Medical Nutrition
International Industry

STATEMENT OF PRINCIPLES

DIFFERENTIATION BETWEEN FOOD FOR SPECIAL MEDICAL PURPOSES (FSMPs) AND GENERAL FOOD WITHIN THE SCOPE OF EU REGULATIONS

NOVEMBER 2022

Disclaimer:

This document is intended to provide information on Foods for Special Medical Purposes (FSMPs) and General / Fortified Food in the context of the European Union (EU) regulatory framework. It is for general information purposes only and does not constitute legal or other professional advice. It does not replace the relevant EU laws. The information provided is without prejudice to national regulations and interpretations.

WHAT ARE GENERAL FOOD (INCL. FORTIFIED FOOD AND FOOD SUPPLEMENTS) AND FSMPs?

Food: 'food' (or 'foodstuff') means any substance or product, whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be ingested by humans. 'Food' includes drink, chewing gum and any substance, including water, intentionally incorporated into the food during its manufacture, preparation or treatment. It includes water after the point of compliance as defined in Article 6 of Directive 98/83/EC and without prejudice to the requirements of Directives 80/778/EEC and 98/83/EC.

'Food' shall not include:

A) feed;

B) live animals unless they are prepared for placing on the market for human consumption;

C) plants prior to harvesting;

D) medicinal products within the meaning of Council Directives 65/65/EEC (1) and 92/73/EEC (2);

E) cosmetics within the meaning of Council Directive 76/768/EEC (3);

F) tobacco and tobacco products within the meaning of Council Directive 89/622/EEC (4);

G) narcotic or psychotropic substances within the meaning of the United Nations Single Convention on Narcotic Drugs, 1961, and the United Nations Convention on Psychotropic Substances, 1971;

H) residues and contaminants;

I) medical devices within the meaning of Regulation (EU) 2017/745 of the European Parliament and of the Council (5).

Reference:
Regulation (EC) No 178/2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety

Fortified food: Food with added vitamins and/or minerals and/or certain other substances in line with Regulation (EC) No 1925/2006 on the addition of vitamins and minerals and of certain other substances to foods.

Vitamins and minerals in a form that is bio-available to the human body may be added to foods, whether or not they are usually contained therein, in order to take into account, in particular:

A) a deficiency of one or more vitamins and/or minerals in the population or specific population groups that can be demonstrated by clinical or sub-clinical evidence of deficiency or indicated by estimated low levels of intake of nutrients; or

B) the potential to improve the nutritional status of the population or specific population groups and/or correct possible deficiencies in dietary intakes of vitamins or minerals due to changes in dietary habits; or

C) evolving generally acceptable scientific knowledge on the role of vitamins and minerals in nutrition and consequent effects on health.

Food supplements: means foodstuffs the purpose of which is to supplement the normal diet and which are concentrated sources of nutrients 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.

Reference:
Directive 2002/46/EC on the approximation of the laws of the Member States relating to food supplements

