SCOTTISH STATUTORY INSTRUMENTS

2008 No. 127

FOOD

The Plastic Materials and Articles in Contact with Food (Scotland) Regulations 2008

Made - - - -	*19th March 2008*
Laid before the Scottish Parliament	*20th March 2008*
Coming into force	
for the purpose of regulation 26(c)	*1st July 2008*
for all other purposes	*1st May 2008*

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General and Supplementary

The Scottish Ministers make the following Regulations in exercise of the powers conferred by sections 16(2), 17(1) and (2), 26(1)(a), (2)(a) and (3), 31 and 48(1) of the Food Safety Act 1990(**a**) and paragraph 1A of Schedule 2 to the European Communities Act 1972(**b**), and all other powers enabling them to do so.

(**a**) 1990 c.16; section 1(1) and (2) (definition of "food") was substituted by S.I. 2004/2990; sections 16(2) and 48(1) were amended by the Food Standards Act 1999 (c.28) ("the 1999 Act"), Schedule 5, paragraph 8; section 17(1) and (2) was amended by 1999 Act, Schedule 5, paragraphs 8 and 12; section 26(3) was amended by the 1999 Act, Schedule 6 and is to be read with section 45 of the Criminal Proceedings etc. (Reform) (Scotland) Act 2007, (asp 6); section 48(4) is disapplied in respect of these Regulations by virtue of section 48(4C) which was inserted by S.I. 2004/2990; amendments made by Schedule 5 to the 1999 Act shall be taken as pre-commencement enactments for the purposes of the Scotland Act 1998 (c.46) (c.46) ("the 1998 Act") by virtue of section 40(2) of the 1999 Act. The functions of the Secretary of State, in so far as within devolved competence, were transferred to the Scottish Ministers by virtue of section 53 of the 1998 Act. In so far as not so transferred, and insofar as relating to food (including drink) including the primary production of food those functions were transferred to the Scottish Ministers by the Scotland Act 1998 (Transfer of Functions to the Scottish Ministers etc.) Order 2005 (S.I. 2005/849).

(**b**) 1972 c.68; paragraph 1A was inserted by the Legislative and Regulatory Reform Act 2006 (c.51), section 28.

These Regulations make provision for a purpose mentioned in section 2(2) of the European Communities Act 1972 and it appears to the Scottish Ministers that it is expedient for references to any Annex to the Community instrument specified in regulation 2(5) to be construed as a reference to that Annex as amended from time to time.

In accordance with section 48(4A) of the Food Safety Act 1990, they have had regard to relevant advice given by the Food Standards Agency(**a**).

There has been consultation 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(**b**).

PART 1

Preliminary

Citation, commencement and extent

1.—(1) These Regulations may be cited as the Plastic Materials and Articles in Contact with Food (Scotland) Regulations 2008, and come into force–

(a) for the purpose of regulation 26(c), on 1st July 2008, and

(b) for all other purposes, on 1st May 2008.

(2) These Regulations extend to Scotland only.

Interpretation

2.—(1) In these Regulations–

"the Act" means the Food Safety Act 1990;

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

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

"business" has the meaning it bears in the Act;

"capable" means capable as established under regulation 13;

"Directive 82/711" means Council Directive 82/711/EEC laying down the basic rules necessary for testing migration of the constituents of plastic materials and articles intended to come into contact with foodstuffs(**c**);

"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(**d**);

"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(**e**);

(**a**) Section 48(4A) was inserted by paragraph 21 of Schedule 5 to the 1999 Act.

(**b**) O.J. No. L 31, 1.2.02, p.1, as amended by Regulation (EC) No. 1642/2003 of the European Parliament and of the Council (O.J. No. L 245, 29.9.03, p.4) and Commission Regulation (EC) No. 575/2006 (O.J. No. L 100, 7.4.06, p.3).

(**c**) O.J. No. L 297, 23.10.82, p.26; as amended by Commission Directive 93/8/EEC (O.J. No. L 90, 14.4.93, p.22) and Commission Directive 97/48/EC (O.J. No. L 222, 12.8.97, p.10)

(**d**) O.J. No. L 372, 31.12.85, p.14.

(**e**) O.J. No. L 345, 14.12.88, p.29; as corrected by a corrigendum dated 15th July 1988 (O.J. No. L 184, 15.7.88, p.61).

"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(**a**);

"the Directive" means Commission Directive 2002/72/EC relating to plastic materials and articles intended to come into contact with foodstuffs(**b**);

"EFSA" means the European Food Safety Authority;

"fatty foods" means foods for which, in migration testing, stimulant D is specified in Directive 85/572/EEC;

"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;

"infants" means children under the age of twelve months;

"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 which is included for the purposes of the Directive among monomers and other starting substances;

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

"plastic functional barrier" means a barrier consisting of one or more layers of plastics which ensure that the finished material or article complies with Article 3 of Regulation 1935/2004 and with the Directive;

"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;

"plastic multi-layer material or article" means a plastic material or article composed of two or more layers of materials each consisting exclusively of plastics, which are bound together by means of adhesives or other means;

"purity criteria" means purity criteria in accordance with Commission Directive 95/31/EC laying down specific criteria of purity concerning sweeteners for use in foodstuffs(**c**), Commission Directive 95/45/EC laying down purity criteria concerning colours for use in foodstuffs(**d**) and Commission Directive 96/77/EC laying down specific purity criteria for food additives other than colour sweeteners(**e**);

"Regulation 1935/2004" means 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(**f**);

"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(**g**);

(**a**) O.J. No. L 40, 11.2.89, p.27; as amended by European Parliament and Council Directive 94/34 (O.J. No. L 237, 10.9.94, p.1).

