STATUTORY INSTRUMENTS

2009 No.

FOOD, ENGLAND

The Plastic Materials and Articles in Contact with Food (England) Regulations 2009

Made - - - -	*2009*
Laid before Parliament	*2009*
Coming into force	*2009*

The Secretary of State makes the following Regulations in exercise of the powers conferred by sections 16(2), 17(1) and (2), 26(1)(a), (2)(a) and (3), 31 and 48(1) of the Food Safety Act 1990(**a**), and now vested in him(**b**), as read with paragraph 1A of Schedule 2 to the European Communities Act 1972(**c**)

[These Regulations make provision for a purpose mentioned in section 2(2) of the European Communities Act 1972 and it appears to the Secretary of State that it is expedient for references to the Annexes to the Community instrument specified in regulation 2(5) to be construed as references to those Annexes as amended from time to time.]

In accordance with section 48(4A) of the Food Safety Act 1990 he has had regard to relevant advice given by the Food Standards Agency.

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

(**a**) 1990 c.16, section 1(1) and (2) (definition of "food") was substituted by S.I. 2004/2990. Sections 17 and 48 were amended by paragraphs 12 and 21 respectively of Schedule 5 to the Food Standards Act 1999 (1999 c.28), "the 1999Act". Section 48 was also amended by S.I. 2004/2990. Section 26(3) was amended by Schedule 6 to the 1999 Act. Section 53(2) was amended by paragraph 19 of Schedule 16 to the Deregulation and Contracting Out Act 1994 (1994 c.40), Schedule 6 to the 1999 Act and S.I. 2004/2990.

(**b**) Functions formerly exercisable by "the Ministers",(being, in relation to England and Wales and acting jointly, the Minister of Agriculture, Fisheries and Food and the Secretaries of State respectively concerned with health in England and food and health in Wales and, in relation to Scotland, the Secretary of State) are now exercisable in relation to England by the Secretary of State pursuant to paragraph 8 of Schedule 5 to the 1999 Act. Functions of "the Ministers" so far as exercisable in relation to Wales were transferred to the National Assembly for Wales by the National Assembly for Wales (Transfer of Functions) Order 1999 (S.I. 1999/672) as read with section 40(3) of the 1999 Act, and thereafter transferred to the Welsh Ministers by paragraph 30 of Schedule 11 to the Government of Wales Act 2006 (2006 c.32). Those functions so far as exercisable in relation to Scotland were transferred to the Scottish Ministers by section 53 of the Scotland Act 1998 (1998 c. 46) as read with section 40(2) of the 1999 Act.

(**c**) 1972 c.68. Paragraph 1A of Schedule 2 was inserted by section 28 of the Legislative and Regulatory Reform Act 2006 (2006, c.51).

(**d**) OJ No. L31, 1.2.2002, p.1.). That Regulation was last amended by Commission Regulation (EC) No. 202/2008 (OJ No. L60, 5.2.2008, p.17).

PART 1

Preliminary

Title, application and commencement

1. These Regulations may be cited as the Plastic Materials and Articles in Contact with Food (England) Regulations 2009, apply in relation to England only and come into force on [—] 2009.

Interpretation

2.—(1) In these Regulations —

"the Act" means the Food Safety Act 1990;

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

"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(**b**);

"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(**c**);

["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(**d**);]

["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(**e**);]

"the Purity Directives" means Commission Directive 2008/60/EC laying down specific purity criteria concerning sweeteners for use in foodstuffs(**f**), Commission Directive 95/45/EC laying down purity criteria concerning colours for use in foodstuffs(**g**) and Commission Directive 96/77/EC laying down specific purity criteria for food additives other than colours or sweeteners(**h**);

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

"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(**j**);

"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(**k**);

(**a**) S.I. 2007/2790, as amended by S.I. 2008/916, 2008/1642 and these Regulations.
(**b**) OJ No. L297, 23.10.1982, p.26,.This was last amended by Commission Directive 97/48/EC (OJ No. L222, 12.8.1997, p.10).
(**c**) OJ No. L372, 31.12.1985, p.14. This was last amended by Commission Directive 2007/19/EC (OJ No. L97, 12.4.2007 p.50).
(**d**) OJ No. L184, 15.7.1988, p.61.
(**e**) OJ No. L40, 11.2.1989, p. 27.
(**f**) OJ No. L158, 18.6.2008, p.17.
(**g**) OJ No. L226, 22.9.1995, p.1. This was last amended by Commission Directive 2004/47, OJ No. L113, 20.4.2004, p.24.
(**h**) OJ No. L339, 30.12.1996, p.1. This was last amended by Commission Directive 2003/95, OJ No. L283, 31.10.2003, p.71.
(**i**) OJ No. L220, 15.8.2002, p.18. This was amended by Commission Directives 2004/1/EC (OJ No. L7, 13.1.2004, p.45), 2004/19/EC (OJ No. L71, 10.3.2004, p.8), 2005/79/EC (OJ No. L302, 19.11.2005, p.35), 2007/19/EC (published in revised and corrected form in OJ No. L97, 12.4.2007, p.50), and 2008/39/EC (OJ No. L63, 7.3.2008, p.6).
(**j**) OJ No. L338, 13.11.2004, p.4).
(**k**) OJ No. L302, 19.11.2005, p.28.

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

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

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

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

"capable" means capable as established under regulation 13;

"EFSA" means the European Food Safety Authority;

"enforcement authority" means an authority having responsibility under regulation 15 for executing and enforcing these Regulations;

"fatty foods" means foods for which, in migration testing, simulant 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 that is included for the purposes of the Directive among monomers and other starting substances;

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

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

"plastic layers or coatings" means plastic layers or plastic coatings forming gaskets in lids that together are composed of two or more layers of different types of materials;

"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;

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

"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 in Part 5 of Schedule 3, any reference to a numbered Annex is a reference to that Annex to 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 Materials and Articles

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

3.—(1) No person may —

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

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

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

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

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

(a) it has been manufactured —

(i) with a monomer which is not a permitted monomer as described in regulation 4(2), or

(ii) with an additive which is not a permitted additive as described in regulation 5(2); or

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

but a plastic material or article meets the required standard if it meets the applicable conditions set out in Schedule 5 (transitional arrangements).

(3) Regulation 5 shall not have effect —

(a) to prohibit the use or sale of a plastic material or article where —

(i) that material or article consists of plastic layers or coatings to which the derogation in Article 4c of the Directive applies, or

(ii) any additive used in its manufacture is a polymerisation production aid to which the derogation in Article 4d of the Directive applies; or

(b) before 1st January 2010 to prohibit the use or sale of a plastic material or article where any additive used in its manufacture is permitted under and used in accordance with the national law of the Member State where the plastic material or article was manufactured.

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 monomer other than a permitted monomer in the manufacture of any plastic material or article.

(2) A permitted monomer is any monomer which is —

(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

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

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

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

(b) epoxy resins;

(c) adhesives and adhesion promoters; or

(d) printing inks.

(4) Paragraph (1) shall not be taken to prohibit the manufacture of any plastic material or article with any substance if the substance in question is a mixture which falls within paragraph 3(c) (relating to mixtures of authorised substances) of Annex II and is of good technical quality.

(5) In any proceedings for an offence under these Regulations where it is alleged that a plastic material or article does not comply with paragraph (1) because it was manufactured with any monomer (whether or not of good technical quality) other than one mentioned in paragraph (2)(b) it shall be a defence for the person accused to prove that 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 in the manufacture of any plastic material or article any additive other than a permitted additive.

(2) A permitted additive is —

(a) an 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 —

(i) is of good technical quality, and

(ii) is 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;

(b) any food additive authorised by [Directive 89/107 or any flavouring authorised by Directive 88/388] that does not migrate 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;

(c) any additive where that additive appears in the provisional list mentioned in Article 4a(3) of the Directive and otherwise complies with the requirements of national law in England;

(d) any additive not mentioned in sub-paragraphs (a) to (c) that is used —

(i) in the manufacture of plastic layers or coatings, or

(ii) as a polymerisation production aid not intended to remain in the finished article

and which otherwise complies with the requirements of national law in England; or

(e) [before 1st January 2010, any other additive used in accordance with the requirements of the Plastic Materials and Articles in Contact with Food (England) Regulations 2008(**a**) and which, but for their revocation, would have been permitted by those Regulations.]

(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 or in the provisional list mentioned in Article 4a(3) of the Directive which is not of good technical quality, it shall be a defence for the person accused to prove that each such additive is present in the finished plastic material or article as an impurity, a reaction intermediate or a decomposition product.

(4) 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

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(**a**) S.I. 2008/916 as amended by S.I. 2008/1642.

monomer, a plastic material or article manufactured from that monomer meets the required standard under this regulation if it is not capable of transferring constituents of that monomer to food with which the plastic material or article may come into contact in quantities exceeding the appropriate limit, and for the purposes of this paragraph the appropriate limit is —

(a) the number of milligrams expressed in column 4 released per kilogram of food in the case of any plastic material or article other than one specified in sub-paragraph (b); and

(b) one sixth of the number of milligrams expressed in column 4 per square decimetre of surface area of the plastic material or article if the plastic material or article comprises —

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

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

(2) A plastic material or article manufactured from any monomer for which a migration limit in mg/kg is expressed in column 4 of Section A or B of Annex II is not deemed to be capable of transferring constituents of that monomer to food with which the plastic material or article may come into contact in quantities exceeding the appropriate limit in paragraph (1) if the only food with which that plastic material or article may come into contact is food to which regulation 9(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 the plastic material or article may come into contact in quantities exceeding the appropriate limit, and for the purposes of this paragraph the appropriate limit is —

(a) the number of milligrams indicated in column 4 released per kilogram of food in the case of any plastic material or article other than one specified in sub-paragraph (b); and

(b) one sixth of the number of milligrams expressed in column 4 per square decimetre of surface area of the plastic material or article if the plastic material or article comprises —

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

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

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

(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 that specified in paragraph (3).

