## SCOTTISH STATUTORY INSTRUMENTS

# 2000 No. 431

# The Plastic Materials and Articles in Contact with Food (Amendment) (Scotland) Regulations 2000

### Citation, commencement and extent

**1.**—(1) These Regulations may be cited as the Plastic Materials and Articles in Contact with Food (Amendment) (Scotland) Regulations 2000 and shall come into force on 31st December 2000.

(2) These Regulations extend to Scotland only.

#### Amendment of the principal Regulations

**2.** The Plastic Materials and Articles in Contact with Food Regulations 1998(1) ("the principal Regulations") shall be amended in accordance with the following regulations.

**3.** In regulation 2 (interpretation), in the definition of "the Directive" for the words "and 96/11/EC" there shall be substituted ", 96/11/EC and 1999/91/EC(2) (as corrected(3))".

**4.** For sub paragraph (a) of regulation 3(4) (restriction on the use, sale or importation of plastic materials and articles) there shall be substituted–

"(a) if-

- (i) (aa) it has been manufactured with a prohibited monomer as described in regulation 4(1);
  - (bb) it has been manufactured with a prohibited additive as described in regulation 5(1);
  - (cc) being a product obtained by bacterial fermentation, it does not comply with regulation 5A; or
  - (dd) it does not comply with regulation 4(5), 5(4) or 7, and
- (ii) no defence indicated in regulation 4(7), 5(2) or 7(5) would be available in proceedings for an offence under these Regulations relating to that manufacture or want of compliance; or".
- 5. In regulation 4 (restriction on manufacture with monomers)-
  - (a) in paragraph (1)(c), for the words "restrictions (if any) specified" there shall be substituted the words "restrictions and specifications (if any) set out"; and
  - (b) paragraph (3)(d) shall be omitted.
- 6. In regulation 5 (restriction on manufacture with additives)-
  - (a) for paragraph (1) there shall be substituted-

"(1) Subject to the following paragraphs of this regulation, no person shall use in the manufacture of plastic materials or articles any prohibited additive, that is to say an

<sup>(1)</sup> S.I. 1998/1376.

<sup>(2)</sup> O.J. No. L 310, 4.12.99, p.41.

<sup>(</sup>**3**) O.J. No. L 249, 4.10.00, p.26.

additive identified by PM/REF No., CAS No. (if any) and name respectively in columns 1, 2 and 3 of Part I of Schedule 2 which–

- (a) is not of good technical quality; or
- (b) is not used in accordance with the restrictions and specifications (if any) set out in the corresponding entry in column 4 of the relevant section of that Part of that Schedule."; and
- (b) there shall be inserted at the end the following paragraphs-

"(4) Subject to paragraph (5) of this regulation, where column 4 of Part I of Schedule 2 expresses a migration limit of mg/kg in relation to any additive, no plastic material or article manufactured containing that additive shall be capable of transferring constituents of that additive to food with which that plastic material or article 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 therein released per kilogram of food in the case of any plastic material or article other than one specified in subparagraph (b) below; and
- (b) one sixth of the number of milligrams expressed therein 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 which can be filled, with a capacity of less than 500 millilitres or more than 10 litres; or
  - (ii) sheet, film or other material which cannot be filled or for which it is impracticable to estimate the relationship between the surface area of that material and the quantity of food in contact with that surface area.

(5) A plastic material or article manufactured containing an additive in respect of which column 4 of Part 1 of Schedule 2 expresses a migration limit of mg/kg shall not be considered capable of transferring constituents of that additive to food with which that plastic material or additive may come into contact in quantities exceeding the appropriate limit in paragraph (4) of this regulation if the only food with which that plastic material or article may come into contact is food to which regulation 7(3) applies.".

7. After regulation 5 there shall be inserted the following regulation-

### "Products obtained by bacterial fermentation

5A. A product obtained by bacterial fermentation complies with this regulation if it is-

- (a) of good technical quality;
- (b) identified by PM/REF No., CAS No. and name respectively in columns 1, 2 and 3 of Schedule 2A; and
- (c) in compliance with the restrictions and specifications set out in column 4 of that Schedule.".
- 8. After regulation 7 (transfer of constituents) there shall be inserted the following regulation-

#### "Specifications

**7A.** Schedule 2B shall have effect for the purpose of giving the specifications referred to in column 4 of Schedules 1, 2 and 2A.".

9. In regulation 10 (offences) the following paragraph shall be added at the end-

"(15) In any proceedings for an offence under these Regulations it shall be a defence to prove that–

- (a) the act was committed in relation to a plastic material or article intended to come into contact with food which was manufactured in the European Community, or imported into the European Community, before 1st January 2003; and
- (b) the matters constituting the offence would not have constituted an offence under these Regulations before the amendments made by the Plastic Materials and Articles in Contact with Food (Amendment) (Scotland) Regulations 2000 came into force.".
- 10. In Schedule 1 (monomers)
  - (a) in Part I, in section A in column 4, for the heading "Restrictions" there shall be substituted the heading "Restrictions and specifications";
  - (b) the item number and letter, PM/REF No., CAS No., name and restriction and specification (if any) for each monomer identified in Part I of Schedule 1 to these Regulations shall be inserted in Section A of Part I of Schedule 1 to the principal Regulations at the place corresponding to the number and letter (if any) specified for that monomer in the column headed "Item" in Part 1 of Schedule 1 to these Regulations;
  - (c) in Part I, in Section A, for the entries in column 4 (restrictions and specifications) against the items which correspond to the items listed in Part II of Schedule 1 to these Regulations, there shall be substituted the corresponding entries specified in column 4 of Part II of Schedule 1 to these Regulations;
  - (d) in Part I, in Section A, in item 196 the entry in column 4 (restrictions and specifications) shall be omitted;
  - (e) in Part I, in Section B, item number 67 and the entries for it shall be omitted;
  - (f) in Part I, in Section B, for the entries in column 4 (restrictions and specifications) against the items which correspond to the items listed in Part III of Schedule 1 to these Regulations, there shall be substituted the corresponding entries specified in column 4 of Part III of Schedule 1 to these Regulations;
  - (g) in Part I, in Section B, after the entries relating to item 77, there shall be inserted the item number and letter, PM/REF No., CAS No., name and restriction for the monomer listed in Part IV of Schedule 1 to these Regulations;
  - (h) in Part I, the items in Section B which are listed in Part V of Schedule 1 to these Regulations, and the entries opposite to and corresponding to them, shall be omitted and there shall be inserted in Section A, at the place corresponding to the number and letter (if any) specified for each item in the column headed "Item No. for Section A" in Part V of Schedule 1 to these Regulations, the entries relating to that item listed in Part V of Schedule 1 to these Regulations; and
  - (i) in Part II there shall be inserted at the end the following paragraph-

