



Guidance for Compliance with Food Law When Communicating with Health Professionals about Infant Formula Products

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1. Background to Guidance

This guidance document was developed by the Food Safety Authority of Ireland (FSAI) and the specialised nutrition member companies of Dairy Industry Ireland (DII).

The World Health Organization (WHO) recommends exclusive breastfeeding for the first six months of life. After six months of age, infants should receive age-appropriate foods while breastfeeding continues for up to two years of age or beyond. The specialised nutrition industry strongly supports this WHO recommendation and believes that breast milk is the optimal source of nutrition as it contains the perfect balance of nutrients, hormones and antibodies. When a mother is unable to breast feed or chooses not to breast feed, however, the only safe alternative for infants <6 months of age is infant formula, i.e. a breast-milk substitute specially manufactured to satisfy, by itself, the nutritional requirements of infants during the first months of life up to the introduction of appropriate complementary feeding. In these scenarios, health professionals play an important role in conducting nutritional assessments and providing scientific advice to meet the nutritional needs of each infant.

Infant formula was regulated under Commission Directive 2006/141/EC but was replaced by Commission Delegated Regulation (EU) 2016/127 on 22 February 2020 and updated by Commission Delegated Regulation (EU) 2021/572 in respect of infant formula and follow-on formula manufactured from protein hydrolysates, to which it shall apply from 22 February 2022. The guidance acknowledges that the eight nutrition and health claims currently permitted on infant formula under Commission Directive 2006/141/EC, for those products complying with this legislation, continue to be permitted. Infant formula is also regulated by Regulation 1169/2011 on Food Information to Consumers and Regulation 609/2013 on Food Intended for Infants and Young Children, Food for Special Medical Purposes, and Total Diet Replacement for Weight Control. In terms of a nutrition declaration, while Regulation 1169/2011 sets down the mandatory declaration and the list of nutrients that can be declared on a food, Regulation (EU) 2016/127 permits other minerals and vitamins to be declared in the nutrition declaration of infant formulae and follow-on formulae.

2. Purpose of this Guidance

The advertising and promotion of infant formula is strictly regulated. However, the rules allow for some latitude in addressing health professionals. The purpose of this document therefore is to provide guidance to the infant formula industry on compliance with food law governing commercial communications to health professionals in relation to infant formula products in Ireland.

Due to the complex legislative framework on which this topic is based, there are several different pieces of legislation referred to throughout this document.

This guidance takes into consideration:

- Commission Directive 2006/141 EC on infant formulae and follow-on formulae and amending Directive 1999/21/EC ¹
- Regulation (EC) no 1924/2006 of the European Parliament and of the Council of 20 December 2006 on Nutrition and Health Claims made on Foods ²
- Regulation (EU) No 609/2013³ of the European Parliament and the Council on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control ('Food for Specific Groups')
- Commission Delegated Regulation (EU) 2016/127 supplementing Regulation (EU) No 609/2013 regarding the specific compositional and information requirements for infant formula and follow-on formula and regarding the requirements on information relating to infant and young child feeding ⁴
- The European Court of Justice (ECJ) Ruling (Case C-19/15) regarding the scope of Regulation 1924/2006 on Nutrition and Health Claims ⁵

¹ Commission Directive 2006/141/EC of 22 December 2006 on infant formulae and follow-on formulae and amending Directive 1999/21/EC ([LINK](#))

² Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods ([LINK](#))

³ 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 ([LINK](#))

⁴ 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 ([LINK](#))

⁵ Judgement of the Court (Third Chamber) 14 July 2016, Case C-19/15 ([LINK](#))

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- Regulation (EU) No. 1169/2011 on Food Information to Consumers⁶
- Commission Delegated Regulation (EU) 2021/572 amending Delegated Regulation (EU) 2016/127 as regards the date of application of certain of its provisions⁷

See [Appendix 1](#) for further detail.

It is envisaged that this guidance will be a living document and will be reviewed as necessary. All commercial communication materials provided by the infant formula industry addressed exclusively to health professionals should adhere to the contents of this guidance in relation to infant formula products.

⁶ Regulation (EU) No. 1169/2011 – Provision of Food Information to Consumers ([LINK](#))

⁷ Commission Delegated Regulation (EU) 2021/572

3. Scope of Guidance

The scope outlines what this guidance is specifically about and to whom it pertains.

There are many different types of infant formula products on the Irish market and a range of commercial communication provided to health professionals. In this context, health professional refers to independent persons having qualifications in medicine, nutrition or pharmacy, or other health professionals responsible for maternal and child care.

