On European Union Law and the Quality of Food Supplements

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Table of contents

List of abbreviations

AHP	-	American Herbal Pharmacopoeia
APA	-	American Psychological Association
API	-	Active pharmaceutical ingredient
cGMP	-	current Good Manufacturing Practices
CJEU	-	Court of Justice of the European Union
DSHEA	-	Dietary Supplement Health and Education Act
EC	-	European Commission
ECJ	-	European Court of Justice
EDQM	-	European Directorate for the Quality of Medicines
EFSA	-	European Food Safety Agency
EMA	-	European Medicines Agency
EMS	-	European Member State
ESCOP	-	European Scientific Cooperative on Phytotherapy
EU	-	European Union
FBO	-	Food business operator
FDA	-	Food and Drug Agency
F&D Act	-	Food and Drugs Act
FD&C Act	-	Food, Drug and Cosmetic Act
GFL	-	General Food Law
GMP	-	Good Manufacturing Practices
HACCP	-	Hazard Analysis and Critical Control Points
HCR	-	Health Claims Regulation
HMP	-	Herbal medicinal product
NDI	-	New dietary ingredient
NHP	-	Natural Health Product

NHPR	-	Natural Health Products Regulations
NNHPD	-	Natural and Non-prescription Health Products Directorate
OSCOLA	-	Oxford Standard for Citation of Legal Authorities
OTC	-	Over-the-counter
Ph. Eur.	-	European Pharmacopoeia
RASFF	-	Rapid Alert System for Food and Feed
REFIT	-	Regulatory Fitness and Performance Programme
RMS	-	Reference Member State
SME	-	Small and medium-sized enterprises
TFEU	-	Treaty on the Functioning of the European Union
THMP	-	Traditional herbal medicinal product
USA	-	United States of America
U.S.C.	-	United States Code of Federal Regulations
USP	-	United States Pharmacopoeia
USP-NF	-	United States Pharmacopoeia National Formulary
WHO	-	World Health Organization

Abstract (German)

Der Markt für Nahrungsergänzungsmittel in der Europäischen Union verzeichnet ein stetiges Wachstum, was auf mehrere miteinander verknüpfte Faktoren zurückzuführen ist: Erstens, das steigende Interesse von Verbrauchern ihre individuelle Gesundheit durch eine optimierte Ernährung zu verbessern. Zweitens, werden Nahrungsergänzungsmittel als risikoarme Alternative zur Anwendung in verschiedenen medizinischen Indikationen und Zuständen wahrgenommen, wobei ihre Nutzung häufig mit „natürlichen" Behandlungsoptionen im Gegensetz zu klassischen Arzneimitteln assoziiert wird. Drittens gestalten Hersteller gezielt Marketingnarrative, um Nahrungsergänzungsmittel als wesentlich für das Erreichen individueller Gesundheitsziele von Verbrauchern darzustellen.

Trotz der wachsenden Bedeutung des Konsums von Nahrungsergänzungsmitteln für Verbraucher zeigt der regulatorische Rahmen der EU strukturelle Schwachpunkte auf, die sich unmittelbar auf die Qualität und Sicherheit der auf dem Binnenmarkt verfügbaren Produkte auswirken. Nahrungsergänzungsmittel gelten rechtlich als Lebensmittel und unterliegen damit allgemeinen Regelungen durch die Verordnung (EG) Nr. 178/2002 (Lebensmittelbasisverordnung). Ergänzend hierzu regelt die Richtlinie 2002/46/EG (Nahrungsergänzungsmittel-Richtlinie) spezifische Aspekte wie die Zulassung von Inhaltsstoffen, Kennzeichnungspflichten oder die Ausgestaltung nationaler Notifizierungsverfahren. Mehrere zentrale Regelungsbereiche der Richtlinie, insbesondere in Bezug auf pflanzliche und andere bioaktive Substanzen, wurden jedoch bislang nicht unionsweit umgesetzt. Auch bei der Verordnung (EG) Nr. 1924/2006 (Health-Claims Verordnung) ist ein ähnlicher Rückstand bei der vollumfänglichen gesetzlichen Umsetzung erkennbar. Die Europäische Kommission und die ihr unterstellte Europäische Behörde für Lebensmittelsicherheit (EFSA) stehen vor erheblichen Herausforderungen, evidenzbasierte regulatorische Entscheidungen etwa zur wissenschaftlichen Absicherung pflanzlicher Health-Claims, der Sicherheitsbewertung pflanzlicher Inhaltsstoffe oder zur Festlegung von Höchstmengen für Vitamine und Mineralstoffe zu treffen – vor allem aufgrund fehlender qualitativ hochwertiger wissenschaftlicher Daten.

Die unvollständige Umsetzung zentraler Vorschriften zur Regulierung des Inverkehrbringens von Nahrungsergänzungsmitteln hat zu einer fragmentierten Rechtslage zwischen den Europäischen Mitgliedsstaaten geführt. In Ermangelung harmonisierter EU-Vorschriften haben nationale Aufsichtsbehörden unterschiedliche regulatorische Ansätze und Praktiken entwickelt. In der Folge sehen sich Lebensmittelunternehmen mit einem komplexen und teils inkonsistenten Regelwerk konfrontiert, was den Verwaltungs- und Rechtsaufwand erhöht und zugleich das Risiko von Sanktionen oder Produktrückrufen durch nationale Lebensmittelsicherheitsbehörden steigert. Zusätzlich erschwert die rechtliche Überschneidung

von Nahrungsergänzungsmitteln und dem Arzneimittelrecht den Marktzugang: Zahlreiche pflanzliche Inhaltsstoffe können gleichzeitig in Nahrungsergänzungsmitteln, pflanzlichen Arzneimitteln (HMP) und traditionellen pflanzlichen Arzneimitteln Anwendung (THMP) finden. Diese Überschneidungsmenge birgt das Risiko unbeabsichtigter Verstöße der Inverkehrbringenden gegen das Arzneimittelrecht und untergräbt das Vertrauen der Verbraucher in die Fähigkeit des EU-Lebensmittelrechts, zwischen den Produktkategorien klar zu unterscheiden.

Parallel dazu mehren sich Hinweise auf Qualitätsprobleme bei Nahrungsergänzungsmitteln auf dem EU-Binnenmarkt, die auf unzureichende Qualitätssicherungs- und Kontrollmaßnahmen seitens der Hersteller und Vertreiber zurückzuführen sind. Die festgestellten Mängel reichen von unzureichender Produktkennzeichnung über Kontamination mit toxikologisch-bedenklichen Substanzen bis hin zur Beimischung nicht zugelassener Inhaltsstoffe oder zur Verfälschung mit pharmazeutischen Wirkstoffen. In jährlich veröffentlichten Berichten der Kommission zur Lebensmittelsicherheit in der EU wird darauf hingewiesen, dass Nahrungsergänzungsmittel regelmäßig zu den Produktkategorien mit den häufigsten Beanstandungen hinsichtlich Qualität und Sicherheit zählen. Diese Entwicklung weist auf ein systemisches regulatorisches Defizit hin, dass die Sicherstellung von Produktqualität und Verbraucherschutz nur unzureichend gewährleistet.

Diese Dissertation untersucht die Interdependenz zwischen regulatorischen Dysfunktionalitäten des EU-Rechtsrahmens für Nahrungsergänzungsmittel und deren Auswirkung auf die Produktqualität. Im Zentrum steht die Frage, inwieweit ein funktionalerer Regulierungsansatz, insbesondere durch die Einführung kodifizierter Qualitätsreferenzstandards, den Zugang zu qualitativ hochwertigen Nahrungsergänzungsmitteln verbessern könnte. Die Arbeit leistet einen Beitrag zum wissenschaftlich-akademischen Diskurs, indem sie das aktuell bestehende System aus öffentlicher und privater Perspektive kritisch betrachtet und internationale Regulierungsmodelle einbezieht.

Methodisch verfolgt die Arbeit einen interdisziplinären Ansatz, der rechtsdogmatische Analyse mit qualitativen empirischen Forschungsmethoden kombiniert. Dieses Design ermöglicht ein kontextualisiertes und intersektionales Verständnis der rechtlichen, wissenschaftlichen und marktbezogenen Dynamiken des EU-Sektors für Nahrungsergänzungsmittel. Ein weiterer zentraler Bestandteil ist die vergleichende Rechtsanalyse internationaler Regulierungssysteme aus Drittstaaten außerhalb der EU, in denen bereits kodifizierte Qualitätsstandards für Nahrungsergänzungsmittel etabliert wurden. Diese Modelle werden hinsichtlich institutioneller Ausgestaltung, Umsetzungsmechanismen und Auswirkungen auf Marktteilnehmer untersucht, mit dem Ziel, deren Übertragbarkeit auf die EU zu bewerten.

Die Arbeit ist in vier aufeinander aufbauende Abschnitte gegliedert. Zunächst wird untersucht, ob sich die Fragmentierung der rechtlichen Rahmenbedingungen für die Anwendung pflanzlicher und anderer bioaktiver Inhaltsstoffe in Nahrungsergänzungsmitteln auf die Vollzugspraktiken der Aufsichtsbehörden auf nationaler Ebene niederschlägt. Zudem wird die Bedeutung von Unionsrecht, das ursprünglich zur Reduktion rechtlicher und regulatorischer Fragmentierung entwickelt wurde, aus Sicht der Behörden bewertet. Im zweiten Abschnitt wird der Zusammenhang zwischen gemeldeten Qualitäts- und Sicherheitsproblemen bei Nahrungsergänzungsmitteln und der Risikokommunikation von Behörden und Unternehmen im Kontext des geltenden EU-Lebensmittelrechts analysiert. Der dritte Abschnitt beleuchtet, wie Inverkehrbringende von Ergänzungsmitteln sich an die rechtliche Fragmentierung anpassen, insbesondere hinsichtlich der Nutzung gesundheitsbezogener Aussagen in Marketingstrategien und der Produktentwicklung. Abschließend zeigt die Dissertation einen funktionalen Regulierungsansatz für die Einführung von qualitätsbezogenen Referenzstandards auf Grundlage des Europäischen Arzneibuchs auf EU-Ebene auf. Dieser letzte Abschnitt bewertet die rechtliche und praktische Umsetzbarkeit eines solchen Modells, mit besonderem Fokus auf Rechtssicherheit und faire Marktbedingungen.

Zusammenfassend stößt die Dissertation Überlegungen zu einem kohärenteren und durchsetzbaren Regulierungsrahmen für Nahrungsergänzungsmittel in der EU an, indem sie die bestehende rechtliche Fragmentierung analysiert, die Perspektiven relevanter Akteure einbezieht und einen Mechanismus zur Einführung einheitlicher Qualitätsreferenzstandards vorschlägt.

Abstract (English)

The market for food supplements in the European Union (EU) has experienced a continuous growth, driven by several interconnected factors. First, the increasing interest of consumers in improving individual health through an optimized diet. Second, the perception of food supplements as a low-risk alternative in various medical conditions, often associated with benefits derived from “natural” treatments as compared to regular pharmaceuticals. Third, manufacturers strategically shaping marketing narratives to position food supplements as essential for achieving personal health goals of consumers.

Despite the growing importance of food supplement consumption to consumers, the EU’s regulatory framework governing these products continues to exhibit structural weaknesses, which impact the quality and safety of products available at the EU market. While food supplements, being legally considered as food, falls under the general scope of Regulation (EC) No 178/2002 (General Food Law), the primary legal act Directive 2002/46/EC (Food Supplements Directive) provides additional specifications regulating ingredient permission, labelling requirements, or the design of national notification procedures. However, several critical aspects of the Directive, such as the regulatory status of botanical and other bioactive substances, have not been fully implemented yet. A similar lack of progress is evident under Regulation (EC) No 1924/2006 (Health Claims Regulation), which governs the use of health-related statements made on food products. The European Commission and its subordinate European Food Safety Agency (EFSA) have encountered considerable challenges in progressing robust and evidence-based regulatory decisions, such as scientifically substantiating botanical health claims, the safety of botanical ingredients, or defining maximum dosages for nutrients, due primarily to a lack of reliable scientific data.

The delay in implementing key aspects of food supplement regulation resulted in a fragmented legal landscape across European Member States. In the absence of harmonizing Union law, national authorities have adopted divergent regulatory approaches. In consequence, food business operators must adapt to a complex and often inconsistent framework of national food quality and safety regulations. This increases their administrative and legal burden, while heightening their risk of being exposed to sanctions or product-recalls enforced by national food safety agencies. Additionally, regulatory overlaps between food supplements and pharmaceuticals complicate market entry for manufacturers. Many botanical ingredients may be classified simultaneously as food supplements, herbal medicinal products (HMP), or traditional herbal medicinal products (THMP). This overlap risks breaches of EU medicines law by food businesses via unintentionally placing unauthorized pharmaceuticals on the market, and undermines consumer trust in the ability of EU food law to effectively delineate the two product categories.

At the same time, the EU has witnessed a proliferation of various supplement quality issues on the internal market, exposing shortcomings in quality control practices implemented by manufacturers and distributors. Identified issues range from insufficient product labelling to contamination with toxic substances, the addition of unauthorized ingredients, or adulteration with pharmaceuticals. Annual food safety reports from the European Commission indicate that food supplement consistently rank among the most frequent violations of food quality and safety standards. These trends point to a systemic regulatory dysfunction that fails to effectively ensure food quality and protect consumer health.

This dissertation investigates the interaction between regulatory dysfunctionalities within the EU food supplement framework and the resulting implications for product quality. Its central objective is to explore how a more functional regulatory approach, characterized by the introduction of codified supplement quality reference standards, could enhance the access to high-quality food supplements. It contributes to academic scholarship by critically assessing the current system from both the public and private perspective, and by drawing on other international regulatory models.

The research employs an interdisciplinary approach, merging doctrinal legal analysis with qualitative empirical research methods. This design enables for a contextualized and intersectional understanding of the legal, scientific, and market dynamics shaping the EU food supplement sector. Finally, a key component is the comparative legal analysis of comparable frameworks outside the EU, that have adopted codified food supplement standards in their respective jurisdictions. These models are assessed in terms of their institutional design, implementation mechanisms, and impact on market stakeholders, with a view on evaluating the transferability to the EU.

The dissertation is structured into four consecutive parts. Initially, the research investigates whether the fragmentation of frameworks governing botanical and other bioactive ingredients has transposed in the enforcement practices of national food safety authorities. Additionally, the relevance of Union law anticipated to decrease legal fragmentation in this aspect to food safety authorities is assessed. Second, it examines the relationship between reported food supplement quality and safety issues and risk communication efforts by the public and private sector under applicable EU food law. Third, it explores how manufacturers adapt to regulatory fragmentation, particularly in their use of health-claims as marketing tool and product development strategies. Finally, the dissertation proposes a functional regulatory pathway for the adoption of supplement-specific quality reference standards based on the European Pharmacopoeia at the EU level. This final section evaluates the legal and practical feasibility of implementation, focusing on key aspects such as enforceability, legal certainty, and the promotion of fair market conditions.

In conclusion, this dissertation seeks to inform efforts toward a more coherent and enforceable regulatory framework conditions for food supplements in the EU by addressing legal fragmentation, incorporating stakeholder perspectives, and proposing a mechanism for uniform quality reference standards.

Chapter 1
General Introduction

1.1 Introduction

1.1.1 Food supplements in the EU

The consumption of food supplements has become increasingly popular with consumers in the European Union (EU) (Djaoudene et al., 2023; Puścion-Jakubik, Bielecka, et al., 2021). Legally defined by Directive 2002/46/EC (Food Supplements Directive) as foodstuff intended to supplement the regular diet with nutrients, botanicals, and other bioactive substances in the form of single-dosed concentrates, a wide range of ingredients and galenic forms is available to consumers on the EU market (Czarnowska-Kujawska et al., 2022; Directive 2002/46/EC, 2002; Zovi et al., 2025). Although supplements can resemble pharmaceutical products in their galenic forms, contained ingredients, or dosages, they are not intended for the treatment of medical conditions (Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements, 2002). Still, the consumption of food supplements is often perceived by consumers as a low-risk benefit to individual health sustainment (Anadón et al., 2021). This development may be further driven by food businesses shaping marketing narratives for their products by promoting food supplements as health-focused to consumers (Fish & Lord, 2023).

As they fall under the definition of food, the regulation of quality and safety of food supplements is based upon the central horizontal EU Regulation (EC) No 178/2002 (General Food Law; GFL) (Regulation (EC) No 178/2002, 2002). Article 14 of the GFL considers food to be safe if it is not injurious to human health or be otherwise unfit for consumption due to safety-impairing product deterioration (Regulation (EC) No 178/2002, 2002). However, EU food law does not explicitly define an enforceable legal term of food quality (Schebesta & Purnhagen, 2024). Instead, within broader market standards such as the World Health Organization's (WHO) Codex Alimentarius, the term quality is referenced as being suitable for consumption (Food and Agriculture Organization of the United Nations [FAO] & World Health Organization [WHO], 2023; Schebesta & Purnhagen, 2024). Suitability in this context extends beyond safety hazards, including other food attributes such as expected composition, sensory characteristics, or compliance to legal specifications (e.g. labeling requirements) (FAO & WHO, 2023). Subsequently, EU food law does not legally define the term of food quality, but instead enforces it indirectly via horizontal food standard specifications (Schebesta & Purnhagen, 2024). The GFL in particular obligates food business operators (FBO) to implement hazard analysis and critical control points (HACCP) as part of quality assurance programs for their manufacturing and distribution operations (Regulation (EC) No, 2002). Additionally, FBOs are advised to follow current Good Manufacturing Procedures (GMP) to establish effective hygiene control, prevent contamination, and ensure properly qualified employees (Regulation (EC) No 178/2002, 2002).

Still, various issues of quality and safety related to food supplement manufacturing continue to be present at a comparatively high level on the EU market (European Commission, 2025). Previous research has identified foodborne risks consumers are exposed to, ranging from low and moderate to high severity. For example, while non-compliance with food labeling regulations or reduced shelf-life represent quality issues of no immediate hazard, the adulteration with pharmaceutical ingredients or contamination with toxins, heavy metals, or pesticides, are notably concerning (Bensa et al., 2023; Czepielewska et al., 2018; Koncz et al., 2020; Poniedziałek et al., 2018). Overall, while EU food law, and the Food Supplement Directive in particular, pursue a high level of consumer protection and streamlined fair market conditions through harmonized food quality standards, ensuring quality and safety remains a concern within the food supplement sector (Schebesta & Purnhagen, 2024; Thakkar et al., 2020).

The challenges surrounding effectively regulating the quality and safety of food supplements can be attributed to two interconnected domains of EU food law enforcement. First, the fragmentation of the EU legal framework conditions due to the incomplete implementation of adopted food safety laws by EU institutions, where, in their absence, national regulations apply at the European Member State (EMS) level. Second, the inconsistent compliance of FBOs with food quality standards established by the EU and national laws, despite their legal obligation placed upon them by the GFL to only release safe food products on the market. However, given that food supplements often straddle the boundary with medicinal products, the development of their regulation has also been shaped by constitutional limits on EU competence under the Treaty on the Functioning of the European Union (TFEU). These constitutional limits will be discussed further in Section 3.3 of the theoretical framework, alongside the principles of risk-based regulation and precaution, as key determinants of the EU's fragmented regulatory approach to food supplements.

1.1.2 Regulatory fragmentation

Under its paradigm of risk-based regulation, the EU has adopted several horizontal food safety acts applicable to food supplements (Vettorazzi et al., 2020). Among these, the Food Supplements Directive represents the central part of the EU food supplement regulatory system, stipulating conditions for permitted ingredients, labeling requirements, or notification procedures at the EMS level (Directive 2002/46/EC, 2002). Regulation (EC) No 1924/2006 (Health Claims Regulation) and Regulation (EC) No 1925/2006 (Food Additives Regulation) also play a pivotal role in the field of regulating food supplements, as they mitigate the use of health-related statements on food products and the restriction of certain of ingredients for use in food respectively (Regulation (EC) No 1924/2006, 2006; Regulation (EC) No 1925/2006, 2006; Vettorazzi et al., 2020). However, although EU food law pursues its stated aims of

consumer protection and fair market conditions by setting horizontally applicable risk-based food standards throughout the Union, a full harmonization of the EU food supplement sector has not been attained yet (Gulati et al., 2014; Gulati et al., 2019; Wengle, 2016). In particular, the European Commission (EC) and its subordinate European Food Safety Agency (EFSA) encountered substantial difficulties in developing regulatory measures and implementing critical provisions of the Food Supplements Directive and the Health Claims Regulation (Gulati et al., 2014; Gulati et al., 2019). Areas of concern which have been addressed by previous research, the European Parliament, or European Member States are the assessment of botanical substances permitted for use as supplement ingredients, the establishment of maximum dosage levels, or the completion of food health claims assessments (Bundesrat, 2021; European Parliament, 2024; Gulati et al., 2019; Noble, 2017).

As an example, the EC was tasked by Article 4(8) of the Food Supplements Directive to develop a positive list for botanical and other bioactive ingredients permitted for use in food supplement, as has been established for nutrients and minerals before (Directive 2002/46/EC, 2002). However, in 2008, the Commission abolished the creation of such a list due to the size and complexity of the task and a lack of reliable scientific data (European Commission, 2008). In another example, the EC and EFSA were tasked by Article 13(3) of the Health Claims Regulation to assess all claims made to food products promoting benefits to human health circulating within the EU, and decide on their permission status based on the claims' scientific substantiation (Regulation (EC) No 1924/2006, 2006). In 2011, EFSA decided to put the assessment of all botanical health claims on hold, again due to a lack of sufficient scientific data (European Parliament, 2024).

