*Ministero della Salute*

**DIPARTIMENTO SANITÀ PUBBLICA VETERINARIA, SICUREZZA ALIMENTARE E ORGANI COLLEGIALI PER LA TUTELA DELLA SALUTE**
**DIREZIONE GENERALE PER L'IGIENE E LA SICUREZZA DEGLI ALIMENTI E LA NUTRIZIONE - UFFICIO IV EX DGSAN**

**Commissione unica per la dietetica e la nutrizione**

# GUIDELINES ON FOODS FOR SPECIAL MEDICAL PURPOSES (FSMP)

*Update December 18, 2013*

## INTRODUCTION

The development of the food legislation has led to the adoption of Regulation (EC) 1924/2006 on nutrition and health claims made on foods that sets specific rules on how food information can target the specific nutritional needs of certain groups of the population claiming an effect on health.

Given that, in the context of the current Directive 2009/39/EC on foodstuffs intended for particular nutritional uses, "dietetic food" for certain categories of persons who are "in special physiological conditions" or "whose digestive processes or metabolism are disturbed" are not anymore justified and moreover difficult to distinguish from a normal food carrying an health claim.

Therefore, in order to simplify the legislation, Regulation (UE) 609/2013 "*on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control"* was adopted.

This Regulation will apply from 20 July 2016 and will repeal the frame work directive 2009/39/EC on products intended for particular nutritional uses, abolishing, as a result, the concept of dietetic product.

However, Regulation (UE) 609/2013 will maintain and strengthen the provision on some nutritionally vulnerable specific groups of consumers, already covered by the current specific directives linked to the framework directive, as follow:

- Directive 2006/141/EC on infant and follow-on formulae;
- Directive 2006/125/EC on processed cereal-based foods and baby foods for infants and young children;
- **Directive 99/21/EC on foods for special medical purposes (FSMP);**
- Directive 96/8/EC on foods intended for use in energy-restricted diets for weight reduction, limited to what is already foreseen on products presented as total diets (Low Calorie Diets: LCD) In addition, provisions will be adopted for products presented for Very Low Calorie Diets (VLCD), with a daily calorie intake less than 800 kcal, currently lacking at European level.

The issue of the correct classification of a product as FSMP according to the definition has been often subject of debate between Member States and the European Commission, revealing an heterogeneous approach.

The recurring dispute is that many products presented as FSMP are not eligible to be considered as such and should be classified as food supplements.
In the new legislative framework, it should also be taken into consideration that art. 3 of Regulation (UE) 609/2013 on "interpretation decisions" gives to the Commission the possibility to decide whether a product is classified as FSMP by a member State should fall into this category.

**PURPOSE**
This document, approved by the Italian National Committee on Dietetics and Nutrition, is intended as a guidance giving the criteria for a proper classification of a product as **FSMP**.

## 1. Regulatory framework of FSMPs

Currently FSMPs are foodstuffs intended for particular nutritional uses within the framework of Directive 2009/39/EC (PARNUTS) which is a recast of the Directive 89/398/EEC, transposed in Italy by the Legislative Decree of 27 January 1992, n. 111.
In this context FSMPs are covered by the specific Directive 1999/21/EC, transposed by the Italian national Presidential Decree of 20 March 2002, n. 57.
The European Commission, by delegated acts under elaboration, is going to transfer the specific provisions on FSMPs into the scope of Regulation (UE) 609/2013 including the necessary updates on the technical-legislative level. This Regulation, as a framework legislation, contains only the definition of FSMP in art. 2, paragraph 2, letter g).

## 2. Definition

According to the definition, FSMPs are:
1) foodstuffs specially processed or formulated and intended for the dietary management of patients, including infants, to be used "under medical supervision";
2) intended for the exclusive or partial feeding of patients with a limited, reduced, impaired or disturbed capacity to take, digest, absorb, metabolize or excrete ordinary foodstuffs or certain nutrients contained therein or metabolites, or with other clinically-determined nutrient requirements;
3) intended for the dietary management of a particular condition (disorder, disease) that cannot be achieved only by modification of the normal diet.
A foodstuff, in order to be proposed and classified as FSMP, has to satisfy the above three conditions. According to condition 3), the use food supplement with a composition suitable to the dietary management of a specific pathological condition has to be considered as a modification (supplementation) of the normal diet. Therefore, as a general rule, the same food can not be classified as FSMP.

## 3 Compositional requirements
With regards to the composition, FSMPs are classified in the following three categories:
1) 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;
2) 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;

3) 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 products referred to in points 1) and 2) may also be used, not only as the sole source of nutrition, but also as a partial replacement or as a supplement to the patient's diet according to the instructions provided on the label or the medical suggestions for the specific case.

