



Food Safety
AUTHORITY OF IRELAND

19

GUIDANCE NOTE

The Notification of Dietary Foods for Special Medical Purposes under the European Communities (Foods for Special Medical Purposes) 1999, S.I. No. 64 of 2001

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for Special Medical Purposes
under the European Communities
(Foods for Special Medical Purposes)
1999, S.I. No. 64 of 2001

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SCOPE

The scope of this document is to provide information on the implementation, enforcement and compliance with the European Commission Dietary Foods for Special Medical Purposes Regulations Directive 1999/21/EC (S.I. No. 64 of 2001), currently being manufactured or placed on the market in Ireland.

This document is produced with manufacturers, importers, distributors and retailers of dietary foods for special medical purposes and the enforcement officers in mind.

DEFINITIONS

¹Competent Authority

Food Safety Authority of Ireland (FSAI)

¹Dietary Foods for Special Medical Purposes

Category of foods for particular nutritional uses specially processed or formulated and intended for the dietary management of patients and to be used under medical supervision.

²Labelling

Shall mean any words, particulars, trade marks, brand name, pictorial matter or symbol relating to a foodstuff and placed on any packaging, document, notice, label, ring or collar accompanying or referring to such foodstuffs.

³Placed on the Market

(a) import (b) sell (c) offer or expose for sale (d) invite the making by a person of an offer to purchase and (e) distribute free of charge (f) supply for any of those purposes in Ireland.

¹European Communities (Dietary Foods for Special Medical Purposes) Regulations, 2001 S.I. No. 64 of 2001

²Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs

³Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 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

1. INTRODUCTION

The Dietary Foods for Special Medical Purposes Regulations, S.I. No. 64 of 2001 implements Directive 1999/21/EC of the European Parliament and of the Council of 25 March 1999 on Dietary Foods for Special Medical Purposes. Directive 1999/21/EC shall be referred to as ‘the Directive’ and S.I. No. 64 of 2001 as ‘the Regulation’. Dietary foods for special medical purposes shall be referred to as FSMPs in this document.

FSMPs may be placed on the market only if they comply with the provisions of the Directive and the Regulations. The name under which FSMPs are to be sold shall be “Food(s) for Special Medical Purposes”.

This Directive applies equally to all sectors of the FSMPs industry; manufacturers, importers, distributors and retailers.

2. ORGANISATION OF THE REGULATIONS

Title, Commencement and Extent

- Contains the title by which the Regulations may be cited, the coming into force

Interpretation

- Includes definitions for specific terms used and refers to the Directive for other terms not specified

Restriction on Sale

- Effectively requires the notification of FSMPs intended for sale in Ireland
- Identifies the ‘competent authority’

Enforcement

- Provides for the authorities responsible for the enforcement of these Regulations

Offences and Penalties

- Gives details of the offences which may be committed under the provisions of these Regulations

Application of Various Provisions of the Food Safety Authority of Ireland Act, 1998

- Lists the sections of the Food Safety Authority of Ireland Act, 1998 which apply.

3. CLASSIFICATION OF FSMPs

FSMPs are classified in the following three categories:

1. Nutritionally complete foods with standard nutrient formulation which, used in accordance with the manufacturer's instructions, may constitute the sole source of nourishment for the persons for whom they are intended, e.g. standard nutritionally complete tube/sip feed
2. Nutritionally complete foods with nutrient – adapted formulation specific for a disease, disorder or medical condition which, used in accordance with the manufacturer's instructions, may constitute the sole source of nourishment for the persons for whom they are intended, e.g. gluten free nutritionally complete tube/sip feed
3. Nutritionally incomplete foods with a standard formulation or a nutrient-adapted formulation specific for a disease, disorder or medical condition which are not suitable to be used as the sole source of nourishment, e.g. phenylalanine free amino acid powder.

These foods may also be used as a partial replacement or as a supplement to the patient's diet.

4. NOTIFICATION OF FSMPs

The Regulations require FSMPs to be notified to the FSAI when placed on the market in Ireland for the first time.

Article 5 of the Directive states that “to facilitate efficient monitoring of Dietary Foods for Special Medical Purposes, Member States may require the manufacturer or the person placing the product on the market in their territory to notify the competent authority of that placing on the market (within seven days of such placement) by forwarding it a model of the label used for the product”. Through the Regulations, Ireland makes use of the provision requiring notification to the FSAI of placing on the market of such products (followed, where necessary, by provision of supplementary material). This requirement applies when the product is manufactured in or imported into Ireland and is being placed on the Irish market for the first time.

A product, which has been notified in another Member State under the Directive, and subsequently, placed on the market in Ireland, is still subject to the notification requirements. Please refer to Section 13.