(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 defence available in paragraph 10(2) of Schedule 2 is 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 which it is composed 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 is not obliged 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 the provisional list or the 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, BDGE and NOGE)

12.—(1) In this regulation —

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

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

(c) for the purpose of Article 6(4) (requirement to disclose date of filling) the competent authority is the authority identified in regulation 15.

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

(a) manufacture,

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

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

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

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

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

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

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

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

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

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

(**a**) OJ No. 196, 16.8.1967, p.1.

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

(6) No person shall without reasonable excuse fail to comply with a request made under Article 6(4).

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 reference number 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 the substance 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(T)” or, as the case may be, “QMA”.

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 (EC) No. 1935/2004;

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

(c) complies with paragraph (2).

(2) A written declaration made 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 information is available.

(3) A person mentioned in paragraph (1) must make available to the enforcement 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 in its area and each port health authority in its district shall execute and enforce —

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

(b) these Regulations.

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) or 14(1);

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

(c) contravenes regulation 12(6), 14(3) or 21(3) or, without reasonable excuse, otherwise fails to give to any person acting in the execution of Regulation 1895/2005 or these Regulations any assistance or information which that person may reasonably require; or

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

is guilty of an offence.

(2) Anyone guilty 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 two years or to a fine or both;

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

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

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

Offences by corporate bodies or Scottish partnerships

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

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

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

that individual as well as the body corporate shall be deemed to be guilty of that offence and liable to be proceeded against and punished accordingly.

(2) Where an offence under these Regulations which has been committed by a Scottish partnership is proved to have been committed with the consent or connivance of or to be attributable to any neglect on the part of a partner, that partner as well as the partnership shall be deemed to be guilty of that offence and liable to be proceeded against and punished accordingly.

Time limit for prosecutions

18. 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.

Offences due to the act or default of a third party

19. Where the commission by a person (A) of an offence under these Regulations is due to the act or default of some other person (B), person B shall be guilty of the offence and may be charged with and convicted of the offence whether or not proceedings are taken against person A.

Defence of exercising due diligence etc

20.—(1) In any proceedings for an offence under these Regulations it shall, subject to paragraph (5), be a defence to prove that the person accused ("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 control of the accused.

(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 control of the accused, 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 plastic material or article or the material or article in question; and

(c) the accused did not know and had no reason to suspect at the time the offence was committed that the 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 that —

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

(b) the sale of which the alleged offence consisted was not a sale under the name or mark of the accused; 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 act or omission would amount to an offence under these Regulations.

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

(a) at least seven clear days before the hearing; and

(b) where the accused has previously appeared before the court in connection with the alleged offence, within one month of the first such appearance,

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

21.—(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 2006/141/EC(**a**), or

(ii) processed cereal-based foods or baby foods for infants and young children as defined by Commission Directive2006/125/EC(**b**), 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 at Item 259A of Part 1 of Schedule 2 to the Plastic Materials and Articles in Contact with Food (England) Regulations 2006(**c**);

(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(**d**).

(3) A person may not without reasonable excuse fail to comply with a request made by the enforcement authority to disclose the date signified by the coded indication mentioned in paragraph (2)(c).

Procedure where a sample is to be analysed

22.—(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

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(**a**) OJ No. L401, 30.12.2006, p.1.
(**b**) OJ No. L339, 6.12.2006, p.16.
(**c**) S.I. 2006/1401
(**d**) OJ No. L109, 6.5.2000, p.29, as last amended by Directive 2003/89/EC (OJ No. L308, 25.11.2003, p.15).

(e) retain one part for future submission under regulation 23.

Secondary analysis by the Government Chemist

23.—(1) Where a sample has been retained under regulation 22 and —

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

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

paragraphs (2) to (7) apply.

(2) The authorised officer —

(a) may of the officer's own volition; or

(b) shall —

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

(ii) if the court so orders; or

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

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

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

(4) Any certificate of the results of analysis sent by the Government Chemist shall 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.

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

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

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

PART 4

General and Supplementary

Application of provisions of the Act

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

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

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

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

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

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

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(**a**) S.I. 1990/2463

Materials and Articles in Contact with Food (England) Regulations 2008 substitute the title and reference of these Regulations.

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

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

(2) In regulation 2(1) —

(a) omit the definition of "the 2008 Regulations";

(b) after the definition of "the Act" insert the following definition —

""the 2009 Regulations" means the Plastic Materials and Articles in Contact with Food (England) Regulations 2009(**a**);".

(3) In regulation 10, in paragraph (4) for "2008"substitute "2009".

(4) In regulation 11, in paragraph (5), for "2008" substitute "2009".

Revocations

27. The following Regulations or parts thereof are revoked —

(a) The Plastic Materials and Articles in Contact with Food (England) Regulations 2008(**b**);

(b) Regulations 2 to 4 of the Plastic Materials and Articles in Contact with Food (England) (Amendment) Regulations 2008(**c**).

Signed by authority of the Secretary of State for Health

name
Minister of State
2009 Department of Health

(**a**) S.I. 2008/
(**b**) S.I. 2008/916
(**c**) S.I. 2008/1642

SCHEDULE 1

Regulations 4 and 5

Supplementary provisions relating to Annexes II and III

28. In Sections A and B of Annexes II and III (for the purposes of this Schedule referred to together as "the Annexes") —

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

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

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

(d) references to specific migration are to be taken to mean specific migration as measured in accordance with Schedules 2 and 3.

29. 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 such extent as is necessary.

30.—(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.

31. In the case of substances listed in Section B of Annex III, the specific migration limits specified 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 Directive 82/711/EEC and 85/572/EEC.

32. 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) above is impracticable, such testing shall be carried out, using either specimens taken from that plastic material or article, or where appropriate, specimens representative of that plastic material or article.

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

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

4.—(1) Any sample of plastic material or article shall be placed in contact with the appropriate simulant or the food for a period and at a temperature which are chosen by reference to the contact conditions in actual use in accordance with the provisions of this Schedule and, where appropriate, Schedule 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 in Annex II, III or IV (for the purposes of this Schedule and Schedule 3 referred to together 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 below) 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 simulant 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 may not be used —

(a) where the plastic material or article is in contact 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 plastic material or article in question shall not be considered to be in compliance.

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

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

(a) the simulant 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 simulant 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 simulant 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 but the period of contact is to be respectively two and three times 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) 12mg/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 total 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 means 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 a fatty food simulant specified in paragraph 4 is used in migration testing and the result of that test shows that a plastic material or article does not comply with any migration limit specified in regulation 9 or 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 of group of foods is described in the column headed "Description of food", and

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

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

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

Table 1: Food types

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

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

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

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

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

(a) where —

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

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

the simulant or simulants so specified;

(b) where —

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

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

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

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

6. The simulant or simulants to be used in testing a plastic material or article which, pursuant to Regulation 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 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 of these Regulations or the description of food in column 2 of that Table which, in either case, corresponds to the food;

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

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, simulant A shall be used;

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

(2) Where the letter "b" is shown in brackets after the "X", the indicated test 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	**Beverages**				
01.01	Non-alcoholic beverages or alcoholic beverages of an alcoholic strength lower than 5% vol: — Waters, ciders, fruit or vegetable juices of normal strength or concentrated, musts, fruit nectars, lemonades and mineral waters, syrups, bitters, infusions, coffee, tea, liquid chocolate, beers and other	X(a)	X(a)		

01.02	Alcoholic beverages of an alcoholic strength equal to or exceeding 5% vol. — Beverages shown under heading 01.01 but with an alcoholic strength equal to or exceeding 5% vol. — Wines, spirits and liqueurs		X[(1)]	X[(2)]	
01.03	Miscellaneous: undenatured ethyl alcohol		X[(1)]	X[(1)]	
02	**Cereals, cereal products, pastry, biscuits, cakes and other bakers' wares**				
02.01	Starches				
02.02	Cereals, unprocessed, puffed, in flakes (including popcorn, cornflakes and the like)				
02.03	Cereal flour and meal				
02.04	Macaroni, spaghetti and similar products				
02.05	Pastry, biscuits, cakes and other bakers' wares, dry: A With fatty substances on the surface B Other				X/5
02.06	Pastry, biscuits, cakes and other bakers' wares, fresh A With fatty substances on the surface B Other	X			X/5
03	**Chocolate, sugar and products thereof Confectionery products**				
03.01	Chocolate, chocolate-coated products, substitutes and products coated with substitutes				X/5
03.02	Confectionery products: A in solid form — with fatty substances on the surface — Other B in paste form: — with fatty substances on the surface — moist	X			X/5 X/3
03.03	Sugar and sugar products A In solid form B Honey and the like C Molasses and sugar syrups	X X			
04	**Fruit, vegetable and products thereof**				
04.01	Whole fruit, fresh or chilled				
04.02	Processed fruit: A Dried or dehydrated fruit, whole or in the form of flour or powder B Fruit in the form of chunks, puree or paste C Fruit preserves (jams and similar products – 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, re-solidified butter)				X
05.02	Margarine, butter and other fats and oils made from water emulsions in oil				X/2
06	**Animal products and eggs**				
06.01	Fish: A Fresh, chilled, salted, smoked B In the form of paste	 X X			 X/3(3) X/3(3)
06.02	Crustaceans and molluscs (including oysters, mussels, snails) not naturally protected by their shells	X			
06.03	Meat of all zoological species (including poultry and game): A Fresh, chilled, salted, smoked B In the form of paste, creams	 X X			 X/4 X/4
06.04	Processed meat products (ham, salami, bacon and other)	X			X/4
06.05	Preserved and part-preserved meat and fish: A In an aqueous medium B In an oily medium	 X(a) X(a)	 X(a) X(a)		 X
06.06	Eggs not in shell: A Powdered or dried B Other	 X			
06.07	Egg yolks: A Liquid B Powdered or frozen	 X			
06.08	Dried white of egg				
07	**Milk products**				
07.01	Milk: A Whole B Partly dried C Skimmed or partly skimmed D Dried				 X(b) X(b) X(b)
07.02	Fermented milk such as yoghurt, buttermilk and such products in association with fruit and fruit products		X		X(b)
07.03	Cream and sour cream		X(a)		X(b)
07:04	Cheeses: A Whole, with non-edible rind				

	B 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]
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 below and to paragraph 4.4 of Chapter II of the Annex to Directive 82/711, when carrying out migration tests the time and temperature used shall be the time and temperature selected from column 2 of the Table to this Part which correspond to the worst foreseeable conditions of contact specified in column 1 of that Table for the plastic material or article being tested and to any labelling information on maximum temperature for use.

