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SCOTTISH STATUTORY INSTRUMENTS

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**2008 No. 127**

**The Plastic Materials and Articles in Contact  
with Food (Scotland) Regulations 2008**

**PART 1**

Preliminary

**Citation, commencement and extent**

1.—(1) These Regulations may be cited as the Plastic Materials and Articles in Contact with Food (Scotland) Regulations 2008, and come into force—

- (a) for the purpose of regulation 26(c), on 1st July 2008, and
- (b) for all other purposes, on 1st May 2008.

(2) These Regulations extend to Scotland only.

**Interpretation**

2.—(1) In these Regulations—

“the Act” means the Food Safety Act 1990;

“BADGE” has the meaning it bears in Article 1(1)(a) of Regulation 1895/2005;

“BFDGE” has the meaning it bears in Article 1(1)(b) of Regulation 1895/2005;

“business” has the meaning it bears in the Act;

“capable” means capable as established under regulation 13;

“Directive 82/711” means Council Directive [82/711/EEC](#) laying down the basic rules necessary for testing migration of the constituents of plastic materials and articles intended to come into contact with foodstuffs<sup>(1)</sup>;

“Directive 85/572” means Council Directive [85/572/EEC](#) laying down the list of simulants to be used for testing migration of constituents of plastic materials and articles intended to come into contact with foodstuffs<sup>(2)</sup>;

“Directive 88/388” means Council Directive [88/388/EEC](#) on the approximation of the laws of the Member States relating to flavourings for use in foodstuffs and to source materials for their production<sup>(3)</sup>;

“Directive 89/107” means Council Directive [89/107/EEC](#) on the approximation of the laws of the Member States concerning food additives authorised in foodstuffs intended for human consumption<sup>(4)</sup>;

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(1) O.J. No. L 297, 23.10.82, p.26; as amended by Commission Directive [93/8/EEC](#) (O.J. No. L 90, 14.4.93, p.22) and Commission Directive [97/48/EC](#) (O.J. No. L 222, 12.8.97, p.10)

(2) O.J. No. L 372, 31.12.85, p.14.

(3) O.J. No. L 345, 14.12.88, p.29; as corrected by a corrigendum dated 15th July 1988 (O.J. No. L 184, 15.7.88, p.61).

(4) O.J. No. L 40, 11.2.89, p.27; as amended by European Parliament and Council Directive [94/34](#) (O.J. No. L 237, 10.9.94, p.1).

“the Directive” means Commission Directive [2002/72/EC](#) relating to plastic materials and articles intended to come into contact with foodstuffs<sup>(5)</sup>;

“EFSA” means the European Food Safety Authority;

“fatty foods” means foods for which, in migration testing, stimulant D is specified in Directive [85/572/EEC](#);

“food” is to be construed in accordance with section 16(5) of the Act;

“good technical quality” means good technical quality as regards the purity criteria;

“handling of food” means use in connection with the storage, preparation, packaging, sale or serving of food;

“import” means import in the course of a business;

“infants” means children under the age of twelve months;

“material or article” means a material or article falling within the definition of materials and articles in Article 1(2) of Regulation [1895/2005](#);

“monomer” means any substance which is included for the purposes of the Directive among monomers and other starting substances;

“NOGE” has the meaning it bears in Article 1(1)(c) of Regulation [1895/2005](#);

“plastic functional barrier” means a barrier consisting of one or more layers of plastics which ensure that the finished material or article complies with Article 3 of Regulation [1935/2004](#) and with the Directive;

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

“plastic multi layer material or article” means a plastic material or article composed of two or more layers of materials each consisting exclusively of plastics, which are bound together by means of adhesives or other means;

“purity criteria” means purity criteria in accordance with Commission Directive [95/31/EC](#) laying down specific criteria of purity concerning sweeteners for use in foodstuffs<sup>(6)</sup>, Commission Directive [95/45/EC](#) laying down purity criteria concerning colours for use in foodstuffs<sup>(7)</sup> and Commission Directive [96/77/EC](#) laying down specific purity criteria for food additives other than colour sweeteners<sup>(8)</sup>;

“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](#)<sup>(9)</sup>;

“Regulation [1895/2005](#)” means Commission Regulation (EC) No. [1895/2005](#) on the restriction of use of certain epoxy derivatives in materials and articles intended to come into contact with food<sup>(10)</sup>;

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(5) O.J. No. L 220, 15.8.02, p.18; as amended by Commission Directive [2004/1/EC](#) (O.J. No. L 7, 13.1.04, p.45), Commission Directive [2004/19/EC](#) (O.J. No. L 71, 10.3.04, p.8), Commission Directive [2005/79/EC](#) (O.J. No. L 302, 19.11.05, p.35), and Commission Directive [2007/19/EC](#) (O.J. No. L 97, 12.4.2007, p.50).

