

EUROPEAN COMMUNITIES (MATERIALS AND ARTICLES INTENDED TO COME INTO CONTACT WITH FOODSTUFFS) REGULATIONS 1991

I, DESMOND O'MALLEY, Minister for Industry and Commerce, in exercise of the powers conferred on me by section 3 of the European Communities Act, 1972 (No. 27 of 1972), and for the purpose of giving effect to Council Directive 78/142/EEC of 30 January, 1978(1), Commission Directive 80/590/EEC of 9 June 1980(2), Commission Directive 80/766/EEC of 8 July, 1980(3), Council Directive 82/711/EEC of 18 October, 1982(4), Council Directive 83/229/EEC of 25 April, 1983(5), Council Directive 84/500/EEC of 15 October, 1984(6), Council Directive 85/572/EEC of 19 December, 1985 (7), Commission Directive 86/388/EEC of 23 July 1986 (8), Council Directive 89/109/EEC of 21 December 1988(9) and Commission Directive 90/128/EEC of 23 February, 1990(10), hereby make the following Regulations:

- (1) O.J. No. L 44/15, 15.2.78.
- (2) O.J. No. L151/21, 19.6.80.
- (3) O.J. No. L213/42, 16.8.80.
- (4) O.J. No. L297/26, 23.10.82.
- (5) O.J. No. L123/31, 11.5.83.
- (6) O.J. No. L277/12, 20.10.84.
- (7) O.J. No. L372/14, 31.12.85.
- (8) O.J. No. L 228/32, 14.8.86.
- (9) O.J. No. L 40/38, 11.2.89.
- (10) O.J. No. L 75/19, 21.03.90.

REG 1

Citation, commencement and revocation.

1. (1) These Regulations may be cited as the European Communities (Materials and Articles intended to come into Contact with Foodstuffs) Regulations, 1991.
- (2) These Regulations shall come into operation on the 16th day of December 1991.
- (3) S.I. No. 60 of 1988 is hereby revoked.

REG 2

Interpretation.

2. (1) In these Regulations.

"antique" means any material or article which is a collector's piece of artistic, archaeological or ethnographic interest or any other material or article of age exceeding 100 years;

"approved examiner" means a person or body appointed by the Minister, the Minister for Finance or the Minister for Health under Regulation 10 of these Regulations for the purpose of these Regulations;

"authorised officer" means—

- (a) an officer of the Minister, or
- (b) an officer of the Director of Consumer Affairs, or
- (c) a person designated by the Minister for Finance or the Minister for Health, or
- (d) a person designated by the approved examiner, who is appointed by the Minister under Regulation 11 to be an authorised officer for the purposes of these Regulations;

"business" includes the undertaking of any club, canteen, school,

hospital or institution whether carried on for profit or not, and any undertaking or activity carried on by a public or local authority;

"Commission Directives" means Commission Directive 80/590/EEC, Commission Directive 80/766/EEC, Commission Directive 86/388/EEC and Commission Directive 90/128/EEC;

"Council Directive" means Council Directive 89/109/EEC;

"import" means import in the course of a business;

"materials and articles" means materials and articles to which the Council Directive, or any of the Specific Directives or any of the Commission Directives, and these Regulations apply;

"the Minister" means the Minister for Industry and Commerce;

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

"sell by retail" means sell to a person buying otherwise than for the purpose of resale, but does not include selling to a caterer for the purpose of his catering business or to a manufacturer for the purpose of his manufacturing business, and "sold by retail" shall be construed accordingly;

"Specific Directives" means Council Directive 78/142/EEC, Council Directive 82/711/EEC, Council Directive 83/229/EEC, Council Directive 84/500/EEC, Council Directive 85/572/EEC and Commission Directive 90/128/EEC;

"trade mark" means a trade mark which is recognised by law in any Member State of the European Economic Community.

(2) A word or expression that is used in these Regulations and is also used in the Council Directive or in any of the Specific Directives or in any of the Commission Directives has, unless the contrary intention appears, the same meaning in these Regulations as it has in the respective Directives.

(3) In these Regulations a reference to a paragraph is to the paragraph of the Regulation in which the reference occurs, unless reference to some other provisions is indicated.

REG 3

Application.

3. (1) These Regulations apply to materials and articles which—
- (a) in their finished state, are intended to come into contact with foodstuffs or which are in contact with foodstuffs and are intended for that purpose, or
 - (b) are in contact with water intended for human consumption.
- (2) These Regulations do not apply to—
- (a) any substance which being used as a covering or a coating for foodstuffs, such as the substances covering cheese rinds, prepared meat products or fruit, forms part of that foodstuff and may be consumed with it,
 - (b) any fixed public or private water supply equipment,
 - (c) antiques,
 - (d) any material or article which is intended for export outside the European Economic Community.

