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SCOTTISH STATUTORY INSTRUMENTS

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**2005 No. 243**

**FOOD**

**The Materials and Articles in Contact  
with Food (Scotland) Regulations 2005**

<i>Made</i>	- - - -	<i>28th April 2005</i>
<i>Laid before the Scottish Parliament</i>	- - - -	<i>29th April 2005</i>
<i>Coming into force</i>	- -	<i>21st May 2005</i>

The Scottish Ministers, in exercise of the powers conferred by sections 6(4), 16(2), 17(1) and (2), 26(1)(a) and (3), 31 and 48(1) of the Food Safety Act 1990<sup>(1)</sup>, and of all other powers enabling them in that behalf, having had regard in accordance with section 48(4A)<sup>(2)</sup> of that Act to relevant advice given by the Food Standards Agency, hereby make the following Regulations:

**PART 1**

**Preliminaries**

**Citation, commencement and extent**

- 1.—(1) These Regulations may be cited as the Materials and Articles in Contact with Food (Scotland) Regulations 2005 and shall come into force on 21st May 2005.
- (2) These Regulations extend to Scotland only.

**Interpretation**

- 2.—(1) In these Regulations—

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(1) 1990 c. 16; section 1(1) and (2) (definition of “food”) was substituted by S.I. 2004/2990; section 6(4) was amended by the Deregulation and Contracting Out Act 1994 (c. 40), Schedule 9, paragraph 6 and by the Food Standards Act 1999 (c. 28) (“the 1999 Act”), Schedule 5, paragraph 10(3); sections 16(2) and 48(1) were amended by the 1999 Act, Schedule 5, paragraph 8; section 17(1) and (2) was amended by the 1999 Act, Schedule 5, paragraphs 8 and 12; section 26(3) was amended by the 1999 Act, Schedule 6; section 48(4) is disapplied in respect of these Regulations by virtue of section 48(4C) which was inserted by S.I. 2004/2990; amendments made by Schedule 5 to the 1999 Act shall be taken as pre commencement enactments for the purposes of the Scotland Act 1998 (c. 46) (“the 1998 Act”) by virtue of section 40(2) of the 1999 Act. The functions of the Secretary of State, in so far as within devolved competence, were transferred to the Scottish Ministers by virtue of section 53 of the 1998 Act. In so far as not so transferred, those functions were transferred to the Scottish Ministers by the Scotland Act 1998 (Transfer of Functions to the Scottish Ministers etc.) Order 2005 (S.I. 2005/849).

(2) Section 48(4A) was inserted by paragraph 21 of Schedule 5 to the 1999 Act.

“the Act” means the Food Safety Act 1990;

“the Agency” means the Food Standards Agency;

“import” means import in the course of a business from a place other than a member State;

“plastics” means those materials and articles to which Commission Directive [2002/72/EC](#) relating to plastic materials intended to come into contact with foodstuffs<sup>(3)</sup>, as corrected by a corrigendum published on 13th February 2002<sup>(4)</sup> and as amended by Commission Directive [2004/1/EC](#)<sup>(5)</sup> and Commission Directive [2004/19/EC](#)<sup>(6)</sup> applies;

“preparation” in relation to food includes manufacture and any form of treatment or process;

“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, but does not include synthetic casings of regenerated cellulose;

“the 1998 Regulations” means the Plastic Materials and Articles in Contact with Food Regulations 1998<sup>(7)</sup>;

“the Community Regulation” means Regulation (EC) No. 1935/2004 of the European Parliament and of the Council on materials and articles intended to come into contact with food and repealing Directives [80/590/EEC](#) and [89/109/EEC](#)<sup>(8)</sup>; and

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

(2) Any reference in these Regulations to a numbered Article is a reference to the Article bearing that number in the Community Regulation.

(3) Expressions used both in these Regulations and the Community Regulation have the same meaning in these Regulations as they have in the Community Regulation.

### Scope

3. These Regulations do not apply to those materials and articles specified in Article 1.3.

## PART 2

### General requirements for materials and articles

#### Enforcement of the Community Regulation

4. Subject to the provisions of Article 27 (transitional arrangements) any person who contravenes or fails to comply with any of the following provisions of the Community Regulation is guilty of an offence—

- (a) Article 3 (general requirements);
- (b) Article 4 (special requirements for active and intelligent materials and articles);
- (c) Article 11.4 and 11.5 (provisions relating to Community authorisation);
- (d) Article 15.1, 15.2, 15.3, 15.4, 15.7 and 15.8 (labelling);

(3) O.J. No. L 39, 13.2.03, p.1.