(6) O.J. No. L 178, 28.7.95, p.1; as amended by Commission Directive [98/66/EC](#) (O.J. No. L 257, 19.9.98, p.35), Commission Directive [2000/51/EC](#) (O.J. No. L 198, 4.8.00, p.41), Commission Directive [2001/52/EC](#) (O.J. No. L 190, 12.7.01, p.18) and Commission Directive [2004/46/EC](#) (O.J. No. L 114, 21.4.04, p.15).

(7) O.J. No. L 226, 22.9.95, p.1; as amended by Commission Directive [1999/75/EC](#) (O.J. L 206, 5.8.99, p.19), Commission Directive [2001/50/EC](#) (O.J. No. L 190, 12.7.01, p.14) and Commission Directive [2004/47/EC](#) (O.J. L 113, 20.4.04, p.24).

(8) O.J. No. L 339, 30.12.96, p.1; as amended by Commission Directive [2001/30/EC](#) (O.J. No. L 146, 31.5.01, p.1), Commission Directive [2002/82/EC](#) (O.J. No. L 292, 28.10.02, p.1), Commission Directive [2003/95/EC](#) (O.J. No. L 283, 31.10.03, p.71) and Commission Directive [2004/45/EC](#) (O.J. No. L 113, 20.4.04, p.19).

(9) O.J. No. L 338, 13.11.2004, p.4.

(10) O.J. No. L 302, 19.11.05, p.28.

“the 1998 Regulations” means the Plastic Materials and Articles in Contact with Food Regulations 1998<sup>(11)</sup>;

“the 2006 Regulations” means the Plastic Materials and Articles in Contact with Food (Scotland) (No. 2) Regulations 2006<sup>(12)</sup>;

“the 2007 Regulations” means the Materials and Articles in Contact with Food (Scotland) Regulations 2007<sup>(13)</sup>;

“sell” includes offer or expose for sale or have in possession for sale, and “sale” is to be construed accordingly; and

“young children” means children aged between one and three years.

(2) For the purposes of these Regulations the supply otherwise than on sale, in the course of a business, of any material or article is deemed to be a sale.

(3) Any other expression used in these Regulations and in the Directive, Directive 82/711, Directive 85/572 or Regulation 1895/2005 bears the same meaning in these Regulations as it bears in that Directive or Regulation.

(4) Except in regulation 11(3) and Part 5 of Schedule 3, any reference to a numbered Annex is a reference to that Annex in the Directive.

(5) Any reference to an Annex to the Directive is a reference to that Annex as amended from time to time.

## PART 2

### Requirements for Plastic Materials and Articles

#### **Restriction on the use, sale or import of plastic materials and articles**

3.—(1) No person may—

(a) use for the handling of food in the course of a business; or

(b) for the purpose of the handling of food—

(i) sell; or

(ii) import from anywhere other than an EEA State,

a plastic material or article which fails to meet the required standard.

(2) For the purposes of this regulation a plastic material or article fails to meet the required standard if it—

(a) has been manufactured with a prohibited monomer as described in regulation 4(2) or a prohibited additive as described in regulation 5(2); or

(b) does not meet the required standards set out in regulation 6, 7, 8, 9, 10 or 11.

#### **Restriction on the use of monomers in the manufacture of plastic materials and articles**

4.—(1) Subject to paragraphs (3), (4) and (5), no person may use any prohibited monomer in the manufacture of any plastic material or article.

(2) A prohibited monomer is any monomer which is not—

(a) of good technical quality;

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<sup>(11)</sup> S.I.1998/1376 as amended by S.S.I. 2000/431, 2002/498, 2003/9, 2004/524 and 2005/92. It was revoked by S.S.I. 2006/314.

<sup>(12)</sup> S.S.I. 2006/517.

<sup>(13)</sup> S.S.I. 2007/471.

