WELSH STATUTORY INSTRUMENTS

2006 No. 2982 (W.273)

FOOD, WALES

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

Made - - - -	*14 November 2006*
Coming into force - -	*19 November 2006*

The National Assembly for Wales 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(**1**), and now vested in it(**2**).

In accordance with section 48(4A) of that Act it 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(**3**), there has been open and transparent public consultation during the preparation and evaluation of these Regulations.

PART 1

Preliminary

Title, application and commencement

1. The title of these Regulations is the Plastic Materials and Articles in Contact with Food (Wales) Regulations 2006, they apply in relation to Wales and come into force on 19 November 2006.

Interpretation

2.—(1) In these Regulations —

"the Act" ("*y Ddeddf*") means the Food Safety Act 1990;

(**1**) 1990 c. 16.
(**2**) Functions of the Secretary of State under the Food Safety Act 1990, 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).
(**3**) OJ No. L31, 1.2.2002, p.1. That Regulation was last amended by Regulation (EC) No. 1642/2003 of the European Parliament and of the Council (OJ No. L245, 29.9.2003, p.4).

"authorised officer" ("*swyddog awdurdodedig*") 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" ("*BADGE*") has the meaning given in Article 1(1)(a) of Regulation 1895/2005;

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

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

"capable" ("*yn gallu*") means capable as established under regulation 11;

"Directive 82/711" ("*Cyfarwyddeb 82/711*") means Council Directive 82/711/EEC(**4**) laying down the basic rules necessary for testing migration of the constituents of plastic materials and articles intended to come into contact with foodstuffs, as last amended by Commission Directive 97/48/EC(**5**);

"Directive 85/572" ("*Cyfarwyddeb 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(**6**);

"Directive 88/388" ("*Cyfarwyddeb 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(**7**);

"Directive 89/107" ("*Cyfarwyddeb 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(**8**);

"the Directive" ("*y Gyfarwyddeb*") means Commission Directive 2002/72/EC(**9**) relating to plastic materials and articles intended to come into contact with foodstuffs, as last amended by Commission Directive 2004/19/EC(**10**) and Commission Directive 2005/79/EC(**11**);

"EEA State" ("*Gwladwriaeth AEE*") means a member State (other than the United Kingdom), Norway, Iceland and Liechtenstein;

"EFSA" ("*EFSA*") means the European Food Safety Authority;

"enforcement authority" ("*awdurdod gorfodi*") means an authority having responsibility under regulation 14 for executing and enforcing these Regulations;

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

"good technical quality" ("*ansawdd technegol da*") means good technical quality as regards the purity criteria;

"handling of food" ("*trin bwyd*") means use in connection with the storage, preparation, packaging, sale or serving of food;

"import" ("*mewnforio*") means import in the course of a business;

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

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

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

(**4**) OJ No. L297, 23.10.1982, p.26.
(**5**) OJ No. L222, 12.8.1997, p.10.
(**6**) OJ No. L372, 31.12.1985, p.14.
(**7**) OJ No. L184, 15.7.1988, p.61.
(**8**) OJ No. L40, 11.2.1989, p.27.
(**9**) OJ No. L220, 15.8.2002, p.18.
(**10**) OJ No. L71, 10.3.2004, p.8.
(**11**) OJ No. L302, 19.11.2005. p.35.

"the 1998 Regulations" ("*Rheoliadau 1998*") means the Plastic Materials and Articles in Contact with Food Regulations 1998(**12**);

"the 2005 Regulations" ("*Rheoliadau 2005*") means the Materials and Articles in Contact with Food (Wales) Regulations 2005(**13**);

"plastic material or article" (" *deunydd neu eitem plastig*") means anything which for the purposes of the Directive is included among those plastic materials and articles and parts thereof to which the Directive applies;

"the Purity Directives" (" *y Cyfarwyddebau Purdeb*") means Commission Directive 95/31/EC laying down specific criteria of purity concerning sweeteners for use in foodstuffs(**14**), Commission Directive 95/45/EC laying down purity criteria concerning colours for use in foodstuffs(**15**) and Commission Directive 96/77/EC laying down specific purity criteria for food additives other than colours or sweeteners(**16**);

"Regulation 1895/2005" ("*Rheoliad 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(**17**);

"sell" ("*gwerthu*") includes offer or expose for sale or have in possession for sale, and "sale" ("*gwerthiant*") is construed accordingly;

(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 Part 5 of Schedule 3, any reference to a numbered Annex is a reference to that Annex to the Directive.

