STATUTORY RULES OF NORTHERN IRELAND

2000 No. 187

FOOD

Medical Food Regulations (Northern Ireland) 2000

Made	*22nd May 2000*
Coming into operation . .	*1st November 2001*

The Department of Health, Social Services and Public Safety(**a**) in exercise of the powers conferred on it by Articles 16(1), 25(1)(*a*) and (3), 26(3) and 47(2) of the Food Safety (Northern Ireland) Order 1991(**b**) and of all other powers enabling it in that behalf and after consultation in accordance with Article 47(3) of that Order with such organisations as appear to it to be representative of interests likely to be substantially affected by the Regulations, hereby makes the following Regulations:

Citation and commencement

1. These Regulations may be cited as the Medical Food Regulations (Northern Ireland) 2000 and shall come into operation on 1st November 2001.

Interpretation

2. In these Regulations—

"the Directive" means Commission Directive 1999/21/EC on dietary foods for special medical purposes(**c**);

"medical food" means food coming within the classification of dietary foods for special medical purposes for which compositional and labelling requirements are laid down in the Directive;

"member State" means a member State of the European Community other than the United Kingdom;

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

"sell" includes possess for sale and offer, expose or advertise (otherwise than by means of a label or wrapper) for sale.

Restrictions on sale

3.—(1) No person shall sell a medical food unless—

(*a*) its formulation and composition comply with Article 3 of the Directive as read with the Annex thereto and its instructions for use

(**a**) Formerly the Department of Health and Social Services; *see* S.I. 1999/283 (N.I. 1), Art. 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. L91, 7.4.99, p. 29, as corrected by a corrigendum published on 5th January 2000 (O.J. No. L2, 5.1.00, p. 79)

are such that its use in accordance with those instructions would so comply;

(*b*) the name under which it is sold complies with Article 4(1) of the Directive; and

(*c*) it is labelled in accordance with Article 4(2) to (5) of the Directive.

(2) No person who, in respect of medical food of a particular type—

(*a*) is a designated notifier, that is to say a manufacturer or an importer covered by Article 5 of the Directive, but

(*b*) has failed to comply with the requirement to notify the competent authority referred to in that Article,

shall sell a medical food of that type.

(3) For the purposes of paragraph (2) the competent authority is the Food Standards Agency.

Enforcement

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

Offences and penalties

5. If any person—

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

(*b*) without reasonable excuse contravenes regulation 3(2),

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

6. In any proceedings for an offence under regulation 3(1) 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

7. The following provisions of the Order shall apply for the purposes of these Regulations and any reference in them 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 (presumption 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 of the Order;

(*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*).

Sealed with the Official Seal of the Department of Health, Social Services and Public Safety on 22nd May 2000.

(L.S.) *Don Hill*

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

EXPLANATORY NOTE

(This note is not part of the Regulations.)

These Regulations implement Commission Directive 1999/21/EC on dietary foods for special medical purposes (O.J. No. L91, 7.4.99, p. 29).

Article 1(2) of the Directive classifies such foods as foods specially processed or formulated for the dietary management, under medical supervision, of patients who require a special diet, and regulation 2 defines medical food as food within that classification.

Article 2 of the Directive calls for member States to ensure that such food may only be marketed if it complies with the Directive, and Articles 3 and 4 of the Directive lay down requirements for formulation, composition and instructions for use of such food, and for its naming and labelling; regulation 3(1) prohibits the sale of medical food unless those requirements are met.

Article 5 of the Directive requires notification to competent authorities of the placing on the market of products covered by the Directive when manufactured in, or imported from outside, the European Community, and regulation 3(2) and (3) prohibits the sale of medical foods by manufacturers and importers covered by a notification requirement unless they have complied with it, and specifies the Food Standards Agency to be the recipient of the notification.

Enforcement responsibilities, offences and penalties, and application of provisions of the Food Safety (Northern Ireland) Order 1991 are set out in regulations 4, 5 and 7. The Regulations also provide a defence in relation to exports, in accordance with Articles 2 and 3 of Council Directive 89/397/EEC (O.J. No. L186, 30.6.89, p. 23) on the official control of foodstuffs (regulation 6).

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