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 (Text with EEA relevance)

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

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) No 609/2013 of the European Parliament and of the Council of 12 June 2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control 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[(1)], and in particular Article 11(1) thereof,

Whereas:

(1) Commission Directive 2006/141/EC[(2)] lays down harmonised rules on infant formula and follow-on formula in the framework of Directive 2009/39/EC of the European Parliament and of the Council[(3)].

(2) Directives 2009/39/EC and 2006/141/EC are repealed by Regulation (EU) No 609/2013. That Regulation lays down general compositional and information requirements for different categories of food, including infant formula and follow-on formula. The Commission has to adopt specific compositional and information requirements for infant formula and follow-on formula, taking into account the provisions of Directive 2006/141/EC.

(3) Infant formula is the only processed foodstuff which wholly satisfies the nutritional requirements of infants during the first months of life until the introduction of appropriate complementary feeding. In order to safeguard the health of those infants, it is necessary to ensure that infant formula is the only product marketed as suitable for such use during that period.

(4) The essential composition of infant formula and follow-on formula must satisfy the nutritional requirements of infants in good health as established by generally accepted scientific data.

(5) Infant formula and follow-on formula are sophisticated products that are specially formulated for a vulnerable group of consumers. In order to ensure the safety and suitability of such products, detailed requirements should be laid down on the composition of infant formula and follow-on formula, including requirements on energy value, macronutrient and micronutrient content. These requirements should be based on the latest scientific advice of the European Food Safety Authority ('the Authority') in its opinion on the essential composition of infant and follow-on formulae[(4)].

(6) 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.

(7) Pursuant to Regulation (EU) No 609/2013, the Commission has to adopt provisions restricting or prohibiting the use of pesticides and on pesticide residues in infant formula and follow-on formula, taking account of those currently established in the Annexes to Directive 2006/141/EC. Adopting provisions that are in line with the current scientific knowledge requires a significant amount of time, given that a comprehensive evaluation has to be carried out by the Authority on a number of aspects, including the appropriateness of the toxicological reference values for infants and young children. Taking into account the date of 20 July 2015 set by Regulation (EU) No 609/2013 for the adoption of this Delegated Regulation, the relevant existing requirements of Directive 2006/141/EC should, at this stage, be taken over. However, it is appropriate to use the terminology of Regulation (EC) No 1107/2009 of the European Parliament and of the Council[(5)].

(8) Directive 2006/141/EC lays down specific requirements on the use of pesticides in products intended for the production of infant formula and follow-on formula and on pesticide residues in such food, based on two opinions given by the Scientific Committee for Food (SCF) on 19 September 1997[(6)] and 4 June 1998[(7)].

(9) A very low residue limit of 0,01 mg/kg for all pesticides is set on the basis of the precautionary principle. In addition, more severe limitations are set for a small number of pesticides or metabolites of pesticides for which even a maximum residue level (MRL) of 0,01 mg/kg might, under worst-case intake conditions, lead to an exposure exceeding the acceptable daily intake (ADI) for infants and young children.

(10) A prohibition of the use of certain pesticides would not necessarily guarantee that infant formula and follow-on formula are free from those pesticides, since some pesticides are persistent in the environment and their residues can be found in the food. For that reason, those pesticides are considered not to have been used if residues are below a certain level.

(11) Infant formula and follow-on formula have to comply with Regulation (EU) No 1169/2011 of the European Parliament and of the Council[8]. In order to take account of the specific nature of infant formula and follow-on formula and in order to promote and protect breast feeding, this Regulation should lay down additions and exceptions to those general rules, where appropriate.

(12) Given the particular role of infant formula and follow-on formula in the diet of infants, it is important to ensure that products exported to third countries provide food information in a language easily understood by parents and caregivers, in the absence of specific relevant provisions established by or agreed with the importing country.

(13) Given the different role of infant formula and follow-on formula in the diet of infants, it is appropriate to lay down provisions requiring that a clear distinction can be made between them, so as to avoid any risk of confusion.

(14) The nutrition declaration for infant formula and follow-on formula is essential in order to guarantee their appropriate use, both for parents and caregivers and for health care professionals who recommend their consumption. For that reason and in order to provide more complete information, the nutrition declaration should include more particulars than those required by Regulation (EU) No 1169/2011. In addition, the exemption provided for in point 18 of Annex V to Regulation (EU) No 1169/2011 should not apply and the nutrition declaration should be mandatory for all infant formula and follow-on formula, irrespective of the package or container size.

(15) Article 30(2) of Regulation (EU) No 1169/2011 contains a limited list of nutrients that may be included on a voluntary basis in the nutrition declaration for food. That Article does not cover all the substances that may be added to infant formula and follow-on formula. In order to ensure legal clarity, it should be laid down explicitly that the nutrition declaration for infant formula and follow-on formula may include such substances. In addition, in certain cases, more detailed information on protein, carbohydrate and fat present in the product could provide additional useful information for parents, caregivers and healthcare professionals. Food business operators should therefore be allowed to provide such information on a voluntary basis.

(16) In order to facilitate product comparisons, the nutrition declaration for infant formula and follow-on formula should be expressed per 100 ml of the product ready for use after preparation in accordance with the manufacturer's instructions.

(17) Infant formula is a 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. The expression of nutrition information on the energy value and the amount of nutrients of infant formula as a percentage of daily reference intake values would mislead consumers and should therefore not be

allowed. Follow-on formula is, on the contrary, a 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. For that reason, and in order to ensure comparisons with other foods that can be included in the diet of such infants, the expression of nutrition information for follow-on formula as a percentage of daily reference intake values should be allowed. Given that healthy infants have different nutritional needs than adults, the use of daily reference intake values set out for the general adult population in Regulation (EU) No 1169/2011 would mislead consumers and should therefore not be allowed. For follow-on formula it should only be allowed to express nutrition information as a percentage of specific reference intakes that are appropriate for the age group.

(18) 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[9]. 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.

(19) Statements relating to the presence or absence of lactose in infant formula and follow-on formula can provide useful information to parents and caregivers. Therefore, it is appropriate to lay down rules on such statements, which might be reviewed taking account of future developments on the market.

(20) The mandatory addition of docosahexaenoic acid (DHA) to infant formula and follow-on formula is a new requirement introduced by this Regulation, as recently recommended by the Authority in its opinion on the essential composition of infant and follow-on formulae. Given that the addition of DHA was allowed on a voluntary basis under Directive 2006/141/EC, and parents and caregivers are familiar with the nutrition claim about the presence of DHA in infant formula, the use of which was permitted under that Directive, food business operators should be allowed to continue to refer to the presence of DHA in infant formula by a statement provided for in this Regulation for a limited period of time in order to avoid confusion. However, it is important that that statement provides full information to consumers about the mandatory presence of DHA in all infant formula products on the market.

