Food Safety
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GUIDANCE NOTE

Guidance for Foods governed under Regulation (EU) No 609/2013 Foods for Specific Groups

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Foods for Specific Groups

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Glossary

Term	Explanation
Advertising	The making of a representation in any form in connection with any trade, business, craft or profession in order to promote the supply of goods or services, including immovable property, rights and obligations (Directive 2006/114/EC).
Authorised Officer	An authorised officer appointed under Section 49 of the Food Safety Authority of Ireland Act, 1998.
Follow-on formula (FoF)	Food intended for use by infants when appropriate complementary feeding is introduced, and which constitutes the principal liquid element in a progressively diversified diet of such infants (Regulation (EU) No 609/2013).
Food for special medical purposes (FSMP)	Food specially processed or formulated and intended for the dietary management of patients, including infants, to be used under medical supervision; it is intended for the exclusive or partial feeding of patients with a limited, impaired or disturbed capacity to take, digest, absorb, metabolise or excrete ordinary food or certain nutrients contained therein, or metabolites, or with other medically-determined nutrient requirements, whose dietary management cannot be achieved by modification of the normal diet alone (Regulation (EU) No 609/2013).
Food information	Information concerning a food and made available to the final consumer by means of a label, other accompanying material, or any other means including modern technology tools or verbal communication (Regulation (EU) No 1169/2011).
Infant	A child under the age of 12 months (Regulation (EU) No 609/2013).
Infant formula	Food intended for use by infants during the first months of life and satisfying by itself the nutritional requirements of such infants until the introduction of appropriate complementary feeding (Regulation (EU) No 609/2013).
Ingredient	Any substance or product, including flavourings, food additives and food enzymes, and any constituent of a compound ingredient, used in the manufacture or preparation of a food and still present in the finished product, even if in an altered form; residues shall not be considered as ‘ingredients (Regulation (EU) No 1169/2011).

Label	Any tag, brand, mark, pictorial or other descriptive matter, written, printed, stencilled, marked, embossed or impressed on, or attached to the packaging or container of food (Regulation (EU) No 1169/2011).
Labelling	Any words, particulars, trademarks, brand name, pictorial matter or symbol relating to a food and placed on any packaging, document, notice, label, ring or collar accompanying or referring to such food (Regulation (EU) No 1169/2011).
Maximum Residual level (MRL)	The upper legal level of a concentration for a pesticide residue in or on food or feed set in accordance with Regulation (EU) No 1169/2011, based on good agricultural practice and the lowest consumer exposure necessary to protect vulnerable consumers.
Pesticide residues	Pesticide residue as referred to in point (c) Article 3(2) of Regulation (EC) No 396/2005.
Placing on the market	The holding of food for the purpose of sale, including offering for sale or any other form of transfer, whether free of charge or not, and the sale, distribution, and other forms of transfer themselves (Regulation (EC) 178/2002).
Young child	A child aged between one and three years (Regulation (EU) No 609/2013).

Background

Regulation EU (No) 609/2013 provides for a new framework establishing general provisions for the following limited number of well-established and defined categories of food that are considered as essential for certain vulnerable groups of the population:

- infant formula and follow-on formula
- processed cereal based food and baby food
- food for special medical purposes
- total diet replacement for weight control.

This guidance note replaces both Guidance Note 6: Guidance on the Implementation of European Communities (Infant Formulae and Follow-on Formulae) Regulations 2007 and 2009 (Revision 1) and Guidance Note 19: The Notification of Dietary Foods for Special Medical Purposes under the European Communities (Foods for Special Medical Purposes) 1999, S.1. No. 187 of 2009 (Revision 1) which are now out of date based on legislative changes.

Updates to this document will be made in line with the entry into force of associated delegated acts as necessary.

Scope

This guidance note was developed to provide competent authorities, manufacturers and retailers of infant formula, follow-on formula and food for special medical purposes (FSMPs), guidance on the implementation of Regulation (EU) No 609/2013 Foods for Specific Groups, Commission Delegated Regulation (EU) 2016/127, Commission Delegated Regulation (EU) 2016/128 and Statutory Instrument (S.I). No. 425 of 2019.

Legal Framework

In Ireland, the rules for the composition, labelling and marketing of infant formulae, follow-on formulae and foods for special medical purposes (FSMPs) are based on European Union legislation. National provisions had also been put into place (see Table 1).

Regulation EU (No) 609/2013 also allows for the provision of delegated acts which lay down the specific compositional and labelling requirements for each of these four categories of food products. Based on several significant changes in terms of the composition and labelling requirements of these products, a transitional period of up to five years was allowed for, see below.

Table 1 Date of application for Regulation (EU) 609/2013 and associated delegated acts

Date of Application	Action
20 July 2016	**Regulation (EU) 609/2013** Foods for Specific Groups (FSG) repeals Directive 2009/39/EC and allows for stocks, placed on the market or labelled before 20 July 2016 and which comply with Directive 2009/39/EC to remain on the market until these stocks are exhausted. Foods not covered by the new FSG Regulation will fall under other general food law e.g. health claims, Food Information to the Consumer (FIC)
22 Feb 2019	**Dietary Foods for Special Medical Purposes** Directive 1999/21/EC (Dietary Foods for Special Medical Purposes) is replaced by **Commission Delegated Regulation (EU) 2016/128** for Food for Special Medical Purposes (FSMPs) developed to satisfy the nutritional requirements of those other than infants
22 Feb 2020	**Dietary Foods for Special Medical Purposes** Directive 1999/21/EC (Dietary Foods for Special Medical Purposes) is replaced by **Commission Delegated Regulation (EU) 2016/128 for Food for Special Medical Purposes (FSMPs)** developed to satisfy the nutritional requirements of infants

22 Feb 2020	**Infant formulae and follow-on formulae** Directive 2006/141/EC (Infant formulae and follow-on formulae) is replaced by **Commission Delegated Regulation (EU) 2016/127**
22 Feb 2022	**Infant formulae and follow-on formulae** Directive 2006/141/EC (Infant formulae and follow-on formulae) is replaced by **Commission Delegated Regulation (EU) 2016/127** for infant formula and follow-on formula manufactured from protein hydrolysates
27 Oct 2022	**Total diet replacement for weight control** 27 Oct 2022 Directive 96/8/EC (Foods intended for use in energy-restricted diets for weight reduction) is replaced by **Commission Delegated Regulation (EU) 2017/1798**
No date as yet	**Processed cereal-based foods and baby foods for infants and young children** Current legislation (2006/125/EC) remains in force and more substantial work is being undertaken to form draft legislation

European legislation

For ease of reading, this section is focussed on the specific rules for infant formulae, follow-on formulae and food for special medical purposes. For completeness, the food legislation to which these products may also need to comply with is listed in the Appendix 1.

