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## EUROPEAN COMMISSION

**Commission Notice on the classification of Food for Special Medical Purposes**

(2017/C 401/01)

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## 1. Introduction

1. Food for Special Medical Purposes (FSMP) is regulated in the EU under Regulation (EU) No 609/2013 of the European Parliament and of the Council <sup>(1)</sup> (also known as the Regulation on 'Food for Specific Groups of the population' or 'FSG Regulation') and Commission Delegated Regulation (EU) 2016/128 <sup>(2)</sup>. The Commission Delegated Regulation (EU) 2016/128 repeals and replaces from 22 February 2019 <sup>(3)</sup> Commission Directive 1999/21/EC <sup>(4)</sup>, which laid down specific requirements for FSMP under the old legislative framework of Directive 2009/39/EC of the European Parliament and the Council <sup>(5)</sup>.
2. Over the past years, Member States' national competent authorities have reported increasing difficulties with the enforcement of the legislative framework applicable to FSMP. Member States' experts have in particular flagged that an increasing number of products are placed on the market as FSMP in their territory, but that doubts arise in certain cases as to whether the products really correspond to the definition of FSMP and therefore correctly fall within the scope of the FSMP legislation.
3. Various considerations can justify a food manufacturer's preference for placing a food on the market as FSMP even when the product does not correspond to the FSMP definition. These can for example include the price that may be charged for it and whether the consumer may be able to obtain reimbursement under his medical insurance scheme for the cost of the food. It has also been highlighted that this state of affairs might be influenced by the on-going implementation of Regulation (EC) No 1924/2006 of the European Parliament and of the Council <sup>(6)</sup>: the legislative framework for FSMP allows operators to place products on the market on the basis of their own assessment that the product falls within the scope of the FSMP legislation, and to lawfully use statements referring to the dietary management of a disease, disorder or medical condition (required on a mandatory basis for FSMP). This can be considered a less stringent regime than the one foreseen by the horizontal rules of EU food law for normal foods (Regulation (EC) No 1924/2006 prohibits the use of nutrition and health claims unless specifically authorised in accordance with that Regulation) and can act as an incentive for some food business operators to incorrectly place products on the market as FSMP.
4. Irrespective of the underlying reasons for the food business operators' decision, the misclassification of FSMP can result in differences in the enforcement of EU law from one Member State to another and may negatively affect the protection of consumers' interest, the free circulation of goods in the EU and fair competition among food business operators.
5. The present Notice on the classification of FSMP aims to provide guidelines to assist both national competent authorities in their enforcement tasks and stakeholders in marketing their products under the appropriate legal framework and in complying with the relevant requirements of EU law.

<sup>(1)</sup> Regulation (EU) No 609/2013 of the European Parliament and of the Council of 12 June 2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control and repealing Council Directive 92/52/EEC, Commission Directives 96/8/EC, 1999/21/EC, 2006/125/EC and 2006/141/EC, Directive 2009/39/EC of the European Parliament and of the Council and Commission Regulations (EC) No 41/2009 and (EC) No 953/2009 (OJ L 181, 29.6.2013, p. 35).

<sup>(2)</sup> Commission Delegated Regulation (EU) 2016/128 of 25 September 2015 supplementing Regulation (EU) No 609/2013 of the European Parliament and of the Council as regards the specific compositional and information requirements for food for special medical purposes (OJ L 25, 2.2.2016, p. 30).

<sup>(3)</sup> Except in respect of food for special medical purposes developed to satisfy the nutritional requirements of infants, to which it shall apply from 22 February 2020.

<sup>(4)</sup> Commission Directive 1999/21/EC of 25 March 1999 on dietary foods for special medical purposes (OJ L 91, 7.4.1999, p. 29).

<sup>(5)</sup> Directive 2009/39/EC of the European Parliament and of the Council of 6 May 2009 on foodstuffs intended for particular nutritional uses (OJ L 124, 20.5.2009, p. 21). Foods for particular nutritional uses (also called 'dietetic foods') were defined by Article 1(2) of Directive 2009/39/EC as '(...) foodstuffs which, owing to their special composition or manufacturing process, are clearly distinguishable from foodstuffs for normal consumption, which are suitable for their claimed nutritional purposes and which are marketed in such a way as to indicate such suitability' and FSMP was considered one category of dietetic food. The FSG Regulation, applicable from 20 July 2016, abolished the concept of dietetic food, repealed Directive 2009/39/EC, included FSMP under its scope, and required the Commission to transfer the rules of Commission Directive 1999/21/EC under the FSG framework and to adapt them as appropriate. This was done through the adoption of Commission Delegated Regulation (EU) 2016/128.

<sup>(6)</sup> 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).

6. It is however important to note that only the Court of Justice of the European Union is entitled to interpret Union law with final binding authority.
7. The adoption of this Notice is without prejudice to Article 3 of the FSG Regulation, whereby ‘in order to ensure the uniform implementation of this Regulation, the Commission may decide, by means of implementing acts: (a) whether a given food falls within the scope of this Regulation; (b) to which specific category of food [covered by the Regulation] a given food belongs. (...)’
8. This Notice is adopted in the context of Article 14 of the FSG Regulation, which establishes that ‘the Commission may adopt technical guidelines to facilitate compliance by food business operators, in particular SMEs, with [the requirements of the Regulation that apply to the different products under its scope (including FSMP)]’.
9. This Notice builds upon informal consultation with Member States’ experts and relevant stakeholders:
  - Member States were in particular consulted: 1) in the context of a dedicated meeting of the Working Group of the Standing Committee on the food chain and animal health that took place on 14 March 2014; 2) in writing, from 23 January to 23 February 2017 and 3) in the meeting of the Expert Group on food intended for infants and young children, food for special medical purposes and total diet replacement for weight control of 12 June 2017. Furthermore, the question of the classification of FSMP was discussed in a number of different meetings of the Standing Committee on plants, animals, food and feed.
  - Stakeholders were in particular consulted in the context of the Advisory Group on the Food Chain, Animal and Plant Health, which held a Working Group meeting dedicated to the subject on 12 April 2017.

