WORKING DOCUMENT

on the adoption of a delegated Regulation on food for special medical purposes pursuant to Article 11(1) of Regulation (EU) No 609/2013

[Supporting Document for the meeting of the Working Group of the Advisory Group on the Food Chain and Animal and Plant Health of 17 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 relevant NGOs and stakeholders 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 food for special medical purposes.

The text included in this Working Document is based on the existing provisions of Commission Directive 1999/21/EC[2]. It is updated taking into account discussions carried out with Member States' experts, relevant NGOs and stakeholders so far.

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 17 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.

[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 1999/21/EC of 25 March 1999 on dietary foods for special medical purposes (OJ L 91, 7.4.1999, p. 29)

A. RECITALS

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

(1) Commission Directive 1999/21/EC[3] lays down, under the framework of Directive 2009/39/EC of the European Parliament and of the Council[4], harmonised rules on dietary foods for special medical purposes.

(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 1999/21/EC and lays down general compositional and information requirements for different categories of foods including food for special medical purposes. The Regulation also foresees the establishment of specific compositional and information requirements for food for special medical purposes by means of delegated acts, taking into account the provisions of Directive 1999/21/EC, by 20 July 2015.

(3) Food for special medical purposes is developed in close cooperation with health care professionals to feed patients with specific diagnosed diseases, disorders or medical conditions that make it impossible or very difficult for those patients to satisfy their nutritional needs through the consumption of other foods.

(4) The composition of food for special medical purposes may differ substantially depending, among others, on the specific disease, disorder or medical condition for the dietary management of which the product is intended, on the age of the patients and the place in which they receive health care support, and the product's intended use. In particular, food for special medical purposes can be classified in different categories depending on whether its composition is standard or specifically nutrient-adapted for a disease, disorder or medical condition and on whether or not it constitutes the sole source of nourishment for the persons for whom it is intended.

(5) Because of the wide diversity of food for special medical purposes, the rapidly evolving scientific knowledge on which it is based, and the need to ensure adequate flexibility to develop innovative products, it is not appropriate to lay down detailed compositional rules for such food products. It is however important to set principles and requirements specific to them in order to ensure that they are safe, beneficial and effective for the persons for whom they are intended on the basis of generally accepted scientific data.

(6) In particular, it is important to set basic rules concerning the content of vitamin and mineral substances in food for special medical purposes in order to ensure the free circulation of food for special medical purposes with different composition and the protection of consumers. Such rules should be based on those of Directive 1999/21/EC, given that they have ensured an adequate framework for food for special medical purposes so far. Rules should include minimum and maximum amounts, in the case of products considered to be nutritionally complete for covering the nutritional requirements of the patient, and maximum amounts only, in the case of products considered to be nutritionally incomplete, without prejudice to modifications

[3] Commission Directive 1999/21/EC of 25 March 1999 on dietary foods for special medical purposes (OJ L 91, 7.4.1999, p. 29)

[4] 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)

for one or more of these nutrients rendered necessary by the intended use of the product.

(7) 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 food for special medical purposes, 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 food for special medical purposes developed to satisfy the nutritional requirements of infants and young children, 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 maximum residue levels (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.

(8) Directive 1999/21/EC does not lay down requirements on the use of pesticides in products intended for the production of food for special medical purposes developed to satisfy the nutritional requirements of infants and young children, and on pesticide residues in such food. On the contrary Commission Directives 2006/125/EC[5] and 2006/141/EC[6] currently lay down specific requirements in this respect for foods for healthy infants and young children, based on two opinions given by the Scientific Committee for Food (SCF) on 19 September 1997[7] and 4 June 1998[8].

(9) 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 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.

(10) Regulation (EU) No 609/2013 foresees that restrictions on and prohibitions of certain pesticides equivalent to those currently established in the Annexes to Directives 2006/125/EC and 2006/141/EC should be taken into account in delegated acts adopted pursuant to this Regulation. When updating such restrictions and prohibitions,

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5 Commission Directive 2006/125/EC on processed cereal-based foods and baby foods for infants and young children (OJ L 339, 6.12.2006, p.16)

6 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)

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)

particular attention should be paid to certain substances of concern, with the objective to ultimately avoid their use.

