

Contents lists available at [ScienceDirect](http://www.sciencedirect.com)

Clinical Nutrition ESPEN

journal homepage: <http://www.clinicalnutritionespen.com>

Original article

Proposal for a new practicable categorization system for food for special medical purposes – Enteral nutritional products



Dietmar Stippler^{a,*}, Volker Bode^b, Magnus Fischer^c, Katrin Kollex^d, Evelyn Rohde^e, Berta Tisowsky^f, Jana Künstner^g, Norbert Pahne^h

^a Nutricia GmbH Erlangen, Allee am Roethelheimpark 11, D-91052 Erlangen, Germany

^b Nestlé HealthCare Nutrition GmbH, Lyoner Strasse 23, D-60528 Frankfurt am Main, Germany

^c Fresenius Kabi Deutschland GmbH, Else-Kröner-Str. 1, D-61352 Bad Homburg, Germany

^d GHD Gesundheits GmbH Deutschland, Fritz-Reuter-Str. 2, D-22926 Ahrensburg, Germany

^e Assist GmbH, In der Bruchwies 10, D-66663 Merzig, Germany

^f Nutricia GmbH, Bahnstr. 14-30, D-61381 Friedrichsdorf, Germany

^g BVMed – German Medical Technology Association, Reinhardtstr. 29 b, D-10117 Berlin, Germany

^h Diätverband e.V. – Federal Association of Producers of Food for Special Dietary Purposes, Godesberger Allee 142-148, D-53175 Bonn, Germany

ARTICLE INFO

Article history:

Received 8 December 2014

Accepted 31 July 2015

Keywords:

Product categorization

Enteral nutrition

Mixtures of amino acids

Tube feeding

Sip feeding

Food for special medical purposes

SUMMARY

Background & aims: Changes in the EU regulation on food for specific groups (FSG) [1] and within the German social law [2] combined with various definitions in the legal and the scientific background led to the need for development of a categorization system for “Food for special medical purposes” (FSMP) for enteral use [3].

Methods: The system was developed by an interdisciplinary working group of two German industry associations, which represent the leading manufacturers and distributors of FSMP in Europe. It aims to minimize the misunderstandings surrounding the different definitions used in relation to enteral nutritional products and incorporate the latest scientific knowledge and medical guidelines [4].

Results: The new proposal consists of a table which shows the product categories and briefly the definitions of the used terms. The text contains the relevant definitions of terms often used within the field of enteral nutrition.

Conclusion: This provides health care professionals with support and the decision making process for the prescription and use of such products. Additionally it also benefits the responsible authorities to formulate new directives, which are user-friendly and reflect the latest knowledge in medical nutrition.

© 2015 The Authors. Published by Elsevier Ltd. on behalf of European Society for Clinical Nutrition and Metabolism. This is an open access article under the CC BY-NC-ND license (<http://creativecommons.org/licenses/by-nc-nd/4.0/>).

1. Introduction

In international publications on enteral nutrition, terms such as “oral nutritional supplements (ONS)”/“sip-feeding” or “tube-feeding” are used to describe the different routes of administration [5,6]. The variation of such terms may lead to different interpretations. Thus for more precise legal and regulatory [7,8] purposes a more clear classification is needed for these products.

The demand for such a classification was initiated by discussions between the industry associations and the regulatory bodies with the overall intention to ensure it is easy to interpret and be transferable into practice.

The German industry associations which represent the manufacturers and distributors of FSMP for enteral nutrition took on-board this responsibility and developed a proposal of a new categorization system. It reflects legal and regulatory requirements [1,2], scientific and medical guidelines [4] and routes of administration of enteral nutrition. The system was introduced to the German Society of medical nutrition and it was published in Germany in 2011 [3]. At the ESPEN congress 2013 the system was presented to an international audience.

* Corresponding author.

E-mail addresses: dietmar.stippler@nutricia.com, di.stippler@nefkom.net (D. Stippler).

