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Joint MNI-SNE FOP Task Force

Explanatory Document on the Labelling of Food for Special Medical Purposes

This explanatory document outlines the regulatory interpretation by Specialised Nutrition Europe ('SNE') and Medical Nutrition International Industry association ('MNI') of several elements of the text on labelling within Commission Delegated Regulation (EU) No 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 ('FSMP Regulation'). It does not constitute an official interpretation of the regulations. It is intended to be used by national associations as a reference for discussions with their local competent authorities.

Although foods for special medical purposes ('FSMP') are subject to the general labelling rules applicable to all foods, there are some additional labelling provisions and derogations in the FSMP Regulation which lay down and explain why labelling of FSMP has its own specificities. The labels on FSMP are intended to provide information both to consumers (patients) and Healthcare Professionals ('HCP'). The use of the products under medical supervision and on the recommendation of a HCP means that consumers are not at risk of being misled by any additional information on the label intended to inform the HCP.

The differences between labelling of general foods and FSMP are not well understood and this has been exacerbated by the implementation of 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 ('Claims Regulation').

To help understand the distinctions between the two, SNE and MNI share here their interpretation of the FSMP Regulation taking into consideration the appropriate use of FSMP in clinical practice.

SNE and MNI conclude:

1. Nutritional properties and characteristics of FSMP are different from nutrient content claims on general foods.
2. Nutritional properties and characteristics can be clearly and prominently labelled on the front of pack and this should not be confused with voluntary front of pack nutrition labelling for general foods or nutrient content claims.
3. The rationale for the nutritional composition and the function of nutrients in the dietary management of diseases or medical conditions is clearly different from a nutrition and health claim on general foods – which describes the role of a nutrient in health.
4. The indication of the key product characteristics or the indication for the product may be described in the name of the FSMP to inform the patient and HCP of the appropriate use.

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1. INTRODUCTION

1.1. What is FSMP?

FSMP is defined in the 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 ('FSG Regulation').

According to the definition of Article 2(g) of the FSG Regulation, FSMP 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**.'*

- FSMP are specialised foods designed to meet the nutritional or dietary needs arising from a wide range of medical conditions that affect patients of all ages from infancy to old age. They cannot be replaced by normal foods marketed to and consumed by healthy people.
- FSMP are for the dietary management of patients who are suffering from a disease, disorder or medical condition which either temporarily or permanently affects their ability to achieve an adequate, appropriate nutritional intake via the normal diet or modification of the normal diet.
- FSMP are developed based on scientific and clinical insights, often in close collaboration with scientists, HCP and patient organisations. They are supported by sound medical and scientific data which may include national, international or professional guidelines.
- FSMP are used on the recommendation of, and under the supervision of a HCP. This necessary and continued HCP supervision clearly distinguishes FSMP from other types of food.

1.2. Regulation of FSMP Labelling

As aforementioned, FSMP is a specific category different from general foods and subject to specific regulation under the FSG Regulation. Recital 15 of the FSG Regulation[1] states that such categories of food are vital for the management of certain conditions and/or are essential to satisfy the nutritional requirements of certain clearly identified vulnerable population groups.
The FSMP Regulation lays down mandatory labelling provisions to ensure the safe and appropriate use of the products which includes both additions and exceptions to the labelling rules for general foods.[2]

Key additional labelling requirements include:[3]

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[1] *'A limited number of categories of food constitute a partial or the sole source of nourishment for certain population groups. Such categories of food are vital for the management of certain conditions and/or are essential to satisfy the nutritional requirements of certain clearly identified vulnerable population groups. Those categories of food include infant formula and follow-on formula, processed cereal-based food and baby food, and food for special medical purposes. Experience has shown that the provisions laid down in Directives 1999/21/EC, 2006/125/EC and 2006/141/EC ensure the free movement of those categories of food in a satisfactory manner, while ensuring a high level of protection of public health […].'*

[2] Recital 13 of the FSMP Regulation states: *'Food for special medical purposes has to comply with Regulation (EU) No 1169/2011 of the European Parliament and of the Council. In order to take account of the specific nature of food for special medical purposes, this Regulation should lay down additions and exceptions to those general rules, where appropriate.'*

[3] *C.f.* Article 4, 5 of the FSMP Regulation.

