 4, a simulant other than the simulant or simulants which, for the purposes of Part 4, 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 4 of these Regulations or the description of food in column 2 of that Table which, in either case, corresponds to the food;

(b) at the retail stage, by using an indication which refers to only a few foods or groups of foods described in the Table to Part 4.

(**a**) OJ No. L338, 13.11.2004, p.4.

Table 2: Simulants to be selected for testing food contact materials in special cases

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

PART 4

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

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

2. For the purposes of this Part —

(a) a reduction factor is the figure which follows an "X" and oblique stroke in the group of columns headed "Simulants to be used" in the Table to this Part;

(b) a reduction factor is specified in relation to a specific food or group of foods where, in the Table —

(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 allowed by an oblique stroke and a reduction factor.

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

4. Where the letter "a" is shown in brackets after the "X", only one of the two simulants specified shall be used in the migration test, that is to say —

(a) if the pH value of the food is higher than 4.5, simulant A shall be used;

(b) if the pH value of the foodstuff is 4.5 or less, simulant B shall be used.

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

Reference Number	*Description of food*	*Simulants to be used*			
		A	B	C	D
01	**Beverages**				

01.01	Non-alcoholic beverages or alcoholic beverages of an alcoholic strength lower than 5% vol: — Waters, ciders, fruit or vegetable juices of normal strength or concentrated, musts, fruit nectars, lemonades and mineral waters, syrups, bitters, infusions, coffee, tea, liquid chocolate, beers and other	X(a)	X(a)		
01.02	Alcoholic beverages of an alcoholic strength equal to or exceeding 5% vol. — Beverages shown under heading 01.01 but with an alcoholic strength equal to or exceeding 5% vol. — Wines, spirits and liqueurs		X[(1)]	X[(2)]	
01.03	Miscellaneous: undenatured ethyl alcohol		X[(1)]	X[(1)]	
02	**Cereals, cereal products, pastry, biscuits, cakes and other bakers' wares**				
02.01	Starches				
02.02	Cereals, unprocessed, puffed, in flakes (including popcorn, 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, biscuits, cakes and other bakers' wares, fresh A With fatty substances on the surface B Other	 X			 X/5
03	**Chocolate, sugar and products thereof Confectionery products**				
03.01	Chocolate, chocolate-coated products, substitutes and products coated with substitutes				X/5
03.02	Confectionery products: A in solid form — with fatty substances on the surface — Other B in paste form: — with fatty substances on the surface — moist	 X			 X/5 X/3
03.03	Sugar and sugar products A In solid form B Honey and the like C Molasses and sugar syrups	 X X			
04	**Fruit, vegetable and products thereof**				
04.01	Whole fruit, fresh or chilled				
04.02	Processed fruit: A Dried or dehydrated fruit, whole or in the form of flour or powder B Fruit in the form of chunks, puree or paste C Fruit preserves (jams and similar products	 X(a)	 X(a)		

	– whole fruit or chunks or in the form of flour or powder, preserved in a liquid medium): — i) In an aqueous medium — ii) In an oily medium — iii) In an alcoholic medium ≥ 5% vol	 X(a) X(a)	 X(a) X(a) X[1]	 X	 X	
04.03	Nuts (peanuts, chestnuts, almonds, hazelnuts, walnuts, pine kernels and others) A Shelled, dried B Shelled and roasted C In paste or cream form	 X	 	 	 X/5[3] X/3[3]
04.04	Whole vegetables, fresh or chilled				
04.05	Processed vegetables: A Dried or dehydrated vegetables whole or in the form of flour or powder B Vegetables, cut, in the form of purees C Preserved vegetables: — i) In an aqueous medium — ii) In an oily medium — iii) In an alcoholic medium (≥ 5% vol)	 X(a) X(a) X(a)	 X(a) X(a) X(a) X[1]	 X	 X	
05	**Fats and oils**					
05.01	Animal and vegetable fats and oils, whether natural or treated (including cocoa butter, lard, re-solidified butter)				X	
05.02	Margarine, butter and other fats and oils made from water emulsions in oil				X/2	
06	**Animal products and eggs**					
06.01	Fish: A Fresh, chilled, salted, smoked B In the form of paste	 X X	 	 	 X/3[3] X/3[3]	
06.02	Crustaceans and molluscs (including oysters, mussels, snails) not naturally protected by their shells	X				
06.03	Meat of all zoological species (including poultry and game): A Fresh, chilled, salted, smoked B In the form of paste, creams	 X 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(a) X(a)	 	 X	
06.06	Eggs not in shell: A Powdered or dried B Other	 X	 	 	 	
06.07	Egg yolks: A Liquid B Powdered or frozen	 X	 	 	 	
06.08	Dried white of egg					
07	**Milk products**					
07.01	Milk: A Whole B Partly dried	 X X	 	 	 	

