A food supplement or a medicinal product?
Borderline products in the EU.

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Abstract

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, are called ‘borderline products’. In most cases, the doubts may arise between medicinal products and food supplements, cosmetics, biocides or medical devices. Even though statutory definitions of each of these categories are explicitly regulated on the EU level, still, there are doubts whether a product in question should be classified as a medicinal product or a food supplement. The settled European case law is full of such examples, yet there is no clear and unequivocal answer on how to approach this kind of legal uncertainty on the EU level and whether there is a way of providing a legal solution that limits the problem. This research assesses the existing regulatory approaches to borderline products, especially in the range food supplements–medicinal products, through the analysis of European legislation and its effect on national law of Member States. The study attempts to formulate recommendations which could contribute to limiting the legal uncertainties concerning the delineation between food supplements and medicinal products in the EU.
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Abbreviations

**EFFL** European Food and Feed Law

**EFRR** European Food Risk Regulatory

**EFSA** European Food Safety Authority

**EU** European Union

**EUCJ** European Court of Justice

**GFL** General Food Law

**PL** Poland

**TFUE** Treaty on Functioning European Union

**UK** United Kingdom

**WHO** World Health Organization
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Chapter I.

Background to the research

Introduction: What is a borderline product?

Gone are those days when food was only considered as a means to prevent hunger and nutritional deficiency. As a result of widely available access to education and knowledge, consumers are trying to reach a high quality of life which they expect to maintain into old age. A diet is part of a lifestyle. Increasing awareness regarding the relationship between the sort of products we eat and our health has changed the way people select their diet ingredients. They aspire to maintain their health through diet and decrease their risk of developing diseases. On the one hand, an adequate and varied diet provides all the necessary nutrients for normal development and maintenance of a healthy life. On the other hand, however, a growing number of well-informed and aware may choose to supplement their intake of certain nutrients through food supplements.

At the same time, being familiar with consumers’ expectations, food companies are increasing their efforts to market various products intended to maintain good health and prevent its deterioration. This tendency is pronounced in the food supplement industry where the market has been expanding over decades. The consumers’ demand is validated by numbers. Already a decade ago, the total size of this European market was estimated to be around 5 billion EUR as early as 2005 (Euromonitor web. 2007). Food supplement sale for the period 2005–2012 indicated a steady increase in growth. Forecasts for this period varied between the EU Member States and ranged from 4% to 45%, with an average of 20% to 25% (European Advisory Service 2007). The most successful food supplements available on the market are fish oils, probiotics, gingko, echinacea and garlic (EU Commission 2008).

The various uses of garlic, for instance, result in great consumer demand on the market. Since times immemorial, garlic is a well-known food component improving flavour of dishes in various cuisines worldwide. On the other hand, it is considered as common knowledge that garlic, beyond being a foodstuff, has a positive effect on health. In many cultures, for example, garlic consumption is recommended during common cold or flu.
While the problem may sound trivial at first sight, at least for classic food such as meat or fruit, the issue is of high complexity in EU law (Lobell-Behrends et al. 2011). Therefore, from the European legal perspective, however, it is a matter to be categorized, whether garlic is a food or a medicine\(^1\). Similar legal questions are raised for several products sharing multiple and varying intended uses with a beneficial effect on human health. A product to mask bad breath for instance, presented as tablets, dissolved in the saliva and which is ultimately swallowed might be considered as food, medicine and even a cosmetic (EU Commission 2007, points 35-36). Similarly, a product which, according to its presentation, is antiseptic or antibacterial, might be identified as a biocide product, a cosmetic product, a medicinal product or even a medical device. Such 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, are called ‘borderline products’ (EU Commission 2011).

![Figure 1.1. Borderline products](image)

\(^1\text{Note. Basically, pharmaceutical legislation covers the whole life-cycle of a medicinal product, from manufacture to clinical trials, to marketing authorisation, to pharmacovigilance and patient information. However, most legal scholars describe EU medicinal products as a part of medicinal law. In this paper ‘pharmaceutical law’ and ‘medicinal law’ are used interchangeably.}

\(^2\text{FS means ‘food supplements’, ATMPs means ‘Advanced Therapy Medicinal Products’. Based on a presentation entitled ‘Medicines and devices. Not so much apart anymore’ made by Erick Vollebregt (a founding partner of AXON LAWYERS in Amsterdam).}
In most cases, the doubts may arise between medicinal products and food (and recently food supplements), cosmetics, biocides or medical devices. Even though a legal scope of each of these categories are explicitly regulated on the EU level, still, these definitions can often overlap and implicate innumerable legal uncertainties. The settled European case law is full of such examples, yet there is no clear and unequivocal answer on how to approach this kind of legal uncertainty on the EU level.

**Definition of the problem**

The term ‘borderline products’ was used for the first time in the Preamble to Directive 2004/27/EEC (passed into force in 2004)\(^3\) which revised the legal definition of medicinal products stipulated in Directive 2001/83\(^4\). That step was taken, among others, as a result of ‘the growing number of so-called borderline products between the medicinal product sector and other sectors reflected in the large number of rulings concerning doubts with regard to legal distinction between medicinal and other products\(^5\). The courtrooms of the EUCJ were the main place where the concept of borderline products has emerged for the first time and is still developing. The first judgment on EU (Community) level, recognised as a fundamental case concerning borderline products, was ruled in 1983 as a result of a criminal investigation undertaken by the Dutch authority against Van Bennekom (C-227/82)\(^6\). The case was evaluated in the context of an ambiguous classification of products fortified with a large quantity of vitamins. The famous ruling did not solve the legal question ‘in relation to the establishment of the dividing line between medicinal product and foodstuff\(^7\) but proposed an (ad-hoc) case-by-case analysis. Although three decades have passed since then, it is still an open legal question whether a product fortified with additional vitamins, categorized under EU law as a food supplement since 2002, should be considered as a medicine or food.

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\(^5\) Directive 2004/27/EC, Recital 7


\(^7\) Case C-227/82 van Bennekom, paragraph 5
Those doubts concerning legal delineation between some types of food – especially food supplements – and medicinal products, may imply several consequences for national authorities and consumers; however the biggest challenge is faced by stakeholders involved in the trade and the functioning of the EU Internal Market (Hemmings 2011).

All relevant EU legislations – food supplement and medicinal products laws – applicable to this demarcation have been introduced in EU directives8. Currently, under the existing EU law, although the directives have stipulated the objective to be attained, each Member State deals with the issue of legal delineation between food supplements and medicinal products in its own way. As a consequence, on the one hand, there may be a problem with the correct legal classification of a product produced and marketed in only one Member State as a result of case-by-case consideration. On the other hand, the lack of a uniform approach on the EU level may cause a situation in which the same product may be differently categorized in various Member States. The fact that a product is classified as a foodstuff in one Member State, according to the settled case law, cannot prevent it from being classified as a medicinal product in another Member State which imports it, if it displays the characteristics of such a product9.

Such complex situations may become clearer after recalling some examples. Thus, let us consider garlic once again. For instance, in Germany, which is one of the biggest producers of herbal medicinal products in the world, garlic may be sold either as an herbal medicinal product or as foodstuff and as a food supplement. According to Kroes’s calculations (2006) the number of garlic medicinal products marketed in Germany that required a pre-marketing authorisation or any notification, exceeded 85 in 2006. Simultaneously, on the same market, several garlic products were sold as foodstuffs without previous authorisation, while garlic food supplements were permitted for sale under specific conditions (Silano et al. 2011).

Thus, in the process of launching a new garlic product in Germany, a (German) producer already meets difficulties in determining the correct legal classification of its product. With a subsequent decision to expand that business to other EU markets, introducing the product might become more complex. When the German garlic supplement is to be marketed in

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8A legal definition of a directive is provided in Article 288 TFUE which stipulates: ‘A directive shall be binding, as to the result to be achieved, upon each Member State to which it is addressed, but shall leave to the national authorities the choice of form and methods’. See more in chapter 1.7.2

9See more, e.g., joined Cases C-211/03, C-299/03 and C-316/03 to C-318/03 HLH Warenvertrieb and Orthica (2005), paragraph 56; Case C-387/99 EU Commission v. Germany paragraphs 36 and 37.
Hungary or Slovenia, then the permission for use in food supplements will be based on domestically established maximum levels of garlic in food supplements. In turn, in Bulgaria or Cyprus the relevant permission will be given on a case-by-case basis following evaluation, considering issues such as the ingredient function. On the Swedish market, on the other hand, garlic is not permitted for use in food supplements nor it is regarded as medicine (Kroes 2006).

It is not surprising that the legal delineation between medicinal and other products, in particular food supplements ‘is a matter of discussions and controversy’ (Silano at al. 2003).

According to the traditional theory of law, law is regarded as a certain system of rules characterised by stability, clarity, uniformity, calculable enforcement, publicity, and predictability (Chowdhury 2014). In an ideal situation with completeness and consistency, products fall under one specific legal category and thus under one legal regime. As explained above, from a regulatory perspective, a classification in which an object has a double or multiple status is not desirable (Ozog 2011) and causes legal uncertainty.

Here it is worth mentioning that some steps have been taken in the field of soft law. The increasing trend in application of non-binding regulations is visible in the matter of borderline products as well. The EU Commission in cooperation with the industry have published a few guidance documents to facilitate the application of the relevant EU legislation in case of doubt, especially in the range of medicinal products and cosmetics, medicinal products and medical devices.10 No guidelines on the demarcation between food supplements and medicinal products have been adopted yet.11 Although those types of documents do not provide legally binding obligations in the light of the EU law, solutions proposed there might be helpful in setting up tools for determining the relevant applicable legislation.

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10 See e.g. Manual on the scope of application of the Cosmetics Directive 76/768/EEC (2007); Manual on Borderline and Classification in the Community Regulatory Framework for Medical Devices, Version 1.16 (07.2014). See more in chapter 2.4.1

11 Except of the document ‘Homeostasis a model to distinguish foods (including food supplements) and medicinal products’ issued by the Council of Europe 2008. See more in chapter 2.4.2
Main objective

The objective of this thesis is:

a) to study the existing regulatory approaches to borderline products, especially in the range food supplements–medicinal products, through the analysis of European legislation and its effect on national law of Member States, and

b) to formulate legal recommendations which could contribute to limiting the legal uncertainties concerning delineation between these two categories in EU law.

Research questions

What regulatory recommendations can be made in order to reduce, in the range of food supplements and medicinal products, the legal uncertainties concerning delineation between these two categories in EU law?

Sub-questions:

1. How has the concept of borderline products, particularly in the range of food supplements and medicinal products, developed in the EU legislation and the EUCJ case law?

2. What is the impact of borderline products on the EU Internal Market?

3. What sorts of approaches to borderline products are applied in Member States, presented on the example of Poland and the UK?

Methodology

The above questions are addressed in six chapters. Sub-questions 1 and 2 are based on an analysis of selected – binding and non-binding – EU legal documents and EUCJ rulings. They are supported by articles, commentaries and opinions published in scientific journals, books and websites. Question 3, dealing with Polish and British rules and approaches to borderline products, is presented referring to the relevant domestic legislations and court rulings, in addition to manuals, scientific articles and legal books and information found on
governmental websites. These observations and analyses will provide the basis for concluding with the main question: the formulation of recommendations to reduce the remaining ambiguity.

As this thesis contains a compilation of legal aspects concerning borderline products, a legal analysis of EU law, including case law and national laws in Poland and the UK is presented. This study also contains, when necessary, references to scientific terminology, as from food toxicology or technology.

**Research Structure**

The thinking behind the structure of this thesis is set out in Figure 1.5. The thesis content is divided into seven chapters.

**Chapter 1**, the current one, serves as the introduction to the research. It provides an explanation of the term ‘borderline products’ and the present concerns associated with it in EU law. Being aware of the complex and multi-layered EU legal system, it introduces also the basic EU legal sources as a background for the next chapter.

**Chapter 2** presents an overview of the evaluation of the food supplement and medicinal products legislation from a historical and legal perspective. It singles out the legal measures provided in regulations in other European sectors with regard to ‘the borderline issues’, such as in cosmetic and medical devices law. In addition, it presents non-binding documents dealing with the problem of delimitation between medicines and other products undertaken by the EU Commission and the European Councils.

**Chapter 3** discusses the EUCJ case law concerning the demarcation between medicinal products and other quasi-products, mainly food supplements.

To capture the broadest possible perspective of the development of the borderline product concept within the current EU law both legislations and juridical rulings are indispensable. **Chapter 4**, hence, gives conclusions to previous chapters and answers question 1.

**Chapter 5** examines the effect of the current food supplement and medicinal product legislation and settled case law in this regard on the principles and rules governed by the EU
Single Market. It contains the answer to question 2. **Chapter 6** focuses on different approaches adopted in selected Member States, namely in Poland and in the United Kingdom, with regard to the difficulties in application of the EU law and case law regarding medicinal products and food supplements. It compares these two national legal approaches. Thus, it deals with question 3. This research culminates in **Chapter 7** which focuses on the central question: ‘What legal recommendations can be made from the perspective of the EU food law, in order to reduce, in the range of food supplements and medicinal products, the legal uncertainties with demarcation between those two categories in EU law?’ It discusses the main findings made in previous chapters to suggest possible approaches and appropriate legal measures on the EU level.

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12 “MS” means Member State; “PL” means Poland; “UK” means the United Kingdom; “FS” means food supplements; “MP” means medicinal products.
Legal background – basic introduction

In light of the foregoing considerations, looking for the very best solution to reduce the uncertainty of application of the relevant legislation for such products seems to be obvious and simple: there is a need to design the EU-wide legal rule applied identically in all doubtful cases concerning delimitation between medicinal products and food supplements within all the EU Member States. This would guarantee transparency in applying a suitable law and prevent all kinds of possible obstacles within domestic markets and the EU Internal Market.

Legal tools available to approach the problem

In general, law, as a scientific discipline, enjoys a broad spectrum of legal tools which are used to establish an appropriate legal solution to any social, economic or political situation (Jablonska–Bonca 2008). These may include: adapting other methods of interpretation to the existing legal provisions which are concerned, amending (revising) current legislation, or introducing a completely new one. Nevertheless, each of these tools should be arranged in accordance with the postulate of completeness and consistency (Zielinski 2012). Looking more precisely into this requirement, it means that the suggested legal measure should be, on the one hand, applicable in practice and on the other hand be conforming to principles already provided in the law. Finally, it should balance the interests of its users.

Substantive and procedural aspects of legal norms

All legal measures are traditionally and universally divided into norms substantive and procedural law (Jablonska–Bonca 2008).

Substantive law is composed of norms which directly regulate the rules that define a particular right and/or duty (Meulen et al. 2014, p.69). In other words, substantive law stipulates who should behave under particular circumstances and how, and often specifies the consequences of lack of compliance with that law.

In turn, procedural law covers legal norms that regulate all the elements related to the mode of proceedings, for example duration of the procedures, type of evidence required.
EU law vs. local laws

In addition, nowadays all legal circumstances are affected by a set of norms regulating relationships between states, for example in the EU legislation or among various international institutions or even private stakeholders involved in a specific issue.

In order to reduce the legal uncertainties concerning demarcation between food supplements and medicinal products, it is indispensable to relate this legal challenge to the abovementioned considerations. Technically, hence, interaction of these laws is always needed to design a complete and applicable legal tool. Having a legal norm, strictly speaking (in this case) a proposal of legal solution regarding borderline products in the range of food supplements and medicinal products, the next point should consider the territorial extension of its application and to what degree it is binding. Putting it another way, the solution should be analysed with regard to the current competencies of the EU Institutions and Member States. It should be considered the most appropriate degree of harmonisation within EU law.

To sum up, constructing a legal measure consisting of two aspects – substantive and procedural – is a common legal practice presented in the theory of law in general. In the meantime, any solution should be found with regard to territorial applicability. In case of the EU, it is a very complex matter. Hence, a short introduction concerning the basic EU law is presented.

Legal Sources in EU Law

The law of the EU is a specific legal order, independent of both public international law and of national laws. It is established not exclusively by the EU’s Member States but also independently by its own institutions. It is a body, derived from treaties, legislations and court judgments, which operates alongside the legal orders of its members. The EU law has a direct effect within the Member States and, when a conflict occurs, takes the priority over national law. In order to balance the interests of all the Member States and to guarantee a constant growth and development of the EU as such, various forms of legislation are established.

- **Primary and secondary legislation**

The core legal norms are outlined in the so-called ‘primary legislation’ – founding treaties and treaties amending them. Primary legislation is an area of the legal order comparable to
the constitutional law at the national level. It lays down the fundamental features of the Union, in particular the decision making process, the responsibilities of the various actors and their power conferred on them. The first treaty, which established the foundation of the EU, was signed on April 18, 1951 in Paris. In the meantime, additional treaties have been signed, either due to the enlargements of new states or modifications of principles and policy priorities. After the Treaty of Lisbon (2007), the fundamental provisions are included in the following treaties: the Treaty on the European Union (TEC or TEU) and the Treaty on Functioning of the European Union (TFUE).

The primary legislation, adopted in treaties, contains predominantly legal norms belonging to the public law. In the case of the present problem, concerns related to the demarcation of the legal application between food supplement and medicinal products laws, the treaties’ provisions are important for issues embracing, for example, the legal grounds which give competences to adopt legal texts or justify limitations to the principle of free movement of goods within the Internal Market.

The significant part of the EU law is the so-called ‘secondary legislation’, namely the law established by the institution of the EU. Basically, on the basis of the EU treaties, the competent institutions may adopt legislation which is then implemented into national legal systems of its Member States. The secondary legislation comprises binding legal instruments (regulations, directives and decisions) and non-binding instruments (recommendations, opinions).

For the purpose of this research, particular attention will be paid to regulations and directives. The main legal document regulating foodstuffs was introduced in Regulation 178/2002. In turn, either food supplements or medicinal products laws are adopted through directives, namely Directive 2002/46 and Directive 2001/83.

Regulations

The main feature which distinguishes regulation and other acts is the general applicability. As stressed in the case Calpak vs. Commission (C-789/79 and C-790/79), a regulation – having a legislative nature – ‘is applicable not to a limited number of persons, defined or

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13 The treaty came into force on 23 July 1952 and expired on 23 July 2002, exactly 50 years later
14 For example Art. 114 TFUE
15 For example Art. 34, 36 TFUE
indefinable, but to categories of persons viewed abstractly and in their entirety.’ Regulation binds it entirely and is directly applicable in all Member States. It means that it does not need a national measure, such as ratification or other legal transformation, to become entirely binding in the domestic system of each member. It also means that the national competent authorities or any national legal measures, even those posterior to the regulation, cannot prevent its application (Borchardt 2010).

**Directives**

Directives on the other hand bind the Member States to which they are addressed to achieve certain results. Imposing an obligation to achieve specific result distinguishes directives from regulations. Although the expected result is set out in the directive, each Member States is free to decide how to transpose this result into domestic law (Craig at all. 2015, p.108). It is, for example, irrelevant, whether the national measures are based on administrative law or contract law, as long as they are binding and as long as they fully meet the requirements mentioned in the directive. Directives are not directly applicable, since they require implementing measures - thus their provisions cannot have a direct effect similar to regulations. For this reason, since a Member State is responsible for transposing directives into national legislation, the State is liable for damage caused to individuals as a result of wrong transpositions (Mathijsen 2004).

- **Judicial divisions of the EUCJ as a source of law**

It is recognised that rulings issued by the EUCJ are additional sources of the EU law (Kramer 2011). The main competences of the EUCJ are stipulated in Articles 267 TFUE and 271 TFUE. The court basically aims to uphold the law, to rule on how to interpret the EU law and to ensures that the Member States apply EU legal provisions in the same way. It can happen that the Court might develop a settled case law used in the whole EU or even create a legal approach which would be adopted later into an official, binding law. Thus, in general, the EUCJ rulings are considered as an unwritten legal sources helping in interpretation of EU law.
Contribution and limitations of this thesis

Borderline products, among others in the range of food supplements and medicinal products, are part of an ongoing discussable issue among scholars, policy makers and stakeholders. The subject has been the topic of several articles and comments. However, these focus on a particular problem: some refer to specific EUCJ rulings (for example, Purnhagen (2010) on case 27/08 in ‘On how to assess a medicinal product by function’, Melchor and Timmermans (2009) about case 88/07 in ‘It’s the dosage, stupid’) or a single aspect derived from the legislation or the case law, for example, Coppens (2008) about botanicals in ‘The Use of Botanicals in Food Supplements and Medicinal Products’. Several aspects of borderline products are also presented as a part of larger elaborations. For example, Chowdhury (2014) dedicated a chapter to borderline products in ‘European Regulation of Medicinal Devices and Pharmaceuticals’, and Lähteenmäki-Uutela (2009) focused on a particular aspect in her doctoral thesis entitled ‘Foodstuffs and medicines as legal categories in the EU and China. Functional foods as a borderline case’.

This thesis attempts to provide a horizontal approach to current problem with legal delineation between medicinal products and food supplements. It aims to consider the problem from several perspectives: from the EU and national level, and then from political, substantive and procedural perspectives recognising the legal initiatives taken through binding and non-binding documents. In general, however, it is limited to selected works available in English and Polish. Furthermore, due to time limitations, many relevant aspects of this issue are not addressed and analysed although they have a significant importance to borderline products in the EU. Outside the scope of this paper, are, among others, subjects concerning the distance selling of food supplements and medicine under existing EU consumer law which may influence the problematic classification of products recognised as borderline. Any comparative studies presenting approaches applicable in other non-EU systems (such as Japanese, the US, Chinese) are not referred to, although they might indeed provide a valuable input to solve the problem with demarcation on the EU level. These points would definitely be worth elaborating.

Chapter II:

Legal Aspects of Borderline Products within EU law.

2.1 Introduction

Basic EU legislation applicable to the legal delineation between medicinal products and other quasi-medicinal products is presented in this chapter. Particular attention is paid to Directives 2002/46/EC on the approximation of the laws of the Member States relating to food supplements and 2001/83/EEC on the Community Code relating to medicinal products for human use. To begin with, a general overview of those directives is provided with special focus on statutory definitions of food supplements and medicinal products. Next, legal relations between medicinal products and cosmetics and medical devices are briefly described. Additionally, trends in the growing role of non-binding regulation concerning borderline products are described.

EU Food and Food Supplements Law

2.1.A. Food Law – basic introduction

Since food supplements are a sub-category of foodstuffs, it is necessary to introduce the basic principles and objects of EU food law. The core legislation concerning food is adopted in Regulation 178/2002, a so-called General Food Law (GFL). Guaranteeing a high level of protection of human life and health (Articles 6–7) and protection of consumers’ interests, including fair practices in trade (Article 8) are the main objectives of this legislation. These goals have to be achieved in compliance with Article 14 of GFL, which is, undoubtedly, the single most important provision in EU food law (Meulen et al. 2014). Food is recognised as unsafe, among others, if it is injurious to health (14 (2) GFL).

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19 Article 14 GFL states: ‘1. Food shall not be placed on the market if it is unsafe. 2. Food shall be deemed to be unsafe if it is considered to be: (a) injurious to health; (b) unfit for human consumption. 3. In determining
This means for food supplement law, generally, that the approach presented in application of Regulation 178/2002 applies to food supplements as long as this directive does not

whether any food is unsafe, regard shall be had: (a) to the normal conditions of use of the food by the consumer and at each stage of production, processing and distribution, and (b) to the information provided to the consumer, including information on the label, or other information generally available to the consumer concerning the avoidance of specific adverse health effects from a particular food or category of foods. 4. In determining whether any food is injurious to health, regard shall be had: (a) not only to the probable immediate and/or short-term and/or long-term effects of that food on the health of a person consuming it, but also on subsequent generations; (b) to the probable cumulative toxic effects; (c) to the particular health sensitivities of a specific category of consumers where the food is intended for that category of consumers. 5. In determining whether any food is unfit for human consumption, regard shall be had to whether the food is unacceptable for human consumption according to its intended use, for reasons of contamination, whether by extraneous matter or otherwise, or through putrefaction, deterioration or decay. 6. Where any food which is unsafe is part of a batch, lot or consignment of food of the same class or description, it shall be presumed that all the food in that batch, lot or consignment is also unsafe, unless following a detailed assessment there is no evidence that the rest of the batch, lot or consignment is unsafe. 7. Food that complies with specific Community provisions governing food safety shall be deemed to be safe insofar as the aspects covered by the specific Community provisions are concerned. 8. Conformity of a food with specific provisions applicable to that food shall not bar the competent authorities from taking appropriate measures to impose restrictions on it being placed on the market or to require its withdrawal from the market where there are reasons to suspect that, despite such conformity, the food is unsafe. 9. Where there are no specific Community provisions, food shall be deemed to be safe when it conforms to the specific provisions of national food law of the Member State in whose territory the food is marketed, such provisions being drawn up and applied without prejudice to the Treaty, in particular Articles 28 and 30 thereof.’
stipulate differently. Hence, the definition of food is of significance for the interpretation of the food supplement directive.

