Journal of Consumer Policy (2024) 47:425–443
https://doi.org/10.1007/s10603-024-09571-0

ORIGINAL PAPER

Has Mutual Recognition in the EU Failed?—A Legal-Empirical Analysis on the Example of Food Supplements Containing Botanicals and Other Bioactive Substances

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Received: 9 February 2023 / Accepted: 13 June 2024 / Published online: 19 July 2024

Abstract
The European Union lacks comprehensive legislation pertaining to food supplements containing botanical or bioactive substances other than nutrients, resulting in disparate regulatory frameworks among European Member States. Previous studies predominantly focused on the doctrinal analysis of these diverse regulations at both European and national levels, offering limited insights into their practical implementation by governing bodies. This research endeavours to scrutinize administrative practices governing legislation on food supplements featuring botanical or other bioactive constituents, which are subject to varying approaches across Member States. Employing a combination of doctrinal and empirical legal research methodologies, this approach involved a meticulous examination of the regulatory landscape governing food supplements at both EU and Member State levels. Simultaneously, an empirical investigation, conducted through expert interviews, aimed to elucidate whether discrepancies among national legal systems translate into discernible variations in the operational strategies of competent authorities. Additionally, this empirical inquiry shed light on the efficacy of specific EU directives aimed at harmonizing food supplement regulations at the national level. These findings delineate a fragmented regulatory environment for botanical and bioactive food supplements across Member States. Noteworthy disparities were observed not only in national legislative frameworks but also in the enforcement practices of regulatory authorities. Union-level governance efforts in particular by adopting a mutual recognition approach to mitigate fragmentation proved ineffective. Consequently, this research underscores an urgent imperative to expedite the harmonization of regulations governing botanicals and other bioactive substances present in food supplements across the European Union.

Keywords Food supplements · Doctrinal analysis · Empirical analysis · Botanicals · Mutual recognition

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Introduction

Food supplements represent products positioned at the juncture of food and pharmaceuticals. As food and pharmaceutical regulation are mutually exclusive, defining criteria for when food supplements are defined as food or pharmaceuticals has been a judicial and scholarly challenge (Domínguez Díaz et al. 2020). In the European Union (EU), Directive 2002/46/EC defines most of the products which are intended to complement the regular diet as food supplements (Directive 2002/46/EC 2002; Konik et al. 2011), leaving, however, the assessment and enforcement to national authorities. This regulatory system poses two challenges, which will be addressed in this paper. First, food supplements are increasingly bought by consumers for their features which are more related to pharmaceuticals, and these food supplements also show risks which are typically assessed in pharmaceutical authorisations, which calls for a unified approach across the EU to effectively manage these risks (Domínguez Díaz et al. 2020). Second, as national authorities are entrusted with the interpretation and enforcement of the Directive, there is a possibility that exactly this risk is dealt with in a fragmented manner across the EU, as EU law may not be applied at all or not efficiently.

Regarding the first challenge, there is an evolving consumer perception where health-centric supplements are increasingly viewed as viable means to support individual health goals (Colombo et al. 2020; Knopf 2017); hence, consumers purchase these products more with a view to features associated with pharmaceuticals, despite of their characterization and risk assessment as food supplements. This is even more worrying, as supplements containing botanicals or other bioactive substances have been associated with toxicological or quality-related risks which are associated with risk assessment for pharmaceuticals (Gurley et al. 2022; Srivatsav et al. 2020). This presents a challenge concerning ensuring of product safety and quality for both regulatory authorities and consumers alike (Low et al. 2017; Stephan 2017).

Regarding the second challenge, the existing EU legislation lacks comprehensive harmonizing regulatory mechanisms for food supplements, such as positive or negative lists, safe maximum levels, or defined conditions of use for substances, across European Member States (EMS) (Breitweg-Lehmann 2017; Noble 2017). Prior studies have evaluated the regulatory systems within various EMS, revealing a fragmentation marked by individual EMS implementing disparate regulatory frameworks for supplements containing botanical or other bioactive substances (Coppens and Pettman 2018; Domínguez Díaz et al. 2020). Yet, empirical data illustrating variations among competent authorities in their regulatory practices for supplements, and the impact of Union law aimed at reducing fragmentation on these practices, remain limited.

