**WORKING DOCUMENT**

**on the adoption of a delegated Regulation on infant formula and follow-on formula pursuant to Article 11(1) of Regulation (EU) No 609/2013**

[Supporting Document for the Expert Group meeting of 18 February 2015]

# Introduction

Article 11(1) of Regulation (EU) No 609/2013 on food intended for infants and young children, food for special medical purposes and total diet replacement for weight control[1] (the FSG Regulation) empowers the Commission to adopt specific compositional and information requirements by the means of delegated acts for the categories of foods covered by the Regulation.

This Working Document seeks the views of experts on the different aspects that shall be covered by the future Commission delegated Regulation to be adopted pursuant to Article 11(1) of the FSG Regulation on infant formula and follow-on formula.

The text included in this Working Document is based on the existing provisions of Commission Directive 2006/141/EC[2]. It is updated taking into account EFSA's Scientific Opinion on the essential composition of infant and follow-on formulae[3] and discussions carried out with Member States' experts, relevant NGOs and stakeholders so far. In particular, it takes into account the discussions held during the Expert Group meeting of 2 February 2015.

This Working Document presents the recitals, Articles and Annexes that are considered for inclusion in the Commission delegated Regulation. As regards Articles and Annexes, the document also provides explanations of the different provisions.

This Working Document is aimed at facilitating the discussions on 18 February 2015 and is without prejudice to the final decision the Commission will take when adopting the delegated Regulation pursuant to Article 11(1) of the FSG Regulation. It was also shared with stakeholders and NGOs and will be discussed with them during a Working Group meeting of the Advisory Group on the Food Chain and Animal and Plant Health on 17 February 2015.

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1 Regulation (EU) No 609/2013 of the European Parliament and of the Council on food intended for infants and young children, food for special medical purposes and total diet replacement for weight control, OJ L 181, 29.6.2013, p. 35

2 Commission Directive 2006/141/EC on infant formulae and follow-on formulae, OJ L 401, 30.12.2006, p.1

3 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, 106 pp. doi:10.2903/j.efsa.2014.3760 http://www.efsa.europa.eu/fr/efsajournal/doc/3760.pdf

# A. RECITALS

*The following text is being considered for the recitals that could be included in the delegated Regulation:*

(1) Commission Directive 2006/141/EC[4] lays down, under the framework of Directive 2009/39/EC of the European Parliament and of the Council[5], harmonised rules on infant formula and follow-on formula.

(2) In the context of the revision of the legislation on foodstuffs intended for particular nutritional uses, Regulation (EU) No 609/2013 repeals Directive 2009/39/EC and Directive 2006/141/EC and lays down general compositional and information requirements for different categories of foods including infant formula and follow-on formula. The Regulation also foresees the establishment of specific compositional and information requirements for infant formula and follow-on formula by means of delegated acts, taking into account the provisions of Directive 2006/141/EC, by 20 July 2015.

(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 the only product marketed as suitable for such use during the period would be infant formula.

(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 provisions should be laid down on the composition of infant formula and follow-on formula, including 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')[6] on the matter and should be updated in the future depending on scientific and technological developments.

(6) In order to ensure innovation and product development, the voluntary addition of ingredients not covered by specific requirements in this Regulation to infant formula and follow-on formula should be possible. However, 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. This is particularly important for ingredients that are not covered by specific requirements in this Regulation. 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.

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

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

6 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

(7) Commission Directive 2006/141/EC lays down specific requirements on the use of pesticides in products intended for the production of and on pesticide residues in infant formula and follow-on formula, based on two opinions given by the Scientific Committee for Food (SCF) on 19 September 1997[7] and 4 June 1998[8]. Because of the scientific uncertainty at that time as to the adequacy of existing acceptable daily intake (ADI) values of pesticides and pesticide residues for the protection of the health of infants and young children, it was considered appropriate to adopt, on the basis of the precautionary principle, a very low common limit for all pesticides. This very low common limit was fixed at 0,01 mg/kg which was in practice the limit of quantification. In addition, more severe limitations were set in the case of 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 ADI for infants and young children. This was the case for pesticides or metabolites of pesticides with an ADI lower than 0,0005 mg/kg body weight/day.

(8) Regulation (EU) No 609/2013 empowers the Commission to adopt specific requirements on the use of pesticides in products intended for the production of the food covered by the Regulation, including infant formula and follow-on formula, and on pesticide residues in such food, when establishing specific requirements for the foods covered by the Regulation, by means of delegated acts. The Regulation also requires that the specific requirements on pesticides for the categories of food for infants and young children under its scope, including infant formula and follow-on formula, should be updated regularly and include, inter alia, provisions to restrict the use of pesticides as much as possible. A restriction on, or a prohibition of use would however not necessarily guarantee that food covered by the Regulation, including food for infants and young children, is free from pesticides, since some pesticides are persistent in the environment and their residues can be found in the food. For this reason Regulation (EU) No 609/2013 foresees that the MRLs in such food should be set at the lowest achievable level to protect vulnerable population groups, taking into account good agricultural practices as well as other sources of exposure, such as environmental contamination.

(9) With respect to infant formula and follow-on formula, Regulation (EU) No 609/2013 foresees that restrictions on and prohibitions of certain pesticides equivalent to those currently established in the Annexes to Directive 2006/141/EC should be taken into account in the delegated act laying down requirements for these foods. When updating such restrictions and prohibitions, particular attention should be paid to certain substances of concern, with the objective to ultimately avoid their use.

(10) Exchanges between the Commission and the Authority have revealed that a thorough update of the rules on pesticides in foods for infants and young children would require a significant amount of time given that a comprehensive evaluation should be carried out on a number of aspects, including the appropriateness of the toxicological reference values for infants and young children as such. For this reason, and in order to respect the provisions of Regulation (EU) No 609/2013 whereby specific compositional and information requirements for infant formula and follow-on formula

[7] 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 19th September 1997)

[8] 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)

should be established by 20 July 2015, the relevant existing requirements of Directive 2006/141/EC should, at this stage, be maintained as they are. These requirements should be updated in the future, taking into account the opinion of the Authority on the matter.

(11) Infant formula and follow-on formula should comply with the provisions of Regulation (EU) No 1169/2011 of the European Parliament and of the Council[9]. 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 lays down additions and exceptions to those general rules, where appropriate.

(12) 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 different formula products so as to avoid any risk of confusion.

(13) The nutrition declaration for infant formula and follow-on formula is essential for parents and caregivers as well as for health care professionals, who recommend their consumption, in order to guarantee their appropriate use. For this reason, in order to provide more complete information to parents, caregivers and healthcare professionals, all infant formula and follow-on formula should provide the mandatory nutrition declaration, irrespective of the package size, and the nutrition declaration should include more particulars than those required by Regulation (EU) No 1169/2011. In addition, 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.

(14) Article 30(2) of Regulation (EU) No 1169/2011 limits the particulars that can be included on a voluntary basis in the nutrition declaration for food. The Annex of Regulation (EU) No 609/2013 lists a series of nutrients that may be added to infant formula and follow-on formula and some of these are not covered by Article 30(2) of Regulation (EU) No 1169/2011. In order to ensure legal clarity, it should be clarified that the nutrition declaration for infant formula and follow-on formula may include indication on nutrients which may be added to the products in question and are listed in Annex of Regulation (EU) No 609/2013. 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.