(**b**) O.J. No. L 220, 15.8.02, p.18; as amended by Commission Directive 2004/1/EC (O.J. No. L 7, 13.1.04, p.45), Commission Directive 2004/19/EC (O.J. No. L 71, 10.3.04, p.8), Commission Directive 2005/79/EC (O.J. No. L 302, 19.11.05, p.35), and Commission Directive 2007/19/EC (O.J. No. L 97, 12.4.2007, p.50).

(**c**) O.J. No. L 178, 28.7.95, p.1; as amended by Commission Directive 98/66/EC (O.J. No. L 257, 19.9.98, p.35), Commission Directive 2000/51/EC (O.J. No. L 198, 4.8.00, p.41), Commission Directive 2001/52/EC (O.J. No. L 190, 12.7.01, p.18) and Commission Directive 2004/46/EC (O.J. No. L 114, 21.4.04, p.15).

(**d**) O.J. No. L 226, 22.9.95, p.1; as amended by Commission Directive 1999/75/EC (O.J. L 206, 5.8.99, p.19), Commission Directive 2001/50/EC (O.J. No. L 190, 12.7.01, p.14) and Commission Directive 2004/47/EC (O.J. L 113, 20.4.04, p.24).

(**e**) O.J. No. L 339, 30.12.96, p.1; as amended by Commission Directive 2001/30/EC (O.J. No. L 146, 31.5.01, p.1), Commission Directive 2002/82/EC (O.J. No. L 292, 28.10.02, p.1), Commission Directive 2003/95/EC (O.J. No. L 283, 31.10.03, p.71) and Commission Directive 2004/45/EC (O.J. No. L 113, 20.4.04, p.19).

(**f**) O.J. No. L 338, 13.11.2004, p.4.

(**g**) O.J. No. L 302, 19.11.05, p.28.

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

"the 2006 Regulations" means the Plastic Materials and Articles in Contact with Food (Scotland) (No. 2) Regulations 2006(**b**);

"the 2007 Regulations" means the Materials and Articles in Contact with Food (Scotland) Regulations 2007(**c**);

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

"young children" means children aged between one and three years.

(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.

(4) Except in regulation 11(3) and Part 5 of Schedule 3, any reference to a numbered Annex is a reference to that Annex in the Directive.

(5) Any reference to an Annex to the Directive is a reference to that Annex as amended from time to time.

PART 2

Requirements for Plastic 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; or

(b) for the purpose of the handling of food–

(i) sell; or

(ii) import from anywhere other than an EEA State,

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 it–

(a) 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) does not meet the required standards set out in regulation 6, 7, 8, 9, 10 or 11.

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 Sections A or B of Annex II; and

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(**a**) S.I. 1998/1376 as amended by S.S.I. 2000/431, 2002/498, 2003/9, 2004/524 and 2005/92. It was revoked by S.S.I. 2006/314.
(**b**) S.S.I. 2006/517.
(**c**) S.S.I. 2007/471.

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

(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 which falls within paragraph 3(c) (relating to mixtures of authorised substances) of Annex II 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 a be defence for the accused to prove that each such monomer─

(a) 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; or

(b) 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) Schedule 1 has effect to supplement this regulation.

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

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

(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 Section A or B of Annex III which is not–

(i) of good technical quality; or

(ii) used in accordance with any restrictions and specifications for that additive set out in the corresponding entry in column 4 of Section A or B of that Annex; 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 Annex III, 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 Section A or B of Annex III, which is not of good technical quality, it shall be a defence for the 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) Schedule 1 has effect to supplement this regulation.

Required standard for non-migration of constituents of monomers

6.—(1) Subject to paragraphs (2) and (3), where a migration limit expressed in mg/kg is indicated in column 4 of the relevant section of Section A or B of Annex II 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 it 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 Section A or B of Annex II is not to be considered capable of transferring constituents of that monomer to food with which it 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(5) applies.

(3) For plastic materials or articles brought or intended to be brought into contact with food for infants and young children the migration limits referred to in paragraph (1) shall always be applied in mg/kg.

Required standard for non-migration of constituents of additives

7.—(1) Subject to paragraphs (2) and (3), where a migration limit expressed in mg/kg is indicated in column 4 of Section A or B of Annex III 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 it 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 Section A or B of Annex III is not to be considered 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(5) applies.

(3) For plastic materials or articles brought or intended to be brought into contact with food for infants and young children the migration limits referred to in paragraph (1) shall always be applied in mg/kg.