The exemption provided in Article 1(d), stating clearly that the product cannot fulfil both definitions of food and medicine at the same time, is the starting point for the legal analysis of the delineation between food and medicine. It emphasizes that EU law separates medicinal law from food law.

2.1.B. EU Food Supplement Law

2.1.B.1. Historical background

Food supplements as foodstuffs, in principle, are regulated by food legislation. The EU was for many years troubled by issues related to marketing food supplements, with various qualifications of those products in different Member States (Korzycka-Iwanow 2010). For this reason, the Green Paper ‘General Principles of Food Law’ proposal of 1997, followed by the ‘White Paper on Food Safety of 2000’ introduced a clear need to harmonise the legal issue of food enriched with nutrients. Even though the EU Commission committed at the beginning of 2000 to presenting a first legislative draft within three months and to adopting the law by September 2000 (Hagenmeyer at al. 2008), the legislation work, which tried to balance the contradictory interests of the stakeholders involved in the food supplement market, took roughly two more years. The drafting stage was widely criticised, among others, by Germany, which wished to draw up a restrictive European legislation based on specific authorisation for food supplements, while Great Britain and the Netherlands resisted on the grounds that this legislation would unnecessarily limit the economic freedom of the manufacturers of food supplements (Watson 2002 p.327, Korzycka-Iwanow 2010). Despite the heated debates, since 10th June 2002 the legal scope of food supplements has been regulated by Directive 2002/46/EC on the EU level.20 The act introduced common legal rules governing the food supplement market within the European market for the first time, although they were not fully harmonised. Due to the fact that the law in question was framed as a directive, it needed to be transferred into the domestic legislation of Member

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20 Shortly after, that Directive was appealed by a number of English food business operators before the EUCJ with the main argument that its legal basis was not considered suitable for harmonising national regulations on food supplements for public health reasons (Silano et. all 2011). Ultimately, in its judgment of 12 July 2005 in the joint cases C-254/04 and C-155/04, the Court confirmed the validity of this legal act. See more in chapter 7.5
States. Article 15 stipulated an obligation for national authorities to comply with the directive as of 1st August 2003 at the latest.\textsuperscript{21}

2.1.B.2. Legal aim

The legal framework of food supplements governing their use and marketing is a \textit{lex specialis} type of legislation in comparison with food legislation (Zboralska 2012). The main rationale for this act, on the one hand, is ensuring a high level of consumer protection and facilitating consumer choices concerning supplementing diet intake with vitamins, minerals and other substances. Additionally, the directive was adopted in order to facilitate trade, and to reduce obstacles in order to apply the principle of free movement of goods and create conditions for equal competition within the EU area.\textsuperscript{22}

2.1.B.3. Scope and definitions

Bearing in mind the legal separation between food and medicine, food supplements, within the meaning of EU law, are introduced in Article 2 \textit{(a)} of the Directive 2002/46 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, where nutrients could be vitamins, minerals, herbal extracts and other ingredients.’

Beyond the definition of food supplements, the directive in question provided harmonisation provisions with regard to composition (Articles 4–5), specific labelling requirements (Articles 6–8), lists of permitted vitamins and minerals in the manufacture of food supplements (Article 4 \textit{(1)} in conjunction with Annex I) and a ‘future’ setting of upper limits for vitamins and minerals in food supplements (Article 4\textsuperscript{(8)}).

With regard to composition, the most characteristic element of this law is the positive list attached to the directive – an annex containing a list of vitamins and minerals which may be

\textsuperscript{21} Moreover, the national laws of Member States shall be applied so as to permit trade in products with the new law from 1 August 2003 and permit trade in products not complying with the new law from 1 August 2005.

\textsuperscript{22} Preamble to Directive 2002/46, Recitals 2–5.
used in the manufacture of food supplements. Generally speaking, legally marketed food supplements containing vitamins or minerals in the EU are placed on a positive list—only those on the list are allowed to be used in food products on the market. The positive list of the Directive 2002/46 includes 13 vitamins with 33 allowed sources and 15 minerals with 89 allowed sources\textsuperscript{23}. In order to keep up with scientific and technological developments, the Preamble announces successive amendments to the list\textsuperscript{24}. This particular legal tool represents only a first step in the creation of European food supplement law, as it focus only on vitamins and minerals. In other words, food supplements containing vitamins and minerals as well as other ingredients should also conform to the specific rules. However, neither a clarification of the term “other substances with a nutritional or physiological effect”, nor a list of examples of such substances are provided. Hence, in general, the shaping of rules concerning the marketing of food supplements containing ‘other substances’ continues to be the subject of national regulations.\textsuperscript{25}

The most relevant legal principle regarding food supplement labelling is stipulated in Article 6 which imposes the obligation to sell products covered by this directive under the name ‘food supplement’. As added in Article 7 the labelling, presentation and advertising must not attribute to a food supplement the property of preventing, treating or curing human disease, or refer to such properties (Karajiannis et al. 2011).

2.1.C. Other relevant laws

The classification of food supplements as food implies automatically that the manufacturing has to be carried out under additional food legislation. In the light of the borderline products in the range ‘food – medicinal products’ the following legal acts should be considered as well.

\textsuperscript{23}EU Commission website. ‘Food Supplements – Food safety’. Available online at http://ec.europa.eu/food/safety/labelling_nutrition/supplements/index_en.htm [Last accessed on 2 March 2016]

• Regulation 1169/2011 on the provision of food information to consumers\textsuperscript{26}

• Regulation 1924/2006 on nutrition and health claims made on foods\textsuperscript{27}

• Regulations on novel food. Regulation 258/1997 of 27 January 1997 concerning novel foods and novel food ingredients\textsuperscript{28} and Regulation 2015/2283 on Novel Food\textsuperscript{29}

• Regulation 609/2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control\textsuperscript{30}

\textbf{Regulation 1169/2011}, which came into force on December 13, 2011, establishes the legal principles of food information, in particular food labelling, in the EU. One of the main purposes is to prohibit the use of information that would mislead the consumer. It does not stipulate specific provisions directly linked to a potential dispute regarding the classification of a product as a medicine or a food. However, Article 7 a–c of this act, introducing the principle of fair information practices, prohibits the use of information that would mislead the consumer in particular as to the characteristics of the food, food effects or properties, or attribute medicinal properties to foods.

\textsuperscript{26}OJ L 304, 22.11.2011
\textsuperscript{27}OJ L 404, 30.12.2006
\textsuperscript{28}OJ L 43, 14.2.1997
\textsuperscript{29}OJ L 327, 11.12.2015, p. 1–22. Regulation No 2015/2283 on Novel Food will replace the current one on January, 1. 2018
\textsuperscript{30}OJ L 181/35 29.6.2013
The prohibition is understood very broadly as a prohibition applicable to the advertising and presentation of foods. It does not introduce any criteria but once again expresses the prohibition of anti-diseases suggestions in food supplements.

**Regulation 1924/2006** on nutrition and health claims made on foods, was adopted in December 2006 and applied from 1st January 2007. This act applies to the nutrition and health claims made in commercial communications, whether in the labelling, presentation or advertising of foods to be delivered as such to the final consumer. Article 2 defines a nutrition claim as any claim which states, suggests or implies that a food has particular beneficial nutritional properties due to the presence, absence, increased or reduced levels of energy or of a particular nutrient or other substance, and includes claims such as ‘source of calcium’, ‘low fat’, ‘high fibre’ and ‘reduced salt’. More relevant for the dispute between classification of a product as food or medicine are health claims. The health claim, under the meaning of this regulation, is defined as any claim that states, suggests or implies that a relationship exists between a food category, a food or one of its constituents and health. Therefore, health claims are different from nutrition claims as they refer to, or imply, a function in the body. For example ‘contains calcium’ only refers to the composition of the food and is a nutrition claim. In contrast ‘calcium is needed for the maintenance of normal

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31 EU Commission, Guidance to compliance with Regulation (EC) 1924/2006, point 24
bones’ refers to the function of calcium in the body and would be considered a health claim. If the presentational aspects of a so-called ‘healthy food’ are scientifically proven and authorised positively by the EUCJ, then EU law permits its sale. On the other hand, under EU law no food can be marketed as a product having medical references. With the possibility of health claims on foods, the borderline between foods and medicine is becoming even thinner. It makes the legal phenomena of on the borderline between food and medicine more complex.

**Regulation 2015/2283** on Novel Food is coming into force on January, 1, 2018. It will replace the current one – **Regulation 258/1997** of 27 January 1997 concerning novel foods and novel food ingredients. ‘Novel food’ means any food that was not used for human consumption to a significant degree within the EU before 15 May 1997, irrespective of the dates of accession of Member States to the EU. A food supplement ingredient may also be classified as a novel food if it was not marketed for human consumption to a significant extent in the EU before 15th May 1997. The definition includes, among others, vitamins, minerals and other substances used in accordance with Directive 2002/46/EC, characterised by:

— a production process not used for food production within the Union before 15 May 1997, which gives rise to significant changes in the composition or structure of a food, affecting its nutritional value, metabolism or level of undesirable substances;
— composition including or consisting of engineered nanomaterials.

Most significantly, before being placed on the market, novel foods must undergo a specific safety assessment after which an authorization decision can be taken. The criteria to judge the marketability of novel foods include absence of: risk to human health, misleading and nutritional disadvantage."

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32 From 1 January 2018, new Regulation 2015/2283 on Novel Food will replace the current one.
33 Article 7 Regulation 2015/2283 has an identical formulation to Article 3 (1) Regulation 258/1997
**Regulation 609/2013**, which is applicable from July 2016, on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control,\(^34\) establishes compositional and information requirements for the following categories of food:

- Infant formula and follow-on formula
- Processed cereal–based food and baby food
- Food for special medical purposes
- Total diet replacement for weight control\(^35\)

With regard to borderline products issues, it should be paid attention to Article 3 of this act. Pursuant to it the EU Commission is entitled to decide – by means of additional acts – about the classification of food categories introduced in the regulation.\(^36\)

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 referred to in Article 1(1) a given food belongs.

![Figure 2.1.Cc: Article 3 Regulation 609/2013 – Interpretation decision](image)

Moreover, Article 7 Regulation 609/2013 foresees a possibility to consult the EFSA on any matter related to the application of this Regulation which is likely to have an effect on public health. Thus, the EFSA advice might be crucial for the EU Commission with regard to adaption of those interpretation decisions under the meaning expressed in Article 3. Subsequently, based on those articles EFSA issued a scientific opinion entitled: ‘Scientific and technical guidance for the assessment of products notified as food for special medical purposes in the context of Article 3 of Regulation 3 (EU) No 609/2013.’ Its scope is limited to issues concerning food for special medical purposes, which are defined as ‘foods intended for the exclusive or partial feeding of patients:

(a) with a limited, impaired or disturbed capacity to take, digest, absorb, metabolise or excrete ordinary foodstuffs or certain nutrients contained therein or metabolites;

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\(^{34}\) OJ. L 181/35 29.6.2013

\(^{35}\) Article 1(1) Regulation 609/2013

\(^{36}\) after 20 July 2016 Article 3 of Regulation 609/2013 becomes applicable
(b) 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.

To sum up, these foods are offered for patients whose ordinary consumption is impossible, very difficult or unrealistic. The main function of this category of food is therefore to feed patients that, because of a particular disease (or disorder or condition), either have problems in consuming ordinary foodstuffs, or have specific medically-determined nutrient requirements whose dietary management cannot be achieved by modifying the normal diet.

The mentioned guideline mainly introduced scientific data required for dossier in order to classify a food as a food for special medicinal purpose. However, the main point which is considered is expected to be the relationship between the product and the disease/disorder/condition for the dietary management of which the product is intended.

In the light of concerns on distinguishing between food and medicines, it is interesting that the EU Commission, with support of EFSA, has become the one who can decide about the legal classification of a product in question. Moreover, Member States may not restrict or forbid the placing on the market of food which complies with this Regulation, for reasons related to its composition, manufacture, presentation or labelling37.

**Medicinal Law**

2.2.1. EU Medicinal Product Law

2.2.1 Historical background

EU regulation concerning medicinal products is the oldest, most extensive and most complex of any product regulatory system (Davis et al. 2013). Up to now, European law on medicines has been a puzzle consisting of EU law and national laws. To make matters more complex, the rules governing medicinal products consist of binding legislation and soft, non-binding laws (Ozog 2011).

The first EU act providing legal scope for medicinal products was adopted in 1965 in the Directive 65/65/EEC. By the end of the 1990s, the EU pharmaceutical legislation could be

37 Article 4(3) Regulation 609/2013
described as fragmented and thus more and more complex, due to the overlapping legal acts on national and European levels (Ozog 2011). In reaction to the fragmentation, the directive was the subject of frequent amendments. One of the most significant ones was the revision provided (Brunet et al. 2005) through the Regulation 2309/93 of 22 July 1993, laying down community procedures for authorisation and supervision of medicinal products for human and veterinary use and establishing the European Medicines Agency. In order to complement national laws and to offer one EU approval regime, the European Agency for the Evaluation of Medicinal Products was created in 1995 in London. Subsequently, in line with previous measures, the EU Commission proposed a fundamental reform of the legislation governing medicinal products in the EU in 2001. As a result, all the rules were collected in ‘The rules governing medicinal products in the EU’ published by the EU Commission (consisting of 10 volumes). For legal matters related to borderline products, the most important directive is Directive 2001/83/EC, in force from 18th of December 2001, which replaced the former Directive 65/65/EEC. Directive 2001/83 established a European code which brings together, in a single legal act, all the provisions in force governing market placement, production, labelling, classification, distribution and advertising of medicinal products for human use (Brunet et al. 2005).

2.2.2. Legal aim

The general revision of the Preamble suggests that the purpose of Directive 2001/83/EC is reflected in four principal objectives: 1) to establish a well-functioning internal market in the pharmaceutical sector, 2) to assure a high level of public health protection for EU citizens, 3) to simplify and unify the authorisation system for medicine and 4) to meet the challenges of the enlargement of the EU38. Therefore, on the one hand, the manufacture and distribution of medicinal products for humans should safeguard public health, namely consumers. However, the goal should be achieved by means which do not hinder the development of the industry and trade in medicinal products in the EU. The main scope of the directive has followed the same objective since 1965 - however it implements an increasingly strict and complex regime. Article 1 (1) of this directive applies to medicinal products for human use intended to be placed on the market in one or more member states and either prepared industrially or manufactured by a method involving an industrial process. According to Article 5 (1) of this directive “medicinal products shall not be placed

38 Recitals 2–5 Directive 2001/83
on the market unless a marketing authorisation has been issued by the competent authorities”.

2.2.3 Legal scope and definitions

According to Article 1 (2) of 2001/83/EC (amended by Directive 2004/27/EC) a medicinal product is defined as:

Medicinal product.

(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.

The central expression ‘physiological functions by exerting a pharmacological, immunological or metabolic action” was added in 2004 in the belief that this clarification of the definition through adding specific types of actions that the medicinal product may exert on physiological function, will facilitate the legal classification of products.

The directive 2004/27/EC introduced also additional provisions significant for the analysis of products falling into “the area of borderline products” category. The provision called the “rule of doubt” is provided under Article 2 (2) to justify the applicability of the legislation on medicinal products to the products at hand. Generally, it is a legal presumption stipulating the prevalence of medicinal products legislation for products which may fall both within the definition of medicinal products and within the definition of products covered by other sectoral legislation.

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.

As emphasised above, extensive regulation has been made around legal conditions regarding authorisation in the EU. Hence, various aspects are regulated, such as, analytical,
toxicological and clinical standards, implementation of common rules on conducting clinical trials, labelling of packaging and packaging leaflets, supply classification, wholesale distribution and advertisements. However, it should be stressed, several issues are partly regulated at national level. For example, member states maintain autonomy on matters dealing with pricing and reimbursement issues (Karajiannis at all. 2011).

### 2.3. Other sectors – EU Cosmetic and Medical device law

Doubts concerning the delineation between two legal categories and their correct application may be noticed with other product categories, especially with regard to the demarcation between cosmetics and medicine or food and between medicinal products and medical devices.

#### 2.3.1. Cosmetics – Regulation 1223/2009 on cosmetic products

Within the EU, cosmetic law has been harmonised for several decades. The essential principle was adopted in 1976 in the Cosmetic Products Directive 76/768/EEC. Recently, European cosmetic law underwent a considerable reform. The new EU Regulation 1223/2009 has been in force since July, 11 2013. One of the regulation’s main purposes is to harmonise the rules in order to assure the functioning of the EU internal market for cosmetic products while ensuring a high level of protection of human health. Although a number of legal tools were introduced with the new law, the legal definition of cosmetic products remains the same and states that.

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The issue of delimitation between cosmetics and other products is listed as a special point according to the new regulation. It is explicitly emphasised that “this regulation relates only to cosmetic products and not to medicinal products, medical devices or biocidal products”. The delimitation, as cited above, should be applied in conjunction with the detailed definition of cosmetics, which refers both to their area of application and the purpose of their use. Importantly, the Preamble clearly stipulates that a legal assessment of whether the product in question is a cosmetic product has to be made through a case-by-case analysis, taking into account all the characteristics of the product.

Parallel to Regulation 1223/2009, attention should be paid to Regulation 655/2013 which lays down common criteria for the justification of claims used in relation to cosmetic products. The main objective of laying down the criteria is to guarantee high quality of final use, especially protecting against misleading claims in relation to cosmetic claims. In general, the criteria are based on legal compliance, truthfulness, evidential support, honesty, fairness and informed decision making. As it can be seen, these criteria sound very general and do not provide any guidelines for their application.

2.3.2. Medical devices

The current framework for EU medical devices consists of Directives 93/42/EEC, 98/79/EC (In vitro diagnostic devices directives) and 90/385 (Active implantable medical devices directive).\textsuperscript{42}

\begin{figure}[h]
\centering
\includegraphics[width=\textwidth]{Figure_2_3_1.png}
\caption{Article 2 (1)a Regulation 1223/2009 – definition of a cosmetic product}
\end{figure}

\textsuperscript{41} Regulation (EU) No 655/2013 of 10 July 2013 laying down common criteria for the justification of claims used in relation to cosmetic products. OJ L 190, 11.7.2013, p. 31–34

The three directives aim to ensure the smooth functioning of the internal market and a high level of protection of human health and safety (Karajannis et al. 2011). These directives stipulate the legal requirements for medical device design, development, manufacture, production release and risk assessment in order to ensure that a product that reaches the public is safe and effective.43 Medical devices, in general, are not subject to any pre-market authorisation provided by a public authority but to a conformity assessment, which, for medium and high risk devices, involves an independent third party (‘notified body’). Once certified by a notified body, devices bear the CE carry certificate which allows them to circulate freely in the EU market.

Article 1 (20) of Directive 93/42/EEC defines a medical device as:

![Medical device](image)

**Figure 2.3.2b. Article 1(20) Directive 93/42/EEC – definition of a medical device**

Despite this harmonised legal basis, differing legal interpretations in the light of specific national laws can lead to different possible legal classifications for one and the same product. When placing a medical device on a market, in general, the manufacturer has to demonstrate that the product is **safe for use** and effective **for its intended purpose**.


43 Directive 93/42/EEC divides medical devices into four classes of risk: class I – low risk (for example sticking plasters), Class II – medium low risk (for example dental filling material), class IIb – medium high risk (for example X-ray machines) and class II – high risk (for example breast implants).
The borderline between medical devices and other products can be a difficult issue. Problems in relation to suitable classification are discussed during expert meetings set up by governmental and non-governmental bodies. In support of the uniform application of directives, non-binding guidance documents (so-called MEDDEV documents) were elaborated with the main idea of helping with decisions on whether a product is considered a medical device or a medicinal product. As can be seen, attempts are being made to resolve the issue of the borderline between medicinal products and medical devices in the area of soft, non-binding law.

2.4. Soft law concerning borderline products

2.4.1. Cosmetics and medical devices in guidelines

In addition to the existing binding legal documents, the EU Commission adopted a list of guidelines with the aim of providing practical guidance on the demarcation between the scope of application of medicinal products legislation and cosmetic, biocides and medicinal devices regulations respectively. No similar guideline, interestingly, intended to help with the determination of the legal status of products which theoretically fall within the definition of medicinal products and food (or food supplements) has been adopted. All documents are the result of discussions between the relevant services of the EU Commission, Member States and representatives of the food and pharmaceutical industry.

Chronologically, the first guidance document was issued on the demarcation between medicinal products and cosmetic products. The ‘Guideline document on the demarcation between the Cosmetic Products Directive 76/768 and the Medicinal Products Directive 2001/83’ became official in 2004. Subsequently, along with the new cosmetics regulation, the guideline was updated in November 2013 and made available as the ‘Manual on the scope of application of the Cosmetic Regulation No 1223/2009 (Art.2.1.a)’.

Next, a very intensified effort was undertaken with regard to the classification of products which may fall both into the medicinal products and medical devices legal scopes. The most recent guideline was issued in 2012 and titled: ‘Manual on Borderline and Classification in the Community Regulatory Framework for Medical Devices’.

It is also crucial to emphasise that these kinds of documents are only considered to be a tool for the case–by–case application of EU legislation by the competent authorities or courts to assess which framework applies. Aside from that, the content of these manuals might appear
useless for the demarcation between definitions of food supplements and medicinal products. Indeed, definitions of cosmetic products and medical devices differ from food supplement definitions. However, it is worth taking a deeper look at the form and the methodology of the regulations. The earlier manuals contained general provisions which provided explanations and examples of products. Now, both manuals for medical devices and cosmetics are more precise documents and contain technical questions and answers.

As it can be seen (Figure 2.4.1), the manuals provide a list of examples of potentially doubtful products and suggested answers. The recommendations in these guidelines are based on published law and case law. However, obviously, that kind of tool cannot provide an exhaustive answers for all possible doubtful cases.

**3.3.4. Products containing substances stimulating hair growth or reducing hair loss**

89. **Question.** Are products containing substances stimulating hair growth or reducing hair loss cosmetic products?

90. **Answer.** The question whether a product or its substance(s) restores, corrects or modifies physiological functions by exerting a pharmacological, immunological or metabolic action has to be taken on a case-by-case basis.

91. The fact that the same substance is not only contained in a cosmetic, but also in medicinal products as an active ingredient is not decisive. However, this may be an indicator for a pharmacological, immunological or metabolic action of the product.

92. In assessing this, one has to consider all characteristics of the product, including, for example, absorption, concentration, route of administration, frequency of application, application site, and the degree of penetration.

93. In particular, the claims may give a useful indication to the competent authorities, without, however, replacing a careful assessment of the mode of action and all the elements indicated above. The claim "promoting hair growth" usually relates to pharmaceutical products, such as, for instance, those containing minoxidil, a substance that is prohibited as a cosmetic ingredient; while the claim "reducing hair loss" usually relates to cosmetic products. A product "preventing hair fall", on the other hand, may be a cosmetic product.

Figure 2.4.1. An example from the Guideline document on the demarcation between the Cosmetic Products Directive 76/768 and the Medicinal Products Directive 2001/83
2.4.2. Homeostasis – a guideline set up by the Council of Europe

A document entitled, “Homeostasis, a model to distinguish between food (including food supplements) and medicinal products’ was adopted in 2008 by the Council of Europe. The Council of Europe is not a part of the EU\textsuperscript{44} and unlike the EU legislator, their institutions do not have the competence to adopt binding law among their members. The general mission of the organisation is to facilitate democratic growth and legal standard development among its members.

The guideline provides advice to help to substantiate and classify products potentially falling into the scope of both Directive 2002/46/EC and Directive 2001/83/EC. As stipulated in the Introduction, the main goal of the model is to establish a ‘pragmatic and feasible system’\textsuperscript{45} to distinguish between these two groups of products, especially in the field of botanicals. The approach tries to define the conditions under which a product is categorised as a food supplement or medicine by virtue of its function. In order to present this, both definitions of food supplements and medicinal products are recalled and briefly analysed, then, the homeostasis model with decisive criteria for distinction is described and explained.

It is summarised that in the context of both legal definitions of food supplement products, the term ‘physiological effect’ should be understood as an optimisation of physiological function and not the restoration, correction or modification of it. In turn, in the context of Directive 2001/81/EC, the following terms are important: ‘restore’, ‘correction’ and ‘modification’. Although the scheme seems logical and clear, the lack of clear terms, explanations and measurable parameters is the main obstacle to judging whether a product is a medicine or a food supplement. In order to distinguish between both definitions, under the proposed solution called the homeostatic model, a product needs to be evaluated against two essential criteria.

- the intended use of the product
- the nature of the induced effect on one or more physiological parameters.

