

2007 No. 471

FOOD

**The Materials and Articles in Contact with Food (Scotland)
Regulations 2007**

<i>Made</i>	- - - -	<i>22nd October 2007</i>
<i>Laid before the Scottish Parliament</i>		<i>23rd October 2007</i>
<i>Coming into force</i>		
<i>for the purpose of regulations 5, 7</i>		
<i>and 15(1)(b)</i>		<i>1st August 2008</i>
<i>for all other purposes</i>		<i>16th November 2007</i>

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The Scottish Ministers make the following Regulations in exercise of the powers conferred by sections 16(2), 17(1) and (2), 26(1)(a) and (3), 31 and 48(1) of the Food Safety Act 1990(a) and paragraph 1A of Schedule 2 to the European Communities Act 1972(b) and all other powers enabling them to do so.

These Regulations make provision for a purpose mentioned in section 2(2) of the 1972 Act and it appears to the Scottish Ministers that it is expedient for the references to Community instruments specified in regulation 2(4) to be construed as references to those instruments as amended from time to time.

In accordance with section 48(4A) of the 1990 Act the Scottish Ministers have had regard to relevant advice given by the Food Standards Agency(c).

There has been consultation as required by Article 9 of Regulation (EC) No. 178/2002 of the European Parliament and of the Council laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety(d).

(a) 1990 c.16; section 1(1) and (2) (definition of “food”) was substituted by S.I. 2004/2990; sections 16 and 48(1) were amended by the Food Standards Act 1999 (c.28) (“the 1999 Act”), section 40(1) and Schedule 5, paragraph 8; section 17 was amended by the 1999 Act, section 40(1) and Schedule 5, paragraphs 8 and 12; section 26(3) was repealed in part by the 1999 Act, Schedule 6; section 48(4) is disapplied in respect of these Regulations by virtue of section 48(4C) which was inserted by S.I.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 should 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).

(b) 1972 c.68; paragraph 1A was inserted by the Legislative and Regulatory Reform Act 2006 (c.51), section 28.

(c) Section 48(4A) was inserted by section 40(1) and paragraph 21 of Schedule 5 to the 1999 Act.

(d) O.J. No. L 31, 1.2.02, p.1. The Regulation was amended by Regulation (EC) No. 1642/2003 of the European Parliament and of the Council (O.J. No. L 245, 29.9.03, p.4) and Commission Regulation (EC) No. 575/2006 (O.J. No. L 100, 8.4.06, p.3).

PART 1

Preliminary

Citation, commencement and extent

- 1.—(1) These Regulations may be cited as the Materials and Articles in Contact with Food (Scotland) Regulations 2007, and come into force—
- (a) for the purposes of regulations 5, 7 and 15(1)(b), on 1st August 2008, and
 - (b) for all other purposes, on 16th November 2007.
- (2) These Regulations extend to Scotland only.

Interpretation

- 2.—(1) In these Regulations—
- “the Act” means the Food Safety Act 1990;
 - “Directive 2002/72/EC” means Commission Directive 2002/72/EC relating to plastic materials and articles intended to come into contact with foodstuffs(a);
 - “Directive 2007/42/EC” means Commission Directive 2007/42/EC relating to materials and articles made of regenerated cellulose film intended to come into contact with foodstuffs(b);
 - “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 Directive 2002/72/EC applies;
 - “preparation” includes manufacture and any form of treatment or process, and “prepare” is to be construed accordingly;
 - “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;
 - “Regulation 1935/2004” 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(c);
 - “Regulation 2023/2006” means Commission Regulation (EC) No. 2023/2006 on good manufacturing practice for materials and articles intended to come into contact with food(d);
 - “sell” includes offer or expose for sale or have in possession for sale, and “sale” and “sold” are to be construed accordingly;
 - “the 2006 Regulations” means the Plastic Materials and Articles in Contact with Food (Scotland) (No. 2) Regulations 2006(e).
- (2) Except in regulations 5 and 7, any reference in these Regulations to a numbered Article is a reference to the Article bearing that number in Regulation 1935/2004.
- (3) Expressions used in these Regulations and in Regulation 1935/2004 or Regulation 2023/2006 bear the same meaning in these Regulations as they bear in those Regulations.
- (4) Any reference to Regulation 2023/2006 or to an Annex of Directive 2002/72/EC or of Directive 2007/42/EC is a reference to that Regulation or that Annex as amended from time to time.