(21) 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.

(22) Regulation (EU) No 609/2013 provides that the labelling, presentation and advertising of infant formula and follow-on formula is to be designed so as not to discourage breastfeeding. There is scientific consensus that breast milk is the preferred food for healthy infants and the Union and its Member States are continuously committed to supporting breastfeeding. The conclusions adopted by the Council on nutrition and physical activity[(10)] invited Member States to promote and support adequate breastfeeding and welcomed the Member States' agreement on an EU Action Plan on Childhood Obesity 2014-2020, which includes a series of actions aimed at increasing breastfeeding rates in the Union. In this context, the EU Action Plan recognised the continuous importance of the World Health Organisation (WHO) International Code of Marketing of Breast-milk Substitutes, on which Directive 2006/141/EC was based. The WHO Code, adopted by the 34th World Health Assembly, aims at contributing to the provision of safe and adequate nutrition for infants, by the protection and promotion of breast-feeding, and by ensuring the proper use of breast-milk substitutes. It includes a series of principles related to, among others, marketing, information and responsibilities of health authorities.

(23) In order to protect the health of infants, the rules laid down in this Regulation and in particular those on labelling, presentation and advertising, and promotional and commercial practices should continue being in conformity with the principles and the aims of the International Code of Marketing of Breast-milk Substitutes bearing in mind the particular legal and factual situation existing in the Union. In particular, evidence shows that advertising directly to the consumer and other marketing techniques influence parents and caregivers in their decisions on how to feed their infants. For this reason, and taking into account the particular role of infant formula in the diet of infants, specific restrictions should be laid down in this Regulation on advertising and other marketing techniques for this type of product. However, this Regulation should not concern the conditions of sale of publications specialising in baby care and of scientific publications.

(24) In addition, information given on infant and young child feeding influences pregnant women, parents and caregivers when choosing the type of nourishment for children. It is therefore necessary to lay down requirements in order that such information ensures

an adequate use of the products in question and is not counter to the promotion of breast feeding, in line with the principles of the WHO code.

(25) Article 17(2) of Regulation (EC) No 178/2002 of the European Parliament and of the Council[11] requires Member States to enforce food law, and monitor and verify that the relevant requirements of food law are fulfilled by food and feed business operators at all stages of production, processing and distribution. In this context, in order to facilitate the efficient official monitoring of infant formula and follow-on formula, food business operators placing infant formula on the market should provide the national competent authorities with a model of the label used and all relevant information considered necessary to demonstrate compliance with this Regulation. A similar obligation should apply in respect of certain types of follow-on formula, unless Member States have a different efficient monitoring system.

(26) In order to enable food business operators to adapt to the new requirements, this Regulation should apply from a date that is four years after its entry into force. Taking into account the number and importance of the new requirements applicable to infant formula and follow-on formula manufactured from protein hydrolysates, in respect of such products this Regulation should apply from a date that is five years after its entry into force,

HAS ADOPTED THIS REGULATION:

Modifications etc. (not altering text)

C1 Regulation modified (31.12.2020) by The Nutrition (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1476), **reg. 8(1)(a)** (as amended (21.2.2021) by 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 (S.I. 2021/168), regs. 1(2), **3(2)**)

Article 1

Placing on the market

1 Infant formula and follow-on formula may only be placed on the market if they comply with this Regulation.

2 No product other than infant formula may be marketed or otherwise represented as suitable for satisfying by itself the nutritional requirements of normal healthy infants during the first months of life until the introduction of appropriate complementary feeding.

Article 2

Compositional requirements

1 Infant formula shall comply with the compositional requirements set out in Annex I taking into account the values for the indispensable and conditionally indispensable amino acids set out in Annex III.

2 Follow-on formula shall comply with the compositional requirements set out in Annex II taking into account the values for the indispensable and conditionally indispensable amino acids set out in Annex III.

3 The values set out in Annexes I and II shall apply to the infant formula and follow-on formula ready for use, marketed as such or after preparation in accordance with the manufacturer's instructions. For such preparation nothing more than the addition of water shall be required.

Article 3

Suitability of ingredients

1 Infant formula shall be manufactured from protein sources as set out in point 2 of Annex I and other food ingredients, as the case may be, whose suitability for infants from birth has been established by generally accepted scientific data.

2 Follow-on formula shall be manufactured from protein sources as set out in point 2 of Annex II and other food ingredients, as the case may be, whose suitability for infants aged over six months has been established by generally accepted scientific data.

3 The suitability referred to in paragraphs 1 and 2 shall be demonstrated by the food business operator through a systematic review of the available data relating to the expected benefits and to safety considerations as well as, where necessary, appropriate studies, performed following generally accepted expert guidance on the design and conduct of such studies.

Article 4

Requirements on pesticides

1 For the purposes of this Article, ‘residue’ means the residue of an active substance as referred to in Article 2(2) of Regulation (EC) No 1107/2009 used in a plant protection product as referred to in Article 2(1) of that Regulation, including metabolites and products resulting from the degradation or reaction of that active substance.

2 Infant formula and follow-on formula shall not contain residues at levels exceeding 0,01 mg/kg per active substance.

Those levels shall be determined by generally accepted standardised analytical methods.

3 By way of derogation from paragraph 2, for the active substances listed in Annex IV, the maximum residue levels specified in that Annex shall apply.

4 Infant formula and follow-on formula shall only be produced from agricultural products for the production of which plant protection products containing the active substances listed in Annex V have not been used.

However, for the purpose of checks, plant protection products containing the active substances listed in Annex V are considered not to have been used if their residues do not exceed a level of 0,003 mg/kg.

5 The levels referred to in paragraphs 2, 3 and 4 shall apply to the infant formula and follow-on formula ready for use, marketed as such or after preparation in accordance with the manufacturer's instructions.

Article 5

Name of the food

1 The name of infant formula and follow-on formula other than infant formula and follow-on formula manufactured entirely from cows' milk or goats' milk proteins shall be as set out in Part A of Annex VI.

2 The name of infant formula and follow-on formula manufactured entirely from cows' milk or goats' milk proteins shall be as set out in Part B of Annex VI.

Article 6

Specific requirements on food information

1 Unless otherwise provided in this Regulation, infant formula and follow-on formula shall comply with Regulation (EU) No 1169/2011.

