S T A T U T O R Y I N S T R U M E N T S

2008 No.

FOOD, ENGLAND

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

Made - - - -	*2008*
Laid before Parliament	*2008*
Coming into force	
for the purpose of regulation 29(c)	*1st July2008*
for all other purposes	*1st May 2008*

CONTENTS

PART 1
Preliminary

PART 2
Requirements for Materials and Articles

PART 3

Execution and Enforcement

PART 4

Application for Authorisation

PART 5

General and Supplementary

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

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 2008, apply in relation to England only and come into force —

(a) For the purposes of regulation 29(c) on 1st July 2008;

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

Interpretation

2.—(1) In these Regulations —

"the Act" means the Food Safety Act 1990;

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

(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. 575/2006 (OJ No. L100, 8.4.2006, p.3).

(e) S.I. 1998/1376, as amended in relation to England by S.I. 2000/3162, S.I. 2002/2364, S.I. 2002/3008, S.I. 2004/3113 and S.I. 2005/325. It was revoked by SI 2006/1401.

"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 95/31/EC laying down specific criteria of purity 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**);

"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;

(a) S.I. 2007/2790.
(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. L178, 28.7.95, p.1. This was last amended by Commission Directive 2004/46, OJ No. L114, 21.4.2004, p.15.
(g) OJ No. L226, 22.9.95, p.1. This was last amended by Commission Directive 2004/47, OJ No. L113, 20.4.2004, p.24.
(h) OJ No. L339, 30.12.96, 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), and 2007/19/EC (published in revised and corrected form in OJ No. L97, 12.4.2007, p.50).
(j) OJ No. L338, 13.11.2004, p.4).
(k) OJ No. L302, 19.11.2005, p.28.

"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 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 with a prohibited monomer as described in regulation 4(2) or a prohibited additive as described in regulation 5(2); or

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

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

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

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

(a) of good technical quality;

(b) identified by PM/REF No, CAS No (if any) and name in columns 1, 2 and 3 respectively of Sections A or B of Annex II; and

(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 prohibited additive.

(2) A prohibited additive is —

(a) any additive identified by PM/REF No, CAS No (if any) and name in columns 1, 2 and 3 respectively of Section A or B of Annex III which —

(i) is not of good technical quality, or

(ii) is not used in accordance with any restrictions and specifications for that additive set out in the corresponding entry in column 4 of Section A or B of that Annex; or

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

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

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

(3) In any proceedings for an offence under these Regulations where it is alleged that the commission of the offence is due to the manufacture of a plastic material or article with any additive identified in Section A or B of Annex III which is not of good technical quality, it shall be a defence for the 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 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 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 stimulant.

(4) For plastic materials or articles intended to be brought into contact or already in contact with food intended for infants and young children, the appropriate limit is always 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 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).

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

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

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

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

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

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

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

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

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

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.

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) 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 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).

Other transitional defences and savings

22.—(1) Notwithstanding the revocation of the 1998 Regulations made by regulation 24 of the Plastic Materials and Articles in Contact with Food (England) Regulations 2006, in relation to any plastic material or article —

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

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

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

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

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

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

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

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

(2) In any proceedings for an offence under these Regulations other than an offence referred to in regulation 21(1), it shall be a defence to prove —

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

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

(3) In any proceedings for an offence under these Regulations other than an offence referred to in regulation 21(1), it shall be a defence to prove —

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

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

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

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

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

Procedure where a sample is to be analysed

23.—(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;

(a) OJ No. L92, 3.4.2007, p.9.

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

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

(e) retain one part for future submission under regulation 24.

Secondary analysis by the Government Chemist

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

Application for Authorisation

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

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

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

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

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

PART 5

General and Supplementary

Application of provisions of the Act

26. 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

27. 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 Materials and Articles in Contact with Food (England) Regulations 2006 substitute the title and reference of these Regulations.

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

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

(2) In regulation 2(1) —

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

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

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

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

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

Revocations

29. The following Regulations or parts thereof are revoked —

(a) The Plastic Materials and Articles in Contact with Food (England) (No.2) Regulations 2006(**c**);

(b) Regulation 24 of the 2007 Regulations;

(c) The Plastic Materials and Articles in Contact with Food (Lid Gaskets) (England) Regulations 2007(**d**).

Signed by authority of the Secretary of State for Health

Dawn Primarolo
Minister of State
Department of Health

2008

(a) S.I. 1990/2463
(b)
(c) S.I. 2006/2687
(d) S.I. 2007/2786.

SCHEDULE 1

Regulations 4 and 5

Supplementary provisions relating to Annexes II and III

1. In Sections A and B of Annexes II and III (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.

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

3.—(1) The items identified in Section A or B of Annex II shall be taken to include—

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

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

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

(2) Salts (including double salts and acid salts) of aluminium, ammonium, calcium, iron, magnesium, potassium and sodium of authorised acids, phenols or alcohols are not included in the lists in the Annexes even if they are authorised and intentionally used; however names containing "…acid(s), salts" do appear in the lists if the corresponding free acid(s) is or are not mentioned

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

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

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

4. In the case of substances listed in Section B of Annex III, the specific migration limits 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.

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

SCHEDULE 2

Regulations 9 and 13

Provisions Applicable when Testing Compliance with the Migration Limits

General Provisions

1. When the results of the migration tests specified in this Schedule and, where appropriate Schedule 3, are analytically determined, the specific gravity of any simulants used shall be assumed to be 1, so that milligrams of any substance released per litre of simulant will correspond numerically to milligrams of that substance released per kilogram of that simulant.

2. Where any migration test specified in this Schedule and, where appropriate, Schedule 3 is carried out on any sample taken from any plastic material or article and the quantities of food or simulant placed in contact with the sample differ from those employed in the actual conditions under which the plastic material or article is used or is to be used, the results obtained should be corrected by applying the formula $M = ((m.a_2/a_1.q).1000)$ where —

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

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

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

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

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

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

(2) In any case where determination in accordance with sub-paragraph (1) 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 lipohilic 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 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 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 material or article shall be considered to be in compliance.

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

Special provisions relating to the correction of specific migration in 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 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 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 $\leq$ 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 allowed by an oblique stroke and a reduction factor.

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

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

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

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

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

Reference Number	*Description of food*	*Simulants to be used*			
		A	B	C	D
01	**Beverages**				
01.01	Non-alcoholic beverages or alcoholic beverages of an alcoholic strength lower than 5% vol: — Waters, ciders, fruit or vegetable juices of normal strength or concentrated, musts, fruit nectars, lemonades and mineral waters, syrups, bitters, infusions, coffee, tea, liquid chocolate, beers and other	X(a)	X(a)		

01.02	Alcoholic beverages of an alcoholic strength equal to or exceeding 5% vol. — Beverages shown under heading 01.01 but with an alcoholic strength equal to or exceeding 5% vol. — Wines, spirits and liqueurs		X[(1)]	X[(2)]	
01.03	Miscellaneous: undenatured ethyl alcohol		X[(1)]	X[(1)]	
02	**Cereals, cereal products, pastry, biscuits, cakes and other bakers' wares**				
02.01	Starches				
02.02	Cereals, unprocessed, puffed, in flakes (including popcorn, cornflakes and the like)				
02.03	Cereal flour and meal				
02.04	Macaroni, spaghetti and similar products				
02.05	Pastry, biscuits, cakes and other bakers' wares, dry: A With fatty substances on the surface B Other				X/5
02.06	Pastry, biscuits, cakes and other bakers' wares, fresh A With fatty substances on the surface B Other	X			X/5
03	**Chocolate, sugar and products thereof Confectionery products**				
03.01	Chocolate, chocolate-coated products, substitutes and products coated with substitutes				X/5
03.02	Confectionery products: A in solid form — with fatty substances on the surface — Other B in paste form: — with fatty substances on the surface — moist	X			X/5 X/3
03.03	Sugar and sugar products A In solid form B Honey and the like C Molasses and sugar syrups	X X			
04	**Fruit, vegetable and products thereof**				
04.01	Whole fruit, fresh or chilled				
04.02	Processed fruit: A Dried or dehydrated fruit, whole or in the form of flour or powder B Fruit in the form of chunks, puree or paste C Fruit preserves (jams and similar products – whole fruit or chunks or in the form of flour or powder, preserved in a liquid medium): — i) In an aqueous medium — ii) In an oily medium — iii) In an alcoholic medium ≥ 5% vol	X(a) X(a) X(a)	X(a) X(a) X(a) X[(1)]	 X	 X
04.03	Nuts (peanuts, chestnuts, almonds, hazelnuts, walnuts, pine kernels and others)				

	A Shelled, dried B Shelled and roasted C In paste or cream form	 X			 X/5(3 X/3(3)
04.04	Whole vegetables, fresh or chilled				
04.05	Processed vegetables: A Dried or dehydrated vegetables whole or in the form of flour or powder B Vegetables, cut, in the form of purees C Preserved vegetables: — i) In an aqueous medium — ii) In an oily medium — iii) In an alcoholic medium (≥ 5% vol)	 X(a) X(a) X(a)	 X(a) X(a) X(a) X(1)	 X	 X
05	**Fats and oils**				
05.01	Animal and vegetable fats and oils, whether natural or treated (including cocoa butter, lard, resolidified butter)				X
05.02	Margarine, butter and other fats and oils made from water emulsions in oil				X/2
06	**Animal products and eggs**				
06.01	Fish: A Fresh, chilled, salted, smoked B In the form of paste	 X X			 X/3(3) X/3(3)
06.02	Crustaceans and molluscs (including oysters, mussels, snails) not naturally protected by their shells	X			
06.03	Meat of all zoological species (including poultry and game): A Fresh, chilled, salted, smoked B In the form of paste, creams	 X X			 X/4 X/4
06.04	Processed meat products (ham, salami, bacon and other)	X			X/4
06.05	Preserved and part-preserved meat and fish: A In an aqueous medium B In an oily medium	 X(a) X(a)	 X(a) X(a)		 X
06.06	Eggs not in shell: A Powdered or dried B Other	 X			
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 X X			
07.02	Fermented milk such as yoghurt, buttermilk and such products in association with fruit and fruit products		X		
07.03	Cream and sour cream	X(a)	X(a)		
07:04	Cheeses: A Whole, with rind				