3.1 Products:

Table 1 Products within the scope of the guidance

Included	Excluded
<ul style="list-style-type: none"> • Infant formula (also known as ‘infant milk’) as defined in Commission Regulation (EU) No 609/2013 	<ul style="list-style-type: none"> • All other ‘Foods for Specific Groups’ within the scope of Regulation (EU) No 609/2013

3.2 Health professionals receiving commercial communication:

Table 2 Health professionals within the scope of the guidance

Included	Excluded
<ul style="list-style-type: none"> • Health Professionals working in Health Service Executive facilities and government funded healthcare facilities • Health Professionals working in voluntary or unpaid positions or in private practice who provide information to other health professionals, parents and caregivers, patients and/or clients • Health professionals and academics involved in the training of registered health professionals 	<ul style="list-style-type: none"> • Health professionals and academics working in research • Communications to all other recipients

4. Guidance on the Principles of Commercial Communications on Infant Formula to Health Professionals

Commercial communication means any form of communication designed to promote, directly or indirectly, the goods, services or image of a company, organisation or person pursuing commercial, industrial or craft activity or exercising a regulated profession.⁸

This guidance document does not apply to non-commercial communications (such as dietary guidelines or advice issued by public health authorities and bodies, or non-commercial communications and information in scientific publications) which can be shared with health professionals and referenced in commercial communication.

4.1 General principles

All commercial communication exclusively addressed to health professionals in written, audiovisual, or verbal communications should abide by the following principles:

Table 3 General principles for infant formula communication to health professionals

Commercial communication must be:	Commercial communication must not:
<ul style="list-style-type: none"> • Scientific • Factual • Objective • Accurate • Verifiable • Sufficiently complete • Legible • Dated • Referenced precisely • Preceded by the words 'Important Notice' or equivalent, 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 or pharmacy, or other professionals responsible for maternal and child care 	<ul style="list-style-type: none"> • Mislead • Present a risk to public health • Be likely to encourage excessive consumption of infant formula • Raise doubts or fears • Claim to treat, prevent or cure a disease, or imply such properties • Be surreptitious • Discourage breastfeeding • Imply or create a belief that bottle feeding is equivalent or superior to breastfeeding

⁸ Article 2(f) Directive 2000/31/EC

4.2 Content of commercial communications to health professionals

Commercial communication to health professionals should be scientific and factual and use appropriate terms and imagery. Examples are provided below:

Table 4 Content principles for infant formula communication to health professionals

Commercial communication must:	Commercial communication must not:
<p>Use appropriate terms and imagery such as:</p> <ul style="list-style-type: none"> • intended to • suitable for • provides • imagery that enables a clear distinction to be made between infant formula and follow-on formula 	<p>Use superlative terms and imagery such as:</p> <ul style="list-style-type: none"> • optimal, maximum, exceptional, excellent, the best, unparalleled, secure • ‘humanised’, ‘maternalised’, ‘adapted’ or similar terms • pictures of infants • pictures that may idealise the use of infant formula

In addition:

Table 5 Content principles for infant formula communication to health professionals

Commercial communication should be:	Commercial communication should not be:
<ul style="list-style-type: none"> • Accessible and available • Relevant • Complete • In the language of the intended recipient 	<ul style="list-style-type: none"> • Information, data and references that may be inaccessible or unavailable to the health professional • Information that is irrelevant to the subject • From an incomplete or incorrect source • Untranslated foreign language studies

5. Commercial Communications: Scope of Scientific and Factual Information Communicated to Health Professionals

Scientific and factual information should empower the health professional to form his/her own opinion of the value of the product to which the material relates. The provision of scientific and factual information to health professionals supports the safe and appropriate use of infant formula.

Table 6 Scope of scientific and factual information communicated to health professionals

Scientific and Factual information may include:	Scientific and Factual information may not include:
<ul style="list-style-type: none"> • Information on energy levels • Information on mandatory nutrients only when accompanied by the statement ‘as required by the legislation of all infant formula’ or a similar statement⁹ • Information on voluntary/approved voluntary nutrients/ingredients • Information on the scientific basis for the product formulation • Information on the target population for the product • Information on directions for use and precautions for use • Information on nutritional guidelines and dietary intakes • Objective information on new scientific developments involving the use of technical or scientific terminology that is supported by evidence published in non-commercial communication 	<ul style="list-style-type: none"> • Information that may create an equivalence or superiority between breast-feeding and infant formula • Incomplete quotation, table or other illustrative matter taken from a scientific journal or text book • Incomplete information that does not provide all of the relevant facts • Colloquialisms for scientific and factual information • Marketing phrases or slogans

⁹ Article 7.1 (c) Regulation 1169/2011 – Provision of Food Information to Consumers

6. Nutrition and Health Claims on Infant Formula

Nutrition and health claims made on infant formula shall comply with the provisions set out in Commission Delegated Regulation 2016/127 and Commission Regulation 1924/2006. As of 22nd February 2020, no nutrition and health claims are allowed on infant formula with the exception of nutrition statements on docosahexanoic acid (DHA) and lactose. The statement relating to DHA is only permitted on infant formula placed on the market before 22 February 2025. Claims allowable in respect of infant formula manufactured from protein hydrolysates will be allowed until 21 February 2022. [Appendix II](#) describes a list of claims permitted for infant formula during the transition from Commission Directive 2006/141/EC to Commission Delegated Regulation 2016/127 and Commission Delegated Regulation (EU) 2021/572.

