Infant and Follow-on Formula Food

The Infant Formula and Follow-on Formula (*) Regs
**England (E): 2007: 3521 FSA and ECA as amended by 2008: 2445, 2011: 3012, 2013: 3243, 2016: 688 aa 2020: 43, 2017: 62 and 2020: 43;*
Scotland (S): 2007: 549 FSA and ECA as amended by 2008: 322 aa 2020: 7; 2014: 12, 2015: 100, 2016: 190 aa 2020: 7 and 2020: 7
**Wales (W): 2007: 3573 FSA and ECA as amended by 2008: 2602 aa 2020: 92, 2014: 123 2014: 1102 and 2016: 639 aa 2020: 92 and 2020: 92;*
**Northern Ireland (NI): 2007: 506 as amended by 2008: 405 aa 2020: 16, 2014: 11 aa 2020: 16, 2016: 251 aa 2020: 16 and 2020: 16*

Application

Applies

- ♣ until 21st February 2021 to food manufactured from hydrolysates.
- ♣ to infant formula and follow-on formula which does not comply with Reg (EU) 2016/127 (see above),
  - ♥ provided
    - ♦ it was placed on the market ***or*** labelled before
      - ♠ 22nd February 2020, ***or***
      - ♠ 22nd February 2021 if it was manufactured from protein hydrolysates, ***and***
    - ♦ it complies with all of the requirements set out below.

Definitions

1). **Infant formula** - a food intended for particular nutritional use by infants (ie aged under 12 months) in good health during the first months of life and satisfying their nutritional requirements until the introduction of appropriate complementary feeding.
2). **Follow-on formula** - a food intended for particular nutritional use by infants when appropriate complementary feeding is introduced and constituting the principal liquid element in a progressively diversified diet.

Manufacturing

1). Infant formula and follow-on formula must

- ♣ be made only from approved ingredients,
- ♣ not contain any substance in such a quantity as to be harmful to infants or young children,
- ♣ not contain any listed pesticide residue in an excessive quantity,
- ♣ need only water to be added to it to be ready for use.

Labelling and Advertising

Infant Formula and Follow-on Formula Food

1). must be marked with

- ♣ the available energy as kJ or kcal,
- ♣ the content of proteins, lipids and carbohydrates in numerical form per 100ml ready for use,

- ♣ the average quantity in numerical form per 100ml of product, ready for use, of
  - ♥ sodium, potassium, chloride, calcium, phosphorous, magnesium, iron, zinc, copper, iodine, selenium, manganese and flouride and where appropriate choline, inositol, and carnitine, ***and***
  - ♥ vitamins A, C, D, E, K, B6, B12, Thiamin, Riboflavin, Niacin, Pantothenic Acid, Biotin, and Folic Acid,
- ♣ instructions for preparation, storage and disposal,
- ♣ a warning against the health hazards of inappropriate preparation and storage,

and, in addition

- ♣ *the labelling must be designed to provide the necessary information about the appropriate use of the product so as not to discourage breast-feeding ***and*** must not include the terms '**humanised**', '**maternalised**', '**adapted**' or any similar term,
- ♣ *the labelling must enable consumers to make a clear distinction between infant formula and follow-on formula so as to avoid any risk of confusion between them.

* The *presentation* (ie shape, appearance or packaging, the packaging materials used, the way in which they are arranged, and the setting in which they are displayed) and the *advertising* of the food must comply with the two asterisked requirements above.

The Food Information (Scotland) Regulations (S): 2014: 312 FSA
The Food Information (Wales) Regulations (W): 2014: 2303 FSA
The Food Information Regulations (Northern Ireland) (NI) 2014: 223 FSA,
(see page F1 for amendments to all the above legislation)

2). In Scotland, Wales and Northern Ireland: food information must not be provided regarding the absence or reduced presence of gluten in infant formulae and follow-on formulae.

3). SEE ALSO 'Food for Specific Groups' (see index on page Fi)

The Infant Formula and Follow-on Formula Regs
(SI numbers and amendments as listed above)

Infant formula food

1). Operators placing on the market infant formula foods that have not yet been placed on the market in the UK must send the (not England: Food Standards Agency) (England: Secretary of State) a model of the label used for the product.

2). Only infant formula may be marketed or otherwise represented as a product suitable for satisfying by itself nutritional requirements of normal healthy infants during the first months of life until the introduction of appropriate complementary feeding.

3). In addition to the above requirements, infant formula must be marked with

- ♣ where the protein source is not entirely cows' ***or*** goats milk - '**infant formula**',
- ♣ where the protein source is entirely cows' ***or*** goats' milk - '**infant milk**',
- ♣ a statement that the product is suitable for a particular nutritional use by infants from birth when they are not breast fed,

