# Notification of follow-on formula (FOF)

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## Contact details

Follow-on Formula Notification

Nutrition Legislation Team

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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 follow-on formula (FOF) manufactured from protein hydrolysates or manufactured from other substances than those listed in Annex II of Commission Delegated Regulation (EU) 2016/127 on the market is a statutory requirement in Great Britain (GB) as stipulated under Article 12 of [Commission Delegated Regulation (EU) 2016/127](https://www.legislation.gov.uk/eur/2016/127) regarding the specific compositional and information requirements for infant formula and follow-on formula.

This requirement is enforced by [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.

Appendix 1 of the guidance on [Commission Delegated Regulation (EU) 2016/127 (supplementing Regulation (EU) No 609/2013)](https://www.gov.uk/government/publications/infant-and-follow-on-formula-and-food-for-special-medical-purposes/commission-delegated-regulation-eu-2016127-supplementing-regulation-eu-no-6092013-guidance) provides further information on the requirements regarding follow-on formula made from protein hydrolysates.

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

The current approach to 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 FOF manufactured from protein hydrolysates or manufactured or manufactured from other substances than those listed in Annex II of Commission Delegated Regulation (EU) 2016/127 via the FSA NI mailbox at nutritionlegislation-ni@food.gov.uk.

As set out under Commission Delegated Regulation (EU) 2016/127 the requirement to notify the competent authority of FOF manufactured from protein hydrolysates or manufactured from other substances than those listed in Annex II of Commission Delegated Regulation (EU) 2016/127 applied from 22 February 2022.

Notification to the competent authority is required when:

* a new FOF manufactured from protein hydrolysates or manufactured from other substances than those listed in Annex II of Commission Delegated Regulation (EU) 2016/127 is placed on the market in GB
* a change of formulation is made or new ingredient is added to a FOF manufactured from protein hydrolysates or manufactured from other substances than those listed in Annex II of Commission Delegated Regulation (EU) 2016/127 already on the GB market

The term 'follow-on formula' 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 FOF manufactured from protein hydrolysates or manufactured from other substances than those listed in Annex II of Commission Delegated Regulation (EU) 2016/127 is placed on the market in GB.

The duty to notify the competent authority falls on the manufacturer or importer of FOF containing other substances than those listed in Annex II of Commission Delegated Regulation (EU) 2016/127.

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

Manufactures of food for special medical purposes and infant 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 any that do not apply)

A FOF containing other substances than those listed in Annex II of Commission Delegated Regulation (EU) 2016/127 to be introduced onto the market

A reformulation of a FOF containing other substances than those listed in Annex II of Commission Delegated Regulation (EU) 2016/127 already on the market in GB

Product description for new products (complete as applicable)

Enter your response here.

Product description for products being re-notified when any changes relating to provisions with the legislation have been made (if there is a reformulation, rename or relabel, please indicate the changes that have been made) (complete as applicable)

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

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?

Please enter your responses in a new line after the question.

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.