Nutrition and health claims made on infant formula must comply with the general provisions set out in Commission Regulation 1924/2006, as well as the more specific provisions set out in Commission Delegated Regulation 2016/127 and Commission Directive 2006/141/EC. (See [Appendix I](#))

While there are provisions for the dissemination of useful, scientific and factual information from industry to health professionals within the legislation, nutrition and health claims cannot be made on infant formula.¹⁰

¹⁰ Article 8 of Regulation 2016/127 'Nutrition and health claims shall not be made on infant formula.'

For nutrition and health claims which are currently permitted and authorised under the legislation referred to above, the following principles shall apply:

Table 7 Principles for nutrition and health claims on infant formula currently permitted

Nutrition and health claims used on infant formula shall:	Nutrition and health claims used on infant formula shall not:
<ul style="list-style-type: none"> • Be authorised and permitted for use in line with the applicable legislation (See Appendix II) • Use authorised wording 	<ul style="list-style-type: none"> • Be a rejected health claim • Be a non-permitted health claim • Be an unauthorised health claim • Be based on additional scientific information in an EFSA submission that has been evaluated and rejected (see note below for further details) • Be exaggerative • Compare infant formula to breast milk*

*This does not preclude the provision of scientific and factual information on the composition of breast milk to health professionals concerning the rationale for adding a nutrient or ingredient to infant formula. Where scientific and factual information on the composition of breast milk is provided to health professionals, information on infant formula can be presented in the same document, provided the information is shown in separate tables, is not linked and the superiority of breastmilk is clearly indicated.

Note: If a nutrition or health claim has been evaluated, considered and rejected by EFSA for use on infant formula, such claims shall not be described as scientific and factual information in commercial communications. A health professional cannot be expected to permanently have all the specialised and up to date scientific knowledge to evaluate new information on a nutrition or health claim and be aware of the status of such nutrition or health claims. ¹¹

11(43-45) Judgement of the Court (Third Chamber) 14 July 2016, Case C-19/15 (LINK) ‘Admittedly, health professionals may be considered to have scientific knowledge superior to that of a final consumer, understood as an average consumer, who is reasonably well informed and reasonably observant and circumvent, as stated in Recital 16 of that regulation. However, those professionals cannot be regarded as being in a position to permanently have all specialised and up-to-date scientific knowledge necessary to evaluate each food and the nutrition and health claims used in the labelling, the presentation or advertising of those foods.’

7. Commercial Communications: Sources and Standard of Scientific and Factual Information

A variety of valid sources of scientific information can be used to communicate on infant formula to health professionals. The legislation gives guidance on the type of appropriate scientific studies that should be used to support new ingredients (see [Appendix IV](#) for more information). Guidance is provided on the way in which information on scientific studies should be presented in [Appendix V](#).

Guidance on acceptable sources of scientific and factual information in commercial communications on infant formula are outlined below when presenting at events/conferences to health professionals or in information materials aimed at health professionals:

Table 8 Acceptable and unacceptable sources of scientific and factual information at events/conferences attended by health professionals

Acceptable Sources of Scientific and Factual Information	Unacceptable Sources of Scientific and Factual Information
<ul style="list-style-type: none"> • National and international public health agencies • Applicable food legislation • Research bodies /Academic institutes • Nutrition associations • Medical associations • Responsible authoritative scientific bodies • Peer-review articles • Text books • Conference proceedings • Conference abstracts • Consensus scientific publications • Compositional laboratory data • Unpublished data on file (see section 7.1) • Health professionals with experience of working in the area of paediatrics, 	<ul style="list-style-type: none"> • Company marketing information (e.g. sales information, market trends) • Influencers and bloggers • Non-academic media personalities

<p>paediatric dietetics or paediatric nursing</p> <ul style="list-style-type: none"> • Academics with experience of working in the area of infant nutrition/feeding • Industry employees (declaration of interest and compliance with this guidance note is required) 	
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Table 9 Acceptable and unacceptable sources of scientific and factual information in information materials aimed at health professionals