	B Processed cheeses C All others	X(a) X(a)	X(a) X(a)		 X/3[3]
07:05	Rennet: A In liquid or viscous form B Powdered or dried	 X(a)	 X(a)		
08	**Miscellaneous products**				
08.01	Vinegar		X		
08.02	Fried or roasted foods: A Fried potatoes, fritters and the like B Of animal origin				 X/5 X/4
08.03	Preparations for soups, broths in liquid, solid or powder form (extracts, concentrates); homogenized composite food preparations, prepared dishes: A Powdered or dried — i) With fatty substances on the surface — ii) Other B Liquid or paste: — i) With fatty substances on the surface — ii) Other	 X(a) X(a)	 X(a) X(a)		 X/5 X/3
08.04	Yeasts and raising agents: A In paste form B Dried	 X(a)	 X(a)		
08.05	Salt				
08.06	Sauces: A Without fatty substances on the surface B Mayonnaise, sauces derived from mayonnaise, salad creams and other oil in water emulsions C Sauce containing oil and water forming two distinct layers	 X(a) X(a) X(a)	 X(a) X(a) X(a)		 X/3 X
08.07	Mustard (except powdered mustard under heading 08.17)	X(a)	X(a)		X/3[3]
08.08	Sandwiches, toasted bread and the like containing any kind of foodstuff: A With fatty substances on the surface B Other				 X/5
08.09	Ice-creams	X			
08.10	Dried foods: A With fatty substances on the surface B Other				 X/5
08.11	Frozen or deep-frozen foods				
08.12	Concentrated extracts of an alcoholic strength equal to or exceeding 5% vol		X[1]	X	
08.13	Cocoa: A Cocoa powder B Cocoa paste				 X/5[3] X/3[3]
08.14	Coffee, whether or not roasted, decaffeinated or soluble, coffee substitutes, granulated or powdered				
08.15	Liquid coffee extracts	X			

08.16	Aromatic herbs and other herbs: Camomile, mallow, mint, tea, lime blossom and others				
08.17	Spices and seasonings in the natural state: Cinnamon, cloves, powdered mustard, pepper, vanilla, saffron and other				

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

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

(3) If it can be demonstrated under regulation 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 materials or articles to comply with the relevant Community provisions or, in their absence, with national provisions applicable to food.

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

(a) 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 material or article.

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

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) (No.2) Regulations 2006,(S.I. 2006/2687), 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 2007/19/EC (corrected version at OJ No. L 97, 12.4.2007, p.50) ("the new Commission Directive"), which introduces new specifications and restrictions relating to plastic multi-layer materials and articles and to substances used in the manufacture of plastic materials and articles in contact with food in general, and amends certain specifications relating to migration testing in fatty foods; and

(b) provision that a reference in these Regulations to an Annex to Commission Directive 2002/72/EC is to be construed as a reference to that Annex as it may be amended from time to time.

2. The Regulations in Part 2 —

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

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

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

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

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

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

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

(h) provide for the execution and enforcement of Regulation 1895/2005 on the restriction of use of certain epoxy derivatives in materials and articles intended to come into contact with food (OJ No. L302, 19.11.2005, p.28), which contains Community provisions relating to the epoxy derivatives known as BADGE, BFDGE and NOGE (*regulation 12*);

(i) specify the methods for determining the capability of a plastic material or article to transfer its constituents to food, and for detecting the presence of any such constituents in food (*regulation 13 and Schedules 2 & 3*);

(j) provide that prior to the retail stage plastic materials and articles must be accompanied by certain specified written information, including a declaration of legislative compliance (*regulation 14 and Schedule 4*).

3. The Regulations in Part 3 —

(a) designate food authorities and port health authorities as the enforcement authorities in their respective areas or districts (*regulation 15*);

(b) specify the offences that may be committed under these Regulations and set out the maximum penalties on conviction (*regulation 16*);

(c) provide that individuals responsible for the actions of a corporate body or Scottish partnership may be co-prosecuted for offences by that body or partnership (*regulation 17*);

(d) specify a time limit for commencing a prosecution (*regulation 18*);

(e) provide for the prosecution of a person who causes the commission of an offence by another person, whether or not proceedings are taken against the original offender (*regulation 19*);

(f) provide for a defence of diligence to offences under these Regulations (*regulation 20*);

(g) provide a defence relating to the sale of glass jars that contain certain foods for infants and young children and that have been sealed with a PVC gasket containing epoxidised soybean oil (*regulation 21*);

(h) provide for transitional defences in relation to certain plastic materials or articles that have already been manufactured or put into circulation in advance of a change in the law that would otherwise have made their manufacture or circulation unlawful (*regulation 22*);

(i) specify the procedure to be followed when sending a sample for analysis (*regulation 23*);

(j) make provision for a reference sample to be analysed by the Laboratory for the Government Chemist (*regulation 24*).

4. Part 4 of the Regulations contains provisions relating to the interim between an application to the European Food Safety Authority for the authorisation of a new additive and the final decision by that Authority (*regulation 25*).

5. The principal Directives implemented by these Regulations are —

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

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

(c) Commission Directive 2002/72/EC (OJ No. L220, 15.8.2002, p.18) relating to plastic materials and articles intended to come into contact with foodstuffs, as amended by Commission Directives 2004/1/EC (OJ No. L7, 13.1.2004, p.45), 2004/19/EC (OJ No. L71, 10.3.2004, p.8) and 2005/79/EC (OJ No. L302, 19.11.2005, p.35), and the new Commission Directive.

6. A full impact assessment of the effect that this instrument will have on the costs of business and the voluntary sector is available from the Chemical Safety Division of the Food Standards Agency, Aviation House, 125 Kingsway, London WC2B 6NH, and is annexed to the Explanatory Memorandum which is available alongside the instrument on the OPSI website.

Summary: Intervention & Options

Department /Agency:	Title:	
Food Standards Agency	**Impact Assessment of The Plastic Materials and Articles in Contact with Food (England) Regulations 2008**	
Stage: Consultation	**Version:** 2	**Date: 1 February 2008**
Related Publications:		

Available to view or download at:

http://www..food.gov.uk

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. Intervention is necessary to implement significant amendments to the main European Commission Directive on plastic materials and articles intended to come into contact with food.

What are the policy objectives and the intended effects?

The policy objectives are two-fold:

a) 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 migrate into the food; and

b) 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 2007/19/EC. It meets the Governments commitment to fulfil its EU obligations and contributes towards the protection of consumers from ingesting harmful levels of chemicals that could migrate

When will the policy be reviewed to establish the actual costs and benefits and the achievement of the desired effects? June 2009

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:

Summary: Analysis & Evidence

Policy Option: 2	Description: The Plastic Materials and Articles in Contact with Food (England) Regulations 2008

COSTS

ANNUAL COSTS	
One-off (Transition)	**Yrs**
£ 209,000	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 = £194,000

One-off cost borne by local authorities £15,000

Total Cost (PV) **£ 209,000**

Other **key non-monetised costs** by 'main affected groups' Transitional costs arising due to initial admin burdens for firms, LA's and Porth Health Authorities through the reading of the new legislation and amending of the Community list of authorised monomers and other starting substances - however, these costs are not thought to be significant

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 a formalisation of existing procedures and an increase in consumer confidence.

Key Assumptions/Sensitivities/Risks

Price Base Year 2006	Time Period Years	**Net Benefit Range** (NPV) **£ N/K**	**NET BENEFIT** (NPV Best estimate) **£ N/K**

What is the geographic coverage of the policy/option?			England	
On what date will the policy be implemented?			1 May 2008	
Which organisation(s) will enforce the policy?			LA's and PHA's	
What is the total annual cost of enforcement for these organisations?			£ 15,000	
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	Small	Medium	Large
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)

Rationale for Government Intervention

1. These proposals fulfil the UK Government's policies of meeting its EU obligations to bring into effect in law harmonised rules that:
   - Reduce the chronic and acute long term health risks to consumers arising from chemical contaminants in 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 over burdensome.
2. Doing nothing will mean that the UK Government will fail to implement it policies. It would also create the potential for the UK to become liable for infraction proceedings. It would not be possible to implement only parts of this proposal.
3. The Food Standards Agency believes that the adoption of these proposals provides for the continuation of consumer protection against food contamination by chemicals whose ingestion would carry serious long-term and unacceptable risk to consumer health, particularly among more vulnerable people. The introduction of harmonised statutory controls would reduce the potential for uncertainty or dispute in interpreting the requirements of the Commission Directive.

OPTION 1 – DO NOTHING

Costs

4. This contradicts the UK Government's commitment to meeting its EU obligations and fulfilling its policy on consumer protection in this area. It would also create potential for the UK to become liable for infraction proceedings and it would not be possible to implement only parts of the 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. Failure to fully implement the Commission Directive would mean that prevailing national legislation would no longer accord with Community provisions. In addition, UK consumers would not have the same health protection from the effect of excessive consumption of substances dealt with in these proposals as consumers in the rest of the EU.