	C Skimmed or partly skimmed D Dried Fermented milk such as yoghurt, buttermilk and such products in association with fruit and fruit products	X	 X		
07.03	Cream and sour cream	X(a)	X(a)		
07:04	Cheeses: A Whole, with rind B Processed cheeses C All others	 X(a) X(a)	 X(a) X(a)		 X/3[(3)]
07:05	Rennet: A In liquid or viscous form B Powdered or dried	 X(a)	 X(a)		
08	**Miscellaneous products**				
08.01	Vinegar		X		
08.02	Fried or roasted foods: A Fried potatoes, fritters and the like B Of animal origin				 X/5 X/4
08.03	Preparations for soups, broths in liquid, solid or powder form (extracts, concentrates); homogenized composite food preparations, prepared dishes: A Powdered or dried — i) With fatty substances on the surface — ii) Other B Liquid or paste: — i) With fatty substances on the surface — ii) Other	 X(a) X(a)	 X(a) X(a)		 X/5 X/3
08.04	Yeasts and raising agents: A In paste form B Dried	 X(a)	 X(a)		
08.05	Salt				
08.06	Sauces: A Without fatty substances on the surface B Mayonnaise, sauces derived from mayonnaise, salad creams and other oil in water emulsions C Sauce containing oil and water forming two distinct layers	 X(a) X(a) X(a)	 X(a) X(a) X(a)		 X/3 X
08.07	Mustard (except powdered mustard under heading 08.17)	X(a)	X(a)		X/3[(3)]
08.08	Sandwiches, toasted bread and the like containing any kind of foodstuff: A With fatty substances on the surface B Other				 X/5
08.09	Ice-creams	X			
08.10	Dried foods: A With fatty substances on the surface B Other				 X/5
08.11	Frozen or deep-frozen foods				
08.12	Concentrated extracts of an alcoholic strength equal to or exceeding 5% vol		X[(1)]	X	
08.13	Cocoa:				

	A Cocoa powder B Cocoa paste				X/5[3] X/3[3]
08.14	Coffee, whether or not roasted, decaffeinated or soluble, coffee substitutes, granulated or powdered				
08.15	Liquid coffee extracts	X			
08.16	Aromatic herbs and other herbs: Camomile, mallow, mint, tea, lime blossom and others				
08.17	Spices and seasonings in the natural state: Cinnamon, cloves, powdered mustard, pepper, vanilla, saffron and other				

[1] Simulant B shall not be used where the pH is more than 4.5.

[2] This test shall be carried out in the case of liquids or beverages of an alcoholic strength exceeding 10% vol with aqueous solutions of ethanol of a similar strength.

[3] If it can be demonstrated under regulation 12(2) or proved by means of an appropriate test that there is to be no fatty contact with the plastic material or article, simulant D shall not be used.

PART 5

Migration Test Conditions (Times and Temperatures)

General criteria

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

Volatile migrants

4. When carrying out a test of the specific migration of volatile substances any test using a simulant shall be performed in a manner which recognises the loss of volatile migrants which may occur in the worst foreseeable conditions of use.

Special cases

5. When carrying out a migration test of a plastic material or article which is intended for use in a microwave oven, if the appropriate time and temperature is selected from the table to this Part, either a conventional oven or a microwave oven may be used.

6. Where the carrying out of a migration test under contact conditions specified in the Table to this Part causes any physical or other change in the test specimen which does not occur under the worst foreseeable conditions of use of the plastic material or article being tested the migration test shall be carried out in the worst foreseeable conditions of use in which such physical or other change does not occur.

7. Where, in actual use, the plastic material or article being tested is intended to be used for periods of less than 15 minutes at any temperature of not less than 70°C and not more than 100°C and such use is indicated by appropriate labelling or instructions no test other than for 2 hours at 70°C shall be carried out on the plastic material or article unless the plastic material or article is also intended to be used for storage at room temperature in which case no test other than for 10 days test at 40°C shall be carried out.

