SCIENTIFIC OPINION

Scientific and technical guidance on foods for special medical purposes in the context of Article 3 of Regulation (EU) No 609/2013[1]

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ABSTRACT

Following a request from the European Commission, the EFSA Panel on Dietetic products, Nutrition and Allergies (NDA) was asked to provide scientific and technical guidance on foods for special medical purposes in the context of Article 3 of Regulation (EU) No 609/2013. The guidance presented in this document is to assist in the preparation and presentation of well-structured dossiers. It presents a common format for the organisation of the information and outlines the information and scientific data which could be included in the dossier, as well as the key issues which should be addressed in the dossier in order to assess the extent to which a food product notified as FSMP falls under the scope of Regulation (EU) No 609/2013, under the proposed use. It is intended that the guidance will be kept under review and will be further amended and updated as appropriate in the light of experience gained from the evaluation of dossiers for specific food products notified as FSMP, and in the light of future Community guidelines and legislation. The scope of this guidance is limited to FSMPs in the context of Article 3 of Regulation (EU) No 609/2013. Out of the scope of this guidance are: a) other categories of food falling under Regulation (EU) No 609/2013, such as infant formula and follow-on formula, processed cereal-based food and baby food, and total diet replacement for weight control; b) meal replacements for weight control; c) "gluten-free" and "lactose-free" foods.

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KEY WORDS

food product, disease, disorder, medical condition, patients, dietary management

[1] On request from the European Commission, Question No EFSA-Q-2014-00736, adopted on 28 October 2015.

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[3] Acknowledgement: The Panel wishes to thank the members of the ad-hoc Working Group on foods for special medical purposes: Hildegard Przyrembel, Alfonso Siani, Dominique Turck and André Van Gossum for the preparatory work on this scientific opinion, and EFSA staff member Silvia Valtueña Martínez for the support provided to this scientific opinion.

Suggested citation: 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

Available online: www.efsa.europa.eu/efsajournal

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SUMMARY

Following a request from the European Commission, the EFSA Panel on Dietetic products, Nutrition and Allergies (NDA) was asked to provide scientific and technical guidance on foods for special medical purposes (FSMPs) to advise on different aspects that the Commission may consider when taking decisions pursuant to Article 3 of Regulation (EU) No 609/2013.

The scope of this guidance is limited to FSMPs in the context of Article 3 of Regulation (EU) No 609/2013. Out of the scope of this guidance are:

- other categories of food falling under Regulation (EU) No 609/2013, such as infant formula and follow-on formula, processed cereal-based food and baby food, and total diet replacement for weight control;
- meal replacements for weight control;
- "gluten-free" and "lactose-free" foods.

The questions which the Commission may ask EFSA to address in specific mandates after 20 July 2016 in order to take decisions pursuant to Article 3 of Regulation (EU) No 609/2013 on the classification of specific food products as FSMPs are the following:

- the extent to which the specific food product is sufficiently characterised, i.e. the extent to which the information provided allows an accurate description of the specific food product regarding the characteristics which may be important for its classification as FSMP.
- the extent to which the disease/disorder/medical condition for which the specific product is intended is sufficiently characterised, i.e. the extent to which the information provided allows to distinguish between patients for whom the specific food product is intended and other individuals for whom the specific food product is NOT intended.
- the extent to which patients suffering from the specific disease/disorder/medical condition for the dietary management of which the product is intended; a) are in the impossibility or difficulty to take, digest, absorb, metabolise or excrete ordinary foodstuffs, or certain nutrients contained therein or metabolites, or b) have specific medically-determined nutrient requirements, typical to the disease/disorder/medical condition, that cannot be reasonably or realistically satisfied by modifying the normal diet, i.e. the extent to which it is impossible, impractical or unsafe for patients for which the specific food product is intended to consume exclusively foodstuffs (including fortified foods and food supplements) that are not FSMPs, and/or the extent to which such patients would have a nutritional or clinical disadvantage from consuming exclusively foodstuffs (including fortified foods and food supplements) that are not FSMPs.
- the specific role of the product in the dietary management of the disease/disorder/medical condition for which it is intended, in particular the extent to which the specific product is different from / more suitable than foods that are not FSMPs, taking into account its composition, its intended use and the proposed instructions of use (including patterns of consumption); i.e. the extent to which the specific food product is different from foodstuffs (including food supplements and fortified foods) that are not FSMPs, owing to its composition, manufacturing process, physical form, mode of administration, pattern of consumption and/or other reasons; the extent to which the use of the specific food product in the dietary management of patients for whom the product is intended is necessary or more practical or safer than the exclusive use of foodstuffs (including fortified foods and food supplements) that are not FSMPs, and/or it has a nutritional or clinical advantage for the patient; the reasons why the specific food product needs to be administered under medical supervision.

- any potential restrictions of use, i.e. whether the specific food product may be unsafe if consumed by subjects other than patients for whom the specific product is intended.

The following information could be provided in the dossier, and the structure could follow a common format, i.e. order and numbering system of different parts, headings and sub-headings. The data provided in the dossier could be organised into **six Parts.**

Part 1 contains administrative and technical data, such as the identification form, information related to the party responsible for the dossier, and the dossier specifications, including the proposed use(s).

Part 2 contains information relative to the characterisation of the specific food product proposed as FSMP, including its name and characteristics, list of ingredients, its energy and nutrient content, any relevant information on the special formulation or processing of the food product, a description of the manufacturing process, and stability information.

