

2004 No. 7

FOOD

**The Infant Formula and Follow-on Formula Amendment
(Scotland) Regulations 2004**

Made - - - - - *15th January 2004*

Laid before the Scottish Parliament *15th January 2004*

Coming into force - - - *6th March 2005*

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

Citation, commencement and extent

1.—(1) These Regulations may be cited as the Infant Formula and Follow-on Formula Amendment (Scotland) Regulations 2004 and shall come into force on 6th March 2005.

(2) These Regulations extend to Scotland only.

Amendment of the Infant Formula and Follow-on Formula Regulations 1995

2. The Infant Formula and Follow-on Formula Regulations 1995(d) are amended in accordance with regulations 3 to 10.

3. In regulation 1(2) (interpretation), in the definition of “the Directive”, for “and Commission Directive 1999/50/EC” substitute “, Commission Directive 1999/50/EC(e) and Commission Directive 2003/14/EC(f)”.

4. In regulations 2(b)(ii) and 3(b) (conditions for the sale of infant formulae and follow-on formulae), for “regulation 12” substitute “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 “11 and 12” substitute “11, 12 and 12A”.

(a) 1990 c.16; section 6(4) was amended by the Deregulation and Contracting Out Act 1994 (c.40), Schedule 9, paragraph 6 and by the Food Standards Act 1999 (c.28) (“the 1999 Act”), Schedule 5, paragraph 10(3); sections 16(1) and 48(1) were amended by the 1999 Act, Schedule 5, paragraph 8; section 17(1) was amended by the 1999 Act, Schedule 5, paragraphs 8 and 12; section 26(3) was amended by the 1999 Act, Schedule 6; amendments made by Schedule 5 to the 1999 Act shall be taken as pre-commencement enactments for the purposes of the Scotland Act 1998 (c.46) (“the 1998 Act”) 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 1998 Act.

(b) Section 48(4A) was inserted by the 1999 Act, Schedule 5, paragraph 21.

(c) Section 48(4B) was inserted by the 1999 Act, Schedule 5, paragraph 21.

(d) S.I. 1995/77; amended by S.I. 1997/451 and S.S.I. 2000/217.

(e) O.J. No. L 139, 2.6.99, p.29.

(f) O.J. No. L 41, 14.2.03, p.37.

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

7. After regulation 12 (composition of infant formulae and follow-on formulae) insert–

“**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. Omit regulation 22(3) (offences and enforcement).

9. For regulation 23 (application of provisions of the Food Safety Act 1990) substitute–

“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 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 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 (obstruction etc. of officers);
- (g) section 35(1) to (3) (punishment of offences) in so far as it relates to offences under section 33(1) and (2) as applied by paragraph (f) above;
- (h) section 36 (offences by bodies corporate);
- (i) section 36A (offences by Scottish partnerships); and
- (j) section 44 (protection of officers acting in good faith).”.

10. After Schedule 7 (the mineral elements in cows' milk) insert as Schedules 7A and 7B the contents of the Schedule to these Regulations.

St Andrew's House,
Edinburgh
15th January 2004

TOM McCABE
Authorised to sign by the Scottish Ministers

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

”

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations amend the Infant Formula and Follow-on Formula Regulations 1995, as amended (“the 1995 Regulations”), in relation to Scotland. These Regulations implement Commission Directive 2003/14/EC amending Directive 91/321/EEC on infant formulae and follow-on formulae.

With effect from 6th March 2005 these 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 being set depending on the pesticide in question (regulations 4, 5, 7 and 10 and Schedule);
- (b) make some consequential amendments (regulations 3, 6 and 8); and
- (c) make some technical changes to the provision applying various provisions of the Food Safety Act 1990 (regulation 9).

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 the analytical methods for determining levels of pesticide residues (regulation 7).

A Regulatory Impact Assessment, which includes a compliance cost assessment of the effects which these Regulations would 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 6NJ.

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