Therefore, this study investigates if the potential fragmentation of legal systems transposes into practices regarding regulation of botanicals and other bioactive substances in supplements by national competent authorities. Further, the influence of Union law intended to harmonize the regulation of food supplements on their regulatory practices is evaluated. A doctrinal legal analysis was carried out to outline the framework conditions for these substances at the EU level and in seven different EMS. Results from an empirical legal analysis by means of expert interviews with representatives from competent national authorities were used to complement the insights obtained from the doctrinal legal analysis.

Methodology

Methods

Doctrinal Legal Analysis

Doctrinal legal analysis describes the collection and ordering of the available legal material, including legislation, jurisprudence, and legal literature, its syntax, and norms (Hutchinson and Duncan 2014). Our doctrinal legal research comprised two sequential components. Initially, we conducted a detailed analysis of the wording and syntax of EU secondary law. Subsequently, we examined the national legislation and pertinent soft law governing the regulation of food supplements across seven EMS: Austria, Belgium, Czech Republic, Ireland, Italy, Slovakia, and Sweden. Including all EMS would have surpassed the scope of this analysis. Hence, our objective was to capture the overarching approaches to food supplement regulation employed in the EU by focusing on a select group of EMSs characterized by diverse regulatory systems. This EMS selection facilitated a thorough examination of varied approaches to food supplement regulation through a comprehensive comparative legal analysis (Hutchinson 2015). We merged doctrinal legal research with empirical insights garnered through expert interviews, embodying an interdisciplinary comparative approach to regulation (compare Hutchinson 2015; Purnhagen et al. 2021; van Hoecke 2015).

Empirical Legal Analysis

The functional approach of comparative legal analysis has been advocated to be enhanced through insights from social sciences (van Hoecke 2015). In striving for a comprehensive understanding on law in practice, particularly when elucidating a foreign legal system, integrating stakeholder interviews into the comparative approach is suggested, broadening the research beyond a reliance solely on case law and legal documents (van Hoecke 2015). Following this methodological stance, previous research has effectively employed expert interviews in comparative legal research (Purnhagen et al. 2021). Therefore, we conducted structured expert interviews to obtain further information on practical aspects of supplement regulation not covered by publicly available documents of the EMS selected for the doctrinal legal analysis (compare Anderson 2010). We opted for expert interviews as our empirical method, recognizing their capacity to furnish pertinent information and institutional insights crucial for the research, which might otherwise be challenging to access (compare Bogner et al. 2009; Helfferich 2022). Expert interviews typically involve a limited number of participants, constituting to a small sample size because it is a method of qualitative research that focuses on analysing the content of generated data rather than generalizing a research subject based on the generated data as quantitative research does (Kaiser 2014; Lamnek and Krell 2016a, 2016b). In qualitative research, an expert can be considered representative of an institution based on his or her process knowledge (Bogner and Menz 2002; Bogner et al. 2014).

Study Materials

EU Legislation

Databases used to retrieve European legislation and other information were EUR-LEX, Curia, DocsRoom, and N-Lex. Only the latest available consolidated versions of each document were used.

National Legislation

Specific national food law provisions and other documents like reports, statements, or guidelines were obtained from N-Lex and other national legislative databases of the respective EMS. Only the latest consolidated versions of each document were used. Older versions of laws were used for reference purposes.

Interviews

Conducting the doctrinal legal analysis enabled the identification of facets within supplement regulation that squarely fall under the jurisdictional purview of food safety authorities. Based on these findings, we developed a questionnaire containing 13 closed questions with predefined multiple-answer choices to be used in the expert interviews (Schnell 2019a). Questions centred on the particular priority accorded by authorities to addressing key aspects: Ensuring food supplement quality and safety, delineating differentiation procedures between supplements and medicinal products, and the utilization of mutual recognition procedures concerning food supplements within the respective EMS.

A series of interviews with experts from competent national authorities, specialized in the regulation of food supplements within their respective departments, were conducted via online video calls (Misoch 2019). Each interview session extended approximately 60 min, providing ample time for interviewees to respond to the questions and select one or more answers from the questionnaire (Schnell 2019b). Interview candidates were provided with consent forms for personal data protection and non-disclosure agreements. Contact information was retrieved from publicly available governmental registries. In total, four competent authorities from Austria, Belgium, the Czech Republic, and Ireland participated in the expert interviews. The competent authority from Slovakia did not participate in the interview but answered and commented on the questionnaire via email communication. Authorities from Sweden and Italy abstained from participating in the interviews, instead referring to publicly available information.

