New Legal Framework for Food for Special Medical Purposes – Implications on Demarcation and Regulatory Requirements at the European Level and in Germany

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Abbreviations

Art.	Article
BfArM	Bundesinstitut für Arzneimittel und Medizinprodukte (The German Federal Institute for Drugs and Medical Devices)
BGH	Bundesgerichtshof (Federal Court of Justice in Germany in Germany)
BVL	Bundesamt für Verbraucherschutz und Lebensmittelsicherheit (The German Federal Office of Consumer Protection and Food Safety)
BVL/BfArM Paper	Joint Position Paper of BVL/BfArM on the Characterisation of FSMP (Original: 'Positionspapier des BVL und des BfArM zur Charakterisierung von Lebensmitteln für besondere medizinische Zwecke (bilanzierte Diäten)')
COM Notice	Commission Notice on the Classification of Food for Special Medical Purposes
DiätV	Verordnung über diätetische Lebensmittel (German Law on Dietetic Food Products)
Diätverband	Verband der Hersteller von Lebensmitteln für eine besondere Ernährung (German Federal Association of Producers of Food for Special Dietary Purposes)
ECJ	European Court of Justice
EFSA Guidance	Scientific and Technical Guidance on Foods for Special Medical Purposes
EFSA	European Food Safety Authority
EMA	European Medicines Agency
EU	European Union
FBO	Food Business Operator
FIR	Food Information Regulation = Regulation (EU) No 1169/2011
Fn	Footnote
FSG Regulation	Food for Specific Groups Regulation = Regulation (EU) No 609/2013
FSMP	Food for Special Medical Purposes (in German: Lebensmittel für besondere medizinische Zwecke (bilanzierte Diät)); previously also dietary FSMP which equates FSMP
FSMP Regulation	Food for Special Medical Purposes Regulation = Commission Delegated Regulation (EU) 2016/128
GFL	General Food Law = Regulation (EC) No 178/2002
NCA	National Competent Authority
p.	Page
para.	Paragraph
PARNUT	Foodstuffs for Particular Nutritional Uses (in German: diätetische Lebensmittel)
sect.	Section
WHO	World Health Organisation

Summary

Food for special medical purposes (FSMP) is vital for the patients for whom it is intended, in order to guard against disease-related malnutrition and its consequences. As a legal category in the borderline between food for normal consumption and medicinal products, FSMP became a trend in the food and the pharmaceutical industry. However, since the previous legislation covering FSMP resulted in inconsistent application across Member States, it has recently been replaced with a new, harmonised framework law.

This thesis illustrates how Regulation (EU) No 609/2013, supplemented by Delegated Regulation (EU) 2016/128 and relevant guidelines, impacts the demarcation of FSMP and regulatory requirements applicable to it in comparison to previous provisions at EU level and in Germany. The intention of this work is to analyse relevant changes that need to be considered when placing FSMP on the market, and to discuss legal difficulties that frequently arise amongst stakeholders, in particular in terms of correct classification.

The findings reveal that distributors and national competent authorities are still left with much flexibility and legal uncertainty, which indicates that differences in the interpretation of the law are likely to last. However, a newly introduced legal act that involves a centralised evaluation of data through EFSA may contribute to more harmonised decisions on notified products in future. While options to advertise FSMP clearly are further restricted, more concrete details on appropriate compositions or scientific evidence required are not ruled.

The demarcation continues to be difficult in borderline cases since ‘pharmacological activity’ which is to be exclusively reserved for medicinal products has not yet been legally defined. Due to minor changes, an indirect requirement for FSMP dossiers may result as a consequence of the new legal environment, while distributors retain with the responsibility to decide the correct classification and the exact scientific data required, also taking into account ongoing developments of scientific research and court judgments.

1. Introduction

Malnutrition not only is a major health problem in developing countries, it also exists in various forms in Europe. According to the WHO malnutrition refers to *"deficiencies, excesses, or imbalances in a person's intake of energy and/or nutrients"* [1] and besides undernutrition also includes overweight, obesity or micronutrient malnutrition. In Europe, approximately 33 million adults are at risk [2]. While obesity regularly hits the headlines, the awareness that malnutrition occurring due to disease-related factors is another public health concern in European countries remains poor, according to EUFIC[1] [3].

Malnutrition increases the risks of infections, impaired wound healing[2], mortality[3], and further is associated with delayed recovery, longer hospitalisation and higher health care costs[4]. The treatment costs of patients suffering disease-related malnutrition in Europe is estimated as twice as much as those from managing obesity and its consequences[5]. Hence, it is timely to recognise the problem, and to establish preventive strategies and solutions not only seen from the perspective of public health, but also from an economic point of view [3].

In case of disease-related malnutrition, the underlying problem can be that it is not feasible for affected individuals to eat normal food, or that their body is not able to sufficiently utilise a balanced diet to adequately meet the nutritional demand. Diseases or medical conditions can interfere with the eating or absorption of regular food, and they can lead to difficulties in swallowing or result in nutritional requirements that are different from those of healthy persons, such as an increased demand for particular nutrients or an inability to metabolise certain nutrients [3]. This may affect infants, children and adults of all ages, independent of body weight, and it can be temporary or permanent. In such cases, special food adapted to specific needs can be a valuable solution to guard against disease-related malnutrition.

This thesis focusses on 'Food for Special Medical Purposes' (FSMP), a legally defined category of special food products that are often better known with more commonly used terms, such as those defined in ESPEN Guidelines[6]:

'Enteral nutrition' or 'enteral tube feeding' are nutritionally complete FSMP used for medical nutrition therapy. They can serve as a full diet, but can also be provided supplemental. Enteral nutrition is supplied through a tube or stoma, via nose or skin, into the stomach or

[1] The European Food Information Council (www.eufic.org); a non-profit organisation, which stands up for science-based information on food and health
[2] Kondrup J et al. (2002), Clin Nutr 21(6):461–468; cited in [3]
[3] Disease-Related Malnutrition: An Evidence-Based Approach To Treatment, edited by Rebecca J Stratton, Ceri J Green, and Marinos Elia, 2003; cited in [3]
[4] Stratton RJ & Elia M. (2007)., Clin Nutr Suppl 2(1):5–2; cited in [3]
[5] Russell CA (2007)., Clin Nutr Suppl 2(1):25–32; cited in [3]
[6] The European Society for Clinical Nutrition and Metabolism: ESPEN Guidelines on definitions and terminology of clinical nutrition. Clin. Nutr. 36 (2017) 49-64, p. 59-60 [4]

small bowel [4]. It aims to improve or sustain the nutritional status of patients for whom normal eating is not feasible (e.g. due to swallowing disorders) or not sufficient (e.g. in case of disease-related weight loss and/or malnutrition, cachexia, or metabolic disorders). Enteral nutrition can have a standard composition and thus be suitable for different adult patient groups that suffer from an impaired ability to take normal food, or be especially adapted for specific nutrient demands of patients that are additionally affected by malabsorption due to an underlying disease, such as for patients with renal failure or short bowel syndrome [5].
'Oral nutrition therapy', mainly given as 'oral nutritional supplements', is also FSMP. These products are for oral use and available as ready to drink liquids or as powders that can be prepared as solutions in different viscosity or added to food. Liquid oral nutritional supplements are often referred to as sip feeds. They can be nutritionally complete, nutritionally incomplete, standard or nutrient-adapted, such as being increased or decreased in specific nutrients in order to meet specific demands for certain diseases [4]. Oral FSMP also covers mixtures with amino acids for rare inborn diseases, such as phenylketonuria and others, which, if left untreated, could lead to severe mental or physical disturbances [5].
Lately, nutritionally incomplete oral FSMP in drug-like dosage forms, such as capsules or tablets, have drawn special interest and gained in importance. They are still much less restrictively regulated than medicinal products, but have a pharma-typical appearance, which makes them an attractive product category for the pharmaceutical industry in the search for alternative ways to market new products [6]. Furthermore, such FSMP has also become a trend in the food sector, since they opened a way to by-pass increasingly restrictive rules on health claims that became applicable to normal food [7]. From a regulatory point of view, these FSMP products are of special interest, since their demarcation from medicinal products can be very challenging, but is nonetheless of significant importance.

Whether nutritionally complete or incomplete, with a standard composition or a nutrient-adapted formulation – as can be seen, the legal category FSMP covers a wide range of products which are collectively designed for patients that require nutritional support with the aim to preserve or improve their nutritional status in order to prevent disease-related malnutrition, and thus to contribute to a better health outcome and quality of life. Since FSMP is always intended for patients, a vulnerable population group, it is with good reason that it is specifically regulated in the EU. However, the interpretation of the applicable law can be complex. The correct classification of FSMP and the clear demarcation challenges responsible distributors and monitoring authorities alike, which is why FSMPs are also referred to as *borderline products*. Since the previous legislation applicable to FSMP in Europe has been recently repealed and replaced, it is reasonable to assess the relevant changes, and to evaluate whether the new law improves legal certainty.

1.1 Aim

The present thesis aims to analyse implications of the new legal environment covering FSMP, namely Regulation (EU) No 609/2013 supplemented by Delegated Regulation (EU) 2016/128 and relevant guidelines, on its demarcation and regulatory requirements in comparison to the previous legislation at the European level and in Germany. The intention is to investigate the main differences that need to be considered when placing FSMP on the European market, and to illustrate the types of complex uncertainties that appear when reflecting on the question whether a product correctly complies with the legal definition of FSMP. From the findings it shall be evaluated whether the new legal framework simplified and clarified legal difficulties that previously arose particularly in view of FSMP.

This work focusses on FSMP that is intended to patients older than 12 months (not infants), and in large aspects particularly refers to nutritionally incomplete FSMP which is marketed in drug-like dosage forms suitable for home use. The comparison considers new and previous European legislations and at the national level addresses German provisions, exclusively. Legal requirements from the specific law are the primary focus while further regulatory requirements, such as those resulting from the General Food Law, are only briefly discussed.

The thesis starts with an historic overview of relevant legislation to highlight the development of FSMP as a legal product category in Europe and Germany in Section 2.
In Section 3, the new regulatory environment applicable to FSMP is presented while the most important reference documents reviewed in this work are introduced in brief.
The core of this thesis is contained in Section 4, where regulatory requirements to place FSMP on the European market according to the new legislation are illustrated, and changes in comparison to the previous law at EU level and in Germany are analysed in parallel. First, single elements of the legal definition of FSMP are discussed to support the current interpretation taking into account latest guidelines, which also includes demarcation criteria to medicinal products. In the second part, provisions on substances, presentation, labelling and advertising, on the notification and the demand for scientific data are addressed.
Finally, the main regulatory changes at European level and in Germany are summarised as a result of this work in Section 5, and conclusions are given in Section 6.

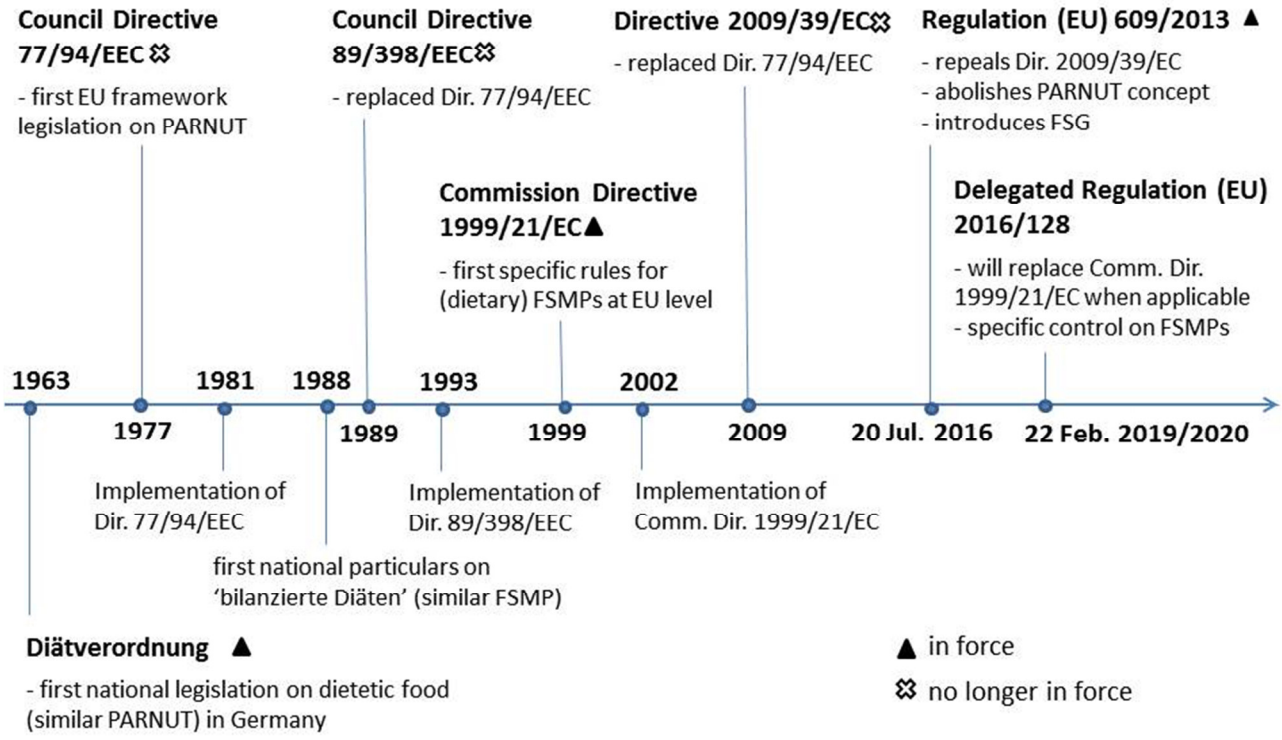
This work is based on situation as per 1.3.2018.

2. Historical Development of relevant Legislation

Introductory to the analysis of regulatory changes with regard to FSMP, some background information shall be provided on the history of significant stages in the development of legal provisions on foodstuffs or foods for particular nutritional uses (in the following referred to as PARNUT) – wherein the specific category of FSMP developed. First, relevant European legislation is examined. Thereafter, national provisions in Germany are focused on. Finally, some court decisions are discussed to illustrate how these further develop the interpretation of the law.

Timelines of the legal definitions of PARNUT and FSMP as well as of the corresponding terms in German legislation ('diätetische Lebensmittel' equate to PARNUT and 'bilanzierte Diäten' to FSMP; PARNUT/FSMP herein is also used in the context of German law) can be found in Annex I and Annex II. A correlation table in Annex III illustrates where relevant aspects from EU legislation have been implemented in German law. For further details on the historic development of legal provisions covering PARNUT/FSMP in Europe and Germany it shall be referred to the work of Hermann [8].

Figure 1: The Development of PARNUT/FSMP Legislation in Europe and Germany



Overview of development stages of EU law (above) and German legislation (below) with relevance to food for particular nutritional purposes (PARNUT) and food for special medical purposes (FSMP).

2.1 Europe

2.1.1 EU Framework Legislation on PARNUT

a) Council Directive 77/94/EEC

At the European level the first Framework Legislation on PARNUT was introduced on 31.1.1977 with Council Directive 77/94/EEC on the approximation of the laws of the Member States relating to foodstuffs for particular nutritional uses [9]**.** The aim of this Directive was to harmonise different national laws relating to PARNUT in EU Member States and this way to improve the free movement of goods, equal the conditions of competition and ensure the functioning of the common market [9, recitals]. Directive 77/94/EEC defined 'foodstuffs for particular nutritional uses', as:

> *"foodstuff, which, owing to their special composition or manufacturing process, are clearly distinguishable from foodstuffs for normal consumption, which are suitable for their claimed nutritional purposes and which are marketed in such a way as to indicate such suitability*" [Art.1(2)(a), Directive 77/94/EEC]
>
> whereas "*A particular nutritional use must fulfil the particular nutritional requirements: (i) of certain categories of persons whose digestive processes or metabolism are disturbed, or (ii) of certain categories of persons who are in a special physiological condition and who are therefore able to obtain special benefit from a controlled consumption of certain substances in foodstuffs, or (iii) of infants or young children in good health.".* [Art. 1(2)(b), Directive 77/94/EEC]

Thus, PARNUT had to be clearly distinguishable from normal food, and were intended to nutritionally benefit people either affected by certain digestive or metabolic disturbances, for those in a special physiological condition, or for healthy infants or young children. Article 2 further ruled PARNUT had to be appropriate for the particular nutritional use intended and generally reserved the application of the adjectives 'dietetic' and 'dietary' to them. Similar to normal food it was prohibited to advertise PARNUT in a way that attributed healing properties to it, namely to *"attribute properties for the prevention, treatment or cure of human disease"* [9, Art.4(1)]. However, useful information and recommendations exclusively intended for qualified experts were allowed [9, Art.4(3)]. This Framework Directive provided the first provisions on PARNUT in general, but did not yet establish any specific rules on FSMP.

b) Council Directive 89/398/EEC

In 1989, Council Directive 77/94/EEC was replaced by Council Directive 89/398/EEC on the approximation of the laws of the Member States relating to foodstuffs for particular nutritional uses [10] that further reinforced the introduction of specific provisions on different product categories within the scope of the Framework Directive since this had not been realised while Directive 77/94/EEC was in force. A concrete list of product categories to which specific acts should be adopted for was provided in its Annex 1, including dietary FSMP (in point 5).

The definition of PARNUT in Council Directive 89/398/EEC remained equivalent to the one given in Directive 77/94/EEC before (see Annex I (a), p.67). A change occurred regarding the intended target group of infants and young children in good health: PARNUT intended for them were no longer allowed to be characterised 'dietetic' or 'dietary' [10, Art.2(1)]. Another alteration was implemented to ease the monitoring of PARNUT that were not subject of specific provisions. Directive 89/398/EEC laid down the requirement that distributors of such products "*shall notify the competent authority of the Member State where the product is being marketed by forwarding it a model of the label used for the product"* [10, Art.9].
During the following twenty years, several directives amending Directive 89/398/EEC were adopted while it remained the Framework Legislation for PARNUT until 2009.

c) Directive 2009/39/EC

There was limited change in comparison to Directive 89/398/EEC when Directive 2009/39/EC of the European Parliament and of the Council on foodstuffs intended for particular nutritional uses [11] repealed and recast it. New elements introduced concerned the committee procedures, only [11, recital 15]. However, since Directive 2009/39/EC has been the last Framework Directive on PARNUT also covering FSMP, it is also referred to in the analysis of latest regulatory changes at EU level in course of this work.

2.1.2 Further EU Legislation with Relevance to FSMP

a) Commission Directive 1999/21/EC

On 7 April 1999 Commission Directive 1999/21/EC on dietary foods for special medical purpose [12] was published in the Official Journal to finally lay down specific compositional and labelling requirements for dietary FSMP within the meaning of Article 4(1) of Council Directive 89/398/EEC. This Specific Act is still in force today until Delegated Regulation 2016/128 will officially start to apply and replace it. In case of conflicts with Regulation 609/2013, the Regulation prevails (such as in case of the currently valid FSMP definition).
Directive 1999/21/EC introduced the first legal definition of FSMP, as follows:

> *"'dietary foods for special medical purposes' means a category of foods for particular nutritional uses specially processed or formulated and intended for the dietary management of patients and to be used under medical supervision. They are intended for the exclusive or partial feeding of patients with 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 only by modification of the normal diet, by other foods for particular nutritional uses, or by a combination of the two"* [Art.1(2)(b), Directive 1999/21/EC].

In this definition the element *to be used under medical supervision* has been applied to specify FSMP in EU legislation. By this time, the term has been a compulsory labelling statement for FSMP in Germany for ten years already (compare sect. 2.2.c, p.9).
Directive 1999/21/EC classifies dietary FSMP, as follows:

> *(a) nutritionally complete foods with a standard nutrient formulation which, used in accordance with the manufacturer's instructions, may constitute the sole source of nourishment for the persons for whom they are intended;*
>
> *(b) nutritionally complete foods with a nutrient-adapted formulation specific for a disease, disorder or medical condition which, used in accordance with the manufacturer's instructions, may constitute the sole source of nourishment for the persons for whom they are intended;*
>
> *(c) nutritionally incomplete foods with a standard formulation or a nutrient-adapted formulation specific for a disease, disorder or medical condition which are not suitable to be used as the sole source of nourishment.*
>
> *The foods referred to in points (b) and (c) may also be used as a partial replacement or as a supplement to the patient's diet.* [Art.1(3), Directive 1999/21/EC]

Regarding the classification of FSMP the national law in Germany had also been earlier. DiätV from 1988 already classified FSMP into *nutritionally complete* and *nutritionally incomplete* (compare sect. 2.2.c, p.9). The EU Directive however extended these categories to the proposed criteria *with standard formulation* or *nutrient-adapted*.
Directive 1999/21/EC lays down provisions referring to the composition of dietary FSMP. It establishes their formulation "*shall be based on sound medical and nutritional principles"* [12, Art.3] and the use according to the manufacturer's instruction shall be *"safe and beneficial and effective in meeting the particular nutritional requirements of the persons for whom they are intended, as demonstrated by generally accepted scientific data"* [12, Art.3]. Additionally, rules on maximum and minimum amounts of vitamins and minerals depending on the FSMP category according to Article 1(3) are provided in the Annex of this Directive. The Specific Act sets further labelling requirements for FSMP, such as a mandatory wording for the legal name that FSMP shall be sold with in different languages in Article 4(1). Other compulsory labelling particulars include a statement that it *"must be used under medical supervision"* [12, Art.4(3)(a)], or a statement on its intended purpose [12, Art.4(4)(a)], amongst others.

b) Commission Directive 2001/15/EC and Commission Regulation (EC) No. 953/2009

In 2001, the Commission published Directive 2001/15/EC on substances that may be added for specific nutritional purposes in foods for particular nutritional uses [13]. As the range of foods in this category, including FSMP, is very wide and diversified the widest possible choice of substances that could be safely used in the manufacture of PARNUT has been listed in the Annex of this Directive – focusing on vitamins, minerals, amino acids, carnitine and taurine, nucleotides, as well as choline and inositol. With regard to these nutritional

substances only the chemical substances listed were allowed to be used for the formulation of PARNUT/FSMP [13, Art.1(1)]. Substances of other categories were permitted if they complied with the relevant law, such as that they were save and fulfilled a particular nutritional purpose for the persons to whom they were intended [13, Art.1(3)].
In 2009, Directive 2001/15/EC was repealed by Regulation (EC) No 953/2009 [14]. This way the equal provisions became directly applicable to all EU Member States.

