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STATUTORY RULES OF NORTHERN IRELAND

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**2000 No. 402**

**FOOD**

**Plastic Materials and Articles in Contact with Food  
(Amendment) Regulations (Northern Ireland) 2000**

*Made - - - - 12th December 2000*

*Coming into operation 5th February 2001*

The Department of Health, Social Services and Public Safety<sup>(1)</sup> in exercise of the powers conferred on it by Articles 15(2), 16(1), 25(1)(a) and 47(2) of the Food Safety (Northern Ireland) Order 1991<sup>(2)</sup> and of all other powers enabling it in that behalf, having had regard in accordance with Article 47(3A) of the said Order to relevant advice given by the Food Standards Agency and after consultation in accordance with Article 47(3) and (3B) of the said Order, hereby makes the following Regulations:

**Citation and commencement**

1. These Regulations may be cited as the Plastic Materials and Articles in Contact with Food (Amendment) Regulations (Northern Ireland) 2000 and shall come into operation on 5th February 2001.

**Amendment of Regulations**

2. The Plastic Materials and Articles in Contact with Food Regulations (Northern Ireland) 1998<sup>(3)</sup> (“the principal Regulations”) shall be amended as follows.

3. In regulation 2(1) (interpretation), in the definition of “the Directive”, for “and 96/11/EC<sup>(4)</sup>” there shall be substituted “, 96/11/EC and 1999/91/EC<sup>(5)</sup> (as corrected<sup>(6)</sup>)”.

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

“(a) if—

(i) it has been manufactured with a prohibited monomer as described in regulation 4(1);

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(1) Formerly the Department of Health and Social Services; see S.I. 1999/283 (N.I. 1) Article 3  
(2) S.I. 1991/762 (N.I. 7) as amended by S.I. 1996/1633 (N.I. 12) and paragraphs 26 to 42 of Schedule 5 and Schedule 6 to the Food Standards Act 1999 c. 28  
(3) S.R. 1998 No. 264  
(4) O.J. No. L161, 12.3.96, p. 26  
(5) O.J. No. L310, 4.12.99, p. 41  
(6) O.J. No. L249, 4.10. 2000, p. 26

- (ii) it has been manufactured with a prohibited additive as described in regulation 5(1);
  - (iii) being a product obtained by bacterial fermentation, it does not comply with regulation 5A; or
  - (iv) it does not comply with regulation 4(5), 5(4) or 7, and 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), after “prohibited monomer,” there shall be inserted “that is to say any monomer”;
  - (b) in paragraph (1)(c), for “restrictions (if any) specified” there shall be substituted “restrictions and specifications (if any) set out”;
  - (c) paragraph (3)(d) shall be deleted.
6. In regulation 5 (restriction on manufacture with additives)—
- (a) for paragraph (1) there shall be substituted—
    - “(1) Subject to the following paragraphs, no person shall use in the manufacture of plastic materials or articles any prohibited additive, that is to say an 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 added at the end the following paragraphs—
      - “(4) Subject to paragraph (5), 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); 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 I 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 article may come into contact in quantities exceeding the appropriate limit in paragraph (4) if the only food which that plastic material or article may come into contact with 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 given 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 in Schedules 1, 2 and 2A.”.

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

“(13) 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) Regulations (Northern Ireland) 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 “Restrictions and specifications”;
- (b) the item number and letter, PM/REF No., CAS No., name, 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 that Part of that Schedule to these Regulations;
- (c) in Part I, in Section A, for the entries in column 4 (restrictions and specifications) opposite to and corresponding to the items listed in Part II of Schedule 1 to these Regulations there shall be substituted the corresponding entries specified in the said Part II;
- (d) in Part I, in Section A, in item 196 the entry in column 4 (restrictions and specifications) shall be deleted;
- (e) in Part I, in Section B, item 67 and the entries for it shall be deleted;
- (f) in Part I, in Section B, for the entries in column 4 (restrictions) opposite to and corresponding to the items listed in Part III of Schedule 1 to these Regulations there shall be substituted the corresponding entries specified in 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 identified 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 for those items in that Section, shall be deleted 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 in the said Part V; and
- (i) in Part II there shall be added at the end the following paragraph—

4. Where an entry in column 4 in Part I 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-epoxy propyl) 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 1 mg/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, 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.) and column 3 (name) for item 38 there shall be substituted the following—

“087826-41-3 Bis(methylbenzylidene) sorbitol  
069158-41-4           ”           ”           ”

054686-97-4       ”       ”       ”  
081541-12-0       ”       ”       ”””;

- (d) in Part I, for the entry in column 2 (CAS No.) for item 179 there shall be substituted the entry “037244-96-5”;
- (e) in Part I, item 195 and the entries for it shall be deleted; and
- (f) 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 1 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 (Northern Ireland) 1987(7).”.

12. After Schedule 2 there shall be inserted as Schedules 2A and 2B the contents of 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 “M<sub>1</sub> and M<sub>2</sub>” there shall be substituted “M<sub>2</sub> and M<sub>3</sub>”.