The interview questionnaire is contained in the supplementary material to this manuscript.

Data Extraction

Interview sessions were recorded and anonymised. Interview questions and answer choices were identical for all participants. We applied thematical analysis as laid down by Braun and Clark (2006) as qualitative analytical method. This method is considered suitable for examining different perspectives of research participants and highlighting differences or

similarities within or across empirical data sets (Clarke and Braun 2016; Nowell et al. 2017). It provides flexibility to qualitative data analysis as it can be applied to small sample sizes and heterogenous data sets and is commonly used for analysis of interviews or qualitative surveys (see Braun and Clarke 2012, 2006; Lack et al. 2011). As we aimed to complement the doctrinal legal research by providing empirical insights not accessible via legal documents, we chose an inductive coding approach, where the identification of themes and codes is primarily derived from the examination of generated data (Braun and Clarke 2006; Swain 2018).

Initially, the chosen answer options from the questionnaire in the expert interviews were compiled in a table using Microsoft Word Version 2013. Subsequently, initial codes were manually devised to initiate the grouping of the answer options. A semantic approach was employed to identify corresponding themes. Through continued data analysis, two key topics and 11 codes were ultimately affirmed (Braun and Clarke 2006; Ilkić et al. 2023). This allowed for qualitative data analysis and interpretation by identification of patterns within the codes in combination with the individual interview material of the different competent authorities (Anderson 2010; Sutton and Austin 2015). One member of the research team was tasked with the identification and development of codes and themes.

Study Limitations

The study was subject to several limitations. National legislation or administrative documents were not always accessible and often had to be translated from the original language into English. Language barriers also could have impacted the interviews, as not all participants were fluent in English. A significant issue was the acquisition of interview candidates, as many regulatory authorities have strict internal legal policies which prevent employees from participating. All obtained data from the interviews had to be anonymised due to non-disclosure agreements. Additionally, countries hosting larger supplement markets did not participate in the interviews.

Outcomes: The European Regulatory Framework

General Food Law Provisions

Primary EU law, particularly provisions concerning the free movement of goods, serves as the foundational framework for EU food law. The European Court of Justice (CJEU) introduced what is later known as the principle of conditional mutual recognition in its Cassis de Dijon decision (Röttger-Wirtz 2020). This principle aims to strike a balance between preserving the diversity of foodstuffs within the Union and establishing unified standards for the free movement of these products (Möstl 2010; Weatherill 2014). If any foodstuff is lawfully sold in one EU country, it can be sold in another, if the respective country cannot present any recognized reason for justification not to sell it (van Cleynenbreugel 2018). Despite of the fact that its significance decreased with the coming into force of Regulation (EC) No 178/2002 (General Food Law), it was introduced into secondary legislation in 2008 (see Regulation (EC) No 764/2008 2008; Weatherill 2017). According to Article 2 of the Mutual Recognition Regulation, a product which is not subject to fully harmonized EU legislation but is lawfully marketed in an EMS may not be denied market access in another EMS (Regulation (EC) No 764/2008 2008). Article 14 (9) General Food Law stipulates

that, in the absence of harmonizing rules at the Union level, 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 (Regulation (EC) No 178/2002 2002). In 2019, the EU reaffirmed its commitment to mitigating trade barriers stemming from diverse national regulations imposed on products sold across the Union, particularly in the absence of unified legislation, through the adoption of the updated Mutual Recognition Regulation (Regulation (EU) 2019/515 2019).

The most fundamental measure of EU food law is the General Food Law, which stipulates the establishment of the internal market, consumer protection, and health protection as major goals of food legislation (Regulation (EC) No 178/2002 2002). Article 14 General Food Law concerns the major principle of market access for foods in the EU, namely that food must not be unsafe for human consumption. This "not unsafe test" combines scientific criteria in the form of risk assessments (Art. 6 General Food Law) and protection of consumers from unfair practices (Art. 8 General Food Law) (Regulation (EC) No 178/2002 2002). To promote fair market conditions and to protect consumers from scientifically unsubstantiated product claims, Regulation (EC) No 1924/2006 established an EU Register for nutrition and health claims approved by the European Food Safety Authority (EFSA) (see Gulati and Berry Ottaway 2006; Regulation (EC) No 1924/2006 2006a). While 267 claims, mainly regarding nutrients, were approved, more than 2000 botanical claims were put on hold by the European Commission in 2010 due to a controversy regarding EFSA's evaluation procedures (Gulati et al. 2014). Food business operators retain the option to utilize these unevaluated claims, subject to approval by the respective national authority (Gulati et al. 2014).