2 In addition to the mandatory particulars listed in Article 9(1) of Regulation (EU) No 1169/2011, the following shall be additional mandatory particulars for infant formula:

a a statement that the product is suitable for infants from birth when they are not breast fed;

b instructions for appropriate preparation, storage and disposal of the product and a warning against the health hazards of inappropriate preparation and storage;

c 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. The particulars referred to in this point shall be preceded by the words ‘important notice’ or their equivalent and shall be given also in the presentation and advertising of infant formula.

3 In addition to the mandatory particulars listed in Article 9(1) of Regulation (EU) No 1169/2011, the following shall be additional mandatory particulars for follow-on formula:

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

b instructions for appropriate preparation, storage and disposal of the product and a warning against the health hazards of inappropriate preparation and storage.

4 Article 13(2) and (3) of Regulation (EU) No 1169/2011 shall also apply to the additional mandatory particulars referred to in paragraphs 2 and 3 of this Article.

5 All mandatory particulars for infant formula and follow-on formula shall appear in a language easily understood by the consumers.

6 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.

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

Article 7

Specific requirements on the nutrition declaration

1 In addition to the information referred to in Article 30(1) of Regulation (EU) No 1169/2011, the mandatory nutrition declaration for infant formula and follow-on formula shall include the amount of each mineral substance and of each vitamin listed in Annex I or Annex II to this Regulation respectively and present in the product, with the exception of molybdenum.

The mandatory nutrition declaration for infant formula shall also include the amount of choline, inositol and carnitine.

By way of derogation from Article 30(1) of Regulation (EU) No 1169/2011, the mandatory nutrition declaration for infant formula and follow-on formula shall not include the amount of salt.

2 In addition to the information referred to in Article 30(2)(a) to (e) of Regulation (EU) No 1169/2011, the content of the mandatory nutrition declaration for infant formula and follow-on formula may be supplemented with one or more of the following:

a the amounts of components of protein, carbohydrate or fat;

b the whey protein/casein ratio;

c the amount of any of the substances listed in Annex I or Annex II to this Regulation or in the Annex to Regulation (EU) No 609/2013, where the indication of any of those substances is not covered by paragraph 1;

d the amount of any of the substances added to the product pursuant to Article 3.

3 By way of derogation from Article 30(3) of Regulation (EU) No 1169/2011, the information included in the mandatory nutrition declaration for infant formula and follow-on formula shall not be repeated on the labelling.

4 The nutrition declaration shall be mandatory for all infant formula and follow-on formula, irrespective of the size of the largest surface of the packaging or container.

5 Articles 31 to 35 of Regulation (EU) No 1169/2011 shall apply to all the nutrients included in the nutrition declaration for infant formula and follow-on formula.

6 By way of derogation from Articles 31(3), 32(2) and 33(1) of Regulation (EU) No 1169/2011, the 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. Where appropriate, the information may in addition refer to 100 g of the food as sold.

7 By way of derogation from Article 32(3) and (4) of Regulation (EU) No 1169/2011, the energy value and the amount of nutrients of infant formula and follow-on formula shall not be expressed as a percentage of the reference intakes set out in Annex XIII to that Regulation.

In addition to the form of expression referred to in paragraph 6, in the case of follow-on formula, the declaration on vitamins and minerals in respect of the vitamins and minerals listed in Annex VII to this Regulation may be expressed as a percentage of the reference intakes set out in that Annex in relation to per 100 ml of the food ready for use after preparation in accordance with the manufacturer's instructions.

8 The particulars included in the nutrition declaration for infant formula and follow-on formula that are not listed in Annex XV to Regulation (EU) No 1169/2011 shall be presented after the most relevant entry of that Annex they belong to or are components of.

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

Article 8

Nutrition and health claims for infant formula

Nutrition and health claims shall not be made on infant formula.

Article 9

Statements related to lactose and docosahexaenoic acid (DHA)

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.

Article 10

Requirements for promotional and commercial practices for infant formula

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

[[F1]The appropriate authority**]** may further restrict or prohibit such advertising. Such advertising shall contain only 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.

2 There shall be no point-of-sale advertising, giving of samples or any other promotional device to induce sales of infant formula directly to the consumer at the retail level, such as special displays, discount coupons, premiums, special sales, loss-leaders and tie-in sales.

3 Manufacturers and distributors of infant formula shall not provide, to the general public or to pregnant women, mothers or members of their families, free or low-priced products, samples or any other promotional gifts, either directly or indirectly via the health care system or health workers.

4 Donations or low-price sales of supplies of infant formula to institutions or organisations, whether for use in the institutions or for distribution outside them, shall only be used by or distributed for infants who have to be fed on infant formula and only for as long as required by such infants.

[F2 5. In this Article, "appropriate authority" means—

a in respect of advertising in England, the Secretary of State;

b in respect of advertising in Wales, the Welsh Ministers;

c in respect of advertising in Scotland, the Scottish Ministers.**]**

Textual Amendments

F1 Words in Art. 10(1) substituted (31.12.2020) by The Nutrition (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1476), regs. 1(3), **8(2)(a)**

F2 Art. 10(5) inserted (31.12.2020) by The Nutrition (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1476), regs. 1(3), **8(2)(b)**

Article 11

Requirements on information relating to infant and young child feeding

1 **[**F3 The appropriate authority**]** shall take measures ensuring that objective and consistent information is provided on infant and young child feeding for use by families and those involved in the field of infant and young child nutrition, and covering the planning, provision, design and dissemination of information and their control.

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

a the benefits and superiority of breast feeding;

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

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

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

e where needed, the proper use of infant formula.

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

3 Donations of informational or educational equipment or materials by manufacturers or distributors shall be made only on request and with the written approval of the **[**F4 appropriate

authority**]** or within guidelines given by that authority for this purpose. Such equipment or materials may bear the donating company's name or logo, but shall not refer to a proprietary brand of infant formula and shall be distributed only through the health care system.

[F5 4. In this Article, "appropriate authority" means—

a in respect of information or educational equipment or materials to be provided in England, the Secretary of State;

b in respect of information or educational equipment or materials to be provided in Wales, the Welsh Ministers;

c in respect of information or educational equipment or materials to be provided in Scotland, the Scottish Ministers.**]**

Textual Amendments

F3 Words in Art. 11(1) substituted (31.12.2020) by The Nutrition (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1476), regs. 1(3), **8(3)(a)**

F4 Words in Art. 11(3) substituted (31.12.2020) by The Nutrition (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1476), regs. 1(3), **8(3)(b)**

F5 Art. 11(4) inserted (31.12.2020) by The Nutrition (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1476), regs. 1(3), **8(3)(c)**

[F6 Article 12

Notification

1. When infant formula is placed on the market, the food business operator shall notify the competent authority of each part of Great Britain where the product concerned is being marketed of the information appearing on the label, by sending to it a model of the label used for the product, and of any other information the competent authority may reasonably request to establish compliance with this Regulation.