Still, the delay in implementing adopted food law provisions is not the result of administrative inertia by the EC and EFSA. It rather stems from a deeper structural issue, which is the reliance of EU institutional bodies on comprehensive, high-quality scientific data to support the implementation of risk-based regulatory measures, legally substantiated in Article 23(a) GFL (Barlow et al., 2015; Wengle, 2016). Generally, this approach to developing legal frameworks for sensitive product categories has proven its effectiveness in delivering product safety, high consumer trust levels, and streamlined market conditions, as for example in the case of the EU pharmaceuticals market (Peschel & Alvarez, 2018). Concerning food supplement regulation, however, the lack of reliable safety data, especially on botanical ingredients, resulted in pronounced difficulties of progressing evidence-based regulatory decisions contributing to harmonsation efforts for the EU market (Warda et al., 2024; Weißenborn et al., 2018). Thus, food supplement regulation is partially achieved at the EU level, while certain critical issues remain subject to individual national regulation by the EMS, creating legal uncertainty and a fragmented regulatory landscape within the EU (Warda et al., 2024).

Although this has been criticised by the Parliament of the European Union and EMS as an obstacle towards EU primary law goals of achieving a high level of consumer protection and developing the free internal market, there has been only small progress since the current EU regulatory framework governing food supplements was adopted (Bundesrat, 2021; European Parliament, 2024).

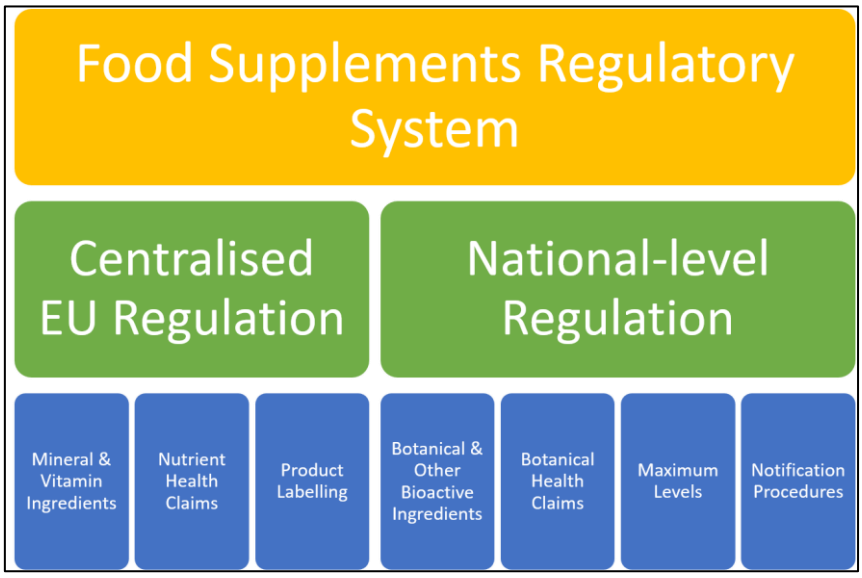

Fig. 1 Overview of the EU's food supplement regulatory system, showing the allocation of responsibilities between EU centralized legislation and EMS regulations

1.1.3 FBO legal compliance burden

The fragmentation of legal framework conditions governing food supplements exerts an impact on the quality of available products, as it affects the criteria by which public safety authorities and private food companies operate. The GFL and the Food Supplements Directive aim to provide a risk-based regulatory framework facilitating a high level of food safety and quality (Regulation (EC) No 178/2002, 2002; Directive 2002/46/EC, 2002). However, the Food Supplements Directive refrains from mandating an authorization procedure requiring proofs of safety, quality, or efficacy, but outlines a simplified notification procedure whose design is left to the individual EMS (Directive 2002/46/EC, 2002). Therefore, following a hybrid mechanism of food law enforcement, the onus of ensuring food quality and safety falls on the FBOs (K. Purnhagen & Molitorisová, 2022). Food safety authorities function as a corrective agent within this system, imposing sanctions or enforcing product recalls in case of detected non-compliance by FBOs (K. Purnhagen & Molitorisová, 2022).

Although FBOs are advised to follow HACCP and GMP guidelines to ensure the compliance with quality standards set by food law, the development of quality control procedures is their own responsibility regardless of the company's size or available resources (Fernández-

Segovia et al., 2014). In the pharmaceutical sector, commonly accepted quality control procedures, reference standards, and formulation monographies have been codified by joint efforts of public and private stakeholders in the European Pharmacopoeia (Ph. Eur.) (Peschel & Alvarez, 2018). Despite similar galenic formulations, contained ingredients, or dosages can be found in food supplements, no analogous compendium on product quality referencing food supplements is available in the EU (Bilia & Costa, 2021).

Furthermore, substantiated in the legal fragmentation and unattained implementation of harmonising regulatory measures, FBOs are forced to partially adapt to EU and national food supplements regulations simultaneously within a single market (Warda et al., 2024). Especially FBOs participating in cross-border activities in the EU are faced with multiple and diversified food quality regimes at the EMS level (Tallon & Kalman, 2025). This facilitates increased spending of resources by FBOs to tailor procedures, advertisements, on-pack labeling, or product compositions to the legal requirements of the respective markets (Tallon & Kalman, 2025). Additionally, multi-market businesses are at risk of being subjected to unequal enforcement practices by food safety authorities, through different interpretations of how to meet EU food safety goals via their individual regulatory approaches (Warda et al., 2024). Hence, compliance with inconsistent food quality standards becomes increasingly complex and resource-demanding for quality assurance programs of food supplement companies (Bose & Sharma, 2025; Tallon & Kalman, 2025). This illustrates how the issue of the fragmentation of the EU's legal framework is interconnected with quality deviations and insufficiencies of food supplements under the responsibility of FBOs. Previous research identified quality fluctuations of food supplements containing similar ingredients and dosages and sold across the EU, further highlighting the interconnection between food quality and legal uncertainty (Czarnowska-Kujawska et al., 2022; Puścion-Jakubik, Bartosiewicz, & Socha, 2021). Meanwhile, EMS food safety authorities are faced with an influx of food supplements potentially not compliant with the respective national regulatory system (Kowalska et al., 2019). Against the background of growing cross-border internet trade with food supplements, this issue might be increased even further in the future (Sfodera et al., 2020).

Fig. 2 Schematic representation of the interaction between supranational and national food law, hazard-based control systems, and the operationalization of quality assurance within the food sector. EU: European Union; FBO: Food Business Operator; GMP: Good Manufacturing Practices; HACCP: Hazard Analysis and Critical Control Points.

Introduced via Regulation (EC) No 764/2008, amended by Regulation (EU) 2019/515, the principle of mutual recognition, whereas products lawfully marketed in one EMS cannot be restricted from entering the market in another EMS, was anticipated by the EC as a remedy to national regulations conflicting within broader EU regulatory systems (Möstl, 2010). However, Jan (2021) concluded that it is of only limited effectiveness due to EMS not completely trusting in each other's regulatory systems (Jan, 2021). Meanwhile, FBOs are unlikely to pursue mutual recognition through legal actions due to anticipated legal costs, administrative burden, and an asymmetrical relationship with responsible food safety authorities, contingent upon their reliance on the authorities' discretion in various regulatory matters (Jan, 2021). Ultimately, consumers remain being at risk of exposure to food supplements of lower quality while harmonization efforts continue to stagnate.

1.1.4 The consumer perspective on food supplement quality and safety

Consumers typically assume that food products comply with horizontal food standards laid down by EU legislation and expect them to be of sufficient quality and safety (Garcia-Alvarez et al., 2014). However, the current EU food supplements regulatory framework contains significant gaps, which may expose consumers to substandard or misleadingly marketed products (Anadón et al., 2021). Substantiated in the regulatory fragmentation, EMS differ in how they monitor and enforce applicable law on food supplements, resulting in inconsistencies of product quality, composition, and regulatory oversight on the internal EU market (Borraz et al., 2022).

In contrast, consumers often perceive food supplement consumption being of low-risk and beneficial to their individual health (Khedkar et al., 2017; Tsartsou et al., 2021). Especially the consumption of botanical supplements is often labeled as a healthier and more "natural" alternative to established and authorized medicines (Samojlik et al., 2013; Willis & Royne Stafford, 2016). Additionally, research has identified difficulties for consumers to clearly delineate between pharmaceutical products and food supplements (Khedkar et al., 2017). Yet, consumers cannot assess supplement quality independently and must rely instead on information provided by FBOs (e.g. advertisements or product labels), or other public entities (e.g. institutional guidance documents or public authority statements). Subsequently, the comprehensive provision of food information and food chain transparency are fundamental consumer rights that enable informed dietary choices (N. Gokani, 2024). As the perceived food quality and safety are factors likely influencing purchasing decisions of consumers, these attributes introduce an additional economic dimension into food supplement regulation (Nikhil Gokani & Grosso, 2024).

Maintaining consumer trust in this regulatory framework is critical, as it underpins the legal legitimacy of the system (Boer, 2019). Conversely, if consumer trust erodes due to perceived inconsistent interpretation and enforcement of EU food law, it undermines the objectives of the EU's risk-based regulatory approach to food governance (Boer, 2019; Kendall et al., 2019). The stagnating harmonization of the food supplement market therefore constitutes a risk factor that may weaken consumer confidence in the EU's legal system governing these products.

These systemic shortcomings underscore the need for a more functional, harmonized approach that addresses not only safety but also quality, compliance, and consumer perception. This dissertation examines how the fragmented EU legal framework has affected the quality of food supplement, with the aim of identifying future options to enhance consumer access while considering the interests of other stakeholders.

1.2 Research aims

This dissertation aims to provide a comprehensive understanding of the interactive dysfunctionalities of the EU regulatory framework governing food supplements. Drawing from obtained research results, a functional approach towards enhanced access for consumers to safe food supplements shall be proposed. This leads to the following main research question:

> How do interacting regulatory dysfunctions within the EU's risk-based regulatory framework affect food supplement quality, and to what extent could pharmacopoeial reference standards serve as a corrective mechanism?

In order to identify issues within the EU's risk-based approach to regulating food supplement safety and quality, the first sub-question must be answered:

1. To what level does the fragmentation of regulatory approaches governing food supplement ingredients extend on the Member State level?

Obtaining an overview of how national regulation of non-harmonised aspects relevant to food supplement manufacturing and distribution interacts with the overarching EU regulatory framework is necessary to develop a fundamental understanding of potentially arising issues therein. Subsequently, this leads to the second sub-question, which needs to be answered:

2. What roles do public and private stakeholders play in risk communication within the food supplement sector under the EU's hybrid food law enforcement mechanism?

Risk communication constitutes a central element of the EU's risk-based approach to food safety and quality governance, requiring the timely exchange of information among institutional and private actors when non-compliance is detected. Understanding the distinct roles assumed by these stakeholders in contributing to the operational goals of food chain transparency is essential to assess its coherency in the broader, fragmented regulatory framework pertaining to food supplements. The degree to which stakeholders engage with risk communication obligations imposed by EU food law may serve as indicator of how effectively legal instruments incentivize accountability and preventive food quality control practices and the operationalization of transparency.

Having outlined the regulatory framework conditions and how they are transposed into practice by public and private entities, it becomes necessary to examine how companies navigate the marketing of food supplement to consumers. Health-related advertising and positioning products as beneficial to individual health hold great significance in the food supplement sector, despite the incomplete implementation of the corresponding EU legal framework. To support the development of a more coherent and functional approach to ensure food supplement quality, it is essential to investigate how health-related claims for such products shape business strategies. The importance of this dimension of food information is further underscored by the influence health claims exert on dietary choices made by consumers. Therefore, the third research sub-question is:

3. How does fragmentation within the EU's food information framework impact the marketing and product development practices of food supplement manufacturers?

Once an overview is established of how legal dysfunctionalities of the regulatory framework conditions impact practices of competent food safety authorities and manufacturers in relation to market surveillance and quality control practices, regulatory measures to further strengthen quality standards applicable to food supplements shall be explored. Given their resemblance to medicinal products, due to comparable galenic forms, dosages, or ingredients, the application of pharmacopoeial quality standards to food supplements has been introduced in

jurisdictions outside the EU. However, in the setting of European law development, additional regulatory measures have to be carefully considered to ensure compatibility with the principle of the free internal market and to avoid unnecessary constrains on innovation in the food supplement sector. The fourth research sub-question is as follows:

4. How could uniform quality standards for food supplements be sustainably integrated in the European Union without impeding internal market dynamics and innovation?

Having assessed different aspects of potential dysfunctionalities within the EU food supplement regulatory framework, such as fragmentation at the EMS level, lack of transparency of the food supply chain, and inefficacy of EU laws intended to alleviate regulatory stress points, a functional approach potentially enhancing food supplement quality within the current regulatory system is discussed. The approach aims to balance the fundamental consumer rights of health protection while acknowledging the impact additional regulation might have on resources of public and private entities, as well as innovation in the food supplement sector.

1.3 Theoretical framework

1.3.1 Risk-based regulatory principles in food safety law

The development of the EU's current food safety legal framework has been primarily driven by the emergence of food safety incidents spreading throughout the Union, such as the BSE crisis in the 1990s (K. Purnhagen & Molitorisová, 2022). In order to address and prevent foodborne threats from reaching the market, the EU has focussed on the adoption of risk- and hazard-based approaches towards food law development (Barlow et al., 2015).

The terms of risk and hazard are closely related to each other, but although often perceived by the public as interchangeable, they convey different levels of gravity in food safety law (Barlow et al., 2015). Hazard indicates an inherent harmfulness of a product, ingredient, or additive due to its presence at any detectable level of exposure, mandating a need for appropriate safety measures (Regulation (EC) No 178/2002, 2002). Risk expresses the probability of harmful effects to occur depending on the amount of exposure, quantified through acceptable estimation criteria (Regulation (EC) No 178/2002, 2002). It is important to note that in the context of food safety, the total avoidance of harmful substances is often not achievable, making the identification and accurate classification into risk or hazard a fundamental regulatory procedure (Barlow et al., 2015). Therefore, a constituent common to both approaches is the reliance on available sufficient scientific data, enabling evidence-based regulatory decisions (Barlow et al., 2015).

Concerning the food supplements sector, there are several examples of EU laws explicitly pertaining to risk- and hazard-based approaches. The Food Supplements Directive prohibits the use of any nutrient for use in supplements which is not listed in its annexes, representing a hazard-based regulatory approach (Directive 2002/46/EC, 2002). The Food Additives Regulation lists in its Annex III Part B conditions of use for several substances primarily added to food supplements, such as monacolins from red yeast rice, recognizing a dose-dependent level of foodborne risk (Regulation (EC) No 1925/2006, 2006).

Risk-based regulation is legally substantiated in the EU's primary goal of protecting consumer health (Bánáti, 2014). Although such measures restrict elements of the free internal market, such as certain manufacturing procedures, ingredients, additives, and advertisement claims or imposing specific labelling requirements, they are warranted by their role in mitigating health risks (Bánáti, 2014; Koutsoumanis & Aspridou, 2016). However, in line with the EU's principle of proportionality, regulatory actions must balance the fundamental rights of consumer health protection based on an identified risk with the need to facilitate the functioning of the internal market (Barlow et al., 2015; Portuese, 2013). CJEU case law has consistently emphasized that any restriction to market access for a specific product, a thorough risk analysis prior to the adoption of a regulatory decision has to be conducted (Portuese, 2013).

1.3.2 The precautionary principle

One of the EU's key principles in guiding risk-based regulation is the principle of precaution, enabling legislative institutions to invoke governance instruments to address potentially emerging product-related risks for which the required scientific evidence is insufficient or uncertain (Lofstedt, 2014). Although only briefly mentioned in Article 19 of the Treaty on the Functioning of the European Union (TFEU), EU secondary food law incorporates the principle as a broad legal foundation for restrictive measures via Article 7 of the GFL (K. P. Purnhagen & Wesseler, 2025). Thus, the principle is defined as where a potential threat to human health is identified while uncertainty regarding its full extent remains on a scientific level, provisional safety measures ensuring a high level of consumer protection may be adopted until further evidence for a concluding risk decision is available (K. P. Purnhagen & Wesseler, 2025).

Although the precautionary principle is firmly established in CJEU case law, and its application requirements were reaffirmed by the EC in 2000 to be proportional, non-discriminatory, subject to review if new scientific data becomes available, and grounded in economic cost-benefit analysis, it has been argued that the principle has not been applied consistently (Garnett & Parsons, 2017; Lofstedt, 2014; K. P. Purnhagen & Wesseler, 2025). Previous research suggested that an epistemic uncertainty regarding the underlying scientific data leads legislators and institutions more likely to an overestimation of an identified risk (Crawford-

Brown & Crawford-Brown, 2011). Garnett & Parsons (2017) described this range of uncertainty between the lower bound of evidence being considered not strong enough, therefore triggering the precautionary principle, and the higher bound where the completion of risk assessments is feasible (Garnett & Parsons, 2017). They argue that this range is subject to varying interpretation, contributing to inconsistent applications of the principle (Garnett & Parsons, 2017).

In the context of food supplement regulation, national food safety authorities have invoked the precautionary principle to compensate for missing harmonised regulatory frameworks. For instance, until 2009, Spanish authorities applied a systematic a priori classification of all botanical preparations as herbal medicinal products, regardless of their lawful categorisation as food supplements in other EMS. This approach reflected a precautionary approach, presuming that in the absence of EU-level positive lists for botanical ingredients under the Food Supplements Directive, such ingredients should be inherently considered unsafe for use in food. However, in its judgement Commission v Spain (Case C-88/07), the CJEU ruled that this regulatory practice was disproportionate and in violation of the principle of free movement of goods. The court held that despite market restrictions may be permissible under the precautionary principle in case scientific uncertainty regarding an ingredient's safety exist, such restrictions must be based on individual risk assessments providing reasonable evidence of potential harm. Consequently, the CJEU considered a generic application of the precautionary principle without considering product-specific safety evaluations as a disproportionate measure for protecting consumer health.

1.3.3 Principle of conferral and the limitations of harmonisation

Alongside the principles of risk-based regulation and precaution, the development of EU food supplement regulation is also shaped by the principle of conferral. According to Article 5(2) TFEU, whereas the Union may act only within the competences conferred upon it by the Member States (Treaty on the Functioning of the European Union, 2012). In the area of public health, Article 168 TFEU precludes harmonization through EU secondary law, thereby upholding EMS competences (Treaty on the Functioning of the European Union, 2012). By contrast, Article 114 TFEU obliges the Commission to consider consumer health protection as a fundamental basis for harmonization measures (Treaty on the Functioning of the European Union, 2012). This creates tension within the doctrinal underpinnings of EU secondary law development, as the Union is not permitted to regulate public health directly, yet it must integrate health protection into its internal market legislation (K. Purnhagen, 2025).

In its landmark ruling *Tobacco Advertising I* (Case C-376/98) of 2000, the ECJ clarified that EU secondary law must be directed at amending obstacles which are likely to impede the

improvement of internal market conditions (*Germany v Parliament and Council (Tobacco Advertising I),* 2000). Introducing the "likely obstacle" test, the ECJ marked that regulation must be framed primarily around the internal market development, while only incidentally pursuing health protection (*Germany v Parliament and Council (Tobacco Advertising I),* 2000).

Reflecting the *Tobacco Advertising I* judgement, the Food Supplement Directive was designed to balance the constitutional conditions set by Article 114 and Article 168 TFEU. In its preamble, the variance in national rules applicable to food supplements, often substantiated by invoking consumer health protection, is explicitly mentioned by Recital 2 and Recital 10 as obstacles to free trade and circulation of these products (Directive 2002/46/EC, 2002). Yet, in conjunction with Recital 5, the directive embeds a high level of consumer protection within its legal rational (Directive 2002/46/EC, 2002). Thus, the Food Supplements Directive exemplifies a dual framing, legally based on market integration but designed to deliver consumer protection. The ECJ further clarified the boundaries of EU and EMS competences in subsequent case law. In its *Alliance for Natural Health* (Joint Cases C-154/04 and C-155/04) ruling from 2005, the court upheld its previously established "likely obstacles" test (*Alliance for Natural Health and others,* 2005). Moreover, it reinforced potential future divergences in national legal systems (compare Recital 10 Food Supplements Directive) as incentive for harmonisation measures by the EC, if they threaten the integrity of the internal market (*Alliance for Natural Health and others,* 2005). In 2007, the court clarified the limits of EMS discretion to regulate food supplements (*Commission v Germany (Garlic Capsules),* 2007). In *Commission v Germany* ("Garlic Judgement", Case C-319/05) the ECJ elaborated that national rules must be proportionate and evidence-based (*Commission v Germany (Garlic Capsules),* 2007). Accordingly, EMS cannot invoke public health competences granted under Article 168 TFEU to justify measures that infringe the internal market freedom under Article 34 TFEU (*Commission v Germany (Garlic Capsules),* 2007).

These ECJ rulings highlight the constitutional compromise under which EU food supplement regulation operates. EU secondary law must achieve market integration while upholding consumer health protection, whereas EMS retain responsibility for public health regulation but are constrained by proportionality and market freedom principles (Purnhagen, 2025). This structural tension between Union and EMS competences contributes to the fragmented legal framework governing the EU food supplement sector (Nowak, 2021).