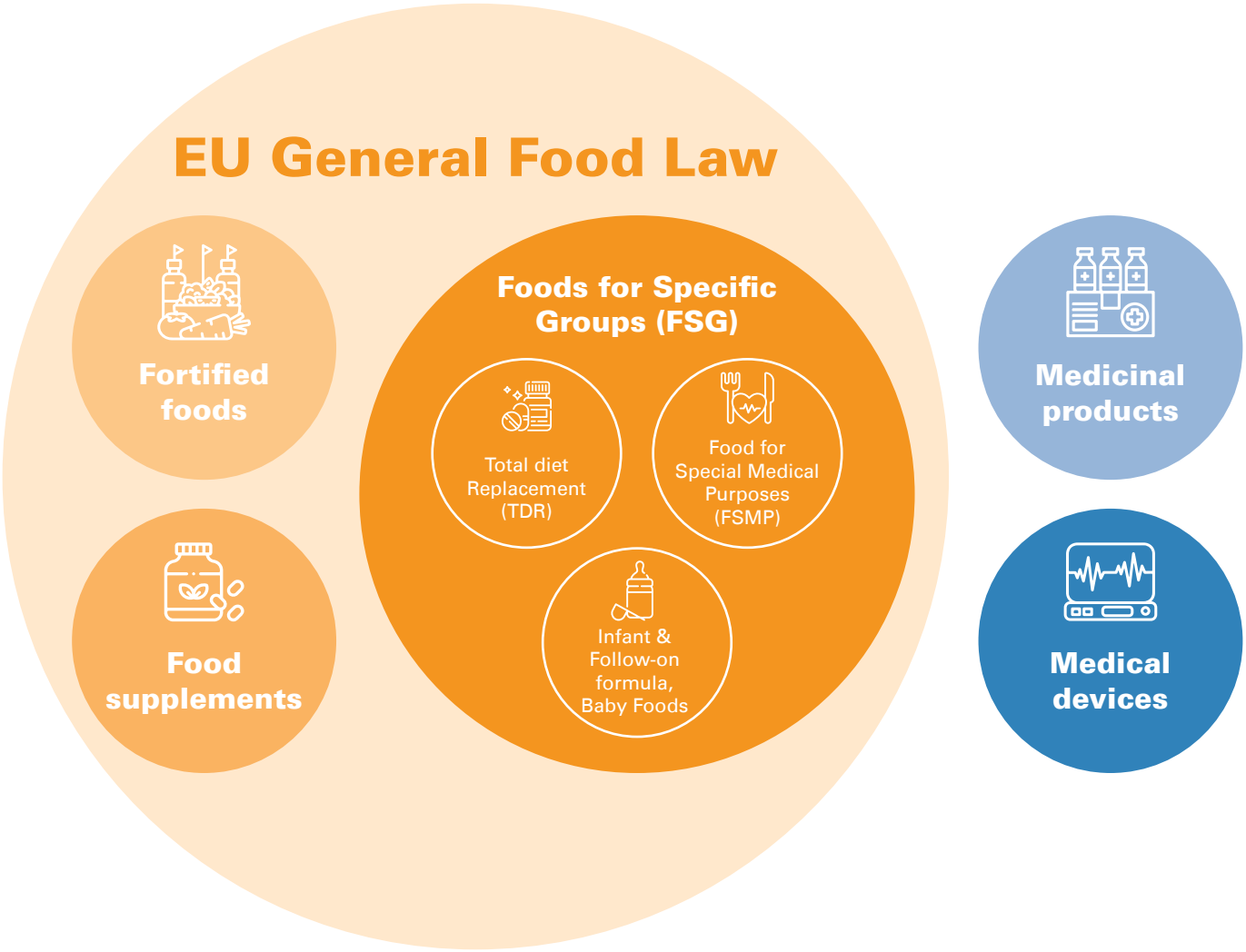
Food for special medical purposes (FSMPs): food specially processed or formulated and intended for the dietary management of patients, including infants, to be used under medical supervision; it is intended for the exclusive or partial feeding of patients with a limited, impaired or disturbed capacity 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 norma diet alone.

Reference:
Regulation (EU) No. 609/2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control.

Furthermore, FSMPs have to comply with specific compositional and information requirements which are well defined in the Commission Delegated Regulation (EU) No 2016/128 which supplements the above Regulation (EU) No 609/2013.

EU FRAMEWORK

The EU general food law is applicable for general food as well as specific food categories such as Fortified Food, Food Supplements and FSMPs for which additional category specific laws exist.