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 Annex IV; and

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

Required standards relating to overall migration limits

9.—(1) Subject to paragraph (5), 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 paragraphs (2) to (4).

(2) Subject to paragraph (4), in the case of any plastic material or article comprising–

(a) an article which is a container or comparable to a container or can be filled, with a capacity of less than 500 millilitres or more than 10 litres; or

(b) sheet, film or any other material or article which cannot be filled or for which it is impracticable to estimate the relationship between the surface area of such material or article and the quantity of food in contact with it,

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) In the case of any other plastic material or article, the appropriate limit is an overall migration limit of 60 milligrams of the constituents released per kilogramme of food or food stimulant.

(4) For plastic materials or articles intended to be brought into contact or already in contact with food intended for infants and young children, the appropriate limit is always 60 milligrams of the constituents released per kilogramme of food or food simulant.

(5) 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 3; and

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

(6) 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 10(2) of Schedule 2 are available as specified in that paragraph.

Required standard for non-migration of primary aromatic amines

10.—(1) Subject to paragraph (4), a plastic material or article manufactured using primary aromatic amines meets the required standard under this regulation if it is not capable of transferring such amines (expressed as aniline) in a detectable quantity to food with which that plastic material or article may come into contact.

(2) Part B of Annex V has effect for the purpose of prescribing, for certain items listed in Section A or B of Annex II, Section A or B of Annex III, or Annex IV, the specifications for those items that are referred to in column 4 of the Annex or Section of Annex concerned.

(3) For the purposes of paragraph (1) a detectable quantity means at least 0.01 milligrams per kilogram of food or food simulant.

(4) The requirement in paragraph (1) does not apply to primary aromatic amines listed in the Directive.

Required standard relating to plastic multi-layer materials and articles

11.—(1) Subject to paragraph (2), a plastic multi-layer material or article meets the required standard if each layer of it complies with these Regulations.

(2) A layer which is not in direct contact with food and is separated from such contact by a plastic functional barrier does not have to comply with the requirements of these Regulations provided that–

(a) the finished material or article complies with the relevant specific and overall migration limits; and

(b) if any substance used in the manufacture of the layer is not included in the Directive or in national lists referred to in that Directive, that substance meets the requirements of paragraphs (3) and (4).

(3) A substance mentioned in paragraph (2)(b) must not belong to the category of those classified–

(a) as proved or suspect "carcinogenic", mutagenic" or "toxic to reproduction" substances in Annex I to Directive 67/548/EEC(**a**), or

(b) under the self-responsibility criteria as "carcinogenic", "mutagenic" or "toxic to reproduction" substances according to the rules of Annex VI to that Directive.

(4) The migration of a substance mentioned in paragraph (2)(b) into a food or simulant must not exceed 0.01 mg/kg, measured and expressed in accordance with the requirements and specifications contained in Article 7a(3) of the Directive.

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

12.—(1) In this regulation–

(a) any reference to a numbered Article is a reference to that Article in Regulation 1895/2005;

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

(c) for the purposes of Article 6(4) the competent authority is the food authority.

(2) Subject to Article 6(1), (2) (transitional provisions) and (4) (requirement to disclose date of filling to competent authority), no person may–

(a) manufacture,

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

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

(i) sell; or

(ii) import,

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; or

(b) for the purpose of the handling of food–

(i) sell; or

(ii) import,

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

(**a**) O.J. No. L 196, 16.8.1967, p.1 as last amended by Directive 2006/121/EC of the European Parliament and of the Council (O.J. No. L 396, 30.12.2006, p.850).

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).

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

13.—(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) or (c) 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 2 (including the analytical tolerances referred to in paragraph 12 of that Schedule) and Schedule 3;

(b) in any case where the extent to which vinyl chloride, as identified in Section A of Annex II, is capable of such transfer falls to be established, by the method referred to in regulation 9(2) of the 2007 Regulations; or

(c) in any case where the extent to which a phthalate listed in Section B of Annex III with PM/Ref No 74640, 74880, 74560, 75100 or 75105 is capable of such transfer falls to be established, by the method referred to in Article 8(5) of the Directive.

(2) In Schedules 2 and 3, references to migration or release of a substance are to be construed as references to the transfer of constituents to the food or simulant representing the food with which it is or 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.

(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 relating to the term "QM(T)", "QMA" or "QMA(T)" as the case may be.

Labelling and documentation

14.—(1) At marketing stages other than the retail stage a person who places on the market any plastic material or article or any substance intended for the manufacture of a plastic material or article must ensure that the plastic material or article or substance is accompanied by a written declaration which–

(a) accords with article 16(1) of Regulation 1935/2004;

(b) contains the information specified in Schedule 4; and

(c) permits an easy identification of the materials, articles or substances for which it is issued.

(2) A written declaration under paragraph (1) must be revised when substantial changes in the production of a plastic material or article for which the declaration is issued bring about changes in the migration or when new scientific data are available.

(3) A person mentioned in paragraph (1) must make available to the food authority on request appropriate documentation to demonstrate that the plastic material or article or substance intended for its manufacture complies with the requirements of these Regulations.