Sealed with the Official Seal of the Department of Health, Social Services and Public Safety on 12th December 2000.

L.S.

*W. B. Smith*  
Senior Officer of the  
Department of Health, Social Services and  
Public Safety

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## SCHEDULE 1

Regulation 10

## 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>  |
|-------------|-------------------|----------------|--|---|
| 28A         | 12761             | 000693-57-2    | 12-Aminododecanoic acid                  | The specific migration of this substance shall not exceed 0.05 mg/kg  |
| 35A         | 13180             | 000498-66-8    | Bicyclo [2.2.1] hept-2-ene (=norbornene) | The specific migration of this substance shall not exceed 0.05 mg/kg  |
| 35B         | 13210             | 001761-71-3    | Bis(4-aminocyclohexyl)methane            | The specific migration of this substance shall not exceed 0.05 mg/kg  |
| 63A         | 14650             | 000079-38-9    | Chlorotrifluoroethylene                  | The quantity of this substance in the finished plastic material or article shall not exceed 0.05 mg/6 dm <sup>2</sup> |
| 68A         | 14841             | 000599-64-4    | 4-Cumylphenol                            | The specific migration of this substance shall not exceed 0.05 mg/kg  |
| 93A         | 16694             | 013811-50-2    | N,N9-Divinyl-2-imidazolidinone           | The quantity of this substance in the finished plastic material or article shall not exceed 5 mg/kg                   |
| 93B         | 16704             | 000112-41-4    | 1-Dodecene                               | The specific migration of this substance shall not exceed 0.05 mg/kg  |

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| <i>Item</i> | <i>PM/REF No.</i> | <i>CAS No.</i>             | <i>Name</i>  | <i>Restrictions and specifications</i>   |
|-------------|-------------------|----------------------------|--|--|
| 147A        | 22331             | 025513-64-8                | Mixture of (40% w/w) 1,6-diamino-2,2,4-trimethylhexane and (60% w/w) 1,6-diamino-2,4,4-trimethylhexane | The quantity of this substance in the finished plastic material or article shall not exceed 5 mg/6 dm <sup>2</sup>   |
| 152A        | 22550             | 000498-66-8                | Norbornene   | The specific migration of this substance shall not exceed 0.05 mg/kg   |
| 163A        | 23175             | 000122-52-1                | Phosphorous acid, triethyl ester   | The quantity of this substance in the finished plastic material or article shall be not detectable (when measured by a method with a detection limit of 1 mg/kg) |
| 169A        | 23547             | 009016-00-6<br>063148-62-9 | Polydimethylsiloxane (MW >6800)  | In compliance with the specifications laid down in Schedule 2B   |
| 206A        | 25080             | 001120-36-1                | 1-Tetradecene  | The specific migration of this substance shall not exceed 0.05 mg/kg   |
| 214A        | 25385             | 000102-70-5                | Triallylamine  | In compliance with the specifications laid down in Schedule 2B   |
| 218A        | 25927             | 027955-94-8                | 1,1,1-Tris(4-hydroxyphenyl)ethane  | The quantity of this substance in the finished plastic material or article shall not exceed 0.5 mg/kg. For use only in polycarbonates                            |



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| <i>Item</i> | <i>PM/REF No.</i> | <i>CAS No.</i> | <i>Name</i>           | <i>Restrictions and specifications</i>  |
|-------------|-------------------|----------------|-----------------------|---|
| 223         | 26155             | 001072-63-5    | 1-Vinylimidazole      | The quantity of this substance in the finished plastic material or article shall not exceed 5 mg/kg                         |
| 225         | 26320             | 002768-02-7    | Vinyltrimethoxysilane | The quantity of this substance in the finished plastic material or article shall not exceed 5 mg/kg                         |
| 226         | 26360             | 007732-18-5    | Water                 | In compliance with Directive <a href="#">98/83/EC</a> on the quality of water intended for human consumption <sup>(8)</sup> |

## Part II

### List of Monomers in Section A of Part I of Schedule 1 to the Principal Regulations for which the content of the column “Restrictions and Specifications” is modified

| <i>Item</i> | <i>PM/REF No.</i> | <i>CAS No.</i> | <i>Name</i>   | <i>Restrictions and specifications</i>                      |
|-------------|-------------------|----------------|---|---|
| 2           | 10060             | 000075-07-0    | Acetaldehyde  | SML(T) = 6 mg/kg (2)  |
| 40          | 13510             | 001675-54-3    | 2,2-Bis(4-hydroxyphenyl) propane bis (2,3-epoxypropyl) ether (=BADGE) | SML(T) = 1 mg/kg (9) Authorised only until 1st January 2005 |
| 56          | 14200             | 000105-60-2    | Caprolactam   | SML(T) = 15 mg/kg (5)                                       |
| 57          | 14230             | 002123-24-2    | Caprolactam, sodium salt  | SML(T) = 15 mg/kg (5) (expressed as caprolactam)            |
| 79          | 15760             | 000111-46-6    | Diethyleneglycol  | SML(T) = 30 mg/kg (3)                                       |