2.2 Germany

2.2.1 Verordnung über diätetische Lebensmittel

Germany has a long tradition in legal history on dietetic food and FSMP – the first national provisions even established before the first ones at EU level. Due to this, German legislation was not only influenced by the European legislation (through the implementation of EU law), but it in turn had an impact on the development of EU law referring to FSMP. In Germany, dietetic food of all kinds has always been regulated collectively by one national law named Verordnung über Diätetische Lebensmittel, commonly called Diätverordnung (DiätV). This legislation adopted EU framework directives on PARNUT and also specific acts of single categories within its scope. It hence comprises both, the general rules on PARNUT ('diätetische Lebensmittel') and the specific provisions on FSMP ('bilanzierte Diäten').

a) DiätV – 1963: First Version

On 28.6.1963 the first version of DiätV [15] was introduced in Germany to regulate dietetic food, nearly fifteen years before the first EU Framework Legislation on PARNUT was published. The text set general rules on substances, labelling or penal provisions. PARNUT (in German: 'diätetische Lebensmittel') were defined (see Annex II (a), p.69), as food intended to serve a dietetic purpose by increasing or reducing the supply of certain nutritional substances, or through supplying them in a predetermined mixing ratio, or in a particular constitution, and that distinguishes significantly from normal food regarding composition or properties. It was further ruled that PARNUT served a dietetic purpose if it contributes to special nutritional needs either due to a disease, disorder, deficiency symptom or hypersensitivity, or during pregnancy, breastfeeding, infancy or early childhood.

b) DiätV – 1981: Implementation of Council Directive 77/94/EEC

In 1981, the first EU Framework Legislation on PARNUT, Directive 77/94/EEC, has been implemented with the 6th amendment of DiätV [16]. Minor changes happened to the legal definition of 'diätetische Lebensmittel' (see in Annex II (a), p.69), since the national legislator

judged[7] that the wording of the German definition basically complied with the PARNUT definition set in the EU Directive [8]. The only adjustment made referred to the wording of the intended purpose due to the setup of the EU Directive: Whereas the former versions of DiätV used the term *diätetischer Zweck* (= dietetic purpose) this 6th amendment introduced the wording *besonderen Ernährungszweck* (= particular nutritional use) to align the wording of the intended purpose with the terms used in the Framework Directive. Another change has been the reversal of a general exemption for PARNUT from the prohibition of disease-related claims that applied to normal food. The German legislator reasoned this with a general trend towards the category of PARNUT and with regulatory developments at EU level where a prohibition to advertise PARNUT in a way it attributes healing properties to it applied. Exceptional rules only remained in force for certain *catalogued* diseases[8] [8].

c) DiätV – 1988: First Specific Provisions on FSMP

Until 1988, FSMP was still not regulated specifically, although it was in the German market and even gained in importance [8]. With a recast of DiätV in 1988 [17] the first provisions particularly on dietetic food that from today's perspective referred to as FSMP, namely: 'bilanzierte Diäten', were finally established through the implementation of Verordnung zur Änderung der Nährwert-Kennzeichnungsverordnung und der Diätverordnung [18]. Thus, specific rules on composition and labelling requirements for FSMP were outlined in German legislation one year before Council Directive 89/398/EEC was published which later resulted in specific rules on (dietetic) FSMP at European level. Germany was the first Member State from all that established specific provisions on FSMP[9].

Although a legal definition had not been implemented yet in DiätV, details on the prevailing understanding of FSMP (bilanzierte Diäten*)* were given in the substantiations – which later influenced[10] the first legal definition of FSMP as established in Directive 1999/21/EC. These details included elements, such as that it is adapted to specific nutritional requirements, has a defined, standardised composition for specific dietetic purposes and thus contributes to the maintenance of physiological metabolic situations or to the adjustment a pathophysiologic metabolic situation, and is used under medical supervision[11] [8].

DiätV from 1988 initially introduced a classification of FSMP into *nutritionally complete* (vollständig bilanzierte Diät) or *nutritionally incomplete* (ergänzend bilanzierte Diät), ruled that

[7] Amtliche Begründung, BR-Drs. 642/80, p. 21; cited in [8] p.34-35

[8] Wasserzier, ZLR 1983, 190; cited in [8]; p.36

[9] Großklaus/Noble, Akt. Ern. Med. 1990: 15: 9, 10; cited in [8], p.38

[10] Großklaus, LMuR 2003, p. 151; cited in [8], p.39

[11] Amtliche Begründung, BR-Drs. 41/88, p. 41 f.; in: Zipfel/Rathke, C 140, Vorb., Rdnr. 5 , 11; cited in [8], p.38

they should be safe for long-term use, and suitable for the assigned nutritional purpose[12] [8]. Furthermore, in §21(1) the German name under which the products shall be sold was established as *'bilanzierte Diät'* and the compulsory labelling that it shall be used under medical supervision has been introduced in §21(2)(2) DiätV ("*nur unter medizinischer Kontrolle verwenden"*) – ten years before a similar element was inserted in the definition of FSMP in Directive 1999/1/EC.

d) DiätV – 1993: Implementation of Council Directive 89/398/EEC

In 1993, the 7th amendment of DiätV [19] implemented Council Directive 89/398/ECC. DiätV now set the legal definition of 'diätetische Lebensmittel' equally worded to the PARNUT definition given in the EU Directive (see Annex II (a), p.70) to extend the scope of DiätV, although only slightly[13] [8]. For PARNUT not belonging to one of the product categories listed in the Annex of Directive 89/398/ECC (and as implemented in DiätV 1993) a notification procedure was introduced, similar to that established in the EU Directive, including the possibility to request scientific data from the distributor in order to control the suitability of products. PARNUT belonging to one of the eight groups listed in the Annex, to which specific acts shall be adopted for (including FSMP), have been excluded from the notification procedure so far.

e) DiätV – 2002: Implementation of Commission Directive 1999/21/EC

The 10th amendment of DiätV [20] finally implemented the specific rules on (dietary) FSMP from Directive 1999/21/EC, including the abstract legal definition of FSMP (bilanzierte Diäten[14]), for the first time. The definition (see Annex II (b), p.70) established in DiätV mainly equaled the one given in Directive 1999/21/EC – with the only exception that the part *"to be used under medical supervision"* has not been included in the German definition but instead has been kept a mandatory labelling particular for FSMP pursuant to §21(2)(6) DiätV. The extended classification as set in Directive 1999/21/EC has been implemented in §1(4a) DiätV. Accordingly, FSMP were no longer classified in *nutritionally complete* and *nutritionally incomplete*, only, but further specified with *standard formulated* or *nutrient-adapted*.

It was ruled in §14b DiätV their formulation shall be based on sound medical and nutritional principles and the use of FSMP shall be safe, beneficial and effective – equally as required pursuant to Article 3 of Directive 1999/21/EC. In §21(2) DiätV compulsory labelling

[12] Amtl.Begründung, BR-Drs. 41/88, p. 45, in: Zipfel/Rathke, C 140, Vorb., Rdnr. 5, 22; cited in [8], p.41

[13] Streinz/Fuchs, Ergänzende bilanzierte Diäten, p.44; cited in [8], p.46

[14] The legislator hereby without doubt assumed that the EU Directive establishing the term „Lebensmittel für besondere medizinische Zwecke (bilanzierte Diäten)" refers to the same products that were previously referred to as ‚bilanzierte Diäten' in DiätV; Zipfel/Rathke, C 140, § 1 DiätVO, Rdnr. 80; cited in [8], p.46

particulars in German language were established, including the suitability statement *„zur diätetischen Behandlung von…“* and the requirement for medical supervision (*“Hinweis, dass das Lebensmittel unter ärztliche Aufsicht verwendet werden muss.”*, §21(2)(6) DiätV*)*.
Finally, the notification has been extended to FSMP (§4a(1) DiätV) and thus it became mandatory to notify FSMP when placing it on the market in Germany.

With the implementation of Directive 1999/21/EC the legislation applicable to FSMP at the European and national level in Germany were finally – more or less – comparable. Since then, only minor or formal changes with relevance to FSMP occurred until the new FSG Regulation came into force. Nevertheless, difficulties in the interpretation of the legislation and legal uncertainty arose. As a consequence, FSMP legislation has been addressed in several court decisions and the resulting judgments continued to influence the general understanding of the legal provisions given, as the following briefly illustrates.

2.2.2 Relevant Court Decisions in Germany

Recent court decisions on FSMP for instance concerned the interpretation of the required extent of scientific evidence. As established by law, FSMP shall be *“safe, beneficial and effective in meeting the particular nutritional requirements of the persons for whom they are intended”* [12, Art.3; equally in 40, §14b]. The interpretation of this requirement by the German Federal Court of Justice (BGH) started with a liberal approach but an increasingly restrictive course has recently developed [21].
In 2008, BGH decided two cases with FSMP products. In the first decision[15] it was judged that the product in question, FSMP intended for the dietary management of androgenic alopecia, does not require a detailed scientific proof of efficacy (such as a detailed proof of the dietetic effect on the efficacy) or evidence of efficacy of every single ingredient, but that rather the scientific data provided, a randomised, controlled clinical study on 30 subjects demonstrating a beneficial effect of the product itself, would be sufficient. In the second case[16], BGH decided that generally accepted scientific data is acceptable since DiätV does not regulate the scientific proof of FSMP in more detail. In general, it was stated that no higher demands on the scientific proof of FSMP than those required proving other health-related claims on efficacy shall be asked for.
With these judgments and reasoning, BGH decided liberally that a randomised, controlled clinical study is not generally required for FSMP, and if a study is available, it is not necessary to provide evidence of every single ingredient but rather the overall benefit is evidence enough. However, a few years later, two cases of dispute on FSMP for the dietary

[15] BGH decision on Priorin from 2.10.2008 - I ZR 51/06 [22]
[16] BGH decision on Mobil-Plus from 2.10.2008 - I ZR 220/05 [23]

management of arthrosis have been judged more restrictive, while the same legal text applied to them.

In a decision in 2011[17], BGH resolved that the efficacy of the product in question, that shall become evident in terms of the consumers wellbeing, *could have been proved* with solely one randomised, controlled clinical study. Later, in 2012, BGH decided another case[18] even more restrictive judging that where objective measurable effects are lacking and the efficacy only relies on subjective opinions of subjects, such as in cases of pain relief, placebo controlled studies *are required* as sufficient scientific evidence for FSMP.

This indicates even though the underlying legal text did not change, the interpretation of it developed from a liberal to a more restrictive approach through court decisions over the time. Therefore, FBOs should always keep an eye on these developments as well, in order to take into consideration the current interpretation of the law. While court proceedings reveal the difficulties that arise from the interpretation of legislation, they also highlight the points where further details are required, and thus may support the development of legislation.

2.3 Summary Historical Development of relevant Legislation

This Section elucidated that PARNUT including FSMP has a long history in European law as well as in national German legislation. Whereas at the European level a framework directive served as legislative act to provide general rules for dietetic food which was further supplemented by separate directives to specifically regulate single product categories, a comprehensive national regulation on dietetic food established in Germany to consolidate both general and specific provisions. The first German provisions established more than fifty years ago and over the years European directives were implemented, in parts equally worded, while the European legislation has also been influenced by prior existing German provisions and interpretations. Since 2002 the legal definition of FSMP and the relevant rules applicable to it were basically comparable in EU and German law – but in small parts variation remained, such as in case of the German definition text that did not include the term *under medical supervision*. Because directives per se are not directly binding to EU Member States but it rather is the responsibility of the Member States' competent authorities to interpret the legal text of EU directives and to devise the national law accordingly, and with the abstract FSMP definition given that left scope of interpretation, national provisions and views still could vary in details. Ongoing difficulties in the interpretation of the law led to court proceedings, to different opinions across Member States and stakeholders, and to conflicts and trade distortions in the internal market. Finally, several facts led to the Commission's decision in 2011 to completely revise the previous legislation, as will be outlined in Section 3.

[17] BGH decision on Orthomol Arthro from 1.6.2011 - I ZR 199/09 [24]

[18] BGH decision on Artrostar Compact from 15.3.20212 - I ZR 44/11 [25]

3. New Legal Environment applicable to FSMP

3.1 Reasons for a new Legal Framework: From PARNUT to FSG

FSMP is an attractive product category for both, food business operators[19] (FBOs) and the pharmaceutical industry, for several reasons. Filling a gap in the borderline area between food for a normal consumption and medicinal products, FSMP on the one hand is directed at patients and labelled with a suitability statement referring to a specific disease, disorder or medical condition, which is contrary to any normal food including food supplements, that is only allowed to be promoted with authorised nutrition and health claims in accordance with Regulation (EC) No 1924/2006 [26], on the other hand FSMP does not need to be approved by authorities such as medicinal products and therefore can be placed on the market much less cost- and time-consuming in comparison to drugs. A trend towards the category of FSMP occurred from both sides – the food and the pharmaceutical sector.

In the food industry this intake was mainly reasoned with legal developments applicable to normal food. Some FBOs did so-called *"legislative shopping"*[20] [7] in order to by-pass provisions, such as those from Regulation 1924/2006 which rules how FBOs can inform consumers about the benefits of food. Since suitability statements or pertinent information of FSMP can be very similar to nutrition and health claims ruled in that legal act but were not as strictly regulated, it represented an incentive to market normal food incorrectly as FSMP [27]. In addition, FSMP belongs to the vital assortment of pharmacies, meanwhile. The search of pharmaceutical companies for quicker, more favourable and more flexible ways to develop and market new products resulted in a trend towards non-medicinal products. Especially FSMP in drug-like dosage forms, as tablets or capsules, due to their pharma-typical appearance gained a lot of interest [6]. Finally, high sales prices can be charged for FSMP and consumers may even be able to obtain reimbursement under their medical insurance scheme which can be further incentives to market a product under FSMP status [27].

According to reports of the Member States' national competent authorities (NCAs) the numbers of products notified as FSMP were increasing over the last years, but in some cases doubts came up if they correctly correspond to the legal definition and appropriately fell within the scope of FSMP legislation [27]. Many products marketed as FSMP would lack sufficient scientific data and a large number rather needs to be classified as medicinal products or dietary supplements, according to German NCAs [28].

[19] 'food business operator' means the natural or legal persons responsible for ensuring that the requirements of food law are met within the food business under their control; Art. 3(3) of Regulation 178/2002

[20] the possibility for businesses to do "legislative shopping" means to select the piece of legislation they prefer to market their products, eventually in order to by-pass important EU rules

Not only difficulties and disagreements with regard to FSMP were on the rise. Due to the broad definition of PARNUT, the diversification and specialisation of dietetic food products within the scope of the PARNUT Directive, and the developments of EU food legislation in parallel, interpretations and decisions on applicable law varied across NCAs. Whereas in some Member States a certain food could be considered a dietetic food, the same product in other Member States has been marketed as a normal food, for instance. It appeared that the legislation on PARNUT resulted in misclassifications and it could also not be ruled out that marketing abuse took place [29]. To protect the consumers' interests and ensure the functioning of the internal market the Commission decided in 2011 that a revision of the PARNUT legislation would be required. This led to time consuming and controversial debates which finally resulted in a draft legislation text that has been only declined from Germany out of 27 Member States entitled to vote [30].

3.1.1 Aim of the new Legal Framework

The aim of the new Framework Legislation, Regulation (EU) No 609/2013 [29], is to eliminate differences in interpretations and to simplify and clarify the regulatory environment of products formerly referred to as PARNUT in order to more effectively ensure the functioning of the internal market, according to its recitals [29]. It was decided to implement a regulation which per se directly binding and thus shall achieve a consistent application of the law in all Member States. Products covered by uniform rules shall create a better environment for businesses, be better enforced by NCAs and would be easier comparable for consumers [7].

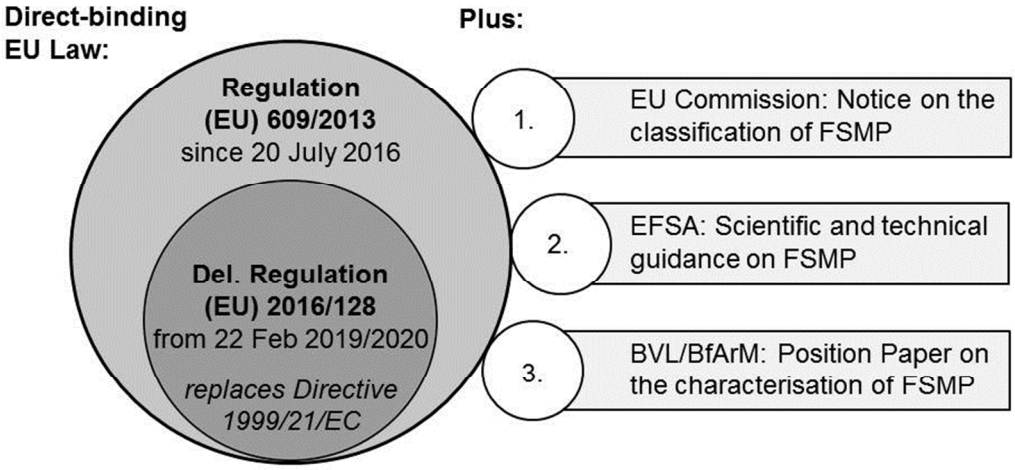
The former concept of dietetic food/PARNUT was completely abolished as it was rated *"no longer effective in ensuring the functioning of the internal market"* [29, recital 12] and it was regarded necessary in order to *"close loopholes (…) and limit the possibility for businesses to do "legislative shopping" "* [7]. The new Framework Legislation strictly focusses on four explicit product categories intended for vulnerable target groups – foods for special groups. These four product categories were seen as *"vital"* for the *"clearly identified vulnerable population groups"* [29, recital 15] to manage their conditions. Products that do not fall within the scope of the new FSG Regulation but were regulated by PARNUTs legislation before are within the control of General Food Law and other Union law, now. As stated in the recitals of Regulation 609/2013 they were seen to be sufficiently regulated by other EU legislation *"with less of an administrative burden and more clarity as to scope and objectives"* [29, recital 11], such as by Directive 2002/46/EC or Regulation 1925/2006.

3.2 Current Regulatory Environment for FSMP
3.2.1 Overview

Currently, FSMP is regulated in the EU under the *new* Regulation 609/2013 and the *old* Specific Act, Directive 1999/21/EC. The latter will be replaced by a *new* Specific Act, Delegated Regulation (EU) 2016/128, on 22 February 2019 (2020 for infant FSMP). From then the general and the specific provisions applicable to FSMP will be laid down in form of EU regulations and thus will be directly binding to all EU Member States.

Important new guidelines at EU level that are also reviewed in course of this work are the Scientific and technical guidance on FSMP from the European Food Safety Authority (= EFSA) and the Commission Notice on the classification of FSMP. In addition, a joint position paper from the German authorities BVL[21] and BfArM[22] on the characterisation of FSMP and a comment hereto from Diätverband[23], is examined. Although these guidelines and comments are not binding law they clarify details of the legislation and this way support in the interpretation of the rules. Therefore, FBOs are advised to consider these documents when placing FSMP on the European market.

Figure 2: Overview of main Documents relevant to the new Regulatory Environment for FSMP in EU and Germany



Modified from Diätverband (2016), Diätrecht, Speziallebensmittel – Relaunch [31]

[21] BVL, the German Federal Office of Consumer Protection and Food Safety (in German: Bundesamt für Verbraucherschutz und Lebensmittelsicherheit) is a higher federal authority within the Federal Ministry of Food and Agriculture and responsible to receive notification of FSMP in Germany. After a formal evaluation, these are forwarded to authorities at federal state which are responsible for spot-check inspections of products in the market.

[22] BfArM, the German Federal Institute for Drugs and Medical Devices (in German: Bundesinstitut für Arzneimittel und Medizinprodukte) is a higher federal authority within the Federal Ministry of Health. It is deciding on the licensing of medicinal products in Germany and also involved in the evaluation whether FSMP products are correctly classified and demarcate from medicinal products.

[23] Diätverband, the German Federal Association of Producers of Food for Special Dietary Purposes (in German: Verband der Hersteller von Lebensmitteln für eine besondere Ernährung), is an Industry Association which represents the manufacturers of special nutrition located in Bonn

3.2.2 Relevant Documents

a) Regulation (EU) No 609/2013

The Regulation (EU) No 609/2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control (…) [29] was published in the Official Journal on 29 June 2013 and is directly applicable to all EU Member States since 20 July 2016. FSMP complying with the previous Framework Law, Directive 2009/39/EC, but not yet with this new Framework Regulation can still be found in the market to sell off until the end of shelf-life. However, to bring out new FSMP in the EU, it has to comply with this Regulation, now.