(15) 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. Expression of nutrition information on the energy value and the amount of nutrients of infant formula as percentage of daily reference intake values would therefore mislead consumers and should 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 this reason, and in order to ensure comparisons with other foods that can be included in the diet of infants and young children together with complementary feeding, expression of nutrition information for follow-on formula as percentage of daily reference intake values

[9] 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 (OJ L 304, 22.11.2011, p. 18)

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 not be allowed. Follow-on formula should only be allowed to express nutrition information as a percentage of specific reference intakes that are appropriate for the age group.

(16) In order to ensure consistency with the approach followed in Regulation (EU) No 609/2013, statements related to the presence or absence of lactose in infant formula and follow-on formula should not be considered as nutrition claims pursuant to Regulation (EC) No 1924/2006 of the European Parliament and of the Council[10]. Such statements provide important information to parents and caregivers and harmonised conditions should be laid down in this Regulation in order to ensure the free movement of the formula bearing such statements and the same high level of protection for consumers in the EU.

(17) Nutrition and health claims are promotional tools that are used on a voluntary basis by operators in commercial communication, in line with the rules of Regulation (EC) No 1924/2006. Given the particular role of infant formula in the diet of infants, only a very limited number of claims should be allowed for infant formula, provided that they are substantiated by generally accepted scientific data. Specific conditions for their use should be set out in this Regulation.

(18) Given the particular role of infant formula in the diet of infants, the use of claims on ingredients of infant formula whose presence is required by the legislation should not be allowed as this could be confusing for parents and caregivers. The mandatory addition of docosahexaenoic acid (DHA) to formula has however been recently recommended by the Authority. Given that addition of DHA was allowed on a voluntary basis in the past, and parents and caregivers are familiar with the nutrition claim about the presence of DHA in infant formula, operators should be allowed to continue to use this claim for a limited period of time in order to avoid confusion. However, it is important that full information is provided to consumers about the mandatory presence of DHA in all formula products on the market.

(19) The use of protein hydrolysates as a source of protein in infant formula and follow-on formula has been allowed under EU legislation 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 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 the legislation currently in force. In its opinion on the essential composition of infant and follow-on formula, 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 for its safety and suitability 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. In order to safeguard the health of infants, the suitability of each formula manufactured from protein hydrolysates with a composition different from the one already positively assessed should be evaluated on a case-by-case basis by the Authority before being authorised for use in the EU. In addition, in

[10] 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)

order to ensure that parents and caregivers are not misled by unsubstantiated claims, the Authority's case-by-case assessment on a specific formula should also precede authorisation of use of a claim on the properties of that product to reduce the risk of developing allergy to milk proteins. The relevant requirements in this Regulation should be updated in the future depending on scientific and technological developments and specific guidelines should be issued by the Commission on the matter.

(20) In an effort to provide better protection for the health of infants, the rules of composition, labelling and advertising laid down in this Regulation should be in conformity with the principles and the aims of the International Code of Marketing of Breast-milk Substitutes adopted by the 34th World Health Assembly, bearing in mind the particular legal and factual situations existing in the EU.

(21) Given the important role which information on infant feeding plays in choosing, by pregnant women, parents and caregivers, the type of nourishment provided to their children, it is necessary for Member States to take appropriate measures in order that this information ensures an adequate use of the products in question and is not counter to the promotion of breast feeding.

(22) This Regulation does not concern the conditions of sale of publications specialising in baby care and of scientific publications.

(23) 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, the competent authorities of Member States may request at any time the food business operator placing infant formula and follow-on formula on the market to produce all relevant elements and data establishing compliance with this Regulation. In addition, given the particular nature of infant formula, additional means to those usually available to monitoring bodies should be available in order to facilitate efficient monitoring of this type of food. Such additional means should also apply to follow-on formula manufactured from protein hydrolysates, taking into account the specific provisions introduced by this Regulation for this type of formula product.

(24) Adequate transitional measures should be foreseen to enable food business operators to adapt to the requirements of this Regulation,

[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)

# B. ARTICLES

*The following text is being considered for the Articles that could be included in the delegated Regulation. Explanations are provided in the boxes.*

## CHAPTER 1

## SUBJECT MATTER, SCOPE AND PLACING ON THE MARKET

### Article 1
### Subject matter and scope

***[cf. Article 1 of Directive 2006/141/EC]***

1. This delegated Regulation lays down specific requirements for infant formula and follow-on formula intended for use by infants in good health in the EU, pursuant to Article 11(1) of Regulation (EU) No 609/2013.

2. This delegated Regulation also provides for Member States to give effect to principles and aims of the International Code of Marketing of Breast-milk Substitutes dealing with marketing, information and responsibilities of health authorities.

➔ As it is the case today in Directive 2006/141/EC, this provision clearly states the subject matter and scope of the delegated Regulation.

### Article 2
### Placing on the market

***[cf. Article 3 of Directive 2006/141/EC]***

1. Infant formula and follow-on formula may be marketed within the Union only 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.

➔ This provision repeats text already present in Directive 2006/141/EC. It establishes the requirement whereby only products complying with the delegated Regulation may be marketed within the EU.

Paragraph 2 lays down additional requirements taking into account the particular nature of infant formula in the diet of infants.

## CHAPTER 2

## REQUIREMENTS ON COMPOSITION AND PESTICIDES

### Article 3
### Suitability of ingredients for infant formula

***[cf. Article 5 of Directive 2006/141/EC]***

Infant formula shall be manufactured from protein sources defined 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.

Such suitability shall be demonstrated 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.

➔ This provision repeats text currently present in Directive 2006/141/EC and establishes the requirement on the suitability of all ingredients used in infant formula.

### Article 4
### Suitability of ingredients for follow-on formula

***[cf. Article 6 of Directive 2006/141/EC]***

Follow-on formula shall be manufactured from protein sources defined 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.

Such suitability shall be demonstrated 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.

➔ This provision repeats text currently present in Directive 2006/141/EC and establishes the requirement on the suitability of all ingredients used in follow-on formula.

### Article 5
### Composition requirements for infant formula and follow-on formula

***[cf. Article 7 of Directive 2006/141/EC]***

1. Infant formula shall comply with the compositional criteria set out in Annex I taking into account the specifications in Annex III.

*2.* Follow-on formula shall comply with the compositional criteria set out in Annex II taking into account the specifications set out in Annex III.

3. Infant formula and follow-on formula manufactured from protein hydrolysates shall, in addition, comply with the specifications for protein set out in Annex IV.

4. In order to make infant formula and follow-on formula ready for use, nothing more shall be required, as the case may be, than the addition of water.

➔ The delegated Regulation will need to lay down detailed compositional requirements for infant formula and follow-on formula. As it is the case in Directive 2006/141/EC, the provisions above foresee that infant formula and follow-on formula shall comply with the detailed provisions laid down in the relevant Annexes (updated on the basis of EFSA's advice) and that only water can be added to make the products ready for use.