Part 3 contains information relative to the proposed use(s) for the specific food product, including the target patient population, the disease/disorder or the medical condition, the conditions of use and, where applicable, the restrictions of use.

Part 4 comprises information relative to the characterisation of the disease/disorder or the medical condition, and of the patients for whom the specific food product is intended for each proposed use, including information on the impact of the disease/disorder or the medical condition on the nutritional status of the patients, if any.

Part 5 contains information on the specific role of the food product in the dietary management of patients under each proposed use, including an explanation on why the use of the specific food product in the dietary management of patients is necessary or why it is more practical or safer than the exclusive use of foodstuffs that are not FSMPs, and/or why it has a nutritional or clinical advantage for the patient.

Part 6 comprises information on the conditions and restrictions of use for each proposed use, including information on the quantity and pattern of consumption, the route of administration, and the reasons why the product should be administered under medical supervision.

Where some of the data described in this guidance document do not apply to a specific food product or proposed use, reasons/justification could be given for the absence of such data in the dossier.

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BACKGROUND AS PROVIDED BY THE EUROPEAN COMMISSION

Existing legal framework for dietary food for special medical purposes (FSMPs) and its application

Commission Directive 1999/21/EC[4] lays down composition and labelling requirements for dietary food for special medical purposes (FSMPs) under the framework of Directive 2009/39/EC of the European Parliament and of the Council on foods intended for particular nutritional uses (also called "dietetic foods")[5].

According to Article 1(2)(b) of Directive 1999/21/EC, "*'dietary foods for special medical purposes' means 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.*"[6]

Article 3 of Directive 1999/21/EC sets the requirement that the formulation of FSMPs shall be based on sound medical and nutritional principles. Their use, in accordance with the manufacturer's instructions, shall be safe and beneficial and effective in meeting the particular nutritional requirements of the persons for whom they are intended, as demonstrated by generally accepted scientific data. Certain compositional criteria for FSMPs are set out in the Annex to the Directive. It is however foreseen that FSMPs can derogate from the compositional requirements if these are contrary to the intended use of the product. This flexibility is needed taking into account the variety of conditions for the dietary management of which FSMPs are intended.

Article 4 of Directive 1999/21/EC sets a series of labelling requirements for FSMPs and Article 5 requires operators to notify the placing on the market of FSMPs to national competent authorities (unless Member States consider this notification not necessary).

National competent authorities have reported that application of the current legislative framework applicable to FSMPs is becoming challenging, that it may differ from one Member State to the other and that particular attention has to be paid to the definition of these products. Member States' experts have in particular flagged that an increasing number of products are notified as FSMPs in their territory, very often with doubts arising on whether these products really comply with the definition of FSMP. This situation may be detrimental to the interests of consumers, can affect competition and may pose challenges for the free circulation of goods in the EU.

In this context, the Commission services have taken note of the requests of Member States to develop a guidance document that could assist Member States' competent authorities in their enforcement tasks and stakeholders in marketing their products under the appropriate legal framework. Work on this guidance is currently on-going.

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

[5] 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.

[6] This definition is similar to that given in the CODEX Standard for the labelling of and claims for foods for special medical purposes (Codex STAN 180-1991). According to Article 1(3) of Directive 1999/21/EC, FSMPs are classified into three categories (a) nutritionally complete foods 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 they are intended; (b) nutritionally complete foods 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 they are intended; (c) nutritionally incomplete foods with a standard formulation or a nutrient-adapted formulation specific for a disease, disorder or medical condition which are not suitable to be used as the sole source of nourishment. The foods 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 new Framework applicable to FSMPs

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[7] (the FSG Regulation) revises the framework applicable to dietetic foods in general and to FSMPs in particular. The Regulation abolishes the concept of dietetic food, includes FSMPs under its scope, maintains the definition of Directive 1999/21/EC with minor adaptations[8] and requires the Commission to establish specific composition and information requirements for FSMPs in a delegated act to be adopted by 20 July 2016. The Commission is currently preparing the delegated act that will maintain the existing rules with adaptations where needed.

In order to ensure uniform implementation of the rules, Article 3 of the FSG Regulation empowers the Commission to decide as of 20 July 2016 (date of entry into application of the Regulation) by means of implementing acts:

- whether a given food falls within the scope of the Regulation and/or
- to which specific category of food covered by the Regulation a given food belongs.

Taking into account that the FSG Regulation does not further specify the procedure to be followed when applying Article 3, the Commission services have started to reflect, together with Member States, on the practical implications of the future application of this Article.

Application of Article 3 of the FSG Regulation for products notified as FSMPs

Given the abovementioned difficulties related to the application of the current FSMPs legislative framework, in particular with respect to the product definition (which has been maintained in the FSG Regulation), it appears evident that Article 3 of the FSG Regulation will be of particular relevance for these products in the future.

In this context, the Commission is considering including in the guidance document for FSMPs it is currently working on clear information on how Article 3 of the FSG Regulation could be applied in the case of products notified at national level as FSMPs. The inclusion of this information in the FSMPs guidance would guarantee transparency both for national competent authorities and stakeholders. In addition, this information could constitute useful advice to national competent authorities when applying the relevant rules on a case-by-case basis to products notified as FSMPs (even before it is decided to adopt a decision under Article 3). Finally, the inclusion of this information in the guidance would help operators market their products in accordance with the appropriate rules.

