STATUTORY INSTRUMENTS

# 1997 No. 451

# FOOD

## The Infant Formula and Follow-on Formula (Amendment) Regulations 1997

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|---|---|
| *Made - - - -* | *24th February 1997* |
| *Laid before Parliament* | *25th February 1997* |
| *Coming into force - -* | *31st March 1997* |

The Minister of Agriculture, Fisheries and Food, the Secretary of State for Health and the Secretary of State for Wales, acting jointly, in relation to England and Wales, and the Secretary of State for Scotland in relation to Scotland, in exercise of the powers conferred on them by sections 6(4), 16(1)(a), (b), (e) and (f), 17(1) and 48(1) of the Food Safety Act 1990(**1**), and of all other powers enabling them in that behalf, after consultation in accordance with section 48(4) of the said Act with such organisations as appear to them to be representative of interests likely to be substantially affected by the Regulations, hereby make the following Regulations:

### Title, commencement and interpretation

**1.**—(1) These Regulations may be cited as the Infant Formula and Follow-on Formula (Amendment) Regulations 1997 and shall come into force on 31st March 1997.

(2) In these Regulations "the principal Regulations" means the Infant Formula and Follow-on Formula Regulations 1995(**2**).

### Amendment of the principal Regulations

**2.** The principal Regulations shall be amended as follows—

(a) in paragraph (2) of regulation 1 for the definition of "food authority" there shall be substituted the following—

""food authority" does not include—

(a) the council of a district in a non-metropolitan county in England except where the county functions have been transferred to that council pursuant to a structural change; or

(**1**) 1990 c. 16; "the Ministers" is defined in section 4(1) of the Act.
(**2**) S.I. 1995/77; to which there is an amendment not relevant to these Regulations.

(b) the appropriate Treasurer referred to in section 5(1)(c) of the Act (which deals with the Inner Temple and the Middle Temple);";

(b) in paragraph (c) of regulation 3 after "14" there shall be inserted ", 14A";

(c) in sub-paragraph (c) of paragraph (1) of both regulation 5 and 6 for the words "the Food (Lot Marking) Regulations 1992" there shall be substituted the words "the Food (Lot Marking) Regulations 1996";

(d) in regulation 12 after the word "infants" there shall be inserted the words "and young children";

(e) in both sub-paragraph (e) of paragraph (1) of regulation 13 and sub-paragraph (d) of regulation 14 (which regulations deal, respectively, with the labelling of infant formulae and of follow-on formulae), after the word "carbohydrates" there shall be inserted the words ", expressed in numerical form,";

(f) in both sub-paragraph (f) of paragraph (1) of regulation 13 and sub-paragraph (e) of regulation 14, for the words "and carnitine" there shall be substituted the words ", carnitine and taurine, expressed in numerical form,";

(g) after paragraph (3) of regulation 13 there shall be inserted the following paragraph—

"(4) The labelling of an infant formula may include the average quantity of nutrients mentioned in Schedule 3 when such is not covered by the provisions of paragraph (1)(f) above, expressed in numerical form, per 100 millilitres of the product ready for use.";

(h) after regulation 14 there shall be inserted the following regulation—

"**14A.** The labelling of a follow-on formula may include the average quantity of nutrients mentioned in Schedule 3 when such is not covered by the provisions of regulation 14(e), expressed in numerical form, per 100 millilitres of the product ready for use and, in addition, information on vitamins and minerals included in Schedule 8, expressed as a percentage of the reference values given in that Schedule, per 100 millilitres of the product ready for use, provided that the quantities present are at least equal to 15 per cent of the reference value.";

(i) after paragraph (2) of regulation 22 there shall be inserted the following paragraph—

"(3) Where an offence under these Regulations is committed by a Scottish partnership and is proved to have been committed with the consent or connivance of, or to be attributable to any neglect on the part of, a partner, he as well as the partnership shall be guilty of the offence and be liable to be proceeded against and punished accordingly.";

(j) in Schedule 1 (essential composition of infant formulae when reconstituted as instructed by the manufacturer)—

(i) for the first sub-paragraph of paragraph 2 and sub-paragraphs 2.1 and 2.2 there shall be substituted the following—

"**Protein**

**2.** (Protein content = nitrogen content × 6.38) for cows' milk proteins.

(Protein content = nitrogen content × 6.25) for soya protein isolates and protein partial hydrolysates.