The provisions of paragraphs 1 and 2, already present in Directive 2006/141/EC, are updated taking into account EFSA's advice that "*Based on the studies which investigated the adequacy of infant formula containing around 1.8 g protein per 100 kcal, the Panel considers that a minimum protein content in infant formula and follow-on formula of 1.8 g/100 kcal (0.43 g/100 kJ) for cow's and goat's milk-based formulae is suitable to satisfy the nutritional requirements of infants*". For this reason, the request for appropriate studies in case of formulae with a low protein content foreseen by Directive 2006/141/EC is deleted.

The provision of paragraph 3 is **new** and is drafted taking into account EFSA's concern that "*the safety and suitability of each specific formula containing protein hydrolysates has to be established by clinical studies. Information on protein sources and the technological process applied should also be provided*". As noted by EFSA, for the moment only "*one particular formula containing partially hydrolysed whey protein has been evaluated for its safety and suitability by the Panel (EFSA, 2005f) and has been authorised for use by Directive 2006/141/EC*". The provision of paragraph 3 foresees that products whose safety and suitability has already been positively assessed should be allowed to continue to be marketed. As it is explained in recital 19, for other products, such safety and suitability shall be demonstrated on a case-by-case basis. It should be assessed by EFSA and, in case of positive assessment, should be authorised in the delegated Regulation [this provision is to be read together with the provision in Annex V, point 2 on the "hypoallergenic" claim]. Adequate transition periods are foreseen to allow operators to comply with this new provision (cf. Article 15).

## Article 6
## Requirements on pesticides

***[cf. Article 10 of Directive 2006/141/EC]***

1. For the purposes of this Article, 'pesticide residue' means the residue in infant formula and follow-on formula of a plant protection product, as referred to in Article 2(1) of Regulation (EC) No 1107/2009 of the European Parliament and of the Council[12], including its metabolites and products resulting from its degradation or reaction.
2. Infant formula and follow-on formula shall not contain residues of individual pesticides at levels exceeding 0,01 mg/kg.

Analytical methods for determining the levels of pesticide residues shall be generally acceptable standardised methods.

3. The pesticides listed in Annex VII shall not be used in agricultural products intended for the production of infant formula and follow-on formula.

However, for the purpose of controls:

[12] 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

(a) pesticides listed in Table 1 of Annex VII are considered not to have been used if their residues do not exceed a level of 0,003 mg/kg. This level, which is considered to be the limit of quantification of the analytical methods, shall be kept under regular review in the light of technical progress;

(b) pesticides listed in Table 2 of Annex VII are considered not to have been used if their residues do not exceed a level of 0,003 mg/kg. This level shall be kept under regular review in the light of data on environmental contamination.

4. By way of derogation from paragraph 2, for the pesticides listed in Annex VIII, the maximum residue levels specified therein shall apply.

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

➔ The provisions in this Article maintain the existing provisions on pesticides and pesticides residues of Directive 2006/141/EC. The FSG Regulation requires that rules on pesticides in infant formula and follow-on formula are updated regularly and include, *inter alia*, provisions to restrict the use of pesticides as much as possible (Article 11(1)(b)). Recitals mention that MRLs should be set at the lowest achievable level and that restrictions equivalent to those laid down in Directive 2006/141/EC should be taken into account in the delegated act.

Exchanges between the Commission and EFSA have revealed that a thorough update of the rules on pesticides in foods for infants and young children would require a significant amount of time given that a comprehensive evaluation should be carried out on a number of aspects, including the appropriateness of the toxicological reference values for infants and young children as such. For this reason, and in order to respect the provisions of Regulation (EU) No 609/2013 whereby specific compositional and information requirements for infant formula and follow-on formula should be established by 20 July 2015, the relevant existing requirements of Directive 2006/141/EC should, at this stage, be maintained as they are. At the same time, EFSA will be requested to provide a full scientific assessment on the matter so that the rules are updated in the future based on the latest scientific advice.

## CHAPTER 3

## REQUIREMENTS ON FOOD INFORMATION

### Article 7
### Name of the food

***[cf. Article 11 of Directive 2006/141/EC]***

Except as provided for in Article 8, the name of infant formula and follow-on formula shall be, respectively:

- in Bulgarian: ‘храни за кърмачета’ and ‘преходни храни’,
- in Spanish: ‘Preparado para lactantes’ and ‘Preparado de continuación’,
- in Czech: ‘počáteční kojenecká výživa’ and ‘pokračovací kojenecká výživa’,
- in Danish: ‘Modermælkserstatning’ and ‘Tilskudsblanding’,
- in German: ‘Säuglingsanfangsnahrung’ and ‘Folgenahrung’,

- in Estonian: ‘imiku piimasegu’ and ‘jätkupiimasegu’,
- in Greek: ‘Παρασκεύασμα για βρέφη’ and ‘Παρασκεύασμα δεύτερης βρεφικής ηλικίας’,
- in English: ‘infant formula’ and ‘follow-on formula’,
- in French: ‘Préparation pour nourrissons’ and ‘Préparation de suite’,
- in Croatian: ‘početna hrana za dojenčad’ and ‘prijelazna hrana za dojenčad’,
- in Italian: ‘Alimento per lattanti’ and ‘Alimento di proseguimento’,
- in Latvian: ‘Mākslīgais maisījums zīdaiņiem’ un ‘Mākslīgais papildu ēdināšanas maisījums zīdaiņiem’,
- in Lithuanian: ‘mišinys kūdikiams iki papildomo maitinimo įvedimo’ and ‘mišinys kūdikiams, įvedus papildomą maitinimą’,
- in Hungarian: ‘anyatej-helyettesítő tápszer’ and ‘anyatej-kiegészítő tápszer’,
- in Maltese: ‘formula tat-trabi’ and ‘formula tal-prosegwiment’,
- in Dutch: ‘Volledige zuigelingenvoeding’ and ‘Opvolgzuigelingenvoeding’,
- in Polish: ‘preparat do początkowego żywienia niemowląt’ and ‘preparat do dalszego żywienia niemowląt’,
- in Portuguese: ‘Fórmula para lactentes’ and ‘Fórmula de transição’,
- in Romanian: ‘preparate pentru sugari’ and ‘preparate pentru copii de vârstă mică’,
- in Slovak: ‘počiatočná dojčenská výživa’ and ‘následná dojčenská výživa’.
- in Slovenian: ‘začetna formula za dojenčke’ and ‘nadaljevalna formula za dojenčke’,
- in Finnish: ‘Äidinmaidonkorvike’ and ‘Vieroitusvalmiste’,
- in Swedish: ‘Modersmjölksersättning’ and ‘Tillskottsnäring’.

➔ The delegated Regulation will include the name of "infant formula" and "follow-on formula" in the different languages, as it is currently the case in Directive 2006/141/EC. The same names mentioned in Directive 2006/141/EC have been taken here.

