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The absence of EU-wide set maximum and minimum amounts of vitamins and minerals in the EU legislation on food supplements: Is a balance between public health and free movement of goods possible?

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While Article 5 of the Food Supplements Directive empowers the Commission to set maximum and minimum amounts of vitamins and minerals in food supplements, no proposal has been put forth to date. In absence of EU-wide set amounts, the Member States have enacted their own rules, often creating legal barriers that hinder the free movement of food supplements and impede the proper functioning of the EU internal market. This study analyses the relationship between the Member States legislating on maximum and minimum levels in food supplements and the EU legislation on food, to understand to what extent the free movement of food supplements and health protection can be guaranteed in the EU internal market. Three main categories of EU legislation are examined: food labelling, nutrition and health claims, and mutual recognition. The research shows the complexity of ensuring a high level of health protection for all EU citizens while ensuring free trade of food supplements in the present situation. Therefore, it reveals the importance for the Commission to advance a proposal based on Article 5 or to establish a stronger system of compliance with the new Mutual Recognition Regulation in the sector of food supplements.

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Chapter 1: Introduction

In the last decades, the market of food supplements gained ever-growing importance in the EU. As many studies with evidence of their benefits on health have been published, the demand from consumers increased.[1] Throughout the EU, the public expenditures for food supplements were raised with the awareness that their positive effect on citizens' health could improve the quality of life and, thus, contain the national healthcare expenditures.[2] This entailed that, already in the late 1990s, the consumption of food supplements was very popular across the EU Member States which increasingly regulated the marketing of these products through national rules.[3] Nonetheless, the trading of food supplements across the different countries started to be problematic for the EU internal market, as the numerous and divergent national rules of the Member States risked hindering the free movement of these products within the EU.[4] The negative impact for traders resulting from the absence of harmonisation in the food supplements sector caught the attention of the EU legislators,[5] and in 2002, the EU adopted the Food Supplements Directive,[6] which provided an EU-wide definition of food supplements and set uniform requirements for their marketing. The aim of the legislation was twofold: to facilitate the free circulation of food supplements within the EU and to ensure the health protection of consumers.[7] The Directive defines food supplements as following:

"food supplements means foodstuffs the purpose of which is to supplement the normal diet and which are concentrated sources of nutrients or other substances with a nutritional or physiological effect, alone or in combination, marketed in dose form, namely forms such as capsules, pastilles, tablets, pills and other similar forms, sachets of powder, ampoules of liquids, drop dispensing bottles, and other similar forms of liquids and powders designed to be taken in measured small unit quantities".[8]

Even after the cornerstone 2002 Directive, the free circulation of food supplements across the Member States and the regulation of these products remained a widely debated topic,[9] and

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[1] European Federation of Associations of Health Product Manufacturers, *Years of the Food Supplements Directive: Major Achievements and the Way Forward* (EHPM 2022) p. 4.
[2] Fiona LeCong, "Food Supplements Directive: An Attempt to Restore the Public Confidence in Food Law" (2007) 29 Loyola of Los Angeles International and Comparative Law Review 105.
[3] Malgorzata Korzycka-Iwanow & Monika Zboralska, "Never-Ending Debate on Food Supplements: Harmonisation or Disharmonisation of the Law" (2010) 5 European Food and Feed Law Review 124.
[4] Ibid.
[5] Justyna Nowak, "Maximum Amounts of Vitamins and Minerals in Food Supplements in Light of Consumer Protection and Free Movement of Goods" (2021) 16 European Food and Feed Law Review 403.
[6] Directive 2002/46/EC on the approximation of the laws of the Member States relating to food supplements [2002] OJ L 183.
[7] Ibid, preamble.
[8] Article 2(a) Directive 2002/46.
[9] Nicole Coutrelis & Caroline Mathias, "Maximum Nutrient Amounts: How to Cope with the European Commission's Inaction: A National Challenge in Light of the ECJ Rulings" (2011) 6 European Food and Feed Law Review 218; Malgorzata Korzycka-Iwanow & Monika Zboralska (see n 3).

some of these legal issues remain unsolved today.[10] Firstly, the definition in the Directive appeared problematic to some scholars due to the possible adverse effects of food supplements on health, especially when consumed uncontrolled.[11] It has indeed been advocated to regulate the advertising and labelling of food supplements in a similar way to medicinal products rather than foodstuffs.[12] Another issue that arose throughout the years is that the Directive does not assess substances other than vitamins and minerals.[13] Therefore, ingredients such as botanical ones are not harmonised yet, and the different legislations of the Member States apply. Some EU countries have very restrictive rules on which herbal ingredients are permitted in the manufacture of food supplements, whereas others generally allow them.[14] Therefore, even after the Directive, the absence of harmonisation concerning botanical ingredients remains problematic for traders that want to export their products to another EU country and therefore hinders the proper functioning of the internal market.[15]

Finally, a core problem concerns the setting of maximum and minimum amounts of vitamins and minerals in food supplements. The 2002 Directive empowers the Commission to set these levels in Article 5.[16] Nonetheless, no proposal from the Commission has been published so far.[17] The absence of EU-wide harmonised maximum and minimum amounts of nutrients in food supplements has a strong legal impact on the EU internal market, as the Member States fix their own requirements through national legislation which results in some products that can be traded in certain Member States but do not fulfil the maximum and minimum amounts criteria for being imported into other EU countries.[18] Therefore, the core legal issue that arises, which is the focus of this study, is that the legal barriers created by the national legislations of the Member States on minimum and maximum amounts of food supplements hinder the free movement of food supplements and impede the proper functioning of the EU internal market. The legal issue of the non-harmonisation of minimum and maximum amounts in food supplements is demonstrated by the rising number of CJEU cases on the matter.[19] As there are no established levels in EU legislation, the principle of mutual recognition must prevail

[10] Justyna Nowak (see n 5).
[11] Malgorzata Korzycka-Iwanow & Monika Zboralska (see n 3), p. 126.
[12] Ibid.
[13] Directive 2002/46 (see n 6); Vittorio Silano et al., “Regulations applicable to plant food supplements and related products in the European Union” (2011) 2 Food & Function 12.
[14] Ibid.
[15] Patrick Coppens, "Food Supplements in the European Union: the Difficult Route to Harmonization. Botanicals and Maximum Levels" (2018) Regulatory Focus, available at: https://www.raps.org/news-and-articles/news-articles/2018/7/food-supplements-in-the-european-union-the-diffic (accessed June 2023).
[16] Art 5(4) Directive 2002/46.
[17] This refers to the first half of 2023, when the study has been conducted.
[18] Nicole Coutrelis & Caroline Mathias (see n 9), p. 219.
[19] Case C-192/01, Commission v Denmark [2003] ECR-1-9693; Case C-41/02, Commission v Netherlands [2004] ECR-1-11375; Case C-24/00, Commission v France [2004] ECR-1-9693; Case C-672/15, Criminal proceeding against Noria Distribution SARL [2017], ECLI:EU:C:2017:310.

among EU countries, however, the CJEU case law shows that the Member States often disregard the principle by invoking the public health ground under Article 36 TFEU or as a mandatory requirement to derogate from the free movement of goods.[20] There is therefore a collision between the principle of the free movement of goods and the protection of health in the trade of food supplements within the EU.

In light of the repercussion that the absence of EU-set levels of micronutrients in food supplements has on the EU internal market, this study examines the following research question:

'How can the free movement of food supplements and public health be guaranteed in the EU internal market in the absence of EU-wide set minimum and maximum amounts of vitamins and minerals?'

