Why Labelling Matters

The specialist nature of labelling of foods for special medical purposes


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Clear, accurate and informative labelling of food is essential to achieve a high level of consumer protection. The name of the food, ingredient list, allergen information, nutrition declaration, storage and preparation instructions, date labelling and net quantity all serve to ensure consumers can make informed decisions about the food they consume. However, the labels of foods for special medical purposes (FSMPs) are unique in that the label is intended for the patients but also for a range of healthcare professionals (HCPs) involved in the provision of optimal nutritional care across healthcare settings. Information is usually provided by means of HCP data cards, as well as physically on the package, ensuring that all healthcare workers have easy access to clear information. This is to support the selection of the right product for the right patient every time, whether at the recommendation or prescribing stage by a dietitian, nurse or GP, or at the point of delivery where a product is selected from a store or fridge by a nurse or a care assistant. This article builds on a previous article,[1] which explored the regulation and reimbursement of FSMPs and draws on the principles of differentiation between FSMPs and other categories of food,[2] with specific reference to labelling and why this matters in clinical practice.

Legal definition of foods and applicable food laws

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 are designed for 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 HCPs. FSMPs include specially formulated enteral tube feeds and oral nutritional supplements for the dietary management of disease-related malnutrition, as well as disease-specific products such as those intended for inborn errors of metabolism, renal disease and intractable epilepsy. They are all very different and distinct from general foods. General food also includes fortified foods and food supplements which are intended to meet the nutritional needs of the general healthy population or sub-groups of the general healthy population (**Table 1**).

Specific labelling rules and responsibilities for FSMPs

Figure 1 illustrates how general food law is applicable for all foods including fortified food, food supplements and FSMPs. However, for FSMPs there is additional category specific law. Regulation (EU) No 609/2013 on Foods for Specific Groups sets the framework for the regulation of products for individuals with specific nutritional needs. The Annex to this regulation contains a list of permitted nutritional substances that may be used in FSMPs to provide vitamins, minerals, amino acids, carnitine, taurine, nucleotides, choline and inositol. Regulation (EU) No 2016/128 on FSMPs sets composition, labelling and notification requirements. 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.

Food business operators are responsible for the correct positioning and labelling of a product as a FSMPs and must notify the Department of Health and Social Care (DHSC) Nutrition Legislation Team (NLT) when placing a FSMPs on the market, whereby the NLT acknowledges the notification. The DHSC works with other government agencies, such as the Food Standards Agency (FSA) and Department for Environment Food & Rural Affairs (DEFRA), on nutrition related labelling, composition and standards. Local authorities are responsible for enforcement of food labelling rules including those on FSMPs. The Advisory Committee on Borderline Substances (ACBS) is responsible for advising on the prescribing and use of borderline substances in NHS primary care and the community and may, during review of applications, express preferences on the information displayed on labels of FSMPs.

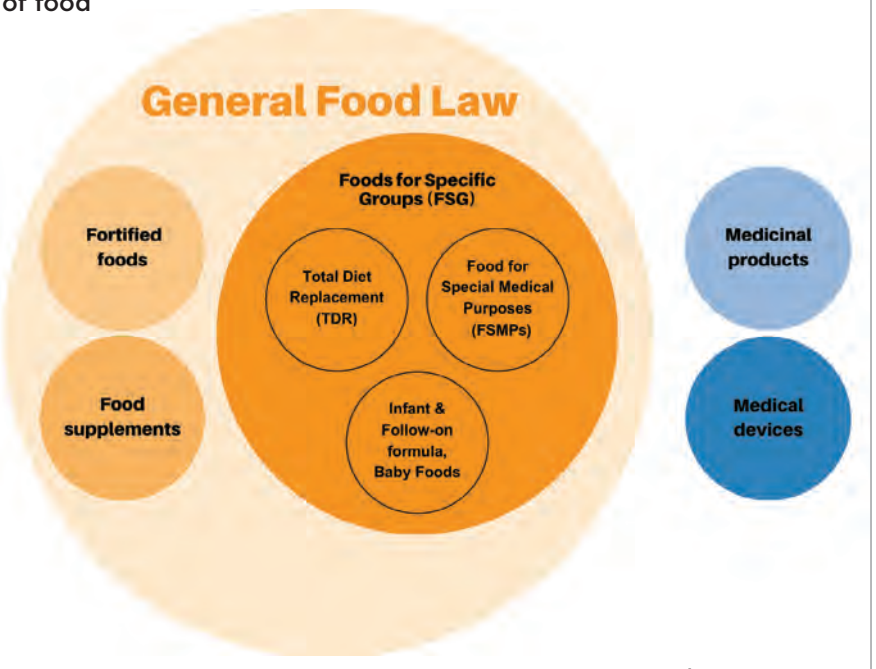
Labelling of FSMPs has some key differences from other foods. **Table 2** summarises how the key features of FSMPs labelling support HCPs and patients in the safe and appropriate use of FSMPs in clinical practice. Healthcare workers must be able to identify the right product easily and accurately for the right patient every time.