## Article 8
## Name of the food for products manufactured entirely from cows' milk or goats' milk protein

***[cf. Article 12 of Directive 2006/141/EC]***

The name of infant formula and follow-on formula manufactured entirely from cows’ milk or goats’ milk proteins shall be respectively:

- in Bulgarian: ‘млека за кърмачета’ and ‘преходни млека’,
- in Spanish: ‘Leche para lactantes’ and ‘Leche de continuación’,
- in Czech: ‘počáteční mléčná kojenecká výživa’ and ‘pokračovací mléčná kojenecká výživa’,
- in Danish: ‘Modermælkserstatning udelukkende baseret på mælk’ and ‘Tilskudsblanding udelukkende baseret på mælk’,
- in German: ‘Säuglingsmilchnahrung’ and ‘Folgemilch’,

- in Estonian: ‘Piimal põhinev imiku piimasegu’ and ‘Piimal põhinev jätkupiimasegu’,
- in Greek: ‘Γάλα για βρέφη’ and ‘Γάλα δεύτερης βρεφικής ηλικίας’,
- in English: ‘infant milk’ and ‘follow-on milk’,
- in French: ‘Lait pour nourrissons’ and ‘Lait de suite’,
- in Croatian: ‘početna mliječna hrana za dojenčad’ and ‘prijelazna mliječna hrana za dojenčad’,
- in Italian: ‘Latte per lattanti’ and ‘Latte di proseguimento’,
- in Latvian: ‘Mākslīgais piena maisījums zīdaiņiem’ un ‘Mākslīgais papildu ēdināšanas piena maisījums zīdaiņiem’,
- in Lithuanian: ‘pieno mišinys kūdikiams iki papildomo maitinimo įvedimo’ and ‘pieno mišinys kūdikiams įvedus papildomą maitinimą’,
- in Hungarian: ‘tejalapú anyatej-helyettesítő tápszer’ and ‘tejalapú anyatej-kiegészítő tápszer’,
- in Maltese: ‘ħalib tat-trabi’ and ‘ħalib tal-prosegwiment’,
- in Dutch: ‘Volledige zuigelingenvoeding op basis van melk’ or ‘Zuigelingenmelk’ and ‘Opvolgmelk’,
- in Polish: ‘mleko początkowe’ and ‘mleko następne’,
- in Portuguese: ‘Leite para lactentes’ and ‘Leite de transição’,
- in Romanian: ‘lapte pentru sugari’ and ‘lapte pentru copii de vârstă mică’;
- in Slovak: ‘počiatočná dojčenská mliečna výživa’ and ‘následná dojčenská mliečna výživa’,
- in Slovenian: ‘začetno mleko za dojenčke’ and ‘nadaljevalno mleko za dojenčke’,
- Finnish: ‘Maitopohjainen äidinmaidonkorvike’ and ‘Maitopohjainen vieroitusvalmiste’,
- in Swedish: ‘Modersmjölksersättning uteslutande baserad på mjölk’ and ‘Tillskottsnäring uteslutande baserad på mjölk’.

➔ The delegated Regulation will include the name of "infant milk" and "follow-on milk" in the different languages, as it is currently the case in Directive 2006/141/EC. The same names mentioned in Directive 2006/141/EC have been taken here.

**Article 9**
**Specific requirements on labelling, presentation and advertising**

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

➔ This **new** paragraph would generally clarify the relation between the FIC Regulation and this delegated Regulation with respect to food information.

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

(a) in the case of infant formula, a statement to the effect that the product is suitable for infants from birth when they are not breast fed ***[cf. Article 13(1)(a) of Directive 2006/141/EC]***;

(b) in the case of follow-on formula, a statement to the effect 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 ***[cf. Article 13(1)(b) of Directive 2006/141/EC]***;

(c) instructions for appropriate preparation, storage and disposal of the product and a warning against the health hazards of inappropriate preparation and storage ***[cf. Article 13(1)(e) of Directive 2006/141/EC]***;

(d) in the case of infant formula, 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 ***[cf. Article 13(4)(a) and (b) of Directive 2006/141/EC]***.

Indication of the particulars referred to in letter (d) shall be preceded by the words 'important notice' or their equivalent and shall be given also in the presentation and advertising of infant formula ***[cf. Article 13(4) and Article 13(8) of Directive 2006/141/EC]***.

➔ This paragraph repeats some of the existing provisions of Directive 2006/141/EC.

3. In addition to the requirement of Article 10 of Regulation (EU) No 609/2013, the labelling, presentation and advertising of infant formula and follow-on formula shall be designed to provide the necessary information about the appropriate use of the products so as not to discourage breast feeding.

The use of the terms 'humanised', 'maternalised', 'adapted', or similar terms shall be prohibited ***[cf. Article (13)(3), 13(5) and Article 13(8) of Directive 2006/141/EC]***.

➔ This paragraph repeats existing provisions of Directive 2006/141/EC and, in addition, refers to the new provisions introduced by the FSG Regulation for infant formula and follow-on formula. Repetitions of provisions laid down by the basic act (e.g. the prohibition to use pictures of infants in the labelling of follow-on formula) should be avoided in the delegated act.

4. The labelling, presentation and advertising of infant formula and follow-on formula shall be designed in such a way that it enables consumers to make a clear distinction between such products so as to avoid any risk of confusion between infant formula and follow-on formula ***[cf. Article 13(7) and Article 13(8) of Directive 2006/141/EC]***.

➔ This paragraph repeats an existing provision of Directive 2006/141/EC.

5. Article 13(2) and (3) of Regulation (EU) No 1169/2011 shall apply to all mandatory particulars for infant formula and follow-on formula.

➔ This **new** paragraph is aimed at ensuring that rules on font size in the FIC Regulation would apply to all mandatory particulars required for infant formula and follow-on formula (and not only those foreseen in FIC).

**Article 10**
**Specific requirements on the nutrition declaration**

1. The mandatory nutrition declaration for infant formula and follow-on formula shall include, in addition to the particulars listed in Article 30(1) of Regulation (EU) No 1169/2011 with the exception of salt, the following:

   (a) the amount of each mineral substance and of each vitamin listed in Annex I and II respectively and present in the product;

   (b) in the case of infant formula, the amount of choline, inositol and carnitine.

   ***[cf. Article 13(1)(c) and (d) of Directive 2006/141/EC]***

➔ This paragraph clarifies that the mandatory nutrition declaration of infant formula and follow-on formula shall include all the nutrients required by FIC with the exception of salt (given that indication could be misleading) as well as other specific nutrients whose indication is useful for the intended use of the product (as currently foreseen by Directive 2006/141/EC).

2. The content of the mandatory nutrition declaration referred to in paragraph 1 may be supplemented, in addition to the particulars listed in Article 30(2)(a) to (e) of Regulation (EU) No 1169/2011, with:

   a) Selectively an indication of the amounts of components of carbohydrate and fat;

   b) An indication of the whey/casein ratio;

   c) An indication of the amount of any of the nutrients listed in Annex of Regulation (EU) No 609/2013, provided that such indication is not covered by the provisions of paragraph 1; ***[cf. Article 13(2)(a) of Directive 2006/141/EC]***

➔ This paragraph introduces two **new** provisions (letters (a) and (b)) in order to allow the continuation of practices currently followed by operators that can provide additional useful information to parents and caregivers (e.g. indication of lactose amounts, indication of specific lipids, indication of the whey/casein ratio). In the absence of these specific provisions in the delegated Regulation, such practices would not be allowed anymore under the rules of FIC. The provision under letter (c) repeats an existing provision of Directive 2006/141/EC.