\textsuperscript{44} Council of Europe. (French: Conseil de l’Europe) is an international organization promoting co-operation between European countries in the areas of legal standards, human rights, democratic development, the rule of law and cultural co-operation. It was founded in 1949. The organization is an independent body, and is not controlled by the European Union. Unlike the European Union and the Eurasian Economic Union, the Council of Europe cannot make binding laws. See more. Council of Europe web. Available online at. http://www.coe.int/en/web/about-us/who-we-are [Last accessed on 2 March 2016]

\textsuperscript{45} Council of Europe, Homeostasis. 2008, Introduction
The term ‘homeostasis’ can be defined as the status of a person whose physiological parameters function within the limits considered normal. In the light of the legal definition of food supplements, food supplements are taken to support, maintain and optimise physiological processes in the body. Thus, they maintain homeostasis without blocking these functions. In turn, medicines are used when physiological functions fall out of normality. In other words, medicines bring processes to normality, namely into homeostasis.

The first criterion is linked with the first part of the medicinal product definition in Directive 2001/83. However, the intended use should be considered in a wider perspective as the presentation criteria stipulated in Article 1 (2) a) of Directive 2001/83. It requires a distinction between whether the product is taken with the intention to maintain, support or optimise immunological, metabolic and other specific physiological parameters (then it is a food) or to correct, modify or restore physiological functions or parameters (then it is a medicine). With that in mind, the homeostasis model limits the application field of food supplements and hence the intended use of products which are intended to be applied as medicines but which function in the normal range and hence maintain homeostasis. However, it requires a precise definition of the relevant parameters with the stipulation which of the given parameters are considered normal.

Figure 2.4.2. Homeostasis model
The second criterion to distinguish between these products is the nature of the induced effect on a specific physiological parameter, which means in the majority of cases, the dosage of the active substances used. The model suggests establishing and defining the minimal therapeutic dosage, defined as the minimum amount of substance which induces a therapeutic effect on a well-defined pathology at which a therapeutic effect/activity still exists. Then, if this is the case, and if the amount of a certain substance in a product is lower than the minimal therapeutic dosage, the product is no longer a medicine (by virtue of function). However, it does not preclude categorizing it as a food supplement. Interestingly, the process of demarcation should take into account the data required for authorization, in particular in clinical tests. If no clinical data on therapeutic effects exists, the appropriate scientific data on “well established use” or adequate scientific bibliographic data on traditional medicine use should be analyzed. If no minimal effective therapeutic dosage is established, then there is no need to restrict the use of these substances in food or medicine.

2.5. Conclusions

First of all, it should be stressed that problems with the legal delination and choice between application of food supplement or medicinal products legislation is predominately a matter of national law, even though both the legal definition of medicinal products and the definition of food supplements are harmonised on the EU level. Despite the fact that European law introduced food (and food supplement), and medicinal product legal definitions, there have been difficulties dealing with borderline cases. European law clearly requires that every product should belong to one legal classification (Wojciechowski, 2010). However, it appears that EU legislators predominantly focused on medicinal law. In assessing whether a product in question falls into medicinal or food supplement law, the priority is given to medicinal law.

Full conclusions to borderline products in EU law are presented in chapter 4 after the introduction of the selected EUCJ judgments.

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46 Regulation 2001/83, Article 10
47 Ibid. Article 16
Chapter 3: Borderline products in EUCJ case law

3.1. Introduction

The main goal of this chapter is describing EU Court of Justice (EUCJ) case law relating to the demarcation between medicinal products and other quasi-products, mainly food supplements. The chapter is divided into three parts.

The first part explains the common principles applicable in all cases, namely, a need for a legal analysis containing a product’s description in light of its presentation and function, way of interpreting those factors and the requirement to assess every case individually.

The second part is dedicated to the juridical interpretation of defining medicinal products by presentation, while the third part describes the criteria of this definition by virtue of function.

3.2. Common principles.

3.2.1. A legal analysis of medicinal product definition in the light of its presentation and function

The concept of borderline products, as mentioned in the previous chapter, has been created and evaluated mainly by the EUCJ. The first judgment focused predominantly (although without using the expression ‘borderline products’) on the qualification of foodstuffs enriched with high amounts of nutrients was issued in 1983 as a result of an investigation undertaken by the Dutch authority against van Bennekom (C-227/82). Since 1983 there have been several juridical rulings regarding borderline products, analysing the question of whether a product concerned meets the legal conditions of medicinal products within the meaning of Directive 2001/83 (or the previous Directive 65/65).

The Bennokom case, although it was ruled under a null and void legal regime, might be considered as a fundament for the ‘borderline products concept’. First of all, in this case the
EUCJ set up a rule whereby the EU legal definition of a medicinal product gives two sub-definitions: by virtue of their presentation and by virtue of their function. Moreover, with this case has been introduced a general principle that the evaluation of a product has to be carried out on a case-by-case basis.\(^\text{48}\)

3.2.2. Phases of the process of interpreting the definition of medicinal products

A product is a medicinal product if it falls within either of those definitions.\(^\text{49}\) In all cases where a legal assessment of a product is being provided, it shall be based on interpretation of medicinal products by function and by presentation.

The EUCJ proceeding begins with interpretation of the first part of the definition. If the functional aspects are not fulfilled, then it is necessary to examine whether a product should nonetheless be considered a medicinal product under the second part. If a substance possesses medical properties ‘but ... is not presented as such’\(^\text{50}\), it falls into the second part of the definition precisely because it possesses those properties and is therefore to be regarded as a medicinal product. For example, although homeopathy products are generally recognised among consumers as medicine, there is, scientifically, little evidence to support these products as an effective treatment for any specific condition.\(^\text{51}\) However, a product or substance which falls neither within the first nor the second part of Article 1 (2) of the Directive 2001/83 cannot be regarded as a medicinal product within the meaning of this law. Summarizing, a product is considered a medicinal product either by virtue of its “presentation” or its “function”. The product constitutes a medicinal product if it falls within

\(^{48}\)See. Case van Bennekom C-227/82 para 8 of the decision. “Council Directive 65/65 defines “medicinal product” in the first place as “Any substance or combination of substances presented for treating or preventing disease in human beings or animals”, and, in the second place, as “Any substance or combination of substances which may be administered to human beings or animals with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in human beings or in animals is likewise considered a medicinal product.”

\(^{49}\)Case van Bennekom C-227/82 para 23, then subsequently case Monteil&Samanni C-60/89 para 11, case Upjohn C-112/89 paras 16-20.

\(^{50}\)Case van Bennekom C-227/82, Written Observation, para 2

either of these two categories. Filling one of these criteria is sufficient to categorize a product.

3.2.3. Case-by-case approach to presentational and functional aspects of a product at issue

In the light of the settled case law relating to borderline products, the legal status of a given product considered of doubt is assessed on a case-by-case basis, taking into account all characteristics. In the cases EU Commission against Germany (C-387/99) and against Austria, (C-150/00), the need of an individual approach was particularly emphasized.

<table>
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<tr>
<th>Factual background for case C-387/99 (EU Commission v Germany)</th>
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<tr>
<td>The dispute was logged by the EU Commission against the Federal Republic of Germany, claiming that food preparations legally produced or marketed as food supplements in other Member States, once imported into Germany, were automatically classified as medicinal products when they contained three times more than the daily amount of vitamins and minerals recommended by the German Food Association.</td>
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</tbody>
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<table>
<thead>
<tr>
<th>Factual background for case C-150/00 (EU Commission v Austria)</th>
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<tbody>
<tr>
<td>In 1998 Austria was charged for systematically classifying vitamin and mineral preparations as medicinal products when they exceed the basic daily amount and, more generally, when they contain vitamins A, D and K or mineral substances in the chromate group, without demonstrating that the increased vitamin content or the vitamins or minerals content poses a serious danger to health.</td>
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</table>

<table>
<thead>
<tr>
<th>The main content of the EUCJ’s judgments.</th>
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</thead>
<tbody>
<tr>
<td>Those Member States have failed to fulfil their obligations under Article 30 TEC when they automatically classify as medicinal products vitamin preparations lawfully manufactured or marketed as food supplements in other Member States where they contain three times more vitamins, other than vitamins A and D, than the daily amount recommended by the national food association.</td>
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</table>

That practice cannot be justified for reasons of protection of the health and life of humans, since it does not make a distinction by reference to the different vitamins added or, in particular, to the level of risk to public health which their addition could entail and, consequently, the automatic nature of that practice does not make it possible to identify and assess a real risk to public health, which requires a detailed assessment on a case-by-case basis of the effects which the addition of the vitamins in question could entail.

Figure 3.2.3a. Summary of the joined cases C-387/99 and C-150/00

52Joint cases C-211/03 and C-299/03 and C-316/03–318/03 HLM Warenvertrieb and Orthica, nota. 49
Those national authorities applied a general administrative practice applicable without distinction to all vitamins preparations stating that products that contained more than 3 times the recommended daily amount (in Germany) or just exceeded the daily amount (in Austria) were classified as a medicine. Subsequently, according to the EUCJ, there is also no mandate to construct a general set of criteria to apply to a specific groups of products (for example botanicals).

Once again, the requirement for an individual approach became a prominent legal issue in the case EU Commission against Kingdom of Spain (C–88/07). A systematic administrative practice was claimed, consisting of prohibiting the marketing of a product on Spanish territory without a licence and classifying by function among medicinal products any product based on medicinal herbs not included in a positive list laid down in Spanish Law.

![Figure 3.2.3b: Summary of case C–88/07](image)

Factual background for case C–88/07 (EU Comm. v. Spain)

The case was prompted by three complaints from Ynsadiet SA, Laboratorios Tegor SL and Laboratorios Taxón SL in 2004. They stated that more than 200 food products in total were withdrawn from the Spanish market due to the fact that those products had no authorisation, since the Spanish Drugs and Health Products Agency classified them as medicinal products. Banned products were produced using herbs which were not included in the annex to the Ministerial Order of 3 October 1973.

The main content of the EUCJ's judgment.

By withdrawing from the market products based on medicinal herbs lawfully produced and/or marketed in another Member State, under an administrative practice consisting in withdrawing from the market any product based on medicinal herbs not included in the annex to the Spanish Ministerial Order, Spain has failed to fulfil its obligation under Article 28 and 30 EC.

On the other hand, it might be assumed that in the settled case law there are several product classification criteria repeated frequently throughout all cases concerning borderline

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53 According to the Spanish Act No 25/1990 on medicinal products
54 The German practice may be regarded as proportionate only if the prohibition on marketing as foodstuffs the vitamin preparations concerned and the obligation to obtain a marketing authorisation for medicinal products are both actually necessary, in each particular case, to ensure the safeguarding of public health.
products. In one of the first cases, the Delattre case (C-369/88), assessing the legal classification of various products\textsuperscript{55}, the two parts of the medicinal product definition with regard to cosmetics considered \textbf{the composition of the product, its use, distribution extent, whether the product is well-known among consumers and the risk connected with use}. (Iwanow-Korzycka 2009). Subsequently, the issue of the criteria re-emerged in later cases. Moreover, other criteria have appeared.

In the cases HLH Warenvertrieb and Orthica\textsuperscript{56} (EU Commission against Germany (C-387/99))\textsuperscript{57} or EU Commission against Spain (C-88/07)\textsuperscript{58} it was indicated that, for the purpose of determining whether a product falls within the definition of a medicinal product by function the national authorities, acting under the supervision of the courts, must decide on a case-by-case basis, taking account of ‘all the characteristics of the product, in particular its composition, its pharmacological properties to the extent to which they can be established in the present state of scientific knowledge, the manner in which it is used, the extent of its distribution, its familiarity to consumers and the risks which its use may entail’.

These criteria are widely commented and analysed in the legal and scientific literature. Likewise legal scholars (Balicki 2011), (Ozog 2009) (Iwanow-Korzycka 2009) (Titz 2006) agree that some schematic approach is presented in the EUCJ decisions regarding classification of products which may fall into more than one legal category. Moreover, they agree that a list of criteria in the context of definition of ‘medicinal product’ has been constituted in virtue of \textbf{presentation and function}. For example, Balicki A. (2011, p. 236–239) specifies three elements described in the definition by presentation: references to the medical research, the place of product distribution and the recognition among consumers. Ozog (2011, p. 54–59) emphasised the criteria related to consumer expectation and impression about a product. In turn, in the light of functionality, Balicki (2011) points out that the EUCJ has examined the following indicators: first of all composition and dose of the substances in the product, scientific evidence and then other criteria, such as way of using and risk for health. Finally, a very extended division of criteria were described by Szymecka – Wesolowska et al. (2013). With regards to the question of classification as a medicinal product by function, in addition to the pharmacological effects, consideration must be given

\textsuperscript{55}EU Commission v Germany C-369/88

\textsuperscript{56}HLH Warenvertrieb and Orthica, para 51.

\textsuperscript{57}EU Commission v Germany (C-387/99), para 55

\textsuperscript{58}EU Commission v Spain (C-140/07), paras 32–33
to the manner of use, the extent of dissemination, while a medical product in virtue of presentation could be described by familiarity to consumers, the place of distribution, references to medical research and form (Szymecka–Wesolowska et al., 2013, p. 250)\textsuperscript{59}.

<table>
<thead>
<tr>
<th>Medicinal product</th>
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<tbody>
<tr>
<td>By virtue of function</td>
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<tr>
<td>Composition</td>
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<tr>
<td>pharmacological properties</td>
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<tr>
<td>extent to which the product’s properties are established in the present scientific knowledge</td>
</tr>
<tr>
<td>risk to health</td>
</tr>
</tbody>
</table>

Figure 3.2.3c. Medicinal product – criteria developed in the EUCJ case law

### 3.3. Presentational aspects

#### 3.3.1. Introduction

The presentational aspect is an aspect which can hardly be defined by legislation (Titz 2006), therefore, only the interpretations of the EUCJ clarify the meaning. The EUCJ emphasised that a certain product may be presented as a medicinal product where there is a direct or indirect link between the presentation and the product\textsuperscript{60}. Thus, an analysis of all cases related to borderline products indicates that the analysis of the product in question should provide a broad legal interpretation of the presentation aspect. The facts do not have to be explicitly stated on the label, in the advertising or in leaflets. It means that the product evaluation does not refer solely to an instruction on the label but also to other means, such as publicity, the press, a prospectus, brochures or even a verbal recommendation of the

\textsuperscript{59}It should be highlighted that although the criteria related to the familiarity to consumers are addressed by the case law within the functionality aspect of the product, in this paper, following the mentioned legal researchers, it is explained as a presentation criterion.

\textsuperscript{60}Case Delattre (C–219/91), para 24
seller\textsuperscript{61}. It is sufficient to consider a product as a medicinal product within the meaning of the Directive 2001/83 if its medical indications are expressly indicated or recommended as such in labels, leaflets or oral representation.\textsuperscript{62}

**Factual background for case C-60/89 (Monteil & Sammanni)**

The question was raised in criminal proceedings for the illegal practice of the profession of pharmacy and complicity therein brought respectively against Daniel Samanni, for selling in the ‘Casino’ store of which he was the manager eosin of a strength of 2% and modified alcohol of a strength of 70%, and against Jean Monteil, as purchasing manager of the “Casino” group, for supplying the first of those two products. Considering French Law of that time, those products must be regarded as medicinal products, thus, the right to sell which is reserved to dispensing pharmacists.

The main content of the EUCJ’s judgment:

- Eosin of a strength of 2% and modified alcohol of a strength of 70% are medicinal products ‘by virtue of their presentation’, when they are presented for treating or preventing disease. That is so not only when they are expressly “indicated” or recommended as such, possibly by means of labels, leaflets or oral representation, but also whenever any averagely well-informed consumer gains the impression, which, provided it is definite, may even result from implication, that the product in question should, having regard to its presentation, have the properties in question. The external form given to the product in question may provide persuasive evidence, but is not the sole or conclusive evidence.
- In classifying products in the light of their function, into account must be taken of the adjuvants also entering into the composition of the product, the manner in which it is used, the extent of its distribution, its familiarity to consumers and the risks which its use may entail.

Figure 3.3.1a. Summary of case C-60/89

The main reason behind this is the protection of consumer interests, the paramount goal of the EU medicine and pharmacological law. The current Directive 2001/81 covers both medicinal products and preparations which do not have any pharmacologically active substances and thus, from an objective view, have any medical use.\textsuperscript{63} The rationale for this approach is to protect consumers not only from harmful medicinal products, but also from a variety of products used instead of the proper remedies.\textsuperscript{64} As a result, the definition of a

\textsuperscript{61}Opinion of Mrs Advocate General Rozes to case C-227/82, delivered on 5 October 1983, ECLI:EU:C:1983:263
\textsuperscript{62} Case Montail&Sammani (C-60/89) para 23
\textsuperscript{63} Case Van Bennekom (C-227/82), para. 17
\textsuperscript{64} Case Van Bennekom (C-227/82) para 18, Garlic case (319/05) para 42
medicinal product by presentation may include not only products which have a real effect on physiological function but also those which do not have the advertised effect.65

<table>
<thead>
<tr>
<th>Factual background for case 112/89 (Upjohn case)</th>
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<td>This case arose between two competitors: Upjohn Company and Upjohn NV and Farzoo Inc. in the Netherlands in the late 1980’s. Upjohn was selling a product as a cosmetic as a treatment for natural baldness. Farzoo marketed the same new product as a medicinal product for the treatment of arterial hypertension.</td>
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<thead>
<tr>
<th>The main content of the EUCJ’s judgment.</th>
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<tbody>
<tr>
<td>• A product which is a medicinal product by virtue of its function is none the less a medicinal product if it may be administered ‘with a view to ... restoring, correcting or modifying physiological functions’. That phrase must be given a sufficiently broad interpretation to cover all substances capable of having an effect on the actual functioning of the body and include not only products which have a real effect on physiological functions but also those which do not have the advertised effect, the marketing of which may thus be prohibited in order to protect consumers.</td>
</tr>
<tr>
<td>• It is for the national courts to determine on a case-by-case basis the classification of each product having regard to its pharmacological properties ascertained in the current state of scientific knowledge, to the way in which it is used, to the extent to which it is sold and to consumers' familiarity with it</td>
</tr>
<tr>
<td>• Even though it may fall within the definition of cosmetic products given in Article 1(1) of Directive 76/768, a product must nevertheless be treated as a medicinal product (…)</td>
</tr>
<tr>
<td>• Such a classification is a necessary consequence of the aim of protecting public health, since the rules governing proprietary medicinal products are stricter than those governing cosmetic products, in view of the particular risks to public health (...).</td>
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</tbody>
</table>

Figure 3.3.1b Summary of case C–112/89

3.3.2. Familiarity to consumers

As highlighted above, the main idea behind the juridical requirements to apply a broad interpretation of Article 2 (1) of the Directive 2001/83 is consumer protection. Thus, consumer attitudes play the significant role in product assessment. The consumer impression is analysed primary in the context of form and packaging of a product. The Bennekom case (C–227/82) dealt with the issue of a high-dose vitamin preparation sold as capsules and pills. The strict interpretation against Bennekom derived from a believe that although a product is not marketed by the producer as a medicinal product, it nonetheless may be classified as such, if the consumer gets such an impression which may even come

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65 Case Upjohn (C–112/89) para 18
from the implication that the product has properties for preventing or curing disease. Hence, a product is presented for medicinal purpose ‘when any averagely well–informed consumer gains the impression, which provided it is definite’ that the product in question should have the effect described. With the current Directive 2002/46 also food supplements are products ‘marketed in dose form, namely forms such as capsules, pastilles, tablets, pills, and other similar forms (...) (Article 2a)’. But it does not mean that, after the legislation comes into force, the consumer’s impression regarding the product’s form has become meaningless. It is still an ambiguous and problematic matter.

**Factual background for case C–319/07 (Garlic case)**

In 2001, the German Federal Ministry of Health refused an application to import and market a garlic preparation in capsule. They indicated that the product in question has therapeutic effects which prevent lesions from occurring in the human body, more specifically prevents from arteriosclerosis. Additionally, it was submitted that this product may be regarded as medicine because its form and the manner in which it is packaged render it sufficiently similar to a medicinal product.

**The main content of the EUCJ’s judgment.**

- By classifying as a medicine a garlic preparation in capsule form not satisfying the definition of a medicinal product by function, Germany has failed to fulfil its obligations under Art. 28 and 30 EC.
- A garlic product in capsule form, whose effect on physiological functions is no more than the effects which a foodstuff consumed in a reasonable quantity may have on those functions, does not have a significant effect on the metabolism and cannot, be classified as a medicine.
- Since risks and contra-indications related to taking garlic preparations are limited and, more importantly, are no different from those linked to taking garlic as a foodstuff, and because the criterion of the method of using of the product concerned cannot be decisive, given that capsule form is not unique to medicinal products, such a preparation cannot be classified as a medicinal product by function.

Figure 3.2.2. Summary of case C–319/07

According to the German authority, in the Garlic case C–319/05 ruled in 2007, garlic products marketed in a similar form to the products classified as medicine on the German market should be sold as medicinal products exclusively. In that context, the external form given to the product served as strong evidence of its classification as a medicinal product by presentation. In spite of this, the EUCJ highlighted the progress in consumers’ awareness that this form is no longer restricted to medicinal products. The form given to a product may

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66 Case Bennekom, para 18

67 Garlic case (C–319/05) paras 44–50
inspire particular confidence similar to that normally inspired in the consumer by proprietary medicinal products, having regard to the safeguards normally associated with their manufacture and marketing. Moreover, the recent case went one step further by describing a form of product as form ‘not only the form of the product itself but also that of its external packaging, which may, for reasons of marketing policy, tend to make it resemble a medicinal product’. Although the external form given to the product may serve as strong evidence of its classification as a medicinal product by presentation, in the eyes of the consumer, the form in which the product is marketed provides only an indication of its classification. For the time being, however, considering the fact that certain foodstuffs or other products are traditionally presented and marketed in a similar form as medicine, the impression of external form should not be taken into account as an decisive argument in classification of products.

3.3.3. Dissemination of information about product

Both medicinal products and food supplements are presented by their producers or stakeholders involved in their supply chain, basically. However, actions taken by others may affect the legal classification of a product as well.

**Factual background for case C-219/91 (Ter Voort)**

Mr Ter Voort was prosecuted for having imported, held, prepared and sold proprietary medicinal products contrary to the Netherlands Law on the Supply of Medicinal Products. Ter Voort traded as ‘Fitness Foundations Nederland’, herbal teas imported from South America. The herbal teas were sold without any indication of any therapeutic properties. However, a foundation, ‘Stichting Nieuwe Horizon’, was sending consumers on request brochures describing the therapeutic or prophylactic properties of these herbal teas.

**The content of the EUCJ’s judgment.**

- A product recommended or described as having prophylactic or therapeutic properties is a medicinal product ‘by virtue of its presentation’, even if it is generally regarded as a foodstuff and even if in the current state of scientific knowledge it has no known therapeutic effect.

- A product whose therapeutic properties are indicated solely in a publication such as a brochure, which is sent, at his request, to the purchaser after sale by the manufacturer or the seller of the product or by a third party where the third party does not act completely independently of the manufacturer or the seller may be categorised as a medicinal product within the meaning of the aforementioned provisions.

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58 Ibid. paras 46–47
In the Ter Voort case (C-219/91), the product in question – herbal teas – were sold without information to consumers about therapeutic properties. After the purchase there was an opportunity to order through an independent organisation brochures containing these data. The EUCJ held that the fact that information was provided by a third party, namely a private foundation rather than the business operators involved in marketing or manufacturing these products, should not influence and change the classification decision. A product without therapeutic effects may be classified as medicinal when the consumer is encouraged by the manufacturer or the seller to obtain information about its properties from a third party.

3.3.4. Place of distribution

The next interesting criterion to emerge is the place of distribution. Originally, it was analysed in the context of a demarcation between medicinal products and cosmetic products; however the following case describes some clues helpful for demarcation of borderline products in general. Basically, in the Clinique case (C-315/92)\(^69\), it had been ruled that use of the word ‘Clinique’ in the product name would mislead consumers. Moreover, it had been emphasised that a product’s not being available in pharmacies but sold exclusively in perfumeries and cosmetic departments is an argument against its categorisation as medicinal\(^70\). Therefore, on the one hand, place of distribution may suggest the type of product. On the other hand, as a single attribute of a product it is not enough to categorise the product in question.

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\(^69\) The case raised in the proceeding concerned the use of the name ‘Clinique’. The party widely marketed cosmetics under the name ‘Clinique’ except in Germany. According the German authority that name could mislead consumers into believing that the products had medicinal properties. C-315/92, paras 2.3 and 5

\(^70\) Ibid. para 21
Factual background for case C-315/92 (Clinique)

This question was raised in proceedings between a trade association, the Verband Sozialer Wettbewerb eV, and the companies Clinique Laboratories SNC and Estée Lauder Cosmetics GmbH concerning the use of the name ‘Clinique’ for the marketing of cosmetic products in the Federal Republic of Germany. Those companies were, respectively, the French and German subsidiaries of the United States company Estée Lauder, and market cosmetics manufactured by that company. Those products have been sold for many years under the name ‘Clinique’ except in the Federal Republic of Germany, where they have been marketed, since their launch in 1972, under the name ‘Linique’. With a view to reducing packaging and advertising costs arising from this difference in names, the company decided to market the products intended for the German market under the name ‘Clinique’.