(4) O.J. No. L 220, 15.8.02, p.18.

(5) O.J. No. L 7, 13.1.04, p.45.

(6) O.J. No. L 71, 10.3.04, p.8.

(7) S.I. 1998/1376, as amended by S.S.I. 2000/431, 2002/498, 2003/9, 2004/524 and 2005/92.

(8) O.J. No. L 338, 13.11.04, p.4.

- (e) Article 16.1 (declaration of compliance); and
- (f) on or after 27th October 2006, Article 17.2 (traceability).

### **Competent authorities for the purposes of the Community Regulation**

- 5. The competent authority for the purposes of–
  - (a) Article 9 shall be the Agency; and
  - (b) Articles 16.1 and 17.2 shall be the Agency and the authority having responsibility for enforcement pursuant to regulation 12(1).

## **PART 3**

### **Requirements for vinyl chloride**

#### **Limits and migration limits**

6.—(1) Materials and articles which in their finished state are intended to come into contact with food, or are in contact with food and are intended for that purpose, 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 7(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 the food as measured by the method of analysis specified in regulation 7(2).
- (2) No person shall–
- (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 that does not comply with this regulation.

#### **Methods of analysis**

7.—(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 6(1)(a) shall be the method specified in the Annex to Commission Directive No. [80/766/EEC](#) 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(9).

(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 6(1)(b) shall be the method specified in the Annex to Commission Directive No. [81/432/EEC](#) laying down the Community method of analysis for the official control of vinyl chloride released by material and articles into foodstuffs(10).

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(9) O.J. No. L 213, 16.8.80, p.42.

(10) O.J. No. L 167, 24.6.81, p.6.

## PART 4

### Requirements for regenerated cellulose film

#### Controls and limits

8.—(1) This Part applies to regenerated cellulose film which—

- (a) constitutes a finished product in itself; or
- (b) is part of a finished product containing other materials,

and is intended to come into contact with food, or by being used for that purpose does come into contact with food.

(2) Any reference in this regulation to Annex II is a reference to Annex II to Directive 93/10/EEC relating to materials and articles made of regenerated cellulose film intended to come into contact with food(11) as amended by Commission Directive 93/111/EC(12) and Commission Directive 2004/14/EC(13).

(3) Subject to paragraph (5) no person shall manufacture any regenerated cellulose film intended to come into contact with food using any substance or group of substances other than the substances named or described—

- (a) in the first column (denominations) of Annex II in the case of—
  - (i) uncoated film; or
  - (ii) coated film where the coating is derived from cellulose; or
- (b) in the first column of the First Part of Annex II in the case of film to be coated, where the coating will consist of plastics;

and other than in accordance with the conditions and restrictions specified in the corresponding entry in the second column of the appropriate Part of Annex II, as read with the preamble to that Annex.

(4) No person shall manufacture any coating to be applied to film referred to in paragraph (3)(b) using any substance or group of substances other than the substances listed in Schedules 1, 2 or 2A to the 1998 Regulations and other than in accordance with the appropriate requirements, restrictions and specifications contained in those Regulations and in the Schedules thereto.

(5) Substances other than those listed in Annex II may be used as colourants or adhesives in the manufacture of a film to which paragraph (3)(a) applies, provided that such film is manufactured in such a way that it does not transfer any of those substances to food in any detectable quantity.

(6) No person shall—

- (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 regenerated cellulose film which has been manufactured in contravention of paragraphs (3), (4) or (5) or which does not comply with paragraph (8).

(7) No person shall use in the course of a business in connection with the storage, preparation, packaging, serving or selling of food—

- (a) where the food contains water physically free at the surface, any regenerated cellulose film which contains bis (2–hydroxyethyl) ether, ethanediol or both these substances;

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(11) O.J. No. L 93, 17.4.93, p.27.

(12) O.J. No. L 310, 14.12.93, p.41.

(13) O.J. No L 27, 30.1.04, p.48.

- (b) any regenerated cellulose film in such a way that any printed surface of that film comes into contact with food.

(8) Any material or article made of regenerated cellulose film, unless by its nature clearly intended to come into contact with food, shall be accompanied at a marketing stage other than the retail stage by a written declaration attesting that it complies with the legislation applicable to it.

