
STATUTORY INSTRUMENTS

1998 No. 1376

**The Plastic Materials and Articles in
Contact with Food Regulations 1998**

Title, commencement and extent

1.—(1) These Regulations may be cited as the Plastic Materials and Articles in Contact with Food Regulations 1998 and shall come into force on 1st July 1998.

(2) These Regulations apply in Great Britain.

Interpretation

2.—(1) In these Regulations, unless the context otherwise requires—

“the Act” means the Food Safety Act 1990;

“additive” means a substance, other than one which directly influences the formation of polymers, which is—

- (a) incorporated into a plastic material or article to achieve a technical effect in the finished product and is intended to be present in the finished product; or
- (b) used to provide a suitable medium in which polymerisation occurs;

“business” has the same meaning as it has in the Act;

“capable” means capable as established under regulation 6;

“Council 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⁽¹⁾, as amended by Commission Directives [93/8/EEC](#)⁽²⁾ and [97/48/EC](#)⁽³⁾;

“the Directive” means Commission Directive ([EEC](#)) No. [90/128](#) relating to plastics materials and articles intended to come into contact with foodstuffs⁽⁴⁾ (as corrected) and as amended by Commission Directives [92/39/EEC](#), [93/9/EEC](#), [95/3/EC](#) and [96/11/EC](#)⁽⁵⁾;

“EEA Agreement” means the Agreement on the European Economic Area⁽⁶⁾ signed at Oporto on 2nd May 1992 as adjusted by the Protocol⁽⁷⁾ signed at Brussels on 17th March 1993;

“EEA State” means a State (other than the United Kingdom) which is a contracting party to the EEA Agreement;

“food” has the same meaning as it has in section 16(5) of the Act;

“good technical quality” means good technical quality as regards the purity criteria;

(1) OJ No. L297, 23.10.82, p.26.

(2) OJ No. L90, 14.4.93, p.22.

(3) OJ No. L222, 12.8.97, p.10.

(4) OJ No. L75, 21.3.90, p.19.

(5) Corrigendum in OJ No. L349, 13.12.90, p.26; amending Directives in OJ No. L168, 23.6.92, p.21, OJ No. L90, 14.3.93, p.26, OJ No. L41, 23.2.95, p.44 and OJ No. L61, 12.3.96, p.26.

(6) OJ No. L1, 3.1.94, p.1.

(7) OJ No. L1, 3.1.94, p.571.

“human consumption” has the same meaning as it has in the Act;

“import” means import in the course of a business;

“monomer” means anything which is included for the purposes of the Directive among monomers and other starting substances;

“the 1987 Regulations” means the Materials and Articles in Contact with Food Regulations 1987⁽⁸⁾;

“the 1992 Regulations” means the Plastic Materials and Articles in Contact with Food Regulations 1992⁽⁹⁾;

“person charged” includes, in Scotland, the accused;

“plastic material or article” means anything which for the purposes of the Directive is included among those plastics materials and articles and parts thereof to which the Directive applies;

“preparation” has the same meaning as it has in the Act; and

“sell” includes offer or expose for sale or have in possession for sale, and “sale” shall be construed accordingly.

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

(3) Any expression, other than one defined in paragraph (1) of this regulation, used both in these Regulations and in the Directive, Council Directive 82/711 or 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⁽¹⁰⁾ has, in so far as the context admits, the same meaning as it bears in the Directive in which it appears.

(4) Any reference in these Regulations to a numbered regulation or Schedule shall unless the context otherwise requires be construed as a reference to the regulation or Schedule bearing that number in these Regulations.

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

3.—(1) A plastic material or article which fails to meet the requisite standards shall not be—

- (a) used by any person in the course of a business in connection with the storage, preparation, packaging, sale or serving of food for human consumption;
- (b) sold by any person for the purpose of its being used in connection with the storage, preparation, packaging, sale or serving of food for human consumption; or
- (c) imported by any person from any place other than an EEA State for the purpose of its being used in connection with the storage, preparation, packaging, sale or serving of food for human consumption.

(2) In any proceedings for an offence under these Regulations where it is alleged that a plastic material or article which fails to meet the requisite standards was used, sold or imported it shall be a defence for the person charged to prove that the plastic material or article in respect of which the offence is alleged to have been committed was intended for export to a country, other than an EEA State, which has legislation analogous to these Regulations and that the plastic material or article complies with such legislation.

(3) In any proceedings for an offence under these Regulations where it is alleged that a plastic material or article which fails to meet the requisite standards was used, sold or imported it shall be a defence for the person charged to prove that the plastic material or article was manufactured—

⁽⁸⁾ S.I. 1987/1523; relevant amending instruments are S.I. 1990/2487 and 1994/979.