(a) O.J. No. L 220, 15.8.02, p.18. This Directive has been amended as at the date these Regulations were made by Commission Directives 2004/1/EC (O.J. No. L 7, 13.1.04, p.45), 2004/19/EC (O.J. No. L 71, 10.3.04, p.8) and 2005/79/EC (O.J. No. L 302, 19.11.05, p.35) and corrected by Corrigendum to Commission Directive 2002/72/EC (O.J. No. L 39, 13.2.03, p.1).

(b) O.J. No. L 172, 30.06.07, p.71.

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

(d) O.J. No. L 384, 29.12.06, p.75.

(e) S.S.I. 2006/517.

Scope

3. The provisions of 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 Regulation 1935/2004

4. Subject to the provisions of Article 27 (transitional arrangements), any person who contravenes any of the following provisions of Regulation 1935/2004 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 (5) (provisions relating to Community authorisation);
- (d) Article 15(1), (2), (3), (4), (7) and (8) (labelling);
- (e) Article 16(1) (declaration of compliance); and
- (f) Article 17(2) (traceability).

Enforcement of Regulation 2023/2006

5. Any person who contravenes the requirements of Article 4 (conformity with good manufacturing practice) of Regulation 2023/2006 is guilty of an offence.

Competent authorities for the purposes of Regulation 1935/2004

6. The following bodies are designated as the competent authorities for the purposes of the provisions of Regulation 1935/2004 as specified below—

- (a) in respect of Article 9, the Food Standards Agency;
- (b) in respect of Articles 16(1) and 17(2), the Food Standards Agency and the authority having responsibility for enforcement pursuant to regulation 15(1).

Competent authority for the purposes of Regulation 2023/2006

7. The competent authority for the purposes of Articles 6(2) and 7(3) of Regulation 2023/2006 is each food authority in its area.

PART 3

Requirements for Vinyl Chloride

Limits and migration limits

8.—(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) must 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 9(1); and

- (b) must 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 9(2).

(2) No person may—

- (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 paragraph (1).

Methods of analysis

9.—(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 8(1)(a) shall be the method specified in the Annex to Commission Directive 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(a).

(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 8(1)(b) shall be the method specified in the Annex to Commission Directive 81/432/EEC laying down the Community method of analysis for the official control of vinyl chloride released by material and articles into foodstuffs(b).

PART 4

Requirements for Regenerated Cellulose Film

Controls and limits

10.—(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) Except in paragraph (4), any reference in this regulation to Annex II is a reference to Annex II to Directive 2007/42/EC.

(3) Subject to paragraph (5), no person may 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;
- (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.

(a) O.J. No. L 213, 16.8.80, p.42.
(b) O.J. No. L 167, 24.6.81, p.6.

(4) No person may manufacture any coating to be applied to film referred to in paragraph (3)(b) using any substance or group of substances, except those listed in Annexes II, III or IV to Directive 2002/72/EC, and other than in accordance with the appropriate requirements, restrictions and specifications contained in those Annexes and in the 2006 Regulations.

(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 colourant or adhesive to food in any detectable quantity.

(6) Subject to regulation 12, no person may—

- (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 the requirements of paragraphs (3), (4) or (5), or which fails to comply with paragraph (8).

(7) No person may 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 containing bis(2-hydroxyethyl) ether, ethanediol or both these substances;
- (b) any regenerated cellulose film in such a way that any printed surface of that film comes into contact with the food.

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

Migration limits for regenerated cellulose film coated with plastics

11.—(1) Subject to paragraph (2), no person may 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; or
- (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 may manufacture or import any material or article made with regenerated cellulose film coated with plastics manufactured with any substance listed in Section A or B of Annex II to Directive 2002/72/EC (authorised monomers and other starting substances) 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 those Sections as read with the general introduction to that Annex.

(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 2 and 3 of the 2006 Regulations as read with regulation 11 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 9(1) or (2) is applicable.

Saving and transitional provisions and defences

12.—(1) Notwithstanding the revocation of the Materials and Articles in Contact with Food Regulations 1987(a), in relation to regenerated cellulose film manufactured before 29th April 1994 the defences in regulation 6A of those Regulations shall apply in relation to offences under these Regulations as it applied to offences under the equivalent provisions in those Regulations.

