No. 432

1987 No. 432

FOOD AND DRUGS

Materials and Articles in Contact with Food Regulations (Northern Ireland) 1987

Made	•	•	•	•	•	24th November 1987
Coming in	to oper	ration				31st December 1987

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The Department of Health and Social Services for Northern Ireland, being a designated Department(**a**) for the purposes of section 2(2) of the European Communities Act 1972(**b**) 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 every other power enabling it in that behalf, hereby makes the following regulations:—

PART I

PRELIMINARY

Citation and commencement

1. These regulations may be cited as the Materials and Articles in Contact with Food Regulations (Northern Ireland) 1987 and shall come into operation on 31st December 1987.

⁽a) Designated by S.I. 1976/2141

 ⁽b) 1972 c. 68; section 2 is subject to Schedule 2 to the Act and is to be read, as respects Northern Ireland, with Article 8 of the Fines and Penalties (Northern Ireland) Order 1984 (S.I. 1984/703 (N.I. 3)). The Fines and Penalties (Northern Ireland) Order 1984 is itself subject to the Criminal Penalties etc. (Increase) Order (Northern Ireland) 1984 (S.R. 1984 No. 253)

Interpretation

- **2.**—(1) In these regulations—
- "authorised officer" means an officer of a district council, authorised by that council in writing, either generally or specially, to act in matters of any specified kind or in any specified matter;
- "business" includes the undertaking of a canteen, club, school, hospital or institution, whether carried on for profit or not, and any undertaking or activity carried on by a district council or other public authority;
- "Department" means the Department of Health and Social Services for Northern Ireland;
- "food" means food intended for human consumption and includes drink, water, natural mineral water, chewing gum and other products of a like nature and use, and articles and substances used as ingredients in the preparation of food, but does not include—
 - (a) live animals or birds,
 - (b) fodder or feeding stuffs for animals, birds or fish, or
 - (c) articles or substances used only as drugs;
- "import" means import in the course of a business;
- "preparation" in relation to food, includes manufacture and any form of treatment or process;
- "public analyst" has the meaning assigned to it by section 31 of the Food and Drugs Act (Northern Ireland) 1958(a);
- "regenerated cellulose film" means a thin sheet material obtained from refined cellulose derived from unrecycled wood or cotton, with or without the addition of suitable substances, either in the mass or on one or both surfaces;
- "registered trade mark" means a trade mark which has effect in any member state of the European Economic Community and is duly registered in accordance with the laws of that state;
- "sell" includes offer or expose for sale or have in possession for sale;
- "sell by retail" means sell to a person buying otherwise than for the purpose of re-sale, but does not include selling to a caterer for the purposes of his catering business or to a manufacturer for the purposes of his manufacturing business;
- "ship" includes any boat or craft, and for this purpose "craft" includes hovercraft.

(2) The Interpretation Act (Northern Ireland) 1954(**b**) shall apply to these regulations as it applies to a Measure of the Northern Ireland Assembly.

Exemptions

3. The provisions of these regulations shall not apply to—

(a) any fixed public or private water supply equipment;

(b) 1954 c. 33 (N.I.)

⁽a) 1958 c. 27 (N.I.); the relevant amending instruments are S.R. & O. (N.I.) 1973 No. 211 and S.I. 1985/1208 (N.I. 15)

- (b) any substance which, being used as a covering or coating for a food, forms part of that food and may be consumed with it, including such a substance used as covering or coating for cheese rind or prepared meat products;
- (c) any material or article intended for export to any place outside the United Kingdom;
- (d) any material or article which is a collector's piece of artistic, archaeological or ethnographic interest or to any other material or article of an age exceeding 100 years.

Part II

Composition and Labelling of Materials and Articles

Sale etc. of materials and articles

4.—(1) This regulation shall apply to materials and articles which are in their finished state and are intended to come into contact with food or which are in contact with food and are intended for that purpose.

(2) Materials and articles to which this regulation applies shall be manufactured in accordance with good manufacturing practice, that is to say in such a way that under normal or foreseeable conditions of use they do not transfer their constituents to foods with which they are, or are likely to be, in contact, in quantities which could—

- (a) endanger human health, or
- (b) bring about a deterioration in the organoleptic characteristics of such food or an unacceptable change in its nature, substance or quality.
- (3) A person shall not—
- (a) sell,
- (b) import, or
- (c) use in the course of a business in connection with the storage, preparation, packaging, selling or serving of food,

any such material or article which does not comply with this regulation.

Vinyl chloride monomer

5.—(1) Materials and articles to which regulation 4 applies and which are manufactured with vinyl chloride polymers or copolymers—

- (a) shall not contain vinyl chloride monomer in a quantity exceeding 1 milligram per kilogram of the material or article as measured by the method of analysis specified in regulation 14(1); and
- (b) shall be manufactured in such a way that they do not transfer to foods with which they are in contact any quantity of vinyl chloride exceeding 0.01 milligrams of vinyl chloride per kilogram of food as measured by the method of analysis specified in regulation 14(2).
- (2) A person shall not—

(a) sell,

- (b) import, or
- (c) use in the course of a business in connection with the storage, preparation, packaging, selling or serving of food,

any such material or article which does not comply with this regulation.