⁽⁹⁾ S.I. 1992/3145; amended by S.I. 1995/360, 1996/694 and 1996/2817.

⁽¹⁰⁾ OJ No. L372, 30.12.85, p.14.

- (a) before 1st July 1998; and
 - (b) in accordance with regulation 5 of the 1992 Regulations as that regulation applied when the plastic material or article was manufactured.
- (4) For the purposes of this regulation a plastic material or article fails to meet the requisite standards—
- (a) if—
 - (i) it has been manufactured with a prohibited monomer as described in regulation 4(1) or a prohibited additive as described in regulation 5(1) or does not comply with regulation 4(5) or 7; and
 - (ii) no defence indicated in regulation 4(7), 5(2) or 7(5) would be available in proceedings for an offence under these Regulations relating to that manufacture or want of compliance; or
 - (b) if it has been manufactured outside Great Britain and sub-paragraph (a) above would have applied to it had it been manufactured in Great Britain.

Restriction on manufacture with monomers

4.—(1) Subject to the following paragraphs of this regulation, no plastic material or article shall be manufactured by any person with any prohibited monomer, that is to say any monomer other than a monomer which is—

- (a) of good technical quality;
 - (b) identified by PM/REF No., CAS No. (if any) and name respectively in columns 1, 2 and 3 of the relevant section of Part 1 of Schedule 1; and
 - (c) used in accordance with the restrictions (if any) specified in the corresponding entry in column 4 of the relevant section of that Part of that Schedule.
- (2) For the purposes of this regulation the relevant section of Part I of Schedule 1 is—
- (a) in the case of a plastic material or article manufactured before 1st January 1999, Section A, B or C;
 - (b) in the case of a plastic material or article manufactured after 31st December 1998 and before 1st January 2002, Section A or B; and
 - (c) in the case of a plastic material or article manufactured after 31st December 2001, Section A.
- (3) Paragraph (1) of this regulation 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) silicones;
 - (c) epoxy resins;
 - (d) products obtained by means of bacterial fermentation;
 - (e) adhesives and adhesion promoters; or
 - (f) printing inks.

(4) Paragraph (1) of this regulation shall not be taken to prohibit the manufacture of any plastic material or article with any substance if the substance is a mixture which falls within paragraph 3(c) of Annex II to the Directive and does not contravene paragraph 4 of that Annex.

(5) Subject to paragraph (6) of this regulation, where column 4 of the relevant section of Part I of Schedule 1 expresses a migration limit of mg/kg in relation to any monomer, no plastic material

or article manufactured from that monomer shall be capable of transferring constituents of that monomer to food with which that 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 therein released per kilogram of food in the case of any plastic material or article other than one specified in sub-paragraph (b) below; and
- (b) one sixth of the number of milligrams expressed therein 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 which can be filled, with a capacity of less than 500 millilitres or more than 10 litres, or
 - (ii) sheet, film or other material which cannot be filled or for which it is impracticable to estimate the relationship between the surface area of that material and the quantity of food in contact with that surface area.

(6) A plastic material or article manufactured from any monomer in respect of which column 4 of the relevant section of Part I of Schedule 1 expresses a migration limit of mg/kg shall not be considered capable of transferring constituents of that monomer to food with which that plastic material or article may come into contact in quantities exceeding the appropriate limit in paragraph (5) of this regulation if the only food which that plastic material or article may come into contact with is food to which regulation 7(3) applies.

(7) 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) of this regulation because it was manufactured with any monomer (whether or not of good technical quality) other than one identified in the relevant section of Part I of Schedule 1, it shall be a defence for the person charged to prove that—

- (a) each such monomer is present in the finished plastic material as an impurity, a reaction intermediate or a decomposition product which falls within paragraph 3(a) of Annex II to the Directive,
- (b) each such monomer is an oligomer or a natural or synthetic macromolecular substance or a mixture thereof which falls within paragraph 3(b) of that Annex, or
- (c) each such monomer falls within either sub-paragraph (a) or sub-paragraph (b) above,

and does not contravene paragraph 4 of that Annex.

(8) Part II of Schedule 1 shall have effect to supplement this regulation and Part I of Schedule 1.

Restriction on manufacture with additives

5.—(1) Subject to the following paragraphs of this regulation, no person shall use in the manufacture of plastic materials or articles any prohibited additive, that is to say an additive identified by PM/REF No., CAS No. (if any) and name respectively in columns 1, 2 and 3 of Part I of Schedule 2 which is not of good technical quality.