- (b) identified by PM/REF No, CAS No (if any) and name in columns 1, 2 and 3 respectively of Sections A or B of Annex II; and
  - (c) used in accordance with any restrictions and specifications for that monomer set out or referred to in column 4 of the corresponding entry.
- (3) Paragraph (1) does not apply to the use of a monomer in the manufacture of any–
- (a) surface coatings obtained from resinous or polymerised products in liquid, powder or dispersion form, including but not limited to varnishes, lacquers and paints;
  - (b) epoxy resins;
  - (c) adhesives and adhesion promoters; or
  - (d) printing inks.
- (4) Paragraph (1) shall not be taken to prohibit the manufacture of any plastic material or article with any substance which falls within paragraph 3(c) (relating to mixtures of authorised substances) of Annex II and is of good technical quality.
- (5) In any proceedings for an offence under these Regulations where it is alleged that a plastic material or article does not comply with paragraph (1) because it was manufactured with any monomer (whether or not of good technical quality) other than one mentioned in paragraph (2)(b), it shall be a defence for the accused to prove that each such monomer\_
- (a) is present in the finished plastic material as an impurity, a reaction intermediate or a decomposition product which falls within paragraph 3(a) of Annex II; or
  - (b) is an oligomer or a natural or synthetic macromolecular substance or a mixture thereof which falls within paragraph 3(b) of that Annex,
- and is of good technical quality.
- (6) Schedule 1 has effect to supplement this regulation.

### **Restriction on the use of additives in the manufacture of plastic materials and articles**

**5.—(1)** Subject to paragraph (3) no person may use any prohibited additive in the manufacture of any plastic material or article.

(2) A prohibited additive is–

- (a) any additive identified by PM/REF No, CAS No (if any) and name in columns 1, 2 and 3 respectively of Section A or B of Annex III which is not–
  - (i) of good technical quality; or
  - (ii) used in accordance with any restrictions and specifications for that additive set out in the corresponding entry in column 4 of Section A or B of that Annex; or
- (b) any food additive authorised by Directive 89/107 or any flavouring authorised by Directive 88/388 that migrates into food–
  - (i) in a quantity that has a technological function in the final food product, or
  - (ii) where the food is of a type for which the use of any such food additive or flavouring is so authorised, in quantities exceeding the limits provided for in Directive 89/107 or Directive 88/388, as appropriate, or in Annex III, whichever is the lower.

(3) In any proceedings for an offence under these Regulations where it is alleged that the commission of the offence is due to the manufacture of a plastic material or article with any additive identified in Section A or B of Annex III, which is not of good technical quality, it shall be a defence for the accused to prove that each such additive is present in the finished plastic material or article as an impurity, a reaction intermediate or a decomposition product.

(4) Schedule 1 has effect to supplement this regulation.

### **Required standard for non migration of constituents of monomers**

6.—(1) Subject to paragraphs (2) and (3), where a migration limit expressed in mg/kg is indicated in column 4 of the relevant section of Section A or B of Annex II in relation to any monomer, a plastic material or article manufactured from that monomer meets the required standard under this regulation if it is not capable of transferring constituents of that monomer to food with which it may come into contact in quantities exceeding the appropriate limit, and for the purposes of this paragraph the appropriate limit is—

- (a) the number of milligrams expressed in column 4 released per kilogram of food in the case of any plastic material or article other than one specified in sub paragraph (b); and
- (b) one sixth of the number of milligrams expressed in column 4 per square decimetre of surface area of the plastic material or article if the plastic material or article comprises—
  - (i) an article which is a container or is comparable to a container or can be filled, having a capacity of less than 500 millilitres or more than 10 litres, or
  - (ii) sheet, film or other plastic material or article which cannot be filled or for which it is impracticable to estimate the relationship between the surface area of the material or article in question and the quantity of food in contact with that surface area.

(2) A plastic material or article manufactured from any monomer for which a migration limit in mg/kg is expressed in column 4 of Section A or B of Annex II is not to be considered capable of transferring constituents of that monomer to food with which it may come into contact in quantities exceeding the appropriate limit in paragraph (1), if the only food with which that plastic material or article may come into contact is food to which regulation 9(5) applies.

(3) For plastic materials or articles brought or intended to be brought into contact with food for infants and young children the migration limits referred to in paragraph (1) shall always be applied in mg/kg.