2. Where the plastic material or article being tested is intended for a food contact application covered by a combination of two or more times and temperatures specified in column 2 of the Table to this Part, the migration test shall be carried out by subjecting the test specimen successively to all the applicable worst foreseeable conditions appropriate to the sample, using the same portion of food simulant.

3. For the purposes of this Part the worst foreseeable conditions of contact are those which are recognised to be the most severe on the basis of scientific evidence.

Volatile migrants

4. When carrying out a test of the specific migration of volatile substances any test using a simulant shall be performed in a manner that 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 that 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 that does not occur under the worst foreseeable conditions of use of the plastic material or article being tested, the migration test shall be carried out in the worst foreseeable conditions of use in which such physical or other change does not occur.

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

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

Conditions of contact in 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 to100°C	100°C or reflux temperature
>100°C but less than or equal to 121°C	121°C (2)
>121°C but less than or equal to 130°C	130°C (2)
>130°C but less than 150°C	150°C (2)
>150°C	175°C (2)

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

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

PART 6

Substitute Fat Test for Overall and Specific Migration

1. Subject to paragraphs 2, 4 and 5, all the test media specified in the Table to this Part shall be used in the substitute fat test for overall or specific migration under the test conditions corresponding to the test conditions for simulant D.

2. Test conditions other than those specified in the Table to this Part may be used in the substitute fat test if the assumptions underlying the test conditions specified in that Table and, where the plastic material or article being tested is a polymer, the existing experience of that type of polymer are taken into account.

3. For each test—

(a) a new test specimen shall be used;

(b) the rules prescribed for simulant D in Parts 3, 4 and 5 of this Schedule shall be applied for each test medium;

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

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

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

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

Conventional conditions for substitute tests

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

[(1)] MPPO = Modified polyphenylene oxide

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

PART 7

Alternative Fat Tests for Overall and Specific Migration

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

(a) the result obtained in a "comparison test" shows that the values are equal to or greater than those obtained in the test with simulant D; and

(b) the migration occurring in either test specified in paragraph 3 does not, after application of the appropriate reduction factor, exceed the appropriate migration limit.

2. The condition in sub-paragraph (a) of paragraph 1 does not have to be fulfilled if it can be shown on the basis of the result of scientific experiment that the values obtained in either of the tests specified in paragraph 3 are equal to or greater than those obtained in any of the migration tests specified in Part 3.

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

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

(b) other tests using media having a very strong extraction power under very severe test conditions where, on the basis of scientific evidence, it is generally recognised that the results using these tests are equal to or higher than those obtained in a test using simulant D.

SCHEDULE 4

Regulation 14

Information to be contained in a declaration of compliance

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

2. The identity of the materials, articles or substances intended for their manufacture.

3. The date of the declaration.

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

5. Adequate information relating to the substances used for which restrictions or specifications are in place under the Directive to allow downstream business operators to ensure compliance with them.

6. Adequate information relating to the substances which are subject to a restriction in food, obtained by experimental data or theoretical calculation about the level of their specific migration and, where appropriate, purity criteria in accordance with the purity Directives to enable the user of the plastic 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 plastic material or article, such as —

(a) the types of food intended to be in contact with it;

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

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

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

SCHEDULE 5

Regulation 3(2)

Transitional arrangements

1. In the case of a plastic material or article manufactured or imported into the European Community before 1st March 2006, the material or article in question meets the required standard if it meets the required standard as it was immediately before the implementation in England on 11th March 2005 of Commission Directive 2004/19/EC(**a**).

2.In the case of a plastic material or article manufactured or imported into the European Community before 19th November 2007, the material or article in question meets the required standard if it meets the required standard as it was immediately before the implementation in England on 19th November 2006 of Commission Directive 2005/79/EC(**b**).

3. In the case of lids containing a gasket that do not comply with the restrictions and specifications for Ref. No.s 30340, 30401, 56800, 76815, 76866, 88640 or 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(**c**), the derogation contained in Article 1 of Commission Regulation (EC) No. 597/2008 amending Commission Regulation (EC) No. 372/2007(**d**) is applicable.

4. In the case of —

(a) a plastic material or article that does not comply with the restrictions and specifications for phthalates under Ref. No.s 74560, 74640, 74880, 75100 or 75105 in Annex III, or

(b) a lid containing a gasket that does not comply with the restrictions and specifications for Ref. No. 36640 (azodicarbonamide) in Annex III

and which was manufactured or imported into the European Community before 1st July 2008, the material or article in question meets the required standard if it meets the required standard as it was immediately before the implementation in England on 1st May 2008 of Commission Directive 2007/19/EC(**e**).

5. In the case of a plastic material or article (other than one mentioned in paragraphs 2 and 3) manufactured or imported into the European Community before 1st May 2009, the material or article in question meets the required standard if it meets the required standard as it was immediately before the implementation in England on 1st May 2008 of Commission Directive 2007/19/EC.

6. In the case of a plastic material or article manufactured or imported into the European Community before 7th March 2010, the material or article in question meets the required standard if it meets the required standard as it was immediately before the implementation in England on [*7th March*] 2009 of Commission Directive 2008/39/EC(**f**).

(**a**) OJ No. L71, 10.3.2004, p.8.
(**b**) OJ No. L302, 19.11.2005, p.35.
(**c**) OJ No. L92, 3.4.2007, p.9.
(**d**) OJ No. L164, 25.6.2008, p.12.
(**e**) OJ No. L91, 31.3.2007, p.17.
(**f**) OJ No. L63, 7.3.2008, p.6.

EXPLANATORY NOTE

(This note is not part of the Regulations)

1. These Regulations, which apply in relation to England only, revoke the Plastic Materials and Articles in Contact with Food (England) Regulations 2008 (S.I. 2008/916), and re-enact those Regulations with certain changes. The main changes are —

(a) implementation of the further amendments made to Commission Directive 2002/72/EC and to Council Directive 85/572/EEC by Commission Directive 2008/39/EC (OJ No. L 63, 7.3.2008, p.6) ("the new Commission Directive"), which introduces new [*DN: to be completed after consultation*].

2.

Summary: Intervention & Options

Department /Agency:	Title:	
Food Standards Agency	Impact Assessment of THE PLASTIC MATERIALS AND ARTICLES IN CONTACT WITH FOOD (ENGLAND) REGULATIONS 2009	
Stage: Consultation	**Version:** 1	**Date:** 1 August 2008

Related Publications: Commission Directive 2008/39/EC amending Directive 2002/72/EC relating to plastic materials and articles intended to come into contact with food

Available to view or download at:
http://www.food.gov.uk/consultations

Contact for enquiries: Nasreen Shah **Telephone:** 020 7276 8553

What is the problem under consideration? Why is government intervention necessary?

Chemical migration from food contact plastics can detrimentally affect consumer health. Most consumers are unable to assess the risk involved when consuming a product because of their lack of knowledge of the chemical migration and production methods and therefore cannot make informed choices about such risk. Government intervention, through the implementation of significant amendments to the main European Commission Directive on *Plastic materials and articles intended to come into contact with food,* is necessary to reduce the risks to health and also to provide greater clarity in enforcement.

What are the policy objectives and the intended effects?

The policy objectives are two-fold:

1) To reduce the long term health risks to consumers in England arising from ingesting chemicals used in the manufacture of plastic food contact materials and articles that can migrate into food; and

2) To provide EU harmonised Regulations that provide businesses with clear provisions that lead to safe products and increase consumer confidence.

What policy options have been considered? Please justify any preferred option.

1. Do nothing. This would leave the UK open to infraction proceedings from the European Commission, contradicting the important role the UK plays in agreeing EU harmonised measures and leave our regulation of food contact materials deficient in comparison with EU legislation.

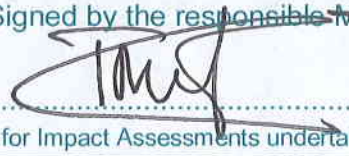
2. To successfully negotiate and implement EU harmonised measures. This preferred option is achieved through provisions of Directive 2008/39/EC. It meets the Government commitment to fulfil EU obligations and contribute towards the protection of consumers from ingesting harmful levels of chemicals that could migrate into foods.

When will the policy be reviewed to establish the actual costs and benefits and the achievement of the desired effects? March 2010

Ministerial/CEO Sign-off For consultation stage Impact Assessments:

I have read the Impact Assessment and I am satisfied that, given the available evidence, it represents a reasonable view of the likely costs, benefits and impact of the leading options.

Signed by the responsible ~~Minister~~/Chief Executive*:



..... Date: 2/9/08.