2. Material and methods

The two German industrial associations Federal Association of Producers of Food for Special Dietary Purposes (“Verband der Hersteller von Lebensmitteln für besondere Ernährung = Diätverband”)¹ and German Medical Technology Association (“Bundesverband Medizintechnologie = BVMed”)² established an interdisciplinary working group to develop a new categorization system. The group consisted of medical, scientific, legal and regulatory specialists. After several meetings the system was finalized and agreed in a consensus meeting.

This system consists of a table for a quick but detailed overview of the different categories of enteral products supplemented by a brief definition of each category. The intended dietary use of the specific products is also included.

Finally an abbreviation table is included detailing all the common terms used in the area of enteral nutritional therapy. Such terms are commonly used but rarely defined, are precisely specified in this document, incorporating the technical, legal and regulatory requirements. This allows products to be easily identified and classified (Table 1).

2.1. Goals of medical, enteral nutrition

The need and the benefit of enteral nutrition is widely accepted [9,10]. Enteral nutrition may be used as a replacement of normal nutrition if this is not feasible (caused by e.g. swallowing disorders, persistent vegetative state). Alternatively, it can be used to supplement normal nutrition if this is not sufficient enough (e.g. disease related weight loss and/or malnutrition, cachexia, metabolic disorders).

The aim of enteral nutrition is either to improve or to sustain the nutritional status of the patient.

The composition of any FSMP product for enteral nutrition is based on international and national legal and regulatory codes [8,11,12,13] and can be adapted to defined diseases or disorders. For such diseases the proportion of macronutrients and special ingredients has to be adopted (e.g. MCT fats for patients suffering from digestion disorders for fatty acids, special micronutrient composition for patients suffering from renal insufficiency).

Special enteral nutrition products are dedicated to the dietary management of rare inborn or pediatric metabolic diseases. These diseases/illnesses lead to severe mental and/or physical disturbances without dietary treatment. Treatment with adequate products is a mandatory part of medical intervention.

In few cases enteral nutrition is used beyond the dietary management for the treatment of the underlying disease. An example is, the use of enteral nutrition in pediatric patients suffering from Crohn's disease. In this specific case, enteral nutrition is recommended as the first line therapy to induce remission [14,17].

2.2. Definitions

For a better understanding the following explanations and definitions of relevant terms are used with FSMP for enteral nutrition.

2.2.1. Balanced diets for enteral nutrition

Balanced diets for enteral nutrition are food for special medical purposes, complying with the legal definition and requirements for

FSMP products [8,11]. They must comply with the current European and national legislation. This includes that the composition of macro- and micronutrients reflects their intended dietetic use.

These products consist of proteins/peptides/amino acids, carbohydrates and/or fats, minerals, trace elements and vitamins. The contents of micronutrients (minerals, trace elements and vitamins) are defined by EU directives [18, pp. 5–8], which clearly claim the minimum and maximum content of these micronutrients for fully balanced products. For products which are not fully balanced, only the maximum contents are defined. These specific requirements are the same all over the EU and so the same products can be used in all these countries.

The composition of macronutrients is not strictly defined. But a product intended to be fully balanced and as a sole source of nutrition must provide at least an adequate amount of essential macronutrients (proteins/peptides/amino acids, essential fatty acids) to meet patient needs. This leads to a composition of approx. 8–30 percent of energy by proteins, approx. 25–40 percent of energy by fat and approx. 30–65 percent of energy by carbohydrates (including fibers).

The products can be used for complete (2.1.1) or supplementary (2.1.2) nutrition and are either balanced completely (2.1.3) or supplementary (2.1.4).

They are intended for a therapeutic dietary treatment (2.2) for patients suffering from

- a limited or disturbed or missing ability of ingesting, digesting, metabolizing or segregating of normal food

OR

- other medically based nutritional needs for a dietary treatment which exceeds modification of normal nutrition or other dietary food or a combination of both.