EFSA's role when Article 3 of the FSG Regulation is applied for products notified as FSMPs

Article 7 of the FSG Regulation foresees the possibility to consult EFSA on any matter related to the application of the Regulation which is likely to have an effect on public health. Clearly, EFSA's advice will be crucial for the Commission after 20 July 2016 when preparing implementing decisions pursuant to Article 3 in the case of products notified as FSMPs.

[7] 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.

[8] Article 2(2)(g): "'*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*".

When deciding to adopt an implementing decision on a specific product notified as FSMP, the main point on which the Commission could need EFSA's advice is expected to be the relationship between the product and the disease/disorder/medical condition for the dietary management of which the product is intended. Indeed, according to the definitions given in Directive 1999/21/EC and the FSG Regulation, FSMPs are intended for the exclusive or partial feeding of patients[9]:

- 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[10].

The main function of FSMPs is therefore to feed patients that, because of a particular disease/disorder/medical condition, either have problems in consuming ordinary foodstuffs, or have specific medically-determined nutrient requirements whose dietary management cannot be achieved by modifying the normal diet. In both the sub-paragraphs of the definition quoted above, there is a clear indication of the difference between FSMPs and other foodstuffs that are not FSMPs: FSMPs are foods whose consumption by patients is necessary because it is impossible, very difficult or unrealistic for these patients to satisfy their nutritional needs through the consumption of foods other than FSMPs[11].

This is why, after 20 July 2016 (when Article 3 of the FSG Regulation becomes applicable), EFSA might be requested to provide advice on a specific product notified as FSMP and to inform the Commission whether it is recognised, on the basis of generally accepted scientific data, that people suffering from the specific disease/disorder/medical condition for the dietary management of which the product is intended:

- are in the impossibility or difficulty to take, digest, absorb, metabolise or excrete ordinary foodstuffs, or certain nutrients contained therein or metabolites, or

- have specific medically-determined nutrient requirements, typical to the disease/disorder/medical condition, that cannot be reasonably or realistically satisfied by modifying the normal diet.

EFSA might be requested to inform the Commission about the degree to which it would be impossible or difficult to consume ordinary foodstuffs and/or to what extent a modification of the normal diet would not reasonably or realistically cater for the specific nutrient requirements of the patient in the specific case. In this context, EFSA might be requested to advise the Commission on the role of the specific product, namely whether and how is the specific product different from/more suitable than foods that are not FSMPs, taking into account its composition, its intended use and the proposed instructions for use (including patterns of consumption).

Requests for EFSA's advice to inform the preparation of Commission's implementing decisions pursuant to Article 3 of the FSG Regulation for products notified as FSMPs will not be sent to EFSA before 20 July 2016.

[9] For the purposes of this exercise, the concept of 'patient' has to be interpreted in a broad way, as people suffering from a diagnosed disease, disorder or medical condition.

[10] Reference to "*foods for particular nutritional uses*" has disappeared in the definition given in the FSG Regulation.

[11] Food supplements or fortified foods are regulated as foods and should therefore, for the purpose of this exercise, be considered as "ordinary foodstuffs" (see first bullet point quoting the definition above). Similarly, a "modification of the normal diet" (see second bullet point quoting the definition above) should be considered as any adjustment to the diet through consumption of foods other than FSMPs and can include use of food supplements or fortified foods.

However, in preparation for future work, the Commission considers it necessary to consult EFSA at this stage regarding the type of data that food business operators should make available to EFSA in the future in order for EFSA to provide scientific advice to the Commission along the lines described above.

This advice from EFSA could eventually also be included in the guidance document currently being drafted by the Commission on FSMPs so that the document would describe procedural aspects of the application of the Article 3 procedure (e.g. details about how to request the Commission's intervention on a specific product) as well as information on how to prepare a dossier for EFSA's assessment.

TERMS OF REFERENCE AS PROVIDED BY THE EUROPEAN COMMISSION

In accordance with Article 29 of Regulation (EC) No 178/2002, the European Commission requests the European Food Safety Authority to issue an opinion on scientific and technical guidance regarding the type of data that will be needed by EFSA for providing scientific advice to the Commission, after 20 July 2016, on specific products notified as FSMPs at national level and for which the Commission intends to adopt implementing decisions pursuant to Article 3 of Regulation (EU) No 609/2013.

In preparing this scientific and technical guidance, EFSA is requested to take into account the type of scientific advice that the Commission will need when taking decisions pursuant to Article 3 of Regulation (EU) No 609/2013. In this context, after 20 July 2016, EFSA might for example be asked to advise on:

- the extent to which the disease/disorder/medical condition for which the specific product is intended is sufficiently characterised;
- the extent to which patients suffering from the specific disease/disorder/medical condition for the dietary management of which the product is intended:
  - are in the impossibility or difficulty to take, digest, absorb, metabolise or excrete ordinary foodstuffs, or certain nutrients contained therein or metabolites, or
  - have specific medically-determined nutrient requirements, typical to the disease/disorder/medical condition, that cannot be reasonably or realistically satisfied by modifying the normal diet;
- the extent to which the specific product is sufficiently characterised;
- the specific role of the product in the dietary management of the disease/disorder/medical condition for which it is intended, in particular the extent to which the specific product is different from / more suitable than foods that are not FSMPs, taking into account its composition, its intended use and the proposed instructions of use (including patterns of consumption);
- any potential restrictions of use.