Figure 3.3.4. Summary to case C-315/92

3.3.5. References to medical research

Factual background for case 369/88 (Delattre)

The dispute was raised in a criminal proceeding brought against Jean-Marie Delattre, a director of Svensson in France, on the ground that certain products marketed by his company – from slimming products and herbal treatment for legs to anti-smoking products – were medicinal products, so that a special authorisation had been obtained for them and they could be lawfully sold to public only through pharmacies.

The main content of the EUCJ’s judgment:

- A given product, even if it falls within the definition of cosmetics, must nevertheless be treated as a ‘medicinal product’ if it is presented as possessing properties for the treatment or prevention of illness or disease or if it is intended to be administered with a view to restoring, correcting or modifying physiological functions.
- A product may be regarded as being a medicinal product ‘by virtue of its presentation’ for the purposes of the first subparagraph of Article 1(2) of Directive 65/65 if its form and the manner in which it is packaged render it sufficiently similar to a medicinal product and, in particular, if on its packing and in the information provided with it reference is made to research by pharmaceutical laboratories, to methods or substances developed by medical practitioners or even to testimonials from medical practitioners commending the qualities of the product. A statement that the product is not medicinal is persuasive evidence which the national court may take into consideration but is not in itself conclusive.
- A monopoly of the right to distribute medicinal or other products, granted to dispensing pharmacists, may constitute a barrier to importation.

Figure 3.3.5. Summary of case C-369/88
Interestingly, other criteria considered by the Court are the medical references regarding a certain product. In the Delattre case (C-319/05) the product’s classification as a medicinal product was based on the assertion that the product contains references to research by pharmaceutical laboratories or to methods or substances developed by doctors, medical practitioners or even testimonials from medical practitioners commending the qualities of the product. 71

### 3.4. Functional aspects

#### 3.4.1. Introduction

Basically, the definition by function of a medicinal product is designed to cover products whose pharmacological ‘properties have been scientifically observed’ and which are genuinely designed to make a medical diagnosis or to restore, correct or modify physiological functions. Therefore, a **strict interpretation of the criteria of the definition shall be applied**.

#### 3.4.2. Composition

The most problematic matter concerning the borderline product in the range between food supplements and medicinal products is the fact that the same substance might compose either a medicinal product or food supplement. On the one hand, the doses in the complete product play an essential role, on the other hand, the quantity of each one is decisive. The complexity of this issue is caused by the fact that the settled case law refers to active substances previously presented in medicine but, recently also in food supplements and in vitamins and minerals.

With regard to active substances, the Court formulated a position that ‘substances which, while having an effect on the human body, do not significantly affect the metabolism and thus do not strictly modify the way in which it functions should not be classified as medicinal products by function’. However, the term ‘significantly’ has not been explained in the case law; it should be assumed that the type of substance and the quantity of the

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71 Case Delattre (C-315/92). para 40
72 E.g. Garlic case (C-319/05). para 51
73 E.g. in Garlic case (C-319/05), case EU Commission v Spain ( C-88/07)
active substance are the basic criteria distinguishing diet supplements from medicinal products. For example, in the Garlic case a product in question was a garlic powder extract containing the equivalent of 7.4 g of fresh raw garlic. The disputable substance in it was an amino acid called allicin, an active ingredient in crushed garlic. The active substance, allicin, is an antiarteriosclerosis medicine. However, all parties agreed that ‘the effect of a body with respect to the prevention of arteriosclerosis may be obtained by consuming 7.4 g garlic as a food as well’. Therefore, under those circumstances, it was held that the product concerned, whose effect on physiological functions is no more than the effects that a foodstuff consumed in a reasonable quantity may have on those same functions, does not have a significant effect on the metabolism and cannot, therefore, be classified as a product capable of restoring, correcting or modifying physiological functions within the meaning of the second subparagraph of Article 1(2) of Directive 2001/83.

In that regard, the Court has held that active substances which, while having an effect on the human body, do not significantly affect the metabolism and thus do ‘not strictly modify the way in which it functions” should not be classified as medicinal products by function. Particular attention should be paid to products containing vitamins and nutrients as the most frequent sort of food supplements. Already in the Bennekom case (C-228/82) it had been mentioned that vitamins, which generally are consumed in small doses, are an inherent part of the diet, and thus cannot be presented as medicinal products. Since the content of vitamins and minerals in food supplements was harmonised in 2002 it should have become clear which substances may constitute a food supplement. However, those which are not included in the Annex to directive 2002/46/EEC may be present in food supplements as well. Moreover, doses of vitamins and minerals stipulated in the Directive, if exceeded, mean that the product might be classified as medicinal. In the case EU Commission against Germany (C-387/99) Germany was claimed for applying a general rule, applicable without distinction to all vitamin preparations regardless of the vitamin in their composition, which classifies them as medicinal products when they contain more than three times the recommended daily amount. The main allegation was lack of distinction in relation to the different vitamins in the preparations examined. Even though it is common ground that no vitamin has the same effects on health in general, and, in particular, no vitamin has the same degree

74 Garlic case (C-319/05) para 57
75 Ibid. para 66
76 Ibid. para 68
of potential harmfulness, an assessment without distinction can therefore have the effect of classifying certain vitamin preparations as medicinal products even though they are not capable of ‘restoring, correcting or modifying human physiological functions’. Within this context, it should be emphasised that the term ‘upper safe limits’ stipulated in Article 5 (1) of the Directive 2002/46 does not play a role in the EUCJ classification of a product. As such, that concept plays no part in the distinction between medicinal products and food supplements. On the one hand, as mentioned in the case ..., it may prove necessary to lay down upper safe levels for certain foodstuffs which cannot be regarded as medicinal products. On the other hand, a product administered in quantities below any upper safe level may constitute a medicinal product either by its function or by its presentation.

Interestingly, a new dimension was emphasised in the Red Rice case (C–140/07), where the EUCJ linked the examination of the composition of the product with respect to its content in active substances – and ‘if used as intended’. This should be assessed as a rational and common-sense addition to the composition criteria. However, no further interpretation was given.

**Factual background for case 140/07 (Red Rice)**

In 2002 Hecht-Pharma, a wholesale pharmaceutical business, obtained a refusal to market in Germany a product composed of fermented red rice under the name ‘Red Rice 330 mg Kapseln’. These capsules were marketed in plastic bottles which stated on their labels, inter alia: ‘One capsule corresponds to 1.33 mg of monacolin k’. According to German Authority monacolin k is synonymous with lovastatin, an inhibitor of cholesterol synthesis which is contained, as an active substance, in a number of prescription medicinal products.

**The main content of the EUCJ’s judgment.**

Article 2(2) of Directive 2001/83 does not apply to a product in respect of which it has not been scientifically established that it is a medicinal product by function, without its being possible to exclude that possibility. Article 1(2)(b) of Directive 2001/83, must be interpreted as meaning that, apart from the case of substances or combinations of substances intended for the purpose of making a medical diagnosis, a product cannot be regarded as a medicinal product within the meaning of that provision where, having regard to its composition – including its content in active substances – and if used as intended, it is incapable of appreciably restoring, correcting or modifying physiological functions.

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77 Red Rice case (C–140/07), paras 59–63
78 Joined cases HLH Warenvertrieb and Orthica C–211/03, paras 53–56
79 Red Rice case C–140/07, 3rd thesis of judgment
3.4.3. Pharmacological properties

The criterion of composition is closely related to the pharmacological properties of the product. As mentioned in the previous chapter, neither the EU legislator, nor the EU judges provide a definition of pharmacological action.

With regard to the borderline products in the range food supplements – medicinal products it should be noted that both legal definitions of these products contain a requirement of physiological effect. In all case law the term ‘pharmacological effect’ is defined by citing and repeating the statutory provision – the Article 2 (2) of Directive 2001/83. For example, in the cases Red rice (C-140/07), the EU Commission against Germany (C-387/99) and the criterion was vaguely explained as “capacity to restore, correct or modify physiological functions” and ‘have an effect on the human body, significantly affect the metabolism and thus do strictly modify the way in which it functions’. Another expression ‘sufficient effect’ was not demystified and remained open as well..

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**Factual background for cases 211/03, 299/03, 317-318/03, 316/00 (HLH Warenvertrieb and Orthica)**

A Dutch company obtained a refusal for permission to place its products on the German market due to following circumstances.

- Probiotic product contained isolated bacterial cultures have medicinal properties (case 211/03).
- Tablet of C1000 results in the daily amount recommended in Germany being exceeded by a factor of more than 15, so that the product cannot be regarded as a foodstuff for general consumption (C-299/03, C-317/00).
- The bioflavonoids contained in the product, in isolated form, should be regarded as a substance with a pharmacological effect (C-316/00).
- Tablet with the dose of vitamin E recommended in Germany being exceeded by a factor of 22 increased ingestion of vitamin E over a prolonged period of time has an injurious effect on health (C-318/03).

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Figure 3.4.3a. Factual background for case HLH Warenvertrieb and Orthica

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A milestone role is played by the judgment in the case Chemische Fabrik (C-308/11) from 2012. The EUCJ has finally attempted to specify the expression ‘pharmacological property’. First of all, it ruled that for the purpose of defining the term ‘pharmacological action’ within
the meaning of the legal definition of a medicinal product by function, the explanation of that term in the ‘Guidance Document on the demarcation between the Cosmetic Products Directive 76/768 and the Medicinal Products Directive 2001/83’ may be taken into account as agreed between the Commission services and the competent authorities of the Member States. This means ‘that, for a substance to be regarded as exerting a “pharmacological action” within the meaning of that provision, it is not necessary for there to be an interaction between the molecules of which it consists and a cellular constituent of the user’s body, as an interaction between that substance and any cellular constituent present within the user’s body may be sufficient.’

**Factual background for case C-308/11 (Chemische Fabrik)**

Chemische Fabrik Kreussler and John O. Butler were competitors on the German market for the marketing of mouthwash solutions containing chlorhexidine. According to Chemische Fabrik, Butler’s product contained a chlorhexidine solution of 0.12% which reduce salivary bacteria and, in this way, has a therapeutic or clinical effect in cases of gingivitis. Consequently, Chemische Fabrik brought an action seeking an injunction requiring John O. Butler to desist from advertising the product PAROEX 0.12% on bottles and/or folding boxes and/or instructions for use and/or from marketing that product for as long as it had not been authorised as a medicinal product. Butler based his defense on the guidance document adopted by the European Commission’s Directorate-General for Enterprise and Industry and entitled ‘MEDICAL DEVICES. Guidance document – Borderline products, drug-delivery products and medical devices incorporating, as an integral part, an ancillary medicinal substance or an ancillary human blood derivative’.

**The main content of the EUCJ’s judgment.**

Article 1(2)(b) of Directive 2001/83 must be interpreted as meaning that, for the purpose of defining the term ‘pharmacological action’ within the meaning of that provision, account may be taken of the definition of that term in the guidance document on the demarcation between the Cosmetic Products Directive and the Medicinal Products Directive.

3.4.4. Extent to which the product’s properties are established in present knowledge

Generally, the assessment of a medicinal product by function has to be done based on the scientific evidence. In the recent judgments, such as the EU Commission against Spain (C-
then the Red Rice (C-140/07), the extent to which properties of the product can be established in the present state of scientific knowledge was listed explicitly as one of the determination criteria.

In the first case, the dispute raised with regard to the Red Rice, in favour of the classification of such a product as a medicinal product rather than a food supplement, was the fact that it contained significant levels of monacolin k. (corresponding to 1.33 mg) which as an active substance is synonymous with lovastatin, an inhibitor of cholesterol synthesis contained in a number of prescription medicinal products in Germany. Therefore, the German authority concluded that the product “was liable to lower excessively high cholesterol levels and therefore contribute to the realization of a therapeutic objective. It added that inhibitors of cholesterol synthesis could also have serious, undesirable side-effects on the muscles and kidneys”. However, these positions were not supported by significant medical research. This means that, “for a product in respect of which it has not been scientifically established that it is capable of restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or that it may be used to make a medical diagnosis the Directive 2001/83 does not apply”.

In the second case, the main issue focused on a Spanish administrative practice consisting of withdrawing from the market any product with herbal constituents, without first submitting each of those products to a detailed scientific analysis, when the constituent was not included in the annex to the Ministerial Order on the creation of a special register of medicinal herb-based preparations. An approach based on a general assessment of substances in a product through an official annex and with regard to general, not specific studies cannot be defended on the basis of the Directive 2001/83. It means that a product’s classification by function assessment requires a specific and detailed scientific analysis.

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80 Case EU Commission v Spain, C-88/07, para 72
81 Case Red Rice, C-140/07, judgment
82 Ibid. para 9
83 Ibid. paras 13-14
84 Ibid. paras 18-22
85 Case EU Commission v Spain, C-88/07, paras 1, 2, 30
3.4.5. Risk to health

The risk to health becomes an additional factor that must be taken into consideration in the context of the classification of the product. In the Upjohn case (C-112/89) already, the process of classification contained an indication that to classify a medicinal product by function the competent authorities have to ascertain if it is intended to restore, correct or modify physiological functions and if it may have an effect on health in general. The risk to health in borderline product cases is linked with their overdose. Consequently, in the case EU Commission against Austria (C-150/00) concerning foodstuffs intended for particular nutritional uses under the Directive 89/398, where products were classified as medicines when containing more than one simple daily amount of vitamin, it was concluded that the product can indeed be fetotoxic, while on the other hand almost all products are potentially harmful to health if they are consumed in excessive quantities. Most recently, in the joined cases HLH Warenvertrieb and Orthica it had been emphasised again that a product which does not pose a real risk to health can nevertheless have an effect on the functioning of the body. But the Member State cannot make an argument and classify as medicine products which are not in general harmful to health but may have an exceptional harmful effect solely if they are overdosed.

3.4.6. Manner of use

Next, in order to determine whether a product is a medicinal product by function or not, the normal conditions of use should be taken into account.

This appeared as a main criterion in the case BIOS Naturprodukte, where the domestic court formulated a question referred for preliminary ruling to decide whether the definition shall be interpreted to the effect that a product intended for human consumption and described as a food supplement is medicine by function if it “contains substances posing a risk for health in the low dose when the recommended intake printed on the packing is observed, without being capable of producing therapeutic effects, but which have therapeutic effects in high dose”. The EUCJ concluded that product assessment should take

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86 Case EU Commission v Austria, C-150/00, paras 72, 75, 74
87 Joined cases HLH Warenvertrieb and Orthica C-211/03 etc. paras 53-54
88 Case Monteil&Sammanni C-60/89 para 17
89 Case BIOS Naturprodukte C-27/08
90 Ibid. para 16
into account the normal condition of use of the product. Moreover, whether this product consumed at a higher dosage than indicated on the packing is capable of having physiological effects, is considered irrelevant.

**Factual background for case C-27/08 (BIOS Naturprodukte)**

This case was raised against BIOS Naturprodukte GmbH with regard to a product contained incense tablets. BIOS was prohibited from continuing to offer that product on the German market on the ground that it was a medicine which had no prior authorization. The product concerned, which was based on Indian incense extract, was produced in India, where the product was in the category of medicine, then imported into Austria, where it is marketed as a food product.

**The main content of the EUCJ’s judgment.**

The definition of medicinal products, amended by Directive 2004/27/EC must be interpreted as meaning that a product which includes in its composition a substance which has a physiological effect when used in a particular dosage is not a medicinal product by function where, having regard to its content in active substances and under normal conditions of use, it constitutes a risk to health without, however, being capable of restoring, correcting or modifying physiological functions in human beings.

Another important point in product classification is associated with the stage of preparation. In the case HLH Warenvertrieb and Orthica the product in question – a probiotic – has to be mixed before consumption with water or with yoghurt. However, that factor is not decisive in itself and does not preclude the characteristics of the product in its initial state, before being mixed with water or with yoghurt, from being taken into account. The Court did not make an unequivocal statement and pointed out that the classification of a product as a medicinal product or as a foodstuff must considered “all the characteristics of the product, established both in the initial stage of the product and where it is mixed, in

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91 Ibid. para 22
92 Ibid. paras 21–23
93 Case HLH Warenvertrieb and Orthica C–211/03 etc., Lactobact omni FOS in powdered form; one gram of powder contained at least 1,000,000,000 organisms from the following bacterial strains: lactobacillus acidophilus, lactococcus lactis, E. faecium, bifidobacterium bifidum, lactobacillus casei and lactobacillus thermophilus; the recommended consumption is approximately 2 g per day, dissolved in half a glass of water or with yoghurt, although the dose is doubled where the need is greater and during the first four weeks of taking it;
accordance with the method by which it is used, with water or with yoghurt. Thus, it should be said that both stages – initial and before consumption – might affect the classification.

### 3.5. Conclusions

The EUCJ has many occasions to analyse the circumstances whether a product in question is a medicinal product or not. Figure 3.5 summarises the products in question analysed in this chapter.

<table>
<thead>
<tr>
<th>No.</th>
<th>Case No. (year)</th>
<th>Product(s) at issue</th>
<th>Initial legal status given by the manufacture</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>C-227/82 (1983)</td>
<td>vitamin and multi-vitamin preparations in pharmaceutical form</td>
<td>food</td>
</tr>
<tr>
<td>2.</td>
<td>369/88 (1991)</td>
<td>Slim 4, Zéro 3, Kilomin, Chlorella, slimming products; Macérat huileux d’ail, a garlic-based product to assist digestion; wheat germ oil with vitamin E, a product for the relief of tiredness; Mineral 23, a product for the joints; Turn off, a product to help people stop smoking</td>
<td>food supplement</td>
</tr>
</tbody>
</table>

Ibid. para 32
<p>| | | |</p>
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</thead>
<tbody>
<tr>
<td><strong>3.</strong></td>
<td>60/89</td>
<td>1991</td>
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<tr>
<td></td>
<td><em>cosin</em> of a strength of 2%</td>
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<tr>
<td></td>
<td><em>modified alcohol</em> of a strength of 70%</td>
<td></td>
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<tr>
<td><strong>4.</strong></td>
<td>112/89</td>
<td>1991</td>
</tr>
<tr>
<td></td>
<td><em>Minoxidil</em>, a product encouraging the growth of hair and a treatment for natural baldness</td>
<td></td>
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<tr>
<td><strong>5.</strong></td>
<td>219/91</td>
<td>1992</td>
</tr>
<tr>
<td></td>
<td><em>herbal teas</em> imported from South America</td>
<td></td>
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<tr>
<td><strong>7.</strong></td>
<td>315/92</td>
<td>1994</td>
</tr>
<tr>
<td></td>
<td>cosmetic line named ‘<strong>Clinique</strong>’</td>
<td></td>
</tr>
<tr>
<td><strong>8.</strong></td>
<td>387/99</td>
<td>2004</td>
</tr>
<tr>
<td></td>
<td><em>vitamin and mineral preparations</em> containing over three times the daily amount according to German Law</td>
<td></td>
</tr>
<tr>
<td></td>
<td><em>vitamin and mineral preparations</em> containing vitamins A, D and K or mineral substances from the chromate group over the basic daily amount according Austrian Law</td>
<td></td>
</tr>
<tr>
<td>No.</td>
<td>Number</td>
<td>Year</td>
</tr>
<tr>
<td>-----</td>
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<tr>
<td>9.</td>
<td>211/03 (2005)</td>
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<tr>
<td></td>
<td>C-299/03 (2005)</td>
<td></td>
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<tr>
<td></td>
<td>C-316/03 (2005)</td>
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<tr>
<td></td>
<td>C-317/03 (2005)</td>
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<td></td>
<td>C-318/03 (2005)</td>
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<tr>
<td>10.</td>
<td>319/05 (2007)</td>
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<tr>
<td>11.</td>
<td>140/07 (2009)</td>
<td></td>
</tr>
<tr>
<td>12.</td>
<td>27/08 (2009)</td>
<td>Weihrauch H 15-Tabletten (H 15 incense tablets) containing 400 mg of Indian incense extract</td>
</tr>
<tr>
<td>12.</td>
<td>88/07 (2009)</td>
<td>different herbals not included in the annex to the Spanish Ministerial Order of 3 October 1973</td>
</tr>
<tr>
<td>13.</td>
<td>308/11 (2012)</td>
<td>PAROEX 0,12% a mouthwash solution with chlorhexidine of 0.12% of the content, helps reduce dental plaque accumulation – Protects gums and maintains oral health.</td>
</tr>
</tbody>
</table>

Figure 3.5. List of products at issue analysed by the EUCJ

The EUCJ may suggest only the answers. It is up to the Member States to decide whether the product is medicine or not. These rulings were issued as a reference for a preliminary ruling, which is a decision on the interpretation of EU law, made at the request of a court or tribunal of Member State. Under Article 267 TFEU a request (or reference) for a preliminary ruling is made by submitting questions to the EUCJ for resolution. However, questions are not answered in abstraction, but rather are submitted together with the circumstances leading up to their being asked. Thus, whilst the EUCJ is limited to deciding the law in question, the EUCJ's ruling frequently leaves little room to rule other than in a certain way. The EUCJ may also decline to give judgement in the absence of a genuine dispute.95

Even though emphasising that decisions have to made on a case–by–case basis whether or not a product fulfils the criteria for a medicinal product in the sense of Directive 2001/83, the EUCJ thereby introduced a system of two tests that need to be concluded to resolve the

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95 Case Pasquale Fogila against Mariella Novello C-244/80, para 18
delimitation between medicinal products and other products. Although the EUCJ explicitly denies that these rulings have any systematising claim, in fact it does nothing else. (Purnhagen 2010). The subsequent judgments are connected with the previous ones, therefore, we can agreed that we have a settled case law concerning borderline products.

More detailed discussion with regard to existing case law is presented in the next chapter.
Chapter 4: Summary of the current approach to borderline products in the EU – legislation and case law

Introduction

The intention of this chapter is to summarise the current development of legislation and case law concerning borderline products in the EU presented in previous chapters. Simultaneously, it attempts to answer sub-question 1. how the concept of borderline products, particularly in the range food supplements–medicinal products, has developed in EU legislation and EUCJ case law.

The EU borderline product concept is a phenomenon evaluated predominantly in the EUCJ’s case law. The main reason for such court cases is caused by several uncertainties regarding the application of the EU definitions of medicinal products as well as food, cosmetic, medical devices, and biocides. In general, it is an assessment designed to decide whether a product in question is a medicine or not. It is agreed that the roots of this concept go back to 1983 and the famous judgment of the EUCJ against van Bennekom (C–227/82): at that time the legal approach was established. As a result, the decision whether a product is a medicine or not is a case–by–case evaluation of the definition of a medicinal product provided in Directive 2001/83 (previously Directive 65/65). It assesses the product concerned in terms of its presentation and function. Several criteria proposed by the EUCJ describe these aspects.

Bearing in mind the relevant legislation and existing case law, some additional characteristic circumstances are noticeable, among others:

- A clear separation between medicinal law and other legislation, for example, food supplement law, is mandatory.
- The distinction between products considered as borderline ones is solely assessed in light of the definition of a medicinal product included in Directive 2001/83.
- There is a lack of explanation of wording and expressions used in the statutory definitions of medicinal products and food supplements as well as criteria evaluated in the case law.
These circumstances are described in detail in the following subsections.

**Bi-polar separation**

Mutually exclusive definitions were envisaged as a legal solution to possible conflicts between these two sets of legislation (Brunet at al., 2005). In order to anticipate any possible conflict, the EU legislator separates these two legal branches of law: medicinal law against food supplement law. Approaching both directives literally, there should not be any concerns. It is clearly stated that one product has to fall into one legal definition and either Directive 2001/83 or Directive 2002/46 should apply. As it is stipulated in Regulation 178/2002, food does not include medicinal products within the meaning of Directive 65/65/EC (now 2001/83). The definition of food has to cover everything that is left out of the definition of a medicinal product. In principle, a product always has to be either a food or a medicine, not both (Lähteenmäki-Uutela, 2009). Medicinal products within the meaning of Directive 2001/83 are excluded from the definition of food as a category. To reinforce this distinction, Directive 2002/46 repeats that EU food supplement law shall not apply to medicinal products law as defined by Directive 2001/83. However, it may appear that the separation is based on an artificial presumption that in the case of doubts, the product should be considered as a medicine.

It seems, however, that the EU legislator and the EUCJ are aware of the overlap of both directives. For example, one of the main reasons to amend Directive 2001/83 was associated with the fact that the number of so-called borderline products between the medicinal product sector and other sectors was growing and due to this phenomena, “the definition of "a medicinal product" is modified so as to avoid any doubt as to the applicable legislation when a product, whilst fully falling within the definition of a medicinal product, may also fall within the definition of other regulated products”. As a solution, a presumption that in case of above mentioned situations when a product is either a food supplement or a medicine, under the meaning of EU law it is a medicinal product was introduced into EU law. A situation where a product falls both within the definition of a medicinal product and within the definition of food is not permitted under the current EU law.

