

# Scottish Statutory Instrument 2003 No. 9

## The Plastic Materials and Articles in Contact with Food (Amendment) (Scotland) Regulations 2003

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### SCOTTISH STATUTORY INSTRUMENTS

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### 2003 No. 9

### FOOD

### The Plastic Materials and Articles in Contact with Food (Amendment) (Scotland) Regulations 2003

<i>Made</i>	<i>9th January 2003</i>
<i>Laid before the Scottish Parliament</i>	<i>10th January 2003</i>
<i>Coming into force</i>	<i>28th February 2003</i>

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

**Citation, commencement and extent**

**1. - (1) These Regulations may be cited as the Plastic Materials and Articles in Contact with Food (Amendment) (Scotland) Regulations 2003 and shall come into force on 28th February 2003.**

**(2) These Regulations shall extend to Scotland only.**

**Amendments to the Plastic Materials and Articles in Contact with Food Regulations 1998**

**2. The Plastic Materials and Articles in Contact with Food Regulations 1998[4] ("the principal Regulations") shall be amended in accordance with regulations 3 to 6.**

**3. - (1) In regulation 10 (offences), after paragraph (20) there shall be inserted-**

**" (21) In any proceedings for an offence under these Regulations, it shall be a defence to prove that-**

**(a) the act constituting the offence was committed in relation to a plastic material or article intended to come into contact with food which was manufactured in or imported into the European Community before 1st March 2004, and that the matter constituting the offence would not have constituted an offence under these Regulations if the amendments made to them by the provisions specified in paragraph (22) had not been in force at the time that matter occurred; or**

**(b) the act constituting the offence was committed in relation to a plastic material or article intended to come into contact with food which was manufactured in or imported into the European Community before 1st March 2003, and that the matter constituting the offence would not have constituted an offence under these Regulations if the amendments made to them by regulation 4(a)(i) and (b) (in so far as they relate to the monomer divinylbenzene) and regulation 6 of the Plastic Materials and Articles in Contact with Food (Amendment) (Scotland) Regulations 2003 had not been in force at the time that matter occurred.**

**(22) The provisions referred to in paragraph (21)(a) are all the provisions of the Plastic Materials and Articles in Contact with Food (Amendment) (Scotland) Regulations 2003, except in so far as they relate to the monomer divinylbenzene."**

**4. In Schedule 1 (monomers authorised without time limit, monomers authorised up to the end of 2001, monomers authorised up to the end of 1998 and supplementary)-**

**(a) in Section A of Part I-**

**(i) in the case of each monomer listed in Part I of Schedule 1 to these Regulations, the item number and letter, PM/REF No. , CAS No. , name**

**and restriction or specification (if any) specified for that monomer in Part I of Schedule 1 to these Regulations shall be inserted in the appropriate numerical position for that item number and letter;**

**(ii) in the case of each monomer listed in the third column of Part II of Schedule 1 to these Regulations, for the item number and letter for that monomer specified opposite to it in the first column of section A of Part I of Schedule 1 to the principal Regulations (item) there shall be substituted the item number and letter for it specified in the second column (new item) of Part II of Schedule 1 to these Regulations;**

**(iii) in the case of the monomer Bis (4-isocyanatocyclohexyl) methane (item 43), for the entry for that monomer specified in column 1 (PM/REF/No. ) there shall be substituted the entry "13560"; and**

**(iv) in the case of each monomer listed in the first column of Part III of Schedule 1 to these Regulations, for the entry for that monomer specified opposite to it in column 4 of section A of Part I of Schedule 1 to the principal Regulations (restrictions and specifications) there shall be substituted the entry for it specified in the second column (restrictions and specifications) of Part III of Schedule 1 to these Regulations;**

**(b) in Section B of Part I, all the entries for the monomers listed in Part IV of Schedule 1 to these Regulations shall be omitted; and**

**(c) in Part II, there shall be inserted at the end of paragraph 4-**

**" (22) SML(T) in this case means that the restriction shall not be exceeded by the sum of the migration levels of the substances having PM/REF/Nos. 13620, 36840, 40320 and 87040.**

**(23) SML(T) in this case means that the restriction shall not be exceeded by the sum of the migration levels of the substances having PM/REF/Nos. 13720 and 40580.**

**(24) SML(T) in this case means that the restriction shall not be exceeded by the sum of the migration levels of the substances having PM/REF/Nos. 16650 and 51570.**

**(25) QM(T) in this case means that the restriction shall not be exceeded by the sum of the residual quantities of the substances having PM/REF/Nos. 14950, 15700, 16240, 16570, 16600, 16630, 18640, 19110, 22332, 22420, 22570, 25210, 25240 and 25270."**

