

Guidance notes on the Notification of Marketing of Food for Particular Nutritional uses Regulations 2002



Important Note

1. These notes have been produced with the aim of providing informal, non-statutory guidance on the following Regulations:
 - the Notification of Marketing of Food for Particular Nutritional Uses (England and Wales) Regulations 2002 (Statutory Instrument 2002 No. 333)
 - the Notification of Marketing of Food for Particular Nutritional Uses (Scotland) Regulations 2002 (Scottish Statutory Instrument 2002 No. 50)
 - the Notification of Marketing of Food for Particular Nutritional Uses Regulations (Northern Ireland) 2002 (Statutory Rules of Northern Ireland 2002 No. 35)
2. The notes are intended to be read in conjunction with:
 - the Regulations listed above
 - Council Directive 89/398/EEC on the approximation of the laws of 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.
3. The examples in these notes are provided for illustration only.
4. The notes and examples should not be taken as an authoritative statement or interpretation of the law, as only the courts have this power.

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Guidance Notes

1. Introduction

These Regulations implement for England and Wales, Scotland and Northern Ireland Article 9 of Council Directive 89/398/EEC 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. Council Directive 89/398/EEC as amended by Directive 1999/41/EC of the European Parliament and of the Council is referred to in these guidance notes as 'the Directive'.

2. Organisation of the Regulations

Title / citation, commencement and extent

- Contains the title by which the Regulations may be cited, the coming into force date and the countries covered.

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 PNU food products intended for sale in the United Kingdom.
- 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 Act 1990 (England and Wales, Scotland); Application of various provisions of the Order (Northern Ireland)

- Lists the sections of the Food Safety Act 1990 or of the Food Safety (Northern Ireland) Order 1991, which apply.

3. What are the rules on notification of foods for particular nutritional uses?

These Regulations effectively require certain foods for particular nutritional uses to be notified to the Food Standards Agency when placed on the market in the United Kingdom for the first time.

Article 9 of the Directive requires notification (followed, where necessary, by provision of supplementary material) to competent authorities of placing on the market of such products. The requirement applies when the product is manufactured or imported.

Regulation 3 of these Regulations prohibits sale of such products by manufacturers and importers covered by the requirement unless they have complied with it. 'Sell' is given an extended meaning in the Regulations to include possess for sale and offer, expose or advertise (otherwise than by means of a label or wrapper) for sale. In accordance with the Food Safety Act 1990 and the Food Safety (Northern Ireland) Order 1991, sale of a food includes the supply, otherwise than on sale, in the course of a business.

4. What is a 'food for particular nutritional use'?

A food for a particular nutritional use is one which:

- owing to its special composition or process of manufacture, is clearly distinguishable from food intended for normal consumption and
- is sold in such a way as to indicate its suitability for its claimed particular nutritional purpose.

A particular nutritional use means the fulfillment of the particular nutritional requirements of:

- certain categories of persons whose digestive processes are, or whose metabolism is, disturbed, or
- 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
- infants or young children in good health

The Regulations effectively require that those foods for particular nutritional uses, which are neither covered, nor to be covered by Directives on specific types of foods for particular nutritional uses be notified to the Food Standards Agency upon first marketing.

5. Should all foods for particular nutritional uses be notified?

No. As mentioned above, the notification requirements apply to foods for particular nutritional uses that are not (or will not) be covered by specific Directives.

The following groups of foods for particular nutritional uses do not need to be notified to the Food Standards Agency under this legislation:

- Infant formulae and follow-on formulae subject to the Infant Formula and Follow-on Formula Regulations 1995, as amended, or the Infant Formula and Follow-on Formula Regulations (Northern Ireland) 1995, as amended;
- Processed cereal-based foods and baby foods for infants and young children subject to the Processed Cereal-based Foods and Baby Foods for Infants and Young Children Regulations 1997, as amended or the Processed Cereal-based Foods and Baby Foods for Infants and Young Children Regulations (Northern Ireland) 1997, as amended;
- Slimming foods subject to the Foods Intended for Use in Energy Restricted Diets for Weight Reduction Regulations 1997 or the Foods Intended for Use in Energy Restricted Diets for Weight Reduction Regulations (Northern Ireland) 1997;
- Dietary foods for special medical purposes subject to the Medical Food (England) Regulations 2000 or the Medical Food (Wales) Regulations 2000, the Foods for Special Medical Purposes (Scotland) Regulations 2000 or the Medical Food Regulations (Northern Ireland) 2000 (these foods need to be notified under that legislation);
- Foods intended to meet the expenditure of intense muscular effort, especially for sportsmen; and
- Foods for persons suffering from carbohydrate-metabolism disorders (diabetes).

In addition to those foods listed above, food products that do not comply with the definition for food for particular nutritional use are not subject to these Regulations and therefore do not need to be notified. Examples include:

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

6. What about gluten-free, wheat-free or dairy-free foods?

Conventional foods bearing a wheat-free claim and/or dairy-free claim are not considered foods for particular nutritional uses. These foods are not subject to these Regulations and need not be notified to the Food Standards Agency.

Specialist gluten-free foods are considered to be foods for particular nutritional uses under the Directive and are therefore subject to the notification requirements (refer to Section 7 below for further information).