Regenerated cellulose film

6.—(1) Subject to paragraph (2), this regulation shall apply to regenerated cellulose film which—

(a) constitutes a finished product in itself; or

(b) is a part of a finished product containing other materials,

and is intended to come into contact with food or is in contact with food and is intended for that purpose.

(2) This regulation shall not apply to-

- (a) regenerated cellulose film which has a coating exceeding 50 milligrams per square decimetre of film on the side intended to come into contact with food;
- (b) synthetic casings of regenerated cellulose.

(3) Regenerated cellulose film to which this regulation applies shall not be manufactured with any substance or group of substances other than the substances named or described in Schedule 1--

(a) in column 1 of Part I, in the case of uncoated film; or

(b) in column 1 of Part II, in the case of coated film,

and used in accordance with the conditions and restrictions specified in the corresponding entry in column 2 of the appropriate Part of Schedule 1, as read with footnotes 1 and 2 to that Schedule.

(4) Regenerated cellulose film to which this regulation applies shall be manufactured in such a way that it does not transfer any adhesive or colourant to food.

(5) Coated regenerated cellulose film to which this regulation applies shall be manufactured in such a way that it does not transfer bis (2-hydroxyethyl) ether, ethanediol or both these substances to food in a quantity exceeding 50 milligrams per kilogram of food.

(6) A person shall not—

- (b) import, or
- (c) use in the course of a business in connection with the storage, preparation, packaging, selling or serving of food,

any such regenerated cellulose film which does not comply with this regulation.

(7) A person shall not use in the course of a business in connection with the storage, preparation, packaging, selling or serving of food—

(a) containing water physically free at the surface, any coated regenerated cellulose film to which this regulation applies and which contains bis (2-hydroxyethyl) ether, ethanediol or both these substances;

⁽a) sell,

(b) any regenerated cellulose film to which this regulation applies in such a way that any printed surface of that regenerated cellulose film comes into contact with the food.

Labelling etc. of materials and articles sold by retail

7.—(1) The following particulars shall be shown with any material or article which, being in its finished state, is intended to come into contact with food but is not already in contact with food when such material or article is sold by retail—

- (a) unless the material or article is by its nature clearly intended to come into contact with food—
 - (i) the description "for food use",
 - (ii) a specific indication of the particular use for which the material or article is intended, or
 - (iii) the symbol that appears in Schedule 2;
- (b) any special conditions to be observed when the material or article is being used; and

(c) 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 of a seller thereof established within the European Economic Community.

- (2) Such particulars shall be shown clearly, legibly and indelibly-
- (a) on the material or article or on its packaging;
- (b) on a label affixed to the material or article or to its packaging; or
- (c) on a sign which is in the immediate vicinity of the material or article and is clearly visible to purchasers, but the particulars mentioned in paragraph (1)(c) shall appear on such a sign only if it was not reasonably practicable for such particulars, or a label bearing them, to be marked on, or affixed to, the material or article or to its packaging at the time of manufacture or sale.

(3) A person shall not sell by retail any such material or article, unless the particulars mentioned in paragraph (1) are shown in the manner required by paragraph (2).

Labelling etc. of materials and articles sold otherwise than by retail

8.—(1) The following particulars shall be shown with any material or article which, being in its finished state, is intended to come into contact with food but is not already in contact with food when such material or article is sold otherwise than by retail or is imported—

- (a) (i) the description "for food use",
 - (ii) a specific indication of the particular use for which the material or article is intended, or
 - (iii) the symbol that appears in Schedule 2;
- (b) any special conditions to be observed when the material or article is being used; and

(c) 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 of a seller thereof established within the European Economic Community.

(2) Such particulars shall be shown clearly, legibly and indelibly—

(a) on the material or article or on its packaging;

(b) on a label affixed to the material or article or to its packaging; or

(c) in the accompanying documents.

(3) A person shall not sell otherwise than by retail or import any such material or article, unless the particulars mentioned in paragraph (1) are shown in the manner required by paragraph (2).

Restrictions on indications of suitability for food use

9.—(1) A person shall not sell any material or article under the description "for food use" or under any other description directly or indirectly leading a purchaser to believe that he is purchasing a material or article suitable for use with food, unless that material or article complies with the provisions of regulation 4(2) and, if applicable, of regulation 5(1) or of regulation 6(3), (4) and (5).

(2) A person shall not sell any material or article in relation to which the symbol that appears in Schedule 2 or any symbol substantially similar thereto is used, unless that material or article complies with the provisions of regulation 4(2) and, if applicable, of regulation 5(1) or of regulation 6(3), (4) and (5).