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

➔ This **new** paragraph is aimed at avoiding that the nutrition declaration (or parts of it) is repeated front of pack given that this kind of labelling would not be appropriate for infant formula and follow-on formula.

4. Article 16(3) of Regulation (EU) No 1169/2011 shall not apply to infant formula and follow-on formula in packaging or containers the largest surface of which has an area of less than 25 $cm^2$.

➔ This **new** paragraph is aimed at guaranteeing that all infant formulae and follow-on formulae provide the nutrition declaration, irrespective of the package size (as it is the case today).

5. Without prejudice to the provisions of paragraph 8 of this Article, Article 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.

➔ This **new** paragraph is aimed at ensuring that the requirements of the FIC Regulation on calculation, expression and presentation of the nutrition declaration apply to all the nutrients in the nutrition declaration of infant formula and follow-on formula (and not only those covered by the FIC Regulation). In its absence, legal uncertainty would exist on certain nutrients (e.g. specific fatty acids, lactose). It should be read together with paragraph 8 which lays down specific requirements on the order of presentation of nutrients in the nutrition declaration.

6. By way of derogation from Article 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 only 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 the product as sold. ***[cf. Article 13(1)(c) and (d) and Article 13(2)(a) and (b) of Directive 2006/141/EC]***

➔ This **new** paragraph is aimed at maintaining the status quo as laid down in Directive 2006/141/EC and at derogating from three provisions of the FIC Regulation:

- Article 31(3) which foresees that reference to the amount of energy and nutrients in the food after preparation may replace the one in the food as sold;

- Article 32(2) which foresees that the energy value and amount of nutrients can be expressed per 100 g or 100 ml and

- Article 33(1) which allows for the voluntary expression of the energy value and amount of nutrients per portion and/or per consumption unit under certain conditions.

The last sentence of the paragraph is aimed at introducing a **new** provision that would additionally allow reference to the product as sold as requested by experts in the meeting of 30 October 2013 to take into account that formula is sometimes provided to institutions such as hospitals.

7. By way of derogation from Article 32(3) and 32(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 of Regulation (EU) No 1169/2011.

In the case of follow-on formula, the declaration on vitamins and minerals listed in Annex VI may be expressed as a percentage of the reference intakes set out therein in relation to per 100 ml of the food ready for use after preparation in accordance with the manufacturer's instructions, in addition to the form of expression referred to in paragraph 6 ***[cf. Article 13(2)(b) of Directive 2006/141/EC]***.

➔ The first part of this paragraph is **new.** It is aimed at derogating from the FIC Regulation that lays down rules for the expression of nutrition information as a percentage of reference intakes for adults laid down therein (as this would mislead parents and caregivers taking into account that formulae are intended for infants).

The second part is aimed at maintaining the status quo as laid down in Directive 2006/141/EC and allowing follow-on formula to additionally express amounts of vitamins and minerals as a percentage of specific reference intakes for infants and young children, as laid down in the delegated Regulation.

8. The particulars included in the nutrition declaration for infant formula and follow-on formula that are not listed in Annex XV of 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 of 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 at the end of the nutrition declaration.

➔ These **new** paragraphs are aimed at ensuring that the presentation of the nutrition declaration of infant formula and follow-on formula follows the format set out in the FIC Regulation but taking into account the additional obligations required in the delegated Regulation for infant formula and follow-on formula.

9. 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.

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".

***[cf. Annex IV, points 1.1 and 1.2, of Directive 2006/141/EC]***

➔ The provisions in this paragraph are aimed at clarifying that the statements "*lactose only*" and "*lactose free*", contrary to Directive 2006/141/EC, should not be considered anymore as nutrition claims. This ensures consistency with the general approach for all foods agreed during the negotiations on the FSG Regulation (where it was agreed that the Commission would set harmonised rules on the absence or reduced presence of lactose in all foods under the framework of the FIC Regulation).

The criteria for using the statements "*lactose only*" and "*lactose free*" are the same as those currently foreseen by Directive 2006/141/EC but use of the "*lactose free*" statement is now also allowed on milk-based formulae (see point 8.2 of Annex I and 6.2 of Annex II). When the statement "lactose free" is used on products that are not soy-based, the label should clarify that the product is not suitable for infants with galactosaemia (in line with scientific advice).

## Article 11
## Nutrition and health claims

***[cf. Article 13(6) and Article 13(8) of Directive 2006/141/EC]***

Nutrition and health claims for infant formula shall only be permitted if they are listed in Annex V and are in conformity with the conditions set out therein.

➔ This Article repeats an existing provision of Directive 2006/141/EC with different wording to ensure consistency with the legislation on claims.

**Article 12**
**Additional requirements for promotional and commercial practices for infant formula**

***[cf. Article 14 of Directive 2006/141/EC]***

1. 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 advertisements for infant formula shall be subject to the conditions laid down in Article 9(2)(d), 9(3), 9(4), 11 of this Regulation and Article 10(2) of Regulation (EU) No 609/2013 and 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.

➔ This Article repeats existing provisions of Directive 2006/141/EC.

**Article 13**
**Specific requirements on information on infant and young child feeding**

***[cf. Article 15 of Directive 2006/141/EC]***

1. Member States shall ensure 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 covering the planning, provision, design and dissemination of information and their control.
2. Member States shall ensure that 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.

When 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. Member States shall ensure that 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 appropriate national 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.

4. Member States shall ensure that 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.

➔ This Article repeats existing provisions of Directive 2006/141/EC.

## CHAPTER 4

## MONITORING

### Article 14
### Notification

***[cf. Article 9 of Directive 2006/141/EC]***

To facilitate efficient official monitoring of all infant formula and of those follow-on formula manufactured from protein hydrolysates, when such a product is placed on the market, the food business operator shall notify the competent authority of the Member States where the product is being marketed by forwarding to it a model of the label used for the product.

➔ This Article repeats an existing provision of Directive 2006/141/EC and is aimed at maintaining the notification requirement for all types of infant formula.

In addition, it establishes a **new** notification requirement for follow-on formula manufactured from protein hydrolysates, in order to facilitate the monitoring of these products following EFSA's concerns and the corresponding new relevant provisions of the delegated Regulation.

## CHAPTER 5

## FINAL PROVISIONS

### Article 15
### Entry into force

This Regulation shall enter into force on the […] day following that of its publication in the *Official Journal of the European Union*.

It shall apply from [3 years after entry into force].

It shall not apply to infant formula and follow-on formula manufactured from protein hydrolysates placed on the market before [5 years after entry into force] and complying with Directive 2006/141/EC.

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

➔ This provision establishes the deferred application of the delegated Regulation in order to give sufficient time to operators to adapt to the new requirements laid down therein. Additional time is provided to operators who manufacture formulae for protein hydrolysates, in order to allow them to carry out appropriate studies on specific products as required by the delegated Regulation.