SCOPE AND INTERPRETATION OF THE TERMS OF REFERENCE

The scope of this guidance document is to summarise the information that EFSA may need to advise risk managers on different aspects that the Commission may consider when taking decisions pursuant to Article 3 of Regulation (EU) No 609/2013. It is out of the scope of this guidance, however, to describe the procedural aspects of placing FSMPs on the market or the procedural aspects for the implementation of Article 3 of Regulation (EU) No 609/2013, which are under the remit of risk managers.

The scope of this guidance is limited to FSMPs in the context of Article 3 of Regulation (EU) No 609/2013. Out of the scope of this guidance are:

- other categories of food falling under Regulation (EU) No 609/2013, such as infant formula and follow-on formula, processed cereal-based food and baby food, and total diet replacement for weight control;
- meal replacements for weight control;
- "gluten-free" and "lactose-free" foods.

As described in the ToR and further explained by the European Commission, the scientific questions which the Commission may ask EFSA to address in future mandates (after 20 July 2016) in order to take decisions pursuant to Article 3 of Regulation (EU) No 609/2013 with respect to the classification of specific food products as FSMPs are:

- **the extent to which** the specific food product is sufficiently characterised, i.e. **the extent to which** the information provided allows an accurate description of the specific food product regarding the characteristics which may be important for its classification as FSMP.

- **the extent to which** the disease/disorder/medical condition for which the specific product is intended is sufficiently characterised, i.e. **the extent to which** the information provided allows distinguishing between patients for whom the specific food product is intended and other individuals for whom the specific food product is NOT intended.

- **the extent to which** patients suffering from the specific disease/disorder/medical condition for the dietary management of which the product is intended; a) are in the impossibility or difficulty to take, digest, absorb, metabolise or excrete ordinary foodstuffs, or certain nutrients contained therein or metabolites, or b) have specific medically-determined nutrient requirements, typical to the disease/disorder/medical condition, that cannot be reasonably or realistically satisfied by modifying the normal diet, i.e. **the extent to which** it is impossible, impractical or unsafe for patients for whom the specific food product is intended to consume exclusively foodstuffs (including fortified foods and food supplements) that are not FSMPs, and/or **the extent to which** such patients would have a nutritional or clinical disadvantage from consuming exclusively foodstuffs (including fortified foods and food supplements) that are not FSMPs.

- the specific role of the product in the dietary management of the disease/disorder/medical condition for which it is intended, in particular the extent to which the specific product is different from / more suitable than foods that are not FSMPs, taking into account its composition, its intended use and the proposed instructions of use (including patterns of consumption); i.e. **the extent to which** the specific food product is different from foodstuffs (including food supplements and fortified foods) that are not FSMPs, owing to its composition, manufacturing process, physical form, mode of administration, pattern of consumption and/or other reasons; **the extent to which** the use of the specific food product in the dietary management of patients for which the product is intended is necessary or is more practical or safer than the exclusive use of foodstuffs (including fortified foods and food

supplements) that are not FSMPs, and/or has a nutritional or clinical advantage for the patient; **the reasons why** the specific food product needs to be administered under medical supervision.

- any potential restrictions of use, i.e. whether the specific food product may be unsafe if consumed by subjects other than patients for whom the specific product is intended.

In the context of the implementation of Article 3 of Regulation (EU) No 609/2013, EFSA will NOT be asked by the European Commission:

- to interpret the definition of FSMPs or to conclude on whether or not a specific food product should be classified as FSMP. Therefore, the specific requirements for the characterisation of specific foods are not addressed in this guidance.

- to address the scientific substantiation of health claims made on specific food products notified as FSMP.

OBJECTIVES

The guidance presented in this document is to assist in the preparation and presentation of well-structured dossiers in the context of Article 3 of Regulation (EU) No 609/2013 for food products notified as foods for special medical purposes (FSMPs).

It presents a common format for the organisation of the information to be provided and outlines:

- the information and scientific data which may be included in the dossier,
- the key issues which should be addressed in the dossier for EFSA to advise on different aspects that the Commission may consider when taking decisions pursuant to Article 3 of Regulation (EU) No 609/2013, under the proposed use(s).

It is not the objective of this guidance to specify the requirements which specific food products should fulfil in order to be classified as FSMP, but rather to guide on the type of information which will be evaluated by EFSA in order to provide its advice to the Commission. Owing to the wide range of food products notified as FSMPs and the wide range of patients suffering from diseases/disorders/medical conditions for which they are intended, and because this guidance aims to cover all products which could be notified as FSMP and all their intended uses, it is possible that the type of information outlined in one or more sections of this guidance is only relevant for some products and/or intended uses and not for others.

It is intended that the guidance will be kept under review and will be further amended and updated as appropriate in the light of experience gained from the scientific assessment of dossiers for specific food products notified as FSMP, and in the light of future Community guidelines and legislation.

GENERAL PRINCIPLES

This document should be read in conjunction with Regulation (EU) No 609/2013 of the European Parliament and of the Council as regards FSMP, with Directive 2002/46/EC of the European Parliament and of the Council on the approximation of the laws of the Member States relating to food supplements, as amended[12], with Regulation (EC) No 1925/2006 of the European Parliament and of

[12] Directive 2002/46/EC of the European Parliament and 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.

the Council on the addition of vitamins and minerals and of certain other substances to foods[13], as amended, and with current and future Community guidelines and Regulations.