Benefits

5. There are no identifiable benefits, (economic, social or environmental) associated with Option 1.

OPTION 2 – IMPLEMENT THE PROVISIONS OF COMMISSION DIRECTIVE 2007/19/EC IN FULL

6. This option fully meets the UK Government's commitment to fulfil its EU obligations and contribute significantly to the up-to-date means 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 throughout the negotiations that developed the Commission Directive to the point of its adoption by the Commission as a formal proposal and we supported its adoption at the Standing Committee on the Food Chain and Animal Health. Under EC legislation we are required to implement Commission Directive. Businesses and enforcement

authorities want the harmonisation of rules between Member States of the EU that the implementation of Commission Directive provides. This view was supported by stakeholders who commented on the consultation carried out in 2006, when these provisions were last amended. Stakeholders, particularly found that full implementation provides scope for a favourable balance between benefits and necessary costs

Administrative Costs

Costs: Option 2

7. The cost analysis is based on the fact that Option 2 fully meets the requirements of the proposal.

8. It is estimated that there will be one-off administrative costs to industry and enforcement authorities for reading and familiarising themselves with the new Regulations and these are summarised below.

Costs to Enforcement Authorities

9. In order to estimate the likely additional administrative burden for enforcement authorities in reading and familiarising with the new single set of Regulations, we have estimated the time that enforcement authorities will typically invest in these activities. There are approximately 435 local authorities in the UK, and we have estimated that one environmental health officer (EHO) in each of the 435 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 person uses one more hour for dissemination to key staff within the organisation. Thus, the time is valued at £17.25/hour (based on 2006 Annual Survey of Hours and Earnings (ASHE) data for EHOs). This equates to an approximate one-off administration cost to enforcement authorities of £15,000.

10. The price base year used to calculate the costs to enforcement authorities is 2006, as the Annual Survey of Hours and Earnings (2006) are used.

11. It is estimated that the total spend for enforcement authorities and port health authorities in relation to food safety is in the region of £98.3 million

12. Local authorities are responsible for enforcing the legislation with respect to food safety and also have the responsibility for enforcing food contact materials legislation, and will therefore be affected by these proposals. There may be a one-off cost for enforcement authorities (as they've indicated in earlier consultations), in reading the proposed regulations but they have been unable to quantify these. There may also be an ongoing and unchanged admin cost to enforcement authorities for monitoring and enforcing the new Regulations. However, given that this is an existing responsibility under other food contact materials legislation, the cost is unlikely to be increased.

Costs to Industry

13. 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. Thus the potential impact for a one-off cost to businesses is based on the same principles as those for LAs. A third of the 13,000 packaging businesses produce plastic materials and articles intended to come into contact with food and these are the 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 @ £22.33/hour (this is based on the 2006 ASHE

(2006) for 'Production and process engineers' (including the assumption of 30% overheads)); this equates to an approximate one-off administrative cost to industry of £194,000.

14. As indicated above, any likely costs associated with the new Regulations relate only to the businessess 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 machinery and equipment) and are not representative of the whole packaging industry. The proposals would apply equally to all businesses across the UK food contact plastics industry, its commercial customers and those that convert and/or import plastic food contact materials and articles, whether small or large.

Impact on other Government Departments

15. Government departments, such as the Food Standards Agency ("the Agency") will 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 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.

Benefits

Option 2

16. The recommended option (Option 2) of implementing the provisions of the Commission Directive into a single consolidated Statutory Instrument (SI) will bring together in one place the amending provisions with existing requirements. Businesses involved in the manufacture of plastic food contact materials are generally likely to gain from the measures in the Commission 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.

17. This option also minimises 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 the risk of illness through exposure to substances that might migrate and might be associated with various adverse effects on 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 estimated that the annual consumer benefit resulting from chemical contaminant controls was worth £900 million. The report is available on the DEFRA website at:

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

Risk Assessment

18. The European Food Safety Authority (EFSA) is responsible for carrying out risk assessments and gives its opinion 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 the protection of public health from any harmful substances that may arise from consumption of food into which the substance may have migrated. Any resulting limits contained in 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 contain additional safety

margins that are built in when determining the level of a substance that may be allowed to migrate into food. The European 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 more vulnerable people, may be prohibited from use.

19. Commission Directive 2007/19/EC 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 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).

Specific Impact Tests: Checklist

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

EU Annex

INTRODUCTION

1. The proposal is for a Statutory Instrument entitled: The Plastic Materials and Articles in Contact with Food (England) Regulations 2008. The objective of the proposed regulations is to implement in England and in its entirety the provisions of Commission Directive 2007/19/EC ("the Commission Directive") that routinely amends Directive 2002/72/EC relating to plastic materials and articles intended to come into contact with food, by 1 May 2008. Scotland Wales and Northern Ireland will make similar legislation.

2. The proposed regulations will also revoke the *Plastic Materials and Articles in Contact with Food (England) (No.2) Regulations 2006* (SI 2006/2687) and re-enact them with necessary amendments thus implementing in one consolidated instrument Directive 2002/72/EC as most recently amended by the Commission Directive.

BACKGROUND

3. Harmonised European Union rules on food contact plastics were originally laid down by Commission Directive 2002/72/EC 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 for public health arising from the migration of chemicals from food contact materials into food. The latest of these amendments are contained in Directive 2007/19/EC that the Regulatory proposals here would implement. The Commission Directive also amends Council Directive 85/572/EEC, which lays down the list of simulants to be used for testing migration of constituents of plastic materials in contact with food. In England, the Plastic Materials and Articles in Contact with Food (England) (No.2) Regulations 2006 implement the provisions of Directives 2002/72/EC and 85/572/EEC as amended in each case.

4. For certain substances, the restrictions already established at Community level have been amended on the basis of new information becoming available. In particular, the Commission Directive provides for new limitations on the use of and migration limits for certain plasticisers including epoxydised soybean oil (ESBO) and some phthalates. Directive 2007/19/EC will also:

   i) Revoke the current suspension on the use of azodicarbonamide as a blowing agent in food contact plastics and replace it with an outright ban;

   ii) Clarify that gaskets in metal lids fall under the scope of Directive 2002/72/EC and provide time for manufacturers to apply for the evaluation of specific additives used in their manufacture. Thus the positive list of authorised additives that is intended for future adoption in relation to plastic materials and articles will not apply to the manufacture of gasket lids. The transitional use of other additives for the manufacture of gasket lids is the subject of an earlier consultation dealing with an EU time-limited Regulation *[Commission Regulation (EC) No. 372/2007/EC laying down transitional migration limits for plasticisers in gaskets in lids intended to come into contact with food].*

   iii) Ban the manufacture and importation into the European Union (EU) of those gaskets in lids which do not meet these restrictions and or specifications;

   iv) Provide clarification for the term 'plastic multi-layer' and distinguish it from 'plastic functional barrier'. There are also provisions for the use of plastic functional barriers to help in reducing the migration of substances below a Specific Migration Limit (SML);

v) Require detailed information on compliance declarations and require that certificates of compliance should attest to the restrictions and/or specifications applicable to them;

vi) Amend Council Directive 85/572/EEC by introducing a fat (consumption) reduction factor (FRF) which can provide a better estimation of consumer exposure to substances migrating into fatty foods;

vii) prohibit the manufacture and importation into the Community of lids containing a gasket which do not comply with the restrictions and specifications for Ref Nos[27]. 30340, 30401, 3664[28], 56800, 76815, 76866, 88640 and 93670 laid down in Directive 2007/72/EC, as amended by Directive 2007/19/EC from 1 July 2008;

viii) Prohibit the manufacture and importation into the Community of plastic materials and articles intended to come into contact with food which do not comply with restrictions and specifications for phthalates Ref No. 74560, 74640 74880, 75100, and 75105 laid down in Directive 2002/72/EC as amended by Directive 2007/19/EC from 1 July 2008; and

ix) Without prejudice to point (b) and (c) above, prohibit the manufacture and importation into the Community of plastic materials and articles intended to come into contact with food which do not comply with Directive 2002/72/EC as amended by Directive 2007/19/EC from 1 May 2009.

Consultation

- **Within Government**

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

- **Public Consultation**

6. During the course of negotiations with the European Commission, the Food Standards Agency officials have frequently conveyed information to interested organisations including industry, research institutes, consumer groups, enforcement authorities and interested parties with an interest in policy issues related to food contact materials. The proposal has also been discussed at regular meetings with stakeholder groups that are likely to be directly affected by the requirements of Directive 2007/19/EC. 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 five years; in 2002, 2004, and 2005 and again in February and March 2006, when these proposals were last amended. Earlier consultation did not raise any adverse comments from stakeholders on these proposals.

Carbon Impact Assessment

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

Human Rights

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

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27 These reference No's are for the plasticisers used in gaskets in lids coming into contact with fatty foods as provided for by Regulation (EC) No. 372/2007, which lays down transitional migration limits for plasticisers in gaskets in lids intended to come into contact with food

28 This reference is to Azodicarbonamide which is now banned outright.

Rural Proofing

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

Policy and Administration Costs

10. There will be a small one-off administration cost to businesses for reading the proposed Regulations; however, this is unlikely to be significant. The Agency will also develop guidance for businesses on the proposed Regulations; such guidance will help minimise costs to businesses of reading the new Regulations.

Enforcement

11. Enforcement of the proposed Regulations is primarily the responsibility of local authorities. While the making of legislation in the UK is the function of central government, the enforcement of food law is primarily (but not solely) the responsibility of the 435 or so local authorities in the UK, and more specifically Environmental Health Officers (EHOs) and Trading Standards Officers (TSOs), together with port health authorities at some sea ports and airports.

12. Local authorities and port health authorities are responsible for enforcing a large proportion of Regulations in relation to food safety and are already doing so in respect of all the legislation on materials and articles intended to come into contact with food. The proposed Plastic Materials and Articles Intended to Come into Contact with Food (England) Regulations 2008 will be enforced by these authorities in the normal way.