Regulation 609/2013 aims to simplify and harmonise the rules governing general compositional and information requirements for foods falling within its scope, namely

(a) infant formulae and follow-on formulae,
(b) processed cereal-based foods and baby foods,
(c) foods for special medical purposes, and
(d) foods intended for total diet replacement for the purpose of weight control.

It repeals the provisions on PARNUT formerly set out in Directive 2009/39/EC and resulting specifics thereof, such as Directive 1999/21/EC and Regulation 953/2009, amongst others. The new Framework Regulation totally abolishes the concept of 'dietetic'/'dietary' food/PARNUT after more than thirty years in EU legislative history and replaces it with provisions on *Food for Special Groups*. From this scope its abbreviated name, FSG Regulation, established. Regulation 609/2013 lays down the currently valid legal definition of FSMP in Article 2(2)(g) and sets the legal framework for the implementation of further specific directives on the food groups within its scope.

aa) Interpretation Decisions

Article 3 of FSG Regulation has introduced a new legal act since 20 July 2016: Provisions on interpretation decisions empower the Commission to decide whether a given food falls within the scope of FSG Regulation or not and to what specific category within its scope it belongs.

> *In order to ensure the uniform implementation of this Regulation, the Commission may decide, by means of implementing acts:*
> *(a) whether a given food falls within the scope of this Regulation;*
> *(b) to which specific category of food [under the scope of the Regulation] a given food belongs. (…)* [29, Art.3]

This procedure shall not be mistaken as a general tool to evaluate all FSMP – FBOs may still place FSMP in the market without authorisation and based on their own assessments while

NCAs remain with the responsibility to monitor the market. The Commission shall rather decide in case disagreements across Member States occur concerning the classification of a notified product, such as on a notified FSMP, in order to ensure a uniform implementation of FSG Regulation and the free movement of goods [27]. If a procedure pursuant to Article 3 is induced, the Commission shall conduct the examination procedure as laid down in Article 5 of Regulation (EU) No 182/2011 [32] and shall be assisted by the Standing Committee on the Food Chain and Animal Health [29, Art.17], which is composed of representatives of the Member States and entitled to vote on the draft. In order to prepare the draft implementation act, the Commission may request the European Food Safety Authority (EFSA) to provide a scientific opinion on the product in question [29, Art.7].

In case the examination committee provides a positive opinion by qualified majority vote, the draft implemented act may be adopted. If a negative opinion is provided, the proposal can be amended and sent to the Committee a second time or it can be referred to an appeal committee. In case no opinion is provided, different consequences may apply. In some cases the draft may directly be adopted, in others not. However, if it is then regarded as necessary or urgent again other rules apply [compare 32, Art.5]. FSG Regulation does not further specify the procedural steps to be followed if Article 3 applies (neither do the Commissions Notes) and so far no interpretation decision has been adopted [27].

Since it is in general the Commission's responsibility to plan, prepare and propose EU legislation and to evaluate if EU laws have been met by the Member States (executive functions), the fact that it in case of Article 3 procedures at the same time is authorised to decide the interpretation of the law, particularly that it is empowered to decide on the classification of products, is also criticised. With this empowerment the Commission may interfere with authority that shall rather be reserved to independent judicative institutes [30]. The Commission itself clarifies that *"only the Court of Justice of the European Union is entitled to interpret Union law with final binding authority"* [27, para.6] and that "*In any event, decisions (…) of the European Commission can be challenged in courts"* [27, Fn 10]. Considering the Commissions role as laid down in Article 17(1) of the Treaty on European Union [33] and the principles of subsidiarity and proportionality as ruled in in Article 5 thereof, whereas EU competence is to be shared with the Member States and shall be subsidiary to national legislation, such as in elements of public health policies [Art.168 Treaty on the Functioning of the European Union [34]), the Commission emphasises the new procedure shall be considered a *"complementary solution"* [27, para.23], only, in case when Member States' divergent approaches on a product might otherwise negatively impact the free circulation of goods. Thus, if Member States disagree with future interpretation decisions of the Commission, cases will maybe be referred to the European Court of Justice (ECJ) for final binding decisions. It might then be interesting to follow the court's reasoning with regard

to the aims to protect the functioning of the internal market as well as to respect domestic public health policies.

Overall, this procedure introduces the possibility that divergent opinions on the question what constitutes FSMP, which is an element of public health policy that may be rated very differently amongst Member States, can lead to binding harmonised decisions based on scientific opinions that result from centralised evaluations of scientific data from EFSA – and thus the procedure may have great impact on the diversification of domestic markets with health remedies and may interfere with domestic health policies, that partly can be considered a cultural field. Currently, it can only be said, it is awaited with interest how relevant such interpretation decisions will be, if resulting decisions will be challenged in court, how many notified products in the market today will be affected from it, and how the practical outcome and consequences of the introduction of this procedure finally will be in the future.

b) Delegated Regulation (EU) 2016/128

Pursuant to Article 11(1) of FSG Regulation the Commission adopted 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 [35] which was published in the Official Journal on 2 February 2016 and starts to apply on 22 February 2019 (on 22 February 2020 in respect of FSMP intended for infants[24]). Until this date the previous Specific Act for FSMP, Directive 1999/21/EC, still applies. In case of any conflicts, FSG Regulation prevails, such as in case of the legal definition which now is established in the Regulation. Delegated Regulation 2016/128, hereafter also referred to as FSMP Regulation, is directly applicable to all Member States. Until 22 February 2019/2020 FBOs may decide if they place FSMP products on the market complying with Directive 1999/21/EC or with the new FSMP Regulation, already. However, they may not mix the provisions from the two legislations but have to fully comply with one of them [37]. From 22 February 2019/2020 onwards only the rules from FSMP Regulation will be in force. Hence, necessary changes within the portfolio or with relevance to new product developments have to be considered in time.

c) EFSA: Scientific and Technical Guidance on FSMP

As illustrated, Article 3 of FSG Regulation establishes a new legal act that empowers the Commission to decide if a given product falls within the scope of FSG Regulation and to what specific category thereof it belongs by means of implementing acts. The Commission again may request EFSA to provide a scientific opinion on any matter related to the application of the Regulation which is likely to have an impact on public health [29, Art.7]. Thus, in the

[24] 'infant' means a child under the age of 12 months; Article 2(2)(a) of Regulation 609/2013

context of preparing Article 3 decision, the Commission may request EFSA to evaluate the information and scientific data of a product in question and to provide a scientific opinion.
In order to specify what kind and form of data FBOs shall provide in this case, the Scientific and technical guidance on foods for special medical purposes in the context of Article 3 of Regulation (EU) No 609/2013 (EFSA Guidance [38]) was published in EFSA Journal in 2015. EFSA Guidance provides a template including a common format and indicates what data and information is suggested relevant for the evaluation if notified FSMP is correctly classified. EFSA especially expects to be requested to evaluate *"the relationship between the product and the disease/disorder/medical condition*" and, considering the specific patient group, to asses *"the degree to which it would be impossible or difficult to consume ordinary foodstuffs",* only [38, p.7]. Based on the evaluation EFSA prepares a scientific opinion stating to what extend the product concerned fulfills the FSMP definition in their point of view. The decision whether the product is correctly classified remains to be made by the Commission.
Although EFSA Guidance is limited to assess FSMP in the context of Article 3 procedures and it is neither prepared to specify requirements a food shall fulfil to be classified as FSMP, or to interpret the definition of FSMP itself, or to address the scientific substantiation of health claims made on FSMP [38], FBOs and NCAs may use it as a tool to estimate how much a product corresponds to the definition of FSMP also in cases when no Article 3 procedure applies, as suggested by the Commission [27].

d) EC: Commission Notice on the Classification of FSMP

On 25.11.2017 the Commission published Commission Notice on the classification of Food for Special Medical Purposes (COM Notice [27]) in the Official Journal in order to assist NCAs and FBOs to interpret the Union law applicable to FSMP. It builds upon former consultation with Member States' experts and stakeholders and was adopted in the context of Article 14 of FSG Regulation. COM Notice describes in more detail single elements of the legal definition of FSMP, addresses frequently questions concerning FSMP legislation, and clarifies the responsibilities of FBOs, NCAs and the Commission's role in context of Article 3 decisions. The statements will be applicable in course of this work. Since no former Commission Guideline on FSMP existed, the comments given in here and referring to legal provisions that did not change due to the new legislation, will anyway be considered, since these new comments in general are now relevant for the interpretation of FSMP law today.

e) BVL/BfArM: Position Paper on the Characterisation of FSMP and Comment Diätverband

In Germany, BVL and BfArM are the two NCAs responsible for the demarcation of medicinal products from foodstuffs, such as FSMP. On 12.09.2016 they published a joint position paper on the characterisation of FSMP (originally: Positionspapier des BVL und des BfArM zur Charakterisierung von Lebensmitteln für besondere medizinische Zwecke (bilanzierte Diäten), abbreviated hereafter as BVL/BfArM Paper [28]) with the aim to support the decision making process especially concerning the demarcation of FSMP from medicinal products. They developed a decision tree based on seven inspection characteristics that are further illustrated in their paper and thus provide insight into their interpretation of legal provisions on FSMP. BVL/BfArM Paper is currently applied by monitoring bodies in Germany and Austria. However, since it contains some mistakes and poorly reasoned conclusions, the German Diätverband provided a statement on it dating from 10.03.2017 (herein referred to as Diätverband Comment [39]) which will also be considered in this work. In general, the COM Notice plays the major role and the BVL/BfArM Paper should be regarded as secondary [39].

f) Applicability of National German Provisions

EU regulations prevail over national provisions as soon as they apply. Currently, DiätV is overlaid by FSG Regulation already. Until Delegated Regulation 2016/128 officially starts to come into force, DiätV in its latest version [40] provisionally continues to be applicable for FSMP in Germany. In case of any conflicts EU legislation prevails.

With coming into force of FSMP Regulation, national provisions on FSMP will not be applicable, anymore. Nevertheless, DiätV continues to apply for products that are not conclusively regulated by FSG Regulation or other harmonised EU law [34, Art.114 in conjunction with Art.2(2)]. EU Member States in general may maintain their previous rules on specific food products or even establish new ones, as long as the products are not conclusively ruled by other EU regulations and the national rules do not infringe any Union law. This could refer to former PARNUT like specific food for athletes, for instance [31].

In addition, the national rules on measures and penalties applicable to infringements as established in DiätV remain in force for FSMP, since this regulatory part lies within the Member States' responsibility [Art.17(2) of GFL]. The procedure ruled in §4a(1) DiätV relating to FSMP equals the provisions in Article 9 of FSMP Regulation (rules on notification). The possibility to temporary prohibit the placing on the market of FSMP as established in §4a(6) DiätV is not explicitly established in the Specific Act but recognised as compatible [41] with the legal responsibility of NCAs to monitor the market according to Article 9 FSMP Regulation and thus may also continue to apply.

4. Comparison and Discussion of Regulatory Requirements for FSMP

This Section indicates and discusses regulatory requirements for placing on the market[25] FSMP that complies with the new Framework Regulation and the specific provisions currently established in Directive 1999/21/EC and from 22 February 2019/2020 onwards in Delegated Regulation (EU) 2016/128, respectively. Relevant changes to the legal definition and to the requirements in comparison to previous provisions are analysed at the European and at a national level, whereby the latter focusses on Germany, exclusively. First, single elements of the FSMP definition are discussed in more detail to clarify frequent difficulties that can arise, including the demarcation, and considering the comments that were recently provided from the Commission. Secondly, further regulatory requirements are discussed and compared to former provisions, in particular provisions on substances, on labelling, presentation and advertising, the notification of FSMP and the demand for scientific data.

Since the demarcation of special food products from medicinal products has been outlined from others before (i.e. Herrmann [8], Slawik [42], Streso [43]), this work highlights the most important points while especially the highest decisions of ECJ are considered.

4.1 The Definition of FSMP and Demarcation

According to Article 17 of Regulation (EC) No 178/2002 [44], the General Food Law (GFL), FBOs are responsible to place food in the market that complies with the legislation applicable to it. The first decision before placing FSMP on the European market is therefore to ensure it fully complies with the current legal definition. Of cause, it is also important for the monitoring bodies to correctly assign a product in question in order to fulfill their responsibilities ruled in Article 17 GFL. The assignment reveals the exact legislation that applies. In case a product fulfills the FSMP definition, FSG Regulation has to be observed according to its Article 4(1).

Since FSG Regulation prevails, the previous definition on (dietetic) FSMP given in Article 1(2)(b) of Directive 1999/21/EC and, as implemented, in DiätV §1(4a) is no longer applicable. Currently, Article 2(2)(g) of Regulation (EU) No 609/2013 establishes the valid legal definition of ‘food for special medical purposes’.

[25] ‘placing on the market’ means the holding of food or feed for the purpose of sale, including offering for sale or any other form of transfer, whether free of charge or not, and the sale, distribution, and other forms of transfer themselves; Art. 3(8) of Regulation 178/2002

> *'food for special medical purposes' means 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*

Current Legal Definition of FSMP (Art.2(2)(g), Regulation (EU) No 609/2013)

First and foremost it can be preceded that the definition itself changed only in minor aspects, as can be seen in full detail in Annex I(b) (p.68). Due to the abolishment of the concept of 'dietetic'/'dietary' food/PARNUT with coming into force of FSG Regulation, the former legal name '*dietary* foods for special medical purposes' formally changed into 'food for special medical purposes'. For the same reason, FSMP is no longer defined as a category within PARNUT. Infants are now explicitly included as a possible target group, but they were also optional target patients before. Finally, the last part of the definition altered slightly in words but with little practical impact, as will be addressed in Section 4.1.5 (p.36).

Altogether, these changes are not of practical consequence when it comes to correctly fulfill the FSMP definition and regarding the scope of products. However, although basically the same definition still applies, its different elements and frequent questions arising from it are discussed in the following. This is justified since differences in the interpretation were one of the reasons to implement a new legislation and, even more important, the Commission just recently published comments to assist in the interpretation, for the first time.

When focusing on single elements of the FSMP definition, it should always be kept in mind that the different aspects cannot be taken in isolation, but need to be interpreted within the context of the relevant provisions, coherently [27].

4.1.1 FSMP is Food – and Demarcation from Medicinal Products

Primarily, Article 2(2)(g) of Regulation 609/2013 defines FSMP as 'food'. When it comes to reflecting on the appropriate classification of a product as FSMP, it is important to ensure it does not fall within the scope of another legal framework, in particular that it is not defined as a 'medicinal product' [27]. A single product cannot belong to both categories at the same time, since the food definition explicitly excludes medicinal products.

According to GFL, 'food' (or 'foodstuff') is defined as: *"… any substance or product, whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be ingested by humans…",* whereas *"(…) 'Food' shall not include: (…) (d) medicinal products*

within the meaning of Council Directives 65/65/EEC and 92/73/EEC" [26] [44, Art.2]. From this definition it can also be derived that food needs to be *ingested*, indicating it shall be delivered and processed via the gastrointestinal tract. Therefore, parenteral nutrition that is usually given intravenously and by-passing the digestive system is not considered a food while enteral nutrition that is given into the intestinal tract (orally, via the nose or stomach) is.
The relevant definition of medicinal product for human use as referred to in the above-noted definition of food is currently given in Article 1(2) of Directive 2001/83/EC [45], as follows:

> *(a) Any substance or combination of substances presented as having properties for treating or preventing disease in human beings; or*
>
> *(b) Any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis.* [45, Art.1(2)]

Hence, a product complying with Article 1(2)(a) (also referred to as *medicinal product by presentation*) or with Article 1(2)(b) (also referred to as *medicinal product by function*) of Directive 2001/83/EC is defined as a medicinal product. It is sufficient if a product falls within either of the two definition parts, nevertheless, for the interpretation both parts must be read conjunctively, as judged by court[27]. In addition, Directive 2001/83/EC establishes the so-called *rule of doubt*, stating that: *"In cases of doubt, where, taking into account all its characteristics, a product may fall within the definition of a 'medicinal product' and within the definition of a product covered by other Community legislation the provisions of this Directive shall apply"* [45, Art. 2(2)]. Accordingly, not only if a product clearly complies with the definition of a medicinal product, but even if it only *may fall* within its definition it may be assigned as one and Directive 2001/83/EC may be preferred in borderline cases.
The demarcation of food and medicinal product is very important to apply the appropriate legislation since the resulting consequences differ largely. Contrary to food, a medicinal product may not be placed on the market without a marketing authorisation according to Article 6(1) of Directive 2001/83/EC, which is depending on time- and cost-intensive approval procedures. An offence against it, in particular placing a product on the market as a food that is considered a medicinal product and consequently placing a medicinal product in the market without marketing authorisation, can have major implications for the distributer. Since FSMP from its definition, due to the intended target group (patients), the suitability statement (referring to diseases or medical conditions) and in some cases also due to its appearance (i.e. if it is marketed in form of tablets or capsules), is the category of food that comes closest

[26] Council Directives 65/65/EEC and 92/73/EEC were repealed and replaced by Directive 2001/83/EC

[27] van Bennekom C-227/82 [48] para.23; Monteil and Samanni C-60/89 [58] para.11; Upjohn C-112/89 [52] paras 16-20; Joint cases C-211/03 and C-299/03 and C-316/03-318/03 HLM Warenvertrieb and Orthica [59] para.49.

to medicinal products, a clear demarcation can be very difficult. Therefore, FSMP are also referred to as *borderline products*[28].

As mentioned above, the definition of medicinal products is divided into a presentational and a functional aspect and both parts need to be paid close attention to in order to evaluate the demarcation from it. This shall be analysed in more detail now.

a) Demarcation from Medicinal Products by Presentation

First, a product classified and marketed as FSMP may not be *presented* as a medicinal product, precisely it may not be "*presented as having properties for treating or preventing disease in human beings"* [45, Art.1(2)(a)]. Regulation (EU) 1169/2011 [46], hereafter also referred to as Food Information Regulation (FIR), prohibits equally to *"attribute to any food the property of preventing, treating or curing a human disease"* [46, Art.7(3)] to protect consumers from misleading information on food and emphasises this also applies to advertising and the presentation, such as the appearance or packaging or the setting in which food is displayed [46, Art.7(4)]. Similar prohibitions are established in Regulation 609/2013 [Art.9(5)] and Directive 2009/39/EC [Art.8(1)]. Mandatory labelling according to FSMP legislation is excepted *lex specialis*. However, any information not covered from specific law, including pictures, leaflets, all surrounding advertising or oral presentation, may attribute healing properties to a product and this way assign it as a medicinal product by presentation, according to court judgments[29].

The intention of the definition of medicinal product by presentation is to protect consumers from products that do not have the effectiveness they may expect from them and from a variety of products used instead of the proper remedies [48, para.17, 49 para.42]. Therefore, ECJ ruled initially in 1983, in a fundamental first case concerning borderline products (C-227/82 - "van Bennekom" [48]), *"when any averagely well-informed consumer gains the impression"* [48, para.18] that a product has the property to prevent, treat or cure human disease, which *"may even result from implication"* [48, para.18], only, the product is considered a medicinal product by its presentation. Furthermore, ECJ judged in another case (C-369/88 - "Delattre" [50]), a product is to be considered a medicinal product by its presentation, *"if its form and the manner in which it is packaged render it sufficiently similar to a medicinal product"* [50, para.41], which includes not only the packaging but also other information provided, references made to pharmaceutical research laboratories or the use of

[28] The term borderline products was used initially in recital (7) of Directive 2004/27/EEC [53] and refers to products, that due to their nature or presentation, do not clearly belong to a specific legal area and for which it is therefore difficult to define the reference regulations to be applied [47]. Most doubts arise between medicinal products and FSMP, food supplements, cosmetics, biocides or medical devices. Although each of these categories is explicitly regulated on the EU level, their definitions often overlap and thus implicate legal uncertainties [42].

[29] C-227/82 - "van Bennekom" [48] para.18; C-369/88 - "Delattre" [50] para.41; C-219/91 - "Wilhelmus Ter Voort" [51] para.39.

testimonials from medical practitioners. It is basically not relevant if the product in fact has any pharmaceutical properties. If only *"a product expressly indicated or recommended as having therapeutic or prophylactic properties"* [51, para.18] it shall be regarded a medicinal product by its presentation *"even if it has no known therapeutic effect"* [51 para.18, 52 para.18]. This also includes the dissemination of information about the product, such as publications or brochures sent upon request after the purchase from FBOs or even from third parties when these do not act completely independently [51], whereas the averagely well-informed consumer shall be considered as the addressee of the presentation [48].

According to the Commission, products containing omega-3 fatty acids and *presented* to prevent cardiovascular disease or products containing zeaxanthin or lutein and *presented* to treat age-related macular degeneration are examples that shall rather be classified as medicinal products than as FSMP, since, even if they are labelled with *for the dietary management of …*, averagely informed consumers could perceive these products were able to prevent or treat diseases [27]. This indicates that from the Commissions perspective many FSMP with drug-like appearances in the market today may be rather seen as medicinal products – due to their overall presentation and the intention consumers may receive.

b) Demarcation from Medicinal Products by Function

Secondly, FSMP is not allowed to *function* as a medicinal product, in particular it may not exert *a "pharmacological, immunological or metabolic action"* [45, Art.1(2)(b)] to modify physiological functions. These modes of action have been added to the definition of medicinal products in 2004 to facilitate the demarcation from borderline products according to recital 7 of Directive 2004/27/EEC [53]. However, over the last years it has been discussed comprehensively amongst experts if these mechanisms of action can be attributed to medicinal products, only. Moreover, they have not yet been defined legally-binding, but definitions are only proposed[30] (compare Annex IV, p.72).