(8) O.J. No. L330, 5.12.1998, p. 32

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| <i>Item</i> | <i>PM/REF No.</i> | <i>CAS No.</i> | <i>Name</i>   | <i>Restrictions and specifications</i>  |
|-------------|-------------------|----------------|---|---|
| 98          | 16990             | 000107-21-1    | Ethyleneglycol                                      | SML(T) = 30 mg/kg (3)   |
| 102         | 17160             | 000097-53-0    | Eugenol   | The specific migration of this substance shall be not detectable (when measured by a method with a limit of detection of 0.02 mg/kg, analytical tolerance included) |
| 128         | 19540             | 000110-16-7    | Maleic acid   | SML(T) = 30 mg/kg (4)   |
| 129         | 19960             | 000108-31-6    | Maleic anhydride                                    | SML(T) = 30 mg/kg (4) (expressed as maleic acid)  |
| 214         | 25360             | —              | Trialkyl(C5-C15) acetic acid, 2,3-epoxypropyl ester | The quantity of this substance in the finished plastic material or article shall not exceed 1 mg/kg (expressed as epoxy group, molecular weight = 43)               |

### Part III

#### List of Monomers in Section B of Part I of Schedule 1 to the Principal Regulations for which the content of the column “Restrictions and Specifications” is modified

| <i>Item</i> | <i>PM/REF No.</i> | <i>CAS No.</i> | <i>Name</i>    | <i>Restrictions and specifications</i>   |
|-------------|-------------------|----------------|----------------|--|
| 34          | 16690             | 001321-74-0    | Divinylbenzene | The quantity of this material in the finished plastic material or article shall not exceed 1 mg/kg or the specific migration of this substance shall |

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| <i>Item</i> | <i>PM/REF No.</i> | <i>CAS No.</i> | <i>Name</i>                              | <i>Restrictions and specifications</i>   |
|-------------|-------------------|----------------|--|--|
|             |                   |                |  | be not detectable (when measured by a method with a limit of detection of 0.02 mg/kg, analytical tolerance included)   |
| 56          | 20590             | 000106-91-2    | Methacrylic acid, 2,3- epoxypropyl ester | The quantity of this material in the finished plastic material or article shall not exceed 5 mg/kg (expressed as epoxy group, molecular weight = 43)               |
| 68          | 22720             | 000140-66-9    | 4-tert-Octylphenol                       | The specific migration of this substance shall be not detectable (when measured by a method with a limit of detection of 0.01mg/kg, analytical tolerance included) |

#### Part IV

#### **Monomer to be added to Section B 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> |
|-------------|-------------------|----------------|---|--|
| 77AA        | 2518255           | 000140-66-9    | 4-(1,1,3,3-Tetramethylbutyl) phenol (=4-tert-octylphenol) | As item 68                             |

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## Part V

### List of Monomers transferred from Section B to Section A of Part I of Schedule 1 to the Principal Regulations

| <i>Item No. in Section B</i> | <i>Item No. for Section A</i> | <i>PM/REF No.</i> | <i>CAS No.</i> | <i>Name</i>                                 | <i>Restrictions and specifications</i>  |
|------------------------------|-------------------------------|-------------------|----------------|---|---|
| 5                            | 13A                           | 11000             | 050976-02-8    | Acrylic acid, dicyclopentadienyl ester      | The quantity of this substance in the finished plastic material or article shall not exceed 0.05 mg/6 dm <sup>2</sup>   |
| 6                            | 13B                           | 11245             | 002156-97-0    | Acrylic acid, dodecyl ester                 | The specific migration of this substance shall not exceed 0.05 mg/kg (1)  |
| 9                            | 23A                           | 12265             | 004074-90-2    | Adipic acid, divinyl ester                  | The quantity of this substance in the finished plastic material or article shall not exceed 5 mg/kg. For use only as comonomer                                      |
| 12                           | 33A                           | 13060             | 004422-95-1    | 1,3,5-Benzenetricarboxylic acid trichloride | The quantity of this substance in the finished plastic material or article shall not exceed 0.05 mg/6 dm <sup>2</sup> (measured as 1,3,5-benzenetricarboxylic acid) |
| 16                           | 49A                           | 13780             | 002425-79-8    | 1,4-Butanediol bis (2,3-                    | The quantity of this  |

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| <i>Item No. in Section B</i> | <i>Item No. for Section A</i> | <i>PM/REF No.</i> | <i>CAS No.</i> | <i>Name</i>                   | <i>Restrictions and specifications</i>  |
|------------------------------|-------------------------------|-------------------|----------------|-------------------------------|---|
|                              |                               |                   |                | epoxypropyl) ether            | substance in the finished plastic material or article shall not exceed 1 mg/kg (expressed as epoxy group, molecular weight equal to 43) |
| 19                           | 52A                           | 14020             | 000098-54-4    | 4-tert-Butylphenol            | The specific migration of this substance shall not exceed 0.05 mg/kg  |
| 22                           | 73A                           | 15130             | 000872-05-9    | 1-Decene                      | The specific migration of this substance shall not exceed 0.05 mg/kg  |
| 30                           | 88A                           | 16360             | 000576-26-1    | 2,6-Dimethylphenol            | The specific migration of this substance shall not exceed 0.05 mg/kg  |
| 32                           | 88B                           | 16450             | 000646-06-0    | 1,3-Dioxolane                 | The specific migration of this substance shall not exceed 0.05 mg/kg  |
| 37                           | 111A                          | 18220             | 068564-88-5    | N-Heptylamino undecanoic acid | The specific migration of this substance shall not exceed 0.05 mg/kg (1)  |
| 41                           | 118A                          | 18820             | 000592-41-6    | 1-Hexene                      | The specific migration of this substance shall not  |