Prominent indication of key properties and characteristics of the product (for example protein and energy) is essential to avoid potential errors and ensure patient safety. Inclusion of key features such as 'Fibre' or 'Complete' in product names helps avoid confusion and saves HCPs having to spend time establishing for themselves whether a product contains fibre or has a nutritionally complete profile.

Summary

The regulation of food labelling is designed to protect consumers. FSMPs are highly regulated products to ensure that their composition and labelling meets the specific needs of the patients for whom they are intended. All stakeholders involved in the provision, regulation or enforcement of labelling for FSMPs have an important part to play in ensuring the food information supports patients' needs and enables the appropriate and safe use of FSMPs by all healthcare workers involved in the delivery of optimal nutritional care across healthcare settings.

Figure 1: The framework of food law applicable to different categories of food



Source: Adapted from Medical Nutrition International Industry Regulatory Affairs Working Group (2022)[2]

Table 1: Brief overview of the legal definition of foods (see references for full definition in each category)

General food *Intended for the general healthy population or sub-groups of the general healthy population*			Food for special medical purposes (FSMPs)[6, 7] *Intended for patients with a disease, disorder or medical condition*
Food:[3]	**Fortified food:**[4]	**Food supplements:**[5]	
"'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."	"Food with added vitamins and/or minerals and/or certain other substances. 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."	"Food supplement 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."	"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."

Source: Adapted from Medical Nutrition International Industry Regulatory Affairs Working Group (2022).[2]

About the British Specialist Nutrition Association

BSNA is the trade association representing the manufacturers of products designed to meet the particular nutritional needs of individuals; these include specialist products for infants and young children (including infant formula, follow-on formula, young child formula and complementary weaning foods), medical nutrition products for diseases, disorders and medical conditions, including oral nutritional supplements, enteral tube feeding and parenteral nutrition, as well as companies who aseptically compound chemotherapy, parenteral nutrition and CIVAS.

References: 1. Bushell C, Birt R. (2022). Foods for Special Medical Purposes, from Regulation to Reimbursement.; CN: 22(5): 42-44. 2. Medical Nutrition International Industry Regulatory Affairs Working Group (2022). Statement of principles: Differentiation between Food for Special Medical Purposes (FSMPs) and general food within the scope of EU regulations. Accessed online: www.medicalnutritionindustry.com/files/user_upload/intranet/FSMP/MNI_statement_FSMPs-vs-GeneralFoods_Final.pdf (Mar 2023). 3. Legislation Gov UK (2002). Retained Regulation (EC) No 178/2002 of the European Parliament and of the Council 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. Accessed online: www.legislation.gov.uk/eur/2002/178/contents# (Mar 2023). 4. Legislation Gov UK (2006). Retained Regulation (EC) No 1925/2006 of the European Parliament and of the Council on the addition of vitamins and minerals and of certain other substances to foods. Accessed online: www.legislation.gov.uk/eur/2006/1925/contents# (Mar 2023). 5. Legislation Gov UK (2002). Directive 2002/46/EC of the European Parliament and of the Council on the approximation of the laws of the Member States relating to food supplements. Accessed online: www.legislation.gov.uk/eudr/2002/46/contents (Mar 2023). 6. Legislation Gov UK (2013). Retained Regulation (EU) No. 609/2013 of the European Parliament and of the Council on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control. Accessed online: www.legislation.gov.uk/eur/2013/609/contents# (Mar 2023). 7. Legislation Gov UK (2016). Retained Commission Delegated Regulation (EU) 2016/128 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. Accessed online: www.legislation.gov.uk/eur/2016/128/contents# (Mar 2023). 8. Legislation Gov UK (2013). Retained Regulation (EU) No 1169/2011 of the European Parliament and of the Council on the provision of food information to consumers. Accessed online: www.legislation.gov.uk/eur/2011/1169/contents# (Mar 2023). 9. Legislation Gov UK (2006). Retained Regulation (EC) No 1924/2006 of the European parliament and of the Council on nutrition and health claims made on foods. Accessed online: www.legislation.gov.uk/eur/2006/1924/contents# (Mar 2023).