## 2. Legal framework applicable to Food for Special Medical Purposes (FSMP)

10. FSMP is defined in Article 2(2)(g) of the FSG Regulation (EU) No 609/2013 as ‘food specially processed or formulated and intended for the dietary management of patients, including infants, to be used under medical supervision; it is intended for the exclusive or partial feeding of patients with a limited, impaired or disturbed capacity to take, digest, absorb, metabolise or excrete ordinary food or certain nutrients contained therein, or metabolites, or with other medically-determined nutrient requirements, whose dietary management cannot be achieved by modification of the normal diet alone’.
11. The FSG Regulation lays down general compositional and information requirements for the foods under its scope, including FSMP.

In particular, Article 9(1) establishes that ‘The composition of food [under the scope of the Regulation] 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(2) establishes that ‘Food [under the scope of the Regulation] shall not contain any substance in such quantity as to endanger the health of the persons for whom it is intended (...)’. Article 9(3) establishes that ‘On the basis of generally accepted scientific data, substances added to food [under the scope of the Regulation] 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’. Article 9(5) establishes that ‘The labelling, presentation and advertising of food [under the scope of the Regulation] shall provide information for the appropriate use of such food, and shall not mislead, or attribute to such food the property of preventing, treating or curing a human disease, or imply such properties’.

12. Pursuant to Article 11(1) of the FSG Regulation, the Commission adopted Delegated Regulation (EU) 2016/128 which supplements the FSG Regulation as regards the specific compositional and information requirements for FSMP.

13. Pursuant to Article 2(1) of Delegated Regulation (EU) 2016/128, FSMP 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' (7).
14. Pursuant to Article 2(2) of Delegated Regulation (EU) 2016/128, '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, beneficial and effective in meeting the specific nutritional requirements of the persons for whom it is intended, as demonstrated by generally accepted scientific data'. In addition, pursuant to Article 2(3), FSMP must comply with specific compositional requirements laid down in Annex I to Delegated Regulation (EU) 2016/128.
15. Article 3 of Delegated Regulation (EU) 2016/128 lays down requirements on pesticides used in FSMP for infants and young children.
16. Articles 4-8 of Delegated Regulation (EU) 2016/128 lay down information requirements for FSMP. In particular, pursuant to Article 5(2): '(...) the following shall be additional mandatory particulars for food for special medical purposes: (...) (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; (...) (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 special processing and formulation, the nutrients which have been increased, reduced, eliminated or otherwise modified and the rationale of the use of the product (...)'.
17. A notification procedure is established for FSMP by Article 9 of Delegated Regulation (EU) 2016/128, which states: 'When food for special medical purposes is placed on the market, the food business operator shall notify the competent authority of each Member State where the product concerned is being marketed of the information appearing on the label, by sending to it a model of the label used for the product, and of any other information the competent authority may reasonably request to establish compliance with this Regulation, unless a Member State exempts the food business operator from that obligation under a national system that guarantees an efficient official monitoring of the product concerned'.
18. Delegated Regulation (EU) 2016/128 repeals and replaces from 22 February 2019<sup>(8)</sup> Commission Directive 1999/21/EC, which laid down specific requirements for FSMP under the old framework on foods for particular nutritional uses (the requirements of Directive 1999/21/EC are very similar to those of Delegated Regulation (EU) 2016/128, see in particular Article 1(3) for the classification into three categories, Article 3 for the compositional requirements, Article 4 for information requirements and Article 5 for the notification procedure).

### 3. The placing on the market of FSMP – rights and responsibilities of food business operators, national competent authorities and the European Commission

19. EU law does not require **food business operators (FBOs)** to seek an authorisation to place FSMP on the market and FBOs can market a specific product as FSMP on the basis of their own assessment that the product falls within the scope of the FSMP legislation (i.e. corresponds to the definition of FSMP) and complies with the relevant legal provisions applicable to the product category.

(7) As mentioned in Article 2(1) second subparagraph, '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'.

(8) Except in respect of food for special medical purposes developed to satisfy the nutritional requirements of infants, to which it shall apply from 22 February 2020.

However, in accordance with Article 17(1) of Regulation (EC) No 178/2002 of the European Parliament and of the Council<sup>(9)</sup> on 'general food law', FBOs at all stages of production, processing and distribution within the businesses under their control act under their own responsibility and must 'ensure that foods (...) satisfy the requirements of food law which are relevant to their activities and shall verify that such requirements are met'.

20. In accordance with Article 17(2) of Regulation (EC) No 178/2002, it is the responsibility of Member States to 'enforce food law, and monitor and verify that the relevant requirements of food law are fulfilled by food (...) business operators at all stages of production, processing and distribution'. In this context, national competent authorities are responsible to enforce the relevant legislation on FSMP on a product-specific basis, taking into account all the different characteristics of the product, and verify whether a product placed on the market as FSMP really falls within the scope of the applicable legislation and, if this is the case, whether it complies with the relevant legal requirements.

In the course of their enforcement activities, the competent authorities of Member States may request, at any time, the food business operator placing a product on the market as FSMP to demonstrate compliance with all the relevant provisions applicable to FSMP through relevant data. The notification procedure (or the equivalent national monitoring system) laid down in Delegated Regulation (EU) 2016/128 enables national competent authorities to carry out their responsibility in this respect.

21. Because the legislation leaves flexibility to FBOs in deciding the detailed composition of FSMP, it is theoretically possible that different Member States' competent authorities have divergent approaches to the classification of the same product as FSMP.
22. In order to ensure the uniform implementation of the legislation, Article 3 of the FSG Regulation has introduced since 20 July 2016 an empowerment for the Commission to adopt 'interpretation decisions' on whether a given food is appropriately classified as FSMP or not<sup>(10)</sup>. No interpretation decision pursuant to Article 3 has been adopted so far.
23. In this context, it is important to clarify that Article 3 of the FSG Regulation leaves the discretion to adopt 'interpretation decisions' in the hands of the Commission and this new empowerment does not replace the legal regime applicable to FSMP, which permits FBOs to market products on the basis of their own assessment as to the compliance of the product with the definition of FSMP and makes national authorities responsible for enforcing EU food law.