5. LABELS FOR FSMPs

The specific labelling requirements of FSMPs are set out in the Directive and require the following mandatory particulars:

Preceded by the word ‘important notice’ or their equivalent:

- A statement that the products must be used under medical supervision
- A statement as to whether the product is suitable for use as a sole source of nourishment
- A statement that the product is intended for a specific age group, as appropriate
- Where appropriate, a statement that the product poses a health hazard when consumed by persons who do not have the diseases, disorders or medical conditions for which the product is intended.

The labelling of FSMPs shall also include:

- The statement ‘For the dietary management of ...’ where the blank shall be filled in with the diseases, disorders or medical conditions for which the product is intended, as the case may be
- Where appropriate, a statement concerning adequate precautions and contra-indications
- A description of the properties and/or characteristics that makes the product useful in particular, as the case may be, relating to the nutrients which have been increased, reduced, eliminated or otherwise modified and the rationale for use of the product
- Where appropriate, a warning that the product is not for parenteral use.

The label will also need to comply with the General Food Labelling Regulations (Directive 2000/13/EC), the Allergens Directive (Directive 2003/89/EC), Nutrition Labelling Directive (1990/496/EC) and legislation on novel foods and genetically modified organisms. For more detailed information on labelling, please refer to the FSAI report ‘The Labelling of Food in Ireland 2002’⁴ which is on the FSAI website.

⁴This document is currently under review for updating.

6. FSMPs TO BE NOTIFIED

Not all FSMPs need to be notified. As previously mentioned, the notification requirements apply to those that are placed on the market in Ireland for the first time since the Directive came into force on the 25th March 1999.

In addition to the above, food products that do not comply with the definition of FSMPs are not subject to these Regulations and therefore do not need to be notified under this Directive. Examples include:

- Conventional food products bearing a nutrition claim or health claim, such as low salt baked beans, reduced salt tomato ketchup, low fat yogurt
- Conventional food products containing added vitamins or minerals, such as vitamin-enriched breakfast cereals
- Food supplements.

These examples have or will have their own specific Directives and Regulations.

7. NOTIFICATION OF VARIATION IN FLAVOUR/PACKAGING SIZE OF A PRODUCT

Notification of a variation in flavour/packaging size for each FSMP is required by the FSAI. This is to ensure that the FSAI is aware of the extent of FSMPs that are on the market. To make this notification, a letter informing the FSAI including a copy of the new label (as appropriate) should be sent to the FSAI. This type of notification can only occur where there has been no change in nutritional composition of products between flavours, packaging size etc. If there are compositional changes to the product, then the notification to the FSAI is required. In this case, the revision section of the form is used.

8. NOTIFICATION OF REFORMULATED FSMPs

A FSMP that has already been notified to the FSAI under these Regulations but which has since been reformulated should be notified as if it was a new product and also a copy of the new label is required.

9. WHEN TO NOTIFY THE FSAI

Notification of FSMPs (followed, where necessary, by provision of supplementary material) to the FSAI is required within seven days of placing such products on the Irish market. This requirement applies when the product is manufactured in or imported into Ireland and placed on the market for the first time.

10. HOW TO NOTIFY THE FSAI

Regulation 11 of S.I. No. 64 of 2001 states that “when a Dietary Food for Special Medical Purposes is placed on the market for the first time in Ireland, the manufacturer, or where a product is manufactured in a third country, the importer shall notify the FSAI within seven days of the product being placed on the market”. Such notification shall be accompanied by:

1. A model of the label to be used for the product
2. A statement as to whether or not the product has been placed on the market in any other Member State, and, if so, the name of such Member State or States and the name of the recipients of the notifications of such placements
3. Any other information the FSAI may require for the purpose of establishing compliance with these regulations”.

The FSAI has developed a form that manufacturers and importers may use to help them with their notification. This is available on the FSAI website in both PDF and Word format:

www.fsai.ie/legislation/notif_forms/FSMP_not_form1.pdf
www.fsai.ie/legislation/notif_forms/fsmp_not_form1.doc⁵

The FSAI is notified by forwarding a completed form with a model of the product label, any associated literature, e.g. advertising, consumer information leaflets, websites etc. and a covering letter which includes contact details from where additional information may be requested. The addresses to which notifications should be sent are listed at the end of this Guidance Note.

⁵Consult Annex 1 for a copy of this form.

11. FURTHER INFORMATION REQUIRED BY THE FSAI

The FSAI may require the manufacturer (or where appropriate, the importer) to produce the scientific work and data establishing the product’s compliance with the definitions for a ‘Dietary Food for Special Medical Purpose’ together with information on the particular elements of the qualitative and quantitative composition or the special manufacturing process which gives the product its particular nutritional characteristics. If such work is contained in a readily available publication, reference to this publication will suffice.