- the legal name 'Food for Special Medical Purposes'
- the statement 'For the dietary management of' the respective disease, disorder or medical condition;
- a statement that the product must be used under medical supervision;
- a statement whether the product is suitable for use as the sole source of nourishment; and
- a **description of the properties and/or characteristics which make the product useful in the management of the disease, disorder or medical condition and the rationale of the use of the product**.

Key exceptions include the following aspects:[4]

- the mandatory nutrition declaration shall include other nutrients and their components the declaration of which would be necessary for the appropriate intended use of the product;
- the energy value and the amount of nutrients of food for special medical purposes shall not be expressed as a percentage of the reference intakes;
- the **information included in the mandatory nutrition declaration shall not be repeated on the labelling**; and
- the **use of nutrition and health claims is prohibited**.

This paper aims to provide an explanation of the specific additional labelling provisions and exceptions to the labelling rules for general foods, specifically those highlighted. Accordingly, the paper is not intended to be a complete review of all the legal requirements governing labelling of FSMP.

1.3. Why is there a need for specific labelling provisions for FSMP?

As explained, FSMP are intended for use in the dietary management of a disease, disorder or medical condition under medical supervision.
FSMP are used in a number of healthcare settings which may include hospitals, care homes or the patients' own home. They may be recommended, prescribed, dispensed or administered by a range of HCP[5] in those settings, including physicians, dietitians, pharmacists, nurses or care assistants. The labelling of FSMP therefore has several intended uses:[6]

- The patient or their carer – who need to identify and understand the use and preparation of the product;
- The recommending or prescribing HCP – who needs to understand the specificities of the nutritional content of the product compared to other FSMP products to assess suitability for individual patients;
- The person dispensing or delivering the FSMP to the patient who needs to be able to identify the correct product in a healthcare setting.

[4] *C.f.* Article 6, 7 of the FSMP Regulation.
[5] Recital 3 of the FSMP Regulation states: *'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.'*
[6] This is supported in Recital 15 of the FSMP regulation: *'The nutrition declaration for [FSMP] is essential in order to guarantee its appropriate use, both for patients consuming that food and for health care professional's who recommend its consumption […].'*

An essential element of providing information to both patients and HCP is the description of the properties and/or characteristics of the product. This is critical in ensuring the appropriate recommendation and use, which is recognised in Recital 14 of the FSMP Regulation and the mandatory labelling particulars described in Article 5(2)(g) of the FSMP Regulation.[7]

There are no specific rules on what information should be provided. Recital 14 of the FSMP Regulation refers broadly to all information necessary to ensure the appropriate use of the product and specifically that this information should include information on the properties and characteristics. There are also no specific provisions on how the information must be presented on the labels of FSMP. Historically, FSMP have prominently displayed information critical to the identification and use of the product on the front of pack. This allows the products and their intended use to be easily identified in a medical or care setting. Necessary information may include:

- Nutrients that are high, low or absent from the product;
- Key nutrient contents of the product *e.g.*, kcal/ml or g protein per serving, addition of functional nutrients such as DHA, arginine;

2. INDICATION OF PROPERTIES AND CHARACTERISTICS VS NUTRITIONAL CONTENT CLAIMS

2.1. Legal provisions which require the indication of product properties and characteristics

Given that the manufacturers of FSMP shall describe the nutritional characteristics of the product, the rationale for the nutritional composition and the disease for which they are intended (rationale of use of the product) as well as other information that is necessary to ensure the appropriate use of FSMP, it is the view of SNE and MNI that none of the above types of information provided prominently on FSMP labelling are prohibited. The information is provided in relation to the disease, disorder or medical condition for which the product is intended. These labelling elements may be similar to and/or perceived to be nutrition and health claims. However, nutrition and health claims and their related criteria, are specific to the content and role of nutrients in general foods intended for healthy individuals.

In accordance with the provisions of the FSMP Regulation, FSMP must include a number of **specific mandatory elements on labels which are, in particular, designed to ensure the intended use of the product**.[8]
As mentioned above, it is required of the manufacturer to **describe the properties and/or characteristics that make a FSMP useful in relation to the dietary management** of the disease, disorder for medical condition for which it is intended.