At the same time, however, the European legislator is not very consistent. An overview of the Preamble to Directive 2002/46 gives the impression that food supplements are not dedicated

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96 Article 2(d) Regulation 178/200 (GFL)

97 Directive 2004/27, Recital 7
to maintain physical health exclusively, but should be used to avoid physical disorders as well. (Iwanow–Korzycka 2010). The Preamble of Directive 2002/46/EC stipulates that ‘an adequate and varied diet could, under normal circumstances, provide all necessary nutrients for normal development and maintenance of healthy life in quantities which meet those established and recommended by generally acceptable scientific data. However, surveys show that this ideal situation is not being achieved for all nutrients, and by all groups of the population across the Community.’ In terms of the first part of this citation, theoretically, there should not be any need for food supplementation. Moreover, it seems that the EU legislator agrees that this ideal situation is not being achieved for all nutrients and by all group of the population. It leads to the conclusion that ‘an inadequate diet lacking of vitamins and nutrients supplementation is a normal state of human affairs’ (Hagenmeyer 2006). These assumptions, paradoxically, point to the opinion that the purpose of food supplement law is not the health advocating aspect, but prevention of potential adverse effects on health (Korzycka–Iwanow 2010). This interpretation can be supported by additional documents: for instance, the White Paper on Food Safety, the draft of the food supplement directive, warned about: ‘(…) a worsening trend of poor diets and low physical activity levels across the EU population which can be expected to increase future levels of a number of chronic conditions, such as cardiovascular disease, hypertension, type 2 diabetes, stroke, certain cancers, musculoskeletal disorders and even a range of mental health conditions. In the long term, this will result in a negative impact on life expectancy in the EU, and a reduced quality of life for many (…)’ This short legal assessment of the notions of a diet and disease under Directive 2002/46/EC may lead to the conclusion that the food supplement definition is more oriented to disease prevention than to health promotion. Moreover, the approach facilitates the interpretation that food supplements are mainly products for preventing diseases.

At the same time, EU legislation has been updated with the introduction of additional food legislation that may cause problems with the product’s classification as food or medicine, in particular Regulation 1924/2006, which is devoted, among others, to authorising health claims on food. It confirms that certain foods which have disease–preventing properties can be presented as such if the law gives permission. Moreover, the EU legislator has accepted that products dedicated for patients whose normal consumption is difficult or impossible are regulated under the scope of food law, namely in Regulation 609/2009.

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98 Directive 2002/46/EC, Recital 3
99 COM (99) 0719 final
Summarising, following Van der Meulen and Bremmers (2015) it should be noticed that EU law struggles with the two regimes - medicinal law and food law - and attempts to separate them. However, this bipolar separation does not comply with reality.

Distinction focuses on medicinal law exclusively

Legal interpretation concerning the distinction between products which may fall into the definition of medicinal products or food supplements, or cosmetic, biocide or medical devices, is currently analysed solely in light of medicinal law. The main goal of the EUCJ is to consider if the product in question is a medicine or not. The EU legal makers, therefore, link the problem with distinction to medicinal law as well. As emphasized in the preamble to Directive 2001/83 (after amendments in 2004), medicinal law needs to be revised due to a growing number of borderline products\(^\text{100}\). To put it simple, under medicinal law no other laws need to be involved in the legal assessment concerning borderline products. Hence, it can be said that under the existing EU law, food law does not affect the decision on the classification of products (Lähteenmäki-Uutela, 2009).

It is worth emphasising that medicinal (pharmacological) law has a longer history than food law in the EU. It is permitted to speak about EU food law in the context of the introduction of Regulation 178/2002 into the legal orders of the Member States in 2002. Previously, the definition of food was a matter of national law. That was the legal background of the Van Bennekom case (C-227/82) in 1983. The EUCJ provided a legal assessment exclusively based on the content of Directive 65/65 and every following ruling has referred to the case from 1983 as the fundamental one. The introduction of statutory definitions of food and, then, of food supplements has not changed the EUCJ approach to this problem. This means that the concept has not been revised over three decades. The following figure shows that the fundamental criteria for the assessment of the distinction essentially emerged and were evaluated on the basis of Directive 65/65.

\(^{100}\) Directive 2004/27, Recital 7
In the joined cases HLH Warenvertrieb and Orthica (C-211/03 etc.) the national court analysed a question of whether a threshold of the ‘upper safe level’ of substance, which was introduced in Directive 2002/46 is relevant for the product’s distinction or if it should be reduced, for instance, because the substances in question are also ingested with food and/or because – at least, where they are taken long-term – various consumer groups and their different sensitivities may have to be considered. It was ruled by EUCJ HLH Warenvertrieb

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101 HLH Warenvertrieb and Orthica (C-211/03 etc.), para 26
and Orthica that the concept of ‘upper safe level’ adopted in article 5(1) a) of Directive 2002/46 as a factor to set the maximum quantities of vitamins and minerals present in food supplements may indeed influence products marketed as food supplements. However, as such, ‘that concept does play no part in the distinction between medicinal products and food supplements’. This example confirms that the assessment is not influenced by non-medicinal legislation.

No explanation of wording and application of case law criteria
The words used in the definition of a medicinal product can hardly be defined by legislation. Neither the medicinal law directives nor any other EU legislation have specified the meaning of technical expressions used, among others: ‘pharmacological’, ‘immunological’, ‘administrated by’, etc. The EUCJ has not made this effort. It chooses other approaches based on an assessment of the legal status of a specific product as either a food supplement or a medicinal product, using a list of criteria related to its presentation and functionality.

Concerning aspects of the product’s presentation, familiarity to consumers understood as an impression gained by an averagely informed consumer about the product concerned, its form, information found on external packaging, dissemination, place of distribution, references to medical research should be examined to answer if the product’s presentation leads to consumers’ belief that it is a medicine. These points have to be considered from a broader perspective, which may include several aspects – from labels and commercials to TV or online advertising. The broad interpretation has gone so far that a product without any properties to treat any disease but presented as such, can be classified as a medicine. As was stressed in the case law, ‘the “presentation” criterion used in the first subparagraph of Article 1(2) is designed to catch not only medicinal products having a genuine therapeutic or medical effect but also those which are not sufficiently effective or which do not have the effect which their presentation might lead to expect, in order to preserve consumers not only from harmful or toxic medicinal products as such but also from a variety of products used instead of the proper remedies. The concept of the “presentation” of a product must therefore be broadly construed’.

In turn, functional aspects defined as composition, pharmacological properties, health risk and manner of use of the product concerned also seem to be ambiguous, although the prerequisite for a strict scientific interpretation is the

102 Ibid., paras 62–63
103 Case Upjohn, C–112/89 para 16
demand in this regard. However, those scientific terminology has not been adopted and defined in law. With the revision of Directive 2001/83 in 2004\textsuperscript{104} the pharmacological properties expression was enriched by another scientific term: ‘immunological and metabolic action’. It is worth referring to their meaning in a medicinal encyclopaedia. Hence, pharmacology, as a field of science, is defined as a study of how chemical substances interact with living systems. If these substances have medicinal properties, they are classified as pharmaceuticals. In most cases, the term ‘pharmacology’ is used with medicinal or pharmacological actions; however, it should not always be viewed in the context of disease, because it should be understood as the process of chemicals interacting with the human organism. That may be one of the reasons why the term ‘pharmacological’ was not used in the previous Directive (Borchardt, 2002). Next, immunology is a branch of biomedical science covering the study of all aspects of the immune system in all organisms. It deals, among others, with the physiological functioning of the immune system in states of both health and disease (...). Metabolism, meanwhile, is a process of chemical modification of chemical compounds in living organisms and cells (Titz 2006).

This short investigation shows that all these terms are not only related to a disease but can be regarded as a simple physiological action in healthy bodies (Titz 2006). These terms can be applied to either food supplements or medicinal products. Therefore, precise criteria concerning the functional aspects of a product are needed.

Because of the lack of a precise explanation for the wording, additional questions emerge. Is it required that all criteria be met to classify a product as a medicine? Is it a medicine if only one criterion suggests the application of Directive 2001/83? Those doubts should be resolved in law.

Here, it is worth highlighting that in the Red Rice case C-140/07) the EUCJ added ‘the intended use of the product’ as a valuable criterion to delimit the definitions of food supplements and medicinal products. Once again, the criterion was not more broadly explained. However, the term ‘intended to’ is a part of the definitions of food, cosmetic products and medical devices. In particular, the latter definition says precisely that medical devices are instruments ‘intended by the manufacturer to be used for human beings for the purpose of (…)’. Next, the guideline Homeostasis, proposed by the Council of Europe in

\textsuperscript{104} By Directive 2004/27
2008, goes further and describes the ‘intended use of a product’ as the main criterion to distinguish between food supplements and medicinal products. According to this document, the fundamental pillar to distinguish between food supplements and medicines is the precise description of the intended use of a product. Finally, in its preamble, Directive 2004/27/EC stresses that ‘Where a product comes clearly under the definition of other product categories, in particular, food, food supplements, medical devices, biocides or cosmetics, this Directive should not apply.’ Having that in mind, the EU legislator should consider whether the criterion of intended use of a product can be useful for the delineation between food supplements and medicinal products.
Chapter 5: Borderline products on the EU Market

Introduction

The main purpose of this chapter is to answer Sub-question 2 focusing on the consequences for the EU market of the existing fragmented, non-fully harmonised European legislation with regard to food supplements and medicinal products. In order to approach the topic, first, the basic legal terms and provisions contained in European primary law, in particular the Treaty of Functioning of the European Union and the Treaty of the European Union are explained, followed by the analysis, based on selected EUCJ cases, presenting the impact of the treaties’ provisions on circulation of food supplements and medicinal products within the EU. The conclusions present the consequences of non-harmonised aspects concerning food supplements and medicinal products that impact of legal issue of borderline products.

5.1. One market in the light of the EU primary legislation

5.1.1. Single Market

European food supplement and medicinal product legislation, introduced in Directives 2001/83 and 2002/46, aims, on the one hand, to facilitate trade between Member States, and on the other hand, to ensure a high level of consumer protection within the EU. These principles, with respect to overall EU legislation, not only to food and medicine law, were constituted as the foundation for European integration in order to gradually extend the relationships between Member States and to create a common, single market covering the area without borders, where the free flow of goods, persons, services and capital is ensured (Jablonska-Bonca, 2010). The EU Single (Internal) Market seeks to guarantee the free circulation of goods, capital, services, and people – the so-called ‘four freedoms’ – between the EU Member States. As a result, it is intended to be conducive to increased competition, increased specialisation, larger economies of scale, and allowing goods and production factors to move to the area where they are most valued, thus improving the efficiency of resource allocation.
5.1.1a. Free movement of goods

For the market’s circulation of food supplements and medicinal products the most important role is played by the principle of free movement of goods. By ‘goods’, under the EU treaties, must be understood ‘all products which can be evaluated in money and which are capable, as such, of forming an object of commercial transactions’105. The rationale for this freedom is that goods can be shipped unimpeded across the whole EU. Among Member States, a product should have the same status in the country where it is produced and in its destination country. This legal situation entails another consequence. Any barriers and legal restrictions adopted in one Member State, even fully justified under its domestic law, should not be in force and the rationale of the principle of free movement of goods prevails. Moreover, the concept of EU trade without obstacles is understood very broadly, from tariffs to non-tariffs barriers and indirect obstacles such as state monopolies or fiscal discriminations (Mathijsen et al.1999). This means that Member States have removed trade barriers among themselves and introduced a unitary common trade policy towards other countries. The overall purpose of the duties is ‘to ensure normal conditions of competition and to remove all restrictions of a fiscal nature capable of hindering the free movement of goods within the Common Market’106.

5.1.1b. Mutual recognition and exceptions

However, every rule has its limitations. In the case of harmonised legislation, the application of similar rules seems to be an obvious requirement since the same legal provisions are applicable equally throughout the EU Member States. Unfortunately, many aspects in the EU, for example with regard to food supplements and medicines, are not fully harmonised. Hence, it is a challenge to the domestic legislation of members which, on the one hand, are entitled to cover the non-harmonised aspects by their own legislation, while on the other hand, any measure taken needs to be in conformity with the rules of the EU treaties, and more specifically with Articles 34 and 36 TFUE, introducing the principle of mutual recognition.

105 Case EU Commission v Italy C-7/68 (1968) E.C.R. 423 at 428
106 Case Fink Frucht C-28/67, ECLI:EU:C:1968:22
Member States are not allowed to prohibit or restrict, or make subject to administrative procedures having an equivalent effect, the import of products from another Member State that is lawfully manufactured in the exporting state. They cannot prohibit the sale of such products on their territory, not even if those products are produced to technical or qualitative specifications that differ from those required in the state of destination.

However, in case of a conflict between national measures of Member States concerning non-harmonized issues, EU law permits restriction on import within the EU. The circumstances that justify the restrictions are specified in Article 36 of TFEU, which mentions:

- Public morality
- Public policy
- Public security
- **Protection, health and life of humans, animals or plants**
  - Protection of national treasures possessing artistic, historic or archaeological value
  - Protection of industrial and commercial property.

The ground for interpretation of Article 36 with relation to Article 34 originated in the Cassis de Dijon\textsuperscript{107} case, and has established through several cases further criteria for the application of these restrictive measures (European Advisory Service, 2007, p.58). Being an

\textsuperscript{107} Case Rewe–Zentral AG v Bundesmonopolverwaltung für Branntwein C–120/78
exception, this principle should always be interpreted restrictively (Coutrelis, 2006). To justify the limitation, the burden of proof is upon the authority to demonstrate that there is a national issue as grounds for one of these conditions. Additionally, any restrictive measure taken has to be compatible not only with its necessity but also with the principle of proportionality\textsuperscript{108}. The principle of proportionality is recognised as a general principle applicable throughout all EU law, as defined in Article 5 of TEC: ‘Any action by the Community shall not go beyond what is necessary to achieve the objectives of this Treaty’.

5.2. Borderline products on the Internal Market

The hindrances to EU trade, under the meaning of 34 and 36 TFUE, result predominantly from differing national measures adopted and applied by national competent authorities (Schroeder 2006). Moreover, different interpretations among competent authorities may occur for aspects that are harmonised within EU law. For the sake of clarity, it is worth presenting the most frequent possibilities concerning trading of food supplements and medicinal products within the EU:

- **SITUATION I.**
  
  In case the product is deemed to be a medicine both by the Member State of production and the Member State of destination.
  
  - With respect to those aspects for which Directive 2001/83 does not (yet) provide for exhaustive harmonisation, Article 36 of TFUE can be used to justify the national measure provided that they meet the requirements for the application of this article, while,
  
  - With respect to those aspects of the trade for which Directive 2002/83 provides harmonisation, the Member State can refuse to admit a medicinal product lawfully manufactured and marketed elsewhere in the EU only on the grounds described in Article 29 (1) Directive 2001/83.

\textsuperscript{108} Ibid.
SITUATION II

In case the product is deemed to be a food supplement both by the Member State of production and of destination, and is lawfully marketed in the Member State of production,

- With respect to those aspects for which Directive 2002/46 does not provide harmonisation, Article 36 TFUE can be used, and
- Article 14 (9) of Regulation 178/2002 may apply as a basic rule, under which the product in question is deemed to be safe when conforming to the specific provisions of the Member State in which it is marketed.\textsuperscript{109}

SITUATION III.

In the case where a product is deemed to be a food supplement in the Member State of production to which specific harmonising provisions apply, but in the Member State of destination is deemed to be a medicinal product.

\textsuperscript{109} Opinion of Mr Advocate General Geelhoed delivered on 3 February 2005 to case HLH Warenvertriebs GmbH (C-211/03) and Orthica BV (C-299/03 and C-316/03 to C-318/03) v Bundesrepublik Deutschland, point 56
- With respect to those aspects for which Directives 2002/46 and 2001/83 do not provide harmonisation, Article 36 TFUE can be used, and
- With respect to those aspects of the trade for which these Directives provide harmonisation, the Member State can refuse the entry of a product by application of Article 95 of TFUE (Klaus 2009)

<table>
<thead>
<tr>
<th>Situation</th>
<th>Production</th>
<th>Medicinal Product</th>
<th>Food Supplement</th>
<th>Non-Harmonized issue</th>
<th>Harmonized issue</th>
</tr>
</thead>
<tbody>
<tr>
<td>I.</td>
<td>Medicinal Product</td>
<td>V</td>
<td></td>
<td>Art. 36 TFUE</td>
<td>Art. 29 (1) Dir. 2001/83</td>
</tr>
<tr>
<td>II.</td>
<td>Food Supplement</td>
<td></td>
<td>V</td>
<td>Art. 36 TFUE</td>
<td>Art. 14 (9) Reg. 178/2002</td>
</tr>
<tr>
<td>III.</td>
<td>Medicinal Product</td>
<td>V</td>
<td></td>
<td>Art. 36 TFUE</td>
<td>Art. 95 TEC</td>
</tr>
</tbody>
</table>

Figure 5.3. Borderline products on the EU Market – inspired by Opinion of Mr Advocate General Geelhoed delivered on 3 February 2005 to case HLH Warenvertriebs GmbH (C-211/03) and Orthica BV (C-299/03 and C-316/03 to C-318/03) v Bundesrepublik Deutschland and article B. Klaus & Capeli F. (2009) Is garlic a food or a drug?

5.3. Circulation of borderline products as a possible source of hindrances to European trade

The last situation – refusing the entry to another market due to the lack of pharmacological authorisations is the most frequent and challenging for the borderline products issues. As a result, the European food supplement and medicinal product sectors are those which face a continuous struggle with the application of the principle of mutual recognition due to the limited harmonisation and different approaches to borderline product issues in every Member State. Some want to continue enforcing their national legislation, even when it is
stricter than the laws of other Member States. This translates into the reality that, at the same
time, the same product can be a medicine or a food supplement depending on appreciation
of the facts.

Once again, as an example, leaves from Ginkgo Biloba L., a popular plant known for
application for cold hands or feet due to mild blood flow disruption in peripheral vessels,
can be used in food supplements in Italy, Germany and France. Moreover, seeds from this
plant are permitted to be used in food supplements in Italy. However, grilled seeds are
permitted in food supplements in Belgium and France. Moreover, in Germany food
supplements containing the leaf of Ginkgo biloba L. can be marketed at additional
conditions. the intake of the daily dose as recommended in the labelling or advertising may
not result in an intake quantity of flavonol glycosides exceeding 2.16 mg and of terpene
lactones exceeding 5.4 mg. In turn, in France, a food supplement with the ginkgolic acid
content cannot be less than 5 ppm. The label of a supplement containing the leaves must
additionally include the warning, ‘Consult your doctor if you are also taking anticoagulants’
(Klaus 2013). All these legal national results have to face the principles regarding free trade
stipulated in the EU treaties.

5.4. Borderline products issues already resolved in the case
law

Disputes with Member States related to the legal status of specific products classified
simultaneously as either food supplements or medicinal products reached the EUCJ with a
preliminary assumption that these are a hindrance to the EU trade and may fail to fulfil
Articles 34 and 36 of the TFUE. To illustrate the approach, 3 cases have been presented.
Bennekom C-227/82, the Garlic case C-319/07 and EU Commission against Spain C-
88/07.

All these practises were recognised as a limitation to free circulation of goods and against
mutual recognition in EU trade. In solving this problem, the EUCJ applied a similar
deduction based on the same steps. After proving that the national measure does not fulfil
the scope of Article 34 TFUE, it was then attempted to justify that measures referring to the
necessary protection of human health in the Member State and considering possible less restrictive solutions then the product ban.

5.4.1 Application of Article 34 TFUE

- **Case Van Bennekom C-227/82**

As discussed in the previous chapter, the judicial decision against Van Bennekom had been taken at the time when the harmonisation of the food supplement sector was far from introduced into EU law. The dispute encompassed the scope of Dutch medical law by comparison with EU law, namely the legal definition of a medicine provided in the *Wet op de Geneesmiddelenvoorziening* and the definition of ‘medicinal product’ stipulated in the Directive 65/65/EC. The term ‘presented for’ which appeared in the EU directive was much more limited in application than the expression ‘intended to be used’ which applied in Dutch law. Hence, the Treaty Articles 34 and 36 (at that time 28 and 30) were analysed by the Dutch court, since according to the Dutch court the definition of a medicinal product at that time in the Dutch law was probably broader than in the directive 65/65/EC. The preliminary legal analysis made by the Dutch court led to the conclusion that the definition of medicinal products in Dutch law, in contrast to the definition contained in the directive, included vitamin preparations, with the result that they must be registered in the same way as medicinal products.\(^\text{110}\) On this basis, Dutch law prohibited the sale of preparations imported from a more liberal Member State and created a barrier to trade within the EU. Indeed, in the light of this prohibition, for the EUCJ it was clear that national legislation which prohibits the marketing of vitamins and vitamin preparations without prior registration constitutes a measure having an effect equivalent to a quantitative restriction on imports in the meaning of the article 30 of the EEC Treaty, since such measure is liable to hinder trade between member states.\(^\text{111}\)

- **The Garlic case C-319/07**

In the Garlic case none of the parties involved in the court procedure denied that the Germans created an obstacle to EU trade. It was agreed that in this case the prohibition of marketing the products, considered outside Germany as foodstuffs but recognised in that

\(^{110}\) Bennekom case C-227/82, para 6

\(^{111}\) Ibid. paras 32–33
market as medicinal products, was an example of a measure having an equivalent effect to a quantitative restriction on imports – prohibited by Article 28 (now 34 of TFUE)\(^{112}\).

**EU Commission v Spain C – 88/07**

In turn, in the case EU Commission v. Spain the Spanish adoption of a consistent administrative practice, which involved the systematic classification of products based on medicinal herbs which were not listed in the Annex to the Ministerial Order of 3 October 1973 as medicinal products by function, without first submitting each of those products to a detailed analysis, deprived these products of a marketing authorisation, and led to their withdrawal from the Spanish market.\(^{113}\) In this case, the Spanish legislation was not in compliance with settled practice in the case law based on the assumption that products which may fall into the definition of medicine and food have to be assessed on a case-by-case basis. Basically, it was not a dispute between domestic and EU legislation but between national law providing a positive list for permitted plant supplements and the EU approach requiring an individual assessment in this regards as formulated by the EUCJ.

**5.4.2. Application of Article 36 TFUE**

In line with the EUCJ’s reasoning, the acknowledgment that a practice or a legislation is a barrier to trade within the Single Market must be followed by a legal analysis of whether there is a relevant justification for a barrier in the light of article 30 of the EC treaty (now 36 TFUE). Since the Van Bennekom decision, it has been recognised that the only permitted excuse for the necessity of authorisations for marketing a product categorised in one Member State as a food and in another as a medicine is granted when there is the aim to protect health in that Member State.\(^{114}\) ‘National rules imposing such restrictions are justified only if authorisations for marketing are granted when they are compatible with the requirements of health protection.’ In practice, this requires providing evidence that the marketing of the product in question creates a **serious risk to public health**.\(^{115}\) In the Garlic case, more detailed assessment with regard to public health protection was provided. Continuing along this line, the German authority recalled that it is for the Member States to

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\(^{112}\) Garlic case C–319/07, paras 78–79

\(^{113}\) EU Commission v Spain C–88/07, paras 29–30

\(^{114}\) Case Bennekom C–227/82, paras 5–6

\(^{115}\) Ibid. paras 39–40
decide on their intended level of protection of human health and life and on whether to require prior authorisation for the marketing of foodstuffs, taking into account the requirements of the free movement of goods within the Community.

However, as noted by the EUCJ, since Article 30 EC provides for an exception, it has to be interpreted strictly, which implies an obligation for the national authorities ‘to show in each case, in the light of national nutritional habits and in the light of the results of international scientific research, that their rules are necessary to give effective protection to the interests referred to in that provision and, in particular, that the marketing of the products in question poses a real risk for public health’.\(^{116}\)

The same reasoning is acknowledged in the case EU Commission v. Spain (C- 88/07). The practice limiting the free circulation of food supplements within the EU can be justified by the need to protect human health, referred to in Article 30 EC, or, additionally, by the overriding requirement of consumer protection, established in the Court’s case-law. Finally, the domestic measure limiting market access has to be assessed with the principles of proportionality and necessity. In both the Garlic and the EU Commission v. Spain cases the court noted that it is up to the Member State to select the measure which is most appropriate. Adopting restriction in the food supplements market flow in addition to public health protection must be balanced with the free movement of goods, so that the steps taken cannot result in obstacles to the free movement of goods which are entirely disproportionate to the pursued aim of protecting health.\(^{117}\) In this respect, for example, the Court noted that Germany could ensure the protection of health by prescribing proper labelling warning consumers of potential risk related to this garlic product.\(^{118}\)

### 5.5. Conclusions

The judgments analysed above confirmed a legal phenomenon appearing throughout EU law that whenever the legal scope of any subject is regulated through a directive, there is always a high possibility that it will interfere with the functioning of the EU market (Sadeleer de 2015).