All legislation referred to in this guidance note is available on the FSAI website (https://www.fsai.ie/legislation.html) and it is advisable to consult this regularly for legislation updates.

Regulation (EU) No 609/2013 Foods for Specific Groups

This regulation came into force on 20 July 2016 (replacing the previous PARNUTs legislation) and it regulates food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control as well as other food for specific groups outside the scope of this guidance note.

Definitions for the following are laid down in Article 2(2) of Regulation (EU) No 609/2013

1. Infant formula
2. Follow-on formula
3. Food for special medical purposes

Article 9 of the regulation refers to general compositional requirements of foods covered by this category and further requirements for composition are set down in the specific delegated regulations.

Articles 9 (5) and 9 (6) of the regulation refers to the labelling, presentation and advertising of food covered by these rules and requires that information for the appropriate use of such foods is provided, which should not mislead or attribute to the food the property of preventing, treating or curing a human disease, or imply such properties.

Commission Delegated Regulation (EU) 2016/127

Commission Delegated Regulation (EU) 2016/127 supplements Regulation (EU) No 609/2013 as regards the specific compositional and information requirements for infant formulae and follow-on formulae and the requirements on information relating to infant and young child feeding.

Infant formulae and follow-on formulae may only be placed on the market if they comply with this regulation and other applicable legislation.

This specific legislation on infant formulae and follow-on formulae covers the following:

- Compositional requirements
- Suitability of ingredients
- Requirements on pesticides – maximum residue levels (MRLs)
- Name of the food
- Specific requirements on food information
- Specific requirements on the nutrition declaration
- Nutrition and health claims for infant formula
- Statements related to ‘lactose only’ and ‘lactose free’
- Statements related to ‘contains Docosahexaenoic acid or ‘contains DHA’ for infant formula
- Requirements for promotional and commercial practises for infant formula
- Requirements on information relating to infant and young child feeding
- Notification to the competent authority.

Commission Delegated Regulation (EU) 2016/128

Commission Delegated Regulation (EU) 2016/128 supplements Regulation (EU) No 609/2013 as regards the specific compositional and information requirements for food for special medical purposes. Foods for special medical purposes can only be placed on the market when they comply with this legislation and other applicable legislation.

This specific legislation on foods for special medical purposes covers the following:

- Compositional requirements and classification of FSMPs
- Requirements on pesticides in food for special medical purposes developed to satisfy the nutritional requirements of infants and young children.
- Name of the food specific requirements on food information
- Specific requirements on the nutrition declaration
- Nutrition and health claims
- Specific requirements for food for special medical purposes developed to satisfy the nutritional requirements of infants
- Notification to the competent authority.

For more guidance on the definition of FSMP, please see Commission Notice on the classification of Food for Special Medical Purposes (2017/C 401/01).

National legislation

Statutory Instrument (S.I). No. 425 of 2019

These Regulations give effect, in Ireland, to Regulation (EU) No. 609/2013 of the European Parliament and of the Council of 12 June 2013, on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control, as amended by Commission Delegated Regulation (EU) 2017/1091 of the European Parliament and of the Council of 10 April 2017.

They also give effect, in Ireland, to Commission Delegated Regulation (EU) 2016/128 of 25 September 2015 supplementing European (EU) No 609/2013 as regards the specific compositional and information requirements for food for special medical purposes.

Statutory Instrument (S.I.) No. 852 of 2007

These Regulations give effect, in Ireland, to Commission Directive 2006/141/EC of 22 December 2006 on compositional, labelling, marketing and informational requirements for infant formulae and follow-on formulae intended for infants and young children.

These national rules will apply until 22 Feb 2022 to allow for the longer transitional period for infant formula and follow-on formula manufactured from protein hydrolysates.

Infant formula and Follow-on formula

Compositional requirements

Article 2 of Commission Delegated Regulation (EU) 2016/127 sets out the compositional requirements for infant formula and follow-on formula. The compositional requirements for infant formula and follow-on formula are set out in Annex I and Annex II of Commission Delegated Regulation (EU) 2016/127 (or as amended) respectively. These values are for the product ready for use, marketed as such or after preparation in accordance with the manufacturer's instruction.

Suitability of ingredients

Article 3 of Commission Delegated Regulation (EU) 2016/127 outlines that infant formula and follow-on formula 'shall be manufactured from protein sources and other food ingredients whose suitability for infants from birth has been established by generally accepted scientific data'.

In line with this, food business operators (FBOs) may be required to submit scientific information in support of their product when notified to the competent authority (i.e. FSAI). To aid food businesses in identifying appropriate scientific evidence, the FSAI has recently published such guidance entitled "Identifying Appropriate Peer Reviewed Scientific Publications".

Labelling

All of the mandatory information required to be labelled on either infant formulae or follow-on formulae must be in a language on the label that is easily understood by the consumers. Therefore, for infant formulae or follow-on formulae placed on the Irish market, the mandatory information as listed below must be in at least English.

Labelling of infant formulae

1. The name of infant formula **other than** infant formula manufactured entirely from cows' milk or goats' milk proteins shall be 'Infant Formula'.

The name of infant formula **manufactured entirely** from cows' milk protein or goats' milk proteins shall be 'Infant Milk[1]'.

2. Infant formula must comply with Regulation 1169/2011 (FIC) on providing food information to the consumer. The mandatory labelling requirements are listed in Appendix 2.
3. In addition to complying with the labelling provisions of FIC, the following additional particulars must be declared on the label of an infant formula, using the mandatory font size as per Article 13(2) of FIC:
    - A statement that the product is suitable for infants from birth when they are not breast fed.
    - Instructions for the appropriate preparation, storage and disposal of the product and a warning against the health hazards of inappropriate preparation and storage.
    - A statement concerning the superiority of breast feeding and a statement recommending that the product be used only on the advice of independent persons having qualifications in medicine, nutrition and pharmacy, or other professionals responsible for maternal and childcare.

    The particulars referred to here must be preceded by the words 'Important Notice' or their equivalent and shall be given in the presentation and advertising of infant formula.
4. In addition to the mandatory nutrition declaration as set down in FIC, the nutrition declaration of infant formula must include the following:
    - The amount of each mineral substance (except molybdenum) and each vitamin listed in Regulation 2016/127 as per annex I
    - The amount of choline, inositol and carnitine
    - The mandatory nutrition declaration shall not include salt.
    - The mandatory nutrition declaration may be **supplemented** by the following:
        i. The amounts of components of protein, carbohydrate and fat;
        ii. The whey protein/casein ratio;
        iii. The amount of any of the substances listed in Annex I to this Regulation or in the Annex to Regulation 609/2013;
        iv. the amount of any of the substances added to the product pursuant to Article 3 *whose suitability for infants from birth has been established by generally accepted scientific data*.