1.4 Methodology

This dissertation employs a variety of socio-legal methods, each of which are detailed in the beginning of the respective chapters. The primary approaches of this research are based on doctrinal legal analysis and comparative legal analysis. Doctrinal legal analysis aims to provide

a comprehensive theoretical account of the assessed legal system by analysing relevant law statutes, their interpretation by regulators, and related case law (Hutchinson & Duncan, 2012). Employing the method for an assessment of the EU's framework for food supplement regulation provides a profound analytical foundation for an understanding of its underlying theoretical assumptions (Hutchinson, 2015).

Comparative legal analysis focuses on illustrating strengths and weaknesses of a legal system by comparatively examining laws, legal systems, or principles employed in different jurisdictions designed for dealing with a comparable socio-legal problem (van Hoecke, 2015). By analysing legal texts, its syntax, and normative assumptions in addition to relevant case law or grey literature such as institutional communication documents, the method enables researchers to draw conclusions on a regulatory system's effectiveness (Coninck, 2010). Thus, comparative legal analysis constitutes a well-established research method in the context of European law development (Purnhagen et al., 2021). In particular, it is suitable for assessing the diversity of EMS legal systems under the EU's institutional framework, and the relationship between EU law and frameworks operating at national or supranational levels beyond the Union (van Hoecke, 2015).

Both of the aforementioned methodological approaches are frequently combined with empirical research methods (Hutchinson, 2015; van Hoecke, 2015). As legal analyses primarily seek to elucidate the underlying rationale of adopted legal systems and its various dimensions of interactions with other legal principles, they often lack a perspective of how laws are applied and enforced in practice (van Hoecke, 2015). By incorporating different empirical research methods, an interdisciplinary research approach enables researchers to capture a political and socio-economic perspective on the legal system (Hutchinson, 2015; Spamann, 2015).

In the context of this dissertation doctrinal legal analysis facilitates the illustration of the EU's food supplement legal framework and identify gaps where harmonisation has not been achieved yet. It further provides an overview on how different EMS have set their respective national approaches in place where EU law provisions are not implemented. The research aim of the conducted comparative legal analysis was to identify a functional approach to enhance access to uniform and codified food supplement quality standards for all stakeholders, as adopted in major supplement markets outside the EU, choosing the United States of America (USA) and Canada as an example.

Empirical data obtained through structured interviews with representatives from food safety authorities provided additional insights on food law enforcement practices pertaining to botanical and other ingredients and the relevance of mutual recognition in relation to food supplements from the perspective of public authorities. Semi-structured interviews with experts from supplement manufacturers offered an overview of adaptive marketing strategies

employed by FBOs in response to regulatory fragmentation. Descriptive and interferential statistical analysis on alerts related to food supplement quality issues notified in the Rapid Alert System for Food and Feed (RASFF) provided an overview which deficiencies reach the EU market and the activity of different stakeholders in participating in food risk communication in relation to adopted food safety laws.

1.5 Structure of the dissertation

This cumulative dissertation is divided into six chapters. While Chapter 1 comprises a general introduction for this research, a discussion of the obtained research results is presented in Chapter 6. As shown in Table 1, Chapters 2-5 are based on articles published or currently under peer-review by scientific journals. The citation styles of each chapter remain the same as when it was finally submitted to the respective scientific journals. In Chapters 2 and 3 American Psychological Association (APA) 7th edition reference style is applied. Chapter 4 uses the Emerald reference style, while Chapter 5 applies Oxford Standard for Citation of Legal Authorities (OSCOLA).

Chapter	**Title**	**Originally published:**
Chapter 1	General Introduction	
Chapter 2	Has Mutual Recognition in the EU Failed?—A Legal-Empirical Analysis on the Example of Food Supplements Containing Botanicals and Other Bioactive Substances	Journal of Consumer Policy (2024) 47:425–443 Available at: https://doi.org/10.1007/s10603-024-09571-0
Chapter 3	The role of the public and private sectors in the EU hybrid safety governance of food supplements – A study on the example of quality issues notified in the RASFF	Under peer review by: Journal of Consumer Policy
Chapter 4	Investigating the impact of EU food information regulation on food supplement marketing strategies – A case study on the German market	Accepted with minor revisions by: British Food Journal
Chapter 5	Could Pharmacopoeial Reference Standards Serve as a Platform to Enhance the Quality and Safety Control Systems of European Food Supplement Businesses?	Accepted for publication by: European Journal of Risk Regulation (in press)
Chapter 6	Conclusion and General Discussion	

Table 1 Structure of the dissertation

Chapter 2 presents the results of doctrinal legal analysis on the EU's regulatory framework concerning botanical and other bioactive substances used as food supplements ingredients, whose governance has not been fully harmonised yet. In particular, the analysis illustrates the fragmented state of this aspect of food supplement regulation on the example of regulatory approaches adopted in seven different EMS. Empirical data from structured expert interviews with food safety authority representatives of the investigated EMS was gathered to elucidate whether discrepancies between national legal systems has transposed into regulatory practices of competent authorities. Furthermore, the impact of secondary EU legislation introducing mutual recognition as a legal tool to decrease regulatory fragmentation at the EMS level is discussed.

Chapter 3 investigates the role of the public and private sector of the EU food supplement market in food risk communication on the example of quality issues notified in the RASFF between 2003 to 2022. First, the chapter encompasses a doctrinal legal analysis, providing a brief overview on the EU's hybrid approach of food law enforcement and the responsibilities of stakeholders concerning food risk communication. The second part entails an empirical data analysis on RASFF notifications pertaining to food supplement quality issues which have reached the EU market. By analysing activity levels of public and private stakeholders from affected EMS in food risk communication facilitated via the RASFF, potential discrepancies in the subject matter or frequency of notified issues depending on the initial reporting entity are investigated. Additionally, the analysis investigates correlations between the adoption of EU food safety legislation and trends in the growth of food supplement RASFF notifications during the observed study period.

Chapter 4 explores the relevance of health claims made on health-focused food supplements to marketing strategies and product development practices by FBOs. Using the German food supplement market as a case study, first a doctrinal legal analysis on the current state of the implementation of the EU Health Claims Regulation is conducted. A subsequent empirical analysis based on semi-structured expert interviews with representatives of seven German food supplement manufacturers, ranging from small and medium sized enterprises (SME) to larger stock companies, is performed. The aim of the empirical analysis is to demonstrate the importance of presenting food supplements as beneficial to consumer health in shaping marketing narratives, and to examine how FBOs adapt their marketing strategies to the unattained harmonisation regarding food-related health claims.

Chapter 5 explores whether pharmacopoeial reference standards, commonly used as common quality references in the pharmaceutical sector, could be applied within the EU's regulatory framework for food supplements. In contrast to the EU, the USA and Canada have revised their respective pharmacopoeias to include food supplements, although the level of statutory

compliance to these codified quality standards varies between them. Canada, in particular, relies on foreign internationally recognized pharmacopoeias, such as the United States Pharmacopoeia (USP) and Ph. Eur., potentially illustrating the “Brussel’s Effect”, whereby EU standards are adopted beyond its borders. By employing comparative legal analysis, the feasibility of incorporating food supplements into the Ph. Eur. and how closely FBOs should adhere to such quality standards is discussed. Considerations on the implications for market access, potential administrative burden, innovation within the EU food supplement market are included into the analysis.

Chapter 6 summarises the research results and discusses their implications in relation to the main research question. The discussion further reflects on the dissertation’s contribution to the academic discourse on enhancing food supplement quality within the EU. Finally, the chapter addresses the study’s limitations, and outlines key areas for future research.

Individual author contributions for each chapter, following the CRediT (Contributor Roles Taxonomy) guidelines, are detailed on the title page of the corresponding chapter.

Chapter 2
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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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.

2.1 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 characterisation 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 & 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 harmonise 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.

2.2 Methodology

2.2.1 Methods

2.2.1.1 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 & 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 characterised 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).

2.2.1.2. 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 & Krell, 2016a; Lamnek & Krell, 2016b). In qualitative research, an expert can be considered representative of an institution based on his or her process knowledge (Bogner et al., 2014; Bogner & Menz, 2002).

2.2.2 Study Materials

2.2.2.1 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.

2.2.2.2 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.

2.2.2.3 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, specialised in the regulation of food supplements within their respective departments, were conducted via online video calls (Misoch, 2019). Each interview session extended approximately 60 minutes, 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.

2.2.3 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 & 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 & 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 & Clarke, 2012, 2016; 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 & Clark, 2006; Swain, 2018).

Initially, the chosen answer options from the questionnaire in the expert interviews were compiled in a table using Microsoft Word 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 eleven codes were ultimately affirmed (Braun & Clark, 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 & Austin, 2015). One member of the research team was tasked with the identification and development of codes and themes.

2.2.4 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.

2.3 Outcomes: The European Regulatory Framework

2.3.1 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 recognised 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, Mutual Recognition Regulation; Weatherill, 2017). According to Article 2 of the Mutual Recognition Regulation, a product which is not subject to fully harmonised 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 & Berry Ottaway, 2006; Regulation (EC) No 1924/2006, 2006). 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 (Regulation (EC) No 1881/2006 2006), and the condition of use of additives (Regulation (EC) No 1333/2008, 2008).

2.3.2 Specific Food Supplement Legislation

Food supplements 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 (Recital 8 and Article 4 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 (C-418/21 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 (C-418/21 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, 2006). 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).

2.3.3 The Commission's Position

In 2007 the Commission published a study that evaluated the need for further market harmonisation 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 harmonise 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 harmonise 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).

2.4. Outcomes: Regulation at Member State Level

2.4.1 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.

2.4.1.1 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 non-exhaustive list of plants and their parts not permitted for use in food (Coppens & 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 und 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 & 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).

2.4.1.2 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 harmonised 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 České republiky, 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 České republiky 2008, 2018). Specific maximum daily amounts refer either to efficacy-determining substances or standardised 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 České republiky, 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 České

republiky, 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).

2.4.2 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 data bases 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 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 data base 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 as pharmaceutical ingredient were 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.

2.5 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 harmonisation 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 harmonisation 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 categorising 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 harmonised 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 traditional herbal medicinal products, considering applicable legislation and CJEU case law (Trovato & Ballabio, 2017). They also pointed out how different regulatory approaches are applied to botanical substances at EMS levels (Trovato & 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.

2.6 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 harmonisation 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 data bases 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 harmonisation by all relevant stakeholders.

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2.9 Annex

2.9.1 Supplementary Material 1

Has Mutual Recognition in the EU failed – A legal-empirical analysis on the Example of Food Supplements containing Botanicals and other Bioactive Substance

Structured Expert Interview Questionnaire

A. Food Quality and Safety:

1. Is the current regulatory legislation of food supplements in [Country] sufficient enough to ensure high levels of food quality and safety?
    a. Yes, it is sufficient
    b. Yes, but improvements need to be made
    c. No, it is not sufficient

2. Under which circumstances are food business operators allowed to place a supplement on the market containing substances not explicitly permitted by legislation?
    a. History of safe use in other Member States
    b. History of safe use outside the EU
    c. Positive scientific opinion by EFSA or Commission
    d. Mutual Recognition Procedure
    e. Case-by-case decision by [Country] authorities
    f. Proof of safety by business operators

3. Based on which data a substance not explicitly permitted by legislation is considered safe for use in food supplements by the authorities?
    a. History of safe consumption in the EU
    b. Analytical proof of safety by the business operator
    c. Analytical proof of safety by national agencies
    d. Positive EFSA scientific opinion
    e. Positive scientific opinion by another European Member State

4. On which data bases are maximum daily amounts for substances and maximum amounts of ingredients of toxicological concern for food supplements determined?
    a. Scientific opinions by EFSA or the Commission
    b. Safety analyses by [Country] authorities
    c. Safety analyses by another European Member State
    d. Scientific publications by independent researchers
    e. Data on product safety provided by business operators
    f. History of use in the EU
    g. There are no defined maximum daily amounts
    h. Other (please specify):

B. Classification Procedure:

1. Which data bases are used by [Authority] in order to differentiate between food

supplements and medicinal products?

a. Scientific opinions by EFSA, EMA or the Commission
b. Publications in scientific journals by independent researchers
c. Data provided by the business operator
d. Data provided by national authorities
e. History of use in the EU
f. History of use outside the EU
g. Advertisement materials & product labels

2. Which data is needed by the [Authority] to determine a pharmacological effect of a substance?
    a. Pharmacodynamic data
    b. Pharmacokinetic data
    c. Toxicological data
    d. Data on product quality
    e. History of safe consumption
    f. Intended use of a product

3. What are the consequences if the data for differentiation between food supplements and medicinal products is not sufficient enough?
    a. The product has to be withdrawn from the market
    b. If possible, the product needs to be changed in such a way it complies with the respective legislation
    c. In case of doubt products are classified as medicinal products due to safety concerns
    d. The product is allowed to stay on the market until further relevant data is available
    e. The case is transferred to another authority or jurisdiction

C. Mutual Recognition Procedure:

1. Does the Mutual Recognition of food supplements play a significant role in the marketing of food supplements in [Country]?
    a. Yes, products are regularly placed on the [Country] market via application this procedure
    b. Only a few products are being placed on the [Country]market via this procedure
    c. No, products are usually not placed on the [Country]market via this procedure

2. If not, why is the Mutual Recognition Procedure not established as a regularly used tool for gaining market access?
    a. It is considered too complicated by business operators
    b. The procedure usually takes too long
    c. Mutual recognition is usually denied
    d. Authorities do not have sufficient capacities for conducting the procedure
    e. The European regulatory framework is not designed well enough
    f. It is not needed to gain market access

3. If yes, why is Mutual Recognition of food supplements established as a tool for gaining market access?
    a. Botanical or other substances can be placed on the market faster
    b. No national positive lists for substances available
    c. Substances already lawfully marketed in other Member States are mostly considered safe
    d. Authorities encourage business operators to make use of this procedure

4. What makes a product to be considered hazardous to the public health leading to a refusal of mutual recognition?
    a. Negative scientific opinion by EFSA or the Commission
    b. Negative scientific opinion by another Member State
    c. Negative scientific opinion by a third country
    d. Missing or insufficient data on safety or quality
    e. Unknown mode of action
    f. Ingredient subjected to prescription control in [Country] or classified as pharmaceutical ingredient
    g. Other (please specify):

5. Are certain other Member States considered particularly suitable as Reference Member States in the eyes of [Country] authorities?
    a. Yes (please specify which):
    b. No

6. Is [Country] frequently cited as Reference Member State during Mutual Recognition procedures for food supplements in other Member States?
    a. Yes
    b. No

Chapter 3
The role of the public and private sectors in the EU hybrid safety governance of food supplements – A study on the example of quality issues notified in the RASFF

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Abstract

In the European Union (EU), food safety enforcement operates within a hybrid regulatory framework involving public and private enforcement mechanisms. Effective participation in risk communication from entities of both sectors is essential for addressing the emergence of food safety incidents within the scope of this hybrid food law enforcement framework. Nonetheless, the effective enforcement of EU food law governing food supplements remains a persisting challenge. This study investigates the engagement levels of public and private stakeholders within the Rapid Alert System for Food and Feed (RASFF) communication network, using the food supplement market as a case study. Drawing on the method of doctrinal legal analysis, the functional and normative structures of the EU legal framework governing food supplements will be assessed. The analysis is supported by an empirical secondary data analysis to investigate stakeholder engagement with the RASFF. First, comparative trend analysis regarding the subject and frequency of notifications is carried out. Second, the impact of the adoption of the EU horizontal food law framework on RASFF engagement levels of food supplement market stakeholders is assessed. The results indicate an imbalance concerning risk communication in relation to food supplement quality issues. The majority of RASFF notifications can be attributed to public entity controls. Food businesses' and consumers' engagements were found to be potentially less affected by the introduction of horizontal food law provisions than safety authorities. Additional empirical research is required to investigate further factors influencing the underlying structures of participation by the private sector in food risk communication.

Keywords

Food Supplements; Food Law; Food Quality; Hybrid Enforcement; RASFF; European Law

3.1 Introduction

The effective enforcement of European Union (EU) food law in general (Weber, 2018) and of the legal framework governing food supplements in particular has proven to be a persistent challenge within the European Union (Warda et al., 2024). Enforcement mechanisms in EU food law have been characterised as employing a hybrid approach, seeking to integrate both public and private enforcement tools. Within this model, public enforcement mechanisms are designed to incentivise self-regulation by food business operators (Purnhagen & Molitorisová, 2022). Consequently, the primary responsibility for compliance rests with private operators, while public authorities are tasked with overseeing and ensuring that these operators fulfil their obligations. Despite this hierarchical allocation of enforcement duties, previous research suggests that the efficacy of such public-private governance models in the realm of food safety depends substantially on the active engagement of all relevant stakeholders (Camanzi et al., 2019; Kowalska & Manning, 2022).

Drawing from this body of literature, the study hypothesises that successfully implementing the EU's food law enforcement paradigm requires the meaningful participation of all stakeholders involved in food law enforcement. In order to assess this hypothesis, the study first undertakes a doctrinal analysis to examine the structural and normative underpinnings of the hybrid enforcement model as it pertains to ensuring quality and safety within the food supplements sector. Subsequently, the study conducts an empirical secondary data analysis of stakeholder engagement with food law enforcement, using the food supplements market as a case study and drawing on data from the Rapid Alert System for Food and Feed (RASFF).

The empirical component consists of two parts. First, it analyses the subject matter and frequency of RASFF notifications concerning food supplements between 2003 and 2022, in relation to their legal bases. Second, it evaluates the impact of EU food safety legislation applicable to food supplements on both public authorities and private operators. In particular, it conducts a comparative trend analysis of reported quality defects during two distinct regulatory periods: (i) the period of active regulatory development (2003–2014), which includes the introduction of the current primary legal framework, and (ii) the subsequent, comparatively less active legislative period (2015–2022). The analysis relies on secondary statistical data to assess trends and draw conclusions regarding stakeholder engagement.

Previous studies have leveraged the RASFF database to investigate trends and correlations in various aspects of food safety. Alshannaq & Yu (2021) investigated notification patterns of mycotoxin contamination of nut products. Leo et al. (2021) tested the relationship between the notifications' origin and other variables of RASFF notifications concerning food contact materials. The researchers further investigated the effect of EU legislation regulating the use of food contact materials by observing notification trends in the RASFF database. A comparable approach was conducted by Pádua et al. (2019), who investigated the impact of food allergen regulation by comparing notification levels pre- and post-adoption of applicable EU food laws. While using RASFF analyses for risk-prediction of future food hazards is disputed, it was demonstrated to be suitable in the context of representative post-analysis of measuring legislative impact via trend developments (Kowalska & Manning, 2021; Pigłowski, 2020). Regarding food supplements, Costa et al. (2019) presented an overview of contaminations and pharmaceutical compounds notified in the RASFF between 1998 and 2018. Other studies analysed the adulteration of supplements with pharmaceutical ingredients, as reported in the RASFF (Czepielewska et al., 2018). Kowalska & Manning (2022) analysed RASFF notifications to investigate the role of the private sector within the EU's hybridised approach of ensuring food safety on the example of fumigation with ethylene oxide. However, studies investigating public and private entities' roles in reporting detected quality issues of supplements on the EU market are largely missing.

3.2 Methodology

3.2.1 The method of doctrinal legal analysis

Doctrinal legal analysis aims to facilitate the understanding and interpretation of the current state of a law or legal system (Hutchinson, 2015). It primarily relies on collecting primary legal sources such as case law and legislative texts to be subjected to conceptual analysis (Taekema, 2018). However, secondary sources such as legal textbooks or scientific research articles may be included in the analysis to increase the depth of the research on a legal system pertaining to a specific socio-legal issue (Hutchinson, 2015). As doctrinal legal analysis primarily focuses on interpreting principles and underlying norms of a legal system, interdisciplinary synthesis with other methodological approaches, such as empirical research, has been recommended to fully capture contextual nuances (Bhat, 2020; Hutchinson, 2015).

3.2.2 The method of secondary data analysis

Secondary data analysis is an empirical research method based on using an existing suitable dataset to address a new research question (Greenhoot & Dowsett, 2012). This method allows for leveraging on compilations of publicly available data, such as review articles, scientific experiment articles, or open-access electronic databases (Windle, 2010). It further enables researchers to access large samples for quantitative analysis, which otherwise would be difficult to obtain (Greenhoot & Dowsett, 2012). Therefore, the approach of secondary analysis of data obtained from public databases as a research method has been well-established in other fields, such as epidemiological or public health studies (Greenhoot & Dowsett, 2012; Windle, 2010).

Although investigators performing a secondary data analysis were not involved in the primary data collection, it is possible to follow a structured approach to carefully interpret the data to gather new scientific insights (Greenhoot & Dowsett, 2012; Williams & Shepherd, 2015). However, a certain degree of data development and conversion is necessary in order to prepare the data set for the researchers' needs (Williams & Shepherd, 2015).

3.2.3 Study period

While the establishment of the EU food law pertaining to supplements began in 2002, notifications of food supplements, specifically, including information on their notification basis, commenced in 2003. Given that the absence of notification basis information served as an exclusion criterion, notifications from 2002 were not incorporated into the analysis. Nevertheless, the timeframe from 2003 to 2022 encompasses the implementation of secondary legislation pertaining to food supplements introduced from 2004 onwards. It also

encompasses the EU's enlargement processes initiated in 2004, thereby mitigating potential fluctuations in notifications stemming from structural changes (Kowalska & Manning, 2021).