\(^{116}\) Garlic case C-319/07, para 83

\(^{117}\) Ibid. para 71

\(^{118}\) Ibid, para 95
As can be seen, the existing case law on borderline products treats two different types of circumstances, depending on the national legislation invoked by the Member State where the considered product – the classification of which can be doubtful – is going to be marketed. Taking into account the situations occurring in the previously mentioned case law, the possible outcomes usually arise when.

1. A Member State refuses to release for consumption on its own national territory a product coming from another Member State because it was not provided with pharmaceutical approval required in the destination state, while analogical authorisation is not essential in the production state where the product is considered as a foodstuff, for example food supplements (most judgments, for example the Garlic case).

2. A Member State prohibits the release for consumption on its own territory of a product which is considered as a food or food supplement in another Member State where it comes from, because it contains substances that in the destination state are normally used to produce medicinal products¹¹⁹ (for example the case EU Commission v Spain).

Pursuant to the line settled by the EUCJ, each such case should be analysed in the light of Article 34 in conjunction with Article 36 of TFUE. However, the case law concerning application of these articles is very extensive with a broad variety of concerned goods. The EUCJ case law contains a long list of similar backgrounds concerning the circulation of different goods within the EU market. Taking into consideration observations made in this chapter, some characteristic findings originating in the national restrictions on the free circulation of food supplements and medicinal products in the EU are noticeable.

First of all, hindrances to the EU trade caused by the different classification of borderline products are the consequence of non-harmonised legal aspects concerning either food supplements or medicinal products. The analysis shows, at the same time, that there are problematic EUCJ cases based on harmonised issues that requires application of Article 114 TFUE (95 TEC). However non-harmonised aspects should correlate with the harmonised ones to achieve compliance with the objective set out in the directive. Thus, it is justified to say that national measures and legislation on food supplements and medicinal products may

¹¹⁹ EU Commission v Spain, para 4
negatively affect the trade between Member States. It should be considered as a part of the discussion whether legal recommendations concerning borderline products should be adopted in a regulation or remain in a directive.

However, secondly, the different perception and thinking about public health in Member States is one of the most problematic ‘harmonisation areas’ for food supplements’ and medicines’ circulation between markets. As shown, the protection of national public health is the main argument to refuse the entry of the doubtful product.

There is no legal definition of what should be understood under the term ‘human health’ in EU law, and competence with regard to this subject is basically in the hands of the Member States. It is worth mentioning that health, and more precisely public health, was introduced as a specific area of EU competence for the first time by the Maastricht Treaty in 1992 and now is found in Article 168 TFEU. The importance of health in the EU is recognised in Article 168 (1) stating that: ‘a high level of human health protection is to be ensured in the definition and implementation of all Union polices and activities.’ The legal protection of human health is a domain in which the EU is limited to a supporting role. As in Article 168 (7) of the EUCJ Treaty, Member States, not EU institutions, are recognised as responsible for their definition of health policy, management of health services, medical care and the allocation of the resources assigned to them. However, in certain aspects relevant for health, the EU shares competence with the Member States. The EU is competent for measures concerning: the quality and safety of organs and blood, some measures in the veterinary area, medicinal products, and medical devices.

With regard to food policy, attention should be paid to Article 114 (formerly Article 95 TEC.). This provision is applied as a legal base for measures adopted in the area of medicines and medical devices, food safety and labelling, cross-border health care and tobacco (UK GOV web., 2013.). As Article 114 (3) states, a high level of health protection is a base for the EU Commission proposals.

With regard to the aforementioned ‘borderline product cases’, the protection of public health can be a relevant argument to refuse the entry of a product considered under one domestic legislation as a food supplement and under the other as a medicine, if it is explained as a protection of the nutritional and local needs of the particular population.
Going deeper, in order to prove this the competent authorities have to present sufficient and scientific evidence that the product in question may pose a serious risk to public health. In the case EU Commission v Spain (C-88/07) the court used the expression ‘a presumption of danger going beyond’\textsuperscript{120}. If we try to simplify the analysis, we can just ask: ‘Is this product safe for a consumer from a particular country?’ One can then conclude that the legal rule set up for justifying these hindrances to trade originate in different levels of domestic public health protection, but to a large extent it is a matter of product safety.

Finally, it is worth pointing out that the EUCJ refers to international scientific evidence assessing the risk to health in a certain Member State. ‘An international scientific evidence’ may contain an endless number of scientific proofs available worldwide. Thus, it should be considered whether there is a way to provide unified international scientific evidence to prove the necessary circumstances concerning potential risk to human health of the products in question.

In the context of the foregoing considerations, with the uncertainty to assess the risk to health, the decision has to be based on scientific research, in particular valid internationally. Lack of a common scientific body competent to solve issues of a scientific nature, which often present aspects of undoubted complexity and difficulty, is tangible (Klaus 2009). It is worth mentioning that in the cases HLH Warenvertrieb and Orthica (C-211/03 etc.) this issue was raised. Under the existing EU law, a national court cannot refer questions on the classification of products to the European Food Safety Authority. An opinion delivered by that Authority, possibly on a matter forming the subject matter of a dispute pending before a national court, may constitute evidence that that court should take into consideration in the context of that dispute\textsuperscript{121}. However, the EUCJ gave a sign that the Authority can provide an opinion corresponding to the subject matter of a dispute pending before a national court, and that that court would have to ascribe to such an opinion the same value as that recognised to an expert report.

\textsuperscript{120} EU Commission v Spain, para 31

\textsuperscript{121} Cases case HLH Warenvertrieb and Orthica C-211/03 etc. , paras 89-93 .
Chapter 6. An approach to borderline products in Member States: the United Kingdom and Poland

Introduction

The previous chapters attempted to describe the relevant aspects of borderline products in the EU legislation, emphasising the concerns arising from legal definitions of ‘food supplement’ and ‘medicinal product’. Lack of full harmonisation on the European level results in different national rules in cases dealing with products that might be either classified as foodstuff or medicine.

This chapter presents, as an example, the British and Polish approaches to the ‘borderline product’ cases. First, the applicable national laws on food supplements and medicinal products are briefly overviewed. Then national legal tools – consisting of substantive and procedural laws – in both states that are applied to determine the legal status of a specific product as either a food supplement or a medicinal product are analysed. The conclusions to this chapter provide the answer to Sub-question 3.

6.1A. The UK and Poland – short overview

It is worth investigating the legal approach to borderline products in Member States on the example of Poland and the UK for at least three reasons.

First, Poland is the biggest market for food supplements in Eastern Europe in terms of sales value. For example, in 2013 Polish consumers purchased over 20% more food supplements than in the previous year (PMR web. 2014). It is also the second fastest growing market for pharmaceutical products in Eastern Europe. In turn, the UK was ranked as the third biggest market for food supplements in Western Europe in 2014, following Germany and Italy (Euromonitor International web. 2014).

Second, both the UK and Poland belong to the EU. However, the duration of their memberships is different; the UK joined in 1973, while Poland has been part of the EU for
12 years (2004). Hence, their experience with application and adoption of EU law is different.

6.2. Applicable laws in relation to borderline products in the UK: food supplements and medicinal products

6.2.1. Food supplements legislation

Within the territory of England, Directive 2002/46/EC was implemented by the Food Supplements (England) Regulation 2003 which came into force on 1st August 2005. Separately, an equivalent legislation was adopted in Scotland, Wales and Northern Ireland.

The scope of these regulations is dedicated predominantly to three significant aspects: composition, labelling and marketing of food supplements. Based on the EU Directive 2002/46/EC, the regulations incorporated lists of vitamins and minerals which may be used in the manufacture of food supplements (in Schedule 1) and forms of vitamins and substances which may be used in food supplements (in Schedule 2). In the context of borderline products, the English legislator stressed in Article 3 (2) of the Food Supplement Regulations that it excludes from its application medicinal products under the meaning given by Directive 2001/83/EC.

6.2.2. Medicinal products legislation

Concerning legal aspects of borderline products in the light of British medical and pharmacological law, attention should be paid to the following acts.

- **The Human Medicines Regulations 2012**

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123Due to the fact that the text of all regulations remains the same, this paper’s analysis is based only on the Food Supplements (England) Regulation 2003.
British legislation, applicable in all cases where it is necessary to determine whether a product is actually a medicine or not, is a sum of binding statutory law and non-binding regulations. However, both are adopted and executed by the competent governmental agencies. Until 2012, the medicinal product legislation was regulated by the Medicines Act 1968 which, contained, inter alia, principles and aims provided in EU Directives 65/65 and later in Directive 2001/83. At the moment, all legal aspects of medicinal products in the UK are regulated under The Human Medicines Regulations 2012.

These Regulations provide that, unless exempt, any medicinal product placed on the market must have a marketing authorisation, traditional herbal registration or certificate of registration as a homeopathic product granted either by the EU Commission or the UK Licensing Authority. The scope of these regulations consists, among others, of chapters regarding authorisation, sale, and supply of medicinal products for human use. The regulations cover also matters relating to the labelling, the containers in which they are supplied, and the manner in which their sale is promoted, whether by advertisement or oral representation (Pitchford 2013).

With regard to borderline products, essentially, Part 9 is dedicated exclusively to this issue. The aim of Articles 159 to 161 is to provide procedural steps in cases when a medicine’s status is in doubt in order to decide whether medicinal or other sectoral legislation should be applied.

In turn, substantive law, answering the question under what kind of determinates the distinction between medicinal products and other quasi-medical products should be made, is described in the UK Guideline No. 8.
6.2.3. Substantive law

6.2.3.1. Legal definitions: food supplements and medicinal products

The statutory definition of food supplement is stipulated in Article 2 (1) of the Regulations 2012. According to that provision, ‘food supplement means any food the purpose of which is to supplement the normal diet and which

(a) is a concentrated source of a vitamin or mineral or other substance with a nutritional or physiological effect, alone or in combination; and

(b) is sold in dose form.’

Additionally, this Article gives a clear explanation of the term ‘dose form’ as a form 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 or powders designed to be taken in measured small unit quantities.

The legal meaning of a medicinal product in British law is provided in Part 1, Regulation 2 of the Regulations 2012 and it is defined as:

- any substance or combination of substances presented as having properties of preventing or treating disease in human beings
- any substance or combination of substances that may be used by or administered to human beings with a view to, restoring, correcting or modifying a physiological function by exerting a pharmacological, immunological or metabolic action, or making a medical diagnosis.

As can be seen, both definitions of food supplement and medicinal product have been taken over from EU Directives, respectively 2001/83 and 2002/46, and do not contain any additional expressions.
6.2.3.2 Determination of products’ legal status

An application of substantive law in cases concerning borderline products should be based on circumstances described in the Guidance No. 8 by the MHRA. Generally speaking, the legal assessment to provide the product’s determination follows the definition of a medicinal product, the criteria set by the EUCJ, domestic case law and ‘all of all available evidences’. It means, so as to be consistent with EU law, that the product’s classification is reached on a case-by-case basis and consists of separate evaluations of the medicinal product’s definition on the basis of its function and presentation.

The principle of this individual approach for assessing is stated in point 20 of the Guideline No.8: ‘determining whether a product comes within either limb of the definition, no single factor or combination of factors will necessarily be conclusive, or more or less important than others. But in relation to particular products, a single factor or combination of factors may be more important than others, and may even be conclusive.’

6.2.3.2.1 Presentation

In assessing whether a product is ‘presented as having properties for treating or preventing disease’¹²⁹, the MHRA considers, in context, any claims which are made for it, and the characteristics of its presentation as a whole. Factors particularly relevant to deciding whether a product is a medicine according to the presentation aspects are:

- any claims made for the product, both explicit and implicit¹³⁰, including those on websites, linked ‘helplines’, testimonials or in linked publications
- the context in which these claims are made
- the overall presentation of the product in question
- the product’s appearance to the public,
- the main target group of the product – the particular target of the marketing information
- the labelling and packaging/package inserts including any graphics

¹²⁷ Guideline Note No. 8, point 3
¹²⁸ Ibid.
¹²⁹ Guideline No. 8, para 24
¹³⁰ Implicit claims may include product names.
- the promotion; literature (testimonials and literature issued by a third party on behalf of the supplier)
- advertisements (on television, the Internet and other media)
- the product form and the manner of use.
- any particular target of the marketing information/advertising material, for example, population groups with, or particularly vulnerable to, specific diseases or adverse conditions.

In addition to general criteria for evaluating the presentation issues, the document indicates a list of approximately 40 phrases with the context, which might be considered as claims suggesting medicinal properties of a product. Among typical words such as ‘prevents’, ‘cures’, ‘treats’, the list includes, among others, ‘alleviates’, ‘avoids’, ‘combats’, ‘controls’, ‘fights’, ‘helps’, ‘protects against’, ‘stops’, ‘traditionally used for’.

### Appendix No 1. (..)

<table>
<thead>
<tr>
<th>WORDS &amp; PHRASES</th>
<th>WHAT THESE MAY SUGGEST OR IMPLY ABOUT A PRODUCT</th>
</tr>
</thead>
<tbody>
<tr>
<td>&quot;Alleviates&quot;</td>
<td>In context, may suggest a claim to treat disease by reducing, ameliorating or correcting disease or an adverse condition.</td>
</tr>
<tr>
<td>&quot;At the first sign of a spot...&quot;</td>
<td>Implied claim to treat ‘spots’, an adverse condition. In context, may be a claim to prevent specific disease(s).</td>
</tr>
<tr>
<td>&quot;Avoids&quot;</td>
<td></td>
</tr>
</tbody>
</table>

Table 6.3.2.1.: Appendix 1 to Guideline Note No.8 – example of words and phrases suggesting a medical claim

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131 In UK law ‘advertisement’ is defined broadly in the Human Regulations 2012 and includes any published materials or any other activity, which are designed to encourage the purchase and medicines by the general public, generally by means of highlighting qualities of the medicine, called product claims (Article 279).

132 Guideline No. 8, point 5. ‘Where a product is sold on or has links to a website which presents that product as a medicine, the website will be used by the MHRA as evidence in the determination process. Similarly, where a customer is directed from a website selling a product, to another website for more information about the substances contained in a product and their uses, this may also be used by the MHRA as evidence in the determination process’.

133 Guideline No. 8, point 25

134 This criterion was not mentioned in the previous Guideline No. 8 issued 2012

135 The words and phrases listed below have all contributed to a determination by the MHRA that the product they were associated with was a medicinal product. But it is not the case that use of any of these words or phrases to promote or describe a product will necessarily lead to the MHRA determining that the product is a medicine. The intended and implied meaning of such words and phrases has to be considered in context.
In the current Guideline No. 8, an additional paragraph relating to food claims is added. Referring to EU Regulation 1169/2011 it is stressed that any claim that a food has the property of preventing, treating or curing human disease is not permitted. This covers any implication that a foodstuff is capable of protecting against, or relieving the symptoms of, disease, infection or other adverse conditions. The MHRA must therefore be mindful of the primary purpose of the product\textsuperscript{136} when investigating whether medicinal claims which are made for food products (including food supplements) should be subject to the Regulations 1169/2011.

6.2.3.2.2. Function

In assessing whether a product is a medicinal product on the basis of its function, the document lists factors that are particularly relevant to deciding on that issue. These are as follows:

- the pharmacological, immunological or metabolic properties of the ingredients and any significant effects the product will have on physiological function in humans
- the composition of the product
- the manner in which the product is used
- the product promotional literature, including testimonials and any literature issued by a third party on behalf of the person who places the product on the market
- the familiarity of the product to consumers and the extent of its distribution in the UK
- the product form, (capsule, tablet, etc.) and the way it is to be used
- the presence of essentially similar licensed, registered or exempt medicines on the UK market
- the risks which use of the product may pose.\textsuperscript{137}

It is emphasised that the MHRA only classifies finished products and not individual substances and ingredients. A product will not be classified as a medicine solely on the basis

\textsuperscript{136} Ibid. point 10.
\textsuperscript{137} Guideline Note No. 8, point 7
that it may be unsafe for human use. A product must be intended for, or be capable of performing, a medicinal function before it can be classified as such.\textsuperscript{138}

\textbf{6.2.4 Procedural law}

The MHRA, on behalf of the UK Licensing Authority, has the competences to determine whether a doubtful product is a medicine or not. A procedure concerning determination of a product’s legal categorisation is applied in all cases where the authority is of the opinion that a product without a specific authorisation (or traditional herbal registration or a certificate of registration as homeopathic medicinal product) is a medicinal product.\textsuperscript{139}

The procedure consists of three main phases:

- noticing a provisional determination
- written or oral procedure and
- making a final determination.

1. **Provisional determination** (Articles 159–160). If a medicinal product without specific authorisation is suspected to be sold on the British market, then the MHRA gives a notice in writing, a so-called ‘provisional determination notice’ to a person who sells, supplies, offers to supply or to whom the product may be sold.

The notice’s content is regulated by law and it must include, among others:

- An information to the recipient that the licensing authority has made a provisional determination that the product is a medicine,
- A justification for the determination.

2. **Written or oral representation** (Articles 161–162).

The entity which revised the provisional notice is entitled within a statutory period of time to request a revision of the determination. In this regard, the recipient (the one who placed on the market the product) is obliged to establish an oral or written representation. As a reaction, in either an oral or written representation the MHRA appoints an independent

\textsuperscript{138} Ibid.

\textsuperscript{139} Article 159 (1) the Human Medicine Regulations 2012
panel. The Panel has an advisory function and is responsible for giving advice to the UK Licensing Authority on whether the product meets the conditions listed in Article 1 Directive 2001/83/EC. The Panel, as a quasi-judging body, considers the written or oral representations from the company and the representations made by the Licensing Authority. During this stage, the company is entitled to submit all types of relevant evidence confirming the present legal categorisation of its product. Once the Panel has completed its deliberations, it will issue its advice to the UK Licensing Authority.

3. **Final determination** (Article 163)

Having the Panel’s advice, the MHRA issues the final determination. It is a decision regarding whether the product in question is a medicinal product, with argumentation of the reasons for it. The Licensing Authority must take into account the Panel reviewer’s advice, however, it is not bound by it.

If the product is categorised as a medicine, pursuant to Article 164 (2) of the Regulations 2012 the determination includes notice to the entity requiring it to stop marketing the product, or not to place it on the market, unless or until the relevant authorization, registration or certification has been granted. Breach of such a notice is a criminal offence. The final determination might be disputed in the court.

The final determinations are registered and published on the MHRA’s website, summarising:

- details of the product names
- the names of the companies to whom the determination notices were issued and
- brief details of the reasons for the determination.

The MHRA also offers advice when an interested entity itself, before any procedure is initiated, has doubts regarding correct legal determination of a product. According to point

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*Figure 6.3.3b. Article 166 The Human Medicine Regulations*

**Article 166 Offences relating to borderline products** (...)

(2) A person guilty of an offence under this regulation is liable—
(a) on summary conviction to a fine not exceeding the statutory maximum; or
(b) on conviction on indictment, to a fine, to imprisonment for a term not exceeding two years or to both.
48 of Guideline Note No. 8 the entity may ask for advice through an advice request form available on the Agency’s website or through a written letter\textsuperscript{140}.

<table>
<thead>
<tr>
<th>2</th>
<th>Product Name:</th>
<th>Manflu Soothing Hot or Shot Drink</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Company to whom notice was issued:</td>
<td>Manflu Ltd</td>
</tr>
<tr>
<td></td>
<td>Panel Advice</td>
<td>The product is a medicine by presentation.</td>
</tr>
<tr>
<td></td>
<td>Licensing Authority’s Determination and reasons</td>
<td>Man Flu is a popular and well recognised colloquial term used to refer to a man with a cold who is exaggerating his symptoms. The product was promoted with graphics showing a man in bed with what would be associated with a first aid symbol. Additionally the product contained Echinacea, Vitamin C and Zinc, all which are commonly associated with the relief and prevention of colds and flu symptoms.</td>
</tr>
</tbody>
</table>

Figure 6.3.3c. An example of final determination – October 2010 - December 2011\textsuperscript{141}

\textsuperscript{140} Guideline Note No.8, paragraph entitled: ‘What to do if you are still unsure of the status of your product?’

6.3. Applicable laws in relation to borderline products in Poland: food supplements and medicinal products

6.3.1. Food supplements law

The introduction of Directive 2002/46 into the Polish market is regulated by the Act of 25 August 2006 on Food and Nutrition Safety. This is the main act regulating food law in Poland governing the implementation and harmonisation of the majority of European food legislations. It consists of substantive and procedural provisions.

The EU food supplement core provisions from Directive 2002/46 were implemented into this Act in Article 27. Additionally, detailed requirements concerning labelling, list of permitted vitamins and minerals and their purity criteria are regulated under the Ordinance of the Minister of Health from 9 October 2007.

In turn, procedural aspects to be applied also in cases concerning products potentially having medicinal properties are stipulated in Articles 29 to 32 of the Act on Food and Nutrition.

6.3.2. Medicinal products law

Both substantive and procedural legal issues relating to medicinal products under the Polish legal system are regulated mainly by the Act of 6 September 2001 Pharmaceutical Law, which implements provisions of Directive 2001/83/EC. The act consists of chapters regulating rules and procedures for authorising medicinal products, for marketing, the conditions of conducting clinical trials, requirements for advertising, trading and manufacturing conditions for medicinal products. Article 3a stipulates that the provisions of pharmaceutical law are applicable to products that meet both the criteria of a

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142 Interestingly, this Act contains more than 53 regulations and over 43 directives.
143 OJ.2007.210 poz. 1540
144 Act of 6 September 2001 Pharmaceutical Law. Article 1
medicinal product and a different category of products, especially a food supplement or a cosmetic.

6.3.3. Substantive law

6.3.3.1. Legal definitions: food supplements and medicinal products

Article 3 (39) of this Act on Food and Nutrition presents the legal definition of a food supplement. It is worth mentioning that Polish law uses the term ‘dietary supplement’ (suplementy diety) rather than ‘food supplement’ (suplementy zywności), which is used in the Polish translation of Directive 2002/46/EC (Wojciechowski 2009). The statutory definition is a word-for-word translation of the term contained in the EU directive, aside from the additional wording including the references to medicinal products (Wojciechowski 2010). Hence, it states that:

‘Dietary supplements means foodstuffs the purpose of which is to supplement the normal diet and which are concentrated sources of nutrients or other substances or other substances with a nutritional or physiological effect, alone or in combination, marketed in dose form, namely forms such as capsules of liquid, drop-dispensing bottles, 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 quantities, excluding products with features of a medicinal product in the meaning stipulated in the provisions of the pharmaceutical law.

Pursuant to Article 2 (32) of the Act on Pharmacological Law, a medicinal product is defined as ‘any substance or combination of substances presented as able to prevent or treat disease in human beings or animals, or administered with a view to making a medical diagnosis or to restoring, correcting, or modifying physiological functions of an organism through pharmacological, immunological or metabolic action’. The above definition contained in Polish law is almost identical with the European definition.

145 The expression ‘administrated with a view’ replaced ‘given to make’ in 2007, by the Act of 30 March 2007 (OJ.07.75.492)
6.3.3.2 Determination of product’s legal status

The substantive Polish law does not provide any provisions explicitly dedicated to cases dealing with products falling potentially into medicinal product and food supplement definitions. In the Act on Food and Nutrition there are a few legal articles which might be helpful in assessing whether a food supplement is or is not a medicine.

According to Article 29 (1) 2.5 of this act, the person placing a food supplement on the market is required to present a significant amount of information, including among others, presence of **active agents** in the product. An “active agent” is a term commonly used in pharmaceutical law and presence of it in a food might suggest that the product is medicinal by function (Zboralska 2012). In the next article, it is mentioned that the Chief of Sanitary Inspectorate (the Chief) may carry out a procedure in order to verify the product specified in the notification with regard to its composition, properties of individual ingredients and indication for use\textsuperscript{146}, hence, it focuses on functional aspects of products. It appears that, if the Chief has any doubts with regard to the product at issue, he or she may launch an investigation. It might contain also doubts on whether the product fulfils the criteria for a medicinal product.\textsuperscript{147}

This act does not contain any provision specifically dedicated to the presentational aspects which should be considered in the assessment of distinguishing medicinal products from food (or food supplements). Previously, there was one provision concerning only labelling, namely Article 46 (2) of the Act on Food and Nutrition, applicable to all food products in Poland, which said that labelling must not ‘**suggesting that the food possesses the property of preventing, treating or curing a human disease**’. This provision was derogated by the Act of 7 November 2014 formulating amendments to the Act on Food and Nutrition. Therefore, it should be assumed that since December 2014 the rules adopted in EU Regulation 1169/2011, in particular Article 7\textsuperscript{148}, must be applied in this regard. It is still

\textsuperscript{146} The Act on Safety of Food and Nutrition, Article 30 (2)

\textsuperscript{147} As pointed out by Zboralska (2012). Also a product that does not fulfil the criteria of a medicinal product is subject to examination, which is extremely unlikely in the case of food supplements.