[1] This will generally be referred to as 'infant formula' throughout this guidance note.

- The energy value and the amounts of nutrients on infant formula must be expressed per 100ml of the food ready for use after preparation following the manufacturers instruction. Where appropriate, this information may also be given per 100g of the food as sold.
- The energy value and the amount of nutrients declared in the nutrition declaration, shall not be expressed as a percentage of the reference intakes as per Annex XIII of FIC.
- The nutrients to be included in the nutrition declaration that are not listed in Annex XV of FIC, must be presented after the most relevant entry they belong to or are components of.
- Particulars not listed in Annex XV of FIC that do not belong to or are not components of any of the entries of that Annex shall be presented in the nutrition declaration after the last entry of that Annex.

The nutrition declaration shall be mandatory on the label of an infant formula irrespective of the size of the largest surface of the packaging or container.

Note: *The mandatory nutrition declaration for infant formula shall not be repeated on the labelling.*

The labelling, presentation and advertising of infant formula shall provide the necessary information about the appropriate use of the product, so as not to discourage breast feeding.

In addition, the labelling, presentation and advertising of infant formula shall not use the terms ‘humanised’, ‘maternalised’, ‘adapted’, or any terms similar to these. For example, the term ‘human milk oligosaccharides (HMOs)’ would not be permitted on an infant formula label.

The labelling, presentation and advertising of infant formula must be designed in such a way that it avoids any risk of confusion between it and follow-on formula and that enables consumers to make a clear distinction between them, in particular as to the text, images and colours used.

Labelling of follow-on formulae

1. The name of follow-on formula **other than** formula-on manufactured entirely from cows' milk or goats' milk proteins shall be 'Follow-on Formula'.

   The name of follow-on formula **manufactured entirely** from cows' milk protein or goats' milk proteins shall be 'Follow-on milk'[2].

2. Follow-on formula must comply with Regulation (EU) 1169/2011 (FIC) on providing food information to the consumer. The mandatory labelling requirements are listed in Appendix 2.
3. In addition to complying with the labelling provisions of FIC, the following additional particulars must be declared on the label of a follow-on formula using the mandatory font size as per Article 13(2) of FIC:
   - A statement that the product is suitable only for infants over the age if six months, that it should form only part of a diversified diet, that it is not to be used as a substitute for breast milk during the first six months of life and that the decision to begin complementary feeding, including any exception to six months of age, should be made only on the advice of independent persons having qualifications in medicine, nutrition or pharmacy, or other professionals responsible for maternal and child care, based on the individual infant's specific growth and development needs;
   - Instructions for appropriate preparation, storage and disposal of the product and a warning against the health hazards of inappropriate preparation and storage
4. In addition to the mandatory nutrition declaration as set down in FIC, the nutrition declaration of follow-on formula must include the following:
   - The amount of each mineral substance (except molybdenum) and each vitamin listed in Annex 2 of Regulation (EU) 2016/127
   - The mandatory nutrition declaration shall not include salt.
   - The mandatory nutrition declaration may be **supplemented** by the following:
     i. The amounts of components of protein, carbohydrate and fat;
     ii. The whey protein/casein ratio;
     iii. The amount of any of the substances listed in Annex II to this Regulation or in the Annex to Regulation 609/2013;

[2] This will generally be referred to as 'infant formula' throughout this guidance note.

iv. the amount of any of the substances added to the product pursuant to Article 3. *whose suitability has been established by generally accepted scientific data*.

- The energy value and the amounts of nutrients on follow-on formula must be expressed per 100ml of the food ready for use after preparation following the manufacturers instruction. Where appropriate, this information may also be given per 100g of the food as sold.
- The energy value and the amount of nutrients declared in the nutrition declaration, shall **not** be expressed as a percentage of the reference intakes as per Article XIII of FIC.
- For follow-on formula, the declaration on vitamins and minerals may be expressed as a percentage of the reference intakes in relation to per 100ml of the food ready for use after preparation in accordance with the manufacturer's instructions
- The nutrients to be included in the nutrition declaration that are not listed in Annex XV of FIC, must be presented after the most relevant entry they belong to or are components of.
- Particulars not listed in Annex XV of FIC that do not belong to or are not components of any of the entries of that Annex shall be presented in the nutrition declaration after the last entry of that Annex.

The nutrition declaration shall be mandatory on the label of follow-on formula irrespective of the size of the largest surface of the packaging or container.

Note: *The mandatory nutrition declaration for follow-on formula shall not be repeated on the labelling*.

The labelling, presentation and advertising of follow-on formula shall provide the necessary information about the appropriate use of the product, so as not to discourage breast feeding.

In addition, the labelling, presentation and advertising of follow-on formula shall not use the terms 'humanised', 'maternalised', 'adapted', or any terms similar to these. For example, the term 'human milk oligosaccharides (HMOs)' would not be permitted on a follow-on formula label.

The labelling, presentation and advertising of follow-on formula must be designed in such a way that it avoids any risk of confusion between it and infant formula and that enables consumers to make a clear distinction between them, in particular as to the text, images and colours used.

Nutrition and health claims made on infant and follow-on formula

Infant formula

Article 8 outlines the requirements for nutrition and health claims on Infant Formula.

Nutrition and health claims are NOT permitted on infant formula. The following statements are permitted according to article 9 of Commission Delegated Regulation 2016/127.

The wording 'lactose only', may be used for infant formula provided that lactose is the only carbohydrate present in the product.
The wording 'lactose free', may be used for infant formula provided that the lactose content in the product is not greater than 2.5 mg/100 kJ (10 mg/100 kcal). When this statement is used on infant formula products made from protein sources other than soya protein isolates, it shall be accompanied by the statement 'not suitable for infants with galactosaemia' using the same size and type of font as 'lactose free' and in close proximity to it.

The statement 'contains Docosahexaenoic acid (as required by the legislation for all infant formula)' or 'contains DHA (as required by the legislation for all infant formula)' may only be used for infant formula placed on the market before 22 February 2025.

An exception to the above rule is an approved claim that relates to the reduction of risk of allergy to milk protein'. This health claim may include terms referring to reduced allergen or reduced antigen properties. This claim may be used on infant formula that meet the Conditions of Use set out in Annex IV of Commission Directive 2006/141/EC and is placed on the market prior to 22 February 2022.