(3) A person shall not publish, or be a party to the publication of, an advertisement for a material or article in which a description of the kind mentioned in paragraph (1) is used, or in which the symbol that appears in Schedule 2 or any symbol substantially similar thereto is used unless the material or article to which the advertisement relates complies with the requirements of regulation 4(2) and, if applicable, of regulation 5(1) or of regulation 6(3), (4) and (5).

(4) In any proceedings brought under paragraph (3) against the manufacturer, producer or importer of any material or article or of any food it shall rest on the person charged to prove that he did not publish, and was not party to the publication of, the advertisement.

(5) In any proceedings brought under paragraph (3) it shall be a defence for the person charged to prove that, being a person whose business it is to publish, or arrange for the publication of, advertisements, he received the advertisement for publication in the ordinary course of business and did not know and had no reason to suspect that its publication would amount to an offence under this regulation.

(6) Where a person sells a material or article to a purchaser in response to a request in which a description of the kind mentioned in paragraph (1) is used, he shall be deemed to have sold that material or article under that description, unless he clearly notifies the purchaser at the time of sale that the material or article is not suitable for use with food.

Materials and articles as prizes etc.

10.—(1) Regulations 4, 5, 6, 7 and 9 shall apply to—

- (a) any material or article which is offered as a prize or reward in connection with any entertainment to which the public are admitted, whether on payment of money or not, as if the material or article were, or had been, exposed for sale by each person concerned in the organisation of the entertainment;
- (b) any material or article which is offered as a prize or reward or given away for the purpose of advertisement, or in furtherance of any trade or business, as if the material or article were, or had been, exposed for sale by the person offering or giving away the material or article; and
- (c) any material or article which is exposed or deposited in any premises for the purpose of being so offered or given away as aforesaid, as if the material or article were, or had been, exposed for sale by the occupier of the premises.

(2) In this regulation, the expression "entertainment" includes any social gathering, amusement, exhibition, performance, game, sport or trial of skill.

Part III

Administration and Enforcement

Enforcement authorities

11. Each district council shall enforce and execute the provisions of these regulations in its district.

Powers of authorised officers

12. An authorised officer may at all reasonable hours and on producing, if so required, some duly authenticated document showing his authority, exercise the following powers, that is to say—

(a) he may, for the purposes of ascertaining whether any offence under these regulations has been committed, inspect any materials or articles and enter---

(i) any premises, other than premises used only as a dwelling, or (ii) any ship, aircraft or vehicle;

- (b) if he has reasonable cause to suspect that an offence under these regulations has been committed he may require any person carrying on a trade or business, or employed in connection with a trade or business, to produce any books or documents relating to the trade or business, and he may take copies of any such book or document, or of any entry in any such book or document;
- (c) he may for the purposes of ascertaining whether any offence under these regulations has been committed purchase or take samples of any material or article to which these regulations apply and of any food which has come into contact with any such material or article.

Analysis, examination and testing

13.—(1) If an authorised officer who has procured a sample of any material or article to which these regulations apply or of any food which has

come into contact with any such material or article considers that it should be analysed, examined or tested he shall submit such sample to be analysed, examined or tested, as the case may be, by the public analyst for the district in which it was procured.

(2) The public analyst shall analyse, examine or test, or have analysed, examined or tested, as soon as practicable any sample submitted to him in pursuance of this regulation.

(3) If---

- (a) the office of a public analyst for a district is vacant; or
- (b) the public analyst determines that he is for any reason unable to perform an effective analysis, examination or test,

the sample shall be submitted or, as the case may be, sent by the public analyst, to such person as the Department may approve, and that person, if he consents to analyse, examine or test the sample, shall do so upon payment to him of such sum as may be agreed upon.

(4) A public analyst who has analysed, examined or tested a sample shall give to the person by whom it was originally submitted a certificate specifying the result of the analysis, examination or test.

(5) Any certificate of the results of an analysis, examination or test given by a public analyst in pursuance of this regulation shall be signed by the public analyst, but the analysis, examination or test may be made by any person acting under the direction of the analyst.

- (6) Where a public analyst—
- (a) carries out any analysis, examination or test under this regulation; and
- (b) that analysis, examination or test is carried out on behalf of or at the instance of a district council,

he shall be deemed to be an officer of that council for the purposes of section 48 of the Local Government Act (Northern Ireland) $1972(\mathbf{a})$.

(7) In paragraphs (4), (5) and (6) references to a public analyst include references to a person approved by the Department under paragraph (3).

Method of analysis

14.—(1) The method used in analysing any sample for the purpose of establishing the quantity of vinyl chloride monomer present in the material or article in order to determine whether it complies with regulation 5(1)(a) shall be the method specified in the Annex to Commission Directive No. 80/766/EEC(b) (which lays down the Community method of analysis for the official control of the vinyl chloride monomer level in materials and articles which are intended to come into contact with foodstuffs).