Under the EU legislation, food supplements fall within the category of foodstuffs,[21] and therefore in addition to the Food Supplements Directive, the general regulatory framework on food is applicable when marketing or legislating on food supplements within the EU. This entails that when the Member States establish at the national level the amounts of micronutrients in food supplements, they still need to comply with the general provisions of EU food law, such as food labelling.

The aim of this paper is to study the relationship between the Member States legislating on maximum and minimum levels in food supplements and the EU legislation on food, to understand to what extent the free movement of food supplements and health protection can be guaranteed. The study is conducted through doctrinal legal analysis of EU secondary legislation, case law and the relevant literature to examine the research question. Three main categories of EU legislation are analysed: food labelling, nutrition and health claims, and mutual recognition. These legislations have a fundamental role in promoting the free circulation of food within the EU while safeguarding consumer and health protection.[22] Thus, this study analyses these legislations in the specific context of food supplements and examines their relationship with Article 5 of the Food Supplements Directive, the legal basis for establishing the minimum and maximum amounts of nutrients in food supplements.

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[20] Ibid.

[21] Directive 2002/46, Article 2(a).

[22] Regulation 1169/2011 of the European Parliament and of the Council on the provision of food information to consumers (FIC) [2011] OJ L 304/18, recital 2; Regulation No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods, [2006] OJ L 404, recital 2; Regulation 2019/515 of the European Parliament and of the Council of 19 March 2019 on the mutual recognition of goods lawfully marketed in another Member State and repealing Regulation (EC) No 764/2008, [2019] OJ L 91, recital 3.

The paper is structured as follows: In Chapter 2, Article 5 of the Food Supplement Directive is analysed. The Commission's attempts to make use of it are investigated to give an overview of the main challenges concerning the set of maximum and minimum amounts at EU level. Then, the Member States' obligations deriving from Article 5, as defined in case law, are examined. The criteria, emerging from the analysis of the Article and the relevant case law, are subsequently applied to the selected legislation to understand the relationship between these requirements and the EU legislation on food supplements. In Chapter 3, the EU legislation on labelling applicable to food supplements is analysed. The preamble of the Food Supplements Directive confers an important role to labelling[23] which it also often had, in EU food case law, a crucial role in balancing the different interests.[24] The relationship between food labelling legislation and Article 5(1)(a) of the Food Supplements Directive is scrutinised. In Chapter 4, the study addresses the framework of nutrition and health claims and once again its relationship with trade and health interests are analysed. The Regulation on Nutrition and Health Claims[25] has as its main objective to address consumer and health protection while ensuring the free movement of food. This chapter investigates the relationship between this Regulation and Articles 5(2) and 5(3) of the Food Supplements Directive. In Chapter 5, the extent to which the principle of mutual recognition is enforced in the EU market of food supplements examined. Through case law, a comparison between the application of the first Mutual Recognition Regulation[26] and the one in force today[27] is made. Lastly, the findings of the study are discussed in the conclusion.

[23] Directive 2002/46, recital 5.
[24] For example: Case C-178/84, Commission v Germany [1967] ECR-01227.
[25] Regulation No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods, [2006] OJ L 404.
[26] Regulation (EC) No 764/2008 of the European Parliament and of the Council of 9 July 2008 laying down procedures relating to the application of certain national technical rules to products lawfully marketed in another Member State and repealing Decision No 3052/95/EC [2008] OJ L 218.
[27] Regulation 2019/515 of the European Parliament and of the Council of 19 March 2019 on the mutual recognition of goods lawfully marketed in another Member State and repealing Regulation (EC) No 764/2008, [2019] OJ L 91.

Chapter 2: The legal basis: Article 5 of Directive 2002/46

This first chapter gives an overview of what the Directive prescribes about maximum and minimum amounts, and the main issues related to free movement and health that arise from its application both at EU and Member State levels. As mentioned in the introduction, Directive 2002/46 partially harmonises the marketing of food supplements in the EU providing a list of authorised vitamins and minerals that the manufacturers may use and establishing a set of rules concerning the labelling of these products. In Article 5, the Directive provides a further step for the integration of the EU market of food supplements, as it foresees the setting of EU-wide minimum and maximum amounts of vitamins and minerals in the products.[28] According to Article 5(4), the levels must be established by the Commission via the Standing Committee on Plants, Animals, Food and Feed (PAFF) through the regulatory procedure with scrutiny (RPS)[29] as provided in Article 5(a) of the old Comitology Decision.[30]

Article 5 of the Food Supplements Directive set the criteria that must be taken into consideration in this process: i. Upper Safe Levels and sensitivity of consumer groups (Article 5(1)(a)), ii. Intake from dietary sources (Article 5(1)(b)), iii. Reference intakes of micronutrients (Article 5(2)). Firstly, in the setting of the maximum amounts, the Upper Safe Levels (USLs) must be observed.[31] A USL is the highest level of substance which is considered safe for human health for the population. It is important, therefore, to distinguish between the maximum amounts of micronutrients in the food supplements *per se* and the USLs which are the maximum quantity in total for the human body. The USLs must be determined through a scientific risk assessment which considers the differences in groups of consumers.[32] Thus, variations in age, region, and lifestyle of the consumers must be taken into consideration. Secondly, the maximum amounts must be set with regard to the intake of vitamins and minerals that a person normally assumes from other dietary sources.[33] The Directive defines food supplements as "concentrated sources of nutrients" that "supplement the normal diet"[34] and, consequently, Article 5 provides that the maximum amounts must be established considering the nutrients the population daily assumes from their consumption of food. Another aspect that must be considered is what is provided in the guidelines on the recommended daily intake

[28] Article 5(1) & 5(3) Directive 2002/46.
[29] Article 5(4) read in conjunction with Article 13(2) Directive 2002/46.
[30] The old Comitology decision as referred in the text is Decision 1999/468 as amended by the Council Decision 2006/512, where article 5(a) was introduced. The old Comitology Decision has been replaced by Regulation 182/2011. Since 2011, the regulatory procedures have been substituted by the examination procedure. Nonetheless, the RPS in Article 5(a) is maintained, and therefore it continues to be used, until the pre-existing acts will refer to it (in our case the Food Supplements Directive).
[31] Article 5(1)(a) Directive 2002/46.
[32] Ibid.
[33] Article 5(1)(b) Directive 2002/46.
[34] Article 2(a) Directive 2002/46.

levels of nutrients necessary for optimal nutrition.[35] This value does not refer to a maximum safe level, as the previous one, but to an average healthy and recommended level. Finally, the Article provides that minimum amounts must be set in order to guarantee that food supplements contain enough vitamins and minerals to be defined as a concentrated form of nutrients.[36]

Whereas Article 5 explicitly provides for an implementing measure on the adoption of maximum and minimum levels, and the different aspects that must be taken into consideration, the Commission's attempts did not lead to a successful proposal. To understand the main issues incurred by the Commission and the Member States while addressing the micronutrients levels, the following sections of this chapter look, firstly, at the steps in the Commission's work and, secondly, at how the CJEU interpreted the relation between Article 5 and the Member States legislations on food supplements.