As for all food, the rules regarding nutrition or health claims made on infant formulae labels applies to all other forms of presentation and advertising such as websites or supporting literature.
There are particular rules governing commercial communications to health professionals in relation to infant formula products in Ireland which are outlined in "Guidance for Compliance with Food Law When Communicating with Health Professionals about Infant Formula Products".

Follow-on Formula

Nutrition, health or disease reduction claims made in respect of follow-on formulae must comply with Regulation (EC) No 1924/2006 on nutrition and health claims made on food.

The following statements are also permitted:

- 'lactose only' may be used for follow-on formula provided that lactose is the only carbohydrate present in the product.

- 'lactose free' may be used for follow-on formula provided that the lactose content in the product is not greater than 2.5 mg/100 kJ (10 mg/100 kcal). When this statement is used on follow on formula products made from protein sources other than soya protein isolates, it shall be accompanied by the statement 'not suitable for infants with galactosaemia' using the same size and type of font as 'lactose free' and in close proximity to it.

Requirements on pesticides – maximum residue levels (MRLs) permitted

Article 4 of Commission Delegated Regulation (EU) 2016/127 sets out the maximum residue levels (MRLs) at 0.01 mg/kg per active substance, except for those pesticides listed in both Annex IV where lower maximum residue levels are specified, and Annex V where those listed have a lower maximum residue level of 0.003 mg/kg. The levels referred to above shall apply to the infant formula and follow-on formula ready for use, marketed as such or after preparation in accordance with the manufacturer's instructions.

Promotional and commercial practices for infant formula

Article 10 of Commission Delegated Regulation (EU) 2016/127 sets out the rules in relation to the advertising of infant formula.

- Advertising of infant formula shall be restricted to publications specialising in baby care and scientific publications.

Such information shall not imply or create a belief that bottle-feeding is equivalent or superior to breast feeding.

- There shall be no point-of-sale advertising, giving of samples or any other promotional device to induce sales of infant formula directly to the consumer at the retail level, such as special displays, discount coupons, premiums, special sales, loss-leaders and tie-in sales. Examples of what is not permitted include: consumers should not receive points on their supermarket loyalty card for purchasing infant formula; Infant formula should not be included in 'end of aisle' specials or should not display discounted specials pricing.
- Manufacturers and distributors of infant formula shall not provide, to the general public or to pregnant women, mothers or members of their families, free or low-priced products, samples or any other promotional gifts, either directly or indirectly via the health care system or health workers.
- Donations or low-price sales of supplies of infant formula to institutions or organisations, whether for use in the institutions or for distribution outside them, shall only be used by or

distributed for infants who have to be fed on infant formula and only for as long as required by such infants.

The FSAI has recently published information on communicating to health professionals "Guidance for Compliance with Food Law When Communicating with Health Professionals about Infant Formula Products".

Requirements on information relating to infant and young child feeding

Article 11 of Commission Delegated Regulation (EU) 2016/127 sets out rules in relation to requirements on information relating to infant and young child feeding.

- Informational and educational materials, whether written or audio-visual, dealing with the feeding of infants and intended to reach pregnant women and mothers of infants and young children, shall include clear information on all the following points:

  (a) the benefits and superiority of breast feeding;

  (b) maternal nutrition and the preparation for and maintenance of breast feeding;

  (c) the possible negative effect on breast feeding of introducing partial bottle feeding;

  (d) the difficulty of reversing the decision not to breast feed;

  (e) where needed, the proper use of infant formula.

  Where such materials contain information about the use of infant formula, they shall include the social and financial implications of its use, the health hazards of inappropriate foods or feeding methods, and, in particular, the health hazards of improper use of infant formula. Such material shall not use any pictures which may idealise the use of infant formula.

- Donations of informational or educational equipment or materials by manufacturers or distributors shall be made only on request and with the written approval of the appropriate national authority or within guidelines given by that authority for this purpose. Such equipment or materials may bear the donating company's name or logo, but shall not refer to a proprietary brand of infant formula and shall be distributed only through the health care system.

The FSAI has recently published information on communicating to health professionals "Guidance for Compliance with Food Law When Communicating with Health Professionals about Infant Formula Products".

Notification of infant Formula and follow-on formula

As per Article 12 of Commission Delegated Regulation (EU) 2016/127, when infant formula is placed on the market, FBOs are required to notify the competent authority (FSAI) by sending a copy of the product label, as well as other information reasonably requested to establish compliance with the legislation.

As per Article 12 of Commission Delegated Regulation (EU) 2016/127, when follow-on formula made from protein hydrolysates or follow-on formula containing substances other than those listed in Annex II of the Regulation, are placed on the market, FBOs are required to send a copy of the product label to the competent authority (FSAI), as well as other information reasonably requested to establish compliance with the legislation.

FBOs should submit their product notifications via the FSAI Notifications System available at https://notifications.fsai.ie/login. The FSAI has developed a number of training videos which can be found in the 'How to Use the Notification System' to assist FBOs in using the notifications system. They can be found in the 'How to Use the Notification System' section. For additional support or queries, FBOs can also email fsgnotifications@fsai.ie.

Export to Third Countries

Infant formula intended for export to Third Counties i.e. countries outside of the European Union must meet the requirements of Article 12 Regulation (EC) No 178/2002.

Infant formulae for export must comply with the appropriate compositional requirements in Article 2 of Commission Delegated Regulation (EU) 2016/127 or the equivalent set out in the Codex Alimentarius. The compositional requirements for infant formula and follow-on formula are detailed in Annex I and Annex II of Commission Delegated Regulation (EU) 2016/127 respectively.

The labelling and presentation of infant formula for export must also comply with the requirements in Articles 6 and 7 of Commission Delegated Regulation (EU) 2016/127.

In addition, infant formulae and follow-on formulae for export must meet the requirements of Council Directive 2011/91 EU on indications or marks identifying the lot to which a foodstuff belongs. Infant formulae or follow-on formulae for export must be labelled in a language easily understood by parents and caregivers, in the absence of specific relevant provisions established by or agreed with the importing country.

The infant formulae or follow-on formulae for export must be labelled in such a way as to avoid the risk of confusion between them and enables consumers to make a clear distinction between them, in particular as to the text, images and colours used.

Infant formula which does not comply with these requirements must not be exported unless a deviation from this requirement is requested or stipulated by the Third Country and subject to Article 12 of Regulation 178/2002, i.e. general requirements for food exported from the EU. DAFM is responsible for the certification of infant formulae and follow-on formulae for export to Third Countries.