The intention of balanced diets for enteral nutrition is not to show pharmaceutical effects as occur with pharmaceutical products. They are also not food supplements and their content reflects the state of the scientific and technical knowledge and these are formulated for patients.

2.2.1.1. Products for complete nutrition. A product which is appropriate for complete nutrition needs to be fully balanced. This means the composition of such a product contains all macro- and micronutrients that are needed to cover the nutritional needs and is suitable to be used as a sole source of nourishment.

2.2.1.2. Products for supplementary nutrition. A balanced diet for supplementary use is intended to be used in combination with other foods and/or forms of nutrition (e.g. normal nutrition or parenteral nutrition). Therefore fully balanced as well as incomplete balanced products can be used [18]. They contain relevant amounts of macro- and micronutrients, which are appropriate for the supplementary nutritional intervention.

2.2.1.3. Completely (fully) balanced diets (nutritionally complete). A completely (fully) balanced diet is a product which fulfills the requirements of the EU directive for all nutrients mentioned there [18]. If used according to the recommendations of the manufacturer it can be the sole source of nutrition for the intended patients.

2.2.1.4. Supplementary balanced diets (nutritionally incomplete). A supplementary balanced diet is a dietary product which is not intended for use as a sole source of nutrition according to the EU directive.

¹ Industry association which represents the manufacturers of special nutrition located in Bonn.

² Industry association which represents the manufacturers and distributors of medical devices located in Berlin.

Table 1
Product categories for enteral nutrition – overview of their new categorization.

BALANCED DIETS FOR ENTERAL NUTRITION							
<p>Definition: All these products are food for special medical purposes for the complete or supplementary nutritional therapy of patients</p> <ul style="list-style-type: none"> - suffering from a missing or disturbed or limited ability of ingesting, digesting, metabolizing or segregating of normal food, - other medically based nutritional needs for a dietary treatment which exceeds modification of normal nutrition or other dietary food or a combination of both. <p>Intention: These products are dedicated</p> <ul style="list-style-type: none"> - to be a replacement or completion of normal nutrition, - for preservation or improvement of the nutritional status of patients (= nutritional therapy), - for the dietary management of a rare inborn respectively pediatric metabolic disease, - in exceptional cases for the direct dietary treatment of the underlying disease (e.g. Crohn's disease) <p>Product characteristics: Products for nutritional therapy</p> <ul style="list-style-type: none"> - comply with the legal requirements for food for special medical purposes (balanced diets) and their content and composition reflect the state of the current scientific and technological art, - show no pharmacological effects comparable to pharmaceutical products, - are no food supplements according to the legislation of this product category, - consist of proteins/peptides/amino acids, carbohydrates and/or fats, minerals, trace elements and vitamins. 							
Oral Balanced Diets for enteral use				TUBE FEEDINGS (TF)			
MIXTURES OF AMINO ACIDS AND OTHER DISEASE-SPECIFIC PRODUCTS FOR RARE INBORN OR PEDIATRIC METABOLIC DISEASES		SIP FEEDINGS – ORAL NUTRITIONAL SUPPLEMENTS (ONS) POWDERS FOR PRODUCTION OF ONS - LIQUIDS OF HIGHER VISCOSITY					
Special characteristics:		- are supplementary or fully balanced, - are dedicated for complete or supplementary nutrition, - don't have to be a sole source of nutrition (but may be).		- are fully balanced, - are dedicated for a complete nutrition, - must be a sole source of nutrition via a tube.			
MIXTURES OF AMINO ACIDS	DISEASE SPECIFIC MODIFIED	STANDARD ¹	SPECIAL ¹		STANDARD ¹	SPECIAL ¹	
			SPECIAL A ¹	SPECIAL B ¹		SPECIAL A ¹	SPECIAL B ¹
For the treatment of phenylketonuria (PKU) and further rare inborn diseases of the protein metabolism. Consist mainly from defined (by quality and quantity) mixtures of amino acids. Are mostly not intended to be a sole source of nutrition. Dependent on the intended medical use - they have to contain the (legally) requested minerals, vitamins, trace elements and - can contain fats and carbohydrates and other ingredients (e.g. food additives, flavoring)	For the treatment of rare inborn diseases in the carbohydrate, fat or energy metabolism (e.g. mitochondrial diseases), cystic fibrosis, epilepsy and further diseases where dietary management is a mandatory part of medical intervention. Product categories: - carbohydrate modified - fat modified - protein-modified - for the treatment of cystic fibrosis - for the treatment of rare inborn metabolic diseases and epilepsy with a ketogenic diet - further nutritionally modified specialized nutrition	see chapter 2.5.1. The composition of standard products is dedicated to patients suffering from a missing or limited ability for a normal nutrition. They are intended for a normal metabolism of adult patients. Such an enteral standard product can be administered all patients who are not suffering from diseases which need to be treated with special adopted products (Special A and B)	see chapter 2.5.2. Special A products show a composition especially dedicated and adopted for the dietary management of patients suffering from a missing or limited ability for a normal nutrition with an additional metabolic demand (e.g. malabsorption). <u>Examples:</u> Products adopted especially for babies and toddlers Products adopted for renal insufficiency Products containing extensively hydrolyzed proteins or mixtures of amino acids for babies or toddlers suffering from cow's milks allergy or patients suffering from multiple food allergies Products containing hydrolyzed fats or carbohydrates or are especially enriched with middle chained triglycerides for patients suffering from disturbances of the fat metabolism or from malabsorption syndrome (e.g. short bowel syndrome)	see chapter 2.5.2. Special B products are additionally to Special A products intended for a direct dietary treatment of the underlying disease (e.g. Crohn's disease). The metabolic demand is based in the nature of the underlying disease. This results in a specific nutritional profile of the products and specific requests for the ingredients.	see chapter 2.5.1. explanation under „Sip feeding – Standard“	see chapter 2.5.2. explanation under „Sip feeding – Special A“	see chapter 2.5.2. explanation under „sip feeding – Special B“