Acceptable Sources of Scientific and Factual Information	Unacceptable Sources of Scientific and Factual Information
<ul style="list-style-type: none"> • Publications from national and international public health agencies, research bodies/academic institutes or nutrition associations • Peer-review articles • Text books • Conference proceedings • Conference abstracts • Consensus scientific publications • Compositional laboratory data • Unpublished data on file (see section 7.1) 	<ul style="list-style-type: none"> • Company marketing information (e.g. sales information, market trends) • Unreferenced information • Influencers and bloggers • Non-academic media personalities

7.1 Unpublished data on file

References to ‘data on file’ should not be used. Instead such supporting information should be referenced as ‘unpublished data on file’ which clarifies that these data have not been peer reviewed and published in a scientific journal. Appropriate information should be provided to the health professional to fully describe such data, i.e. type of study, population studied, study results and study conclusions. Should the health professional request the

unpublished data or study referenced within a material, such information/studies should be provided within four weeks.

7.2 Referencing scientific evidence

Scientific information on infant formula products should be appropriately referenced in communications to health professionals. Referencing should be in accordance with normal scientific citation. The full name of the paper must be provided. To allow a health professional to assess the weight of evidence referenced in support of an infant formula product, the type of study e.g. case study, observational study, randomised controlled trial should be clearly stated in descriptive passages.

In situations where the study findings have not been submitted for publication in a scientific journal, this should be made known to the health professional. For example, if the findings of the study have been presented at a scientific conference but there are no accepted peer-reviewed publications on the study, this should be acknowledged. An example of appropriate text in this situation would be *'the findings of this study have been presented at [name and date of conference]. The study findings have also been submitted for publication and are currently undergoing the peer review process/have not been submitted for publication'*.

8. Restriction of Communication to Health Professionals

Information provided to health professionals is scientific and factual and is not intended for the general public. To reinforce this point the following should be adhered to:

- All information provided to health professionals should contain a prominent statement *“For Health Professional Use Only”* (or similar wording)
- For information accessed electronically (e.g. company apps, websites etc.) the health professional should be required to also confirm their status as a health professional before being able to access the information. This may be done via a ‘checkbox’ option.

9. Appendices

Appendix I: Legislative framework for infant formula

The [following section](#) provides additional information on the legislation behind this document. There are four Regulations and one European Court of Justice Ruling that the development of this guidance has focused on. The details of these legislative pieces and their relevance to communicating to health professionals on infant formula are outlined below;

1. **Regulation (EU) No 609/2013** of the European Parliament and the Council on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control ('Food for Specific Groups') was adopted on 12 June 2013. Recital 28 clarifies the scope of this Regulation. ¹²

This Regulation:

- replaced Directive 2009/39/EC on foodstuffs for particular nutritional uses¹³
- establishes general compositional and information requirements for a number of categories of food, including infant formula
- has been applicable since 20 July 2016

Article 9(5) Regulation 609/2013¹⁴ states that the action of treating, preventing or curing a disease shall not be attributed to products legislated for in the FSG framework, nor should any labelling, presentation or advertising have the ability to mislead.

¹² (28) Regulation (EC) No 1924/2006 establishes the rules and conditions for the use of nutrition and health claims on food. Those rules should apply as a general rule to the categories of food covered by this Regulation, unless otherwise specified in this Regulation or delegated acts adopted pursuant to this Regulation. ([LINK](#))

¹³ Directive 2009/39/EC of the European Parliament and of the Council of 6 May 2009 on foodstuffs intended for particular nutritional uses ([LINK](#))

¹⁴ "The labelling, presentation and advertising of food referred to in Article 1(1) shall provide information for the appropriate use of such food, and shall not mislead, or attribute to such food the property of preventing, treating or curing a human disease, or imply such properties."

Article 9(6) Regulation 609/2013¹⁵ legislates for the allowance of the dissemination of useful information or recommendations exclusively intended for persons having qualifications in medicine, nutrition, pharmacy, or for other health professionals responsible for maternal care and childcare.

Article 10(2)¹⁶ outlines the requirements for the labelling, presentation and advertising of infant formula. As per this article, 'The labelling, presentation and advertising of infant formula and the labelling of follow-on formula shall not include pictures of infants, or other pictures or text which may idealise the use of such formulae'. However, graphic representations for easy identification of infant formula and for illustrating methods of preparation shall be permitted.

2. Commission Delegated Regulation (EU) 2016/127¹⁷ supplements Regulation 609/2013 by laying down more specific requirements for infant formula. This Delegated Regulation:

- replaces Commission Directive 2006/141/EC¹⁸
- establishes more specific advertising and information requirements for infant formula
- outlines the compositional requirements for infant formula (see Appendix IV)
- Is applicable from 22 February 2020, except in respect of infant formula and follow-on formula manufactured from protein hydrolysates, to which it shall apply from 22 February 2022. In the interim, the requirements of Commission Directive 2006/141/EC are applicable.