3.2.4 Data extraction

All notifications on food supplements are placed in the “dietetic foods, food supplements, and fortified foods” category of the iRASFF web portal. Notifications of this category from 1 January 2022 until 31 December 2022 were obtained from the iRASFF website via download in .xls format. Due to maintenance issues, prior notifications were inaccessible through the iRASFF website. Instead, RASFF notification data sets from 1st January 2002 to 31st December 2020, and 1st January to 31st December 2021 were obtained from the European data portal data.europa.eu under the search term “RASFF” via download in .xls format. In total, 5208 notifications were extracted on the 2nd May 2023. European legislative texts were retrieved from the EUR-Lex database.

3.2.5 RASFF Notifications

RASFF notifications contain the following information: Numerical Identifier, Category, Notification Basis, Subject, Notifying Country, Country of Origin, Risk Classification, Product Type, Action Taken, Distribution Status, Hazard Category, Substance/Finding.

3.2.6 Data preparation

The RASFF “dietetic foods, food supplements, and fortified foods” category also contains notifications on product types other than food supplements. Therefore, notifications on subjects not dealing with food supplements were removed from the dataset. Terms considered not matching supplement notifications were: “Baby food”, “infant formula”, “milk powder”, “dietetic foods”, “energy drink”, “follow-on formula”, “tube nutriment”, “instant food”, “baby milk”, “low-calorie sweetener”. In total, 422 notifications matched these terms and were subsequently excluded.

Supplement notifications containing multiple product issues but only listed for one subject were divided into individual notifications on each issue to obtain a better representation of product defects (see Postolache et al., 2020). Thereby, the number of notifications grew by 240 to 5026 in total. Twenty-seven notifications from 2002 and two from 2003 contained no information on the notification basis and were excluded. 4997 notifications remained in the data set.

Notification basis refers to the stakeholder who first detected a product defect and reported it to the responsible local safety authority. As performed in other RASFF analyses (compare Pádua et al, 2019), the research team re-categorised the notification bases listed in the dataset to represent the three stakeholder groups, namely authorities, companies, and consumers,

more effectively. Border controls, monitoring of media, and official controls were allocated to Authority Control. Consumer complaint and food poisoning were allocated to Consumer Warning. Company's own check was renamed to Company Check. In total, three notification bases remained.

To make reported product defects more accessible to our analysis, streamlining the pre-determined hazard categories was necessary (compare Padúa et al., 2019). Depending on the notifications' subject, the research team placed all notifications in one of the following categories: Adverse Reaction, Authorisation, Bioactive Substance, Chemical Contaminant, Dosage: Bioactive Ingredient, Dosage: Minerals & Vitamins, Food Additive, GMO, Heavy Metal, Herbal, Microbial Contaminant, Mineral & Vitamins, Novel Food: Bioactive Substance, Novel Food: Herbal, Organoleptic Issue, Other Substance, Pesticide, Pharmaceutical, Radiation, Toxin, Undeclared Allergen.

3.2.7 Data analysis

Descriptive statistical analysis was performed to investigate the development of notifications placed in the RASFF from 2003 to 2022. Characteristics examined in this study were the distribution of notification bases in relation to the notifying countries, risk category, the notifications' subjects, and their assigned hazard categories.

Interferential statistical analysis was performed to determine correlations between the development of notifications on food supplements placed in the RASFF and the adoption of EU food safety legislation applicable to food supplements. Bivariate linear regression was performed to determine growth rates of the total food supplement notifications and each individual notification basis. One-sample *t*-test was performed to investigate the significance of growth rates, one-sample *F*-test was performed to test for variability. R-squared (R2) was calculated to test the strength of the relationship between the analysed data and the linear model. The level of significance was set as $\alpha = 0.05$ for all tests. For each group, the analysis was performed for the periods from 2003 to 2014 and 2015 to 2022. Group sizes are depicted in Table 1. Two outliers were identified in the entire data set based on the confidence band around the bilinear model used. They were replaced by the mean response value calculated by performing one-way ANOVA.

All calculations were conducted using JMP® software (Version 16.1; SAS Institute Inc., 2023). Descriptive analysis was performed by using Microsoft Excel (Version 2019, Microsoft Corporation, 2019).

3.2.8 Limitations

The study's main limitation may be related to the source of the baseline data. The source data were exclusively extracted from the RASFF database, meaning that the National Contact Points (NCPs) and the European Commission approved the notifications. However, some studies report that not every problem identified can be reported to the RASFF database. (D.'Amico et al., 2018; Leo et al., 2021). Member States also have different levels of engagement with the RASFF (Lorenzen et al., 2021). In some instances, identical notified product issues were placed into different hazard categories depending on the notifying RASFF network member, potentially impacting the study results. A comparison of reported issues with available products on the market is not possible, as no reliable details are publicly available.

3.3 Results

3.3.1 Doctrinal analysis: EU food law's hybrid enforcement model and the driving factors to meet quality and safety in the food supplement market

In EU law, food supplements are considered "food" (Regulation (EC) No 178/2002, General Food Law or GFL). They are defined in Directive 2002/46/EC as concentrated nutrients in a pre-dosed form (Directive 2002/46/EC, 2002, Food Supplement Directive). In response to several food crises, the Commission articulated in its white paper published in 2000 a strategy to increase food chain transparency and improve consumer protection by adopting a new preventive regulatory framework which attributes safe food production to the private sector. Following this, the EU has adopted a range of horizontal food safety laws that are also applicable to food supplements. These concern food hygiene (Regulation (EC) No 852/2004), health claims (Regulation (EC) No 1924/2006), restricted ingredients (Regulation (EC) No 1925/2006), novel foods (Regulation (EU) 2015/2283), food additives (Regulation (EC) No 1333/2008), or limits for pesticide residues (Regulation (EC) No 396/2005) and contaminants (Commission Regulation (EC) No 1881/2006, repealed by Regulation (EU) 2023/915). As the majority of this new safety framework was completed by 2014, the EU's focus shifted towards a less legally active period beginning from 2015 onwards, which focused primarily on enforcement by national agents and European Court (ECJ) case law (van der Meulen, 2013; Weber, 2018).

To facilitate communication on foodborne risks between national food safety authorities, the European Commission and the European Food Safety Agency (EFSA), the current Rapid Alert System for Food and Feed (RASFF) was established after adopting the GFL in 2002 (Regulation (EC) No 178/2002, 2002). Stakeholders of the European food supplement market, including authorities, food companies, and consumers, may notify their national contact point regarding a defective product which has already entered the EU market. After evaluating and

validating a defect report, the responsible national authority notifies the Commission and the other network members via the RASFF about the issue. Each defect notification is classified as either an alert, information, or border rejection. Alert notifications are triggered in case a product represents a serious health risk to consumers and requires rapid action from authorities, such as market withdrawal or ordering recalls. Information notifications concern issues that are not an immediate threat, while border rejections concern food products that are prevented from entering the EU market upon inspection.

The enforcement mechanism of food safety law in the EU has been described as a hybrid one, including the public sector, represented by food safety authorities on one end, and the private sector, represented primarily by food business operators (FBOs), on the other (Purnhagen & Molitorisová, 2022; Weber, 2018). FBOs are obliged to meet and verify all requirements of applicable food law during all stages of production, processing, and distribution of food products. The GFL requires them to take enforcement measures already when the FBO "considers or has a reason to believe" that a foodstuff under its control is "not in compliance with the food safety requirements" (Art. 19 GFL). Further, the GFL also obliges FBOs to communicate foodborne risks to other authorities and consumers (Purnhagen & Molitorisová, 2022). If non-compliance with safety legislation is registered by themselves or another entity, FBOs must inform and collaborate with authorities immediately (Regulation (EC) No 178/2002, 2002). While FBOs must perform sufficient and continuous internal compliance controls themselves, public authorities are required to perform external controls of food businesses to ensure and monitor FBO compliance (compare Article 17 GFL). Regardless of the mode of its detection, authorities may issue product recalls, on-site inspections, and other punitive actions as corrective measures, depending on the extent and seriousness of a quality issue (Purnhagen & Molitorisová, 2022).

Previous research indicates that in public-private approaches to food safety governance, the active involvement of all stakeholders is crucial for the efficacy of such hybrid models (Camanzi et al., 2019; Kowalska & Manning, 2022). Literature also endorsed that sharing information on issues in the food supply chain between stakeholder groups is essential to maintaining food safety (Brooks et al., 2017; Kendall et al., 2019). The law (Art. 19 (3,4) GFL) and the judiciary (Federal Court of Justice, 2024) likewise stipulate such a "principle of cooperation" in food law enforcement. However, FBOs may exhibit a degree of rational apathy towards fulfilling their legal obligations due to concerns about potential financial or reputational risks associated with self-reporting compliance issues (Purnhagen & Molitorisová, 2022). Additionally, concerns about data confidentiality, distrust in competitors, and additional administrative work and costs may lead FBOs to further refrain from sharing information (Minnens et al., 2019). To a lesser extent, private enforcement of EU food law involves consumer claims. Due to the small claims

nature of most food claims and the related non-beneficial cost-benefit ratio for the individual consumer of bringing such a claim to court or notifying competent authorities, the onus of such claims or notifications is on representative actions of consumer organisations (Purnhagen & Molitorisová, 2022). This presents an obstacle to the European public-private approach to enforcing food safety law, which relies inter alia on all market stakeholders having an interest in participating in sharing such information via suitable risk communication networks (Brooks et al., 2017).

The RASFF represents a vital tool for sharing such information between stakeholders, although notifications in the RASFF pertain only to issues of products which have already entered the market (Pigłowski, 2020). However, food supplements have consistently ranked among the most frequently notified product categories within the RASFF for several years, with the second-highest total number of RASFF notifications recorded in 2022 (European Commission, 2023; Manning et al., 2022). Safety issues such as microbial and chemical contamination or adulteration with pharmaceuticals and other unauthorised ingredients remained present with supplements on the EU market (Bandara et al., 2021; Gil et al., 2021; Gurley et al., 2022; White, 2020). Against an increased interest in consumption, ensuring consumer access to supplements of high quality and safety, therefore, continues to be significant (Arlauskas et al., 2022; Skotnicka et al., 2021).

3.3.2 Secondary data analysis of RASFF notifications

3.3.2.1 RASFF notifications by stakeholders

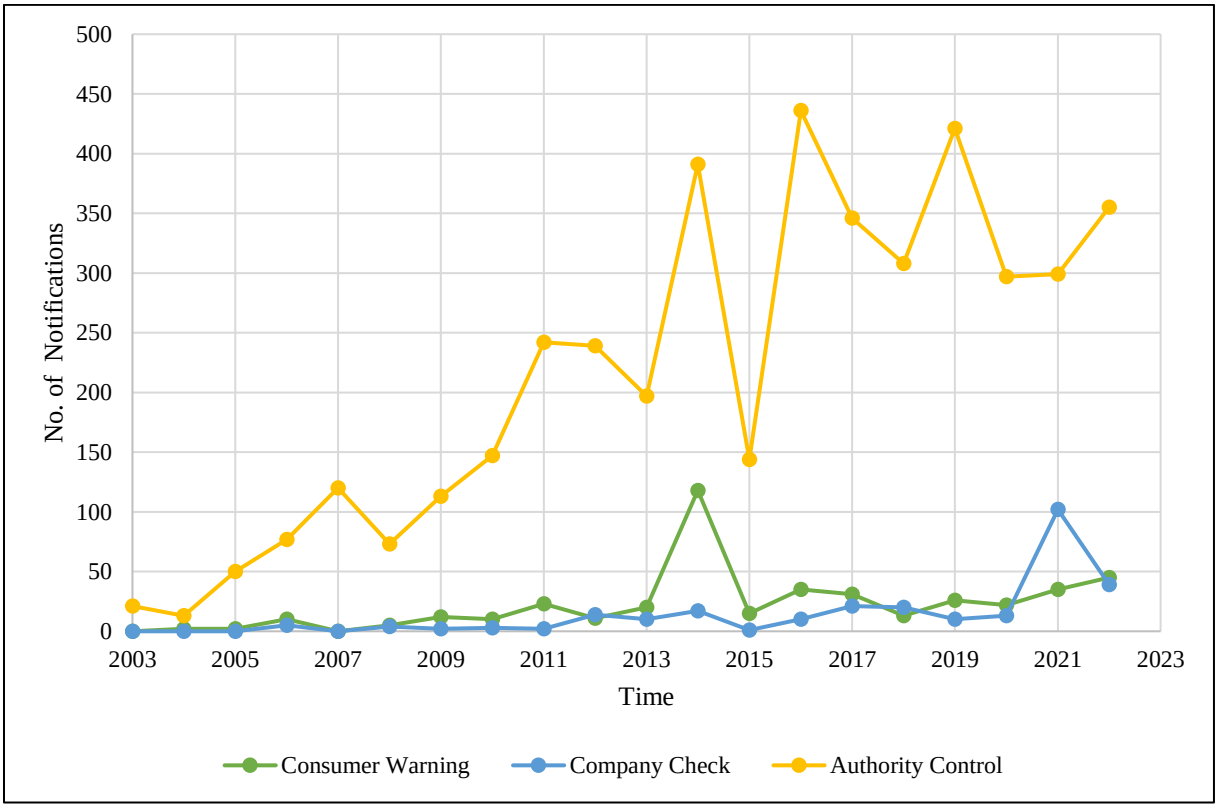

Fig. 1 Distribution of food supplement notifications from 2003 to 2022 by consumer warning, company check, and authority control

From 2003 to 2022, 4997 notifications on food supplements were placed in the RASFF. Of these, a majority of 4289 (85.8%) were based on authority controls. 273 (5.46 %) were based on company checks, and 435 (8.71%) were based on consumer warnings. Although notifications from all bases have increased during the observed study period, Fig. 1 shows that notifications were consistently more often based on authority controls than company checks or consumer warnings. Furthermore, while an increase in notifications can be observed from 2003 to 2014, Fig. 1 shows that it reached a comparatively stable level between 2015 and 2022.

Authority control-based notifications were placed into the RASFF by all Member States. However, most of the notifications were documented by German authorities (n = 837), followed by Poland (n = 367), Sweden (n = 345), and Finland (n = 249). The highest number of company check-related notifications came from the Netherlands (n = 68) and Germany (n = 59). Most consumer warning-based notifications originated from Lithuania (n = 164), Germany (n = 50), and Sweden (n = 40). Table 1 shows an overview of the frequency of notifications by the eight

most active Member States per stakeholder and in total. A summary containing all observed Member States is provided in Supplementary Material 1.

	Authority Controls	Company Check	Consumer Warning	Total
Germany	837	59	50	946
Sweden	345	11	40	396
Poland	367	8	2	377
Finland	249	1	9	259
Czech Republic	223	0	14	237
United Kingdom	204	19	9	232
Belgium	178	34	14	226

Table 1 Occurrence of RASFF notifications on food supplements (2003 – 2022) in the eight most active countries by stakeholder.

Considering the notifications' risk category, the majority of notifications were classified as information notifications (n = 2824), which do not require immediate action from concerned safety authorities. Still, 1662 notifications were flagged as alerts, implying a foodborne hazard to which responsible authorities should rapidly respond. 511 notifications were border rejections stemming from products of insufficient quality detected by authorities at the EU border entry. Again, German authorities reported the most notifications concerning information and alert RASFF signals. Other notable contributors to alerts were Sweden, the Netherlands, France, Belgium, and the Czech Republic. Sweden, Poland, and Lithuania were also major contributors to information signals.

3.3.2.2 RASFF notifications by hazard categories

As shown in Fig. 2, with a total of 1159, the highest number of RASFF notifications concerned the adulteration of food supplements with pharmaceutical ingredients. While authorities detected 1088 cases of drug adulteration, 59 were based on consumer complaints, and only 12 were first reported by companies. Underscoring the risk of unintentional consumption of undeclared pharmaceutical active ingredients, 513 notifications were placed as alert signals in the RASFF. In summary, while pharmaceutical adulteration scored the highest amount of all alert signals, it also scored the highest number of information signals (n = 518) and border rejections (n = 128).

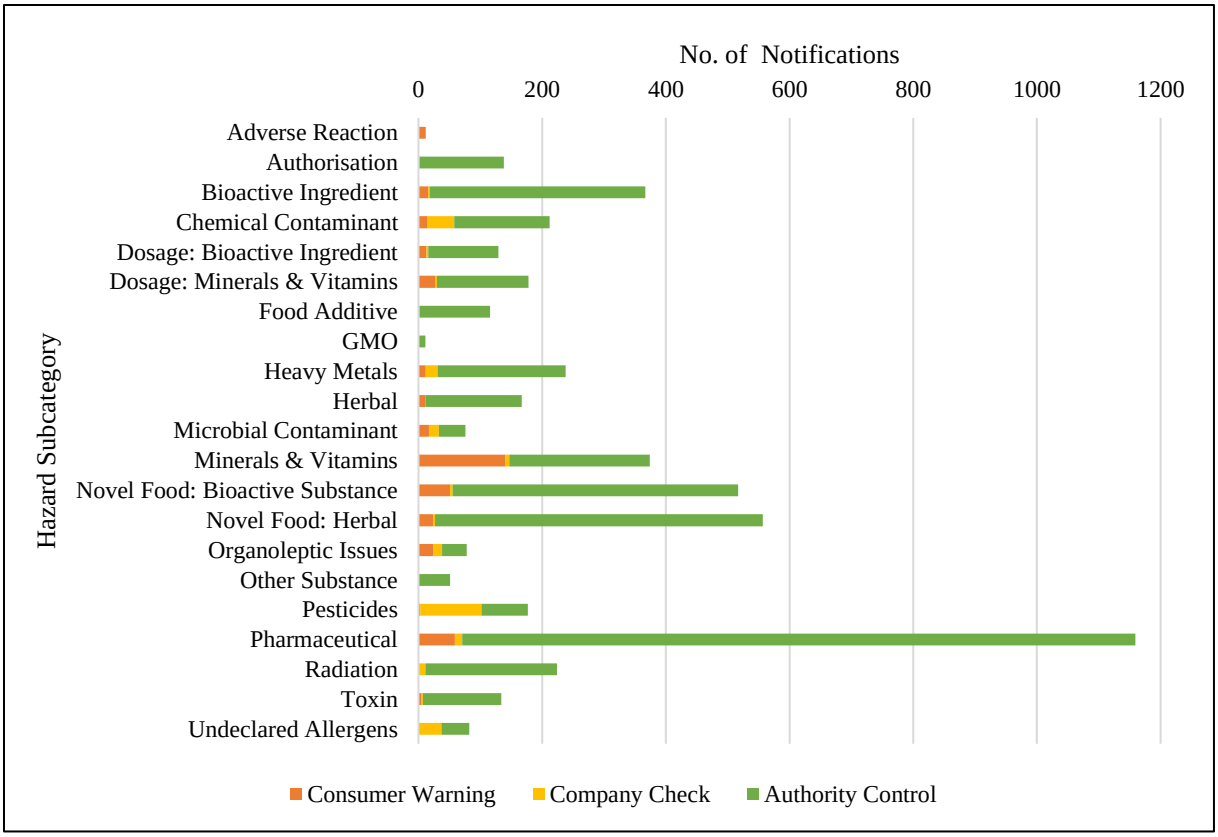

Fig. 2 Distribution of total supplement RASFF notifications across hazard categories per notification basis from 2003 to 2022

After pharmaceutical adulteration, the addition of unauthorised novel food ingredients to supplements was the most prevalent issue. Fig. 2 shows that herbal novel food notifications amounted to 551 signals, while bioactive substances considered novel foods reached 523. The number of alert signals indicating the need for immediate regulatory response remained comparatively low (Novel Food: Herbal: n = 49; Novel Food: Bioactive Substance: n = 67), while the majority was reported as information (Novel Food: Herbal: n = 423; Novel Food: Bioactive Substance: n = 454). Again, authorities first detected and reported most novel food-related issues, while companies only reported 3 and 4 notifications for herbals and bioactive substances, respectively.

Although contamination issues were registered to a lesser extent individually, the categorisation of a majority of them as alerts underscores the health risks associated with their consumption. For example, while 238 notifications concerned contamination with heavy metals, 207 of them were flagged as alerts. While companies reported product contamination more actively than other quality-impairing defects, such as the addition of unauthorised ingredients, authorities identified more issues throughout almost all categories. An exception would be reporting pesticide residues, as companies reported 99 issues versus 75 by

authorities. However, companies reported only two cases of toxin contamination and 11 cases of illegal food radiation, whereas authorities identified 127 and 213 of these issues.

An overview of the reported issues, the relation between hazard categories and notification bases, and notification types and risk categories is provided in Supplementary Materials 2 – 4.