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[7] Recital 14 of the FSMP Regulation states: *'Providing all information that is necessary to ensure the appropriate use of food for special medical purposes should be mandatory for this type of food. That information should include information on the properties and characteristics in relation to, among others, the special processing and formulation, nutritional composition and rationale of use of the product that make it useful for its specific intended purpose. Such information should not be considered as nutrition and health claims within the meaning of Regulation (EC) No 1924/2006 of the European Parliament and of the Council.'*
Article 5(2)(g) of the FSMP Regulation specifies: *'In addition to the mandatory particulars listed in Article 9(1) of Regulation (EU) No 1169/2011, the following shall be additional mandatory particulars for food for special medical purposes: […] a 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 […].'*

[8] *C.f.* fn. 7.

These properties and characteristics may be related to the processing, formulation or more commonly to the nutrients which have been increased, reduced, eliminated or otherwise modified to meet the requirements of a disease or a specific target patient population.
The description of the properties and/or characteristics does not have to include a description of the full content of the product, which is already indicated in the nutrition table. Rather, the compositional and other elements that determine the rationale for the use of the product in a particular patient, and distinguish the product from similar products in the category, shall be presented.
The rationale for the statements to communicate the properties and characteristics of FSMP will be dependent on the product formulation and its intended clinical use and will be determined on a case-by-case basis depending on the nature and the intended use of the product. In this case indication of nutritional properties and characteristics will not be considered to be nutrient content claims within the meaning of the Claims Regulation, as per Recital 14 of the FSMP Regulation.

2.2. The importance of prominent indication of properties and characteristics

The properties and characteristics of a product may be indicated in a description of the product or by a more prominent indication of the product content on the pack. Prominent indication of the specific properties and characteristics of a FSMP is essential to ensure that they can be correctly identified in a clinical, hospital or homecare setting by healthcare workers. The mandatory information included in labelling of FSMP is designed to meet the needs of several target audiences:

- The patient or their carer – who need to identify and understand the use and preparation of the product;
- The recommending or prescribing HCP – who needs to quickly understand the specificities of the nutritional content of the product compared to other FSMP to assess suitability for individual patients;
- The person dispensing or delivering the FSMP to the patient who needs to be able to correctly identify the correct product in a healthcare setting.

In the case of FSMP with a **disease specific nutrient adapted formulation** – the description of the disease specific properties and characteristics of the product may include the specific nutrients that have been reduced, increased, are absent, or to the specific source or nature of the ingredients used (*e.g.*, amino acid based), or to other disease specific elements based on medical guidelines. In this case, reference to specific nutrients constitute properties and characteristics of the product and such reference is not a nutrient content claim.

Table 1 below provides examples of some properties and characteristics that may be described on a disease-specific FSMP (non-exhaustive list)

Characteristics that may be indicated on a FSMP	Rationale for indicating the product characteristic related to the intended use of the product	Examples of clinical indication
Amino acids	The product is specially formulated with its protein source based on amino acids. This is important where whole protein sources cannot be tolerated or metabolised by the patient.	• Phenylketonuria • Severe cow milk allergy and/or multiple food protein intolerance • Severe malabsorption
High in medium chain triglycerides ('MCT')/ low in long chain triglycerides ('LCT')	The product is specially formulated with its fat source based predominantly on MCT. This is important where LCT cannot be absorbed or metabolised by the patient.	• Fatty acid oxidation disorders • Severe malabsorption • Chylothorax

Low in potassium	The product is specially formulated to have a low potassium content. This is important for patients with renal failure who suffer with high blood potassium levels.	• Chronic kidney disease

Equally, FSMP with a **standard nutrient composition** (non-disease specific formulation) may be used in a diverse range of medical conditions or diseases. Their composition in terms of nutrients, ingredients or product format may vary, *e.g.*, protein, energy, fibre content, in order to provide HCPs with options appropriate for the specific clinical need. As a result, the necessary description of the properties and/or characteristics for appropriate use by the HCP and patient may include descriptions such as, 'With Fibre', 'High Energy', 'High Protein', or 'Lactose Free'. These descriptions are important so that all involved in prescribing, dispensing and selecting a product for a particular patient can quickly and easily identify its content and suitability. This labelling information should not be considered a voluntary nutrient content claim.