According to Racchi et al. *"ambiguity arises first from the lack of a defined demarcation between a mechanism of action and the connected reaction by the human body and also from the lack of an analysis of the essential characteristics of the pharmacological, immunological, or metabolic mechanisms of action"* [55, sect.3.1]. While it would be necessary to establish objective criteria for a demarcation between pharmacological and nutritional activity, the practical experience illustrates that in borderline-cases this is not feasible from a scientific view. Instead, research reveals that food also exerts activities that were previously only known from medicinal products, such as to induce or inhibit enzymes,

[30] A Commission Guidance to Medical Devices (MEDDEV 2.1/3 rev. 3 [54] provides definitions of these terms, which, however, are not legally binding – herein 'pharmacological means' refers to an interaction between a molecule and a cellular constituent (receptor) and a dose-response correlation is indicative for pharmacologic al effects; it has been referred to this proposal in a court judgment already (Case C-308/11); Racchi et al. [55] suggest further specifications (see Annex IV, p.72)

function as receptor antagonist or influence gene expression[31] [6]. Moreover, current scientific knowledge indicates, that to *any* stimuli *"the body always responds with pharmacological, immunological, or metabolic means"* [55, sect.3.1]. Thus, in light of latest scientific findings and with the rise of special food products claimed to have additional health benefits the distinction from medicinal products gets increasingly difficult since the transition of effects seems to be fluent. Ongoing legal insecurity remains particularly due to the fact that *pharmacological action*, which is currently seen as the most important decisive criterion between food and medicinal products from courts [56], has not been defined by EU legislation. Research to develop legal definitions and thresholds based on benchmark doses and science is ongoing [55, 57].

According to ECJ[32], to define a medicinal product by function, case-by-case analyses have to be done, taking into account "*the manner in which it is used, the extent of its distribution, its familiarity to consumers and the risks which its use may entail"* [58, para.30] as well as *"its composition, its pharmacological properties to the extent to which they can be established in the present state of scientific knowledge"*, amongst others [59, para.51]. A general systematic approach, as it was once applied in Germany, when all vitamin preparations were classified as medicinal products if they contained more than three times the recommended daily amounts, has been criticised by EJC and judged not reasonable [60].

One ECJ ruling in 2007 against the Federal State of Germany, who refused an application to import garlic extract capsules as a food supplement, since similar products were in the German market as medicinal products, was of particular interest (C-319/05 - garlic case [49]). Here, EJC judged that a product which, when taken in its recommended dosage, results in the same effect like conventional garlic in reasonable amounts, does not have a *significant* effect on the metabolism and shall therefore not be classified as a medicinal product by function [49, para.68]. While pharmacological properties of garlic extract were well-known, EJC referred in their decision to a former case ruling (C-112/89 - Upjohn [52]) that already decided the legal definition of medicinal products by function is broad enough to also include products which, "*although they are capable of having an effect on bodily functions have in fact another purpose"* [52, para.2], and that products shall not be recognised as medicinal products, if they, *"do not significantly affect the metabolism and thus do not strictly modify the way in which it functions"* [52, para.22]. EJC continued the definition of medicinal products by function shall cover products *"whose pharmacological properties have been scientifically observed and which are genuinely designed to (…) restore, correct*

[31] Hahn, Ströhle A, Wolters M: Deutsche Apotheker Zeitung Nr. 45, 144. Jahrgang, 5111-5126, 4.11.2004, and Hahn A, Ströhle A, Wolters M: Ernährung – physiologische Grundlagen, Prävention, Therapie, 2. Auflage, Wissenschaftliche Verlagsgesellschaft, Stuttgart, 2006; cited in [6]

[32] Case C-60/89 – "Monteill and Samanni" [58]; Joint Cases HLH Warenvertriebs GmbH (C-211/03) and Orthica BV (C-299/03 and C-316/03 to C-318/03 [59].

or modify physiological functions" [49, para.61] while products *"whose effect on physiological functions is no more than the effects of a foodstuff consumed in a reasonable quantity"* [49, para.68] cannot be rated as capable of restoring, correcting or modifying body functions in the meaning of medicinal products. Thus, it is recognised by ECJ meanwhile that food exerts similar modes of action like medicinal products and *significance* became an important criterion. However, materiality thresholds or a definition of significance has not been defined by the court in this context.

A following ruling in 2008 (C-140/07 - red rice case [61]) decided similar that the definition of medicinal products does not apply to a product that *"if used as intended, is incapable of appreciably restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action"* [61, para.45] and further that it *"does not apply to a product in respect of which it has not been scientifically established that it is a medicinal product by function"* [61, para.29]. Accordingly, ECJ ruled a product can only be considered a medicinal product by function if its pharmacological, immunological or metabolic activity based on the intended use and dosage is *significant* by means to be able to restore, correct or modify physiological function, and further this significant effect has to be *scientifically established*. In other words, if a product's significant activity based on the recommended dosage has not been proven (yet), or if no minimal therapeutic dosage is established, it should not directly be considered a medicinal product. This ruling made it harder to define a product in case of doubt as a medicinal product pursuant to Article 2(2) of Directive 2001/83/EC. It even arose the question if this judgment means the reversal of the rule of doubt [62], and some rate this rule meaningless and useless, already [42].

Latest judgments[33] clarified that the proven, significant pharmacological activity of a product also has to be "*beneficial*" [63, para.38] and "*therapeutic"* [63, para.47] to regard it as a medicinal product by function. A therapeutic effect is regarded an *appreciable* modification of physiological functions. A solely negative modification of body functions is not considered pharmacological activity.

In conclusion, the criteria to define a product as medicinal product have been further developed by EJC rulings, as summarized in Table 1 (p.28). The interpretation of a medicinal product by presentation is broad and seems to be rated high by the Commission. The demarcation from medical products by function continues to be difficult in case of products with ambivalent status since legislation is lacking a legal definition of pharmacological activity and thresholds to define minimum therapeutic dosages and clearly draw the borderline. Debates and research are ongoing and *"it remains possible that differences will continue to exist between Member States in the classification of products"* [27, para.41].

[33] C-358/13 and C-181/14 on legal highs [63]

Table 1: Criteria to define a product as medicinal product, developed by ECJ case law

Medical product by presentation	Medical product by function
– Form and packaging of a product – Descriptions of the product (indication of therapeutic properties) – Place of distribution – Impression averagely well-informed consumers gain – Dissemination of information about the product – References to medical or pharmaceutical research institutes or medical practitioners or use of such testimonials	– Composition – Pharmacological properties; the extent to which they are established in current state of scientific knowledge (significant by means to be able and genuinely designed to appreciably restore, correct or modify physiological functions, based on the intended use/dosage) – the manner in which it is used, the extent of its distribution, its familiarity to consumers and potential risks to health

The current practice remains to consider all characteristics of a product in question on a case-by-case basis to evaluate the correct classification. In terms of borderline products, like FSMP, FBOs are left with legal insecurity and advised to follow further developments of relevant court decisions and scientific research in order to ensure to always be up to date when deciding the classification of their products.

In a so-called „non-Paper" in 2014[34] the Commission listed various product examples difficult to demarcate due to their compositions or indications, which constitutes a kind of *black list* since these products are to be observed further [64] which FBOs shall also take into account. So far only two examples are mentioned in COM Notice that shall rather be considered as medicinal products than FSMP (omega-3 fatty acids/cardiovascular disease and zeaxanthin or lutein/age-related macular degeneration). However, these two examples indicate that the Commission rates high what impression consumers perceive from a products presentation. It needs to be awaited if further, similar assessments of listed products will follow and if their interpretation will eventually be equally supported by court decisions – which could largely affect the current market of nutritionally-incomplete FSMP in drug-like dosage forms.

4.1.2 FSMP is specially processed or formulated

According to the definition FSMP is food that is *specially processed or formulated*. These notations are explained in more detail in COM Notice. Accordingly, "*FSMP is the result of a specific and voluntary effort of the manufacturer to realize a product for a specific intended use",* [27, para.46]. *Specially processed* in the Commissions opinion, pointing to a legal

[34] EU Food Policy May 16, 2014, p. 1; cited in [64]

definition on 'processing'[35] provided in Regulation 852/2004, shall refer to the manufacturing stages that substantially alter the initial product in order to make it suitable for the intended purpose, namely for the dietary management of the patients they will be directed at [27]. This can be the modification of consistency to improve the swallowing, for instance. BVL/BfArM mention the hydrolysis of food protein with the aim to select certain amino acids, or the transesterification of fats as further examples [28].

The Commission clarifies that *specially formulated* refers to the theoretical development of the product including the choice of selected ingredients to formulate a receipt that is suitable for the dietary management of the intended patient groups, such as foreseeing their specific needs. A product may be either specially processed or specially formulated or both to comply with this definition element. However, if it did not undergo any specially processing and has not been specially formulated, either, such as it would be the case with products occurring in their pure natural state, it cannot be considered a FSMP, although this shall not preclude that FSMP formulations may contain ingredients in their natural states [27].

4.1.3 FSMP is intended for Patients – and Demarcation from Food Supplements

Another criterion from the FSMP definition is the target group for whom it is intended. First, FSMP is intended *for patients.* This illustrates FSMP is not intended for the healthy population [27]. Since it is for patients, FSMP is also to be used under medical supervision. This qualifier is of relevance to distinguish FSMP from food supplements, which is another legal category of food and marketed in similar dosage forms like some FSMP (i.e. capsules, tablets). Therefore, they are very close to each other. However, different legislation applies to them and htherefore their demarcation is important. Directive 2002/46/EC [65] defines food supplements as:

> *"'(…) 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"* [65, Art.2(a)].

From this definition the purpose of food supplements is to supplement the normal diet. While some years ago it was still discussed whether food supplements are considered as part of the normal diet from EU legislator or not (compare [8], p.112-118), today and specifically in the context of FSMP and for the criterion *modification from the normal diet*, as will be seen later (sect.4.1.5, p.36), the Commission clarifies that food supplements by supplementing the

[35] "'processing' means any action that substantially alters the initial product (…)", Art. 2(1)(m) of Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs, OJ L 139, 30.4.2004, p.1

normal diet become part of the normal diet [27]. Contrary, FSMP is not part of the normal diet but a food intended for the special diet of specific patients, only. Food supplements, as agreed on by experts today, are primarily intended for the normal, healthy population [66]. Neither do they have a regulatory requirement to meet any specific purpose, nor do they need to be intended for a specified group. It is basically not relevant if consumers have a specific need or if the food supplement benefits them at all – as long as it is safe food [6].

a) What Patients are appropriate in the Context of FSMP?

Since the term *patient* that makes one of the qualifiers to distinguish FSMP from food supplements (or other foodstuff) is not thoroughly defined by the relevant legislation[36], different opinions persist on the question what kind or degree of a disease, disorder or medical condition qualify persons suffering from it as appropriate patient groups in the context of intended patients for FSMP.

Regulation 2016/128 establishes in its recitals that FSMP *"is developed in close cooperation with health care professionals to feed patients affected by or malnourished because of a specific diagnosed disease, disorder or medical condition that makes it impossible or very difficult for those patients to satisfy their nutritional needs through the consumption of other foods"* [35, recital 3]. Thus, patient groups may be considered appropriate if persons are affected by a disease, disorder or medical condition that can be *specifically diagnosed* and that is *connected* to their inability to sufficiently meet their nutritional demands with normal food, only. The Commission equally states *"patients should be considered as people suffering from specific diagnosed diseases, disorders or medical conditions who, as a result (…) need to consume FSMP"* [27, para.49] and further interprets recitals 4 and 5 of the Delegated Act to conclude: *"flexibility is called for when reflecting on the specific disease/disorder/medical condition"* [27, para.72]. Hence, while the interpretation shall be narrow on the one hand, in terms that only diseases or medical conditions are appropriate that can be linked to the specific nutrient demand of patients and result in a need to consume FSMP, the Commission reinforces the importance to maintain flexibility beyond that. Some examples of diseases considered appropriate to be addressed from FSMP are provided in COM Notice (see also sect.4.1.3.b, p.32).

EFSA states *"the concept of 'patient' has to be interpreted in a broad way"* [38, p.7] and establishes definitions on the terms 'patient', 'disease/disorder' and 'medical condition' to be applied in the context of EFSA Guidance, whereas a patient is a "*person (…) affected by the disease/disorder or the medical condition"*, disease and disorder synonymous mean *"a pathological process, acute or chronic, inherited or acquired, of known or unknown origin,*

[36] 'patient', according to Pschyrembel, basically describes any ill person, who is suffering from a disease or symptoms of a disease, and who is under a physician`s care; Pschyrembel Klinisches Wörterbuch, 256. edition, de Gruyter-Verlag

having a characteristic set of signs and symptoms which are used for its diagnosis (…)", and 'medical condition' is defined as *"any structural or functional alteration, either acute or chronic, which may result from one or more diseases or disorders"* [38, p.11]. Further, diseases/disorders and medical conditions in this context shall require to be managed with nutritional interventions *under medical supervision*. EFSA lists positive examples for adequate diseases/disorders and medical conditions in non-exhaustive lists, such as Crohn's disease, phenylketonuria or liver failure/dysphagia/respiratory failure/short bowel syndrome resulting due to different reasons, or disease-related malnutrition resulting from cancer or inflammatory bowel disease, for instance [38, Fn 14,15; p.11]. Hence, EFSA supports the interpretation of appropriate patients for FSMP providing definitions of terms that are not otherwise legally defined and with non-exhaustive lists of diseases/disorders or medical conditions that are considered appropriate to be managed with FSMP.

BVL/BfArM quote Kügel/Müller/Hofmann[37] stating that healthy consumers who are only occasionally affected from non-pathological disorders or conditions of everyday life, such as menstruation, pregnancy, senility or fatigue, if they do not exceed normal values, would not be regarded as appropriate target group in context of FSMP. In their opinion a patient has to be clearly assigned to a specific, diagnosed disease since only based on a clear assignment a special nutritional requirement could be defined. BVL/BfArM mention *tumor patients* or *patients with cardiovascular disease* as not sufficiently specified patient groups and state that if a specific nutritional demand is present in such groups, at all, the concrete dietary need could vary significantly within a group. As positive examples they list *patients with phenylketonuria with specific protein demand* or *patients with renal failure and protein restriction* [28, part 4.1]. However, Diätverband rates for this narrow interpretation of the law, concluding that a specified patient group even needs to be further concretised – such as directing FSMP towards special cases within an indication, as their example *patients with phenylketonuria with specific protein demand* could imply – a legal basis does not exist [39].

It is currently not required to assign patient groups that FSMP shall be intended for to a strictly defined, diagnosed disease or medical condition according to ICD catalogue[38] in every case. However, too broad or vague indications, such as fatigue symptoms, lack of concentration or immunodeficiency will probably not be sufficiently specific [67], either. Important is, however, to consider all other details, including those that specify the patient groups further, as follows.

[37] Kügel/Müller/Hofmann; Arzneimittelgesetz - Kommentar; C. H. Beck, 1. Auflage, § 2, Rn. 173 and Rn. 79 (2012); cited in [28], part 4.1, para.2

[38] WHO´s International Statistical Classification of Diseases and Related Health Problems

b) Specific Patient Groups

Continuing reading the FSMP definition, the target group does not compromise all but specific patients, only, in particular those either suffering from

a) *"a limited, impaired or disturbed capacity to take, digest, absorb, metabolise or excrete ordinary food or certain nutrients contained therein, or metabolites"* or having
b) *"other medically-determined nutrient requirements".*

Any patient not falling into one of these two groups does not fall within the scope of FSMP.

The first group basically describes patients with different types of impaired food intake or utilization. FSMP addressed to them could supply suitable nutrients to compensate a higher demand of certain nutrients, or aim to avoid certain nutrients, or provide nutrients in a more suitable dosage form, such as liquid. The EFSA Guidance lists possible reasons to substantiate FSMP for this group in section 4.2(a)-(e), such as the inability or reduced ability to chew and/or swallow, or to digest foodstuffs that are not FSMP, or the inability/reduced ability to absorb, metabolise and/or utilize or to excrete nutrients contained in foodstuffs that are not FSMP [38]. The Commission provides concrete examples of diseases/medical disorders for this group in a non-exhaustive list (para.55), additionally. The Commission indicates an inability to take sufficient quantities of ordinary food could be due to mechanical impairments or swallowing difficulties linked to a disease, condition or injury, such as head and neck cancer, or that an inability to adequately digest or absorb normal food could result from an impaired gastrointestinal tract due to short bowel syndrome or a treatment, like gastrectomy, for example [27].

The second group of patients shall have a specific nutrient requirement due to *other* medically-determined causes, hence not due to a reason included in the possible reasons of the first group. This part of the definition leaves more scope of interpretation and thus leads to more discussion and divergent opinions. Contrary to the first group, no list with particularly appropriate reasons for the second group is provided in EFSA Guidance. However, the Commission comments *other medically-determined nutrient requirements* shall refer to specific nutrient requirements taking into account the definition of 'nutrient' given in Regulation (EU) No 1169/2011[39] since it is not defined in the specific law, and shall further be based on medical evidence and be associated with the specific disease/disorder/medical condition of the patients for whom the FSMP is intended. As examples the Commission lists *"increased requirements for protein or other specific nutrients (e.g. glutamine) in patients pre or post-surgery, with severe wounds, burns or pressure sores or in patients suffering from specific diseases (e.g. vitamin A for patients suffering from cystic fibrosis)"* [27, para.55].

[39] Regulation (EU) No 1169/2011 in Article 2(2)(s) defines 'nutrient' as "protein, carbohydrate, fat, fibre, sodium, vitamins and minerals" as listed in its Annex (in point 1 of Part A of Annex XIII) and substances which belong to or are components of those categories

c) Is a Causal Relation required?

The term *medically-determined* could be interpreted in a broad perspective. In 2008, for instance, BGH judged[40] a case concerning FSMP that supplied patients suffering from inflammatory joint disorders with Omega-3 fatty acids, whom in the consequence could reduce their amount of anti-inflammatory drugs. BGH concluded this was a *medically-determined nutrient requirement* since the patients had a benefit [28, p.10]. However, according to BVL/BfArM a clear cause-effect relation should be present and only if a disease/disorder or medical condition is *causal* for a specific nutrient requirement this nutrient demand could be considered medically-determined [28]. Diätverband on the other hand reconfirms the view of BGH and refers to Article 2(2) of FSMP Regulation that establishes the use of FSMP shall be *beneficial* to the patients. Neither the FSMP Regulation nor the Commission's Draft to COM Notice [68] provide statements indicating a requirement to prove a causal relation and thus no legal basis exists to substantiate BVL/BfArM's opinion in this point. Instead, BGH clearly ruled that no detailed scientific proof of efficacy or evidence of efficacy of every single ingredient is required to substantiate FSMP but rather the resulting benefit from a product would be sufficient. Diätverband adds that also from current practice a cause-effect relationship would not be established prior to nutritional interventions. The nutritional status of patients instead is determined applying screening methods and from that adequate dietary intervention is deduced. Finally, it is referred to the fact that according to EFSA Guidance's listing (in its section 4.2) the *leading of a disease, disorder or medical condition to a specific dietary requirement* only represents one out of eight possible options to adequately reason a products status as FSMP with regard to the characterisation of patients [39]. Thus, a cause-effect relationship is not legally required.

In conclusion, the legislation leaves some scope of interpretation concerning what kind or degree of a certain disease/disorder or medical condition is appropriate in the context of FSMP target groups, in general – as long as all other aspects of the FSMP definition are considered – and thus, preserves flexibility for the development of products for heterogeneous patient groups. Patients do not necessarily need to be assigned to clearly diagnosed diseases or medical conditions such as according to ICH catalogue. However, FBOs should remember, in case they are requested to provide scientific data according to EFSA Guidance, information on the extent to which a disease/disorder or medical condition is sufficiently characterised and details on the specific patient group addressed, to distinguish them from persons not in need of the FSMP, shall be provided, nevertheless.

An important criterion for a disease or medical condition to be appropriate for FSMP clearly is the association to a specific nutrient demand that makes the nutritional intervention with FSMP necessary. A cause-effect-relation is not legally required. Positive examples of

[40] BGH decision on MobilPlus from 2.10.2008, I ZR 220/05 [23]

diseases and medical conditions are provided in non-exhaustive lists in COM Notice and EFSA Guidance, while the so-called black list may indicate problematic indications for FSMP, such as Alzheimer's or psoriasis. In general, products that are intended for the healthy population, or addressing unpleasant conditions of everyday life, such as fatigue or a lack of concentration or energy, should rather be marketed as food supplements than as FSMP.

4.1.4 The Intended Purpose of FSMP is the Dietary Management

The intended purpose of FSMP is *the dietary management* of patients by their definition. This definition element further strengthens their legal separation from medicinal products or food supplements. However, since the concept of dietary management is not legally defined, it remains part of ongoing discussions.