Enforcement of infant formula legislation

The FSAI, the HSE and DAFM are responsible for the enforcement of applicable food legislation. The manufacture of infant formulae and follow-on formulae is supervised by the Dairy Controls and Certification Division of DAFM. Once placed on the market, official controls are carried out on infant formulae and follow-on formulae by the Environmental Health Services of the HSE.

The Regulations set out offences including the following:

1. Failure to comply with the Regulations when FBOs:
    a) Place product on market without notification to the FSAI as required in the Regulations by forwarding a model of the label used for the product.
    b) Place product on the market with non-compliant or misleading information as food information shall be accurate, clear and easy to understand for the consumer.
    c) Place product on the market which is not prepacked.
    d) Place product on the market whereby the composition is not appropriate to satisfy the nutritional requirements of and is not suitable for those to whom the product is intended, in accordance with scientific data.
    e) Place product on the market which contains a substance in such a quantity as to endanger the health of those for whom the product is intended.
    f) Place products on the market which have added substances to meet nutritional requirements of the food when the added substances are not in an available form for the body; do not have a nutritional or physiological effect or are not suitable for those to whom the food is intended.
    g) Place product on the market which is not labelled, presented or advertised with information on the appropriate use of the food; is misleading or attributes medicinal properties to the product.
    h) Place infant formula and follow-on formula on the market which does not comply with the mandatory particulars listed in Article 9(1) of Regulation (EU) No 1169/2011.

i) Omit a statement that infant formula is suitable for infants from birth when they are not breast fed.

j) Fail to provide instructions for the appropriate preparation, storage and disposal of infant formula and do not provide a warning against the health hazard of inappropriate preparation and storage.

k) Omit a statement on infant formula and associated presentation and advertising of infant formula that begins with the words 'important notice' or their equivalent, concerning the superiority of breast feeding; omission of a statement recommending that the infant formula be used only on the advice of independent persons having qualifications specified in Article 6,2(c) of Commission Delegated Regulation (EU) 2016/127.

l) Place follow on formula on the market which does not provide the additional mandatory information:

- a statement that the product is suitable only for infants over the age of six months;
- that it should form only part of a diversified diet;
- that it is not to be used as a substitute for breast milk during the first six months of life;

that the decision to begin complementary feeding, including any exception to six months of age should be made only on the advice of qualified independent persons, based on the individual infant's specific growth and development need.

m) Fail to provide instructions for the appropriate preparation, storage and disposal of follow-on formula and do not provide a warning against the health hazard of inappropriate preparation and storage.

n) Place product on the market in which the labelling, presentation or advertising of that food discourages breastfeeding.

o) Place product on the market whereby the labelling, presentation or advertising contains pictures of infants or text that may idealise the use of the product.

p) Add to infant formulae a substance not prescribed in the Annex to Regulation 609/2013 or not to comply with the particular requirements in the Annex for the addition of that substance.

q) Place product on the market which does not comply with the compositional requirements set down in Annex I and Annex II to Commission Delegated Regulation (EU) 2016/127 when ready for use.

r) Place infant formula and follow-on formula manufactured on the market, that are manufactured from protein sources and other food ingredients when the protein

sources do not comply with the requirements of point 2 of Annex I or Point 2 of Annex II of of Commission Delegated Regulation (EU) 2016/127 and other food ingredients, as the case may be, whose suitability for infants from birth has not been established by generally accepted scientific data and does not comply with the requirements of Article 3 of Commission Delegated Regulation (EU) 2016/127.

s) Place product on the market that contains excessive pesticide residue levels as specified in Article 4 and Annex IV and Annex V to Commission Delegated Regulation (EU) 2016/127.

t) Place product on the market that does not provide mandatory information in a language that is easily understood by consumers.

u) Label, present and advertise products that are placed on the market, which do not allow consumers to make a distinction between infant formula and follow-on formula.

v) Place infant formula on the market which does not meet the specific requirements on the nutrition declaration prescribed in Article 7 of Commission Delegated Regulation (EU) 2016/127.

w) To place nutrition and health claims on infant formula

x) Place infant formula on the market which does not meet the requirements for promotional and commercial practices prescribed in Article 10 of Commission Delegated Regulation (EU) 2016/127.

2. To forge the certificate of analysis or other documents or use a forged document

3. To alter a certificate of analysis or other documents or use an altered document

4. Be in unlawful possession of a forged document or an altered document

5. Tamper with anything to misrepresent the substance sampled

6. Tamper or interfere with any sample taken.

A person who is guilty of an offence under these Regulations shall be liable on summary conviction to a class A fine or at the discretion of the Court, to imprisonment for a term not exceeding 6 months or both.
A person who is guilty of an offence under these Regulations shall be liable on conviction on indictment to a fine not exceeding €500,000 or at the discretion of the Court, to imprisonment for a

term not exceeding 6 months or both.

The HSE and DAFM enforce the Regulations under service contract with the FSAI and undertake routine and coordinated programmes on the sampling and analysis of relevant food products to check for compliance. In addition to the specific powers available in S.I. No. 425 of 2019, authorised officers have powers to seize, detain and destroy products that fail to comply with food legislation.

Food for special medical purposes

Classification of food for special medical purposes (FSMP)

Definition

'Food for special medical purposes' is defined in Article 2.2 (g) of Regulation (EU) No 609/2013, see also the glossary section of this guidance note.

Further guidance on the definition of a FSMP is given in Commission Notice on the classification of Food for Special Medical Purposes (2017/C 401/01).

Different types

There are three different types of FSMPs as set out in article 2.1 of Commission Delegated Regulation (EU) 2016/128

Food for special medical purposes is classified in the following three categories:

(a) nutritionally complete food with a 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;
(b) nutritionally complete food 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 it is intended;
(c) nutritionally incomplete food with a standard formulation or a nutrient-adapted formulation specific for a disease, disorder or medical condition which is not suitable to be used as the sole source of nourishment.

The food referred to in points (a) and (b) of the first subparagraph may also be used as a partial replacement or as a supplement to the patient's diet.

Compositional requirements

- Food for special medical purposes developed to satisfy the nutritional requirements of infants shall comply with the compositional requirements set out in Part A of Annex I of Commission Delegated Regulation (EU) 2016/128.
- Food for special medical purposes other than that developed to satisfy the nutritional requirements of infants shall comply with the compositional requirements set out in Part B of Annex I of Commission Delegated Regulation (EU) 2016/128.
- The compositional requirements set out in Annex I of Commission Delegated Regulation (EU) 2016/128 shall apply to the food for special medical purposes ready for use, marketed as such or after preparation in accordance with the manufacturer's instructions.