### **Required standard for non migration of constituents of additives**

7.—(1) Subject to paragraphs (2) and (3), where a migration limit expressed in mg/kg is indicated in column 4 of Section A or B of Annex III in relation to any additive, a plastic material or article manufactured containing that additive meets the required standard under this regulation if it is not capable of transferring constituents of that additive to food with which it may come into contact in quantities exceeding the appropriate limit, and for the purposes of this paragraph the appropriate limit is—

- (a) the number of milligrams indicated in column 4 released per kilogram of food in the case of any plastic material or article other than one specified in sub paragraph (b); and
- (b) one sixth of the number of milligrams expressed in column 4 per square decimetre of surface area of the plastic material or article if the plastic material or article comprises—
  - (i) an article which is a container or is comparable to a container or can be filled, having a capacity of less than 500 millilitres or more than 10 litres, or
  - (ii) sheet, film or other plastic material or article which cannot be filled or for which it is impracticable to estimate the relationship between the surface area of the material or article in question and the quantity of food in contact with that surface area.

(2) A plastic material or article manufactured containing an additive for which a migration limit in mg/kg is expressed in column 4 of Section A or B of Annex III is not to be considered capable of transferring constituents of that additive to food with which the plastic material or article may come into contact in quantities exceeding the appropriate limit in paragraph (1), if the only food with which that plastic material or article may come into contact is food to which regulation 9(5) applies.

(3) For plastic materials or articles brought or intended to be brought into contact with food for infants and young children the migration limits referred to in paragraph (1) shall always be applied in mg/kg.

#### **Required standard for products obtained by bacterial fermentation**

**8.** A product obtained by bacterial fermentation meets the required standard under this regulation if it is—

- (a) of good technical quality;
- (b) identified by PM/REF No, CAS No and name in columns 1, 2 and 3 respectively of Annex IV; and
- (c) in compliance with the restrictions and specifications set out in column 4 of that Annex.

#### **Required standards relating to overall migration limits**

**9.—(1)** Subject to paragraph (5), a plastic material or article meets the required standard under this regulation if it is not capable of transferring its constituents to food with which it may come into contact in quantities exceeding the appropriate limit specified in paragraphs (2) to (4).

(2) Subject to paragraph (4), in the case of any plastic material or article comprising—

- (a) an article which is a container or comparable to a container or can be filled, with a capacity of less than 500 millilitres or more than 10 litres; or
- (b) sheet, film or any other material or article which cannot be filled or for which it is impracticable to estimate the relationship between the surface area of such material or article and the quantity of food in contact with it,

the appropriate limit is an overall migration limit of 10 milligrams per square decimetre of the surface area of the plastic material or article.

(3) In the case of any other plastic material or article, the appropriate limit is an overall migration limit of 60 milligrams of the constituents released per kilogramme of food or food stimulant.

(4) For plastic materials or articles intended to be brought into contact or already in contact with food intended for infants and young children, the appropriate limit is always 60 milligrams of the constituents released per kilogramme of food or food simulant.

(5) For the purposes of this regulation a plastic material or article is not deemed to fail to meet the required standard under paragraph (1) if the only food with which that material or article may come into contact is food—

- (a) which is specified in the table to Part 4 of Schedule 3; and
- (b) where there is no “X” placed anywhere in the group of columns headed “Simulants to be used” opposite that food.

(6) In any proceedings for an offence under these Regulations where it is alleged that a plastic material or article does not comply with this regulation, the defences available in paragraph 10(2) of Schedule 2 are available as specified in that paragraph.

#### **Required standard for non migration of primary aromatic amines**

**10.—(1)** Subject to paragraph (4), a plastic material or article manufactured using primary aromatic amines meets the required standard under this regulation if it is not capable of transferring such amines (expressed as aniline) in a detectable quantity to food with which that plastic material or article may come into contact.

(2) Part B of Annex V has effect for the purpose of prescribing, for certain items listed in Section A or B of Annex II, Section A or B of Annex III, or Annex IV, the specifications for those items that are referred to in column 4 of the Annex or Section of Annex concerned.

(3) For the purposes of paragraph (1) a detectable quantity means at least 0.01 milligrams per kilogram of food or food simulant.

(4) The requirement in paragraph (1) does not apply to primary aromatic amines listed in the Directive.