The "chemical index" shall mean the lowest of the ratios between the quantity of each essential amino acid of the test protein and the quantity of each corresponding amino acid of the reference protein.

**2.**—(2.1) Formulae manufactured from cows' milk proteins

| *Minimum* | *Maximum* |
|---|---|
| 0.45g/100 kJ | 0.7g/100 kJ |
| (1.8g/100 kcal) | (3g/100 kcal) |

For an equal energy value, the formula must contain an available quantity of each essential and semi-essential amino acid at least equal to that contained in the reference protein (breast milk, as defined in Schedule 5); nevertheless, for calculation purposes, the concentration of methionine and cystine may be added together.

(2.2) Formulae manufactured from protein partial hydrolysates

| *Minimum* | *Maximum* |
|---|---|
| 0.56 g/100 kJ | 0.7g/100 kJ |
| (2.25g/100 kcal) | (3g/100 kcal) |

For an equal energy value, the formula must contain an available quantity of each essential and semi-essential amino acid at least equal to that contained in the reference protein (breast milk, as defined in Schedule 5); nevertheless, for calculation purposes, the concentration of methionine and cystine may be added together.

The protein efficiency ratio (PER) and the net protein utilisation (NPU) must be at least equal to those of casein.

The taurine content shall be equal to at least 10 μmoles/100 kJ (42 μmoles/100 kcal) and the L-carnitine content shall be equal to at least 1.8 μmoles/100 kJ (7.5 μmoles/100 kcal).";

(ii) in paragraph 3 for the amounts "0.8g/100 kJ" and "(3.3g/100 kcal)" there shall be substituted the following amounts—

| *"(Minimum)* |
|---|
| 1.05g/100 kJ |
| (4.4g/100 kcal)"; |

(iii) in paragraph 3.1 the words "—fats containing more than 8% trans isomers of fatty acids" shall be deleted;

(iv) after paragraph 3.4 there shall be inserted the following paragraphs—

"**3.5.** The alpha-linolenic acid content shall not be less than 12 mg/100 kJ (50 mg/100 kcal).

The linoleic/alpha-linolenic acid ratio shall not be less than 5 nor greater than 15.

**3.6.** The trans fatty acid content shall not exceed 4% of the total fat content.

**3.7.** The erucic acid content shall not exceed 1% of the total fat content.

**3.8.** Long chain (20 and 22 carbon atoms) polyunsaturated fatty acids (LCP) may be added. In that case their content shall not exceed:

1% of the total fat content for n-3 LCP, and

2% of the total fat content for n-6 LCP (1% of the total fat content for arachidonic acid)

The eicosapentaenoic acid (20:5 n-3) content shall not exceed that of docosahexaenoic (22:6 n-3) acid content.";

(v) in paragraph 5.1, after the entry relating to Iodine, there shall be inserted the following entry—

| | "(per 100 kJ) (minimum) | (maximum) | (per 100 kcal) (minimum) | (maximum) |
|---|---|---|---|---|
| Selenium[(2)] (µg) | — | 0.7 | — | 3", |

and after the first footnote to that paragraph there shall be inserted the following footnote—

"(2) Limit applicable to formulae with added selenium.";

(vi) in paragraph 6, for the entry relating to Nicotinamide there shall be substituted the following entry—

| | "(per 100 kJ) (minimum) | (maximum) | (per 100 kcal) (minimum) | (maximum) |
|---|---|---|---|---|
| Niacin (mg-NE) | 0.2 | — | 0.8 | —"; |