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

(**12**) S.I. 1998/1376, as amended in relation to Wales by S.I. 2001/1236 (W.70), S.I. 2002/2834 (W.272)S.I. 2003/302 (W.44), S.I. 2005/182 (W.15) and S.I. 2005/1649 (W.130).
(**13**) S.I. 2005/1647 (W.128).
(**14**) OJ No. L178, 28.7.97, p.1, as last amended by Commission Directive 2004/46, OJ No. L114, 21.4.2004, p.15.
(**15**) OJ No. L226, 22.9.95, p.1, as last amended by Commission Directive 2004/47, OJ No. L113, 20.4.2004, p.24.
(**16**) OJ No. L339, 30.12.96, p.1, as last amended by Commission Directive 2003/95, OJ No. L283, 31.10.2003, p.71.
(**17**) OJ No. L302, 19.11.2005, p.28.

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

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

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

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

(a) of good technical quality;

(b) identified by PM/REF No., CAS No. (if any) and name in columns 1, 2 and 3 respectively of 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) must 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 is 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 is 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 paragraph (2), 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(3) applies.

Required standard for non-migration of constituents of additives

7.—(1) Subject to paragraph (2), where a migration limit expressed in mg/kg is indicated in column 4 of 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(3) applies.

Required standard for products obtained by bacterial fermentation

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

(a) of good technical quality;

(b) identified by PM/REF No., CAS No. and name in columns 1, 2 and 3 respectively of 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 (3), a plastic material or article meets the required standard under this regulation if it is not capable of transferring its constituents to food with which it may come into contact in quantities exceeding the appropriate limit specified in paragraph (2).

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

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

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

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

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

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

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

(a) which is specified in the table to Part 4 of Schedule 3; and

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

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

Required standard for non-migration of primary aromatic amines

10.—(1) Subject to paragraph (3), a plastic material or article manufactured using isocyanates or colourants prepared by diazo-coupling meets the required standard under this regulation if it is

not capable of transferring in a detectable quantity primary aromatic amines (expressed as aniline), not being primary aromatic amines listed in the Directive, 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 the Annex concerned.

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

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

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

(a) in any case other than one to which sub-paragraph (b) applies, and subject to Article 8.4 of the Directive (which may be applied on compliance with the conditions stated therein), by the verification methods specified in Schedule 2 (including the analytical tolerances referred to in paragraph 8 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 7(2) of the 2005 Regulations.

(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 simulant representing the food or, as the case may be, food with which it may come into contact.

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

Labelling

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

(a) accords with the requirements of Article 16(1) of Regulation (EC) No. 1935/2004 of the European Parliament and of the Council(**18**); and

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

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

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

(2) In establishing which descriptions of food a material or article may come into contact with, it is to be assumed until the contrary is proved that, for the purposes of these Regulations, if particulars are shown in relation to that material or article in accordance with paragraph (1)(a), those particulars

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

are accurate and that unless the particulars so indicate, there are no restrictions on the intended conditions of contact.

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

13.—(1) In this regulation —

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

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

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

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

(a) manufacture,

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

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

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

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

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

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

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

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

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

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

(5) Subject to Article 6(3) (transitional provisions relating to materials and articles brought into contact with food before 1 January 2007), no person may 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 may without reasonable excuse fail to comply with a request made under Article 6(4) (requirement to disclose date of filling to competent authority).

PART 3

Execution and Enforcement

Enforcement

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

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

(b) these Regulations.