- ♣ *the words '**Important Notice**' immediately followed by a statement
  - ♥ concerning the superiority of breast-feeding,
  - ♥ recommending that the product be used only on the advice of an independent person qualified in medicine, nutrition or pharmacy ***or*** other professional responsible for maternal and child care,

and, in addition,

- ♣ *the labelling may include a graphic representation for easy identification of the product ***or*** for illustrating methods of preparation ***but*** must not show any picture of an infant or any other picture or text which may idealise the use of the product,
- ♣ *infant formula may bear the following nutrition and health claims:
  - ♥ having lactose only - in which case lactose must be the only carbohydrate present),
  - ♥ being lactose free – only where the lactose content is not more than 2.5mg/100kj (10mg/100kcal),
  - ♥ added LCP, or an equivalent nutrition claim related to the addition of docosahexaenoic acid – where the docosahexaenoic acid content is not less than 0.2% of the total fatty acid content,
  - ♥ nutrition claims on the addition of the following optional ingredients: taurin, fructo-oligosaccharides and galacto-oligosaccharides, and nucleotides – where they are voluntarily added at a level that would be appropriate for the intended particular use by infants and in accordance with the prescribed conditions,
  - ♥ reduced risk of allergy to milk proteins (this claim may include terms referring to reduced allergen or reduced antigen properties) – where the label states that the product must not be consumed by infants allergic to the intact proteins from which the product is made ***unless*** generally accepted clinical tests provide proof of the formulae's tolerance in more than 90% of infants (to a confidence level of 95%) hypersensitive to proteins from which the hydrolysate is made),
- ♣ the labelling may include the average quantity of the nutrients specified in Annex III of 2006/141/EC in numerical form per 100ml of the product, ready for use.

* The *presentation* (ie shape, appearance or packaging, the packaging materials used, the way in which they are arranged and the setting in which they are displayed) and the *advertising* of infant formula must comply with the three asterisked requirements above.

Infant formula food - further advertising requirements

Infant formula may be advertised only

- ♣ in a scientific publication, ***or***
- ♣ for the purposes of trade prior to the retail stage, in a publication which is not intended for the general public,

and the advertisement

- ♣ must contain only information of a scientific and factual nature,

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

Follow-on formula food

In addition to the above requirements, follow-on formula food must be marked with

- where the protein source is
  - not entirely cows' ***or*** goats' milk – '**follow-on formula**',
  - entirely cows' ***or*** goats' milk – '**follow-on milk**',
- a statement to the effect that
  - the product is only suitable for particular nutritional use by infants over four months,
  - it should be part of a diversified diet, ***and***
  - it is not to be used as a substitute for breast milk during the first four months of life,
  - the decision to begin complementary feeding (including any decision as to making an exception to the principle of not using follow-on formula before six months of age) should be made only on the advice of an independent person qualified in medicine, nutrition or pharmacy, or other professionals responsible for maternal or child care, based on the individual infant's specific growth and development needs,

and, in addition,

- the labelling may include the average quantity of the nutrients specified in Annex III (see below) in numerical form per 100ml of product, ready for use,
- in addition to numerical information, information on the following vitamins and minerals, expressed as a percentage of the reference values given in Annex VII of 2006/141/EC per 100 ml of the product ready for use: vitamins A, B1, B2, B6, B12, D, Biotin, Calcium, Chloride, Copper, Folate, Iodine, Iron, Magnesium, Manganese, Niacin, Pantothenic acid, Phosphorus, Potassium, Riboflavin, Selenium, Sodium, Thiamin, and Zinc.

Promotion

Infant formula food

1). Where infant formula food is sold by retail no person may

- advertise any infant formula food,
- make any special display designed to promote sales,
- give away any free sample or discount voucher,
- promote the sale of infant formula food by means of premiums, special sales, loss leaders, tie-in sales, ***or***
- undertake any other promotional activity to induce sales.

2). A manufacturer or distributor must not, in order to promote sales, provide any infant formula food for free, at a reduced or discounted price, ***or*** offer any gift, to

- the general public,
- pregnant women or their families,
- mothers or their families,

either directly, or indirectly through the healthcare system, health workers (including private), nurseries or childcare institutions.

3). Informational or educational materials intended for pregnant women and mothers of infants or young children dealing with the feeding of infants must include clear information on

- ♣ the benefits and superiority of breast-feeding,
- ♣ maternal nutrition,
- ♣ the preparation for-, and the maintenance of-, breast-feeding,
- ♣ the possible negative effect on breast-feeding of introducing partial bottle feeding,
- ♣ the difficulty in reversing the decision not to breast feed, ***and***
- ♣ where needed, the proper use of infant formula feed,

and where it contains information about the use of infant formula it must

- ♣ include information about
  - ♥ the social and financial implications of its use,
  - ♥ the health hazards of inappropriate foods or feeding methods, ***and***
  - ♥ the health hazards of improper use of infant formula,
- ♣ not use any pictures which idealise the use of infant formula.

4). A manufacturer or distributor must not make a donation of any informational or educational equipment or materials ***except*** where

- ♣ the intended recipient has made a request,
- ♣ the donation is approved by the Secretary of State or is in accordance with guidelines drawn up by him,
- ♣ they are not marked or labelled with the name of a proprietary brand of infant formula, ***and***
- ♣ they are distributed only through the health care system.

5). An institution or organisation which receives any infant formula free or at a reduced rate must, if that infant formula is for use in (***or*** distribution outside) the institution or organisation, - use it (***or*** distribute it) only for infants who have to be fed on infant formula and only for as long as required by those infants.

Improvement notice

E, W and NI: the Improvement Notice provisions in the FSA apply ***except*** that the references to the proprietor of a food business are replaced by 'person'. It is an offence to fail to comply with an Improvement Notice.