(2) In any proceedings for an offence under these Regulations, where it is alleged that the commission of the offence is due to the manufacture of a plastic material or article with any additive identified in Part I of Schedule 2 which is not of good technical quality, it shall be a defence for the person charged 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.

(3) Part II of Schedule 2 shall have effect to supplement this regulation and Part I of Schedule 2.

Method of testing capability of transferring constituents

6.—(1) For the purposes of these Regulations, a plastic material or article shall be treated as being capable of transferring constituents to food with which it may come into contact to the extent that it is established for those purposes—

- (a) in any case other than one to which sub-paragraph (b) below relates, by the verification methods specified in Schedules 3 and 4;
- (b) in any case where the extent to which vinyl chloride, as identified in Section A of Part I of Schedule 1, is capable of such transfer falls to be established, by the method referred to in regulation 14(2) of the 1987 Regulations.

(2) In Schedules 3 and 4, references to migration or release of a substance shall 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) In paragraph (1)(a) above analytical tolerances, as referred to in paragraph 8 of Schedule 3, shall be treated as included among verification methods.

Transfer of constituents

7.—(1) No plastic material or article shall be capable of transferring its constituents to food with which it may come into contact in quantities exceeding the appropriate limit.

(2) For the purposes of this regulation a plastic material or article shall not be considered capable of transferring its constituents to food with which it may come into contact, in quantities exceeding the appropriate limit, if the only food which that plastic material or article may come into contact with is food to which paragraph (3) below applies.

(3) This paragraph applies to food which is specified in the Table to Part IV of Schedule 4 where there is no “X” placed anywhere in the group of columns headed “Simulants to be used” opposite that food.

(4) For the purposes of this regulation the appropriate limit is—

- (a) an overall migration limit of 60 milligrams of constituents released per kilogram of food in the case of any plastic material or article comprising—
 - (i) an article which is a container or is comparable to a container or which 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;
 - (iii) a cap, gasket, stopper or similar device for sealing, and
- (b) in the case of any other plastic material or article, an overall migration limit of 10 milligrams per square decimetre of the surface area of the plastic material or article.

(5) In any proceedings for an offence under these Regulations an element of which is that a plastic material or article does not comply with this regulation the defences in paragraph 6(2) and 7(2) of Schedule 3 shall be available as specified therein.

Labelling

8.—(1) Subject to paragraph (2) of this regulation, at marketing stages other than the retail stage a person who is in possession of any plastic material or article which is intended to come into contact with food shall ensure that that plastic material or article is accompanied by a written declaration attesting that it complies with the legislation applicable to it.

(2) Paragraph (1) of this regulation shall not apply to a person in possession of any plastic material or article which by its nature is clearly intended to come into contact with food.

Enforcement

9.—(1) Each authority which is the enforcement authority for the 1987 Regulations shall enforce and execute in its area the provisions of these Regulations.

(2) Nothing in this regulation shall be taken as authorising in Scotland an enforcement authority to institute proceedings for an offence against these Regulations.

Offences

10.—(1) Any person who contravenes or fails to comply with regulation 3, 4(1), 5(1) or 8 shall be guilty of an offence.

(2) Any person who—

- (a) intentionally obstructs any person acting in the execution of these Regulations, or
- (b) without reasonable cause, fails to give to any person acting in the execution of these Regulations any assistance or information which that person may reasonably require of him for the performance of his functions under these Regulations, shall be guilty of an offence.

(3) Nothing in paragraph (2)(b) of this regulation shall be construed as requiring any person to answer any question or give any information if to do so might incriminate him.

(4) Any person who, in purported compliance with any such requirement as is mentioned in paragraph (2)(b) of this regulation—

- (a) furnishes information which he knows to be false or misleading in a material particular, or
- (b) recklessly furnishes information which is false or misleading in a material particular, shall be guilty of an offence.

(5) 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, and in Scotland, any partner of a partnership, or
- (b) any person who was purporting to act in any such capacity,

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

(6) For the purposes of paragraph (5) of this regulation “body corporate” shall in Scotland include a partnership.

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

(8) In any proceedings for an offence under these Regulations it shall, subject to paragraph (12) below, be a defence for the person charged to prove that he took all reasonable precautions and exercised all due diligence to avoid the commission of the offence by himself or by a person under his control.

(9) Without prejudice to the generality of paragraph (8) of this regulation, a person charged with an offence under these Regulations who neither—

- (a) prepared the plastic material or article in respect of which the offence is alleged to have been committed, nor
- (b) imported it into Great Britain,

shall be taken to have established the defence provided by that paragraph if he satisfies the requirements of paragraph (10) or (11) of this regulation.