Table 2 below provides examples describing why it is necessary to indicate certain properties and characteristics on a standard nutritionally complete enteral feed to ensure its appropriate clinical use (non-exhaustive list)

Characteristics that may be indicated on a FSMP	**Rationale for indicating the product characteristic related to the intended use of the product**	**Clinical importance of indicating the specific characteristic to reduce risk of incorrect use of the FSMP in a healthcare setting**
With/Contains Fibre	Some patients develop constipation on enteral feeding with a low residue tube feed – addition of fibre helps to maintain better gut function.	Provision of fibre-containing feed directly into the GI tract may cause protracted diarrhoea in sensitive patients with associated risk of dehydration and additional care needs.
High Protein	Some patients require additional protein in their feed – for example those with wounds or post-surgery.	Provision of high protein feed to a patient with renal insufficiency will be detrimental to kidney function and may cause symptoms of acute renal failure.
High Energy	Some patients require additional energy or reduced fluid intake – for example children with congenital heart disease.	Provision of a high energy/low volume feed could lead to insufficient fluid intake and dehydration in patients with normal energy and fluid requirements.

2.3. Properties and Characteristics of FSMP are different from nutrient content claims

Nutrient content claims on general foods are regulated by the Claims Regulation.

The Claims Regulation defines a 'claim' in Article 2(2) as *'any message or representation, which is **not mandatory** under Community or national legislation, including pictorial, graphic or symbolic representation, in any form, which states, suggests or implies that a food has particular characteristics.'*

Pursuant to Article 1(5)(a) of the Claims Regulation the Regulation shall apply without prejudice to the Directive 89/398/EEC and Directives adopted relating to foodstuffs for particular nutritional uses.

These provisions clarify that the requirements of the Claims Regulation need to take into consideration, in their implementation, the specificities related to products regulated as foodstuffs for particular nutritional uses, (now referred to as Food for Specific Groups) including FSMP . For FSMP specifically, there is a mandatory requirement to describe the properties and/or characteristics of the product that make it useful in particular related to its intended use in the dietary management of patients. This may include specific nutrients and the rationale of the use. Such mandatory statements do not fall within the definition of a claim which is defined as 'not mandatory'.

This is interpreted to mean that

- Statements around the levels of nutrients (*e.g.*, 'high', 'low', 'reduced') where they are specifically properties and characteristics **related to the intended use** of the FSMP are not nutrient content claims and therefore do not fall under the prohibition on the use of nutrition and health claims under Article 7 of the FSMP Regulation.
- Properties and characteristics can relate to the special processing and formulation. As such the description of the ingredient or nutrient formulation of FSMP is not a nutrient content claim.
- This is the case whether the wording of the statement is the same as an approved nutrient content claim or a statement that concerns a nutrient where there is no approved nutrient content claim related to the effect of the nutrient in general health, provided that it constitutes a description of the properties and/or characteristics that make the product useful for the disease within the meaning of Article 5(2)(g) of the FSMP Regulation.

This can be clearly illustrated by the use of statements related to protein content. There is a series of ESPEN guidelines and consensus papers on nutritional management of patients in hospital and home settings which clearly set recommended levels of certain nutrients in the diet.

For example, the recommendations of the ESPEN guideline on Hospital Nutrition[9] set down the protein or energy level that the patient may need to consume. These recommendations are expressed in grams of protein or energy in kcal/kg body weight/day and the following are examples of some of the terms that have been established:

ESPEN Descriptor of patient requirements	ESPEN Guideline Recommended Intake
Low protein	0.6 – 0.79 g/kg/day
Normal protein	0.8 – 1.0 g/kg/day
High protein	1.1 – 1.3 g/kg/day
Extra high protein	>1.3 g/kg/day
Normal energy	25 kcal/kg/day
High energy	30 kcal/kg/day

Although the term 'high protein' is used, this should not be viewed in the same way as the nutrition claim 'high protein' specified in the Claims Regulation. The criteria for the regulated nutrient content

[9] *Thibault* et al., ESPEN guideline on Hospital Nutrition, Clinical Nutrition 40 (2021), pp 5684-5709, https://doi.org/10.1016/j.clnu.2021.09.039.

claim 'high protein' is based on the percentage of energy derived from protein of a food intended for healthy adults. However, in a clinical context the criteria for stating 'high protein' take into consideration the whole diet of patients assessed as having increased protein requirements as a result of a disease, disorder or medical condition. It is evident that although the wording 'high protein' may be the same, the terms are used differently, with different criteria applied, and should not be confused with each other.