Offences and Penalties

15.—(1) Any person who —

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

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

(c) contravenes regulation 13(6) or 17(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 convicted of an offence under these Regulations is liable —

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

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

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

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

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

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

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

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

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

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

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

General defences

16.—(1) In any proceedings for an offence under these Regulations it is, subject to paragraph (5), a defence for the person accused to prove that he or she took all reasonable precautions and exercised all due diligence to avoid the commission of the offence by him or herself or by a person under his or her control.

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

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

(b) import it into the United Kingdom,

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

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

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

(b) that either —

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

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

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

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

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

(b) that the sale of which the alleged offence consisted was not a sale under his or her name or mark; and

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

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

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

(b) where he or she has previously appeared before the court in connection with the alleged offence, within one month of his or her first such appearance,

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

Transitional defence relating to PVC gaskets containing epoxidised soybean oil

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

(a) which contains

(i) infant formula or follow-on formula as defined by Commission Directive 91/321/EC(**19**), or

(**19**) OJ No.L175, 4.7.1991, p.35, as last amended by Directive 2003/14/EC (OJ No. L41, 14.2.2003, p.37)

(ii) processed cereal-based foods or baby foods for infants and young children as defined by Commission Directive 96/5/EC(**20**), 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 is a defence to prove the matters set out in paragraph (2)

(2) The matters to be proved are that —

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

(b) 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

(c) the labelling or marking with the particulars mentioned in sub-paragraph (b) 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(**21**).

(3) No person may 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)(b).

Other transitional defences and savings

18.—(1) Notwithstanding the revocations made in regulation 25, in relation to any plastic material or article —

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

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

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

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

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

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

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

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 mentioned in regulation 17(1), it is 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 19 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 Wales at the time the matter occurred.

(**20**) OJ No.L49, 28.2.1996, p.17, as last amended by Directive 2003/13/EC (OJ No. L41, 14.2.2003, p.33)
(**21**) OJ No. L109, 6.5.2000, p.29, as last amended by Directive 2003/89/EC (OJ No.L308, 25.11.2003, p.15).

Procedure where a sample is to be analysed

19.—(1) An authorised officer who has procured a sample under section 29 of the Act and who considers it should be analysed must 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 must divide the sample into parts by putting the containers into three lots, and each lot is treated as being a part.

(3) The authorised officer must—

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

(b) mark each part or container;

(c) as soon as reasonably practicable, give one part to the owner and notify him or her 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 20.

Secondary analysis by the Government Chemist

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

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

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

paragraphs (2) to (7) apply.

(2) The authorised officer —

(a) may of his or her own volition;

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

(c) must if the court so orders; or

(d) must (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 must analyse the part sent to him or her under paragraph (2) and send to the authorised officer a certificate of analysis.

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

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

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

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

PART 4

Application for Authorisation

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

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

(2) The application mentioned in paragraph (1), including supporting data, must be made to EFSA before 1 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 the law of England and Wales, continue to be so used until EFSA has issued an opinion, provided the supplementary information 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 1 January 2007.

PART 5

General and Supplementary

Application of provisions of the Act

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

(a) section 3 (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

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

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

24.—(1) The 2005 Regulations are amended in accordance with paragraphs (2) to (4).

(2) In regulation 2(1) —

(a) In the appropriate place in alphabetical order insert the following definition—

> ""Directive 2002/72/EC" ("*Cyfarwyddeb 2002/72/EC*") means Commission Directive 2002/72/EC relating to plastic materials and articles intended to come into contact with foodstuffs(**23**), as last amended by Commission Directive 2005/79/EC(**24**)

(b) In the appropriate place in alphabetical order insert the following definition—

(**22**) S.I. 1990/2463.
(**23**) OJ No. L220, 15.8.2002, p.18. This Directive has been previously amended by Commission Directives 2004/1/EC (OJ No. L7, 13.1.2004, p.45) and 2004/19/EC (OJ No. L71, 10.3.2004, p.8).
(**24**) OJ No. L302, 19.11.2005, p.35,

""the 2006 Regulations" ("*Rheoliadau 2006*") means the Plastic Materials and Articles in Contact with Food (Wales) Regulations 2006(**25**)."

