



Department  
of Health &  
Social Care

# **DHSC Guidance Notes on Commission Delegated Regulation (EU) 2016/127 (supplementing Regulation (EU) No 609/2013)**

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## Nutrition law

The UK left the European Union (EU) on 31 December 2020. From that point, regulation became an autonomous matter for both Great Britain and EU as two separate legal and regulatory systems. 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).

From 1 January 2021, EU Regulations and tertiary legislation relating to nutrition were retained under the powers contained within the [European Union \(Withdrawal\) Act 2018](#) as UK law. Retained EU Regulations and tertiary legislation were subsequently amended by the [Nutrition \(Amendment etc.\) \(EU Exit\) Regulations 2019](#) and the [Nutrition \(Amendment etc.\) \(EU Exit\) Regulations 2020](#).

The Nutrition (Amendment etc.) (EU Exit) Regulations 2019 and the Nutrition (Amendment etc.) (EU Exit) Regulations 2020 transferred responsibilities from EU organisations involved in the risk assessment and risk management processes covered by nutrition legislation to bodies in Great Britain (GB).

NI continues to play a vital role in policy development for nutrition legislation in GB, as NI's full participation in risk assessment and risk management processes ensure that any decisions taken in GB account for the potential impacts across the UK, as set out under the arrangements agreed in the UK-wide provisional common framework for Nutrition Related Labelling, Composition and Standards (NLCS). This is to ensure that any impacts on the UK internal market are minimised.

# Intended audience

This guidance is aimed at companies that manufacture, process, distribute, use, sell or import infant formula and follow-on formula, and those local authorities who are responsible for enforcing the legislation in this area.

Legislation on infant formula and follow-on formula is a devolved matter for the UK. While these Guidance Notes have been developed by the Department for Health and Social Care (DHSC) and specifically refers to England, the principles are similar throughout GB (Scotland and Wales). 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).

Equivalent guidance will be issued for Scotland, Wales and Northern Ireland.

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# Executive summary

The guidance provides information, advice and sets out DHSC's interpretation of the requirements of the legislation on infant formula and follow-on formula under [Commission Delegated Regulation \(EU\) 2016/127](#). Commission Delegated Regulation (EU) 2016/127 comes under the overarching Regulation on [Food for Specific Groups \(EU\) No 609/2013, on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control](#), which was adopted on 12 June 2013 and applied from 20 July 2016. This is enforced in England by [The Food for Specific Groups \(Information and Compositional Requirements\) \(England\) 2016](#). Similar enforcement legislation applies in Scotland, Wales and NI.

Commission Delegated Regulation (EU) 2016/127 was adopted in 2016 and applied from 22 February 2020 except in respect of infant formula and follow-on formula manufactured from protein hydrolysates, which was initially due to apply from 22 February 2021, but will now apply from 22 February 2022 (in both GB and the EU).

Commission Delegated Regulation (EU) 2016/127 specifies rules on the composition, labelling and advertising of infant and follow-on formula. It 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](#).

From its date of application Commission Delegated Regulation (EU) 2016/127 replaced [Commission Directive 2006/141/EC](#), which was implemented by [The Infant Formula and Follow-on Formula \(England\) Regulations 2007](#), except for infant and follow-on formula made from protein hydrolysates where the requirements of Commission Directive 2006/141/EC continue until 22 February 2022 .

These Guidance Notes do not apply to infant and follow-on formula made from protein hydrolysates until 22 February 2022, and until this date the guidance on [The Infant Formula and Follow-on Formula \(England\) Regulations 2007](#) continues to be available and includes guidance for infant and follow-on formula made from protein hydrolysates. Further explanation on the requirements for infant and follow-on formula made from protein hydrolysates is available in Appendix I.

# 1. Introduction

1. The content of these Guidance Notes has been prepared by the Department of Health and Social Care (DHSC). The content reflects DHSC's interpretation of [Commission Delegated Regulation \(EU\) 2016/127](#) (referred to throughout this document as 'the Commission Delegated Regulation').
2. These Guidance Notes aim to help industry, local authority enforcement officers and other interested parties interpret the provisions of the Commission Delegated Regulation.
3. In these Guidance Notes, references to 'Annexes' refer to the Annexes of the Commission Delegated Regulation and references to 'Appendices' refer to the Appendices of these Guidance Notes.
4. **The Guidance Notes:**
  - Focus on the provisions of the Commission Delegated Regulation which include labelling, notification, avoidance of risk of confusion between infant formula and follow-on formula, advertising, promotion, and the provision of information and education relating to infant and child feeding.
  - Replace previous guidance notes on [The Infant Formula and Follow on Formula \(England\) Regulations 2007](#) (which are referred to throughout this document as 'the 2007 Regulations') except in relation to infant and follow-on formula manufactured from protein hydrolysates, where the Guidance on [The Infant Formula and Follow-on Formula \(England\) Regulations 2007](#) will continue to apply until 22 February 2022.
  - Provide guidance on interpreting the requirements set out in the Commission Delegated Regulation and should be read in conjunction with the [legislation](#) itself. The text should not be taken as an authoritative statement or how the law should be interpreted, as this would be for a court to determine. Every effort has been made to ensure that these guidance notes are as helpful as possible. However, it is ultimately the responsibility of individual businesses to ensure their compliance with the law. Businesses with specific queries may wish to seek the advice of their local enforcement agency, which will usually be the Trading Standards/ environmental health department of the local authority or Port Health Authority.
5. These Guidance Notes have been developed by DHSC and refer to the implementation and enforcement legislation for England. The corresponding legislation for each of the four UK countries is as follows:

**England:**

[The Nutrition \(Amendment\) and Food for Specific Groups \(Food for Special Medical Purposes for Infants, Infant Formula and Follow-on Formula\) \(Information and Compositional Requirements\) \(Amendment\) Regulations 2021](#)

[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](#)

[Food for Specific Groups \(Information and Compositional Requirements\) \(England\) Regulations 2016](#)

[The Infant Formula and Follow on Formula \(England\) Regulations 2007](#)

**Scotland:**

[The Food for Specific Groups \(Infant Formula and Follow-on Formula\) \(Scotland\) Amendment Regulations 2021](#)

[The Food for Specific Groups \(Medical Foods for Infants\) and Addition of Vitamins, Minerals and Other Substances \(Scotland\) Amendment Regulations 2020](#)

[The Foods for Specific Groups \(Scotland\) Regulations 2016](#)

[The Infant Formula and Follow-on Formula \(Scotland\) Regulations 2007](#)

**Wales:**

[The Food for Specific Groups \(Information and Compositional Requirements\) \(Wales\) \(Amendment\) Regulations 2020](#)

[The Food for Specific Groups \(Information and Compositional Requirements\) \(Wales\) Regulations 2016](#)

[The Infant Formula and Follow-on Formula \(Wales\) Regulations 2007](#)

**Northern Ireland:**

[The Food Safety \(Information and Compositional Requirements\) \(Amendment\) Regulations \(Northern Ireland\) 2019](#)

[The Food Safety \(Information and Compositional Requirements\) Regulations \(Northern Ireland\) 2016](#)



[The Infant Formula and Follow-on Formula Regulations \(Northern Ireland\) 2007](#)

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## 2. Background

### Food for Specific Groups

6. Commission Delegated Regulation (EU) 2016/127 comes under the overarching Regulation on Food for Specific Groups (EU) No 609/2013 (referred to throughout this document as 'the FSG Regulation') on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control.
7. The FSG Regulation was adopted on 12 June 2013 and applied from 20 July 2016. From 1 January 2021, the FSG Regulation was retained under the powers contained within the European Union (Withdrawal) Act 2018 as UK law. This retained EU legislation was subsequently amended by the Nutrition (Amendment etc.) (EU Exit) Regulations 2019 and the Nutrition (Amendment etc.) (EU Exit) Regulations 2020. It is enforced in England by the [Food for Specific Groups \(Information and Compositional Requirements\) \(England\) Regulations 2016](#).
8. **The FSG Regulation covers:**
  - Infant and follow-on formula;
  - Processed cereal-based food and baby food;
  - Food for specific medical purposes; and
  - Total diet replacement for use in energy restricted diets for weight control.
9. Further information on the FSG Regulation can be found in the [Nutrition Legislation Information Sheet](#).
10. The FSG Regulation sets out provisions to empower the appropriate authority (the competent authority in this respect for England means Secretary of State for Health and Social Care) to adopt delegated acts on general compositional, advertisement and labelling rules for the categories of foods covered by the regulation (as above).
11. The FSG Regulation defines the categories listed above, sets out information requirements and a 'GB list' of substances that may be added to these categories of food.

The following terms defined in the FSG Regulation apply for the purposes of the Commission Delegated Regulation:

'infant' means a child under the age of 12 months

'young child' means a child aged between one and three years

'infant formula' means 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

'follow-on formula' means 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

### **Appropriate complementary feeding**

The Scientific Advisory Committee on Nutrition (SACN), who provides advice to the UK Government on nutrition and related health matters includes the following definition of complementary feeding in their 2018 report on "feeding in the first year of life".

The WHO defines complementary feeding as “the process starting when breast milk alone is no longer sufficient to meet the nutritional requirements of infants” so that “other foods and liquids are needed, along with breast milk.” (PAHO, 2003). For the purposes of this report, complementary feeding refers to the period when solid foods are given in addition to either breast milk or infant formula to complement the nutrients provided by breast milk (and/or infant formula) when breast milk (and/or infant formula) alone is not sufficient to meet the nutritional requirements of the growing infant. Complementary feeding replaces the term ‘weaning’ which can be misinterpreted to mean the cessation of breastfeeding rather than the introduction of solid foods. Complementary feeding includes all liquids, semi-solid and solid foods, other than breast milk and infant formula.