ESPEN also describes the content of enteral feeds (FSMP) that would be selected to meet these specific requirements in their introductory to the enteral guidelines.[10]

ESPEN Descriptor of enteral feed content	ESPEN criteria/conditions of use
High protein	20% energy from protein
Low energy	0.9 kcal/ml or less
Normal energy	1.0 – 1.2 kcal/ml
High energy	>1.2 kcal/ml

Although these terms again can appear very similar to a nutrient content claim, the recommendation is clearly for the content of an enteral feed (FSMP) used in the dietary management of disease-related malnutrition. For the HCP, these descriptive terms therefore have a meaning in their clinical practice in relation to specific patient needs and are unrelated to nutrient content claims intended for the general population.

3. PROMINENT INDICATION OF KEY NUTRITIONAL CHARACTERISTICS ON FRONT OF PACK

3.1. Legal Provisions regarding Front of Pack Nutrition Labelling

The nutrition labelling on the front of the pack – *i.e.*, the prominent indication of the nutritional content of a food product is permitted under 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 ('FIC Regulation') and is intended to inform the consumer about the content of a food so that they can make healthy food choices as part of a balanced diet. Article 30(3) of the FIC Regulation stipulates in this regard:
'*Where the labelling of a prepacked food provides the mandatory nutrition declaration referred to in [Article 30(1) of the FIC Regulation], the following information may be repeated thereon:*
(a) the energy value; or
(b) the energy value together with the amounts of fat, saturates, sugars […].'

Articles 5 and 6 of the FSMP Regulation contain specific labelling provisions for FSMP which are either additional to, or providing a derogation from the requirements of, the FIC Regulation. Article 6(2) of the FSMP Regulation provides as follows:
'*By way of derogation from Article 30(3) [of the FIC Regulation], the information included in* ***the mandatory nutrition declaration for food for special medical purposes shall not be repeated on the labelling***.'

[10] *Lochs et al.*, Introductory to the ESPEN Guidelines on Enteral Nutrition: Terminology, definitions and general topics. Clinical Nutrition Volume 25 (2006), pp 180-186.

This provision was included in the labelling requirements for FSMP to ensure that any future mandatory front of pack nutrition labelling requirements would not apply to FSMP. This is an essential derogation since any front of pack nutrition labelling schemes developed to inform the general 'healthy' consumer would not be appropriate and would be misleading for patients who have very specific nutritional needs, which differ significantly from the recommendations for nutritional intake in relation to maintaining general good health.
However, prominent indication of nutritional characteristics of FSMP is critical to their identification and appropriate use. These key nutritional characteristics are very specific to the particular intended use of the FSMP and may or may not be related to nutrients that are declared within the nutrition information table.

3.2. Prominent Indication of Key Nutritional Characteristics

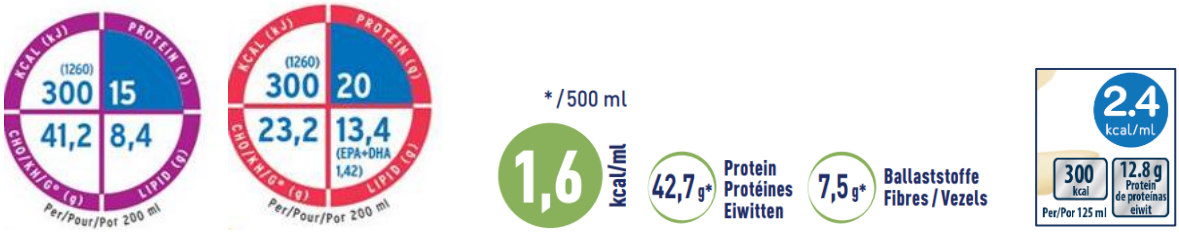
It is common practice to prominently indicate particular properties and characteristics of FSMP that are useful in relation to the dietary management of the disease, disorder or medical condition for which the product is intended.

These properties and characteristics may be related to the processing, formulation and/or nutrients which have been increased, reduced, eliminated, or otherwise modified. **In the case of FSMP, these properties and characteristics most often relate to the levels or amount of certain nutrients or ingredients that are important to determine the specific use of the product**.