(4) The documentation referred to in paragraph (3) shall contain the conditions and results of testing, calculations, other analysis, and evidence on the safety or reasoning demonstrating compliance.

PART 3

Execution and Enforcement

Enforcement

15. Each food authority shall execute and enforce–

(a) the provisions of Regulation 1895/2005 referred to in regulation 12, and

(b) these Regulations,

in its area.

Offences and Penalties

16.—(1) Any person who–

(a) contravenes or fails to comply with regulation 3(1), 4(1), 5(1), 12(2) to (5), 14(1) or 14(3) to (4);

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

(c) fails to comply with regulation 12(6) or 18(3), or otherwise fails without reasonable excuse 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) Any person convicted of an offence under these Regulations is liable–

(a) in the case of an offence under paragraph (1)(a) or (d)–

(i) on conviction on indictment to a term of imprisonment not exceeding 2 years or to a fine or both;

(ii) on summary conviction to a term of imprisonment not exceeding 12 months or to a fine not exceeding the statutory maximum or both;

(b) in the case of any other offence under these Regulations, on summary conviction to a term of imprisonment not exceeding 3 months or to a fine not exceeding level 5 on the standard scale or to 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 that person.

(4) 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.

(5) For the purposes of this regulation, a certificate signed by or on behalf of the prosecutor and stating the date on which evidence sufficient in the prosecutor's opinion to warrant the proceedings came to the knowledge of the prosecutor, shall be conclusive evidence of that fact.

(6) A certificate stating that matter and purporting to be so signed shall be deemed to be so signed unless the contrary is proved.

General defences

17.—(1) In any proceedings for an offence under these Regulations it shall, subject to paragraph (5), be a defence to prove that the accused took all reasonable precautions and exercised all due diligence to avoid the commission of the offence by the accused or by a person under the accused's 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 the requirements of paragraphs (3) and (4) are satisfied.

(3) The requirements of this paragraph are satisfied if it is proved that–

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

(b) either–

(i) the accused 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 the accused to rely on checks carried out by the person who supplied the accused with the plastic material or article or the material or article in question; and

(c) the accused did not know and could not reasonably have been expected to know at the time the offence was committed that the accused's act or omission would amount to an offence under these Regulations.

(4) The requirements of this paragraph are satisfied if the offence is one of sale and it is proved–

(a) that the commission of the offence was due to the act or default of some other person who was not under the accused's 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 the accused's name or mark; and

(c) that the accused did not know and could not reasonably have been expected to know at the time the offence was committed that the accused's act or omission would amount to an offence under these Regulations.

(5) If 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 accused shall not without leave of the court be entitled to rely on that defence unless by the earlier of–

(a) a date 7 days before the trial diet (not being a notional trial diet); or

(b) a date 28 days after the first appearance of the accused before a court in connection with the alleged offence,

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

(6) For the purposes of paragraph (2), "prepare" includes manufacture or subject to any form of treatment or process.

Transitional defence relating to PVC gaskets containing epoxidised soybean oil

18.—(1) In any proceedings for an offence under regulation 3 concerning the sale of a glass jar–

(a) which contains–

(i) infant formulae or follow-on formulae as defined by Commission Directive 91/321/EC(**a**); or

(**a**) O.J. No. L 175, 4.7.1991, p.35; as amended by Commission Directive 96/4/EC (O.J. No. L 49, 28.2.1996, p.12), Commission Directive 1999/50/EC (O.J. No. L 139, 2.6.1999, p.29) Commission Directive 2003/14/EC (O.J. No. L 41, 14.2.2003, p.37) and Commission Directive 2006/82/EC (O.J. No. L 362, 20.12.2006). Commission Directive 91/32/EC was repealed by Commission Directive 2006/141/EC (O.J. No. L 401, 30.12.2006). The definitions of infant formulae and follow-on formulae remain the same.

(ii) processed cereal-based foods or baby foods for infants and young children as defined by Commission Directive 96/5/EC(**a**); and

(b) the lid of which is sealed by means of a PVC gasket containing epoxidised soybean oil having PM/Ref No 88640 in Section A of Annex III,

it shall be a defence to prove the matters set out in paragraph (2).

(2) The matters to be proved are that–

(a) the PVC gasket mentioned in paragraph (1)(b) was compliant with the relevant restrictions and specifications in column 4 of item 259A of Part 1 of Schedule 2 to the Plastic Materials and Articles in Contact with Food (Scotland) Regulations 2006(**b**);

(b) the glass jar was filled and sealed before 19th November 2006;

(c) the date of filling or a coded indication of that date was present on the jar or its lid at the time of sale; and

(d) the labelling or marking with the particulars mentioned in sub-paragraph (c) at the time of sale complied with the requirements relating to durability in Article 2(1)(a) of Directive 2000/13/EC of the European Parliament and of the Council on the approximation of the laws of the member States relating to the labelling, presentation and advertising of foodstuffs(**c**).

(3) No person shall without reasonable excuse fail to comply with a request made by the food authority to disclose the date signified by the coded indication mentioned in paragraph (2)(c).