### 3. Commission Delegated Regulation (EU) 2016/127

12. The Commission Delegated Regulation provides the detailed labelling and compositional rules for infant and follow-on formula and replaced the 2007 Regulations, except for infant and follow-on formula made from protein hydrolysates where the requirements of the 2007 Regulations will continue until 22 February 2022.
13. The Commission Delegated Regulation, updates and sets additional provisions to those of the 2007 Regulations. Differences in the requirements of the two regulations include prohibiting the use of nutrition and health claims; strengthening the requirement for infant and follow-on formula labels to be clearly distinct from each other; the mandatory addition of Docosahexaenoic acid (DHA); the inclusion of statements on DHA and lactose; the requirement to notify the authority when placing infant formula on the market; and from 22 February 2022, the pre authorisation and notification required when placing follow-on formula on the market when it is manufactured from protein hydrolysates or substances other than those listed in Annex II of the Commission Delegated Regulation.
14. Unless otherwise specified in the Commission Delegated Regulation, infant and follow-on formula shall also comply with labelling information requirements set out in [Regulation \(EU\) No 1169/2011 on the provision of food information to consumers](#). Guidance on Regulation (EU) No 1169/2011 available on the [GOV.UK website](#).
15. The Commission Delegated Regulation is enforced in England 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](#).
16. The Commission Delegated Regulation consolidates legislation on the composition, labelling and marketing of infant formula and follow-on formula. The Commission Delegated Regulation reflects the latest scientific advice on the essential composition of infant formula and follow-on formula. The Commission Delegated Regulation and the overarching FSG Regulation together give effect to the principles and aims of the [1981 WHO Code on the Marketing of Breastmilk Substitutes](#) covering marketing, information and responsibilities of health authorities, as they set provisions which regulates labelling and restricts advertising and presentation of infant and follow-on formula so as not to discourage breastfeeding.

## **The provisions of the Commission Delegated Regulation, which supplements the FSG Regulation, relate to:**

- Placing on the market (Article 1)
- The compositional requirements of infant formula and follow-on formula (Article 2)
- The suitability of ingredients for infant and follow-on formula (Article 3)
- The requirements on pesticides for infant and follow-on formula (Article 4)
- The name of the food (Article 5)
- The requirement for the packaging of infant and follow-on formula to differ from each other (Article 6)
- The requirements under Regulation (EU) No 1169/2011 on the provision of food information to consumers including the specific requirements on food information for infant and follow-on formula (Articles 6 and 7)
- The provisions of advertising infant formula and follow-on formula (Articles 6 and 10). Further information on what is considered advertising can be found in Appendix II of this guidance.
- The specific requirements on the nutrition declaration for infant and follow-on formula (Article 7)
- The prohibition of nutrition and health claims on infant formula (Article 8)
- Statements relating to lactose and docosahexaenoic acid (DHA) (Article 9)
- Presentation of the products relating to the way in which infant formula and follow-on formula are arranged for sale and the setting in which they are displayed (Article 10)
- Provision of informational and educational material dealing with the feeding of infants (Article 11)
- The notification to the authority required when placing infant formula on the market and from 22 February 2022, the notification required when placing follow-on formula on the market when it is manufactured from protein hydrolysates or substances other than those listed in Annex II of the Commission Delegated Regulation (Article 12)

## Specific requirements on food information

### Article 6 of the Commission Delegated Regulation:

17. Article 6(2)(a) requires the following statement to be included on infant formula: 'suitable for infants from birth when they are not breast fed'.
18. Article 6(2)(b) and (3)(b) requires that instructions are provided for appropriate preparation, storage and disposal of infant formula and follow-on formula.

DHSC recommend that these instructions should include information on the process for safe and appropriate preparation and the storage of formula. This information can be found on the [NHS website](#).

19. Article 6(2)(b) and 3(b) require, in addition to instructions for appropriate preparation, storage and disposal of the infant formula or follow-on formula, a 'warning about the health hazards of inappropriate preparation and storage'. This warning statement should stress the importance of the correct preparation of infant formula or follow-on formula without which there is an increased risk to the baby's health including the baby suffering from serious stomach upsets, diarrhoea, constipation etc. This statement should appear on the label in a conspicuous place and be clearly visible and easily understandable. The statement should include wording such as 'Failure to follow instructions may make your baby ill'.
20. Article 6(2)(c) relates to the 'Important Notice' requirement. The Important Notice is required only on infant formula and must state the superiority of breast feeding and make a statement recommending that the product is to be used only on the advice of independent persons having qualifications in medicine, nutrition or pharmacy, or other professionals responsible for maternal and child care. The Important Notice should be clearly visible and understandable and should be afforded a high degree of prominence on the label. Please refer to Appendix III of this guidance for advice on the presentation of 'Important Notice' information on websites.
21. Article 6(3)(a) provides further labelling requirements for follow-on formula. Follow-on formula must state 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 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.

The NHS provides guidance on types of formula. This information can be found on the [NHS website](#).

The guidance states:

Follow-on formula is suitable from 6 months of age (but ask a health visitor for advice first) and that follow-on formula should never be fed to babies under 6 months old.

Research shows that switching to follow-on formula at 6 months has no benefits for your baby. Your baby can continue to have first infant formula as their main drink until they are 1 year old.

The labels on follow-on formula can look very similar to those on first infant formula. Read the label carefully to avoid making a mistake

22. Article 6(6) seeks to ensure that the labelling of infant formula and follow-on formula provides the necessary information about the appropriate use of the products so as not to discourage breast feeding and does not contain the terms 'humanised', 'maternalised' and 'adapted' or any similar terms.
23. Article 6(6) also requires infant and follow-on formula to be clearly distinct from each other in order to prevent confusion. This is to ensure parents and caregivers provide the most suitable product for their child. They must differ in relation to text, images and colours used on the packaging. All three of these elements must be different. DHSC do not consider using different shades of the same colour to be an appropriate difference. This requirement also serves to prevent the indirect marketing of infant formula by advertising a product that looks almost identical. Further information on the requirements for distinct packaging can be found in Appendix IV.