Further horizontal legal provisions which apply to food supplements are the Novel Food Regulation (Regulation (EU) 2015/2283 2015) or concern hygiene of foodstuffs (Regulation (EC) No 852/2004 2004), maximum levels for pesticide residues (Regulation (EC) No 396/2005 2005) and contaminants (Commission Regulation (EC) No 1881/2006 2006), and the condition of use of additives (Regulation (EC) No 1333/2008 2008).

Specific Food Supplement Legislation

Food supplement regulation within the Union is specifically addressed by the Food Supplements Directive 2002/46/EC (see further Noble 2017). It defines supplements as concentrated sources of nutrients or other substances to supplement the normal diet, marketed in a pre-dosed form (Directive 2002/46/EC 2002). While the Directive aims to establish an encompassing legal framework, the regulation primarily focuses on harmonization concerning nutrients (Directive 2002/46/EC 2002). Article 2b defines nutrients as minerals and vitamins, while Annexes I and II contain positive lists for nutrients and their molecular forms permitted for supplement use (Directive 2002/46/EC 2002). However, the development of safe upper levels for nutrients, as required by Article 5, was only recently continued by EFSA (EFSA NDA Panel et al. 2022). Substances other than nutrients are vaguely defined in recital 6 as herbal extracts, amino acids, essential fatty acids, fibre, and plants (Directive 2002/46/EC 2002). Additionally, the establishment of further specific regulations for those substances was postponed by Article 4(8) until more scientific data would be available (Directive 2002/46/EC 2002). Until then, EFSA published guidance documents in 2009 and 2014 for the safety assessment of botanicals intended for supplement use (EFSA Scientific Committee 2009, 2014). EFSA also published its Compendium on Botanicals, a database of botanicals and naturally occurring substances of potential toxicological

concern to humans, to assist regional authorities in their product safety assessments (European Food Safety Authority 2012). Although the risks of differing national regulations due to lack of Union legislation, such as the creation of trade barriers, have been emphasized in Directive 2002/46/EC, certain aspects of regulation were left to the individual Member States (Directive 2002/46/EC 2002). These include safety measures such as establishing product notification procedures and suspending or restricting potentially hazardous products in their territory (Directive 2002/46/EC 2002).

Though utilizing approved health claims in the marketing of food supplements is permitted by law, Article 6(2) of the Food Supplements Directive explicitly forbids their presentation as treatments or management options for medical conditions (Colombo et al. 2020; Directive 2002/46/EC 2002). The use of food products in medical conditions was prominently addressed by the CJEU in case C-418/21. To classify a food product as food for special medical purposes (FSMP), as defined by Regulation (EU) 609/2013, there needs to be a causal relationship between a medical condition and the resulting nutritional need, which is to be specifically met by the product (*Orthomol* (2022)). A general nutritional benefit in the management of a medical condition alone which the product might provide to consumers is not enough to delineate it from regular food, including food supplements (*Orthomol* (2022)).

Regulation (EC) No 1925/2006 on the addition of vitamins and minerals and of certain other substances to foods is another relevant legal act to be considered. It defines other substances as substances other than nutrients that have a physiological or nutritional effect (Regulation (EC) No 1925/2006 2006b). Under the provisions of Article 8 and Annex III, the use of certain substances in food in the EU can, following a scientific assessment by the EMS or EFSA, be restricted or be placed under scrutiny, such as monacolins from red yeast rice, or prohibited as it is the case for Yohimbe and Ephedra preparations. However, to this date, only a few substances have been placed in the annexes (Regulation (EC) No 1925/2006 2006).

