2003 No. 529

FOOD

Infant Formula and Follow-on Formula (Amendment) Regulations (Northern Ireland) 2003

Made - - - - 12th December 2003

Coming into operation 6th March 2005

The Department of Health, Social Services and Public Safety(a) in exercise of the powers conferred on it by Articles 15(1)(a) and (f), 16(1), 25(1) and (3) and 47(2) of the Food Safety (Northern Ireland) Order 1991(b) 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 both 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 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 Infant Formula and Follow-on Formula (Amendment) Regulations (Northern Ireland) 2003 and shall come into operation on 6th March 2005.

Amendment of the Infant Formula and Follow-on Formula Regulations (Northern Ireland) 1995

- **2.** The Infant Formula and Follow-on Formula Regulations (Northern Ireland) 1995(**d**) shall be amended in accordance with regulations 3 to 9.
- **3.** In regulation 1(2) (interpretation), in the definition of "the Directive", for "Commission Directive 1999/50/EC" there shall be substituted "Commission Directive 2003/14/EC(e)".
- **4.** In regulation 2(1)(ii) and (2)(b) (conditions for the sale of infant formulae and follow-on formulae), for "regulation 4(12)" there shall be substituted "regulation 4(12) to (17)".
 - 5. In regulation 3 (export of infant formulae and follow-on formulae to third countries) –
 - (a) in paragraph (1)(a), for "4(1)-(4), (9), (10), (11) and (12)" there shall be substituted "4(1) to (4) and (9) to (17)";
 - (b) in paragraph (4)(a), for "4(5)-(12)" there shall be substituted "4(5) to (17)".

⁽a) Formerly the Department of Health and Social Services; see S.I. 1999/283 (N.I. 1), Article 3

⁽b) 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

⁽c) O.J. No. L31, 1.2.2002, p. 1

⁽d) S.R. 1995 No. 85; the relevant amending Regulations are S.R. 1997 No. 213 and S.R. 2000 No. 235

⁽e) O.J. No. L41, 14.2.2003, p. 37

- **6.** In regulation 4(2) and (6) (composition of infant formulae and follow-on formulae), the words from "and it shall not" to the end shall be omitted.
- **7.** After paragraph (12) of regulation 4 (composition of infant formulae and follow-on formulae) there shall be inserted the following paragraphs
 - "(13) 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.

- (14) 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.
- (15) 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.
- (16) The levels referred to in paragraphs (13) to (15) 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.
- (17) Analytical methods for determining levels of pesticide residues for the purposes of this regulation shall be generally acceptable standardised methods.".
- **8.** In regulation 11 (application of provisions of the Food Safety (Northern Ireland) Order 1991), after paragraph (f) there shall be inserted the following paragraph
 - "(g) Article 36 (punishment of offences) in so far as it relates to offences under Article 34(1) and (2) as applied by paragraph (f).".
- **9.** After Schedule 7 (the mineral elements in cows milk) there shall be inserted as Schedules 7A and 7B the contents of the Schedule.

Sealed with the Official Seal of the Department of Health, Social Services and Public Safety on 12th December 2003.

(L.S.) Denis McMahon

A Senior Officer of the Department of Health, Social Services and Public Safety

SCHEDULE

Regulation 9

NEW SCHEDULES 7A AND 7B TO BE INSERTED IN THE INFANT FORMULA AND FOLLOW-ON FORMULA REGULATIONS (NORTHERN IRELAND) 1995

"SCHEDULE 7A

Regulation 4(13)

and (15)

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

Haloxyfop (sum of haloxyfop, its salts and esters including conjugates, expressed as haloxyfop)

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 4(14) and (15)

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

Column 1 Chemical name of the substance	Column 2 Maximum residue level (mg/kg)
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.)

These Regulations, which amend the Infant Formula and Follow-on Formula Regulations (Northern Ireland) 1995, as amended, implement Commission Directive 2003/14/EC amending Directive 91/321/EEC on infant formulae and follow-on formulae.

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, such levels being dependent on the pesticide in question (regulations 4, 5, 7 and 9 and the Schedule); and
- (b) make some consequential amendments (regulations 3 and 6).

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).

The Regulations also amend the provision applying various provisions of the Food Safety (Northern Ireland) Order 1991 (regulation 8).

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