## **Article 10 of the FSG Regulation**

24. Article 10(2) of the FSG Regulation states that the labelling of infant formula and follow-on formula shall not include a picture of an infant or any other picture or text which may idealise the use of the product. The labelling may include graphic representations for easy identification of the product or for illustrating methods of preparation.

**Examples of representations which may be considered to 'idealise' the use of infant or follow-on formula should they feature on infant or follow-on formula labelling include (this list is not exhaustive):**

Pictures of infants, young children or carers (e.g. mothers or fathers)

Graphics that represent nursing mothers and pregnant women

Pictures or text which imply that infant health, happiness or wellbeing, or the health, happiness and wellbeing of carers, is associated with infant or follow-on formula

References to infant's or carer's emotions

Baby or child related subjects and anthropomorphic characters, pictures and logos

Non-mandatory pictures or text which refers, directly or indirectly, to 'the best' or 'the ideal method' of infant feeding.

References to non-mandatory text or pictures on infant formula and follow-on formula labelling which refers to 'human milk', 'human milk oligosaccharides (HMO)', 'breastmilk', 'breastfeeding', 'moving on from breastfeeding' or 'closer to/inspired by breastmilk'.

**In light of these requirements, DHSC recommend that manufacturers should ensure the following when producing infant formula and follow-on formula labelling:**

The specific terms 'infant formula' and 'follow-on formula' should be clearly featured on the packaging, in a font size no smaller than the brand name.

Non-mandatory references to breastmilk or breastfeeding should not be made on follow-on formula packaging as consumers may associate these terms with feeding infants from birth, whereas follow-on formula should be used only from six months.

## **Specific requirements on the nutrition declaration**

The nutrition declaration of infant and follow-on formula shall comply with labelling information requirements set out in Regulation (EU) No 1169/2011.

Article 7(1) of Regulation (EU) No 1169/2011 states food information should not be misleading, particularly by suggesting that the food possesses special characteristics when in fact all similar foods possess such characteristics, in particular by specifically emphasising the presence or absence of certain ingredients and/or nutrients.

**In light of these requirements, DHSC recommend the highlighting of mandatory nutrients should not be included on the labelling of infant and follow-on formula as it could be considered that it implies that the product possesses special characteristics when all similar foods possess such characteristics.**



## **Article 7 of the Commission Delegated Regulation:**

25. Dictates the mandatory nutrition information that must be included on the packaging of infant formula and follow-on formula irrespective of the size of the packaging or container. The article also refers to the supplementary nutrition information that can be included on the packaging.
26. Under Article 7(1), in addition to the mandatory particulars in Article 30(1) of Regulation (EU) No 1169/2011, the nutrition declaration of infant and follow-on formula must include the amount of the minerals and vitamins listed in Annex I and Annex II of the Commission Delegated Regulation.
27. Under Article 7(3), the information included in the mandatory nutrition declaration for infant and follow-on formula shall not be repeated on the labelling.
28. An exception to Article 30(1) of Regulation (EU) No 1169/2011 is the inclusion of salt on the mandatory nutrition declaration of infant and follow-on formula. Under Article 7(1), infant and follow-on formula must not have the amount of salt on the label.
29. Under Article 7(1), the mandatory nutrition declaration for infant formula must include the amount of choline, inositol and carnitine.
30. The nutrition declaration for infant and follow-on formula may be supplemented with the amounts of nutrients as described in Article 7(2).
31. Article 7(6) notes that energy value and the amounts of nutrients of infant formula and follow-on formula shall be expressed per 100 ml of the food ready for use after preparation in accordance with the manufacturer's instructions rather than as sold.
32. The use of daily reference intake is not permitted on infant formula.

## **Nutrition and health claims for infant formula**

### **Article 8 of the Commission Delegated Regulation states:**

33. Nutrition and health claims are prohibited on infant formula.

The following definitions, which are set out in Regulation (EC) No 1924/2006 on nutrition and health claims made on foods, apply for the purposes of the Commission Delegated Regulation:

'claim' means any message or representation, which is not mandatory under any enactment, including pictorial, graphic or symbolic representation, in any form, which states, suggests or implies that a food has particular characteristics;

'nutrition claim' means any claim which states, suggests or implies that a food has particular beneficial nutritional properties due to:

(a) The energy (calorific value) it

(i) Provides

(ii) Provides at a reduced or increased rate; or

(iii) It does not provide; and/or

(b) The nutrients or other substances it

(i) Contains

(ii) Contains in reduce or increased proportions; or

(iii) Does not contain;

'health claim' means any claim that states, suggests or implies that a relationship exists between a food category, a food or one of its constituents and health;

'reduction of disease risk claim' means any health claim that states, suggests or implies that the consumption of a food category, a food or one of its constituents significantly reduces a risk factor in the development of a human disease.