The Commission's Position

In 2007, the Commission published a study that evaluated the need for further market harmonization and EMS' approaches to regulating botanicals and other substances. Notification procedures, decreased trade barriers, and the establishment of a robust legal framework were identified as influential factors affecting the market. The conclusion drawn was that the regulation of various substances in the EU continues to exhibit fragmentation, primarily attributed to diverse national regulatory practices, the intricate overlap of botanical substances, especially concerning the pharmaceutical market, and sporadic implementation of mutual recognition (EAS Strategies Ltd 2007). In 2008, per Article 4(8) of the Food Supplements Directive, the Commission submitted a report on the feasibility of establishing specific legislation for other substances to the Council and the European Parliament (European Commission 2008). In the report, existing Union legislation was considered sufficient to harmonize regulation in the EU. The concept of mutual recognition, as substantiated further by Regulation (EC) No 764/2008, has been addressed as essential to assure the free movement of supplements in the EU. Additionally, it was anticipated that adopting the Health Claims Regulation would significantly reduce borderline issues between supplements and medicinal products. Finally, Article 8 and Annex III of Regulation (EC) No 1925/2006 were seen as critical tools to harmonize the conditions of use

for certain other substances (EAS Strategies Ltd 2007). Overall, the Commission considered establishing further specific rules for botanical and bioactive substances other than nutrients scientifically challenging and of limited effectiveness, but also unnecessary (European Commission 2008).

Outcomes: Regulation at Member State Level

Fragmentation of National Regulatory Systems

In the seven investigated EMS, food safety authorities are responsible for the regulation of supplements and are subordinate to the respective national ministry responsible for health or agriculture (European Commission 2005). They may be integrated as departments within the respective ministry or independent bodies (European Commission 2005). Austrian authorities are further assisted in carrying out their tasks by a state agency (European Commission 2005). Most of these EMS require food business operators to notify the responsible authority before placing a supplement on the market (Directive 2002/46/EC 2002; European Commission 2017). Austria or Sweden renounced notification procedures because food supplements are foodstuffs that must not be unsafe according to the General Food Law (European Commission 2017; Regulation (EC) No 178/2002 2002). Additionally, notification fees for food business operators vary between the Member States, while others completely waive them (European Commission 2017). A product is usually notified by submission of a notification file, whose requirements and scope differ between countries (European Commission 2017). Table 1 shows the classification of the national regulatory approaches of the investigated EMS regarding the use of botanicals and bioactive substances other than nutrients as ingredients for food supplements. Table 2 shows different measures applied in the EMS to regulate the use in botanicals and bioactive substances as ingredients in food supplements. The measures include notification procedures, positive and negative ingredient lists, ingredient-specific warning labels, restrictions of use, and maximum daily amounts.

Guideline-Based Approaches

Swedish, Austrian, and Irish authorities refer to guidance documents to which they operate and which companies should consider. Swedish authorities used to provide a

Table 1 Classification of approaches to regulating the use of botanicals and bioactive substances in food supplements in seven European Member States

	Member States						
	Austria	*Belgium*	*Czech R*	*Ireland*	*Italy*	*Slovakia*	*Sweden*
BOT Laws		X	X		X		
BOT Guidelines	X	X		X	X		X
BAS Laws		X	X				
BAS Guidelines		X		X	X		X

Regulative measures applied in the respective EMS are marked with X; *BOT:* botanical substances, *BAS:* bioactive substances

non-exhaustive list of plants and their parts not permitted for use in food (Coppens and Pettman 2018). The Swedish Medicines Agency continues to provide a list indicating whether they consider certain substances or preparations as food or medicinal products (Läkemedelsverket 2020). Austrian authorities refer to a comparable substance list prepared by German authorities for orientation purposes (Bundesministerium für Gesundheit and Frauen 2016). Although no positive or negative list for botanicals or other active substances exists in Ireland, the Irish Health Products Regulatory Authority provides a guideline under which certain types or ingredients of food supplements could be considered as medicine (Coppens and Pettman 2018; Health Products Regulatory Authority 2020).

Food supplement regulation in Slovakia is primarily based on Union legislation, as no specifications regarding botanicals and other substances were introduced. However, in 2009, a ministerial decree containing recommended daily amounts for nutrients was published (Ministerstvo Pôdohospodárstva Slovenskej republiky & Ministerstvo Zdravotníctva Slovenskej republiky 2009).