2. When follow-on formula manufactured from protein hydrolysates or follow-on formula containing other substances than those listed in Annex II are placed on the market, the food business operator shall notify the competent authority of each part of Great Britain where the product concerned is being marketed of the information appearing on the label, by sending to it a model of the label used for the product, and of any other information the competent authority may reasonably request to establish compliance with this Regulation.

3. In this Article, "competent authority" means—

a in respect of infant formula, or follow-on formula manufactured from protein hydrolysates or follow-on formula containing other substances than those listed in Annex II being placed on the market in England, the Secretary of State;

b in respect of infant formula, or follow-on formula manufactured from protein hydrolysates or follow-on formula containing other substances than those listed in Annex II being placed on the market in Wales, the Welsh Ministers;

c in respect of infant formula, or follow-on formula manufactured from protein hydrolysates or follow-on formula containing other substances than those listed in Annex II being placed on the market in Scotland, Food Standards Scotland.**]**

Textual Amendments

F6 Art. 12 substituted (31.12.2020) by The Nutrition (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1476), regs. 1(3), **8(4)**

F7 Article 13

Directive 2006/141/EC

. . . . . .

Textual Amendments

F7 Art. 13 omitted (31.12.2020) by virtue of The Nutrition (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1476), regs. 1(3), **8(5)**

F8 Article 14

Entry into force and application

. . . . . .

Textual Amendments

F8 Art. 14 omitted (31.12.2020) by virtue of The Nutrition (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1476), regs. 1(3), **8(5)**

This Regulation shall be binding in its entirety and directly applicable in all Member States.

ANNEX I

COMPOSITIONAL REQUIREMENTS REFERRED TO IN ARTICLE 2(1)

1. ENERGY

Minimum	Maximum
250 kJ/100 ml	293 kJ/100 ml
(60 kcal/100 ml)	(70 kcal/100 ml)

2. PROTEINS

(Protein content = nitrogen content × 6,25)

2.1. Infant formula manufactured from cows' milk or goats' milk proteins

Minimum	Maximum
0,43 g/100 kJ	0,6 g/100 kJ
(1,8 g/100 kcal)	(2,5 g/100 kcal)

For an equal energy value, infant formula manufactured from cows' milk or goats' milk proteins must contain an available quantity of each indispensable and conditionally indispensable amino acid at least equal to that contained in the reference protein as set out in Section A of Annex III. Nevertheless, for calculation purposes, the concentration of methionine and cysteine may be added together if the methionine:cysteine ratio is not greater than 2, and the concentration of phenylalanine and tyrosine may be added together if the tyrosine:phenylalanine ratio is not greater than 2. The ratio of methionine:cysteine and of tyrosine:phenylalanine may be greater than 2, provided that the suitability of the product concerned for infants is demonstrated in accordance with Article 3(3).

The L-carnitine content shall be at least equal to 0,3 mg/100 kJ (1,2 mg/100 kcal).

2.2. Infant formula manufactured from soya protein isolates, alone or in a mixture with cows' milk or goats' milk proteins

Minimum	Maximum
0,54 g/100 kJ	0,67 g/100 kJ
(2,25 g/100 kcal)	(2,8 g/100 kcal)

Only protein isolates from soya shall be used in manufacturing this infant formula.

For an equal energy value, infant formula manufactured from soya protein isolates, alone or in a mixture with cows' milk or goats' milk proteins, must contain an available quantity of each indispensable and conditionally indispensable amino acid at least equal to that contained in the reference protein as set out in Section A of Annex III. Nevertheless, for calculation purposes, the concentration of methionine and cysteine may be added together if the methionine:cysteine ratio is not greater than 2, and the concentration of phenylalanine and tyrosine may be added together if the tyrosine:phenylalanine ratio is not greater than 2. The ratio of methionine:cysteine and of tyrosine:phenylalanine may be greater than 2, provided that the suitability of the product concerned for infants is demonstrated in accordance with Article 3(3).

The L-carnitine content shall be at least equal to 0,3 mg/100 kJ (1,2 mg/100 kcal).

2.3. Infant formula manufactured from protein hydrolysates

Minimum	Maximum
0,44 g/100 kJ	0,67 g/100 kJ
(1,86 g/100 kcal)	(2,8 g/100 kcal)

2.3.1. Protein source

Demineralised sweet whey protein derived from cows' milk after enzymatic precipitation of caseins using chymosin, consisting of:

(a) 63 % caseino-glycomacropeptide free whey protein isolate with a minimum protein content of 95 % of dry matter and protein denaturation of less than 70 % and a maximum ash content of 3 %; and

(b) 37 % sweet whey protein concentrate with a minimum protein content of 87 % of dry matter and protein denaturation of less than 70 % and a maximum ash content of 3,5 %.

2.3.2. Protein processing

Two-stage hydrolysis process using a trypsin preparation with a heat-treatment step (from 3 to 10 minutes at 80 to 100 °C) between the two hydrolysis steps.

2.3.3. Indispensable and conditionally indispensable amino acids and L-carnitine

For an equal energy value, infant formula manufactured from protein hydrolysates must contain an available quantity of each indispensable and conditionally indispensable amino acid at least equal to that contained in the reference protein as set out in Section B of Annex III. Nevertheless, for calculation purposes, the concentration of methionine and cysteine may be added together if the methionine:cysteine ratio is not greater than 2, and the concentration of phenylalanine and tyrosine may be added together if the tyrosine:phenylalanine ratio is not greater than 2. The ratio of methionine:cysteine and of tyrosine:phenylalanine may be greater than 2, provided that the suitability of the product concerned for infants is demonstrated in accordance with Article 3(3).

The L-carnitine content shall be at least equal to 0,3 mg/100 kJ (1,2 mg/100 kcal).

2.4. In all cases, amino acids may be added to infant formula solely for the purpose of improving the nutritional value of the proteins, and only in the proportions necessary for that purpose.

3. TAURINE

If added to infant formula, the amount of taurine shall not be greater than 2,9 mg/100 kJ (12 mg/100 kcal).