FSMP are used to manage disease-related malnutrition which may arise as a result of a disease, disorder or medical condition. Effective management of such conditions is most often addressing a deficit of energy and/or protein. The indication of properties or characteristics of FSMP might be related to the nutrient content (*e.g.*, are they high in energy/protein or have a standard energy content) or the formulation and composition of the macronutrients providing the energy or protein (*e.g.*, hydrolysed proteins or medium chain triglycerides). The important characteristics of FSMP and the basis of selection, therefore, are generally, but not exclusively, their energy and protein content. Other important characteristics may include fibre content, as fibre-containing feeds are used to normalise gut function and to reduce constipation associated with liquid feeds. For disease specific FSMP there may also be other specific nutrients that are particular to the intended use of the product in that disease, disorder or medical condition such as eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA) in inflammatory conditions.

Examples of front of pack indications of properties and characteristics include:

Nutrient	Front of pack indication
Protein	20 % energy from protein
	20 g protein per 200ml bottle
Energy	1.5 kcal per ml
	400 kcal per 200 ml bottle
DHA	40 mg DHA per 200 ml bottle
Fibre	6 g fibre per 200 ml bottle



3.3. Importance of Clear Presentation of Properties and Characteristics in FSMP Labelling

There is no provision as to how or where these properties and characteristics are displayed on the label and they may appear on the front of pack. It is common practice to provide factual information on the nutritional content of a product both as part of the product description and in an easily visible and visual way on the labels to support product identification. The description of the properties and/or characteristics should include those elements that make the product useful in particular and does not have to include a description of the full content of the product, which is already indicated in the nutrition table. They are the elements that determine the rationale for the use of the product for a particular patient, and therefore will vary depending on the product and the target patient group.
The specific labelling rules laid down for FSMP within the FSMP Regulation reflect the dual nature of the labelling – being intended both to provide food information to patients and information to HCP using the products within a healthcare setting. Whereas a Dietitian, Physician or Nutrition Specialist Nurse may recommend the use of a specific FSMP for a patient, the product will often be dispensed or delivered to the patient by other HCPs such as pharmacists, nursing staff, care home staff or dietetic assistants. It is critical that these healthcare providers can identify the correct FSMP product at the point of delivery. **The prominent indication of the properties and characteristics of a specific FSMP can help to differentiate and identify the correct product for a particular patient in a healthcare setting**. This principle is supported by HCP professional bodies who confirm the usefulness of this information in practice.

Front of pack indication of composition or nutrient content should not be considered to be repetition of mandatory information from the nutrition declaration if:

- it indicates one or more important/useful properties and characteristics of the product related to the intended use (including specific nutrients such as energy, protein, composition of proteins/fats etc.); and
- its expression is not repeated from the mandatory nutrition declaration (*i.e.*, per 100g or 100ml).

Furthermore, the indication does not need to be accompanied in the same field of vision with any other mandatory statement required on the labelling, as the positioning of this indication (*e.g.*, 'for the dietary management of') is not specified in the FSMP Regulation.