(2) The method used in analysing any food for the purpose of establishing the quantity of vinyl chloride present in the food in order to determine whether a material or article which is or has been in contact with the food complies with regulation 5(1)(b) shall be the method specified in the Annex to Commission Directive No. 81/432/EEC(c) (which lays down the Community

⁽a) 1972 c. 9 (N.I.)

⁽b) O.J. No. L213, 16.8.80, p. 42
(c) O.J. No. L167, 24.6.81, p. 6

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method of analysis for the official control of vinyl chloride released by materials and articles into foodstuffs).

Obstruction

- 15. A person shall not—
- (a) intentionally obstruct an authorised officer acting in execution of these regulations; or
- (b) without reasonable cause fail to give to any such authorised officer acting as aforesaid any assistance or information or to provide such facilities as the authorised officer may reasonably require of him for the purposes of his functions under these regulations.

Confidentiality

16. Information obtained from any books or documents produced in accordance with regulation 12(b) shall not, without the previous consent in writing of the person carrying on the trade or business in question, be disclosed except for the purpose of any proceedings for an offence against any of these regulations or any report of those proceedings.

Part IV

LEGAL PROCEEDINGS

Offences and penalties

17. If any person contravenes any of the provisions of these regulations, he shall be guilty of an offence and liable on summary conviction in the case of regulation 15 to a fine not exceeding $\pounds 1,000$ and in any other case to a fine not exceeding $\pounds 2,000$.

Offences by corporations

18.—(1) Where an offence under these regulations 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, any director, manager, secretary or other similar officer of the body corporate or to any person purporting to act in any such capacity, he as well as the body corporate shall be deemed to be guilty of the offence.

(2) In this regulation the expression "director", in relation to any body corporate which is established by or under any enactment for the purpose of carrying on under national ownership any industry or part of an industry or undertaking and whose affairs are managed by its members, means a member of that body.

Evidence of analysis

19.—(1) In any proceedings for an offence under these regulations the production by one of the parties of a document purporting to be a certificate under regulation 13(4), or of a document supplied to him by the other party as being a copy of such a certificate, shall be sufficient evidence of the facts stated therein, unless, in the first-mentioned case, the other party requires that the analyst shall be called as a witness.

(2) In any such proceedings, if a person charged intends to produce a certificate of a public analyst, or under paragraph (1) to require that the analyst shall be called as a witness, notice of his intention, together, in the first-mentioned case, with a copy of the certificate, shall be given to the other party at least three clear days before the hearing or trial, and, if this requirement is not complied with, the court may, if it thinks fit, adjourn the hearing or trial on such terms as it thinks proper.

Analysis by Government Chemist

20.—(1) The court before which any proceedings are taken under these regulations, may, if it thinks fit for the purposes of the proceedings, cause—

- (a) any material or article which is the subject of the proceedings and, if it has already been analysed, examined or tested, is capable of being further analysed, examined or tested; or
- (b) any food which has been in contact with any such material or article,

to be sent to the Government Chemist, who shall make such analysis, examination or test as is appropriate and transmit to the court a certificate of the result thereof, and the costs of the analysis, examination or test shall be paid by the prosecutor or the person charged as the court may order.

(2) If in a case where an appeal is brought, no action has been taken under paragraph (1), the provisions thereof shall apply also in relation to the court by which the appeal is heard.

(3) Any certificate of the results of an analysis, examination or test transmitted by the Government Chemist under this regulation shall be signed by or on behalf of the Government Chemist, but the analysis, examination or test may be made by any person under the direction of the person by whom the certificate is signed; and any certificate so transmitted by the Government Chemist shall be evidence of the facts stated therein unless any party to the proceedings requires that the person by whom it is signed shall be called as a witness.

Offences due to fault of other person

21. 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 may be charged with and convicted of the offence by virtue of this regulation whether or not proceedings are taken against the first-mentioned person.

Defence of due diligence

22.—(1) In any proceedings for an offence under these regulations it shall 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 such an offence.

(2) If in any case the defence provided by paragraph (1) involves the allegation that the commission of the offence was due to the act or default of another person, the person charged shall not, without leave of the court, be entitled to rely on that defence unless, within a period ending seven clear days before the hearing or trial, 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.

Warranty pleaded as defence

23.—(1) In any proceedings for an offence under these regulations, being an offence consisting of selling, advertising for sale, importing or using any material or article, it shall be a defence for the person charged to prove—

- (a) that he purchased it as being a material or article which could lawfully be sold, advertised for sale, imported or used and with a written warranty to that effect;
- (b) that he had no reason to believe at the time of the commission of the alleged offence that it was otherwise; and
- (c) that it was then in the same state as when he purchased it.

(2) A warranty shall only be a defence in proceedings under these regulations if—

- (a) the person charged—
 - (i) has, not later than three clear days before the date of the hearing or trial, sent to the prosecutor a copy of the warranty with a notice stating that he intends to rely on it and specifying the name and address of the person from whom he received it, and
 - (ii) has also sent a like notice of his intention to that person; and
- (b) in the case of a warranty given by a person resident outside the United Kingdom, the person charged proves that he had taken reasonable steps to ascertain, and did in fact believe in, the accuracy of the statement contained therein.