4. CHOLINE

Minimum	Maximum
6,0 mg/100 kJ	12 mg/100 kJ
(25 mg/100 kcal)	(50 mg/100 kcal)

5. LIPIDS

Minimum	Maximum
1,1 g/100 kJ	1,4 g/100 kJ
(4,4 g/100 kcal)	(6,0 g/100 kcal)

5.1. The use of the following substances shall be prohibited:
— sesame seed oil,
— cotton seed oil.

5.2. The *trans* fatty acid content shall not exceed 3 % of the total fat content.

[[F9]5.3. The erucic acid content shall not exceed 0,4 % of the total fat content.**]**

Textual Amendments

F9 Substituted by Commission Delegated Regulation (EU) 2019/828 of 14 March 2019 amending Delegated Regulation (EU) 2016/127 with regard to vitamin D requirements for infant formula and erucic acid requirements for infant formula and follow-on formula (Text with EEA relevance).

5.4. Linoleic acid

Minimum	Maximum
120 mg/100 kJ	300 mg/100 kJ
(500 mg/100 kcal)	(1 200 mg/100 kcal)

5.5. Alpha-linolenic acid

Minimum	Maximum
12 mg/100 kJ	24 mg/100 kJ
(50 mg/100 kcal)	(100 mg/100 kcal)

5.6. Docosahexaenoic acid

Minimum	Maximum
4,8 mg/100 kJ	12 mg/100 kJ
(20 mg/100 kcal)	(50 mg/100 kcal)

5.7. Other long-chain (20 and 22 carbon atoms) polyunsaturated fatty acids may be added. In that case the content of long-chain polyunsaturated fatty acids shall not exceed 2 % of the total fat content for n-6 long-chain polyunsaturated fatty acids (1 % of the total fat content for arachidonic acid (20:4 n-6)).

The eicosapentaenoic acid (20:5 n-3) content shall not exceed that of docosahexaenoic (22:6 n-3) acid content.

6. PHOSPHOLIPIDS

The amount of phospholipids in infant formula shall not be greater than 2 g/l.

7. INOSITOL

Minimum	**Maximum**
0,96 mg/100 kJ	9,6 mg/100 kJ
(4 mg/100 kcal)	(40 mg/100 kcal)

8. CARBOHYDRATES

Minimum	**Maximum**
2,2 g/100 kJ	3,3 g/100 kJ
(9 g/100 kcal)	(14 g/100 kcal)

8.1. Only the following carbohydrates may be used:
— lactose,
— maltose,
— sucrose,
— glucose,
— glucose syrup or dried glucose syrup,
— malto-dextrins,
— pre-cooked starch (naturally free of gluten),
— gelatinised starch (naturally free of gluten).

8.2. Lactose

Minimum	**Maximum**
1,1 g/100 kJ	—
(4,5 g/100 kcal)	—

Those minimum levels shall not apply to infant formula:
— in which soya protein isolates represent more than 50 % of the total protein content, or
— bearing the statement ‘lactose free’ in accordance with Article 9(2).

8.3. Sucrose

Sucrose may only be added to infant formula manufactured from protein hydrolysates. If added, the sucrose content shall not exceed 20 % of the total carbohydrate content.

8.4. Glucose

Glucose may only be added to infant formula manufactured from protein hydrolysates. If added, the glucose content shall not exceed 0,5 g/100 kJ (2 g/100 kcal).

8.5. Glucose syrup or dried glucose syrup

Glucose syrup or dried glucose syrup may be added to infant formula manufactured from cows' milk or goats' milk proteins or infant formula manufactured from soya protein isolates (alone or in a mixture with cows' milk or goats' milk proteins) only if its dextrose equivalent does not exceed 32. If glucose syrup or dried glucose syrup is added to these products, the glucose content resulting from glucose syrup or dried glucose syrup shall not exceed 0,2 g/100 kJ (0,84 g/100 kcal).

The maximum glucose amounts laid down in point 8.4 shall apply if glucose syrup or dried glucose syrup is added to infant formula manufactured from protein hydrolysates.

8.6. Pre-cooked starch and/or gelatinised starch

Minimum	Maximum
—	2 g/100 ml, and 30 % of the total carbohydrate content

9. FRUCTO-OLIGOSACCHARIDES AND GALACTO-OLIGOSACCHARIDES

Fructo-oligosaccharides and galacto-oligosaccharides may be added to infant formula. In that case their content shall not exceed: 0,8 g/100 ml in a combination of 90 % oligogalactosyl-lactose and 10 % high molecular weight oligofructosyl-saccharose.

Other combinations and maximum levels of fructo-oligosaccharides and galacto-oligosaccharides may be used, provided that their suitability for infants is demonstrated in accordance with Article 3(3).

10. MINERAL SUBSTANCES

10.1. Infant formula manufactured from cows' milk or goats' milk proteins or protein hydrolysates

	Per 100 kJ		Per 100 kcal	
	Minimum	Maximum	Minimum	Maximum
Sodium (mg)	6	14,3	25	60
Potassium (mg)	19,1	38,2	80	160
Chloride (mg)	14,3	38,2	60	160
Calcium (mg)	12	33,5	50	140
Phosphorus (mg)[a]	6	21,5	25	90
Magnesium (mg)	1,2	3,6	5	15
Iron (mg)	0,07	0,31	0,3	1,3
Zinc (mg)	0,12	0,24	0,5	1
Copper (µg)	14,3	24	60	100
Iodine (µg)	3,6	6,9	15	29
Selenium (µg)	0,72	2	3	8,6

a Total phosphorus.

Manganese (µg)	0,24	24	1	100
Molybdenum (µg)	—	3,3	—	14
Fluoride (µg)	—	24	—	100

a Total phosphorus.

The calcium:available phosphorus molar ratio shall not be less than 1 nor greater than 2. The amount of available phosphorus shall be calculated as 80 % of total phosphorus for infant formula manufactured from cow's milk protein, goats' milk protein or protein hydrolysates.

10.2. Infant formula manufactured from soya protein isolates, alone or in a mixture with cows' milk or goats' milk proteins

All requirements of point 10.1 shall apply, except for those concerning iron, phosphorus and zinc, which shall be as follows:

	Per 100 kJ		**Per 100 kcal**	
	Minimum	**Maximum**	**Minimum**	**Maximum**
Iron (mg)	0,11	0,48	0,45	2
Phosphorus (mg)[a]	7,2	24	30	100
Zinc (mg)	0,18	0,3	0,75	1,25

a Total phosphorus.

The calcium:available phosphorus molar ratio shall not be less than 1 nor greater than 2. The amount of available phosphorus shall be calculated as 70 % of total phosphorus for infant formula manufactured from soya protein isolates.