13. The Food Standards Agency also has an enforcement role with regard to the EC Regulation 1935/2004 in respect of declarations of compliance, as indicated in Article 16 of that Regulation. Article 9(1) and 9(2) of Directive 2007/19/EC require that appropriate documentation be made available to competent authorities on demand to show that their products comply with the legislation. This is not any new burden on industry, as this is an existing requirement under Regulation (EC) No. 1935/2004, which is being reinforced by the provisions contained in Directive 2007/19/EC

Sanctions

14. No changes to the sanctions are being proposed to those contained in the current Regulations, which are considered to be proportionate and the minimum needed to enable the policy to be implemented effectively. A person found guilty of an offence under these and other Regulations dealing with materials and articles in contact with food is liable on conviction on indictment to a fine or imprisonment for a term not exceeding two years or both; on summary conviction to a fine not exceeding the statutory maximum or to a term of imprisonment not exceeding 6 months or to both. These penalties are in line with The Food Safety Act 1990.

Compensatory simplification

15. The opportunity is being taken to continue to simplify the Regulations to 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 two stages, first in February 2006 and then again in March 2006. This will help those that need to refer to the EU technical lists of substances by ensuring that they have as few documents to consult as possible, as well as reducing the risk of errors that may arise in repeating those lists in our regulations.

Monitoring

16. The authorities in England routinely monitor foodstuffs on sale to the public to ensure compliance with 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/research/researchinfo/contaminantsresearch/

17. We shall therefore, routinely survey materials and articles on the market to ensure compliance with the Regulations. The Food Standards Agency will work with enforcement authorities where problems 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. We shall continue to routinely talk to industry to ensure that no foreseen difficulties arise from these Regulations. The proposed Regulations will be reviewed in June 2009.

Abbreviations used in the IA

ASHE - Annual Survey of Hours and Earnings
EC European Commission

EFSA – European Food Safety Authority

EHO – Environmental Health Officer

ESBO – Epoxydised soybean oil

EU – European Union

FRF – Fat Reduction Factor

LA – Local Authority

PHA – Port Health Authority

SI – Statutory Instrument

TSO – Trading Standards Officer

CORRIGENDA

Corrigendum to Commission Directive 2007/19/EC of 30 March 2007 amending Directive 2002/72/EC relating to plastic materials and articles intended to come into contact with food and 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

(Official Journal of the European Union L 91 of 31 March 2007)

Directive 2007/19/EC should read as follows:

COMMISSION DIRECTIVE 2007/19/EC

of 2 April 2007

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

(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,

After consulting the European Food Safety Authority (the Authority),

Whereas:

(1) Commission Directive 2002/72/EC [2] is a specific Directive within the meaning of the framework Regulation (EC) No 1935/2004, harmonising the rules for the plastics materials and articles intended to come into contact with food.

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

(3) Information provided to the Commission demonstrates that the plasticizers used e.g. in polyvinyl chloride (PVC) gaskets in lids may migrate into fatty foods in quantities that could endanger human health or bring about an unacceptable change in the composition of the foods. It should therefore be made clear that, even if they are part of e.g. metal lids, gaskets fall under the scope of Directive 2002/72/EC. At the same time, specific rules should be laid down as regard the use of additives for the manufacture of those gaskets. It is appropriate to take account of the need of lid manufacturers to have sufficient time to adapt to some of the provisions of Directive 2002/72/EC. In particular, taking into account the time needed to prepare an application for the evaluation of specific additives used for the manufacture of gaskets of lids, it is not yet possible to establish a timetable for their evaluation. Therefore, in a first stage, the positive list of authorised additives that will be adopted in the future for plastic materials and articles should not apply for the manufacture of gaskets in lids, so that the use of other additives will remain possible, subject to national law. This situation should be reassessed at a later stage.

(4) On the basis of new information related to the risk assessment of substances evaluated by the Authority and the need to adapt to technical progress the existing rules for calculating migration, Directive 2002/72/EC should be updated. For reasons of clarity definitions of technical terms used should be introduced.

(5) The rules for overall migration and specific migration should be based on the same principle and should therefore, be aligned.

(6) Specific rules should be introduced to improve the protection of infants, since infants ingest more food in proportion to their body weight than adults.

(7) The verification of compliance with the specific migration limits (SML) in simulant D for additives listed in Annex III, Section B, to Directive 2002/72/EC should be applied at the same time as the other provisions for calculating migration introduced in this Directive for better estimation of the real exposure of the consumer to those additives. Therefore, the deadline for application of the abovementioned verification of compliance should be extended.

[1] OJ L 338, 13.11.2004, p. 4.
[2] OJ L 220, 15.8.2002, p. 18. Directive as last amended by Directive 2005/79/EC (OJ L 302, 19.11.2005, p. 35).

(8) The status of additives acting as polymerisation production aids (PPA) should be clarified. The PPA which also function as additives are to be evaluated and included in the future positive list of additives. Some of them are already included in the current incomplete list of additives. As regards additives which exclusively act as PPA and are therefore not intended to remain in the finished article, it should be made clear that their use will remain possible, subject to national law, even after the adoption of the future positive list of additives. That situation should be reassessed at a later stage.

(9) Studies have shown that azodicarbonamide decomposes into semicarbazide during high temperature processing. In 2003 the Authority was asked to gather data and to assess the possible risks posed by semicarbazide in food. Until that information was obtained and in accordance to Article 7 of Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 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 ([1]), the use of azodicarbonamide in plastic materials and articles was suspended by Commission Directive 2004/1/EC ([2]). In its opinion of 21 June 2005, the Authority ([3]) concluded that carcinogenicity of semicarbazide is not of concern for human health at the concentrations encountered in food, if the source of semicarbazide related to azodicarbonamide is eliminated. Therefore it is appropriate to maintain the prohibition of use of azodicarbonamide in plastic materials and article.

(10) The concept of the plastic functional barrier, that is a barrier within plastic materials or articles preventing or reducing the migration from behind this barrier into the food should be introduced. Only glass and some metals may ensure complete blockage of migration. Plastics may be partial functional barriers with properties and effectiveness to be assessed and may help reducing the migration of a substance below a SML or a limit of detection. Behind a plastic functional barrier, non-authorised substances may be used, provided they fulfil certain criteria and their migration remains below a given detection limit. Taking into account foods for infants and other particularly susceptible persons as well as the difficulties of this type of analysis affected by a large analytical tolerance, a maximum level of 0,01 mg/kg in food or a food simulant should be established for the migration of a non-authorised substance through a plastic functional barrier.

([1]) OJ L 31, 1.2.2002, p. 1. Regulation as last amended by Commission Regulation (EC) No 575/2006 (OJ L 100, 8.4.2006, p. 3).
([2]) OJ L 7, 13.1.2004, p. 45.
([3]) The EFSA Journal (2005) 219, 1-36.

(11) Article 9 of Directive 2002/72/EC provides that materials and articles must be accompanied by a written declaration of compliance attesting that they comply with the rules applicable to them. In accordance with Article 5(1)(h) and (i) of Regulation (EC) No 1935/2004, to strengthen the co-ordination and responsibility of the suppliers at each stage of manufacture, including that of the starting substances, the responsible persons should document the compliance with the relevant rules in a declaration of compliance which is made available to his customer. Further, at each stage of manufacture, supporting documentation, substantiating the declaration of compliance, should be kept available for the enforcement authorities.

(12) Article 17(1) of Regulation (EC) No 178/2002 requires the food business operator to verify that foods are compliant with the rules applicable to them. To this end subject to the requirement of confidentiality, food business operators should be given access to the relevant information to enable them to ensure that the migration from the materials and articles to food complies with the specifications and restrictions laid down in food legislation.

(13) Compliance with Article 3 of Regulation (EC) No 1935/2004 for substances non-listed in Annexes II and III of Directive 2002/72/EC such as impurities or reaction products referred to in point 3 of Annex II and point 3 of Annex III to Directive 2002/72/EC should be assessed by the relevant business operator in accordance with internationally recognised scientific principles.

(14) For a more adequate estimation of exposure of the consumer, a new reduction factor should be introduced in migration testing, called Fat Reduction Factor (FRF). Until now, the exposure to substances migrating predominantly into fatty food (lipophilic substances) was based on the general assumption that a person ingests daily 1 kg of food. However, a person ingests at most 200 g of fat on a daily basis. This should be taken into consideration through the correction of the specific migration by the FRF applicable to lipophilic substances in accordance with the opinion of the Scientific Committee on Food (SCF) ([4]) and the opinion of the Authority ([5]).

([4]) SCF opinion of 4 December 2002 on the introduction of a Fat (Consumption) Reduction Factor (FRF) in the estimation of the exposure to a migrant from food contact materials. http://ec.europa.eu/food/fs/sc/scf/out149_en.pdf
([5]) Opinion of the Scientific Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food (AFC) on a request from the Commission related to the introduction of a Fat (consumption) Reduction Factor for infants and children, The EFSA Journal (2004) 103, 1-8.

(15) On the basis of new information related to the risk assessment of monomers and other starting substances evaluated by the Authority [1], certain monomers provisionally admitted at national level as well as new monomers should be included in the Community list of authorised substances. For others, the restrictions and/or specifications already established at Community level should be amended on the basis of the new information available.

(16) The incomplete list of additives which may be used in the manufacture of plastic materials and articles should be amended so as to include other additives evaluated by the Authority. For certain additives, the restrictions and/or specifications already established at Community level should be amended on the basis of those new evaluations available.

(17) Commission Directive 2005/79/EC [2] introduced the changes in the restrictions and/or specifications for substance Ref. No 35760 in section A instead of section B of Annex III to Directive 2002/72/EC and for substance Ref. No 67180 the changes were introduced in section B instead of section A of that Annex. In addition, for substances Ref. No 43480, 45200, 81760 and 88640 the indication to the restrictions and/or specifications in Annex III to Directive 2002/72/EC is ambiguous. Therefore, for legal certainty, there is a need to place substances Ref. No 35760 and 67180 in the appropriate section of the list of additives and reintroduce the restrictions and specifications for substances Ref. No 43480, 45200, 81760 and 88640.