**5. In Schedule 2 (additives and supplementary)-**

**(a) in Part I-**

**(i) in the case of each additive listed in Part I of Schedule 2 to these Regulations, the item number and letter, PM/REF No. , CAS No. , name and restriction or specification specified for that additive in Part I of Schedule 2 to these Regulations shall be inserted in the appropriate numerical position for that item number and letter;**

**(ii) in the case of the entry at item number 38B for the additive Bis**

(polyethyleneglycol) hydroxymethylphosphonate, there shall be inserted in column 2 of that Part (CAS No. ) the entry "68951 - 50 - 8"; and

(iii) in the case of the additive listed of Part II of Schedule 2 to these Regulations, for the entry for that additive in Part I of Schedule 2 to the principal Regulations there shall be substituted the entry for it specified in Part II of Schedule 2 to these Regulations;

**(b) in Part II-**

(i) in the case of each additive listed in Part III of Schedule 2 to these Regulations, the item number and letter, PM/REF/No. , CAS No. , name and restriction or specification (if any) specified for that additive in Part III of Schedule 2 to these Regulations shall be inserted in the appropriate numerical position for that item number and letter; and

(ii) in the case of each additive listed in the first column of Part IV of Schedule 2 to these Regulations, for the entry for that additive specified opposite to it in column 4 of Part II of Schedule 2 to the principal Regulations (restrictions and specifications) there shall be substituted the entry for it specified in the second column (restrictions and specifications) of Part IV of Schedule 2 to these Regulations; and

**(c) in Part III-**

(i) in note (11) of paragraph 4, after "36800" there shall be inserted ", 36840"; and

(ii) at the end of paragraph 4, there shall be inserted-

" (22) SML(T) in this case means that the restriction shall not be exceeded by the sum of the migration levels of the substances having PM/REF/Nos. 13620, 36840, 40320 and 87040.

(23) SML(T) in this case means that the restriction shall not be exceeded by the sum of the migration levels of the substances having PM/REF/Nos. 13720 and 40580.

(24) SML(T) in this case means that the restriction shall not be exceeded by the sum of the migration levels of the substances having PM/REF/Nos. 16650 and 51570."

**6. In Schedule 2B (specifications), in the case of the substance specified in Schedule 3 to these Regulations, the item number and letter, PM/REF No. and specification set out for that substance shall be inserted in the appropriate numerical position for that item number and letter.**

**MARY MULLIGAN**

**Authorised to sign by the Scottish Ministers**

**St Andrew's House, Edinburgh  
9th January 2003**

**SCHEDULE 1****Regulation 4(a)(i), (ii) and (iv) and (b)****PART I****LIST OF MONOMERS TO BE ADDED TO SECTION A OF PART I OF  
SCHEDULE 1 TO THE PRINCIPAL REGULATIONS**

<i>Item</i>	<i>PM/REF No.</i>	<i>CAS No.</i>	<i>Name</i>	<i>Restrictions and Specifications</i>
33B	13075	00091-76-9	Benzoguanamine	As item 76A
47B	13620	10043-35-3	Boric acid	SML(T) - 6 mg/kg (22) (expressed as boron) without prejudice to the provisions of Directive 98/83/EC on water for human consumption[5]
49A	13720	00110-63-4	1,4-Butanediol	SML(T) = 0.05 mg/kg (23)
76A	15310	00091-76-9	2,4-Diamino-6-phenyl-1,3,5-triazine	QMA = 5 mg/6 dm <sup>2</sup>
92A	16650	00127-63-9	Diphenyl sulphone	SML(T) = 3 mg/kg (24)
93A	16690	01321-74-0	Divinylbenzene	QMA = 0.01 mg/6 dm <sup>2</sup> or SML = ND (DL = 0.02 mg/kg, analytical tolerance included) for the sum of divinylbenzene and ethylvinylbenzene and in compliance with the specifications laid down in Schedule 2B
93C	16697	00693-23-2	n-Dodecanedioic Acid	
120A	18897	16712-64-4	6-Hydroxy-2-naphthalenecarboxylic acid	SML = 0.05 mg/kg
120B	18898	103-90-2	N-(4-Hydroxyphenyl) acetamide	Only to be used in liquid crystals and behind a barrier layer in multi-layered plastics
147B	22332	28679-16-5	Mixture of (40% w/w) 2,2,4-trimethylhexane-1,6-diisocyanate and (60% w/w) 2,4,4-trimethylhexane-1,6-diisocyanate	QM(T) = 1 mg/kg (expressed as NCO) (25)
217A	25840	03290-92-4	1,1,1-trimethylolpropane	SML = 0.05 mg/kg

			trimethacrylate	
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PART II

LIST OF MONOMERS FOR WHICH THE ENTRY CONTAINED IN THE FIRST COLUMN (ITEM) OF SECTION A OF PART I OF SCHEDULE 1 TO THE PRINCIPAL REGULATIONS IS TO BE AMENDED