11. VITAMINS

	Per 100 kJ		**Per 100 kcal**	
	Minimum	**Maximum**	**Minimum**	**Maximum**
Vitamin A (µg-RE)[a]	16,7	27,2	70	114
[[F9]**Vitamin D (µg)**	0,48	0,6	2	2,5**]**
Thiamine (µg)	9,6	72	40	300
Riboflavin (µg)	14,3	95,6	60	400
Niacin (mg)[b]	0,1	0,36	0,4	1,5
Pantothenic acid (mg)	0,1	0,48	0,4	2

a Preformed vitamin A; RE = all *trans* retinol equivalent.

b Preformed niacin.

c Dietary folate equivalent: 1 µg DFE = 1 µg food folate = 0,6 µg folic acid from formula.

d Based on vitamin E activity of RRR-α-tocopherol.

Vitamin B_6 (µg)	4,8	41,8	20	175
Biotin (µg)	0,24	1,8	1	7,5
Folate (µg-DFE)[c]	3,6	11,4	15	47,6
Vitamin B_{12} (µg)	0,02	0,12	0,1	0,5
Vitamin C (mg)	0,96	7,2	4	30
Vitamin K (µg)	0,24	6	1	25
Vitamin E (mg α-tocopherol)[d]	0,14	1,2	0,6	5

a Preformed vitamin A; RE = all *trans* retinol equivalent.

b Preformed niacin.

c Dietary folate equivalent: 1 µg DFE = 1 µg food folate = 0,6 µg folic acid from formula.

d Based on vitamin E activity of RRR-α-tocopherol.

12. NUCLEOTIDES

The following nucleotides may be added:

	Maximum[a]	
	(mg/100 kJ)	**(mg/100 kcal)**
cytidine 5′-monophosphate	0,60	2,50
uridine 5′-monophosphate	0,42	1,75
adenosine 5′-monophosphate	0,36	1,50
guanosine 5′-monophosphate	0,12	0,50
inosine 5′-monophosphate	0,24	1,00

a The total concentration of nucleotides shall not exceed 1,2 mg/100 kJ (5 mg/100 kcal).

ANNEX II

COMPOSITIONAL REQUIREMENTS REFERRED TO IN ARTICLE 2(2)

1. ENERGY

Minimum	**Maximum**
250 kJ/100 ml	293 kJ/100 ml
(60 kcal/100 ml)	(70 kcal/100 ml)

2. PROTEINS

(Protein content = nitrogen content × 6,25)

2.1. Follow-on formula manufactured from cows' milk or goats' milk proteins

[F10Minimum	**Maximum**
0,38 g/100 kJ	0,6 g/100 kJ
(1,6 g/100 kcal)	(2,5 g/100 kcal)**]**

Textual Amendments

F10 Substituted by Commission Delegated Regulation (EU) 2018/561 of 29 January 2018 amending Delegated Regulation (EU) 2016/127 with regard to protein requirements for follow-on formula (Text with EEA relevance).

For an equal energy value, follow-on formula manufactured from cows' milk or goats' milk proteins must contain an available quantity of each indispensable and conditionally indispensable amino acid at least equal to that contained in the reference protein as set out in Section A of Annex III. Nevertheless, for calculation purposes, the concentration of methionine and cysteine and the concentration of phenylalanine and tyrosine may be added together.

2.2. Follow-on formula manufactured from soya protein isolates, alone or in a mixture with cows' milk or goats' milk proteins

Minimum	**Maximum**
0,54 g/100 kJ	0,67 g/100 kJ
(2,25 g/100 kcal)	(2,8 g/100 kcal)

Only protein isolates from soya shall be used in manufacturing this follow-on formula.

For an equal energy value, follow-on formula manufactured from soya protein isolates, alone or in a mixture with cows' milk or goats' milk proteins, must contain an available quantity of each indispensable and conditionally indispensable amino acid at least equal to that contained in the reference protein as set out in Section A of Annex III. Nevertheless, for calculation purposes, the concentration of methionine and cysteine and the concentration of phenylalanine and tyrosine may be added together.

2.3. Follow-on formula manufactured from protein hydrolysates

Minimum	**Maximum**
0,44 g/100 kJ	0,67 g/100 kJ
(1,86 g/100 kcal)	(2,8 g/100 kcal)

2.3.1. Protein source

Demineralised sweet whey protein derived from cows' milk after enzymatic precipitation of caseins using chymosin, consisting of:

(a) 63 % caseino-glycomacropeptide free whey protein isolate with a minimum protein content of 95 % of dry matter and protein denaturation of less than 70 % and a maximum ash content of 3 %; and

(b) 37 % sweet whey protein concentrate with a minimum protein content of 87 % of dry matter and protein denaturation of less than 70 % and a maximum ash content of 3,5 %.

2.3.2. Protein processing

Two-stage hydrolysis process using a trypsin preparation with a heat-treatment step (from 3 to 10 minutes at 80 to 100 °C) between the two hydrolysis steps.

2.3.3. Indispensable and conditionally indispensable amino acids

For an equal energy value, follow-on formula manufactured from protein hydrolysates must contain an available quantity of each indispensable and conditionally indispensable amino acid at least equal to that contained in the reference protein as set out in Section B of Annex III. Nevertheless, for calculation purposes, the concentration of methionine and cysteine and the concentration of phenylalanine and tyrosine may be added together.

2.4. In all cases, amino acids may be added to follow-on formula solely for the purpose of improving the nutritional value of the proteins, and only in the proportions necessary for that purpose.

3. TAURINE

If added to follow-on formula, the amount of taurine shall not be greater than 2,9 mg/100 kJ (12 mg/100 kcal).

4. LIPIDS

Minimum	**Maximum**
1,1 g/100 kJ	1,4 g/100 kJ
(4,4 g/100 kcal)	(6,0 g/100 kcal)

4.1. The use of the following substances shall be prohibited:
— sesame seed oil,
— cotton seed oil.

4.2. The *trans* fatty acid content shall not exceed 3 % of the total fat content.

[[F9]4.3. The erucic acid content shall not exceed 0,4 % of the total fat content.**]**

4.4. Linoleic acid

Minimum	**Maximum**
120 mg/100 kJ	300 mg/100 kJ
(500 mg/100 kcal)	(1 200 mg/100 kcal)

4.5. Alpha-linolenic acid

Minimum	**Maximum**

12 mg/100 kJ	24 mg/100 kJ
(50 mg/100 kcal)	(100 mg/100 kcal)

4.6. Docosahexaenoic acid

Minimum	**Maximum**
4,8 mg/100 kJ	12 mg/100 kJ
(20 mg/100 kcal)	(50 mg/100 kcal)

4.7. Other long-chain (20 and 22 carbon atoms) polyunsaturated fatty acids may be added. In that case the content of long-chain polyunsaturated fatty acids shall not exceed 2 % of the total fat content for n-6 long-chain polyunsaturated fatty acids (1 % of the total fat content for arachidonic acid (20:4 n-6).