#### **Migration limits for regenerated cellulose film coated with plastics**

9.—(1) Subject to paragraph (2) no person shall manufacture or import any material or article made with regenerated cellulose film coated with plastics which—

- (a) is intended to come into contact with food; and
- (b) is capable of transferring its constituents to food in quantities exceeding an overall migration limit of 10 milligrams per square decimetre of the surface of the material or article in contact with food.

(2) In the case of any material or article made with regenerated cellulose film coated with plastics which—

- (a) is 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;
- (b) can be filled and for which it is impracticable to estimate the surface area in contact with food; or
- (c) is a cap, gasket, stopper or similar device for sealing,

the overall migration limit shall be 60 milligrams of constituents transferred per kilogram of food.

(3) No person shall manufacture or import any material or article made with regenerated cellulose film coated with plastics manufactured with any substance listed in Part I of Schedule 1 to the 1998 Regulations (authorised monomers) which—

- (a) is intended to come into contact with food; and
- (b) is capable of transferring its constituents to food in quantities exceeding the specific migration limits set out in column 4 of that Part as read with Part II of that Schedule.

(4) Where the migration limit for a substance mentioned in paragraph (3) is expressed in milligrams per kilogram, in the case of regenerated cellulose film coated with plastics which—

- (a) is 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
- (b) cannot be filled or for which it is impracticable to estimate the relationship between the surface area of the film and the quantity of food in contact with it,

the migration limit shall be divided by the conversion factor of 6 in order to express it in milligrams of constituents transferred per square decimetre of the material or article in contact with food.

(5) Subject to paragraph (6), the verification of compliance with migration limits shall be conducted in accordance with the provisions of Schedules 3 and 4 of the 1998 Regulations as read with regulation 6 of those Regulations and for the purposes of this paragraph any reference in those provisions to a plastic material or article shall be construed as a reference to regenerated cellulose film coated with plastics.

(6) Paragraph (5) shall not apply in any circumstances to which regulation 7(1) or (2) is applicable.

### **Saving and transitional provisions**

**10.**—(1) Notwithstanding the revocations in regulation 16, regulation 6A of the Materials and Articles in Contact with Food Regulations 1987<sup>(14)</sup> shall apply to offences under these Regulations as it applied to offences under the equivalent provisions of those Regulations.

(2) In any proceedings for an offence under regulation 8(3), (4) or (6) or regulation 9(1) or (3) it shall be a defence to prove that—

- (a) the act constituting the offence was committed in relation to regenerated cellulose film which was manufactured or imported into the European Community before 29th January 2006; and
- (b) the act constituting the offence would not have constituted an offence under the 1987 Regulations as they were in force immediately before the coming into force of these Regulations.

## **PART 5**

### **General**

#### **Offences, penalties and defence in relation to exports**

**11.**—(1) Any person who contravenes or fails to comply with the provisions of regulations 6, 8 or 9 shall be guilty of an offence.

- (2) Any person found guilty of an offence under paragraph (1) or under regulation 4 is liable—
  - (a) on conviction on indictment to a fine or to imprisonment for a term not exceeding two years or to both;
  - (b) on summary conviction to a fine not exceeding the statutory maximum or to a term of imprisonment not exceeding 6 months or to both.
- (3) 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 the date on which evidence sufficient in the opinion of the prosecutor to warrant proceedings comes to the knowledge of the prosecutor,

whichever is the earlier.

(4) For the purposes of paragraph (3), a certificate signed by or on behalf of the prosecutor, and stating the date on which evidence sufficient in the prosecutor's opinion to warrant the proceedings came to the knowledge of the prosecutor, shall be conclusive evidence of that fact.

(5) A certificate stating that matter and purporting to be so signed shall be deemed to be so signed unless the contrary is proved.

(6) In any proceedings for an offence of contravening or failing to comply with these Regulations it shall be a defence for the accused to prove that the material or article in respect of which the offence is alleged to have been committed was intended for export to a country that is not a member State and that the material or article could lawfully be exported there in the circumstances provided for in relation to food and feed in Article 12 of Regulation [\(EC\) No. 178/2002](#)<sup>(15)</sup>.

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<sup>(14)</sup> S.I. 1987/1523; as amended by S.I. 1990/2487, 1991/1476 and 1994/979; regulation 6A was inserted by S.I. 1994/979.

<sup>(15)</sup> O.J. No. L 31, 1.2.02, p.1.

## **Enforcement**

**12.**—(1) Subject to paragraph (2) it shall be the duty of each food authority to enforce and execute these Regulations and the provisions of the Community Regulation mentioned in paragraphs (a) to (f) of regulation 4 within its area.