(3) Where the person charged is an employee of the person who purchased the material or article under a warranty, he shall be entitled to rely on the provisions of this regulation in the same way as his employer would have been entitled to do if he had been the person charged.

(4) The person by whom the warranty is alleged to have been given shall be entitled to appear at the hearing or trial and to give evidence and the court may, if it thinks fit, adjourn the hearing or trial to enable him to do so.

(5) For the purposes of this regulation, a description entered in an invoice shall be deemed to be a written warranty that the article or substance to which the entry refers can be sold or otherwise dealt with under that description by any person without contravening any of the provisions of these regulations.

Part V

REVOCATIONS

Revocations

24. The regulations specified in Schedule 3 are hereby revoked.

Sealed with the Official Seal of the Department of Health and Social Services for Northern Ireland on 24th November 1987.

Z. I. Davies

Under Secretary

(L.S.)

No. 432

SCHEDULE 1

Regulation 6(3)

Substances permitted for use in the manufacture of Regenerated Cellulose Film

Part I

Substances permitted for use in the manufacture of Uncoated Regenerated Cellulose Film

Column 1 Substances	Column 2 Conditions and restrictions
1. Regenerated cellulose	Not less than 72%
2. Additives	
Softeners — 1,3-butanediol — glycerol	Not more than 27% in total
 -1,2-propanediol [= 1,2-propylene glycol] polyethylene oxide [= polyethylene glycol] -1,2-polypropylene oxide [= 1,2-polypropylene glycol] 	Average molecular weight between 250 and 1,200 Average molecular weight shall not exceed 400; free 1,3-propanediol content shall not exceed 1%
— sorbitol — triethylene glycol — urea	· · · ·
Other additives First class	Not more than 1% in total The quantity of the substance or group of substances in each entry shall not exceed 2 mg/dm ²
 acetic acid and its NH₄, Ca, Mg, K and Na salts 	
 ascorbic acid and its NH₄, Ca, Mg, K and Na salts 	
 benzoic acid and sodium benzoate 	
 formic acid and its NH₄, Ca, Mg, K and Na salts 	
 — linear fatty acids, saturated or unsaturated, with an even number of carbon atoms from 8 to 20 inclusive and also behenic 	

Column 1 Substances	Column 2 Conditions and restrictions
and ricinoleic acids and the NH ₄ , Ca, Mg, K, Na, A1, Zn salts of these acids	
 citric, dl-lactic, maleic, tartaric acids and their Na and K salts sorbic acid and its NH₄, Ca, Mg, K and Na salts 	
 amides of linear fatty acids, saturated or unsaturated, with an even number of carbon atoms from 8 to 20 inclusive and also the amides of behenic acid and ricinoleic acid 	
 natural edible starches and flours edible starches and flours modified by chemical treatment 	
 amylose calcium and magnesium carbonates and chlorides 	
 esters of glycerol with linear fatty acids, saturated or unsaturated, with an even number of carbon atoms from 8 to 20 inclusive and/or with adipic, citric, 12-hydroxystearic (oxystearin) and ricinoleic acid 	
 esters of polyoxyethylene (8-14 oxyethylene groups) with linear fatty acids, saturated or unsaturated, with an even number of carbon atoms from 8 to 20 inclusive 	
— esters of sorbitol with linear fatty acids, saturated or unsaturated, with an even number of carbon atoms from 8 to 20 inclusive	
 mono- and/or di-esters of stearic acid with ethanediol and/or bis (2-hydroxyethyl) ether and/or triethylene glycol 	
 oxides and hydroxides of aluminium, calcium, magnesium and silicon and silicates and hydrated silicates of aluminium, calcium, magnesium and potassium 	

2022

Column 1	Column 2
Substances	Conditions and restrictions
 polyethylene oxide [= poly- ethylene glycol] sodium propionate 	Average molecular weight between 1,200 and 4,000
Second class	Not more than 1 mg/dm ² in total; the quantity of the substance or group of substances in each entry shall not exceed 0.2 mg/dm ² (or a lower limit where one is specified)
 — sodium alkyl (C_s to C₁₈) benzene sulphonate 	
 — sodium isopropyl naphthalene sulphonate 	
 — sodium alkyl (C₈ to C₁₈) sulphate — sodium alkyl (C₈ to C₁₈) sulphonate 	
— sodium dioctylsulphosuccinate	
 — distearate of dihydroxyethyl- diethylenetriamine monoacetate 	Not more than 0.05 mg/dm ² in total on the side for contact with food
 ammonium, magnesium and potassium lauryl sulphates 	,
— N,N'-distearoyl diaminoethane [= N,N'-distearoyl ethylene- diamine] and	
N,N'-dipalmitoyl diamino- ethane $[= N,N'$ -dipalmitoyl ethylenediamine] and	
N,N'-dioleoyl diaminoethane [= N,N'-dioleoyl ethylene- diamine]	
2-heptadecyl-4,4'-bis- (methylenestearate) oxazoline	
 polyethylene aminostearamide ethyl sulphate 	Not more than 0.1 mg/dm ² in total on the side for contact with food
Third class — Anchoring agents	Not more than 1 mg/dm ² in total
 condensation product of melamine-formaldehyde unmodified, or modified with one or more of the following products: 	Free formaldehyde content on the side for contact with food shall not exceed 0.5 mg/dm ² ; free melamine content on the side for contact with food shall not exceed 0.3 mg/dm ²
butanol, diethylenetriamine, ethanol, triethylenetetramine, tetraethylenepentamine, tris (2-hydroxyethyl)amine,	

