

EU REGULATION

Inside FSMP: A Policy Challenge

Crucial for a successful notification of foods for special medical purposes (FSMP) is the documentation of the dietary purpose. A look at the latest regulatory changes.

by Dr. Bettina Dörr

Companies marketing Food for Special Medical Purposes (FSMP) have to pay attention to new (delegated) regulations. On July 20, 2016, regulation EU 609/2013 came into force. It

covers food intended for infants and young children, food for special medical purposes and total diet replacement for weight control. Foods such as sports food, meal replacement and foods for patients

with celiac diseases no longer fall under this regulation.

The delegated regulation 2016/128 has passed and will come into force in February 2019 and 2020 (FSMP for infants), respectively.

A short description of the key messages/changes concerning FSMP (not intended for infants) can be found in the box.

Crucial for a successful notification of FSMPs is the documentation of the dietary purpose, based on sound medical and nutritional principles.

The wording of the mandatory statement “for the dietary management of...” followed by the disease, disorder or medical condition for which the product is intended, is the basis and key for a successful notification. For this reason, it is helpful to define the meaning of “medical purpose” and “dietary management.”

Classification by Category

FSMP can still belong to three different categories (article 2 EU 2016/128):

Table 1: Key Messages in the (Delegated) Regulation EU 609/2013 and EU 2016/128

(Delegated) Regulation	EU 609/2013	EU 2016/128
Description	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	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
Date of coming into force	20-07-2016	22-02-2019/2020 (FSMP for infants)
Key messages/changes for FSMP	<p>Article 2: same categorization in 3 categories as in the past</p> <p>Article 3: the Commission may decide, by means of implementing acts:</p> <p>(a) whether a given food falls within the scope of this Regulation;</p> <p>(b) to which specific category of food referred to in Article 1(1) a given food belongs</p> <p>EFSA guidelines available how to characterize medical purpose of FSMP</p>	<p>Mandatory statement “for the dietary management of...” (in Germany/Austria in the past: for the dietary treatment of...)</p> <p>Art. 7: health and nutritional claims (EU 432/2012) forbidden</p> <p>Art 9 VO:</p> <ul style="list-style-type: none"> • Notification to the competent authority of each Member State where the product concerned is being marketed still open, • which documents besides the label will be requested by national authorities and • when EC or EFSA will be brought on board, respectively; <p>Art. 6: information included in the mandatory nutrition declaration for FSMP shall not be repeated on the labeling</p> <p>Recital 3: Target group: patients with 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.</p>

1a) Nutritionally complete food with a standard nutrient formula -> sole source of nourishment.

1b) Nutritionally complete food with a nutrient-adapted formulation specific for a disease, disorder or medical condition -> sole source of nourishment.

1c) nutritionally incomplete food with a standard formulation or a nutrient-adapted formulation specific for a disease, disorder or medical condition -> not suitable to be used as sole source of nourishment.

Above all, tube feeding and sip feeding are used as the sole source of nourishment belong to the categories 1a) and 1b). They are intended for patients who cannot meet their nutritional requirements by normal food intake. For these patients, there is no need to discuss the medical purpose. It is clear that they need this kind of special food.

Dietary Purpose Debate

On the contrary, there are different opinions regarding FSMP belonging to category 1c), which are not suitable to be used as the sole source of nourishment. Above all, this kind of FSMP is intended for patients with issues such as kidney disease, inborn error of amino acid and of protein metabolism.

Depending on the disease, it is impossible or very difficult for these patients to meet their specific nutritional needs. For these patient groups, there should be no discussion about the medical purpose of FSMP developed to meet the special disease-related requirement of nutrients.

There remains a further group of patients with special nutritional requirements, where FSMP is not suitable as the sole source of nourishment. This kind of FSMP usually contains only some nutrients and adapted to diseases such as immune deficiencies, rheumatic arthritis, migraine, etc. For these products, the dietary purpose is often being questioned. For this reason, it is necessary to define the meaning of the mandatory statement "dietary management" as a decision-making tool for the assessment as FSMP.

To explain the meaning, first, the expression is divided in its two components "dietary" and "management" followed by the definition of its combination.

Definition of "Diet(-ary)":

There is no clear legal definition in the European regulations cited above.

The origin of the formulation "diet" goes back to the Greek work "diaita," meaning "kind of life." According to the Oxford dictionaries, diet is defined as "the kinds of food that a person, animal,

or community habitually eats," "a special course of food to which a person restricts themselves, either to lose weight or for medical reasons," or in some cases restricted to "a food or a drink with reduced fat or sugar content." In summary, "diet" or its adjective "dietary" respectively can be equated with the term "kind of food."

Definition of "Management": There is no clear legal definition in the European regulations cited above. According to the Oxford dictionaries, "management" can be defined by the process of dealing with or controlling things or people, the responsibility for and control of a company or organization. In the case of medicine and psychiatry, management means: "the treatment or control of diseases or disorders, or the care of patients who suffer from them."

Definition of "Dietary Management": The combination of the above cited meaning of "diet" and "management" to "dietary management" leads to the formulation of dietary management. Its' meaning can be supported by definitions in dictionaries such as Wikipedia or medical journals, where "dietary management" can be explained by the practice of providing nutritional options for individuals and groups with diet concerns, e.g. dietary management of diabetes, obesity, cancer, hypertension or malnutrition. Taken together, dietary management means "dietary approaches to influence/treat a disease." Dietary approaches are made by food or nutrients respectively. This fact requires a definition of food/nutrition and nutrients (see below).