Table 2 on next page

Table 2: Comparison of regulatory labelling requirements between general food and FSMPs

	Foods for special medical purposes (FSMPs)*	General food/Fortified foods/ Food supplements*	Why specific FSMPs labelling matters in clinical practice
Legal name	'Food for special medical purposes' must appear on the label as outlined in Annex IV of Regulation (EU) No 2016/128[7] on FSMPs.	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.	Clearly distinguishes FSMPs from a general food, fortified food or food supplement.
Dietary management statement	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, or specific approved nutrition and health claims).	Clearly identifies that the food is intended for patients with a disease, disorder or medical condition and is not intended for the general healthy population. Identifies the specific target population for which the product is intended.
Description of properties and characteristics	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. Such information should not be considered as nutrition and health claims within the meaning of Regulation (EC) No 1924/2006.[7]	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 and health claims cannot be made for FSMPs. Recital 17 Regulation (EU) No 2016/128[7] 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"*. The properties and characteristics of FSMPs and rationale for use are related to the disease, disorder or medical condition for which the product is intended. As such, the nutrient levels are adjusted to meet those needs and different nutritional criteria may be applied. It is vital to note that nutrition (nutrient content) claims are declared on a voluntary basis on general foods and the conditions of use are based on a general healthy population. However, properties and characteristics are a mandatory labelling requirement for FSMPs and describe the nutrient content in relation to their intended use in a disease, disorder or medical condition. The common and established practice of displaying statements regarding the properties and characteristics on FSMPs product labels has a clear benefit to HCPs. They present an immediately accessible view of key criteria which are useful in determining the appropriate product for a patient. In addition, patients have the reassurance that the product that they are taking is in line with the therapeutic dietary intervention prescribed by their HCP.
Use under 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.	Alerts HCPs and patients as to the need for medical supervision for the safe and appropriate use of the product.
Nutrition labelling Expression in % of daily reference intake	Mandatory declaration of the amount of each mineral substance and of each vitamin listed in Annex I of Regulation (EU) No 2016/128 on FSMPs.[7] Not allowed Consumers of FSMPs have different nutritional needs to the general healthy population. The expression of nutrition information on the energy value and the amount of nutrients of FSMPs as a percentage of daily reference intake values set out in Regulation (EU) No 1169/2011[8] would mislead consumers and should therefore not be required as it would be for general/fortified food (recital 16).	The declaration of vitamins and minerals is voluntary unless a claim is made. Specific rules apply for food supplements labelling. Mandatory if vitamins and minerals declaration is provided. When provided, the declaration on vitamins and minerals shall also 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[8] on the provision of food information to consumers] in relation to per 100 g or per 100 ml.	Detailed nutritional information is essential on labels and HCP data cards to assist with appropriate product selection to support meeting specific patient needs. This declaration of the nutrient content per 100 g/100 ml or per portion ensures that information on the label is appropriate to calculate the specific nutritional intake needs of patients for whom the FSMPs product is intended.
Sole source of nutrition	A statement whether the product is suitable for use as the sole source of nourishment. Only infant formula, total diet replacement or FSMPs specifically designed for that purpose can use such a statement.	Not allowed	All of these statements are mandatory on FSMPs and are essential for the safe and appropriate use of the product.
Age group	A statement that the product is intended for a specific age group, as appropriate.	Not required	
Precautions	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.	
Nutrition and health claims	Not allowed Information must be provided on the properties and characteristics (see section above 'Description of properties and characteristics'). Such information should not be considered as nutrition and health claims within the meaning of Regulation (EC) No 1924/2006.[7]	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[9] on nutrition and health claims made on foods. These foods cannot suggest or imply that the product can be used for the dietary management of patients, including infants.	It is not permitted to use nutrition and health claims on FSMPs as it could be considered misleading to the patient because the conditions of use of nutrient content claims are based on content in general food in relation to health of the general population. Conversely, the rationale for use and properties and characteristics of FSMPs are related to the disease, disorder or medical condition for which the product is intended (see section above 'Description of properties and characteristics'). Although descriptions of nutritional content in FSMPs (properties and characteristics) can be very similar in wording to nutrient content claims, they are not related to general health and therefore different criteria apply depending on the intended target patient population.

Source: Adapted from Medical Nutrition International Industry Regulatory Affairs Working Group (2022).[2]
*See Table 1 for legal definitions.