Column 1 Substances	Column 2 Conditions and restrictions
 3,3'-diaminodipropylamine, 4,4'-diaminodibutylamine condensation product of mela- mine-urea-formaldehyde modi- fied with tris (2-hydroxyethyl) amine 	Free formaldehyde content on the side for contact with food shall not exceed 0.5 mg/dm ² ; free melamine content on the side for contact with food shall not exceed 0.3 mg/dm ²
 cross-linked cationic polyalkyleneamines: 	
(a) polyanide-epichlorohydrin resin based on diamino- propylmethylamine and epichlorohydrin	• •
 (b) polyamide-epichlorohydrin resin based on epichloro- hydrin, adipic acid, capro- lactam, diethylenetriamine and/or ethylenediamine 	
(c) polyamide-epichlorohydrin resin based on adipic acid, diethylenetriamine and epichlorohydrin, or a mixture of epichlorohydrin and ammonia	
(d) polyamide-polyamine- epichlorohydrin resin based on epichlorohydrin, dimethyl adipate and diethylene- triamine	
(e) polyamide-polyamine- epichlorohydrin resin based on epichlorohydrin, adipamide and diamino- propylmethylamine	
 — polyethyleneamines and poly- ethyleneimines 	Not more than 0.75 mg/dm^2 in total
 condensation product of urea- formaldehyde unmodified, or modified with one or more of the following products: 	Free formaldehyde content on the side for contact with food shall not exceed 0.5 mg/dm ²
aminomethyl sulphonic acid, sulphanilic acid, butanol, diaminobutane, diaminodi- propylamine, diaminopropane, diethylenetriamine, ethanol, guanidine, methanol, tetraethy- lenepentamine, triethylene- tetramine, sodium sulphite	

Column 1 Substances	Column 2 Conditions and restrictions
Fourth class — products resulting from the reaction of the amines of edible oils with polyethylene oxide — monoethanolamine lauryl sulphate	Not more than 0.01 mg/dm ² in total
3. Adhesives and colourants	In accordance with regulation 6(4)

Part II

Substances permitted for use in the manufacture of Coated Regenerated Cellulose Film

Column 1 Substances	Column 2 Conditions and restrictions
1. Regenerated cellulose	For that part of the film other than the coating Not less than 72%
2. Additives	For that part of the film other than the coating
Softeners (a) Any softener specified in item 2 of Part I (b) - bis(2-hydroxyethyl) ether [= diethylene glycol] - ethanediol [= monoethylene glycol]	Not more than 27% in total Any condition or restriction specified in relation to that additive In accordance with regulation 6(5)

Column 1 Substances	Column 2 Conditions and restrictions
Other additives	Not more than 1% in total
Any other additive specified in item 2 of Part I	Any condition or restriction specified in relation to that additive
3. Coating substances	
Polymers	
 ethyl, hydroxyethyl, hydroxy- propyl and methyl ethers of cellulose 	
— cellulose nitrate	Not more than 20 mg/dm ² on the side for contact with food; nitrogen content between 10.8 and 12.2%
 polymers, copolymers and their mixtures made with the follow- ing monomers: 	
, vinyl acetals derived from saturated aldehydes (C_1 to C_6)	
vinyl acetate	
alkyl C_1 to C_4 vinyl ethers	
acrylic, crotonic, itaconic, maleic, methacrylic acids and their esters	
butadiene	
styrene	
methylstyrene	
vinylidene chloride	
acrylonitrile	
methacrylonitrile	
ethylene, propylene, 1- and 2- butylene	
vinyl chloride	In accordance with regulation 5
 Resins — casein — colophony and/or its products of polymerization, hydrogenation, or disproportionation, and their esters of methyl, ethyl or C₂ to C₆ polyhydric alcohols, or mixtures of these alcohols 	Not more than 12.5 mg/dm ² in total on the side for contact with food and solely for the preparation of regenerated cellulose films with coatings based on nitrocellulose or polymers or copolymers of vinyl chloride and vinyl acetate