(11) Exchanges between the Commission and the European Food Safety Authority ('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 food for special medical purposes should be established by 20 July 2015, the relevant existing requirements of Directive 2006/125/EC and 2006/141/EC should, at this stage, be extended to food for special medical purposes developed to satisfy the nutritional requirements of infants and young children. These requirements should be updated in the future, taking into account the opinion of the Authority on the matter.

(12) Food for special medical purposes 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 food for special medical purposes, this Regulation lays down additions and exceptions to those general rules, where appropriate.

(13) The provision of food information on all the particulars that are necessary to ensure the appropriate use of food for special medical purposes should be mandatory for this type of food, including information on the properties and characteristics making the food useful for its specific intended purpose.

(14) The nutrition declaration for food for special medical purposes is essential for patients consuming that food and for health care professionals, who recommend its consumption, in order to guarantee its appropriate use. For this reason, in order to provide more complete information to patients and healthcare professionals, all food for special medical purposes 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.

(15) Consumers of food for special medical purposes have different nutritional needs than the normal population. Expression of nutrition information on the energy value and the amount of nutrients of food for special medical purposes as percentage of daily reference intake values set out in Regulation (EU) No 1169/2011 would therefore mislead consumers and should not be allowed.

(16) 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 of the European Parliament and of the Council[10]. Permitted nutrition and health claims relate to foods to be delivered as such to the final consumer and describe beneficial nutritional and physiological effects for the general healthy population or sub-groups thereof obtained from the consumption of such foods. The use of nutrition and health claims authorised under Regulation (EC) No 1924/2006 to promote food for special medical purposes would be misleading since consumers of these products are patients suffering from a disease, disorder or condition and are, therefore, not part

[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)

[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)

of the general healthy population. In addition, food for special medical purposes is to be used under medical supervision and its consumption should not be promoted through the use of nutrition and health claims directly targeting consumers. For these reasons, the use of nutrition and health claims should not be allowed for food for special medical purposes.

(17) The composition of food for special medical purposes developed to satisfy the nutritional requirements of infants should be based on the compositional requirements of infant formula and follow-on formula as laid down in [delegated act on IF-FF], in order to take into account the specificities of the nutritional requirements of this category of the population. However, taking into account that infant formula and follow-on formula are intended for healthy infants, derogations should be foreseen for food for special medical purposes developed to satisfy the nutritional requirements of infants when this is necessary for the intended use of the product.

(18) In the past years, an increasing number of products have been placed on the market as food for special medical purposes developed to satisfy the nutritional requirements of infants. These products are sometimes promoted with means directly targeting consumers that are not subject to the restrictions foreseen by the legislation applicable to infant formula and follow-on formula. In order to avoid possible abuses linked to the misclassification of products, reduce confusion for consumers on the nature of the different products being offered to them and guarantee conditions of fair competition, it seems appropriate to introduce additional restrictions on the labelling, presentation, advertising, and promotional and commercial practices of food for special medical purposes developed to satisfy the nutritional requirements of infants. These restrictions should be inspired by similar provisions applicable to infant formula and follow-on formula for healthy infants as laid down in [delegated act on IF-FF] but should not be conflicting with the intended use of the product. Given that food for special medical purposes is to be used under medical supervision, these restrictions should not make it more difficult for operators to provide useful information exclusively intended for health care professionals and should allow health care professionals to test and evaluate the suitability of the products for their intended use.

(19) 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 food for special medical purposes on the market to produce all relevant elements and data establishing compliance with this Regulation. In addition, given the particular nature of food for special medical purposes, additional means to those usually available to monitoring bodies should be available in order to facilitate efficient monitoring of this type of food.

(20) 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(1) of Directive 1999/21/EC*]

This delegated Regulation lays down specific requirements for food for special medical purposes, including food for special medical purposes developed to satisfy the nutritional requirements of infants, pursuant to Article 11(1) of Regulation (EU) No 609/2013.

➔As it is the case today in Directive 1999/21/EC, this provision clearly states the subject matter and scope of the delegated Regulation.

Article 2
Placing on the market

[cf. Article 2 of Directive 1999/21/EC]

Food for special medical purposes may be marketed within the Union only if it complies with this Regulation.

➔ This provision repeats text already present in Directive 1999/21/EC. It establishes the requirement whereby only products complying with the delegated Regulation may be marketed within the EU.

