SNE Specialised Nutrition Europe

Medical Nutrition International Industry

FOODS FOR SPECIAL MEDICAL PURPOSES (FSMP)

AN EDUCATIONAL PACKAGE EXPLAINING THE CATEGORY AND ITS REGULATION IN THE EUROPEAN UNION

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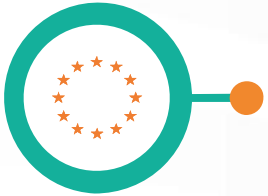
SNE **Educational Package** on Food for Special Medical Purposes (FSMP)

Aim: To provide a package of educational materials for use by SNE, MNI and National Associations at both European and national level.

The materials are to be shared with various stakeholders – regulators, policy makers and key opinion leaders (KOLs) to improve their understanding of the FSMP category and its regulation.

About SNE



SNE is the trade association representing the interests of the specialised nutrition industry across Europe

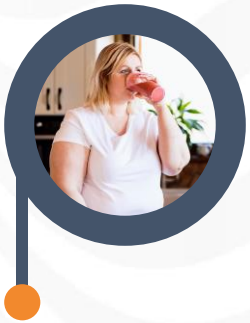
SNE members provide tailor-made dietary solutions for populations with very specific nutritional needs

SNE members are committed to the highest safety and quality standards, and continuous innovation (5% of turnover is invested in research)

Our products are vital for EU consumers

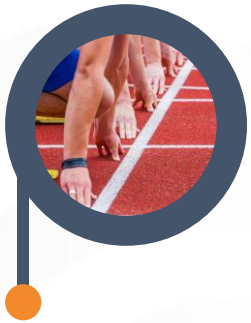
Infant and young child nutrition

Foods for Special Medical Purposes



Foods intended for weight control

Gluten-free foods



Foods intended for sportspeople

About MNI

The Medical Nutrition International Industry association - MNI - is the voice of the medical nutrition industry at international level.

Vision: Together we are dedicated to advancing better care through better nutrition.

Oral Nutritional Supplements

Enteral Nutrition

Parenteral Nutrition

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What are Foods for Special Medical Purposes (FSMP)?

FSMPs support the management of disease in patients from infancy to old age

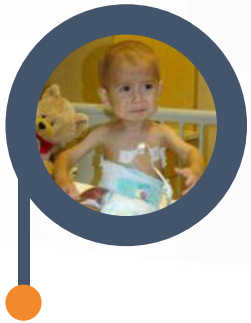
Designed to meet nutritional or dietary needs arising from a wide range of medical conditions that affect patients of all ages from infancy to old age.

For the dietary management of patients who suffer from a disease, disorder or medical condition which either temporarily or permanently affects their ability to achieve a suitable nutritional intake using normal foods.

Developed based on scientific and clinical evidence, often in close collaboration with scientists and Healthcare Professionals (HCPs). They are supported by sound medical and scientific data which may include national, international or professional guidelines.

Used on the recommendation of, and under the supervision of a HCP. This necessary and continued HCP supervision clearly distinguishes FSMPs from other food types. They are consumed across all healthcare settings – in hospitals, care homes, clinics and in private homes.

FSMPs are used in a wide variety of medical conditions – examples across all age groups



Cows milk allergy
Renal disease

Inborn errors of metabolism

Stroke or neurological conditions

Disease-related Malnutrition

FSMPs are used in different forms and compositions to respond to different patient needs

Enteral tube feeds – adult & paediatric
Tube feeding is the delivery of a feed into the gastrointestinal tract via a feeding tube. It may be required due to: an inability to swallow, partial functioning of the gut and/or high nutritional requirements. They may be used as a sole source or partial source of nutrition.

Oral Nutritional Supplements (ONS) - adult & paediatric
ONS provide macronutrients and micronutrients. As they are designed to be consumed orally, the taste and format are important.
They are an effective and non-invasive solution to tackle Disease Related Malnutrition (DRM) and provide functional benefits in patients who are typically able to consume some normal food, but not enough to meet all of their nutritional needs.

Disease specific - adult & paediatric
These are designed specifically for use in certain diseases or medical conditions, with adapted formulations to meet specific nutritional requirements or to provide additional benefits.

FSMPs are used in different forms and compositions to respond to different patient needs

Specialised infant feeds
A variety of FSMPs intended for infants are available and essential for normal growth and development in infants with medical conditions.

Metabolic and rare conditions, e.g. Phenylketonuria (PKU)
Some conditions that require FSMP are extremely rare and life-long dietary management with FSMP is often required.

Other – nutritionally incomplete modules
Food and fluid thickeners are used to manage dysphagia, allowing patients to meet their fluid and nutritional requirements. Modules containing one or several nutrients i.e. protein, fat and/or carbohydrate are essential for bespoke dietary regimes.

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How Foods for Special Medical Purposes are Used

FSMPs are used to support nutritional intervention in many different patient groups with diverse nutritional challenges

Dietary Advice and food fortification

Oral nutritional supplements

Partial tube feeding e.g. overnight

Complete tube feeding

Partial or total Parenteral nutrition

Orthopaedic fracture

Renal disease

Cystic Fibrosis

Head and neck cancer

Intestinal failure

Examples of patients malnourished or at risk of malnutrition

Healthcare Professionals play a key role in addressing the nutritional needs of patients using FSMP

	Medical		Dietetics	Pharmacy	Nursing		Catering
Ward	Doctors		Dietitians	Pharmacists	Nurses		Ward Hostess
Supervisory	Patient's Consultant(s)	Team Consultant(s)	Specialist Dietitian	Specialist Pharmacist	Nutrition Nurse Specialist	Nurse Managers	Catering Managers
Organisational	Clinical Directorate		Lead Dietitian	Lead Pharmacist	Hospital Nursing Leads		Lead Caterer
Hospital Governance	Medical Director		Director of Operations	Director of Operations	Nursing Director		Director of Operations

Nutrition Support Team

The role of the Healthcare Professional

Involvement in the development and clinical evaluation of FSMP intended to meet the needs of patients with a specific disease, disorder or medical condition.