<i>Previous Item</i>	<i>Item</i>	<i>Name</i>
49A	49B	1,4-Butanediol bis(2,3- epoxypropyl)ether
49B	49C	1,4-Butanediol formal
76A	76B	1,6-Diamino-2,2,4-trimethylhexane
76B	76C	1,6-Diamino-2,4,4-trimethylhexane
93A	93B	N,N'-Divinyl-2-imidazolidone
93B	93D	1-Dodecene
217A	217B	Trioxane

PART III

LIST OF MONOMERS FOR WHICH THE ENTRY CONTAINED IN COLUMN 4 (RESTRICTIONS AND SPECIFICATIONS) OF SECTION A OF PART I OF SCHEDULE 1 TO THE PRINCIPAL REGULATIONS IS TO BE AMENDED

<i>Name</i>	<i>Restrictions and specifications</i>
Chlorotrifluoroethylene	QMA = 0.5 mg/6 dm <sup>2</sup>
Cyclohexyl isocyanate	QM(T) = 1 mg/kg (expressed as NCO) (25)
Dicyclohexylmethane-4,4'-diisocyanate	QM(T) = 1 mg/kg (expressed as NCO) (25)
3,3'-Dimethyl-4,4'-diisocyanatobiphenyl	QM(T) = 1 mg/kg (expressed as NCO) (25)
Diphenylether-4,4'-diisocyanate	QM(T) = 1 mg/kg (expressed as NCO) (25)
Diphenylmethane-2,4'-diisocyanate	QM(T) = 1 mg/kg (expressed as NCO) (25)
Diphenylmethane-4,4'-diisocyanate	QM(T) = 1 mg/kg (expressed as NCO) (25)
Hexamethylene diisocyanate	QM(T) = 1 mg/kg (expressed as NCO) (25)
1-Isocyanato-3-isocyanatomethyl-3,5,5-trimethylcyclohexane	QM(T) = 1 mg/kg (expressed as NCO) (25)

1,5-Naphthalene diisocyanate	QM(T) = 1 mg/kg (expressed as NCO) (25)
Octadecyl isocyanate	QM(T) = 1 mg/kg (expressed as NCO) (25)
2,4-Toluene diisocyanate	QM(T) = 1 mg/kg (expressed as NCO) (25)
2,6-Toluene diisocyanate	QM(T) = 1 mg/kg (expressed as NCO) (25)
2,4-Toluene diisocyanate dimer	QM(T) = 1 mg/kg (expressed as NCO) (25)

**PART IV**

**LIST OF MONOMERS FOR WHICH THE ENTRIES CONTAINED IN SECTION B OF PART I OF SCHEDULE 1 TO THE PRINCIPAL REGULATIONS ARE TO BE DELETED**

<i>Item</i>	<i>Name</i>
7	Benzoguanamine
8	1,4-Butanediol
11	2,4-Diamino 6 phenyl 1,3,5 triazine
14	Divinylbenzene
15	Dodecanedioic acid
25	1,1,1-Trimethylolpropane trimethacrylate

**SCHEDULE 2**

**Regulation 5(a)(i) and (iii) and (b)**

**PART I**

**LIST OF ADDITIVES TO BE ADDED TO PART I OF SCHEDULE 2 TO THE PRINCIPAL REGULATIONS**

<i>Item</i>	<i>PM/REF No.</i>	<i>CAS No.</i>	<i>Name</i>	<i>Restrictions and Specifications</i>
27B	36840	12007-55-5	Barium tetraborate	SML(T) = 1 mg/kg expressed as barium (11) and SML(T) = 6 mg/kg (22) (expressed as boron) without prejudice to the provisions of Directive 98/83/EC on water for human consumption
38C	40320	10043-	Boric acid	SML(T) = 6 mg/kg (22) (expressed as

		35-3		boron) without prejudice to the provisions of Directive 98/83/EC on water for human consumption
40A	40580	00110-63-4	1,4-Butanediol	SML(T) = 0.05 mg/kg (23)
188B	71670	178671-58-4	Pentaerythritol tetrakis (2-cyano-3,3-diphenylacrylate)	SML(T) = 0.05 mg/kg
246A	87040	01330-43-4	Sodium tetraborate	SML(T) = 6 mg/kg (22) (expressed as boron) without prejudice to the provisions of Directive 98/83/EC on water for human consumption

**PART II****ADDITIVE FOR WHICH THE ENTRY CONTAINED IN PART I OF SCHEDULE 2 TO THE PRINCIPAL REGULATIONS IS TO BE SUBSTITUTED**