Law-Based Approaches

In contrast, Belgian, Czech, and Italian legislators put specific requirements for supplements containing botanicals and substances other than nutrients into national law. The Belgian Royal Decree on Plants includes a positive list of plants permitted for use in supplements, their conditions of use, warning labels, and a negative list of plants prohibited in all food (Arrêté royal du 31 août 2021). In Italy, D.M. 9 July 2012 regulates the use of botanicals, whose positive lists in the annexes were updated most recently by D.M. 10 August 2018 (Ministero della Salute 2012a, 2018). The Italian Ministry of Health additionally provides guidelines for business operators on documentation and quality standards for the production of food supplements (Ministero della Salute 2012b, 2015). Since 2013, Belgium and Italy have been, together with France, members of the BELFRIT project, which aims at defining a harmonized positive list of botanicals eligible for use in food supplements (Biagi et al. 2016; Cousyn et al. 2013). Both countries adopted the BELFRIT list into national law, Italy in 2014 and Belgium in 2017, complementing already existing legislation (Biagi et al. 2016; Cousyn et al. 2013). However, specific preparation techniques for obtaining herbal extracts or preparations or using particular analytical methods are not imposed on business operators in Italy (Biagi et al. 2016). In contrast, Belgian authorities require quality certificates complying with standards formulated in the European Pharmacopoeia for essential oils used in food supplements. Food business operators must also provide the authorities with detailed safety data on the non-clinical and clinical toxicity of the essential oil used (SPF Santé Publique 2012). The Royal Decree of 29 August 2021 and a specifying ministerial decree with a positive list regulate the use of substances other than nutrients or botanicals in food supplements in Belgium (Arrêté royal du 29 août 2021; SPF Santé Publique 2022). In Italy, only such a positive list has been issued by the Ministry of Health (Ministero della Salute 2019).

Comparable to the Belgian and Italian legislation, the Czech Republic implemented a legal framework for supplement regulation by adopting Decree No. 446/2004 (Ministerstvo zdravotnictví 2004). The annexes of its amendments, Decree No. 225/2008 and No. 58/2018, include, besides nutrients and their forms permitted by Directive 2002/46/EC, positive lists and maximum daily amounts for botanicals and substances other than plants (Ministerstvo zdravotnictví 2008; Ministerstvo zemědělství 2018). Specific maximum daily amounts refer either to efficacy-determining substances or standardized extracts like

synephrine in Citrus aurantium or Gingko biloba leaf dry extracts. Decree No. 58/2018 includes lists of plants and other substances prohibited in food production and warning labels mandatory for certain substances of concern (Ministerstvo zemědělství 2018). Decree No. 446/2004 specifically prohibits using plants for pharmaceutical and therapeutic purposes, listed in the annex of Decree No. 343/2003, in food supplements (Ministerstvo zdravotnictví 2004). To demonstrate a product's safety, business operators in the Czech Republic can apply for the Health Safety Certificate from the State Health Institute (SZÚ), which issues an expert opinion and a laboratory safety assessment (Act No. 258/2000 Coll. 2000).

Expert Interviews

In the following, we present the results of the expert interviews conducted. Their purpose was to gather additional insights into regulatory aspects not sufficiently covered by the studied legal source material. Thematic analysis was performed to identify patterns regarding preferences for databases used in regulatory actions and practical application of legal measures to manage market access of food supplements.

Mutual recognition of food supplement products, intended to facilitate market access, was not considered relevant by all interviewed experts for business operators to obtain permission for market entry. Interviewees indicated that its use is not established because it is considered not well-designed enough or unnecessary for businesses to obtain market access. Instead, all interview participants found the respective national legal framework sufficient in ensuring the quality and safety of food supplements. Also, none of the interviewees considered any other EMS a particularly suitable Reference Member State (RMS) for mutual recognition procedures to be conducted in their own respective countries. Additionally, experts had no insights if EMS were cited as RMS in mutual recognition procedures in another EMS.

When business operators place or intend to place a product containing a substance not previously permitted for use in food on the market, interviewees indicated that such permission is decided on a case-by-case basis. If a product cannot be identified as a food supplement or a medicinal product, some respondents indicated that it must either be modified to meet the requirements set by legislation and the competent authority or be withdrawn from the market. Other respondents indicated that such products could remain on the market until more data is available for reassessment. If that is not possible, the cases are transferred to another authority or jurisdiction. However, interviewees reported that the assessment of potential borderline products is referred to the responsible medicines agency or a commission tasked with evaluating borderline products.

Thematic analysis further revealed different general preferences in the use of databases for decision-making within the competent regulatory authorities, as reported by the interviewees. While some EMS use a very open approach towards using databases provided by other stakeholders, others rely on more selected databases. In general, interviewees from all investigated EMS stated that data provided by national authorities is frequently accessed. In contrast, data provided by European institutions regarding food supplement products seemed to be of lesser significance to the interviewees. Other frequently used data sets are those provided by business operators, while data generated in countries outside the EU seem to be almost irrelevant to interview participants. Differences also exist in using data provided by other EMS and independent research, as interviewees considered them

not equally significant as national databases in regulatory decisions. A similar pattern can be observed in the history of safe use, as this data type was considered relevant in only a few cases.