(vii) after paragraph 6 there shall be inserted the following paragraph—

"**7.** The following nucleotides may be added:

| | maximum* (mg/100 kJ) | (mg/100 kcal) |
|---|---|---|
| cytidine 5'-monophosphate | 0.60 | 2.50 |
| uridine 5'-monophosphate | 0.42 | 1.75 |
| adenosine 5'-monophosphate | 0.36 | 1.50 |
| guanosine 5'-monophosphate | 0.12 | 0.50 |
| inosine 5'-monophosphate | 0.24 | 1.00"; |

* The total concentration of nucleotides shall not exceed 1.2 mg/100 kJ (5 mg/100 kcal).

(k) in Schedule 2 (essential composition of follow-on formulae when reconstituted as instructed by the manufacturer)—

(i) in paragraph 2—

(aa) in the first sub-paragraph following the statement of minimum and maximum amounts, after the word "casein" there shall be inserted the words "or breast milk";

(bb) after the fourth such sub-paragraph there shall be inserted the following sub-paragraph—

— "For an equal energy value, these formulae must contain an available quantity of methionine at least equal to that contained in breast milk as defined in Schedule 5.";

(ii) in paragraph 3.1 the words "—fats containing more than 8% trans isomers of fatty acids" shall be deleted;

(iii) after paragraph 3.4 there shall be inserted the following paragraphs—

"**3.5.** The trans fatty acid content shall not exceed 4% of the total fat content.

**3.6.** The erucic acid content shall not exceed 1% of the total fat content.";

(iv) after paragraph 6 there shall be inserted the following paragraph—

"**7.** The following nucleotides may be added:

| | maximum* (mg/100 kJ) | (mg/100 kcal) |
|---|---|---|
| cytidine 5'-monophosphate | 0.60 | 2.50 |
| uridine 5'-monophosphate | 0.42 | 1.75 |
| adenosine 5'-monophosphate | 0.36 | 1.50 |
| guanosine 5'-monophosphate | 0.12 | 0.50 |
| inosine 5'-monophosphate | 0.24 | 1.00"; |

* The total concentration of nucleotides shall not exceed 1.2 mg/100 kJ (5 mg/100 kcal).

(l) in Schedule 3 (nutritional substances)—

(i) in section 2 (mineral substances), after the entry relating to Potassium, there shall be inserted the following entry—

| *"(Mineral substances)* | *(Permitted salts)* |
|---|---|
| Selenium (Se) | Sodium selenate<br>Sodium selenite;" |

(ii) in section 3 (amino acids and other nitrogen compounds), after the item "taurine", there shall be inserted the following items—

"Cytidine 5'-monophosphate and its sodium salt

Uridine 5'-monophosphate and its sodium salt

Adenosine 5'-monophosphate and its sodium salt

Guanosine 5'-monophosphate and its sodium salt

Inosine 5'-monophosphate and its sodium salt";

(m) in Schedule 4 (compositional criteria for infant formulae, warranting a corresponding claim), after entry number 6, there shall be added the following entry—

| *"(Claim related to)* | *(Conditions warranting the claim)* |
|---|---|
| **7.** Reduction of risk to allergy to milk proteins. This claim may include terms referring to reduced allergen or reduced antigen properties. | (a) The formulae shall satisfy the provisions laid down in paragraph 2.2 of Schedule 1 and the amount of immunoreactive protein measured with methods |

| *"(Claim related to)* | *(Conditions warranting the claim)* |
|---|---|
| | generally acceptable as appropriate shall be less than 1% of nitrogen-containing substances in the formulae;<br>(b) the label shall indicate that the product must not be consumed by infants allergic to the intact proteins from which it is made unless generally accepted clinical tests provide proof of the formulae's tolerance in more than 90% of infants (confidence interval 95%) hypersensitive to proteins from which the hydrolysate is made;<br>(c) the formulae administered orally should not induce sensitisation, in animals, to the intact proteins from which the formulae are derived;<br>(d) objective and scientifically verified data as proof to the claimed properties must be available.";|