REG 4

General prohibitions.

4. No person shall—

- (a) manufacture,
- (b) sell,
- (c) import, or
- (d) use in the course of any business in connection with the storage, preparation, packaging, selling or serving of foodstuffs, any materials and articles to which these Regulations apply unless such materials and articles are manufactured in compliance with good manufacturing practice so that, under their normal or foreseeable conditions of use, they do not transfer their constituents to foodstuffs in quantities which could—
 - (i) endanger human health, or
 - (ii) bring about an unacceptable change in the composition of the foodstuffs or a deterioration in the organoleptic characteristics thereof.

REG 5

Labelling of materials and articles.

5. (1) A person shall not sell or import materials and articles not already in contact with foodstuffs unless they are accompanied by the following particulars—

- (a) a notice giving the description "for food use" or a notice giving the description "for food use" and "le haghaidh bia", or
- (b) a specific indication as to their use, such as a coffee-machine, wine bottle, soup spoon, or
- (c) a notice showing the symbol which is reproduced in the Annex to Commission Directive 80/590/EEC (being the symbol referred to in the last indent of Article 6 (1) (a) of the Council Directive), and—

- (i) where appropriate, an indication of any special conditions to be observed when the materials or articles are being used, and
- (ii) either—

- (I) the name or trade name and address or registered office, or
- (II) the registered trade mark, of the manufacturer or processor of the material or article, or a seller thereof established within the European Economic Community.

(2) Any particulars displayed pursuant to this Regulation shall be deemed not to comply with this Regulation unless such particulars are easily visible, clearly legible and indelibly shown—

(a) at the retail stage—

- (i) on the materials and articles or on their packaging, or

- (ii) on labels affixed to the materials and articles or to their packaging, or

- (iii) on a sign in the immediate vicinity of the materials and articles and clearly visible to purchasers, but this option shall apply in the case of a notice displayed pursuant to clause (ii) of paragraph (1) only if the relevant particulars or a label bearing them cannot for technical reasons be affixed to the materials and articles or to its packaging at either the manufacturing or marketing stage, and

(b) at the marketing stages other than the retail stage or at the importation stage—

(i) on the materials and articles themselves or on their packaging, or

(ii) on labels affixed to the materials and articles or to their packaging, or

(iii) on the accompanying documents.

(3) A person shall not sell by retail materials and articles in the State if the particulars required under subparagraphs (a) or (b) and, where appropriate, clause (i) of paragraph (1) are not shown on a label, packaging or sign on the materials and articles, or a sign in the vicinity of the materials and articles, in English or English and Irish.

(4) Subparagraphs (a), (b) and (c) of paragraph (1) shall not apply to materials and articles sold by retail in the State where such materials and articles are by their nature clearly intended to come into contact with foodstuffs.

(5) A person shall not sell or import any materials and articles accompanied by the information required by such paragraphs (a), (b) and (c) and, where appropriate, clause (i) of paragraph (1) unless, where any of the specific Directives apply to such materials or articles, they comply with the specific Directives, and in any other case comply with the provisions of Regulation 4 of these Regulations.

REG 6

Vinyl chloride monomer.

6. (1) No person shall—

(a) manufacture,

(b) sell,

(c) import, or

(d) use in the course of any business in connection with the storage, preparation, packaging, selling or serving of foodstuffs, any materials and articles prepared with vinyl chloride polymers or copolymers and which contain vinyl chloride monomer in a quantity exceeding 1 milligram per kilogram of the material or article, being the quantity laid down by Council Directive 78/142/EEC.

(2) The analysis necessary for the control of the vinyl chloride monomer level in materials and articles shall be performed according to the method of analysis described in the Annex to Commission Directive 80/766/EEC so as to ensure conformity with the criteria specified in annex II to council Directive 78/142/EEC.

REG 7

Regenerated cellulose film.

7. (1) This Regulation applies to regenerated cellulose film within the meaning of the description given to it in Annex I to council Directive 83/229/EEC which either—

(a) constitutes a finished product in itself, or

(b) is part of a finished product containing other materials and is intended to or, in accordance with its purpose, comes into contact with foodstuffs.