* for Impact Assessments undertaken by non-ministerial departments/agencies and NOT being considered by Parliament

Summary: Analysis & Evidence

Policy Option: 2	Description: To successfully negotiate and implement EU harmonised measures

COSTS

ANNUAL COSTS	
One-off (Transition)	**Yrs**
£ 160,800	1
Average Annual Cost (excluding one-off)	
£ 0	

Description and scale of **key monetised costs** by 'main affected groups'

One-off cost borne by businesses = £145,500

One-off cost borne by local authorities = £13,900

One-off cost borne by port health authorities = £1,400

Total Cost (PV) **£ 160,800**

Other **key non-monetised costs** by 'main affected groups' are in relation to the amendment of the authorised Community list of authorised monomers, additives and other substances and Government bodies such as the Food Standards Agency may be affected as and when they carry out any surveys on food, e.g. additional research into the migration of substances.

BENEFITS

ANNUAL BENEFITS	
One-off	**Yrs**
£ 0	1
Average Annual Benefit (excluding one-off)	
£ 0	

Description and scale of **key monetised benefits** by 'main affected groups'

Total Benefit (PV) **£ 0**

Other **key non-monetised benefits** by 'main affected groups' Increased protection of public health and the preservation of exports to other Member States. Greater clarity for business and enforcement officials through formalisation of existing procedures and maintenance of consumer confidence.

Key Assumptions/Sensitivities/Risks

Price Base Year 2007	Time Period Years 1	**Net Benefit Range** (NPV) **£ -160,800**	**NET BENEFIT** (NPV Best estimate) **£ -160,800**

What is the geographic coverage of the policy/option?				England	
On what date will the policy be implemented?				7 March 2009	
Which organisation(s) will enforce the policy?				LA's and PHA's	
What is the total annual cost of enforcement for these organisations?				£ 15,300	
Does enforcement comply with Hampton principles?				Yes	
Will implementation go beyond minimum EU requirements?				No	
What is the value of the proposed offsetting measure per year?				£ N/A	
What is the value of changes in greenhouse gas emissions?				£ Negligible	
Will the proposal have a significant impact on competition?				No	
Annual cost (£-£) per organisation (excluding one-off)	Micro **N/K**	Small **N/K**	Medium **N/K**	Large **N/K**	
Are any of these organisations exempt?	No	No	N/A	N/A	

Impact on Admin Burdens Baseline (2005 Prices) (Increase - Decrease)

Increase of £ 0 Decrease of £ 0 **Net Impact** **£** 0

Key: **Annual costs and benefits: Constant Prices** **(Net) Present Value**

Evidence Base (for summary sheets)

Reason for Consideration and Rationale for Government Intervention

1. Chemical migration from food contact plastics can create a negative cost to others, through detrimentally affecting consumer health. Most consumers are unable to assess the risks involved when consuming a product because they cannot observe the level of chemical migration and do not have full information on the production methods. Therefore, they cannot make informed choices about such risk. Government intervention is required to reduce these impacts on health, to address the lack of lack of informed consumer choice and also to provide greater clarity in enforcement.

2. These proposals fulfil the UK Government's policies of meeting its European Union (EU) obligations to bring into effect in law harmonised rules that:

   - Reduce the chronic and acute health risks to consumers arising from chemical contaminants in the food they eat; and
   - Meet the intergovernmental Lisbon Agenda aimed at improving the competitiveness of businesses in Europe by providing harmonised rules within which businesses can compete on an equal footing that are not overly burdensome.

3. The Food Standards Agency ("the Agency") believes that the adoption of these proposals provides for the continuation of consumer protection against food contamination by chemicals whose ingestion could carry serious long-term and unacceptable risk to consumer health, particularly among more vulnerable people. Full implementation of the Commission proposal will contribute to the achievement of improved uniform standards across the EU, benefiting both consumers and businesses.

Intended effect

4. To reduce the long term health risks to consumers in England arising from ingesting chemicals used in the manufacture of plastic food contact materials and articles that may migrate into food by providing harmonised rules within which business can compete. And to provide EU harmonised Regulations that provide businesses with clear provisions that lead to safe products and increase consumer confidence.

5. The legislation also aims to protect the nature and quality of the food concerned; to provide clear and consistent conditions for the trade in goods and to provide the enforcement authorities and industry with one set of harmonised rules that apply throughout the EU, instead of a plethora of different national rules in each of the twenty-seven Member States. It is also our aim to simplify the way the rules governing these articles and materials are presented in England to make them as plain as possible to those that need to refer to them. This decision was taken with industry support.

6. The proposal is for a Statutory Instrument (SI) entitled *The Plastic Materials and Articles in Contact with Food England (Regulations) 2009*. The objective of the proposed Regulations is to implement by 7th March 2009 in England in its entirety the provisions of European Commission Directive 2008/39/EC ("the new Directive") that routinely amends Directive 2002/72/EC ("the principal Directive") relating to plastic materials and articles intended to come into contact with food.

7. The proposed Regulations will also revoke *The Plastic Materials and Articles in Contact with Food (England) Regulations 2008* (SI 2008/916) ("the 2008 Regulations") and re-enact them with necessary amendments, thus implementing in one consolidated instrument the principal Directive as most recently amended by the new Directive.

8. The proposed Regulations will not re-enact a number of provisions in the 2008 Regulations which are considered to be no longer relevant. These are:

- regulation 22(1) (a) to (f) that contain transitional arrangements relating to the manufacture and/or importation of materials and articles into the European Community by given dates and
- regulation 25 that relates to the application for the inclusion of an additive in the Community list of authorised additives. This requirement related to transitional arrangements that were time limited, the time limit has now expired.

Consultation questions

Stakeholders are asked to comment on the proposal not to re-enact regulation 22(1) (a) to (f) and regulation 25 of the 2008 Regulations in the proposed new Regulations. If you disagree with this assessment, please provide evidence to support your views.

Background

9. Harmonised EU rules on food contact plastics are laid down by the principal Directive and this is routinely amended to improve the clarity of the rules and to keep up with technological innovation. This latter point arises from improving technical and scientific knowledge that enables experts within the European Food Safety Authority (EFSA) to evaluate and re-evaluate risk to public health arising from the migration of chemicals from food contact materials into food. The latest of these amendments are contained in the new Directive which the regulatory proposals here would implement. This Directive was adopted by the Standing Committee on the Food Chain and Animal Health (SCoFCAH) in December 2007 and the adopted proposal was published in the Official Journal (OJ) of the European Union on 7 March 2008 (OJ L63 07.03.2008 p 6-13). In England, *The Plastic Materials and Articles in Contact with Food (England) Regulations 2008* currently implement the provisions of the principal Directive as last amended by Directive 2007/19/EC as read with Commission Regulation (EC) No. 597/2008 (amending Regulation (EC) No. 372/2007).

10. For certain substances, the restrictions already established at Community level have been amended on the basis of new information becoming available. As such Annexes II, III, IVa, V and VI of the principal Directive are amended accordingly. The new Directive also:

    i) Lays down the dates by which the list of additives in food contact plastics will be closed and makes interim arrangements for those additives that were petitioned for authorisation by the deadline of December 2006;

    ii) Routinely updates the lists of authorised substances, taking into account the published opinions of EFSA and sets a date of 31 December 2009 up to which additives not on the positive list may continue to be used. This period until December 2009 is to enable EFSA to obtain any additional information it might need for its risk assessment of those additives on the provisional list;

    iii) Prohibits the use of additives not on the Community list of additives used for the manufacture of plastic materials and articles from 1 January 2010 (the positive list);

    iv) Permits the trade in and use of plastic material and articles intended to come into contact with food and complying with the principal Directive, as amended by the new Directive 2008/39/EC from 7 March 2009; and

    v) Prohibits as from 7 March 2010 the manufacture and importation into the Community of plastic materials and articles intended to come into contact with food and which do not comply with the principal Directive as amended by the new Directive. In effect this creates a phase-out period for substances that have either been removed from the Community lists, or in the case of additives have not been adopted on to the Community authorised list or the provisional list.

11. The Commission has published its provisional list of those additives that are the subject of an application for authorisation. An additive will be removed from the provisional list either when it is included in the positive list, or when a decision is taken not to include it in the

positive list, or if additional information asked by the EFSA is not provided. The provisional list is available from the EC website at:

http://ec.europa.eu/food/food/chemicalsafety/foodcontact/documents_en.htm

Options

Option 1 – Do Nothing

Costs

12. This contradicts the UK Government's commitment to meeting EU obligations and fulfilling policy on consumer protection in this area. It would also create potential for the UK to become liable to infraction proceedings. It would not be appropriate to implement only parts of this proposal. It would contradict the important role the UK plays in negotiating the adoption of these rules to achieve its wider policy objectives for consumers and business and it would leave the regulation of food contact materials deficient in many ways in comparison with the main food legislation that now applies across the rest of the EU.

13. Failure to fully implement the new Directive would mean that the prevailing national legislation would no longer accord with Community provisions. Businesses would have to comply with the proposals being made here for their goods to be legally compliant elsewhere in the EU. In addition, UK consumers would not have the same health protection from the excessive consumption of substances dealt with in these proposals as consumers in the rest of the EU.

Benefits

14. There are no identifiable incremental benefits for this Option

Option 2 – Full Implementation of Commission Directive 2008/39/EC

15. This option fully meets the UK Government's commitment to fulfil its EU obligations and contributes significantly to our agreed policy objective of protecting consumers from ingesting harmful levels of chemicals that could have migrated from materials and articles that were intended to be brought into contact with food. The UK was involved with the Commission and other Member States (MS) throughout the negotiations that developed the new Directive to the point of its adoption by the Commission as a formal proposal and we supported its adoption at the SCoFCAH. Under Treaty obligations we are required to implement the provisions of the new Directive. It is in the interest of businesses and enforcement authorities to have harmonised EU rules across all MS.