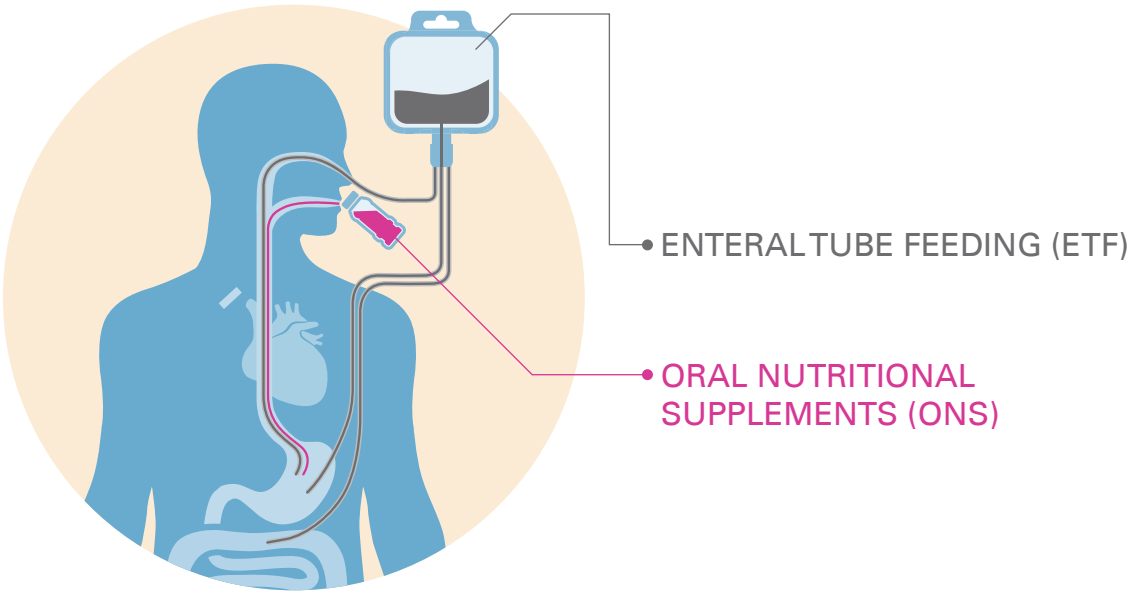


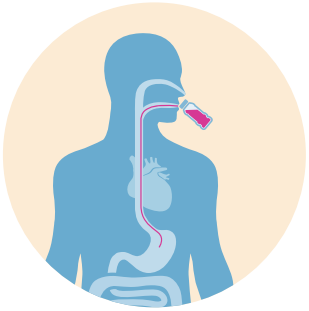
FSMPs are designed to meet nutritional or dietary needs arising from a wide range of medical conditions that affect patients of all ages from infancy to old age.They focus on the dietary management of patients who suffer from a disease, disorder or medical condition, and have been developed based on scientific and clinical evidence, often in close collaboration with scientists and Healthcare Professionals (HCPs).FSMPs include both:

A) Oral nutritional supplements

B) Enteral Tube Feeding

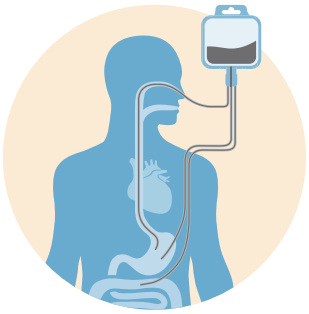
FSMPS INCLUDE ORAL NUTRITIONAL SUPPLEMENTS AND ENTERAL TUBE FEDING





ORAL NUTRITIONAL SUPPLEMENTS (ONS)

Oral Nutritional Supplements provide macronutrients and micronutrients and are designed to be consumed orally, thus taste and format are important considerations. ONS are available as ready-to-drink liquids or powders that can be prepared as drinks (also called 'sip feeds') but are also available in pre-thickened form. They may be suitable as a sole source of nutrition but are most commonly used as a supplement to normal foods. ONS are an effective and non-invasive solution to tackle disease-related malnutrition (DRM) in patients who are typically able to consume some normal food, but not enough to meet all of their nutritional needs. ONS are effective in a large number of diseases and their management - including cancer, stroke, neurological and gastrointestinal conditions, and surgery.



ENTERAL TUBE FEEDING (ETF)

Enteral Tube Feeding is administered into the gastrointestinal tract via a nasogastric, nasoenteric or percutaneous tube. ETF is required when a patient is unable to consume sufficient nutrition via the oral route. Examples include severe cystic fibrosis, cerebral palsy, after a stroke or major surgery, such as head and neck surgery, and critical illness. ETF can be supplementary to oral intake or parenteral nutrition, or can be the sole source of nutrition.