Taking into account considerations of subsidiarity and proportionality of EU action<sup>(11)</sup> and the role of the Commission as guardian of the application of EU law<sup>(12)</sup>, this empowerment must therefore be considered as a complementary solution to take decisions on cases in which Member States' divergent approaches on the same product might create problems to the free circulation of goods in the Internal Market, rather than a tool to systematically classify all FSMP at EU level.

More information on the procedural steps preceding the eventual adoption by the Commission of interpretation decisions pursuant to Article 3 of the FSG Regulation can be found on the website of the European Commission.

<sup>(9)</sup> 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).

<sup>(10)</sup> 'In order to ensure the uniform implementation of this Regulation, the Commission may decide, by means of implementing acts: (a) whether a given food falls within the scope of this Regulation; (b) to which specific category of food [under the scope of the Regulation] a given food belongs. (...)'. In any event, decisions of national authorities and of the European Commission can be challenged in courts, and the ultimate responsibility for the interpretation of EU law lies with the Court of Justice of the EU.

<sup>(11)</sup> The principles of 'subsidiarity' and 'proportionality' are laid down in Article 5 of the Treaty on European Union. Under the principle of 'subsidiarity', in areas which do not fall within its exclusive competence, the Union shall act only if and in so far as the objectives of the proposed action cannot be sufficiently achieved by the Member States, either at central level or at regional and local level, but can rather, by reason of the scale or effects of the proposed action, be better achieved at Union level. Under the principle of 'proportionality', the content and form of Union action shall not exceed what is necessary to achieve the objectives of the Treaties.

<sup>(12)</sup> Article 17(1) of the Treaty on European Union establishes that 'The Commission shall promote the general interest of the Union and take appropriate initiatives to that end. It shall ensure the application of the Treaties, and of measures adopted by the institutions pursuant to them. It shall oversee the application of Union law under the control of the Court of Justice of the European Union. (...)'.

#### 4. Relevance of the 'mutual recognition' principle for the FSMP classification

24. It has been asked whether a product lawfully marketed as FSMP in a Member State should be automatically classified as such in all other Member States on the basis of the principle of 'mutual recognition'. This is not the case for the reasons provided below.
25. The principle of mutual recognition derives from the case-law of the Court of Justice of the EU on Articles 34-36 of the Treaty on the Functioning of the EU (TFEU) related to the free circulation of goods in the internal market (starting with the judgment in the case '*Cassis de Dijon*'<sup>(13)</sup>). This principle was discussed in the Commission Interpretative Communication of 3 October 1980<sup>(14)</sup> and is one of the means of ensuring the free movement of goods within the internal market.
26. The principle of mutual recognition applies to products which are not subject to EU harmonisation legislation, or to aspects falling outside the scope of such legislation. It states that a product lawfully marketed in a Member State or in Turkey, or which is originating and lawfully manufactured in an EFTA State that is a contracting party to the EEA Agreement<sup>(15)</sup>, should in principle be allowed to be marketed in any other Member State without being subject to additional controls, even when the product does not fully comply with the technical rules<sup>(16)</sup> of the Member State of destination.
27. The Member State of destination may refuse the marketing of a product in its current form only where it can show that it does not provide an equivalent level of protection of the various legitimate interests at stake (for example, public safety, health or environment) compared with that sought by its own national rules. In that case, the Member State of destination must also demonstrate that its measure is necessary and the least trade-restrictive measure. Articles 34 to 36 TFEU (as well as the principle of mutual recognition) are directly applicable in all Member States and have an impact on any national technical rule creating unjustified obstacles to intra-EU trade.
28. In line with a consolidated case-law, however, the principle of mutual recognition is not relevant in areas where EU legislation is harmonised. This is due to the fact that harmonising legislation substantiates the free movement of goods principle by establishing actual rights and duties to be observed in the case of specific products in order to ensure the establishment and functioning of the internal market for those products. As explained by the Court, where a matter is regulated in a harmonised manner at EU level, any national measure relating thereto must be assessed in the light of the provisions of that harmonising measure and not of the Articles of the Treaty<sup>(17)</sup>.
29. With respect to FSMP, it is uncontested that the FSG Regulation and Delegated Regulation (EU) 2016/128 provide harmonised rules, including the definition of these products, which are applicable throughout the EU. The principle of mutual recognition should therefore not be invoked to justify the classification of products as FSMP. Consideration of whether a specific product notified as FSMP is appropriately classified as such is part of national competent authorities' competence and responsibility and their actions should be exclusively assessed in the light of the harmonised provisions of EU legislation and the corresponding definition of FSMP.

#### 5. Relevance of novel food authorisations for the FSMP classification

30. It has been asked whether the authorisation for the placing on the market of a substance as a novel food ingredient to be used in FSMP would automatically classify a product containing that substance as FSMP. This is not the case for the reasons provided below.

<sup>(13)</sup> Judgment of the Court of 20 February 1979 — *Rewe-Zentral AG v Bundesmonopolverwaltung für Branntwein* — Case 120/78, European Court Reports 1979-00649.

<sup>(14)</sup> Communication from the Commission concerning the consequences of the judgment given by the Court of Justice on 20 February 1979 in case 120/78 ('*Cassis de Dijon*') (OJ C 256, 3.10.1980, p. 2). Information on the practical application of this principle is laid down in the Commission interpretative communication on facilitating the access of products to the markets of other Member States: the practical application of mutual recognition (2003/C 265/02) (OJ C 265, 4.11.2003, p. 2).

<sup>(15)</sup> The Agreement on the European Economic Area (EEA), which entered into force on 1 January 1994, brings together the EU Member States and the three EEA EFTA States (Iceland, Liechtenstein and Norway).

<sup>(16)</sup> A technical rule means a technical specification which defines the characteristics required of a product, such as its composition (quality level or fitness for use, performance, safety, dimensions, markings, symbols, etc.), its presentation (the name under which the product is sold, its packaging, its labelling) or testing and test methods within the framework of conformity assessment procedures, which is obligatory, in fact or in law, to market or use the product in the Member State of destination (Commission interpretative communication on facilitating the access of products to the markets of other Member States: the practical application of mutual recognition (2003/C 265/02)).