\textsuperscript{148} Article 7 Regulation 1169/2011 says, ‘food information shall not be misleading, particularly, as to the characteristics of the food and, in particular, as to its nature, identity, properties, composition, quantity, durability, country of origin or place of provenance, method of manufacture or production; by attributing to the food effects or properties which it does not possess; by suggesting that the food possesses special
unclear how Polish law approaches the legal definition of medicinal products by virtue of their presentation. It should be assumed that the assessment refers exclusively to the criteria developed in the EUCJ case law.

6.3.3. 3 Procedural law

In Polish law a potential problem with classification of a product on the border between food supplements and medicinal products is related to the general legal rules concerning marketing of a food supplement, stipulated in articles 29 to 32 of the Act on Food and Nutrition. The Act of Pharmacological Law does not contain any procedural norms helpful in these sorts of cases.

- Notification procedure

Basically, in order to place a food supplement on the Polish market, it is necessary to carry out a notification procedure, consisting in notifying the Chief Sanitary Inspectorate. The notification of a food supplement is done prior to or simultaneously with placing a product on the market. However, the law does not specify the time and limitation for this procedure, either regarding initiation or closing of the Chief’s actions.

If the Chief has any doubts regarding the product, a so-called “investigation procedure” might be opened. One type of doubt might be considering whether the product fulfils the criteria for medicine, not for food. Pursuant to Article 30 (1) 2 of the Act of Safety of Food and Nutrition, ‘the Chief may carry out a procedure in order to verify if the product specified in the notification with regard to its composition, properties of individual ingredients and intention for use is, among others, not fully fitting the legal criteria for another type of products for human use, in particular medicinal products according to pharmaceutical law, cosmetic products under cosmetic law or medical devices according to medical devices regulations’.

characteristics when in fact all similar foods possess such characteristics, in particular by specifically emphasising the presence or absence of certain ingredients and/or nutrients; by suggesting, by means of the appearance, the description or pictorial representations, the presence of a particular food or an ingredient, while in reality a component naturally present or an ingredient normally used in that food has been substituted with a different component or a different ingredient’.

93
Opinion of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products.

Next, having suspected that the product is a medicine, the Chief is obliged to consult the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products (the Registration Office). This office is independent of the Sanitary Inspectorate Agency and it is supervised directly by the Ministry of Health, which issues decisions regarding medicinal products and biocidal products on the basis of documentation drafted by the President of this office\(^{149}\). However, not the Chief but the applicant is called to submit an additional opinion from the Registration Office. Again, provisions of the Act do not specify any form or deadline for issuing such an opinion. However, as it is clearly stated in Article 31 (3) that the opinion of the Registration Office is binding for the particular procedure. Opinions issued by the Registration Office contain, in many cases, only one sentence: ‘The product can be classified as a medicinal product’ or ‘The product cannot be classified as a medicinal product.’ Basically, no additional motivation is given (Zborowska 2012).\(^{150}\)

Completion of the notification procedure

The law does not provide any regulations on the manner and form of completion of the investigation procedure. The only reference to this is included in the Ordinance of the Minister of Health of 20 June 2007 on registration of products marketed in the Republic of Poland for the first time as foodstuffs, on the form of notification and methods for calculating the costs of issuing an opinion on these products. The appendix to this act entitled ‘Form of the Registration of the products subject to notification of their first marketing as foodstuffs’ contains a footnote explaining: ‘the Chief notifies the notifying entity of the reception of notification of the product in the case when in terms of its composition and properties the product meets the qualification requirements adopted by the manufacturer or importer of the product at the date of the notification or other requirements, e.g. a medicinal product on the basis of the documentation supplied.’

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\(^{149}\) The Office was appointed on the basis of the Act of 27 July 2001 on the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products (Dz.U. no. 126 item 1379 with amendments).

\(^{150}\) Since those opinions are not considered as an administrative decision, a motivation is not deemed necessary. Polish administrative procedure recognizes an opinion from other public authorities. Basically, opinions issued by other entities are considered as additional evidence and, thus, are not binding for the final decision. They are just considered helpful advice.
Therefore, the final decision, which is not a typical decision in the meaning of an administrative law, is considered as an information letter by the Chief with acceptance or not of the notification of marketing of the food supplement (Zboralska 2012). Since it is not an administrative decision under the meaning of Polish administrative law, the business is not entitled to defend his position. It means that all actions taken during the procedure are not subject to any further verification either by a second, higher instance or court supervision.

However, there are some measures undertaken in case of suspicion or decision of the Chief that the product is not a food supplement but medicine. Those actions are taken by a third agency: the Powiat\textsuperscript{151} Sanitary Inspection. It can be noted that during the investigation procedure, before the decision is reached, a measure can be taken forbidding the marketing of the product in question. The Powiat Sanitary Inspector’s decision is a formal administrative decision, thus, this gives an applicant the right to defend and supervise the governmental measures by another authority.

\textbf{Article 32 (1) of the Act on Food and Nutrition}

In case of any suspicion that the food product specified in the article 29 par. 1 (e.g. food supplement), does not meet the requirements specified for this product and is on the market, a competent public Powiat Sanitary Inspector shall decide on a temporary suspension of the marketing of the product or withdrawing the product from the market until the completion of the investigation procedure (...)

Figure 6.5.3. Article 32 (1) the Act on Food and Nutrition

\textsuperscript{151} A powiat is the second-level unit of local government, most equivalent to a district or a prefecture in other countries
6.4. Conclusions

The main aim of this section is to compare the different approaches to the concept of borderline products in two Member States, Poland and the UK. It provides a comparative analysis of these two legal systems under the following criteria:

1. Field of law applicable to the borderline product cases
2. Competent authority empowered to decide on the distinction between food supplements and medicinal products
3. Approach to this topic in substantive law: source of law (3a), the determination elements of legal assessment (3b) and the analysis of main criteria in the assessment (3c-f)
4. Approach to the topic in procedural law: source of law (4a), the determination procedure (4b), conclusion of the procedure (4c), granted rights of the party (4d), publication of the final outcome (4e).

Figure 6.4 summarises the comparison of these criteria

<table>
<thead>
<tr>
<th>Criterion</th>
<th>The UK</th>
<th>Poland</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Branch of law</td>
<td>Pharmaceutical (medicinal) law</td>
<td>Food law</td>
</tr>
<tr>
<td>2. Competent authority</td>
<td>The Medicines Healthcare Product Regulatory Agency (MHRA)</td>
<td>Chief of Sanitary Inspectorate; The Registration Office; The Powiat Sanitary Inspection;</td>
</tr>
</tbody>
</table>

Substantive Law

| 3a. Source of law | MHRA Guideline Note No 8 – A guide to what is a medicinal product (2016) | Lack of legal provisions dedicated exclusively to borderline products |
| 3b. Way of determination | Case-by-case following EUCJ and domestic case law and any relevant evidence | Case-by-case following EUCJ case law |
| 3c. Criterion of functional aspects | yes | Not specified

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152 Article 29 (1) Act on Food and Nutrition per analogiam
### Ad.1–2. Branch of law and empowered authorities

In general, all issues related to borderline products under British law are subject to pharmaceutical (medical) law and as such are predominantly in the hand of one governmental authority: the Medicines and Healthcare Products Regulatory (the MHPR). In turn, under Polish law, the borderline products issue, especially with regard to delimitation between medicinal product and food supplement, do not have an exclusive regulation either with regard to substantive or procedural law. Therefore, in any doubtful case posing the question whether a product is a medicine or not, to some extent referring to procedural aspects, general, statutory provisions concerning first notification regarding launching on the market are applied. It might be assumed that those cases are a matter of food legislation. Competences are fragmented between three authorities: the Chief of Sanitary Inspectorate, the Registration Office and The Powiat Sanitary Inspection. This can have as result that the same case might be conducted by three independent public authorities at the same time.

### Ad.3 a–d). Substantive law

- **The UK**

  As mentioned, in the UK the decision whether a product in question is a medicine or not is the result of determinants being analysed in the light of the Guideline No. 8. Two findings
should be stressed. First, evaluating the criteria being analysed in such cases in a non-binding document follows the EU trend visible in other sectors, namely cosmetic or medical devices. These documents contain a list of advisories helping with the demarcation. Second, it should be acknowledged that enforcing national statutory and binding provisions within British territory, in the situation where EU law lacks binding provisions, might be an obstacle for any non-English entity entering the market. Ultimately, it would be an unjustifiable restriction with regard to free movement of goods within the EU. Therefore, at this moment, the only legal solution is to provide a non-statutory tool in accordance with the settled EUCJ case law. The requirement of an individual approach to every case and the analysis of the EU medicinal product definition including aspects either by virtue of ‘presentation’ or ‘function’ are several times emphasised.

With regard to assessing a product in the light of the medicinal product’s definition under the limb of functionality, the Guidance Note No. 8 repeats criteria developed in the EUCJ cases. Significantly, more details are dedicated to assessing the product in the light of its presentation. On the one hand, the British system recognises, following the EU case law, a very broad interpretation of this criterion. For the purposes of determining product status, the MHRA takes into account everything and anything that may come to the general public’s attention. This includes labelling, leaflets, packaging, use of graphics, advertisements, customer testimonials, internet promotions, editorials and broadcasts. It is the message conveyed rather than the actual wording that is taken into account and, where this is deemed inappropriate, regulatory action will be taken. On the other hand, the Guidance Note no. 8 provides a list of typical expressions suggesting that a product might or might not be a medicine. However, those expressions are not assessed on a base of a literal investigation of the label or other information for consumers containing one of these words but having in mind the context of the presentation at issue.

- Poland

The borderline products issue, especially with regard to delimitation between medicinal product and food supplement, does not have an exclusive regulation with regard to substantive law. Obviously, the broader context is the fact that Poland is obliged to consider the EUCJ case law concerning borderline products, but in addition, no domestic legal articles specifically applicable for borderline product cases have been introduced. In general,

153 Guidance no.8, p.45
statutory provisions concerning the first notification of a food supplement in order to launch it on the market are applied in this regard. In case of doubt, the decisions to distinguish a food supplement from a medicinal product are made on a case-by-case basis by the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products. The law does not stipulate any criteria under which the Registration Office makes their decisions.

As emphasised by Wesolowska et al. (2013) the Registration Office issues their opinions taking always into account both functional and presentational aspects of the EU medicinal products definition. With regard to functional criteria, one can apply factors stipulated in Article 30 of the Act on Food and Nutrition: composition, properties of individual ingredients and indication for use of the product. More problematic are the presentational criteria. A potential solution for the presentation dilemma of borderline products was developed in the case law, grounded on the unfair commercial practices law (Kondrat 2012). In order to assess the medicinal product by presentation, legal practitioners refer to the Act of 23 August 2007 on combating unfair commercial practices\textsuperscript{154}

This act defines commercial practices very broadly as a ‘\textit{trader’s act or omission, course of conduct, commercial statement or information, in particular advertising and marketing, which is directly associated with the promotion or sale of a product to a consumer}’ (Art. 2 (4)). Relevant to presentational aspects of borderline products is Article 5, applicable when a practice of a trader is considered as a misleading act.

It should be stressed that that either an entrepreneur (a competitor) or the President of the Office of Competition and Consumer Protection is entitled to open a case against a trader who misleads consumers in the light of this act.

\textsuperscript{154}OJ.2007.171 item. 1206
Ad 4 a–e). Procedural law

- The UK

With reference to procedural aspects of borderline products, the English system provides a systematic administrative procedure guaranteeing a revision of the final decision by the court. Alternatively, the MHRA offers an independent opinion on the request of an applicant. From the moment a person, called in the law the ‘recipient’, is charged with placing on the market or planning to launch a product without specific permission, the statutory procedure stipulated in the Medicinal Regulations 2016 provides a transparent and predictable procedure – on the one hand, explaining actions taken during all stages by the governmental agency, and on the other hand, providing a formal guarantee for the rights of the individuals. All decisions made by the MHRA, either a provisional determination or a final determination, must be reasoned and explained. Simultaneously, the recipient is entitled to present his own statements and any evidence during all stages. The final determinations are published on their websites with free access for all interested parties.
Thanks to the public availability and the court’s control of the determinations, this approach in assessing the classification of borderline products can help all food business operators in anticipating and avoiding a potential control and governmental investigation.

- **Poland**

There is no specific procedure such as that in the UK, dedicated to cases regarding borderline products. Basically, provisions regulating the notifying procedure of placing food supplement on the market are applied.

The only specific measure adopted to verify if a product fulfils the category of food supplement or medicinal product are the Registration Office opinions which are binding only with regard to the specific notification procedure. Issuing an opinion by the Office provokes a lot of controversy in the industry and legislation (Zboralska 2012). The decision often appears arbitrary, both for lack of substantive criteria and its non-administrative form. As a consequence, it is an open question what data the opinion is based on. Generally, in order to verify if a product may be granted an authorisation as a medicinal product, it is necessary to provide an extremely detailed and complex dossier on the product, including results of clinical studies (Korzycka-Iwanow 2010). However, according to the Registration Office a product at issue might be classified as a medicine without these documents on the basis of particularly scarce data provided by the launching entity. (Korzycka–Iwanow 2010). Another weakness of the Polish solution concerns the lack of time specifications in the notification procedure, including no deadline for issuing the Office’s opinion. According to Article 29 the Chief is only obliged to inform the entity of initiation of the procedure. Such freedom is unjustified (Wojciechowski 2010), since the investigation procedure does not result in drafting an administrative act. As a result, the entity suspected of launching a medicinal product on the market cannot predict the duration of the procedure.

Finally, the business has no possibility to defend itself, as the final opinion issued during the investigations is not a subject to any further verification by a second instance or court supervision. The result of the investigation might be considered as a guideline for The Powiat Sanitary Inspectorate, who has the power to provide a binding decision (in order to withdraw or prohibit a product on the market). During the procedure the entrepreneur has a possibility of presenting their view on the content of the Registration Office opinions and the letter issued by the Chief.
5.6.4 Summary

Obviously, as long as the matter of classification of products potentially having a double legal status as either food or medicine is predominantly in the hands of domestic legislation, the legal measures will differ. Poland and the UK are only two examples illustrating the complexity of the borderline product issues. Both states have dealt in different ways with the challenge of the legal uncertainty of the EU framework.

As already seen, in the UK legal tools dealing with potential doubts concerning demarcation between food supplements and medicinal products are considered a transparent and consciously adopted system providing both substantive and procedural norms. Together, all measures work as a quite complete ‘legal package’ providing a systematic and transparent legal concept to improve compliance and decision enforcement (Latheenmaki 2012).

Attempting to summarise the Polish approach undertaken in procedural law to the situations dealing with delimitation between definitions of food supplements and medicinal products, the vast majority of commentators find it very negative (Korzycka–Iwanow 2010, Zboralska 2012). The main concerns are lack of transparency and predictability. Moreover, the unclear solutions applied in Poland not only do not facilitate solving problems posed by the classification of borderline products, but they might cause even more difficulties, which, unfortunately, hamper the free movement of goods of the EU internal market (Wojciechowski 2010).
Chapter 7 Recommendations

7.1. Introduction

This chapter presents and discusses the main uncertainties and weaknesses with regard to the current legal assessment concerning the distinction between the definitions of a medicinal product and a food supplement. It is attempted to propose the best solutions to reduce the problematic issues and thus to answer the main question of this research. The recommendations presented below are listed taking into consideration the aspects of substantive and procedural law. Then, suggested recommendations are presented with regard to their territorial applicability, namely the extension of the level of EU law harmonisation and its desired interactions with legislations of the EU Member States.

7.2. Substantive law

7.2.1. Summary of the current approach concerning borderline products in the EU

With regard to current EU law, a certain number of borderline cases have given rise, or may give rise, to situations where a product at issue is initially permitted for marketing as a food supplement, and then, the same product is considered as a medicinal product. Having in mind all aspects presented in the previous chapters, it can be concluded that in the context of substantive law, the framework of borderline products focuses predominantly on the legal analysis of Article 1 (2) of Directive 2001/83 and case law in this regard. Generally, the decision on whether the product is a medicine or not is based on a case-by-case assessment containing a description of functional and presentational aspects of the product at issue. These aspects are explained through a number of criteria developed by the EUCJ, such as the composition, its pharmacological properties to the extent to which they can be established in the present state of scientific knowledge, the manner in which it is used, the extent of its distribution, its familiarity to consumers, and the risk which its use may involve. The necessary requirement is to interpret the functional criteria very strictly and in light of scientific facts; in turn, presentational criteria, in order to protect consumers, should be considered very broadly and may refer to any direct or indirect link between the presentation and the product. As a result, application of these criteria may cause several uncertainties.
7.3.2. Recommendation for functional criteria

Both the definition of ‘food supplement’ and the sub-paragraph on the definition of medicinal products adopt a scientific terminology but without explanation.

The EU legislator formulated the definition of medicinal products and food supplements with reference to scientific terminology, namely ‘pharmacological and nutritional effects’ (in food supplements law) and ‘pharmacological, immunological and metabolic action’ (medicinal product law). No additional explanation is provided in the law. For its part the EUCJ suggests referring to ‘pharmacological properties’ as one criterion to assess functional characteristics of a product, describing them as properties having ‘a significant effect’ on the body. This is not an adequate way to define scientific terminology. In the vast majority of cases, a scientific term is not a part of common language, and thus needs to be described precisely using quantifiable, measurable parameters. It is desirable that the policy makers and legislators decide to incorporate in the legal text the meaning (definitions) of particular scientific terms. Otherwise, interpretation always will be a matter at anyone’s discretion.

According to Hagenmeyer (2006) since it is unclear what the pharmacological effect is and starting with what dosage it might be achieved, the borderline products will regularly remain unclear. Hence, it is mandatory to adopt a legal meaning of the term. The gap, to some extent, might be fulfilled by a non-binding manual concerning the application of the Medical Devices Directives – ‘Guidelines relating to application of the council Directive 90/385/EEC (...).’ It formulates the definition of ‘pharmacological’ as ‘an interaction between the molecules of the substance in question and a cellular constituent, usually referred to as a receptor, which either result in a direct response, or which lead the response to another agent’. Although it is not a completely indefectible criterion, the presence of a dose-response correlation is indicative of a pharmacological effect. In the case Chemische Fabrik (C-308/11), the EUCJ permitted use of this manual in order to provide the demarcation between medicinal products and cosmetics. Thus, it might be presumed that this explanation could be used for demarcation between a medicinal product and a food supplement by virtue of its function. Moreover, it shows that the analysis of functional aspects can be simplified to one criterion, which technically covers the rest, such as dose, composition, etc. Up to now, criteria adopted by the EUCJ have no hierarchy, no one is more relevant than another and the decision relies on a particular case. Here, the aspects are

155 E.g. in Case C-88/07 the EU Commission v Spain, Case C-140/07 Red Rice Case.
straightforward, in order to assess the functionality, the content of the product — pharmacological properties of a product understood as a dose of active substances — must be examined.


This criterion, as a purely scientific one however, demands ‘a correlative, quantifiable parameter’ (Council of Europe 2008) that could serve the purpose of demarcation between products on the borderline between food supplements and medicinal products. Valuable hints can be found in the Council of Europe’s Homeostasis document (Melchor 2009). This guidance suggests that a pragmatic approach to help to differentiate between the use of a substance as either a food supplement or a medicinal product would best be done by defining the minimal therapeutic dosage. This is the minimum amount of the substance necessary to induce a therapeutic effect on a well-defined pathological state, for which a proof of therapeutic activity exists. When the dose of a product contains a substance present at levels below its minimal therapeutic dosage, the product is no longer a medicinal product. This document, however, has not detailed any further how to determine minimal therapeutic dosage.

This gap has been filled, among others, by Schrenk (2011), who suggests the benchmark dose (BMD) concept as a valid model to establish scientifically a dose–response relationship. It is important to notice that thus, a product can have a pharmacological action either in a medicinal product or in food (Hahn, 2011). As any pharmacological action depends on the concentration of an active substance in the body and thus indirectly on the ingested amount of this substance, a numerical threshold, above which a pharmacological action can be assumed, for each compound should be defined.

The BMD is the point on the dose–response curve that characterises a specified effect, the so-called benchmark response (BMR). The values are based on data from the entire dose–response curve and the variability in the data for the critical effect (IPCS, 2009). The BMD approach was developed initially for risk assessment of genotoxic carcinogens. Only recently, the BMD approach was widened to include other agents with a wide range of effects, for example pesticides, mycotoxins, and natural toxins. (Muri et al., 2009). Finally, it is suggested by EFSA as being applicable to all chemicals in food, irrespective of their
category or origin, especially when identification of a No-Observed-Adverse-Effect-Level (NOAEL) is uncertain (EFSA, 2009).

The observation of an application of BMD methodology is able to determine the border between a dose acceptable for food supplements or a medicine (Lechnmeier 2012). The figure below illustrates the concept.

It is interesting as well to provide an example as well. The Figure 7.3.2b. describes the BMD for lovastatin.

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**Figure 7.3.2a.** Suggestion for demarcation of foods and medicinal products using the BMD approach (Lechnmeier 2012)

**Figure 7.3.2b.** BMD for lovastatin (Lechnmeier 2012)
Lovastatin is an interesting example as it was the first statin drug introduced to the market for lowering cholesterol levels. It was isolated under the name monacolin K (Lamson et al., 2002). A product contained this substance was a subject of judgment in the case (C-140/07) Red Rice, where Germany classified a food supplement with 1.4 mg/day of monacolin K as a medicine. However, based on the BMD-modelling as shown in table 7.3.2., the BMD is 6.0 mg/day. As pointed by Schrenk (2012) this level is considerably higher than what is found in some commercial products sold within the EU, which are therefore classified as medicinal products rather than as food supplements.

Based on that, it can be concluded that the determination of the dosage of active substances is the key word in determining whether a product containing medicinal herbs, vitamins, or minerals is regarded as a medicine. This shows the distinction between medicines and foodstuffs is often merely gradual; furthermore, for several active substances doses are set beforehand (Lähteenmäki-Uutela 2009).

The advantage of the criterion of functionality based on the pharmacological action referring to a virtual dose of the active substance in the product in question is objective, transparent and based on scientific knowledge. Moreover, an application of similar methodology in order to determine doses will unify the decision. However, although several scientists recommend the BDM method as the most relevant, the current state of science may change and other ways of calculation ought to be considered in the future. However, the dose-correlation should stay as a core of the distinction.

7.3.4. Recommendation for presentational aspects.

The current law did not specify the expression ‘presented as having’ adopted in the definition of medicinal products. The EUCJ case law has permitted adoption of a very liberal and broad approach. The presentational criteria may implicate a variety of means which can be taken into consideration, including shape, packaging, labelling, recommendations or advertisement. These are examined in the light of a consumer's impression. The settled case law shows that not the overall impression but a single element of it can be decisive. For example, in the Bennekom case (C-227/82), the public authority assumed that the form of tablets justified the product's classification as medicine; in the Garlic case, the picture and
the content of the label were contested. The importance of the consumer’s impression goes so far that a product without any active agents as ingredients and without any intended purpose to that any disease but presented as such, as in the Ter Voort case (C-112/89) may be considered a medicine by presentation. Such an approach should be criticised (Inwanow-Korzycka 2010). First of all, it narrows down the concept of presentation to a single communication in isolation from its overall context. Moreover, orienting the criterion of presentation to the consumer's impression makes the technical assessment very subjective and unpredictable. Every consumer, obviously, is different. It is worth noticing that EU legislation referring explicitly in its provisions to an average consumer was adopted as directive, namely Directive 2005/29/EC on unfair business-to-consumer commercial practices\textsuperscript{156}. This directive provides a precise EU law definition of a consumer. According to point 18 of the Preamble to this act: “In line with the principle of proportionality, and to permit the effective application of the protections contains in it, this Directive takes as a benchmark the average consumer, who is reasonable well-informed and reasonable observed and circumspect, takin into account social, cultural and linguistic factors, as interpreted by the Court of Justice (…). The range of categories of consumers is so extensive that any Member State or any court would introduce different standards in assessing their possible impressions (Zborowska 2011).

It is worth looking into the textual meaning of the word ‘presentation’. In the Merriam Dictionary the term ‘presentation’ is defined as\textsuperscript{157}.