<i>Item</i>	<i>PM/REF No.</i>	<i>CAS No.</i>	<i>Name</i>	<i>Restrictions and specifications</i>
38B	40120	68951-50 8	Bis (polyethyleneglycol) hydroxymethylphosphonate	SML = 0.6 mg/kg

**PART III****LIST OF ADDITIVES TO BE ADDED TO PART II OF SCHEDULE 2 TO THE PRINCIPAL REGULATIONS**

<i>Item</i>	<i>PM/REF No.</i>	<i>CAS No.</i>	<i>Name</i>	<i>Restrictions and specifications</i>
27A	45650	6197-30-4	2-Cyano-3,3-diphenylacrylic acid, 2-ethylhexyl ester	SML = 0.05 mg/kg
82A	68860	04724-48-5	n-Octylphosphonic acid	SML = 0.05 mg/kg
111A	95000	28931-67-1	Trimethylolpropane trimethacrylate-methyl methacrylate copolymer	

**PART IV****LIST OF ADDITIVES FOR WHICH THE ENTRY CONTAINED IN COLUMN 4 (RESTRICTIONS AND SPECIFICATIONS) OF PART II OF SCHEDULE 2 TO THE PRINCIPAL REGULATIONS IS TO BE AMENDED**

<i>Item</i>	<i>Name</i>	<i>Restrictions and specifications</i>
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15	N,N-bis(2-hydroxyethyl)alkyl (C8-C18) amine hydrochlorides	SML(T) = 1.2 mg/kg (12) expressed as tertiary amine (expressed excluding HCl)
49	Diphenyl sulphone	SML(T) = 3 mg/kg (24)

SCHEDULE 3

Regulation 6

SUBSTANCE TO BE ADDED TO SCHEDULE 2B TO THE PRINCIPAL REGULATIONS

Item	PM/REF No.	Specifications
1	16690	DIVINYLBENZENE  It may contain up to 40% of Ethylvinylbenzene

EXPLANATORY NOTE

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

These Regulations, which extend to Scotland only, amend for the third time the Plastic Materials and Articles in Contact with Food Regulations 1998 (S.I. 1998/1376, "the 1998 Regulations").

The Regulations implement Commission Directive 2002/17/EC amending Directive 90/128/EEC relating to plastic materials and articles intended to come into contact with foodstuffs (O.J. No. L58, 28.2.2002, p.19) (in so far as it is not already implemented in relation to camphor and benzaldehyde by the Plastic Materials and Articles in Contact with Food (Amendment) (Scotland) Regulations 2002).

The Regulations amend the 1998 Regulations by-

- (a) adding new substances to the list of monomers which may be used in the manufacture of plastic materials or articles and amending the conditions of use of certain monomers used in such manufacture (regulation 4);
- (b) adding new substances to the non exhaustive list of additives used in the manufacture of plastic materials or articles and amending the conditions of use of certain additives used in such manufacture (regulation 5);
- (c) adding one substance to the list of substances whose specifications are set out in Schedule 2B to the 1998 Regulations (regulation 6); and
- (d) inserting a transitional provision in relation to offences which may be committed under the 1998 Regulations (regulation 3).

A Regulatory Impact Assessment, which includes a compliance cost assessment of the

**effect which these Regulations are likely to 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 6NJU.**

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*Notes:*

- [1] 1990 c.16; section 6(4) was amended by paragraph 6 of Schedule 9 to the Deregulation and Contracting Out Act 1994 (c.40) and by paragraph 10(3) of Schedule 5 to the Food Standards Act 1999 (c.28) ("the 1999 Act"); sections 16(2) and 48(1) were amended by paragraph 8 of Schedule 5 to the 1999 Act; section 17(1) was amended by paragraphs 8 and 12 of Schedule 5 to the 1999 Act; section 26(3) was amended by Schedule 6 to the 1999 Act; amendments made by Schedule 5 to the 1999 Act which extend to Scotland shall be taken as pre-commencement enactments for the purposes of the Scotland Act 1998 (c.46) by virtue of section 40(2) of the 1999 Act. The functions of the Secretary of State were transferred to the Scottish Ministers by virtue of section 53 of the Scotland Act 1998.back**
- [2] Section 48(4A) was inserted by paragraph 21 of Schedule 5 to the Food Standards Act 1999.back**
- [3] Section 48(4B) was inserted by paragraph 21 of Schedule 5 to the Food Standards Act 1999.back**
- [4] S.I. 1998/1376, amended by S.S.I. 2000/431 and 2002/498.back**
- [5] O.J. No. L 330, 5.12.1998, p.32.back**

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