All detailed information on a product will be kept confidential except in the case where the product may be considered a medicine and therefore it is the duty of the FSAI to notify the Irish Medicines Board of the case for their opinion.

12. RESPONSIBILITY FOR NOTIFICATION TO THE FSAI

It is the responsibility of the manufacturer or importer based in Ireland to notify the FSAI of products requiring such. For FSMPs requiring notification which are manufactured in the European Union and who's first marketing is in Ireland, it is the responsibility of the manufacturer to notify the FSAI. For FSMPs manufactured outside the European Union and who's first marketing is in Ireland, the responsibility falls to the importer.

13. PRODUCTS ALREADY NOTIFIED IN ANOTHER MEMBER STATE

A product, which has been notified in another Member State under the Directive, and subsequently, placed on the market in Ireland, is still subject to the notification requirements. The product must be notified to the FSAI by the manufacturer or, where appropriate, the importer based in Ireland using a model of the label (see Annex 2 for example of a compliant label) and details of the recipient of the first notification in the European Union.

If products have been notified in another Member State, a letter from the competent authority will be accepted as proof of compliance as assessed by that Member State. However, the FSAI will still request a copy of the label.

14. PROCESSING OF NOTIFICATION PROVIDED TO THE FSAI

The FSAI will acknowledge receipt of notification. The FSAI may require further information about a particular product (see Section II of this Guidance Note).

Details about the notification, such as the product label, date of notification and contact details of the notifier, will be kept centrally and in confidence by the FSAI.

The FSAI will list FSMPs notified under the Regulations on its website for use by official agencies. However this listing will only include the name of the product and the manufacturer/distributor. Prior to the advent of the Directive and Regulation, notification was not required for FSMPs being placed on the market.

15. CHECKING FOR COMPLIANCE BY THE FSAI FOR FSMPs LABELLING

It is the responsibility of the manufacturer/importer to ensure that a FSMP complies with the relevant legislation. A product must not be placed onto the Irish market unless it has satisfactorily presented itself as meeting the requirements of the legislation. Failure to meet these requirements is an offence under the Regulations.

After notification and submission of a proposed label, the FSAI will check the product for compliance with regards to labelling and provide appropriate advice. However, the notification of a FSMP under these Regulations should not be viewed in any way as approval from the FSAI. The label cannot contain any statements suggesting such an approval.

In general, the FSAI will acknowledge receipt of the notification and product label within a week of receipt. Assessment of labels would normally take up to eight weeks. Should any additional information be sought, it may take up to a further six weeks before an opinion is given by the FSAI.

In the event that the requirements of the Regulations are met, the product is free to remain on the market. The FSAI will issue a letter after assessment stating such.

In the event that the requirements of the regulations are not met, the product may need to be removed from the market on the advice of the FSAI, until such a time as the requirements are met. The FSAI will issue a letter stating such.

16. WARRANTY THROUGH THE CHAIN FOR RETAILERS

It is the responsibility of the retailer to ensure that the products sold on their premises are compliant with the legislation. In order to be certain that the products are of a high standard, the certificate of analysis and where relevant, the letter from the FSAI with regards to notification procedure and labelling compliance should be made available to the retailer by the importer/distributor.

The retailer also needs to ensure that they have a traceability system in place, back to their supplier and forward to their customers, in cases of selling on to other retailers.

17. FSMPs CONTAINING COMPOUNDS NOT LISTED BY THE DIRECTIVE

FSMPs must comply with the compositional criteria specified in the Annex to the Directive and may be placed on the Irish market only when they do so.

18. MARKETING FSMPs WITHOUT NOTIFICATION

If the product is subject to the notification requirements then it must be notified in line with the Regulations. Failure to do so is an offence (see Section 19 for offences).

FSMPs may be placed on the market only if they comply with the provisions laid down in the Regulations and the Directive.

19. ENFORCEMENT OF FSMPs DIRECTIVE

Enforcement of food law is the responsibility of Health Service Executive (HSE), usually through environmental health officers. The FSMP legislation is food law and has the following offences set out.

⁶Offences

It is an offence to:

- Fail to comply with the Regulations
 - Place product on market for the first time without prior notification
 - Retain the product on the market with incompliant labelling
- To issue or forge the certificate of analysis or other documents
- To alter and issue a certificate of analysis or other documents
- Be unlawfully in possession of a forged document or an altered document
- Tamper with anything to misrepresent the substance sampled
- Tamper or interfere with any sample taken
- Failure to produce information on the particular elements of the qualitative and quantitative composition or the special manufacturing process which gives the product its particular nutritional characteristics without reasonable excuse.