The differences in database preferences further translate into specific regulatory aspects such as substance safety assessment or refusal of mutual recognition of a food supplement. Concerning the safety assessment of substances not previously permitted, most interview candidates considered a combination of safety data collected from governmental institutions at the national level, a history of safe use in the EU, and other EMS's scientific opinions as relevant. While one interviewee indicated safety data from national institutions to be more relevant, another expressed preference for data provided by European institutions, such as scientific opinions from EFSA. Several interview candidates indicated that food safety authorities also review additional sources of information such as advertisement materials or the history of use in the EU. However, interviewees reported that food safety authorities generally do not assess a substance's potential pharmacological effect and rely on data from the respective medicine agencies.

Refusal of mutual recognition is, according to the interviewees, primarily based on classification of a substance as dangerous to public health due to missing or insufficient data on product quality or safety. Especially an unknown mode of action or a substance being considered pharmaceutical ingredient was mentioned in this regard. Negative scientific opinions from other EMS as additional factors influencing the decision to refuse recognition were mentioned more often than negative opinions by European institutions such as EFSA. Only one interviewee stipulated that negative scientific assessments from third countries are also relevant to such a decision.

Discussion

Our research aims to investigate if the fragmentation of regulatory systems at the EMS level transposes into the regulatory practices of the responsible authorities. Furthermore, the investigation aims to assess the practical significance of Union law designed to enhance harmonization in supplement regulation for these authorities. The results from our legal analysis indicate that a cluster of non-harmonized regulatory systems emerged in the EU. The outcomes from our expert interview confirmed that fragmentation is also present in practical aspects of regulation in action. Mutual recognition as a means of managing diversity of food law in the Union had regarding supplements no significant impact on the regulatory activities of the investigated responsible authorities.

The expert interviews provided insights into the regulatory practices of responsible national authorities and their approaches to non-explicitly regulated substances, which have not been described before. The present data indicate that the significant differences in the general regulatory systems of the investigated EMS also continue in evaluating substances not previously permitted for use in supplements. This can be implied in decision-making about permission and the selection of databases used for safety assessments of these substances. Regarding the dealing of national authorities with borderline products, interview results confirmed similarities between the EMS in that the evaluation of products and substances that may fall under the definition of medicinal products is the responsibility of national medicines agencies rather than the food safety authorities. However, differences became apparent if the evaluation process was unsuccessful, as borderline products either stay on the market until more data is available or must be modified to meet national requirements. As introduced through Regulation (EC)

No 768/2008, mutual recognition has been described as an alternate mode of product governance besides harmonization and national legislation (Schmidt 2007). However, the interview results indicate that this procedure has little to no significance regarding food supplement regulation in the examined countries. This is in line with a statement by the Commission from 2017 that business operators adapted their products to national requirements instead of spending resources on the enforcement of recognition (European Commission 2017). Despite the update in 2019, Jan concluded in 2021 that the new mutual recognition regulation will still not effectively implement the procedure throughout the EU due to a lack of trust in regulatory standards between EMS (Jan 2021). Data from our interviews support this hypothesis, as other EMS were usually not considered particularly suitable as RMS by interview candidates. Weatherill's claim that mutual recognition is always conditional on its acceptance by the respective Member States seems to be supported by our research (Weatherill 2014). Especially in comparison with the European pharmaceutical market, which underwent extensive harmonization efforts and where mutual recognition of marketing authorisations is well established, suggests a dysfunctionality of this procedure in the food supplement sector (Röttger-Wirtz 2020).

Results in Table 1 allow for categorizing national regulation of supplements containing substances other than nutrients as law-based or guideline-based, as discussed by the Commission's study in 2007 (EAS Strategies Ltd 2007). The results in Table 2 highlight that the designs of particular systems vary across the investigated EMS, including the adoption of positive or negative lists, restrictions of use, or maximum daily amounts. The efforts made by Belgium and Italy to implement the BELFRIT list into national law could be interpreted as a reflection of a need for continuous efforts towards a harmonized regulation for food supplements as formulated by previous current research (Bailey 2020; Domínguez Díaz et al. 2020).

