COMMISSION STAFF WORKING DOCUMENT

on certain requirements for FSMPs

[Supporting Document for the Expert Group meeting of 7 February 2014]

Introduction

Following the discussions in the Expert Group meeting of 13 September 2013, this Working Document seeks the views of experts on a number of elements related to the delegated act to be adopted on food for special medical purposes, pursuant to Article 11 of the FSG Regulation.

Part A of the Working Document covers a series of elements that could be included in the delegated act. Particular attention of the experts is required on the provisions related to food information, where consistency with the provisions of Regulation (EU) No 1169/2011 on food information to consumers (FIC)[1] needs to be ensured.

Part B of the Working Document requires the view of experts on the issue of nutrition and health claims made on Food for Special Medical Purposes.

This document does not cover the aspects specific to FSMPs for infants[2].

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A. Specific elements to include in the delegated act

1. Subject matter and scope

The following text is being considered **[see Article 1(1) of Directive 1999/21/EC]**:

This delegated act 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.

➔ The subject matter and scope of the act need to be clearly stated.

[1] 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

[2] The various aspects related to FSMPs for infants are summarized in a separate Working Document of the Commission.

2. Categories of food for special medical purposes

The following text is being considered **[see Article 1(3) of Directive 1999/21/EC]**:

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.

➔ The three categories of FSMPs currently foreseen by Directive 1999/21/EC should be transferred in the new delegated act.

3. Composition

The following text is being considered **[see Article 3 of Directive 1999/21/EC]**:

1. 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 nutritional requirements of the persons for whom it is intended, as demonstrated by generally accepted scientific data.]

2. Food for special medical purposes must comply with the compositional criteria specified in the Annex.

➔ Article 9 of the FSG Regulation lays down the general compositional and information requirements for foods covered by the scope and, in its paragraphs 1 and 3, includes rules[3] that can be seen as equivalent to the provision in square brackets above.

The repetition in the delegated acts of provisions already included in the basic act should be avoided.

[3] *Article 9(1) "The composition of food referred to in Article 1(1) shall be such that it is appropriate for satisfying the nutritional requirements of and is suitable for, the persons for whom it is intended in accordance with generally accepted scientific data."*
Article 9(3) "On the basis of generally accepted scientific data, substances added to food referred to in Article 1(1) for the purposes of the requirements under paragraph 1 of this Article shall be bio-available for use by the human body, have a nutritional or physiological effect and be suitable for the persons for whom the food is intended.

Experts are invited to comment on whether they agree that the text in square brackets could be deleted since it is already covered by Articles 9(1) and (3) of the FSG Regulation.

4. Name of the food

The following text is being considered **[see Article 4(1) of Directive 1999/21/EC]**:

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

(…)

➔ The delegated act 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.

5. Specific requirements on food information

The text currently being considered below reflects the discussions had with experts during the meeting of 13 September. The aim is to ensure consistency with the requirements of FIC, by derogating/adding to it where necessary:

1. Unless otherwise specified in this act, 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 relationship between the FIC Regulation and this delegated act 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 food/product must be used under medical supervision **[see 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 **[see Article 4(3)(b) of Directive 1999/21/EC]**;
   c) a statement that the product is intended for a specific age group, as appropriate **[see 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 diseases, disorders or medical conditions for which the product is intended **[see 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 diseases, disorders or medical conditions for which the product is intended **[see Article 4(4)(a) of Directive 1999/21/EC]**;
   f) where appropriate a statement concerning adequate precautions and contra-indications **[see 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 diseases, disorders or medical conditions 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 **[see Article 4(4)(c) of Directive 1999/21/EC]**;

h) where appropriate a warning that the product is not for parenteral use **[see Article 4(4)(d) of Directive 1999/21/EC]**;
i) instructions for the appropriate preparation, the use and the storage of the product after the opening of the container, as appropriate **[see 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 **[see Article 4(3) of Directive 1999/21/EC].**

➔ This paragraph repeats some of the existing provisions of Directive 1999/21/EC with a suggestion for consideration in letter (g) to improve legal clarity.

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 by FIC).

4. 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 cm^2.