REGULATORY REQUIREMENTS COMPARED BETWEEN GENERAL FOOD (INCL. FORTIFIED FOOD AND FOOD SUPPLEMENTS) AND FSMPs

	FSMPs	General Food / Fortified Foods / Food Supplements
Definition	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.	Food with added vitamins and/or minerals and/or certain other substances in line with Regulation (EC) No 1925/2006 on the addition of vitamins and minerals and of certain other substances to foods. Foods fortified or containing sufficient amounts of protein in line with "high protein" criteria in Regulation (EC) No 1924/2006 on nutrition and health claims made on foods. Food supplements: Food containing concentrated sources of nutrients or other substances in line with directive 2002/46/EC.
Legal Name	"Food for special medical purposes" must appear on the label of the product in the appropriate language, as outlined in Annex IV of Regulation (EU) No 2016/128 on FSMP.	No specific legal name, except for 'food supplement'. Name cannot imply/suggest special medical purpose in the management of a disease, disorder or medical condition.
Composition	Regulation (EU) No 609/2013 on Foods for Specific Groups: sets the framework for the regulation of products for individuals with specific nutritional needs. Regulation (EU) No 2016/128 on FSMP: sets composition, labelling and notification requirements. The Annex to Regulation (EU) No 609/2013 contains a list of permitted nutritional substances that may be used in FSMP to provide vitamins, minerals, amino acids, carnitine, taurine, nucleotides, choline and inositol (see Annex in link above). FSMPs are developed in close cooperation with health care professionals. FSMPs shall be safe, beneficial and effective in meeting the specific nutritional requirements of the persons for whom it is intended, as demonstrated by generally accepted scientific data.	Regulation (EC) No 1925/2006 on the addition of vitamins and minerals and of certain other substances to foods regulates which nutrients can be fortified and which substances can be added to fortified foods. Regulation (EC) No 1924/2006 on nutrition and health claims made on foods regulates the amount of a nutrient that must be added for the purposes of making a nutrient content claim in labelling. For food supplements, Directive 2002/46/EC defines the category and establishes the list of vitamins and minerals and their sources.
Nutrition & health claims	**Not allowed** Nutritional and health claims cannot be made for FSMPs Recital Regulation (EU) No 2016/128 not 1924/2006 says it is not appropriate since "consumers of such products are patients suffering from a disease, disorder or condition and are, therefore, not part of the general healthy population". **Information must be provided 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 (see also section 'Description & characteristics').** Such information should not be considered as nutrition and health claims within the meaning of Regulation (EC) No 1924/2006.	**Allowed** Fortified foods and food supplements are intended for the general healthy population. Criteria for making a nutrient content or health claim are regulated by Regulation (EC) No 1924/2006 on nutrition and health claims made on foods. For example, a claim that a food is high in protein, and any claim likely to have the same meaning for the consumer, may only be made where at least 20% of the energy value of the food is provided by protein. These foods cannot suggest or imply that the product can be used for the dietary management of patients, including infants.

	FSMPs	General Food / Fortifies Foods / Food Supplements
Medical Supervision	Mandatory statement that the product must be used under medical supervision.	These are designed for the general population and are not required to be used under medical supervision.
Description & characteristics	A statement whether the product is suitable for use as the sole source of nourishment. Only infant formula, total diet replacement or foods for special medical purposes specifically designed for that purpose can use such a statement.	**Not permitted**
	A statement that the product is intended for a specific age group, as appropriate	**Not required**
	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.	**Not allowed** As the product cannot be indicated for use in a specific disease, disorder or medical condition.
	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.	**Not allowed** Only certain statements allowed under general labelling or claims regulations (e.g., specific labelling like gluten free, specific category like meal replacement for weight control or specific approved nutrition and health claims).
	Where appropriate, a statement concerning adequate precautions and contra-indications.	Not required unless specifically established in a relevant regulation.
	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.	**Not allowed** Description of the nutrient content of the product only via regulated nutrient content claims. The function of a nutrient can only be described via a regulated health claim.
Nutrition labelling	Mandatory declaration of the amount of each mineral substance and of each vitamin listed in Annex I of Regulation (EU) No 2016/128 on FSMP.	The declaration of vitamins and minerals is voluntary unless a claim is made. Specific rules for Food Supplements labelling.
Expression in % of Daily reference Intake	**Not allowed** Consumers of FSMPs have different nutritional needs than the normal population. The expression of nutrition information on the energy value and the amount of nutrients of food for special medical purposes as a percentage of daily reference intake values set out in Regulation (EU) No 1169/2011 would mislead consumers and should therefore not be required as it would be for general/fortified food (recital 16).	Mandatory if vitamins and minerals declaration is provided. When provided, the declaration on vitamins and minerals shall, in addition to the form of expression referred to in paragraph 2, be expressed as a percentage of the reference intakes set out in point 1 of Part A of Annex XIII [of Regulation (EU) No 1169/2011 on the provision of food information to consumers] in relation to per 100 g or per 100 ml.
Notification of product	Specified as a requirement in Regulation (EU) No 2016/128.	May be required for fortified food or food supplements by certain Member States.
Additives' categories & Additives authorized	Permitted for all foods in line with good manufacturing practice (GMP), category 13 and relevant subcategories or other relevant food categories	General categories of food additives that are permitted for all foods GMP & Other relevant food categories.

Medical Nutrition International Industry

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