<sup>(17)</sup> See for example §32 of the Judgment of the Court of 13 December 2001, *DaimlerChrysler AG v. Land Baden-Württemberg*, Case C-324/99, European Court Reports 2001 p. I-9897

31. Regulation (EC) No 258/97 of the European Parliament and of the Council on novel foods <sup>(18)</sup> lays down a series of requirements (including authorisation procedures) for the placing on the market within the EU of foods and food ingredients which have not been used for human consumption to a significant degree within the EU before 15 May 1997.
32. The rules of Regulation (EC) No 258/97 will be repealed and replaced on 1 January 2018 by Regulation (EU) 2015/2283 of the European Parliament and of the Council <sup>(19)</sup>. This Regulation changes the authorisation procedure but maintains similar principles for authorisation: novel foods and novel food ingredients can only be authorised if they do not pose a safety risk to human health, their intended use does not mislead the consumer and they do not differ from the food they are intended to replace in such a way that its normal consumption would be nutritionally disadvantageous for the consumer.
33. Examples can be found of decisions taken by the Commission under Regulation (EC) No 258/97 which specifically authorised the use of a substance in FSMP (e.g. citicoline) <sup>(20)</sup>. Those authorisations are however granted provided that the substance complies with the requirements of the novel food legislation and do not have any impact on the classification of a product as FSMP: an assessment of whether a specific product containing the specific substance should be classified as FSMP must only be based on the FSMP definition as laid down in the FSG Regulation. Food business operators remain responsible for this assessment and national competent authorities must verify that the product is correctly classified as FSMP, in their role of enforcers of EU law.

## 6. Understanding the definition of FSMP

34. Article 2(2)(g) of the FSG Regulation provides the following definition of FSMP: “food for special medical purposes” means food specially processed or formulated and intended for the dietary management of patients, including infants, to be used under medical supervision; it is intended for the exclusive or partial feeding of patients with a limited, impaired or disturbed capacity to take, digest, absorb, metabolise or excrete ordinary food or certain nutrients contained therein, or metabolites, or with other medically-determined nutrient requirements, whose dietary management cannot be achieved by modification of the normal diet alone’.
35. The definition of FSMP is very detailed and includes a series of different elements. Some interpretative guidance is provided below on some of these elements. However, it is essential to bear in mind that, in order to appropriately classify a product as FSMP, the different elements cannot be interpreted in isolation but must be understood within the context of the entire definition.

### 6.1. The difference between FSMP and products other than food (e.g. medicinal products)

36. According to the definition of FSMP laid down in Article 2(2)(g) of the FSG Regulation, FSMP is food. When reflecting on the appropriate classification of a product as FSMP it is, therefore, first of all important to make sure that the product should not rather be classified under a different legal framework and, in particular, as a medicinal product.
37. Article 1(2) of Directive 2001/83/EC of the European Parliament and of the Council <sup>(21)</sup> defines a medicinal product as: ‘(a) Any substance or combination of substances presented as having properties for treating or preventing disease in human beings; or (b) Any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis.’

<sup>(18)</sup> Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients (OJ L 43, 14.2.1997, p. 1).

<sup>(19)</sup> Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001 (OJ L 327, 11.12.2015, p. 1).

<sup>(20)</sup> Commission Implementing Decision 2014/423/EU of 1 July 2014 authorising the placing on the market of citicoline as a novel food ingredient under Regulation (EC) No 258/97 of the European Parliament and of the Council (OJ L 196, 3.7.2014, p. 24)

<sup>(21)</sup> Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67).

38. In view of the need for the strict supervision of medicinal products, any doubts as to whether a product is a medicinal product are to be resolved by bringing that product within the scope of the regime for medicinal products. To this end, Article 2(2) of Directive 2001/83/EC provides that: 'In cases of doubt, where, taking into account all its characteristics, a product may fall within the definition of a "medicinal product" and within the definition of a product covered by other Community legislation the provisions of this Directive shall apply.'
39. The clear separation between medicinal products and other products is reinforced in the case of foodstuffs by Article 2 of Regulation (EC) No 178/2002 laying down the general principles and requirements of food law, which defines 'food' (or 'foodstuff') as: '(...) any substance or product, whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be ingested by humans. (...) "Food" shall not include: (...) (d) medicinal products within the meaning of Council Directives 65/65/EEC and 92/73/EEC;' <sup>(22)</sup>.
40. Following the rationale of the legislation quoted above, EU food law provides that 'food information shall not attribute to any food the property of preventing, treating or curing a human disease, nor [to] refer to such properties' (Article 7(3) of Regulation (EU) No 1169/2011 on the provision of food information to consumers) <sup>(23)</sup>.
41. Whilst the definitions of food and medicinal products are mutually exclusive, it remains possible that differences will continue to exist between Member States in the classification of products, as national authorities must decide whether a product is to be classified as a medicinal product 'on a case-by-case basis, taking account of all the characteristics of the product, in particular its composition, its pharmacological properties, to the extent to which they can be established in the present state of scientific knowledge, the manner in which it is used, the extent of its distribution, its familiarity to consumers and the risks which its use may entail' <sup>(24)</sup>.
42. For the purposes of this document, it is important to note that, from a combined reading of the different definitions quoted above, products presented for the prevention of a disease (e.g. a product containing omega-3 fatty acids presented for the prevention of cardiovascular disease) should be considered as medicinal products and cannot be considered as food. In this context, as these products cannot be considered as food they cannot be classified as FSMP either.
43. The same reasoning applies to products presented for treating a disease (e.g. a product containing zeaxanthin, or lutein presented for the treatment/dietary treatment of age-related macular degeneration). These products should be considered as medicinal products and cannot be classified as FSMP.
44. In this context, it must also be recalled that, in line with a consolidated case-law of the Court of Justice of the EU, the term 'presentation' of a product must be interpreted broadly: in particular, a product is 'presented for treating or preventing disease' within the meaning of Directive 2001/83/EC not only when it is expressly 'indicated' or 'recommended' as such (possibly by means of labels, leaflets or oral representation), but also 'whenever any averagely well-informed consumer gains the impression, which, provided it is definite, may even result from implication, that the product in question should, having regard to its presentation, have the properties in question' <sup>(25)</sup>.