¹⁵“Paragraph 5 shall not prevent the dissemination of any useful information or recommendations exclusively intended for persons having qualifications in medicine, nutrition, pharmacy, or for other health professionals responsible for maternal care and childcare.”

¹⁶ “The labelling, presentation and advertising of infant formula and the labelling of follow-on formula shall not include pictures of infants, or other pictures or text which may idealise the use of such formulae.”

¹⁷ 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 ([LINK](#))

¹⁸ Commission Directive 2006/141/EC of 22 December 2006 on infant formulae and follow-on formulae and amending Directive 1999/21/EC ([LINK](#))

Article 6.6¹⁹ outlines the requirements for the labelling, presentation and advertising of infant formula. It states that such mediums of communication shall not use terms ‘humanised’, ‘maternalised’, ‘adapted’ or similar terms, nor shall they discourage breastfeeding. As a result, such terms shall not be used on health professional materials.

Article 10.1²⁰ outlines the scope for advertising of infant formula. It states that advertising of infant formula shall be limited to scientific publications and publications specialising in baby care. It states that such advertising shall contain only information of a scientific and factual nature and shall not imply or create a belief that bottle feeding is equivalent or superior to breast-feeding. Commission Delegated Regulation (EU) 2016/127 also allows for the possibility of product innovation and product development for infant formula (See Appendix IV). It foresees the voluntary addition of ingredients to infant formula.

3. Regulation (EC) No 1924/2006 Nutrition and Health Claims Made on Foods²¹.

General rules on nutrition and health claims have been established by this Regulation.

The Regulation became applicable on 1 July 2007. Its objective is to ensure that any claim made on a food's labelling, presentation or advertising in the European Union is clear, accurate and based on scientific evidence. Food bearing claims that could mislead consumers are prohibited on the EU market. As a result of the ECJ C-19/15 ruling, this Regulation applies to all commercial communications, including communications from industry to health professional²². Whilst this judgment ruled

¹⁹ “The labelling, presentation and advertising of infant formula and follow on formula shall provide the necessary information about the appropriate use of the products, so as not to discourage breast feeding. The labelling, presentation and advertising of infant formula and follow-on formula shall not use the terms ‘humanised’, ‘maternalised’, ‘adapted’, or terms similar to them.” ([LINK](#))

²⁰ “Advertising of infant formula shall be restricted to publications specialising in baby care and scientific publications. Member states may further restrict or prohibit such advertising. Such advertising shall only contain information of a scientific and factual nature. Such information shall not imply or create a belief that bottle-feeding is equivalent or superior to breast feeding.” ([LINK](#))

²¹ Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods ([LINK](#))

²² “Article 1(2) of Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods, as amended by Commission Regulation (EU) No 1047/2012 of 8 November

that Regulation 1924/2006 applies to health professional materials and commercial communications, nevertheless it allows for the dissemination of objective scientific information on new developments involving the use of technical or scientific terminology.²³

Although a small number of nutrition and health claims are currently permitted on infant formula under Commission Directive 2006/141/EC, these will no longer be permitted under Delegated Regulation 2016/127 Article 8. As per article 8²⁴ of Regulation 2016/127, there are no nutrition or health claims allowed on infant formula. Recital 18 of Delegated Regulation 2016/127 provides contextual insight into why this is the case²⁵. However, provisions are included in Recital 21 for future consideration for allergy claim on formula manufactured from protein hydrolysates.²⁶

4. Regulation (EU) No 1169/2011 on Food Information to Consumers.⁶

2012, must be interpreted as meaning that nutrition or health claims made in a commercial communication on a food which is intended to be delivered as such to the final consumer, if that communication is addressed not to the final consumer, but exclusively to health professionals, falls within the scope of that regulation.” ([LINK](#))

²³ “However, it cannot be inferred from that that any objective information from food business operators addressed to health professionals about new scientific developments involving the use of technical or scientific terminology, as, in the present case, the use of the words ‘atopic dermatitis’ is prohibited.” ([LINK](#))

²⁴ Article 8 Delegated Regulation 2016/127 “Nutrition and health claims shall not be made on infant formula”. ([LINK](#))

²⁵ Recital (18) Delegated Regulation 2016/127 ‘Nutrition and health claims are promotional tools that are used on a voluntary basis by food business operators in commercial communication, in line with the rules of Regulation (EC) No 1924/2006 of the European Parliament and of the Council (1). Given the particular role of infant formula in the diet of infants, the use of nutrition and health claims should not be allowed for infant formula ([LINK](#))