¹As well as beneath the main categories "Sip feeding" and "Tube feeding" you will find the same subcategories in this table. This is due to the same demands on both of the main categories.

This definition also covers products which contain single nutrients in a higher concentration and which are therefore not appropriate to be a sole source of nutrition.

2.2.2. Enteral nutritional therapy

A nutritional therapy is an intervention which is intended to improve or at least to sustain the nutritional status. Alternatively it is used for the dietary treatment of a disease which requires a dietary intervention to protect the patients suffering from this disease, from complications or exacerbations.

Enteral nutrition is needed if patients suffer from a limited or missing ability to meet their nutritional needs with normal or modified or fortified food and if medical or nursing or other nutritional support like counseling or food fortification is not

sufficient to improve or sustain the situation of the patient. Official and evaluated scientific and/or medical guidelines can help to identify these patients.

Enteral nutrition and nutritional counseling as well as food fortification can be used together to complement the nutritional composition of the patient's diet.

Before starting the therapy and whilst treating a patient the nutritional status of the patient should be evaluated by adequate methods. Therefore scientifically tested and evaluated tools like Mini Nutritional Assessment (MNA[®]), Subjective Global Assessment (SGA), Malnutrition Universal Screening Tool (MUST) or Nutritional Risk Screening (NRS 2002) can be used. For pediatric patients (children) percentile curves should be used. In Europe the European society for clinical nutrition and metabolism (ESPEN)

recommends for hospitalized adult patients the use of the validated NRS 2002 and for outpatients the MUST [15].

For patients suffering from rare inborn metabolic diseases, which left untreated may develop into severe mental or physical disturbances, a specially adopted nutritional therapy is essential. For these patient groups the above mentioned malnutrition assessment tools are not required.