Therefore, a product should be considered as a medicinal product (and cannot be classified as FSMP) even when it is presented for the 'dietary management' of a particular disease if it can be perceived by an averagely well-informed consumer as being intended for the treating of the disease in question (further information on the concept of 'dietary management' is provided in section 6.4 below).

<sup>(22)</sup> Council Directives 65/65/EEC and 92/73/EEC were repealed and replaced by Directive 2001/83/EC.

<sup>(23)</sup> Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004 (OJ L 304, 22.11.2011, p. 18). This is a general principle of food law that is also present in the FSG Regulation (Article 9(5)).

<sup>(24)</sup> As for example Case C-211/03 *HLH Warenvertriebs GmbH and Others v Bundesrepublik Deutschland*, EU:C:2005:370, at §30. For further reference on the borderline between medicinal products and other products, cf. the 'guidance document on the demarcation between the cosmetic products Directive 76/768/EC and the medicinal products Directive 2001/83/EC as agreed between the Commission services and the competent authorities of Member States', [http://ec.europa.eu/consumers/sectors/cosmetics/files/doc/guidance\\_doc\\_cosm-medical\\_en.pdf](http://ec.europa.eu/consumers/sectors/cosmetics/files/doc/guidance_doc_cosm-medical_en.pdf)

<sup>(25)</sup> Case C-319/05, *Commission of the European Communities v Federal Republic of Germany*, at §43-46



### 6.2. Specially processed or formulated food

45. According to the definition of FSMP laid down in Article 2(2)(g) of the FSG Regulation, FSMP is food that is 'specially processed or formulated'.
46. These qualifiers are not further defined in the FSMP legislation, but aim at explaining that FSMP is the result of a specific and voluntary effort of the manufacturer to realize a product for a specific intended use, namely the dietary management of patients (see section 6.4 for further detail on the concept of 'dietary management'): this makes FSMP different from normal, standard foods that can be found on the market:
- 'Specially processed' refers to the product manufacturing stage and describes any action that substantially alters the initial product to make it suitable for the dietary management of a specific group of patients (e.g. giving a specific consistency or viscosity to a product for the dietary management of dysphagia) <sup>(26)</sup>.
  - 'Specially formulated' refers to the theoretical product development stage that precedes the manufacturing itself and describes the choice of specific ingredients when developing the product recipe to make it suitable for the dietary management of a specific group of patients (e.g. foreseeing specific levels of energy and nutrients for products for patients suffering from kidney failure).
47. The use in the definition of the word 'or' between 'processed' and 'formulated' means that an FSMP can be specially processed without being specially formulated and vice versa. Thus, the definition covers the widest possible range of cases in which a product has been specifically created for the dietary management of patients. At the same time, *a contrario*, this wording excludes from the definition of FSMP products that are neither specially processed nor formulated: a naturally occurring foodstuff used in its natural state, without undergoing any special processing or formulation, should not be considered as FSMP. This of course does not preclude the possibility that FSMP contains ingredients of a 'natural composition'.

### 6.3. FSMP is for patients and must be used under medical supervision

48. According to the definition of FSMP laid down in Article 2(2)(g) of the FSG Regulation, consumers of FSMP are patients and FSMP is to be 'used under medical supervision' <sup>(27)</sup>.
49. No definition of 'patient' is provided in the FSMP legislation but recital 3 of Delegated Regulation (EU) 2016/128 provides useful information in this respect, as it states that: 'Food for special medical purposes is developed in close cooperation with health care professionals to feed patients affected by or malnourished because of a specific diagnosed disease, disorder or medical condition that makes it impossible or very difficult for those patients to satisfy their nutritional needs through the consumption of other foods. For that reason, food for special medical purposes must be used under medical supervision, which may be applied with the assistance of other competent health professionals'.

Similar references are made in other parts of the Delegated Regulation (e.g. Article 5(2)(d) which establishes that one mandatory labelling requirement for FSMP is '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') and it can therefore be inferred that, in the context of the legislation on FSMP, patients should be considered as people suffering from specific diagnosed diseases, disorders or medical conditions who, as a result of such disease, disorder or medical condition need to consume FSMP.

<sup>(26)</sup> This is in line with the definition of 'processing' provided in Article 2(1)(m) of Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs (OJ L 139, 30.4.2004, p. 1), whereby "processing" means any action that substantially alters the initial product (...)'.

<sup>(27)</sup> Apart from the reference in the definition, Article 5(2)(a) of Delegated Regulation (EU) 2016/128 establishes that one mandatory labelling requirement for FSMP is 'a statement that the product must be used under medical supervision'.

50. In line with the above, it appears clear that products intended for consumers not suffering from any disease/disorder/medical condition should not be considered as FSMP (e.g. products intended for healthy infants, healthy pregnant women, sportspeople ...).
51. Following a similar logic, given that the use of the product under medical supervision is a characterising element of FSMP, a product that can be used without medical supervision, in the context of the dietary management of a patient, should not be considered as FSMP.
52. The reference in the FSMP definition to the product's use under medical supervision is very important to understand that health care professionals play a key role in recommending and supervising the use of FSMP, taking into account the specific situation of the patients, on a case-by-case basis. In this context, it is however also important to note that health care professionals, in the exercise of their profession, have the discretion to choose what they consider the most appropriate way to ensure the medical follow-up of their patients and may recommend consumption of a number of products other than FSMP (e.g. medicinal products), including foods that are not FSMP (e.g. vitamin D food supplements for infants).

For this reason, the recommendation of a health care professional cannot be the decisive element in classifying a product as FSMP; only an analysis of all the elements of the definition of FSMP, on a product-specific basis, can indicate whether a product is to be classified as FSMP or not.