CHAPTER 2

REQUIREMENTS ON COMPOSITION AND PESTICIDES

Article 3
Composition

1. Food for special medical purposes is classified in the following three categories:

   (a) nutritionally complete food with a standard nutrient formulation which, used in accordance with the manufacturer's instructions, may constitute the sole source of nourishment for the persons for whom it is intended;

   (b) nutritionally complete food with a nutrient-adapted formulation specific for a disease, disorder or medical condition which, used in accordance with the manufacturer's instructions, may constitute the sole source of nourishment for the persons for whom it is intended;

   (c) nutritionally incomplete food with a standard formulation or a nutrient-adapted formulation specific for a disease, disorder or medical condition which is not suitable to be used as the sole source of nourishment.

The food referred to in points (a) and (b) may also be used as a partial replacement or as a supplement to the patient's diet. [***cf. Article 1(3) of Directive 1999/21/EC***]

2. The formulation of food for special medical purposes shall be based on sound medical and nutritional principles. Its use, in accordance with the manufacturer's instructions, shall be safe and beneficial and effective in meeting the specific nutritional requirements of the persons for whom it is intended, as demonstrated by generally accepted scientific data.

3. Food for special medical purposes shall comply with the compositional criteria specified in Annex I. ***[cf. Article 3 of Directive 1999/21/EC]***

➔ This Article repeats existing provisions of Directive 1999/21/EC. The first paragraph transfers the three categories of FSMPs currently foreseen by Directive 1999/21/EC. The second and third paragraph transfer the composition requirements for FSMPs.

Article 4
Requirements on pesticides

1. For the purposes of this Article, 'pesticide residue' means the residue in food for special medical purposes developed to satisfy the nutritional requirements of infants and young children 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. Food for special medical purposes developed to satisfy the nutritional requirements of infants and young children 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 II shall not be used in agricultural products intended for the production of food for special medical purposes developed to satisfy the nutritional requirements of infants and young children.

However, for the purpose of controls:

(a) pesticides listed in Table 1 of Annex II 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 II 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 III, 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.

➔ This Article introduces **new** provisions on the use of pesticides and on pesticides residues in FSMPs developed to satisfy the nutritional requirements of infants and young children.

[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

Article 11(1)(b) of the FSG Regulation requires that rules on pesticides in FSMPs developed to satisfy the nutritional requirements of infants and young children are updated regularly and include, inter alia, provisions to restrict the use of pesticides as much as possible. 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 on infant formula and follow-on formula and Directive 2006/125/EC on processed cereal-based foods and baby foods 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 FSMPs should be established by 20 July 2015, the relevant existing requirements of Directive 2006/125/EC and 2006/141/EC should, at this stage, be extended to FSMPs developed to satisfy the nutritional requirements of infants and young children. 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 5
Name of the food

[cf. Article 4(1) of Directive 1999/21/EC]

The name of food for special medical purposes shall be respectively:

- in Bulgarian: ‘Храни за специални медицински цели’
- in Spanish: ‘Alimento para usos médicos especiales’
- in Czech: ‘potravinami pro zvláštní lékařské účely’
- in Danish: ‘fødevare til særlige medicinske formål’
- in German: ‘Lebensmittel für besondere medizinische Zwecke’
- in Estonian: ‘Meditsiinilisel näidustusel kasutamiseks ettenähtud toit’
- in Greek: ‘Τρόφιμα για ειδικούς ιατρικούς σκοπούς’
- in English: ‘Food(s) for special medical purposes’
- in French: ‘denrée alimentaire destinée à des fins médicales spéciales’
- in Croatian: ‘Hrana za posebne medicinske potrebe’
- in Italian: ‘Alimento a fini medici speciali’
- in Latvian: ‘Īpašiem medicīniskiem nolūkiem paredzēta pārtika’
- in Lithuanian: ‘Specialios medicininės paskirties maisto produktai’
- in Hungarian: ‘speciális gyógyászati célra szánt élelmiszer’
- in Maltese: ‘Ikel għal skopijiet mediċi speċjali'

- in Dutch: 'Voeding voor medisch gebruik'
- in Polish: 'żywność specjalnego przeznaczenia medycznego'
- in Portuguese: 'Alimentos para fins medicinais específicos'
- in Romanian: 'alimente destinate unor scopuri medicale speciale'
- in Slovak: 'potraviny na osobitné lekárske účely'
- in Slovenian: 'živila za posebne zdravstvene namene'
- in Finnish: 'erityisiin lääkinnällisiin tarkoituksiin tarkoitetulla elintarvikkeella'
- in Swedish: 'Livsmedel för speciella medicinska ändamål'.