Column 1 Substances	Column 2 Conditions and restrictions
2	
 — colophony and/or its products of polymerization, hydrogenation, or disproportionation, condensed with acrylic, maleic, citric, fumaric and/or phthalic acid and/or bisphenol formal-dehyde and esterified with methyl, ethyl or C₂ to C₆ polyhydric alcohols or mixtures of these alcohols — esters derived from bis- 	
 (2-hydroxyethyl) ether with addition products of β-pinene and/or dipentene and/or diterpene and maleic anhydride edible gelatine 	
 castor oil and its products of dehydration or hydrogenation and its condensation products with polyglycerol, adipic, citric, maleic, phthalic and sebacic acids 	
 — natural gum [= damar] — poly- β-pinene [= terpenic resins] 	
 urea-formaldehyde resin (see Anchoring agents in item 2 of Part I) 	
 Plasticisers di-isobutyl and di-n-butyl adipate di-n-hexyl azelate butyl benzyl phthalate butyl methylcarboxybutyl phthalate [= butylphthalyl butyl glycolate] di-n-butyl phthalate and di-isobutyl phthalate dicyclohexyl phthalate di (methylcyclohexyl) phthalate and its isomers [= sextolph- thalate] 	Not more than 12.5 mg/dm ² in total on the side for contact with food and, except as specified below, solely for the preparation of regenerated cellulose films with coatings based on nitrocellulose or polymers or copolymers of vinyl chloride and vinyl acetate
2-ethylhexyl diphenyl phosphate	Not more than 2.5 mg/dm ² on the side for contact with food

Column 1 Substances	Column 2 Conditions and restrictions
— glycerol monoacetate [= mono- acetin]	
— glycerol diacetate [= diacetin]	
- glycerol triacetate [= triacetin]	
 methyl methylcarboxyethyl phthalate [= methylphthalyl ethyl glycolate] 	
— dibutyl sebacate	
— di-n-butyl tartrate and di-isobutyl tartrate	
— tributyl acetyl citrate	Also for the preparation of
tris (2-ethylhexyl) acetyl citrate	regenerated cellulose films with coatings based on vinylidene chloride provided that they bear a distinctive indication that the film coating is based on vinylidene chloride and contains tributyl acetyl citrate or tris-(2-ethylhexyl) acetyl citrate, as the case may be
Other coating additives	Not more than 6 mg/dm^2 in total on the side for contact with food
(a) Any additive specified in item 2 of Part I	Any condition or restriction speci- fied in relation to that additive
(b) Specific coating additives	The quantity of the substance or group of substances in each entry may not exceed 2 mg/dm^2 (or a lower limit where one is specified) on the side for contact with food
 hexadecan-l-ol and octadecan-l-ol 	
 esters of linear fatty acids, saturated or unsaturated, with an even number of carbon atoms from 8 to 20 inclusive and of ricinoleic acid with ethyl, butyl, amyl and oleoyl linear alcohols 	· · · · ·
 montan waxes, comprising purified montanic (C₂₆ to C₃₂) acids and/or their esters with ethanediol and/or 1,3-butanediol and/or their calcium and potassium salts 	

Column 1 Substances	Column 2 Conditions and restrictions
— carnauba wax	
— beeswax	
— esparto wax	
— candelilla wax	
— dimethylpolysiloxane	Not more than 1 mg/dm^2 on the side for contact with food
 epoxidized soya-bean oil (oxirane content 6 to 8%) 	
 refined paraffin and micro- crystalline waxes 	
— pentaerythritol tetrastearate	
 mono- and bis (octadecyl- diethyleneoxide) phosphates 	Not more than 0.2 mg/dm ² on the side for contact with food
 — aliphatic acids (C₈ to C₂₀) esterified with mono- or bis (2-hydroxyethyl) amine 	
— 2- and 3-tert. butyl- 4-hydroxyanisole [= butylated hydroxyanisole - BHA]	Not more than 0.06 mg/dm ² on the side for contact with food
— 2,6-di- <i>tert</i> . butyl-4-methyl- phenol [= butylated hydroxy- toluene - BHT]	Not more than 0.06 mg/dm^2 on the side for contact with food
di-n-octyltin-bis (2-ethylhexyl) maleate	Not more than 0.06 mg/dm ² on the side for contact with food
4. Solvents for coating substances	Total quantity of all solvents may not exceed 0.6 mg/dm ² on the side for contact with food
— n-butyl acetate	
ethyl acetate	
— isobutyl acetate	
— isopropyl acetate	
— propyl acetate	
butan-l-ol [= butyl alcohol]	
— ethanol [= ethyl alcohol]	
butan-2-ol [= isobutyl alcohol]	
— propan-2-ol [= isopropyl alcohol]	· · ·
— propan-l-ol [= propyl alcohol]	
— cyclohexane	
 ethanediol monobutyl ether [= ethylene glycol monobutyl ether], 	

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Column 1 Substances	Column 2 Conditions and restrictions
 ethanediol monobutyl ether acetate [= ethylene glycol monobutyl ether acetate] ethanediol monoethyl ether [= ethylene glycol monoethyl ether] ethanediol monoethyl ether acetate [= ethylene glycol monoethyl ether acetate] ethanediol monomethyl ether [= ethylene glycol monomethyl ether] ethanediol monomethyl ether [= ethylene glycol monomethyl ether] ethanediol monomethyl ether acetate 	· ·
[= ethylene glycol monomethyl ether acetate]	
 — acetone — butanone [= methyl ethyl ketone] 	
— 4-methylpentan-2-one [= methyl isobutyl ketone]	
— tetrahydrofuran	
— toluene	
5. Adhesives and colourants	In accordance with regulation 6(4)

(1) All percentages specified in this Schedule are by weight and are to be calculated in relation to the total quantity of anhydrous regenerated cellulose film.