#### 6.4. *The concept of 'dietary management'*

53. According to the definition of FSMP laid down in Article 2(2)(g) of the FSG Regulation, FSMP is intended for the 'dietary management of patients' and understanding the concept of 'dietary management' is key to correctly classifying a product as FSMP. Useful elements to correctly frame this concept are provided in the definition of FSMP.
54. More specifically, FSMP is 'intended for the exclusive or partial feeding' of patients who, because of the disease/disorder/medical condition they are suffering from:
- either have 'a limited, impaired or disturbed capacity to take, digest, absorb, metabolise or excrete ordinary food or certain nutrients contained therein, or metabolites;'
  - or have 'other medically-determined nutrient requirements' <sup>(28)</sup>.

The common condition for these two categories of patients is the fact that the dietary management of the disease/disorder/medical condition these patients are suffering from 'cannot be achieved by modification of the normal diet alone.'

55. Below are some concrete examples (non-exhaustive) to illustrate the different cases mentioned in the definition:
- an inability to take sufficient quantities of ordinary foods: this may result from mechanical impairment or swallowing difficulties associated with a disease, condition or injury (e.g. head and neck cancer or surgery), or from neurological impairment associated with stroke;
  - an inability to digest or absorb sufficient foods/nutrients: this may result from impairments of the gastrointestinal tract linked to a disease (e.g. short bowel syndrome) or a treatment (e.g. gastrectomy);

<sup>(28)</sup> In both bullet points, a reference is made to 'nutrients'. While no definition of 'nutrient' is given in the FSMP legislation, Regulation (EU) No 1169/2011 on the provision of food information to consumers defines 'nutrient' as 'protein, carbohydrate, fat, fibre, sodium, vitamins and minerals listed in point 1 of Part A of Annex XIII to this Regulation, and substances which belong to or are components of one of those categories' (Article 2(2)(s)). The same definition is provided in Article 2(2)(2) of Regulation (EC) No 1924/2006 on nutrition and health claims made on foods.

- an inability to metabolise specific nutrients: this may result from inherited metabolic disorders such as phenylketonuria or Maple Syrup Urine Disease, where whole protein cannot be metabolized and its intake must be severely limited;
  - an inability to excrete certain nutrients or their metabolites: this may result from diseases of the renal, liver or respiratory systems where it is important to control intakes of the offending nutrient to prevent build-up of toxic levels of the nutrients or their metabolites (e.g. phosphate and potassium for patients suffering from kidney failure);
  - other medically-determined nutrient requirements: these are specific nutrient requirements (see footnote 28 for the definition of ‘nutrient’) that are, based on medical evidence, linked to the particular disease/disorder/medical condition, such as increased requirements for protein or other specific nutrients (e.g. glutamine) in patients pre or post-surgery, with severe wounds, burns or pressure sores or in patients suffering from specific diseases (e.g. vitamin A for patients suffering from cystic fibrosis).
56. In all the cases mentioned above, it is impossible, impractical, unsafe or nutritionally/clinically disadvantageous for the patients suffering from the specific disease/disorder/medical condition to satisfy their nutritional needs through the exclusive consumption of foods other than FSMP. The aim of FSMP is therefore to provide nutritional support to patients suffering from a specific disease/disorder/medical condition and FSMP is food whose consumption is nutritionally necessary for patients suffering from the specific disease/disorder/medical condition. *A contrario*, a product cannot be placed on the market as FSMP for the dietary management of patients suffering from a specific disease/disorder/medical condition if the nutritional needs of that group of patients can be satisfied by consuming exclusively food that is not FSMP (i.e. by a modification of the normal diet, see section 6.5 below).
57. This restrictive interpretation of the concept of ‘dietary management’ has been consistently given by the Commission<sup>(29)</sup> and is well summarised in recital 3 of the Commission Delegated Regulation (EU) 2016/128.
58. Evidently, this theoretical analysis must be concretely applied on a case-by-case basis to specific products when they are placed on the market. This is the responsibility of FBOs, when placing the products on the market as FSMP, and national competent authorities when considering whether these are appropriately classified as FSMP. In concrete terms, this means that when reflecting on whether a product is to be classified as FSMP, FBOs and national competent authorities must judge how impossible, impractical, unsafe or nutritionally/clinically disadvantageous it is for the patient suffering from the disease/disorder/medical condition for which the product is intended to satisfy his/her nutritional needs through the exclusive consumption of foods other than FSMP.
59. From a different angle, the explanations provided above also allow to clarify that there is a clear difference between the ‘dietary management’ of patients suffering from a specific disease/disorder/medical condition and the treatment of the specific disease/disorder/medical condition: FSMP are not intended to treat diseases and, as explained in section 6.1, products presented for treating a disease should be considered as medicinal products and cannot be classified as FSMP.
- 6.5. *The concept of ‘modification of the normal diet’*
- i. Does it include use of food supplements and fortified foods?
60. A question that is often asked is whether the concept of ‘modification of the normal diet’, referred to in the definition of FSMP, includes the use of food supplements (within the meaning of Directive 2002/46/EC on the approximation of the laws of the Member States relating to food supplements<sup>(30)</sup>), or of ‘fortified foods’ (falling within Regulation (EC) No 1925/2006 on the addition of vitamins and minerals and of certain other substances to foods<sup>(31)</sup>). In other words, the question is whether food supplements and fortified foods are to be taken into account in determining whether the patient’s dietary requirements can be met by a modification of the diet rather than by recourse to FSMP.

<sup>(29)</sup> For example in the conclusions of the Standing Committee on the Food Chain and Animal Health of 10 February 2014 (item A.04) [https://ec.europa.eu/food/sites/food/files/safety/docs/reg-com\\_gfl\\_20140210\\_sum.pdf](https://ec.europa.eu/food/sites/food/files/safety/docs/reg-com_gfl_20140210_sum.pdf)

<sup>(30)</sup> Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements (OJ L 183, 12.7.2002, p. 51).

<sup>(31)</sup> Regulation (EC) No 1925/2006 of the European Parliament and of the Council of 20 December 2006 on the addition of vitamins and minerals and of certain other substances to foods (OJ L 404, 30.12.2006, p. 26).