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

5. The mandatory nutrition declaration of 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 any of the vitamins or minerals listed in the Annex and present in the product **[see Article 4(2)(b) of Directive 1999/21/EC]**;
b) selectively the content 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 **[see Article 4(2)(c) of Directive 1999/21/EC]**;
c) information on the osmolality or the osmolarity of the product where appropriate **[see 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 **[see Article 4(2)(e) of Directive 1999/21/EC]**.

➔ This paragraph repeats some of the existing provisions of Directive 1999/21/EC with a proposed change in letter (d) to improve legal clarity (source of the protein).

6. 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).

7. The energy value and the amounts of nutrients included in the nutrition declaration of food for special medical purposes shall be those of the food as sold and where appropriate may relate to the food ready for use 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.

8. Article 30(2)(f) and 32(3) of Regulation (EU) No 1169/2011 shall not apply to food for special medical purposes.

   ➔ This **new** paragraph is aimed at ensuring that indications on vitamins and minerals in FSMPs is not subject to the provisions of the FIC Regulation on the presence in significant amounts, or on the indication as a percentage of the reference intakes set out therein.

9. Article 34 of Regulation (EU) No 1169/2011 shall apply to food for special medical purposes without prejudice to the adaptations necessary to comply with the obligations resulting from this Article, in particular with respect to the requirements of paragraph 5 letter (b).

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

   ➔ This **new** paragraph is 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 for FSMPs. It also specifies how salt and sodium should be indicated for labelling purposes.

6. Notification

The following text is being considered **[see Article 5(1) of Directive 1999/21/EC]**:

To facilitate efficient official monitoring of food for special medical purposes, when a product is placed on the market, the manufacturer, or where a product is manufactured in a third country, the importer, 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.

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.

➔ The text above is a simple transfer of the provision of Article 5(1) of Directive 1999/21/EC.

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B. Nutrition and health claims on FSMPs

Directive 1999/21/EC on dietary foods for special medical purposes does not lay down specific rules on the use of nutrition and health claims on FSMPs. In the absence of such rules any nutrition or health claim made on FSMPs would have to comply with Regulation (EC) No 1924/2006 on nutrition and health claims made on foods[4].

Directive 1999/21/EC on FSMPs requires mandatory labelling of the "*description of the properties and/or characteristics that make the product useful 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*" (Article 4(4)(c)).

Several Member States have reported that FSMPs often bear 'claims like statements' not authorised by Regulation (EC) No 1924/2006. However food business operators justify the introduction of those statements using the argument that they only comply with the mandatory labelling requirements of Article 4(4) of Directive 1999/21/EC.

According to some national competent authorities it is difficult to judge if a statement used on the label of FSMPs is to be considered as a nutrition or a health claim or a mandatory labelling statement within the meaning of Article 4(4) of Directive 1999/21/EC. If the statement is considered as an authorised nutrition or health claim, questions also arise on the relevance of the conditions of use required for the claim when such claim is made on FSMPs. Indeed, FSMPs are very particular products that do not target the healthy population or a sub-group thereof. Conditions of use can therefore in certain cases not match the specific needs of consumers of FSMPs.

➔ FSMPs are products developed in close cooperation with health care professionals to manage the dietary needs of patients with specific diagnosed medical conditions and whose dietary management cannot be achieved by modification of the normal diet alone.

[4] Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims on foods, OJ L 404, 30.12.2006, p.9.

It is therefore important that these products clearly provide information on the properties and characteristics that make them useful for their specific intended purpose. This is currently required on a mandatory basis by Article 4(4)(c) of Directive 1999/21/EC and will continue to be required by the future delegated act. As it appears from Part A of the Working Document, however, a refinement of the text is foreseen, in order to clarify that this mandatory requirement only relates to those properties and characteristics that make the product useful in relation to the diseases, disorders or medical conditions for the dietary management of which the product is intended.

Nutrition and health claims are promotional tools which form part of commercial communication. Taking into account that the current situation has left room for potential abuses, the use of nutrition and health claims on FSMPs should be further considered. In particular, the following non exhaustive list of questions should be considered:

- Should claims be allowed on FSMPs, given that they are not in direct competition with food for normal consumption?
- What would be the advantages of having claims allowed on FSMPs and what would be the disadvantages?
- If claims are to be allowed, should the rules of Regulation (EC) No 1924/2006 on nutrition and health claims apply (in particular with respect to conditions of use)?

Experts are invited to provide views on the abovementioned questions