**Examples of 'claims' on infant formula that could be considered as 'non-permitted' claims include:**

Highlighting the addition or exclusion of ingredients such as:

Taurine

Fructo-oligosaccharides and galacto-oligosaccharides (GOS/FOS)

Nucleotides

DHA without accompaniment of either of the statements in Article 9

'Contains all the nutrients your baby needs to grow strong and healthy'

'Easy to digest'

'Gentle'

## **Statements related to lactose and docosahexaenoic acid (DHA)**

### **Article 9 of the Commission Delegated Regulation:**

34. Article 9(1) dictates when the statement 'lactose only' is permitted on the packaging of infant and follow-on formula.
35. Article 9(2) dictates when the statement 'lactose free' is permitted on the packaging of infant and follow-on formula. Article 9(2) also specifies the circumstances in which the wording 'not suitable for infants with galactosaemia' must be included on the packaging.
36. Article 9(3) refers to the mandatory addition of Docosahexaenoic acid (DHA) in infant formula. Due to this addition being mandatory, packaging that wishes to highlight the presence of DHA in the formula must include either of the following statements:
  - a. 'contains Docosahexaenoic acid (as required by the legislation for all infant formula)' or;
  - b. 'contains DHA (as required by the legislation for all infant formula)'.
37. The statement should be in close proximity to the area of packaging highlighting the presence of DHA.
38. The statements may only be used for infant formula that has been placed on the market before 22 February 2025. After this date, highlighting of the presence of DHA will be prohibited.

## Requirements for promotional and commercial practices for infant formula

### Article 10 of the Commission Delegated Regulation:

39. When advertising to the public or health care professionals, infant formula manufacturers must comply with the requirements of Article 10. Further information on what may constitute as advertising can be found in Appendix II.

40. The aims of Article 10 are to ensure that:

- Infant formula can only be advertised in scientific publications or publications specialising in baby care (Article 10(1)). Further information on scientific publications can be found in Appendix V.
- Point-of-sale advertising, the giving of samples and any other promotional devices are prohibited. Companies should not use prominent shop window displays, free standing displays or 'shelf-talkers' which relate to infant formula products. (Article 10(2))
- Manufacturers and distributors of infant formula shall not provide free or subsidised products, samples or any other promotional gifts to members of the general public including pregnant women, mothers or members of their families. This includes multi packs (bulk buys), loyalty/reward card schemes, free formula, price reductions, discounts or mark downs and buy one get one free. Gifts provided via baby clubs or similar activities are also prohibited (Article 10(3)).
- When advertising follow-on formula, it must be clear that the advertisements for follow-on formula relate exclusively to products for older babies and not infant formula. These advertisements should not promote, either directly or indirectly, infant formula, or formula milks/bottle-feeding in general.

#### **It is advised that when advertising follow-on formula, companies do not:**

Promote a range of formula products by making the brand the focus of the advert, rather than specific products (e.g. where specific products are mentioned only in a footnote or in a picture of a tin of formula within the advertisement).

text or images which relate to pregnancy (e.g. pregnancy test kits) or the feeding or care of infants under six months.

Include pictures or text which directly or indirectly relate or compare products to breastmilk.

Focus on carers' emotions in relation to the feeding or care of infants under six months.

Feature babies which consumers may perceive as being under six months (even if they are over six months).

Focus primarily on the promotion of ingredients, or the effect of ingredients, which are common to both follow-on formula and infant formula.

## Requirements on information relating to infant and young child feeding

### Article 11 of the Commission Delegated Regulation:

41. Article 11 requires information and educational material (whether this is written or audio-visual) that deals with feeding of infants and is intended to reach pregnant women, to include certain information. This information must not use any images or text which idealise the use of infant formula.

#### Article 11(2) states that the following information must be included:

- The benefits and superiority of breastfeeding;
  - Maternal nutrition and the preparation for and the maintenance of breastfeeding;
  - The possible negative effect on breastfeeding of introducing partial bottle feeding;
  - The difficulty of reversing the decision not to breastfeed; and
  - Where needed, the proper use of infant formula.
- **Where materials contain information about the use of an infant formula Article 11(2) states that the following information is included:**
    - 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.

42. Article 11(3) regulates the donation of informational or educational materials and explains the requirement to seek approval from the appropriate authority to approve the donation of informational or educational materials to third parties. The appropriate authority in England is DHSC.

**The following is a non-exclusive list of some of the types of materials which would be controlled by Article 11(3)**

CDs and DVDs

Wallcharts, posters

Booklets or leaflets which are designed for reference purposes

Electronic files that can be downloaded directly from a website

Online videos such as YouTube videos

43. To gain approval from the appropriate authority, such informational or educational materials:

- a. should contain information which is consistent with current government policies on breastfeeding and the promotion and advertising of infant formula and follow-on formula,
- b. must not be marked or labelled with the name of a proprietary brand of infant formula and,
- c. must only be distributed through the healthcare system, such as via GPs, nurses midwives and other healthcare professionals. Donations may only be made on request and with the written approval of the appropriate authority.