Definition of "food/nutrition" and "nutrients": Nutrition results from the intake of food, which is legally defined by regulation EU 178/2002, Art. 2. "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.

The next question must be answered; must a food be complex or can it consists of a single substance/nutrient? According to the above cited definition, including "water" and "any substance," as well as looking at common food e.g. sugar, oil, salt, we can conclude that food can also be a single substance.

Definition of "Nutrient": In the early stages of nutritional science, nutrition was considered to deliver enough nutrients according to the known requirements and to prevent malnutrition.

Today, nutrients are considered to have much more functions such as to maintain health and well-being and to prevent diseases or its progression, respectively. For this reason, not only energy providing nutrients such as carbohydrates, amino acids, fat and vitamins/minerals belong to nutrients, but also further nutrients that are present in food such as polyphenols, probiotics, carotenoids and phytochemicals.

An extended definition can be found in Codex Alimentarius (CAC/GL 9-1987, rev. 2015). "Essential nutrient" means any substance normally consumed as a constituent of food which is needed for growth and development and/or the maintenance of life. Nutrients can contribute to preventing/reducing the risk of, or correcting, a demonstrated deficiency in maintaining or improving health.

Definition of medical purpose: Food for special medical purposes are defined to deliver nutrient(s) adapted to the medical situation of a patient.

Therefore we have to define "medical" and "medicine," respectively. "Medical" relates

to the science or practice of medicine.

A medicine is a drug or other preparation for the treatment or prevention of disease (Oxford dictionaries). In conclusion, the medical purpose of a food or its containing nutrient(s), respectively, means that the nutrient must have the property to treat or prevent a disease.

In this context, it seems adequate to raise the question, if drugs containing nutrients are "old-fashioned," in the age of EU 609/2013 and 2016/128, respectively.

There is a contradiction between the medical purpose and art. 9 (5) EU 609/2013, whereas FSMP does not have the property of preventing, treating or curing a human disease, or imply such properties.

Free Movement of Goods?

The delegated regulation 2016/128 contains the formulation of the mandatory statement "dietary management of..." The translation of this formulation was made in the different country adapted regulations. It is very interesting that the translation of this wording into different languages leads to different meanings. For example:

- German: "Diätmanagement" (in the past: dietary treatment).
- French language: "pour les besoins nutritionnels en cas de..." (=requirement).
- Italian language: "per le esi-

genze nutrizionali in caso di..." (=requirement).

- Spanish language: "Para el tratamiento dietético de" (= treatment).
- Netherlands: "Dieetvoeding bij..." (= nutrition).

Some German Context

As an expert in FSMP who is resident in Germany, let me explain the change of wording in Germany and Austria. In these countries, the mandatory statement "dietary management" was translated as "dietary treatment" in the past.

The currently changed delegated regulation 2016/128 in the German language - now prescribes the same wording as in the English text, "Diätmanagement" (=dietary management).

There are many discussions about the different meaning of "management" and "treatment." Let me conclude that the meaning in the medical context is the same.

A company that intends to market an FSMP in Italy or France does not need to worry about the different meaning of "management" or "treatment," because - according to their translated regulation - they only have to demonstrate that special requirements exist in case of the disease/disorder/medical condition. For Germany/Austria, there is a different situation because "treatment/management" can be interpreted different as "requirement."

In Summary

As in the past, FSMP can belong to three different categories, depending to its use as sole source of nourishment (yes or no) and on its formulation (standard or disease specific). FSMP have to be labeled using the mandatory statement of "dietary management of..." followed by the disease, disorder or medical condition, for which the product is intended.

For submitting the medical purpose:

- Give a clear description/characterization of the relevant nutrient.
- Demonstrate bioavailability and safety.
- Provide human data to prove the efficacy. Important is that dosage, target group and active substance are identical between planned product as FSMP and the parameters of the clinical study. The concerned disease should be characterized by medically accepted parameters.
- Use the same medical designation for the mandatory statement "for the dietary management of..." as investigated in the clinical trials.
- Check and fill the items from the EFSA technical guidance on how to submit a dossier to get an impression if your planned FSMP can be successfully notified.

To be successfully classified as FSMP, the active substance(s) should be (a) nutrient(s) with documented positive effects for the disease. The demarcation to drugs cannot be clearly done, because a nutrient used for a medical purpose automatically has a therapeutic/curing property. It remains an individual decision and is dependent on the overall view. ▼

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› 7 Key Takeouts on FSMP Regulation

1. Essential regulations for the successful placement of Food for Special Medical Purposes (FSMP) are the European delegated regulations 609/2013 and 2016/128.
2. Products containing only one nutrient (not suitable to be used as a sole source of nourishment) can be considered as food (for special medical purposes).
3. Nutrients = energy providing nutrients + nutrients to maintain or improve health.
4. Management in the medical context = responsible treatment/control of diseases.
5. Dietary management = nutritional approaches to treat a disease, disorder or medical condition
6. Medical purpose of nutrient(s) = Nutrient(s) for the treatment or prevention of a disease, disorder or medical condition.
7. To be successfully classified as FSMP, the active substance(s) should be (a) nutrient(s) with documented positive effects for the disease, demonstrated by human data. ▼