2.1. The Commission's attempts in 2006 and 2021

Four years after the publication of the Food Supplements Directive, the Health and Consumer Protection Directorate-General of the Commission issued a Discussion Paper to initiate a dialogue with the Member States and other stakeholders in order to establish what is provided in Article 5.[37] The Commission once again recognized the necessity of setting the levels to ensure human health and promote the free circulation of goods,[38] Therefore, first, the Scientific Committee of Food (SCF), and then its successor the European Food Safety Agency (EFSA), have been requested to deliver scientific opinions on the micronutrients listed in the Annexes of the Directive.[39] In its work, the EFSA could establish Upper Safe Levels (USLs) only for 16 micronutrients out of the 29 listed in the Annexes, due to the lack of scientific data for the other substances. For some of these remaining nutrients, it was however observed that no adverse effects could result from overconsumption of the nutrients, whereas for others the possibility of toxicity was identified but no numerical USLs could be determined.[40]

As this lack of data and numerical certainty from the EFSA raised concerns regarding the establishment of maximum and minimum levels, the Commission consulted Member States and stakeholders, to identify their opinions. The majority of the Discussion Paper[41] is devoted to the maximum amounts, as they are the ones that raise safety concerns and, therefore, the

[35] Article 5(2) Directive 2002/46.
[36] Article 5(3) Directive 2006/46.
[37] Directorate for Health and Consumer Protection, *Discussion Paper on the setting of maximum and minimum amounts for vitamins and minerals in foodstuffs* (European Commission 2006).
[38] Ibid, para.14-15.
[39] Ibid, para 25.
[40] Ibid, para 27.
[41] Directorate for Health and Consumer Protection (see n 37).

most controversial and debated topic. In the last section, the Commission addresses the minimum amounts, necessary only to guarantee the efficacy of the food supplements. The discussion paper is structured following the different steps required in Article 5. Therefore, concerning the maximum amounts of micronutrients, the Commission first asks questions concerning the USLs and the different sensitivity in consumer groups, as provided in Article 5(1)(a). The second topic is the connection with the intake of micronutrients from dietary sources (Article 5(1)(b)). Thirdly, the role of the reference intakes of vitamins and minerals (Article 5(2)). Analysing the single questions asked by the Commission, it is clear that the underlying problem which emerges is the lack of uniformity in scientific data across the EU and the substantial limitations on the existing ones.[42] Consequently, this leads to divergences in the responses and opinions of the Member States. For example, based on the requirement in Article 5(1)(a), the Commission asks how the EU legislators should approach the micronutrients where there are no scientifically accepted numbers on USLs.[43]

When examining the responses submitted by the Member States on USLs, we already notice the differences in opinions. Some countries, such as Denmark, Finland and Hungary, suggest the use of provisional guidance levels.[44] Others advocate not to regulate those nutrients as a lack of data could be connected with an absence of undesirable effects, and therefore no need in establishing a maximum level.[45] Some argue for a case-by-case-based analysis for those nutrients,[46] whereas other Member States prefer to set the level as to the optimal intake based on Recommended Daily Allowance (RDA) and Reference Nutrient Intake (RNI).[47] This is a clear example of how the lack of scientific certainty on the matter leads to the hesitancy of the Commission in how to proceed but also a polarity in the Member States and a deadlock of the entire process. For this reason, even after extensive consultation with Member States and

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[42] Ibid; European Federation of Associations of Health Product Manufacturers, *EHPM proposal for maximum and minimum levels for vitamins and minerals: food supplements for adults and children sold in Europe* (EHPM 2021) p. 9.

[43] Directorate for Health and Consumer Protection (see n 37), p. 11.

[44] Danish Veterinary and Food Administration, *Comments from The Danish Veterinary Food Administration on the Discussion Paper, June 2006, on the setting of maximum and minimum amounts for vitamins and minerals in foodstuffs* (September 2006); Finnish Ministry of Trade and Industry, *View of a Finnish expert group on the Discussion paper on the setting of maximum and minimum amounts for vitamins and minerals in foodstuffs* (September 2006); Hungary, *Comments on Discussion Paper on the setting of maximum and minimum amounts for vitamins and minerals in foodstuffs* (September 2006).

[45] Ministry of Health of the Czech Republic, *Reply to the Discussion Paper on setting maximum and minimum amounts for vitamins and minerals in foodstuffs (*October 2006).

[46] German Federal Institute for Risk Assessment, *Comments of the German Federal Institute for Risk Assessment (BfR) on the Discussion Paper on the setting of maximum and minimum amounts for vita- mins and minerals in foodstuffs* (2006).

[47] Irish Department of Health and Children*, Response from Ireland:*
Discussion Paper on the setting of maximum and minimum amounts for vitamins and minerals in foodstuffs, (November 2006).

other stakeholders, the Commission did not reach a conclusion and did not advance a proposal.

In 2021, the Commission resumed the work, setting as its objective the publication by the end of the year and the completion of the work by the end of its mandate in 2024.[48] Following the request of the Commission, EFSA once again published guidance for establishing levels for vitamins and minerals. In this framework, Member States, such as Germany,[49] and stakeholders, such as the European Federation of Associations of Health Products Manufacturers (EHPM),[50] proposed specific models to establish these levels and submitted them to the Commission. Nonetheless, the Commission did not publish a proposal yet.[51]

2.2. Interpretation in case law: Member States must comply with Article 5

As the Commission's attempts to harmonise did not lead to successful actions so far, each Member State retains the freedom to singularly legislate and determine their respective national minimum and maximum amounts. The possibility to introduce national legislation when there is no EU harmonisation is clear from Article 11(2) of the Food Supplements Directive. Nonetheless, as provided in Article 3, Member States must always comply with the Directive when it concerns the marketing of food supplements. Therefore, it remained unclear how the authorities of the Member States had to include what is provided in Article 5 of the Food Supplements Directive in their different national legislations when setting the maximum and minimum amounts. Several cases arose in front of the CJEU for further clarification. The Court provided two important interpretations of the Article in the French cases Solgar Vitamin's[52] and Noria Distribution.[53] Both cases concerned the 2006 French Law that established minimum and maximum amounts of vitamins and minerals that can be used to manufacture food supplements in France. In both instances, the applicants argued that the French legislation was incompatible with EU law.[54]

For the first time, in the Solgar Vitamin's case, the Court confirmed that, as long as the Commission did not make use of Article 5(4) of the Food Supplements Directive, Member States are competent to establish their amounts, and the national provisions on the matter are applicable.[55] Nonetheless, while doing so, they must comply with EU law and pursue the goals

[48] EHPM (see n 42).
[49] German Federal Institute for Risk Assessment, *Updated recommended maximum levels for the addition of vitamins and minerals to food supplements and conventional foods* (BfR Opinion No 009/2021,15 March 2021).
[50] EHPM (see n 42).
[51] See n 17.
[52] Case C-446/08, Solgar Vitamin's France and others v Ministre de l'économie, des Finances et the l'Emploi and others [2010] ECR- 1-3973.
[53] Case C-672/15, Criminal proceeding against Noria Distribution SARL [2017], ECLI:EU:C:2017:310.
[54] Solgar Vitamins, para 15-17; Noria Distribution, para 11-13.
[55] Solgar Vitamins, para 23-24; Noria Distribution, para 15.