# C. ANNEXES

*The following text is being considered for the Annexes that could be included in the delegated Regulation.*

## ANNEX I

## ESSENTIAL COMPOSITION OF INFANT FORMULA AFTER PREPARATION IN ACCORDANCE WITH THE MANUFACTURER'S INSTRUCTIONS

***[cf. Annex I of Directive 2006/141/EC]**. Explanation will be provided only on provisions that are different from the corresponding requirements of Directive 2006/141/EC*

The values set out in this Annex refer to the food ready for use, marketed as such or after preparation in accordance with the manufacturer's instructions.

➔ The corresponding provision of Directive 2006/141/EC is adjusted to ensure consistency with language used in the FIC Regulation (e.g. Article 31(3))

### 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, the infant formula must contain an available quantity of each indispensable and conditionally indispensable amino acid at least equal to that contained in the reference protein (breast milk, as defined in 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 for use by infants is demonstrated through appropriate studies, performed following generally accepted expert guidance on the design and conduct of such studies.

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

➔ The provision in point 2.1 is updated on the basis of EFSA's advice. More specifically, the maximum protein amount is lowered, requirements for appropriate studies for low-protein formula are removed and amino-acid criteria are updated.

L-carnitine's addition is now required for all types of infant formulae (and not only for infant formulae manufactured from soy protein or protein hydrolysates).

**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 the infant formula must contain an available quantity of each indispensable and conditionally indispensable amino acid at least equal to that contained in the reference protein (breast milk, as defined in 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 for use by infants is demonstrated through appropriate studies, performed following generally accepted expert guidance on the design and conduct of such studies.

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

➔ The provision in point 2.2 is updated on the basis of EFSA's advice. More specifically, the maximum protein amount is lowered, and amino-acid criteria are updated.

**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) |

For an equal energy value, the infant formula must contain an available quantity of each indispensable and conditionally indispensable amino acid at least equal to that contained in the reference protein (breast milk, as defined in Annex III or, in the case of infant formula referred to in Annex IV, as defined therein). 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 for use by infants is demonstrated through appropriate studies,

performed following generally accepted expert guidance on the design and conduct of such studies.

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

➔ The provision in point 2.3 is updated on the basis of EFSA's advice. More specifically, the maximum protein content is lowered, and amino-acid criteria are updated.

Most importantly, the minimum protein content is adjusted to ensure consistency with Annex IV (setting specific conditions for formulae manufactured from protein hydrolysates).

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) |

➔ The provision in point 4 is updated on the basis of EFSA's advice. More specifically, the minimum choline content is increased.

**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.

➔ No change is introduced in point 5.1 when compared to Directive 2006/141/EC. It should however be noted that point 5.2 of Annex I of Directive 2006/141/EC is deleted following EFSA's advice that "*there is no evidence which allows for the proposal of lower or upper bounds of a range for specific types of SFA (MCFAs or lauric, myristic or palmitic acid) in infant formula or follow-on formula*".

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

5.3 The erucic acid content shall not exceed 1 % of the total fat content.

**5.4 Linoleic acid**

| **Minimum** | **Maximum** |
|---|---|
| 120 mg/100 kJ | 300 mg/100 kJ |
| (500 mg/100 kcal) | (1200 mg/100 kcal) |

➔ The provision in point 5.4 is updated on the basis of EFSA's advice. The minimum LA content is increased. The requirement that LA should come in the form of glycerides is removed for consistency with other lipids.

**5.5 Alpha-linolenic acid**

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

➔ The provision in point 5.5 is updated on the basis of EFSA's advice. A fixed maximum amount is proposed and no LA-ALA ratio exists anymore.

**5.6 Docosahexaenoic acid**

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

➔ The provision in point 5.6 is a **new** requirement on the basis of EFSA's advice.

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.

➔ The provision in point 5.7 is updated on the basis of EFSA's advice and taking into account other proposed changes (e.g. mandatory addition of DHA). Addition of other n-3 and n-6 LCP is still allowed under certain conditions.

**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 | 10 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, including syrup-type forms, liquid or dried,
- malto-dextrins,
- pre-cooked starch (naturally free of gluten)
- gelatinised starch (naturally free of gluten)

➔ The provision in point 8.1 is updated on the basis of EFSA's advice. The proposed wording clarifies that glucose syrup is to be considered as a source of glucose and thus the restriction of point 8.4 on the use of glucose (i.e. its use is authorised only on formulae manufactured from protein hydrolysates to mask the bitter taste) applies even to syrups.

**8.2 Lactose**

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

This provision 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 line with the conditions laid down in Article 10(9)

➔ The provision in point 8.2 is updated to make it possible for all infant formulae to bear the statement "*lactose-free*" (unlike today where this statement is reserved *de facto* to formulae manufactured from isolated soy protein) provided that they comply with the conditions of use. This modification would make it unnecessary for operators to market their milk-based lactose-free formulae as FSMPs (it has been argued that since Directive 2006/141/EC does not allow the use of the "*lactose-free*" statement on milk-based formulae, operators are forced to market them as FSMPs). This provision would reflect EFSA's advice that while lactose should be the preferred carbohydrate in formulae because of its predominance in human milk, the new-born's capacity to hydrolyse it from human milk, and the absence of advantages of other glycaemic carbohydrates, there is strictly speaking no lactose requirement for infants.

**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, including syrup-type forms, liquid or dried**

Glucose, including syrup-type forms, liquid or dried, 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).

➔ The provision in point 8.4 is updated on the basis of EFSA's advice and for consistency with point 8.1.

**8.5 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 in accordance with Article 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 | 25 | 60 |
| **Potassium (mg)** | 19,1 | 38 | 80 | 160 |

| | | | | |
|---|---|---|---|---|
| **Chloride (mg)** | 14,3 | 38 | 60 | 160 |
| **Calcium (mg)** | 12 | 33 | 50 | 140 |
| **Phosphorus (mg)** | 6 | 22 | 25 | 90 |
| **Magnesium (mg)** | 1,2 | 3,6 | 5 | 15 |
| **Iron (mg)** | 0,07 | 0,3 | 0,3 | 1,3 |
| **Zinc (mg)** | 0,12 | 0,24 | 0,5 | 1,0 |
| **Copper (µg)** | 14,3 | 25 | 60 | 100 |
| **Iodine (µg)** | 3,6 | 6,9 | 15 | 29 |
| **Selenium (µg)** | 0,72 | 2,05 | 3 | 8,6 |
| **Manganese (µg)** | 0,24 | 25 | 1 | 100 |
| **Molybdenum (µg)** | 0,1 | 3,3 | 0,4 | 14 |
| **Fluoride (µg)** | — | 25 | — | 100 |

The calcium:available phosphorus molar ratio shall not be less than 1 nor greater than 2.

➔ The provisions in point 10.1 are updated on the basis of EFSA's advice. Minimum amounts are revised as proposed by EFSA on the basis of intake levels the Panel had considered adequate for virtually all infants below six months of age for optimal growth and development and an average amount of formula consumed during this period.