(3) In regulation 8 —

(a) at the beginning of paragraph (2) add the expression "Except in paragraph (4),":

(b) for paragraph (4) substitute the following paragraph —

"(4) No person may manufacture any coating to be applied to film referred to in paragraph (3)(b) using any substance or group of substances except those listed in Annexes II, III or IV to Directive 2002/72/EC and other than in accordance with the appropriate requirements, restrictions and specifications contained in those Annexes and in the 2006 Regulations.".

(4) In regulation 9 —

(a) in paragraph (3), for the expression "in Part I of Schedule 1 to the 1998 Regulations" substitute "in Section A or B of Annex II to Directive 2002/72/EC";

(b) in sub-paragraph (b) of paragraph (3), for the expression "that Part as read with Part II of that Schedule." substitute "those Sections as read with the general introduction to that Annex.";

(c) in paragraph (5), for the expression "Schedules 3 and 4" substitute "Schedules 2 and 3".

Revocations

25. The following Regulations or parts thereof are revoked —

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

(b) the Plastic Materials and Articles in Contact with Food (Amendment) (Wales) Regulations 2001(**26**);

(c) the Plastic Materials and Articles in Contact with Food (Amendment) (Wales) Regulations 2002(**27**);

(d) the Plastic Materials and Articles in Contact with Food (Amendment) (Wales) Regulations 2003(**28**);

(e) the Plastic Materials and Articles in Contact with Food (Amendment) (Wales) Regulations 2005(**29**);

(f) the Plastic Materials and Articles in Contact with Food (Amendment) (No.2) (Wales) Regulations 2005(**30**);

(g) regulation 15 of the 2005 Regulations.

(**25**) S.I. 2006/2982 (W.273).
(**26**) S.I. 2001/1263 (W.70).
(**27**) S.I. 2002/2834 (W.272).
(**28**) S.I. 2003/302 (W.44).
(**29**) S.I. 2005/182 (W.15).
(**30**) S.I. 2005/1649 (W.130).

Signed on behalf of the National Assembly for Wales under section 66(1) of the Government of Wales Act 1998(**31**).

D. Elis-Thomas
14 November 2006 The Presiding Officer of the National Assembly

(**31**) 1998 c. 38.

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 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 must 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 must be that indicated for the individual compound and the entry applying to the generic term must be treated as varied to such extent as is necessary.

3.—(1) The items identified in Section A or B of Annex II are 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 has 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 is subject to a note relating to that number as set out in Annex IV.

SCHEDULE 2

Regulations 9 and 11

Provisions Applicable Provisions when Testing Compliance with the Migration Limits

General Provisions

1. When the results of the migration tests specified in this Schedule and, where appropriate Schedule 3, are analytically determined, the specific gravity of any simulants used is 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.a2/a1.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) a1 is the surface area in square decimetres of the sample in contact with the food or simulant during the migration test;

(d) a2 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 must 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 must 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 must 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 must 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 must 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 must 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 must 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") must 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 must 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 must (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 must be treated as the level relevant to that test.

Special provisions relating to overall migration

6.—(1) Subject to sub-paragraph (2), any method of analytical determination may be used to prove excess of an overall migration limit in relation to a plastic material or article.

(2) In any proceedings for an offence under these Regulations where it is alleged that a plastic material or article does not comply with regulation 9 it is 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—

(c) a sample of the plastic material or article had been weighed before and after contact with the simulant;

(d) the simulant absorbed by the sample had been extracted and determined quantitatively;

(e) the quantity of simulant so found had been subtracted from the weight of the sample measured after contact with the simulant; and

(f) the difference between the initial and corrected final weights had been determined to represent the overall migration of the sample examined,

there would have been no such excess so determined.