Sectors and groups affected

16. Any likely costs to industry associated with the new Regulations relate only to the businesses that manufacture plastic materials and articles intended to come into contact with food (including things like food packaging, cookware, cutlery, tableware, work surfaces and food contact parts of processing equipment) and are not representative of the whole packaging industry. The primary business sectors affected by these proposals will be those that manufacture, use, import or sell plastic food packaging and other plastic materials and articles intended for food contact. The proposals would apply equally to all businesses across England's food contact plastics industry, its commercial customers and those that convert and/or import plastic food contact materials and articles, whether small or large.

17. Local authorities and port health authorities will continue to benefit from the greater clarity of having the relevant rules and powers contained in one consolidated document.

18. Charities and voluntary organisations are unaffected by this proposal.

19. Businesses, LAs and PHAs will all need to read the new regulations and take appropriate actions to achieve high levels of compliance.

Costs to Enforcement Authorities

20. Each local authority (LA) in its area and each port health authority (PHA) in its district are responsible for enforcing the legislation with respect to food safety and/or food hygiene; and thus have the responsibility for enforcing food contact materials legislation and will, as outlined above, be affected by these proposals. There may also be ongoing and unchanged costs to food authorities for monitoring and enforcing the new Regulations. However, given that this is an existing responsibility under other food contact materials legislation, there are unlikely to be any annual incremental costs from this new piece of legislation.

21. We have estimated the time that enforcement authorities will typically invest in reading and familiarising themselves with the new single set of Regulations. There are 389 local authorities in England. We have estimated that one enforcement officer in each of the 389 local authorities (LAs) is expected to read the Regulations and that it takes them one hour to do so. In addition, we have estimated that each person uses one hour for dissemination to key staff. Their time is valued at £17.89/hour (based on the 2007 Annual Survey of Hours and Earnings (ASHE) data for EHOs uprated by 30% to include overheads). This equates to an approximate one-off cost to LAs of £13,900.

22. There are 39 Port Health Authorities in England. We have estimated that one enforcement officer in each of the 39 PHAs is expected to read the Regulations and that it takes them one hour to do so. In addition, we have estimated that each person uses one hour for dissemination to key staff. The assumption is made that their wage rates are the same as EHO's and their time is valued at £17.89/hour (based on the 2007 Annual Survey of Hours and Earnings (ASHE) data for EHOs uprated by 30% to include overheads). This equates to an approximate one-off cost to PHAs of £1,400.

Costs to Industry

23. There will be a one-off cost to industry arising from reading and familiarising themselves with the proposed Regulations. The Agency will develop guidance for businesses on the proposed Regulations and such guidance will minimise costs to businesses of reading the Regulations. A brief summary of the guidance is given at section paragraph 30. The costs to industry are summarised below.

24. Plastic packaging accounts for approximately a third of the turnover of the food and drink packaging sector. The food and drink packaging industry is highly fragmented and diverse and is served by a large number of suppliers. A 2003 study of the UK's packaging industry identified 13,000 packaging companies in the UK; combined they employ 250,000 people.[a] If we assume businesses are roughly equally spread by population size then 11,000 businesses in England could be affected by this proposal.

25. About a third of the packaging businesses produce plastic materials and articles intended to come into contact with food and these are businesses that would need to comply with the new Regulations. It is assumed that one person per business reads the Regulations and it takes them an hour to do this. In addition, a further hour may be required to disseminate the requirements of the regulation to key staff within the organisation. Their time is valued @ £19.84/hour (this is based on the 2007 ASHE (2007) for 'Production and process engineers' (including the assumption of 30% overheads)); this equates to an approximate one-off administrative cost to industry of £145,000.

Impact on Other Government Departments Bodies

26. Government Departments, such as the Food Standards Agency ("the Agency"), may also be affected as and when they carry out any surveys on foods. This impact may involve having to carry out more research into the migration of substances from food contact materials, including work to establish methodologies for determining such migration and to ensure

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[1] Food and Drink Packaging, Mintel 2003

compliance with the legislation. These are carried out to inform consumers, monitor trends and assess dietary exposure, and to ensure that legislation is effective in protecting consumers from exposure to harmful substances in food packaging.

Consultation questions

Stakeholders are asked to comment on whether the assumption that it will take one hour to read and familiarise with the new Regulations is a sensible estimate for enforcement authorities and businesses. If you disagree with this assessment, please provide evidence to support your views.

Stakeholders are also asked to comment on any other costs that might be associated with the new Directive or the proposed Regulations and whether they introduce any additional burden. Please provide evidence to support your views.

Benefits – Option 2

27. The recommended option (Option 2) of implementing the provisions of the new Directive into a single consolidated SI will bring together in one place the amending provisions of the Directive with the existing requirements. Businesses involved in the manufacture of plastic food contact materials are generally likely to gain from the measures in the new Directive by ensuring a non-discriminatory competitive environment both domestically and throughout the EU, which in turn may facilitate further trade. They will benefit from maintaining and/or increasing consumer confidence in their products by complying with improved health protection measures throughout the EU.

28. Industry will also benefit from having clearer rules regarding permitted substances they may incorporate into the plastic material. This arises because permitted substances are risk assessed at EU level and any necessary health-related restrictions are provided for them (see paragraph 32 below); the alternative is that every business using a substance not specifically regulated would carry out its own research in order to make its own risk assessment. Having formal lists of permitted substances avoids all the duplication of the past among separate businesses and saves considerable sums across the industry as a whole.

Consultation question

Stakeholders are asked to comment on our assessment that using only substances from a formal list of substances provides financial benefits. If you disagree, please provide evidence to support your views.

Guidance on the proposed Regulations

29. The guidance mentioned in paragraph 24 above, is aimed primarily at those businesses that are likely to be affected by the proposed Plastic Materials and Articles in Contact with Food (England) Regulations 2009. It is aimed at those businesses that manufacture, use, import or sell plastic materials and articles intended for use in contact with food. It may also be of use to others with an interest in the legislation, such as enforcement authorities. The guidance provides a short summary of the changes proposed and have been produced to provide formal non-binding advice on the requirements of the draft Regulations and should be read in conjunction with the legislation itself.

30. This option will also minimise the potential for consumers to be exposed to harmful levels of substances migrating from food contact materials and articles to the food itself. Whilst the potential health benefits are difficult to quantify they are likely to include reduced risk of illness through exposure to substances that might migrate and might be associated with various effects to human health. In 1999, the Department of Environment, Food and Rural Affairs (DEFRA) published a report presenting economic evaluation of UK policy on chemical contaminants in food, which estimated that the annual consumer benefit resulting

from chemical contaminant controls was worth £900 million. The aim of the evaluation was to assess whether current controls on chemical contaminants and naturally occurring toxicants were cost effective and how these could be improved, taking into account the impact of such controls on consumers and the food supply chain. One of the reports conclusions was that the main beneficiaries were consumers, whilst the majority of the quantifiable costs had been borne by central government. The report is available on the DEFRA website at:

http://statistics.defra.gov.uk/esg/evaluation/chemcont/default.asp

31. EFSA is responsible for carrying out risk assessments and gives its opinions on substances used in the manufacture of food contact plastics based on risk assessment dossiers submitted by industry seeking approval for use of a particular substance. These opinions are given on the basis of protection of public health from any harmful substances that may arise from the consumption of food into which the substance may have migrated. Any resulting limits contained in the EFSA's opinions have margins of safety to ensure that the health of consumers who may eat contaminated foodstuffs would not be affected over their lifetime. The resulting European Commission proposals reflect these safety margins when determining the level of a substance that may be allowed to migrate into food. The Commission routinely amends these technical limits and refines definitions of categories used for limiting migration as scientific understanding of the substances and their health effects improves. Substances that are deemed to cause unacceptable risk to consumer health, particularly among vulnerable people, may be prohibited for use.

32. The new Directive reflects improved scientific knowledge of particular chemicals in relation to human health and changes the lists of substances that may be used in manufacturing food contact plastics. Some substances have been deleted from the Community list of permitted monomers and additives either because satisfactory data has not been submitted by applicants for completion of the necessary risk assessment by EFSA, or because risk assessments have deemed that the substances should no longer be used (e.g. total ban on the substance azodicarbonamide).

Consultation

- **Within Government**

33. Other Government Departments including the Department of Health, the Department for Business, Enterprise and Regulatory Reform, the Foreign and Commonwealth Office, the Cabinet Office and DEFRA were kept informed of progress throughout the negotiations relating to the new Directive through regular progress reports. To date, no adverse comments have been received from any Department.

- **Public Consultation**

34. During the course of negotiations with the Commission, the Agency's officials have frequently conveyed information to interested organisations including industry, research institutes, consumer groups, enforcement authorities, public analysts and other interested parties with an interest in policy issues related to food contact materials. The proposals have also been discussed at regular meetings with stakeholder groups that are likely to be directly affected by the requirements of the new Directive. Any comments received from interested organisations have, where appropriate, been incorporated into the UK's negotiating line. Consultations on the initial development of these proposals have spanned six years; in 2002, 2004, 2005, 2006, 2007 and February 2008, when these proposals were last amended.

35. An informal consultation was carried out in October 2007, setting out the details of the provisions of the new Directive. However, no comments were received.