### **Required standard relating to plastic multi-layer materials and articles**

**11.**—(1) Subject to paragraph (2), a plastic multi layer material or article meets the required standard if each layer of it complies with these Regulations.

(2) A layer which is not in direct contact with food and is separated from such contact by a plastic functional barrier does not have to comply with the requirements of these Regulations provided that—

- (a) the finished material or article complies with the relevant specific and overall migration limits; and
- (b) if any substance used in the manufacture of the layer is not included in the Directive or in national lists referred to in that Directive, that substance meets the requirements of paragraphs (3) and (4).

(3) A substance mentioned in paragraph (2)(b) must not belong to the category of those classified—

- (a) as proved or suspect “carcinogenic”, “mutagenic” or “toxic to reproduction” substances in Annex I to Directive [67/548/EEC\(14\)](#), or
- (b) under the self responsibility criteria as “carcinogenic”, “mutagenic” or “toxic to reproduction” substances according to the rules of Annex VI to that Directive.

(4) The migration of a substance mentioned in paragraph (2)(b) into a food or simulant must not exceed 0.01 mg/kg, measured and expressed in accordance with the requirements and specifications contained in Article 7a(3) of the Directive.

### **Provisions relating to the use of certain epoxy derivatives (BADGE, BFDGE and NOGE)**

**12.**—(1) In this regulation—

- (a) any reference to a numbered Article is a reference to that Article in Regulation 1895/2005;
- (b) paragraphs (2) to (5) are subject to Article 1(3) (exception relating to certain storage containers and pipelines);
- (c) for the purposes of Article 6(4) the competent authority is the food authority.

(2) Subject to Article 6(1), (2) (transitional provisions) and (4) (requirement to disclose date of filling to competent authority), no person may—

- (a) manufacture,
- (b) use for the handling of food in the course of a business; or
- (c) for the purpose of the handling of food—
  - (i) sell; or
  - (ii) import,

any material or article in contravention of Article 3 or Article 4 (prohibitions relating to BFDGE and NOGE respectively).

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(14) O.J. No. L 196, 16.8.1967, p.1 as last amended by Directive [2006/121/EC](#) of the European Parliament and of the Council (O.J. No. L 396, 30.12.2006, p.850).

(3) No person may manufacture any material or article in such a way as to contravene the requirements of Article 2 (controls on the migration of BADGE from materials and articles).

(4) Subject to Article 6(1), no person may—

- (a) use for the handling of food in the course of a business; or
- (b) for the purpose of the handling of food—
  - (i) sell; or
  - (ii) import,

any material or article that has been manufactured in such a way as to contravene the requirements of Article 2.

(5) Subject to Article 6(3) (transitional provisions relating to materials and articles brought into contact with food before 1st January 2007), no person shall contravene or fail to comply with the requirements of Article 5 (obligations regarding the provision of a written statement when marketing materials or articles containing BADGE or its derivatives).

(6) No person shall without reasonable excuse fail to comply with a request made under Article 6(4).

### **Method of testing the capability of plastic materials or articles to transfer constituents, and methods of analysis**

13.—(1) A plastic material or article shall be treated as capable of transferring constituents to food with which it may come into contact to the extent that such capability is established—

- (a) in any case other than one to which sub paragraph (b) or (c) applies, and subject to Article 8(4) of the Directive (which may be applied on compliance with the conditions stated therein), by the verification methods specified in Schedule 2 (including the analytical tolerances referred to in paragraph 12 of that Schedule) and Schedule 3;
- (b) in any case where the extent to which vinyl chloride, as identified in Section A of Annex II, is capable of such transfer falls to be established, by the method referred to in regulation 9(2) of the 2007 Regulations; or
- (c) in any case where the extent to which a phthalate listed in Section B of Annex III with PM/Ref No 74640, 74880, 74560, 75100 or 75105 is capable of such transfer falls to be established, by the method referred to in Article 8(5) of the Directive.

(2) In Schedules 2 and 3, references to migration or release of a substance are to be construed as references to the transfer of constituents to the food or simulant representing the food with which it is or may come into contact.

(3) The specific migration of a constituent from a plastic material or article shall where applicable be determined in the manner specified in the relevant sub paragraph of paragraph 8 of Annex II.

(4) The quantity of a constituent in a plastic material or article shall where applicable be determined in the manner specified in the sub paragraph of paragraph 8 of Annex II relating to the term “QM(T)”, “QMA” or “QMA(T)” as the case may be.