- This guidance applies to FSMP as described in Regulation (EU) No 609/2013, i.e. "*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*".

- In the context of this guidance:

  Disease/disorder means a pathological process, acute or chronic, inherited or acquired, of known or unknown origin, having a characteristic set of signs and symptoms which are used for its diagnosis and the management of which requires nutritional intervention under medical supervision. In this guidance document, the terms disease and disorder are considered as synonymous and have the same meaning[14].

  Medical condition denotes any structural or functional alteration, either acute or chronic, which may result from one or more diseases or disorders, the management of which requires nutritional intervention under medical supervision[15].

  Patient refers to a person (including infants and young children) affected by the **disease/disorder or the medical condition**.

  Food product denotes any food suitable for human consumption[16] (i.e. to be administered by the oral or enteral route) which provides energy-containing macronutrients (e.g. carbohydrates, protein, fats), and/or micronutrients (e.g. vitamins, minerals), and/or other substances which may contribute to fulfilling the nutritional requirements of **patients**.

  Food supplements means foodstuffs whose purpose is to supplement the normal diet and which are concentrated sources of nutrients (i.e. vitamins, minerals) or other substances with a nutritional or physiological effect, alone or in combination, marketed in dose form, namely forms such as capsules, pastilles, tablets, pills and other similar forms, sachets of powder, ampoules of liquids, drop dispensing bottles, and other similar forms of liquids and powders designed to be taken in measured small unit quantities[17].

[13] Regulation (EC) No 1925/2006 of the European Parliament and of 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.

[14] Examples (non-exhaustive list) of diseases/disorders are, e.g. inborn errors of metabolism (e.g. phenylketonuria), Crohn's disease.

[15] Examples (non-exhaustive list) of medical conditions resulting from different diseases/disorders are, e.g.: a) liver failure resulting from e.g. viral hepatitis, hemochromatosis, Wilson's disease; b) dysphagia resulting from e.g. cancer of the upper gastrointestinal tract, neurological disorders (e.g. multiple sclerosis, muscular dystrophy, Parkinson's disease); c) respiratory failure resulting from e.g. cystic fibrosis, Duchenne myopathy, α 1-antitrypsin deficiency; d) short bowel syndrome resulting from e.g. inflammatory bowel disease, necrotizing enterocolitis; e) chronic metabolic acidosis resulting from e.g. inherited renal tubular acidosis, organic acidaemias (e.g. maple syrup urine disease, propionic acidaemia); f) disease-related malnutrition resulting from e.g. cancer, inflammatory bowel diseases.

[16] Products intended for administration via other routes (e.g. intravenous, intramuscular, cutaneous, by inhalation) are out of the scope of this guidance.

[17] Adapted from Directive 2002/46/EC of the European Parliament and 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.

Fortified food means a foodstuff to which vitamin(s), mineral(s), other substances, or a combination of them, have been added[18].

Proposed use denotes a specific context in which the specific food product is proposed as FSMP. This includes the target **patient** population, the **disease/disorder or the medical condition,** the conditions of use (e.g. quantity and pattern of consumption, directions for preparation and use), and, where applicable, the restrictions of use.

- The term **dossier** hereafter means a stand-alone package containing the information and scientific data submitted for the scientific evaluation of a food product notified as FSMP under the proposed use.

- One dossier should be prepared for each individual food product; this means that only **one food product can be the object of each dossier**. However, multiple versions[19] of the specific food product can be the object of the same dossier, provided that the scientific evidence is valid for all proposed versions of the food product. Similarly, multiple proposed uses can be the object of the same dossier, provided that the scientific evidence is valid for all proposed uses.

- The dossier should contain all pertinent information and scientific data (published and unpublished, data in favour and not in favour) relative to the assessment of the specific food product as FSMP under the proposed use(s).

- The entire dossier may not be claimed as confidential. Specific parts, sections, words, graphs or datasets considered as confidential by the party responsible for the dossier should be kept to a minimum and clearly identified as such. The party responsible for the dossier is required to provide detailed and verifiable justification for every part of the dossier claimed as confidential.

- This guidance presents a common format for the organisation of the information. Adherence to this format will also facilitate access to the information by the NDA Panel in order to conduct the evaluation and deliver scientific advice in an effective and consistent way.

- Not all the information and data specified in this guidance may be relevant for each dossier. However, reasons/justification could be given for the absence of such data in the dossier.

ORGANISATION AND CONTENT OF THE DOSSIER

The following information could be provided in the dossier, and the structure could follow a common format, i.e. order and numbering system of different parts, headings and sub-headings. The data provided in the dossier could be organised into **six Parts.**

Part 1 contains administrative and technical data, such as the identification form, information related to the party responsible for the dossier, the dossier specifications, including the proposed use(s), and any confidentiality claims.

Part 2 contains information relative to the characterisation of the specific food product proposed as FSMP, including its name and characteristics, list of ingredients, its energy and nutrient content, any relevant information on the special formulation or processing of the food product, a description of the manufacturing process, and stability information.

[18] As laid down in Regulation (EC) No 1925/2006 of the European Parliament and of 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, as amended.

[19] For example, a food product available in different flavours (e.g. vanilla, chocolate) or formats (tablets, powder, liquid).

Part 3 contains information relative to the proposed use(s) for the specific food product, including the target patient population, the disease/disorder or the medical condition, the conditions of use and, where applicable, the restrictions of use.