‘an activity in which someone shows, describes, or explains something to a group of people, or the way in which something is arranged, designed, etc., the act of giving something to someone in a formal way or in a ceremony’. This definition highlights that presentation should be focused on the one who is presented and his communication to somebody else, rather than on somebody’s impression on that. It a appears that in context of the describing a product in the virtue of its presentation, the very important circumstance concerning the presentation of the product is not enough considered The presentation criterion relates to what a product promises (Van der Meulen & Bremmers 2015). It is a message of a producer or a seller to a consumer, hence, the purpose of the product is one of the decisions made at the early stage of product development. The business intention to create the impression that

\textsuperscript{156}OJ.L. 149 11.06.2005

a product is a food supplement or a medicinal product implicates automatically the relevant legislation which should remain in place.

Therefore, in analogy to assessments provided in order to distinguish between medicinal products and medical devices or medicinal products and cosmetics, the intended use of the questioned product given by manufacturer should be considered as the crucial ‘presentational criterion’ distinguishing between medicines and food supplements as well. That approach will shift the assessment from an analysis containing a subjective speculation on the possible impression with regard to the product by any consumer to a more objective determinant focusing on the initial decision of a manufacturer or a seller, in this case, the intention to introduce a food supplement or a medicinal product. It should be pointed out, that under existing food law, food business operators are the ones who are fully responsible for the product at any stage in the supply chain, as expressed in Articles 3 and 17 of Regulation 178/2002. It is no longer the legislator who decides which laws companies need to follow; it is the manufacturer who establishes a product’s legal status and assures compliance with the respective rules of the applicable legal framework (Coppens 2008).

Introducing this criterion will resolve another weakness of the current approach to borderline products. First of all, as mentioned previously, the current analysis aims to answer the question if the product at issue is a medicine or not, and thus, it focuses only on medicinal law. In turn, if the first question to consider is ‘what is the intended use of the product’, it will determinate the applicable framework from the beginning (Coppens 2008). Consequently, either food supplement or medicinal law can be chosen and the other aspects, including the functional criteria, would be assessed in the context of the chosen legislation. It will also prevent current situations where a product is classified as a medicine only because of the way it is presented but without having any therapeutic or disease preventing properties. In reality, this kind of product cannot obtain a positive pre-authorisation to enter the market as a medicinal product. This solution does not ignore the necessity of

158 According to Article 3 Regulation 178/2002, ‘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. Article 17 GFL says: ‘Food and feed business operators at all stages of production, processing and distribution within the businesses under their control shall ensure that foods or feeds satisfy the requirements of food law which are relevant to their activities and shall verify that such requirements are met.’

159 It is worth emphasising that the food operator must describes the intended used of the products as a mandatory part (principle 3) o HACCP plan as well. It is a great indication helping with the product classification. See more. FAO web: http://www.fao.org/docrep/005/y1390e/y1390e0a.htm
consumers' protection and their right to obtain the correct information about the product. Consumers are indeed protected by EU food law. Aspects of consumer’s protection are introduced in several acts: Article 9 of Regulation 178/2002 as a leading principle of the whole food law or Article 7 of Regulation 1169/2011, to name a few.

7.3.5. Recommendations for Article 2 (2) of Directive 2001/83

Article 2 (2) of Directive 2001/83 is one factor influencing the current approach of the EU where medicinal law takes priority over food supplement law. For this reason, many controversies are associated with Article 2(2) of Directive 2001/83, as it is called, ‘rule of doubts’. Generally speaking, currently Article 2(2) of Directive 2001/83 is applicable in cases of doubt, where taking into account all the characteristics, a product may fall both within the definition of a medicinal product and within a definition covered by other EU sectoral legislation. It does confirm the priority of medicinal law over food law (Van der Meulen & Bremmers 2015). However, it is not the only negative effect of this provision. It goes as far as to say that the legal nature and application of the rule of doubt has not been determined (conceptualised) yet. Does the provision provide a substantive norm or a procedural one? How and to what should the provision be applied? How, in the light of this article, should the criteria developed in the case law of the EUCJ be weighed? How many criteria in favour of a medicinal product should be met in order to categorize the product as a medicine? Is it sufficient to justify only one criterion against the rest to make this decision? This article implicates several doubts indeed.

The provision is built on a legal presumption. However, any approach to interpreting this article does not give a clue as to what sort of a legal presumption it is.

Legal science recognises, for example, in the field of substantive law, a presumption as a rule of law which permits to assume a fact as true until there is a preponderance of evidence which disproves or outweighs (rebuts) the presumption. A presumption is rebuttable insofar as it can be refuted by factual evidence. One can present facts to persuade the judge that the presumption is not true.\textsuperscript{160} Epstein (1973) described a legal presumption in substantive law

\textsuperscript{160}Examples. a child born of a husband and wife living together is presumed to be the natural child of the husband unless there is conclusive proof it is not; a person who has disappeared and has not been heard from for a specific number of years is presumed to be dead, but the presumption could be rebutted if he/she is found alive. See more. http://legal-dictionary.thefreedictionary.com/Presumption
as an anticipation of something yet unproved. To sum up, it can be said that a substantive presumption is made without further consideration and without presenting the contrary evidence (Jablonska-Bonca 2010). In many cases, it is an arbitrary decision made by a legislator.

In turn, a presumption in the area of procedural aspects is a norm built on a belief that as long as there are some doubts, the circumstances in question cannot be contested as true. For instance, in a criminal trial the presumption of innocence means that the accused person is to be presumed innocent until all the evidence and facts prove without a doubt that the person is guilty. It implicates automatically that any doubt concerning presented evidence is recognised in favour of the defendant (Epstein 1973).

Now again, with regard to Article 2 (2) of Directive 2001/83, on one hand, the Member States have considered this article, over and over again, as an arbitrary choice made by the EU legislator. Hence, they have adopted a practice based on the substantive presumption, that since the entity (a manufacturer or a seller) fails to prove the absence of the criteria developed by the EUCJ, medicinal legislation prevails, without being required to establish that the product corresponds to the definition of a medicinal product (Timmermans et al.2009). In the case of the EU Commission v. Spain (C-88/07) the claimed administrative practice was based on an a priori classification of products as medicines, if they contained ingredients that were not listed in the annex to the Ministerial Order of 1973. 161 Similarly, in the Red Rice case (C-140/07) the German authority rejected automatically a product as a food supplement since the plaintiff did not provide absence of pharmacological action sufficient for medicines in a red rice capsule containing specially fermented rice. 162

It appears that any product should be presumed to fall out of the scope of Directive 2001/83 unless the national authority having regard to the entire scope of both legal definitions: first of the food supplement one, then, if needed, the medicinal product one, proves the contrary. In any case, it does not facilitate the distinction. Thus, a rule which only favours medicinal law should be deleted from Directive 2001/83. Under already existing law and following the solutions recommended here, the provision seems to be unhelpful and meaningless for the demarcation process between food supplements and medicinal products.

161 See more, p. 34 of this thesis

162 Case C-140/07 Red Rice, paragraphs 15-17
7.4. Recommendation for Procedural law

It can be assumed that as long as the substantial legal criteria for the distinction between food supplements and medicinal products are effective, additional steps would not be needed. The best solution would help to avoid any intervention of public or juridical authority right from the beginning (Klaus 2009). However, to make the issue complete, legal solutions focusing on procedural law are indispensable.

Although it is possible to present the criteria under which the distinction between medicinal products and food supplements can be made, the procedural aspects of products considered as borderline ones are nowadays under the responsibility of the Member States. Not surprisingly, as demonstrated in Chapter 6 with regard to Poland and the UK, the procedures differ. Hence the approach presented in the case law does not cast doubts and it is still possible that differences in the classification of products as medicinal products or as foodstuffs will continue to exist between the Member States. However, doubts concerning the correct classification of a product can also arise within one Member State, where only domestic legislation is examined. As it is stressed in Chapter 5.5, recent cases, for example, the HLH Warenvertrieb and Orthica (joined cases 211/03 etc.) or Red Rice (C–140/07), have shown that beyond the fact of a lack of full harmonisation of the borderline product issue, the sort of evidence, or more precisely the multiple sorts of evidence, cause the uncertainties as well. As emphasised in this ruling, ‘(...) it thus cannot be ruled out that one Member State considers a product as a medicine, whereas another one takes the view that according to the current scientific knowledge, it has not been proved that the product is a medicinal product by function’.163 This frequently cited acknowledgement in the case might conclude that as long as the parties (understood as either in the dispute between the Member States or between public authority and a company) present different scientific opinions, the agreement with regard to classification cannot be made. Looking at this problem from the procedural aspects which are faced by judges, in case of doubts with regard to classification of borderline products, both parties are able to marshal enough scientific evidence to support their contention. And a court, being usually a legal specialist, is unable to sift through and assess adequately the validity of the scientific arguments made (Chowdhury 2014). In the same manner, it is worth citing Offit (2004) who said that ‘judges are not

163 HLH Warenvertrieb and Orthica (C–211/03 etc.), para. 56, or Red Rice case paras.28–29
doctors and a court is an institution established to resolve disputes, not mediate in terms of scientific truth’). On the one hand, a judge does not spontaneously express the desire to carry out the scientific assessment; on the other hand, as both food and medical laws are generally science-based, the exercise of technical areas cannot be totally excluded from the judicial review (Jasanoff 1994).

The issue is not a completely new one. For instance, EU patent law when faced with a similar discussion finished by establishing the separate patent court wherein the judges have specialist expertise in the subject matter. Imitating this approach, Chowdhury (2014) proposes the same solution in order to limit the problem with the distinction of borderline products, especially on the range medicinal products - medical devices. Setting up a completely independent agency – a supranational body exclusively dedicated to borderline products – would probably be a very good solution, where the scientific expert body may examine any borderline product with a similar scientific approach. Indeed, that would be a successful solution in bridging the gap and addressing this problem, however, it is a quite revolutionary concept, but perhaps disproportionate to the problem.

In order to reduce the uncertainty and establish a uniform and non-discriminating approach both in inter trade and on national levels, the EU lawmaker should consider the resources already available in the EU. A supportive argument to this point is given in the Advocate General Opinion for case HLH Warenvertrieb and Orthica (C–211/03 etc.): ‘(…) although they [the national judges of all Member States] are not entitled to apply directly to the European Food Safety Authority for the solution of specific questions [they] are obliged to take into account the opinions of EFSA itself if such opinions consider problems similar to the ones the judges have to solve.’ In this case, the EFSA opinion was assessed as one of the pieces of evidence provided by an expert, but it appears mandatory to adopt the requirements of EFSA’s opinion in EU law if – after examination of substantive conditions concerning the distinction between food supplements and medicinal products – there is still a need to provide scientific evidence to prove the doubtful circumstances, in particular with regard to the determination of the medicinal product definition in light of functional aspects. There are two direct benefits to this solution; first, this would allow for pooling scientific resources at the European level—similar to what has happened under the European Medicines Agency with regards to centralised pharmaceutical authorisation on
the EU level (Klaus 2009). Second, this will also considerably hasten harmonisation and, as a consequence, cut down the number of cases brought before the EUCJ.

Although EFSA does not have any regulatory powers, its scientific opinions are crucial while drawing up food safety measures within the framework of food law.

It is worth noticing the measure stipulated in Article 16 of Regulation 1924/2006. EFSA plays the key role in the authorisation procedure in the treatment of health claims. It evaluates the scientific substantiation of the petitioned health claim and provides an opinion in which it endorses or rejects the application. The opinion is decisive for the positive authorisation of the health claim. Recently, Regulation 609/2013 implicated the EFSA to consult on any matter related to the application of this regulation which is likely to have an effect on public health. Moreover, looking deeper into the General Food Law it can be recognised that EFSA was created to become an authoritative point of reference, whose reputation would put an end to competition in scientific matters among national authorities in the Member States (Byrne 2002).

Nonetheless, the EU legislator should consider carefully all the necessary procedural steps which have to be undertaken in order to receive the EFSA opinion by the national entity. It means that laws should stipulate, among others, the amount of time required to present the opinion or type of documents needed to be submitted by the applicants. It would avoid the situation existing in Poland where the Registration Office is free and not restricted by any provisions in this regard. A public access to final opinions, as in the UK, should be considered as well.

7.5. Territorial range of force: a directive or a regulation?

Finally, these recommendations should consider their territorial range of force within the EU. To put it simply, it is necessary to answer if those legal suggestions should be regulated by EU law exclusively or, in contrast, by national laws exclusively. The current situation under which the subjects concerning food supplements and medicinal products are regulated in directives, gives shared competence both to the EU and national legislation.

164 See more in chapter 2.2.3
165 See more in chapter 6.3.3.3.
However, basically, Member States are entitled to decide whether a product is a food supplement or medicinal.

Obviously, the main alternative to a directive which can be considered is a regulation. Article 288 TFUE introduced a regulation as the most effective form of law’s harmonization in the EU. Regulations oblige all the Member States to apply their norms in the same manner. In the context of the borderline products, one of the main consequences of adopting a regulation is that Articles 34 and 36 TFUE, as applicable for non-fully harmonised issues within EU law, would not matter anymore. Next, it will prevent all situations where the definition of food supplements or medicinal products is broader than the one in the directive (Lähteenmäki-Uutela 2009).

However, having in mind that the legal assessment on the distinction between medicinal products and food supplements is an element of public health policy, the decision referring to the degree of harmonisation must consider all legal limitations stipulated in Articles 114 TFUE (previously 95 TEC) and 168 TFUE (previously 152 TEC).

The public health policy, regulated in the primary law in Article 168 TFUE, is one of those spheres where the EU institutional competence is limited and shared with the Member States. According to Article 168 TFUE a high level of human health protection has to be taken into consideration in all Union policies and activities. However, it is stipulated: ‘EU actions, which shall complement national policies, shall be directed towards improving public health, preventing physical and mental illness and diseases, and obviating sources of danger to physical and mental health. Such action shall cover the fight against the major health scourges, by promoting research into their causes, their transmission and their prevention, as well as health information and education, and monitoring, early warning of and combating serious cross-border threats to health.’

Hence, public health policy is an area where EU legislation has to be subsidiary to national legislation. In legal terms, this means that the EU institutions may act only where the founding treaties have given them power to act if necessary. Those circumstances are often examined in light of the ‘principle of conferred powers’ set out in Article 5 TFUE, which states that ‘the EU shall act within the limits of the powers conferred upon it by the treaty

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166 This does not mean that when an aspect is harmonised on the EU level, there are no doubtful cases. Then, Article 114 TFUE (instead of 34, 36 TFUE) applies. With respect to harmonised aspects concerning borderline products, there has not been any case based on Article 95 TFUE.
and objectives assigned to it therein’. In areas that do not fall within its exclusive competence the EU must act in accordance with the principle of subsidiarity expressed in Article 5 (2) TEC. It means also that the power of a Member State to regulate the health issues can be limited only if another public policy regulated in the founding treaties (for example: social policy, energy policy, security policy) is recognised as more important. Both Directives 2001/83 and 2002/46 focus on 3 significant policies: free movement of goods, consumer protection and public health policy. A valuable approach is presented by Szymecka-Wesolowska (et al. 2013) suggesting that the order of sentences in preamble (in the EU acts) reflects the importance of stipulated goals. The most important is mentioned as the first one. In cases where a conflict of these policies may arise, the order stipulated in directives suggests that the first prevails over the second one. In the case of Directive 2002/46 the first recitals are focusing on the necessity of facilitating the free movement (1–5), and the following ones on human and consumer protection. Applying this interpretation, protection of trade and free circulation of goods in the EU has precedence.

The conflict between public health policy and other policies has been analysed by the EUCJ as well. The remarkable judgment the joined cases Alliance for Natural Health (C-154/04) and National Association of Health Stores (C-155/04) illustrating those concerns regarding food supplements and medicinal products. When Directive 2002/46 came into force in 2002, the British industry, being against the harmonisation of food supplement law on the EU level, brought an action against this act in order to annul it. The main argument against it was based on an assumption that a part of Directive 2002/46 is invalid due to the inadequacy of Article 95 TEC (now 114 TFUE) as a legal basis. The claimants submitted, first of all, that the directive does not contribute to improving the conditions for establishment and functioning of the internal market. As a consequence, there is no justification to apply Article 95 TEC, because it does not provide measures which prevail over any national health issue. According to the UK, the degree of interference into the national public health policy was not justified. The EUCJ evaluated whether there is a reason to invalidate this directive. The EUCJ ruled again that Article 95 gives to the EU institution competence to exclude the Member States from specific health-food related issues, which is aimed at improving the health policy in Member States and within the EU. Moreover, it agreed with the EU Commission that the food supplement issues can fall under the scope of Article 95 TEC.
It confirms that Article 95 TEC is a suitable basis for health-food related issues. In addition, it is worth noticing that is a relevant legal basis for health-food aspects covered in Regulations: either Regulation 178/2002 or Regulation 1924/2006 refers to this article.

Finally, it is worth pointing out that Article 95 TEC gives Member States tools to maintain their own national legislation. Its paragraph 4 imposes on the Member State wish to maintain its own legislation as ‘national provisions justified on the grounds of need referred to in Article 36”? (Klaus 2009). They have to notify their decision to the EU Commission in advance. It is a valuable measure because it informs the business in advance about restrictions maintained in a certain Member States. It will facilitate any business decisions of food companies on whether or not to enter the local market.

7.6. Summary

It is significant to approach the problem of delineation between food supplement and medicinal product legislation by applying substantive, and procedural norms. They should coexist and comply with each other to provide a transparent and useful solution which will limit the existing uncertainties and weaknesses with regard to borderline products.

From the perspective of EU law, medicinal law does not prevail over food supplement legislation and thus, in the decision whether the product in question is a medicine or a food supplement, both legislations are involved. This change in the way of approaching the legal relation of medicinal products and food (including food supplements) implies several consequences on the level of substantive and procedural laws.

First of all, Article 2 (2) of Directive 2001/83 containing a presumption of the priority of medicinal law over other sectoral legislation, regardless of its categorisation as a substantive or formal legal presumption, becomes meaningless and, hence, the provision is useless itself.

Significantly, in order to delimit the scope of the EU legal definitions of a food supplement and a medicinal product, the product at issue needs to be evaluated against two fundamental parameters.

- the pharmacological effect on the body referring to a virtual dose of the active substance in the product in question and proven by current scientific knowledge, and
the intended use of the product given by the manufacturer. In light of these considerations, the assessment should take into account the legal status given initially. In practice it is usually a food supplement.

The model should be supported, if necessary, with procedural norms. In regard to the constant development of both sectors, and being legally entitled, here EFSA, to provide an opinion, it would be a step closer to make the issue unified and harmonised. Finally, the changes could be lawfully introduced in a regulation.

As pointed out in the Introduction, this research aspires to suggest a legal solution that limits the uncertainties concerning delineation between definitions of food supplements and medicinal products in EU law. The principle of legal certainty is a general principle of law that expresses the desire to provide predictable rules applicable in any doubtful case on borderline products. On one hand, one might have an expectation that this approach will create a clear and gapless system; on the other hand, some might worry whether this approach will limit opportunities to develop new products. Having in mind that the food industry is rapidly developing, we must note that law follows and adjust to the reality, not the other way around. Recommendations listed in this chapter will not limit or negatively affect the market but will propose a uniform legal base to think about the delineation between food supplements and medicinal products.

**SUMMARY**

To provide a horizontal approach to the problem with legal delimitation between food supplements and medicinal products, the study consider several legal perspectives. EU and national law and the classification of law into substantive and procedural legislation. The main findings and problematic aspects to consider were grouped around 3 sub-questions and the main question formulated at the beginning. Below, the graphical summary of contents, aims and main findings of previous chapters is presented.

Sub-question 1. **How has the concept of borderline products, particularly in the range of food supplements and medicinal products, developed in the EU legislation and the EUCJ case law?**
**Sub-question 1, chapters 2,3,4**

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<td>• <strong>exclusively EU medicinal product</strong> directive refers explicitly to</td>
<td>example, food supplement law</td>
</tr>
<tr>
<td>borderline product issue</td>
<td>• distinction between products considered as borderline ones is solely</td>
</tr>
<tr>
<td>• borderline products issue is also analyzed with relation to <strong>cosmetics</strong></td>
<td>assessed in light of the definition of a medicinal product</td>
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<tr>
<td>and medical devises</td>
<td>• criterion of intentional use is not applied in the ‘classification’</td>
</tr>
<tr>
<td>• several <strong>non-binding documents</strong> were issues with regard to the</td>
<td>assessment of food supplements and medicinal products (comparing with</td>
</tr>
<tr>
<td>delimitation</td>
<td>other sectoral legislation).</td>
</tr>
<tr>
<td>• <strong>no EU guideline</strong> on demarcation between <strong>food supplements</strong> and</td>
<td>• lack of explanation of expressions used in definitions of medicinal</td>
</tr>
<tr>
<td>medicinal products</td>
<td>products and food supplements as well as criteria evaluated in the caselaw</td>
</tr>
</tbody>
</table>

Chapter 4. Summary of chapter 2&3
Sub-question 2. **What is the impact of borderline products on the EU Internal Market?**

<table>
<thead>
<tr>
<th><strong>Chapter 5. Borderline products on EU Market</strong></th>
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<tbody>
<tr>
<td><strong>CONTENT</strong></td>
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<td><strong>AIM</strong></td>
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<td><strong>MAIN FINDINGS</strong></td>
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<tr>
<td><strong>ASPECTS TO CONSIDER IN RECOMMENDATIONS</strong></td>
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<td></td>
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</tbody>
</table>

Sub-question 3. **What sorts of approaches to borderline products are applied in Member States, presented on the example of Poland and the UK?**
**Chapter 6. Borderline products in the UK and PL**

| CONTENT | Analysis of:
| --- | --- |
|  | • Food Supplement Regulation 2003 (UK)
|  | • The Human Medicines Regulation 2012 (UK)
|  | • MHRA Guidance Note No. 8 (UK)
|  | • Act on Food and Nutrition Safety (PL)
|  | • Act on Pharmaceutical Law (PL)

| AIM | • analysis of **approaches** to borderline products in different Member States
|  | • **comparison** of these approaches in a virtue of procedural and substantive norms
|  | • recognition of **useful legal solution** helpful for demarcation between food supplements and medicinal products

| MAIN FINDINGS | • **very different approaches** to borderline products in Member States leading to **potential trade hindrance** between these states
|  | • different level of legal protection for business manufacturing food and medicines
|  | • establishing in both countries special **authorities** dealing with borderline products cases

| ASPECTS TO CONSIDER IN RECOMMENDATIONS | • consideration whether there is a need to maintain the differences between Member States
|  | • assessment whether any legal solution provided in the UK or PL can be **adopted/copied on the EU level**

Main question: **What legal recommendations can be made in order to reduce, in the range of food supplements and medicinal products, the legal uncertainties concerning delineation between these two categories in EU law?**

| Chapter 7. Recommendations | **MAIN FINDINGS**
| --- | --- |
|  | • **substantive law**
|  | In order to delimit the scope of the EU legal definitions of a food supplement and a medicinal product, the product at issue needs to be evaluated against two
<table>
<thead>
<tr>
<th>Fundamental parameters:</th>
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<tbody>
<tr>
<td>- the pharmacological effect on the body referring to a virtual dose of the active</td>
</tr>
<tr>
<td>substance in the product in question and proven by current scientific knowledge (as</td>
</tr>
<tr>
<td>functional main functional criterion)</td>
</tr>
<tr>
<td>- the intended use of the product given by the manufacturer (as main presentational</td>
</tr>
<tr>
<td>criterion)</td>
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<tr>
<td>- Article 2(2) Dir. 2001/83 should be deleted</td>
</tr>
<tr>
<td><strong>Procedural law</strong></td>
</tr>
<tr>
<td>- the EFSA can be entitled to provide an opinion suggesting the legal classification of</td>
</tr>
<tr>
<td>doubtful product</td>
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<tr>
<td><strong>EU v national laws</strong></td>
</tr>
<tr>
<td>- the changes could be lawfully introduced in a regulation</td>
</tr>
</tbody>
</table>


Case C-7/68 *Commission v Italy* (1968) E.C.R. 423 at 428 Judgment of the Court of 20 February 1979., ECLI:EU:C:1979:23


Case C-150/00, Judgment of the EUCJ of 29 April 2004. *EU Commission v Austria*, ECLI:EU:C:2004:237


Case C-319/05, Judgment of the EUCJ of 15 November 2007. EU Commission v Federal Republic of Germany. ECLI:EU:C:2007:678


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Cases (joined) C-211/03, C-299/03 and C-316/03 to C-318/03, judgment of the EUCJ of 9 June 2005. HLH Warenvertriebs GmbH (C-211/03) and Orthica BV (C-299/03 and C-316/03 to C-318/03) v Federal Republic of Germany. ECLI:EU:C:2005:370


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Opinion of Mr Advocate General Geelhoed delivered on 3 February 2005. HLH Warenvertriebs GmbH (C-211/03) and Orthica BV (C-299/03 and C-316/03 to C-318/03) v Bundesrepublik Deutschland, ECLI:EU:C:2005:78

Opinion of Mrs Advocate General Rozes to Case C-227/82, delivered on 5 October 1983. ECLI:EU:C:1983:263


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