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| <i>Item No. in Section B</i> | <i>Item No. for Section A</i> | <i>PM/REF No.</i> | <i>CAS No.</i> | <i>Name</i>                                    | <i>Restrictions and specifications</i>  |
|------------------------------|-------------------------------|-------------------|----------------|--|---|
| 42                           | 121A                          | 19060             | 000109-53-5    | Isobutyl vinyl ether                           | The quantity of this substance in the finished plastic material or article shall not exceed 5 mg/kg   |
| 43                           | 121B                          | 19150             | 000121-91-5    | Isophthalic acid                               | The specific migration of this substance shall not exceed 5 mg/kg   |
| 49                           | 130A                          | 19990             | 000079-39-0    | Methacrylamide                                 | The specific migration of this substance shall be not detectable (when measured by a method with a limit of detection of 0.02 mg/kg, analytical tolerance included) |
| 50                           | 131A                          | 20050             | 000096-05-9    | Methacrylic acid, allyl ester                  | The specific migration of this substance shall not exceed 0.05 mg/kg  |
| 55                           | 135A                          | 20530             | 002867-47-2    | Methacrylic acid, 2-(dimethylamino)ethyl ester | The specific migration of this substance shall be not detectable (when measured by a method with a limit of detection   |

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| <i>Item No. in Section B</i> | <i>Item No. for Section A</i> | <i>PM/REF No.</i> | <i>CAS No.</i> | <i>Name</i>                          | <i>Restrictions and specifications</i>   |
|------------------------------|-------------------------------|-------------------|----------------|--------------------------------------|--|
|                              |                               |                   |                |                                      | of 0.02 mg/kg, analytical tolerance included)  |
| 61                           | 145A                          | 21730             | 000563-45-1    | 3-Methyl-1-butene                    | The quantity of this substance in the finished plastic material or article shall not exceed 0.006 mg/6 dm <sup>2</sup> . For use only in polypropylene |
| 70                           | 159A                          | 22937             | 001623-05-8    | Perfluoropropyl perfluorovinyl ether | The specific migration of this substance shall not exceed 0.05 mg/kg   |
| 71                           | 173A                          | 23770             | 000504-63-2    | 1,3-Propanediol                      | The specific migration of this substance shall not exceed 0.05 mg/kg   |
| 72                           | 177A                          | 23920             | 000105-38-4    | Propionic acid, vinyl ester          | SML(T) = 6 mg/kg (2) (expressed as acetaldehyde)   |
| 74                           | 198A                          | 24760             | 026914-43-2    | Styrenesulphonid acid                | The specific migration of this substance shall not exceed 0.05 mg/kg   |
| 83                           | 224                           | 26170             | 003195-78-6    | N-Vinyl-N-methylacetamide            | The quantity of this substance in the finished plastic material or article shall   |

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| <i>Item No. in Section B</i> | <i>Item No. for Section A</i> | <i>PM/REF No.</i> | <i>CAS No.</i> | <i>Name</i> | <i>Restrictions and specifications</i> |
|------------------------------|-------------------------------|-------------------|----------------|-------------|--|
|                              |                               |                   |                |             | not exceed 2 mg/kg                     |

## SCHEDULE 2

Regulation 11

List of additives to be inserted in 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>                             |
|-------------|-------------------|----------------|--|--|
| 2A 7A       | 30080 30610       | 004180-12-5 —  | Acetic acid, copper salt<br>Acids C2-C24<br>aliphatic, linear monocarboxylic, from natural oils and fats and their mono-, di- and triglycerol esters (branched fatty acids at naturally occurring levels are included) | SML(T) = 30 mg/kg (7) (expressed as copper)                        |
| 7B          | 30612             | —              | Acids C2-C24<br>aliphatic, linear, monocarboxylic, synthetic and their mono-, di- and triglycerol esters   |  |
| 9A          | 31530             | 123968-25-2    | Acrylic acid, 2,4-di-tert-pentyl-6-[1(3,5-di-tert-pentyl-2-hydroxyphenyl) ethyl] phenyl ester  | The specific migration of this substance shall not exceed 5 mg/kg  |
| 12A         | 33801             | —              | <i>n</i> -Alkyl (C10-C13) benzenesulphonic acid  | The specific migration of this substance shall not exceed 30 mg/kg |
| 12B         | 34240             | —              | Alkyl(C10-C20) sulphonic acid, esters with phenols   | The specific migration of this substance shall not exceed 6 mg/kg  |



