Guidance Notes on the Notification of Marketing of Foods for Particular Nutritional Uses, Medical foods and Infant Formula

This guidance applies to the whole of the UK and was prepared by the Department of Health in association with the Welsh Government, and Food Standards Agency in Scotland and Northern Ireland

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Intended audience

This guidance is aimed at all companies who intend to market for the first time in the UK foods for particular nutritional uses, medical foods and infant formula, and those local authorities who are responsible for enforcing the legislation in this area.

Legislation on foods for particular nutritional uses, medical foods and infant formula is implemented on a devolved basis, however this guidance applies across the UK.

Executive summary

In order to permit efficient official monitoring, EU Directive 2009/39/EC of 6 May 2009 on foodstuffs for particular nutritional uses requires such foods to be notified when they are first placed upon the market in each European Member State. In addition, medical foods and infant formulae are also required to be notified to the competent authority.

The information set out in this document aims to provide non-statutory guidance on the notification rules, which apply to foods for particular nutritional uses, medical foods and infant formula.

Updated April 2014 to remove incorrect reference to offences relating to written declarations. No other significant changes have been made other than amending the contact details for England.

1. These notes have been produced with the aim of providing non-statutory guidance for the notification of the marketing of Foods for Particular Nutritional Uses (Parnuts), Medical foods and Infant Formula.
2. These guidance notes are split into three sections covering each of the specific notification requirements and should be used in conjunction with the relevant notification form.
    - Foods for Particular Nutritional Uses (PNU Foods) (see Section A)
    - Medical foods (see Section B)
    - Infant Formula (see Section C)
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.

Contact details for the UK competent authorities are as follows:[1]

England: Department of Health, Nutrition Legislation Team Health and Wellbeing Department of Health Wellington House 133-155 Waterloo Road London SE1 8UG Tel: 020 7972 4340 Fax No. 020 7972 4227 E-mail: nutritionlegislation@dh.gsi.gov.uk	**Wales:** Health Improvement Division Welsh Government Cathays Park Cardiff CF10 3NQ Tel: 02920 825724 Email: Lifestyles@wales.gsi.gov.uk
Scotland: Food Standards Agency (Scotland) Parnuts Food Notification Professional Advice Branch 6th Floor St Magnus House 25 Guild Street Aberdeen AB11 6NJ Tel: 01224 285175 Fax: 01224 285110 E-mail: parnutnotification@foodstandards.gsi.gov.uk	**Northern Ireland:** Food Standards Agency (Northern Ireland) Parnuts Food Notification Professional Unit 10c Clarendon Road Belfast BT1 3BG Tel: 028 9041 7714 Fax: 028 9041 7726 E-mail: parnutnotification@foodstandards.gsi.gov.uk

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

The Office of Public Sector Information (Tel: 0870 600 5522; www.opsi.gov.uk).

[1] Responsibility for legislation on the Notification of Marketing of Foods for Particular Nutritional Uses, Medical Foods and Infant Formula in England and Wales transferred from the Food Standards Agency (FSA) to the respective health departments (Department of Health in England and Health Improvement Division, Welsh Government), on 1 October 2010. The FSA offices in Scotland and Northern Ireland have retained these responsibilities.

SECTION A: Guidance notes on the Notification of Marketing of Food for Particular Nutritional uses Regulations 2007

A1. Introduction

Important Note

These notes have been produced with the aim of providing non-statutory guidance on the following Regulations:

- the Notification of Marketing of Food for Particular Nutritional Uses (England) Regulations 2007 (Statutory Instrument 2007 No. 181)
- the Notification of Marketing of Food for Particular Nutritional Uses (Scotland) Regulations 2007 (Scottish Statutory Instrument 2007 No. 37)
- the Notification of Marketing of Food for Particular Nutritional Uses Regulations (Northern Ireland) 2007 (Statutory Rules of Northern Ireland 2007 No. 60)
- Notification of Marketing of Food for Particular Nutritional Uses Regulations (Wales) 2007 (Welsh Statutory Instrument 2007 No W.100)

The notes are intended to be read in conjunction with:

- the Regulations listed above
- Council Directive 2009/39/EC of the European Parliament and of the Council on foodstuffs intended for particular nutritional uses.

These Regulations implement for England, Wales, Scotland and Northern Ireland Article 11 of Council Directive 2009/39/EC on the approximation of the laws of the Member States relating to foodstuffs intended for particular nutritional uses, referred to in these guidance notes as 'the Directive'.

Any reference to 'competent authority' shall be read as meaning whichever UK country authority is notified.

A2. 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.