Several previous studies described the regulatory framework conditions for food supplements at the EU level. Colombo et al. described in 2020 the regulation of botanical substances in the EU and, to a certain extent, at national levels against the background of the Health Claims Regulation (Colombo et al. 2020). Trovato and Ballabio laid down delineation issues between food supplements containing botanical substances and

Table 2 Application of national regulatory measures for the use of botanical and bioactive substances as ingredients for food supplements in seven European Member States

	Member States						
	Austria	*Belgium*	*Czech R*	*Ireland*	*Italy*	*Slovakia*	*Sweden*
Notification		X	X	X	X	X	
Positive list BOT	X	X	X		X		
Negative list BOT		X	X		X		
Positive list BAS		X	X		X		
Negative list BAS							
Use restriction BOT		X	X	X	X		X
Use restriction BAS		X	X	X	X		X
Warning labels	X	X	X		X		
MDA		X	X		X		

Regulative measures applied in the respective EMS are marked with X; *BOT:* botanical substances, *BAS*: bioactive substances, *MDA:* maximum daily amounts

traditional herbal medicinal products, considering applicable legislation and CJEU case law (Trovato and Ballabio 2017). They also pointed out how different regulatory approaches are applied to botanical substances at EMS levels (Trovato and Ballabio 2017). Noble laid down in 2017 which regulations and directives the European supplement regulation consists of and described legislative issues such as borderline products, infrequent application of Regulation (EC) No 1925/2006, missing maximum daily amounts, and botanical health claims being on hold (Noble 2017). The results of previous studies, indicating that the EMS adopted widely different regulatory systems to especially deal with the usage of botanicals and bioactive substances other than nutrients or botanicals in food supplements and issues such as borderline products due to missing Union legislation, align with those from our research.

The outcomes of the conducted doctrinal legal analysis, revealing fragmentation in the regulation of food supplements containing botanicals and other bioactive substances at the EMS level, alongside the empirical research findings highlighting disparities in the implementation of regulatory measures by national authorities, indicate that mutual recognition holds limited significance for the surveyed authorities. These results indicate the successful achievement of the research objectives outlined in this study. However, both the results from the doctrinal legal analysis and the empirical research should not be applied directly to other EMS or the EU in general, due to the diversity of each regulatory system and the food supplement market structure.

Conclusion

Our research highlighted the fragmentation of food supplement regulation at the EMS level regarding the responsible authorities' legislative frameworks and regulatory practices. It also endorsed the claim that the functionality of mutual recognition is dependent on EMS acceptance and illustrated that mutual recognition of food supplements is not accepted by EMS and hence not functional as a governance mode in practice. We assume that the fragmentation of the regulation of food supplements in the EU is associated with the dysfunctionality of mutual recognition of food supplements at the EU level. Strengthening the harmonization of food supplement regulation could enhance access to safe food supplements and the free movement of goods throughout the EU. Improved secondary legislation on product safety databases or communication procedures between authorities should be considered. Initiatives such as the BELFRIT project demonstrate that this is explicitly desired by EMS. Continued research in this area, with a focus on the involvement of other EU countries and an inclusion of new participants, e.g., business operators, food supplement quality and safety laboratories, consumers, and others, could initiate a deep revision and acceleration of the food supplement harmonization by all relevant stakeholders.

Supplementary Information The online version contains supplementary material available at https://doi.org/10.1007/s10603-024-09571-0.

Acknowledgements We would like to thank all interviewees for participating in this study and sharing their experiences with us.

Funding Open Access funding enabled and organized by Projekt DEAL.

Data Availability The interview data that support the findings of this study contain sensitive information and personal data and are not publicly available. Data are available from the authors only upon reasonable request and with permission of the concerned third party. The code book detailing the thematic analysis

performed in this study is available in the Open Science Framework repository: https://doi.org/10.17605/OSF.IO/VQWPB.

Declarations

Ethical Approval Ethical approval for the conduction of expert interviews during this study was obtained from the Ethics Committee of the University of Bayreuth. Kai Purnhagen is a member of the Ethics Committee of the University of Bayreuth. The authors declare that he was not involved in the Committee's approval procedure at any stage and that his role was restricted to an applicant during the whole process.

Consent to Participate All interview participants were informed about and consented to the scientific and academic purposes of the conducted interviews.

Competing Interests Kai Purnhagen is a member of the editorial board of the Journal of Consumer Policy. The authors declare that no other competing interests exist.

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