The eicosapentaenoic acid (20:5 n-3) content shall not exceed that of docosahexaenoic (22:6 n-3) acid content.

5. PHOSPHOLIPIDS

The amount of phospholipids in follow-on formula shall not be greater than 2 g/l.

6. CARBOHYDRATES

Minimum	**Maximum**
2,2 g/100 kJ	3,3 g/100 kJ
(9 g/100 kcal)	(14 g/100 kcal)

6.1. The use of ingredients containing gluten shall be prohibited.

6.2. Lactose

Minimum	**Maximum**
1,1 g/100 kJ	—
(4,5 g/100 kcal)	—

Those minimum levels shall not apply to follow-on formula:

— in which soya protein isolates represent more than 50 % of the total protein content, or

— bearing the statement ‘lactose free’ in accordance with Article 9(2).

6.3. Sucrose, fructose, honey

Minimum	**Maximum**
—	separately or as a whole: 20 % of the total carbohydrate content

Honey shall be treated to destroy spores of *Clostridium botulinum*.

6.4. Glucose

Glucose may only be added to follow-on formula manufactured from protein hydrolysates. If added, the glucose content shall not exceed 0,5 g/100 kJ (2 g/100 kcal).

6.5. Glucose syrup or dried glucose syrup

Glucose syrup or dried glucose syrup may be added to follow-on formula manufactured from cows' milk or goats' milk proteins or follow-on formula manufactured from soya protein isolates (alone or in a mixture with cows' milk or goats' milk proteins) only if its dextrose equivalent does not exceed 32. If glucose syrup or dried glucose syrup is added to these products, the glucose content resulting from glucose syrup or dried glucose syrup shall not exceed 0,2 g/100 kJ (0,84 g/100 kcal).

The maximum glucose amounts laid down in point 6.4 shall apply if glucose syrup or dried glucose syrup is added to follow-on formula manufactured from protein hydrolysates.

7. FRUCTO-OLIGOSACCHARIDES AND GALACTO-OLIGOSACCHARIDES

Fructo-oligosaccharides and galacto-oligosaccharides may be added to follow-on formula. In that case their content shall not exceed: 0,8 g/100 ml in a combination of 90 % oligogalactosyl-lactose and 10 % high molecular weight oligofructosyl-saccharose.

Other combinations and maximum levels of fructo-oligosaccharides and galacto-oligosaccharides may be used, provided that their suitability for infants is demonstrated in accordance with Article 3(3).

8. MINERAL SUBSTANCES

8.1. Follow-on formula manufactured from cows' milk or goats' milk proteins or protein hydrolysates

	Per 100 kJ		**Per 100 kcal**	
	Minimum	**Maximum**	**Minimum**	**Maximum**
Sodium (mg)	6	14,3	25	60
Potassium (mg)	19,1	38,2	80	160
Chloride (mg)	14,3	38,2	60	160
Calcium (mg)	12	33,5	50	140
Phosphorus (mg)[a]	6	21,5	25	90
Magnesium (mg)	1,2	3,6	5	15
Iron (mg)	0,14	0,48	0,6	2
Zinc (mg)	0,12	0,24	0,5	1
Copper (µg)	14,3	24	60	100
Iodine (µg)	3,6	6,9	15	29
Selenium (µg)	0,72	2	3	8,6

a Total phosphorus.

Manganese (µg)	0,24	24	1	100
Molybdenum (µg)	—	3,3	—	14
Fluoride (µg)	—	24	—	100

a Total phosphorus.

The calcium:available phosphorus molar ratio shall not be less than 1 nor greater than 2. The amount of available phosphorus shall be calculated as 80 % of total phosphorus for follow-on formula manufactured from cow's milk protein, goats' milk protein or protein hydrolysates.

8.2. Follow-on formula manufactured from soya protein isolates, alone or in a mixture with cows' milk or goats' milk proteins

All requirements of point 8.1 shall apply, except for those concerning iron, phosphorus and zinc, which shall be as follows:

	Per 100 kJ		**Per 100 kcal**	
	Minimum	**Maximum**	**Minimum**	**Maximum**
Iron (mg)	0,22	0,6	0,9	2,5
Phosphorus (mg)[a]	7,2	24	30	100
Zinc (mg)	0,18	0,3	0,75	1,25

a Total phosphorus.

The calcium:available phosphorus molar ratio shall not be less than 1 nor greater than 2. The amount of available phosphorus shall be calculated as 70 % of total phosphorus for follow-on formula manufactured from soya protein isolates.

9. VITAMINS

	Per 100 kJ		**Per 100 kcal**	
	Minimum	**Maximum**	**Minimum**	**Maximum**
Vitamin A (µg-RE)[a]	16,7	27,2	70	114
Vitamin D (µg)	0,48	0,72	2	3
Thiamine (µg)	9,6	72	40	300
Riboflavin (µg)	14,3	95,6	60	400
Niacin (mg)[b]	0,1	0,36	0,4	1,5
Pantothenic acid (mg)	0,1	0,48	0,4	2

a Preformed vitamin A; RE = all *trans* retinol equivalent.

b Preformed niacin.

c Dietary folate equivalent: 1 µg DFE = 1 µg food folate = 0,6 µg folic acid from formula.

d Based on vitamin E activity of RRR-α-tocopherol.

Vitamin B_6 (µg)	4,8	41,8	20	175
Biotin (µg)	0,24	1,8	1	7,5
Folate (µg-DFE)[c]	3,6	11,4	15	47,6
Vitamin B_{12} (µg)	0,02	0,12	0,1	0,5
Vitamin C (mg)	0,96	7,2	4	30
Vitamin K (µg)	0,24	6	1	25
Vitamin E (mg α-tocopherol)[d]	0,14	1,2	0,6	5

a Preformed vitamin A; RE = all *trans* retinol equivalent.

b Preformed niacin.

c Dietary folate equivalent: 1 µg DFE = 1 µg food folate = 0,6 µg folic acid from formula.

d Based on vitamin E activity of RRR-α-tocopherol.

10. NUCLEOTIDES

The following nucleotides may be added:

	Maximum[a]	
	(mg/100 kJ)	**(mg/100 kcal)**
cytidine 5′-monophosphate	0,60	2,50
uridine 5′-monophosphate	0,42	1,75
adenosine 5′-monophosphate	0,36	1,50
guanosine 5′-monophosphate	0,12	0,50
inosine 5′-monophosphate	0,24	1,00

a The total concentration of nucleotides shall not exceed 1,2 mg/100 kJ (5 mg/100 kcal).