Other transitional defences and savings

19.—(1) Notwithstanding the revocation of the 1998 Regulations by regulation 24 of the 2006 Regulations, in relation to any plastic material or article–

(a) manufactured before 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 as it applied to offences under the equivalent provisions in those Regulations.

(**a**) O.J. No. L 41, 14.2.03, p.37; as amended by Commission Directive 98/36/EC (O.J. No. L 167, 12.2.1998, p.23), Commission Directive 1999/39/EC (O.J. No. L 124, 18.5.1999, p.8) and Commission Directive 2003/13/EC (O.J. No. L 41, 14.2.2003, p.33). Commission Directive 96/5/EC was repealed by Commission Directive 2006/125 (O.J. No. L 339, 6.12.2006). The definitions of processed cereal-based foods or baby foods remain the same.

(**b**) S.S.I 2006/314; revoked by S.S.I. 2006/517.

(**c**) O.J. No. L 109, 6.5.00, p.29; as corrected by a Corrigendum published on 25th May 2000 (O.J. No. L 124, 25.5.00, p.66), and as amended by Commission Directive 2001/101/EC (O.J. No. L 310, 28.11.01, p.19), (which was itself amended by Commission Directive 2002/86/EC (O.J. No. L 305, 7.11.02, p.19), the Act concerning the conditions of accession of the Czech Republic, the Republic of Estonia, the Republic of Cyprus, the Republic of Latvia, the Republic of Hungary, the Republic of Malta, the Republic of Poland, the Republic of Slovenia and the Slovak Republic and the adjustments to the Treaties on which the European Union is founded (O.J. No. L 236, 23.9.03, p.33) and Directive 2003/89/EC (O.J. No. L 308, 25.11.03, p.15).

(2) In any proceedings for an offence under these Regulations other than an offence mentioned in regulation 18(1) it shall be a defence to prove –

(a) that the act constituting the alleged offence was committed in relation to a plastic material or article which was manufactured or imported into the European Community before 19th November 2007; and

(b) that the matter constituting the alleged offence would not otherwise have constituted an offence under these Regulations if the amendments to the Directive made by Commission Directive 2005/79/EC had not been implemented at the time the matter occurred.

(3) In any proceedings for an offence under these Regulations other than an offence referred to in regulation 18(1), it shall be a defence to prove–

(a) in the case of–

(i) lids containing a gasket that do not comply with the restrictions and specifications for Ref. No.'s 30340, 30401, 36640, 56800, 76815, 76866, 88640 and 93760 contained in the Annex to Commission Regulation (EC) No. 372/2007 laying down transitional migration limits for plasticisers in gaskets in lids intended to come into contact with foods(**a**), or

(ii) plastic materials and articles which do not comply with the restrictions and specifications for phthalates under Ref. No.'s 74560, 74640, 74880, 75100 and 75105 contained in Annex III,

that the act constituting the alleged offence was committed in relation to a plastic material or article which was manufactured or imported into the European Community before 1st July 2008; or

(b) in any case other than those mentioned in sub-paragraph (a), that the act constituting the alleged offence was committed in relation to a plastic material or article which was manufactured or imported into the European Community before 1st May 2009; and

(c) that the matter constituting the alleged offence would not otherwise have constituted an offence under these Regulations if the amendments to the Directive made by Commission Directive 2007/19/EC had not been implemented in Scotland at the time the matter occurred.

Procedure where a sample is to be analysed

20.—(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 the owner 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 21.

Secondary analysis by the Government Chemist

21.—(1) Where a sample has been retained under regulation 20 and–

(a) a decision has been made to send a report to the procurator fiscal or proceedings have been commenced against a person for an offence under these Regulations; and

(**a**) O.J. No. L 92, 3.4.2007, p.9.

(b) the result of the analysis carried out in accordance with regulation 20(3)(d) is to be adduced as evidence,

paragraphs (2) to (8) apply.

(2) The authorised officer–

(a) may, of the officer's own volition prior to a report being sent to the procurator fiscal; and

(b) shall–

(i) if requested by the prosecutor;

(ii) if the court so orders on the application of the prosecutor or the accused; or

(iii) if requested by the accused (subject to paragraph (5)),

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

(3) The Government Chemist shall analyse the part sent under paragraph (2) and where the analysis is carried out–

(a) under paragraph (2)(a) or (b)(i) or (iii), provide the authorised officer; or

(b) under paragraph (2)(b)(ii), provide the prosecutor and the accused,

with a certificate specifying the results of the analysis.

(4) The authorised officer shall immediately on receipt of the Government Chemist's certificate under paragraph (3)(a) supply the prosecutor and the accused with a copy.

(5) Where a request is made under paragraph (2)(b)(iii) the authorised officer may give notice in writing to the accused requesting payment of a fee specified in the notice in respect of the functions mentioned in paragraph (3), and in the absence of agreement by the accused to pay the fee the authorised officer may refuse to comply with the request.

(6) Any certificate specifying the results of the analysis transmitted by the Government Chemist under this regulation must be signed by or on behalf of the Government Chemist, but the analysis may be carried out by any person under the direction of the person who signs the certificate.