Screening for malnutrition or risk of malnutrition related to their disease or medical condition and **assessing the individual patient's needs.**

Recommending a suitable FSMP / nutritional intervention depending on the disease or medical condition, the stage of treatment and their nutritional status.

Monitoring the use of the FSMP and the ongoing nutritional status of the patient.

Advising the patient on continuation of the FSMP, adaptation of their intake during the course of their medical management and, when suitable, discontinued use of FSMP.

Case Studies – Use of FSMPs

Stroke -Tube feeding

Stroke can cause neurological damage leading to dysphagia – a disorder in the swallowing process.
In early stages complete nutrition may be given via enteral feeding tube.
During recovery food and fluid texture may need to be modified.
Feeding difficulties may lead to poor nutritional intake requiring support.

Cancer - DRM

Cancer can lead to fatigue, poor appetite and reduced food intake.
Cancer treatment (radiotherapy or chemotherapy) can lead to side effects that further reduce food intake eg nausea, vomiting, sore mouth.
Nutritional support needs to be considered in all stages of cancer.

Epilepsy -Ketogenic diet

Epilepsy can be resistant to drug treatment – a dietary approach may be appropriate.
A special diet high in fat and very low in carbohydrate can be used to induce ketosis.
FSMP are used either where patients are neurologically damaged and require tube feeding or to provide practical help and compliance with the difficult ketogenic dietary regimen.

MSUD - IEM

Maple Syrup Urine Disease is an inherited metabolic disorder.
Patients with MSUD cannot metabolise certain amino acids within dietary protein.
The main medical management is a very low protein diet.
Protein intake for growth and development is maintained by use of a specialised protein substitute excluding toxic amino acids.

Cow's milk allergy

It is estimated that 2-3% of infants develop allergy to cow's milk.
Some infants who develop a severe allergy to cow's milk and other proteins cannot be breastfed and require specialised infant FSMP formulas from the time of diagnosis to ensure normal growth and development during infancy and beyond.

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What is Disease-Related Malnutrition?

What is malnutrition?

"A state resulting from lack of intake or uptake of nutrition that leads to altered body composition (decreased fat free mass) and body cell mass leading to diminished physical and mental function and impaired clinical outcome from disease"[1,2].

The term **'malnutrition'** encompasses overweight and obesity as well as under-nutrition, but in line with common practice internationally, the term **'malnutrition'** is used here to refer to **'under-nutrition'**.

Disease-related malnutrition (DRM) is caused by inadequate intake of energy, protein and/or other nutrients as a result of diseases, or their treatment, or increased losses of nutrients, and can impact individuals at any stage of life.

DRM is very common in healthcare settings – 1 in 4 patients admitted to hospital are at risk of malnutrition or are already malnourished. It also affects patients living at home.

Malnutrition is a 'hidden' problem that affects all age groups in all care settings

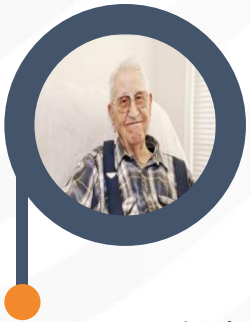
"Malnutrition is Europe's hidden major health problem…repeatedly reported from every kind of care situation"[1]

Hospitals

About **1 in 4 patients** in hospital are at risk of malnutrition[2-8]

Almost **1 in 5 children** admitted to hospital are at risk[13]

Community



Around **1 in 3 older people living independently** at risk[9]

Care homes

More than **1 in 3 people** in care homes at risk[1,9,10-12]

Tools to identify malnutrition risk

- Practical, validated tools are available to screen for malnutrition and risk of malnutrition
- Specifically designed for different patient groups and care settings

Examples include:

For hospital and community patients	For older people	For adult hospital patients	For children
BAPEN 'MUST'	HAS Stratégie de prise en charge en cas de dénutrition protéino-énergétique chez la personne âgée	NRS 2002	STAMP Strong$_{kids}$

However, lack of routine use means that **malnutrition often goes undetected.**

Consequences of malnutrition for individuals

Markedly increased morbidity and mortality rates [1-2]

Malnourished patients experience more complications than well nourished patients; the risk of infection is more than three times greater in hospitalised malnourished patients [2-4]

Associated with poorer quality of life [1]

Malnutrition has a particularly high adverse impact in the older person [4] - impairing function, mobility and independence [5]

Malnutrition has an adverse **impact on growth and development in children** [1,5]

In cancer patients malnutrition is associated with **poor response to therapy, poor outcome and poor quality of life** [6]

FSMPs play a key role in combatting Disease-Related Malnutrition (DRM)


complications


length of hospital stay


mortality

DRM


independence/QOL


healthcare costs

Economic consequences of malnutrition

The cost of malnutrition

Country	Cost of malnutrition	Note
England[1]	£19.6 billion	Public expenditure on malnutrition in 2011-12
Germany[2]	€9 billion	Additional costs due to malnutrition across all care sectors in 2003
The Netherlands[3]	€1.9 billion	Additional costs due to malnutrition in 2011
Republic of Ireland[4]	€1.4 billion	Public expenditure on malnutrition in 2007
Croatia[5]	€97.4 million	Cost of malnutrition for selected diagnoses in 2012

In Europe malnutrition costs healthcare systems an estimated €170 billion per year[6]