ANNEX III

INDISPENSABLE AND CONDITIONALLY INDISPENSABLE AMINO ACIDS IN BREAST MILK

For the purposes of point 2 of Annexes I and II, breast milk shall be used as reference protein as set out in Sections A and B of this Annex, respectively.

A. Infant formula and follow-on formula manufactured from cows' milk or goats' milk proteins and infant formula and follow-on formula manufactured from soya protein isolates, alone or in a mixture with cows' milk or goats' milk proteins

For the purposes of points 2.1 and 2.2 of Annexes I and II, the indispensable and conditionally indispensable amino acids in breast milk, expressed in mg per 100 kJ and 100 kcal, are the following:

	Per 100 kJ[a]	**Per 100 kcal**
Cysteine	9	38
Histidine	10	40
Isoleucine	22	90
Leucine	40	166
Lysine	27	113
Methionine	5	23
Phenylalanine	20	83
Threonine	18	77
Tryptophan	8	32
Tyrosine	18	76
Valine	21	88

a 1 kJ = 0,239 kcal.

B. Infant formula and follow-on formula manufactured from protein hydrolysates

For the purposes of point 2.3 of Annexes I and II, the indispensable and conditionally indispensable amino acids in breast milk, expressed in mg per 100 kJ and 100 kcal, are the following:

	Per 100 kJ[a]	**Per 100 kcal**
Arginine	16	69
Cysteine	6	24
Histidine	11	45
Isoleucine	17	72
Leucine	37	156
Lysine	29	122
Methionine	7	29
Phenylalanine	15	62
Threonine	19	80
Tryptophan	7	30
Tyrosine	14	59
Valine	19	80

a 1 kJ = 0,239 kcal.

ANNEX IV

ACTIVE SUBSTANCES REFERRED TO IN ARTICLE 4(3)

Chemical name of the substance	Maximum residue level(mg/kg)
Cadusafos	0,006
Demeton-S-methyl/demeton-S-methyl sulfone/oxydemeton-methyl (individually or combined, expressed as demeton-S-methyl)	0,006
Ethoprophos	0,008
Fipronil (sum of fipronil and fipronil-desulfinyl, expressed as fipronil)	0,004
Propineb/propylenethiourea (sum of propineb and propylenethiourea)	0,006

ANNEX V

ACTIVE SUBSTANCES REFERRED TO IN ARTICLE 4(4)

Chemical name of the substance (residue definition)

Aldrin and dieldrin, expressed as dieldrin

Disulfoton (sum of disulfoton, disulfoton sulfoxide and disulfoton sulfone expressed as disulfoton)

Endrin

Fensulfothion (sum of fensulfothion, its oxygen analogue and their sulfones, expressed as fensulfothion)

Fentin, expressed as triphenyltin cation

Haloxyfop (sum of haloxyfop, its salts and esters including conjugates, expressed as haloxyfop)

Heptachlor and *trans*-heptachlor epoxide, expressed as heptachlor

Hexachlorobenzene

Nitrofen

Omethoate

Terbufos (sum of terbufos, its sulfoxide and sulfone, expressed as terbufos)

ANNEX VI

NAMES REFERRED TO IN ARTICLE 5

PART A

Name referred to in Article 5(1)

The name of infant formula and follow-on formula other than infant formula and follow-on formula manufactured entirely from cows' milk or goats' milk proteins shall be respectively **[**F11“ Infant formula ” and “Follow-on formula”.**]**

Textual Amendments

F11 Words in Annex 6 Pt. A substituted (31.12.2020) by The Nutrition (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1476), regs. 1(3), **8(6)(a)**

PART B

Name referred to in Article 5(2)

The name of infant formula and follow-on formula manufactured entirely from cows' milk or goats' milk proteins shall be respectively **[**F12“Infant milk” and “Follow-on milk”.**]**

Textual Amendments

F12 Words in Annex 6 Pt. B substituted (31.12.2020) by The Nutrition (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1476), regs. 1(3), **8(6)(b)**

ANNEX VII

REFERENCE INTAKES REFERRED TO IN ARTICLE 7(7)

Nutrient	Reference intake
Vitamin A	(µg) 400
Vitamin D	(µg) 7
Vitamin E	(mg TE) 5
Vitamin K	(µg) 12
Vitamin C	(mg) 45
Thiamine	(mg) 0,5
Riboflavin	(mg) 0,7
Niacin	(mg) 7

Vitamin B_6	(mg) 0,7
Folate	(µg) 125
Vitamin B_{12}	(µg) 0,8
Pantothenic acid	(mg) 3
Biotin	(µg) 10
Calcium	(mg) 550
Phosphorus	(mg) 550
Potassium	(mg) 1 000
Sodium	(mg) 400
Chloride	(mg) 500
Iron	(mg) 8
Zinc	(mg) 5
Iodine	(µg) 80
Selenium	(µg) 20
Copper	(mg) 0,5
Magnesium	(mg) 80
Manganese	(mg) 1,2

(**1**) OJ L 181, 29.6.2013, p. 35.

(**2**) Commission Directive 2006/141/EC of 22 December 2006 on infant formulae and follow-on formulae and amending Directive 1999/21/EC (OJ L 401, 30.12.2006, p. 1).

(**3**) Directive 2009/39/EC of the European Parliament and of the Council of 6 May 2009 on foodstuffs intended for particular nutritional uses (OJ L 124, 20.5.2009, p. 21).

(**4**) EFSA NDA Panel (EFSA Panel on Dietetic Products, Nutrition and Allergies), 2014. Scientific Opinion on the essential composition of infant and follow-on formulae. EFSA Journal 2014;12(7):3760.

(**5**) Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC (OJ L 309, 24.11.2009, p. 1).

(**6**) Opinion of the Scientific Committee for Food on a maximum residue limit (MRL) of 0,01 mg/kg for pesticides in foods intended for infants and young children (expressed on the 19 September 1997).

(**7**) Further advice on the opinion of the Scientific Committee for Food expressed on the 19 September 1997 on a Maximum Residue Limit (MRL) of 0,01 mg/kg for pesticides in foods intended for infants and young children (adopted by the SCF on 4 June 1998).

(**8**) Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004 (OJ L 304, 22.11.2011, p. 18).

(**9**) 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 (OJ L 404, 30.12.2006, p. 9).

(**10**) OJ C 213, 8.7.2014, p. 1.

(**11**) Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1).

Status:
Point in time view as at 21/02/2021.

Changes to legislation:
There are currently no known outstanding effects for the Commission Delegated Regulation (EU) 2016/127.