Part 4 comprises information relative to the characterisation of the disease/disorder or the medical condition, and of the patients for whom the specific food product is intended for each proposed use, including information on the impact of the disease/disorder or the medical condition on the nutritional status of the patients, if any.

Part 5 contains information on the specific role of the food product in the dietary management of patients under each proposed use, including an explanation on why the use of the specific food product in the dietary management of patients is necessary or why it is more practical or safer than the exclusive use of foodstuffs that are not FSMPs, and/or why it has a nutritional or clinical advantage for the patient.

Part 6 comprises information on the conditions and restrictions of use for each proposed use, including information on the quantity and pattern of consumption, the route of administration, and the reasons why the product should be administered under medical supervision.

Where some of the data described in this guidance document do not apply to a specific food product or proposed use, reasons/justification could be given for the absence of such data in the dossier.

1. Part 1: Administrative and technical data

1.1. Comprehensive table of contents of the dossier

1.2. Identification form

Please use the identification form provided in the **Appendix**.

1.3. Party responsible for the dossier

1.3.1. Company/organisation

Provide the name and address of the company or organisation[20].

1.3.2. Contact person

Indicate the contact person authorised to communicate with EFSA on behalf of the party responsible for the dossier[21].

1.4. Specifications

1.4.1. Specific food product

1.4.2. Specify whether the dossier refers to:

☐ A ***nutritionally complete*** food product 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.

☐ A ***nutritionally complete*** food product 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.

☐ A ***nutritionally incomplete*** food product 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***.

1.4.3. Describe the proposed use(s) for the specific food product

For each proposed use, please identify the target patient population, the disease/disorder or the medical condition, the standard conditions of use and, where applicable, the restrictions of use.

Proposed use No.1

Proposed use No.2

Proposed use No.x

1.5. Confidential data

State whether the dossier includes confidential data ☐ yes ☐ no

[20] In case more than one company or organisation submits dossier, provide their names and addresses. EFSA requires that **only one contact person be authorised to communicate with EFSA**.

[21] To facilitate communication, EFSA requires that there be only **one contact person per dossier**.

If yes, please specify the related Part in the dossier, stating section and page number, and providing verifiable justification(s)/declaration(s) (see also general principle 6 of this guidance document).

2. Part 2: Characterisation of the specific food product

2.1. Name and characteristics

Please provide the source and specifications of the food product (e.g. physical and chemical properties, composition, and where applicable microbiological constituents), the list of ingredients and their sources, as well as the energy and nutrient content of the product as consumed. Please specify the methodology used to assess the energy and nutrient content of the specific product. Batch to batch variability should also be addressed.

If analytical methods are applied to provide a quantitative analysis of the energy and nutrient content, please provide information on the measures in place to ensure the quality and consistency of the data. Please also indicate whether the measurements have been performed in a competent laboratory that can certify the data. Whenever a quality system is in place for control/documentation (e.g. GLP and ISO17025), the particular system should be indicated.

Please indicate any relevant information on the special formulation of the product (i.e. explain why this product has a formulation which is different from foodstuffs, including fortified foods and food supplements, that are not FSMPs), where appropriate.

2.2. Manufacturing process

Please provide a description of the manufacturing process. If the production follows a quality system (e.g. GMP) the particular system should be indicated. If the manufacturing process is claimed as confidential, a non-confidential summary of the manufacturing process should also be provided in the dossier for transparency reasons.

Please indicate any relevant information on the special processing of the product (i.e. explain why this product has a manufacturing process which is different from foodstuffs, including fortified foods and food supplements, that are not FSMPs), where appropriate.

2.3. Stability information

Where applicable, a brief summary of the studies undertaken (e.g. conditions, batches and analytical procedures), and of the results and conclusions of the stability studies, should be provided. Conclusions with respect to storage conditions and shelf-life should be given.

2.4. References

References and supporting documentation quoted under Part 2 should be given here (no particular format required), together with copies/reprints of published data and/or full reports of unpublished data.

3. Part 3: Proposed use(s)

Please briefly describe the proposed use(s) for the specific food product. For each proposed use, please identify the target patient population, the disease/disorder or the medical condition, the conditions of use and, where applicable, the restrictions of use.

Proposed use No.1:

Proposed use No.2:

Proposed use No.x:

Note 1: *If more than one use is proposed for the specific food product, parts 4, 5 and 6 of this guidance should be filled out for each proposed use.*

Note 2: *If one or more parts are common to two or more proposed uses, please indicate this.*

Parts 4, 5 and 6 for proposed use No.1

4. Part 4: Characterisation of the disease/disorder or the medical condition, and of the patients for whom the specific food product is intended

4.1. Diagnosis of the disease/disorder – description of the medical condition

For the disease/disorder or the medical condition for which the specific food product is intended, please specify whether:

a) It is a disease or disorder[22], the diagnosis of which relies on widely accepted, well-defined, objective criteria (i.e. the criteria used for diagnosis are widely accepted by the medical community and can be verified by a physician)

☐ yes ☐ no

If yes, please specify the criteria used for diagnosis of the disease or disorder. Please provide guidelines/consensus papers published by scientific (medical) societies in which the criteria used for diagnosis are described, if available.

b) It is a medical condition[23]

☐ yes ☐ no

If yes, please specify and describe in detail the medical condition.