7.—(1) Where a plastic material or article is intended to come into repeated contact with food and it is technically impossible to carry out the test described in paragraph 5, the test must be so modified as to enable the level of migration occurring during the third such test to be determined and, subject to sub-paragraph (2), such a determination may be used to prove excess of an overall migration limit in relation to a plastic material or article.

(2) 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 above and the overall migration determined (M1);

(b) the second and third samples are to be subjected to the same conditions of temperature but the period of contact had been two and three times that specified and overall migration had been determined in each case (M2 and M3).

(3) Where a modified test has been carried out in accordance with sub-paragraph (2), provided that either M1 or M3 — M2 did not exceed that overall migration limit, the plastic material or article subject to that test is deemed to be in compliant with that limit.

8.—(1) Any plastic material or article which exceeds its overall migration limit by an amount not exceeding the analytical tolerance specified in sub-paragraph (2) is deemed for the purposes of these Regulations not to exceed its overall migration limit.

(2) The following analytical tolerances are 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.

SCHEDULE 3 Regulations 9 and 11

Overall and Specific Migration Testing Using Food Simulants

PART 1

Basic Rules

1. Subject to paragraphs 2, 3 and 4 of this Part, migration tests for the determination of specific and overall migration must 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 must be carried out if the migration test using the fatty food simulants specified in Part 3 is not feasible for technical reasons connected with the method of analysis.

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

4. In migration testing it is permissible to—

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

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

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

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

PART 2

Food Simulants to be used in Migration Testing

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

1 *Abbreviation*	*2* *Food Simulant*
Simulant A:	Distilled water or water of equivalent quality
Simulant B:	3% Acetic acid (w/v) in aqueous solution
Simulant C:	10% Ethanol (v/v) in aqueous solution save that the concentration of ethanol solution must be adjusted to the actual alcoholic strength of the food if it exceeds 10% (v/v)
Simulant D:	Rectified olive oil having the characteristics specified in paragraph 3 of this Part of this Schedule or, subject to paragraph 5 of this Part of this Schedule, any of the fatty food simulants specified in paragraph 4 of this Part of this Schedule

2. For the purposes of this Schedule a reference to an abbreviation in column 1 of the Table 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 —

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

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

(e) Saponification number = 188 to 193

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

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

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

Fatty acid distribution

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

Purity

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

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

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

5. Where a fatty food simulant specified in paragraph 4 is used in migration testing and the result of that test shows that a plastic material or article does not comply with any migration limit specified in regulation 9 or the Annexes, verification that the plastic material or article does not comply with the specified migration must 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 is 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 must 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, must be applied to the test result; and

(b) the plastic material or article is 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 is applied to a test result by dividing the result by that reduction factor.

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

Table 1:

Food types

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

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

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

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

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

(a) where —

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

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

the simulant or simulants so specified;

(b) where —

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

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

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

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

6. The simulant or simulants to be used in testing a plastic material or article which, pursuant to Regulation (EC) No. 1935/2004 of the European Parliament and of the Council on materials and articles intended to come into contact with food(**32**) ("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 must 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 are—

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

(b) where the indication states that the plastic material or article should not be used with any food or group of foods described in column 2 of Table to Part 4, a simulant other than the simulant or simulants which, for the purposes of Part 4, is or are specified in relation to that food or group of foods.

8. A specific indication referred to in paragraph 7 is expressed in accordance with this paragraph if it is expressed—

(a) at a marketing stage other than retail, by using the reference number in column 1 of the Table to Part 4 of these Regulations or the description of food in column 2 of that Table which, in either case, corresponds to the food;

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

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

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

Contact foods	*Simulant*
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 is 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 is 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 is used in the migration test, that is to say —

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

(b) if the pH value of the foodstuff is 4.5 or less, simulant B must 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	X[(1)]	X[(2)]		

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

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

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

Reference Number	*Description of food*	*Simulants to be used*			
		A	B	C	D
	under heading 01.01 but with an alcoholic strength equal to or exceeding 5% vol. — Wines, spirits and liqueurs				
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				