Maximum amounts for zinc, iodine and selenium are recalculated and lowered taking into account EFSA's concern that, assuming an energy intake from formula of 700 kcal/day (highest observed mean energy intakes in infants below six months of age), regular consumption of a formula by an infant containing the currently permitted maximum amounts of zinc, iodine, vitamin A, folate (if the whole amount is provided in the form of folic acid) and selenium would imply that the ULs would be exceeded for these nutrients. The proposed maximum amounts ensure that, assuming an energy intake from formula of 700 kcal/day, the UL are not exceeded.

Given that addition of molybdenum is currently not required by Directive 2006/141/EC, no maximum amount exists in the Directive. The proposed maximum amount for molybdenum is calculated assuming an energy intake from formula of 700 kcal/day and under the condition that the UL should not be exceeded.

### 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 | 0,5 | 0,45 | 2 |
| **Phosphorus (mg)** | 7,2 | 25 | 30 | 100 |
| **Zinc (mg)** | 0,18 | 0,3 | 0,75 | 1,25 |

➔ The provision in point 10.2 is updated on the basis of EFSA's advice. Both the minimum and maximum amounts are increased taking into account that the increased content of phytic acid present in soy-based formulae can reduce the availability of certain minerals.

## 11. VITAMINS

| | Per 100 kJ | | Per 100 kcal | |
|---|---|---|---|---|
| | **Minimum** | **Maximum** | **Minimum** | **Maximum** |
| **Vitamin A (µg-RE)** [(1)] | 16,7 | 27,2 | 70 | 114 |
| **Vitamin D (µg)** | 0,48 | 0,72 | 2 | 3 |
| **Thiamin (µg)** | 9,6 | 72 | 40 | 300 |
| **Riboflavin (µg)** | 14,3 | 95 | 60 | 400 |
| **Niacin (mg)** [(2)] | 0,10 | 0,375 | 0,4 | 1,5 |
| **Pantothenic acid (mg)** | 0,10 | 0,475 | 0,4 | 2 |
| **Vitamin $B_6$ (µg)** | 4,8 | 42 | 20 | 175 |
| **Biotin (µg)** | 0,24 | 1,8 | 1 | 7,5 |
| **Folate (µg-DFE)** [(3)] | 3,6 | 6,9 | 15 | 29 |
| **Vitamin $B_{12}$ (µg)** | 0,02 | 0,12 | 0,1 | 0,5 |
| **Vitamin C (mg)** | 0,96 | 7,5 | 4 | 30 |
| **Vitamin K (µg)** | 0,24 | 6 | 1 | 25 |
| **Vitamin E (mg α-tocopherol)** [(4)] | 0,14 | 1,2 | 0,6 | 5 |

([1]) Preformed vitamin A; RE = all trans retinol equivalent.
([2]) Preformed niacin.
([3]) Dietary folate equivalent: 1 µg DFE = 1 µg food folate = 0.6 µg folic acid from formula
([4]) Based on vitamin E activity of RRR-α-tocopherol

➔ The provisions of point 11 are updated on the basis of EFSA's advice. Minimum amounts are revised and maximum amounts for Vitamin A and folate are recalculated and lowered (see point 10.1).

The maximum amount for Vitamin D is equalised to the existing maximum amount for follow-on formula. The value ensures that even with an energy intake from formula of 700 kcal/day the UL should not be exceeded.

Specific conditions for certain vitamins are also updated on the basis of EFSA's advice (e.g. introduction of the concept of dietary folate equivalent, to take into account different absorption efficiency of folates depending on their chemical form).

## 12. NUCLEOTIDES

The following nucleotides may be added:

| | **Maximum[(1)]** | |
|---|---|---|
| | **(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 |

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

# ANNEX II

## ESSENTIAL COMPOSITION OF FOLLOW-ON FORMULA AFTER PREPARATION IN ACCORDANCE WITH THE MANUFACTURER'S INSTRUCTIONS

***[cf. Annex II of Directive 2006/141/EC]****. Explanation will be provided only on provisions that are different from those explained in Annex I for infant formula and from the corresponding requirements of Directive 2006/141/EC. For the other changes, the same reasoning as provided in Annex I should apply.*

The values set out in this Annex refer to the food ready for use, marketed as such or after preparation in accordance with the manufacturer's instructions.

### 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

| **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, the follow-on formula must contain an available quantity of each indispensable and conditionally indispensable amino acid at least equal to that contained in the reference protein (breast milk, as defined in Annex III). Nevertheless, for calculation purposes, the concentration of methionine and cysteine and the concentration of phenylalanine and tyrosine may be added together.

➔ The provision in point 2.1 is updated on the basis of EFSA's advice. No restrictions with respect to amino-acid ratios is needed for follow-on formula, because complementary foods will contribute to amino-acid intakes and the metabolism of older infants is more mature with respect to the capacity to convert methionine to cysteine and phenylalanine to tyrosine**.**

The same reasoning explains why there is no minimum requirement for L-carnitine.

**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, the follow-on formula must contain an available quantity of each indispensable and conditionally indispensable amino acid at least equal to that contained in the reference protein (breast milk, as defined in Annex III). Nevertheless, for calculation purposes, the concentration of methionine and cysteine and the concentration of phenylalanine and tyrosine may be added together.

➔ The provision in point 2.2 is updated on the basis of EFSA's advice. No restrictions with respect to amino-acid is needed for follow-on formula, because complementary foods will contribute to amino-acid intakes and the metabolism of older infants is more mature with respect to the capacity to convert methionine to cysteine and phenylalanine to tyrosine**.**

The same reasoning explains why there is no minimum requirement for L-carnitine.

**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) |

For an equal energy value, the follow-on formula must contain an available quantity of each indispensable and conditionally indispensable amino acid at least equal to that contained in the reference protein (breast milk, as defined in Annex III or, in the case of follow-on formula referred to in Annex IV, as defined therein). Nevertheless, for calculation purposes, the concentration of methionine and cysteine and the concentration of phenylalanine and tyrosine may be added together.

➔ The provision in point 2.3 is updated on the basis of EFSA's advice. No restrictions with respect to amino-acid ratios is needed for follow-on formula, because complementary foods will contribute to amino-acid intakes and the metabolism of older infants is more mature with respect to the capacity to convert methionine to cysteine and phenylalanine to tyrosine**.**

The same reasoning explains why there is no minimum requirement for L-carnitine.

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.

4.3 The erucic acid content shall not exceed 1 % of the total fat content.

**4.4 Linoleic acid**

| **Minimum** | **Maximum** |
|---|---|
| 120 mg/100 kJ | 300 mg/100 kJ |
| (500 mg/100 kcal) | (1200 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) | - |

This provision 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 line with the conditions laid down in Article 10(9)

### 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, including syrup-type forms, liquid or dried

Glucose, including syrup-type forms, liquid or dried, 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).