4. ANNEXES

ANNEX 1 – REGULATORY TEXTS CONCERNING LABELLING

Regulatory Text (Article or Recital)	Legal Interpretation of the text
Regulation (EU) No 609/2013	
Article 9(5) *'The labelling, presentation and advertising of food referred to in Article 1(1) 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.'* **Article 9(6)** *'[Article 9] Paragraph 5 shall not prevent the dissemination of any useful information or recommendations exclusively intended for persons having qualifications in medicine, nutrition, pharmacy, or for other healthcare professionals responsible for maternal care and childcare.'* **Recital 25** *'The labelling, presentation or advertising of food covered by this Regulation should not attribute to such food the property of preventing, treating or curing a human disease nor should they imply such properties. Food for special medical purposes, however, is intended for the dietary management of patients with a limited, impaired or disturbed capacity, for example, to take ordinary food because of a specific disease, disorder or medical condition. Reference to the dietary management of diseases, disorders or medical conditions for which the food is intended should not be considered as attribution of the property of preventing, treating or curing a human disease.'*	**Article 9(5)** stipulates that the product labelling, presentation, and advertising shall not be misleading and shall not suggest that the food has properties of preventing, treating, or curing a human disease. Accordingly, the provision does not contain any content on the question of how the properties and characteristics of the product should be characterized. The dissemination of additional information to HCP is permitted according to **Article 9(6)**. Thus, implying that the information on properties and characteristics of a FSMP could be provided in a different format. However, this position ignores the realities in clinical practice, where healthcare professionals need to make informed decisions often under time pressure. Pursuant to **Recital 25** reference to dietary management of diseases, disorders or medical conditions should not be considered as attributing properties of preventing, treating or curing a human disease. Similarly they cannot be considered to be claims related to health in the context of general foods.
Regulation (EU) No 2016/128	
The Regulation reiterates how the application of clear product properties and characteristics to labels enables the HCP to administer products correctly and efficiently, and how these products are developed in close cooperation with HCP.	
Recital 3 *'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.'*	**Recital 3** highlights that FSMP are *'*developed in close cooperation with health care professionals.*'* This includes not only the composition but also the presentation. Thus, it has been confirmed among HCP that they find prominent information on the properties and characteristics helpful in making choices in a clinical setting. Written feedback from HCP professional bodies such as ESPEN confirmed this aspect.
Article 5(2) *'In addition to the mandatory particulars listed in Article 9(1) of Regulation (EU) No 1169/2011, the following shall be additional mandatory particulars for food for special medical purposes:* *(a) a statement that the product must be used under medical supervision;*	**Article 5(2)** provides for specific requirements on food information in addition to the mandatory particulars listed in Article 9(1) of FIC Regulation, including the description of properties and/or characteristics. The provision does not conclusively regulate how this information is to be implemented. It does, however, impose an obligation to precede the particulars referred to in points (a) to (d) by

(b) a statement whether the product is suitable for use as the sole source of nourishment; *(c) a statement that the product is intended for a specific age group, as appropriate;* *(d) where appropriate, a statement that the product poses a health hazard when consumed by persons who do not have the disease, disorder or medical condition for which the product is intended;* *(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;* *(f) where appropriate, a statement concerning adequate precautions and contra-indications;* *(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;* *(h) where appropriate, a warning that the product is not for parenteral use;* *(i) instructions for appropriate preparation, use and storage of the product after the opening of the container, as appropriate.* *The particulars referred to in points (a) to (d) shall be preceded by the words 'important notice' or their equivalent.'*	the words 'important notice' or their equivalent, which would imply that they should appear together in the same field of vision. However, for other elements of the information provided under Article 5(2), there is no indication of where they should appear or that any of them must appear together or be linked.
Recital 14 *'Providing all information that is necessary to ensure the appropriate use of food for special medical purposes should be mandatory for this type of food. That information should include information on the properties and characteristics in relation to, among others, the special processing and formulation, nutritional composition and rationale of use of the product that make it useful for its specific intended purpose. Such information should not be considered as nutrition and health claims within the meaning of Regulation (EC) No 1924/2006 of the European Parliament and of the Council.'*	**Recital 14**: states that information on properties and characteristics in relation to the processing, formulation and nutritional composition should not be considered as nutrition and health claims. Therefore, the indication of a property or characteristic of a FSMP that makes it useful for its specific intended purpose, even if this is prominently indicated on the front of pack for the easy identification by a HCP, should not be considered as a nutrition and health claim.
Recital 15 *'The nutrition declaration for food for special medical purposes is essential in order to guarantee its appropriate use, both for patients consuming that food and for health care professionals who recommend its consumption. For that reason and in order to provide more complete information to patients and healthcare professionals, the nutrition declaration should include more particulars than those required by Regulation (EU) No 1169/2011. In addition, the exemption provided for in point 18 of Annex V to Regulation (EU) No 1169/2011 should not apply and the nutrition declaration should be mandatory for all food for special medical purposes, irrespective of the package or container size.'*	**Recital 15** emphasizes the importance of providing a complete nutrition declaration to HCP. However, the addition of the properties and characteristics assists the HCP in making a pre-selection or perhaps excluding products, which are immediately not appropriate.
Article 6 *'1. In addition to the information referred to in Article 30(1) of Regulation (EU) No 1169/2011, the mandatory nutrition*	**Article 6** lays down specific requirements on the nutrition declaration. Thus information to be provided in addition to the requirements for foods within FIC Regulation and derogations from the FIC Regulation are regulated.