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

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

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

Reference Number	*Description of food*	*Simulants to be used*			
		A	B	C	D
02.05	Pastry, biscuits, cakes and other bakers' wares, dry:				
	A With fatty substances on the surface				X/5
	B Other				
02.06	Pastry, biscuits, cakes and other bakers' wares, fresh				
	A With fatty substances on the surface				X/5
	B Other	X			
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				X/5

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

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

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

Reference Number	*Description of food*	*Simulants to be used*			
		A	B	C	D
	— Other				
	B in paste form:				
	— with fatty substances on the surface				X/3
	— moist	X			
03.03	Sugar and sugar products				
	A In solid form				
	B Honey and the like	X			
	C Molasses and sugar syrups	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	X(a)	X(a)		
	C Fruit preserves (jams and				

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

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

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

Reference Number	*Description of food*	*Simulants to be used*			
		A	B	C	D
	similar products				
	— whole fruit or chunks or in the form of flour or powder, preserved in a liquid medium):				
	— In an aqueous medium	X(a)	X(a)		
	— In an oily medium	X(a)	X(a)		X
	— In an alcoholic medium > 5% vol		X[(1)]	X	
04.03	Nuts (peanuts, chestnuts, almonds, hazelnuts, walnuts, pine kernels and others)				
	A Shelled, dried				
	B Shelled and roasted				X/5[(3)]
	C In paste or cream form	X			X/3[(3)]
04.04	Whole vegetables, fresh or chilled				
04.05	Processed vegetables:				

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

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

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

Reference Number	*Description of food*	*Simulants to be used*			
		A	B	C	D
	A Dried or dehydrated vegetables whole or in the form of flour or powder				
	B Vegetables, cut, in the form of purees	X(a)	X(a)		
	C Preserved vegetables:				
	— In an aqueous medium	X(a)	X(a)		
	— In an oily medium	X(a)	X(a)		X
	— In an alcoholic medium (> 5% vol)		X[(1)]	X	
05	Fats and oils				
05.01	Animal and vegetable fats and oils, whether natural or treated (including cocoa butter, lard, re-solidified butter)				X
05.02	Margarine, butter and other fats and oils made from water emulsions in oil				X/2

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

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

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

Reference Number	*Description of food*	*Simulants to be used*			
		A	B	C	D
06	Animal products and eggs				
06.01	Fish:				
	A Fresh, chilled, salted, smoked	X			X/3[(3)]
	B In the form of paste	X			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	X			X/4
	B In the form of paste, creams	X			X/4
06.04	Processed meat products (ham, salami, bacon and other)	X			X/4
06.05	Preserved and part-preserved meat and fish:				

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

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

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

Reference Number	*Description of food*	*Simulants to be used*			
		A	B	C	D
	A In an aqueous medium	X(a)	X(a)		
	B In an oily medium	X(a)	X(a)		X
06.06	Eggs not in shell:				
	A Powdered or dried				
	B Other	X			
06.07	Egg yolks:				
	A Liquid	X			
	B Powdered or frozen				
06.08	Dried white of egg				
07	Milk products				
07.01	Milk:				
	A Whole	X			
	B Partly dried	X			
	C Skimmed or partly skimmed	X			
	D Dried				
	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:				

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

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

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

Reference Number	*Description of food*	*Simulants to be used*			
		A	B	C	D
	A Whole, with rind				
	B Processed cheeses	X(a)	X(a)		
	C All others	X(a)	X(a)		X/3[(3)]
07:05	Rennet:				
	A In liquid or viscous form	X(a)	X(a)		
	B Powdered or dried				
08	Miscellaneous products				
08.01	Vinegar		X		
08.02	Fried or roasted foods:				
	A Fried potatoes, fritters and the like				X/5
	B Of animal origin				X/4
08.03	Preparations for soups, broths in liquid, solid or powder form (extracts, concentrates); homogenized composite food preparations, prepared dishes:				
	A Powdered or dried				