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

- (a) that the commission of the offence was due to an act or default of another person who was not under his control, or to reliance on information supplied by such a person;
 - (b) that he carried out all such checks of the plastic material or article in question as were reasonable in all the circumstances, or that it was reasonable in all the circumstances for him to rely on checks carried out by the person who supplied the plastic material or article to him; and
 - (c) that he did not know and had no reason to suspect at the time of the commission of the alleged offence that his act or omission would amount to an offence under these Regulations.
- (11) A person satisfies the requirements of this paragraph if the offence is one of sale and he proves—
- (a) that the commission of the offence was due to an act or default of another person who was not under his control, or to reliance on information supplied by such a person;
 - (b) that the sale of which the alleged offence consisted was not a sale under his name or mark; and
 - (c) that he did not know, and could not reasonably have been expected to know, at the time of the commission of the alleged offence that his act or omission would amount to an offence under these Regulations.
- (12) If in any case the defence provided by paragraph (8) of this regulation involves the allegation that the commission of the offence was due to an act or default of another person, or to reliance on information supplied by another person, the person charged shall not, without leave of the court, be entitled to rely on that defence unless—
- (a) at least seven clear days before the hearing, and
 - (b) where he has previously appeared before a court in connection with the alleged offence, within one month of his first such appearance,
- he has served on the prosecutor a notice in writing giving such information identifying or assisting in the identification of that other person as was then in his possession, and in this paragraph any reference to appearing before a court shall be construed as including a reference to being brought before a court.
- (13) Any person guilty of an offence under these Regulations shall be liable on summary conviction to a fine not exceeding the statutory maximum or to imprisonment for a term not exceeding three months or to both and on conviction on indictment to a fine or to imprisonment for a term not exceeding two years or both.
- (14) No prosecution for an offence under these Regulations shall be begun after the expiry of—
- (a) three years from the commission of the offence; or
 - (b) one year from its discovery by the prosecutor,
- whichever is the earlier.

Presumption as to food with which a plastic material or article is to come into contact

11. In establishing which descriptions of food a plastic material or article may come into contact with it shall be assumed for the purposes of these Regulations, until the contrary is proved, that, if particulars are shown in relation to that plastic material or article in accordance with the 1987 Regulations, those particulars are accurate and that, unless the particulars so indicate, there are no restrictions on the intended conditions of contact.

Application of other provisions

12.—(1) The following provisions of the 1987 Regulations shall apply in relation to plastic materials or articles as they apply to materials and articles for the purposes of those Regulations, as if those provisions formed part of these Regulations—

- (a) regulation 12 (powers of authorised officers);
- (b) regulation 13 (analysis, examination and testing);
- (c) regulation 16 (confidentiality);
- (d) regulation 17 (authorised officer acting in good faith);
- (e) regulation 20 (evidence of analysis); and
- (f) regulation 21 (analysis by Government chemist).

(2) Section 3(4) of the Act (relating to the presumption of intention for human consumption) shall apply for the purposes of these Regulations as it applies for the purposes of the Act.

(3) Sections 29 and 30 of the Act (which deal with procurement and analysis of samples) shall, in so far as they relate to plastic materials or articles, be modified to the extent necessary to avoid restricting the scope of paragraph (1)(a), (b), (e) and (f) above.

Amendment of existing Regulations

13. In the Food Safety (Sampling and Qualifications) Regulations 1990(**11**) in Schedule 1 (provisions to which those Regulations do not apply) for the title and reference of the 1992 Regulations there shall be substituted the title and reference of these Regulations.

Revocation of existing Regulations

14. The 1992 Regulations, the Plastic Materials and Articles in Contact with Food (Amendment) Regulations 1995(**12**), the Plastic Materials and Articles in Contact with Food (Amendment) Regulations 1996(**13**) and the Plastic Materials and Articles in Contact with Food (Amendment) (No. 2) Regulations 1996(**14**) are hereby revoked.

28th May 1998

Jeff Rooker
Minister of State, Ministry of Agriculture,
Fisheries and Food

Signed by authority of the Secretary of State for Health

1st June 1998

Tessa Jowell
Minister of State for Public Health,
Department of Health

(11) [S.I. 1990/2463](#); relevant amending instruments is [S.I. 1995/360](#).

(12) [S.I. 1995/360](#).

(13) [S.I. 1996/694](#).

(14) [S.I. 1996/2817](#).

Signed by the authority of the Secretary of State for Wales

28th May 1998

Win Griffiths
Parliamentary Under Secretary of State, Welsh
Office

29th May 1998

Sam Galbraith
Parliamentary Under Secretary of State, Scottish
Office