3.3.2.3 RASFF notifications per individual issues

Most often identified were prescription agents used for the treatment of erectile dysfunction, like phosphodiesterase-5 (PDE-5) inhibitors (n = 352) (e.g. sildenafil, tadalafil, and derivatives thereof) and yohimbine (n = 145). Sympathomimetic drugs are often used in supplements as adulterants intended to enhance athletic performance or increase weight loss. Among such identified stimulants were aliphatic amines (n = 177) (e.g. dimethylamylamines, octopamine, oxilofrin), phenylethylamines (n = 128) (e.g. amphetamine, ephedrine, synephrine), 2,4-dinitrophenol (n = 114), and vinpocetine (n = 47). Other identified adulterants typically used for increasing weight loss were the appetite suppressant sibutramine or the laxative phenolphthalein. An overview of all pharmaceutical adulterants is provided in Supplementary Material 2. The unauthorised addition of bioactive novel food ingredients mainly concerns agmatine sulphate (n = 154) and cannabidiol (CBD) (n = 159). In the case of herbal novel foods, a large variety of unlawfully added ingredients were reported in the RASFF. However, most notifications concerned the addition of *Epimedium ssp.* (n = 94), *Hoodia gordonii* (n = 72), and *Acacia rigidula* (n = 30).

Table 2 shows that among the five most reported issues, two pharmaceuticals (sildenafil and yohimbine) and two bioactive novel foods are represented, further underscoring the significance of the two hazard categories in relation to supplement adulteration. However, the quality issue most often reported was the identification of traces of unlawful or undeclared irradiation. It is most likely related to the exposure of raw ingredients to ionising radiation due to its antimicrobiological effects in phytosanitation. Although food irradiation is legal and regulated by Directive 1999/1/EC and Directive 1999/2/EC its use is uncommon in the EU, primarily due to consumer concerns (Ehlermann, 2016).

Notification Subject	Alert	Information	Border Control	Total
Irradiation	32	134	58	224
Sildenafil	144	43	25	212
Cannabidiol (CBD)	22	135	2	159
Agmatine sulphate	10	145	0	155
Yohimbine	49	7	89	145

Table 2 Five most common food supplement quality issues reported in the RASFF (2003 – 2022) by risk category and in total.

3.3 Food safety legislation impact on reporting quality incidents with the RASFF by food supplement market stakeholders

During the study period from 2003 to 2022, several horizontal food safety acts applicable to food supplements have been adopted in the EU. Notably, these regulations concerned food hygiene, food contamination, the use of health claims, fortified foods, food additives, and food information. While Regulation (EC) No 258/97 has been in place before, the updated Novel Food Regulation was first adopted in 2015 and has been fully enacted since 2018 (Regulation (EC) No 258/97, Regulation (EU) 2015/2283). While changes such as a streamlined approval procedure or the amended definition of novel foods were applied immediately, a transitional period for business operators and stakeholders to adjust accordingly was implemented. Therefore, the study period can be segmented into a regulatory expansion period from 2003 to 2014 and a legislative consolidation period between 2015 and 2022. The sample sizes of the different study groups for each period are shown in Table 3.

Stakeholder	2003 – 2014	2015 – 2022
Authority Control	1683	2606
Company Check	57	216
Consumer Warning	213	222
Total	1953	3044

Table 3 Number of food supplements RASFF notifications per stakeholder.

Bivariate linear regression analysis was performed to investigate whether these periods are reflected in the RASFF database and how stakeholders have reacted to the legal developments. The results regarding the trend analysis of notifications in total and for the stakeholders' safety authorities, FBOs, and consumers are depicted in Fig. 3.

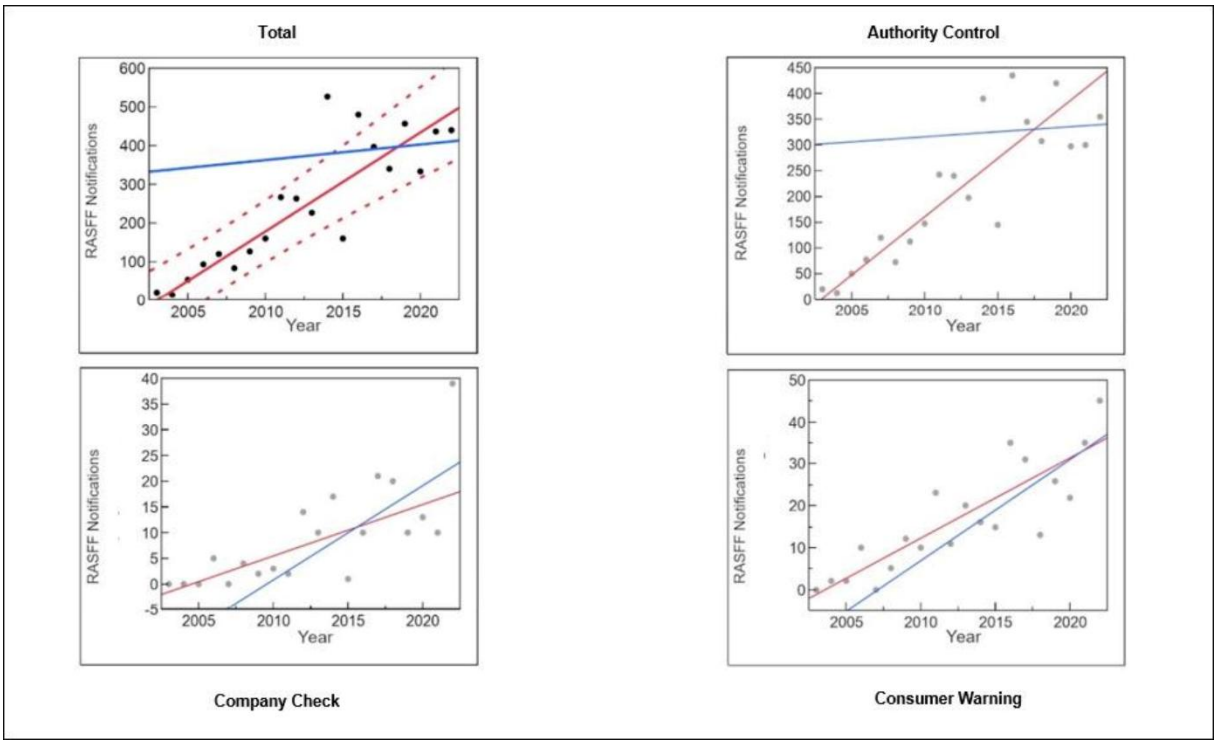

Fig. 3 Relation between the adoption of horizontal food safety legislation pertaining to food supplements and active engagement of food supplement stakeholders, expressed by the annual number of RASFF notifications (dots) during the study periods 2003 – 2014 (red line) and 2015 – 2022 (blue line)

The first indicator of food supplement notification trends correlating with the regulatory expansion (2003 - 2014) and the consolidation period (2015 - 2022) can be observed from the total number of notifications. In the first period, an annual average of 129.7 notifications was reported, while the annual increase of 25.6 notifications was significant ($p < 0.01$). The R^2 value of 0.88 indicates that time was a strong predictor of the increase in notifications, which followed a predictable pattern from 2003 to 2014. In contrast, while from 2015 to 2022 the average of 396.7 reported notifications was higher than in the previous period, the annual increase of 4.01 notifications from 2015 to 2022 was insignificant ($p = 0.80$). Additionally, the R^2 value of 0.01 suggests that time no longer meaningfully accounts for a predictable pattern, reflecting a shift from the observed linear growth in the first period, 2003 - 2014, to a plateau suggestive of saturation in the second period, 2015 - 2022.

The general trend of linear growth of RASFF notifications from 2003 to 2014, characterised by higher and significant growth rates and lower annual average reports, converting to high-level saturated plateaus from 2015 to 2022, continues for all three individual stakeholder groups. During both periods, most reported issues can be attributed to authorities, followed by consumer warnings and company checks, although both are at a much lower level. Authority controls as the primary source of RASFF supplement notifications also showed the highest

growth rates ($p < 0.01$), again followed by consumer warnings ($p < 0.01$) and then company checks ($p = 0.01$) at much lower levels. It should be noted that the average reported notifications and annual growth rates of notifications attributed to consumer warnings were nearly twice as much as company checks during both periods. R^2 values calculated for each subgroup showed a similar pattern as described for the total study population. However, while the decrease of R^2 from 0.53 to 0.22 for company checks and from 0.67 to 0.37 for consumer warnings suggests that the temporal trend weakened considerably, indicating a plateau being approached, the remaining variances indicate that a certain fluctuation persists in both groups. Table 4 shows an overview of all calculated average annual notifications, R^2 and *p*-values, and annual growth rates during both periods.

	2003 – 2014				**2015 – 2022**			
	$\bar{x}$	R^2	Δn	*p*	$\bar{x}$	R^2	Δn	*p*
Total	129.7	0.88	25.6	< 0.01	396.7	0.01	4.01	0.80
Authority Control	117.5	0.86	22.7	< 0.01	333.0	< 0.01	1.97	0.87
Company Check	3.64	0.53	1.00	0.01	15.7	0.22	1.83	0.20
Consumer Warning	8.64	0.67	1.91	< 0.01	26.4	0.37	2.42	0.08

Table 4 Bilinear regression analysis of RASFF food supplement notifications in 2003-2014 and 2015-2022. $\bar{x}$: mean annual value of notifications, Δn: annual growth rate of notifications, R^2: calculated R-squared value, *p:* calculated *p*-value.

3.4 Discussion

This study aimed to determine the extent of engagement of different stakeholder groups of the EU food supplement market with the RASFF. Further, the influence of introducing Union law from 2002 to 2014, implementing a safety and quality framework, has had on stakeholder engagement levels with the RASFF was subject to this research. The study results indicate that authorities are more active in reporting detected quality issues than companies or consumers. Furthermore, regional differences between Member States placing notifications into the RASFF have been identified. The analysis further highlighted that authorities could potentially be more strongly affected by the EU's supplement regulatory framework than other stakeholders. Underscoring the risks associated with consuming low-quality supplements, a significant number of notifications were considered alerts, while adulteration with pharmaceuticals has been reported the most.

The findings of this study, which indicate that a majority of notifications can be attributed to authority control, align with other RASFF analyses. Although aimed at investigating food contact material recalls, Leo et al. (2021) described a similar pattern, whereas only a fraction

of observed notifications were triggered by companies or consumers. D'Amico et al. (2018) attributed this to a tendency of national agencies not to report single or sporadic occurrences of quality defects. This, however, could represent an obstacle to ensuring food chain transparency. Considering that nearly a third of all observed notifications were flagged as alert signals further underscores the risk associated with low-quality supplements, where even small occurrence levels represent a serious hazard. In this regard, the identified drug adulteration is especially concerning, as the unintentional or unsupervised consumption of prescription drugs can have serious consequences for consumer health. The addition of pharmaceuticals which have been banned even from the EU medicines market, such as sibutramine, 2,4-dinitrophenol, or phenolphthalein, further increases these risks.

The linear trend of increasing RASFF notifications from 2003 to 2014 correlates with the adoption of secondary EU food safety laws applying to food supplements. During this study period, the Food Hygiene Regulation in 2004, the Food Pesticides Regulation in 2005, Food Contamination, Health Claims, and Fortified Foods Regulation in 2006, Food Additives Regulation in 2008 and the Food Information Regulation in 2011 were adopted (Thakkar et al., 2020). This increase in RASFF notifications is in line with other research, which described an increase concerning different food products following the adoption of food safety laws (Leo et al., 2021; Pádua et al., 2019). Nogales et al. (2023) also identified a connection between the adoption of stricter food policies and a greater increase in notifications. The results of this study further supported the hypothesis by illustrating stagnation at a high level during a period of regulatory consolidation, where only a few additional regulations were adopted.

The reported R^2 value of 0.88 of the total notifications group in the first observation period indicates that time explained for 88% of the variance in RASFF notifications. This supports the assumption that the annual growth rates are connected to the adoption of food safety laws in this period. The subgroup of authority controls demonstrated a similar R^2 value ($R^2 = 0.86$), indicating a strong model fit as well. However, the reported R^2 values for the subgroup of company checks ($R^2 = 0.53$) and consumer complaints ($R^2 = 0.63$) indicate that factors other than time may have influenced notifications from these groups.

As mentioned, authorities do not necessarily report every detected issue to the RASFF, which could have influenced the data analysis (Leo et al., 2021). Additionally, previous research has described that despite the risk of punitive action from authorities, companies may exercise rational apathy in communicating quality defects due to fear of financial or reputational repercussions (Purnhagen & Molitorisová, 2022). Meanwhile, consumers may choose not to report quality defects due to legal costs or the perceived small claims nature of the issue (Purnhagen & Molitorisová, 2022). However, the data derived from the RASFF is limited in accounting for these additional factors during linear regression analysis.

The regional differences in reporting product issues via the RASFF also align with other research. Warda et al. (2024) described a legal fragmentation concerning the regulation of food supplement ingredients at the Member States' level due to missing harmonisation efforts, which also transposes into regulatory practices by authorities. The leading national food safety authorities are also usually the Member States' RASFF contact points, which function as a gateway by deciding which issues are notified in the system. Hence, differing legal cultures and fragmentation of legal systems could have influenced notification patterns (D'Amico et al., 2018). Other factors, such as market sizes or resources and structures of different national safety authorities, could also have impacted the identified regional fragmentation of RASFF notifications. For example, Czepielwska et al. (2018) described Germany as the primary contributor to food supplement drug adulteration notifications. This was linked to the country hosting the largest supplement market and being a main entrance point to the EU. At the same time, German authorities have specialised units actively monitoring the online sale of potentially hazardous products. As this study also identified Germany as the top notifier, these findings could also apply.

It has been argued that the RASFF database analysis may be subject to an internal bias. In contrast, FBOs report only a few issues simply due to a generally high compliance level (Lorenzen et al., 2021). However, the findings, whereas authority controls report the majority of issues, align with other RASFF analyses investigating various aspects of food safety in the EU. Furthermore, all issues that have been identified originate from products that were already on the market and, therefore, should have been subject to sufficient quality control procedures. As mentioned in Section 2.5, using the RASFF database is subject to several limitations, such as miscategorisation of issues or different regional activity levels.

3.5 Conclusion

This analysis highlights an imbalance between stakeholders of the EU supplement market concerning their engagement levels in the RASFF for reporting detected quality issues. Authority controls primarily triggered the placement of notifications into the RASFF. This could indicate an underrepresentation of the private sector in sharing information on foodborne hazards related to supplements, which is considered a vital aspect of the EU's hybridised food safety governance approach. Statistical analysis further illustrated that adopting additional horizontal food safety laws has significantly influenced authorities to report issues more actively than the private sector. The importance of active participation in sharing such information is underscored by the identified number of alert signals and types of issues representing serious challenges to food chain integrity. Therefore, the objective of this study to obtain insights on the effective employment of the EU's hybrid enforcement paradigm by investigating the participation levels of relevant stakeholders of the European food supplement

market with the RASFF risk communication network has been met. Additional empirical research might provide further insights on how to accelerate the engagement of the private sector in food risk communication.

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3.7 Annex

3.7.1 Supplementary Material 1

The role of the public and private sectors in the EU hybrid safety governance of food supplements – A study on the example of quality issues notified in the RASFF

RASFF notifications from 2003 - 2022 on food supplements quality issues by notifying country per notification basis authority control, company check, and consumer warning.

	Notification Basis		
Notifying Country	**Authority Control**	**Company Check**	**Consumer Warning**
AUSTRIA	78	1	5
BELGIUM	178	34	14
BULGARIA	7	1	2
CROATIA	30	2	0
CYPRUS	127	0	1
CZECH REPUBLIC	223	0	14
DENMARK	177	14	24
ESTONIA	41	0	1
EUROPEAN COMMISSION	5	0	1
FINLAND	249	1	9
FRANCE	129	12	8
GERMANY	837	59	50
GREECE	6	0	0
HUNGARY	100	0	6
ICELAND	1	2	0
IRELAND	89	0	4
ITALY	115	8	27
LATVIA	95	3	0
LITHUANIA	140	5	164
LUXEMBOURG	45	2	0
MALTA	47	0	3
NORWAY	123	4	12
POLAND	367	8	2
PORTUGAL	60	1	1
ROMANIA	23	1	2
SLOVAKIA	52	0	1
SLOVENIA	78	6	4
SPAIN	173	9	14
SWEDEN	345	11	40
SWITZERLAND	63	2	4
THE NETHERLANDS	82	68	13
UNITED KINGDOM	204	19	9

3.7.2 Supplementary Material 2

The role of the public and private sectors in the EU hybrid safety governance of food supplements – A study on the example of quality issues notified in the RASFF

RASFF notifications from 2003 - 2022 on food supplements quality issues by identified individual issues per assigned hazard category.

The data set is shown on the following pages.

	Subcategory																				
Issue	Adverse Reaction	Authorisation	Bioactive Substance	Dosage: Bioactive Substance	Dosage: Minerals & Vitamins	Food Additive	GMO	Heavy Metals	Herbal	Chemical Contaminants	Microbial Contaminant	Minerals & Vitamins	Novel Food: Bioactive Substance	Novel Food: Herbal	Organoleptic Issues	Other Substance	Pesticide	Pharmaceutical	Radiation	Toxin	Undeclared Allergen
p35S and tNos papaya powder	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0
1,2-Dimethyl-aminoethanol (1,2-DMAE)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0
1,2-Dimethylbutyl-amine (1,2-DMBA)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	2	0	0	0
1,3-Dimethyl-aminoethanol (1,3-DMAE)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	2	0	0	0
1,3-Dimethylamylamine (1,3-DMAA)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	119	0	0	0
1,3-Dimethylbutyl-amine (1,3-DMBA)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	19	0	0	0
11-Hydroxy-yohimbine	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0
2,4-Dinitrophenol (DNP)	0	4	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	110	0	0	0
2-Amino-4-Methylheptane (2,4-DMHA)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0
2-Amino-6-Methylheptane (DMHA)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	11	0	0	0
2-Aminoisoheptane	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0
2-Dimethylamino ethanol (2-DMAE)	0	0	0	0	0	0	0	0	0	0	0	0	16	0	0	0	0	0	0	0	0
2-Hydroxyisocaproic Acid (HICA)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	2	0	0	0
2-Chloroethanol	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	62	0	0	0	0
3,3'-Diindolyl-methane (DIM)	0	0	0	0	0	0	0	0	0	0	0	0	18	0	0	0	0	0	0	0	0
3-Monochlor-1,2-Propanediol (3-MCPD)	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0
4,9-Estradien -3,17-Dione	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0
4-Hydroxy-isoleucine	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0
5-alpha-Hydroxy-Laxogenin	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0
5-Hydroxy-Tryptophan	0	0	0	0	0	0	0	0	0	0	0	0	20	0	0	0	0	0	0	0	0
7,17-Dimethyl-testosterone	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0
Acacia rigidula	0	0	0	0	0	0	0	0	0	0	0	0	0	30	0	0	0	0	0	0	0
Acanthopanax senticosus	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0
Acetamiprid	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0
Acetildenafil	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	4	0	0	0
Acetyl-L-Carnitine	0	0	4	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Adansonia digitata	0	0	0	0	0	0	0	0	0	0	0	0	0	2	0	0	0	0	0	0	0
Additive (E171)	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Additives (unspecified)	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Adenophora root	0	0	0	0	0	0	0	0	0	0	0	0	0	3	0	0	0	0	0	0	0
Adulteration (unspecified)	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Adverse Reaction (unspecified)	12	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Aegeline	0	0	0	0	0	0	0	0	0	0	0	0	7	0	0	0	0	0	0	0	0
Aegilops ssp.	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0
Agaricus blazei	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0
Agmatine sulphate	0	0	1	0	0	0	0	0	0	0	0	0	154	0	0	0	0	0	0	0	0
Achyrantes bidentata	0	0	0	0	0	0	0	0	0	0	0	0	0	2	0	0	0	0	0	0	0
Achyranthes aspera	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0
Aloe vera	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0
Aloin	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
alpha-Glyceryl-phosphoryl-choline	0	0	9	0	0	0	0	0	0	0	0	0	9	0	0	0	0	0	0	0	0
alpha-Lipoic Acid	0	0	7	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Aluminium	0	0	0	0	7	0	0	7	0	0	0	0	0	0	0	0	0	0	0	0	0
Amaranthus cruentus	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0
Ambrosia artemisiifolia	0	0	0	0	0	0	0	0	0	0	0	0	0	2	0	0	0	0	0	0	0
Amphetamine	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0
Amygdaline	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	4	0
Anabolic-Androgenic Steroids	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	2	0	0	0
Androstenedione	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	10	0	0	0
Angelica sinensis	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0
Annona muricata	0	0	0	0	0	0	0	0	0	0	0	0	0	6	0	0	0	0	0	0	0
Anthraquinone	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Antimony	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0
Aqua Armeniacae	0	0	0	0	0	0	0	0	0	0	0	0	0	2	0	0	0	0	0	0	0
Areca catechu	0	0	0	0	0	0	0	0	2	0	0	0	0	0	0	0	0	0	0	0	0
Arecoline Hydrobromide	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Arginine alpha-ketoglutarate	0	0	18	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