(2) In any proceedings for an offence of contravening regulation 10(3), (4), (6) or (7), or regulation 11(1) or (3) it shall be a defence to prove that—

- (a) the act constituting the offence was committed in relation to a material or article made with 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 Materials and Articles in Contact with Food Regulations 1987 immediately before the coming into force of the Materials and Articles in Contact with Food (Scotland) Regulations 2005(b).

PART 5

General

Offences and penalties

13.—(1) Any person who—

- (a) contravenes the provisions of regulation 8(2), 10(3), (4), (6) or (7), or 11(1) or (3);
- (b) intentionally obstructs any person acting in the execution of Regulation 1935/2004, Regulation 2023/2006 or these Regulations or without reasonable excuse fails to provide any assistance or information that that person may reasonably require; or
- (c) in purported compliance with any requirement mentioned in sub-paragraph (b), knowingly or recklessly supplies information that is false or misleading in any material particular,

is guilty of an offence.

(a) S.I. 1987/1523, as amended by S.I. 1990/2487, S.I. 1991/1476 and S.I. 1994/979. These regulations were revoked by S.S.I. 2005/243.

(b) S.S.I. 2005/243. These Regulations were amended by S.S.I. 2006/314 and 517.

- (2) Any person guilty of an offence under these Regulations 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.

General defences

14.—(1) In any proceedings for an offence under these Regulations it shall, subject to paragraph (5), be a defence to prove that the accused took all reasonable precautions and exercised all due diligence to avoid the commission of the offence by the accused or by a person under the accused's control.

(2) Without prejudice to the generality of paragraph (1), a person accused of an offence under these Regulations who did not—

- (a) prepare the material or article in respect of which the offence is alleged to have been committed; nor
- (b) import it into the United Kingdom,

shall be taken to have established the defence provided by paragraph (1) if the requirements of paragraphs (3) and (4) are satisfied.

- (3) The requirements of this paragraph are satisfied if it is proved—
 - (a) that the commission of the offence was due to the act or default of some other person who was not under the accused's control, or to reliance on information supplied by such a person;
 - (b) that either—
 - (i) the accused carried out all such checks of the material or article in question as were reasonable in all the circumstances, or
 - (ii) it was reasonable in all the circumstances for the accused to rely on checks carried out by the person who supplied the accused with that material or article; and
 - (c) that the accused did not know and could not reasonably have been expected to know at the time the offence was committed that the accused's act or omission would amount to an offence under these Regulations.
- (4) The requirements of this paragraph are satisfied if the offence is one of sale and it is proved—
 - (a) that the commission of the offence was due to the act or default of some other person who was not under the accused's control, or to reasonable reliance on information supplied by such a person;
 - (b) that the sale of which the offence consisted was not a sale under the accused's name or mark; and
 - (c) that the accused did not know and could not reasonably be expected to know at the time the offence was committed that the accused's act or omission would amount to an offence under these Regulations.

(5) If in any case the defence provided by this regulation involves the allegation that the commission of the offence was due to the act or default of another person, or to reliance on information supplied by another person, the accused shall not without leave of the court be entitled to rely on that defence unless at the earlier of—

- (a) a date 7 days before the trial diet (not being a notional trial diet); or
- (b) a date 28 days after the first appearance of the accused before a court in connection with the alleged offence,

the accused has served on the prosecutor a written notice giving such information identifying or assisting in the identification of that other person as was then in the possession of the accused.

Enforcement

15.—(1) Subject to paragraph (2) it shall be the duty of each food authority within its area to execute and enforce—

- (a) the provisions of Regulation 1935/2004 mentioned in regulation 4,
- (b) the provisions of Regulation 2023/2006 mentioned in regulation 5, and
- (c) these Regulations.

(2) In addition, the Food Standards Agency may, if it considers it appropriate to do so, execute and enforce the provisions of Articles 16(1) and 17(2).

Procedure where a sample is to be analysed

16.—(1) An authorised officer who has procured a sample under section 29 of the Act and who considers it should be analysed shall divide the sample into three parts.

(2) If the sample consists of sealed containers and opening them would, in the opinion of the authorised officer, impede a proper analysis, the authorised officer shall divide the sample into parts by putting the containers into three lots, and each lot shall be treated as being a part.

(3) The authorised officer shall—

- (a) if necessary place each part in a suitable container and seal it;
- (b) mark each part or container;
- (c) as soon as reasonably practicable, give one part to the owner and notify the owner in writing that the sample will be analysed;
- (d) submit one part for analysis in accordance with section 30 of the Act; and
- (e) retain one part for future submission under regulation 17.