A person who is guilty of an offence under these Regulations shall be liable, on summary conviction to a fine not exceeding € 1,950 or at the discretion of the Court to imprisonment for a term not exceeding six months or both.

The HSE will be directed, through arrangements of the service contracts, on the priority of enforcement of the Regulations and as part of routine and co-ordinated sampling programmes on the sampling and analysis of FSMPs to check for compliance.

⁶Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 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.

20. CONTACT DETAILS

Notification of FSMPs subject to these Regulations should be forwarded to:

Chief Specialist in Public Health/ Public Health Nutrition	Food Safety Authority of Ireland, Abbey Court, Lower Abbey Street, Dublin 1	Tel: + 353 817 1300 Fax: + 353 817 1301
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Copies of the legislation mentioned in this Guidance Note are available from:

Statutory Instruments	Government Publications Sales Office, Sun Alliance House, Molesworth Street, Dublin 2	Tel: + 353 679 3515
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EU Documents	European Commission Representation in Ireland European House, Dawson Street, Dublin 2	Tel: + 353 634 1111 Fax: + 353 634 1112
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EU Documents	Alan Hanna, 270 Lower Rathmines Road, Dublin 6.	Tel: + 353 496 7399
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Further information can be found on the websites listed below:

Irish Statute Book	http://193.120.124.98/front.html
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European Law	http://europa.eu.int/eur-lex/
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Food Safety Authority of Ireland	www.fsai.ie/legislation/index.asp
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ANNEX 1: NOTIFICATION FORM FOR FSMPs

IMPORTANT NOTICE

- 1. Notification** of Dietary Foods for Special Medical Purposes is a statutory requirement under Commission Directive 1999/21/EC and S.I. No. 64 of 2001, which cover the enforcement of food legislation in the area of Dietary Foods for Special Medical Purposes.
2. Notification is required when a medical food is **placed on the market** in Ireland.
3. The term **'medical food'** means food coming within the classification of Dietary Foods for Special Medical Purposes for which the compositional and labelling requirements are laid down in Commission Directive 1999/21/EC on Dietary Foods for Special Medical Purposes.
4. This form may be used to notify the **Food Safety Authority of Ireland (FSAI)** when a medical food is placed on the Irish market. The duty to notify falls on the manufacturer if the product is manufactured in Ireland and on the importer if the product is imported into Ireland.
5. A **separate** form is required for each product.

Manufacturer Details:

Name: _____

Address: _____

Tel: _____ Fax: _____

E-mail: _____

Importer Details:

Name: _____

Full postal address: _____

Tel: _____ Fax: _____

E-mail: _____

A. Product Details

Product name: _____

Product description: _____

Product category (see Commission Directive 1999/21/EC for details):

Please tick as appropriate

(a) Nutritionally complete food with standard nutrient formulation

(b) Nutritionally complete food with nutrient adapted formulation

(c) Nutritionally incomplete food

For which disease/disorder/medical condition is this product intended?

B. Revision of a Product

Product name: _____

When was this product notified? _____

What revision has been made to the product? _____

What is the reason for this revision? _____

C. Accompanying Documentation

A model of the product label and accompanying product literature should be provided to the FSAI. Please tick here to confirm

Has the intended use of the product rendered it necessary to modify the compositional requirements from those laid down in Directive 1999/21/EC?

Yes No

If yes, please attach supplementary information relevant to this notification.

Please tick here to confirm

Signature: _____ Name in block letters: _____

Date: _____

ANNEX 2: EXAMPLE OF COMPLIANT LABEL

VITAMIN C DRINK	
Orange flavour	
Food for special medical purpose	
For the dietary management of vitamin C deficiency in children and adults	
Nutritional Analysis	Per 100ml
Protein	15g
Fat	30g
Carbohydrate	55g
Vitamin C	120mg
Ingredients	
Whey protein, Glucose, MCT oil, Vitamin C (L-ascorbic acid)	
Directions for Use	
Take as prescribed by a medical practitioner, dietician or pharmacist. <ul style="list-style-type: none">• Must be used under medical supervision.• Not suitable as a sole source of nutrition.<ul style="list-style-type: none">• Not suitable for intravenous use.• Do not consume if allergic to ascorbic acid.	
Net weight: 200ml	Best before date: 01/12/2004
Manufactured by (or imported by): Dietary Foods for Special Medical Purposes Limited, 63, Foods for Special Medical Purposes Road, Co. Dublin, Ireland	



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