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Combatting Disease-Related Malnutrition (DRM)

A snapshot of national actions

The situation in the United Kingdom

Prevalence of DRM

3 million people in the UK are malnourished[1]

1 in 3 in care homes

1 in 4 hospital admissions

1 in 10 visiting their GP

Cost

Annual cost of **£19.6 bn** in England – representing **15%** of total public expenditure on health and social care[2]

Appropriate use of ONS could save the NHS **£101.8m** per year and better nutritional care could be the **6th** largest cost saving in the NHS

VALUE of liquid Oral Nutritional Supplements (ONS) vs routine care	VALUE of Enteral tube feeding vs routine care
33% reduction in mortality in hospital patients.[1]	**50% reduction in mortality** in hospital patients.[5]
33% reduction in complications in hospital patients.[1]	**30% reduction in complication rates** in hospital patients.[5]
2 days shorter length of stay.[1]	Allows a **safe discharge from hospital,** with **47,000** tube fed patients in UK able to live independently in their own homes.
30% reduction in complications post hospital discharge.[2]	**Improved body weight and muscle mass** in patients in the community. [5]
50% reduction in falls post hospital in malnourished older adults for high protein ONS.[3]	
30% reduction in readmissions for high protein ONS. [4]	

Malnutrition in **England** has an annual cost of

£19.6 bn

representing **15%** of total public expenditure on health and social care.[2]

The situation in the United Kingdom

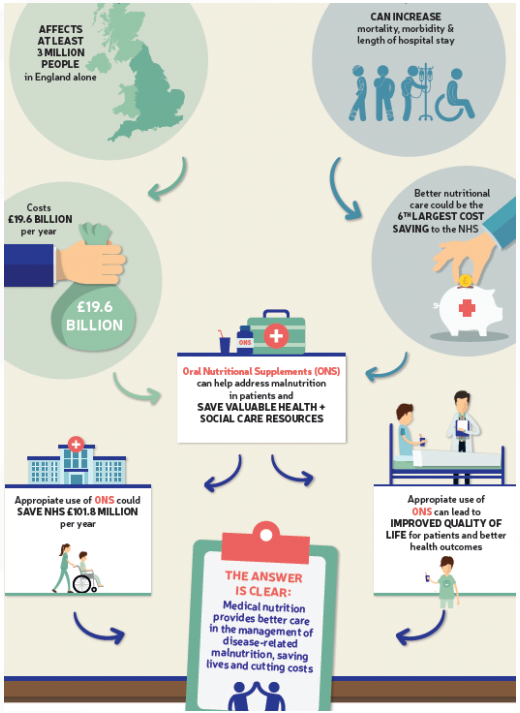
Actions and opportunities

FSMPs are approved by the Advisory Committee on Borderline Substances (ACBS) and are reimbursed by the National Health Service.

The UK Malnutrition Awareness Week was founded by the Malnutrition Task Force and BAPEN in 2018 to raise awareness of malnutrition and dehydration in the UK:
www.malnutritiontaskforce.org.uk/get-involved/uk-malnutrition-awareness-week

The government announced a Hospital Food Review in August 2019, to improve food quality in hospitals and provide consistently safe, nutritious and tasty food.

Malnutrition is under reported in the UK. All patients should be screened by 'MUST' screening tool and an individual care plan implemented following assessment.
www.bsna.co.uk/uploads/knowledge-hub/FINAL-Malnutrition-Map-20-February-2018.docx.pdf



The situation in France

Prevalence of DRM

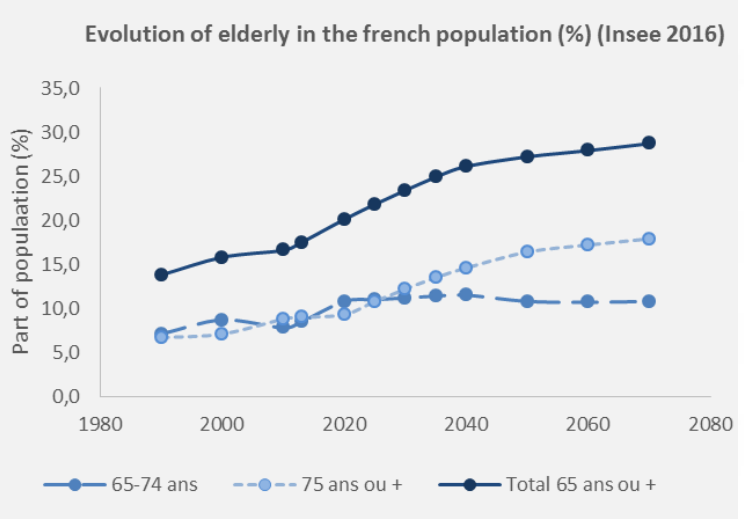
2 million people in France suffer from malnutrition

Elderly (**4-10%**), approx. 400 ,000 people

The elderly population at risk of disease-related malnutrition is growing

Patients with disease, **20-40%** of hospitalized patients

1 out of 10 hospitalized children, 50% of whom are under 3 years of age



The situation in France

Actions and opportunities

Creation of collective fight against malnutrition with a video campaign to raise awareness on the topic: **https://www.luttecontreladenutrition.fr/** and 14 proposals to fight malnutrition

Medical nutrition is broadly reimbursed in France in the community + part of hospital budget.

The national nutrition and health strategy includes as one of the key points: prevention of DRM with the focus on malnutrition screening, and set up every year a national week of malnutrition

A recent medico-economic study shows that ONS (Oral Nutritional Supplementation) prescription in malnourished elderly patients generated no extra heath care cost. High energy and protein intake from ONS was associated with a reduced risk of hospitalisation and health care costs (Seguy&al).

