New Regulation for Food for Special Medical Purposes (FSMPs) in the EU: the role of EFSA

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Optimal Nutritional Care for All: Medical Nutrition Supports Cost-Effective Care
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Legal context

Directive 2009/39/EC :

- Defined '**foodstuffs for particular nutritional uses**'
- Established a notification procedure **prior to being placed in the market**
- **Specific labelling requirements**

But

- an **increasing number** of foodstuffs are currently marketed and labelled as FSMPs
- **broad definition,** interpreted differently in different Member States

Legal context (cont.)

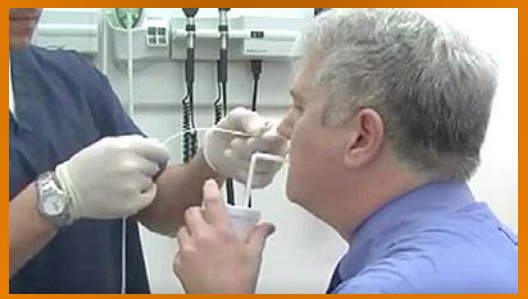
Regulation (EC) No 609/2013

OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 12 June 2013

food intended for infants and young children

Total diet replacement for weight control

Food for special medical purposes



Legal context (cont.)

Defines FSMPs as:

- Foods **specifically** processed or formulated
- Intended for the dietary management of **patients**, including infants
- To be used under **medical supervision**
- 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**

  - wit other **medically-determined nutrient requirements**

  - whose dietary management **cannot be achieved by modification of the normal diet**

Legal context (cont.)

✓ Maintains the notification procedure at national level

BUT

✓ Aims at the harmonisation of the EU market

Legal context (cont.)

Regulation (EC) No 609/2013 foresees:

- **Article 3** allows the Commission to decide whether a food can/cannot be classified as FSMP

- **Article 7** foresees the possibility of consulting EFSA

EFSA Guidance

European Food Safety Authority

EFSA Journal 2015;13(11):4300

SCIENTIFIC OPINION

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

EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA)[2, 3]

European Food Safety Authority (EFSA), Parma, Italy

EFSA Guidance

Scope:

✓**FSMPs in the context of Article 3**

Excludes:

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

EFSA Guidance

The Commission could ask EFSA one or more of the following questions:

The extent to which the information provided allows:

i. an accurate description of the specific food product regarding the **characteristics** which may be important for its classification as FSMP

ii. to **distinguish between patients** for whom the specific food product is intended **and other individuals** for whom it is NOT intended

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EFSA Guidance

Questions (cont.)

The extent to which:

iii. it is **impossible**, **impractical** or **unsafe** to feed the target patients exclusively with foodstuffs (including fortified foods and food supplements) that are not FSMPs, and/or would have a **nutritional or clinical disadvantage**;

iv. the specific food product is **different** from foodstuffs that are not FSMPs, owing to its composition, manufacturing process, physical form, mode of administration, pattern of consumption and/or other reasons;

v. the use of the specific food product in the dietary management of patients is **necessary** or **more practical** or **safer**, or has a **nutritional or clinical advantage**, than the exclusive use of foods which are not FSMPs

EFSA Guidance

Questions (cont.)

vi. The reasons why the product needs to be administered under **medical supervision**.

vii. **Any potential restrictions of use**, i.e. whether the specific food product may be unsafe if consumed by subjects other than patients for whom itis intended.

EFSA's role

- Provides scientific advice to the European Commission and Member States
- On one or more aspects which are considered important for the classification of a product as FSMP
- Only upon request

- DOES NOT evaluate applications sent directly by industry
- DOES NOT decide or advise on whether or not a food product could/should be classified as FSMP

THANK YOU FOR YOUR ATTENTION