(7) Any certificate transmitted by or on behalf of the Government Chemist in accordance with paragraph (6) shall be taken as sufficient evidence of the facts stated therein unless any party to the proceedings requests that the person by whom the certificate is signed be called as a witness.

(8) In this regulation "accused" includes a person in respect of whom the authorised officer intends to submit a report to the procurator fiscal.

PART 4

Application for Authorisation

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

22.—(1) This regulation applies where a person has made an application, including supporting data, for the inclusion of an eligible additive in the Community list referred to in Article 4 of the Directive before 1st January 2007.

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

(3) 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

23. The following provisions of the Act apply for the purposes of these Regulations as they apply for the purposes of the Act–

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

(b) section 20 (offences due to fault of another person);

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

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

(e) section 36A (offences by Scottish Partnerships); and

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

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

24. In Schedule 1 (provisions to which these Regulations do not apply) to the Food Safety (Sampling and Qualifications) Regulations 1990(**a**), for the title and reference of the 2006 Regulations substitute the title and reference of these Regulations.

Amendments to the Materials and Articles in Contact with Food (Scotland) Regulations 2007

25.—(1) The 2007 Regulations are amended in accordance with paragraphs (2) to (4).

(2) In regulation 2(1)–

(a) omit the definition of "the 2006 Regulations";

(b) after the definition of "sell" insert the following definition–

""the 2008 Regulations" means the Plastic Materials and Articles in Contact with Food (Scotland) Regulations 2008(**b**).".

(3) In regulation 10, in paragraph (4) for "2006" substitute "2008".

(4) In regulation 11, in paragraph (5) for "2006" substitute "2008".

Revocations

26. The following are revoked–

(a) the 2006 Regulations;

(b) regulation 21 of the 2007 Regulations; and

(c) the Plastic Materials and Articles in Contact with Food (Lid Gaskets) (Scotland) Regulations 2007(**c**).

S ROBISON
Authorised to sign by the Scottish Ministers

St Andrew's House,
Edinburgh
19th March 2008

(**a**) S.I. 1990/2463.
(**b**) S.S.I. 2008/127
(**c**) S.S.I. 2007/433.

SCHEDULE 1

Regulations 4 and 5

Supplementary Provisions Relating to Annexes II and III

1. In Sections A and B of Annexes II and III (in this Schedule referred to together as "the Annexes")–

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

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

(c) the name of any substance is its chemical name, and to the extent that there is any inconsistency between 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 2 and 3.

2. If a substance appearing in the Annexes 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 the extent necessary.

3.—(1) The items identified in Section A or B of Annex II 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) Salts (including double salts and acid salts) of aluminium, ammonium, calcium, iron, magnesium, potassium and sodium of authorised acids, phenols or alcohols are not included in the lists in the Annexes even if they are authorised and intentionally used; however names containing "…acid(s), salts" do appear in the lists if the corresponding free acid(s) is or are not mentioned.

(3) Salts (including double salts and acid salts) of zinc of authorised acids, phenols or alcohols are not included in the lists in the Annexes even if they are authorised and intentionally used. For these salts a Group SML = 25/mg/kg (expressed as Zn) applies. The same restriction for Zn applies to–

(a) substances whose name contains "…acid(s), salts" which appear in the lists, if the corresponding free acid(s) is or are not mentioned; and

(b) substances referred to in note 38 of Annex VI.

4. In the case of substances listed in Section B of Annex III, the specific migration limits listed in column 4 shall have effect where the verification of compliance is carried out in Simulant D or in test media of substitute tests as prescribed in Directives 82/711 and 85/572.

5. Where an entry in column 4 of the Annexes (restrictions and specifications) includes a bracketed number, that entry shall be subject to a note relating to that number as set out in Annex VI.

SCHEDULE 2

Regulations 9 and 13

Provisions Applicable 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 3, 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 3 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) 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 3.

(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 or Annexes II, III or IV (for the purposes of this Schedule and Schedule 3 referred to as "the Annexes") 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 or the Annexes 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 3.

5. Where a plastic material or article is intended to come into repeated contact with food, any migration test shall (subject to paragraph 7) be carried out three times on a single sample in accordance with the conditions laid down in this Schedule and, where appropriate, Schedule 3 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 the fat reduction factor

6.—(1) Subject to paragraph 7, the results of tests for specific migration in foods containing more than 20% fat shall be corrected by the fat reduction factor ("FRF"), being a factor between 1 and 5 (expressed as M_{FRF}) by which measured migration of lipophilic substances listed in Annex IVa into a fatty food or stimulant D and its substitutes are divided before comparison with specific migration limits.

(2) The following equations shall be applied before comparison with the specific migration limit–

(a) $M_{FRF} = M/FRF$, and

(b) FRF = (g fat in food/kg of food)/200 = (% fat x 5)/100.