61. The concept of 'modification of the normal diet' is not defined but only mentioned in the FSMP definition ('food (...) intended for the exclusive or partial feeding of patients (...) whose dietary management cannot be achieved by modification of the normal diet alone'). In line with the interpretative elements provided above with respect to the concept of 'dietary management', it appears evident that the concept of 'modification of the normal diet' must be interpreted in a broad way, as any adjustment to the diet through consumption of foodstuffs other than FSMP, and therefore includes use of food supplements or fortified foods.
62. This interpretation is confirmed by the legislative history of the development of the relevant measures of EU food law. The definition of FSMP laid down in the FSG Regulation follows very much the definition laid down in Directive 1999/21/EC, which defined FSMP as 'a category of foods for particular nutritional uses specially processed or formulated and intended for the dietary management of patients and to be used under medical supervision. They are intended for the exclusive or partial feeding of patients with a limited, impaired or disturbed capacity to take, digest, absorb, metabolise or excrete ordinary foodstuffs or certain nutrients contained therein or metabolites, or with other medically-determined nutrient requirements, whose dietary management cannot be achieved only by modification of the normal diet, by other foods for particular nutritional uses, or by a combination of the two' (Article 1(2)(b)).
63. Directive 1999/21/EC was adopted before Directive 2002/46/EC on food supplements, and Regulation (EC) No 1925/2006 on fortified foods. At that time, there was only Council Directive 89/398/EEC <sup>(32)</sup>, which defined 'foods for particular nutritional uses' as 'foodstuffs which, owing to their special composition or manufacturing process, are clearly distinguishable from foodstuffs for normal consumption, which are suitable for their claimed nutritional purposes and which are marketed in such a way as to indicate such suitability' (Article 1(2)(a)) and defined FSMP as one category of 'foods for particular nutritional uses'.
64. In this context, the last sentence of the old definition of FSMP ('whose dietary management cannot be achieved only by modification of the normal diet, by other foods for particular nutritional uses, or by a combination of the two') was aimed at describing all possible ways to manage the diet of patients through foods that are not FSMP. More specifically, 'modification of the normal diet' referred to any adjustments to the diet by consuming foods for normal consumption (i.e. foods that are not 'foods for particular nutritional uses'). This was completed by reference to the possible consumption of 'foods for particular nutritional uses' different from FSMP ('by other foods for particular nutritional uses') and the combination of all foods other than FSMPs together ('or by a combination of the two').
65. The adoption of the legislation on food supplements in 2002, or on fortified foods in 2006 did not change the basic distinction between foodstuffs for normal consumption and FSMP. Food supplements are defined in Article 2(a) of Directive 2002/46/EC as 'foodstuffs the purpose of which is to supplement the normal diet (...)'. In supplementing the normal diet they become part of the normal diet and thus are apt to modify the normal diet. The same reasoning applies to foods covered by Regulation (EC) No 1925/2006. That Regulation is about the addition of vitamins and minerals and other substances to food. Clearly, such addition does not affect the qualification of such foods as normal food that is part of the normal diet and apt to modify it.
66. The definition of FSMP in the FSG Regulation has remained mostly the same, and the changes introduced are mainly linked to the abolition of the concept of 'food for particular nutritional uses'. The last sentence of the definition ('whose dietary management cannot be achieved by modification of the normal diet alone') is slightly different from the old one. However, it still describes, in a simpler way, all possible ways to manage the diet of patients through foods that are not FSMP, including through food supplements and fortified foods.

<sup>(32)</sup> Council Directive 89/398/EEC of 3 May 1989 on the approximation of the laws of the Member States relating to foodstuffs intended for particular nutritional uses (OJ L 186, 30.6.1989, p. 27). This Directive was then recast into Directive 2009/39/EC of the European Parliament and of the Council of 6 May 2009 on foodstuffs intended for particular nutritional uses (OJ L 124, 20.5.2009, p. 21).

ii. How should the potential for modification of the diet be assessed?

67. Although the definition of FSMP must be interpreted narrowly, FBOs and national competent authorities must keep in mind the importance of a number of considerations when deciding whether a product is to be classified as FSMP or not. These types of considerations are, in particular, important when assessing whether the dietary management of the patients concerned ‘cannot be achieved by modification of the normal diet alone’.
68. While in certain cases it could be theoretically possible to find alternative ways of satisfying the nutritional needs of the patients suffering from a specific disease/disorder/medical condition for which the FSMP is intended without consumption of the FSMP, those alternatives might be unrealistic or not practical. This is particularly the case for nutritionally incomplete FSMP.

One example is the case of cystic fibrosis: in the absence of FSMP, a patient suffering from cystic fibrosis could theoretically satisfy the increased micronutrient requirements resulting from the disease by consuming a mix of normal foods, fortified foods or food supplements. However, given the very considerable difference in requirements between healthy subjects and those suffering from cystic fibrosis, it is not practical to satisfy the nutritional requirements of these patients by exclusive consumption of foods other than FSMP (e.g. to consume dozens of vitamin A supplements that are marketed for the healthy population).

69. Therefore, when reflecting on the possible classification of a product as FSMP, the phrase ‘cannot be achieved by modification of the normal diet alone’ should be interpreted restrictively, but not to the extent of an absolute impossibility. It needs to be pragmatically assessed whether and to what extent it is possible to satisfy the nutritional needs of the patients suffering from a specific disease, disorder or other medical condition without FSMP.
70. In this context, it can be useful to analyse whether the use of the specific product is more practical or safer than the exclusive use of foodstuffs that are not FSMP, or whether it has a nutritional or clinical advantage for the patient. This assessment requires a case-by-case analysis by FBOs and the national competent authorities and should take into account factors such as:
- the stage of development or severity of the disease/disorder/medical condition (e.g. cancer patients might be in need of FSMP only when the disease progresses);
  - the impact on the patients’ health of not meeting, for a specific amount of time, their nutritional needs, and to what extent this may be the case;
  - the role of the specific product, and its differences from food that is not FSMP, taking into account the product’s composition, its intended use and the proposed instructions for use (including patterns of consumption);
  - the availability of other food products (including food supplements and fortified foods) with a similar composition (e.g. it would be difficult to consider as FSMP a product in dose form containing concentrated amounts of a number of micronutrients for the dietary management of a certain disease/disorder/medical condition when food supplements exist with the same/very similar composition);
  - the practical difficulty to modify the diet without FSMP and to ensure compliance with the patients’ specific nutritional needs.