Secondary analysis by the Government Chemist

17.—(1) Where a sample has been retained under regulation 16 and—

- (a) a decision has been made to send a report to the procurator fiscal or proceedings have been commenced against a person for an offence under these Regulations; and
- (b) the result of the analysis carried out in accordance with regulation 16(3)(d) is to be adduced as evidence,

paragraphs (2) to (6) apply.

(2) The authorised officer—

- (a) may of the officer's own volition prior to a report being sent to the procurator fiscal; and
- (b) shall—
 - (i) if requested by the prosecutor;

- (ii) if the court so orders on the application of the prosecutor or the accused; or
- (iii) if requested by the accused (subject to paragraph (5)),

send the retained part of the sample to the Government Chemist for analysis.

(3) The Government Chemist shall analyse the part sent under paragraph (2) and where the analysis is carried out—

- (a) under paragraph (2)(a) or (b)(i) or (iii), provide the authorised officer; or
- (b) under paragraph (2)(b)(ii), provide the prosecutor and the accused,

with a certificate of analysis.

(4) The authorised officer shall immediately on receipt of the Government Chemist's certificate of analysis under paragraph 3(a) supply the prosecutor and the accused with a copy.

(5) Where a request is made under paragraph (2)(b)(iii) the authorised officer may give notice in writing to the accused requesting payment of a fee specified in the notice in respect of the functions under paragraph (3), and in the absence of agreement by the accused to pay the fee the authorised officer may refuse to comply with the request.

(6) Any certificate of the results of analysis transmitted by the Government Chemist shall be signed by or on behalf of the Government Chemist, but the analysis may be carried out by any person under the direction of the person who signs the certificate.

(7) Any certificate transmitted by or on behalf of the Government Chemist in accordance with paragraph (6) 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.

(8) In this regulation “accused” includes a person in respect of whom the authorised officer intends to submit a report to the procurator fiscal.

Application of various provisions of the Act

18.—(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 (extending meaning of “sale” etc);
- (b) section 20 (offences due to fault of another person);
- (c) section 30(8) (which relates to documentary evidence);
- (d) section 36 (offences by bodies corporate); and
- (e) 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 Regulation 1935/2004 or, as appropriate, to Regulation 2023/2006.

(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 Regulation 1935/2004 or, as appropriate, to Regulation 2023/2006, and to these Regulations—

- (a) section 3 (presumptions that food is 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; and
- (b) section 44 (protection of officers acting in good faith) with the modification that references to “a food authority” shall include “the Food Standards Agency”.

Amendment of the Ceramic Articles in Contact with Food (Scotland) Regulations 2006

19. In the Ceramic Articles in Contact with Food (Scotland) Regulations 2006(a), in regulation 8(2), for the figure “2006” substitute the figure “2005”.

Amendment of the Food Safety (Sampling and Qualifications) Regulations 1990

20. In the Food Safety (Sampling and Qualifications) Regulations 1990(b), in Schedule 1 (provisions to which those Regulations do not apply) for the title and reference of the Materials and Articles in Contact with Food (Scotland) Regulations 2005 substitute the title and reference of these Regulations.

Consequential amendments to the 2006 Regulations

21.—(1) The 2006 Regulations are amended in accordance with paragraphs (2) and (3).

(2) In paragraph (1) of regulation 2 (interpretation) omit the definition of “the 2005 Regulations”.

(3) In paragraph (1)(b) of regulation 11 (method of testing the capability of materials or articles to transfer constituents, and methods of analysis), for the expression “regulation 7(2) of the 2005 Regulations” substitute “regulation 9(2) of the Materials and Articles in Contact with Food (Scotland) Regulations 2007(c).”

Revocations

22. The following Regulations or parts thereof are revoked—

- (a) Article 3(3) of the Food Safety Act 1990 (Consequential Modifications) (No. 2) (Great Britain) Order 1990(d);
- (b) The Materials and Articles in Contact with Food (Scotland) Regulations 2005(e); and
- (c) Regulation 24 of the 2006 Regulations.

SHONA ROBISON

Authorised to sign by the Scottish Ministers

St Andrew’s House,
Edinburgh
22nd October 2007

(a) S.S.I. 2006/230.

(b) S.I. 1990/2463, relevantly amended by S.S.I. 2006/314.