(n) after Schedule 7 (the mineral elements in cows' milk) there shall be inserted the following Schedule—

"SCHEDULE 8 Regulation 14A

REFERENCE VALUES FOR NUTRITION LABELLING FOR FOODS INTENDED FOR INFANTS AND YOUNG CHILDREN

| *Nutrient* | | *Labelling reference value* |
|---|---|---|
| Vitamin A | (µg) | 400 |
| Vitamin D | (µg) | 10 |
| Vitamin C | (mg) | 25 |
| Thiamin | (mg) | 0.5 |
| Riboflavin | (mg) | 0.8 |
| Niacin equivalents | (mg) | 9 |
| Vitamin B6 | (mg) | 0.7 |
| Folate | (µg) | 100 |
| Vitamin B12 | (µg) | 0.7 |
| Calcium | (mg) | 400 |
| Iron | (mg) | 6 |

| *Nutrient* | | *Labelling reference value* |
|---|---|---|
| Zinc | (mg) | 4 |
| Iodine | (µg) | 70 |
| Selenium | (µg) | 10 |
| Copper | (mg) | 0.4” |

**Transitional provision**

**3.** In any proceedings in respect of any sale or export before 31st March 1999 which is alleged to constitute a contravention of regulation 2, 3, 5, 6 or 7 of the principal Regulations the defendant shall not be convicted of an offence under regulation 22 of the principal Regulations if that sale or export would not have been a contravention of regulation 2, 3, 5, 6 or 7, as appropriate, of the principal Regulations before amendment by these Regulations.

*Angela Browning*
Parliamentary Secretary, Ministry of Agriculture, Fisheries and Food
24th February 1997

Signed by authority of the Secretary of State for Health:

*Cumberlege*
Parliamentary Under Secretary of State, Department of Health
21st February 1997

Signed by authority of the Secretary of State for Wales:

*Gwilym Jones*
Parliamentary Under Secretary of State, Welsh Office
20th February 1997

*Lindsay*
Parliamentary Under Secretary of State, Scottish Office
19th February 1997

## EXPLANATORY NOTE

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

These Regulations, which apply to Great Britain, come into force on 31st March 1997.

The Regulations amend The Infant Formula and Follow-on Formula Regulations 1995 (S.I.1995/77) ("the principal Regulations"), which implemented *inter alia* Commission Directive 91/321/EEC (OJNo. L175, 4.7.91, p.35) on infant formulae and follow-on formulae, so as to take account of amendments made to that Directive by Commission Directive 96/4/EC (OJ No. L49, 28.2.96, p.12).

The amendments now being made relate to the labelling of infant and follow-on formulae (regulation 2(e), (f), (g) and (h)), and to compositional criteria etc. including those contained in various Schedules (regulation 2(d), (j), (k), (l) and (m)). A new schedule, Schedule 8 (reference values for nutrition labelling for foods intended for infants and young children), is added (regulation 2(n)).

The definition of "food authority" is amended to take account of changes brought about by local government reorganisation (regulation 2(a)). There is an amendment to regulation 3 so that the sale of infant formulae or follow-on formulae which do not comply with the labelling requirements of regulation 14A (inserted in the principal Regulations by these Regulations) is prohibited (regulation 2(b)). References to the Food (Lot Marking) Regulations are updated (regulation 2(c)) and a provision is inserted in relation to offences committed by Scottish partnerships and partners (regulation 2(i)).

Regulation 3 contains a transitional provision which provides that it is not an offence, before 31st March 1999, to sell or export infant formulae or follow-on formulae which do not comply with the principal Regulations but which do comply with the provisions of the principal Regulations before amendment by these Regulations.

A Compliance Cost Assessment in relation to these Regulations has been placed in the libraries of both Houses of Parliament and copies can be obtained from the Food Labelling and Standards Division of the Ministry of Agriculture, Fisheries and Food, Ergon House, 17 Smith Square, London SW1P 3JR.