Recital (5) of Commission Delegated Regulation (EU) 2016/128 states that

“Because of the wide diversity of food for special medical purposes, the rapidly evolving scientific knowledge on which it is based, and the need to ensure adequate flexibility to develop innovative products, it is not appropriate to lay down detailed compositional rules for such food products. It is however important to set principles and requirements specific to them in order to ensure that they are safe, beneficial and effective for the persons for whom they are intended on the basis of generally accepted scientific data”.

This flexibility in terms of the nutritional composition of an FSMP is reflected in the wording of Part A and Part B of Annex I of Commission Delegated Regulation (EU) 2016/128 i.e. ‘which apply without prejudice to modifications of one or more nutrients rendered necessary by the intended use of the product’

Scientific evidence

Article 2.2. of Commission Delegated Regulation (EU) 2016/128 states that

“The formulation of food for special medical purposes shall be based on sound medical and nutritional principles. Its use, in accordance with the manufacturer's instructions, shall be safe, beneficial and effective in meeting the specific nutritional requirements of the persons for whom it is intended, as demonstrated by generally accepted scientific data”.

In line with this, FBOs may be required to submit other information the FSAI may reasonably request to establish compliance with this regulation.

This data may be requested to demonstrate the product meets the definition of an FSMP or in support of products where the compositional requirements differ from those laid out in Annex I of Commission Delegated Regulation (EU) 2016/128 (see section below for further information).To

aid food businesses in identifying appropriate scientific evidence, the FSAI has recently published such guidance entitled "Identifying Appropriate Peer Reviewed Scientific Publications".

Labelling

The labelling requirements for food for special medical purposes is set out in Articles 5 and 6 of Commission Delegated Regulation (EU) 2016/128.

Article 5 outlines the specific requirements on food information.

Article 5.2. states that

In addition to the mandatory particulars listed in Article 9(1) of Regulation (EU) No 1169/2011 (FIC), the following shall be additional mandatory particulars for food for special medical purposes:

a) a statement that the product must be used under medical supervision;
b) a statement whether the product is suitable for use as the sole source of nourishment;
c) a statement that the product is intended for a specific age group, as appropriate;
d) where appropriate, a statement that the product poses a health hazard when consumed by persons who do not have the disease, disorder or medical condition for which the product is intended;
e) the statement 'For the dietary management of …' where the blank shall be filled in with the disease, disorder or medical condition for which the product is intended;
f) where appropriate, a statement concerning adequate precautions and contra-indications;
g) a description of the properties and/or characteristics that make the product useful in relation to the disease, disorder or medical condition for the dietary management of which the product is intended, in particular, as the case may be, relating to the special processing and formulation, the nutrients which have been increased, reduced, eliminated or otherwise modified and the rationale of the use of the product;
h) where appropriate, a warning that the product is not for parenteral use;
i) instructions for appropriate preparation, use and storage of the product after the opening of the container, as appropriate.

The particulars referred to in points (a) to (d) shall be preceded by the words 'important notice' or their equivalent.

In relation to Article 5.2 (h), the statement "For enteral use only" can be alternatively used.

Article 6 lays out the specific requirements on the nutrition declaration.

1. In addition to the information referred to in Article 30(1) of Regulation (EU) No 1169/2011, the mandatory nutrition declaration for food for special medical purposes shall include the following:
    a) the amount of each mineral substance and of each vitamin listed in Annex I to this Regulation and present in the product;
    b) the amount of components of protein, carbohydrate, fat and/or of other nutrients and their components, the declaration of which would be necessary for the appropriate intended use of the product;
    c) information on the osmolality or the osmolarity of the product where appropriate;
    d) information on the source and the nature of the protein and/or protein hydrolysates contained in the product.
2. By way of derogation from Article 30(3) of Regulation (EU) No 1169/2011, the information included in the mandatory nutrition declaration for food for special medical purposes shall not be repeated on the labelling.
3. The nutrition declaration shall be mandatory for all food for special medical purposes, irrespective of the size of the largest surface of the packaging or container.
4. Articles 31 to 35 of Regulation (EU) No 1169/2011 shall apply to all the nutrients included in the nutrition declaration for food for special medical purposes.
5. By way of derogation from Article 31(3) of Regulation (EU) No 1169/2011, the energy value and the amounts of nutrients of food for special medical purposes shall be those of the food as sold and, where appropriate, those of the food ready for use after preparation in accordance with the manufacturer's instructions.
6. By way of derogation from Article 32(3) and (4) of Regulation (EU) No 1169/2011, the energy value and the amount of nutrients of food for special medical purposes shall not be expressed as a percentage of the reference intakes set out in Annex XIII to that Regulation.
7. The particulars included in the nutrition declaration for food for special medical purposes that are not listed in Annex XV to Regulation (EU) No 1169/2011 shall be presented after the most relevant entry of that Annex they belong to or are components of.

Particulars not listed in Annex XV to Regulation (EU) No 1169/2011 that do not belong to or are not components of any of the entries of that Annex shall be presented in the nutrition declaration after the last entry of that Annex.

The indication of the amount of sodium shall appear together with the other minerals and may be repeated next to the indication of the salt content as follows: ‘Salt: X g (of which sodium: Y mg)’.

Interpretation of Article 5.2 (g), Article 6.2 and Article 7

Commission delegated Regulation (EU) 2016/128 lays down exceptions to the general labelling rules of Regulation (EU) 1169/2011, such as the derogation from Article 30(3) thereof, in order to take account of the specific nature of FSMPs. Contrary to foods intended for the general population, FSMPs are to be used under medical supervision by consumers, who have different nutritional needs than the normal population. The purpose served by front-of-pack (FOP), as provided for in recital 41 of Regulation (EU) 1169/2011, is to help consumers to easily see the essential nutrition information when purchasing foods. Such a purpose is irrelevant for FSMPs. Patients and healthcare professionals need complete nutritional information that can guarantee the appropriate use of FSMPs.

Whilst a description of the properties and characteristics of the product is mandatory to allow healthcare professionals to understand the purpose of a product, the presentation of such information should not be used as a means of marketing or promoting the product. Article 5(2)(g) of Commission Regulation 2016/128 may not be relied upon to circumvent the prohibition of Article 6(2). A repetition of the mandatory nutrition declaration cannot be considered as a description of the properties and/or characteristics that make the product useful in relation to the disease, disorder or medical condition for the dietary management of which the product is intended.