Reading the details of the FSMP definition comprehensively shall help to understand the concept. First, FSMP is always directed to patients, more precisely to specific patients as addressed above, and the specific disease or medical condition results in an inability to sufficiently meet specific nutrient requirements without FSMP. Therefore, FSMP aims to provide nutritional support to patients for whom their consumption is *"nutritionally necessary*" [27, para.56]. The Commission refers to recital 3 of Regulation 2016/128 which would summaries the concept well, stating FSMP *"is developed (…) to feed patients affected by or malnourished because of a specific diagnosed disease, disorder or medical condition that makes it impossible or very difficult (…) to satisfy their nutritional needs through the consumption of other foods (…)"* [35, recital 3]. According to the Commission, stakeholders shall consider on a case-by-case basis how impractical, impossible, unsafe or nutritionally or clinically disadvantageous it would be for the patients if they could not consume FSMP, since the purpose *dietary management* contains a certain *need* of the product[27].

BVL/BfArM publish a very strict opinion regarding the interpretation of the concept. They assume the change of wording concerning the intended purpose statement of FSMP in German *(Zur diätetischen Behandlung von …* changes into *Zum Diätmanagement bei …*, as outlined in Section 4.3.6.b (p.48)) implies that no therapeutic treatment, but only interventions in the area of nutrition shall be covered from the purpose of FSMP [28]. Further, they provide a figure wherein product categories are assigned in relation to different statuses of nourishment (Figure 3). Accordingly, if an *optimum or normally* status is present, products would belong to food for a normal consumption, like food supplements. If a *clinical deficiency* of nutrients exists, it could only be treated with medicinal products. FSMP, having a specific nutritional and physiological effect, would serve to *maintain* a normally nourished status of patients for whom they are intended.

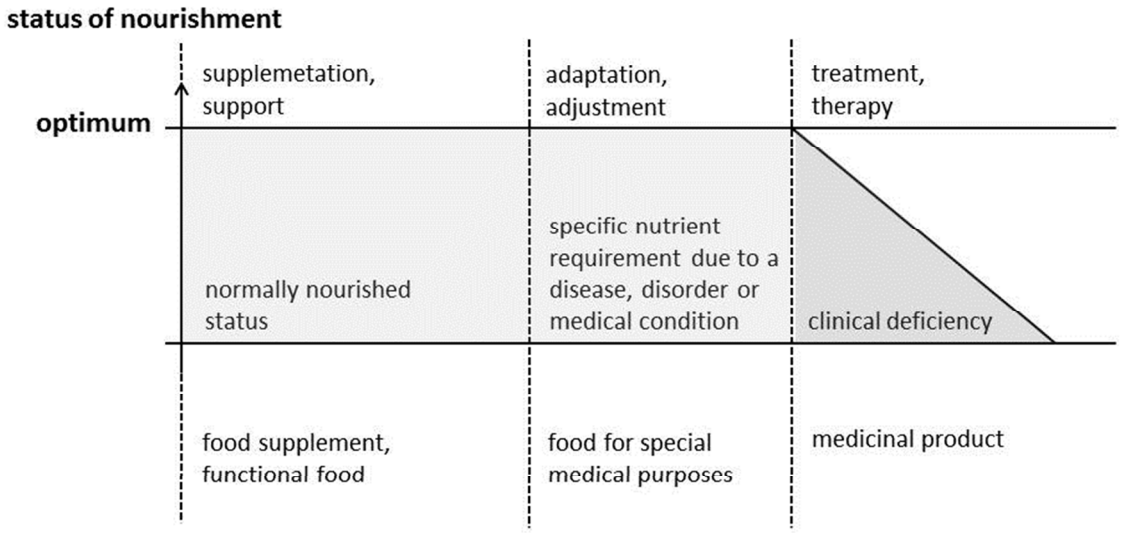


Figure 3: Stages of Nourishment – modified from BVL/BfArM, [28, p.13]

In BVL/BfArM's opinion, a clinical deficiency of a specific nutrient cannot be treated with nutritional intervention but only with medicinal products. After a sufficient treatment with medicinal products, when a normally nourished status is achieved again, it could be maintained with food supplements or FSMP. BVL/BfArM do not see their interpretation against recital 3 of Regulation 2016/128 indicating that FSMP is also intended for patients *malnourished* due to a specific diagnosed disease since these cases of malnourishment would only refer to nutrient deficiencies caused from the certain disease and in such cases it would be difficult or impossible to meet the demand with normal food. Furthermore, in such cases a treatment with medicinal products would not stringently be required (yet) and nutritional intervention with FSMP would also be applicable to eliminate the deficiency. However, they conclude in general a clinical deficiency of a nutrient cannot be handled with nutritional intervention, only and as such would be *"an indication for the application of a medicinal product"* [28, p.12, translated from the author].

Diätverband criticises these interpretations would neither be oriented to current law nor consider generally accepted scientific guidelines, such as those from DGEM[41] or ESPEN[42]. These guidelines define different forms of malnutrition and recommend appropriate, scientifically based nutritional interventions that explicitly include FSMP for the management of disease-related malnutrition. The separation of three stages of nourishment and the associated assignment of product categories thereto would neither be legally correct nor sustainable from current scientific knowledge and thus could not be regarded appropriate to be applied for the demarcation of FSMP from food or medicinal products [39].

[41] The German Society for Nutritional Medicine (in German: Deutsche Gesellschaft für Ernährungsmedizin, DGEM)

[42] European Society for Clinical Nutrition and Metabolism (ESPEN)

Similar, Hermann illustrates that from current scientific understanding nutrition clearly has a central role in the development of various diseases which led to the insight that its effects go beyond the plain fulfilment of nutritive demands and rather include the prevention or improvement of diseases and medical conditions, and therefore the interpretation of the intention of FSMP could be rather broad. While the prohibition to advertise food with disease-related claims shall just protect consumers from misleading information, it may however be possible a food contributes to a therapeutic benefit [8]. The transition of effects are fluent and according to Zipfel/Rathke[43] a separation between treating/healing effects and nutritional activity is barely possible – instead does the supply of specific nutrients constitute a part of the treatment itself and sometimes even the only one.

Hence, the purpose *dietary management* emphasises to meet specific nutrient demands of patients for whom FSMP is *necessary* and while it may not be the primary focus to treat diseases or medical conditions, from current scientific knowledge it is clear that the effects of nutrients cannot be separated from contributing to therapeutic benefits, either. Rather can the supplementation of necessary nutrients in the context of dietary management make an important part of the treatment of patients, as also indicated from wordings used in context of FSMP in praxis, like *medical nutrition therapy*. An important aspect of the concept of dietary management is the necessary role of FSMP, in particular that it meets specific nutrient demands that cannot be otherwise achieved, as will be further detailed in the following.

4.1.5 Modification of the Normal Diet

The requirement that FSMP is intended for patients whose dietary management *cannot be achieved by modification of the normal diet alone,* the so-called *clause of subsidiarity* [39], has slightly changed in words in comparison to the previous definition of FSMP, where it was stated the dietary management *“cannot be achieved only by modification of the normal diet, by other foods for particular nutritional uses, or by a combination of the two”* [12, Art.1(2)(b)]. However, it shall still describe, in a simpler way, that all possible ways to manage a patients’ diet through foodstuff other than FSMP shall be considered when evaluating the possibility to modify the normal diet, including food supplements (within the meaning of Directive 2002/46/EC) and fortified foods[44] (falling within Regulation (EC) No 1925/2006 [69]), according to the Commission [27]. This is in line with earlier interpretations from EFSA, stating a *"modification of the normal diet (…) should be considered as any adjustment to the diet through consumption of foods other than FSMPs and can include use of food*

[43] Zipfel/Rathke C 140, §1 DiätVO, Rdnr. 11 a; Klaus, Der gemeinschaftliche Lebensmittelberiff, p. 85; cited in [8], p.88

[44] ‘fortified food’ means foodstuff to which vitamin(s), mineral(s), other substances , or a combination of them have been added

supplements or fortified foods" [38, p.7, Fn 11]. The change in words, which is formally consistent with the abolishment of the PARNUT concept, thus has no practical impact [39] on the interpretation of the definition or products in scope. Accordingly, to put it the other way around: If a specific nutrient requirement of patients for whom a product is intended can sufficiently be met with any foodstuff that is not FSMP, a product cannot correctly be classified as FSMP.

However, the Commission emphasises that a possible modification of the normal diet shall also be realistic and practical [27]. For instance, if a requirement of a certain nutrient is much higher than that of the healthy population, and the patients would require dozens of food supplements to meet their specific demand, it would not be considered practical. The phrase *cannot be achieved by modification of the normal diet alone* should therefore be *"interpreted restrictively, but not to the extent of an absolute impossibility"* [27, para.69]. It shall rather be assessed *to what extent* it would be impossible to satisfy the specific nutritional requirements without FSMP and weather and how the use of FSMP would be more practical, safer or nutritionally/clinically advantageous for the patients, considering the stage of development or severity of the disease, disorder or medical condition, as well as the impact on the patients' health, or how the product differentiates from other foodstuff [27]. These details are equally addressed in EFSA Guidance in parts 4.2, 4.3 and 5, as outlined (see sect.4.5.2, p.52).

In a former draft to COM Notice [68] it was stated that FSMP is the only residual category of food for the patients whom they are intended for, as there is no chance with a normal diet to meet their special nutritional needs, and the term *last resort* has been applied. This provides a strong and memorable picture of the meaning of FSMP and of the concept *modification from the normal diet*. However, this wording has not been transferred to the final version of COM Notice – maybe it appeared overly dramatic.

BVL/BfArM illustrate diabetes mellitus Type 1 or hyperlipidaemia as examples for diseases that, in light of current scientific evidence, could be sufficiently managed by the modification of the normal diet, solely. Accordingly, patients suffering from these diseases do not depend on FSMP and therefore products targeted to them could not be correctly classified as FSMP [28]. Similarly, products for patients with diabetes were also included in the black list of the Commission [64].

Consequently, to estimate the correct classification of a product as FSMP, FBOs have to decide based on their own assessment if a modification of the normal diet can be sufficiently handled by the patients addressed with other food products only, or if they regard it as impossible, impractical, unsafe or nutritionally/clinically disadvantageous. Thus, a scope of interpretation remains. The Commission explicitly clarified that food supplements and fortified foods shall be considered as part of the normal diet in this context.

4.1.6 Summary and Checklist: Does a Product meet the Definition of FSMP?

To correctly place FSMP on the European market it primarily has to comply with the legal definition currently given in Article 2(2)(g) of Regulation 609/2013 which only changed slightly and without practical impact in comparison to the former one. Hence, the difficulties that arose with the interpretation of the previous definition are likely to last. Additional comments recently provided in relevant guidelines can help in the interpretation of the law, whereas COM Notice prevails over the BVL/BfArM Paper. The EFSA Guidance points out indicative criteria to estimate the extent to which a product in question fulfills the definition of FSMP.

Table 2: Checklist: Does a Product meet the Definition of FSMP?

To be correctly classified a FSMP a product needs to fulfill all of the following criteria:

- ✓ It is a *food* as legally defined and clearly does not meet the definition of a medical product or another product, i.e. food supplement.
- ✓ It is *specially processed or formulated* and its specific properties are not due to a pure natural composition.
- ✓ It is intended *for patients*
  a) with a limited, impaired or disturbed capacity to take, digest, absorb, metabolise or excrete ordinary food or certain nutrients contained therein, *or*
  b) with other medically-determined nutrient requirements,

  neither for the general, healthy population nor for patients that do not fall within one of these two *specific patient groups*.
- ✓ The *intended purpose* of the product is the *dietary management* of the patients.
- ✓ The specific nutritional requirements of the patients addressed *cannot be achieved consuming other foodstuff than FSMP exclusively;* it is *impossible, impractical, unsafe or nutritionally/clinically disadvantageous* for them – whereas a modification of the diet shall be considered including food supplements and fortified foods.

Overall, in some definition elements scope of interpretation remains and so does legal insecurity. Especially the demarcation from medicinal products continues to be difficult in case products have an ambivalent status, since *pharmacological activity* and thresholds clearly indicating medicinal products by function have not been legally defined. When reflecting the questing if a product is appropriately classified as FSMP, FBOs must keep in mind that the FSMP definition as a whole and as seen within the context of relevant provisions, coherently, is of relevance. What constitutes FSMP shall be interpreted narrowly, such as that a specific nutritional demand shall be associated with the disease or medical condition addressed and that the patients affected cannot meet this requirement adequately with any other foodstuff than FSMP. With regard to the latter, the Commission clarifies that food supplements and fortified food are part of the normal diet, in this context. However, to demarcate FSMP from medicinal products, ongoing research and developments of relevant court decisions still have to be considered in addition to the law and guidelines.

4.2 Substances and Amounts

Whereas the former relevant law, Regulation 953/2009, used the term *nutritional substances*, FSG Regulation, that repealed Regulation 953/2009, applies *substances*. Both terms are not legally defined and reading the relevant provisions in a whole reveals that this change of words does not impact the requirements on substances in FSMP. Currently, FSG Regulation establishes the general provisions on substances and provides a positive list (Union list), while the delegated acts set further rules and list maximum and minimum values for vitamins and minerals.

4.2.1 General Provisions

According to Article 6(1) of FSG Regulation, FSMP needs to comply with any general provision according to Union law applicable to food. Provisions given in Regulation 609/2013 prevail over conflicting requirements pursuant to its Article 6(2).

FSG Regulation establishes the composition of FSMP shall be *"appropriate for satisfying the nutritional requirements of, and is suitable for, the persons for whom it is intended (…)"* [29, Art. 9(1)]. Further, pursuant to Article 9(2), FSMP may not contain substances that endanger the target patients and, in case of engineered nanomaterials, compliance with Article 9(1) shall be demonstrated. Substances used in the formulation with the intention to satisfy the nutritional requirement of target persons shall finally be *"bio-available for use by the human body, have a nutritional or physiological effect and be suitable for the persons for whom the food is intended"* [29, Art.9(3)], in accordance with generally accepted scientific data.

A single list or *Union list* of substances that meet the requirements of FSG Regulation is established in its Annex pursuing to its Article 15(1). The list fully corresponds with the previous listing of permitted substances set out in Regulation 953/2009 and so far only contains six categories of substances: (1) vitamins, (2) minerals, (3) amino acids, (4) carnitine and taurine, (5) nucleotides, (6) choline and inositol. Categories of substances may be added or removed *"in order to take into account technical progress, scientific developments or the protection of consumers' health"* [29, Art.15(6)]. Pursuant to Article 15(7) substances belonging to categories not listed in the Union list but complying with Articles 6 and 9 and, where applicable, with specific requirements may also be added to FSMP. In other words any substance beyond substance categories of the Union list that complies with the rules on substances applicable to FSMP is permitted in its composition.

The Regulation leaves FBOs much flexibility to choose suitable ingredients to formulate FSMP. However, especially to comply with the provisions of its Article 9 can be challenging. According to Article 9(3) the substances shall have a *nutritional or physiological* effect. As demonstrated earlier (compare sect. 4.1.1 b, p.25), in some cases it can be very difficult to

decide, if an effect due to a substance/amount is to be considered nutritional/physiological or pharmacological, since the modes of action and thresholds have not been legally defined.

4.2.2 Specific Provisions

The Specific Acts both establish equal provisions on the composition of FSMP, whereas it *"(…) 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 specific nutritional requirements of the persons for whom it is intended, as demonstrated by generally accepted scientific data"* [12, Art.3; equally 35, Art.2(2)]. Furthermore, they list the same minimum and maximum amounts of vitamins and minerals in their Annexes and apply similar rules with regard to amounts for nutritionally complete and nutritionally incomplete FSMP. Basically, maximum and minimum values of vitamins and minerals to add to FSMP are related to the energy value of the product. To allow deviations, which can especially be required in case of nutritionally incomplete FSMP, one or more vitamin/mineral may be modified in order to meet the specific nutritional requirements of target patient groups.
Hence, the specific provisions on substances in FSMP do not change. The EU legislator, according to the recitals of FSMP Regulation, rated the basic rules on vitamin and mineral content as established in the Directive have ensured an adequate framework for FSMP, so far and that adequate flexibility would need to be ensured due to rapidly evolving scientific knowledge, since the composition of FSMP *"may differ substantially depending (…) on the specific disease, disorder or medical condition (…), the age of the patients and the place in which they receive health care support (…)"* [35, recital 4] and based on whether the formulation is standard or specifically nutrient-adapted, amongst others.

4.2.3 National provisions in Germany

DiätV combines the general and specific provisions on substances as implemented from previous EU law. It lists permitted substances in Annex 2 and establishes the provisions on amounts of vitamins and minerals in FSMP in §14b in conjunction with Annex 6. Substances listed in FSG Regulation (Union list) but not yet in DiätV may also be added, since the Regulation is overlaying national law. As soon as Regulation 2016/128 is in force, FSG Regulation and FSMP Regulation will be the new references for permitted substances and amounts in FSMP in Germany, respectively – replacing DiätV as a reference. However, these are formal changes only without practical impact.

4.2.4 Guidelines and Comments

The Commission concludes that the Framework Law aims to maintain flexible rules to enable the development of innovative products for a large variety of patients and thus leaves the decision on the detailed composition of FSMP to FBOs [27]. The Commission furthermore

provides comments on the classification of FSMP, as laid down in Article 1(3) of Directive 1999/21/EC (in detail in sect. 2.1.2.a, p.7) and equally in Article 2(1) of Regulation 2016/128, to explain in more detail the impact of classification and composition, as follows:
In case of *nutritionally complete FSMP with a standard formulation* all necessary nutrients shall be included in its composition at appropriate levels in order to be able to replace a total diet if taken in adequate amount. *Nutritionally complete FSMP with a nutrient-adapted formulation*, by contrast, is supposed to consider specific nutritional needs linked to a disease or range of diseases/disorders or medical conditions, while such FSMP shall also be able to serve as a sole source of nutrition – hence shall supply all nutrients required from the specific patient group. Finally, *nutritionally incomplete FSMP* does not need to contain all necessary nutrients, which is also the reason why it cannot be used as the sole source of nutrition [27]. These explanations may support the understanding that FSMP in form of capsules or tablets will most likely belong to the third category, while enteral nutrition possibly falls within the first or second category (suitable to replace a full diet).

BVL/BfArM state that according to §7b(1) DiätV FSMP may only contain substances and amounts that meet the specific nutritional requirements of the patient groups for whom they are intended. From this they argue that any substance that does not meet the nutritional demand of the specific patients, such as adding general mixtures of vitamins without concrete relation to their nutritional needs, would not be permitted in FSMP [28]. Diätverband comments there is no legal basis for this interpretation of the law. Instead does the classification of FSMP explicitly include those with a *standard formulation* which can be seen as *"one size fits all"* [39, p.9]. BVL/BfArM already acknowledged that corrections are required in terms of this view in their paper [39].

4.2.5 Summary and Checklist: Permitted Substances in FSMP

In summary, EU legislation concerning substances/amounts in FSMP lays down only a few explicitly permitted substances according to currently six categories in a Union list and sets minimum and maximum amounts of vitamins and minerals. All other substances may be added to FSMP if they have a nutritional or physiological effect, are bio-available, safe, beneficial and effective for the persons for whom they are intended and the composition is appropriate to satisfy their specific nutritional requirements – according to generally accepted scientific data. The new legislation does not change significantly in comparison to the former law. FSG Regulation only introduces the requirement for substances to be *bio-available* (Article 9(3)) and explicitly considers *nanomaterials* (Article 9(2)), if suitable and appropriate. The Specific Acts basically establish the equal rules, each.

Table 3: Checklist: Permitted Substances in FSMP

- ✓ In general: Complying with Union law applicable to food if no prevailing law applies according to Article 6 FSG Regulation
- ✓ Currently six categories listed in Union list in Annex of FSG Regulation, *only to be used as specified*: vitamins, minerals, amino acids, carnitine and taurine, nucleotides, choline and inositol
- ✓ Vitamins and Minerals: *minimum and maximum amounts to be considered* according to specific provisions (Annexes of Directive 1999/21/EC, FSMP Regulation), taking into account the specific classification of FSMP

Any other substance (not a substance category in Union list) permitted if:

in accordance with Article 9 FSG Regulation, in particular:

- ✓ *Safe* for the patients for whom it is intended, including nanomaterial
- ✓ *Bio-available* for use by the human body, has a *nutritional or physiological effect* and is *suitable for the person for whom it is intended* – in accordance with generally accepted scientific data
- ✓ The composition of food is *appropriate for satisfying the nutritional requirements* – in accordance with generally accepted scientific data

and in accordance with specific provisions (Art. 3 of Directive 1999/21/EC, or Art. 2(2) of Delegated Regulation 2016/128, respectively), in particular:

- ✓ Based on sound medical and nutritional principles
- ✓ Its use, according to the manufacturer's instructions, is *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

Thus, FBOs still have to decide based on their own assessment if they regard other substances and amounts as nutritional or physiological taking into account current scientific knowledge and relevant court decisions. Legal insecurities remain since the modes of action and thresholds defining medicinal products by function, primarily pharmacological activity, have not been defined in EU law – which would allow a clear demarcation of food and nutritional or physiological effects of certain substances/amounts. Based on a strict borderline it would also be easier to extent the Union list. However, as long as the law is lacking the relevant definitions and no comprehensive positive list of substances is provided in harmonised EU law, it remains difficult in some cases to decide appropriate compositions of FSMP and may continue to lead to divergent opinions amongst Member States with regard to the correct classification. Consequently, a major aspect that resulted in different applications of the previous law (i.e. same product formulation but different opinions on classification), which also has been one reason for the implementation of a new legal framework, has not been solved, yet. The legislator declares due to the diversity of foods within FSMP and rapidly evolving scientific knowledge it would not be appropriate to establish more detailed compositional provisions. While the pleasant news to FBOs may be that they remain with a lot of flexibility which entails chances to develop innovative products, they are also left with uncertainties and eventually take the risks. For monitoring bodies the

flexible provisions on substances do not ease the performance of their legal obligations. However, in case of discrepancies on notified products amongst Member States concerning the classification of FSMP, they may initiate the new Article 3 procedure that could result in more harmonised views on substances and amounts in the future.