(18) It has been shown that distilled water, which is used at present is not an adequate simulant for some milk products. It should be replaced by 50 % ethanol, which better simulates their fatty character.

(19) Epoxidised soybean oil (ESBO) is used as plasticizer in gaskets. Taking into account the opinion of the Authority adopted on 16 March 2006 [3] concerning exposure of adults to ESBO used in food contact materials, it is appropriate to set a shorter deadline for the compliance of gaskets of lids with the restrictions of ESBO and its substitutes set out in Directive 2002/72/EC. The same deadline should apply as regards the prohibition of use of azodicarbonamide.

(20) Certain phthalates are used as plasticizers in gaskets and in other plastic applications. In its opinions on certain phthalates [4] published in September 2005 the Authority set tolerable daily intakes (TDI) for certain phthalates and estimated that the exposure of humans to certain phthalates is in the same range as the TDI. Therefore, it is appropriate to set a shorter deadline for the compliance of plastic materials and articles with the restrictions set in Directive 2002/72/EC for those substances.

(21) Council Directive 85/572/EEC [5] and Directive 2002/72/EC should therefore be amended accordingly.

(22) 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. Article 1 is amended as follows:

(a) paragraph 2 is replaced by the following:

'2. This Directive shall apply to the following materials and articles which, in the finished product state, are intended to come into contact or are brought into contact with foodstuffs and are intended for that purpose (hereafter referred to as "plastic materials and articles"):

(a) materials and articles and parts thereof consisting exclusively of plastics;

(b) plastic multi-layer materials and articles;

(c) plastic layers or plastic coatings, forming gaskets in lids that together are composed of two or more layers of different types of materials.'

[1] The EFSA Journal (2005) 218, 1-9.
The EFSA Journal (2005) 248, 1-16.
The EFSA Journal (2005) 273, 1-26.
The EFSA Journal (2006) 316 to 318, 1-10.
The EFSA Journal (2006) 395 to 401, 1-21.
[2] OJ L 302, 19.11.2005, p. 35.
[3] The EFSA Journal (2006) 332, 1-9.
[4] The EFSA Journal (2005) 244, 1-18.
The EFSA Journal (2005) 245, 1-14.
The EFSA Journal (2005) 243, 1-20.
The EFSA Journal (2005) 242, 1-17.
The EFSA Journal (2005) 241, 1-14.
[5] OJ L 372, 31.12.1985, p. 14.

(b) paragraph 4 is replaced by the following:

'4. Without prejudice to paragraph 2(c), this Directive shall not apply to materials and articles composed of two or more layers, one or more of which does not consist exclusively of plastics, even if the one intended to come into direct contact with foodstuffs does consist exclusively of plastics.'

2. The following Article 1a is inserted:

'Article 1a

For the purpose of this Directive the following definitions shall apply:

(a) "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 by other means;

(b) "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 (EC) No 1935/2004 of the European Parliament and of the Council (*) and with this Directive;

(c) "non-fatty foods" means foods for which in migration testing simulants other than simulant D are laid down in Directive 85/572/EEC.

(*) OJ L 338, 13.11.2004, p. 4.'

3. Article 2 is replaced by the following:

'Article 2

1. Plastic materials and articles shall not transfer their constituents to foodstuffs in quantities exceeding 60 milligrams of the constituents released per kilogram of foodstuff or food simulant (mg/kg) (overall migration limit).

However, this limit shall be 10 milligrams per square decimetre of surface area of material or article (mg/dm^2) in the case of the following:

(a) articles which are containers or are comparable to containers or which can be filled, with a capacity of less than 500 millilitres (ml) or more than 10 litres (l);

(b) sheet, film or other material or articles 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 therewith.

2. For plastic materials and articles intended to be brought into contact with or already in contact with food intended for infants and young children, as defined by Commission Directives 91/321/EEC (*) and 96/5/EC (**), the overall migration limit shall always be 60 mg/kg.

(*) OJ L 175, 4.7.1991, p. 35.
(**) OJ L 49, 28.2.1996, p. 17.'

4. In Article 4(2), the date of '1 July 2006' is replaced by '1 May 2008'.

5. The following Articles 4c, 4d and 4e are inserted:

'Article 4c

For the use of additives for the manufacture of plastic layers or plastic coatings in lids referred to in Article 1(2)(c), the following rules shall apply:

(a) for the additives listed in Annex III, the restrictions and/or specifications on their use set out in that Annex shall apply, without prejudice to Article 4(2);

(b) by way of derogation from Article 4(1) and Article 4a(1) and (5), additives not listed in Annex III may continue to be used, until further review, subject to national law;

(c) by way of derogation from Article 4b Member States may continue to authorise additives for the manufacture of plastic layers or plastic coatings in lids referred to in Article 1(2)(c) at national level.

Article 4d

For the use of additives exclusively acting as polymerisation production aids which are not intended to remain in the finished article (hereinafter PPAs), for the manufacture of plastic materials and articles, the following rules shall apply:

(a) for the PPAs listed in Annex III, the restrictions and/or specifications on their use set out in Annex III shall apply, without prejudice to Article 4(2);

(b) by way of derogation from Article 4(1) and Article 4a(1) and (5), the PPAs not listed in Annex III may continue to be used, until further review, subject to national law;

(c) by way of derogation from Article 4b, Member States may continue to authorise PPAs at national level.

Article 4e

The use of azodicarbonamide, Ref. No 36640 (CAS No 000123-77-3) in the manufacture of plastic materials and articles is prohibited.'

6. In Article 5a paragraph 2 is replaced by the following:

'2. At the marketing stages other than the retail stages, plastic materials and articles which are intended to be placed in contact with foodstuffs and which contain additives referred to in paragraph 1 shall be accompanied by a written declaration containing the information referred to in Article 9.'

7. In Article 7 the following paragraph is added:

'For plastic materials and articles intended to be brought into contact with or already in contact with food for infants and young children, as defined by Directives 91/321/EEC and 96/5/EC, the SMLs shall always be applied as mg/kg.'

8. The following Article 7a is inserted:

'*Article 7a*

1. In a plastic multi-layer material or article, the composition of each plastic layer shall comply with this Directive.

2. By way of derogation from paragraph 1, a layer which is not in direct contact with food and is separated from the food by a plastic functional barrier, may, provided that the finished material or article complies with the specific and overall migration limits specified in this Directive:

(a) not comply with the restrictions and specifications set in this Directive,

(b) be manufactured with substances other than those included in this Directive or in the national lists concerning the plastic materials and articles intended to come into contact with food.

3. The migration of the substances referred to in paragraph 2(b) into food or simulant shall not exceed 0,01 mg/kg, measured with statistical certainty by a method of analysis in accordance with Article 11 of Regulation (EC) No 882/2004 of the European Parliament and of the Council (*). This limit shall always be expressed as concentration in foods or simulants. It shall apply to a group of compounds, if they are structurally and toxicologically related, in particular isomers or compounds with the same relevant functional group, and shall include possible set-off transfer.

4. The substances referred to in paragraph 2(b) shall not belong to either of the following categories:

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

(b) substances classified under the self-responsibility criteria as 'carcinogenic', 'mutagenic' or 'toxic to reproduction' according to the rules of Annex VI to Directive 67/548/EEC.

(*) OJ L 165, 30.4.2004, p. 1, as corrected by OJ L 191, 28.5.2004, p. 1.
(**) OJ 196, 16.8.1967, p. 1.'

9. In Article 8 the following paragraph 5 is added:

'5. Notwithstanding paragraph 1, for phthalates (Ref. No 74640, 74880, 74560, 75100, 75105) referred to in Annex III Section B, the verification of the SML shall only be performed in food simulants. However, verification of the SML may be performed in food where the food has not already been in contact with the material or article and is pre-tested for the phthalate and the level is not statistically significant or greater than or equal to the limit of quantification.'

10. Article 9 is replaced by the following:

'*Article 9*

1. At the marketing stages other than the retail stage, plastic materials and articles as well as the substances intended for the manufacturing of those materials and articles, shall be accompanied by a written declaration in accordance with Article 16 of Regulation (EC) No 1935/2004.

2. The declaration referred to in paragraph 1 shall be issued by the business operator and shall contain the information laid down in Annex VIa.

3. Appropriate documentation to demonstrate that the materials and articles as well as the substances intended for the manufacturing of those materials and articles comply with the requirements of this Directive shall be made available by the business operator to the national competent authorities on request. That documentation shall contain the conditions and results of testing, calculations, other analysis, and evidence on the safety or reasoning demonstrating compliance.'

11. Annexes I, II and III are amended in accordance with Annexes I, II and III to this Directive.

12. The text in Annex IV to this Directive is inserted as Annex IVa.

13. Annexes V and VI are amended in accordance with Annexes V and VI to this Directive.

14. The text in Annex VII to this Directive is inserted as Annex VIa.

Article 2

The Annex to Directive 85/572/EEC is amended in accordance with Annex VIII to this Directive.

Article 3

1. Member States shall adopt and publish, by 1 May 2008 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.

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 1 May 2008;

(b) prohibit the manufacture and importation into the Community of lids containing a gasket which do not comply with restrictions and specifications for Ref. No 30340; 30401; 36640; 56800; 76815; 76866; 88640 and 93760 laid down in Directive 2002/72/EC as amended by this Directive from 1 July 2008;

(c) prohibit the manufacture and importation into the Community of plastic materials and articles intended to come into contact with food which do not comply with restrictions and specifications for phthalates Ref. No 74560; 74640; 74880; 75100; 75105 laid down in Directive 2002/72/EC as amended by this Directive from 1 July 2008;

(d) without prejudice to point (b) and (c), prohibit the manufacture and importation into the Community of plastic materials and articles intended to come into contact with food which do not comply with Directive 2002/72/EC as amended by this Directive from 1 May 2009.