	Subcategory																				
Issue	Adverse Reaction	Authorisation	Bioactive Substance	Dosage: Bioactive Substance	Dosage: Minerals & Vitamins	Food Additive	GMO	Heavy Metals	Herbal	Chemical Contaminants	Microbial Contaminant	Minerals & Vitamins	Novel Food: Bioactive Substance	Novel Food: Herbal	Organoleptic Issues	Other Substance	Pesticide	Pharmaceutical	Radiation	Toxin	Undeclared Allergen
Arginine ethyl-ester	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Arginine malate	0	0	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Arginine nitrate	0	0	4	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Arginine pyroglutamate	0	0	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Argyreia nervosa	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0
Aristotelia chilensis	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0
Arsenic	0	0	0	0	0	0	0	41	0	0	0	0	0	0	0	0	0	0	0	0	0
Artemisia annua	0	0	0	0	0	0	0	0	0	0	0	0	0	19	0	0	0	0	0	0	0
Artemisinin	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Asparagus racemosus	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0
Asparagus sarmentosus	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0
Atractylodes macrocephala	0	0	0	0	0	0	0	0	0	0	0	0	0	2	0	0	0	0	0	0	0
Atropine	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0
Avanafil	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0
a-Yohimbine	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Azadirachta indica	0	0	0	0	0	0	0	0	0	0	0	0	0	2	0	0	0	0	0	0	0
Bacillus cereus	0	0	0	0	0	0	0	0	0	0	16	0	0	0	0	0	0	0	0	0	0
Bacterial Contamination (unspecified)	0	0	0	0	0	0	0	0	0	0	9	0	0	0	0	0	0	0	0	0	0
Barley	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1
Bauhinia purpurea	0	0	0	0	0	0	0	0	0	0	0	0	0	6	0	0	0	0	0	0	0
Bee venom	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0
Beef Bile	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0
Benzalkonium chloride (BAC)	0	0	0	0	0	0	0	0	0	16	0	0	0	0	0	0	0	0	0	0	0
Benzethonium chloride	0	0	0	0	0	0	0	0	0	25	0	0	0	0	0	0	0	0	0	0	0
Benzo(a)pyrene	0	0	0	0	0	0	0	0	0	68	0	0	0	0	0	0	0	0	0	0	0
Benzocaine	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0
Benzoic acid	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Berberine	0	0	4	0	0	0	0	0	0	0	0	0	3	0	0	0	0	0	0	0	0
Bergenin	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
beta-Alanine	0	0	31	0	0	0	0	0	0	0	0	0	2	0	0	0	0	0	0	0	0
beta-Asarone	0	0	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
beta-Carboline Alkaloids	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0
Betaine	0	0	1	0	0	0	0	0	0	0	0	0	22	0	0	0	0	0	0	0	0
Beta-Methylphen-ethylamine	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0
Beta-Phenylethylamine	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0
Beta-Phenylmethylamine	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	4	0	0	0
Black Cohosh	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0
Boerhavia diffusa	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0
Bombyx mori	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0
Boron citrate	0	0	0	0	0	0	0	0	0	0	0	20	0	0	0	0	0	0	0	0	0
Boron glycinate	0	0	0	0	0	0	0	0	0	0	0	2	0	0	0	0	0	0	0	0	0
Boron chelate	0	0	0	0	0	0	0	0	0	0	0	7	0	0	0	0	0	0	0	0	0
Bovine colostrum concentrate	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0
Brahmi (Bacopa monnieri)	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0
Bromelain	0	0	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Bt 63 organic rice protein powder	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Bulbine natalensis	0	0	0	0	0	0	0	0	0	0	0	0	0	2	0	0	0	0	0	0	0
Butea superba	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0
Cadmium	0	0	0	0	0	0	0	13	0	0	0	0	0	0	0	0	0	0	0	0	0
Caffeine	0	0	1	73	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Caffeinemaleate	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0
Calcium amino acid chelate	0	0	0	0	0	0	0	0	0	0	0	2	0	0	0	0	0	0	0	0	0
Calcium caprylate	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0
Calcium Potassium phosphate-citrate	0	0	0	0	0	0	0	0	0	0	0	9	0	0	0	0	0	0	0	0	0
Calea zacatechichi	0	0	0	0	0	0	0	0	2	0	0	0	0	0	0	0	0	0	0	0	0
Canavalia gladiate	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0
Cannabidiol (CBD)	0	0	0	0	0	0	0	0	0	0	0	0	159	0	0	0	0	0	0	0	0
Cetyl myristate	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0
Ciprofloxacin	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0
Cirsium oligophyllum	0	0	0	0	0	0	0	0	0	0	0	0	0	6	0	0	0	0	0	0	0
Cissus quadrangularis	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0
Cistanche deserticola	0	0	0	0	0	0	0	0	0	0	0	0	0	4	0	0	0	0	0	0	0
Citicoline	0	0	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Citrinin	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	2	0
Citrulline	0	0	17	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Clinoptilolite	0	0	0	0	0	0	0	0	0	0	0	0	8	0	0	0	0	0	0	0	0
Cnidium monnieri	0	0	0	0	0	0	0	0	0	0	0	0	0	9	0	0	0	0	0	0	0
Cobalt	0	0	0	0	0	0	0	0	0	0	0	3	0	0	0	0	0	0	0	0	0
Coenzyme Q10	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Colour	0	0	0	0	0	59	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Conjugated Linoleic Acid	0	0	0	0	0	0	0	0	0	0	0	0	2	0	0	0	0	0	0	0	0
Copper	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0
Copper chelate	0	0	0	0	0	0	0	0	0	0	0	20	0	0	0	0	0	0	0	0	0
Coptis chinensis	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0

Cordyceps militaris	0	0	0	0	0	0	0	0	0	0	0	0	0	4	0	0	0	0	0	0	0	
	Subcategory																					
Issue	**Adverse Reaction**	**Authorisation**	**Bioactive Substance**	**Dosage: Bioactive Substance**	**Dosage: Minerals & Vitamins**	**Food Additive**	**GMO**	**Heavy Metals**	**Herbal**	**Chemical Contaminants**	**Microbial Contaminant**	**Minerals & Vitamins**	**Novel Food: Bioactive Substance**	**Novel Food: Herbal**	**Organoleptic Issues**	**Other Substance**	**Pesticide**	**Pharmaceutical**	**Radiation**	**Toxin**	**Undeclared Allergen**	
Cordyceps sinensis	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	
Coriolus versicolor	0	0	0	0	0	0	0	0	0	0	0	0	0	12	0	0	0	0	0	0	0	
Coumaphos	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	
Coumarin	0	0	0	4	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
Crataegus monogyna	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	
Crataegus nigra	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	
Creatine derivative	0	0	0	0	0	0	0	0	0	0	0	0	18	0	0	0	0	0	0	0	0	
Creatine nitrate	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
Creatinol phosphate	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	
Creatinol-o-phosphate	0	0	3	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
Croton lechleri	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	
Crustaceans	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	6	
Curcumin	0	0	1	14	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
Cuscuta japonica	0	0	0	0	0	0	0	0	0	0	0	0	0	2	0	0	0	0	0	0	0	
Cyanide	0	0	0	0	0	0	0	0	0	3	0	0	0	0	0	0	0	0	0	1	0	
Cyclic Dextrine	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
Cymbopogon citratus	0	0	0	0	0	0	0	0	4	0	0	0	0	0	0	0	0	0	0	0	0	
D-Aspartic Acid	0	0	3	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
Dehydroepi-androsterone (DHEA)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	11	0	0	0	
Dendrobium nobile	0	0	0	0	0	0	0	0	0	0	0	0	0	5	0	0	0	0	0	0	0	
Desmethyl-Carbodenafil	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	
D-Glucosamine	0	0	3	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
Diatomaceous Earth	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	
Dibencozide	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	
Di-Caffeine-maleate	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	4	0	0	0	
Didecyldimethyl-ammonium chloride (DDAC)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	4	0	0	0	0	
Diiodthyronine	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	
Dimethomorph	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	
Dimethylsildenafil	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	14	0	0	0	
Dioxins	0	0	0	0	0	0	0	0	0	12	0	0	0	0	0	0	0	0	0	0	0	
D-L-Phenylalanine	0	0	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
Dosage (unspecified)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	2	0	0	0	0	0	0	
Doxylamine	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	
E 200 - Sorbic Acid	0	0	0	0	0	6	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
E 210 - Benzoic Acid	0	0	0	0	0	7	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
E 216 - Propyl-p-Hydroxybenzoate	0	0	0	0	0	6	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
E 218 - Methyl-p-Hydroxybenzoate	0	0	0	0	0	4	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
E 385 - calcium disodium ethylene diamine tetra acetate (CDEDTA)	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
E 912 - Montan Acid Esters	0	0	0	0	0	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
E 926 - Chlorine Dioxide	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
Egg	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	3	
Emblica officinalis	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	
Emu Oil	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	
Ephedra	0	0	0	0	0	0	0	0	12	0	0	0	0	0	0	0	0	0	0	0	0	
Ephedrine	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	5	0	0	0	
Epigallocathechine gallate	0	0	5	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
Epimedium grandiflorum	0	0	0	0	0	0	0	0	0	0	0	0	0	45	0	0	0	0	0	0	0	
Epimedium pubescens	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	
Epimedium sagittatum	0	0	0	0	0	0	0	0	0	0	0	0	0	13	0	0	0	0	0	0	0	
Epimedium ssp.	0	0	0	0	0	0	0	0	0	0	0	0	0	35	0	0	0	0	0	0	0	
Ergot-Alkaloids	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	
Eria jarensis	0	0	0	0	0	0	0	0	0	0	0	0	0	2	0	0	0	0	0	0	0	
Escherichia coli	0	0	0	0	0	0	0	0	0	0	5	0	0	0	0	0	0	0	0	0	0	
Ethylbenzene	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	
Ethylene oxide	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	89	0	0	0	0	
Ethylenediamin-etetraacetic acid (EDTA)	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
Euryale ferox	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	
Eurycoma longifolia	0	0	0	0	0	0	0	0	0	0	0	0	0	26	0	0	0	0	0	0	0	
Evodia rutaecarpa	0	0	0	0	0	0	0	0	0	0	0	0	0	3	0	0	0	0	0	0	0	
Evodiamine	0	0	10	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
Fipronil	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	
Fish	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	3	
Flos Farfarae	0	0	0	0	0	0	0	0	0	0	0	0	0	2	0	0	0	0	0	0	0	
Folic Acid	0	0	0	5	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	
Folium Eriobotryae	0	0	0	0	0	0	0	0	0	0	0	0	0	2	0	0	0	0	0	0	0	
Foreign Body	0	0	0	0	0	0	0	0	0	0	0	0	0	0	15	0	0	0	0	0	0	

	Subcategory																				
Issue	**Adverse Reaction**	**Authorisation**	**Bioactive Substance**	**Dosage: Bioactive Substance**	**Dosage: Minerals & Vitamins**	**Food Additive**	**GMO**	**Heavy Metals**	**Herbal**	**Chemical Contaminants**	**Microbial Contaminant**	**Minerals & Vitamins**	**Novel Food: Bioactive Substance**	**Novel Food: Herbal**	**Organoleptic Issues**	**Other Substance**	**Pesticide**	**Pharmaceutical**	**Radiation**	**Toxin**	**Undeclared Allergen**
Forskolin	0	0	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
FP 967 linseed	0	0	0	0	0	0	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Fritillaria cirrhosa bulbs	0	0	0	0	0	0	0	0	0	0	0	0	0	3	0	0	0	0	0	0	0
Fulvic Acid	0	0	3	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
gamma-Amino-butyric Acid (GABA)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	4	0	0	0
Garcinia cambogia	0	0	0	2	0	0	0	0	10	0	0	0	0	0	0	0	0	0	0	0	0
Germanium	0	0	0	0	0	0	0	0	0	0	0	3	0	0	0	0	0	0	0	0	0
Ginger	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Gingko biloba	0	0	0	0	0	0	0	0	2	0	0	0	0	0	0	0	0	0	0	0	0
Ginkolide A	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0
Ginsenosides	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0
Glucosamine	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0
Glutamine alphaketoglutarate	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Gluten	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	5
Glycidyl esters	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0
Glycine	0	0	4	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Glycine-Propionyl-L-Carnithine	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Gold	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	13	0	0	0	0	0
Grifola frondosa	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0
Growth Hormone Releasing Peptide-2 (GHRP-2)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	2	0	0	0
Guggulsterone	0	0	3	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Gymnema sylvestre	0	0	0	0	0	0	0	0	0	0	0	0	0	7	0	0	0	0	0	0	0
Gynostemma pentaphyllum	0	0	0	0	0	0	0	0	0	0	0	0	0	6	0	0	0	0	0	0	0
Halostachine	0	0	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Hemidesmus indicus	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0
Higenamine	0	0	14	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Hintonia latiflora	0	0	0	0	0	0	0	0	0	0	0	0	0	2	0	0	0	0	0	0	0
Hoodia gordonii	0	0	0	0	0	0	0	0	0	0	0	0	0	72	0	0	0	0	0	0	0
Hordenine	0	0	11	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Huperzia serrata	0	0	0	0	0	0	0	0	2	0	0	0	0	2	0	0	0	0	0	0	0
Huperzine A	0	0	8	0	0	0	0	0	0	0	0	0	18	0	0	0	0	0	0	0	0
Hydrastis canadensis	0	0	0	0	0	0	0	0	2	0	0	0	0	3	0	0	0	0	0	0	0
Hydrogen Peroxide	0	0	0	0	0	0	0	0	0	0	0	0	2	0	0	0	0	0	0	0	0
Hydroxyanthracene derivatives	0	0	4	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Hypericum perforatum	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0
Chia	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0
Chloramphenicol	0	0	0	0	0	0	0	0	0	13	0	0	0	0	0	0	0	0	0	0	0
Chlorate	0	0	0	0	0	0	0	0	0	3	0	4	0	0	0	0	0	0	0	0	0
Chlorine	0	0	0	0	0	0	0	0	0	2	0	0	0	0	0	0	0	0	0	0	0
Chloroform	0	0	0	0	0	0	0	0	0	2	0	0	0	0	0	0	0	0	0	0	0
Chlorpropham	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0
Chlorpyrifos	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	3	0	0	0	0
Chromium	0	0	0	0	1	0	0	3	0	0	0	0	0	0	0	0	0	0	0	0	0
Chromium amino acid chelate	0	0	0	0	0	0	0	0	0	0	0	11	0	0	0	0	0	0	0	0	0
Chromium amino acid chelate	0	0	0	0	0	0	0	0	0	0	0	11	0	0	0	0	0	0	0	0	0
Chromium nicotinate glycinate chelate	0	0	0	0	0	0	0	0	0	0	0	6	0	0	0	0	0	0	0	0	0
Chromium picolinate	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0
Chromium Yeast	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0
Ibutamoren	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0
Idebenone	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	5	0	0	0
Illegal Import	0	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Imidacloprid	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0
Immunoglobulin G	0	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Incorrect Labelling	0	0	0	0	0	0	0	0	0	0	0	0	0	0	39	0	0	0	0	0	0
Indole-3-carbinol	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0
Ingredient (unspecified)	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Inonotus obliquus	0	0	0	0	0	0	0	0	2	0	0	0	0	2	0	0	0	0	0	0	0
Insects	0	0	0	0	0	0	0	0	0	0	0	0	0	0	2	0	0	0	0	0	0
Iodine	0	0	0	0	7	0	0	0	0	0	0	14	0	0	0	0	0	0	0	0	0
Ipomoea turphetum	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0
Iron	0	0	0	0	1	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0
Iron amino acid chelate	0	0	0	0	0	0	0	0	0	0	0	3	0	0	0	0	0	0	0	0	0
Irradiation	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	224	0	0
Irvingia gabonensis	0	0	0	0	0	0	0	0	0	0	0	0	0	2	0	0	0	0	0	0	0
Isopropyl-Octopamine	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	4	0	0	0
Isoprothiolane	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0
Junglans regia	0	0	0	0	0	0	0	0	0	0	0	0	0	2	0	0	0	0	0	0	0

	Subcategory																				
Issue	Adverse Reaction	Authorisation	Bioactive Substance	Dosage: Bioactive Substance	Dosage: Minerals & Vitamins	Food Additive	GMO	Heavy Metals	Herbal	Chemical Contaminants	Microbial Contaminant	Minerals & Vitamins	Novel Food: Bioactive Substance	Novel Food: Herbal	Organoleptic Issues	Other Substance	Pesticide	Pharmaceutical	Radiation	Toxin	Undeclared Allergen
Lactoprotein	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	4
Lactose	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	4
Lagerstroemia speciosa	0	0	0	0	0	0	0	0	0	0	0	0	0	4	0	0	0	0	0	0	0
lambda-Cyhalothrin	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0
Larrea tridentata	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0
L-Carnitine fumarate	0	0	5	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
L-Citrulline	0	0	3	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Lead	0	0	0	0	0	0	0	100	0	0	0	0	0	0	0	0	0	0	0	0	0
Leontopodium alpinum	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0
Lepidium meyenii	0	0	0	0	0	0	1	0	2	0	0	0	0	0	0	0	0	0	0	0	0
Lepidium peruvianum	0	0	0	0	0	0	0	0	7	0	0	0	0	2	0	0	0	0	0	0	0
Lilium brownii	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0
Lithium	0	0	0	0	0	0	0	0	0	0	0	7	0	0	0	0	0	0	0	0	0
L-Norvaline	0	0	6	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Loranthus europaeus	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0
L-Theanine	0	0	4	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Lycium barbarum	0	0	0	0	0	0	0	0	0	0	0	0	0	2	0	0	0	0	0	0	0
Lycium chinense	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Magnesium	0	0	0	0	1	0	0	0	0	0	0	6	0	0	0	0	0	0	0	0	0
Magnesium aspartate	0	0	0	0	0	0	0	0	0	0	0	40	0	0	0	0	0	0	0	0	0
Magnesium caprylate	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0
Magnesium Creatine chelate	0	0	0	0	0	0	0	0	0	0	0	8	0	0	0	0	0	0	0	0	0
Magnesium chelate	0	0	0	0	0	0	0	0	0	0	0	6	0	0	0	0	0	0	0	0	0
Magnesium L-threonate	0	0	0	0	0	0	0	0	0	0	0	5	3	0	0	0	0	0	0	0	0
Magnesium orotate	0	0	0	0	0	0	0	0	0	0	0	3	0	0	0	0	0	0	0	0	0
Manganese	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Manganese chelate	0	0	0	0	0	0	0	0	0	0	0	19	0	0	0	0	0	0	0	0	0
Melamine	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0
Melatonin	0	0	20	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Mephedrone	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	3	0	0	0
Mercury	0	0	0	0	0	0	0	67	0	0	0	0	0	0	0	0	0	0	0	0	0
Mesophiles	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0
Metal fragment	0	0	0	0	0	0	0	0	0	0	0	0	0	0	7	0	0	0	0	0	0
Methasterone	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0
Methylcobalamin	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0
Methylhexanamine	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0
Methylliberine	0	0	1	0	0	0	0	0	0	0	0	0	2	0	0	0	0	0	0	0	0
Methylsulfonylmethane	0	0	7	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Methylsynephrine	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0
Milk	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	21
Missing Health Certificate(s)	0	21	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Mitragyna speciosa	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0
MMS	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Molluscs	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	2
Molybdenum amino acid chelate	0	0	0	0	0	0	0	0	0	0	0	21	0	0	0	0	0	0	0	0	0
Monacolin K	0	0	32	4	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Monosodium-Aspartate	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Morinda citrifolia	0	0	0	0	0	0	0	0	0	0	0	0	0	12	0	0	0	0	0	0	0
Moulds	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0
Mucuna pruriens	0	0	0	0	0	0	0	0	2	0	0	0	0	23	0	0	0	0	0	0	0
Mustard	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1
Myrica rubra	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0
N,N-Dimethyl-2-Phenylpropan-1-Amine	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0
N-Acetyl Tyrosine	0	0	8	1	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0
N-Acetylcysteine	0	0	12	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
N-Acetylglutamine	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
N-Acetyl-Tyrosine	0	0	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Nandrolone	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0
Nardostachys jatamansi	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0
N-Carbamylglutamate	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0
Nelumbo nucifera	0	0	0	0	0	0	0	0	5	0	0	0	0	0	0	0	0	0	0	0	0
Niacinamide	0	0	3	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Nickel	0	0	0	0	0	0	0	3	0	0	0	8	0	0	0	0	0	0	0	0	0
Nicotinamide Mononucleotide	0	0	0	0	0	0	0	0	0	0	0	0	4	0	0	0	0	0	0	0	0
Nicotinic Acid	0	0	24	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Nimesulide	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	4	0	0	0
N-Methyl-D-Aspartate	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0
N-Methylphenyl-ethylamine (NMPEA)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0
N-Methyl-Tyramine	0	0	3	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
N-nicotinoyl-GABA	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	2	0	0	0
nor-Acetildenafil	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	3	0	0	0
Norcoclaurine	0	0	0	0	0	0	0	0	0	0	0	0	7	0	0	0	0	0	0	0	0
Norephedrine	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	3	0	0	0
Nortadalafil	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	5	0	0	0
Novaluron	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0
Nuts	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	2
Ocimum sanctum	0	0	0	0	0	0	0	0	2	0	0	0	0	0	0	0	0	0	0	0	0
Octopamine	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	7	0	0	0