prescribed in the Directive.[56] Therefore, the criteria outlined in Article 5(1) and (2), which were set to guide the Commission's work, apply as well to the Member States when they establish the national maximum and minimum amounts of vitamins and minerals in food supplements. A core problem that emerged from these cases is that the national authorities based their findings on the needs of their national population, as opposed to the whole EU population, and only looked at national data on the matter instead of considering international scientific opinions as well.[57] This is obviously problematic to reconcile with the objective of the Directive of creating an EU market of food supplements, where the free movement of goods is ensured and the public health of all EU citizens is preserved.[58] Therefore, the Court held that, whereas Article 5(1)(a) emphasises the necessity of taking into account the diverse needs of the different groups in the population, a Member State cannot prohibit the marketing of food supplements only because the maximum levels adopted are exclusively based on data concerning the national population.[59] In addition, Article 5(1)(a) requires taking into consideration the "scientific risk assessment based on generally accepted scientific data".[60] This has been interpreted as the obligation of a Member State to consider available international data on the matter as well, and not only national scientific opinion, as France did.[61] Finally, in establishing these levels, a Member State must also comply with Articles 34 and 36 TFEU, therefore the French barrier prohibiting the trading of food supplements that are lawfully marketed in other Member States, but do not comply with the French limits, can be justified only when two criteria are fulfilled.[62] Firstly, the manufacturers not complying with the French decree must be able to ask for authorisation to market them in France, and secondly, this authorisation can be refused only if they represent a genuine risk to public health, as provided by the risk assessment following the steps in Article 5.[63]

Therefore, we can observe how the issues deriving from an absence of complete EU scientific data on the matter lead Member States to rely on their national scientific assessments and their specific groups of consumers, fragmenting even more the market. As the criteria in Article 5 remain a must to follow both in case of EU-set amounts or national ones, the following chapters analyse how the requirement in Article 5 can be addressed even in the absence of EU-wide set amounts, and both health concerns and free movement of goods be guaranteed.

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[56] Ibid, para 26-27.
[57] Case C-446/08, Solgar Vitamin's France; Case C-672/15, Criminal proceeding against Noria Distribution.
[58] Directive 2002/46, recitals 2-4.
[59] Case C-672/15, Criminal proceeding against Noria Distribution, para 51.
[60] Article 5(1)(a) Directive 2002/46.
[61] Ibid, para 46.
[62] Ibid, para 19.
[63] Ibid.

Chapter 3: Labelling

The labelling of food supplements is harmonised under the Food Supplements Directive. The significant role of labelling is already explicated in the preamble, in recital 5, which provides that food supplements must "bear adequate and appropriate labelling" to ensure a high level of protection for consumers.[64] Labelling has often had a crucial role in the EU internal market in balancing the different interests. An example is the famous 1987 *Reinheitsgebot* or Beer Purity Law case,[65] examined by the CJEU at a moment in which there was a high scientific uncertainty concerning the adverse effects of additives in food on human health, and therefore concerns for both health and consumer protection.[66] In that case law, the Court held that suitable labels could constitute an appropriate measure to balance the free movement of goods and the health/consumer protection dilemma regarding food additives.[67] As labelling already has a prominent role in food supplements and its usefulness in solving internal market conflicts has been often raised by the CJEU, this chapter answers the question of whether adequate and appropriate labelling could address the need to guarantee the free circulation of food supplements while ensuring health protection in absence of EU-wide set of maximum and minimum amounts. Firstly, a short overview of the EU legal framework for labelling of food supplements is presented, and then its role in addressing the health and free movement interests in view of the criteria in Article 5 of the Food Supplements Directive is examined.

3.1. The legal framework of food supplements labelling

The Food Supplements Directive[68] establishes labelling criteria applicable to food supplements, in addition to the ones required in the general food labelling rules, which can be found in Regulation 1169/2011 on the provision of food information to consumers (FIC Regulation).[69] Article 6(3) of the Food Supplements Directive provides that the labelling must contain information about the nutrients or substances that characterise the product,[70] the recommendation per daily consumption,[71] a warning not to exceed this recommended dose per day,[72] a statement that food supplements must not substitute a healthy diet,[73] and a

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[64] Directive 2002/46, recital 5.
[65] Case 178/84, Commission v Germany [1967] ECR-01227.
[66] Ibid.
[67] Ibid, para 95.
[68] Directive 2002/46 (see n 6).
[69] The Food Supplements Directive refers to the Directive 2000/13 on labelling, presentation and advertising on foodstuffs which is no longer into force. It has been repealed by the FIC Regulation: Regulation (EU) No 1169/2011 of the European Parliament and of the Council on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC, and Commission Regulation (EC) No 608/2004, [2011] OJ L 304/18.
[70] Article 6(3)(a) Directive 2002/46.
[71] Article 6(3)(b) Directive 2002/46.
[72] Article 6(3)(c) Directive 2002/46.
[73] Article 6(3)(d) Directive 2002/46.

statement that the product must be stored far from children.[74] The labelling cannot imply that a balanced diet cannot provide the right amount of micronutrients.[75] According to the requirements in the FIC Regulation, the label must include certain mandatory elements such as the name of the foodstuff, a list of ingredients, the net quantity, use-by date instructions for use (if necessary), the operator's name and address and a nutrition declaration.[76]

3.2. Labelling and Article 5(1)(a)

Appropriate labelling could address one main issue arising from the application of Article 5 by the single Member States, namely the scientific uncertainty related to certain Upper Safe Levels (USLs) and the need to take into consideration the different sensitivity of certain consumer groups (Article 5(1)(a)). The possibility of solving this problem through adequate labelling was raised by the *Conseil d'État* as a preliminary question in the previously mentioned Solgar's Vitamins case.[77] The French national court asked, *inter alia*, whether Member States can set the maximum national amounts based on the assumption that appropriate labelling could dissuade groups of consumers which are particularly at risk from excessive consumption.[78] This is asked in the context of the question of whether Article 5(1)(a) of the Food Supplements Directive allows the setting of maximum amounts for the entire population based on the USLs for a specific sensitive segment of consumers, such as children.[79]

The Court started by recalling its judgments in two previous cases, the first one on a French law which exhaustively listed the nutrients which could be added to foodstuffs,[80] and the second one on the German classification of garlic preparations in capsules as a medicinal product instead of food supplements.[81] In the French case, the Court held that appropriate labels could enable sensitive consumers, which could be at risk in case of overconsumption, to decide themselves whether to use a certain food product.[82] In the German case, it was established that such a practice of appropriate labelling, in light of sensitive consumers, could at the same time protect public health and guarantee the free movement of goods.[83] Nonetheless, concerning the case at stake, the Court held that the national courts bear the task to assess whether appropriate labelling informing the consumers could effectively guarantee the health protection of sensitive consumers more at risk in case of

[74] Article 6(3)(e) Directive 2002/46.
[75] Article 7 Directive 2002/46.
[76] Article 9 Regulation 1169/2011.
[77] Case C-446/08, Solgar Vitamin's France (see n 52).
[78] Ibid, para. 49.
[79] Ibid.
[80] Case C-24/00 Commission v France [2004] ECR I-1277.
[81] C-319/05 Commission v Germany [2007] ECR I-09811.
[82] Ibid, para 51.
[83] Ibid.

overconsumption, such as children.[84] The Court provided an example of the role of labelling and maximum amounts, namely the case of fluoride and ozone-enriched air for water. The Directive 2003/40 on the limits, concentration limits and labelling requirement for ozone-enriched air for the treatment of water, provides that, to protect the sensitive group of children, the label of the water should display when the amounts of fluoride exceed the levels recommended by the World Health Organisation.[85] The Court gave this example to the national court as a starting point for its assessment. Nonetheless, it concluded by holding that the mere fact that appropriate labelling could protect sensitive consumers does not entail that labelling becomes a criterion in Article 5 of the Food Supplements Directive.[86] Therefore, even when the national court assesses that specific categories of consumers can be protected, by making clear what could constitute a danger for them, labelling is not mentioned at all in Article 5 and, therefore, maximum amounts must be set regardless.

