STATUTORY RULES OF NORTHERN IRELAND

2002 No. 264

FOOD

Food for Particular Nutritional Uses (Addition of Substances for Specific Nutritional Purposes) Regulations (Northern Ireland) 2002

Made - - - - 5th August 2002
Coming into operation in accordance with regulation 1(2) and (3)

The Department of Health, Social Services and Public Safety(**1**) in exercise of the powers conferred on it by Articles 15(1)(f), 16(1), 25(3), 26(3) and 47(2) of the Food Safety (Northern Ireland) Order 1991(**2**) 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(**3**) 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.—(1) These Regulations may be cited as the Food for Particular Nutritional Uses (Addition of Substances for Specific Nutritional Purposes) Regulations (Northern Ireland) 2002.

(2) Regulations 1, 5 and 10, and regulations 2 and 6 to 9 in so far as they relate to regulation 5, come into operation on 16th September 2002.

(3) The remainder of these Regulations comes into operation –

(a) on 16th September 2002 in relation to an L-tryptophan food; and

(b) in any other case on 1st April 2004.

Interpretation

2.—(1) In these Regulations –

(**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**) O.J. No. L31, 1.2.2002, p. 1

"designated PNU food" means any PNU food other than infant formulae, follow-on formulae, processed cereal-based foods and baby foods intended for infants and young children;

"Directive 89/398" means Council Directive 89/398/EEC(**4**) on the approximation of the laws of the member States relating to foodstuffs intended for particular nutritional uses, as amended by Directive 1999/41/EC of the European Parliament and of the Council(**5**);

"Directive 2001/15" means Commission Directive 2001/15/EC(**6**) (as corrected(**7**)) on substances that may be added for specific nutritional purposes in foods for particular nutritional uses;

"the Order" means the Food Safety (Northern Ireland) Order 1991;

"L-tryptophan food" means any designated PNU food being a food to which L-tryptophan, or any of its sodium, potassium, calcium or magnesium salts or its hydrochloride, has been added for a specific nutritional purpose;

"particular nutritional use" means the fulfilment of the particular nutritional requirements of –

(a) certain categories of persons whose digestive processes are, or whose metabolism is, disturbed, or

(b) certain categories of persons whose physiological condition renders them able to obtain a special benefit from the controlled consumption of any substance in food, or

(c) infants or young children in good health;

"PNU food" means a food for a particular nutritional use which –

(a) owing to its special composition or process of manufacture, is clearly distinguishable from food intended for normal consumption, and

(b) is sold in such a way as to indicate its suitability for its claimed particular nutritional purpose; and

"sell" includes possess for sale and offer, expose or advertise for sale.

(2) Other expressions used both in these Regulations and in Directive 89/398 or 2001/15 have the same meaning in these Regulations as they have in the Directive concerned.

Restrictions on sale

3.—(1) No person shall sell any designated PNU food being a food to which a substance falling within one of the categories mentioned in paragraph (2) has been added for a specific nutritional purpose unless that substance –

(a) is listed under that category –

(i) in the case of any food for special medical purposes, in Schedule 1 or 2; and

(ii) in any other case, in Schedule 1; and

(b) complies with the relevant purity criteria referred to in paragraph (3).

(2) For the purposes of paragraph (1), the categories are –

(a) vitamins,

(b) minerals,

(c) amino acids,

(d) carnitine and taurine,

(**4**) O.J. No. L186, 30.6.89, p. 27
(**5**) O.J. No. L172, 8.7.1999, p. 38
(**6**) O.J. No. L52, 22.2.2001, p. 19
(**7**) O.J. No. L253, 21.9.2001, p. 34

(e) nucleotides, and

(f) choline and inositol.

(3) The relevant purity criteria for the purposes of paragraph (1)(b) are –

(a) the purity criteria, specified by Community legislation for the use of the substance in question in the manufacture of food for purposes other than those covered by Directive 2001/15, or

(b) in the absence of such purity criteria, generally acceptable purity criteria for the substance in question recommended by international bodies.

(4) No person shall sell any designated PNU food in the manufacture of which any substance has been used for a specific nutritional purpose unless that food –

(a) is safe when used in accordance with the manufacturer's instructions (if any); and

(b) fulfils the particular nutritional requirements of the persons for whom it is intended,

as established by generally accepted scientific data.

Verification of regulation 3(4)

4. The manufacturer or, as the case may be, the importer of a designated PNU food in the manufacture of which a substance has been used for a specific nutritional purpose shall supply to the Food Standards Agency on request –

(a) a copy of the scientific work and data establishing that the use of that substance in the manufacture of that food results in a food which meets the criteria in regulation 3(4), or

(b) if such work and data are contained in a publication which is readily available, a reference to that publication.