2.2.3. Oral balanced diets

Oral balanced diets are food for special medical purposes according to the EU directive intended for oral use. They are not necessarily the sole source of nutrition. Oral balanced diets cover mixtures of amino acids, further products especially adopted for rare inborn respectively pediatric metabolic diseases, sip feedings, powders for making sip feedings and liquids of higher viscosity.

2.2.3.1. Mixtures of amino acids and further products especially adopted for rare inborn respectively pediatric metabolic diseases. Mixtures of amino acids are foods for special medical purposes for the dietary treatment of phenylketonuria (PKU) and other rare inborn defects of the protein metabolism.

Further products especially formulated for rare inborn or pediatric metabolic diseases are food for special medical purposes especially formulated and modified for rare inborn defects of the carbohydrate or lipid or energy metabolism (e.g. mitochondrial diseases), cystic fibrosis, epilepsy and further diseases where dietary management is a mandatory part of medical intervention.

2.2.3.2. Sip feedings, powders for making sip feedings and liquids of higher viscosity. These products are food for special medical purposes of different viscosity or powders (to produce the required viscosity). They can be completely or supplementary balanced diets. They are intended for oral ingestion and are used within a nutritional therapy under medical supervision.

2.2.4. Tube feedings

Tube feedings are fully balanced food for special medical purposes. They are intended to be given as a sole source of nutrition via a tube. Tube feedings are liquids or powders to prepare liquid nutrition.

2.2.5. Subcategories for sip – and tube feedings

2.2.5.1. Standard products. The composition of standard products is dedicated to patients suffering from a missing or limited ability for a normal nutrition. They are intended for a normal metabolism of adult patients. Standard products can be used for most of the patients, who require tube or sip feeds.

Such an enteral standard product can be administered to all patients who are not suffering from diseases which need to be treated with special adopted products. One example for such a disease is renal insufficiency.

2.2.5.2. Special products. Special products are especially formulated and adopted for the dietary management of patients suffering from a missing or limited ability for normal nutrition with an additional metabolic demand (e.g. malabsorption). This subgroup is called **Special A**. Furthermore there are some special products which are intended for a direct dietary treatment of the underlying disease (e.g. Crohn's disease) which are called **Special B**.

The metabolic demand is based on the nature of the underlying disease. This results in a specific nutritional profile of the products and specific requests for the ingredients.

Examples for such adopted nutritional profiles are:

- Products adopted especially for infants and young children.

- Products adopted for renal insufficiency.
- Products containing extensively hydrolyzed proteins or mixtures of amino acids for infants and young children suffering from cow's milk allergy or patients suffering from multiple food allergies.
- Products containing hydrolyzed fats or carbohydrates or which are especially enriched with middle chained triglycerides for patients suffering from proven disturbances of the fat metabolism or from digestion disorders for fatty acids (e.g. short bowel syndrome).

3. Demarcation of food and pharmacological products

Food for special medical purposes currently belongs to the dietary food category. Food is traditionally divided into two categories – food for common use and dietary food. Based on the new regulation on food for specific groups a dietary food category will no longer be existent from 2016 on. Food for special medical purpose will then belong to the category of food for special groups [16].

Dietary food is dedicated to people, who suffer from diseases or disorders with special metabolic and nutritional demands. Dietary food is not a pharmaceutical product but a special food category.

4. Discussion

This categorization system aims to summarize the definitions and demands for FSMP products for enteral use for users. Based on a system developed for Germany, it is intended to start the discussion with other countries, whether such a system is useful to implement either in countries or EU wide. May be it has to be adopted or changed for different countries but it can be a starting point for this process.

5. Summary

The development of this new categorization system for food for special medical purposes for enteral use was driven by two main challenges. Firstly the upcoming changes in the German social law which will affect reimbursement of the products. Further many different and sometimes misleading definitions which are used to describe enteral nutrition in the scientific and legislative context. This new system incorporates the latest published research and guidelines in the area of medical nutrition.