### **Labelling and documentation**

14.—(1) At marketing stages other than the retail stage a person who places on the market any plastic material or article or any substance intended for the manufacture of a plastic material or article must ensure that the plastic material or article or substance is accompanied by a written declaration which—

- (a) accords with article 16(1) of Regulation 1935/2004;
- (b) contains the information specified in Schedule 4; and



- (c) permits an easy identification of the materials, articles or substances for which it is issued.
- (2) A written declaration under paragraph (1) must be revised when substantial changes in the production of a plastic material or article for which the declaration is issued bring about changes in the migration or when new scientific data are available.
- (3) A person mentioned in paragraph (1) must make available to the food authority on request appropriate documentation to demonstrate that the plastic material or article or substance intended for its manufacture complies with the requirements of these Regulations.
- (4) The documentation referred to in paragraph (3) shall contain the conditions and results of testing, calculations, other analysis, and evidence on the safety or reasoning demonstrating compliance.

## PART 3

### Execution and Enforcement

#### Enforcement

- 15. Each food authority shall execute and enforce—
  - (a) the provisions of Regulation 1895/2005 referred to in regulation 12, and
  - (b) these Regulations,in its area.

#### Offences and Penalties

- 16.—(1) Any person who—
  - (a) contravenes or fails to comply with regulation 3(1), 4(1), 5(1), 12(2) to (5), 14(1) or 14(3) to (4);
  - (b) intentionally obstructs any person acting in the execution of Regulation 1895/2005 or these Regulations;
  - (c) fails to comply with regulation 12(6) or 18(3), or otherwise fails without reasonable excuse to give to any person acting in the execution of Regulation 1895/2005 or these Regulations any assistance or information which that person may reasonably require; or
  - (d) in purported compliance with any requirement mentioned in sub paragraph (c), knowingly or recklessly supplies information that is false or misleading in any material particular,is guilty of an offence.
- (2) Any person convicted of an offence under these Regulations is liable—
  - (a) in the case of an offence under paragraph (1)(a) or (d)—
    - (i) on conviction on indictment to a term of imprisonment not exceeding 2 years or to a fine or both;
    - (ii) on summary conviction to a term of imprisonment not exceeding 12 months or to a fine not exceeding the statutory maximum or both;
  - (b) in the case of any other offence under these Regulations, on summary conviction to a term of imprisonment not exceeding 3 months or to a fine not exceeding level 5 on the standard scale or to both.
- (3) Nothing in paragraph (1)(c) is to be construed as requiring any person to answer any question or give any information if to do so might incriminate that person.

(4) No prosecution for an offence under these Regulations shall be begun after the expiry of three years from the commission of the offence or one year from its discovery by the prosecutor, whichever is the earlier.

(5) For the purposes of this regulation, 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.

(6) 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**

17.—(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 plastic material or article or, as the case may be, 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 that—

- (a) 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) either—
  - (i) the accused carried out all such checks of the plastic material or article or 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 the plastic material or article or the material or article in question; and
- (c) 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 alleged 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 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.

(5) If 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 by 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 notice in writing giving such information identifying or assisting in the identification of that other person as was then in the possession of the accused.

(6) For the purposes of paragraph (2), “prepare” includes manufacture or subject to any form of treatment or process.

### **Transitional defence relating to PVC gaskets containing epoxidised soybean oil**

**18.—**(1) In any proceedings for an offence under regulation 3 concerning the sale of a glass jar—

- (a) which contains—
  - (i) infant formulae or follow on formulae as defined by Commission Directive [91/321/EC](#)(**15**); or
  - (ii) processed cereal based foods or baby foods for infants and young children as defined by Commission Directive [96/5/EC](#)(**16**); and
- (b) the lid of which is sealed by means of a PVC gasket containing epoxidised soybean oil having PM/Ref No 88640 in Section A of Annex III,

it shall be a defence to prove the matters set out in paragraph (2).

- (2) The matters to be proved are that—
  - (a) the PVC gasket mentioned in paragraph (1)(b) was compliant with the relevant restrictions and specifications in column 4 of item 259A of Part 1 of Schedule 2 to the Plastic Materials and Articles in Contact with Food (Scotland) Regulations 2006(**17**);
  - (b) the glass jar was filled and sealed before 19th November 2006;
  - (c) the date of filling or a coded indication of that date was present on the jar or its lid at the time of sale; and
  - (d) the labelling or marking with the particulars mentioned in sub paragraph (c) at the time of sale complied with the requirements relating to durability in Article 2(1)(a) of Directive [2000/13/EC](#) of the European Parliament and of the Council on the approximation of the laws of the member States relating to the labelling, presentation and advertising of foodstuffs(**18**).