(2) This Regulation does not apply to—

- (a) regenerated cellulose film which, on the side intended to or, which in accordance with its purpose comes into contact with foodstuffs, has a coating exceeding 50 milligrams per square decimetre;
- (b) synthetic casings of regenerated cellulose.
- (3) Subject to paragraph (4), no person shall—
 - (a) manufacture,
 - (b) sell,
 - (c) import, or
 - (d) use in the course of any business in connection with the storage, preparation, packaging selling or serving of foodstuffs, regenerated cellulose film unless—
 - (i) only those substances or groups of substances listed in Annex II to Council Directive 83/229/EEC are used in the manufacture of the regenerated cellulose film, and
 - (ii) the regenerated cellulose film is manufactured under the conditions in the said Annex.
- (4) A person may use substances other than those listed in the said Annex II when these substances are employed as colouring matter (dyes and pigments) or as adhesives provided there is no trace of migration of the substances into or onto the foodstuffs.
- (5) A person shall not permit printed surfaces of regenerated cellulose film to come into contact with foodstuffs.

REG 8

Ceramic articles.

- 8. (1) In this Regulation "ceramic articles" has the meaning assigned to it by article 1.3 of Council Directive 84/500/EEC.
- (2) No person shall—
 - (a) manufacture,
 - (b) sell,
 - (c) import, or
 - (d) use in the course of any business in connection with the storage, preparation, packaging, selling or serving foodstuffs, ceramic articles which in their finished state are intended to come into contact with foodstuffs or which are in contact with foodstuffs and are intended for that purpose, and which transfer to foodstuffs a quantity of lead or cadmium in excess of the limits laid down by Article 2.4 of Council Directive 84/500/EEC.
- (3) The quantities of lead and cadmium transferred from ceramic articles shall be determined by means of a test, the conditions of which are specified in Annex I to Council Directive 84/500/EEC, using the method of analysis described in Annex II to the said Council Directive.
- (4) Where a ceramic article consists of a vessel fitted with a ceramic lid, the lead or the cadmium limit which may not be exceeded shall be that which applies to the vessel alone and, for the purpose of calculating the lead or cadmium release from the vessel, the vessel alone and the inner surface of the lid shall be tested separately and under the same conditions and the sum of the two lead or cadmium extraction levels thus obtained shall be related as appropriate to the surface area or the volume of the vessel alone.

REG 9

Plastics.

9. (1) This Regulation applies to plastic materials and articles, that is to say, to materials and articles and parts thereof:

- (a) consisting exclusively of plastics, or
 - (b) composed of two or more layers of materials, each consisting exclusively of plastics, which are bound together by means of adhesives or by any other means,
- which, in their finished state are intended to come into contact with foodstuffs or are brought into contact with foodstuffs and are intended for that purpose.

(2) In this Regulation "plastics" means the organic macromolecular compounds obtained by polymerization, polycondensation, polyaddition or any other similar process from molecules with a lower molecular weight or by chemical alteration of natural macromolecules. Silicones and other similar macromolecular compounds shall also be regarded as plastics. Other substances or matter may be added to such macromolecular compounds.

However, the following shall not be regarded as "plastics":

- (i) varnished or unvarnished regenerated cellulose film;
- (ii) elastomers and natural and synthetic rubber;
- (iii) paper and paperboard, whether modified or not by the addition of plastics;
- (iv) surface coatings obtained from:
 - paraffin waxes, including synthetic paraffin waxes, and/or micro-crystalline waxes;
 - mixtures of the waxes listed in the first indent with each other and/or with plastics;
- (v) ion-exchange resins.

(3) This Regulation shall not apply to—
materials and articles composed of two or more layers, one or more of which does not consist exclusively of plastics, even if the one intended to come into direct contact with foodstuffs does consist exclusively of plastics.

(4) Before 1 January 1993 a person shall use in the manufacture of plastic materials and articles only those monomers and other starting substances listed in Annex II Sections A and B to Directive 90/128/EEC.

(5) From 1 January 1993 a person shall use in the manufacture of plastic materials and articles only those monomers and other starting substances listed in Annex II Section A to Directive 90/128/EEC.

(6) For the purposes of paragraphs (4) and (5) plastic materials and articles do not include—

- surface coatings obtained from resinous or polymerised products in liquid, powder or dispersion form, such as varnishes lacquers, paints etc.,
- silicones,
- epoxy resins,
- products obtained by means of bacterial fermentation,
- adhesives and adhesion promoters,
- printing inks.