(c) S.S.I. 2007/471.

(d) S.I. 1990/2487 to which there are amendments not relevant to these regulations.

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

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations revoke the Materials and Articles in Contact with Food (Scotland) Regulations (S.S.I. 2005/243) (“the 2005 Regulations”) and re-enact or re-enact with amendments provisions contained in those Regulations. These Regulations 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 (O.J. No. L 338, 13.11.04, p.4) (“Regulation 1935/2004”).

The Regulations also provide for the enforcement of Commission Regulation (EC) No. 2023/2006 on good manufacturing practice for materials and articles intended to come into contact with food (O.J. No. L 384, 29.12.06, p.75) (“Regulation 2023/2006”), and implement Commission Directive 2007/42/EC relating to materials and articles made of regenerated cellulose film intended to come into contact with foodstuffs (O.J. No. L 172, 30.6.07, p.71) (“Directive 2007/42”). This Directive repealed and consolidated Commission Directive 93/10/EEC (O.J. No. L 93, 17.4.93, p.27) as last amended by Commission Directive 2004/14/EC (O.J. No. L 27, 30.1.04, p.48).

These Regulations—

- (a) provide that references to a certain EC instrument or specified parts of certain EC instruments are to be construed as references to the instrument or specified part of it as it may be amended from time to time (*regulation 2(4)*);
- (b) do not apply to materials or articles outside the scope of Regulation 1935/2004 (*regulation 3*);
- (c) contain provisions which make it an offence to contravene certain requirements of Regulation 1935/2004 (Regulation 1935/2004 being the principal framework Regulation on materials and articles in contact with food) (*regulation 4*), and of Regulation 2023/2006 (*regulation 5*);
- (d) provide for designation of the competent authorities for the various purposes identified in Regulations 1935/2004 and 2023/2006 (*regulations 6 and 7*);
- (e) re-enact, without substantive amendments, the provisions of the 2005 Regulations relating to vinyl chloride (*regulations 8 and 9*);
- (f) re-enact provisions of the 2005 Regulations relating to regenerated cellulose film (“RCF”) with minor amendments to implement Directive 2007/42 (*regulations 10 and 11*).
- (g) in regulation 10—
 - (i) control which 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 which substances may be used to manufacture plastic coatings for RCF, and under what conditions (*paragraph (4)*);
 - (iii) create a conditional 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) and (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)*).

- (h) in regulation 11–
 - apply to plastic coated RCF the existing controls (derived from Commission Directive 2002/72/EC) 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) and (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) and (4)*); and
 - (iii) applying the prescribed methods and procedures for checking compliance with migration limits (*paragraphs (5) and (6)*).
- (i) include savings and transitional provisions which–
 - (i) preserve the defences available under the 2005 Regulations for any RCF manufactured before 29th April 1994 that may still be in circulation; and
 - (ii) preserve the defence in relation to RCF manufactured in or imported into the European Community before 29th January 2006 (*regulation 12*).
- (j) contain general administrative and enforcement provisions which–
 - (i) penalise contravention of these Regulations or obstruction of those enforcing them (*regulation 13*);
 - (ii) provide for a defence of due diligence to an offence under these Regulations (*regulation 14*);
 - (iii) designate enforcement authorities for various functions under the Regulations (*regulation 15*);
 - (iv) specify the procedure to be followed when sending a sample for analysis (*regulation 16*);
 - (v) make provision for a sample to be analysed by the Government Chemist (*regulation 17*); and
 - (vi) apply certain provisions of the Food Safety Act 1990 (*regulation 18*).
- (k) make amendments and revocations by–
 - (i) amending regulation 8(2) to the Ceramic Articles in Contact with Food (Scotland) Regulations 2006 (S.S.I. 2006/230) (*regulation 19*).
 - (ii) making consequential amendments to the Plastic Materials and Articles in Contact with Food (Scotland) (No. 2) Regulations 2006 (S.S.I. 2006/517) and the Food Safety (Sampling and Qualifications) Regulations 1990 (S.I. 1990/2463) (*regulations 20 and 21*); and
 - (iii) revoking the 2005 Regulations and subsequent amending legislation as well as a spent provision in the Food Safety Act 1990 (Consequential Modifications) (No. 2) (Great Britain) Order 1990 (S.I. 1990/2487) (*regulation 22*).

A full regulatory impact assessment of the effect that this instrument will have on business costs 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 6NJ.

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