## 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 in accordance with Article 4.

## 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 | 25 | 60 |
| **Potassium (mg)** | 19,1 | 38 | 80 | 160 |
| **Chloride (mg)** | 14,3 | 38 | 60 | 160 |
| **Calcium (mg)** | 12 | 33 | 50 | 140 |
| **Phosphorus (mg)** | 6 | 22 | 25 | 90 |
| **Magnesium (mg)** | 1,2 | 3,6 | 5 | 15 |
| **Iron (mg)** | 0,14 | 0,5 | 0,6 | 2 |
| **Zinc (mg)** | 0,12 | 0,24 | 0,5 | 1,0 |
| **Copper (µg)** | 14,3 | 25 | 60 | 100 |
| **Iodine (µg)** | 3,6 | 6,9 | 15 | 29 |
| **Selenium (µg)** | 0,72 | 2,05 | 3 | 8,6 |
| **Manganese (µg)** | 0,24 | 25 | 1 | 100 |
| **Molybdenum (µg)** | 0,1 | 3,3 | 0,4 | 14 |
| **Fluoride (µg)** | — | 25 | — | 100 |

The calcium:available phosphorus molar ratio shall not be less than 1 nor greater than 2.

### 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 | 0,65 | 0,9 | 2,5 |
| **Phosphorus (mg)** | 7,2 | 25 | 30 | 100 |
| **Zinc (mg)** | 0,18 | 0,3 | 0,75 | 1,25 |

## 9. VITAMINS

| | Per 100 kJ | | Per 100 kcal | |
|---|---|---|---|---|
| | **Minimum** | **Maximum** | **Minimum** | **Maximum** |
| **Vitamin A (µg-RE)** [(1)] | 16,7 | 27,2 | 70 | 114 |
| **Vitamin D (µg)** | 0,48 | 0,72 | 2 | 3 |
| **Thiamin (µg)** | 9,6 | 72 | 40 | 300 |
| **Riboflavin (µg)** | 14,3 | 95 | 60 | 400 |
| **Niacin (mg)** [(2)] | 0,10 | 0,375 | 0,4 | 1, 5 |
| **Pantothenic acid (mg)** | 0,10 | 0,475 | 0,4 | 2 |
| **Vitamin $B_6$ (µg)** | 4,8 | 42 | 20 | 175 |
| **Biotin (µg)** | 0,24 | 1,8 | 1 | 7,5 |
| **Folate (µg-DFE)** [(3)] | 3,6 | 6,9 | 15 | 29 |
| **Vitamin $B_{12}$ (µg)** | 0,02 | 0,12 | 0,1 | 0,5 |
| **Vitamin C (mg)** | 0,96 | 7,5 | 4 | 30 |
| **Vitamin K (µg)** | 0,24 | 6 | 1 | 25 |
| **Vitamin E (mg α-tocopherol)** [(4)] | 0,14 | 1,2 | 0,6 | 5 |

([1]) Preformed vitamin A; RE = all trans retinol equivalent.
([2]) Preformed niacin.
([3]) Dietary folate equivalent - 1 µg DFE = 1 µg food folate = 0.6 µg folic acid from formula
([4]) Based on vitamin E activity of RRR-α-tocopherol

## 10. NUCLEOTIDES

The following nucleotides may be added:

| | **Maximum**[1] | |
|---|---|---|
| | **(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 |
| [1] 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

***[cf. Annex V of Directive 2006/141/EC]***

For the purpose of this Regulation, 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 [(1)]** | **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 |
| [(1)] 1 kJ = 0,239 kcal. | | |

➔ This Annex transfers Annex V of Directive 2006/141. Reference is made to cysteine (instead of cystine, as it is the case today) given that cystine (disulphide) is a molecule which is made up of two molecules cysteine (amino-acid). This is also consistent with EFSA's advice.

# ANNEX IV

## SPECIFICATIONS FOR INFANT FORMULA AND FOLLOW-ON FORMULA MANUFACTURED FROM PROTEIN HYDROLYSATES

***[cf. Annex VI of Directive 2006/141/EC]***

### 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. 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.

### 3. Protein quality

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[(1)]** | **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 |
| [(1)] 1 kJ = 0,239 kcal. | | |

➔ This Annex transfers Annex VI of Directive 2006/141/EC. The provisions are updated in line with the new requirements applying to formulae manufactured from protein hydrolysates laid down in Article 5(3).

# ANNEX V

## NUTRITION AND HEALTH CLAIMS FOR INFANT FORMULA AND CONDITIONS OF USE OF THE CLAIMS

***[cf. Annex IV of Directive 2006/141/EC]***

1. NUTRITION CLAIMS

| **Nutrition claim** | **Conditions of use of the claim** |
|---|---|
| 1.1 "*Contains Docosahexaenoic acid / DHA (as required by the legislation for all infant formula)*" | Compliance with the requirements laid down in point 5.6 of Annex I |

The possibility to use this claim shall be limited to products placed on the market before [5 years after entry into application]

➔ The list of permitted nutrition claims on infant formula is updated taking into account EFSA's advice. Three nutrition claims on substances that can be added on a voluntary basis to infant formula (taurine, FOS/GOS and nucleotides) are removed. The wording and conditions of use of the claim on DHA content are modified taking into account that it is now proposed to require DHA addition to all formulae. It is proposed to allow use of the claim for a limited period of time, and with a wording that ensures full information to parents and caregivers about the mandatory presence of DHA in all formulae.

2. HEALTH CLAIMS

| **Health claim** | **Conditions of use of the claim** |
|---|---|
| 2.1 Reduction of risk of developing allergy to milk proteins | Authorisation to use the claim for a specific product shall be granted by the Commission, after a scientific assessment by the European Food Safety Authority, on the basis of appropriate studies, performed on the specific product following generally accepted expert guidance on the design and conduct of such studies |

➔ Conditions of use of the claim are updated taking into account EFSA's concerns on the importance of appropriate studies to be carried out on the specific product. Authorisation to use the claim will be provided by the Commission after an assessment by EFSA, as it is the case under the provisions of Regulation (EC) No 1924/2006.

Relevant guidance on the issue should be provided by the Commission services.

# ANNEX VI

## REFERENCE VALUES FOR NUTRITION LABELLING FOR FOODS INTENDED FOR INFANTS AND YOUNG CHILDREN

***[cf. Annex VII of Directive 2006/141/EC]***

| **Nutrient** | **Labelling reference value** |
|---|---|
| Vitamin A | (µg) 400 |
| Vitamin D | (µg) 7 |
| Vitamin E | (mg TE) 5 |
| Vitamin K | (µg) 12 |
| Vitamin C | (mg) 45 |
| Thiamin | (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 |

## *ANNEX VII*

## PESTICIDES WHICH SHALL NOT BE USED IN AGRICULTURAL PRODUCTION INTENDED FOR THE PRODUCTION OF INFANT FORMULA AND FOLLOW-ON FORMULA

***[cf. Annex VIII of Directive 2006/141/EC]***

*Table 1*

| Chemical name of the substance (residue definition) |
|---|
| Disulfoton (sum of disulfoton, disulfoton sulfoxide and disulfoton sulfone expressed as disulfoton) |
| 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) |

*Table 2*

| Chemical name of the substance |
|---|
| Aldrin and dieldrin, expressed as dieldrin |
| Endrin |

## *ANNEX VIII*

## SPECIFIC MAXIMUM RESIDUE LEVELS OF PESTICIDES OR METABOLITES OF PESTICIDES IN INFANT FORMULA AND FOLLOW-ON FORMULA

***[cf. Annex IX of Directive 2006/141/EC]***

| **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 |