(2) In addition, the Agency may, if it considers it appropriate to do so, enforce and execute Articles 16.1 and 17.2.

## **Analysis by Government Chemist**

**13.**—(1) The sheriff before whom any criminal proceedings are taken under these Regulations shall, on the application of either the prosecutor or the accused, cause—

- (a) any material or article which is the subject of the proceedings and which, if it has already been tested is capable of being further 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 carry out such testing as is appropriate and transmit to the court a certificate of the result and the costs of the testing shall be borne by the prosecutor or the accused as the sheriff may order.

(2) Any certificate of the results of testing transmitted by the Government Chemist under this regulation shall be signed by or on behalf of the Government Chemist, and the testing may be carried out by any person under the direction of the person who signs the certificate.

(3) Any certificate transmitted by the Government Chemist in accordance with paragraph (2) shall be taken as sufficient evidence of the facts stated therein unless any party to the proceedings requests that the person by whom the certificate is signed be called as a witness.

(4) In this regulation “testing” includes examination and analysis, and “tested” shall be construed accordingly.

## **Application of various provisions of the Act**

**14.**—(1) The following provisions of the Act apply for the purposes of these Regulations with the modification that any reference in those provisions to the Act or Part thereof shall be construed as a reference to these Regulations—

- (a) section 2 (extended meaning of “sale” etc.);
- (b) section 20 (offences due to fault of another person);
- (c) section 21 (defence of due diligence) with the modification that in subsection (4) the references to “sale” shall be deemed to include references to “placing on the market”;
- (d) section 30(8) (which relates to documentary evidence);
- (e) section 35(1) to (3) (punishment of offences) in so far as it relates to offences under section 33(1) and (2) as applied by paragraph (3)(b);
- (f) section 36 (offences by bodies corporate); and
- (g) section 36A (offences by Scottish partnerships).

(2) In the application of section 32 of the Act (powers of entry) for the purposes of these Regulations, the reference in subsection (1) to the Act shall be construed as including a reference to the Community Regulation.

(3) The following provisions of the Act apply for the purposes of these Regulations with the modification that any reference in those provisions to the Act shall be construed as including a reference to the Community Regulation and these Regulations—

- (a) section 3 (presumptions that food intended for human consumption) with the modifications that the references to “sold” and “sale” shall be deemed to include references to “placed on the market” and “placing on the market” respectively;
- (b) section 33 (obstruction etc. of officers); and
- (c) section 44 (protection of officers acting in good faith) with the modification that references to “a food authority” shall include “the Agency”.

### **Amendments to the 1998 Regulations**

**15.**—(1) The 1998 Regulations are amended in accordance with paragraphs (2) to (6).

(2) In regulation 2 (interpretation)—

- (a) omit the definition of “the 1987 Regulations”;
- (b) after the definition of “the 1992 Regulations” insert—

““the 2005 Regulations” means the Materials and Articles in Contact with Food (Scotland) Regulations 2005;”(16).

(3) In regulation 6(1)(b) (method of testing the capability of plastic materials or articles to transfer constituents and methods of analysis)(17) for “regulation 14(2) of the 1987 Regulations” substitute “regulation 7(2) of the 2005 Regulations”.

(4) In regulation 9(1) (enforcement) for “the 1987 Regulations” substitute “the 2005 Regulations”.

(5) In regulation 11 (presumption as to food with which a plastic material or article, adhesive or material or article covered by a surface coating is to come into contact) for “the 1987 Regulations” substitute “Regulation (EC) No. 1935/2004 of the European Parliament and of the Council”(18).

(6) For regulation 12 (application of other provisions)(19) substitute—

#### **“Application of other provisions**

**12.**—(1) The following provisions of the Act shall apply for the purposes of these Regulations as they apply for the purposes of the Act—

- (a) section 3 (presumptions that food intended for human consumption);
- (b) section 30(8) (relating to documentary evidence); and
- (c) section 44 (protection of officers acting in good faith).

(2) Regulation 13 of the 2005 Regulations shall apply in relation to proceedings taken under these Regulations as it does to proceedings taken under those Regulations.”.

### **Revocations**

**16.** The following Regulations or parts thereof are revoked—

- (a) the Materials and Articles in Contact with Food Regulations 1987(20);
- (b) regulation 3 of the Food Safety (Export) Regulations 1991(21);
- (c) The Materials and Articles in Contact with Food (Amendment) Regulations 1994(22).