(7) No person shall—

- (a) manufacture,
- (b) sell,
- (c) import, or
- (d) use in the courses of any business in connection with the storage, preparation, packaging, selling or serving of foodstuffs, any plastic materials and articles which transfer their constituents to foodstuffs—
 - (i) in quantities exceeding 10 milligrams per square decimetre of surface area of material or article (mg/dm²) (overall migration limit) except in the following cases where the limit shall be 60 milligrams of the constituents released per kilogram of foodstuffs (mg/kg)—
 - (I) articles which are containers or are comparable to containers or which can be filled, with a capacity of not less than 500 millilitres (ml) and not more than 10 litres (l);
 - (II) articles which can be filled and for which it is impracticable to estimate the surface area in contact with foodstuffs;
 - (III) caps, gaskets, stoppers or similar devices for sealing, or
 - (ii) in quantities exceeding the specific migration limits set out in the list in Annex II to Directive 90/128/EEC.
- (8) In the following cases the specific migration limits set out in Annex II to Directive 90/128/EEC, expressed in mg/kg, shall be divided by the conventional conversion factor of 6 in order to express them in mg/dm².
 - (a) articles which are containers or are comparable to containers or which can be filled, with a capacity of less than 500 ml or more than 10 l;
 - (b) sheet, film or other materials which cannot be filled or for which it is impracticable to estimate the relationship between the surface area of such materials and the quantity of foodstuff in contact therewith.
- (9) The simulants, and the concentration of the simulants, to be used for testing migration of the constituents of plastic materials and articles—
 - (i) intended to come into contact with foodstuffs of all types — shall be those indicated in Chapter I.1. of the Annex to Directive 82/711/EEC,
 - (ii) intended to come into contact with a single foodstuff or specific group of foodstuffs — shall be as indicated in the Annex to Directive 85/572/EEC.
- (10) Verification of compliance with the migration limits shall be carried out in accordance with the rules laid down in Directives 82/711/EEC, 85/572/EEC and Directive 90/128/EEC Annex I.
- (11) The verification of compliance with the specific migration limits provided for in paragraph (10) shall not be compulsory, if it can be established that compliance with the overall migration limit provided for in paragraph 7 (i) implies that the specific migration limits are not exceeded.
- (12) No person shall place on the market other than at the retail stages plastic materials and articles unless they are accompanied by a written declaration attesting that they comply with the provisions of these Regulations.
- (13) Paragraph (12) of this Regulation does not apply to plastic materials and articles which by their nature are clearly intended to

come into contact with foodstuffs.

(14) From 1 January 1993 a person shall not engage in trade in, or in use of, plastic materials and articles unless they comply with the provisions of this Regulation.

REG 10

Approved examiners.

10. The Minister, the Minister for Finance or the Minister Approved for Health may appoint a person or body to be an approved examiner for the purposes of these Regulations.

REG 11

Authorised officers.

11. (1) The Minister may appoint persons to be authorised officers for the purposes of these Regulations and may revoke such appointment.

(2) An authorised officer shall be furnished with a warrant of his appointment and when exercising any power to which the provisions of these Regulations apply shall, if so required, produce the warrant to any person affected.

REG 12

Powers of authorised officers.

12. (1) An authorised officer may, on production of the authorisation of the officer if so required—

(a) enter, inspect, examine and search at all reasonable times—

(i) any premises which he has reasonable cause to believe are being used for or in connection with the manufacture, storage, packing or sale of any materials and articles,

(ii) any ship or other vessel, aircraft or railway wagon or other vehicle in or on which he has reasonable cause to believe any materials and articles are present;

(b) in case he enters any premises, ship or other vessel, aircraft or railway wagon or other vehicle pursuant to this Regulation—

(i) require the person who appears to be in charge of the premises, ship or other vessel, aircraft or railway wagon or other vehicle to produce any materials and articles which are in his possession or under his control;

(ii) require such person, or any such person employed in or on such premises, ship or other vessel, aircraft or railway wagon or other vehicle, to produce any books, records or other documents which relate to transactions concerning any materials and articles which are in his possession or under his control;

(iii) inspect any materials and articles and any book, record or other document produced in pursuance of a requirement under this Regulation and, if he thinks fit, copy any such entry in such book, record or document;

(iv) take such samples of any materials and articles and of any foodstuff which has come into contact with such materials and articles as he may consider appropriate;

(c) make such examination or inquiry as may be necessary to ascertain whether these Regulations are being complied with.

(2) An authorised officer may take with him a member of the Garda Síochána if he has reasonable cause to apprehend any serious obstruction in the exercise of his duty.