4.3 Labelling, Presentation and Advertising

4.3.1 General Provisions

First, the labelling, presentation and advertising of FSMP shall comply with any requirement of Union law applicable to food [29, Art.6(1)]. FSG Regulation further establishes, it *"shall provide information for the appropriate use (…), and shall not mislead, or attribute (…) the property of preventing, treating or curing a human disease (…)"* [29, Art.9(5)]. Accordingly, it is prohibited to present FSMP in a way that customers perceive it would be able to prevent, treat or cure diseases, as discussed (see sect. 4.1.1.a, p.24). The previous Framework Directive set an equal prohibition in Article 8(1). In comparison to the Directive, FSG Regulation introduced the term *"shall provide information for the appropriate use",* in this context. FSMP Regulation further clarifies the meaning of what information is considered relevant for the appropriate use in case of FSMP, as will be outlined, shortly.

According to Regulation 609/2013 it is still allowed to provide any useful information or recommendations that are exclusively intended for specific qualified persons, namely for those *"having qualifications in medicine, nutrition, pharmacy, or for other healthcare professionals responsible for maternal care and childcare"* [29, Art.9(6)]. Hence, defined qualified persons may still be supplied with information on the properties and characteristics of FSMP that go beyond those allowed to be directed to consumers. This could include information that would otherwise attribute properties to the product that could put it at risk for being considered a medicinal product or could be regarded a claim pursuant to Regulation 1924/2006. In comparison to Article 8(2) of Directive 2009/39/EC, which laid down similar provisions, the group of specified people is extended: Healthcare professionals responsible for maternal care and childcare have been added as specifically qualified persons.

Article 10 of FSG Regulation rules the labelling, presentation and advertising of infant food which aims not to discourage breast-feeding or to idealise the use of infant formula.

4.3.2 Specific Provisions: Legal Name

According to Article 4 of Regulation 2016/128 the name of the product (legal name) shall be as referred to in its Annex IV. Before, Directive 1999/21/EC set the name under which FSMP shall be sold in its Article 4(1). Comparing the list of names reveals that the name in German language, amongst others, needs to be changed, as will be outlined in detail in Section 4.3.6.a (p.47).

4.3.3 Specific Provisions: Mandatory Labelling Particulars

Specific rules on food information for FSMP are provided in Article 5 of FSMP Regulation. First, Article 5(1) clarifies, unless not otherwise established, Regulation 1169/2011 applies to FSMP. Therefore, FSMP has to comply with the provisions on mandatory labelling according to Article 9(1) of Regulation 1169/2011 (list of mandatory particulars) – also considering its Article 13(1) (easily visible, clearly legible, and indelible). In addition, no exceptional rule from Article 13(2) of FIR is set out in FSMP Regulation – hence, all mandatory information has to observe the defined font size. This is also required for additional mandatory information on FSMP [35, Art.5(3)]. Further mandatory labelling particulars are established in Article 5(2) and required to provide more complete information to patients and healthcare experts [35, recital 15]. These include:

(a) a statement that the product must be used under medical supervision;

(b) a statement whether the product is suitable for use as the sole source of nourishment;

(c) a statement that the product is intended for a specific age group, as appropriate;

(d) 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;

(e) 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;

(f) where appropriate, a statement concerning adequate precautions and contra-indications;

(g) 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;

(h) where appropriate, a warning that the product is not for parenteral use;

(i) instructions for appropriate preparation, use and storage of the product after the opening of the container, as appropriate.

The particulars referred to in points (a) to (d) shall be preceded by the words 'important notice' or their equivalent. [Art. 5(2) of Regulation (EU) 2016/128]

While Article 9 of Regulation 609/2013 prohibits to present FSMP in a way it attributes properties to prevent, treat or cure diseases to it, and Article 7 of FSMP Regulation prohibits to label claims (outlined shortly), Article 5(2)(a) of FSMP Regulation establishes that a statement *"must be used under medical supervision"* is required and Article 5(2)(e) of Delegated Regulation 2016/128 explicitly lays down to label the mandatory statement *"For the dietary management of …"* to be complemented by the disease, disorder or medical condition. In this context it is not only allowed but obligatory to associate the product with a disease, disorder or medical condition since it is required *lex specialis* [70] as a mandatory labelling particular according to specific law and thus not regarded a 'claim'.

Mandatory labelling should also not directly put FSMP at risk for being considered as a medicinal product, however, it seems to develop in a direction that in some cases they may nevertheless be regarded medicinal products by presentation (compare 4.1.1.a), p.24).

a) Pertinent Information

According to Article 5(2)(g) of Delegated Regulation 2016/128 a description of the properties and/or characteristics that make the FSMP product useful is mandatory. This paragraph changed in comparison to the former (an otherwise equal list of additional mandatory labelling particulars for FSMP is established in Article 4(3) and 4(4) of Directive 1999/21/EC). When FSMP Regulation applies, this description (hereafter referred to as pertinent information) shall be explicitly *"in relation to the disease, disorder or medical condition for the dietary management of which the product is intended"* [35, Art.5(2)(g)], and also, as the case may be, relate to "*the special processing and formulation"* [35, Art.5(2)(g)]. These two terms have been added and constrict the scope of interpretation of what shall be regarded a mandatory description within the context of pertinent information. It also specifies the intended meaning of the general term "*information for the appropriate use"* [29, Art.9(5)].

Before, Directive 2009/39/EC ruled that FSMP shall *"be accompanied by an indication of its particular nutritional characteristics*" [11, Art.9(2)] and Directive 1999/21/EC further specified it shall be labelled with *"a description of the properties and/or characteristics that make the product useful"* [12, Art.4(4)(c)]. This, however, could result in descriptions of nutritional properties or quality attributes by-passing the strict provisions on claims as defined and ruled in Regulation 1924/2006. Since that Regulation established a non-affection clause for PARNUT [26, Art.1(5)(a)], any obligatory labelling for FSMP was not judged a 'claim' as defined in Regulation 1924/2006 in Article 2(2)(1). This way, FBOs were able to label FSMP with descriptions very similar to claims but by-passing the Claims Regulation, while referring to the requirement of a mandatory description according to 4(4)(c) of Directive 1999/21/EC. To close this gap the new Specific Act more restrictively rules that only descriptions with a clear relation to the specific disease, disorder or medical condition shall be made as pertinent information.

Hence, FBOs should bear in mind that any description not directly linked to the specific disease will no longer be covered from specific law and may be considered a prohibited claim when FSMP Regulation applies. For example, a description that certain amino acids were removed in a product intended for the dietary management of patients with renal failure could be specifically related, whereas the information that the same product intended for the same patient group is characterised by a high content of dietary fiber would not. Consequently, products complying with FSMP Regulation will be stricter ruled regarding the pertinent information than those complying with the previous Specific Act.

4.3.4 Specifics Provisions: Nutrition Declaration

According to Article 29(2) of FIR a non-affection clause for PARNUT applied in terms of nutrition declaration. The Delegated Regulation now clarifies the applicability of the horizontal rules from FIR and establishes further specific rules on nutrition declaration in Article 6. Mandatory information in addition to the one referred to in Article 30(1) of FIR, the so-called *Big 7*, is given in Article 6(1) of FSMP Regulation. The provisions herein basically correspond to the previous ones set in Article 4(2) of Directive 1999/21/EC with the exception that some particulars that were formerly ruled from the Specific Directive, are now established in Regulation 1169/2011, such as rules on the declaration of nutritional values per portion. Besides the mandatory *Big 7*, the amounts of each mineral and vitamin present in the product and listed in the Annex of FSMP Regulation shall be labelled [35, Art.6(1)(a)]. The expression of energy value and amount of nutrients as a percentage of daily reference intake values as set in Regulation 1169/2011 is not allowed for FSMP, since the nutritional demands of intended patient groups differ from the general population [35, recital 16].

Diätverband recommends [71] to remain the order of nutrition declaration as listed in Annex XV of FIR, the amount of components of macro nutrients or other nutrients or components thereof may be added *"after the most relevant entry (…) they belong to"* [35, Art.6(7)] if they are *"necessary for the appropriate intended use of the product"* [35, Art.6(1)(b)]. Thus, specific nutrients may still be labelled if they are considered relevant for the appropriate use, which further specifies the intended meaning of Article 6(1) of FSG Regulation. Further, according to recital 15, the nutrition declaration is essential to guarantee the appropriate use of FSMP and therefore requires more details and is mandatory irrespective of the size of the packaging or container. Point 18 of Annex V of Regulation 1169/2011 thus does not apply to FSMP [35, Art.6(3)]. Pursuant to Article 6(4) of the Delegated Act the Articles 31-35 of FIR apply to all nutrients declared (i.e. mandatory declaration per 100 g/ml, rules on expression per portion), which ensures consistency with the horizontal rules, while the exceptions set out in Article 6(5) and 6(6) of FSMP Regulation need to be considered (values shall be those after preparation, where appropriate and not expressed as percentage of reference intakes as set in Annex of FIR).

Regulation 2016/128 introduces a new restriction establishing that *"information included in the mandatory nutrition declaration for food for special medical purposes shall not be repeated"* [35, Art.6(2)]. Since Directive 1999/21/EC does not set such a restriction but instead the general rule for food as currently established in Article 30(3) of Regulation 1169/2011 applies to products complying with the Directive, FBOs are still able to repeat nutrition declaration on FSMP for promoting purposes under the previous Specific Act, which may be another incentive to comply with the Directive for as long as possible.

4.3.5 Specific provisions: Nutrition and Health Claims

Another new rule applying to FSMP that cuts down the options to advertise it is established in Article 7 of Regulation 2016/128 stating that *"Nutrition and health claims shall not be made on food for special medical purposes"* [35, Art.7]. Recital (17) of the Delegated Regulation reasons this with the fact that FSMP is not directed at the general healthy population but to patients and thus it is not appropriate to promote the consumption of FSMP, which is to be used under medical supervision, through using nutrition and health claims directly targeting consumers. By contrast, nutrition and health claims may still be used if FSMP comply with Directive 1999/21/EC.

Article 8 of Regulation 2016/128 rules specific particulars on labelling, presentation and advertisement of FSMP intended for infants. Basically, restrictions applicable to formula for healthy infants were extended to infant FSMP with necessary adjustments considering the intended use of these products [72].

4.3.6 German Specifics

a) Legal Name

Article 4(1) of Directive 1999/21/EC sets the legal names under which FSMP shall be sold in different languages, including:

in German:	*Diätetisches/Diätetische Lebensmittel für besondere medizinische Zwecke (Bilanzierte Diäten)*
in English:	*Food(s) for special medical purposes*

In §21(1) DiätV the legal name has been implemented accordingly: *"Für bilanzierte Diäten ist die Bezeichnung "Diätetisches Lebensmittel für besondere medizinische Zwecke (Bilanzierte Diät)" Verkehrsbezeichnung im Sinne der Lebensmittel-Kennzeichnungsverordnung".* However, when Regulation 2016/128 applies, the reference for the legal name will be its Annex IV and herein the German name changed. Therefore, the labelling of the name has to be adapted in German while the English legal name, for instance, remains the same:

in German:	*Lebensmittel für besondere medizinische Zwecke (bilanzierte Diät)*
in English:	*Food for special medical purposes*

The word 'dietätische(s)' (= dietary/dietetic) has to be excluded from the German legal name due to the general abolishment of the dietetic concept with coming into force of Regulation 609/2013. The English legal name, by contrast, did not include the words 'dietetic' or 'dietary' before and thus is not affected. Further legal names that change for the same reason like the German one include the Spanish, the French, or the Italian name, amongst others. The

additional labelling ‘bilanzierte Diät’ in the German name, which has been used from the very beginning in DiätV, may stay as an exception – even though the word *diet* is applied, here.

b) Statement on Intended Purpose

Another labelling particular that needs to be adapted in German according to FSMP Regulation is the intended purpose or suitability statement, a mandatory labelling pursuant to its Article 5(2)(e). While the relevant English provision does not differ in wording (currently the mandatory statement is *for the dietary management of …* according to Article 4(4)(a) of Directive 1999/21/EC and it is equally *for the dietary management of …* according to Article 5(2)(e) of Regulation 2016/128), the translation of the German statement changed.

When Directive 1999/21/EC has been implemented into national German law, the English statement from the Directive (*for the dietary management of …)* was translated with *Zur diätetischen Behandlung von …,* and has been equally implemented in DiätV §21(2)(1). In the German version of FSMP Regulation [36] however, the wording in Article 5(2)(e) is now established with *Zum Diätmanagement bei …* . Hence, the mandatory statement has to be adapted from *Zur diätetischen Behandlung von …* into *Zum Diätmanagement bei*… when FSMP Regulation is applicable – from 22 February 2019/2020 at the latest.

If FBOs decide to place FSMP on the German market complying with FSMP Regulation before 22 February 2019/2020, both changes mentioned above need to be considered accordingly to ensure full compliance with the new Specific Act.

4.3.7 Summary Labelling, Presentation and Advertising

To sum up this subsection, the labelling and advertisement of FSMP has to comply with the mandatory particulars of Regulation 1169/2011, with the rules established in the new Framework Regulation. and fully with the specific act that applies. The comparison results in the finding that most relevant changes are due to FSMP Regulation and hence will be mandatory latest from 22 February 2019/2020. In general, the labelling and advertising shall not imply FSMP would be able to prevent, treat or cure any disease. Associations to medical or disease shall only be made if covered by the specific law, such as mandatory labelling of the legal name, the intended purpose statement or descriptions required as pertinent information – while the latter shall relate to information *for the appropriate use* and as soon as FSMP Regulation applies need to be directly related to the specific disease, which narrows the scope of interpretation. Further recommendations may still be given, if they are exclusively intended for qualified persons – whereas the new Specific Act extends the circle to other healthcare professionals responsible for maternal care and childcare.

FSMP Regulation further restricts the advertising of FSMP: Nutrition and health claims are prohibited and repeated nutrition declaration is not allowed according to the new Specific Act. Currently and until 22 February 2019/2020 FBOs have the choice to place FSMP on the market either fully complying with Directive 1999/21/EC or with FSMP Regulation in its entirety. Considering the promotional advantages, they may prefer to comply with the previous legislation for as long as possible. However, they need to keep in mind to adjust all labeling and advertisement in due time according to the new regulation. With regard to FSMP on the German market the legal name and the suitability statement on the intended purpose have to be modified to comply with Delegated Regulation 2016/128.

4.4 Notification

In general, FSMP does not require a marketing authorisation but FBOs are fully responsible for its safety and compliance with the relevant legislation according to Articles 14(1) and 17(1) of GFL. The enforcement of food law, the monitoring and verification that food products meet relevant legal requirements is the Member States' responsibility [Art.17(2) of GFL]. To facilitate the official monitoring of FSMP, a notification is required.

According to Directive 1999/21/EC, when FSMP is placed on the market the FBO "*shall notify the competent authority of the Member States where the product is being marketed by forwarding to it a model of the label"* [12, Art.5(1)]. Member States may waive this obligation if they can demonstrate that a notification is not required to efficiently monitor FSMP in their territory. In Germany, the notification has been implemented in §4a DiätV. FBOs are currently obliged to notify the BVL, the NCA in Germany, when FSMP is placed on the market by supplying a model of the label and some general information, such as the name, its intended use, and if it is a nutritionally complete or incomplete FSMP.

Delegated Regulation 2016/128 establishes the notification for FSMP in Article 9. In comparison to the former provision the rule changes slightly. FBOs, when placing FSMP on the market, shall then notify the NCA of each Member State *"by sending to it a model of the label used for the product, and of any other information the competent authority may reasonably request to establish compliance with this Regulation"* [35, Art.9]. Accordingly, in addition to a model of the label, the new Specific Act demands FBOs to send *any other information* the NCAs request, also referred to as extended notification. Since *any other information* in this context is not legally defined or explained in more detail, new questions arise from this altered rule. It remains unclear what exact information may be requested from NCAs as reasonable to monitor their markets. Eventually it may result in extensive demands of data. However, the requirement for scientific data itself is not new, only the timing when FBO shall submit it to NCAs may change in some Member States.

In Germany, BVL plans to establish extended notifications for FSMP applying the EFSA Guidance [64, 73]. Whereas currently it is still sufficient if FBOs have further data on hold in case BVL requests it (ruled in DiätV §7b: *"auf Verlangen"*), scientific data in structure and form of a dossier as suggested in EFSA Guidance (hereafter FSMP-Dossier) may be requested, soon. Since the legislation does not exactly define what kind and extend of data is required and no other standard on scientific data for FSMP exists so far, EFSA Guidance may possibly be referred to from more NCAs if they decide to request other information besides a model of the label for the notification of FSMP. The Commission even suggests NCAs to apply EFSA Guidance to evaluate the correct classification of FSMP [27, para.78]. Some Member States already request FSMP-Dossiers, now – what implies an *indirect dossier obligation* for FBOs. Furthermore, FSMP-Dossiers may also be required in case of competitive disputes [64].

Since Member States are also responsible to establish rules on measures and penalties [44, Art.17(2)], they may adapt these. It is possible that FSMP-Dossiers will not only be requested but also more frequently evaluated on a national level to effectively monitor the market. In case the scientific data is considered insufficient, national penalties may occur, such as a temporary ban to place the product on the market. Furthermore, the Commission is responsible to monitor that Member States effectively ensure the enforcement of EU law in their territories and in case the Commission judges a Member State fails, it may request improvements or initiate infringement proceedings. It will be interesting to follow, if the possible request of FSMP-Dossiers in context of extended notifications and furthermore a potential regular evaluation thereof will establish broadly in Europe and/or will even be considered *necessary* by the Commission to effectively monitor the market, in the future.

Currently, the changed rule on notification leaves the Member States' with the decision if they will request further data an what data they request in that case. Referring to EFSA Guidance and requesting FSMP-Dossiers presently seems the easiest way to demand all data in a well-structured form that may be reasonably requested and be potentially relevant to evaluate the correct classification. If and how FSMP-Dossiers would then be evaluated on a national level, must be awaited.
FBOs remain with legal uncertainty if the scientific evidence of their products will be requested in context of extended notifications until NCAs clarify the issue. But even if it is decided – what exact data is finally sufficient remains unclear and a case-to-case decision, as will be further outlined in the next Section.

4.5 Scientific Data

4.5.1 Legal Provisions and Comments

As discussed, *generally accepted scientific data* is required by law to provide evidence that FSMP is *"appropriate for satisfying the nutritional requirements of, and is suitable for, the persons for whom it is intended"* [29, Art.9(1)] and, to prove its use is *"safe and beneficial and effective in meeting the particular nutritional requirements of the persons for whom it is intended"* [35, Art.2(2); equally in 12, Art.3]. In Germany, this requirement has been equally implemented in §7b and §14b(1) DiätV. The demand of scientific data for FSMP is not new but instead had been equally established in the previous legislation.

According to GFL, FBOs are responsible that food they distribute complies with the law and thus it also is and remains their duty to be able to demonstrate the safety, benefit and effectiveness of FSMP they place on the market. NCAs may request the relevant data of notified products, at any time. As discussed above, in accordance with FSMP Regulation FBOs may also be requested to submit scientific data in context of extended notifications, and some Member States already do this. In addition, if a notified product needs to be evaluated pursuant to Article 3 procedures, FBOs also have to provide FSMP-Dossiers.

Neither the previous nor the new legislation clearly defines what kind and extend of data is required as *generally accepted scientific data* in context of FSMP and thus, FBOs remain with legal uncertainty and scope of own interpretation. As reasoned from the Commission, it is not possible to describe in advance, what specific data will be required per se and it needs to be assessed based on case-by-case analysis from FBOs and NCAs. The data shall objectively provide evidence that the product complies with the FSMP definition, such as that the specific group of patients, which shall be clearly identifiable as different from persons that do not require the FSMP, suffers from a disease/disorder or medical condition that is associated with a specific nutritional demand that is impossible, impractical, unsafe or nutritionally/clinically disadvantageous to be satisfied with other foodstuff, exclusively [27].