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

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

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

Reference Number	*Description of food*	*Simulants to be used*			
		A	B	C	D
	— With fatty substances on the surface				X/5
	— Other				
	B Liquid or paste:				
	— With fatty substances on the surface	X(a)	X(a)		X/3
	— Other	X(a)	X(a)		
08.04	Yeasts and raising agents:				
	A In paste form	X(a)	X(a)		
	B Dried				
08.05	Salt				
08.06	Sauces:				
	A Without fatty substances on the surface	X(a)	X(a)		
	B Mayonnaise, sauces derived from mayonnaise, salad creams and other oil in water emulsions	X(a)	X(a)		X/3
	C Sauce containing oil and water forming two distinct layers	X(a)	X(a)		X
08.07	Mustard (except powdered	X(a)	X(a)		X/3[(3)]

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

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

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

Reference Number	*Description of food*	*Simulants to be used*			
		A	B	C	D
	mustard under heading 08.17)				
08.08	Sandwiches, toasted bread and the like containing any kind of foodstuff:				
	A With fatty substances on the surface				X/5
	B Other				
08.09	Ice-creams	X			
08.10	Dried foods:				
	A With fatty substances on the surface				X/5
	B Other				
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				X/5[(3)]
	B Cocoa paste				X/3[(3)]
08.14	Coffee, whether or not roasted, decaffeinated or soluble, coffee				

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

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

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

Reference Number	*Description of food*	*Simulants to be used*			
		A	B	C	D
	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 must not be used where the pH is more than 4.5.

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

(3) If it can be demonstrated under regulation 12(2) or proved by means of an appropriate test that there is to be no fatty contact with the plastic material or article, simulant D must 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 must 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 must 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 must be performed in a manner which recognises the loss of volatile migrants which may occur in the worst foreseeable conditions of use.

Special cases

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

6. Where the carrying out of a migration test under contact conditions specified in the Table to this Part causes any physical or other change in the test specimen which does not occur under the worst foreseeable conditions of use of the plastic material or article being tested the migration test must 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 70oC and not more than 100oC and such use is indicated by appropriate labelling or instructions no test other than for 2 hours at 70oC must 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 40oC must be carried out.

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

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

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

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

Conditions of contact in worse foreseeable use	*Test conditions*
>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 must be used only for simulant D. For simulant A, B or C the test may be replaced by a test at 100oC 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 must 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 must be used;

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

(c) subject to paragraph 4, compliance with a migration limit must 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 must 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 must not be used.

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

Conventional conditions for substitute tests

Test conditions simulant D	*Test conditions with isooctane*	*Test conditions with ethanol 95%*	*Test conditions with 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 1 and 2 are —

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

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

EXPLANATORY NOTE

(This note is not part of the Regulations)

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

2. The Regulations in Part 2 —

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

(b) prohibit the use of monomers and additives in the manufacture of plastic materials and articles other than in accordance with specified conditions (regulation 4 and Schedule 1 in the case of monomers and regulation 5 and Schedule 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 methods for determining the capability of a plastic material or article to transfer its constituents to food, and for detecting the presence of any such constituents in food (regulation 11 and Schedules 2 and 3);

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

(i) provide for the enforcement of Regulation 1895/2005 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 13).

3. The Regulations in Part 3 —

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

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

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

(d) provide for a transitional defence relating to the sale of jars in foods for infants and young children sealed PVC gaskets containing epoxidised soybean oil; (regulation 17);

(e) 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 18);

(f) specify the procedure to be followed when sending a sample for analysis (regulation 19);

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

4. Part 4 of the Regulations contains provisions relating to the procedure to be followed and the time limit to be observed where a person wishes apply to the European Food Safety Authority for the authorisation of a new additive (regulation 21).

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

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

(b) Council Directive 85/572/EEC laying down the list of 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);

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

6. A full regulatory appraisal has been prepared for these Regulations and has been placed in the Library of the National Assembly for Wales along with a copy of the transposition note relating to these Regulations. Copies are also available from the Food Standards Agency, 11th Floor, Southgate House, Cardiff CF10 1EW.