FSMP composition has to be built in order to manage the specific dietary management for which has been intended, i.e. to prevent or counteract the malnutrition, as for the content of:

- "nutritional substances" or "nutrients" as defined by Regulation (EU) 1169/2011 (Article 2, paragraph 2, letter s), and
- "other substances" as defined by Regulation (EC) 1924/2006 (Article 2, paragraph 2, point 3): substances other than nutrients that have a nutritional or physiological effect.

Directive 99/21/EC (with the amended levels of manganese introduced by Directive 2006/141/EC) establishes maximum levels of vitamins and minerals allowed in FSMPs. Such limits may be exceeded when it is required in order to manage the specific nutritional needs of disease or disorder for which the product is intended.
Regulation (EC) 953/2009 on *"substances that may be added for specific nutritional purposes in foods for particular nutritional uses",* as amended by Regulation (EU) 1161/2011, listed in the annex the sources of vitamins and minerals, amino acids, carnitine and taurine, nucleotides, choline and inositol, that can be added to dietetic food including the FSMPs or exclusively to FSMPs.
The abovementioned list of substances has been included in the single Union list of the Regulation (UE) 609/2013, where also some new sources of vitamins and minerals authorized as novel foods according to Regulation /EC) 258/97 have been included.

The use of substances other than the ones listed in Regulation (EC) 609/2013 is allowed without prejudice to the applicability of Regulation (EC) 258/97 as a safety measure.
The authorizations granted under the Regulation (EC) 258/97 admit the use of a novel food ingredient in FSMPs if:

- the authorization is for all food;
- the authorization lists the FSMPs among the categories of food where the ingredient can be used.

Authorization decisions according to Regulation (EC) 258/97 which clearly foreseen the use of novel foods also in FSMPs are listed in annex 1.

**4 Specific labelling provisions**

In addition to the labelling provisions provided by the general food legislation, there are several specific labeling rules that are intended for a correct use of FSMPs..
It's mandatory the presence of the nutrition labelling with the content in *"nutrients"* and, where appropriate, in amino acids, sugars and fatty acids (essential and polyunsaturated), as well as that of "*other substances*" that contribute to adapt the product to its specific destination.
The labelling must bear:

- the statement *'For the dietary management of…*' where the blank shall be filled in with the diseases, disorders or medical conditions for which the product is intended,

- an *'important notice'* followed by:
- 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;* where appropriate a statement that the product is intended for a *specific age group* and that *the product poses a health hazard when consumed by persons who do not have the diseases, disorders or medical conditions* for which the product is intended. Examples of FSMPs which may pose a health hazard when consumed by persons other than their specific target are the products intended for the dietary management of Congenital Metabolic Diseases (CMDs), whose composition does not include one or more essential aminoacids.

The specific indication, related to the dietary management of disease, disorder or medical condition for which the FSMP is intended, does not have the significance either of an health claim under Regulation (EC) 1924/2006 or of an attribution of any therapeutic properties.
In particular in the FSMP labeling Regulation (EC) 1924/2006:

- applies to any indication that may be regarded as an health claim.
  I.e. an FSMP for the dietary management of malnutrition cannot claim any health effect related to some of its specific constituents if those claims are not compliant with the Regulation (EC) 1924/2006;
- not necessarily applies in respect of nutritional claims, taking into account the condition established for these claims by the Annex of the same Regulation.

**5. FSMPs FEATURES**

What distinguishes FSMPs from other food is their ability to fully or partially compensate the special nutritional needs deriving from a disease, disorder or medical condition (and the consequent malnutrition), or otherwise to facilitate its dietary management (i.e. the "food thickeners" designed to facilitate feeding of subjects suffering from dysphagia).
The composition of FSMPs is really various depending on whether the product is intended as the sole source of nourishment, or on the medical condition of the patients for whom they are intended or on the age of the subjects or where they receive health care support, or on other factors.

Another key requirement to recognize a product as FSMP is the real need to subordinate its use to medical supervision in order to guarantee the proper use indispensible for reaching the expected benefits. Moreover, such use, when the product is not the only source of nourishment, must necessarily be integrated within a total diet adapted to the specific medical condition and the specific individual requirements.

A product can be classified as FSMP only if the food (including food supplements) already available or their combinations are not sufficient to ensure a complete and effective dietary management of a particular disorder or disease.