7.—(1) Correction by the FRF does not apply–

(a) where the plastic material or article is or is intended to be brought into contact with foods intended for infants and young children;

(b) for substances listed in the Annexes having a restriction in column (4) of SML = ND;

(c) for substances not listed in the Annexes and used behind a plastic functional barrier with a migration limit of 0.01 mg/kg;

(d) except in the circumstances specified in sub-paragraph (2), for plastic materials or articles–

(i) for which it is impracticable to estimate the relationship between the surface area and the quantity of food in contact with it, due to shape, use or other factors, and

(ii) where the migration is calculated using the conventional surface area/volume conversion factor of 6 dm^2/kg.

(2) For containers and other fillable articles with a capacity of less than 500 millilitres or more than 10 litres and for sheets and films in contact with foods containing more than 20% fat–

(a) the migration may be calculated as concentration (expressed as mg/kg) in the food or food simulant and corrected by the FRF; or

(b) the migration may be re-calculated as mg/dm^2 without applying the FRF,

and, provided the value resulting from the calculation under either sub-paragraph (a) or (b) is below the SML, the plastic material or article shall be considered to be in compliance.

8. If use of the FRF under paragraph 6 or 7(2) produces a result that indicates the overall migration limit has been exceeded, the material or article in question shall not be considered to be in compliance.

Special provisions relating to the correction of specific migration in stimulant D

9. The specific migration of those lipophilic substances listed in Annex IVa into stimulant D and its substitutes shall be corrected by–

(a) the stimulant D reduction factor ("DRF"), being the reduction factor referred to in paragraph 2(2) of Part 3 and paragraphs 2 and 3 of Part 4 of Schedule 3, provided that–

(i) in cases where the specific migration into stimulant D is higher than 80% of the content of the substance in the finished plastic material or article, it can be demonstrated by scientific or experimental evidence, such as testing with the most critical foods, that the DRF is appropriate, and

(ii) the substance is not one mentioned in paragraph 7(1)(b) or (c);

(b) the FRF, provided that the fat content of the food to be packed is known and the requirements of paragraphs 6, 7 and 8 are fulfilled; or

(c) the total reduction factor ("TRF"), being the factor–

(i) by which a measured specific migration into stimulant D or a substitute shall be divided before comparison with the specific migration limit, and

(ii) which is obtained by multiplying the DRF by the FRF with a maximum value of 5, when both factors are applicable.

Special provisions relating to overall migration

10.—(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 3 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.

11.—(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 modified in accordance with sub-paragraph (2) or in such other way so as to enable the level of migration occurring during the third such test to be determined, and such a determination may be used as evidence of the overall migration in relation to a plastic material or article.

(2) Three identical samples of the plastic material or article are to be procured, following which–

(a) the first sample is to be subjected to the appropriate test according with paragraph 4 and the overall migration determined (M_1);

(b) the second and third samples are to be subjected to the same conditions of temperature as the first but the period of contact is to be two and three times respectively that specified and the overall migration determined in each case (M_2 and M_3).

(3) Where a modified test has been carried out in accordance with sub-paragraph (2), provided that either M_1 or $M_3 – M_2$ did not exceed the overall migration limit, the plastic material or article subjected to the test shall be deemed to be in compliance with that limit.

12.—(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) 12 mg/kg or, as the case may be, 2 milligrams per square decimetre in migration tests using other simulants referred to in Schedule 3.

Special provisions relating to caps, lids, gaskets, stoppers and similar sealing articles

13.—(1) If the intended use is known, caps, lids, gaskets, stoppers and similar sealing articles shall be tested by applying them to the containers for which they are intended under conditions of closure corresponding to the normal or foreseeable use and on the assumption that such articles are in contact with a quantity of food filling the container.

(2) The results of any tests carried out under sub-paragraph (1) shall be expressed in mg/kg or mg/dm^2 as appropriate in accordance with the requirements of regulation 9(2), taking into account the whole contact surface of sealing article and container that is potentially in contact with the food.

(3) If the intended use of an article of the type mentioned in sub-paragraph (1) is not known, it shall be–

(a) tested separately from the container for which it is intended, with the result being expressed in mg/article; and

(b) the value added, if appropriate, to the quantity migrated from that container.

SCHEDULE 3

Regulations 9 and 13

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 case 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 except that the concentration of ethanol solution shall be adjusted to the actual alcoholic strength of the food if it exceeds 10% (v/v)
Simulant D:	Rectified olive oil having the characteristics specified in paragraph 3 or, subject to paragraph 5, any of the fatty food simulants specified in paragraph 4

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

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

(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									

5. Where 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 the Annexes, 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 the Annexes 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 or group of foods is described in the column headed "Description of food", and

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

(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 as follows–

Table 1: Food types

Definition	*Meaning*
Aqueous foods having a pH > 4.5	Foods in relation to which stimulant A only is specified in the Table to Part 4
Acidic foods having a pH ≤ 4.5	Foods in relation to which stimulant B only is specified in the Table to Part 4
Alcoholic foods	Foods in relation to which stimulant C only is specified in the Table to Part 4
Fatty foods	Foods in relation to which stimulant 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 stimulant B, stimulant C and stimulant 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 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 one specified for the purposes of Part 4 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 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.