The system was developed by an interdisciplinary working group representing the German industrial associations and it was introduced to the German scientific society. It was discussed within the experts from the scientific field and their feedback was integrated.

This product categorization system consists of a table, which briefly describes the different kinds of products for enteral use and their main composition. Additionally there is an explanation of the currently used terms in the area of enteral nutrition. This system is intended to support medical/health care professionals as well as health insurance companies and other stakeholders.

The system and the categories reflect the practical application of medical nutritional products as well as the current scientific guidelines and the legal requirements. This should enable prescribers of products to easily categorize the products and also payers to carefully identify the rationale for receiving a product, thus enabling products to be used securely and minimize uncertainty associated sometimes with their use. This should enable such products to be used clearly and securely, thereby fulfilling their legal requirements.

Conflicts of interests

All authors either work for companies, which produce or sell medical nutritional products or work for industry associations of such companies.

Contribution of the authors

All authors were active members of the interdisciplinary working group, which developed the described categorization system. They collected the knowledge of their companies and made this available for the working group. They also took care of the acceptance within their organization.

References

- [1] http://ec.europa.eu/food/food/labellingnutrition/medical/index_en.htm.
- [2] German Social Law Book 5; § 31 para 5 (Fünftes Sozialgesetzbuch (SGB V) §31 Abs. 5).
- [3] Stippler D, Bode V. Vorschlag zur praxisorientierten Kategorisierung diätetischer Lebensmittel für besondere medizinische Zwecke. *Aktuel Ernährungsmed* 2011;36:169–73.
- [4] <http://www.awmf.org/leitlinien/aktuelle-leitlinien/II-liste/deutsche-gesellschaft-fuer-ernaehrungsmedizin.html>.
- [5] Lochs H, Allison SP, Meier R, Pirlich M, Kondrup J, Schneider St, et al. „Introductory to the ESPEN guidelines on enteral nutrition: terminology, definitions and general topics. *Clin Nutr* 2006;25:180–6.
- [6] Stratton RJ, Green CJ, Elia M. *Disease-related malnutrition: an evidence based approach to treatment*. Oxon: CABI Publishing; 2003.
- [7] Guideline of the German Federal Joint Committee (Gemeinsamer Bundesausschuss) for reimbursement of pharmaceuticals chapter I §§ 18 – 26.
- [8] German regulation about dietetic food (Diätverordnung) § 4 (Verordnung über diätetische Lebensmittel (Diätverordnung) §4 (zuletzt geändert durch Art. 1 V v. 1.10.2010 I 1306)).
- [9] ESPEN guidelines on enteral nutrition. *Clin Nutr* 2006;25:177–360.
- [10] Deutsche Gesellschaft für Ernährungmedizin e.V. DGEM-Leitlinien enterale Ernährung Kurzfassung. Georg Thieme Verlag KG Stuttgart; 2008, ISBN 978-3-13148091-0.
- [11] Food for special medical purposes Commissions directive 1999/21/EG March 25th. 1999.
- [12] Commission Regulation (EC) No 953/2009.
- [13] <http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32009R0953>.
- [14] Akobeng AK, Thomas AG. Enteral nutrition for maintenance of remission in Crohn's disease. *Cochrane Database Syst Rev* 2007 Jul 18;3:CD005984.
- [15] Kondrup J, Allison SP, Elia M, Vellas B, Plauth M. ESPEN guidelines for nutritional screening 2002. *Clin Nutr* 2003;22:415–21.
- [16] REGULATION (EU) No 609/2013.
- [17] Consensus guidelines of ECCO/ESPGHAN on the medical management of pediatric Crohn's disease. *J Crohn's Colitis* 2014;8:1179–207. <https://www.ecco-ibd.eu/index.php/publications/ecco-guidelines-science/published-ecco-guidelines.html>.
- [18] <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:31999L0021&from=EN>.