8. The Table to this Part shall be read with the notes to it.

Conditions of contact in worse foreseeable use	*Test conditions*
Contact time:	**Test time:**
less than or equal to 5 minutes	(1)
>5 minutes but less than or equal to 0.5 hours	0.5 hours
>0.5 hours but less than or equal to 1 hour	1 hour
>1 hour but less than or equal to 2 hours	2 hours
>2 hours but less than or equal to 4 hours	4 hours
>4 hours but less than or equal to 24 hours	24 hours
>24 hours	10 days
Contact temperature:	**Test temperature:**
less than or equal to 5°C	5°C
>5°C but less than or equal to 20°C	20°C
>20°C but less than or equal to 40°C	40°C
>40°C but less than or equal to 70°C	70°C
>70°C but less than or equal to100°C	100°C or reflux temperature
>100°C but less than or equal to 121°C	121°C (2)
>121°C but less than or equal to 130°C	130°C (2)
>130°C but less than 150°C	150°C (2)
>150°C	175°C (2)

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

(2) This temperature shall be used only for simulant D. For simulant A, B or C the test may be replaced by a test at 100°C or at reflux temperature for a duration of four times the time selected in accordance with paragraph 1 of this Part.

PART 6

Substitute Fat Test for Overall and Specific Migration

1. Subject to paragraphs 2, 4 and 5, all the test media specified in the Table to this Part shall be used in the substitute fat test for overall or specific migration under the test conditions corresponding to the test conditions for 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 Parts 3, 4 and 5 of this Schedule shall be applied for each test medium;

(c) subject to paragraph 4, compliance with a migration limit shall be determined by selecting the highest value using all the test methods.

4. Where carrying out a migration test causes any physical or other change in the test specimen which does not occur under the worst foreseeable conditions of use of the plastic material or article the result of that test shall not be used to ascertain compliance with a migration limit.

5. Any test conditions in the Table to this Part which are generally recognised on the basis of scientific evidence as not being appropriate for the material or article to be tested shall not be used.

6. The Table to this Part shall be read with the notes to it.

Conventional conditions for substitute tests

Test conditions with simulant D	*Test conditions with isooctane*	*Test conditions with ethanol 95%*	*Test conditions with MPPO[(1)]*
10 days at 5°C	0.5 days at 5°C	10 days at 5°C	
10 days at 20°C	1 day at 20°C	10 days at 20°C	
10 days at 40°C	2 days at 20°C	10 days at 40°C	
2 hours at 70°C	0.5 hours at 40°C	2 hours at 60°C	
0.5 hours at 100°C	0.5 hours at 60°C[(2)]	2.5 hours at 60°C	0.5 hours at 100°C
1 hour at 100°C	1 hour at 60°C[(2)]	3 hours at 60°C[(2)]	1 hour at 100°C
2 hours at 100°C	1.5 hours at 60°C[(2)]	3.5 hours at 60°C[(2)]	2 hours at 100°C
0.5 hours at 121°C	1.5 hours at 60°C[(2)]	3.5 hours at 60°C[(2)]	0.5 hours at 121°C
1 hour at 121°C	2 hours at 60°C[(2)]	4 hours at 60°C[(2)]	1 hour at 121°C
2 hours at 121°C	2.5 hours at 60°C[(2)]	4.5 hours at 60°C[(2)]	2 hours at 121°C
0.5 hours at 130°C	2 hours at 60°C[(2)]	4 hours at 60°C[(2)]	0.5 hours at 130°C
1 hour at 130°C	2.5 hours at 60°C[(2)]	4.5 hours at 60°C[(2)]	1 hour at 130°C
2 hours at 150°C	3 hours at 60°C[(2)]	5 hours at 60°C[(2)]	2 hours at 150°C
2 hours at 175°C	4 hours at 60°C[(2)]	6 hours at 60°C[(2)]	2 hours at 175°C

[(1)] MPPO = Modified polyphenylene oxide

[(2)] The volatile test media are used up to a maximum temperature of 60°C. A precondition of using these tests is that the material or article will withstand the test conditions that would otherwise be used with simulant D. Immerse a test specimen in olive oil under the appropriate conditions. If the physical properties are changed (eg melting, deformation) then the material is considered unsuitable for use at that temperature. If the physical properties are not changed then proceed with the substitute tests using new specimens.

PART 7

Alternative Fat Tests for Overall and Specific Migration

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

(a) the result obtained in a "comparison test" shows that the values are equal to 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 tests specified in paragraph 3 are equal to or greater than those obtained in any of the migration tests specified in Part 3.