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|-------------|-------------------|----------------|---|--|
|             |                   |                |   | kg. Authorised only until 1st January 2002   |
| 27A         | 36640             | 000123-77-3    | Azodicarbonamide  | For use only as a blowing agent  |
| 31A         | 37360             | 000100-52-7    | Benzaldehyde  | (10)   |
| 36A         | 38320             | 005242-49-9    | 4-(2-Benzoxazolyl)-49-(5-methyl-2-benzoxazolyl) stilbene  | In compliance with the specifications laid down in Schedule 2B                                     |
| 36B         | 38510             | 136504-96-6    | 1,2-Bis(3-aminopropyl)ethylene polymer with N-butyl-2,2,6,6-tetramethyl-4-piperidinamine and 2,4,6-trichloro-1,3,5-triazine | The specific migration of this substance shall not exceed 5 mg/kg                                  |
| 36C         | 38515             | 001533-45-5    | 4,49-Bis(2-benzoxazolyl)stilbene  | The specific migration of this substance shall not exceed 0.05 mg/kg (1)                           |
| 36D         | 38810             | 080693-00-1    | Bis(2,6-di-tert-butyl-4-methylphenyl) pentaerythritol diphosphite   | The specific migration of this substance shall not exceed 5 mg/kg (sum of phosphite and phosphate) |
| 36E         | 38879             | 135861-56-2    | Bis(3,4-dimethylbenzylidene)sorbitol  |  |
| 37A         | 39200             | 006200-40-4    | Bis (2-hydroxyethyl)-2-hydroxypropyl-3-(dodecyloxy) methylammonium chloride   | The specific migration of this substance shall not exceed 1.8 mg/kg                                |
| 37B         | 39815             | 182121-12-6    | 9,9 bis(methoxymethyl)fluorene  | The quantity of this substance in the finished plastic material or article shall not               |

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|-------------|-------------------|----------------|--|---|
|             |                   |                |  | exceed 0.05 mg/6 dm <sup>2</sup>  |
| 38A         | 40120             | —              | Bis(polyethyleneglycol) specific hydroxymethylphosphonate                        | The specific migration of this substance shall not exceed 0.6 mg/kg. Authorised only until 1st January 2002                             |
| 44A         | 41680             | 000076-22-2    | Camphor  | (10)  |
| 47A         | 42320             | 007492-68-4    | Carbonic acid, copper salt   | SML(T) = 30 mg/kg (7) (expressed as copper)   |
| 57A         | 43515             | —              | Chlorides of choline esters of coconut oil fatty acids                           | The quantity of this substance in the finished plastic material or article shall not exceed 0.9 mg/6 dm <sup>2</sup>                    |
| 59A         | 45195             | 007787-70-4    | Copper bromide   | SML(T) = 30 mg/kg (7) (expressed as copper)   |
| 59B         | 45200             | 001335-23-5    | Copper iodide  | SML(T) = 30 mg/kg (7) (expressed as copper) and the specific migration of this substance shall not exceed 1 mg/kg (expressed as iodine) |
| 60A         | 45450             | 068610-51-5    | <i>p</i> -Cresol-dicyclopentadiene isobutylene, copolymer                        | The specific migration of this substance shall not exceed 0.05 mg/kg (1)  |
| 72A         | 46880             | 065140-91-2    | 3,5-Di-tert-butyl-4-hydroxybenzyl phosphonic acid, monoethyl ester, calcium salt | The specific migration of this substance shall not exceed 6 mg/kg   |
| 73A         | 47680             | 000111-46-6    | Diethyleneglycol   | SML(T) = 30 mg/kg (3)   |

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|-------------|-------------------|----------------|--|--|
| 73B         | 48460             | 000075-37-6    | 1,1-Difluoroethane   |  |
| 73C         | 49485             | 134701-20-5    | 2,4-Dimethyl-6-(1-methylpentadecyl)phenol                            | The specific migration of this substance shall not exceed 1 mg/kg    |
| 75A         | 51700             | 147315-50-2    | 2-(4,6-Diphenyl-1,3,5-triazin-2-yl)-5-(hexyloxy)phenol               | The specific migration of this substance shall not exceed 0.05 mg/kg |
| 86A         | 53610             | 054453-03-1    | Ethylenediaminetetraacetic acid, copper salt                         | SML(T) = 30 mg/kg (7) (expressed as copper)                          |
| 86B         | 53650             | 000107-21-1    | Ethyleneglycol   | SML(T) = 30 mg/kg (3)  |
| 90A         | 54300             | 118337-09-0    | 2,2-Ethylidenebis(4,6-di-tert-butylphenyl)fluorophosphonite          | The specific migration of this substance shall not exceed 6 mg/kg    |
| 92A         | 54930             | 025359-91-5    | Formaldehyde-1-naphthol, copolymer [poly (1-hydroxynaphthylmethane)] | The specific migration of this substance shall not exceed 0.05 mg/kg |
| 125A        | 57800             | 018641-57-1    | Glycerol tribehenate   |  |
| 140A        | 60480             | 003864-99-1    | 2-(2-Hydroxy-3,5-di-tert-butylphenyl)-5-chlorobenzotriazole          | The specific migration of this substance shall not exceed 30 mg/kg   |
| 169A        | 66560             | 004066-02-8    | 2,2'-Methylenebis(4-methyl-6-cyclohexylphenol)                       | SML(T) = 3 mg/kg (6)   |
| 169B        | 66580             | 000077-62-3    | 2,2'-Methylenebis[4-methyl-6-(1-methylcyclohexyl)phenol]             | SML(T) = 3 mg/kg (6)   |
| 172A        | 66755             | 002682-20-4    | 2-Methyl-4-isothiazolin-3-one  | The specific migration of this                                       |