In analysing the Solgar Vitamin's case, the legal scholars Coutrelis and Mathias[87] illustrated the outcome of the CJEU's judgment and the following decisions of the French court in assessing whether appropriate labelling could address the health concerns of several micronutrients. The first substance assessed by the French Court was fluoride in food supplements, for which the *Conseil d'État* established that it was correct that the maximum amounts permitted corresponded to the USLs of sensitive consumers. As the consumers' group could not calculate their dietary intake of fluoride, and therefore take an independent decision just by looking at the labels, adequate labelling could not protect them enough.[88] On the other hand, while assessing the maximum amounts for vitamin K, the French court concluded that consumer information through labelling was adequate and could effectively protect the sensitive group of consumers.[89]

This CJEU judgement, and the subsequent French court decisions, are illustrative to understand the role of labelling in the context of this study. It has emerged that appropriate labelling can , only in certain situations and with specific substances, be an asset in protecting human health and sensitive consumers for which overconsumption could be especially dangerous. Its role cannot be overgeneralized in the context of food supplements. Moreover, it cannot address the legal obstacles to the free movement of these products. It is arguable that this judgment created even more fragmentation in the EU market of food supplements and

[84] Case C-446/08, Solgar Vitamin's France, para 57.
[85] Ibid, para. 58.
[86] Ibid, para. 61.
[87] Nicole Coutrelis & Caroline Mathias (see n 9).
[88] Ibid, p. 223.
[89] Ibid.

more divergences in the setting of national maximum amounts. The national authorities are indeed given great discretion in assessing whether to set maximum amounts that correspond to USLs for sensitive groups or the whole population but then employ adequate labelling to protect these consumers. The Court decided not to give to labelling the role of balancing health protection and freedom of movement, as it is not a criterion included by the legislators in Article 5. Therefore, whereas labelling could have facilitated the trade of food supplements across Member States, this is not the case. Nonetheless, this interpretation of Article 5(1)(a) and labelling is coherent with the primal role of the article. It was indeed created by the legislators as a legal basis to empower the Commission to establish the maximum and minimum amounts. Only later, as a consequence of the inaction of the Commission, the criteria in the Article were transformed into a duty to the Member States. Therefore, this chapter showed that adequate labelling could not solve the health protection–free movement of goods dilemma in light of the absence of EU-wide set maximum and minimum amounts of micronutrients in food supplements.

Chapter 4: Nutrition and health claims

As stated in Recital 3 of the Food Supplements Directive, food supplements have the fundamental role of addressing the low amounts of nutrients that the average population consumes in its daily diet.[90] Therefore, by supplementing nutrients, these products can have beneficial effects on health. Whereas the regular assumption of food supplements cannot cure any disease, in certain cases they can mitigate the risk factor of some of them.[91] In the EU, the claims on the relationship between health and food supplements, and their beneficial nutritional properties, are strictly regulated by the Regulation on nutrition and health claims.[92] In its preamble, we read that the harmonisation of nutrition and health claims in EU food law has as its main objective to address consumer and health protection while ensuring the free movement of goods in the EU market. It is, therefore, important to analyse the role of the Regulation on nutrition and health claims in the EU legislative framework of food supplements, in light of maximum and minimum amounts. This chapter examines to what extent health and nutrition claims in food supplements address the free movement of goods and health protection in the EU market of food supplements and what is the relationship with Article 5 of the Directive. The first subsection focuses on nutrition claims, and it analyses the significant amounts necessary for nutrition claims and the set of minimum amounts of nutrients in food supplements. In the second sub question, the framework for health claims is examined in light of the setting of maximum amounts.

4.1. Nutrition claims and minimum amounts

The Regulation on nutrition and health claims defines, in Article 2(2)(4), a nutrition claim as "any claim which states, suggests, or implies that a food has particular nutritional properties", in the case of food supplements, "due to nutrients that it contains".[93] Nutrition claims are only permitted when they are listed in the Annex of the Regulation,[94] which is regularly updated.[95]

An example of approved nutrition claims, which we often find in food supplements, is "source of 'name of vitamin/mineral' ".[96] In the Annex, we can read that this claim can only appear in the label, packaging, advertising or the presentation for the sale of the product when the foodstuff, in our case the food supplement, contains at least the 'significant amount' provided in the Directive 90/496 on nutrition labelling which was replaced by Regulation 1169/2011 on

[90] Directive 2002/46 (see n 6), preamble, recital 3.
[91] EHPM (see n 1), p. 4.
[92] Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods, [2006] OJ L 404.
[93] Ibid, Art. 2(2)(4).
[94] Ibid, Art. 8.
[95] European Commission, 'Nutrition Claims,' accessed July 4, 2023, [https://food.ec.europa.eu/safety/labelling-and-nutrition/nutrition-and-health-claims/nutrition-claims_en].
[96] Ibid.

the provision of food information to consumers.[97] Therefore, there is a strong connection between the Nutrition and Health Claims Regulation (NHCR) and the Regulation on Food Information to Consumers (FIC), especially in the context of food supplements. The FIC Regulation defines the significant amount that it is required to display the nutrition claim approved in the NHCR. The FIC Regulation provides that the significant amount must be 15% of the Recommended Daily Allowance for 100mg or 100ml.[98] As this 'significant amount' for nutritional claims is a fixed value, it is questionable what is the relationship between this amount, necessary for the nutrition claim, and the 'minimum amounts' of nutrients in food supplements that must be set by the Commission, as provided in Article 5(3) of the Food Supplements Directive. It is therefore necessary to understand the relation between 'significant amounts' for nutrition claims and 'minimum amounts' to understand to what extent the EU nutrition claims system could help to guarantee free movements of food supplements in the absence of EU minimum amounts.

As it appears in the Discussion Paper of 2006, the relationship between 'significant amounts' and 'minimum amounts' has been one of the debated issues since the first attempts to set maximum and minimum amounts.[99] As food supplements are "concentrated sources of nutrients",[100] the question is whether the 'minimum amounts' of vitamins and minerals in food supplements should be set in accordance with the 'significant amounts', or in a different way. A relevant number of Member States responded to this issue in the Discussion Paper stating that the minimum amounts should correspond to the value required for the "source of 'name of vitamin/mineral'" nutritional claim, otherwise, it would be difficult to inform the consumers appropriately and they would risk being confused by the different amounts. Therefore, they argue that the minimum amount should be as well 15% of the Recommended Daily Allowance.[101] Other Member States asserted that, as the food supplements are concentrated sources of nutrients, the 15% value is not enough,[102] moreover the 15% threshold is set for 100gm/100ml of products, whereas food supplements are normally only a few grams.[103] We, therefore, observe that the main concern of the Commission and the Member States is

[97] Regulation 1169/2011 (see n 22).
[98] Ibid.
[99] Directorate for Health and Consumer Protection (see n 37).
[100] Directive 2002/46, Art 2(a).
[101] Service Public Fédéral, Santé Publique, Sécurité de la chaine alimentaire et environnement (Belgian authorities), *Discussion Paper one Setting Maximum and Minimum Amounts for Vitamins and Minerals* (2006); Danish Veterinary and Food Administration (see n 44); Swedish National Food Administration, *Comments to the Commission's "Discussion Paper on the setting of maximum and minimum amounts for vitamins and mineral in foodstuffs"* (2006).
[102] Finnish Ministry of Trade and Industry (see n 44); Irish Department of Health and Children (see n 47).
[103] Dutch Ministry of Health, Welfare and Sport, *Response of the Ministry of Health, Welfare and Sport (The Netherlands) on the Discussion Paper on the setting of maximum and minimum amounts for vitamins and minerals in foodstuffs* (2006).

consumer protection. The set of minimum amounts does not involve food safety issues and protection of human health. In addition, Member States that set maximum amounts of food supplements in their national legislation, such as France and Denmark, did not establish minimum amounts themselves.[104] Therefore, there is a significantly lower impact of minimum amounts on free movement, than the ones caused by the maximum amounts. This is also demonstrated by an absence of case law on the matter from the CJEU.[105] The relationship between 'significant amounts' for nutrition claims and 'minimum amounts' in Article 5(3) is, thus, a matter on guaranteeing consumer protection rather than addressing the health concerns and free movements of goods dilemma.