(2) Substances named or described in this Schedule shall be of good commercial quality.

Food and Drugs SCHEDULE 2

Regulations 7(1), 8(1), 9(2) and (3)

Symbol that may accompany Materials and Articles intended for Contact with Food



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Food and Drugs SCHEDULE 3

Regulations Revoked

Column 1 (Regulations Revoked)	Column 2 References
Materials and Articles in Contact with Food Regulations (Northern Ireland) 1981	S.R. 1981 No. 285
Materials and Articles in Contact with Food (Amendment) Regulations (Northern Ireland) 1982	S.R. 1982 No. 144
Materials and Articles in Contact with Food (Amendment) Regulations (Northern Ireland) 1983	S.R. 1983 No. 28
Regulation 5 of the Food (Revision of Penalties and Mode of Trial) Regulations (Northern Ireland) 1987	S.R. 1987 No. 38

Food and Drugs EXPLANATORY NOTE

(This note is not part of the Regulations.)

These regulations revoke, and re-enact with amendments, the Materials and Articles in Contact with Food Regulations (Northern Ireland) 1981, as amended. The regulations come into operation on 31st December 1987.

The regulations continue to implement the following European Economic Community obligations—

- (a) Council Directive No. 76/893/EEC (O.J. No. L340, 9.12.76, p. 19) on the approximation of the laws of the Member States relating to materials and articles intended to come into contact with foodstuffs;
- (b) Commission Directive No. 80/590/EEC (O.J. L151, 19.6.80, p. 21) determining the symbol that may accompany materials and articles intended to come into contact with foodstuffs;
- (c) Commission Directive No. 80/766/EEC (O.J. No. L213, 16.8.80, p. 42) laying down the Community method of analysis for the official control of the vinyl chloride monomer level in materials and articles which are intended to come into contact with foodstuffs;
- (d) Council Directive No. 78/142/EEC (O.J. No. L44, 15.2.78, p. 15) on the approximation of the laws of the Member States relating to materials and articles which contain vinyl chloride monomer and are intended to come into contact with foodstuffs;
- (e) Commission Directive No. 81/432/EEC (O.J. No. L167, 24.6.81, p. 6) which lays down the Community method of analysis for the official control of vinyl chloride released by materials and articles.

The regulations now additionally implement the following Community obligations—

- (a) Council Directive No. 83/229/EEC (O.J. No. L123, 11.5.83, p. 31); and
- (b) Commission Directive No. 86/388/EEC (O.J. No. L228, 14.8.86, p. 32),

both Directives being on the approximation of the laws of the Member States relating to materials and articles made of regenerated cellulose film intended to come into contact with foodstuffs.

The principal changes to the regulations are in implementation of the two most recent Directives mentioned above, and are contained in regulation 5(1)(b) (setting out maximum levels of vinyl chloride which may be transmitted to food), and regulation 6 and Schedule 1 (laying down conditions relating to materials and articles made of regenerated cellulose film, prescribing the substances which they may contain and setting out conditions and restrictions on use).

The regulations re-enact provisions which apply to materials and articles which are in their finished state and are intended to come into contact with food or which are in contact with food and are intended for that purpose and

Food and Drugs

forbid the sale, importation or commercial use of materials and articles which fail to comply with the regulations. They require that materials and articles shall not, under normal or foreseeable conditions of use, transfer their constituents to food in quantities which could endanger human health or bring about an unacceptable change in the nature, substance or quality of the food (regulation 4).

For materials and articles manufactured with vinyl chloride polymers or copolymers, limits are prescribed to the quantity of vinyl chloride monomer which they may contain (regulation 5(1)(a)).

The regulations also—

- (a) specify requirements for the labelling of materials and articles sold by retail and otherwise than by retail (regulations 7 and 8 respectively and Schedule 2);
- (b) restrict to materials and articles which comply with the regulations, descriptions and symbols indicating suitability for use with food (regulation 9 and Schedule 2);
- (c) apply regulations 4, 5, 6, 7 and 9 to materials and articles offered as prizes (regulation 10);
- (d) make provision for administration and enforcement of the regulations and for legal proceedings (regulations 11-23);
- (e) revoke regulation 5 of the Food (Revision of Penalties and Mode of Trial) Regulations (Northern Ireland) 1987 (regulation 24 and Schedule 3).