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|-------------|-------------------|----------------|---|--|
|             |                   |                |   | substance shall be not detectable (when measured by a method with a limit of detection of 0.02 mg/kg, analytical tolerance included)   |
| 173A        | 67170             | —              | Mixture of (80 to 100% w/w) 5,7-di-tert-butyl-3-(3,4-dimethylphenyl)-2(3H)-benzofuranone and (0-20% w/w) 5,7-di-tert-butyl-3-(2,3-dimethylphenyl)-2(3H)-benzofuranone | The specific migration of this substance shall not exceed 5 mg/kg  |
| 173B        | 67180             |                | Mixture of (50% w/w) phthalic acid n-decyl n-octyl ester, (25% w/w) phthalic acid di-n-decyl ester, and (25% w/w) phthalic acid di-n-octyl ester                      | The specific migration of this substance shall not exceed 5 mg/kg (1)  |
| 179A        | 68145             | 080410-33-9    | 2,2',2''-Nitrilo[triethyl tris(3,3',5,5'-tetra-tert-butyl-1,1'-biphenyl-2,2'-diyl) phosphite]   | The specific migration of this substance shall not exceed 5 mg/kg (sum of phosphite and phosphate)   |
| 188A        | 71635             | 025151-96-6    | Pentaerythritol dioleate  | The specific migration of this substance shall not exceed 0.05 mg/kg. Not for use with foods for which simulant D is laid down in Directive <a href="#">85/572/EEC</a> laying down the list of simulants |

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| <i>Item</i> | <i>PM/REF No.</i> | <i>CAS No.</i>           | <i>Name</i>  | <i>Restrictions and specifications</i>  |
|-------------|-------------------|--------------------------|--|---|
|             |                   |                          |  | to be used for testing migration of constituents of plastic materials and articles intended to come into contact with foodstuffs <sup>(9)</sup>                     |
| 191A        | 73720             | 000115-96-8              | Phosphoric acid, trichloroethyl ester  | The specific migration of this substance shall be not detectable (when measured by a method with a limit of detection of 0.02 mg/kg, analytical tolerance included) |
| 191B        | 74010             | 145650-60-8              | Phosphorous acid, bis(2,4-di-tert-butyl-6-methylphenyl) ethyl ester  | The specific migration of this substance shall not exceed 5 mg/kg (covering the sum of phosphite and phosphate)   |
| 195A        | 76721             | 009016-00-6, 063148-62-9 | Polydimethylsiloxane (mw >6800)  | in compliance with the specifications laid down in Schedule 2B  |
| 195B        | 76865             | —                        | Polyesters of 1,2-propanediol and/ or 1,3- and/ or 1,4-butanediol and/ or polypropyleneglycol with adipic acid, also end-capped with acetic acid or fatty acids C10-C18 or n-octanol and/ or n-decanol | The specific migration of this substance shall not exceed 30 mg/kg  |
| 198A        | 77895             | 068439-49-6              | Polyethyleneglycol (EO = 2-6)  | The specific migration of this substance shall  |

<sup>(9)</sup> O.J. No. L372, 31.12.85, p. 14

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|-------------|-------------------|----------------|--|---|
|             |                   |                | monoalkyl (C16-C18) ether  | not exceed 0.05 mg/kg   |
| 208A        | 81515             | 087189-25-1    | Poly(zinc glycerolate)   |   |
| 210A        | 81760             | —              | Powders, flakes and fibres of brass, bronze, copper, stainless steel, tin and alloys of copper, tin and iron | SML(T) = 30 mg/kg (7) (expressed as copper); the specific migration of this substance shall not exceed 48 mg/kg (expressed as iron) |
| 239A        | 85360             | 000109-43-3    | Sebacic acid, dibutyl ester  |   |
| 240A        | 85610             | —              | Silicates, natural, silanated (with the exception of asbestos)   |   |
| 240B        | 85840             | 053320-86-8    | Silicic acid, lithium magnesium sodium salt  | SML(T) = 0.6 mg/kg (8) (expressed as lithium)   |
| 244A        | 86285             | —              | Silicon dioxide, silanated   |   |
| 259A        | 88640             | 008013-07-8    | Soybean oil, epoxidized  | In compliance with the specifications laid down in Schedule 2B  |
| 263A 263B   | 89200 89440       | 007617-31-4 —  | Stearic acid, copper salt<br>Stearic acid, esters with ethyleneglycol  | SML(T) = 30 mg/kg (7) (expressed as copper)<br>SML(T) = 30 mg/kg (3)  |
| 270A        | 92030             | 010124-44-4    | Sulphuric acid, copper salt  | SML(T) = 30 mg/kg (7) (expressed as copper)   |
| 276A        | 92700             | 078301-43-6    | 2,2,4,4-Tetramethyl-20-(2,3-epoxypropyl)-7-oxa-3,20-diazadispiro-[5.1.11.2]-                                 | The specific migration of this substance shall not exceed 5 mg/kg   |