4.2. Health claims and RDA

The Regulation on nutrition and health claims defines a health claim as "any claim that states, suggests or implies that a relationship exists between a food category, a food or one of its constituent and health".[106] Once again only approved health claims can be used as a statement in the label, packaging, advertising, or the presentation for the sale of the product. Both the health claims that have been approved, and the ones that have been rejected, are listed in the EU Register of Health Claims. To be approved by the Commission, the claim must be based on scientific evidence and easily understandable by consumers. It is the European Food Safety Authority that assesses the scientific evidence for health claims.[107] The Regulation divides health claims into three categories. The first one is the 'functional' claims, in Article 13, which relates to the growth, development and functions of the body the psychological, and behavioural functions and weight control.[108] The second category is the 'risk reduction' claims, in Article 14(1)(a), on the risk reduction impact of a specific foodstuff on a specific disease, and the last category is the 'claims referring to children's development', in Article 14(1)(b).[109]

Considering the role of food supplements in mitigating the risk of some diseases, it is relevant to analyse in particular the category of risk reduction health claims. Two important characteristics of approved risk reduction health claims are that they are often accompanied by additional requirements for the manufacturer and by a higher adequate intake value/recommended daily allowance.[110] An example is the approved health claim for vitamin

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[104] French Decree No. 2006-352 of 20 March 2006 relating to food supplements (2006); Danish Executive Order on food supplements (2018).
[105] Court of Justice of the European Union 'InfoCuria, Case Law' accessed July 2023 https://curia.europa.eu/juris/recherche.jsf?language=en.
[106] Regulation (EC) No 1924/2006 (see n 92), Art 2(2)(5).
[107] European Commission, 'Health Claims', accessed July 4, 2023 https://food.ec.europa.eu/safety/labelling-and-nutrition/nutrition-and-health-claims/health-claims_en.
[108] Regulation (EC) No 1924/2006, Art 13(1).
[109] Regulation (EC) No 1924/2006, Art 14.
[110] Justyna Nowak (see n 5); Food Supplements Europe, *'How Food Supplements Can Help Contribute to Public Health in Europe'* (2019, FSE).

D and calcium which states that “calcium and vitamin D help to reduce the loss of bone mineral in post-menopausal women. Low bone mineral density is a risk factor for osteoporotic bone fractures”.[111] This health claim can be only used with an additional statement that osteoporosis is made of more factors, and calcium and vitamin D can only address one factor of this disease.[112] Moreover, the claim can only be used for products clearly addressed to women that are 50 years and older.[113] As previously mentioned the adequate intake recommended for the intake of vitamins by EFSA is 15%. Nonetheless, the presence of the claim about ‘vitamin D, bone minerals and post-menopausal woman’ can be used only if the vitamin amount corresponds to 20%.[114] Another claim that has been approved on vitamin D concerns the prevention of falls due to postural instability and muscle weakness, which can be a risk of bone fractures for people 60 years and older.[115] Even in this case, adequate intake has been increased from 15% to 20%.[116] Therefore, we observe how the Recommended Daily Allowance (RDA), which is usually a fixed value, can vary in case of presence of health claims in the presentation of the product. As the Recommended Daily Allowance has an important role in the setting of maximum amounts, Article 5(2) provides that it is one of the factors that must be considered, it is interesting to examine the impact of the health claims on the national setting of maximum amounts and the free movement of food supplements.

The EU system of health claims is voluntary, as it is an additional option for the European manufacturers which can decide whether to display on their products the EU approved health claims. Nonetheless, we observed that when a food supplement is connected to a health claim, the percentage of the recommended amounts can vary instead of remaining a fixed value. As mentioned above, the RDA has a direct link with the set of maximum amounts. Therefore, this choice of the manufacturers can also have an impact on the free movement of food supplements, especially because the same type of food supplements, such as vitamin D, can contain different amounts only depending on whether it contains a health claim. This change in RDA value can have a strong impact on the free movement of goods and eventually create legal barriers to the free trade of food supplements. For example, this could be particularly problematic in countries such as Bulgaria, where there is a national prohibition on the insertion of health claims on food supplements.[117] This means that the food supplements of vitamin D

[111] EU Register of Health Claims https://ec.europa.eu/food/food-feed-portal/screen/health-claims/eu-register.
[112] Justyna Nowak (see n 5), p. 406.
[113] Ibid.
[114] Food Supplements Europe (see n 110).
[115] EU Register of Health Claims (see n 111).
[116] Food Supplements Europe (see n 110).
[117] Elina S. Petkova-Gueorguieva et al. 'Regulatory Requirements for Food Supplements in the European Union and Bulgaria' (2018) 61 Folia Medica 1, p. 39.

that bear the osteoporosis claim cannot be imported to Bulgaria. Even if the same product is imported without the claim, the whole dosage should be changed as the percentage from the RDA has been increased from 15% to 20% to permit the use of the health claim. This is surely a great burden for an economic operator that wants to trade the same product across the EU. Therefore, whereas the EU health claims system clearly promotes an EU-wide protection of public health and consumer, on the other hand, the variability of RDA could have a negative impact on the set of maximum and minimum amounts, especially in light of Article 5(2), and on the guarantee of free movement of food supplements in absence of EU-wide set amounts.

Chapter 5: Mutual recognition of food supplements

Mutual recognition is a fundamental principle for the EU internal market and more specifically the free movement of goods. It first emerged in the Dassonville case,[118] and it was then further elaborated in the Cassis de Dijon case.[119] It applies in situations where there is no EU harmonisation and the goods, imported from one Member State to the other, do not meet the requirements in the national technical rules of the country of importation.[120] The principle of mutual recognition of goods provides that, when a good is lawfully marketed in a Member State, then it must be marketed also in the other EU countries. The exceptions to this rule are the public health, public safety, and environmental grounds.[121] It is therefore based on high levels of reciprocal trust among EU countries. To ensure its proper application, mutual recognition was further elaborated in secondary legislation, namely Regulation 764/2008, which is no longer in force today.[122] This first Regulation on mutual recognition established detailed procedures to be followed by the national authorities when the application of a national technical rule prohibited the circulation of a product lawfully marketed in another country. It also required the establishment of product contact points in the national territories.[123] The first Mutual Recognition Regulation constituted an important step for the EU market as it set the EU-wide procedures for the application of the principle and the legislation was directly applicable to all the Member States from its entering into force.[124] Nonetheless, the Member States did not resort to the procedures in the Regulation and, when they did, the principle of mutual recognition was not correctly applied. In addition, the required administrative process was considered complex for the companies, especially SMEs.[125] Therefore, a new regulation was elaborated and, in 2020, Regulation 2019/515[126] replaced the previous one. In the context of food supplements, in the non-harmonised area of the minimum and maximum amounts of vitamins and minerals in food supplements, the principle of mutual recognition has been poorly