(3) A person in charge of any premises, ship or other vessel, aircraft, railway wagon or other vehicle shall—

(a) afford to the authorised officer such facilities and assistance as are reasonably necessary to enable the officer to perform his functions under this Regulation;

(b) produce to an authorised officer any books, documents or other records which he may reasonably require;

(c) give to an authorised officer any information which he may reasonably require regarding—

(i) any materials and articles or any foodstuffs which have come into contact with such materials and articles on the premises, ship or other vessel, aircraft, railway wagon or other vehicle,

(ii) any books, documents or other records produced to him pursuant to this Regulation.

(4) A person shall not obstruct or impede an authorised officer in the exercise of a power conferred on him by this Regulation and shall comply with a requirement made by an authorised officer under this Regulation.

REG 13

Testing of Ceramic articles.

13. (1) In this Regulation—

"an article" means a ceramic article selected from a group of ceramic articles of a particular shape, dimension, decoration and glaze and "articles" shall be construed accordingly;

"the Directive" means Council Directive 84/500/EEC;

"limits" means the limits set by Article 2.4 of the Directive;

"the owner" includes a person appearing to be authorised by the owner;

"test" means a test carried out under the conditions laid down in Annexes I and II to the Directive.

(2) Where, upon a test being made on any article (being an article taken by an authorised officer under Regulation 12 (1) (b) (iv) of these Regulations), the quantity of lead or cadmium extracted from such article does not exceed the limits by more than 50 per cent, paragraph (3) of this Regulation shall apply.

(3) The authorised officer referred to in paragraph (2) shall request the owner of an article to select three other articles from the same group as the first article taken by the said authorised officer and if, on a test being made on the said three articles, the average quantity of lead or cadmium extracted from the said three articles does not exceed the limits with none of the articles exceeding those limits by more than 50 per cent, then, all the articles in the group from which the four articles were taken for sampling shall be deemed to satisfy the provisions of the Directive.

REG 14

Samples and reports.

14. (1) Where a sample is taken pursuant to these Regulations by an authorised officer he may submit such a sample to an approved examiner.

(2) The approved examiner shall submit a report to the authorised officer specifying the results of the examination, analysis or test made by the approved examiner.

REG 15

Fees.

15. (1) An approved examiner may charge a fee (the "appropriate fee") which shall be equal to the amount of costs which the approved examiner estimates he will incur in, or in connection with, carrying out or causing to be carried out the functions referred to in these Regulations.

(2) Where the costs incurred are greater than the appropriate fee, the difference between those costs and that fee shall be payable by the manufacturer or his authorized representative to the approved examiner in the State, and where those costs are less than the appropriate fee, the difference between those costs and that fee shall be repayable by the approved examiner to the manufacturer or his authorized representative, as the case may be.

REG 16

Offences.

16. (1) Any person who contravenes Regulation 4, 5 (1), 5 (3), 5 (5), 6, 7 (3), 7 (5), 8 (2), 9 (4), 9 (5), 9 (7), 9 (10), 9 (12), 9 (14), 12 (3) or 12 (4) of these Regulations shall be guilty of an offence under these Regulations.

(2) A person guilty of an offence under these Regulations shall be liable on summary conviction to a fine not exceeding £1,000, or at the discretion of the Court to imprisonment for a term not exceeding six months or to both such fine and such imprisonment.

(3) Where an offence under these Regulations is committed by a body corporate and the offence is proved to have been committed with the consent or connivance of, or to be attributable to any neglect on the part of, any person (or any person acting on his behalf) being a director, manager, secretary, member of the committee of management or other controlling authority of any such body or being any other similar officer of any such body, that person or the person so acting as the case may be shall also be guilty of an offence and shall be liable to be proceeded against and punished accordingly.

(4) Notwithstanding section 10 (4) of the Petty Sessions (Ireland) Act, 1851, proceedings for an offence under these Regulations may be instituted—

(a) in respect of manufacturing a material or article in contravention of a provision of these Regulations, at any time subsequent to its manufacture, and

(b) in respect of all other cases, within 18 months from the date of the offence.

REG 17

17. A prosecution under these Regulations may be brought by the Minister.

GIVEN under my Official Seal, this 3rd day of December 1991.
DESMOND O'MALLEY,
Minister for Industry and Commerce.

EXPLANATORY NOTE.

The purpose of these Regulations is to give legal effect to EEC Directives on the approximation of the laws of the Member States relating to materials and articles intended to come into contact with foodstuffs and also for the administration and enforcement of the regulations.