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 4

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

Article 5

This Directive is addressed to the Member States.

Done at Brussels, 2 April 2007.

For the Commission
Markos KYPRIANOU
Member of the Commission

ANNEX I

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

(1) The following points 2a and 2b are inserted:

'2a. Correction of specific migration in foods containing more than 20 % fat by the Fat Reduction Factor (FRF):

"Fat Reduction Factor" (FRF) is a factor between 1 and 5 by which measured migration of lipophilic substances into a fatty food or simulant D and its substitutes shall be divided before comparison with the specific migration limits.

General rules

Substances considered "lipophilic" for the application of the FRF are listed in Annex IVa. The specific migration of lipophilic substances in mg/kg (M) shall be corrected by the FRF variable between 1 and 5 (M_{FRF}). The following equations shall be applied before comparison with the legal limit:

$M_{FRF} = M/FRF$

and

FRF = (g fat in food/kg of food)/200 = (% fat × 5)/100

This correction by the FRF is not applicable in the following cases:

(a) when the material or article is or is intended to be brought in contact with food containing less than 20 % fat;

(b) when the material or article is or is intended to be brought in contact with food intended for infants and young children as defined by Directives 91/321/EEC and 96/5/EC;

(c) for substances in the Community lists in Annexes II and III having a restriction in column (4) SML= ND or non-listed substances used behind a plastic functional barrier with a migration limit of 0,01 mg/kg;

(d) for materials and articles for which it is impracticable to estimate the relationship between the surface area and the quantity of food in contact therewith, for example due to their shape or use, and the migration is calculated using the conventional surface area/volume conversion factor of 6 dm^2/kg.

This correction by the FRF is applicable under certain conditions in the following case:

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, either the migration is calculated as concentration in the food or food simulant (mg/kg) and corrected by the FRF, or it is re-calculated as mg/dm^2 without applying the FRF. If one of the two values is below the SML, the material or article shall be considered in compliance.

The application of the FRF shall not lead to a specific migration exceeding the overall migration limit.

2b. Correction of specific migration in food simulant D:

The specific migration of lipophilic substances into simulant D and its substitutes shall be corrected by the following factors:

(a) the reduction factor referred to in point 3 of the Annex to Directive 85/572/EEC, hereinafter termed simulant D Reduction Factor (DRF).

The DRF may not be applicable when the specific migration into simulant D is higher than 80 % of the content of the substance in the finished material or article (for example thin films). Scientific or experimental evidence (for example testing with the most critical foods) is required to determine whether the DRF is applicable. It is also not applicable for substances in the Community lists having a restriction in column (4) SML = ND or non-listed substances used behind a plastic functional barrier with a migration limit of 0,01 mg/kg.

(b) the FRF is applicable to migration into simulants, provided the fat content of the food to be packed is known and the requirements mentioned in point 2a are fulfilled.

(c) the Total Reduction Factor (TRF) is the factor, with a maximum value of 5, by which a measured specific migration into simulant D or a substitute shall be divided before comparison with the legal limit. It is obtained by multiplying the DRF by the FRF, when both factors are applicable.'

(2) The following point 5a is inserted:

'5a. Caps, lids, gaskets, stoppers and similar sealing articles:

(a) If the intended use is known, such 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. It is assumed that these articles are in contact with a quantity of food filling the container. The results shall be expressed in mg/kg or mg/dm^2 in accordance to the rules of Articles 2 and 7 taking into account the whole contact surface of sealing article and container.

(b) If the intended use of these articles is unknown, such articles shall be tested in a separate test and the result be expressed in mg/article. The value obtained shall be added, if appropriate, to the quantity migrated from the container for which it is intended to be used.'

ANNEX II

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

(1) Section A 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)
'15267	000080-08-0	4,4′-Diaminodiphenyl sulphone	SML = 5 mg/kg
21970	000923-02-4	N-Methylolmethacrylamide	SML = 0,05 mg/kg
24886	046728-75-0	5-Sulphoisophthalic acid, mono-lithium salt	SML = 5 mg/kg and for lithium SML(T) = 0,6 mg/kg ([8]) (expressed as lithium)'

(b) for the following monomers and other starting substances, the content of the column 4 'Restrictions and/or specifications' is replaced by the following:

Ref. No	CAS No	Name	Restrictions and/or specifications
(1)	(2)	(3)	(4)
'12786	000919-30-2	3-Aminopropyltriethoxysilane	Residual extractable content of 3-aminopropyltriethoxysilane to be less than 3 mg/kg filler when used for the reactive surface treatment of inorganic fillers and SML = 0,05 mg/kg when used for the surface treatment of materials and articles.
16450	000646-06-0	1,3-Dioxolane	SML = 5 mg/kg
25900	000110-88-3	Trioxane	SML = 5 mg/kg'

(2) In section B, the following monomers and other starting substances are deleted:

Ref. No	CAS No	Name	Restrictions and/or specifications
(1)	(2)	(3)	(4)
'21970	000923-02-4	N-Methylolmethacrylamide'	

ANNEX III

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)
'38885	002725-22-6	2,4-Bis(2,4-dimethylphenyl)-6-(2-hydroxy-4-n-octyloxyphenyl)-1,3,5-triazine	SML = 0,05 mg/kg. For aqueous foods only.
42080	001333-86-4	Carbon black	In compliance with the specifications laid down in Annex V.
45705	166412-78-8	1,2-cyclohexanedicarboxylic acid, diisononyl ester	
62020	007620-77-1	12-Hydroxystearic acid, lithium salt	SML(T) = 0,6 mg/kg ([8]) (expressed as lithium)
67180	—	Mixture of (50 % w/w) phthalic acid n-decyl n-octyl ester, (25 % w/w) phthalic acid di-n-decyl ester, (25 % w/w) phthalic acid di-n- octyl ester.	SML = 5 mg/kg ([1])
71960	003825-26-1	Perfluorooctanoic acid, ammonium salt	Only to be used in repeated use articles, sintered at high temperatures.
74560	000085-68-7	Phthalic acid, benzyl butyl ester	To be used only as: (a) plasticizer in repeated use materials and articles; (b) plasticizer in single-use materials and articles contacting non-fatty foods except for infant formulae and follow-on formulae as defined by Directive 91/321/EEC and products according to Directive 96/5/EC; (c) technical support agent in concentrations up to 0,1 % in the final product. SML = 30 mg/kg food simulant.
74640	000117-81-7	Phthalic acid, bis (2-ethylhexyl) ester	To be used only as: (a) plasticizer in repeated use materials and articles contacting non-fatty foods; (b) technical support agent in concentrations up to 0,1 % in the final product. SML = 1,5 mg/kg food simulant.

(1)	(2)	(3)	(4)
74880	000084-74-2	Phthalic acid, dibutyl ester	To be used only as: (a) plasticizer in repeated use materials and articles contacting non-fatty foods; (b) technical support agent in polyolefines in concentrations up to 0,05 % in the final product. SML = 0,3 mg/kg food simulant.
75100	068515-48-0 028553-12-0	Phthalic acid, diesters with primary, saturated C_8-C_{10} branched alcohols, more than 60 % C_9.	To be used only as: (a) plasticizer in repeated use materials and articles; (b) plasticizer in single-use materials and articles contacting non-fatty foods except for infant formulae and follow-on formulae as defined by Directive 91/321/EEC and products according to Directive 96/5/EC; (c) technical support agent in concentrations up to 0,1 % in the final product. SML(T) = 9 mg/kg food simulant ([42]).
75105	068515-49-1 026761-40-0	Phthalic acid, diesters with primary, saturated C_9-C_{11} alcohols more than 90 % C_{10}	To be used only as: (a) plasticizer in repeated use materials and articles; (b) plasticizer in single-use materials and articles contacting non-fatty foods except for infant formulae and follow-on formulae as defined by Directive 91/321/EEC and products according to Directive 96/5/EC; (c) technical support agent in concentrations up to 0,1 % in the final product. SML(T) = 9 mg/kg food simulant ([42]).
79920	009003-11-6 106392-12-5	Poly(ethylene propylene) glycol	
81500	9003-39-8	Polyvinylpyrrolidone	In compliance with the specifications laid down in Annex V.
93760	000077-90-7	Tri-n-butyl acetyl citrate	
95020	6846-50-0	2,2,4-Trimethyl-1,3-pentanediol di-isobutyrate	SML = 5 mg/kg food. To be used in single-use gloves only.
95420	745070-61-5	1,3,5-tris (2,2-dimethylpropanamido)-benzene	SML = 0,05 mg/kg food.'

(b) for the following additives, the entries in columns 3 'Name' and 4 'Restrictions and/or specifications' are replaced by the following:

Ref. No	CAS No	Name	Restrictions and/or specifications
(1)	(2)	(3)	(4)
'43480	064365-11-3	Charcoal, activated	In compliance with the specifications laid down in Annex V.
45200	001335-23-5	Copper iodide	SML(T) = 5 mg/kg ([7]) (expressed as copper) and SML = 1 mg/kg ([11]) (expressed as iodine)
76845	031831-53-5	Polyester of 1,4-butanediol with caprolactone	The restriction for Ref. No 14260 and Ref. No 13720 shall be respected. In compliance with the specifications laid down in Annex V.
81760	—	Powders, flakes and fibres of brass, bronze, copper, stainless steel, tin and alloys of copper, tin and iron	SML(T) = 5 mg/kg ([7]) (expressed as copper); SML = 48 mg/kg (expressed as iron)
88640	008013-07-8	Soybean oil, epoxidised	SML = 60 mg/kg. However in the case of PVC gaskets used to seal glass jars containing infant formulae and follow-on formulae as defined by Directive 91/321/EEC or containing processed cereal-based foods and baby foods for infants and young children as defined by Directive 96/5/EC, the SML is lowered to 30 mg/kg. In compliance with the specifications laid down in Annex V.'