²⁶ Recital (21) Regulation 2016/127 ‘The use of protein hydrolysates as a source of protein in infant formula and follow-on formula has been allowed under Directive 2006/141/EC for many years and the use of protein hydrolysates in the manufacturing of formula is widespread in the market. This is due, in particular, to the possibility, recognised by that Directive, to make a health claim on infant formula manufactured from protein hydrolysates describing the role of such formula in reducing the risk of developing allergy to milk proteins, under certain conditions laid down in that Directive. In its opinion on the essential composition of infant and follow-on formulae, the Authority noted that the safety and suitability of each specific formula containing protein hydrolysates has to be established by clinical evaluation and that only one formula containing partially hydrolysed whey protein has been positively evaluated so far. The Authority also noted that clinical studies are necessary to demonstrate if and to what extent a particular formula reduces the risk of developing short and long-term clinical manifestations of allergy in at-risk- infants who are not breast-fed. Taking into account the Authority’s opinion, infant formula and follow-on formula manufactured from protein hydrolysates should only be allowed to be placed on the market if their composition corresponds to the requirements of this Regulation.

Those requirements may be updated in order to allow the placing on the market of formula manufactured from protein hydrolysates with a composition different from the one already positively assessed, following a case-by-case evaluation of their safety and suitability by the Authority.

In addition, after the assessment by the Authority, on the basis of studies, where it is 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.’ ([LINK](#))

This regulation which came into effect on 13th December 2014 covers all food information made available to the final consumer. Food information is defined as ‘...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’⁶

This legislation lists the mandatory food information that must be available to consumers which includes a nutrition declaration. While the nutrition declaration is specific in the nutrients that can be declared on a food, Article 7 of Regulation (EU) 2016/127 permits other minerals and vitamins to be declared in the nutrition declaration of infant formulae and follow-on formulae.

5. The European Court of Justice Ruling (Case C-19/15)²⁷ regarding the scope of Regulation 1924/2006 on nutrition and health claims

Providing clarity on the application of Commission Regulation 1924/2006, the European Court of Justice Ruling C-19/15 decided that commercial communications between food companies and health professionals falls within the scope of communications referred to and governed by Commission Regulation 1924/2006. This means that while there is provision for information pertaining to new scientific developments to be given to health professionals from infant formula companies, any and all information disseminated should be objective scientific information and factual. This information, however, must not take the form of a rejected nutrition or health claim.

6. Commission Delegated Regulation (EU) 2021/572 of 20 January 2021 amending Delegated Regulation (EU) 2016/127 as regards the date of application of certain of its provisions states the date of application of Directive 2006/141/EC shall continue until 21 February 2022 to infant formula and follow-on formula manufactured from protein hydrolysates. Delegated Regulation (EU) 2016/127 lays down, amongst others, specific compositional requirements for infant and follow-on formula manufactured from protein hydrolysates. The European Food Safety Authority states that the safety and suitability of each specific formula containing protein

²⁷ Judgement of the Court (Third Chamber) 14 July 2016, Case C-19/15 ([LINK](#))

hydrolysates has to be established by clinical evaluation. The COVID 19 pandemic has caused unexpected delays in the scientific assessments of the formulae currently under evaluation by the Authority.

Appendix II: Claims permitted on infant formula

Table 1 Claims relating to Infant Formula manufactured from intact protein

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Type of Claim/Statement	Claim/Statement relating to.....	Permitted ON Infant Formula (i.e. information 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)		Permitted IN Commercial Communications to Health Professionals (i.e. information made available to health professionals by means of a label, other accompanying material, or any other means including modern technology tools or verbal communication)	
		Before 21 Feb 2020	From 22 Feb 2020	Before 21 Feb 2020	From 22 Feb 2020
		Nutrition	Lactose only	Yes – NOTE 1	Yes – NOTE 2
	Lactose Free	Yes – NOTE 1	Yes – NOTE 2	Yes – NOTE 1	Yes – NOTE 2
	LCP / DHA	Yes – NOTE 1	Yes – NOTE 2	Yes – NOTE 1	Yes – NOTE 2
	Taurine	Yes – NOTE 1	No	Yes – NOTE 1	No
	Fructo-oligosaccharides and galacto-oligosaccharides	Yes – NOTE 1	No	Yes – NOTE 1	No
	Nucleotides	Yes – NOTE 1	No	Yes – NOTE 1	No
	A new scientific development which could be perceived as a nutrition claim	No	No	Yes – NOTE 3	Yes – NOTE 3
Health	A new scientific development which could be perceived as a health claim	No	No	Yes – NOTE 3	Yes – NOTE 3

NOTE 1: Conditions for use of these claims are outlined in Appendix IV of Commission Directive 2006/141/EC.

