

**2003 No. 3208**

**FOOD, ENGLAND**

**The Infant Formula and Follow–on Formula (Amendment)  
(England) Regulations 2003**

*Made* - - - - - *8th December 2003*

*Laid before Parliament* *15th December 2003*

*Coming into force* *6th March 2005*

The Secretary of State, in exercise of the powers conferred by sections 16(1)(a) and (f), 17(1), 26(1) and (3) and 48(1) of the Food Safety Act 1990(a) and now vested in him(b), having had regard in accordance with section 48(4A) of that Act to relevant advice given by the Food Standards Agency and after consultation as required by Article 9 of Regulation (EC) No. 178/2002 of the European Parliament and of the Council(c) laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety and in accordance with section 48(4) and (4B) of that Act, makes the following Regulations:

**Title, application and commencement**

1. These Regulations may be cited as the Infant Formula and Follow–on Formula (Amendment) (England) Regulations 2003; they apply in relation to England only and come into force on 6th March 2005.

**Amendment of the Infant Formula and Follow–on Formula Regulations 1995**

2. The Infant Formula and Follow–on Formula Regulations 1995(d) shall be amended (in so far as they apply in relation to England) in accordance with regulations 3 to 10.

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(a) 1990 c.16.

(b) Functions formerly exercisable by “the Ministers” (being, in relation to England and Wales and acting jointly, the Minister of Agriculture, Fisheries and Food and the Secretaries of State respectively concerned with health in England and food and health in Wales and, in relation to Scotland, the Secretary of State) are now exercisable in relation to England by the Secretary of State pursuant to paragraph 8 of Schedule 5 to the Food Standards Act 1999 (1999 c. 28), and paragraphs 12 and 21 of that Schedule amend respectively sections 17 and 48 of the 1990 Act. Functions of “the Ministers” so far as exercisable in relation to Wales were transferred to the National Assembly for Wales by the National Assembly for Wales (Transfer of Functions) Order 1999 (S.I. 1999/672), as read with section 40(3) of the 1999 Act, and those functions so far as exercisable in relation to Scotland were transferred to the Scottish Ministers by section 53 of the Scotland Act 1998 (1998 c. 46), as read with section 40(2) of the 1999 Act. Regulation 13(4) of S.I. 2000/656 expressly authorises the Secretary of State to amend or revoke existing Regulations made or having effect as if made by the Minister of Agriculture, Fisheries and Food (whether with others or not) under the 1990 Act.

(c) OJ No. L31, 1.2.2002, p.1.

(d) S.I. 1995/77; the relevant amending instrument is S.I. 2000/1509.

3. In regulation 1(2) (interpretation), in the definition of “the Directive”, for the words “Commission Directive 1999/50/EC” there shall be substituted the words “Commission Directive 2003/14/EC(a)”.

4. In regulations 2(ii) and 3(b) (conditions for the sale of infant formulae and follow-on formulae), for the expression “regulation 12” there shall be substituted the expression “regulations 12 and 12A”.

5. In regulations 5(1)(a) and 6(1)(a) (export of infant formulae and follow-on formulae to third countries), for the expression “11 and 12” there shall be substituted the expression “, 11, 12 and 12A”.

6. In regulations 8(2) and 9(2) (composition of infant formulae and follow-on formulae), the words from “and it shall not” to the end shall be omitted.

7. After regulation 12 (composition of infant formulae and follow-on formulae) there shall be inserted the following regulation —

**“12A.—(1) No infant formula or follow-on formula shall contain —**

- (a) any pesticide residue of a pesticide specified in Schedule 7A; or
- (b) any omethoate, where it is a metabolite of a pesticide not specified in Schedule 7A, or any product resulting from degradation or reaction of that metabolite,

at a level exceeding 0.003 mg/kg.

(2) No infant formula or follow-on formula shall contain any pesticide residue of a pesticide specified in column 1 of Schedule 7B at a level exceeding that specified in column 2 of that Schedule in relation to that pesticide.

(3) No infant formula or follow-on formula shall contain any pesticide residue of any individual pesticide which is not specified in Schedule 7A or column 1 of Schedule 7B at a level exceeding 0.01 mg/kg.

(4) The levels referred to in paragraphs (1) to (3) apply to the infant formula or follow-on formula —

- (a) manufactured as ready for consumption, or
- (b) if it is not so manufactured, as reconstituted according to its manufacturer’s instructions.

(5) Analytical methods for determining levels of pesticide residues for the purposes of this regulation shall be generally acceptable standardised methods.”.

8. In regulation 22 (offences and enforcement) —

- (a) in paragraph (2) there shall be inserted at the beginning the words “Except where paragraph (2A) below applies,”;
- (b) after paragraph (2) there shall be inserted the following paragraph —  
“(2A) Each port health authority shall enforce and execute these Regulations in its district in relation to imported food.”.

9. For regulation 23 (application of provisions of the Food Safety Act 1990) there shall be substituted the following regulation —

**“Application of various provisions of the Act**

**23.** The following provisions of the Act shall apply for the purposes of these Regulations (except regulation 21) with the modification that any reference in those provisions to the

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(a) OJ No. L41, 14.2.2003, p.37.