#### 7. The composition of FSMP and its classification in categories

71. Recitals (4) and (5) of Delegated Regulation (EU) 2016/128 state that:

‘(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.'
72. Thus, the provisions of Delegated Regulation (EU) 2016/128 are aimed at establishing a flexible framework in order to allow FBOs to develop innovative products intended for a large variety of specific nutritional needs, each of them depending on the nature, symptoms and consequences of the disease/disorder/medical condition in question. In this context, the notion of what might constitute FSMP (i.e. the definition) has to be interpreted narrowly, so as to distinguish it from foodstuffs other than FSMP (see section 6), whereas flexibility is called for when reflecting on the specific disease/disorder/medical condition which give rise to the patient's nutritional need which can only be met by the consumption of FSMP (i.e. the target patient group).
73. In order to provide an indication of the different varieties of FSMP that can exist, Article 2(1) of Delegated Regulation (EU) 2016/128 lists the three categories in which FSMP can be classified:
- (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<sup>(33)</sup>.
74. Understanding the different categories can be useful to FBO/national competent authorities when reflecting on whether a specific product corresponds to the definition of FSMP or not. With this in mind, a short explanation of the main characteristics of the three categories of FSMP is provided below.
- a) *Nutritionally complete products with a standard formulation*: these products contain all the necessary nutrients at appropriate levels so that they may be used as the sole source of nutrition for a patient when taken in a sufficient quantity. This quantity will depend for example on the age, bodyweight and medical condition of the patient as recommended by a health care professional. They may be used as a sole source of nutrition to replace the total diet, either orally or via an enteral tube. They may also be used for partial feeding of the patient, depending on nutritional needs and in accordance with the recommendations of the health care professional.
  - b) *Nutritionally complete products with a nutrient-adapted formulation*: these products are aimed at taking into account the specific nutritional needs associated with a disease or range of diseases, disorders or medical conditions. They contain all the necessary nutrients at appropriate levels so that they may be used as the sole source of nutrition for a patient when taken in sufficient quantity. They may also be used for partial feeding of the patient, in accordance with the recommendations of the health care professional. This category includes for example FSMP developed to satisfy the nutritional requirements of infants from birth who suffer from specific diseases/disorders/medical conditions where breastfeeding (or consumption of formula for healthy infants) is not recommended by health care professionals.
  - c) *Nutritionally incomplete products with a standard or nutrient-adapted formulation*: these products either do not contain all the essential nutrients or contain them in quantities or balance that means the products are not suitable to be used as the sole source of nutrition. They are used for partial feeding and are used by the patient in addition to normal foods, an adapted diet, other FSMP products or parenteral nutrition.

<sup>(33)</sup> 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.

**8. What data are needed to demonstrate that a product is correctly placed on the market as FSMP<sup>(34)</sup>?**

75. It is not possible to describe in advance what specific data are necessary to demonstrate that a product is correctly placed on the market as FSMP. This analysis has to be carried out, on a case-by-case basis, by the FBO (when designing, producing and finally distributing the FSMP) and by the national competent authority (when enforcing the relevant legislation). Those data should however objectively demonstrate the correspondence of the product to the definition of FSMP. In other words, data should demonstrate in an objective way that the patients suffering from the disease/disorder/medical condition for which the FSMP is intended:
- have, because of that disease/disorder/medical condition, a limited, impaired or disturbed capacity to take, digest, absorb, metabolise or excrete ordinary food or certain nutrients contained therein, or metabolites; or
  - have other medically-determined nutrient requirements linked to the disease/disorder/medical condition they are suffering from; and
  - in both cases, it is impossible, impractical, unsafe or nutritionally/clinically disadvantageous for these patients to satisfy their nutritional needs through exclusive consumption of food that is not FSMP.
76. The data must therefore demonstrate that the specific group of patients suffering from a disease/disorder/medical condition for which the product is intended have nutritional needs that are impossible, impractical, unsafe or nutritionally/clinically disadvantageous to satisfy through the exclusive consumption of food other than FSMP. In this respect, the people for whom consumption of FSMP is necessary/useful should be clearly identifiable as different from other people who do not need the product. The possibility to modify the normal diet through food other than FSMP is to be assessed on a case-by-case basis by reference to a typical person suffering from the disease, disorder or other medical condition for which the FSMP is intended.
77. The European Food Safety Authority (EFSA) issued scientific and technical guidance on foods for special medical purposes in the context of Article 3 of Regulation (EU) No 609/2013<sup>(35)</sup>. Pursuant to Article 3 of the FSG Regulation, the Commission can adopt decisions stating whether a specific product placed on the market as FSMP is appropriately classified as such or not. In this context, the Commission might decide to consult EFSA for scientific advice and the guidance adopted by EFSA gives an indication of the type of data that EFSA will need when answering such requests of the Commission.
78. While the guidance was primarily adopted to provide transparency on the work of EFSA in the context of possible future Article 3 decisions, it can also prove useful for FBOs and national competent authorities reflecting on the type of data that might be relevant for deciding whether a product is correctly placed on the market as FSMP or not.

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<sup>(34)</sup> As explained in section 3, in accordance with Article 17(1) of Regulation (EC) No 178/2002, the FBO placing a product on the market as FSMP is responsible to ensure that the product satisfies all the relevant requirements of food law and to verify that such requirements are met. This section focuses only on the data which are needed to demonstrate that a product is correctly classified as FSMP (i.e. corresponds to the definition laid down in the legislation), and does not elaborate on what data are needed to demonstrate compliance with all the other relevant requirements of EU food law applicable to FSMP, as the latter is out of the scope of this Commission Notice.

<sup>(35)</sup> EFSA NDA Panel (EFSA Panel on Dietetic Products, Nutrition and Allergies), 2015. Scientific and technical guidance on foods for special medical purposes in the context of Article 3 of Regulation (EU) No 609/2013. EFSA Journal 2015;13(11):4300, 24 pp. doi:10.2903/j.efsa.2015.4300.