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| <i>Item</i> | <i>PM/REF No.</i> | <i>CAS No.</i> | <i>Name</i>  | <i>Restrictions and specifications</i>                            |
|-------------|-------------------|----------------|--|---|
| 276B        | 92930             | 120218-34-0    | heneicosan-21-one, polymer<br>Thiodiethanolbis(5-methoxycarbonyl-2-dimethyl-1,4-dihydropyridine-3-carboxylate) | The specific migration of this substance shall not exceed 6 mg/kg |
| 280A        | 94960             | 000077-99-6    | 1,1,1-Trimethylolpropanem  | The specific migration of this substance shall not exceed 6 mg/kg |
| 281A        | 95725             | 110638-71-6    | Vermiculite, reaction product with citric acid, lithium salt   | SML(T) = 0.6 mg/kg (8) (expressed as lithium)                     |
| 281B        | 95855             | 007732-18-5    | Water  | In compliance with Directive <a href="#">98/83/EC</a>             |
| 281C        | 95859             | —              | Waxes, refined, derived from petroleum based or synthetic hydrocarbon feedstocks                               | In compliance with the specifications laid down in Schedule 2B    |
| 281D        | 95883             | —              | White mineral oils, paraffinic, derived from petroleum based hydrocarbon feedstocks                            | In compliance with the specifications laid down in Schedule 2B    |

## SCHEDULE 3

Regulation 12

## “SCHEDULE 2A

Regulation 5A

## Products obtained by bacterial fermentation

| <i>Item</i> | <i>PM/REF No.</i> | <i>CAS No.</i> | <i>Name</i>               | <i>Restrictions and specifications</i>                    |
|-------------|-------------------|----------------|---------------------------|---|
| 1           | 18888             | 80181-31-3     | 3-hydroxybutanoic acid-3- | The specific migration of this substance shall not exceed |

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|-------------|-------------------|----------------|----------------------------------|---|
|             |                   |                | hydroxypentanoic acid, copolymer | 0.05 mg/kg for crotonic acid (as impurity), and in compliance with the specifications laid down in Schedule 2B” |

SCHEDULE 4

Regulations 8 and 12

“SCHEDULE 2B

Regulation 7A

**Specifications**

| <i>Item</i> | <i>PM/REF No.</i> | <i>Specifications</i>   |
|-------------|-------------------|---|
| 1           | 18888             | <p>3-HYDROXYBUTANOIC ACID-3-HYDROXYPENTANOIC ACID, COPOLYMER</p> <p><i>Definition</i></p> <p>These copolymers are produced by the controlled fermentation of <i>Alcaligenes eutrophus</i> using mixtures of glucose and propanoic acid as carbon sources. The organism used has not been genetically engineered and has been derived from a single wild-type organism <i>Alcaligenes eutrophus</i> strain H16 NCIMB 10442. Master stocks of the organism are stored as freeze-dried ampoules. A submaster/working stock is prepared from the master stock and stored in liquid nitrogen and used to prepare inocula for the fermenter. Fermenter samples will be examined daily both microscopically and for any changes in</p> |



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| Item | PM/REF No. | Specifications   |
|------|------------|--|
|      |            | <p>colonial morphology on a variety of agars at different temperatures. The copolymers are isolated from heat treatment bacteria by controlled digestion of the other cellular components, washing and drying. These copolymers are normally offered as formulated, melt formed granules containing additives such as nucleating agents, plasticisers, fillers, stabilisers and pigments which all conform to the general and individual specifications.</p> |
|      |            | <p>Chemical name Poly (3-D-hydroxybutanoato-co-3-D-hydroxypentanoate).</p>   |
|      |            | <p>CAS number 80181-31-3.</p>  |
|      |            | <p>Structural formula</p> $  \begin{array}{ccccccc}  & & & & \text{CH}_3 & & \\  & & & &   & & \\  & & & & \text{O} & & \\  & & & &    & & \\  \text{CH}_3 & & & & \text{CH}_2 & & \text{O} \\    & & & &   & &    \\  (-\text{O}-\text{CH}-\text{CH}_2-\text{C}-)_m & - & & & (\text{O}-\text{CH}-\text{CH}_2-\text{C}-)_n  \end{array}  $  |
|      |            | <p>where <math>n/(m+n)</math> greater than 0 and less or equal to 0.25</p>   |
|      |            | <p>Average molecular weight Not less than 150,000 Daltons (measured by gel permeation chromatography).</p>   |
|      |            | <p>Assay Not less than 98% poly (3-D-hydroxybutanoato-co-3-D-hydroxypentanoate) analysed after hydrolysis as a mixture of 3-D-</p>   |