declaration for food for special medical purposes shall include the following: *(a) the amount of each mineral substance and of each vitamin listed in Annex I to this Regulation and present in the product;* *(b) the amount of components of protein, carbohydrate, fat and/or of other nutrients and their components, the declaration of which would be necessary for the appropriate intended use of the product;* *(c) information on the osmolality or the osmolarity of the product where appropriate;* *(d) information on the source and the nature of the protein and/or protein hydrolysates contained in the product.* *2. By way of derogation from Article 30(3) of Regulation (EU) No 1169/2011, the information included in the mandatory nutrition declaration for food for special medical purposes shall not be repeated on the labelling.* *3. The nutrition declaration shall be mandatory for all food for special medical purposes, irrespective of the size of the largest surface of the packaging or container.* *4. Articles 31 to 35 of Regulation (EU) No 1169/2011 shall apply to all the nutrients included in the nutrition declaration for food for special medical purposes.* *5. By way of derogation from Article 31(3) of Regulation (EU) No 1169/2011, the energy value and the amounts of nutrients of food for special medical purposes shall be those of the food as sold and, where appropriate, those of the food ready for use after preparation in accordance with the manufacturer's instructions.* *6. By way of derogation from Article 32(3) and (4) of Regulation (EU) No 1169/2011, the energy value and the amount of nutrients of food for special medical purposes shall not be expressed as a percentage of the reference intakes set out in Annex XIII to that Regulation.* *7. The particulars included in the nutrition declaration for food for special medical purposes that are not listed in Annex XV to Regulation (EU) No 1169/2011 shall be presented after the most relevant entry of that Annex they belong to or are components of. Particulars not listed in Annex XV to Regulation (EU) No 1169/2011 that do not belong to or are not components of any of the entries of that Annex shall be presented in the nutrition declaration after the last entry of that Annex.* *The indication of the amount of sodium shall appear together with the other minerals and may be repeated next to the indication of the salt content as follows: 'Salt: X g (of which sodium: Y mg)'.'*	**Article 6(2)** provides for a specific derogation from the provision in the general labelling rules concerning the repetition of nutrients. The derogation refers specifically to voluntary repetition of mandatory nutrients in Article 30(3) of the FIC Regulation for pre-packaged food, *i.e.*, energy value, or the energy value together with the amounts of fat, saturates, sugars, and salt. When considered in isolation, this provision may be interpreted to mean that none of the information which is mandatory within the nutrition declaration can be repeated on the labelling in any other field of vision. This should include the amount, and the measurement unit per 100 g or 100 ml. However, when considered in combination with other labelling provisions pertaining to FSMP, this does not preclude the provision of information on some nutrients that are properties and characteristics of the product that are useful in particular and specifically related to its intended use under Article 5(g) (as above) as long as this is not directly repeated from the nutrition table. It can be concluded that outlining specific nutritional properties and characteristics of the product is not repetition of the mandatory nutrition declaration (per 100g or 100ml as sold). Given that the clinically important properties and characteristics of a FSMP are also likely to be nutrients that are mandatorily declared within the nutrition declaration, it should be understood that the prohibition under Article 6(2) does not apply to additional prominent labelling indications of nutritional properties and characteristics of a FSMP. **Article 6(5)** states that expression of the amounts of nutrients shall be 'as sold' and, where appropriate 'those of the food ready for use' in accordance with the manufacturer's instructions. According to **Article 6(6)** the amount of nutrients shall not be expressed as a percentage of the reference intakes. Therefore it is not a mandatory particular.

ANNEX 2 – REFERENCES

i. 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. *Official Journal of the European Union 29. July 2013 L 181 pp 35 - 56.*

ii. 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. *Official Journal of the European Union 2. February 2016 L 25 pp 30 – 43.*

iii. 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. *Official Journal of the European Union 22. November 2011 L 304 p 18.*

iv. 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. *Official Journal of the European Union 30. December 2006 L 404 p 9*.

v. *Thibault* et al., ESPEN Guideline on Hospital Nutrition. *Clinical Nutrition Volume 40 (2021), pp 5684-5709.*

vi. *Lochs et al.*, Introductory to the ESPEN Guidelines on Enteral Nutrition: Terminology, definitions and general topics. *Clinical Nutrition Volume 25 (2006), pp 180-186.*