7. Examples of foods for particular nutritional uses which require notification?

Examples of foods for particular nutritional uses that would require notification include:

- Foods intended for infants or young children but which are not covered by the Infant Formula and Follow-on Formula Regulations 1995, as amended, or the Processed Cereal-based Foods and Baby Foods for Infants and Young Children Regulations 1997, as amended
- Specialist gluten-free products, such as a product which has undergone a technological process to specifically remove or reduce the gluten content of a gluten-containing ingredient or one which has undergone a recipe change to replace part or all of a gluten-containing ingredient that is normally present in that food (e.g. pasta made using corn and/or rice flours rather than wheat flour), and which bear a claim to this fact
- Specialist low sodium or low salt products, such as reduced sodium table salt alternatives, but not conventional products manufactured to contain less salt and which bear reduced or low salt/sodium claims (see Section 5 of these guidance notes)

8. Is it necessary to notify each flavour or packaging size of a product individually?

A separate notification is required for each food product. However, separate notifications for every packaging size variation are not necessary.

As different flavours for a product are likely to result in different formulations, separate notifications should be made for each flavour of a product line.

9. What about reformulated foods?

A food that has already been notified to the Food Standards Agency under these Regulations but which has since been reformulated should be notified as if it is a new product.

10. When should the Food Standards Agency be notified?

Article 9 of the Directive requires that notification be given when products are placed on the market for the first time.

The Regulations prohibit the sale of products if the manufacturer/importer has failed to comply with the requirement to notify the competent authority or produce additional information to the competent authority, if required. 'Sell' is given an extended meaning (refer to Section 3 of these guidance notes).

11. How do I notify the Food Standards Agency?

Article 9 of the Directive requires that a model of the label of any product requiring notification be forwarded to the competent authority of the Member State where the product is to be marketed. In the United Kingdom, the competent authority is the Food Standards Agency.

The Food Standards Agency has developed a form that manufacturers and importers may use to help them with their notification. Copies of the form will be made available on our website: www.food.gov.uk and are available from the Food Standards Agency (contact details at the end of these Guidance Notes).

The addresses to which notifications should be sent are given at the end of these Guidance Notes.

12. Will further information be required by the Food Standards Agency?

The Food Standards Agency 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 'foodstuffs for particular nutritional uses' and 'a particular nutritional use' (Article 9(3) of the Directive) 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 (as provided for in Article 7(3)(a) of the Directive). If such work is contained in a readily available publication, reference to this publication will suffice.

Failure to produce such information without reasonable excuse is an offence under the Regulations.

13. Whose responsibility is it to notify the Food Standards Agency?

The Regulations specify that it is the responsibility of the manufacturer or importer of a food requiring notification to carry out this task.

For foods requiring notification which are manufactured in the European Union and whose first marketing is in the United Kingdom, it is the responsibility of the manufacturer to notify.

For foods manufactured outside the European Union and whose first marketing is in the United Kingdom, the responsibility falls to the importer.

14. What about 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 the United Kingdom, is still subject to the notification requirements. The product must be notified to the Food Standards Agency by the manufacturer or, where appropriate, the importer using a model of the label and an indication of the recipient of the first notification in the European Union.

15. Should I notify each country separately if I want to market my product throughout the United Kingdom?

No. It is not necessary to notify each country within the UK separately. One notification to a Food Standards Agency office in London, Cardiff, Aberdeen or Belfast meets the requirements of the Regulations.

16. What happens after notification is provided to the Food Standards Agency?

The Food Standards Agency will acknowledge receipt of notification and may require further information about a particular product (see Section 12 of these guidance notes). The Agency will then inform the relevant local authorities – who enforce the food regulations – that the product has been notified in accordance with the Notification of Marketing of Food for Particular Nutritional Uses Regulations 2002.

17. What happens to the information provided in a notification?

Details about the notification, such as the product label, date of notification and contact details of the notifier, will be kept centrally by the Food Standards Agency.

18. Will the Food Standards Agency check compliance of a product with the definition for a food for particular nutritional use or its labelling?

No. Notification of a food product under these Regulations should not be viewed in any way as Food Standards Agency 'approval'.

The Food Standards Agency may request further information as to the product's compliance with the definitions and compositional elements or manufacturing process that gives the product its particular characteristics (see Section 12 of these guidance notes). However, it is the responsibility of the manufacturer/importer to ensure that a food product complies with the relevant legislation.

Enforcement of food law is the responsibility of local authorities, usually through trading standards or environmental health departments. Guidance on compliance of specific products with food legislation should be sought from your local trading standards or environmental health department.

19. Can I market my food for particular nutritional use without notifying it?

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 and subject to a fine up to £5000 in the event of a successful prosecution.

20. Contact details?

Notification of foods for particular nutritional uses subject to these Regulations should be forwarded to:

Food Standards Agency Parnuts Food Notification Nutrition Division Nutrition Labelling, Promotions and Dietetic Foods Branch Room 115B Aviation House 125 Kingsway London WC2B 6NH Tel: 020 7276 8065 Fax: 020 7276 8193 E-mail: parnutnotification@foodstandards.gsi.gov.uk	Food Standards Agency (Wales) Parnuts Food Notification Local Authority Enforcement Branch 1 st Floor Southgate House Wood Street Cardiff CF10 1EW Tel: 029 2067 8909 Fax: 029 2067 8918
Food Standards Agency (Scotland) Parnuts Food Notification Professional Advice Branch 6 th Floor St Magnus House 25 Guild Street Aberdeen AB11 6NJ Tel: 01224 285175 Fax: 01224 285110	Food Standards Agency (Northern Ireland) Parnuts Food Notification Professional Unit 10c Clarendon Road Belfast BT1 3BG Tel: 028 9041 7714 Fax: 028 9041 7726

Copies of the legislation mentioned in these Guidance Notes are available from:

The Stationery Office
(Tel: 0870 600 5522; www.hmso.gov.uk).

Nutrition Division
Food Standards Agency