➔ The delegated Regulation will include the name of "food for special medical purposes" in the different languages as it is currently the case in Directive 1999/21/EC. Given that the name of the food has changed in the FSG Regulation (i.e. from "dietary food for special medical purposes" to "food for special medical purposes"), the names above are taken from the different translations given to "food for special medical purposes" in the FSG Regulation.

Article 6
Specific requirements on labelling, presentation and advertising

1. Unless otherwise specified in this Regulation, food for special medical purposes 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 food for special medical purposes:

(a) a statement that the product must be used under medical supervision [***cf. Article 4(3)(a) of Directive 1999/21/EC]***;

(b) a statement whether the product is suitable for use as the sole source of nourishment ***[cf. Article 4(3)(b) of Directive 1999/21/EC]***;

(c) a statement that the product is intended for a specific age group, as appropriate ***[cf. Article 4(3)(c) of Directive 1999/21/EC]***;

(d) where appropriate a statement that the product poses a health hazard when consumed by persons who do not have the disease, disorder or medical condition for which the product is intended ***[cf. Article 4(3)(d) of Directive 1999/21/EC]***;

(e) the statement 'For the dietary management of…' where the blank shall be filled in with the disease, disorder or medical condition for which the product is intended ***[cf. Article 4(4)(a) of Directive 1999/21/EC]***;

(f) where appropriate a statement concerning adequate precautions and contra-indications ***[cf. Article 4(4)(b) of Directive 1999/21/EC]***;

(g) a description of the properties and/or characteristics that make the product useful in relation to the disease, disorder or medical condition for the dietary management of which the product is intended, in particular, as the case may be, relating to the nutrients which have been increased, reduced, eliminated or otherwise modified and the rationale of the use of the product ***[cf. Article 4(4)(c) of Directive 1999/21/EC]***;

(h) where appropriate a warning that the product is not for parenteral use ***[cf. Article 4(4)(d) of Directive 1999/21/EC]***;

(i) instructions for appropriate preparation, use and storage of the product after the opening of the container, as appropriate ***[cf. Article 4(5) of Directive 1999/21/EC]***.

Indication of the particulars referred to in letter (a) to (d) shall be preceded by the words 'important notice' or their equivalent **[cf. Article 4(3) of Directive 1999/21/EC]**.

➔ This paragraph repeats some of the existing provisions of Directive 1999/21/EC with a change in letter (g) to improve legal clarity on the intended use of the product.

3. Article 13(2) and (3) of Regulation (EU) No 1169/2011 shall apply to all mandatory particulars for food for special medical purposes.

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

Article 7
Specific requirements on the nutrition declaration

1. The mandatory nutrition declaration for food for special medical purposes shall include, in addition to the particulars listed in Article 30(1) of Regulation (EU) No 1169/2011, the following:

(a) the amount of each mineral substance and of each vitamin listed in Annex I and present in the product ***[cf. Article 4(2)(b) of Directive 1999/21/EC]***;

(b) selectively the amount of components of protein, carbohydrate and fat and/or of other nutrients and their components, the declaration of which would be necessary for the appropriate intended use of the product ***[cf. Article 4(2)(c) of Directive 1999/21/EC]***;

(c) information on the osmolality or the osmolarity of the product where appropriate ***[cf. Article 4(2)(d) of Directive 1999/21/EC]***;

(d) information on the source and the nature of the protein and/or protein hydrolysates contained in the product ***[cf. Article 4(2)(e) of Directive 1999/21/EC]***.

➔ This paragraph clarifies that the mandatory nutrition declaration of FSMPs shall include all the nutrients required by FIC as well as other specific nutrients whose indication is useful for the intended use of the product (as currently foreseen by Directive 1999/21/EC). A change in letter (d) is aimed at improving legal clarity (i.e. reference to "source of the protein" rather than "origin of the protein").

2. By way of derogation from Article 30(3) of Regulation (EU) No 1169/2011, the particulars included in the nutrition declaration for food for special medical purposes 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 FSMPs.