PNU Foods are defined as a food for particular nutritional use 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,

but does not fall into any of the following classifications –

- infant formulae and follow-on formulae (see section C),
- processed cereal-based foods and baby foods for infants and young children,
- foods intended for use in energy-restricted diets for weight reduction,
- dietary foods for special medical purposes (see section B),
- foods intended to meet the expenditure of intense muscular effort, especially for sportsmen, and
- foods for persons suffering from carbohydrate-metabolism disorders (diabetes).

Restriction on sale

- Effectively requires the notification of PNU food products intended for sale in the United Kingdom.
- Identifies the 'competent authority'.

Declaration

Where a UK authority has detailed grounds for establishing that a foodstuff intended for a particular nutritional use which does not belong to one of the groups listed in the Directive or does not comply with the Directive; the UK authority may by written declaration suspend or restrict trade in that product.

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 (as amended) (England and Wales, Scotland); Application of various provisions of the Order (Northern Ireland) (as amended)

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

A3. What are the rules on notification for PNU foods?

These Regulations effectively require certain foods for PNU Foods to be notified when placed on the market in the United Kingdom for the first time.

Article 11 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.

A4. What is a 'PNU food'?

A PNU food 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.

but does not fall into any of the following classifications –

- infant formulae and follow-on formulae (see section C),
- processed cereal-based foods and baby foods for infants and young children,
- foods intended for use in energy-restricted diets for weight reduction,
- dietary foods for special medical purposes (see section B),
- foods intended to meet the expenditure of intense muscular effort, especially for

sportsmen, and

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

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 a UK competent authority upon first marketing.

A5. 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 (i.e. PNU Foods).

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

- Infant formulae and follow-on formulae subject to the Infant Formula and Follow-on Formula (England) Regulations 2007 No. 3521, the Infant Formula and Follow-on Formula Regulations (Wales) Regulations 2007 WSI No. 3573 (W.316) the Infant Formula and Follow-on Formula (Scotland) Regulations 2007 SSI No. 549, and the Infant Formula and Follow-on Formula Regulations (Northern Ireland) Regulations 2007 SRNI No. 506 **(Note: infant formula need to be notified under that legislation);**
- 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 2003, as amended or the Processed Cereal-based Foods and Baby Foods for Infants and Young Children Regulations (Northern Ireland) 2003, as amended;
- Slimming foods subject to the Foods Intended for Use in Energy Restricted Diets for Weight Reduction Regulations 1997 as amended or the Foods Intended for Use in Energy Restricted Diets for Weight Reduction Regulations (Northern Ireland) 1997 as amended;
- Dietary foods for special medical purposes subject to the Medical Food (England) Regulations 2000 as amended or the Medical Food (Wales) Regulations 2000 as amended. the Foods for Special Medical Purposes (Scotland) Regulations 2000 as amended or the Medical Food Regulations (Northern Ireland) 2000 as amended **(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.

A6. 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.

Foods which have been specially manufactured to ensure that they are gluten-free are considered to be foods for particular nutritional uses under the Directive and are therefore subject to the notification requirements (refer to Section A7 below for further information).

A7. Examples of foods for particular nutritional uses which require notification

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

- Specialist gluten-free products, which have 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.

A8. 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 unless there are significant changes to labelling content.

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.

A9. What about reformulated foods?

A food that has already been notified under these Regulations but which has since been reformulated such that there is a consequential labelling change should be notified as if it is a new product.

A10. When should a UK competent authority be notified?

Article 11 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 A3 of these guidance notes).

A11. How do I notify a UK competent authority?

Article 11 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.

A form is available for manufacturers and importers to use to help them with their notification. Copies of the form are available on our website foods for particular nutritional uses (parnuts) notification requirements Please note that the form can be completed and submitted either in hard copy by post or electronically via email together with an electronic version of the product label.

The addresses to which notifications should be sent are given at page 4 of these Guidance Notes.

A12. Will further information be required by the competent authority?

Manufacturers may be required (or where appropriate, the importer) to produce evidence 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).

Failure to produce such information is an offence under the Regulations.

A13. Whose responsibility is it to notify the competent authority?

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.

A14. 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 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.

A15. 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 competent authority office in London, Cardiff, Aberdeen or Belfast meets the requirements of the Regulations. The addresses to which notifications should be sent are given on page 4 of these Guidance Notes.

A16. What happens after notification is provided to a competent authority?

The competent authority will acknowledge receipt of notification and may require further information about a particular product from the notifying company (see Section A12 of these guidance notes). The competent authority 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 2007.

A17. 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 notified competent authority.

A18. Will the competent authority 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 competent authority 'approval'.

The competent authority 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.

A19. What action will be taken if the competent authority does not accept a notification?

The competent authority will not accept a notification if it considers that the notified product does not comply with the Directive. The competent authority may then suspend or restrict trade in that product by means of a written declaration.