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[118] Case C-8/74, Dassonville [1974] ECR-837.
[119] Case 120/78, Rewe-Zentral AG v Bundesmonopolverwaltung für Branntwein (Cassis de Dijon) [1979] ECR 649.
[120] Magdalini Selanikli, "Lifting Barriers to Food Supplements Trade in the EU: The EU's Novel Toolbox under Regulation (EU) 2019/515" (2022) 17 European Food and Feed Law Review 228, p. 229.
[121] European Commission, 'Mutual recognition of goods', accessed July 9, 2023 https://single-market-economy.ec.europa.eu/single-market/goods/free-movement-sectors/mutual-recognition-goods_en#:~:text=The%20mutual%20recognition%20principle%20ensures,can%20be%20sold%20in%20another.
[122] Regulation (EC) No 764/2008 of the European Parliament and of the Council of 9 July 2008 laying down procedures relating to the application of certain national technical rules to products lawfully marketed in another Member State and repealing Decision No 3052/95/EC [2008] OJ L 218. The Regulation is no longer in force since 2020 and has been repealed by the Regulation 2019/515.
[123] Ibid.
[124] Magdalini Selanikli (see n 120), p. 230.
[125] Ibid.
[126] Regulation (EU) 2019/515 of the European Parliament and of the Council of 19 March 2019 on the mutual recognition of goods lawfully marketed in another Member State and repealing Regulation (EC) No 764/2008.

applied and legal barriers were not easily overcome.[127] In this chapter, therefore, we further analyse how the lack of EU-wide maximum and minimum amounts has been addressed in the framework of the 'old' Mutual Recognition Regulation and then the 'new' one.

5.1. The shortcomings of Regulation 764/2008

The Noria Distribution case[128] was examined by the CJEU in 2017 when the first Mutual Recognition Regulation was still in force. It is an explicative example of the application of the mutual recognition procedure and the problems that emerged in the context of maximum amounts of nutrients in food supplements. The examined issue by the CJEU on mutual recognition arose from the fact that the French Decree, setting the maximum amounts of nutrients in food supplements, which therefore prohibited the marketing of Noria Distribution's products, did not provide a procedure to request the authorisation to the French authorities to place food supplements in the French market, even if they exceeded the levels.[129] Therefore, the applicant had no possibility to start a mutual recognition procedure in France. The Court held that the French legislation must have included the possibility of starting this procedure when a company wanted to import food supplements that did not comply with the set maximum amounts. Moreover, this procedure must have been easily accessible, in reasonable time and, if the authorisation was denied, challengeable in front of a court.[130] The French authorities could have indeed refused the authorisation to Noria Distribution on the grounds of public health, but only in the context of this procedure. As other scholars already noticed, it is interesting that both the principle of mutual recognition and the Mutual Recognition Regulation were never mentioned by the CJEU, even if the authorisation procedure, to which the Court referred, was clearly the procedure provided in the Regulation.[131] It is further puzzling to observe that, on the contrary, the Advocate General (AG) Bobek clearly referred to the mutual recognition procedure in his Opinion. This could be interpreted as the willingness of the Court to make the focus of the case the principle of good administration, by referring to accessibility time limits and judicial review, rather than the principle of mutual recognition of goods.[132] A second interesting point is whether the procedure mentioned by the Court entails the possibility of challenging in its entirety the French maximum amounts of nutrients for food supplements. As already mentioned, the authorisation under the mutual recognition procedure can be refused on the ground of public health, based on a scientific assessment by the national

[127] See n 19.
[128] Case C-672/15, Criminal proceeding against Noria Distribution SARL [2017], ECLI:EU:C:2017:310.
[129] Ibid, para 15.
[130] Ibid, para. 22.
[131] Benjamin Jan, "Mutual Recognition's Failure in the Light of Free Movement of Food Supplements: Judgment of the CJEU, 27 April 2017, Noria Distribution SARL (Case C-672/15)" (2018) 45 Legal Issues of Economic Integration 3.
[132] Ibid.

authorities. Therefore, if there is no new data since the moment the Member State established the maximum levels, the national authorities can argue that it is scientifically assessed that the maximum amounts already set are the ones safe for the population and therefore the authorisation refused.[133] The AG Bobek suggested that the mutual recognition procedure must be used to challenge and review the already set standards.[134] Nonetheless, the Court decided not to follow the AG's Opinion and not to specify whether the mutual recognition procedure must be always used to review the previously established levels. Therefore, the Member States have the discretion to decide whether to reassess the previously established data or whether to conduct an independent procedure.[135] It is arguable that this decision leaves even greater discretion to the Member States and the use of the mutual recognition procedure.

The Noria Distribution case has shown that the mutual recognition procedure was not automatically inserted, as it should have been, in the national legislation on the set maximum amounts of nutrients in food supplements. Therefore, in these situations, the principle of mutual recognition could not be invoked by the companies. On the contrary, this led companies, such as Noria Distribution, to face criminal proceedings. Moreover, we observed that the Court did not even refer to the first Mutual Recognition Regulation, which highlights the weakness of this legislation. Finally, the relationship between scientific assessment and the mutual recognition procedure was left open. All this showed that the framework in the former Regulation could not properly address the concerns of the Member States and ensure the free movement of food supplements in the absence of EU-harmonised maximum amounts.

5.2. Improvements under Regulation 2019/515?

As above mentioned, in 2020, Regulation 2019/515 officially replaced Regulation 764/2008. The main aim of the new Regulation is to strengthen the safeguards for companies when mutual recognition is refused, by establishing clearer assessment procedures.[136] The national administration authorities have to follow more defined mandatory steps, as well as respect stricter time limits. An important innovation is the introduction of the voluntary mutual recognition declaration. Before the assessment by the national authorities, companies have now the possibility to submit a document with all the necessary pieces of evidence to prove that the good is lawfully marketed in another EU Member State. [137] Moreover, once the national authorities adopt a decision on the relevant goods, the companies can make use of the

[133] Pieter Van Cleynenbreugel, "Maximum Vitamin Amounts in Food Supplements: Towards Science-based and Streamlined EU Mutual Recognition and Risk Assessment Procedures?" (2018) 1 European Journal of Risk Regulation 9.
[134] Ibid.
[135] Ibid.
[136] Regulation 764/2008 (see n 122), preamble, recital 8.
[137] Ibid, Article 4.

problem-solving procedure SOLVIT as a national remedy. The SOLVIT centres can request the Commission to give an opinion on the case and assess whether the administrative decision is compatible with the mutual recognition procedure. [138]