Enforcement

36. Enforcement of the proposed Regulations is primarily the responsibility of LAs and PHAs as defined by the Food Safety Act 1990 and designated in our Regulations. While the making of legislation in England is the function of central government, the enforcement of food is primarily (but not solely) the responsibility of 389 LAs and 39 PHAs in England. In relation to local authorities, there is no clear distinction made on the face of the Regulations between county councils, district councils and unitary authorities. However, in non-unitary council areas in England, the food standards work is carried out by the county council and food hygiene work by district councils. In areas under unitary local government local authorities are responsible for both services.

Sanctions

37. No changes to the sanctions are being proposed to those contained in the current Regulations, which are considered proportionate and the minimum needed to enable the policy to be implemented effectively.

Simplification

38. The opportunity is being taken to maintain a simplified single set of Regulations that avoid numerous amendments. This will ensure that we reduce the number of places in which substance restrictions and other substance usage information is recorded. An earlier simplification of the regulation of food contact materials legislation was carried out in a two stage exercise in February and March 2006. Since then we have continued to propose simplified single-set regulations to minimise the burden on industry and enforcement authorities. This will help those that need to refer to the Regulations.

Implementation and Review

39. The proposed Regulations will come into force on 7th March 2009. We shall continue to regularly communicate with industry to ensure that no foreseen difficulties arise from the proposed Regulations, which will be reviewed in March 2010.

Monitoring

40. Central and local authorities in England routinely monitor foodstuffs on sale to the public to ensure compliance with the regulations. The results of this work carried out by the Agency are published and are openly available on the Agency's website at:

    http://www.food.gov.uk/science/researchinfo/contaminantsresearch/

41. We shall therefore, routinely survey materials and articles on the market to ensure compliance with the Regulations. The Agency will work with enforcement authorities where problems arise or suspected infringements of the Regulations arise. The effectiveness of the proposed Regulations will also be monitored via feedback from stakeholders as part of the ongoing policy process.

Specific Impact Tests: Checklist

Use the table below to demonstrate how broadly you have considered the potential impacts of your policy options.

Ensure that the results of any tests that impact on the cost-benefit analysis are contained within the main evidence base; other results may be annexed.

Type of testing undertaken	***Results in Evidence Base?***	***Results annexed?***
Competition Assessment	No	Yes
Small Firms Impact Test	No	Yes
Legal Aid	No	No
Sustainable Development	No	Yes
Carbon Assessment	No	Yes
Other Environment	No	No
Health Impact Assessment	No	No
Race Equality	No	Yes
Disability Equality	No	Yes
Gender Equality	No	Yes
Human Rights	No	Yes
Rural Proofing	No	Yes

Annexes

Competition Assessment

We have fully considered the questions posed in the Office of Fair Trading competition assessment test[33] and conclude that the proposed Regulations that implement the new Directive are unlikely to hinder the number or range of businesses or the ability for operators to compete. As such, the proposals are unlikely to significantly affect competition as the impact of reading the new Regulations is likely to be small and apply equally across all food contact industries. The proposals do not contain a strong competition element nor any new or additional burden as the new Directive they implement is amending existing legislation on food contact plastics. This is unlikely therefore to impact on businesses operating in this area, nor in their competitiveness or incentive to compete. Charities and voluntary organisations are also unlikely to be affected by these proposals.

Small Firms Impact Test

We do not consider the impact on small businesses in general to be significant. This view has been supported by industry following earlier consultations (June and October 2007), which indicated that the proposals would not disproportionately affect small or medium sized businesses, nor would they hinder competitiveness. Such businesses are always encouraged to respond to issues which they feel may have an impact on their ability to compete in the wider market.

Sustainable development

The Agency's remit is to protect the interest of consumers in relation to food safety, both now and in the future. In doing so, the Agency will take sustainable development into account in all of its activities and policy decisions. The proposal has a positive impact on public heath, without any significant negative impact on the other Government principles of sustainable development.

Race equality issues

Members of the ethnic communities are not affected by these proposals any differently to others.

Gender equality issues

There is unlikely to be any impact on gender equality.

Disability equality issues

Disabled people are unlikely to be affected by these proposals.

Carbon Impact Assessment

The proposal is unlikely to have any significant impact on emissions of greenhouse gases.

Human Rights

It is not considered that this proposal will have a negative impact on the Human Rights of those affected by it.

Rural Proofing

The proposal is unlikely to have any significant impact on rural areas.

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[2] http://www.oft.gov.uk/shared_oft/reports/comp_policy/oft876.pdf

DIRECTIVES

COMMISSION DIRECTIVE 2008/39/EC

of 6 March 2008

amending Directive 2002/72/EC relating to plastic materials and articles intended to come into contact with food

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC [1], and in particular Article 5(2) thereof,

Whereas:

(1) Commission Directive 2002/72/EC [2] is a specific Directive within the meaning of Regulation (EC) No 1935/2004 and harmonises the rules on the authorisation of plastic materials and articles intended to come into contact with food.

(2) Directive 2002/72/EC establishes lists of authorised substances for the manufacture of these materials and articles, in particular additives and monomers, restrictions on their use, as well as rules on labelling and on the information to be given to consumers or food business operators for the correct use of these materials and articles.

(3) The current list of additives contained in Directive 2002/72/EC is an incomplete list inasmuch as it does not contain all substances currently accepted in one or more Member States.

(4) According to Article 4(1) of Directive 2002/72/EC as it stands, the list of additives is considered to be an incomplete list until the Commission decides, in accordance with Article 4a, that it becomes a positive Community list of authorised additives.

(5) For those additives which are currently permitted in the Member States, the time limit for the submission of data for their safety evaluation by the European Food Safety Authority (hereinafter the Authority) with a view to their inclusion in the Community list expired on 31 December 2006. Therefore the date when the Community list of additives becomes a positive list can now be set. Taking into account the time the Authority will need to evaluate all valid applications submitted on time this date should be January 2010.

(6) It is also appropriate to clarify the role of the provisional list referred to in Article 4a (4) and (5) of Directive 2002/72/EC as it stands and how it will be updated. The provisional list contains those additives for which the necessary data were supplied on time and in accordance with the Authority's requirements, but where no decision on their inclusion in the positive list has yet been taken.

(7) This provisional list provides information to the public on the additives that are under evaluation in view of their possible inclusion in the Community list of additives. As it is impossible to know if the evaluations for all the additives included in the provisional list will be completed by the date when the list of additives becomes a positive list, it should be possible to continue to use those additives, in accordance with national law, until their evaluation is completed and a decision is taken on their inclusion in the positive list of additives.

(8) When an additive included in the provisional list is inserted in the Community list of additives or when it is decided not to include it in the Community list, that additive should be removed from the provisional list of additives.

(9) If, during the examination of the data on an additive included in the provisional list, the Authority calls for supplementary information, that additive should be maintained in the provisional list until a decision is taken in relation to it, provided that the information is submitted within the time limits specified by the Authority.

[1] OJ L 338, 13.11.2004, p. 4.
[2] OJ L 220, 15.8.2002, p. 18. Directive as last amended by Directive 2007/19/EC (OJ L 97, 12.4.2007, p. 50).

(10) On the basis of new information related to the risk assessment of monomers and additives evaluated by the Authority [1], certain additives admitted at national level as well as new monomers and additives should be included in the respective Community lists of authorised substances. For other substances, the restrictions and/or specifications already established at Community level should be amended on the basis of this new information. Therefore, Annexes II, III, IVa, V and VI of Directive 2002/72/EC should be amended accordingly.

(11) Commission Directive 2005/79/EC [2] introduced in the list of additives the additive Ref. No 30340 with the name *12-(Acetoxy)stearic acid, 2,3-bis(acetoxy)propyl ester* and CAS number 330198-91-9. The name and CAS number introduced in that Directive reflect only the main component of the application. However the opinion delivered by the Authority covers the mixture of substances referred to in the application and not only its main component. The mixture of substances is now registered in the CAS register under CAS number 736150-63-3 with the name *Glycerides, castor-oil mono-, hydrogenated, acetates*. For this reason it is now appropriate to change the name and CAS number to update the authorisation to all substances in the mixture. Taking into account the change of name a new Ref. No 55910 is assigned. As the substance is now covered by Ref. No 55910, Ref. No 30340 should be deleted.

(12) As a consequence, Directive 2002/72/EC should be updated to take account of new information related to the risk assessment of substances evaluated by the Authority, to establish the date when the list of additives becomes a positive list and to clarify the role of the provisional list of additives.

(13) The measures provided for in this Directive are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Directive 2002/72/EC is amended as follows:

1. In Article 4, paragraph 1 is replaced by the following:

'1. A Community list of additives which may be used for the manufacture of plastic materials and articles, together with the restrictions and/or specifications on their use, is set out in Annex III.

Until 31 December 2009, additives which are not included in the Community list of additives may continue to be used subject to national law.

As from 1 January 2010, only additives included in the Community list of additives may be used for the manufacture of plastic materials and articles (positive list).'

2. Article 4a is amended as follows:

(a) Paragraphs 3 and 4 are replaced by the following:

'3. A provisional list of additives that are under evaluation by the Authority shall be made public by the Commission by 11 April 2008 at the latest. It shall be kept updated.

4. By derogation from the third subparagraph of Article 4(1), additives not included in the Community list referred to in that Article may continue to be used subject to national law after 1 January 2010 for as long as they are included in the provisional list.'

(b) Paragraph 6 is added:

'6. An additive shall be removed from the provisional list:

(a) when it is included in the Community list of additives; or

(b) when a decision is taken by the Commission not to include it in the Community list of additives; or

(c) if during the examination of the data, the Authority calls for supplementary information and that information is not submitted within the time limits specified by the Authority.'

3. Annexes II, III, IVa, V and VI are amended in accordance with Annexes I, II, III, IV and V to this Directive.

Article 2

1. Member States shall adopt and publish, by 7 March 2009 at the latest, the laws, regulations and administrative provisions necessary to comply with this Directive. They shall forthwith communicate to the Commission the text of those provisions and a correlation table between those provisions and this Directive.