44. Companies who wish to seek approval from DHSC for their donation should write to (preferably via email as there may be a significant delay in receiving and responding to postal enquiries):

Nutrition Legislation Team  
Healthy Weight, Food and Nutrition Branch  
Population Health Directorate  
Department of Health and Social Care  
39 Victoria Street  
London SW1H 0EU  
Tel: 020 7972 4340  
E-mail: [nutritionlegislation@dhsc.gov.uk](mailto:nutritionlegislation@dhsc.gov.uk)

## Notification

### Article 12 of the Commission Delegated Regulation:

45. Article 12 provides that no food business operator may place an infant formula on the market unless they have given prior notice to the competent authority where the product is being marketed. The competent authority in this respect for England means the Secretary of State for Health and Social Care (DHSC).
46. DHSC is centrally coordinating notification forms for all 3 GB nations (England, Scotland and Wales) for the purposes of notifying each of the applicable competent GB authorities. Please see the [notification form](#).
47. The "food business operator" must forward a model of the label used for the product and any other information the competent authority may reasonably request to establish compliance with this Commission Delegated Regulation.

A "food business operator" means the natural or legal persons responsible for ensuring that the requirements of food law are met within the food business under their control.

A "food business" means any undertaking, whether for profit or not and whether public or private, carrying out any of the activities related to any stage of production, processing and distribution of food.

As defined by [Regulation \(EC\) No 178/2002](#) which lays down the general principles and requirements of food law.

48. Further guidance on how and when to notify the relevant competent authority can be found [here](#). Additionally, the link provides guidance on placing an infant formula on the market in the European Union and Northern Ireland.
49. When follow-on formula is manufactured from protein hydrolysates or contains substances other than those listed in Annex II of the Commission Delegated Regulation, the food business operator must notify the relevant competent authority. Further information is available in Appendix I.

# Appendix I - Infant and follow-on formula made from protein hydrolysates

50. Under paragraph 21 of the introductory text of the Commission Delegated Regulation, manufacturers of infant formula and follow-on formula which are made from protein hydrolysates must demonstrate that the product's safety and suitability for infants has been established by generally accepted scientific data. Additionally, Article 12(2) of the Commission Delegated Regulation requires follow-on formula made from protein hydrolysates to be notified by the food business operator to the competent authority where the product is being marketed. For this Article, the competent authority in England is the Secretary of State for Health and Social Care (DHSC).
51. In order to comply with the Commission Delegated Regulation, clinical studies will be required to demonstrate if, and to what extent, a particular formula reduces the risk of developing short or long term clinical symptoms or signs of allergy to milk proteins in at-risk infants who are not breastfed.
52. Providing it has been demonstrated that a specific formula manufactured from protein hydrolysates reduces the risk of developing allergy to milk proteins, further consideration will be given to how to adequately inform parents and caregivers about that property of the product in order to ensure that nutrition or health claims are not made.
53. [The Nutrition \(Amendment\) and Food for Specific Groups \(Food for Special Medical Purposes for Infants, Infant Formula and Follow-on Formula\) \(Information and Compositional Requirements\) \(Amendment\) Regulations 2021](#) came into force on 21 February 2021. This statutory instrument (SI) amended the Nutrition (Amendment etc.) (EU Exit) Regulations 2020 in order to make an amendment to the Commission Delegated Regulation (EU) 2016/127. This resulted in a change to the date of application for the provision related to infant and follow-on formula made from protein hydrolysates in England, Scotland and Wales from 22 February 2021 to 22 February 2022. It also amended the date of enforcement of the same provisions in England. [Scotland](#) and Wales have similarly amended their enforcing SIs to reflect this new date and Northern Ireland are progressing similar changes.
54. The EU also introduced new provisions that extended the date of application from 22 February 2021 to 22 February 2022, relating to infant and follow-on formula made from protein hydrolysates. The Protocol on Ireland/Northern Ireland (NIP) means that the EU provisions apply in Northern Ireland.
55. Therefore, until 22 February 2022 the requirements of Directive 2006/141/EC continue to apply to infant and follow-on formula made from protein hydrolysates.



56. The EU also introduced new provisions that extended the date of application from 22 February 2021 to 22 February 2022, relating to infant and follow-on formula made from protein hydrolysates. The Protocol on Ireland/Northern Ireland (NIP) means that the EU provisions apply in Northern Ireland.
57. This change in application date of the Commission Delegated Regulation to infant and follow-on formula made from protein hydrolysates was also implemented by the EU Commission in the corresponding EU legislation by amending [Article 14 of the equivalent Commission Delegated Regulation](#). This EU amendment is automatically applicable in Northern Ireland under the terms of the Withdrawal Agreement and the Protocol on Ireland/ Northern Ireland (NIP).
58. To apply for the authorisation of the safety and suitability of protein hydrolysates used to manufacture infant and follow-on formula, please see the appropriate application form and guidance here [LINK]. The guidance and application form sets out the steps which applicants need to follow for the authorisation of protein hydrolysates used in infant and follow-on formula. The process to submit an application for the safety and suitability of protein hydrolysates used to manufacture infant and follow-on formula has been agreed and will be reflected as part of the NLCS common framework.

## Appendix II - 'Advertising'

59. All advertising of infant and follow-on formula must comply with the requirements of the Commission Delegated Regulation
60. Article 6 and Article 10 of the Commission Delegated Regulation restrict the advertising, including promotional and commercial practices, of infant formula.
61. Article 11 of the Commission Delegated Regulation provides information on the requirements for producing and publishing information and educational material relating to infant and young feeding when it is permitted. Informational and educational materials which fulfil the requirements of Article 11 would not be considered to be advertising however the provisions for advertising also apply to advertising in scientific journals aimed at health professionals. Whether a representation of information is considered informational or educational material or as advertising will depend on its content and context, regardless of whether it is claimed to be informational or educational material.