[22] As defined in general principle 2 of this guidance document
[23] As defined in general principle 2 of this guidance document

4.2. Characterisation of the patients for whom the specific food product is intended

- Please specify the patients suffering from the disease/disorder or the medical condition for whom the specific food product is intended. Information should be provided on whether the specific food product is intended for all patients suffering from the disease/disorder or the medical condition. If the specific food product is intended only for a particular subgroup of patients, please specify the characteristics of such patients (e.g. age, sex, stage of the disease, clinical condition).

- Please specify the reason(s) why it is impossible, impractical or unsafe for patients for whom the specific food product is intended to consume exclusively foodstuffs (including fortified foods and food supplements) that are not FSMPs, and/or the reason(s) why such patients would have a nutritional or clinical disadvantage from consuming exclusively foodstuffs (including fortified foods and food supplements) that are not FSMPs (one or more of the reasons below may apply):

  a) Inability (or reduced ability) to ***chew and/or swallow*** foodstuffs that are not FSMPs

  ☐ yes ☐ no

  If yes, please specify the reason why the disease/disorder or the medical condition for which the specific food product is intended would lead to the inability (or reduced ability) to chew and/or swallow foodstuffs that are not FSMPs.

  b) Inability (or reduced ability) to ***digest*** foodstuffs that are not FSMPs

  ☐ yes ☐ no

  If yes, please specify the reason why the disease/disorder or the medical condition for which the specific food product is intended would lead to the inability (or reduced ability) to digest foodstuffs that are not FSMPs.

  c) Inability (or reduced ability) to ***absorb*** nutrients contained in foodstuffs that are not FSMPs

  ☐ yes ☐ no

  If yes, please specify the reason why the disease/disorder or the medical condition for which the specific food product is intended would lead to the inability (or reduced ability) to absorb nutrients (please specify which nutrients) contained in foodstuffs that are not FSMPs.

  d) Inability (or reduced ability) to ***metabolise and/or utilise*** nutrients contained in foodstuffs that are not FSMPs

  ☐ yes ☐ no

If yes, please specify the reason why the disease/disorder or the medical condition for which the specific food product is intended would lead to the inability (or reduced ability) to metabolise and/or utilise nutrients (please specify which nutrients) contained in foodstuffs that are not FSMPs.

e) Inability (or reduced ability) to ***excrete*** nutrients contained in foodstuffs that are not FSMPs, and/or their metabolites

☐ yes ☐ no

If yes, please specify the reason why the disease/disorder or the medical condition for which the specific food product is intended would lead to the inability (or reduced ability) to excrete nutrients (please specify which nutrients) contained in foodstuffs that are not FSMPs, and/or their metabolites (please specify which metabolites).

f) The disease/disorder or the medical condition is triggered or aggravated by the consumption of foodstuffs that are not FSMPs [24].

☐ yes ☐ no

If yes, please provide evidence that the disease/disorder or the medical condition is triggered or aggravated by the consumption of foodstuffs that are not FSMPs and specify the foodstuffs which trigger or aggravate the disease/disorder or the medical condition, and the reason why (if known).

g) The disease/disorder or the medical condition leads to specific medically-determined nutrient requirements, typical of the disease/disorder or the medical condition.

☐ yes ☐ no

If yes, please specify whether the disease/disorder or the medical condition typically leads to specific requirements of:

☐ Energy	☐ Carbohydrates	☐ Fat/fatty acids
☐ Protein/amino acids	☐ Vitamins	☐ Minerals
☐ Water/electrolytes	☐ Other substances.	Please specify:

Please provide evidence that the disease(s)/disorder(s) or the medical condition(s) lead(s) to specific nutrient requirements, identify the nutrients/other substances for which the requirements are specific (where appropriate), and provide evidence/a rationale for the reason(s) why such requirements cannot be fulfilled/are difficult to fulfil by the exclusive consumption of foodstuffs that are not FSMPs.

[24] For example, consumption of protein-containing ordinary foodstuffs triggers sign(s)/symptom(s) of phenylketonuria due to the reduced ability of the body to metabolise the amino acid phenylalanine.

h) Other reasons

☐ yes ☐ no

If yes, please specify

4.3. Impact of the disease/disorder or the medical condition on the nutritional status of the patients for whom the specific food product is intended

The disease/disorder or the medical condition may have an impact on the nutritional status of the patients for whom the specific food product is intended:

☐ yes ☐ no

If no, please proceed to Part 5

If yes, please specify whether the disease/disorder or the medical condition leads to (one or more of the options below may apply):

a) Energy/protein malnutrition

☐ yes ☐ no

If yes, please provide evidence that the disease/disorder or the medical condition leads to energy/protein malnutrition

b) Excess/deficiency of essential amino acids

☐ yes ☐ no

If yes, provide evidence that the disease/disorder or the medical condition leads to deficiency or excess of (essential) amino acid(s) and specify which amino acids are affected

c) Excess/deficiency of essential fatty acids

☐ yes ☐ no

If yes, provide evidence that the disease/disorder or the medical condition leads to essential fatty acid excess or deficiency and specify which essential fatty acid(s) are affected

d) Vitamin deficiency

☐ yes ☐ no

If yes, please provide evidence that the disease/disorder or the medical condition leads to vitamin deficiency and specify which vitamins are affected.

e) Excess/deficiency of minerals

☐ yes ☐ no

If yes, please provide evidence that the disease/disorder or the medical condition leads to mineral excess or deficiency and specify which minerals are affected.

f) Other impacts on nutritional status

☐ yes ☐ no

If yes, please specify

4.4. References

References and supporting documentation quoted under **Part 3** should be given here (no particular format required), together with copies/reprints of published data and/or full reports of unpublished data.