3. Article 16(3) of Regulation (EU) No 1169/2011 shall not apply to food for special medical purposes in packaging or containers the largest surface of which has an area of less than 25 cm2.

➔ This **new** paragraph is aimed at guaranteeing that all FSMPs provide the nutrition declaration, irrespective of the package size (as it is the case today).

4. Without prejudice to the provisions of paragraph 7 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 food for special medical purposes.

➔ 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 FSMPs (and not only those covered by the FIC Regulation). In its absence, legal uncertainty would exist on certain nutrients (e.g. aminoacids). It should be read together with paragraph 8 which lays down specific requirements on the order of presentation of nutrients in the nutrition declaration.

5. By way of derogation from Article 31(3) of Regulation (EU) No 1169/2011, the energy value and the amounts of nutrients of food for special medical purposes shall be those of the food as sold and where appropriate those of the food ready for use after preparation in accordance with the manufacturer's instructions.

➔ This **new** paragraph is aimed at maintaining the status quo and derogating from the FIC Regulation which foresees in Article 31(3) that the calculation of the amount of energy and nutrients in the food after preparation may replace the one in the food as sold.

6. 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 food for special medical purposes shall not be expressed as a percentage of the reference intakes set out in Annex XIII of Regulation (EU) No 1169/2011.

➔ 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 healthy adults laid down therein (as this would be misleading taking into account that FSMPs are not intended for the healthy population).

7. The particulars included in the nutrition declaration for food for special medical purposes 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.

Indication of the amount of sodium shall appear together with the other minerals and shall be repeated next to the indication of the salt content as follows: “Salt: X g (of which sodium: Y mg)”.

➔ These **new** paragraphs are aimed at ensuring that the presentation of the nutrition declaration of FSMPs follows the format set out in the FIC Regulation but taking into account the additional obligations required in the delegated Regulation for FSMPs. It also specifies how salt and sodium should be indicated for labelling purposes.

Article 8
Nutrition and health claims

Food for special medical purposes shall not bear nutrition and health claims.

➔ This **new** Article forbids the use of nutrition and health claims on FSMPs. The use of claims would be misleading since consumers of these products are patients suffering from a disease, disorder or condition and are, therefore, not part of the general healthy population. In addition, FSMPs are to be used under medical supervision and their consumption should not be promoted through the use of nutrition and health claims directly targeting consumers.

CHAPTER 4

REQUIREMENTS ON FOOD FOR SPECIAL MEDICAL PURPOSES DEVELOPED TO SATISFY THE NUTRITIONAL REQUIREMENTS OF INFANTS

Article 9
Specific requirements for food for special medical purposes developed to satisfy the nutritional requirements of infants

1. The labelling, presentation and advertising of food for special medical purposes developed to satisfy the nutritional requirements of infants shall not include pictures of infants, nor shall it include other pictures or text which may idealise the use of the product. It may, however, have graphic representations for easy identification of the product and for illustrating methods of preparation.

2. The labelling, presentation and advertising of food for special medical purposes developed to satisfy the nutritional requirements of infants shall be designed in such a way that it enables consumers to make a clear distinction between such products and infant formula and follow-on formula so as to avoid any risk of confusion.

3. Advertising of food for special medical purposes developed to satisfy the nutritional requirements of infants shall be restricted to publications specialising in baby care and scientific publications. Member States may further restrict or prohibit such advertising. Such advertisements shall be subject to the conditions laid down in this Article and contain only information of a scientific and factual nature.

The provisions of this paragraph shall not prevent the dissemination of information exclusively intended for health care professionals.

4. There shall be no point-of-sale advertising, giving of samples or any other promotional device to induce sales of food for special medical purposes developed to satisfy the nutritional requirements of infants directly to the consumer at the retail level, such as special displays, discount coupons, premiums, special sales, loss-leaders and tie-in sales.

5. Manufacturers and distributors of food for special medical purposes developed to satisfy the nutritional requirements of infants shall not directly 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.

➔ This **new** Article complies with the requirements of the FSG Regulation whereby FSMPs for infants should comply with the same restrictions on advertising and promotional practices applicable to infant formula and follow-on formula, provided that these are not incompatible with the products' intended use. The provisions are taken from Directive 2006/141/EC and adjusted as relevant.