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 followed 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.—(1) 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, stimulant A shall be used;

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

(2) Where the letter "b" is shown in brackets after the "X", the indicated text shall be carried out with ethanol 50% (v/v).

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 01.01	**Beverages** 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				

Reference Number	*Description of food*	*Simulants to be used*			
		A	B	C	D
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 – 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(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, resolidified 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			

Reference Number	*Description of food*	*Simulants to be used*			
		A	B	C	D
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 C Skimmed or partly skimmed D Dried				 X(b) X(b) X(b)
07.02	Fermented milk such as yoghurt, buttermilk and similar products		X		X(b)
07.03	Cream and sour cream		X(a)		X(b)
07:04	Cheeses: A Whole, with non-edible rind C All others	 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)]

Reference Number	*Description of food*	*Simulants to be used*			
		A	B	C	D
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 13(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 and to paragraph 4.4 to this Part 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 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 or 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 worst 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 to 100°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 stimulant 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 the 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 stimulant 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 paragraph 1(a) 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 stimulant 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.

SCHEDULE 4

Regulation 14

Information to be contained in a declaration of compliance

1. The identity and address of the business operator which manufactures or imports the plastic materials or articles or the substances intended for the manufacturing of those materials or articles.

2. The identity of the materials, the articles or the substances intended for the manufacturing of those materials and articles.

3. The date of the declaration.

4. Confirmation that the plastic materials or articles meet relevant requirements laid down in the Directive and Regulation 1935/2004.

5. Adequate information relative to the substances used for which restrictions and/or specifications are in place under this Directive to allow the downstream business operators to ensure compliance with those restrictions.

6. Adequate information relative to the substances which are subject to a restriction in food, obtained by experimental date or theoretical calculation about the level of their specific migration and, where appropriate, the purity criteria to enable the user of these materials or articles to comply with the relevant Community provisions or, in their absence, with national provisions applicable to food.

7. Specifications on the use of the material or article, such as–

   (a) type or types of food with which it is intended to be put in contact;

   (b) time and temperature of treatment and storage in contact with the food;

   (c) ratio of food contact surface area to volume used to establish the compliance of the material or article.

8. Confirmation that, when a plastic functional barrier is used in a plastic multi-layer material or article, the material or article complies with the requirements of Article 7a(2), (3) and (4) of the Directive.

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations revoke the Plastic Materials and Articles in Contact with Food (Scotland) (No. 2) Regulations 2006 and re-enact those Regulations with changes.

The main changes are–

The regulations in Part 2–

(a) prohibit specified activities in relation to any plastic material of 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 1 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);

(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 required standard relating to plastic multi-layer materials and articles (regulation 11);

(h) provide for the execution and enforcement of Regulation 1895/2005 (O.J. No. L 302, 19.11.05, p.28), which contains Community provisions relating to the epoxy derivatives known as BADGE, BFDGE and NOGE (regulation 12);

(i) 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 13 and Schedules 2 and 3);

(j) provide for a written declaration in accordance with article 16(1) of Regulation 1935/2004 (regulation 14 and Schedule 4).

The regulations in Part 3–

(a) provide for enforcement (regulation 15);

(b) specify offences and penalties (regulation 16);

(c) provide for defences to offences under regulation 16 (regulation 17);

(d) provide a transitional defence relating to the sale of glass jars that contain certain foods for infants and young children and that have been sealed with a PVC gasket containing epoxidised soybean oil (regulation 18);

(e) provide for other 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 19);

(f) specify the procedure to be followed when sending a sample for analysis (regulation 20);

(g) make provision for a reference sample to be analysed by the Government Chemist (regulation 20).

The regulations in Part 4 set out the procedure to be followed in relation to applications to the European Food Safety Authority for the authorisation of a new additive made before 1st January 2007 (regulation 22).

The regulations in Part 5–

(a) apply sections of the Food Safety Act 1990 (regulation 23); and

(b) make consequential amendments and revocations (regulations 24, 25 and 26).

The principal Directives implemented by these Regulations are–

(a) Council Directive 82/711/EEC (O.J. No. L 297, 23.10.82, 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 (O.J. No. L 90, 14.4.93, p.22) and 97/48/EC (O.J. No. L 222, 12.8.97, p.10);

(b) 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 (O.J. No. L 372, 31.12.85, p.14);

(c) Commission Directive 2002/72/EC (O.J. No. L 220, 15.8.02, p.18) relating to plastic materials and articles intended to come into contact with foodstuffs, as amended by Commission Directives 2004/1/EC (O.J. No. L 7, 13.1.04, p.45), 2004/19/EC (O.J. No. L 71, 10.3.04, p.8), 2005/79/EC (O.J. No. L 302, 19.11.05, p.35) and 2007/19/EC (O.J. No. L 91, 31.3.2007, p.17).

A full regulatory impact assessment of the effect that this instrument will have on business costs has been prepared and placed in the Scottish Parliament Information Centre. Copies may be obtained from the Foods Standards Agency, 6th Floor, St Magnus House, 25 Guild Street, Aberdeen AB11 6NJ.

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