	Subcategory																				
Issue	Adverse Reaction	Authorisation	Bioactive Substance	Dosage: Bioactive Substance	Dosage: Minerals & Vitamins	Food Additive	GMO	Heavy Metals	Herbal	Chemical Contaminants	Microbial Contaminant	Minerals & Vitamins	Novel Food: Bioactive Substance	Novel Food: Herbal	Organoleptic Issues	Other Substance	Pesticide	Pharmaceutical	Radiation	Toxin	Undeclared Allergen
Ochratoxin A	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	3	0
Ornithine alphaketogluturate	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Oxilofrine	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	8	0	0	0
Oxytetracycline	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0
Packaging Error	0	0	0	0	0	0	0	0	0	0	0	0	0	0	4	0	0	0	0	0	0
Panax ginseng	0	0	0	0	0	0	0	0	0	0	0	0	0	3	0	0	0	0	0	0	0
Papain	0	0	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Papain enzyme	0	0	0	0	0	0	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Paulownia extract	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0
Peanut	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1
Perchlorate	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	1	0	0	0	0
Permethrin	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0
pH level	0	0	0	0	0	0	0	0	0	0	0	0	0	0	7	0	0	0	0	0	0
Phellinus linteus	0	0	0	0	0	0	0	0	0	0	0	0	0	2	0	0	0	0	0	0	0
Phellodendron amurense	0	0	0	0	0	0	0	0	0	0	0	0	0	2	0	0	0	0	0	0	0
Phenethylamine	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	28	0	0	0
Phenolphthalein	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	23	0	0	0
Phenylethylamine Derivatives	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	2	0	0	0
Phyllantus emblica	0	0	0	0	0	0	0	0	4	0	0	0	0	0	0	0	0	0	0	0	0
Phytosterols	0	0	0	0	0	0	0	0	0	0	0	0	0	3	0	0	0	0	0	0	0
Pikatropin	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0
Pinellia rhizome	0	0	0	0	0	0	0	0	0	0	0	0	0	3	0	0	0	0	0	0	0
Piper methysticum	0	0	0	0	0	0	0	0	0	0	0	0	0	3	0	0	0	0	0	0	0
Piperidenafil	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0
Piperine	0	0	0	19	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Platostoma pallustre	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0
Platycodon root	0	0	0	0	0	0	0	0	0	0	0	0	0	3	0	0	0	0	0	0	0
Plectranthus barbatus	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0
Pleurotus eryngii	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0
PAHs	0	0	0	0	0	0	0	0	0	51	0	0	0	0	0	0	0	0	0	0	0
Polygonum cuspidatum	0	0	0	0	0	0	0	0	2	0	0	0	0	0	0	0	0	0	0	0	0
Polygonum multiflorum	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0
Polymethylsiloxane Polyhydrate	0	0	0	0	0	0	0	0	0	0	0	0	2	0	0	0	0	0	0	0	0
Potassium aspartate	0	0	0	0	0	0	0	0	0	0	0	2	0	0	0	0	0	0	0	0	0
Potassium caprylate	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0
Potassium chelate	0	0	0	0	0	0	0	0	0	0	0	3	0	0	0	0	0	0	0	0	0
Probiotic	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Procymidone	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0
Product Defect (unspecified)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0
Progesterone	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	8	0	0	0
Propamocarb	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	2	0	0	0	0
Propiconazole	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0
Propionyl-L-Carnitine	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Propylene-Glycol	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Pseudovardenafil	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0
Psoralea corylifolia	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0
Ptychopetalum spp.	0	0	0	0	0	0	0	0	6	0	0	0	0	0	0	0	0	0	0	0	0
Pueraria lobata	0	0	0	0	0	0	0	0	1	0	0	0	0	1	0	0	0	0	0	0	0
Pueraria mirifica	0	0	0	0	0	0	0	0	0	0	0	0	0	3	0	0	0	0	0	0	0
Pyrrolizidine Alkaloids	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	13	0
Radix Polygalae	0	0	0	0	0	0	0	0	0	0	0	0	0	2	0	0	0	0	0	0	0
Raspberry ketone	0	0	0	0	0	0	0	0	0	0	0	0	4	0	0	0	0	0	0	0	0
Rauwolfia canescens	0	0	0	0	0	0	0	0	0	0	0	0	0	12	0	0	0	0	0	0	0
Rauwolfia serpentina	0	0	0	0	0	0	0	0	2	0	0	0	0	1	0	0	0	0	0	0	0
Rauwolfia vomitoria	0	0	0	0	0	0	0	0	0	0	0	0	0	11	0	0	0	0	0	0	0
Recombinant Human Intrinsic Factor	0	0	0	0	0	0	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Rehmannia elata	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0
Reindeer velvet antlers	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0
Rhodamine B	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Rhodiola rosea	0	0	0	0	0	0	0	0	0	0	0	0	0	5	0	0	0	0	0	0	0
Rosa laevigata	0	0	0	0	0	0	0	0	0	0	0	0	0	2	0	0	0	0	0	0	0
Rye Grass pollen extract	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0
Salacia	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0
Salmonella enterica	0	0	0	0	0	0	0	0	0	0	20	0	0	0	0	0	0	0	0	0	0
S. enterica ser. Aberdeen	0	0	0	0	0	0	0	0	0	0	2	0	0	0	0	0	0	0	0	0	0
S. enterica ser. Durban	0	0	0	0	0	0	0	0	0	0	2	0	0	0	0	0	0	0	0	0	0
S. enterica ser. Give	0	0	0	0	0	0	0	0	0	0	2	0	0	0	0	0	0	0	0	0	0
S. enterica ser. Infantis	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0
S. enterica ser. Jerusalem	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0
S. enterica ser. Matopeni	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0

	Subcategory																				
Issue	Adverse Reaction	Authorisation	Bioactive Substance	Dosage: Bioactive Substance	Dosage: Minerals & Vitamins	Food Additive	GMO	Heavy Metals	Herbal	Chemical Contaminants	Microbial Contaminant	Minerals & Vitamins	Novel Food: Bioactive Substance	Novel Food: Herbal	Organoleptic Issues	Other Substance	Pesticide	Pharmaceutical	Radiation	Toxin	Undeclared Allergen
S. enterica ser. Montevideo	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0
S. enterica ser. Poona	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0
S. enterica ser. Rissen	0	0	0	0	0	0	0	0	0	0	7	0	0	0	0	0	0	0	0	0	0
S. enterica ser. Virchow	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0
S. enterica ser. Weltevreden	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0
Salmonella ssp.	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0
Salmonella Typhimurium	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0
Salvia hispanica	0	0	0	0	0	0	0	0	0	0	0	0	0	2	0	0	0	0	0	0	0
Salvia miltiorrhiza	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0
Sceletium tortuosum	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0
Scopolamine	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0
Scutellaria baicalensis	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0
Scutellaria elliptica	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0
Scutellaria lateriflora	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0
Selaginella tamariscina	0	0	0	0	0	0	0	0	1	0	0	0	0	2	0	0	0	0	0	0	0
SARMs	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	13	0	0	0
Selenium	0	0	0	0	1	0	0	0	0	0	0	2	0	0	0	0	0	0	0	0	0
Selenium chelate	0	0	0	0	0	0	0	0	0	0	0	16	0	0	0	0	0	0	0	0	0
Semicarbazide (SEM)	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0
Senna angustifolia	0	8	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Serenoa repens	0	0	0	0	0	0	0	0	6	0	0	0	0	0	0	0	0	0	0	0	0
Serratiopeptidase	0	0	0	0	0	0	0	0	0	0	0	0	3	0	0	0	0	0	0	0	0
Sesame	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1
Schisandra chinensis	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0
Sibutramine	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	87	0	0	0
Sida cordifolia	0	0	0	0	0	0	0	0	2	0	0	0	0	0	0	0	0	0	0	0	0
Sildenafil	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	212	0	0	0
Silver	0	0	0	0	0	0	0	0	0	0	0	28	0	0	0	0	0	0	0	0	0
Silybum marianum	0	0	0	0	0	0	0	0	3	0	0	0	0	4	0	0	0	0	0	0	0
Simmondsia chinensis	0	0	0	0	0	0	0	0	0	0	0	0	0	2	0	0	0	0	0	0	0
Siphonostegia chinensis	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0
Siraitia grosvenorii	0	0	0	0	0	0	0	0	0	0	0	0	0	6	0	0	0	0	0	0	0
Smallanthus sonchifolius	0	0	0	0	0	0	0	0	0	0	0	0	0	3	0	0	0	0	0	0	0
Smilax scobinicaulis	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0
Sodium Boron hydride	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0
Na-glycerolphosphate	0	0	0	0	0	0	0	0	0	0	0	2	0	0	0	0	0	0	0	0	0
Sodium Chlorite	0	0	0	0	0	15	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Solanum nigrum	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	2	0
Sophora japanica	0	0	0	0	0	0	0	0	0	0	0	0	0	2	0	0	0	0	0	0	0
Sorbic acid	0	0	0	0	0	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Sorbus torminalis	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0
Soya	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	8
Stanozolol	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	2	0	0	0
Stevia rebaudiana	0	0	0	0	0	0	0	0	0	0	0	0	0	22	0	0	0	0	0	0	0
Strontium	0	0	0	0	0	0	0	0	0	0	0	3	0	0	0	0	0	0	0	0	0
Strychnine	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Sulbutiamine	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0
Sulfamethazine	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0
Sulphite	0	0	0	0	0	3	0	0	0	0	0	0	0	0	0	0	0	0	0	0	16
Sulphur	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0
Superoxide Dismutase	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Sutherlandia frutescens	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0
Sweetener (unspecified)	0	0	0	0	0	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Swertia chirata	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0
Symphytum spp.	0	0	0	0	0	0	0	0	0	0	0	0	0	2	0	0	0	0	0	0	0
Synephrine	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	75	0	0	0
Synsepalum dulcificum	0	0	0	0	0	0	0	0	0	0	0	0	0	3	0	0	0	0	0	0	0
Tabebuia impetiginosa bark extract	0	0	0	0	0	0	0	0	0	0	0	0	0	3	0	0	0	0	0	0	0
Tadalafil	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	92	0	0	0
Taste Disturbance	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0
Tebuconazole	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0
Testosterone	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0
Tetradecylthioacetic Acid	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0

	Subcategory																				
Issue	**Adverse Reaction**	**Authorisation**	**Bioactive Substance**	**Dosage: Bioactive Substance**	**Dosage: Minerals & Vitamins**	**Food Additive**	**GMO**	**Heavy Metals**	**Herbal**	**Chemical Contaminants**	**Microbial Contaminant**	**Minerals & Vitamins**	**Novel Food: Bioactive Substance**	**Novel Food: Herbal**	**Organoleptic Issues**	**Other Substance**	**Pesticide**	**Pharmaceutical**	**Radiation**	**Toxin**	**Undeclared Allergen**
Tetrahydrocannabinol	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	94	0
Thallium	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0
Theacrine	0	0	0	0	0	0	0	0	0	0	0	0	5	0	0	0	0	0	0	0	0
Theanine	0	0	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Theobromine	0	0	5	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Thermopsis lanceolata	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0
Thyroid tissue	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0
Tin	0	0	0	0	0	0	0	0	0	0	0	7	0	0	0	0	0	0	0	0	0
Titanium dioxide	0	0	0	0	0	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Tocotrienol	0	0	0	0	0	0	0	0	0	0	0	3	0	0	0	0	0	0	0	0	0
Tolfenpyrad	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	2	0	0	0	0
Toluene	0	0	0	0	0	0	0	0	0	2	0	0	0	0	0	0	0	0	0	0	0
Toxic Herbal Extracts (unspecified)	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	8	0
Trametes versicolor	0	0	0	0	0	0	0	0	0	0	0	0	0	7	0	0	0	0	0	0	0
Trans-Resveratrol	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Triazophos	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0
Tribulus terrestris	0	0	0	0	0	0	0	0	7	0	0	0	0	1	0	0	0	0	0	0	0
Tri-Creatine-Malate	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Trimethyl-Sulfonium	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0
Turnera diffusa	0	0	0	0	0	0	0	0	2	0	0	0	0	0	0	0	0	0	0	0	0
Ulmus pumila	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0
Unauthorised Health Claims	0	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Unauthorised Operator	0	6	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Unauthorised placing on the Market	0	90	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Usnic Acid	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0
Vanadium	0	0	0	0	0	0	0	0	0	0	0	36	0	0	0	0	0	0	0	0	0
Vanadyl sulphate	0	0	0	0	0	0	0	0	0	0	0	11	0	0	0	0	0	0	0	0	0
Vardenafil	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	19	0	0	0
Vinburnine	0	0	8	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Vincamine	0	0	8	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Vinpocetine	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	47	0	0	0
Viscum coloratum	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0
Vitamin A	0	0	0	0	16	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Vitamin B12	0	0	0	0	3	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Vitamin B15	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0
Vitamin B6	0	0	0	0	61	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Vitamin C	0	0	0	0	3	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Vitamin D3	0	0	0	0	24	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Vitamin E	0	0	0	0	14	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Vitamins (unspecified)	0	0	0	0	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Wheat	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	4
whole grain brown rice protein concentrate	0	0	0	0	0	0	2	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Withania somnifera	0	0	0	0	0	0	0	0	25	0	0	0	0	0	0	0	0	0	0	0	0
Xanthoparmelia scabrosa	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0
Xylene	0	0	0	0	0	0	0	0	0	2	0	0	0	0	0	0	0	0	0	0	0
Yeasts	0	0	0	0	0	0	0	0	0	0	2	0	0	0	0	0	0	0	0	0	0
Yohimbe bark extract	0	0	0	0	0	0	0	0	25	0	0	0	0	0	0	0	0	0	0	0	0
Yohimbine	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	144	0	0	0
Zeolite	0	0	0	0	0	0	0	0	0	0	0	0	8	0	0	0	0	0	0	0	0
Zinc	0	0	0	0	36	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Zinc aspartate	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0
Zinc caprylate	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0
Zinc chelate	0	0	0	0	0	0	0	0	0	0	0	16	0	0	0	0	0	0	0	0	0
Zinc picolinate	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0
Ziziphus jujuba	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0
Zopiclone	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0

3.7.3 Supplementary Material 3

The role of the public and private sectors in the EU hybrid safety governance of food supplements – A study on the example of quality issues notified in the RASFF

RASFF notifications from 2003 - 2022 on food supplements quality issues by notification bases authority control, company check, and consumer warning per assigned hazard category.

The data set is shown on the following page.

Subcategory	Notification Basis		
Notification Basis	Consumer Warning	Company Check	Authority Control
Adverse Reaction	12	0	0
Authorisation	2	0	136
Bioactive Substance	16	2	343
Dosage: Bioactive Substance	13	3	113
Dosage: Minerals & Vitamins	27	3	148
Food Additive	2	0	114
GMO	0	0	11
Heavy Metals	12	19	207
Herbal	11	0	162
Chemical Contaminants	15	43	154
Microbial Contaminant	17	16	43
Minerals & Vitamins	140	7	227
Novel Food: Bioactive Substance	51	4	468
Novel Food: Herbal	24	3	524
Organoleptic Issues	24	14	40
Other Substance	0	0	51
Pesticide	3	99	75
Pharmaceutical	59	12	1088
Radiation	0	11	213
Toxin	5	2	127
Undeclared Allergen	2	35	45

3.7.4 Supplementary Material 4

The role of the public and private sectors in the EU hybrid safety governance of food supplements – A study on the example of quality issues notified in the RASFF

RASFF notifications from 2003 - 2022 on food supplements quality issues by notification types per notification bases authority control, company check, and consumer warning.

	Notification Basis		
Notification Type	**Authority Control**	**Company Check**	**Consumer Warning**
alert	1337	188	137
border rejection	443	0	0
border rejection notification	68	0	0
information	331	8	14
information for attention	940	34	62
information for follow-up	1170	43	221
news	0	0	1

Chapter 4
Investigating the Impact of EU Food Information Regulation on Food Supplement Marketing Strategies – A Case Study on the German Market

Warda, R., Purnhagen, K.

Accepted with minor revisions by British Food Journal.

CRediT author statement

Warda, Roman: Conceptualization, Data curation, Investigation, Methodology, Project administration, Resources, Validation, Visualization, Writing – original draft, Writing – review & editing. Purnhagen, Kai: Project administration, Supervision, Writing – original draft, Writing – review & editing.

Abstract

Purpose

This study examines how the incomplete implementation of Regulation (EC) No 1924/2006 (Health Claims Regulation) affects marketing strategies in the European Union (EU) food supplement sector. It explores how national-level interpretations of the regulation influences the use of health-claims on food products

Methodology

An interdisciplinary approach combining doctrinal legal analysis and qualitative empirical research has been employed. Germany was selected as the case study object due to its leading market size in the EU. The regulatory framework conditions governing the use of health-claims in the German food supplement market were examined. Semi-structured expert interviews were conducted with seven German food supplement manufacturers ranging in size from small to medium-sized enterprises to larger companies.

Findings

Results indicate that companies adopt diverse strategies to adapt to the inconsistent enforcement of the Health Claims Regulation. Its fragmented legal implementation was considered an obstacle to market entry, increasing administrative and legal burdens, and elevates the risk of sanctions by regulatory authorities.

Originality

This research provides novel insights into the intersection of EU food law and marketing practices. It underscores the urgent need to advance regulatory coherence concerning the usage of health claims in the EU, to ensure fair market conditions, legal certainty for manufacturers, but also consumer protection and trust in health-related food information.

Keywords

Food Information; Food Supplements; Health Claims; Food Law; Nutrition Claims

Declarations and Statements

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.

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.

Conflict of Interests

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.

4.1 Introduction

Under the paradigm of a risk-based regulatory approach, the European Union (EU) has adopted several horizontal food safety laws to promote educated consumer choices concerning their diet (Edinger, 2016). This approach aims to balance fundamental consumer rights, such as the right to information and the freedom of choice (Ramos and Squeff, 2020; European Commission, 2020d). It also contributes to the EU's primary goal of developing a harmonized free internal market by, among other regulatory measures, streamlining competition and food advertisement conditions (Gokani, 2024). The relationship between nutrition and the sustainment or improvement of individual health has long been established by research in the medical and food-science fields (Samtiya *et al.*, 2021). Following, food business operators (FBO) have recognized the potential benefits of science-based food-related health claims for the brand communication of their products (van Buul and Brouns, 2015). Likewise, as consumers' interest in health improvement through an optimized diet has increased in recent years, health claims on food products serve a pivotal role in brand recognition and driving sales by influencing consumer choices (Principato *et al.*, 2025). Therefore, to protect consumers from fraudulent claims and provide fair market competition conditions between stakeholders, a comprehensive and effective legal framework is necessary (Gokani, 2024). As food supplements are considered foodstuffs by Directive 2002/46/EC (Food Supplements Directive), the regulatory approach of promoting educated consumer choices also applies to them (Directive 2002/46/EC, 2002). The increasing perception of consumers' viewing supplements as viable options for personal dietary health improvement and their

galenic similarities with pharmaceuticals underscores the need for a robust legal framework governing food-related health claims (Lordan, 2021; Gokani, 2024).

Although the current EU Food Information Regulation (Regulation (EU) No 1169/2011) and Health Claims Regulation (HCR) (Regulation (EC) No 1924/2006) have been adopted between 2007 and 2011, a certain number of their provisions have not been fully implemented so far (European Parliament, 2024). Components of concern of the Food Information Regulation mainly pertain to technical details and on-package statements (Reese *et al.*, 2015; Ramos and Squeff, 2020). However, despite the aim of the European Parliament and the European Commission (EC) to fully harmonize health claims applicable to food within the EU via subsequent scientific assessment by the European Food Safety Agency (EFSA), the procedure has not been concluded since the HCR's adoption (European Parliament, 2024). Moreover, EFSA decided to put their safety assessment of all claims for botanical food ingredients on hold due to a lack of available scientific data, a practice endorsed by the European Court of Justice (EFSA Panel on Dietetic Products, Nutrition and Allergies, 2016; European Court of Justice, 2025). The ineffective enforcement of both regulations contributes to the already fragmented legal framework regulating the manufacturing and sale of food supplements in the EU (Gulati *et al.*, 2014). The EC has largely abandoned the development of a positive list of botanical and other bioactive ingredients permitted for use in supplements, as stipulated by Art. 4(8) of the Food Supplements Directive, due to scientific complexity and anticipated harmonizing effects of other regulations (European Commission, 2008). Following, in absence of harmonized Union law, the use of botanical ingredients is currently mostly regulated individually at the European Member State (EMS) level (Warda *et al.*, 2024). The suspension of botanical claim assessments further complicates the addition of botanicals to food supplements and their subsequent sale and distribution by food businesses, as only claims permitted by EFSA are eligible for use by businesses (Gulati *et al.*, 2014; Regulation (EC) No 1924/2006, 2006).

This study aims to investigate the influence of the fragmented application of the EU food information regulatory framework conditions on businesses manufacturing and distributing food supplements. Doctrinal legal analysis is carried out to illustrate the current legal system within the scope of food information and presentation applicable to food supplements. The analysis is supported by an empirical case study on the German food supplement market, drawing on expert interviews with representatives of affected manufacturing companies. The empirical analysis part primarily focuses on two subjects. First, the use and role of health claims for developing and distributing supplement products. Second, the significance and challenges of presenting supplements as health-focused dietary options to consumers are investigated.