NOTE 2: Conditions for use of these statements are outlined in Article 9 of Commission Delegated Regulation (EU) 2016/127/EC:

1. The statement ‘lactose only’ may be used for infant formula and follow-on formula provided that lactose is the only carbohydrate present in the product.
2. The statement ‘lactose free’ may be used for infant formula and follow-on formula provided that the lactose content in the product is not greater than 5 mg/100 kJ (10 mg/100 kcal). When the statement ‘lactose free’ is used for infant formula and follow-on formula manufactured from protein sources other than soya protein isolates, it shall be accompanied by the statement ‘not suitable for infants with galactosaemia’, which shall be indicated with the same font size and prominence as the statement ‘lactose free’ and in close proximity to it.
3. 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.

NOTE 3: If quoted in accordance with Section 5 of the Guidance Document (which includes a consideration expressed in the ECJ ruling C-19/15 and provides for ‘objective information on new scientific developments involving the use of technical or scientific terminology’) and if all other requirements of this guidance document are met.

Table 2: Claims relating to infant formula manufactured from protein hydrolysates*

Type of claim	Claim relating to.....	Permitted ON Infant Formula manufactured from protein hydrolysates (i.e. information 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)		Permitted IN Commercial Communications to Health Professionals (i.e. information made available to health professionals by means of a label, other accompanying material, or any other means including modern technology tools or verbal communication)	
		Before 21 Feb 2022	From 22 Feb 2022	Before 21 Feb 2022	From 22 Feb 2022
		Nutrition	Lactose only	Yes – NOTE 1	Yes – NOTE 2
	Lactose Free	Yes – NOTE 1	Yes – NOTE 2	Yes – NOTE 1	Yes – NOTE 2
	LCP / DHA	Yes – NOTE 1	Yes – NOTE 2	Yes – NOTE 1	Yes – NOTE 2
	Taurine	Yes – NOTE 1	No	Yes – NOTE 1	No
	Fructo-oligosaccharides and galacto-oligosaccharides	Yes – NOTE 1	No	Yes – NOTE 1	No
	Nucleotides	Yes – NOTE 1	No	Yes – NOTE 1	No
	A new scientific development which could be perceived as a nutrition claim	No	No	Yes – NOTE 3	Yes – NOTE 3
Health	Reduces the risk of developing allergy to milk proteins	Yes – NOTE 1	Possibly – NOTE 4	Yes – NOTE 1	Possibly – NOTE 4
	A new scientific development which could be perceived as a health claim	No	No	Yes – NOTE 3	Yes – NOTE 3

*Protein hydrolysates complying with the compositional requirements for protein hydrolysates set out in Appendix I (2.3, 2.31, 2.32) Regulation 2016/127

NOTE 1: Conditions for use of these claims are outlined in Appendix IV of Commission Directive 2006/141/EC.

NOTE 2: Conditions for use of these claims are outlined in Article 9 of Commission Delegated Regulation (EU) 2016/127/EC:

1. The statement 'lactose only' may be used for infant formula and follow-on formula provided that lactose is the only carbohydrate present in the product.
2. The statement 'lactose free' may be used for infant formula and 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 the statement 'lactose free' is used for infant formula and follow-on formula manufactured from protein sources other than soya protein isolates, it shall be accompanied by the statement 'not suitable for infants with galactosaemia', which shall be indicated with the same font size and prominence as the statement 'lactose free' and in close proximity to it.
3. 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.

NOTE 3: If quoted in accordance with Section 5 of the Guidance Document (which includes a consideration expressed in the ECJ ruling C-19/15 and provides for 'objective information on new scientific developments involving the use of technical or scientific terminology') and if all other requirements of this guidance document are met.

NOTE 4: Recital 21 of Commission Delegated Regulation (EU) 2016/127/EC, lays down provisions for the future authorisation of claims relating to reduction of the risk of developing allergy to milk proteins.

Appendix III: Definitions

The [following section](#) provides clarity on the meaning of several terms and phrases referred to throughout the document, as defined in legislation.

1. **'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 ²⁸
2. **'Infant'** means a child under the age of 12 months ²⁹
3. **'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) does not provide; and/or
 - (b) the nutrients or other substances it
 - (i) contains;
 - (ii) contains in reduced or increased proportions; or
 - (iii) does not contain ³⁰
4. **'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 ³¹

²⁸ Article 2.2 (c), Regulation (EU) No 609/2013 ([LINK](#))

²⁹ Article 2.2(a), Regulation (EU) No 609/2013 ([LINK](#))

³⁰ Article 2.2.4, Regulation 1924/2006 on Nutrition & Health Claims made on foods ([LINK](#))

³¹ Article 2.2.5, Regulation 1924/2006 on Nutrition & Health Claims made on foods ([LINK](#))