Any additional reference on the label, to nutrients (outside of the mandatory nutrition declaration) which are increased, reduced, eliminated or modified, must relate to **all** of nutrients that make the product useful for the dietary management of the disease, disorder or medical condition for which the product is intended. Nutrients should not be repeated with the intention of emphasising certain nutrients only. In line with this determination, the FSAI may, as part of its' assessment of the information on the label, require food businesses to provide evidence that shows that the additional information labelled relates to the rationale for the use of the product.

Nutrition and health claims

The requirements for nutrition and health claims on FSMPs are set out in Article 7.

Nutrition and health claims are NOT permitted on foods for special medical purposes.

FSMPs must include a description of the properties and/or characteristics that make the product useful in relation to the disease, disorder or medical condition for the dietary management of which the product is intended. In particular, as the case may be, relating to the special processing and formulation, the nutrients which have been increased, reduced, eliminated or otherwise modified and the rationale of the use of the product; taking into account the intended use of the product and without prejudice to the need to provide food information to patients and health care professionals to ensure the product's appropriate use. Statements relating to this requirement will not be considered a nutrition or health claim.

Requirements on pesticides in food for special medical purposes developed to satisfy the nutritional requirements of infants and young children – maximum residue levels (MRLs) permitted

Article 3 of Commission Delegated Regulation (EU) 2016/128 sets out the maximum residue level set for pesticides at 0.01 mg/kg per active substance, except for those pesticides listed in both Annex II where lower maximum residue levels are specified, and Annex III where those listed have a lower maximum residue level of 0.003 mg/kg.

Specific requirements of food for special medical purposes for infants

Article 8 of Commission Delegated Regulation (EU) 2016/128 outlines the requirements on the labelling, presentation, advertising and promotional and commercial practices of FSMPs developed to satisfy the nutritional requirements of infants similar to that of infant formula and follow-on formula.

1. All mandatory particulars for food for special medical purposes developed to satisfy the nutritional requirements of infants shall appear in a language easily understood by the consumers.
2. The labelling, presentation and advertising of food for special medical purposes developed to satisfy the nutritional requirements of infants shall not include pictures of infants, or other pictures or text which may idealise the use of the product.

However, graphic representations for easy identification of the product and for illustrating methods of preparation shall be permitted.

3. The labelling, presentation, and advertising of food for special medical purposes developed to satisfy the nutritional requirements of infants shall be designed in such a way that it enables consumers to make a clear distinction between such products and infant formula and follow-on formula, in particular as to the text, images and colours used, so as to avoid any risk of confusion.
4. Advertising of food for special medical purposes developed to satisfy the nutritional requirements of infants shall be restricted to publications specialising in baby care and scientific publications.

Member States may further restrict or prohibit such advertising. Such advertising shall contain only information of a scientific and factual nature.

The first and second subparagraphs shall not prevent the dissemination of information exclusively intended for health care professionals.

5. There shall be no point-of-sale advertising, giving of samples or any other promotional device to induce sales of food for special medical purposes developed to satisfy the nutritional requirements of infants directly to the consumer at the retail level, such as special displays, discount coupons, premiums, special sales, loss-leaders and tie-in sales.
6. Manufacturers and distributors of food for special medical purposes developed to satisfy the nutritional requirements of infants shall not directly provide, to the general public or to pregnant women, mothers or members of their families, free or low-priced products, samples or any other promotional gifts.

Export to third countries

FSMP intended for export to Third Counties i.e. countries outside of the European Union must meet the requirements of Article 12 Regulation (EC) No 178/2002.

FSMP for export must comply with the appropriate compositional requirements in Article 2 of Commission Delegated Regulation (EU) 2016/128 or the equivalent set out in the Codex Alimentarius. The compositional requirements for FSMP are detailed in Annex I of Commission Delegated Regulation (EU) 2016/128 respectively.

The labelling and presentation of FSMP for export must also comply with the requirements set out in Articles 6 and 7 of Commission Delegated Regulation (EU) 2016/128.

In addition, FSMP for export must meet the requirements of Council Directive 2011/91 EU on indications or marks identifying the lot to which a foodstuff belongs. FSMP for export must be labelled in a language easily understood by parents and caregivers, in the absence of specific relevant provisions established by or agreed with the importing country.

The FSMP for export must be labelled in such a way as to avoid the risk of confusion between them and enables consumers to make a clear distinction between them, in particular as to the text, images and colours used.

FSMP which does not comply with these requirements must not be exported unless a deviation from this requirement is requested or stipulated by the Third Country and subject to Article 12 of Regulation 178/2002, i.e. general requirements for food exported from the EU. DAFM is responsible for the certification of FSMP for export to Third Countries.

Notification of FSMP

Article 9 of Commission Delegated Regulation (EU) 2016/128 states that

“When food for special medical purposes is placed on the market, the food business operator shall notify the competent authority of each Member State where the product concerned is being marketed of the information appearing on the label, by sending to it a model of the label used for the product, and of any other information the competent authority may reasonably request to establish compliance with this Regulation, unless a Member State exempts the food business operator from that obligation under a national system that guarantees an efficient official monitoring of the product concerned”.

FBOs are required to submit their notifications via the FSAI Notifications System available at https://notifications.fsai.ie/login. The FSAI has developed a number of training videos to assist

FBOs in using the notifications system. For additional support or queries, FBOs can also email fsgnotifications@fsai.ie.

Enforcement of FSMP legislation

The FSAI, the HSE and DAFM are responsible for the enforcement of applicable food legislation. Enforcement of the Regulations is the responsibility of the FSAI and is carried out by the HSE and DAFM under service contract, through the Environmental Health Service of the HSE and Dairy Controls and Certification Division of DAFM and official laboratories.