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

(a) a test carried out using volatile media including isooctane, ethanol 95%, other volatile solvents or a mixture of solvents at such contact conditions as would result in values equal to or greater than those obtained in a test using 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.

EXPLANATORY NOTE

(This note is not part of the Regulations)

1. These Regulations, which apply in relation to England only, revoke the Plastic Materials and Articles in Contact with Food Regulations 1998 as amended ("the 1998 Regulations") in so far as they apply in relation to England, and re-enact or re-enact with changes certain provisions contained in those Regulations. The principal Directives that continue to be implemented by these Regulations are listed in paragraph 5 below. These Regulations also provide for the execution and enforcement of Commission Regulation (EC) No 1895/2005 on the restriction of use of certain epoxy derivatives in materials and articles intended to come into contact with food ("Regulation 1895/2005").

2. The Regulations in Part 2 —

(a) prohibit specified activities in relation to any plastic material or article (as defined in *regulation 2*) which fails to meet the appropriate required standards set out in the Regulations (*regulation 3*);

(b) prohibit the use of monomers and additives in the manufacture of plastic materials and articles other than in accordance with specified conditions (*regulation 4 and Schedule 1 in the case of monomers and regulation 5 and Schedule 2 in the case of additives*);

(c) specify the required standards relating to the capability of a monomer or an additive to confer its constituents to food (*regulation 6 for monomers and regulation 7 for additives*);

(d) specify the required standard for products obtained by bacterial fermentation (*regulation 8 and Schedule 3*);

(e) specify the required standard relating to overall migration limits from plastic materials or articles to food (*regulation 9*);

(f) specify the required standards relating to the migration of primary aromatic amines from plastic materials or articles to food (*regulation 10*);

(g) specify the methods for determining the capability of a plastic material or article to transfer its constituents to food, and for detecting the presence of any such constituents in food (*regulation 11 and Schedules 5 & 6*);

(h) provide that prior to the retail stage plastic materials and articles must be accompanied by certain specified written information, including a declaration of legislative compliance (*regulation 12*);

(i) provide for the enforcement of Regulation 1895/2005, which contains Community provisions relating to the epoxy derivatives known as BADGE, BFDGE and NOGE (*regulation 13*).

3. The Regulations in Part 3 —

(a) designate food authorities and port health authorities as the enforcement authorities in their respective areas or districts (*regulation 14*);

(b) specify the offences that may be committed under these Regulations and set out the maximum penalties on conviction (*regulation 15*);

(c) provide for defences of a general nature, such as exercise of due diligence etc, to offences under regulation 15 (*regulation 16*);

(d) provide for transitional defences in relation to certain plastic materials or articles that have already been manufactured or put into circulation in advance of a change in the law that would otherwise have made their manufacture or circulation unlawful (*regulation 17*);

(e) specify the procedure to be followed when sending a sample for analysis (*regulation 18*);

(f) make provision for a reference sample to be analysed by the Laboratory for the Government Chemist (*regulation 19*);

4. Part 4 of the Regulations contains provisions relating to the procedure to be followed and the time limit to be observed where a person wishes apply to the European Food Safety Authority for the authorisation of a new additive (*regulation 20*).

5. The principal Directives implemented by the 1998 Regulations which these Regulations continue to implement are —

(a) Council Directive 82/711/EEC (OJ No. L297, 23,10,1982, p.26) laying down the basic rules necessary for testing migration of the constituents of plastic materials and articles intended to come into contact with foodstuffs, as amended by Commission Directives 93//8/EEC (OJ No. L90, 14.4.1993, p.22) and 97/48/EC (OJ No. L222, 12.8.1997, p.10);

(b) Council Directive 85/572/EEC laying down the list of stimulants to be used for testing migration of constituents of plastic materials and articles intended to come into contact with foodstuffs (OJ No. L372, 31.12.1985, p.14);

(c) Commission Directive 2002/72/EC (OJ No. L220, 15.8.2002, p.18) relating to plastic materials and articles intended to come into contact with foodstuffs, as amended by Commission Directives 2004/1/EC (OJ No. L7, 13.1.2004, p.45) and 2004/19/EC (OJ No. L71, 10.3.2004, p.8).

6. A full regulatory impact assessment of the effect that this instrument will have on the costs of business has been prepared and placed in the library of each House of Parliament. Copies may be obtained from the Chemical Safety Division of the Food Standards Agency, Aviation House, 125 Kingsway, London WC2B 6NH.

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