BVL/BfArM claim that *in general* evidence-based data such as randomised, controlled double-blind studies shall be available to prove a products' suitability in the context of dietary management for the patients addressed [28, p.17]. They refer to a judgment of BGH[45] where it was decided that in case objective measurable effects are lacking, placebo controlled studies are required and continue to cite a joint statement of an expert working group[46] on

[45] BGH decision on Artrostar Compact from 15.3.2012 (I ZR 44/11 [25]

[46] A working group of food chemistry experts of the federal states and the federal office of Consumer Protection and food safety (ALS, Arbeitskreis Lebensmittelchemischer Sachverständiger der Länder und des Bundesamtes für Verbraucherschutz und Lebensmittelsicherheit), the German Federation for Food Law and Food Science (Bund für Lebensmittelrecht und Lebensmittelkunde), and the German Federal Association of Manufacturers of Dietary Food (Diätverband)

FSMP[47] stating that from the perspective of nutritional medicine and science a randomised, double blind intervention study in human is considered the *golden standard* [28]. Hereto, Diätverband comments that the expert groups' statement on golden standard indeed clarifies the kind of study which is currently regarded as unexcelled, but that BVL/BfArM's interpretation such studies would be required *in general* is exaggerated. They point out that COM Notice states case-by-case analyses are needed to decide what kind of data is required and note the word *studies* is not even mentioned in this context [39]. BVL/BfArM also declare the scientific data needs to be comparable to the FSMP in terms of composition and dosage [28]. However, although it is plausible from scientific knowledge that ingredients may interact, it is neither required to prove the efficacy of every FSMP with clinical studies nor to apply the combination and amount of ingredients as formulated in a product by law.
EFSA Guidance currently is proposed as a supportive tool to estimate if FSMP is classified correctly. It establishes indicative criteria, proposes a form, provides templates, and points out what data may be relevant to prove FSMP complies with the legal definition. Although it was adopted to prepare scientific opinions in the context of Article 3 decisions only, the Commission suggests FBOs and NCAs to apply it whenever reflecting on the question whether a product is correctly classified as FSMP. Since no exact details on the scientific data required are ruled by law, EFSA Guidance will possibly be referred to as a new *standard* [64] on how to compose scientific data for FSMP in more occasions than for Article 3 decisions, only. It shall therefore be observed closer.

4.5.2 EFSA Guidance

According to EFSA Guidance the information and scientific data proving a notified FSMP is correctly classified shall be presented in form of a dossier, including 6 parts (see Table 4) to which the Guidance provides templates. A detailed overview of the data proposed in each dossier part can be found in Annex V (p.73).

Table 4: Parts of FSMP-Dossiers as suggested by EFSA Guidance

Part 1:	administrative and technical data
Part 2:	information relative to the characterisation of the specific food product
Part 3:	information relative to the proposed use(s)
Part 4:	information relative to the characterisation of the disease/disorder or the medical condition, and of the patients for whom the specific food product is intended for *
Part 5:	information on the specific role of the food product in the dietary management of patients under the proposed use *
Part 6:	information on conditions and restrictions of use' *

(part 4, 5, 6 for each proposed use as indicated in part 3, if several)*

[47] DLR Band 103.2007, 331 f.; cited in: [28], p.17

a) Part 4: Characterisation of the Disease/Disorder or the Medical Condition, and of the Patients

Within part 4 FBOs shall specify, if the disease/disorder can be diagnosed based on widely accepted, well-defined, objective criteria, or how the medical condition can be described in detail (part 4.1). The EFSA Guidance establishes definitions of 'disease/disorder', 'medical condition' and 'patient' to be applied in this context (see detailed in sect.4.1.3.a, p.30). The target patient group shall be characterised with regard to age, sex, stage of the disease and clinical condition (part 4.2). For the purpose to indicate and reason why it is impossible, impractical, unsafe or nutritionally/clinically disadvantageous for the patients to exclusively consume foodstuff other than FSMP, a questionnaire (4.2(a)-(e)) lists plausible reasons for the first defined target patient group *(with a limited, impaired or disturbed capacity to take, digest, absorb, metabolise or excrete …)*, while some concrete examples of diseases, disorders or medical conditions hereto are provided in COM Notice. No separate questionnaire listing of plausible reasons for the second defined patient group (*other medically-determined nutrient requirements)* is established in EFSA Guidance. However, in COM Notices (para.55) some examples for this group are also indicated, such as an increased requirement for protein or other specific nutrients in patients' pre or post-surgery, those with severe wounds or suffering from burns or pressure sores.

If the disease is triggered by regular foodstuff it can also be indicated, here (4.2(f)), such as it would be with normal foodstuff containing protein in case of phenylketonuria. Finally, may be flagged if the disease or medical condition typically leads to specific medically-determined nutrient requirements (part 4.2(g)) or if other reasons apply (part 4.2(h)). As stated in the Guidance, one or more of the listed reasons may me indicated. Evidence shall be provided or the reasons shall be further specified. Finally, FBOs shall point out in another questionnaire (4.3(a)-(f)) if the disease/disorder or medical condition impacts the nutritional status of the patients, such as if it leads to an excess or deficiency of certain nutrients, while in this case evidence is requested. According to Diätverband [31], a correlation, to specify how the disease/disorder or medical condition affects the nutritional status of patients, would however be difficult to be proved for many FSMP products in the German market, today.

b) Part 5: Specific Role of the Food in the Dietary Management of the Patients

In Part 5 the rationale for the specific formulation of FSMP shall be described to explain the specific role of the product in the dietary management of the patients (part 5(a)). Hence, a plausible reasoning for the specific composition with respect to the pathology of the specific disease/disorder or medical condition for which the product is intended is required [67]. In addition, FBOs shall state why the use of the FSMP is necessary or safer or more practical in comparison to other foodstuff or how the product has a nutritional or clinical advantage for the patients (part 5(b)). The term *clinical advantage* has primarily been used in connection

with FSMP here, and may indicate that benefits such as a shortened hospital stay will also be regarded a relevant reason [67]. The Commission similarly claims if a nutritional or clinical disadvantage results for patients whom are only able to consume food other than FSMP, it would be a plausible reasoning for the FSMP and emphasises alternatives shall also be realistic and a possible modification of the normal diet shall be *"interpreted restrictively, but not to the extent of an absolute impossibility"* [27, para.69]. Finally, EFSA Guidance suggests to supply *"any available human data documenting the use of the specific food product for the dietary management of patients for whom it is intended"* [38, p.20] (part 5(c), referring to published or unpublished data) and *"any other information"* [38, p.20] considered pertinent regarding the specific role of the food under the proposed use (part 5(e)).

Consequently, FSMP-Dossiers besides general information on the product shall include comprehensive details on the characterisation of the disease/disorder or medical condition and the intended patient group in order to clearly identify it different from people whom not require the particular FSMP, and shall include information on how the disease or medical condition is associated with the specific nutrient requirement that make the FSMP necessary or advantageous for the patients in comparison if they only consumed normal food.
Against a former draft of EFSA Guidance that described the requirement for human studies documenting the use of FSMP for the dietary management of patients, which was then interpreted as a requirement for clinical studies on finished products [67], the EFSA Guidance in its current published version does not state that clinical studies shall be supplied, not even is the term *clinical study* used. However, FBOs are requested to indicate references to guidelines and/or consensus papers from scientific or medical societies were applicable, and shall provide any published and unpublished available human data documenting the use of the FSMP. Nevertheless, the option to provide sufficient evidence with reasonable comments, rationales and references to other scientific data, and without submitting specific studies on the final product or any clinical studies, is maintained. This may encourage small and medium size entrepreneurs to develop innovative products in this market, whom would otherwise fail to conduct cost-intensive studies. Anyway, in some cases a clinical study may be necessary – if sufficient evidence cannot be otherwise performed [67], as also indicated by increasingly restrictive court decisions on this issue, as outlined earlier (compare sect.2.2.2, p.11).
EFSA Guidance mainly addresses details on the compensation of nutrient deficiencies, rather than possible benefits that additional nutrient supplies could have for the patients. This is due to the fact that the Guidance has been prepared from experts on enteral nutrition and supplementary, nutritionally incomplete FSMP were not given great priority [67]. It is awaited with interest, if or how many nutritionally-incomplete drug-like FSMP products on the market,

that constituted part of the trend towards the category of FSMP, will be supported by sufficient scientific data, when FSMP-Dossiers will eventually be requested for these products. With the EFSA Guidance at hand, it may be easier for NCAs to find FSMP that are not appropriately backed with data. For regulators new working areas could arise as responsible persons to compile and govern FSMP-Dossiers within the industry or eventually in the role to evaluate the data on behalf of authorities.

4.5.3 Summary Scientific Data

To sum it up, scientific data is required from FBOs distributing FSMP in order to prove their use is safe, beneficial and effective. NCAs may request it at any time and, according to FSMP Regulation, also directly when FBOs notify FSMP in their territories. If notified FSMP need to be evaluated pursuant to the new Article 3 procedure, FBOs will also be requested to submit it.

In comparison to the previous law, the rules on scientific data do not change – only new timings to provide it are possible. It is still not clarified what exact data is required for FSMP per se but remains to be decided based on case-by-case analysis while relevant court decisions should be considered. However, the new EFSA Guidance now supports the estimation if a product complies with the definition and points out what scientific data may be relevant to prove this. The Commission suggests applying EFSA Guidance when reflecting the correct classification of FSMP and it is hence likely that NCAs will refer to it if they decide to request additional data for extended notifications. Consequently, FSMP-dossiers may become indirectly mandatory.

FSMP-Dossiers shall include information on the disease/disorder or medical condition, on the specific patient group, and on the association of the disease/disorder or medical condition and the specific nutritional requirement that make the FSMP necessary or advantageous. While any available human data demonstrating the use of FSMP shall be provided, it is still possible to supply sufficient evidence without clinical data. However, FBOs shall consider that recent court decisions judged in some cases a clinical study is required.

In general, legal certainty what data proves that FSMP fully complies with the definition and applicable law cannot be achieved in every case and discussion or court proceedings may continue. In addition, if clinical studies are available, the debate could go on, whether the resulting benefits are significant and due to nutritional and/or physiological activity or due to pharmacological activity already, since these modes of action are not defined, as discussed. Hence, depending on the specific study findings a product may eventually be rather classified a medicinal product (by function) than FSMP. Since these details are not yet clarified, it needs to be awaited and followed how future court decisions continue to develop the interpretation of the law – including the extent of scientific data required for FSMP and

the demarcation from medicinal products. Currently, FBOs shall continue to assess and decide on their own responsibility if the safety and efficiency of FSMP is sufficiently scientifically established – which leaves them with much responsibility.

4.5.4 Excursus: Develop FSMP to be strictly regulated like medicinal products?

The new law leaves flexibility and scope of interpretation, but also introduces modifications that may lead to a more restrictive monitoring of FSMP. NCAs may decide to broadly establish extended notifications and may request FSMP-Dossiers. In their responsibility to monitor the market, while rules on measures and penalties are decided on a national level, they may also evaluate the data regularly. The Commission even suggests NCAs to apply EFSA Guidance. Moreover, the Commission also monitors if Member States achieve to enforce EU law. Perhaps in some time, it may be considered *necessary* in order to effectively monitor the market, to perform regular evaluations of FSMP-Dossiers at a national level – which could be one step closer towards an authorisation. Furthermore, the new law implemented the possibility for central evaluations of scientific data. If Article 3 applies, EFSA assesses FSMP-Dossiers to provide a scientific opinion, while the Commission (or optionally the Court) finally decides. Clearly, with this procedure a role of EU Competence is introduced in FSMP law – which could be one step closer towards central assessments.

These developments are reminiscent to the regulatory environment of medicinal products. Of cause, the regulatory requirements of medicinal products still differ largely to the ones of FSMP or food supplements (see also comparison in Annex VI, p.75). Nevertheless, these slightly changed rules and the latest developments of the interpretation of the law, which reveal to be increasingly restrictive, such as in terms of scientific evidence, also contribute to a stricter regulatory environment for FSMP. Even though these are small steps, only – one should keep in mind, that the very restrictive regulatory environment of medicinal products today has also developed over several years, step by step, and still continues to develop, while the first legally binding requirement for a marketing authorisation based on clinically proven therapeutic benefit was only established a little more than fifty years ago (Directive 65/65/EWG). In terms of FSMP, future court rulings on scientific evidence or the interpretation of effective monitoring could become increasingly stringent, and without necessary changes to the current legal text, that leaves scope for interpretation, could result in the fact that *based on case-by-case analysis* more and more FSMP require clinical studies that need to be presented in indirectly mandatory FSMP-Dossiers that may be seen as required to be requested and evaluated from NCAS, by the Commission. However, currently FSMP remain to be much less restrictively regulated than medicinal products for human use.

5. Result

Table 5: Summary of main Regulatory Changes for FSMP due to Regulation 609/2013 (a) and Delegated Regulation 2016/128 (b) at European Level and in Germany

(a) Regulation 609/2013

Entry into force:	Since 20 July 2016
Applicability:	Directly applicable in its entirety in all EU Member States
Aims:	Simplify and clarify the regulatory environment of products previously referred to as PARNUT to improve the functioning of the internal market. Abolishes the concept of 'dietetic/dietary' food/PARNUT (repeals Directive 2009/39/EC, Directive 1999/21/EC, Regulations 953/2009, amongst others); introduces harmonised general compositional and information requirements applicable to four categories of *Food for Special Groups*, including FSMP.
New Legal Act:	→ Introduces 'Interpretation Decisions' In case divergent opinions on the correct classification of a notified product within the scope of FSG Regulation occur across Member States, the Commission is empowered to decide; Art.3 If Article 3 procedure is initiated, EFSA requests scientific data from FBO as suggested in EFSA Guidance for evaluation to prepare a scientific opinion. Details on the procedural steps are not yet conclusively regulated. The relevance and consequences of the outcome need to be awaited.
New in Legal Definition:	→ Legal name formally changes: '~~dietary~~ food~~s~~ for special medical purposes' according to FSMP definition; Art.2(2)(g) → *"…patients, including infants";* infants now explicitly included in definition text; Art.2(2)(g) – but infants were also potential target patients before → *"…whose dietary management cannot be achieved by modification of the normal diet alone";* FSMP definition in Art.2(2)(g) – COM Notice clarifies that (still) all other foodstuff than FSMP shall be considered as part of the normal diet, including food supplements and fortified food
New in Substances:	→ establishes Union List (similar as formerly set out in Reg. 953/2009, formally new reference for permitted substances); Annex → Substances shall be "*bio-available*" for the human body; Art.9(3) → Nanomaterial permitted if safe and suitable to fulfil the nutritional requirements of intended patient group, as demonstrated with adequate test methods; Art.9(2)
New in Labelling, Presentation and Advertising:	→ Information *"for the appropriate use"* to be provided; Art.9(5) – further clarified in specific act (i.e. pertinent information, nutrition declaration) → Extension of the circle of named specific qualified persons for exclusive information: now also includes *"other healthcare professionals responsible for maternal care and childcare";* Art.9(6)

(b) Delegated Regulation 2016/128

Entry into force:	From 22 February 2019 (22 February 2020 for infant FSMP) *	
Applicability:	Directly applicable in its entirety in all EU Member States	Changes specifically to FSMP in the German market
Aims:	Updates specific compositional and information requirements for FSMP (replaces Directive 1999/21/EC); i.e. clarifies applicability of Reg. 1169/2011	
New in Substances:	→ New reference for maximum/minimum amounts of vitamins/minerals (same rules apply); Annex	→ Reference changes from DiätV to FSG Regulation (Union List) and Annex of Del. Reg.
New in Labelling, Presentation and Advertising:	→ Mandatory labelling explicitly has to comply with Reg. 1169/2011 acc. to Art.5(1)); with Art.9(1) FIR, 13(1) FIR (easily visible, clearly legible, and indelible) and Articles 13(2) + (3) FIR (defined font size to be observed) – the latter refers to all mandatory particulars of FSMP; Art.5(3) → Description of properties and/or characteristics that make the product useful (pertinent information) narrowed: shall be *"in relation to the disease, disorder or medical condition"* and in particular, as the case may be, *"relating to the special processing and formulation"*; Art.5(2)(g) → Nutrition declaration shall not be repeated; Art.6(2) → Nutrition declaration mandatory irrespective of the size of the packaging or container; Art.6(3) → All nutrients declared to comply with Articles 31-35 of FIR with respect of exceptions set in Articles 6(5) + 6(6); acc. to Art.6(4) (= new reference for rules on expression and presentation of nutrition declaration) → Nutrition and health claims shall not be made; Art.7 → Restrictions applicable to formula for healthy infants extended to infant FSMP with necessary adjustments; Art.8	→ Legal name has to be adapted; Art.4 and Annex IV: *„~~Diätetisches~~ Lebensmittel für besondere medizinische Zwecke (bilanzierte Diät)"*; → Statement on intended purpose has to be changed; Art. 5(2)(e) of German version of Del. Regulation 2016/128: from *"~~Zur diätetischen Behandlung von~~ …"* into *„Zum Diätmanagement bei …"*
New in Notification:	→ *"any other information the competent authority may reasonably request*" to be provided; Art.9 Extended notification may result in extensive demands of scientific data and in indirect mandatory FSMP-dossiers	

* FBOs may decide to fully comply with this Regulation, already.

6. Conclusions

FSMP is vital for the patients for whom it is intended to guard them against disease-related malnutrition. As a legal category between normal food and medicinal products it is attractive for both, the food and the pharmaceutical industry. Since the previous legal framework applicable to FSMP resulted in inconsistencies across Member States, it has recently been abolished. The fact that provisions specifically regulating FSMP have been maintained to be established within a new EU framework law indicates the importance the legislator still attaches to this category. This work illustrates how the new legislation covering FSMP impacts its demarcation and regulatory requirements applicable to it in comparison to previous provisions at EU level and in Germany. Legal complexities are discussed, and the main changes to be considered when placing FSMP on the market are summarised.

The FSMP definition changed marginally – thus previously occurring complexities, such as to clearly distinguish it from other legal categories are likely to last. A strict demarcation can continue to be difficult particularly since *pharmacological action* as the main criterion to separate medicinal products by function has not been legally defined, and an exhaustive list of substances that may be used in FSMP has not been determined, either. To account for the possibility of future divergent opinions amongst Member States, the new Framework Law introduces a new legal procedure in its Article 3 that authorises the Commission to decide the correct classification of notified products in its scope in such cases.

While it is criticised this procedure empowers the Commission to interfere with judicial power, it may also contribute to harmonised decisions, eventually with fewer burdens to courts. However, the practical relevance of resulting implemented acts needs to be awaited. It may also reveal as a way to refer legally unsolved questions to the ECJ for evaluation and binding decisions considering the aims to protect the functioning of the internal market and domestic public health policies. Clearly, the procedure may affect the diversity of the market for foods for special groups and initially introduces a role for EU competence in law relating to them.

From 22 February 2019/2020 at the latest, FSMP has to comply with the new Specific Act that introduces altered mandatory labelling in some languages and through different rules further restricts the advertising directed to consumers. FBOs will most likely extract the promotional advantages from the previous Directive, as long as possible. The Delegated Act enables NCAs to request further information when FSMP is notified, which, in association with EFSA Guidance, may lead to indirect mandatory requirements of FSMP-Dossiers.

It is still not clarified what scientific data certainly proves a product fully complies with the FSMP definition and applicable law and although new guidelines may be supportive, stakeholders retain to decide the classification and required scientific evidence based on their own assessments and case-by-case analysis. To fulfill their legal responsibilities they cannot rely on the law solely, but also have to constantly follow and evaluate developments

of scientific research and related court rulings to ensure the compliance of their products as best as they can.

These findings indicate that the new legal environment does not significantly simplify the decision making if a product is correctly classified as FSMP and stakeholders still face legal uncertainties in terms of demarcation, composition and scientific evidence – which, taken together, seem mainly due to the lack of a clear borderline between food and medicinal products. While the law does not strictly regulate details in terms of scientific evidence and the Commission refers to the need of case-by-case analysis, court judgments decided already in some cases clinical studies are required. If clinical studies exist, it may however not be clear if the achieved effects indicate a FSMP or rather a medicinal product. A more specific definition of medicinal products (by function) based on objective demarcation criteria would solve this potential problem and furthermore facilitate the evaluation of additional substances/amounts to extend the Union list. However, the legislator seems to struggle with a strict separation which may be due to the fluid transition of effects from food ingredients and pharmaceutical substances that gets more and more uncovered by science and illustrates that drawing a clear borderline may just not comply with reality anymore.

On the other hand, by not over-regulating scientific data and composition and due to slightly changed rules the new legal environment may also increase the protection of customer's interests and public health. First, the legal flexibility may encourage the development of new products in this niche market, including FSMP for minorities, which would maybe not be developed if cost- and time-intensive studies were required. Secondly, the assessment of scientific data may intensify and contribute to a higher quality of available FSMP. If extended notifications establish broadly, it could result in requests and even regular evaluations of FSMP-Dossiers at the national level. Further, Article 3 procedures may lead to a clearance of not properly classified FSMP from the market and cut down the availability of non-effective remedies. Thirdly, the restricted rules on advertising may also improve the quality and efficacy of available FSMP since it further limits promotional incentives to distribute normal food inappropriately as FSMP to patients whom expect a substantiated benefit from it.

This thesis reveals challenges that appear where science and regulatory action meet: While it is not clear yet from a scientific perspective where exactly healthy nutrition ends and the healing of pharmaceuticals begins, from a regulatory point of view both sides differ greatly. Consequently, the regulation of products with ambivalent status, like FSMP, remains to be a responsible and demanding position. It is awaited with interest how the interpretation of the law will continue to develop and how Article 3 procedures will affect the market for FSMP in EU Member States in the future. Certainly, for regulators FSMP legislation remains a highly challenging and dynamic field to operate to ensure high quality and efficacy of vital solutions that preserve or improve the health of individuals in need for whom they are the *last resort*.

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Annex I: Timeline of Definitions of 'foodstuffs for particular nutritional uses' (PARNUT) (a) and '(dietary) food for special medical purposes' (FSMP) (b) in EU Legislation.