The following list includes some examples of the means by which a 'representation' of information could be considered to be within the context of advertising.

**The list is not definitive due to the fact that the nature of advertising is always changing and is intended as guidance only.**

Newspapers, magazines, brochures, leaflets, circulars, direct mailings, e-mails, text transmissions, catalogues, follow-up literature and other electronic and printed material (including advertorials)

Publications for healthcare professionals which are not scientific publications

Posters and other promotional media in public places, including moving pictures

Cinema and video commercials

Non-broadcast electronic media such as YouTube videos, Instagram or other social media, (refer to Appendix III for further guidance with regard to the internet)

Television and radio broadcast commercials

Correspondence between a trade, business or company and their customers, in writing, orally (including telephone calls and company carelines), electronically or by other means

Press releases and other public relations material and activities that can be accessed by consumers

Tickets, timetables and price lists

Celebrity endorsements in connection with a trade, business, or company

Product placement in websites

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# Appendix III – Guidance on website information relating to infant formula, follow-on formula and infant feeding

62. All website content, including editorial text, pictures or videos, that may constitute an advertisement, is subject to the provisions of the Commission Delegated Regulation, supplementing the provisions of the FSG Regulation.

63. All website content must comply with the requirements of the Commission Delegated Regulation, including Article 6 and Article 10.

## Online sale of infant formula

- In the case of websites where infant formula can be purchased, only the information that is permitted on the label should be provided, with no particular emphasis given to any of that information. The information provided must comply with the labelling requirements of infant formula set out in Article 6 and Article 10 of the Commission Delegated Regulation.

## Informational and educational material

- DHSC advise that any informational and educational material about infant formula, or infant feeding, which is included on the website should be accessed only by means of an intermediate page which includes statements which inform the user that:
  - by proceeding, they will be able to view information about 'Brand X' infant formula and other formula products and that if they choose to proceed, they are accepting that 'Brand X' is supplying this information at their individual request.
- Those responsible for preparing the website are legally obliged to ensure that the content relating to infant formula may not constitute advertising and may only constitute information.
- Where informational and educational material about infant formula is provided by means of a website, such information should comply with the requirements of Articles 10 and 11 of the Commission Delegated Regulation.
- The information described in the above paragraphs should have the same readability as the main text of the website. Any button which must be clicked to progress beyond the information described above should be positioned at the end

of the text to ensure the reader has been presented with all the required information.

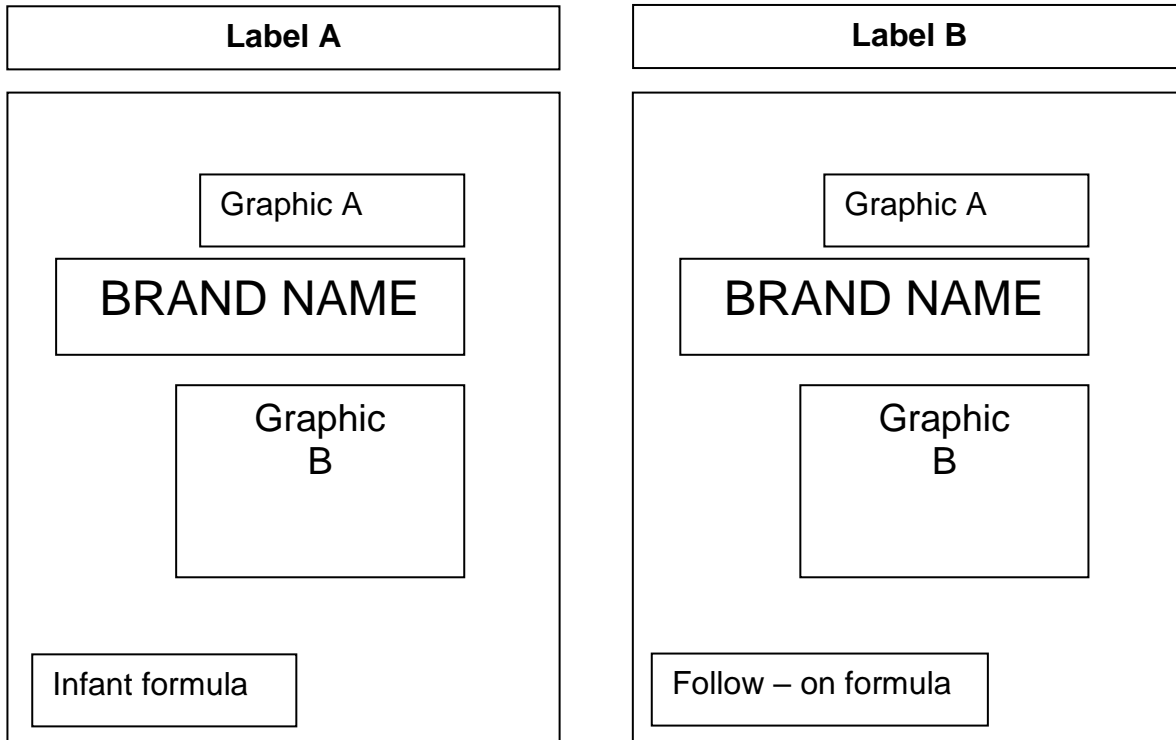
The Advertising Standards Authority (ASA) regulates advertising across all media in the UK. Since September 2010, this also includes advertiser's own marketing communications on their own websites and in other non-paid-for space under their control, such as social networking sites like Facebook and Twitter.