The fundamental role of this new Regulation for the EU food supplements market, and more specifically the absence of set maximum and minimum amounts, is demonstrated by the fact that the first Commission Opinion that arose from the SOLVIT procedure, as prescribed in the Directive, was on this topic.[139] The Commission was requested to give its first Opinion under the new Regulation by a SOLVIT centre in Bulgaria in conjunction with the Greek SOLVIT centre. The case concerned a Greek company that lawfully marketed vitamin D supplements in Greece and Romania. The company decided to enter the Bulgarian market which had national rules on the maximum amounts of vitamins and minerals in food supplements. The goods in question did not satisfy the Bulgarian technical rules, as the amount of vitamin exceeded the one prescribed by law. The Bulgarian authorities refused to accept the circulation of the product in the national market without starting a mutual recognition procedure.[140] In its Opinion, the Commission started by reminding that the Mutual Recognition Regulation is binding and directly applicable to the Member States, and therefore the Bulgarian authorities were supposed to apply the Regulation to the case at hand.[141] The Bulgarian Agency argued that the company did not submit any mutual recognition declaration with its request of authorisation for the vitamin D product and therefore, for this reason, Bulgaria did not resort to the Mutual Recognition Regulation. Nonetheless, the Commission stated that the declaration is a voluntary additional document that the economic operators might submit, but they are not obliged to. In any case, the Member States must apply the Regulation and follow the procedure in Article 5.[142] Once the company notified the national authority, it is the latter that has the duty to contact the former, and inform it about the relevant national technical rules, the assessment that it will conduct and the possibility of submitting the declaration. Therefore, in this situation, the Bulgarian authority must have informed the economic operator about the national rule in the Bulgarian Regulation on requirements for food supplements, that they would have carried the assessment based on that law and the economic operators could have submitted a declaration illustrating that the vitamin D supplements was already marketed in Greece and

[138] Ibid, Article 8.
[139] Commission Opinion of 30.9.2021 on the application of the principle of mutual recognition and the requirements of Regulation (EU) 2019/515 regarding food supplements based on Article 8 of Regulation (EU) 2019/515 on the mutual recognition of goods [2021].
[140] Ibid, p. 2.
[141] Ibid, p. 3.
[142] Ibid, p. 4.

Romania.[143] If the Bulgarian authorities decide to refuse the product they should show in their decision that the refusal is appropriate to achieve the public health goal and it is proportionate. The Commission reminded us that the proportionality criterion must be carried out in every case, and it cannot be generalised.[144] Therefore, the Commission concluded that the Bulgarian decision is contrary to the procedure in Article 5 of the Mutual Recognition Regulation.[145]

We can observe that the new Regulation and, in particular the possibility of requiring the Commission's Opinion in the framework of the SOLVIT procedure, is particularly relevant for the market of food supplements in the EU. The cruciality of the minimum and maximum amounts issue is demonstrated by the Bulgarian case. Whereas in the framework of the 'old' Regulation of Mutual Recognition, the Court did not specifically apply the legislation but generally referred to the administration procedures, in this case, we see a strengthened process in which the Articles of the new Regulation allow a strong application of the principle of Mutual Recognition. It is arguable therefore that the new Regulation is able to address the free movement interests while ensuring the protection of public health in the context of maximum and minimum amounts of food supplements. Nonetheless, this can be more complex than it appears. The legislators have now ensured a proper procedure to ensure a constant application of mutual recognition, nonetheless, the precondition for the principle is trust among countries. Even with clearly delineated steps, if the Member States are not willing to accept that assessment of other countries on the amounts of nutrients in food supplements could be acceptable for the population of its own country, the smooth enforcement of mutual recognition becomes more complicated. It is indeed possible to observe that the fact that this topic has been the first one that required the Commission's Opinion can reveal the complexity and scepticism of the Member States to apply the Regulation when it comes to food supplements and health concerns. Whereas the new Regulation on mutual recognition is an important step forward, it might be too early to state that the Member States changed their attitude and are now ready to apply the mutual recognition principle smoothly in the absence of EU-wide set amounts of minerals and vitamins in food supplements. Therefore, as the situation stands today, it is still necessary to find an agreement to legislate on the topic and establish levels that could ensure the proper functioning of the EU market and a high level of health and consumer protection ensured.

[143] Ibid.
[144] Ibid, p. 5.
[145] Ibid, p.6.

Chapter 6: Conclusion

This study addressed the following research question: 'How can the free movement of food supplements and public health be guaranteed in the EU internal market in the absence of EU-wide set minimum and maximum amounts of vitamins and minerals?' The research revealed that independently of whether it is the Commission or the individual Member States that set minimum and maximum amounts, a list of strict requirements must be fulfilled.[146] According to Article 5 of the Food Supplements Directive, the criteria that must be taken into consideration are the following: Upper Safe Levels and sensitivity of consumer groups,[147] intake from dietary sources[148] and reference intakes of micronutrients.[149] Concerning the national minimum and maximum amounts set by the Member States, the necessity of complying with these requirements, and the scientific uncertainty, leads to a tendency of the countries to rely on their national scientific data and to address the needs of their own population. The legal barriers that result from these actions cannot be overcome, or only partially, by the main EU legislations that apply to food supplements, namely the regulatory framework on labelling,[150] the Health and Nutrition Regulation[151] and the Mutual Recognition Regulation.[152] Therefore, this study showed that without EU law harmonising the maximum and minimum amounts of vitamins and minerals in food supplements, the free movement of these products and a high level of health protection for all EU citizens cannot be guaranteed in the EU internal market.

This finding is based on the analysis of the EU legislation and case law on three main topics. The research first assessed the possible role of adequate labelling, as in the past it has proven to be an important tool in addressing the dilemma of the free movement of goods and health protection in the absence of EU harmonisation. It has been argued that, in the context of food supplements, it could particularly help in reconciling the difficulty in meeting the first criteria in Article 5, namely Upper Safe Levels and sensitivity of consumers. Nonetheless, the research showed that the Member States have the discretion to decide whether labelling is an adequate instrument on a case-by-case assessment, and the CJEU ruled that the criteria in Article 5 must be met independently of labelling. It has also been demonstrated that, for health concerns, labelling can be a solution only in certain cases and its role cannot be

[146] Article 5 Directive 2002/45; Case C-446/08, Solgar Vitamin's France and others v Ministre de l'économie, des Finances et the l'Emploi and others [2010] ECR- 1-3973.
[147] Article 5(1)(a) Directive 2002/45.
[148] Article 5(1)(b) Directive 2002/45.
[149] Article 5(2) Directive 2002/45.
[150] Regulation 1169/2011 of the European Parliament and of the Council on the provision of food information to consumers [2011] OJ L 304/18.
[151] Regulation 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods, [2006] OJ L 404.
[152] Regulation 2019/515 of the European Parliament and of the Council of 19 March 2019 on the mutual recognition of goods lawfully marketed in another Member State and repealing Regulation (EC) No 764/2008, [2019] OJ L 91.

overgeneralized for the free movement of food supplements. The second topic examined was nutrition and health claims. Nutrition claims have proven to be a useful tool to address consumer protection in relation to the establishment of minimum amounts. Nonetheless, as minimum amounts do not create health safety concerns or legal barriers for the free movement, its relationship with nutrition claims cannot address the need of guaranteeing a functioning EU market of food supplements. Concerning health claims, the research studied the relationship with the recommended daily intake criteria in Article 5(2). It has been shown that the presence of health claims on a food supplements product often entails a variation of the recommended daily intake, which could create an additional burden for manufactures that wish to export their products to certain EU countries. Finally, the Mutual Recognition Regulations have been examined. It has been observed that the former Regulation was poorly applied for food supplements. On the other hand, the new Regulation provides a clear procedure that could help in addressing the free movement of goods-health concerns dilemma. Nonetheless, the precondition of high levels of trust among Member States is not optimal yet and therefore, for now, it cannot be considered the solution.

In highlighting the shortcomings of an EU internal market of food supplements without EU-set minimum and maximum amounts, this research revealed the importance for the Commission to complete its resumed work in 2021 and advance a draft proposal on the matter. If this will result once again in a failed attempt, another valuable option would be to form a stronger system of compliance with the new Mutual Recognition Regulation by, for example, publishing further guidelines on its application in the sector of food supplements.

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