A20. Can I continue to market a food if it is subject to a declaration?

It is an offence to continue to market a food which is subject to a declaration. A company which continues to market a food which is subject to a declaration may be fined up to £5000 in the event of a successful prosecution.

A21. 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.

SECTION B: Guidance notes on the Notification of Medical Foods

B1. Introduction

These notes have been produced with the aim of providing informal, non-statutory guidance on the notification requirement within the following Regulations:

- the Medical Food (England) Regulations 2000 (Statutory Instrument 2000 No. 845)
- the Food for Special Medical Purposes(Scotland) Regulations 2000 (Scottish Statutory Instrument 2000 No. 130)
- the Medical Food Regulations (Northern Ireland) 2000 (Statutory Rules of Northern Ireland 2000 No. 187)
- the Medical Food Regulations (Wales) 2000 (Welsh Statutory Instrument 2000 No W125)

These notes are intended to be read in conjunction with:

- the Regulations listed above
- Commission Directive 1999/21/EC (as amended) on dietary foods for special medical purposes.

These Regulations implement for England, Wales, Scotland and Northern Ireland Commission Directive 1999/121/EC on dietary foods for special medical purposes. Commission Directive 1999/121/EC, as amended, is referred to in these guidance notes as 'the Directive'. The notification requirement for medical foods is set out in Article 5 of the Directive.

Any reference to 'competent authority' shall be read as meaning whichever UK country authority is notified.

B2. 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 that any medical food intended for sale in the United Kingdom meets the compositional and labeling requirements set out in the Directive
- Effectively requires the notification of medical 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 (as amended) (England and Wales, Scotland); Application of various provisions of the Order (Northern Ireland) (as amended)

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

B3. What are the rules on notification of medical foods?

These Regulations effectively require all medical foods to be notified to the competent authority when placed on the market in the United Kingdom for the first time.

Article 5 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.

B4. What is a 'medical food'?

Medical foods are a 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.

They are intended for the exclusive or partial feeding of patients with a limited, impaired or disturbed capacity to take, digest, absorb, metabolise or excrete ordinary foodstuffs or certain nutrients contained therein or metabolites, or with other medically-determined nutrient requirements, whose dietary management cannot be achieved only by modification of the normal diet, by other foods for particular nutritional uses, or by a combination of the two.

Medical Foods are classified in the following three categories:

- nutritionally complete foods with a standard nutrient formulation which, used in accordance with the manufacturer's instructions, may constitute the sole source of nourishment for the patient.
- nutritionally complete foods with a 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. These foods may also be used as a partial replacement or as a supplement to the patient's diet.
- 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. These foods may also be used as a partial replacement or as a supplement to the patient's diet.

B5. Should all medical foods be notified?

Yes; Article 5 of the Directive requires that notification be given for **all** medical foods placed on the market in the UK.

B6. 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 unless there are significant changes to labelling content.

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.

B7. What about reformulated foods?

A food that has already been notified to the competent authority under these Regulations but which has since been reformulated such that there is a consequential labelling change should be notified as if it is a new product.

B8. When should the competent authority be notified?

Article 5 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).

B9. How do I notify the competent authority?

Article 5 of the Directive requires that a model of the label of any medical food be forwarded to the competent authority of the Member State where the product is to be marketed.

A form is available that manufacturers and importers may use to help them with their notification. Copies of the form will be made available on our website: Medical food notification form. Please note the form can be completed and submitted either in hard copy by post or electronically via email together with an electronic version of the product label.

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

B10. Will further information be required by the competent authority?

The competent authority may require the notifying company to produce the evidence to establish the product's compliance with the definitions for 'medical food' (Article 1(2) of the Directive) together with information on the particular elements of the qualitative and quantitative composition. If such work is contained in a readily available publication, reference to this publication will suffice.

Failure to produce such information may lead to your product being regarded as non-compliant with Directive 1999/21/EC and subject to enforcement action by local authorities.

Medical foods which are nutritionally incomplete are permitted to contain vitamin and mineral levels above the levels set in the legislation if such modification is required to fulfil the particular nutritional use of the product. For any such products, the competent authority requests the following information be supplied with the initial notification:

- a list of the vitamin and mineral content of the product per 100kcal
- the rationale behind the product deviations (i.e. why the vitamin and mineral content deviates from that set within the Directive)
- how the product is used
- the recommended daily intake of the product

B11. Whose responsibility is it to notify the competent authority?

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.

B12. 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 competent authority 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.

B13. 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 competent authority office in London, Cardiff, Aberdeen or Belfast meets the requirements of the Regulations. The addresses to which notifications should be sent are given on the first page of these Guidance Notes.