CHAPTER 5

MONITORING

Article 10
Notification

[cf. Article 5(1) of Directive 1999/21/EC]

1. To facilitate efficient official monitoring of food for special medical purposes, when 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.

2. Member States may, if they can demonstrate that notification is not necessary in order to monitor those products efficiently in their territory, not impose that obligation.

➔ This Article repeats an existing provision of Directive 1999/21/EC and is aimed at maintaining the notification requirement for FSMPs.

CHAPTER 6

FINAL PROVISIONS

Article 11
Entry into application

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]

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.

C. ANNEXES

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

Annex I

ESSENTIAL COMPOSITION OF FOOD FOR SPECIAL MEDICAL PURPOSES
[cf. Annex I of Directive 1999/21/EC]

The specifications refer to the food ready for use, marketed as such or after preparation in accordance with the manufacturer's instructions.

1. Products referred to in Article 3(1)(a) developed to satisfy the nutritional requirements of infants will contain the vitamins and mineral substances as specified in Table 1.

2. Products referred to in Article 3(1)(b) developed to satisfy the nutritional requirements of infants will contain the vitamins and mineral substances as specified in Table 1, without prejudice to modifications for one or more of these nutrients rendered necessary by the intended use of the product.

3. Maximum levels of vitamins and mineral substances present in products referred to in Article 3(1)(c) developed to satisfy the nutritional requirements of infants shall not exceed those specified in Table 1, without prejudice to modifications for one or more of these nutrients rendered necessary by the intended use of the product.

4. Where this is not contrary to the requirements dictated by the intended use, foods for special medical purposes developed to satisfy the nutritional requirements of infants shall comply with the provisions relating to other nutrients applicable to infant formula and follow-on formula, as the case may be, laid down in [Delegated act on IF-FF].

5. Products referred to in Article 3(1)(a), other than those developed to satisfy the nutritional requirements of infants will contain the vitamins and mineral substances as specified in Table 2.

6. Products referred to in Article 3(1)(b) other than those developed to satisfy the nutritional requirements of infants will contain the vitamins and mineral substances as specified in Table 2 without prejudice to modifications for one or more of these nutrients rendered necessary by the intended use of the product.

7. Maximum levels of vitamins and mineral substances present in products referred to in Article 3(1)(c) other than those developed to satisfy the nutritional requirements of infants shall not exceed those specified in Table 2, without prejudice to modifications for one or more of these nutrients rendered necessary by the intended use of the product.

➔ The Annex transfers the existing provisions of the Annex of Directive 1999/21/EC. A minor change in language is foreseen in the introductory sentence, to ensure consistency with language used in the FIC Regulation (e.g. Article 31(3))

TABLE 1
Values for vitamins and minerals in food for special medical purposes developed to satisfy the nutritional requirements of infants

		Per 100 kJ		Per 100 kcal	
		Minimum	**Maximum**	**Minimum**	**Maximum**
Vitamins					
	Vitamin A (µg-RE) (1)	16,7	43	70	180
	Vitamin D (µg)	0,48	0,75	2	3
	Vitamin K (µg)	0,24	6	1	25
	Vitamin C (mg)	0,96	7,5	4	30
	Thiamin (µg)	9,6	72	40	300
	Riboflavin (µg)	14,3	100	60	450
	Vitamin B_6 (µg)	4,8	75	20	300
	Niacin (mg) (2)	0,1	0,75	0,4	3
	Folate (µg-DFE) (3)	3,6	12	15	50
	Vitamin B_{12} (µg)	0,02	0,12	0,1	0,5
	Panthotenic Acid (mg)	0,1	0,5	0,4	2
	Biotin (µg)	0,24	5	1	20
	Vitamin E (mg α-tocopherol) (4)	0,14	1,2	0,6	5
Minerals					
	Sodium (mg)	6	14	25	60
	Chloride (mg)	14,3	38	60	160
	Potassium (mg)	19,1	38	80	160
	Calcium (mg)	12	60	50	250
	Phosphorus (mg) (5)	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	0,6	0,5	2,4
Copper (µg)	14,3	29	60	120
Iodine (µg)	3,6	12	15	50
Selenium (µg)	0,72	2,2	3	9
Manganese (µg)	0,24	25	1	100
Chromium (µg)	-	2,5	-	10
Molybdenum (µg)	0,1	2,5	0,4	10
Fluoride (µg)	-	50	-	200