The situation in Germany

Prevalence of DRM

1.5 million people in Germany are malnourished – up to 6 million considering underreporting

2-7% of the population in care homes

1 in 4 hospital admissions including children

1 in 10 visiting their GP

Cost per annum

€ 170 bn spending in healthcare (but limited budgets and intense competition on allocation)

11.1% health expenditure per GDP

€ 10 bn additional costs due to DRM across all healthcare settings

€ 4 bn additional costs due to prolonged hospital stays caused by DRM (2.5 days longer length of stay)

€ 55 mil expected costs for introduction of mandatory nutritional screenings in hospitals (4 mins time investment per patient for nutritional screening)

€ 3 bn expected cost savings for hospitals if DRM would be identified and managed systematically

The situation in Germany

Actions and opportunities

NATIONAL MULTIDISCIPLINARY EFFORTS Supported by Diatverband

„TO RAISE AWARENESS" Competence Network 'Clinical Nutrition' (established in 2011) – with print and online information individually tailored for both physicians and patients, and policymakers – www.trinknahrung.pro

Establishment of an expert network fighting for maintaining current or establishing sustainable new reimbursement rules (www.kn.ee.de)

Tube feeding is quite common in German healthcare settings: approx. 100.000 patients receive FSMP's via tube.

The situation in the Netherlands

Prevalence of DRM[1]

22% in hospitals

1 in 5 children hospitalised is malnourished[2]

The hospital stay of patients who are malnourished is on average **28%** longer than those who are not

17% in residential care and nursing homes

22% of elderly living in their own homes

Malnutrition results in more than **400 deaths per year**

Cost per annum

1.8 bn €

1. measurement was done in 2012. LPZ Maastricht 2012
2. Joosten KF et al Arch Dis Child 2010 95: 141-5

The situation in the Netherlands

Actions and opportunities

In the Netherlands food for special medical purposes are reimbursed by the medical insurance companies.

For each euro that is invested in the treatment of a malnourished person society saves € 1,90 to € 4,20.

Dutch Steering Group for Malnutrition - a national multidisciplinary knowledge centre for the awareness, prevention, identification and treatment of malnutrition.

Dutch Malnutrition Steering Group

Important for the Dutch approach; tools for screening and treatment.

More information and a multidisciplinary guideline on malnutrition can be found on **www.fightmalnutrition.eu**

The situation in Spain (based on Predyces study)

Prevalence

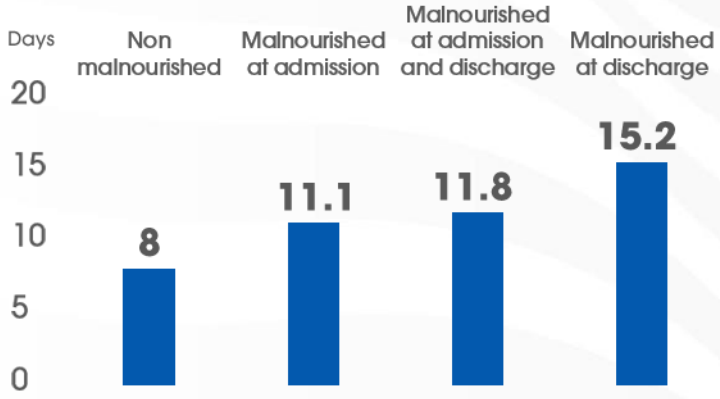
Approximately 1 in 4 patients admitted to hospital are malnourished

Condition more related to elderly patients admitted to medical wards with cancer

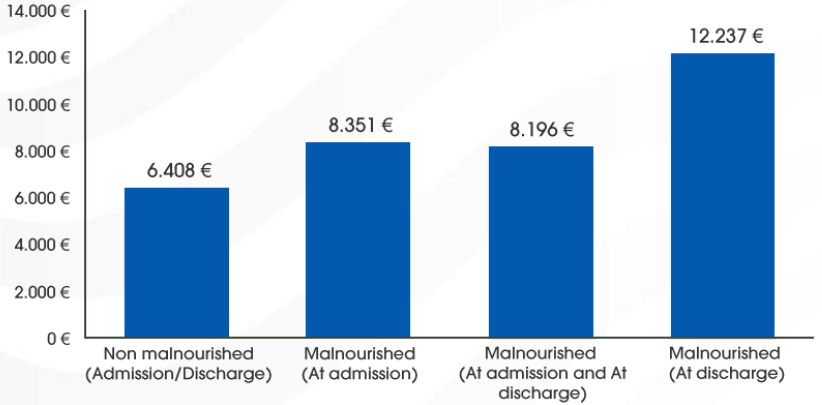
Consequences of hospital malnutrition are: higher incidence of complications, longer length of stay and higher costs

Between 25% and 90% higher costs associated with the presence and evolution of malnutrition during hospitalisation.

Average length of stay (In-hospital stay)



Mean costs according to nutritional status during hospitalization:



The situation in Italy

Increase the awareness of the value of clinical nutrition at institutional and regional level in order to gain access to reimbursement of ONS for oncology patients

Prevalence of DRM in Cancer patients

In 2018 **3.4 million** people in Italy are living with a cancer diagnosis and **369,000** new cases were diagnosed.[1]

Cancer is one of the chronic diseases with the highest frequency of malnutrition reported – **between 31% and 39%.**[2]

The systematic use of ONS can prevent the suspension of therapy in about **10%** of the cancer population.[3]

The situation in Italy

Starting point: publication in 2017 of The **«Nutritional guidelines for the oncologic patients»** approved by State-Regions Conference with focus on the importance of the nutritional screening in the patient's pathway.