Given that, products containing levels of vitamins and minerals within the maximum limits set by Italian ministerial guidelines on food supplements (pending harmonization of the maximum level of vitamins and minerals at Community level) are classified as food supplement and therefore they cannot be presented as FSMP.
However, a product containing levels of vitamins and minerals exceeding the limits above cited can be classified as FSMP when this composition is justified by the specific nutritional needs of a particular disease (i.e. the case of high level of vitamin A required in cystic fibrosis

patients: see guidelines for proper prescription of dietetic products intended for patients with cystic fibrosis - www.salute.gov.it). Of course, this is the case where the label must contain a warning that the use of the product, adapted to the particular nutritional requirements of patients with cystic fibrosis, can cause health risks for the general population.

This approach need to be followed to avoid the classification of a food supplements as FSMPs only to bear indications for the dietary management, overcoming the Regulation 1924/2006 limitations.
Possible exceptions to this principle have to be strongly justified.
Here some of the allowed exception in Italy:

- products with high dose of glutammine, classified as FSMPs for the dietary management of patients treated by radiotherapy, in order to compensate the over-consumption of this aminoacid at bowel level resulting for the treatment;
- products with one or more macronutrients to modulate the nutritional intake of a basal enteral diet;
- products with DHA for the dietary management of cystic fibrosis, reimbursed at national level by the sanitary system;
- products with butirrate for the dietary management of colon diseases where there is an alteration of mucose trophysm;
- products with "thickening" substances for the management of dysphagia.

To summarize, in order to classify correctly a product as FSMP:
1) the product is NOT already available as food supplement;
2) there is a scientific rationale to justify the role as an effective tool for the dietary management of diseases or disorders. Moreover, the possible benefits deriving from its use on the course and symptoms have to be linked to this role (see Guidelines to evaluate studies on safety and properties of food products - www.salute.gov.it );
3) the rationale is supported by solid scientific evidences;
4) it is justified to subordinate its use to the "medical supervision" in order to guarantee the proper use indispensible for reaching the expected benefits.

Only when the above four conditions are met a product can be classified as FSMP.

## 6. SCIENTIFIC DOCUMENTATION SUPPORTING FSMP CLASSIFICATION

In order to classify a product as FSMP for the dietary management of a specific disease, disorder or medical condition it is necessary that its composition must meet reliable criteria of medical and nutritional science and result plausible on the basis of all pertinent and available data and evidence generally accepted by the scientific community. The pertinent data should be published in indexed and peer-reviewed journals.
Clinical studies must be approved by the Ethics Committee and carried out according to the principles of good clinical practice, in order to bring objective criteria for assessing efficacy (see the above mentioned Guidelines to evaluate studies on safety and properties of food products)
The Ministry of Health may require to provide all relevant elements and data proving that the use of the product as FSMP meets the criteria and conditions outlined.

## 7. FSMPs CATEGORIES*

** The list is not meant to be exhaustive*

### *7.1 Nutritionally complete FSMPs*

**FSMP infant formulas, including preterm or low-birth-weight infant formulas**

The Directive 99/21/EC, point 4 of the Annex, states as follows:

*"Where this is not contrary to the requirements dictated by the intended use, foods for special medical purposes intended specifically for infants shall comply with the provisions relating to other nutrients applicable to infant formulas and follow-on formulas, as the case may be, laid down in Directive 91/321/EEC and its subsequent modifications".*

Directive 91/321/EEC is now replaced by Directive 2006/141/EC, transposed at national level by Ministerial Decree 9 April 2009, n. 82.

The composition requirements set by the current Directive 2006/141/EC (see recital 31 and art. 17) apply also to FSMP infant formulas unless of the specific composition adaptation made to fulfill the particular nutritional aim for which they are intended.

Based on what mentioned above, an infant formula can be considered FSMP only if its composition differs from the standard criteria established by Directive 2006/141/EC for nutrient adaptation needs.

Consequently, with the indication of the specific dietary management, permitted claims on FSMP infant formula are only those listed in Annex 4 of Directive 2006/141/EC.

Anyhow, taking into consideration the Article 16 of Ministerial Decree 9 April 2009, n. 82, even FSMP infant formulas should report on the label a statement about the superiority and of breast-feeding practice when the adoption of this practice is not contraindicated**.**

At the European level, the current provisions on FSMP infant formulae are under revision according to Regulation (UE) 609/2013 and the new provisions will be updated with the latest scientific evidence.

In the context of the above revision, also FSMP formulae intended for infants will be revised. The scope is to evaluate the variety of FSMP intended for infant that have been marketed, in order to harmonize the European approach and when it is the case to include some of them within the general standard provision of formulae.

**Enteral diets**

These products, standard or adapted, are intended for oral and/or probe administration as complete "diets" because of their content in proteins, carbohydrates, fats, vitamins and minerals and are currently available in a wide range of nutritional variants.