For more information on the ASA and rulings relating to infant formula, please visit their [website](#).

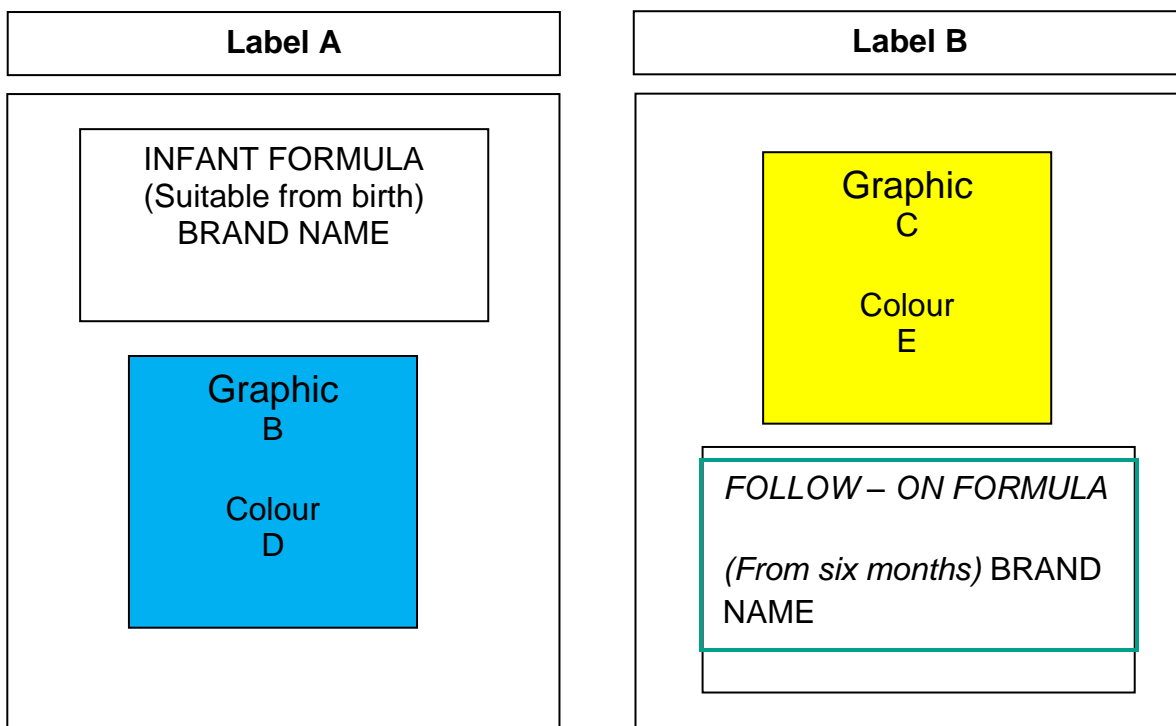
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# Appendix IV – Differentiating infant formula and follow-on formula

The lack of differentiation between the following examples of product labels (same colour, graphics and placement and style of text) may prevent consumers being able to easily distinguish between infant formula and follow-on formula.



The following examples of product labels where the packaging style differs in text (both placement and style), graphics and colours, should allow consumers to distinguish between infant and follow-on formula.



## Appendix V – Guidance on scientific publications and information of a scientific or factual nature

Article 10 of the Commission Delegated Regulation only allows infant formula to be advertised in scientific publications and publications specialising in baby care and puts in place controls on the content of such advertisements. Below is guidance on what constitutes a scientific publication and also guidance on the nature of the information that can be included in advertisements for infant formula.

### Scientific Publication

Scientific publications are usually published periodically and aimed at academic and/or professionals in a scientific field, such as GPs, nurses and midwives. They consist of an aggregation of original articles by different authors published under an umbrella title. Articles included in scientific publications are those that report new scientific research or review existing scientific research. In addition, scientific publications may also include editorials, opinion pieces and book or other reviews dealing with a scientific theme.

In addition, they

- are static, rather than dynamic (i.e. the core content is fixed at the time of publication), and
- may have been assigned an International Standard Serial Number (ISSN).

### Content of Infant Formula Advertisements

Where advertisements for infant formula are permitted, the advertisements can only include information that is of a scientific and factual nature (Article 10(1)). In DHSC's view, to comply with this requirement, manufacturers must be capable of supporting any further information provided with research from peer-reviewed scientific journals.

All nutrition and health claims are prohibited on infant formula, including the advertising of infant formula. [The nutrition and health claim section](#) of this guidance provide information on what constitutes a nutrition or health claim.

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Population Health Directorate/Healthy Weight, Food and Nutrition Branch/Nutrition  
Legislation Team

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