In selected regions

Regione Lombardia

REGIONE TOSCANA

Meeting with KOLs in the regional healthcare system

At national level

In February of 2019 the Ministry of Health Nutrition Committee approved a document where burden of disease, epidemiology, estimation of the number of oncology patients potentially malnourished or at risk and total potential costs for the NHS have been reported.

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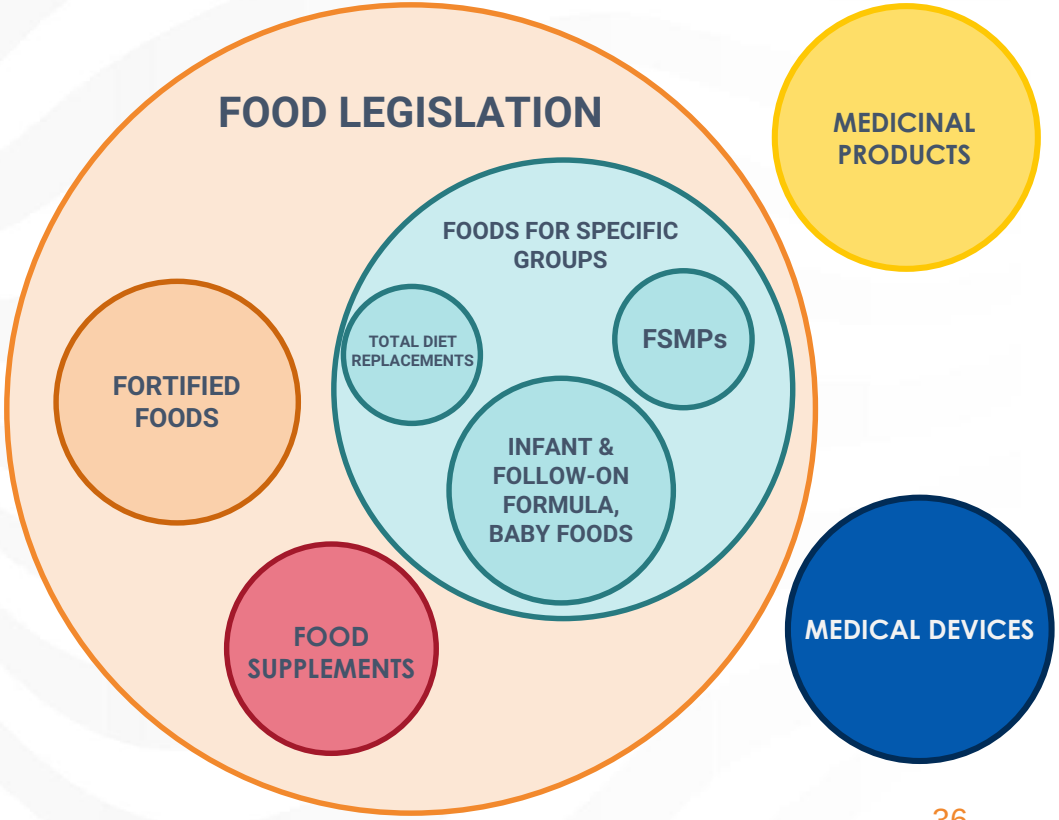
The EU Regulatory Framework for FSMP

FSMPs have their own specific regulatory framework

They are:

- A distinct category within Food Legislation
- Not medicinal products
- Not medical devices



The EU Regulatory Landscape for FSMPs

EU Regulations

- Guarantee:
  - a high level of protection of human life and health and of consumer interests
  - fair practices in the food trade, and take into account animal health and welfare, plant health and the environment

In addition legislation on foods for specific groups:

- Strengthens provisions on foods for vulnerable population groups to ensure their protection (Food for Specific Groups)

- Defines FSMPs and differentiates them within the legal framework, **acknowledging that they are foods with specific roles in the dietary management of vulnerable patients**

- Provides a legal framework for FSMPs to ensure optimal levels of protection and information for patients and for healthcare professionals recommending them

The Definition of Food for Special Medical Purposes

Food specially **processed** or **formulated** for its intended use

For the **dietary management** of **patients**, including infants.

Used under **medical supervision**

May be intended for the partial or exclusive **feeding of patients**

For those who have a **limited, impaired or disturbed** capacity to **take, digest, absorb, metabolise or excrete** ordinary foodstuffs 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**

Four elements within a solid framework ensure that products placed on the market as FSMP are appropriate for their intended use:

- **Regulation (EU) No 609/2013 on Foods for Specific Groups:** sets the framework for the regulation of products for individuals with specific nutritional needs
- **Delegated Regulation (EU) No 2016/128 on FSMP:** sets composition, labelling and notification requirements
- **EU Commission Guidance on FSMP:** explains the FSMP definition and classification
- **EFSA scientific and technical guidance:** outlines the elements that need to be considered when determining the appropriate positioning of products as FSMP

Specifics covered by the regulation

Specifics covered by the regulation

Foods for Specific Groups **Regulation (EU) 609/2013**

Definition of FSMP

- patients are at the centre of the FSMP category
- FSMP are used under HCP supervision to address specific nutritional needs caused by a disease disorder or medical condition

Innovation

- innovation enables consumers to benefit from technical and scientific progress
- use of new nutrition substances or ingredients is possible providing that safety, suitability, and efficacy is established

Specifics covered by the regulation

Foods for Specific Groups **Regulation (EU) 609/2013**

HCP Communication provision

- need for clear information to be provided to HCPs to ensure they make appropriate choices to meet their patients dietary needs

Notification/Article 3:

- requires notification to the Member State Competent Authority
- enables Member States to assess the extent to which a food product notified as FSMP falls under the scope of the FSG regulation

