STATUTORY RULES OF NORTHERN IRELAND

1998 No. 264

FOOD

Plastic Materials and Articles in Contact with Food Regulations (Northern Ireland) 1998

Made - - - -	*27th July 1998*
Coming into operation	*14th September 1998*

The Department of Health and Social Services for Northern Ireland, in exercise of the powers conferred on it by Articles 15(2), 16(1), 25(1)(*a*) and (3), 32 and 47(2) of the Food Safety (Northern Ireland) Order 1991(**1**) and, being a designated Department(**2**) for the purposes of section 2(2) of the European Communities Act 1972(**3**) in relation to materials and articles in contact with food or drink or intended for such contact, in exercise of the powers conferred on it by the said section 2(2) and of all other powers enabling it in that behalf and after consultation in accordance with Article 47(3) of the said Order with such organisations as appear to it to be representative of interests likely to be substantially affected by these Regulations (in so far as the Regulations are made in exercise of the said Order), hereby makes the following Regulations:

Citation and commencement

1. These Regulations may be cited as the Plastic Materials and Articles in Contact with Food Regulations (Northern Ireland) 1998 and shall come into operation on 14th September 1998.

Interpretation

2.—(1) In these Regulations—

"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;

"capable" means capable as established under regulation 6;

(**1**) S.I.1991/762 (N.I. 7) as amended by S.I. 1996/1633 (N.I. 12). *See* Article 2(2) for the definitions of "the Department concerned" and "regulations"
(**2**) S.I. 1976/2141
(**3**) 1972 c. 68

"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(**4**), as amended by Commission Directives 93/8/EEC(**5**) and 97/48/EC(**6**);

"the Directive" means Commission Directive (EEC) No. 90/128 relating to plastic materials and articles intended to come into contact with foodstuffs(**7**) (as corrected) and as amended by Commission Directives 92/39/EEC, 93/9/EEC. 95/3/EC and 96/11/EC(**8**);

"EEA Agreement" means the Agreement on the European Economic Area(**9**) signed at Oporto on 2nd May 1992 as adjusted by the Protocol(**10**) 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 Article 15(5) of the Order;

"good technical quality" means good technical quality as regards the purity criteria;

"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 Order" means the Food Safety (Northern Ireland) Order 1991;

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

"sell" includes offer or expose for sale or have in possession for sale;

"the 1987 Regulations" means the Materials and Articles in Contact with Food Regulations (Northern Ireland) 1987(**11**);

"the 1993 Regulations" means the Plastic Materials and Articles in Contact with Food Regulations (Northern Ireland) 1993(**12**).

(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), 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(**13**) has the same meaning as it bears in the Directive in which it appears.

(4) The Interpretation Act (Northern Ireland) 1954(**14**) shall apply to these Regulations as it applies to a Measure of the Northern Ireland Assembly.

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—

(**4**) O.J. No. L297, 23.10.82, p. 26
(**5**) O.J. No. L90, 14.4.93, p. 22
(**6**) O.J. No. L222, 12.8.97, p. 10
(**7**) O.J. No. L75, 21.3.90, p. 19
(**8**) Corrigendum in O.J. No. L349, 13.12.90, p. 26; amending Directives in O.J. No. L168, 23.6.92, p. 21, O.J. No. L90, 14.3.93, p. 26, O.J. No. L41, 23.2.95, p. 44 and O.J. No. L61, 12.3.96, p. 26
(**9**) O.J. No. L1, 3.1.94, p. 1
(**10**) O.J. No. L1, 3.1.94, p. 571
(**11**) S.R. 1987 No. 432; the relevant amending Regulations are S.R. 1991 Nos. 203 and 344 and S.R. 1994 No. 174
(**12**) S.R. 1993 No. 173; the relevant amending regulations are S.R. 1995 No. 107 and S.R. 1996 Nos 164 and 580
(**13**) O.J. No. L372, 30.12.85, p. 14
(**14**) 1954 c. 33 (N.I.)

(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—

(a) before 14th September 1998; and

(b) in accordance with regulation 4 of the 1993 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 Northern Ireland and sub-paragraph (*a*) would have applied to it had it been manufactured in Northern Ireland.

Restriction on manufacture with monomers

4.—(1) Subject to the following paragraphs, no plastic material or article shall be manufactured by any person with any prohibited 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) does not apply to the use of a monomer in the manufacture of any—

(a) surface coatings obtained from resinous or polymerized 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) 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), 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*); 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 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) 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) 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*)

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, 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*) 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*) 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) 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