(16) S.S.I. 2005/ 243 .

(17) Regulation 6(1) was inserted by S.S.I. 2002/498.

(18) O.J. No. L 338, 13.11.04, p.4.

(19) Regulation 12 was amended by S.S.I. 2002/498.

(20) S.I. 1987/1523, amended by S.I. 1990/2487, 1991/1476 and 1994/979.

(21) S.I. 1991/1476.

(22) S.I. 1994/979.

St Andrew's House, Edinburgh  
28th April 2005

*RHONA BRANKIN*  
Authorised to sign by the Scottish Ministers

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## EXPLANATORY NOTE

*(This note is not part of the Regulations)*

These Regulations, which extend to Scotland only, revoke the Materials and Articles in Contact with Food Regulations 1987 (S.I. [1987/1523](#), as amended) (“the 1987 Regulations”) and re enact or re enact with amendments certain provisions contained in those Regulations. These Regulations also provide for the enforcement of Regulation (EC) No. [1935/2004](#) of the European Parliament and of the Council on materials and articles intended to come into contact with food and repealing Directives [80/590/EEC](#) and [89/109/EEC](#) (“the Community Regulation”).

These Regulations—

- (a) do not apply to those materials and articles described in Article 1.3 of the Community Regulation (regulation 3);
- (b) contain provisions for the enforcement of the Community Regulation (regulation 4);
- (c) provide for designation of the competent authorities for the various purposes identified in the Community Regulation (regulation 5);
- (d) re enact, without substantive amendments, the provisions of the 1987 Regulations relating to vinyl chloride (regulations 6 and 7);
- (e) re enact provisions of the 1987 Regulations relating to regenerated cellulose film (“RCF”), amended as necessary to implement the requirements of Commission Directive [2004/14/EC](#) amending Directive [93/10/EC](#) (regulations 8 & 9);
- (f) in regulation 8—
  - (i) control what substances may be used in the manufacture of RCF, which may vary according to whether or not it is coated with plastics (paragraph (3));
  - (ii) regulate what substances may be used to manufacture plastic coatings for RCF, and under what conditions (paragraph (4));
  - (iii) create a derogation from paragraph (3) in respect of substances used as colourants or adhesives in the manufacture of non-plastic coated RCF (paragraph (5));
  - (iv) create offences in relation to the sale, import or business use of non-compliant RCF (paragraphs (6) & (7)); and
  - (v) create a requirement for RCF, when marketed prior to the retail stage, to be accompanied by a declaration of legislative compliance (paragraph (8));
- (g) in regulation 9—
  - apply to plastic coated RCF the existing controls (derived from Commission Directive 2002/72 and implemented by the Plastic Materials and Articles in Contact with Food Regulations 1998 (S.I. [1998/1376](#), as amended) (“the 1998 Regulations”) on migration of constituents of plastic materials and articles into food, in particular by—
    - (i) specifying overall migration limits for plastic coated RCF (paragraphs (1) & (2));
    - (ii) applying to plastic coated RCF the specific migration limits applicable to certain substances used in the manufacture of plastic materials and articles (paragraphs (3) & (4)); and

- (iii) applying the prescribed methods and procedures for checking compliance with migration limits (regulation 9(5) & (6));
- (h) include savings and transitional provisions which–
  - (i) preserve the defences available under the 1987 Regulations for any RCF manufactured before 29th April 1994 that may still be in circulation;
  - (ii) create a defence in relation to RCF manufactured in or imported into the European Community before 29th January 2006 (regulation 10); and
- (i) contain general administrative and enforcement provisions which–
  - (i) penalise contravention of these Regulations or of specified provisions of the Community Regulation and provide a defence in relation to exports (regulation 11);
  - (ii) designate enforcement authorities (regulation 12);
  - (iii) provide for substances to be submitted to the Government Chemist for analysis at the request of the prosecutor or the accused (regulation 13);
  - (iv) apply certain provisions of the Food Safety Act 1990 (regulation 14);
  - (v) make consequential amendments to the 1998 Regulations (regulation 15); and
  - (vi) revoke the 1987 Regulations and subsequent amending legislation (regulation 16).

A regulatory impact assessment, which includes a compliance cost assessment of the effect which these Regulations would have on businesses has been prepared and placed in the Scottish Parliament Information Centre. Copies may be obtained from the Food Standards Agency, 6th Floor, St Magnus House, 25 Guild Street, Aberdeen AB11 5NJ.