Notification requirement

5.—(1) Subject to paragraph (2), the manufacturer or, where appropriate, the importer of any notifiable food shall not sell any such food unless at least 3 months before placing food of that particular type on the market in Northern Ireland for the first time he notifies the Food Standards Agency in writing by forwarding to it a model of the label to be used for that food and details of the composition of the food.

(2) Paragraph (1) shall not apply if the manufacturer or, where appropriate, the importer has already notified the Food Standards Agency before placing food of that particular type on the market elsewhere in the United Kingdom for the first time in accordance with an equivalent provision having effect there.

(3) In this regulation, "notifiable food" means any L-tryptophan food which is –

(a) intended for use in energy-restricted diets for weight reduction;

(b) intended to meet the expenditure of intense muscular effort, especially for sportsmen; or

(c) for persons suffering from carbohydrate-metabolism disorders (diabetes).

Enforcement

6. Each district council shall enforce and execute these Regulations within its district.

Offences and penalties

7. If any person –

(a) contravenes regulation 3(1) or (4), or

(b) without reasonable cause contravenes regulation 4 or 5(1),

he shall be guilty of an offence and liable on summary conviction to a fine not exceeding level 5 on the standard scale.

Defence in relation to exports

8. In any proceedings for an offence under these Regulations it shall be a defence for the person charged to prove that the food in respect of which the offence is alleged to have been committed was intended for export to a country (other than a member State) which has legislation analogous to these Regulations and that the food complies with that legislation.

Application of various provisions of the Order

9. The following provisions of the Order shall apply for the purposes of these Regulations and any reference in those provisions to the Order shall be construed as a reference to these Regulations –

(a) Articles 2(4) and 3 (extended meaning of "sale" etc.);

(b) Article 4 (presumptions that food intended for human consumption);

(c) Article 19 (offences due to fault of another person);

(d) Article 20 (defence of due diligence) as it applies for the purposes of Article 7, 13 or 14;

(e) Article 21 (defence of publication in the course of business);

(f) Article 30(8) (which relates to documentary evidence);

(g) Article 34 (obstruction, etc., of officers);

(h) Article 36 (punishment of offences) in so far as it relates to offences under Article 34(1) and (2) as applied by paragraph (g).

Amendment of the Tryptophan in Food Regulations (Northern Ireland) 1990

10.—(1) The Tryptophan in Food Regulations (Northern Ireland) 1990(**8**) shall be amended in accordance with paragraph (2).

(2) In regulation 2 (prohibition on sale, etc. of food containing tryptophan) –

(a) in paragraphs (1) and (2), for "Subject to paragraph (4)" there shall be substituted "Subject to paragraphs (4) and (4A)";

(b) in paragraph (3) there shall be inserted at the beginning "Subject to paragraph (4A),";

(c) after paragraph (4) there shall be inserted the following paragraph –

"(4A) Paragraphs (1) to (3) shall not apply in respect of –

(a) laevorotatory tryptophan added to any infant formula or follow-on formula;

(b) laevorotatory tryptophan added to any processed cereal-based food or baby food; or

(c) laevorotatory tryptophan, its sodium, potassium, calcium or magnesium salts or its hydrochloride, added to any designated PNU food for a specific nutritional purpose in compliance with Commission Directive 2001/15/EC(**9**) (as corrected(**10**)) on substances that may be added for specific nutritional purposes in foods for particular nutritional uses.";

(d) in paragraph (7) –

(**8**) S.R. 1990 No. 329, to which there are amendments not relevant to these Regulations
(**9**) O.J. No. L52, 22.2.2001, p. 19
(**10**) O.J. L253, 21.9.2001, p. 34

(i) after the definition of "appropriate medical certificate" there shall be inserted the following definition –

""designated PNU food" has the meaning assigned to it by the Food for Particular Nutritional Uses (Addition of Substances for Particular Nutritional Purposes) Regulations (Northern Ireland) 2002;"

(ii) after the definition of "hospital", "and" shall be omitted and there shall be inserted the following definitions –

""infant formula" and "follow-on formula" have the meaning assigned to them by the Infant Formula and Follow-on Formula Regulations (Northern Ireland) 1995(**11**);

"processed cereal-based foods" and "baby foods" have the meaning assigned to them by the Processed Cereal-based Foods and Baby Foods for Infants and Young Children Regulations (Northern Ireland) 1997(**12**); and".

Sealed with the Official Seal of the Department of Health, Social Services and Public Safety on 5th August 2002.

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

(**11**) S.R. 1995 No. 85, to which there are amendments not relevant to these Regulations
(**12**) S.R. 1997 No. 432, to which there are amendments not relevant to these Regulations