The Regulations set out offences including the following:

1. Failure to comply with the Regulations when FBOs:
    a. Place product on market without notification to the FSAI in the manner laid down in the Regulations.
    b. Place product on the market with non-compliant or misleading information as food information shall be accurate, clear and easy to understand for the consumer.
    c. Place product on the market which is not prepacked.
    d. Place product on the market whereby the composition is not appropriate to satisfy the nutritional requirements of and is not suitable for those to whom the product is intended, in accordance with scientific data.
    e. Place product on the market which contains a substance in such a quantity as to endanger the health of those for whom the product is intended.
    f. Place product on the market which have added substances to meet nutritional requirements of the food when the added substances are not in an available form for the body; do not have a nutritional or physiological effect or are not suitable for those to whom the food is intended.
    g. Place product on the market which is not labelled, presented or advertised with information on the appropriate use of the food; is misleading or attributes medicinal properties to the product.
    h. Add to food for special medical purposes a substance not in compliance with the Annex to Regulation 609/2013 or the particular requirements in the Annex for the addition of that substance.

i. Place product on the market which is unsafe and/or does not comply with the compositional requirements set down in Part A and Part B of Annex I to Commission Delegated Regulation (EU) 2016/128, when ready for use,
j. Place product on the market that contains excessive pesticide residue levels as specified in Annex II and Annex III to Commission Delegated Regulation (EU) 2016/128.
k. Place product on the market that is not named “food for special medical purposes”.
l. Place product on the market which does not provide the mandatory information prescribed in Articles 5.2 of Commission Delegated Regulation (EU) 2016/128.
m. Provide mandatory information on the product which is not clearly legible and not in compliance with Annex IV of Regulation (EU) No1169/2011
n. Place product on the market which fails to include a nutrition declaration in accordance with Article 15 of S.I. 425 of 2019.
o. Make nutrition or health claims on food for special medical purposes.
p. Place product on the market that does not comply with the specific requirements for food for special medical purposes developed to satisfy the nutritional requirements of infants, as provided for in Article 8 of Commission Delegated Regulation (EU) 2016/128.

2. To forge the certificate of analysis or other documents or use a forged document

3. To alter a certificate of analysis or other documents or use an altered document

4. Be in unlawful possession of a forged document or an altered document

5. Tamper with anything to misrepresent the substance sampled

6. Tamper or interfere with any sample taken

A person who is guilty of an offence under these Regulations shall be liable on summary conviction to a class A fine or at the discretion of the Court, to imprisonment for a term not exceeding 6 months or both.
A person who is guilty of an offence under these Regulations shall be liable on conviction on

indictment to a fine not exceeding €500,000 or at the discretion of the Court, to imprisonment for a term not exceeding 6 months or both.

The HSE enforces the Regulations under service contract with the FSAI and undertakes routine and coordinated programmes on the sampling and analysis of relevant food products to check for compliance. In addition to the specific powers available in S.I. No. 425 of 2019, authorised officers have powers to seize, detain and destroy products that fail to comply with food legislation.

Appendix 1: Legislation relating to infant formula, follow-on formula and food for special medical purposes*

	EU Legislation	National Legislation
General Food Law	Council Regulation (EC) No 178/2002 of 28 January 2002 laying down the general principles of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety as amended	S.I. No. 747 of 2007 (HSE) S.I. No. 498 of 2010 (HSE) S.I. No. 500 of 2011 (HSE) S.I. No. 432 of 2009 (DAFM) S.I. No. 164 of 2012 (DAFM)
General Labelling	Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004	European Union (Provision of Food Information to Consumers) Regulations 2014 (S.I. No. 556 of 2014)

	EU Legislation	National Legislation
Foods for Specific Groups	Regulation (EU) No 609/2013 of the European Parliament and of the Council of 12 June 2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control and repealing Council Directive 92/52/EEC, Commission Directives 96/8/EC, 1999/21/EC, 2006/125/EC and 2006/141/EC, Directive 2009/39/EC of the European Parliament and of the Council and Commission Regulations (EC) No 41/2009 and (EC) No 953/2009	European Union (Food Intended for Infants and Young Children, Food for Special Medical Purposes, and Total Diet Replacement for Weight Control) Regulations 2019 (S.I. No. 425/2019)
Infant Formula and Follow-on Formula	Commission Delegated Regulation (EU) 2016/127 of 25 September 2015 supplementing Regulation (EU) No 609/2013 of the European Parliament and of the Council as regards the specific compositional and information requirements for infant formula and follow-on formula and as regards requirements on information relating to infant and young child feeding Commission Directive 2006/141/EC of 22 December 2006 on infant formulae and follow-on formulae and amending Directive 1999/21/EC Regulation (EC) No 1243/2008 of 12 December amending Annexes III and IV to Directive 2006/141/EC as regards compositional requirements for certain infant formulae	European Union (Food Intended For Infants And Young Children, Food For Special Medical Purposes, And Total Diet Replacement For Weight Control) Regulations 2019 (S.I. No. 425/2019) S.I. No. 852 of 2007 S.I. No. 209 of 2009
Food for special medical purposes	Commission Delegated Regulation (EU) 2016/128 of 25 September 2015 supplementing Regulation (EU) No 609/2013 of the European Parliament and of the Council as regards the specific compositional and	European Union (Food Intended for Infants and Young Children, Food for

	EU Legislation	National Legislation
	information requirements for food for special medical purposes	Special Medical Purposes, and Total Diet Replacement for Weight Control) Regulations 2019 (S.I. No. 425/2019)
Nutrition and health claims made on food	Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on food as amended	European Communities (Nutrition and Health Claims made on Food) Regulations 2014 (S.I. No. 11 of 2014)

* All legislation referred to in this guidance note is available on the FSAI website (https://www.fsai.ie/legislation.html) and it is advisable to consult this regularly for legislation updates.

Appendix 2

Mandatory Information as per Article 9 of Regulation 1169/2011

The following mandatory information must appear on the label of a prepacked food:

(a) the name of the food*
(b) the list of ingredients
(c) any allergenic ingredient or processing aid used in the manufacture or preparation of a food and still present in the finished product, even if in an altered form
(d) the quantity of certain ingredients or categories of ingredients (QUID)
(e) the net quantity of the food*
(f) the date of minimum durability or the 'use by' date
(g) any special storage conditions and/or conditions of use
(h) the name or business name and address of the food business operator referred to in Article 8(1) of FIC
(i) the country of origin or place of provenance where its absence may mislead the consumer as to the true origin or provenance of the food or where country of origin is specifically required under legislation
(j) instructions for use where it would be difficult to make appropriate use of the food in the absence of such instructions
(k) with respect to beverages containing more than 1.2 % by volume of alcohol, the actual alcoholic strength by volume*
(l) a nutrition declaration

must appear in the same field of vision

Members of the Working Group

Members

This guidance note has been developed by a working group composed of experts within the Food Safety Authority of Ireland (FSAI), enforcement officers from the Department of Agriculture, Food and the Marine (DAFM) and Health Service Executive (HSE), with invited comment from manufacturers of infant formula, follow-on formula and food for special medical purposes (FSMPs).

Comments were invited from the following industry groups:

- Dairy Industry Ireland (DII)
- Nualtra Ltd
- Vitaflo Ireland
- Mead Johnson Nutrition – part of Reckitt Benckiser
- Abbott Nutrition
- Fresenius Kabi Ltd, UK
- Nestle Nutrition
- Danone.

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