Specifics covered by the regulation

Delegated Regulation (EU) No 2016/128 on **FSMP**

Compositional Categories

- nutritionally complete foods with a standard formulation
- nutritional complete foods with a nutrient adapted formulation
- nutritionally incomplete with a standard or nutrient adapted formulation

Nutrition & Labelling

- comply with general food information labelling requirements + mandatory requirements specific to FSMPs i.e. use under medical supervision, age suitability, indication for use, precautions & contraindications
- information on properties and characteristics is mandatory and distinct from nutrition and health claims which are not permitted
- nutrition declaration must provide more particulars than general food to ensure appropriate use

Specifics covered by the regulation

Delegated Regulation (EU) No 2016/128 on **FSMP**

Nutritional Composition:

- suitability for intended use based on generally accepted scientific data
- basic compositional requirements on vitamins and minerals with provisions to modify the levels and sources of nutrients to accommodate the special dietary needs of patients

Communication

- communication provisions for infant FSMP - similar to infant and follow-on formula
- provision to provide food information to patients and healthcare professionals to ensure the product's appropriate use
- information should allow HCPs to assess the suitability of different products for their intended use

Key elements in the Regulation of FSMP

FSMP Defined: Three specific FSMP sub-categories are defined. This provides legal certainty on the FSMP scope and ensures that both the diversity of the category and future innovation are considered for the benefit of patients

Specific Labelling Provisions: labelling provisions in the Food Information to Consumers legislation (FIR) and additional specific FSMP labelling provisions ensure availability of relevant information for patients and HCPs

Flexibility in Composition: flexibility in composition, and the ability to deviate from the compositional requirements, enable FSMPs to meet the nutritional requirements of a specific disease, disorder or medical condition

Communication on FSMPs to HCPs and Patients: providing information to patients and HCPs is necessary to ensure appropriate use of FSMPs products, and enables HCPs to assess the suitability of different products for patients

Notification of Placing on the Market: notification procedures allow Competent Authorities to adequately monitor products placed on the market

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Guidance from the EU Commission and EFSA

Guidance from the EU Commission and EFSA

EU Guidance on FSMP

- "Commission Notice on the classification of Food for Special Medical Purposes" published November 2017
- Developed to assist both National Competent Authorities in their enforcement tasks and stakeholders in marketing their products under the appropriate legal framework
- Provides interpretative guidance - mainly on the key elements of the definition of FSMPs

EFSA Guidance on FSMP

- Developed to provide increased clarity on the EU legal framework for FSMPs
- Provides a clearly defined framework to assist in ensuring that products are appropriately classified and placed on the market as FSMPs

The Scientific and Clinical Evidence Base Supporting FSMPs

Sources of Scientific Evidence

Article 2 of Regulation 2016/128 – the formulation of FSMP shall be based on sound medical and nutritional principles. Its use, in accordance with the manufacturer's Instructions, shall be safe, beneficial and effective in meeting the particular nutritional requirements of the persons for whom it is intended, **as demonstrated by generally accepted scientific data.**

The type of scientific evidence for FSMPs will vary depending on the patient group and the requirement for, or feasibility of, conducting intervention studies.
Many nutritional interventions are well-recognised in the scientific literature.
It is not possible to conduct clinical trials in very small/variable populations.

There are a variety of scientific sources to draw on:
Journal articles, reviews, text books, conference proceedings, consensus papers.
Clinical use – case studies, surveys, historical data review, expert opinion.

There may be ethical considerations in intervention studies:
Often not possible to have a non-intervention group with nutrition studies.
May not be ethical to repeat studies in vulnerable patients if science established.

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Detailed Case Studies on the use of FSMPs

Case study I: Stroke

Stroke: occurs when blood supply to part of the brain is disrupted, resulting in problems with movement, balance and speech and swallowing difficulties (dysphagia).[1]
Stroke is the second most common single cause of death in Europe, accounting for 405,000 deaths (9%) in men and 583,000 deaths (13%) in women each year.[2]

Nutritional Impact

Dysphagia can cause anxiety at mealtimes due to risk that food or drink enters the patients lungs causing them to aspirate.
Patients may have difficulty self-feeding or may permanently lose swallowing ability placing them at risk of chest infections/pneumonia.
All these factors lead to risk of malnutrition, affecting recovery and increased risk of mortality.

Case study I: Stroke

Dietary Management of Stroke

Nutritional intervention in stroke patients follows different pathways depending on the individual and stage of recovery. Where there is permanent loss of swallowing, risk of aspiration and consumption of normal food is not possible, medical nutrition is required for life.

Dietary Management with FSMP can include tube feeding, use of texture modified diets, thickened fluids or oral nutritional supplements (ONS), depending on the needs of the individual patient. Specialist dietary advice is required.

The key objective is to ensure adequate intake of fluids and nutrients and prevent malnutrition that can result from both reduced intake and increased protein and calorie needs. Ensuring adequate intake in post-stroke patients can help improve function and mobility and consequently improve rehabilitation.[1]

Case study I: Stroke

Use of FSMP in the Dietary Management of a patient with Dysphagia

Mrs B had a minor stroke.

After an initial recovery period, she developed difficulties in swallowing. As a result, **Mrs B** restricted her intake of fluid and foods as she was fearful of coughing or spilling food and drinks.

Over the next 8 weeks, due to the reduced dietary intake, **Mrs B** lost 10 kg in weight, became weak and had reduced ability to care for herself independently.

The swallowing difficulties had resulted in silent aspiration of food and drink into her lungs. **Mrs B** developed pneumonia and was admitted to hospital.