(3) No person shall without reasonable excuse fail to comply with a request made by the food authority to disclose the date signified by the coded indication mentioned in paragraph (2)(c).

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(15) O.J. No. L 175, 4.7.1991, p.35; as amended by Commission Directive [96/4/EC](#) (O.J. No. L 49, 28.2.1996, p.12), Commission Directive [1999/50/EC](#) (O.J. No. L 139, 2.6.1999, p.29) Commission Directive [2003/14/EC](#) (O.J. No. L 41, 14.2.2003, p.37) and Commission Directive [2006/82/EC](#) (O.J. No. L 362, 20.12.2006). Commission Directive [91/32/EC](#) was repealed by Commission Directive [2006/141/EC](#) (O.J. No. L 401, 30.12.2006). The definitions of infant formulae and follow-on formulae remain the same.

(16) O.J. No. L 41, 14.2.03, p.37; as amended by Commission Directive [98/36/EC](#) (O.J. No. L 167, 12.2.1998, p.23), Commission Directive [1999/39/EC](#) (O.J. No. L 124, 18.5.1999, p.8) and Commission Directive [2003/13/EC](#) (O.J. No. L 41, 14.2.2003, p.33). Commission Directive [96/5/EC](#) was repealed by Commission Directive 2006/125 (O.J. No. L 339, 6.12.2006). The definitions of processed cereal-based foods or baby foods remain the same.

(17) [S.S.I 2006/314](#); revoked by [S.S.I. 2006/517](#).

(18) O.J. No. L 109, 6.5.00, p.29; as corrected by a Corrigendum published on 25th May 2000 (O.J. No. L 124, 25.5.00, p.66), and as amended by Commission Directive [2001/101/EC](#) (O.J. No. L 310, 28.11.01, p.19), (which was itself amended by Commission Directive [2002/86/EC](#) (O.J. No. L 305, 7.11.02, p.19), the Act concerning the conditions of accession of the Czech Republic, the Republic of Estonia, the Republic of Cyprus, the Republic of Latvia, the Republic of Hungary, the Republic of Malta, the Republic of Poland, the Republic of Slovenia and the Slovak Republic and the adjustments to the Treaties on which the European Union is founded (O.J. No. L 236, 23.9.03, p.33) and Directive [2003/89/EC](#) (O.J. No. L 308, 25.11.03, p.15).

### Other transitional defences and savings

**19.**—(1) Notwithstanding the revocation of the 1998 Regulations by regulation 24 of the 2006 Regulations, in relation to any plastic material or article—

- (a) manufactured before 1st July 1998, the defence in regulation 3(3) of the 1998 Regulations;
- (b) manufactured or imported into the European Community before 1st January 2003, the defence in regulation 10(15) of the 1998 Regulations;
- (c) put into free circulation in the European Community before 30th November 2002, the defence in regulation 10(16) of the 1998 Regulations;
- (d) manufactured or imported into the European Community before 1st March 2004, the defence in regulation 10(21)(a) of the 1998 Regulations;
- (e) manufactured or imported into the European Community before 1st March 2003, the defence in regulation 10(21)(b) of the 1998 Regulations;
- (f) containing azodicarbonamide and brought into contact with food before 2nd August 2005, the defence in regulation 10(23) of the 1998 Regulations; or
- (g) manufactured or imported into the European Community before 1st March 2006, the defence in regulation 10(25) of the 1998 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 under these Regulations other than an offence mentioned in regulation 18(1) it shall be a defence to prove –

- (a) that the act constituting the alleged offence was committed in relation to a plastic material or article which was manufactured or imported into the European Community before 19th November 2007; and
- (b) that the matter constituting the alleged offence would not otherwise have constituted an offence under these Regulations if the amendments to the Directive made by Commission Directive [2005/79/EC](#) had not been implemented at the time the matter occurred.