(c) the following additive is deleted:

Ref. No	CAS No	Name	Restrictions and/or specifications
(1)	(2)	(3)	(4)
'35760	001309-64-4	Antimony trioxide	SML = 0,04 mg/kg ([39]) (expressed as antimony).'

(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)
'35760	001309-64-4	antimony trioxide	SML = 0,04 mg/kg ([39]) (expressed as antimony)
47500	153250-52-3	N,N′-Dicyclohexyl-2,6-naphthalene dicarboxamide	SML = 5 mg/kg.

(1)	(2)	(3)	(4)
72081/10	—	Petroleum hydrocarbon resins (hydrogenated)	SML = 5 mg/kg ([1]) and in compliance with the specifications laid down in Annex V
93970	—	Tricyclodecanedimethanol bis(hexahydrophthalate)	SML = 0,05 mg/kg.'

(b) for the following additives, the entries in columns 3 'Name' and 4 'Restrictions and/or specifications' are replaced by the following:

Ref. No	CAS No	Name	Restrictions and/or specifications
(1)	(2)	(3)	(4)
'47600	084030-61-5	Di-n-dodecyltin bis(isooctyl mercaptoacetate)	SML(T) = 0,05 mg/kg food ([41]) (as sum of mono-n-dodecyltin tris(isooctyl mercaptoacetate), di-n- dodecyltin bis(isooctyl mercaptoacetate), mono-dodecyltin trichloride and di-dodecyltin dichloride) expressed as the sum of mono- and di-dodecyltin chloride
67360	067649-65-4	Mono-n-dodecyltin tris(isooctyl mercaptoacetate)	SML(T) = 0,05 mg/kg food ([41]) (as sum of mono-n-dodecyltin tris(isooctyl mercaptoacetate), di-n- dodecyltin bis(isooctyl mercaptoacetate), mono-dodecyltin trichloride and di-dodecyltin dichloride) expressed as the sum of mono- and di-dodecyltin chloride'

(c) The following additives are deleted:

Ref. No	CAS No	Name	Restrictions and/or specifications
(1)	(2)	(3)	(4)
'67180	—	Mixture of (50 % w/w) phthalic acid n-decyl n-octyl ester, (25 % w/w) phthalic acid di-n-decyl ester, (25 % w/w) phthalic acid di-n- octyl ester.	SML = 5 mg/kg ([1])
76681	—	Polycyclopentadiene, hydrogenated	SML = 5 mg/kg ([1])'

ANNEX IV

'ANNEX IVa

LIPOPHILIC SUBSTANCES FOR WHICH THE FRF APPLIES

Ref. No	CAS No	Name
31520	061167-58-6	Acrylic acid, 2-tert-butyl-6-(3-tert-butyl-2-hydroxy-5-methylbenzyl)-4-methylphenyl ester
31530	123968-25-2	Acrylic acid, 2,4-di-tert-pentyl-6-[1-(3,5-di-tert-pentyl-2-hydroxyphenyl)ethyl] phenyl ester
31920	000103-23-1	Adipic acid, bis(2-ethylhexyl) ester
38240	000119-61-9	Benzophenone
38515	001533-45-5	4,4′-Bis(2-benzoxazolyl)stilbene
38560	007128-64-5	2,5-Bis(5-tert-butyl-2-benzoxazolyl)thiophene
38700	063397-60-4	Bis(2-carbobutoxyethyl)tin-bis(isooctyl mercaptoacetate)
38800	032687-78-8	N,N′-Bis(3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionyl)hydrazide
38810	080693-00-1	Bis(2,6-di-tert-butyl-4-methylphenyl)pentaerythritol diphosphite
38820	026741-53-7	Bis(2,4-di-tert-butylphenyl)pentaerythritol diphosphite
38840	154862-43-8	Bis(2,4-dicumylphenyl)pentaerythritoldiphosphite
39060	035958-30-6	1,1-Bis(2-hydroxy-3,5-di-tert-butylphenyl)ethane
39925	129228-21-3	3,3-Bis(methoxymethyl)-2,5-dimethylhexane
40000	000991-84-4	2,4-Bis(octylmercapto)-6-(4-hydroxy-3,5-di-tert-butylanilino)-1,3,5-triazine
40020	110553-27-0	2,4-Bis(octylthiomethyl)-6-methylphenol
40800	013003-12-8	4,4′-Butylidene-bis(6-tert-butyl-3-methylphenyl-ditridecyl phosphite)
42000	063438-80-2	(2-Carbobutoxyethyl)tin-tris(isooctyl mercaptoacetate)
45450	068610-51-5	p-Cresol-dicyclopentadiene-isobutylene, copolymer
45705	166412-78-8	1,2-cyclohexanedicarboxylic acid, diisononyl ester
46720	004130-42-1	2,6-Di-tert-butyl-4-ethylphenol
47540	027458-90-8	Di-tert-dodecyl disulphide
47600	084030-61-5	Di-n-dodecyltin bis(isooctyl mercaptoacetate)
48800	000097-23-4	2,2′-Dihydroxy-5,5′-dichlorodiphenylmethane
48880	000131-53-3	2,2′-Dihydroxy-4-methoxybenzophenone
49485	134701-20-5	2,4-Dimethyl-6-(1-methylpentadecyl)-phenol
49840	002500-88-1	Dioctadecyl disulphide
51680	000102-08-9	N,N′-Diphenylthiourea
52320	052047-59-3	2-(4-Dodecylphenyl)indole

Ref. No	CAS No	Name
53200	023949-66-8	2-Ethoxy-2′-ethyloxanilide
54300	118337-09-0	2,2′-Ethylidenebis(4,6-di-tert-butyl phenyl) fluorophosphonite
59120	023128-74-7	1,6-Hexamethylene-bis(3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionamide)
59200	035074-77-2	1,6-Hexamethylene-bis(3-(3,5-di-tert-butyl–4-hydroxyphenyl)propionate)
60320	070321-86-7	2-[2-Hydroxy-3,5-bis(1,1-dimethylbenzyl)phenyl]benzotriazole
60400	003896-11-5	2-(2′-Hydroxy-3′-tert-butyl-5′-methylphenyl)-5-chlorobenzotriazole
60480	003864-99-1	2-(2′-Hydroxy-3,5′-di-tert-butylphenyl)-5-chlorobenzotriazole
61280	003293-97-8	2-Hydroxy-4-n-hexyloxybenzophenone
61360	000131-57-7	2-Hydroxy-4-methoxybenzophenone
61600	001843-05-6	2-Hydroxy-4-n-octyloxybenzophenone
66360	085209-91-2	2,2′-Methylene bis(4,6-di-tert-butylphenyl) sodium phosphate
66400	000088-24-4	2,2′-Methylene bis(4-ethyl-6-tert-butylphenol)
66480	000119-47-1	2,2′-Methylene bis(4-methyl-6-tert-butylphenol)
66560	004066-02-8	2,2′-Methylene bis(4-methyl-6-cyclohexylphenol)
66580	000077-62-3	2,2′-Methylene bis(4-methyl-6-(1-methyl-cyclohexyl) phenol)
68145	080410-33-9	2,2′,2′-Nitrilo[triethyl tris(3,3′,5,5′-tetra-tert-butyl-1,1′-bi-phenyl-2,2′-diyl)phosphite]
68320	002082-79-3	Octadecyl 3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate
68400	010094-45-8	Octadecylerucamide
69840	016260-09-6	Oleylpalmitamide
71670	178671-58-4	Pentaerythritol tetrakis (2-cyano-3,3-diphenylacrylate)
72081/10	—	Petroleum Hydrocarbon Resins (hydrogenated)
72160	000948-65-2	2-Phenylindole
72800	001241-94-7	Phosphoric acid, diphenyl 2-ethylhexyl ester
73160	—	Phosphoric acid, mono- and di-n-alkyl (C_{16} and C_{18}) esters
74010	145650-60-8	Phosphorous acid, bis(2,4-di-tert-butyl-6-methylphenyl) ethyl ester
74400	—	Phosphorous acid, tris(nonyl- and/or dinonylphenyl) ester
76866	—	Polyesters of 1,2-propanediol and/or 1,3- and/or 1,4-butanediol and/or poly-propyleneglycol with adipic acid, also end-capped with acetic acid or fatty acids C_{12}-C_{18} or n-octanol and/or n-decanol
77440	—	Polyethyleneglycol diricinoleate
78320	009004-97-1	Polyethyleneglycol monoricinoleate

Ref. No	CAS No	Name
81200	071878-19-8	Poly[6-[(1,1,3,3-tetramethylbutyl)amino]-1,3,5-triazine-2,4-diyl]-[(2,2,6,6-tetramethyl-4-piperidyl)-imino]hexamethylene[(2,2,6,6-tetramethyl-4-piperidyl)imino]
83599	068442-12-6	Reaction products of oleic acid, 2-mercaptoethyl ester, with dichlorodimethyltin, sodium sulphide and trichloromethyltin
83700	000141-22-0	Ricinoleic acid
84800	000087-18-3	Salicylic acid, 4-tert-butylphenyl ester
92320	—	Tetradecyl-polyethyleneglycol(EO=3-8) ether of glycolic acid
92560	038613-77-3	Tetrakis(2,4-di-tert-butyl-phenyl)-4,4′-biphenylylene diphosphonite
92700	078301-43-6	2,2,4,4-Tetramethyl-20-(2,3-epoxypropyl)-7-oxa-3,20-diazadispiro[5.1.11.2]-heneicosan-21-one, polymer
92800	000096-69-5	4,4′-Thiobis(6-tert-butyl-3-methylphenol)
92880	041484-35-9	Thiodiethanol bis(3-(3,5-di-tert-butyl-4-hydroxy phenyl) propionate)
93120	000123-28-4	Thiodipropionic acid, didodecyl ester
93280	000693-36-7	Thiodipropionic acid, dioctadecyl ester
95270	161717-32-4	2,4,6-Tris(tert-butyl)phenyl-2-butyl-2-ethyl-1,3-propanediol phosphite
95280	040601-76-1	1,3,5-Tris(4-tert-butyl-3-hydroxy-2,6-dimethylbenzyl)-1,3,5-triazine-2,4,6(1H,3H,5H)-trione
95360	027676-62-6	1,3,5-Tris(3,5-di-tert-butyl-4-hydroxybenzyl)-1,3,5-triazine-2,4,6(1H,3H,5H)-trione
95600	001843-03-4	1,1,3-Tris(2-methyl-4-hydroxy-5-tert-butylphenyl) butane’

ANNEX V

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

(1) Part A is replaced by the following:

'*Part A:* **General specifications**

Plastic material and articles shall not release primary aromatic amines in a detectable quantity (DL = 0,01 mg/kg of food or food simulant). The migration of the primary aromatic amines appearing in the lists in Annex II and III is excluded from this restriction.'