Case study I: Stroke

Use of FSMP in the Dietary Management of a patient with Dysphagia

In hospital, **Mrs B** was assessed by a multi-disciplinary team where **severe dysphagia** and **malnutrition** were diagnosed.

Mrs B was initially placed nil by mouth and tube fed with a standard FSMP with increased protein content and she also received swallowing rehabilitation to regain at least some swallowing ability.

After 3 days, **Mrs B** had regained some strength and started to gradually take increasing amounts of pre-thickened drinks and pre-thickened foods orally under the supervision of a speech and language therapist. The use of thickening powder and pre-thickened oral nutritional supplements provided reliable and consistent textures and consistencies which was not always possible with pureed foods.

Gradually **Mrs B** was able to take enough thickened fluids, and foods orally so that tube feeding was no longer necessary. She was discharged home to live independently.

Case Study II: Cancer

Cancer is a group of diseases involving uncontrolled cell growth with the potential to spread to other parts of the body.
Cancer is the second most important cause of death and morbidity in Europe, with lung, breast, stomach, liver and colon cancer causing the most cancer deaths each year.[1]

Nutritional Impact

Weight loss is often a symptom in cancer [2,3] due to reduced oral intake, malabsorption of nutrients and metabolic imbalances with loss of muscle mass.[4]
In addition, patients undergoing chemotherapy / radiotherapy often have altered taste, nausea or swallowing problems.
Patients may also experience depression and anxiety.

As a result, disease related **malnutrition** is particularly prevalent in patients with cancer. More than 1 in 3 are malnourished and they run a higher risk of malnutrition - especially those with advanced cancer.
Cancer-related malnutrition affects a patients' physical activity, morbidity, tolerance and response to treatment, survival, length of hospital stay and quality of life (QOL).[5]

Case Study II: Cancer

Dietary Management of Disease Related Malnutrition in Cancer

Nutritional support needs to be considered In all stages of cancer

During treatment, FSMPs help maintain or improve nutritional intake and reduce metabolic dysfunction in order to preserve skeletal muscle mass, physical function, and QOL. They also prevent treatment-related complications and enable patients to complete planned treatment.

Key Nutritional Interventions with FSMP include:

Oral Nutritional Supplements (ONS)

Nutritional intervention with ONS is used to improve protein and energy intake and reduce weight loss in cancer patients, as well as to improve QOL outcomes. Patients undergoing radiotherapy benefit from regular nutrition intervention (dietary counselling with ONS) to improve their dietary intake and nutritional status. Patients with altered taste can benefit from trialling different flavours of ONS or different styles, e.g. pudding-style ONS.

Enteral tube feeding (ETF)

If a patient cannot feed orally, or cannot receive sufficient nutrients orally, because of the cancer (for example narrowing of the oesophagus) then they may be fed enterally via a tube as sole source or supplemental nutrition.

Case Study II: Cancer

Use of FSMP in a patient with Disease Related Malnutrition

Mrs C is 65 years old and has been a smoker for 40 yrs. Over recent months, Mrs C has lost 15 kg and has a persistent cough and general fatigue. After investigation at her medical centre a small cell lung cancer was diagnosed.

Treatment with radiotherapy and chemotherapy was started immediately , Mrs C also received dietary counselling and was prescribed a standard ONS twice daily.
After 2 weeks, Mrs C returned with mouth sores, nausea and had lost an additional 3 kg.
Her status caused her to miss 2 treatment days for radiotherapy and her compliance with ONS and dietary counselling was low. She was advised to consume a high calorie, high protein diet.

After a further 2 weeks, Mrs C returned with a fever. She was hospitalised and treated for pneumonia. The doctor recommended counselling for her dietary intake and to take a high protein high calorie ONS twice a day with close monitoring.

Mrs C was discharged from hospital 10 days later with improved nutritional status and recovered from pneumonia. Although her cancer treatment was interrupted due to hospitalisation, she completed further treatment without interruption.

More than 1 month after discharge, Mrs C continues to comply with the dietary advice she received and is consuming high calorie high protein food as well as drinking the prescribed ONS. She is no longer losing weight, her mouth sores have partially healed and her feeling of fatigue has improved.

Case study III: Drug-resistant Epilepsy

Epilepsy is a chronic disorder of the brain. It is the most prevalent neurological disorder beside migraine, and affects around 6 million people in Europe.[1]
Seizures may involve part of the body (partial) or the entire body (generalised) and may vary in duration and intensity from the briefest lapses of attention (absence seizures) or muscle jerks, to severe and prolonged convulsions. They can vary in frequency from less than one per year to several hundred per day.
While pharmacological treatment is successful for many, an estimated 20-30% of patients develop medically refractory epilepsy, which is a failure to respond to two or more anti-epileptic drugs (AED's).

Dietary Management of Drug Resistant Epilepsy

Some severely neurologically damaged patients with intractable epilepsy - usually as a result of genetic syndromes - may require tube feeding due to poor swallow or other feeding difficulties.
Other patients may respond to the use of a ketogenic diet (KD), which is very high in fat and very low in carbohydrate (75-90% of energy as fat/ 4-20 % as CHO) and can be a highly efficacious alternative management, especially in children.[2]

Case Study III: Epilepsy

Use of FSMP in a patient on a ketogenic diet (KD)

Patient A has a rare genetic neurodegenerative disorder resulting in early onset epilepsy at 6 months of age, initially responsive to medication.

At the age of 4 years her development was severely delayed and the severity and frequency of seizures worsened and became resistant to multiple anti-epileptic drug therapies (AEDs). Side effects of medication included drowsiness and irritability.

KD commenced with a nutritionally complete FSMP via a feeding tube. Within a few days the seizures reduced from 20 per day to 10 per day, with some seizure-free days.