(3) In any proceedings for an offence under these Regulations other than an offence referred to in regulation 18(1), it shall be a defence to prove—

- (a) in the case of—
  - (i) lids containing a gasket that do not comply with the restrictions and specifications for Ref. No.'s 30340, 30401, 36640, 56800, 76815, 76866, 88640 and 93760 contained in the Annex to Commission Regulation [\(EC\) No. 372/2007](#) laying down transitional migration limits for plasticisers in gaskets in lids intended to come into contact with foods(**19**), or
  - (ii) plastic materials and articles which do not comply with the restrictions and specifications for phthalates under Ref. No.'s 74560, 74640, 74880, 75100 and 75105 contained in Annex III,

that the act constituting the alleged offence was committed in relation to a plastic material or article which was manufactured or imported into the European Community before 1st July 2008; or

- (b) in any case other than those mentioned in sub paragraph (a), that the act constituting the alleged offence was committed in relation to a plastic material or article which was manufactured or imported into the European Community before 1st May 2009; and

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(19) O.J. No. L 92, 3.4.2007, p.9.

- (c) that the matter constituting the alleged offence would not otherwise have constituted an offence under these Regulations if the amendments to the Directive made by Commission Directive [2007/19/EC](#) had not been implemented in Scotland at the time the matter occurred.

#### **Procedure where a sample is to be analysed**

**20.**—(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 21.

#### **Secondary analysis by the Government Chemist**

**21.**—(1) Where a sample has been retained under regulation 20 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 20(3)(d) is to be adduced as evidence,

paragraphs (2) to (8) 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 specifying the results of the analysis.

(4) The authorised officer shall immediately on receipt of the Government Chemist's certificate 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

mentioned in 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 specifying the results of the analysis transmitted by the Government Chemist under this regulation must 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.

## PART 4

### Application for Authorisation

#### **Applications for inclusion of an additive in the Community list of authorised additives**

**22.**—(1) This regulation applies where a person has made an application, including supporting data, for the inclusion of an eligible additive in the Community list referred to in Article 4 of the Directive before 1st January 2007.

(2) If during examination of the data referred to in paragraph (2), EFSA has called or calls for supplementary information, the eligible additive may, if otherwise permitted to be used under Scots law, continue to be so used until EFSA has issued an opinion, provided the supplementary information is submitted within the time limits specified by EFSA.

(3) For the purposes of this regulation, an eligible additive is one whose use is permitted in one or more Member States before 1st January 2007.

## PART 5

### General and Supplementary

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

**23.** The following provisions of the Act 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 20 (offences due to fault of another person);
- (c) section 30(8) (relating to documentary evidence);
- (d) section 36 (offences by bodies corporate);
- (e) section 36A (offences by Scottish Partnerships)(**23**); and
- (f) section 44 (protection of officers acting in good faith).

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(23) Section 36A was inserted by section 40 of, and Schedule 5 to the [Food Standards Act 1999 \(c.28\)](#).

### **Amendment to the Food Safety (Sampling and Qualifications) Regulations 1990**

24. In Schedule 1 (provisions to which these Regulations do not apply) to the Food Safety (Sampling and Qualifications) Regulations 1990(20), for the title and reference of the 2006 Regulations substitute the title and reference of these Regulations.

### **Amendments to the Materials and Articles in Contact with Food (Scotland) Regulations 2007**

- 25.—(1) The 2007 Regulations are amended in accordance with paragraphs (2) to (4).
- (2) In regulation 2(1)—
- (a) omit the definition of “the 2006 Regulations”;
  - (b) after the definition of “sell” insert the following definition—  
““the 2008 Regulations” means the Plastic Materials and Articles in Contact with Food (Scotland) Regulations 2008(21).”.
- (3) In regulation 10, in paragraph (4) for “2006” substitute “2008”.
- (4) In regulation 11, in paragraph (5) for “2006” substitute “2008”.

### **Revocations**

26. The following are revoked—
- (a) the 2006 Regulations;
  - (b) regulation 21 of the 2007 Regulations; and
  - (c) the Plastic Materials and Articles in Contact with Food (Lid Gaskets) (Scotland) Regulations 2007(22).

St Andrew’s House,  
Edinburgh  
19th March 2008

*S ROBISON*  
Authorised to sign by the Scottish Ministers

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(20) S.I. 1990/2463as relevantly amended by S.S.I. 2006/517.

(21) S.S.I. 2008/127

(22) S.S.I. 2007/433.