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

➔ The provisions of Table 1 are transferred from the corresponding requirements in Annex of Directive 1999/21/EC. Some update is foreseen as follows:

Minimum amounts: these are the minimum amounts proposed by EFSA in its 2014 opinion on the essential composition of infant and follow-on formulae. In that opinion EFSA noted that "*the general considerations and the specifications with respect to nutrients or other ingredients proposed in the present opinion may serve as a basis for defining compositional requirements for foods for special medical purposes for infants, unless the disease conditions for which such foods are to be used necessitate other compositional aspects*". This approach would ensure that all FSMPs for infants contain amounts that are adequate for virtually all infants below six months of age for optimal growth and development. The same approach was followed in Directive 1999/21/EC on the basis of previous SCF advice for infant formula and follow-on formula.

Maximum amounts: these are either the existing values of Directive 1999/21/EC or the values to be set in the delegated act on infant formula and follow-on formula, depending on which of the two is higher in order to ensure adequate flexibility for FSMPs.

TABLE 2

Values for vitamins and minerals in food for special medical purposes other than those developed to satisfy the nutritional requirements of infants

		Per 100 kJ		Per 100 kcal	
		Minimum	**Maximum**	**Minimum**	**Maximum**
Vitamins					
	Vitamin A (µg-RE)	8,4	43	35	180
	Vitamin D (µg)	0,12	0,65/0,75 (1)	0,5	2,5/3 (1)
	Vitamin K (µg)	0,85	5	3,5	20
	Vitamin C (mg)	0,54	5,25	2,25	22
	Thiamin (mg)	0,015	0,12	0,06	0,5
	Riboflavin (mg)	0,02	0,12	0,08	0,5
	Vitamin B_6 (mg)	0,02	0,12	0,08	0,5
	Niacin (mg NE)	0,22	0,75	0,9	3
	Folic Acid (µg)	2,5	12,5	10	50
	Vitamin B_{12} (µg)	0,017	0,17	0,07	0,7
	Panthotenic Acid (mg)	0,035	0,35	0,15	1,5
	Biotin (µg)	0,18	1,8	0,75	7,5
	Vitamin E (µg α-RE)	0,5 / g of polyunsaturated fatty acids expressed as linoleic acid but in no case less than 0,1 mg per 100 available kJ	0,75	0,5 / g of polyunsaturated fatty acids expressed as linoleic acid but in no case less than 0,1 mg per 100 available kJ	3
Minerals					
	Sodium (mg)	7,2	42	30	175

Chloride (mg)	7,2	42	30	175
Potassium (mg)	19	70	80	295
Calcium (mg)	8,4/12 (1)	42/60 (1)	35/50 (1)	175/250 (1)
Phosphorus (mg)	7,2	19	30	80
Magnesium (mg)	1,8	6	7,5	25
Iron (mg)	0,12	0,5	0,5	2
Zinc (mg)	0,12	0,36	0,5	1,5
Copper (µg)	15	125	60	500
Iodine (µg)	1,55	8,4	6,5	35
Selenium (µg)	0,6	2,5	2,5	10
Manganese (µg)	0,012	0,12	0,05	0,5
Chromium (µg)	0,3	3,6	1,25	15
Molybdenum (µg)	0,72	4,3	3,5	18
Fluoride (mg)	-	0,05	-	0,2

(1) For products intended for children of 1 to 10 years of age.

➔ Provisions in Table 2 are transferred from Directive 1999/21/EC with no change

ANNEX II

PESTICIDES WHICH SHALL NOT BE USED IN AGRICULTURAL PRODUCTION INTENDED FOR THE PRODUCTION OF FOOD FOR SPECIAL MEDICAL PURPOSES DEVELOPED TO SATISFY THE NUTRITIONAL REQUIREMENTS OF INFANTS AND YOUNG CHILDREN

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 III

SPECIFIC MAXIMUM RESIDUE LEVELS OF PESTICIDES OR METABOLITES OF PESTICIDES IN FOOD FOR SPECIAL MEDICAL PURPOSES DEVELOPED TO SATISFY THE NUTRITIONAL REQUIREMENTS OF INFANTS AND YOUNG CHILDREN

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