The presence of dietary fibre is not a necessary condition for considering a product nutritionally complete.

All enteral diets labelling must also include information on the osmolality or the osmolarity, on the essential fatty acids amount and also a warning that "the product should not be administered parenterally".

The main identifiable parameters to distinguish a standard formulation from a nutrient-adapted one are:

- state of the ingredients (monomeric or polymeric)
- energy distribution,
- energy density.

The typical composition of a standard diet can be made by combining the three following requirements:
- ingredients in polymeric form,
- energy distribution: 15% proteins (*), 55% carbohydrates, 30% fats,
- energy density: 1 kcal/ml

*(*) Nevertheless protein intake by 20% is generally considered compatible with a standard formula because it may be used to counteract or prevent malnutrition in artificially-fed subjects.*

Standard diets are designed for subjects that, given their particular state, cannot meet their nutritional needs through ordinary food consumption but without particular nutritional requirements imposed by specific diseases.

A nutrient-adapted diet can vary in different ways from standard diet requirements according to the special nutritional needs it is intended to manage. In this case the label shall bear a statement that the product poses a health risk if consumed by persons not suffering from the specific disease, disorder or medical condition the product is intended to.

**Very Low Calorie Diets (VLCDs)**
Compositional requirements reference for these products is still the Codex Alimentarius rule "Codex Standard for formula foods for use in very low energy diets for weight reduction (Codex Stan 203-1995)", which prescribes a daily energy intake between 450 and 800 kcal.
It should be indicated on the label that consumption by persons other than those to whom it is intended can pose health risks.

*7.2 Nutritionally incomplete FSMPs*

**Breast milk fortifiers for preterm or low-birth-weight infants**
They are used to supplement (mono or multicomponent fortifiers) the nutritional intake of human milk for promoting growth in low-birth-weight or preterm infants.

**FSMP for infants and young children or older children**
These are foods with highly variable composition for infants and children suffering from CMDs or other diseases.
An example is given from amino acids mixtures devoid of the amino acid (or amino acids) that cannot be metabolized by subjects suffering from a specific CMD as those devoid of phenylalanine for phenylketonuric people.

**Nutrient modules**
These products, containing one or two macronutrients sources (mono or bi-component modules), are intended to modulate energy and/or protein intake provided by the basic diet.

**Products intended for malnutrition dietary management**
These products, intended for the dietary management of subjects suffering from malnutrition, may present a composition with various degrees of complexity as for the content in nutrients and or other substances.

**Oral Rehydration Solutions (ORS)**
These products are intended to manage oral rehydration in case of diarrhea.

**Protein free products and low protein products**

Those products are intended for the dietary management of subject with chronic renal failure or CMDs.

Substitutes of foods with significant protein content such as bread, pasta, etc:

a) with a protein content not exceeding 1% are considered "protein free"

b) with a protein content between 1 and 2% are considered "low-protein content".

Substitutes of drinks, that are source of proteins of any origin, can be considered “protein free” if the protein content is not more than 0.5%.

Taking into account the possible use of the products even by subjects with CMDs, the statement on the label of the residual protein content: "protein not exceeding ..." can be followed by: "of which ..." with the indication of the content of the specific aminoacids.

The labelling should also mention the sodium, potassium and phosphorus content, that must be anyway the lowest possible.

**Dysphagia treatment products**

These products are intended for the dietary management of patients with functional or mechanical swallowing problems (i.e. neurological patients) and include both texture modifiers, such as thickeners and gelling agents, and texture modifier ready to use.

**ANNEX 1**

***Authorisation Decisions according to Regulation (EC) 258/97 that explicitly foreseen the use of novel foods in FSMPs***

- Oil rich in DHA (docosahexaenoic acid) from the microalgae *Schizochytrium sp* (Decision 2003/427/EC);
- Refined Echium oil as source of stearidonic acid (Decision 2008/558/EC);
- Arachidonic acid-rich oil from *Mortierella alpina* for use in FMSP infant formula (Decision 2008/968/EC);
- Vitamin K2 (menaquinone) (Decision 2009/345/EC);
- Synthetic lycopene (Decision 2009/348/EC and Decision 2009/362/EC); lycopene oleoresin from tomatoes (Decision 2009/355/EC); lycopene from *Blakeslea trispora* (Decision 2009/365/EC);
- Lipid extract from Antarctic Krill *Euphausia superba* (Decision 2009/752/EC);
- Phosphatidylserine from soya phospholipids (Decision 2011/513/UE);
- Bovine Lactoferrin (Decision 2012/725/UE and Decision 2012/727/UE).