[1] The EFSA Journal (2007) 555 to 563, 1-32.
The EFSA Journal (2007) 516 to 518, 1-12.
The EFSA Journal (2007) 452 to 454, 1-10.
The EFSA Journal (2006) 418 to 427, 1-25.

[2] OJ L 302, 19.11.2005, p. 35.

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

They shall apply those provisions in such a way as to:

(a) permit the trade in and use of plastic materials and articles intended to come into contact with food and complying with Directive 2002/72/EC, as amended by this Directive, from 7 March 2009;

(b) prohibit the manufacture and importation into the Community of plastic materials and articles intended to come into contact with food and which do not comply with Directive 2002/72/EC, as amended by this Directive, from 7 March 2010.

2. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

Article 3

This Directive shall enter into force on the 20th day following its publication in the *Official Journal of the European Union*.

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 6 March 2008.

For the Commission
Androulla VASSILIOU
Member of the Commission

ANNEX I

Section A of Annex II to Directive 2002/72/EC is amended as follows:

(a) the following monomers and other starting substances are inserted, in the appropriate numerical order:

Ref. No	CAS No	Name	Restrictions and/or specifications
(1)	(2)	(3)	(4)
'15404	000652-67-5	1,4:3,6-Dianhydrosorbitol	SML = 5 mg/kg. Only for use as a co-monomer in poly(ethylene-co-isosorbide terephthalate)
19180	000099-63-8	Isophthalic acid dichloride	SML(T) = 5 mg/kg (43) (expressed as isophthalic acid)
26305	000078-08-0	Vinyltriethoxysilane	SML = 0,05 mg/kg. Only to be used as a surface treatment agent'

(b) for the following monomers and starting substances, the content of the column 'Restrictions and/or specifications' is replaced by the following:

Ref. No	CAS No	Name	Restrictions and/or specifications
(1)	(2)	(3)	(4)
'19150	000121-91-5	Isophthalic acid	SML(T) = 5 mg/kg (43)'

ANNEX II

Annex III to Directive 2002/72/EC is amended as follows:

(1) Section A is amended as follows:

(a) The following additives are inserted in the appropriate numerical order:

Ref. No	CAS No	Name	Restrictions and/or specifications
(1)	(2)	(3)	(4)
'38875	002162-74-5	Bis(2,6-diisopropylphenyl) carbodiimide	SML = 0,05 mg/kg. For use behind a PET layer
45703	491589-22-1	cis-1,2-Cyclohexanedicarboxylic acid, calcium salt	SML = 5 mg/kg
48960	—	9,10-dihydroxy stearic acid and its oligomers	SML = 5 mg/kg
55910	736150-63-3	Glycerides, castor-oil mono-, hydrogenated, acetates	
60025	—	Hydrogenated homopolymers and/or copolymers made of 1-decene and/or 1-dodecene and/or 1-octene	In compliance with the specifications laid down in Annex V. Not to be used for articles in contact with fatty foods.
62280	009044-17-1	Isobutylene-butene copolymer	
70480	000111-06-8	Palmitic acid, butyl ester	
76463	—	Polyacrylic acid, salts	SML(T) = 6 mg/kg (36) (for acrylic acid)
76723	167883-16-1	Polydimethylsiloxane, 3-aminopropyl terminated, polymer with dicyclo-hexylmethane-4,4′-diisocyanate	In compliance with the specifications laid down in Annex V
76725	661476-41-1	Polydimethylsiloxane, 3-aminopropyl terminated, polymer with 1-isocyanato-3-isocyanatomethyl-3,5,5-trimethylcyclohexane	In compliance with the specifications laid down in Annex V
77732	—	Polyethylene glycol (EO = 1-30, typically 5) ether of butyl 2-cyano 3-(4-hydroxy-3-methoxyphenyl) acrylate	SML = 0,05 mg/kg. Only for use in PET
77733	—	Polyethyleneglycol (EO = 1-30, typically 5) ether of butyl-2-cyano-3-(4-hydroxyphenyl) acrylate	SML = 0,05 mg/kg. Only for use in PET
77897	—	Polyethyleneglycol (EO = 1-50) monoalkylether (linear and branched, C_8-C_{20}) sulphate, salts	SML = 5 mg/kg
89120	000123-95-5	Stearic acid, butyl ester	
95858	—	Waxes, paraffinic, refined, derived from petroleum based or synthetic hydrocarbon feedstocks	SML = 0,05 mg/kg and in compliance with the specifications laid down in Annex V. Not to be used for articles in contact with fatty foods.'

(b) for the following additives, the content of the column 'Restrictions and/or specifications' of the table is replaced by the following:

Ref. No	CAS No	Name	Restrictions and/or specifications
(1)	(2)	(3)	(4)
'39815	182121-12-6	9,9-Bis(methoxymethyl)fluorene	SML = 0,05 mg/kg
66755	002682-20-4	2-Methyl-4-isothiazolin-3-one	SML = 0,5 mg/kg. Only to be used in aqueous polymer dispersions and emulsions and at concentrations which do not result in an anti-microbial effect at the surface of the polymer or on the food itself.'

(c) the following additives are deleted:

Ref. No	CAS No	Name	Restrictions and/or specifications
(1)	(2)	(3)	(4)
'30340	330198-91-9	12-(Acetoxy)stearic acid, 2,3-bis (acetoxy)propyl ester'	

(2) Section B is amended as follows:

(a) the following additives are inserted in the appropriate numerical order:

Ref. No	CAS No	Name	Restrictions and/or specifications
(1)	(2)	(3)	(4)
'34130	—	Alkyl, linear with even number of carbon atoms (C_{12}-C_{20}) dimethylamines	SML = 30 mg/kg
53670	032509-66-3	Ethylene glycol bis[3,3-bis(3-tert-butyl-4-hydroxyphenyl)butyrate]	SML = 6 mg/kg'

(b) for the following additives, the content of the column 'Restrictions and/or specifications' of the table is replaced by the following:

Ref. No	CAS No	Name	Restrictions and/or specifications
(1)	(2)	(3)	(4)
'72081/10	—	Petroleum Hydrocarbon Resins (hydrogenated)	In compliance with the specifications laid down in Annex V'

ANNEX III

In Annex IVa to Directive 2002/72/EC the following substances are inserted in the appropriate numerical order:

Ref. No	CAS No	Name
'34130	—	Alkyl, linear with even number of carbon atoms (C12-C20) dimethylamines
39815	182121-12-6	9,9-Bis(methoxymethyl)fluorene
53670	032509-66-3	Ethylene glycol bis[3,3-bis(3-tert-butyl-4-hydroxyphenyl)butyrate]'

ANNEX IV

In Part B of Annex V to Directive 2002/72/EC the following new specifications are inserted, in the appropriate numerical order:

Ref. No	Other specifications
'60025	Specifications: — Minimum viscosity (at 100 °C) = 3,8 cSt — Average Mw > 450
76723	Specifications: The fraction with molecular weight below 1 000 should not exceed 1,5 % w/w
76725	Specifications: The fraction with molecular weight below 1 000 should not exceed 1 % w/w
95858	Specifications: — Average molecular weight not less than 350 — Viscosity at 100 °C min 2,5 cSt — Content of hydrocarbons with carbon number less than 25, not more than 40 % w/w'

ANNEX V

Annex VI to Directive 2002/72/EC is amended as follows:

(1) Note (36) is replaced by the following:

'([36]) SML(T) in this specific case means that the restriction shall not be exceeded by the sum of the migration levels of the following substances mentioned as Reference Nos 10690, 10750, 10780, 10810, 10840, 11470, 11590, 11680, 11710, 11830, 11890, 11980, 31500 and 76463.'

(2) Note (43) is added:

'([43]) SML(T) in this specific case means that the restriction shall not be exceeded by the sum of the migration levels of the following substances mentioned as Reference Nos 19150 and 19180.'

	Guidance On The Plastic Materials And Articles In Contact With Food (England) Regulations 2009	
	Version 1 June 2008	

If you require this information in an alternative format – such as audio, large print, or Braille – please contact us.

CONTACT TELEPHONE 020 7276 8553

Summary

Intended audience:	The aims in producing this guidance are to help those that manufacturer, use, import or sell food packaging materials and articles made from plastic for use in contact with food.
Regional coverage:	The guidance notes provide a short summary of the changes introduced by the new English Regulations only.
Legal status:	These guidance notes have been created to give informal, non-binding advice on some of the legal requirements of The Plastic Materials and Articles in Contact with Food (England) Regulations 2009 and should be read in conjunction with the legislation itself.
Purpose:	These guidance notes provide a short summary of the changes introduced by the new Regulations.

REVISION HISTORY

Revision No.	Revision date	Purpose of revision	Revised by
1		Regulatory Guidance	

CONTENTS

INTENDED AUDIENCE

1. This guidance is aimed primarily at businesses (including SMEs, which may either use the guidance directly or learn about it via trade associations or enforcement authority contacts) that manufacture, use, import or sell materials and articles made from plastic that are intended for use in contact with food. It may also be of use to others with an interest in the legislation, such as enforcement authorities. These guidance notes provide a short summary of the changes proposed by the new Regulations in so far as they apply to England only. The devolved administrations in Wales, Scotland and Northern Ireland will make separate but parallel legislation.