Act or Part thereof shall be construed as a reference to these Regulations (except regulation 21) —

- (a) section 2 (extended meaning of “sale” etc.);
- (b) section 3 (presumptions that food is intended for human consumption);
- (c) section 20 (offences due to fault of another person);
- (d) section 21 (defence of due diligence) as it applies for the purposes of section 8, 14 or 15;
- (e) section 30(8) (which relates to documentary evidence);
- (f) section 33(1) (obstruction etc. of officers);
- (g) section 33(2), with the modification that the reference to “any such requirement as is mentioned in subsection (1)(b) above” shall be deemed to be a reference to any such requirement as is mentioned in that subsection as applied by paragraph (f) above;
- (h) section 35(1) (punishment of offences) in so far as it relates to offences under section 33(1) as applied by paragraph (f) above;
- (i) section 35(2) and (3) in so far as it relates to offences under section 33(2) as applied by paragraph (g) above;
- (j) section 36 (offences by bodies corporate); and
- (k) section 44 (protection of officers acting in good faith).”.

**10.** After Schedule 7 (the mineral elements in cows’ milk) there shall be inserted as Schedules 7A and 7B the contents of the Schedule to these Regulations.

Signed by authority of the Secretary of State for Health

8th December 2003

*Melanie Johnson*  
Parliamentary Under Secretary of State,  
Department of Health

## SCHEDULE

Regulation 10

### NEW SCHEDULES 7A AND 7B TO BE INSERTED IN THE INFANT FORMULA AND FOLLOW-ON FORMULA REGULATIONS 1995

#### “SCHEDULE 7A

Regulation 12A

### PESTICIDES WHOSE RESIDUES MUST NOT BE PRESENT IN INFANT FORMULAE OR FOLLOW-ON FORMULAE AT A LEVEL EXCEEDING 0.003 mg/kg

#### **Chemical name**

Aldrin and dieldrin, expressed as dieldrin

Disulfoton (sum of disulfoton, disulfoton sulfoxide and disulfoton sulfone expressed as disulfoton)

Endrin

Fensulfothion (sum of fensulfothion, its oxygen analogue and their sulfones, expressed as fensulfothion)

Fentin, expressed as triphenyltin cation

Haloxypop (sum of haloxypop, its salts and esters including conjugates, expressed as haloxypop)

Heptachlor and *trans*-heptachlor epoxide, expressed as heptachlor

Hexachlorobenzene

Nitrofen

Omethoate

Terbufos (sum of terbufos, its sulfoxide and sulfone, expressed as terbufos)

SCHEDULE 7B

Regulation 12A

SPECIFIC MAXIMUM RESIDUE LEVELS OF CERTAIN  
PESTICIDES IN INFANT FORMULAE OR FOLLOW-ON  
FORMULAE

<i>Column 1</i> <i>Chemical name of the substance</i>	<i>Column 2</i> <i>Maximum residue level</i> <i>(mg/kg)</i>
Cadusafos	0.006
Demeton-S-methyl/demeton-S-methyl sulfone/oxydemeton-methyl (individually or combined, expressed as demeton-S-methyl)	0.006
Ethoprophos	0.008
Fipronil (sum of fipronil and fipronil-desulfinyl, expressed as fipronil)	0.004
Propineb/propylenethiourea (sum of propineb and propylenethiourea)	0.006

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## **EXPLANATORY NOTE**

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

**1.** These Regulations amend the Infant Formula and Follow-on Formula Regulations 1995, as amended (“the 1995 Regulations”), in relation to England. The 1995 Regulations extend to Great Britain. These Regulations implement for England Commission Directive 2003/14/EC amending Directive 91/321/EEC on infant formulae and follow-on formulae. The Regulations come into force on 6th March 2005.

**2.** In implementation of Directive 2003/14/EC the Regulations —

- (a) prohibit the sale, or export to third countries, of infant formulae or follow-on formulae containing pesticide residues above certain levels. Different levels are set depending on the pesticide in question (regulations 4, 5, 7 and 10 and Schedule); and
- (b) make some consequential amendments (regulations 3 and 6).

**3.** In implementation of the final sentence of Article 6(2) of Directive 91/321/EEC as substituted by Commission Directive 1999/50/EC, provision is made as to analytical methods for determining levels of pesticide residues (regulation 7).

**4.** The Regulations also —

- (a) give port health authorities a role in enforcement (regulation 8); and
- (b) make some technical changes to the provision applying various provisions of the Food Safety Act 1990 (regulation 9).

**5.** A full regulatory impact assessment of the effect that this instrument will have on the costs of business has been prepared and placed in the Library of each House of Parliament together with a Transposition Note setting out how the main elements of Directive 2003/14/EC are transposed in these Regulations. Copies may be obtained from the Food Labelling and Standards Division of the Food Standards Agency, Aviation House, 125 Kingsway, London WC2B 6NH.



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STATUTORY INSTRUMENTS

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