# Notification of food for special medical purposes (FSMP)

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## Contact details

Food for Special Medical Purposes Notification

Nutrition Legislation Team

Population Health Directorate

Department of Health and Social Care

6th Floor

39 Victoria Street

SW1H 0EU

Telephone: 020 7210 4850

Email: nutritionlegislation@dhsc.gov.uk

1. For Department of Health and Social Care use only.
2. Date notification received:
3. Date confirmation of notification sent to manufacturer or importer:
4. Date local authority notified:

## Important notes

Notifying the competent authority of when first placing a food for special medical purposes (FSMP) on the market is a statutory requirement in Great Britain (GB) as stipulated under Article 9 of [Commission Delegated Regulation (EU) 2016/128](https://www.legislation.gov.uk/eur/2016/128) regarding the specific compositional and information requirements for FSMPs.

For FSMPs this requirement is enforced by:

* [The Food for Specific Groups (Information and Compositional Requirements) (Amendment) (England) Regulations 2019](https://www.legislation.gov.uk/uksi/2019/44/made)
* in the case of FSMPs specifically for infants, [The Food for Specific Groups (Food for Special Medical Purposes for Infants, Infant Formula and Follow-on Formula) (Information and Compositional Requirements) (Amendment etc.) (England) Regulations 2020](https://www.legislation.gov.uk/uksi/2020/43/made)

Similar enforcement legislation applies in Scotland and Wales.

The Department of Health and Social Care (DHSC) is centrally coordinating notification of FSMPs for all 3 GB nations.

The Protocol on Ireland/Northern Ireland (NIP) means that EU legislation relating to nutrition, as detailed in Annex 2 of the NIP, continues to be directly applicable in Northern Ireland (NI). Therefore manufacturers or importers to NI will have to notify FSMPs via the FSA NI mailbox at nutritionlegislation-ni@food.gov.uk.

The requirement to notify the competent authority under Commission Delegated Regulation (EU) 2016/128 applied from 22 February 2019 except in respect of FSMPs for infants, to which it applied from 22 February 2020.

The term ‘food for special medical purposes’ is defined in [Regulation (EU) No 609/2013](https://www.legislation.gov.uk/eur/2013/609)

### Notification form

This form may be used as a means of giving the necessary notification to the competent authority when a FSMP is placed on the market in GB.

The duty to notify the competent authority falls on the manufacturer or importer of the FSMP.

An FSMP should be notified under one of 3 product categories:

* Nutritionally complete food with standard nutrient formulation
* Nutritionally complete food with nutrient-adapted formulation
* Nutritionally incomplete food

A separate form should be completed for each product. A copy of the product label must accompany each form.

You will receive an acknowledgement from DHSC on receipt of the notification application.

After reviewing the notification form and product label, if necessary, DHSC may require importer/manufacturer to return further information about the product’s compliance with the legislation

If you have any queries about the completion of this form, please contact the Nutrition Legislation team at the DHSC using the email address or telephone number given at the start of this form.

### Returning the form

Return this form using the email address at the start of this form.

### Other products

Manufacturers of infant formula and follow-on formula which require notification should use the appropriate notification form available on GOV.UK.

## Form for completion

### Product details

Please provide details of the product below.

Product name

Enter your response here.

Product category (delete the 2 that do not apply). Note: the foods referred to in the first 2 categories may also be used as a partial replacement or supplement to the patient’s diet.

Nutritionally complete food 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 it is intended.

Nutritionally complete food 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 it is intended.

Nutritionally incomplete food with a standard formulation or nutrient-adapted formulation specific for a disease, disorder or medical condition which is not suitable to be used as a sole source of nourishment.

Product description (if there is a reformulation or rename, please indicate the changes that have been made)

Enter your response here.

For which disease, disorder or medical conditions is this product intended?

Enter your response here.

Date this product is being put on the market in GB

Enter your response here.

A model of the product label should be sent or emailed with this form to the DHSC at the addresses given at the start of this form. Please confirm that you have done so (delete as applicable)

Yes

No

Has the intended use of the product rendered it necessary to modify the compositional requirements from those laid down in Commission Delegated Regulation (EU) 2016/128? (delete as applicable)

Yes

No

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

Signature

Enter your signature here.

Name in capital letters

Enter your name here.

Date

Enter the date here.

### Local authority details

Please provide your local authority details below.

Name of the local food enforcement authority for your company

Enter your response here.

Address of the local food enforcement authority for your company (in full)

Enter your response here.

Contact name

Enter your response here.

Telephone number (including national dialling code)

Enter your response here.

Email address

Enter your response here.

### Manufacturer or importer details

Please provide your manufacturer or importer details below.

Are you the manufacturer or the importer or GB distributor? (delete as applicable)

Manufacturer

Importer or GB distributor

What is the name of the manufacturer or importer or GB distributor?

Enter your response here.

Address (in full)

Enter your response here.

Contact name

Enter your response here.

Telephone number (including national dialling code)

Enter your response here.

Email address

Enter your response here.

If imported, in which country is the product manufactured?

Enter your response here.