(2) In Part B, the following new specifications are inserted, in the appropriate numerical order:

Ref. No	OTHER SPECIFICATIONS
'42080	Carbon black *Specifications:* — Toluene extractables: maximum 0,1 %, determined according to ISO method 6209. — UV absorption of cyclohexane extract at 386 nm: < 0,02 AU for a 1 cm cell or < 0,1 AU for a 5 cm cell, determined according to a generally recognised method of analysis. — Benzo(a)pyrene content: max 0,25 mg/kg carbon black. — Maximum use level of carbon black in the polymer: 2,5 % w/w
72081/10	Petroleum hydrocarbon resins (hydrogenated) *Specifications:* Petroleum hydrocarbon resins, hydrogenated are produced by the catalytic or thermal polymerisation of dienes and olefins of the aliphatic, alicyclic and/or monobenzenoid arylalkene types from distillates of cracked petroleum stocks with a boiling range not greater than 220 °C, as well as the pure monomers found in these distillation streams, subsequently followed by distillation, hydrogenation and additional processing. *Properties:* Viscosity: > 3 Pa.s at 120 °C. Softening point: > 95 °C as determined by ASTM Method E 28-67. Bromine number: < 40 (ASTM D1159) The colour of a 50 % solution in toluene < 11 on the Gardner scale Residual aromatic monomer ≤ 50 ppm
76845	Polyester of 1,4-butanediol with caprolactone MW fraction < 1 000 is less than 0,5 % (w/w)
81500	Polyvinylpyrrolidone The substance shall meet the purity criteria established in Commission Directive 96/77/EC (*)
88640	Soybean oil, epoxidized Oxirane < 8 %, iodine number < 6

(*) OJ L 339, 30.12.1996, p. 1.'

ANNEX VI

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

(1) Note ([8]) is replaced by the following:

'([8]) 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 Ref. Nos: 24886, 38000, 42400, 62020, 64320, 66350, 67896, 73040, 85760, 85840, 85920 and 95725.'

(2) The following notes 41 and 42 are added:

'([41]) 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 Ref. Nos: 47600, 67360.

([42]) 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 Ref. Nos: 75100 and 75105.'

ANNEX VII

'ANNEX VIa

DECLARATION OF COMPLIANCE

The written declaration referred to in Article 9 shall contain the following information:

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

(2) the identity of the materials, the articles or the substances intended for the manufacturing of those materials and articles;

(3) the date of the declaration;

(4) confirmation that the plastic materials or articles meet relevant requirements laid down in this Directive and Regulation (EC) No 1935/2004;

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

(6) adequate information relative to the substances which are subject to a restriction in food, obtained by experimental data or theoretical calculation about the level of their specific migration and, where appropriate, purity criteria in accordance with Directives 95/31/EC, 95/45/EC and 96/77/EC to enable the user of these materials or articles to comply with the relevant Community provisions or, in their absence, with national provisions applicable to food;

(7) specifications on the use of the material or article, such as:

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

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

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

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

The written declaration shall permit an easy identification of the materials, articles or substances for which it is issued and shall be renewed when substantial changes in the production bring about changes in the migration or when new scientific data are available.'

ANNEX VIII

The Annex to Directive 85/572/EEC is amended as follows:

(1) Point 3 is replaced by the following:

'3. When "X" is followed by an oblique stroke and a figure, the result of the migration tests should be divided by the figure indicated. In the case of certain types of fatty food, this conventional figure, known as "Simulant D Reduction Factor" (DRF), is used to take account of the greater extractive capacity of the simulant compared to the food.'

(2) The following point 4a is inserted:

'4a. Where the letter (b) is shown in brackets after the "X", the indicated test shall be carried out with ethanol 50 % (v/v).'

(3) In the table, Section 07 is replaced by the following:

'07	**Milk products**				
07.01	Milk:				
	A. Whole				X(b)
	B. Partly dried				X(b)
	C. Skimmed or partly skimmed				X(b)
	D. Dried				
07.02	Fermented milk such as yoghurt, buttermilk and similar products		X		X(b)
07.03	Cream and sour cream		X(a)		X(b)
07.04	Cheeses:				
	A. Whole, with non-edible rind				
	B. All others	X(a)	X(a)		X/3*
07.05	Rennet				
	A. In liquid or viscous form	X(a)	X(a)		
	B. Powdered or dried'				

Annexes

Competition Assessment

The proposals are unlikely to significantly affect competition as the impact of reading the new Regulations is likely to be small. The proposals do not include any new or additional burden, as the Commission Directive they implement is merely amending existing legislation on food contact plastics and does not introduce any new provisions. Furthermore, the requirement in Article 9 (1) and (2) for detailed information on compliance declarations as indicated in the EU Annex attached, does not raise any new burden on industry. This requirement is an existing requirement under Article 16 of Regulation (EC) No. 1935/2004, which is being reinforced by the provisions contained in the Commission Directive.

Small Firms Impact Test

We do not consider that the impact on small businesses in general to be significant. This view has been supported by industry following earlier consultations (February and March 2006), which indicated that the proposals would not disproportionately affect small or medium sized businesses, nor would they hinder competitiveness.

Sustainable development

The Food Standards 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 health 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. Charities and voluntary organisations are also unlikely to be affected by these proposals.

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.

LIST OF INTERESTED PARTIES

Name	Company
Mr Alan Turner OBE	
Julia Scott	
Mr Paul Anthony Taylor	
Nigel Barnwell	
Joy Hardinge OBE	AJH Consulting
Dr P Donnelly	APD Scientific Limited
Mr Stuart MacConnacher	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
Barbara Gallani	British Retail Consortium
Lucy Pearson	British Soft Drinks Association
Mr Roger Hamby	CATRA
Alex Cole	Cadbury Schweppes
John Hammond	Campden & Chorleywood Food Research Association
Mr N Byrd	Campden & Chorleywood Food Research Association
Mr Keith Warren	Catering Equipment Suppliers Association
Dr S Parry	Centre for Analytical Research in the Environment
Dr Joanne Lloyd	Chemical Industries Association
Ms K Goodburn	Chilled Food Association
Victoria Sayer	Colormatrix Europe
Andrew Barnetson	Confederation of Paper Industries
Richard Whittaker	Crown Corporate Technologies
Mr J Begg	Dairy Industry Federation
Mr Brian McMullen	Danapak Flexibles Limited
	Department for Business, Enterprise and Regulatory Reform
Mr John Askew	Dexter Packaging Products
Liz Fleming	Eclipse Scientific Group
	Enterprise Directorate
	Federation of Small Businesses
Martin Unwin	Flexible Packaging Association
Ann Davison	FOODAWARE
Mr Richard Ratcliffe	Food Additives and Ingredients Association
Andrew Curtis	Food And Drink Federation
Dr Stephen Fellows	Food Policy Update
	Friends of the Earth
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
Mr Richard Armstrong	Innovia Films
Mr Jeff Graham	JEFPAC Limited
Mr Darren Prosser	Kenwood Limited
Mr John Webb-Jenkins	Kirkstone Plastics Limited
John Marriott	Laboratory of the Government Chemist
Mr Les Bailey	LACORS

LIST OF INTERESTED PARTIES

Name	Company
Jon Averns	London Port Health Authority
Mr Christopher Sherlock	Lovell White Durrant
John Wight	Marks & Spencer Plc
Mr D A Smith	Metal Packaging Manufacturers Association
Mr A Woods	Metal Packaging Manufacturers Association
Sue Dibb	National Consumer Council
Mrs A Townshend	National Consumers' Federation
Katsuji Shibata	Nippon Gohsei
	Office of Fair Trading
Mr Roger Parry	Packaging and Films Association
Mr David Tyson	Packaging and Industrial Films Association
David Creek	Pillsbury Europe
Martin Addicott	Pulse Speciality Products
Mr I Cooper	PIRA International
Mr J Sidwell	RAPRA Technology Limited
Mr Roy Dixon	RDA Packaging Consultants
Mr Trefor Owen	Rexam Plastic Packaging
Ms L Creighton	SafePharm Laboratories Limited
John Figgins	Sainsburys Supermarkets Limited
Mr Stan Webb	Sinclair International Limited
Mrs L Freeman	Society of Chemical Industry
Sandra Blake	Somerfield Plc
	Sustain
Mr John Swift	SCA Packaging
Ms Lynda Hamilton	Technical Indexes
Dr Catherine Humphries	The Co-operative Group
Mr Ken Hardman	The Industrial Packaging Association
Mr Pete Watts	Toxicology Advice & Consulting Limited
Mr N Cull	Trading Standards Institute
Mr Barry Pamplin	United Biscuits (UK) Limited
Kay Flett	UNIVAR Limited
Mr D Finnegan	Weetabix Limited
Ms A Bristow	WHICH
Mr Ronald Pierre-Davis	Wilsanco Plastics Limited