Over the following year on KD she was weaned off AEDs. This and the reduced severity and frequency of seizures lead to more alertness, the ability to crawl and improved quality of life for both **patient A** and her parents.

Case Study IV: Maple Syrup Urine Disease

Maple Syrup Urine Disease (MSUD) is an inborn error of metabolism (IEM) - a disease caused by a genetic mutation - which results in the incorrect synthesis of an enzyme required to breakdown specific amino acids in the body.

Without treatment, IEMs such as MSUD, frequently result in the accumulation of toxic substances and subsequent organ damage. The brain, liver and kidneys are the most frequently affected organs. The most common and severe form is classical MSUD, where symptoms start soon after birth. It can lead quickly to coma and death if not treated early. [1]

IEMs are individually rare, but collectively numerous. The incidence of MSUD is 1:185.000 new-borns worldwide, but it occurs in some communities much more frequently.[2]

Dietary Management and Nutritional Impact of MSUD

In MSUD, optimal dietary management involves closely monitoring biochemical and clinical status, ensuring optimal growth by providing adequate nutrients, while restricting intake of branched chain amino acids that naturally occur in foods.

Key elements of dietary management are the use of an amino acid-based FSMP as a protein substitute and a protein restricted diet. In MSUD there is a risk of metabolic decompensation during trauma, illness, dietary non-compliance or surgery, which can escalate quickly leading to coma or death. These situations require aggressive nutrition management.[3]

MSUD, like most amino acid disorders, will require lifelong dietary management.

Case Study IV: Maple Syrup Urine Disease

Use of an FSMP in dietary management of a patient with MSUD

Baby Nina was born after a normal pregnancy and delivery. At 2 weeks after birth, Nina started to refuse breast milk and appeared drowsy.

Nina's parents were increasingly worried and took her to the emergency department where she already appeared comatose. She was admitted to ICU and subsequently diagnosed with MSUD

Treatment was started immediately following diagnosis, to prevent further deterioration. Nina was fed an infant amino acid based FSMP low in branched chain amino acids and small amounts of breast milk.

Nina improved in the following days once dietary management started

Case Study IV: Maple Syrup Urine Disease

Use of an FSMP in dietary management of a patient with MSUD

Baby Nina will need to be compliant with a specific diet for the rest of her life. This diet will involve severe restriction to intake of natural protein combined with an FSMP containing essential amino acids, but excluding those amino acids whose breakdown is blocked in MSUD A diet so highly restricted in protein, will not provide the recommended intake of other essential nutrients such as long chain fatty acids, vitamins, minerals and trace elements. Hence these will also need to be supplied by the FSMP.

The restriction of natural protein in the MSUD diet means that high protein products - such as milk, eggs, meat and chicken - will be excluded from the diet. Other cereal-based foods will be highly restricted for Nina.

Baby Nina's main nutritional needs - both amino acid-based protein substitute, and specially processed low protein foods , such as low protein bread, cookies, pasta and rice - will be provided by FSMPs.

Case study V: Cow's Milk Allergy

Cows Milk Allergy (CMA) is an adverse reaction to cow's milk proteins which can result in immediate or delayed symptoms. Typically, CMA results in skin (e.g. urticaria, atopic eczema), respiratory (e.g. runny nose, wheezing and chronic coughing), and/or gastrointestinal symptoms (e.g. vomiting, diarrhoea, regurgitation, colic). In some cases, anaphylaxis - a life threatening reaction to the ingestion of cow's milk protein – may occur.[1]

CMA is the leading cause of food allergy in infants and young children[2], affecting 2 to 5% of infants worldwide.[3]

Nutritional Impact of CMA

Without treatment, allergic symptoms continue and the ongoing inflammation can lead to faltering growth and nutritional deficiencies.[4] Feeding difficulties - such as delayed weaning, fussy or restricted eating - have also been reported as higher in children with food allergies than in the general population, and these may further impact nutrient intake.[5]

Dietary Management of CMA

Infants with CMA are managed by the exclusion of cows milk protein. When breast feeding is not possible an infant may be initiated on a specially formulated infant FSMP based on extensively hydrolysed proteins or amino acids, under the supervision of a Health Care Professional. The specialised infant FSMP provides their energy, protein and micronutrients needed to support growth. Approximately 90% of infants can be managed with extensively hydrolysed infant FSMP and around 10% require amino acid based infant FSMP.

Case study V: Cow's Milk Allergy (CMA)

Use of an FSMP in the Dietary Management of CMA

Baby L was exclusively breastfed from birth. Mum described breastfeeding as a struggle with feeds taking up to 1 ½ hours, episodes of discomfort during feeding, and the baby's body was covered with severe eczema.

At a regular 3 month old health check-up it was noticed that **Baby L**'s weight had dropped more than 2 centile lines (1 SD) over 1 month. The mother was encouraged to continue breastfeeding but to follow a strict cow's milk elimination diet for 4 weeks as allergy to cows milk protein was suspected and **Baby L** was referred to a specialist Allergy Clinic.

The Allergy Clinic noted that although **Baby L** was doing better with now only mild eczema on his body – he still had continued discomfort after feeding and a disrupted sleeping pattern due to scratching. His weight had only increased slightly from the previous appointment and his length and head circumference were also not following his expected pattern.
At this appointment mum expressed her wish to stop breastfeeding, as she felt exhausted.
Baby L was therefore started on an amino acid-based formula (AAF).

A follow-up appointment 6 weeks later indicated significant improvement of skin symptoms and he was also starting to show significant catch-up growth, with up to 5-10g/kg/day weight gain, placing him back on the 50th centile for growth.

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