5. Part 5: Specific role of the food product in the dietary management of patients under the proposed use

a) Please describe the rationale for the specific composition and/or formulation of the food product in relation to the proposed use.

b) Please explain why the use of the specific food product in the dietary management of patients for whom the product is intended is necessary or why it is more practical or safer than the exclusive use of foodstuffs that are not FSMPs, and/or why it has a nutritional or clinical advantage for the patient.

c) Please provide any available human data documenting the use of the specific food product for the dietary management of patients for whom it is intended.

d) If available, please provide guidelines/consensus papers published by scientific (medical) societies addressing the dietary management of patients for whom the specific food product is intended.

e) Please provide any other information you may consider pertinent regarding the specific role of the food product under the proposed use.

5.1. References

References and supporting documentation quoted under **Part 5** should be given here (no particular format required), together with copies/reprints of published data and/or full reports of unpublished data.

6. Part 6: Conditions and restrictions of use

6.1. Conditions of use

a) Indicate the standard quantity and pattern of consumption of the specific food product for the proposed use.

b) The food product is intended to be used as (one or more of the options below may apply):

☐ the sole source of nourishment

☐ a partial replacement of other dietary sources

☐ a supplement/integration to the patient's diet

c) Route of administration. The food product is intended for (one or more of the options below may apply):

☐ oral nutrition

☐ tube feeding: in the stomach ☐

in the jejunum ☐

d) Specify, where applicable, directions for preparation and/or use.

e) Specify, where applicable, the reasons why the use of the specific food product requires medical supervision (e.g. tube feeding, adverse effects, control of clinical and/or laboratory outcomes, adjustment or discontinuation of therapy, other reasons).

6.2. Restrictions of use

a) Provide, where appropriate, a statement addressed to those individuals who should avoid using the food product proposed as FSMP, and include the rationale.

b) Specify, where applicable, other restrictions of use, and provide a rationale.

6.3. References

References and supporting documentation quoted under **Part 6** should be given here (no particular format required), together with copies/reprints of published data and/or full reports of unpublished data.

Parts 4, 5 and 6 for proposed use No.2

Part 4: Characterisation of the disease/disorder or the medical condition and of the patients for whom the specific food product is intended

[…]

Part 5: Specific role of the food product in the dietary management of patients under the proposed use

[…]

Part 6: Conditions and restrictions of use

[…]

Parts 4, 5 and 6 for proposed use No.x

Appendix A. Identification form

IDENTIFICATION FORM

●●●●●

The identification form should be used for a dossier on a specific food product for a scientific evaluation by the European Food Safety Authority (EFSA) in the context of Article 3 of Regulation (EU) No 609/2013.

DECLARATION and SIGNATURE

Name of the specific food product:

Proposed uses[25]:

Proposed use No.1:
Proposed use No.2:
Proposed use No.x:

Party responsible for the dossier (Company) name:
Address:
Country:

Contact person's name:

Address:
Country:
Telephone:
Fax:
e-mail:

It is hereby confirmed, to the best of our knowledge, that all existing data which are relevant to the dossier have been supplied, as appropriate.

On behalf of the applicant:

Signature
Name
Function
Place and date (yyyy-mm-dd)

[25] This refers to the context in which the food product is proposed as FSMP, including the target patient population, the disease/disorder or the medical condition, the conditions of use and, where applicable, the restrictions of use.

GLOSSARY AND ABBREVIATIONS

Disease/disorder	a pathological process, acute or chronic, inherited or acquired, of known or unknown origin, having a characteristic set of signs and symptoms which are used for its diagnosis, the management of which requires nutritional intervention under medical supervision
Dossier	a stand-alone package containing the information and scientific data submitted for the scientific evaluation of a food product notified as FSMP under the proposed use
Food product	any food suitable for human consumption (i.e. to be administered by the oral or enteral route) which provides energy-containing macronutrients (e.g. carbohydrates, protein, fats), micronutrients (e.g. vitamins, minerals), and/or other substances which may contribute to fulfilling the nutritional requirements of patients
Food supplements	foodstuffs the purpose of which is to supplement the normal diet and which are concentrated sources of nutrients (i.e. vitamins, minerals) or other substances with a nutritional or physiological effect, alone or in combination, marketed in dose form, namely forms such as capsules, pastilles, tablets, pills and other similar forms, sachets of powder, ampoules of liquids, drop dispensing bottles, and other similar forms of liquids and powders designed to be taken in measured small unit quantities
Fortified food	a foodstuff to which vitamin(s), mineral(s), other substances, or a combination of them, have been added
FSG Regulation	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
FSMP	Food for special medical purposes
Medical condition	any structural or functional alteration, either acute or chronic, which may result from one or more diseases or disorders, the management of which requires nutritional intervention under medical supervision
Patient	a person (including infants and young children) affected by the disease/disorder or medical condition
Proposed use	context in which the food product is proposed as FSMP, including the target patient population, the disease/disorder or medical condition, the conditions of use (i.e. quantity and pattern of consumption, directions for preparation and use), and, where applicable, the restrictions of use