

Current regulations for infant formula marketed in the UK

Regulations governing the composition and marketing of infant milks changed on the 22nd February 2020 when the new EU directive informing UK SI Regulations on Foods for Specific Groups (FSG) (609/2013) came into force. The directive contains delegated acts, EU delegated regulation 2016/127 relates to infant and follow-on formula. The UK has adopted these regulations and they will remain in force until any alternative regulatory arrangements are made.

Infant formula manufactured from the 22nd February 2020 must comply with the new regulations. Infant formula available instore and online from UK retailers in 2020 are likely to be a combination of those that comply with old regulations and those that comply with new regulations until remaining stocks are sold. It should be noted that formula made from protein hydrolysates will not be subject to the updated regulations until February 2022.

Key changes in the new regulations:

- No nutrition and health claims permitted for infant formula.
- A reduction in the upper limit of protein
- An increase in the lower limit for linoleic acid
- A maximum limit for alpha-linolenic acid content
- The mandatory addition of Docosahexaenoic acid (DHA)
- Infant formula with glucose syrup as the main carbohydrate is permitted under an exception clause for lactose free infant formula
- Some minor changes to the upper and lower limits of micronutrients
- The term folic acid will be replaced by the term folate.
- Labelling, presentation and marketing must make a clear distinction between infant and follow-on formula, particularly in respect of the text, images and colours used, to avoid confusion between them

The full interpretation of the new legislation as it pertains to infant formula and follow on formula (but not infant milks marketed as foods for special medical purposes) is set out in Guidances Notes updated by the Department of Health and Social Care in September 2021.

Whereas the previous Guidance Notes made explicit that claims are subject to regulation wherever they appear on the labelling, on a website or in advertising or presentation, and that it is not the case that statements constitute claims only when they appear in headings or banners, this clarification has been removed from the updated Guidance Notes.

Some of the changes that we expect to see in response to the new regulations are set out below.

New regulations should have impacts on infant formula product labelling and marketing such as:

- Nutrition claims related to the addition of taurine, fructo-oligosaccharides and galacto-oligosaccharides (GOS/FOS) and nucleotides to infant formula would not be allowed.
- Products that add DHA for the first time will not be able to highlight this; products that previously added DHA can use the statement ‘contains DHA (as required by the legislation for all infant formula)’
- There should be greater visual distinction between the packaging of infant and follow-on formula milks belonging to the same brand and so the current practice of almost identical colours, texts and images on packaging should end

Labelling and marketing regulations

Current regulations	Previous regulations
<ul style="list-style-type: none"> • Nutrition and health claims shall not be made on infant formula. • However, the statement ‘lactose only’ may be used for when lactose is the only carbohydrate present in the product. • The statement ‘lactose free’ may be used when the lactose content is not greater than 10mg/100kcal. • 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 previously placed on the market. 	<p>The labelling of infant formula may bear nutrition claims only in the cases listed and in accordance with the conditions set out. These claims include:</p> <ul style="list-style-type: none"> • Lactose only and Lactose free • Added LCP or equivalent nutrition claim related to the addition of docosahexaenoic acid • Nutrition claims on the addition of the following optional ingredients: <ul style="list-style-type: none"> ○ Taurine ○ Fructo-oligosaccharides and galacto-oligosaccharides ○ Nucleotides • A health claim is allowed related to the reduction of risk to allergy to milk proteins, reduced allergen or reduced allergen properties provided certain conditions are met

Current regulations	Previous regulations
<ul style="list-style-type: none"> Any labelling, presentation and marketing of infant formula should be designed in a way that enables consumers to make a clear distinction between infant and follow-on formula, particularly in respect of the text, images and colours used, to avoid confusion between them. Advertising is restricted to publications specialising in baby care and scientific publications. All advertising must only provide information that is scientific and factual in nature and must not imply or create a belief that bottle-feeding is equivalent or superior to breastfeeding. There shall be no point-of-sale advertising or the giving of samples or other promotional devices to induce sales at the retail level. Manufacturers and distributors of infant formula shall not directly provide free or subsidised products, samples or any other promotional gifts to members of the general public (including mothers, pregnant women and their families). 	<ul style="list-style-type: none"> Any labelling of infant formula shall not include pictures of infants, or other pictures or text which may idealise the use of the product, although graphic representation which easily identifies the product and for illustrating methods of preparation may be used. It should be labelled in a way that enables consumers to make a clear distinction between such products to avoid confusion between infant formula and follow-on formula. <p>Consistent with new regulations</p> <p>Consistent with new regulations</p> <p>Consistent with new regulations</p>
<ul style="list-style-type: none"> The labelling shall be designed to provide the necessary information about the appropriate use of the products so as not to discourage breastfeeding The use of the terms ‘humanised’, ‘maternalised’, ‘adapted’ or similar terms shall not be used. 	<p>Consistent with new regulations</p> <p>Consistent with new regulations</p>
<ul style="list-style-type: none"> There must be a clearly stated ‘important notice’ concerning the superiority of breastfeeding and a statement recommending that the product be used only on the advice of an independent and qualified person. 	<p>Consistent with new regulations</p>