B14. What happens after notification is provided to the competent authority?

The competent authority will acknowledge receipt of notification and may require further information about a particular product (see Section 10 of these guidance notes). The competent authority will then inform the relevant local authorities – who enforce the food regulations – that the product has been notified in accordance with the Medical Food Regulations 2000.

B15. 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 competent authority.

B16. Will the competent authority check compliance of a product with the definition for a medical food or its labelling?

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

The competent authority 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 10 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.

B17. Can I market a medical food without notifying it or if a notification has been rejected?

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.

SECTION C: Guidance notes on the Notification of Infant Formula

C1. Introduction

These notes have been produced with the aim of providing informal, non-statutory guidance on the notification requirement within the following Regulations:

- the Infant Formula and Follow-on Formula (England) Regulations 2007 (Statutory Instrument 2007 No. 3521) (as amended)
- the Infant Formula and Follow-on Formula (Scotland) Regulations 2007 (Scottish Statutory Instrument 2007 No. 549) (as amended)
- the Infant Formula and Follow-on Formula (Northern Ireland) 2007 (Statutory Rules of Northern Ireland 2007 No. 506) (as amended)
- the Infant Formula and Follow-on Formula (Wales) 2007 (Welsh Statutory Instrument 2007 No.3573 (W.316) (as amended)

The notes are intended to be read in conjunction with:

- the Regulations listed above
- Commission Directive 2006/141/EC on infant formulae and follow-on formulae.

These Regulations implement for England, Wales, Scotland and Northern Ireland Commission Directive 2006/141/EC on infant formulae and follow-on formulae. Commission Directive 2006/141/EC is referred to in these guidance notes as 'the Directive'. The notification requirement for infant formula is set out in Article 9 of the Directive.

Any reference to 'competent authority' shall be read as meaning whichever UK country authority is notified.

C2. What are the rules on notification of infant formula?

Regulation 13 effectively requires all infant formula to be notified when placed on the market in the United Kingdom for the first time after 1st January 2008. The requirement applies when the product is manufactured or imported.

Regulation 13 provides that no food business operator may place an infant formula on the market that has not yet been placed on the market in the United Kingdom unless he has given prior notice to the competent authority by forwarding to it a model of the label used for the product. '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.

C3. What is an 'infant formula'?

'Infant formulae' is defined in the Directive as 'foodstuffs intended for particular nutritional use by infants during the first months of life and satisfying by themselves the nutritional requirements of such infants until the introduction of appropriate complementary feeding'.

C4. Should all infant formula be notified?

Article 9 of the Directive requires that notification be given for **all** infant formula placed on the market in the UK.

C5. Do I need to notify follow-on formula?

No. There is no requirement for notification of follow-on formula in these Regulations.

C6. Is it necessary to notify each packaging size of a product individually?

A separate notification is required for each infant formula product. However, separate notifications for every packaging size variation are not necessary unless there are significant changes to labelling content.

C7. What about reformulated foods?

An infant formula that has already been notified to the competent authority under these Regulations but which has since been reformulated such that there is a consequential labelling change should be notified as if it is a new product.

C8. When should the competent authority be notified?

Article 9 of the Directive requires that notification be given when infant formula 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 C3 of these guidance notes).

C9. How do I notify the competent authority?

Article 9 of the Directive requires that a model of the label of any infant formula be forwarded to the competent authority of the Member State where the product is to be marketed.

A form is available that manufacturers and importers may use to help them with their notification. Copies of the form are available on our website: notification of Infant formula (contact details at the beginning of these Guidance Notes). Please note the form can be completed and submitted either in hard copy by post or electronically via email together with an electronic version of the product label.

C10. Whose responsibility is it to notify?

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

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

C11. What about products already notified in another Member State?

An infant formula, 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 an authority 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.

C12. 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 UK office in London, Cardiff, Aberdeen or Belfast meets the requirements of the Regulations.

C13. What happens after notification is provided ?

The authority will acknowledge receipt of notification and may require further information about a particular product (see Section A10 of these guidance notes). The authority will then inform the relevant local authorities – who enforce the food regulations – that the product has been notified in accordance with the Infant Formula and Follow-on formula Regulations 2007.

C14. 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 by the authorities.

C15. Will the authority check compliance of a product with the definition for a food for particular nutritional use or its labelling?

No. Notification of an infant formula under these Regulations should not be viewed in any way as an official 'approval'.

Authorities 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. 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.

C16. What action will be taken if the authority does not accept a notification?

Notification will not be accepted if the authority considers that the notified product does not comply with the Directive.

C17. Can I market my infant formula without notifying it or if a notification has been rejected?

If the infant formula 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.