PURPOSE AND LEGAL STATUS

2. These guidance notes have been produced to provide informal, non-binding advice on some of the legal requirements of The Plastic Materials and Articles in Contact with Food (England) Regulations 2009 and should be read in conjunction with the legislation itself. The text should not be taken as an authoritative statement or interpretation of the law, as only the courts have this power. Every effort has been made to ensure that these guidance notes are as helpful as possible. However, it is ultimately the responsibility of individual businesses to ensure their compliance with the law. Businesses with specific queries may wish to seek the advice of their local enforcement agency, which will usually be the trading standards/environmental health department of the local authority.

WHY YOU SHOULD READ THIS NOTE - COMPLIANCE

3. Within the European Union, it is the responsibility of the manufacturer, importer, distributor or seller of food contact materials and articles, or those

who place them in contact with food prior to sale, to ensure that their products comply with the appropriate legislation. Unlike the system administered by the Food and Drug Administration (FDA) in the United States of America that many businesses will be familiar with, there is no system of prior approval or authorisation of food contact materials within the EU. Instead of approving the product, constituents of the materials, such as monomers and other starting substances and additives used for a technical effect on the polymer, are subject to specific, conditional authorisation at EC level.

4. In the event of prosecution for an alleged offence under these Regulations, defendants may seek to avail themselves of the defence of 'due diligence' provided for at regulation 20 of the Regulations. In order to succeed, such a defence requires proof that the defendant had taken all reasonable precautions to avoid committing the alleged offence, including, probably, documentary evidence purporting to show that the goods complied with the law and on which it was reasonable for the defendant to have relied. It is in any event a legal requirement that any business which places on the market relevant goods or substances prior to the retail stage provides such documentary evidence to support the mandatory declaration of compliance with the law. The detail of this requirement is set in Schedule 4 to the Regulations, as read with regulation 14.

THE EUROPEAN LEGISLATION

5. The European Commission and the Member States of the European Union are working towards a fully harmonised set of rules that will apply to food contact materials and articles across the EU. The aim is to protect consumers from any harmful effects of eating food contaminated by chemicals that might have migrated from materials and articles with which the food had been in intentional contact or from which it might reasonably

be expected that a substance might migrate into the food. In addition to protecting consumers, this harmonisation will provide businesses with one set of rules to comply with throughout the EU instead of a plethora of national rules in different EU Member States. Since the principal legislation on plastic food contact materials and articles was introduced in 1990, it has been regularly amended as better scientific understanding has developed about the nature and detection of chemical migrants from food contact materials and articles.

DETAIL

6. EC Directive 2008/39/EC ("the amending Directive") amends Commission Directive 2002/72/EC on plastic materials and articles intended to come into contact with food ("the Directive") for the fifth time. The amending Directive lays down the dates by which the list of additives in food contact plastics will be closed and makes interim arrangements for those additives for which an application for authorisation had been made by the deadline of December 2006. It also sets a deadline of 31st December 2009 up to which additives not on the positive list may continue to be used and prohibits their use from 1st January 2010. This period until December 2009 will enable EFSA to obtain any additional information it may need for its risk assessment of those additives on the provisional list.

7. The amending Directive required that the European Commission publish its provisional list of those additives that are subject of an application for authorisation by 11th April 2008 and that the list be kept up-to-date. However, an additive will be removed from the provisional list either when it is included in the positive list, or if additional information asked for by EFSA is not provided. The list has been published and is available on the Commission's Website and can be accessed at http://ec.europa.eu/food/food/chemicalsafety/foodcontact/documents_en.htm

8. For certain substances, the restrictions already established at Community level have been amended on the basis of new information becoming available. As such Annexes II, III, IVa, V and VI of Directive 2002/72/EC are amended accordingly. The amending Directive also:

9. Permits the trade and use of plastic materials and articles intended to come into contact with food and complying with Directive 2002/72/EC, as amended by the amending Directive from 7th March 2009.

10. Prohibits, as from 7th March 2010, the manufacture and importation into the Community of plastic materials and articles intended to come into contact with food that do not comply with Commission Directive 2002/72/EC, as amended by the amending Directive.

CHANGES TO THE ENGLISH REGULATIONS

11. The proposed Plastic Materials and Articles in Contact with Food (England) Regulations 2009 that are the subject of this guidance, implement the amending Directive detailed above. The Regulations will revoke the Plastic Materials and Articles in Contact with Food (England) Regulations 2008 and remake them with necessary amendments. This continues our practice of ensuring that, apart from occasional short term measures, we only have one set of Regulations in relation to the law on food contact plastics in England.

SUMMARY OF CHANGES

12. The table below provides summary details of how the individual Articles in the amending Directive have been implemented in the Regulations

Articles and Annexes of Directive 2008/39/EC	Objectives	Implementation in the Plastic Materials and Articles in Contact with Food (England) Regulations 2009
Article 1(1) amending Article 4 of Directive 2002/72/EC	Article 1(1) inserts a new first paragraph at Article 4 relating to the Community list of additives which may be used for the manufacture of materials and articles, together with the restrictions and/or specifications on their use, as set out in Annex III	These provisions are implemented in Regulation 5 – paragraphs (1) and (2) have been amended (these set up a prohibition on using any additive other than one in the Community list of additives. A new paragraph (3)(a) has been added to create a time limit for materials and articles made in other MS not on the Community list may continue to be used.
Article 1(2) amending Article 4a of Directive 2002/72/EC	Article 1(2) amends Article 4a by replacing paragraphs 3 and 4. Paragraph 3 states that a provisional list of additives that are under evaluation by the Authority shall be made public by the Commission and shall be kept updated. Paragraph 4 states that by way of derogation from the third sub-paragraph of Article 4(1), additives not included in the Community list referred in that Article may continue to be used subject to national law after 1st January 2010 for as long as they are included in the provisional list.	Paragraph 4 of the amended Article 4a the only provision requiring implementation here, and is implemented by Regulation 5(3)(b), which gives effect to the derogation for additives that are on the provisional list pending a decision on Community authorisation.
Article 1(3) and Annexes I	Makes changes to the lists	Implementation is

to V amending Annexes to Directive 2002/72/EC	of approved substances and related specifications annexed to Directive 2002/72/EC	unnecessary as the Annexes are implemented by ambulatory reference in UK legislation
Article 2(1)(a)	Requires Member States to permit the trade in and use of plastic materials and articles intended to come into contact with food that comply with the provisions of Directive 2002/72/EC as amended by Directive 2008/39/EC from 7th March 2009.	The coming into force of the Regulations on 7th March 2009 has the effect of meeting this requirement.
Article 2(1)(b)	Prohibits the manufacture and import into the Community from 7th March 2010 of plastic materials and articles intended to come into contact with food and which do not comply with Directive 2002/72/EC, as amended by Directive 2008/39/EC	The provision is implemented by Regulation 5(3) as read with regulation 3(2) and Schedule 5 (transitional arrangements)

FURTHER INFORMATION

12. If you have any questions about these or any other Regulations governing food contact materials and articles, please contact:

Nasreen Shah,
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Room 4C, Aviation House,
125 Kingsway,
London, WC2B 6NH.
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13. Other information about food contact materials is available from the Agency's website at:

    www.food.gov.uk/industry/foodcontactmaterials

14. The information that is available includes explanatory notes and guidance notes on all food contact material legislation and United Kingdom research and development and chemical surveillance on food contact materials. The results of completed surveillance can be viewed from this point at:

    http://www.food.gov.uk/science/research/researchinfo/contaminantsresearch/contactmaterials/

15. Although work predating the formation of the Agency can be accessed from the site archive, you can also access information about the work of The Working Party on Chemical Contaminants from Food Contact Materials in determining and reviewing work on research and development in this area.

LIST OF INTERESTED PARTIES

Name	Company
Mr Alan Turner OBE	
Julia Scott	
Mr Paul Anthony Taylor	
Nigel Barnwell	
Joy Hardinge OBE	AJH Consulting
Mr A J Newbould	AJN Solutions
Dr P Donnelly	APD Scientific Limited
Mr Alex Martin	AMDEA
Anton Davis	Alba Plastics
	Association of Consumer Research
	Association of Port Health Authorities
Mrs R McBrown	Avent Limited
Nicola Smith	Bird and Bird
Dr Steve Owen	Boots PDQ Centre
Mr A J Newbould	British Coatings Federation
	British Disposable Products Association
Dr Mercia Gick	British Plastics Federation
Sarah Plant	British Plastics Federation
Sally Barber	British Retail Consortium
Lucy Pearson	British Soft Drinks Association
Peter Vincent	BPIF
Mr Roger Hamby	CATRA
Alex Cole	Cadbury Schweppes
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Mr J Begg	Dairy Industry Federation
Mr Brian McMullen	Danapak Flexibles Limited
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Liz Fleming	Eclipse Scientific Group
	Enterprise Directorate
	Federation of Small Businesses
Ann Davison	FOODAWARE
Mr Richard Ratcliffe	Food Additives and Ingredients Association
Andrew Curtis	Food And Drink Federation
Dr Stephen Fellows	Food Policy Update
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Ian Blakemore	Halton Borough Council
Mr R Colwell	H J Heinz
Mr Julian Stocker	H J Heinz
David Eaves	ICI Paints
Mr J Plaistowe	ICI Packaging Coatings Limited
	Industry Council for Packaging and the Environment
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Mr Darren Prosser	Kenwood Limited
Mr John Webb-Jenkins	Kirkstone Plastics Limited
Dr Derek Craston	Laboratory of the Government Chemist
Dr John Francis	Laboratory of the Government Chemist
Mr Les Bailey	LACORS

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Mr Stan Webb	Sinclair International Limited
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Iain Ferguson	The Co-operative Retail Group (CWS) Ltd
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Mr Barry Pamplin	United Biscuits (UK) Limited
Kay Flett	UNIVAR Limited
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Mr Ronald Pierre-Davis	Wilsanco Plastics Limited