"4. Where an entry in column 4 in Part I of this Schedule, includes a bracketed number, that entry shall be subject to the note relating to that number as follows:

(1) Warning: there is a risk that the specific migration limit could be exceeded in fatty food simulants.

(2) SML (T) in this specific case means that the restriction shall not be exceeded by the sum of the migration of the following substances mentioned as PM/REF Nos: 10060 and 23920.

(3) SML (T) in this specific case means that the restriction shall not be exceeded by the sum of the migration of the following substances mentioned as PM/REF Nos: 15760, 16990, 47680, 53650, 89440.

(4) SML (T) in this specific case means that the restriction shall not be exceeded by the sum of the migration of the following substances mentioned as PM/REF Nos: 19540, 19960.

(5) SML (T) in this specific case means that the restriction shall not be exceeded by the sum of the migration of the following substances mentioned as PM/REF Nos: 14200, 14230.

(9) SML (T) in this specific case means that the restriction shall not be exceeded by the sum of the migration of the following substances:-

- (a) Badge (=2,2-bis(4 hydroxyphenyl) propane bis(2,3 epoxypropyl) ether
- (b) Badge.H<sub>2</sub>O
- (d) Badge.HCl
- (e) Badge.2HCl
- (f) Badge.H<sub>2</sub>O.HCl

However in aqueous food simulants, the SML (T) should also include Badge.2H<sub>2</sub>O(c) unless the material or article is labelled for use in contact only with those foods and beverages for which it has been demonstrated that the sum of the migration levels of the five above mentioned substances (a)(b)(d)(e)(f) cannot exceed 1mg/kg.".

- 11. In Schedule 2 (additives)-
  - (a) in Part I there shall be added an extra column, numbered "4" and headed "Restrictions and specifications";
  - (b) the item number and letter, PM/REF No., CAS No., name and restriction and specification (if any) for each additive identified in Schedule 2 to these Regulations shall be inserted in Part I of Schedule 2 to the principal Regulations at the place corresponding to the number and letter specified for that additive in the column headed "Item" in Schedule 2 to these Regulations;
  - (c) in Part I, for the entries in column 2 (CAS No.) for item 38 there shall be substituted the following:-

(d) in Part I, for the entries in column 3 (name) for item 38 there shall be substituted the following:-

"Bis (methylbenzylidene) sorbitol

. . . . . .

" " " " " ",

<sup>&</sup>quot;087826-41-3 069158-41-4 054686-97-4 081541-12-0";

- (e) in Part I, for the entry in column 2 (CAS No.) for item 179 there shall be substituted the entry "037244-96-5";
- (f) in Part I, item 195 and the entries for it shall be deleted; and
- (g) in Part II, there shall be inserted at the end the following paragraph-

"4. Where an entry in column 4 (restrictions and specifications) in Part I of this Schedule includes a bracketed number, that entry shall be subject to the note relating to that number as follows:

(1) Warning: there is a risk that the specific migration limit could be exceeded in fatty food simulants.

(3) SML (T) in this specific case means that the restriction shall not be exceeded by the sum of the migration of the following substances mentioned as PM/REF Nos: 15760, 16990, 47680, 53650, 89440.

(6) SML (T) in this specific case means that the restriction shall not be exceeded by the sum of the migration of the following substances mentioned as PM/REF/Nos: 66560 and 66580.

(7) SML (T) in this specific case means that the restriction shall not be exceeded by the sum of the migration of the following substances mentioned as PM/REF Nos: 30080, 42320, 45195, 45200, 53610, 81760, 89200, 92030.

(8) SML (T) in this specific case means that the restriction shall not be exceeded by the sum of the migration of the following substances mentioned as PM/REF Nos: 85840 and 95725.

(10) Warning: there is a risk that the migration of the substance deteriorates the organoleptic characteristics of the food in contact and then, that the finished product does not comply with regulation 4(2) of the Materials and Articles in Contact with Food Regulations 1987(4)."

**12.** After Schedule 2 there shall be inserted as Schedules 2A and 2B as set out in Schedules 3 and 4 to these Regulations.

13. In Schedule 3 (provisions applicable when testing compliance with the migration limits)-

- (a) in paragraph 4(3) and (4), for "regulation 7 or Schedule 1" in each case there shall be substituted "regulation 7, Schedule 1 or Schedule 2"; and
- (b) in paragraph 7(2)(c) for "M1 and M2" there shall be substituted "M2 and M3".

St Andrew's House, Edinburgh 30th November 2000

MALCOLM CHISHOLM Authorised to sign by the Scottish Ministers