(a) PARNUT

Date	European Directives	Definition
1977	Council Directive 77/94/EEC	Foodstuffs for particular nutritional uses are foodstuffs which, owing to their special composition or manufacturing process, are clearly distinguishable from foodstuffs for normal consumption, which are suitable for their claimed nutritional purposes and which are marketed in such a way as to indicate such suitability. [Art.1(2)(a)] A particular nutritional use must fulfil the particular nutritional requirements: (i) of certain categories of persons whose digestive processes or metabolism are disturbed, or (ii) of certain categories of persons who are in a special physiological condition and who are therefore able to obtain special benefit from a controlled consumption of certain substances in foodstuffs, or (iii) of infants or young children in good health. [Art.1(2)(b)]
1989	Council Directive 89/398/EEC	Foodstuffs for particular nutritional uses are foodstuffs which, owing to their special composition or manufacturing process, are clearly distinguishable from foodstuffs for normal consumption, which are suitable for their claimed nutritional purposes and which are marketed in such a way as to indicate such suitability. [Art.1(2)(a)] A particular nutritional use must fulfil the particular nutritional requirements: (i) of certain categories of persons whose digestive processes or metabolism are disturbed, or (ii) of certain categories of persons who are in a special physiological condition and who are therefore able to obtain special benefit from a controlled consumption of certain substances in foodstuffs, or (iii) of infants or young children in good health. [Art.1(2)(b)] *Comment: No change to previous definition.*
2009	Directive 2009/39/EC	Foodstuffs for particular nutritional uses are foodstuffs which, owing to their special composition or manufacturing process, are clearly distinguishable from foodstuffs for normal consumption, which are suitable for their claimed nutritional purposes and which are marketed in such a way as to indicate such suitability. [Art.1(2)] A particular nutritional use shall fulfil the particular nutritional requirements: (a) of certain categories of persons whose digestive processes or metabolism are disturbed; or (b) of certain categories of persons who are in a special physiological condition and who are therefore able to obtain special benefit from controlled consumption of certain substances in foodstuffs; or (c) of infants or young children in good health. [Art.1(3)] *Comment: No change to previous definition.* *(Table continues on next page.)*

(b) FSMP

Date	European Directives and Regulations	Definition
1999	Commission Directive 1999/21/EC	'**dietary** foods for special medical purposes' means **a category of foods for particular nutritional** uses specially processed or formulated and intended for the dietary management of patients and to be used under medical supervision. They are intended for the exclusive or partial feeding of patients with 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 only by modification of the normal diet, by other foods for particular nutritional uses, or by a combination of the two.** [Art.1(2)(b)]
2013	Regulation (EU) No 609/2013	'food for special medical purposes' means 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.** [Art.2(2)(g)] *Comment: This definition mainly corresponds to the one given previously with the exception that the former 'dietary foods for special medical purposes' are now referred to as 'food for special medical purposes' since the concept of `dietetic/dietary` food is abolished with coming into force of FSG Regulation. Additionally, FSMPs are no longer defined as a category within 'foods for particular nutritional uses' for the same reason and the last part changed in words although this basically has no practical impact. Infants have been explicitly included to the definition text but were included also a potential target group previously.*

Annex II: Timeline of Definitions of 'diätetische Lebensmittel' (a) and 'bilanzierte Diäten' (b) in German Legislation.

(a) 'diätetische Lebensmittel' (similar to PARNUT)

Date	National Law	Definition
1963	DiätV	Diätetische Lebensmittel sind Lebensmittel, die bestimmt sind, einem **diätetischen Zweck** dadurch zu dienen, dass sie die Zufuhr bestimmter Nährstoffe oder anders ernährungsphysiologisch wirkender Stoffe steigern oder verringern oder die Zufuhr solcher Stoffe in einem bestimmten Mischungsverhältnis oder in bestimmter Beschaffenheit bewirken. Diätetische Lebensmittel müssen sich von anderen Lebensmitteln vergleichbarer Art durch ihre Zusammensetzung oder ihre Eigenschaften maßgeblich unterscheiden. [§1(1)] Lebensmittel dienen einem **diätetischen Zweck**, wenn sie dazu beitragen, besonderen Ernährungserfordernissen 1. auf Grund von Umständen wie Krankheit, Mangelerscheinungen, Funktionsanomalie und Überempfindlichkeit gegen einzelne Lebensmittel oder deren Bestandteile, 2. während der Schwangerschaft und Stillzeit sowie beim Säugling und Kleinkind zu entsprechen. [§1(3)]
1981	6th amendment of DiätV	Diätetische Lebensmittel sind Lebensmittel, die bestimmt sind, einem **besonderen Ernährungszweck** dadurch zu dienen, dass sie die Zufuhr bestimmter Nährstoffe oder anders ernährungsphysiologisch wirkender Stoffe steigern oder verringern oder die Zufuhr solcher Stoffe in einem bestimmten Mischungsverhältnis oder in bestimmter Beschaffenheit bewirken. Diätetische Lebensmittel müssen sich von anderen Lebensmitteln vergleichbarer Art durch ihre Zusammensetzung oder ihre Eigenschaften maßgeblich unterscheiden. [§1(1)] Lebensmittel dienen einem **besonderen Ernährungszweck**, wenn sie dazu beitragen, besonderen Ernährungserfordernissen 1. auf Grund von Umständen wie Krankheit, Mangelerscheinungen, Funktionsanomalie und Überempfindlichkeit gegen einzelne Lebensmittel oder deren Bestandteile, 2. während der Schwangerschaft und Stillzeit sowie beim Säugling und Kleinkind zu entsprechen. [§1(3)] *Comment: Council Directive 77/94/EEC has been implemented; whereas the former versions of DiätV used the term 'diätetischer Zweck' (= dietetic purpose) in the definition of 'diätetische Lebensmittel' this 6th version introduced the wording 'besonderen Ernährungszweck' (= particular nutritional use) to specify the intended purpose equally worded with the terms as used in the European Framework Directive.*

(Table continues on next page.)

Date	National Law	Definition
1993	7th amendment of DiätV	Diätetische Lebensmittel sind Lebensmittel, die für eine besondere Ernährung bestimmt sind. Lebensmittel sind für eine besondere Ernährung bestimmt, wenn sie 1. den besonderen Ernährungserfordernissen folgender Verbrauchergruppen entsprechen: a) bestimmter Gruppen von Personen, deren Verdauungs- oder Resorptionsprozess oder Stoffwechsel gestört ist oder b) bestimmter Gruppen von Personen, die sich in besonderen physiologischen Umständen befinden und deshalb einen besonderen Nutzen aus der kontrollierten Aufnahme bestimmter in der Nahrung enthaltener Stoffe ziehen können, oder c) gesunder Säuglinge oder Kleinkinder, 2. sich für den angegebenen Ernährungszweck eignen und mit dem Hinweis darauf in den Verkehr gebracht werden, dass sie für diesen Zweck geeignet sind, 3. sich auf Grund ihrer besonderen Zusammensetzung oder des besonderen Verfahrens ihrer Herstellung deutlich von den Lebensmitteln des allgemeinen Verzehrs unterscheiden. [§1] *Comment: Implementation of Council Directive 89/398/ECC; DiätV now contained the definition of 'diätetische Lebensmittel' equal to the definition of PARNUT of the European provision. This definition, although it changed in words, did not change much the products in scope of DiätV or the provision itself.*

(b) 'bilanzierte Diäten' (similar to FSMP)

Date	National Law	Definition
2002	10th amendment of DiätV	Im Sinne dieser Verordnung sind diätetische Lebensmittel für besondere medizinische Zwecke (bilanzierte Diäten) Erzeugnisse, die auf besondere Weise verarbeitet oder formuliert und für die diätetische Behandlung von Patienten bestimmt sind. Sie dienen der ausschließlichen oder teilweisen Ernährung von Patienten mit eingeschränkter, behinderter oder gestörter Fähigkeit zur Aufnahme, Verdauung, Resorption, Verstoffwechslung oder Ausscheidung gewöhnlicher Lebensmittel oder bestimmter darin enthaltener Nährstoffe oder ihrer Metaboliten oder der Ernährung von Patienten mit einem sonstigen medizinisch bedingten Nährstoffbedarf, für deren diätetische Behandlung eine Modifizierung der normalen Ernährung, andere Lebensmittel für eine besondere Ernährung oder eine Kombination aus beiden nicht ausreichen. [§1(4a)] *Comment: Implementation of Commission Directive 1999/21/EC; the definition mainly corresponds to the one given in the EU Directive with the exception that the part "to be used under medical supervision" has not been included in the German definition text but instead has been kept as a mandatory labelling requirement in §21 (2) 6) DiätV.*

Annex III: Correlation Table and Overview of Regulatory Aspects relevant to PARNUT/FSMP in EU Legislation and National German Law.

	Directive 2009/39/EC	**Directive 1999/21/EC**	**Regulation 609/2013**	**Regulation 2016/128**	**Diätverordnung****
Legal Force	repealed	in force (EU), repealed with effect from 22 February 2019/2020	in force (EU)	applicable from 22 February 2019* (EU)	in force (Germany), overlaid by Regulations 609/2013 and 2016/128
Definition of PARNUT	Article 1(2) + 1(3)				§ 1(1) + 1(2)
Definition of FSMP		Article 1(2)(b)	Article 2(2)(g)		§ 1(4a)
Classification of FSMP		Article 1(3)		Article 2(1)	§ 1(4a)1 + 2
Requirement for FSMP to be safe, beneficial, effective		Article 3		Article 2(2)	§ 14b(1)
Positive List for Substances			Annex: Union list (adapted from Regulation 953/2009)		Annex 2
Amounts (maximum/minimum)		Annex		Annex	§ 14b in conjunction with Annex 6
Legal Name for FSMP		Article 4(1)		Article 4	§ 21(1)
Mandatory Labelling Particulars for FSMP		Article 4(3) + 4(4)		Article 5(2)	§ 21(2)
Prohibition to attribute Properties for Prevention, Treatment, Cure	Article 8(1)		Article 9(5)		§ 3(1)
Exclusive Information for Qualified Persons	Article 8(2)		Article 9(6)		
Monitoring Particulars / Notification		Article 5		Article 9	§ 4a(1)

* Except in respect of FSMP developed to satisfy the nutritional requirements of infants, to which it shall apply from 22 February 2020.

** Diätverordnung in its latest version from 28 April 2005, latest amended 5 July 2017 [40]

Annex IV: Proposed Definitions of Modes of Action.

Note: The definitions provided in MedDEV 2.1/3 rev. 3 are not legally binding but provide guidance on the meaning of the terms, only. Moreover, the document is prepared with the intention to support the demarcation of medical device from medicinal products, primarily, not to distinguish food from medicinal products.

Modes of Action	**Definitions provided in MedDEV 2.1/3 rev. 3**[48] [54, A.2.1.1]	**Further Proposals from Racci et al.**[49] [55, Table 5]
"Pharmacological means"	is understood as an interaction between the molecules of the substance in question and a cellular constituent, usually referred to as a receptor, which either results in a direct response, or which blocks the response to another agent. Although not a completely reliable criterion, the presence of a dose–response correlation is indicative of a pharmacological effect.	is understood as a TARGETED interaction between the molecules of the substance in question and a cellular constituent, usually referred to as a receptor, which either results in a direct response, or which blocks the response to another agent. Although not a completely reliable criterion, the presence of a dose–response correlation is indicative of a pharmacological effect. * (see comment below)
"Immunological means"	is understood as an action in or on the body by stimulation and/or mobilization of cells and/or products involved in a specific immune reaction.	is understood as a TARGETED action in or on the body by stimulation and/or mobilization of cells and/or products involved in a specific immune reaction.
"Metabolic means"	is understood as an action which involves an alteration, including stopping, starting or changing the speed of the normal chemical processes participating in, and available for, normal body function.	is understood as a TARGETED action which involves an alteration, including stopping, starting or changing the speed of the chemical processes participating in AND MODULATING THE USE OF ENDOGENOUS OR EXOGENOUS SUBSTANCES FOR THE GENERATION OR STORAGE OF ENERGY AND ANY CATABOLIC OR ANABOLIC PROCESS IN THE BODY.

*Comment of Racchi et al.:

"If the interaction of a substance with a biological component (considered a receptor) leads to direct and specific modifications of a biological pathway (signal) related to a physiological response, the mechanism of action of the substance is considered to be pharmacological.

(…) in the case that the interaction leads to direct and specific modifications of the immune system, the mechanism of action is considered to be immunological (…) in the case that the interaction leads to direct and specific modifications in basal cell metabolism, the mechanism of action is considered to be metabolic.

Thus, the definitions of immunological and metabolic mechanism of action derive mostly from what has been said above regarding the pharmacological mechanism of action." [55, sect.4.2.1]

[48] European Commission, Medical devices: guidance document, MEDDEV 2.1/3 rev. 3 – Dec 2009. [54]

[49] Racchi et al. (2016), Insights into the definition of terms in European medical device regulation, Expert Review of Medical Devices, 13:10, p. 907-917 [55]

Annex V: Overview of Data proposed within the Parts of FSMP-Dossier.

Dossier Parts	Details	
	Parts 1,2, 3 provide general information on the product	
Part 1 Administrative and technical data	1.1 Table of contents 1.2 Identification form 1.3 Party responsible for the dossier 1.4 Specifications 1.5 Confidential data	1.2: Identification form as provided in the Annex of EFSA Guidance 1.3: including address(es) of companies/organisations and **one** contact person authorised to communicate with EFSA on behalf of the party responsible for the dossier 1.4: The specification of the product (1.4.1) includes its classification (nutritionally complete/incomplete; standard nutrient formulation or nutrient-adapted in 1.4.2), an identification of the target patient population and the disease/disorder or medical condition for each proposed use of the product, as well as conditions of use and, if applicable, restrictions of use (1.4.3) 1.5: Statement, if confidential data is included in the dossier
Part 2 Characterisation of the specific food product	2.1 Name and characteristics 2.2 Manufacturing process 2.3 Stability information 2.4 References	2.1: Source and specifications of the food including physical and chemical properties, composition, where applicable microbiological constituents; a list of ingredients and sources, energy and nutrient content of the food – supplying adequate attachments can be suitable, such as the formulation of the product, specifications of raw materials, and a packaging labelling 2.2: If the production process follows a quality system, like GMP, it should be indicated; any relevant information on special processing of the product that explains why it is different from any other food not being FSMP should be indicated to provide evidence that the food is specially processed or formulated 2.3: summaries of study details (conditions, batches, analytical procedures), results and conclusions with respect to storage conditions and shelf-life should be given
Part 3 Proposed use(s)	Proposed use(s)	Similar to 1.4.3: a description of each proposed use of the product, if several – with an identification of target patient populations, disease/disorder or medical condition, condition of use and restrictions of use, where applicable

(Table continues on next page.)

Parts 4, 5, 6 to be filled for each proposed use of the product		
Part 4 Characterisation of the disease/disorder or the medical condition, and of the patients for whom the specific food product is intended for	4.1 Diagnosis of the disease/disorder – description of the medical condition 4.2 Characterisation of the patients for whom the product is intended 4.3 Impact of the disease/disorder on the medical condition on the nutritional status of the patients for whom the product is intended 4.4 References	4.1: Indication if the disease/disorder can be diagnosed, if yes description of the generally accepted, well-defined objective criteria (provision of guidelines, consensus papers describing the criteria, if applicable); indication if it is a medical condition, if yes detailed specification and description of the condition 4.2: Characterisation of the target patient population including information if the food is intended for all of them or a subgroup (sex, age, stage of the disease, clinical condition), indication and reasoning why it is impossible, impractical or unsafe for them to consume exclusively foodstuff other than FSMP and supply of evidence that disease, disorder, medical condition leads to a specific nutrient requirement (identification of nutrients/substances, if applicable) and evidence or rationale for the reason(s) why it cannot adequately be fulfilled by other foodstuff than FSMP or indication if disease/disorder or medical condition is triggered by other foodstuff. 4.3: Indication, if the disease, disorder or medical condition impacts the nutritional status of the patients, if yes supply of specification and evidence. 4.4: References and supporting data quoted under Part 3 should be given here, together with copies/reprints of published data and/or full reports of unpublished data
Part 5 Specific role of the food product in the dietary management of patients under the proposed use	5.1 References	a) Description of the rationale for specific formulation in relation to the proposed use. b) Why is the use within dietary management, safer, more practical or necessary than other foodstuff? Why does it have a nutritional or clinical advantage for the patient? c) Supply of human data (published, unpublished) documenting the use of the specific food product for the dietary management of patients for whom it is intended. d) If possible, Guidelines / consensus papers addressing the specific case, or e) Any other information considered pertinent regarding the specific role of the food under the proposed use.
Part 6 Conditions and restrictions of use	6.1 Conditions of use 6.2 Restriction of use 6.3 References	6.1: Standard quantity and pattern of consumption, indication if the food is sole source of nourishment, partial replacement or supplementing a diet, indication of route of administration, if applicable specification of preparation, and if applicable reasoning why the use of the product requires medical supervision. 6.2: If appropriate, a statement addressed to persons who should avoid the food including a rationale. 6.3: Provision of supporting documentation published / unpublished

Annex V; modified from EFSA Journal 2015;13(11):4300 [38]

Annex VI: Overview of Regulatory Differences: Medicinal Products – FSMP – Food Supplements (situation as from 22 Feb 2019/2020).

	Medicinal Product	**FSMP**	**Food Supplement**
Relevant EU Legislations (selection)	Directive 2001/83/EC Clinical Trial Regulation 536/2014	Regulation 178/2002 Regulation (EU) No 609/2013 Delegated Regulation (EU) 2016/128 Regulation 1169/2011	Regulation 178/2002 Directive 2002/46/EC Regulation 1169/2011 Regulation 1924/2004
Legal Definition	Article 1(2) of Directive 2001/83/EC (a) Any substance or combination of substances presented as having properties for treating or preventing disease in human beings; or (b) Any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis.	Article 2(2)(g) of Regulation 609/2013 'food for special medical purposes' means 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	Article 2(a) of Directive 2002/46/EC 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
Intended Purpose	to restore, correct, or modify physiological functions (or to make a medical diagnosis)	for the dietary management; for the exclusive or partial feeding	to supplement the normal diet; no specific purpose
Target Group	patients	specific patients	primarily for the healthy population, as generally agreed on by experts
Activity of the (active) Substance(s)	pharmacological, immunological or metabolic; physiological functions: restore, correct, modify	nutitional or physiological	nutritional or physiological; physiological functions: maintain, support, optimise [50]

[50] Council of Europe, 2008. Homeostasis a model to distinguish foods (including food supplements) and medicinal products, Strasburg, France; cited in [42]

(Table continues on next page)

Legal Prerequisites for Distribution	Regulated very restrictive. Marketing authorisation is required before placing on the market.	Regulated less restrictive. Notification at time of first placing on the market required.	Regulated even less restrictive. Notification may be required in MS.
Scientific Evidence	Comprehensive data on quality, efficacy and safety required (Art.8(3) of Directive 2001/83, point I) – incl.pharmacokinetic, pharmacodynamic and toxicological data, pre-clinical and randomised, controlled clinical studies (Phase I-VI studies according to provisions and as approved in study protocols) considering GMP/GCP for risk-benefit evaluation. Minimum of two confirmatory, double blind, controlled studies for marketing application. Benefit-risk balance has to be favourable and therapeutic efficacy needs to be sufficiently substantiated to receive marketing authorisation (Directive 2001/83; Article 26).	Generally accepted scientific data required to prove the FSMP is safe, beneficial and effective in meeting the particular nutritional requirements of the persons for whom it is intended. However, details are not yet strictly regulated and the scientific data is not evaluated from authorities before the launch of the product. Currently, according to Guidelines, the extent of scientific data required has to be assessed based on case-by-cases analyses. Studies on pharmacokinetics, pharmacodynamics, toxicological data or human clinical studies – none is explicitly required by law. A scientific rational and any scientific data may be sufficient.	Not required for the product. (Only authorised nutrition and health 'claims' to be made in accordance with Regulation (EU) No 1924/2006, which have been scientifically established.)
Involved Authorities	EU level: EMA/Committees/Working Parties/others National: NCAs (Germany: BfArM)	EU level: EFSA/EC in case of Article 3 decisions National: NCAs (Germany: BVL)	EU level: (EFSA evaluates 'claims') National: NCAs (Germany: BVL)
Shared Responsibilities	Since competent authorities evaluate relevant data (dossier), they take over certain responsibility for a products safety and efficacy before providing the approval and *before* a product is placed on the market. Of cause, the holder of the marketing authorisation is responsible that the product always complies with the dossier and with all provisions applicable. This also includes duties after authorisation, i.e. adverse reactions reports, periodic safety update reports, information on variations and eventually further studies.	FBO take full responsibility at all stages of production, processing and distribution that FSMP complies with GFL; FBO has to ensure correct classification to apply appropriate law based on own assessment; according to specific FSMP law FBO is also responsible for the products safety and efficacy in terms of meeting the particular nutritional demands, as established with scientific data; NCAs take responsibility for the enforcement of the law and monitor the market, but only *after* a product is already launched.	FBO takes full responsibility at all stages of production, processing and distribution that the food complies with general food law; FBO has to ensure the correct classification to apply the appropriate legislation based on own assessment; NCAs enforce food law and monitor.

Eidesstattliche Versicherung

Hiermit erkläre ich an Eides statt, die Arbeit selbständig verfasst und keine anderen als die angegebenen Hilfsmittel verwendet zu haben.

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Ort, Datum Unterschrift