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| <i>Item</i> | <i>PM/REF No.</i> | <i>Specifications</i>   |
|-------------|-------------------|---|
|             |                   | hydroxybutanoic and 3-D-hydroxypentanoic acids.   |
|             |                   | <i>Description</i><br>White to off-white powder after isolation.  |
|             |                   | <i>Characteristics</i>  |
|             |                   | Identification tests:<br>Solubility<br>Soluble in chlorinated hydrocarbons such as chloroform or dichloromethane but practically insoluble in ethanol, aliphatic alkanes and water. |
|             |                   | Migration<br>The migration of crotonic acid should not exceed 0.05 mg/kg food.  |
|             |                   | Purity<br>Prior to granulation the raw material copolymer powder must contain:  |
|             |                   | – Nitrogen<br>Not more than 2,500 mg/kg of plastic  |
|             |                   | – Zinc<br>Not more than 100 mg/kg of plastic  |
|             |                   | – Copper<br>Not more than 5 mg/kg of plastic  |
|             |                   | – Lead<br>Not more than 2 mg/kg of plastic  |
|             |                   | – Arsenic<br>Not more than 1 mg/kg of plastic   |
|             |                   | – Chromium<br>Not more than 1 mg/kg of plastic  |
| 2           | 23547             | <b>POLYDIMETHYLSILOXANE (MW&gt;6800)</b>  |
|             |                   | Minimum viscosity 100 centistokes at 25°C   |
| 3           | 25385             | <b>TRIALLYLAMINE</b>  |
|             |                   | 40 mg/kg hydrogel at a ratio of 1 kg food to a maximum of 1.5 grams of hydrogel. For use only in hydrogels intended for non-direct food contact use.                                |

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| <i>Item</i> | <i>PM/REF No.</i> | <i>Specifications</i>  |
|-------------|-------------------|--|
| 4           | 38320             | <p><b>4-(2-BENZOXAZOLYL)-4'-(5-METHYL-2-BENZOXAZOLYL) STILBENE</b></p> <p>Not more than 0.05% w/w (quantity of substance used/quantity of the formulation)</p>   |
| 5           | 76721             | <p><b>POLYDIMETHYLSILOXANE (Mw&gt;6800)</b></p> <p>Minimum viscosity <math>100 \times 10^{-6}</math> m<sup>2</sup>/s (=100 centistokes) at 25°C</p>  |
| 6           | 88640             | <p><b>SOYBEAN OIL, EPOXIDIZED</b></p> <p>Oxirane &lt;8%, iodine number &lt;6</p>   |
| 7           | 95859             | <p><b>WAXES, REFINED DERIVED FROM PETROLEUM BASED OR SYNTHETIC HYDROCARBON FEEDSTOCKS</b></p> <p>The product shall have the following specifications:</p> <ul style="list-style-type: none"> <li>— Content of mineral hydrocarbons with carbon number less than 25: not more than 5% (w/w)</li> <li>— Viscosity not less than <math>11 \times 10^{-6}</math> m<sup>2</sup>/s (=11 centistokes) at 100°C</li> <li>— Average molecular weight not less than 500</li> </ul>       |
| 8           | 95883             | <p><b>WHITE MINERAL OILS, PARAFFINIC DERIVED FROM PETROLEUM BASED HYDROCARBON FEEDSTOCKS</b></p> <p>The product shall have the following specifications:</p> <ul style="list-style-type: none"> <li>— Content of mineral hydrocarbons with carbon number less than 25: not more than 5% (w/w)</li> <li>— Viscosity not less than <math>8.5 \times 10^{-6}</math> m<sup>2</sup>/s (=8.5 centistokes) at 100°C</li> <li>— Average molecular weight not less than 480”</li> </ul> |

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## EXPLANATORY NOTE

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

These Regulations amend the Plastic Materials and Articles in Contact with Food Regulations (Northern Ireland) 1998 (“the 1998 Regulations”) in implementation of Commission Directive [1999/91/EC](#) amending Directive [90/128/EEC](#) relating to plastic materials and articles intended to come into contact with foodstuffs.

The Regulations—

- (a) update the lists of monomers and additives which can be used in the manufacture of plastic materials and articles intended to come into contact with food (regulations 10 and 11 and Schedules 1 and 2);
- (b) impose restrictions and specifications in respect of some of those monomers and additives (regulations 5(a), 6, 8, 10, 11 and 12 and Schedules 1, 2 and 4); in particular, a new type of restriction is introduced (maximum permitted quantity of the substance in the finished material or article expressed as mg per 6 dm<sup>2</sup> of the surface in contact with food);
- (c) bring products obtained by bacterial fermentation within the scope of the 1998 Regulations and impose restrictions and specifications for such products (regulations 4, 5(b), 7 and 12 and Schedule 3);
- (d) include a transitional provision (regulation 9); and
- (e) make some consequential amendments (regulations 3 and 13(a)) and a drafting correction (regulation 5(a)), and correct two errors in the 1998 Regulations (regulations 10(d) and 13(b)).