5. **‘Health professional’** Although no definition exists in European legislation, both Regulation 609/2013 & Delegated Regulation 2016/127 refer to independent persons having qualifications in medicine, nutrition or pharmacy, or other health professionals responsible for maternal and child care^{32 33}.
6. **‘Commercial communication’** any form of communication designed to promote, directly or indirectly, the goods, services or image of a company, organisation or person pursuing a commercial, industrial or craft activity or exercising a regulated profession. The following do not in themselves constitute commercial communications:
- Information allowing direct access to the activity of the company, organisation or person, in particular a domain name or an electronic-mail address.
 - Communications relating to the goods, services or image of the company, organisation or person compiled in an independent manner, particularly when this is without financial consideration.
7. **Audio-visual commercial communication** ‘means images with or without sound which are designed to promote, directly or indirectly, the goods, services or image of a natural or legal entity pursuing an economic activity. Such images accompany or are included in a programme in return for payment or for similar consideration or for self-promotional purposes. Forms of audio-visual commercial communication include, inter alia, television advertising, sponsorship, teleshopping and product placement,³⁴

³² Article 6.2(c), Commission Delegated Regulation (EU) 2016/127 ([LINK](#))

³³ Article 9.6. Regulation (EU) 609/2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control ([LINK](#))

³⁴ Article 1(h) Directive 2010/13/EU ([LINK](#))

8. **‘Surreptitious audio-visual commercial communication** ‘means the representation in words or pictures of goods, services, the name, the trade mark or the activities of a producer of goods or a provider of services in programmes when such representation is intended by the media service provider to serve as advertising and might mislead the public as to its nature. Such representation shall, in particular, be considered as intentional if it is done in return for payment or for similar consideration” ³⁵.

³⁵ Article 1(j) Directive 2010/13/EU ([LINK](#))

Appendix IV: Compositional requirements

The [following section](#) provides information on the compositional requirements of infant formula as established in Commission Directive 2006/141/EC and Regulation (EC) 2016/127.

To ensure the safety and suitability of such products, detailed compositional requirements are established in European legislation (Appendix I of Commission Directive 2006/141/EC and Appendix I of Commission Delegated Regulation (EU) 2016/127). These include requirements on energy value, macronutrient (protein, fats and carbohydrate) and micronutrient (vitamins and minerals) content.

In addition, Commission Delegated Regulation (EU) 2016/127 allow for the possibility of product innovation and product development for infant formula Recital 6³⁶ and Article 3³⁷. This is similar to Articles 5 and 6 of Directive 2006/141/ EC³⁸ Guidance on the design and conduct of the appropriate studies for such ingredients is contained in Recital 6 of Regulation 2016/127³⁶.

Considering this, clinical studies that are designed in support of infant formula products based on protein hydrolysates should use the principles set out in the EFSA Scientific Opinion on “Scientific and technical guidelines for the preparation and presentation of an application for authorisation of an infant and/or follow-on formula manufactured from protein hydrolysates”³⁹.

³⁶Recital (6) Commission Delegated Regulation 2016/127; In order to ensure innovation and product development, the voluntary addition to infant formula and follow-on formula of ingredients not covered by specific requirements of this Regulation should be possible. All ingredients used in the manufacture of infant formula and follow-on formula should be suitable for infants and their suitability should have been demonstrated, when necessary, by appropriate studies. It is the responsibility of food business operators to demonstrate such suitability and of national competent authorities to consider, on a case-by-case basis, whether this is the case. Guidance on the design and conduct of appropriate studies has been published by expert scientific groups such as the Scientific Committee on Food, the UK Committee on the Medical Aspects of Food and Nutrition Policy, and the European Society for Paediatric Gastroenterology, Hepatology and Nutrition. Such guidance should be taken into consideration in the manufacturing of infant formula or follow-on formula ([LINK](#))

³⁷ Article 3 Commission Delegated Regulation 2016/127 ([LINK](#))

³⁸ Article 5 Directive 2006/141/EC ([LINK](#))

Article 6 Directive 2006/141/EC ([LINK](#))

³⁹ EFSA Scientific Opinion on ‘Scientific and technical guidance for the preparation and presentation of an application for authorisation of an infant and/or follow-on formula manufactured from protein hydrolysates.’ ([LINK](#))

Clinical studies based on new ingredients should also use the principles outlined in section 3.4 of this EFSA Scientific Opinion.

Appendix V - Presenting scientific information

Clinical studies should be presented in a clear and precise manner. To ensure consistency, below is the minimum information that should be presented:

Study aim and objectives

- Population studied – study number, power calculation, parameters measured including measures of growth, tolerance of the products and adverse events reported, number of dropouts and withdrawals, reasons for dropouts and withdrawals
- Study type e.g. observational, randomized controlled trial
- Study results, on measures of growth in relation to national/international growth standards, tolerances to feed and adverse events reports including statistical analysis
- Study conclusions including study limitations

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