The European food supplement market is expanding and is projected to reach approximately 48 billion dollars by 2026 (Statista, 2023). Revenue and production volumes in the German market have shown consistent growth in recent years (Statista, 2024). Herbal formulations have become more popular with consumers, mostly due to perceived health benefits derived from their consumption (Restani *et al.*, 2018). Companies seeking to enter the supplement market face the regulatory risk arising from insufficiently clear demarcation between supplements and pharmaceuticals, commonly referred to as borderline issues (Bilia and Costa, 2021). Especially botanical formulations have the potential to create such issues, as similar ingredients, galenic forms, and dosages can be used in food supplements, herbal medicinal products (HMPs), or traditional herbal medicinal products (THMPs) (Bilia and Costa, 2021). Crossing the line between food and medicines can have significant impacts on companies' business operations, as the sale and marketing of the latter is subject to stricter safety regulations (Tallon and Kalman, 2025). As positive lists or the permission of health claims for botanical supplements have not been implemented, the evaluation into which category a borderline product falls is often subject to jurisdictional disputes between companies and responsible safety authorities (Anadón *et al.*, 2021). In the past, the Court of Justice of the European Union (CJEU) has defined certain delineation criteria which, besides nutritional and pharmacological effect threshold levels, focused on product presentation and advertisement to consumers or the intended product use (Gawronski, 2024).

While FBOs are legally obligated by Article 2 of Regulation (EC) No 178/2002 (General Food Law; GFL) to fulfill all requirements to not meet the criteria of a pharmaceutical product, the application of delineation criteria established by CJEU case law is with the subjective assessment of national safety authorities (Lenssen and Boer, 2025). This could jeopardize the EU's goals of creating a harmonized internal market and the realization of the free movement of goods, as companies have to spend additional human and financial resources to ensure the lawful marketing of food supplements within the Union (Tallon and Kalman, 2025). Therefore, highlighting the perspective of private supplement stakeholders on adapting to the current regulatory food information and advertisement framework may contribute to accelerating options for its future development.

4.2 Methodology

4.2.1 Doctrinal legal analysis

Doctrinal legal analysis as a research method aims to systematically address the underlying normative principles and concepts governing a specific legal framework, which in turn is designed to define or resolve certain socio-legal issues (Hutchinson, 2015). Since the studied legal system represents both the study object and the analytical framework, the research

method enables researchers to formulate argumentative suggestions for improvements or changes (Smits, 2015). Doctrinal legal analysis does not focus exclusively on assessments of legal texts; rather, it relies on extracting general principles by synthesis of all available sources, including case law or institutional communications (Pradeep M. D., 2019). By conducting a comprehensive analysis of all relevant elements, researchers are able to identify inconsistencies within the studied legal system (Smits, 2015; Pradeep M. D., 2019).

Legal documents and institutional communications were obtained from the EUR-Lex database and the EU database data.europa.eu.

4.2.2 Empirical analysis

Among legal scholarly debate, the inclusion of empirical analysis methods has been advocated as a possible contribution to a variety of legal analysis methods (van Hoecke, 2015). An interdisciplinary approach which draws on merging doctrinal legal analysis with empirical analysis enables researchers to acquire a more comprehensive perspective on how provisions of a legal system are applied in practice (van Hoecke, 2015; Hutchinson, 2015). Qualitative research focuses on carefully interpreting and reflecting on the content of generated data instead of aiming towards generalizing observations (Sutton and Austin, 2015). Expert interviews as an empirical research method allow for gathering research results relating to social concepts and behaviors, which otherwise would be difficult to obtain (Helfferich, 2022; Anderson, 2010). In qualitative research, based on their individual knowledge and experiences of internal processes, experts are considered a functional information source within the institution they represent (Helfferich, 2022; Braun and Clarke, 2006; Soest, 2023). Thus, although typically limited to a small sample size of participants, qualitative analysis of data gathered through expert interviews contributes to the creation of meaningful research results (Kaiser, 2014; Lamnek and Krell, 2016; Soest, 2023).

4.2.3 Expert Interviews

In this study, we conducted semi-structured expert interviews with representatives from seven German food supplement businesses. For this type of interviews, which focuses on extracting exclusive knowledge of institutional practices beyond the level of the individual interviewee, an interview guide provides a beneficial structure reflecting theoretical assumptions into the interview questions (Kaiser, 2014; Schnell, 2019a; Soest, 2023). Interview guides based on open questions provide the opportunity for researchers and interviewees to choose a flexible approach towards a thematic discussion (Schnell, 2019a).

Given that the inclusion of experts from multiple EMS would have exceeded the methodological scope of this research, Germany was selected as the jurisdictional case study. The country

constitutes the EU's largest market for food supplements, both in absolute value and market share, and plays a particularly influential role in the implementation and enforcement of EU food supplement regulation.

FBOs were eligible for inclusion in the study if they were registered in Germany and were engaged in the sale of food supplements on the German market. Participants qualified as experts if they held a leading role in the economic or marketing activities of the respective company. Participants were recruited via publicly available email addresses or contact forms listed on company websites (Schnell, 2019b). Interviewees included in the study were directly responsible for developing products, food law-related legal advice, or overseeing customer engagements, mostly at the executive level. Company sizes varied from small to medium-sized enterprises (SME), as defined by EU law, ranging from below ten to 250 employees, to larger stock corporations (European Commission, 2003). Although the participating companies are registered in Germany, most of them also reported business activities in other EMSs.

Interviews were conducted as online video calls, which lasted around 30 minutes and were recorded for subsequent analysis (Schnell, 2019b; Soest, 2023). The created audio files were then transcribed into written text files using Microsoft Word Version 2013 and anonymized (Microsoft Corporation, 2019). In total, six interviews were conducted, one participant answered the questions in written form.

The interview question guide is attached in Supplementary Material 1.

4.2.4 Data Analysis

The anonymized transcript files were analyzed using the method of structured content analysis by Mayring (Mayring, 2019). This methodological approach assigns primary data to defined analytical themes and subsequent codes (Mayring, 2019). Data irrelevant to the original research question can be excluded, which is an essential step for analyzing data derived from open-ended questions (Mayring, 2019).

We chose a deductive a priori approach, implying that the development of analytical codes is based on the research questions and prior theoretical knowledge of the research topic (Azungah, 2018; Mayring, 2019). Moreover, analytical codes were created independently from the research data before the start of the analysis (Mayring, 2019). While this approach potentially diminishes flexibility in creating new codes and themes, its narrower focus aligns with the aim of extracting expert knowledge on a specific research question (Kiesler, 2024; Meuser and Nagel, 2009). However, it is still possible within the scope of deductive approaches to amend or modify the coding system at later stages (Mayring, 2019).

Through continuous data analysis, a member of the research team affirmed two themes and eight subsequent codes, primarily derived from the questions provided by the interview guide. The primary interview data were then categorized and coded using the qualitative analytical software MAXQDA (Verbi Software, 2024). The extracted information was then summarized and triangulated with data obtained through the doctrinal legal analysis. The developed codes and themes can be found in Supplementary Material 2.

4.3 Results

4.3.1 Doctrinal legal analysis

Food supplements are considered foodstuffs in the EU by Article 2 of the GFL (Regulation (EC) No 178/2002, 2002). The Food Supplements Directive aims to harmonize the manufacturing, distribution, permitted ingredients, and general labelling and advertising aspects across the Union (European Parliament & Council of the European Union, 2002a). However, due to the incomplete enforcement of certain provisions, such as the creation of positive lists for botanical and other bioactive ingredients, different national regulatory approaches apply across individual EMS (Warda *et al.*, 2024). The regulatory fragmentation at the EMS level has been identified to further transpose into the enforcement practices of responsible food safety authorities (Warda *et al.*, 2024).

In Germany, the Ministry of Agriculture (BMEL) and its subordinate Federal Office of Consumer Protection (BVL) are responsible for enforcing applicable food safety laws. Germany represents one of the EU's major food supplement markets, valued at approximately EUR 4 billion (Statista, 2025). Analyses on the Rapid Alert System for Food and Feed indicate persisting quality issues of products available on the German and other EMS markets, including mislabeled items (Kowalska *et al.*, 2019). The issue of borderline products arising from so-called dual-use substances, primarily botanical ingredients found identically in food supplements, HMPs, and THMPs, has been recognized by German authorities as a potential hazard to consumer health (Bundesamt für Verbraucherschutz und Lebensmittelsicherheit, 2014). In response, the BVL has formed the Joint Commission in cooperation with the Federal Institute for Drugs and Medical Devices (BfArM) (Bundesministerium für Gesundheit and Bundesministerium für Ernährung, Landwirtschaft und Verbraucherschutz, 2012). The Joint Commission has published a non-exhaustive list of botanical ingredients, which are typically considered herbal medicines or food ingredients by German authorities (Bundesamt für Verbraucherschutz und Lebensmittelsicherheit, 2014).

The regulatory overlap between herbal medicines and supplements brings into focus how the potential health benefits of food products are marketed to consumers. According to Article 1(2) of Directive 2001/83/EC (Medicines Directive), products advertised as having medical

properties are considered as medicinal products by presentation, thereby being subjected to pharmaceutical regulations (Directive 2001/83/EC, 2001). Thus, the ambiguous status of certain food supplement ingredients raises questions concerning consumer-facing product statements, which fall within the scope of food information regulation (Breitweg-Lehmann *et al.*, 2019). Generally, food information serves a crucial function in guiding consumers in their nutritional decisions and promoting a healthier diet (Gokani, 2024). In the EU, Regulation (EU) No 1169/2011 sets framework conditions for nutritional labelling requirements and additional food information provisions mandatory for inclusion in advertisement materials to final consumers and on-pack labelling (Regulation (EU) No 1169/2011, 2011). The significance of establishing a legal foundation for informed consumer choices and the prevention of misleading consumers and unfair business practices, emphasized by Article 7 of the Food Information Regulation, is particularly evident in the context of food supplement marketing by the inclusion of additional labeling requirements in the Food Supplements Directive (Directive 2002/46/EC, 2002; Regulation (EU) No 1169/2011, 2011). Beyond the scope of mandatory aspects, regulating food information also encompasses voluntary statements, such as the communication of health-related statements. Adopted in 2007, the HCR seeks to promote EU policy goals by streamlining advertising statements pertaining to the health and nutritional benefits of food products (Regulation (EC) No 1924/2006, 2006). Its underlying rationale stated in Article 1(1) HCR is consumer protection and the harmonization and development of the free internal market. Stated in Recital 28 and 35 HCR, additional objectives are the pursuit of truthful and scientifically based claims as a contribution towards healthy dietary consumer choices and the promotion of agri-food research and innovation (Regulation (EC) No 1924/2006, 2006). While the Food Information Regulation addresses mandatory and voluntary on-package labeling provisions, the HCR pertains explicitly to voluntary advertisement claims relating to health and nutrition (Regulation (EC) No 1924/2006, 2006). Its reference towards food supplements in particular (compare Article 2(1)(b)) underscores again the significance of health and nutritional claims for this food category (Regulation (EC) No 1924/2006, 2006).

The HCR delineates between different types of claims that food businesses may be eligible to voluntarily use for advertising their products (Regulation (EC) No 1924/2006, 2006). Nutritional claims generally refer to assertions that a food product possesses distinctive nutritional properties due to its caloric value or contained nutrients (Regulation (EC) No 1924/2006, 2006). In contrast, health claims state or suggest a beneficial relationship between a food product or specific ingredients and the sustainment or improvement of individual health (Regulation (EC) No 1924/2006, 2006). Furthermore, the HCR delineates between several subtypes of health claims. First, Article 10(3) HCR defines unspecific health claims which refer to general benefits of a food ingredient for overall good health and specific health claims, referring to an individual nutritional benefit on human health. However, Article 10(3) HCR also

sets narrow conditions of use for unspecific health claims, as their use is only permitted if they are combined with a specific health claim. Specific health claims are further divided by Article 13 HCR into functional health claims, pertaining to the role of a substance in the development or function of the body, and cognitive health claims, which relate to psychological and behavioral effects. Additionally, Article 14(1)(a) HCR introduces disease reduction claims, concerning statements that the consumption of an ingredient may reduce risk factors for developing a disease. Lastly, Article 14(1)(b) HCR also covers children's development claims. An overview of the different claim categories and examples of health claims is respectively provided in Table 1 and Supplementary Material 3.

Category	**HCR Basis**	**EFSA Approval**	**Permitted Alone**
Nutrition Claim	Art. 2(2)(4)	Yes	Yes
Health Claim	Art. 2(2)(5)	Yes	Yes
Specific Health Claim	Art. 13, 14	Yes	Yes
Unspecific Health Claim	Art. 10(3)	No	No, only in combination with Art. 13(1)
Functional Claim	Art. 13(1)(a)	Yes	Yes
Cognitive Health Claim	Art. 13(1)(b)	Yes	Yes
Botanical Claim (Traditional Claim)	Art. 28(6)	No	Conditionally allowed
Disease Reduction Claim	Art. 14(1)(a)	Yes	Yes
Children's Development Claim	Art. 14(1)(b)	Yes	Yes

Table 1 Overview of different categories of health claims in relation their legal basis, approval status, and conditions of use. HCR: Health Claims Regulation; EFSA: European Food Safety Agency

The HCR sets specific conditions concerning the use of health claims, which operate on a default prohibition with allowance by exception, requiring prior authorization by the EC based on a scientific assessment by EFSA (Regulation (EC) No 1924/2006, 2006). Pursuant to Article 13(2) and 13(3) HCR, national food safety agencies were tasked with aiding EFSA to develop a consolidated list of approved claims by collecting and submitting health claims permitted in their respective jurisdictions by 2008 (Regulation (EC) No 1924/2006, 2006). Until 2011, EFSA reviewed around 2300 submitted claims, of which around 260 have been approved and subsequently placed in the EU register (European Parliament, 2024). However, the assessment of more than 2000 health claims pertaining to botanical ingredients has been put on hold by EFSA since 2012 due to a lack of scientific evidence (European Parliament, 2024). EFSA's decision is substantiated on Article 6(1) and Article 15(1) HCR, stipulating that the agency shall consider all available scientific data (Regulation (EC) No 1924/2006, 2006). Article 22(6) of the GFL mandates the agency's scientific advice to be of the highest possible standard (Regulation (EC) No 178/2002). This policy is reflected in Recital 17 HCR, which specifically states that claims shall only be adopted following a scientific assessment of the

highest possible standard (Regulation (EC) No 1924/2006, 2006). However, as human intervention studies and clinical trials, often regarded as essential for assessing nutritional and pharmacological effects, are largely lacking for botanicals, no meaningful progress has been made (Buttriss, 2015). Although Article 13(5) HCR provides food businesses the opportunity to obtain exclusive proprietary rights to a health claim for a five-year term in case sufficient evidence is provided during its application procedure, most businesses refrain from it due to methodological difficulties and financial costs of performing clinical studies (Regulation (EC) No 1924/2006, 2006; Buttriss, 2015).

As the assessment and subsequent authorized use of botanical claims has been temporarily suspended, FBOs may draw upon another approach laid out by the HCR. Article 28(6) contains a transitional provision, whereas in the absence of horizontal regulation, national regulations still apply, providing a possibility for an ongoing use of unapproved botanical claims as long as they meet certain conditions (Regulation (EC) No 1924/2006, 2006). Generally, such claims must have circulated in the EU prior to the HCR's adoption in 2007 and need to be scientifically plausible (Regulation (EC) No 1924/2006, 2006). FBOs may obtain such proof via herbal pharmaceutical monographies provided by the Committee on Herbal Medicinal Products (HMPC) or European Scientific Cooperative on Phytotherapy (ESCOP) (Bilia and Costa, 2021). However, FBOs have to ensure they are not using a medical claim for food supplement advertisements (Bilia and Costa, 2021; Tallon and Kalman, 2025). This could present a significant legal challenge for FBOs due to similar ingredients and dosages found in food supplements, herbal medicines, and traditional herbal medicinal products (Tallon and Kalman, 2025).

The current fragmentary state of health claims authorization and the obstacles it presents to the EU's goals of consumer protection and free market progression have been criticized by several institutions (European Parliament, 2024; Bundesregierung, 2021; Bundesrat, 2021). In accordance with its Regulatory Fitness and Performance Programme initiative (REFIT) of assessing EU legal acts' governance effectiveness, the EC published a report which highlighted the consequences of the HCR's provisions not being fully enacted by 2020 (European Commission, 2020c). Primary concerns included the creation of trade barriers within the EU for FBOs, as several aspects of supplement regulation being fall under national regulation with traditional health claims similarly fragmented across EMS (European Commission, 2020c). The EC also highlighted that consumers' limited ability to distinguish between botanical food supplements and pharmaceuticals poses challenges for pharmaceutical companies, which face stricter regulations and higher costs despite competing virtually the same products (European Commission, 2020c). Moreover, continuous consumer exposure to non-assessed traditional botanical claims with the perception of such products as

particularly beneficial for health, was described as a potential health risk (European Commission, 2020c). The significance of non-fully attained goals of the HCR was subsequently reflected in the EC's Farm to Fork strategy paper in 2022 (European Commission, 2020a). Despite the EC's stated aim to improve conditions for developing health claims, little progress has been made in effectively addressing the identified regulatory issues (European Commission, 2020a). In response, the European Parliament adopted Resolution 2023/2081 in 2024, strongly criticizing the continued suspension of botanical health claims evaluations and urged the EC and EFSA to resume process (European Parliament, 2024). The resolution emphasized the role of health claims in influencing consumer dietary choices and reduing borderline issues involving dual-use botanical ingredients (European Parliament, 2024). It further noted that enabling science-based claims contributes to meeting the consumers' right to comprehensive food information and may encourage healthier food choices (European Parliament, 2024). Similar concerns were rais by regarding the use of non-assessed traditional claims. In 2021, the German Federal Council called on the national government to fully apply the HCR to protect consumers from scientifically unsubstantiated claims and prevent the misperception of botanical supplements as HMPs (Bundesrat, 2021). The German Ministries of Health and Agriculture supported this position, citing the EC's intended progress in line with the Farm to Fork policy (Bundesregierung, 2021).

The urgency of progressing the assessment of botanical claims was further underscored by CJEU case law. In its recent judgement C-386/23, the court decided, in accordance with Article 10(3) HCR, against the use of non-specific claims for botanical products, despite the assessment of specific botanical claims being suspended (European Court of Justice, 2025). Therefore, FBOs may only rely on traditional claims under the transitional provisions of Article 28(6) HCR. The CJEU did not consider the unavailability of approved botanical claims as an obstacle to the freedom of movement of goods, since FBOs are allowed to place botanical supplements on the market without using claims or by adapting to national regulations applicable to traditional claims under Article 28(6) (European Court of Justice, 2025). However, in a previous judgement from 2017, the CJEU stated that a prolongation of the transitional period concerning botanical claims assessment set by Article 13(3) HCR until 31 January 2010 does not meet consumers' needs for scientifically substantiated claims recognized in Recital 23 HCR (European Court of Justice, 2017). Despite CJEU case law, the EC Farm to Fork roadmap does not explicitly mention botanical claims assessments (European Commission, 2020b).

4.3.2 Expert interviews

The following section presents the results of expert interviews conducted to obtain insights into how German supplement manufacturers have adapted to the current health claims regulatory

framework, as these aspects are insufficiently addressed in the legal texts and institutional communications examined in the doctrinal analysis. Structured content analysis was applied to identify systematic approaches to the employment of health claims during customer engagement practices and product development procedures of.

Generally, interview participants perceived the German food supplement market as dynamic with high potential for future growth. Depending on company size and its establishment within the market, two divisions of customer target groups were identified. Larger companies typically aimed to exhibit market growth within the food supplement mass market, appealing to a wide range of customer profiles. Although not limited to them, comparatively smaller companies instead reported to focus their portfolio and subsequent customer engagement to specific customer target groups. As stated by the interviewees, among them are women and individuals experiencing gynecological conditions, professional and amateur athletes, seniors at risk of developing or suffering from loss of joint or bone health, vegans and vegetarians. Consumers who are interested in supporting their individual health through an optimized diet and daily nutrition were also a major focus group. Sales channels which candidates mentioned for distributing their products on the German market were national drug store chains, pharmacies, or online shops. Two interviewees mentioned that an exclusive sale via pharmacies was chosen to mutually benefit from product promotion through health care professionals.

This aligns with other interview statements, whereas the communication of potential individual health benefits derived from food supplement consumption was considered a significant factor in marketing narratives. However, all interviewees mentioned that solely EFSA-approved health claims are used to make health-related statements. One interviewee mentioned the use of approved health claims as beneficial for consumers to better delineate between food supplements and medicinal products containing the same ingredient. Although FBOs may vary from the official claims wording, if keeping its original meaning, interviewees identified such divergence as a risk factor for increased authority controls, legal and financial repercussions, including recalls and fines. Hence, a majority of interviewees stated dissatisfaction with the current discontinuation of botanical health claims assessments by EFSA.

In line with this finding, the advertisement and promotion of botanical ingredients in single or multi-ingredient supplements was considered difficult by most candidates. Three approaches to the marketing of botanicals by FBOs under the current implementation state of the HCR were identified. First, FBOs indicated to refrain from using traditional health claims, and benefit from recognition by consumers based on general ingredient knowledge or pre-existing health-related interests instead. Second, interview participants indicated that in multi-ingredient supplements, botanical ingredients were frequently combined with minerals or vitamins, for which health claims are approved. Thereby, botanical ingredients benefit from consumers

associating them with mineral or vitamin claims. Finally, one interviewee stated that their company chose to market botanical ingredients as pharmaceuticals, citing Germany's traditional focus on HMPs, avoidance of borderline issues, and a clearer foundation for making health-related claims.

The issue of creating borderline issues by notifying a product as a food supplement instead of seeking authorization as a medicinal product or vice versa was known to all participants. Despite not all of them mentioning them as specific regulatory or legal issues within their institution, borderline issues were perceived as a substantial risk fore reputational and financial sanctions. To avoid such negative consequences, companies were reported as spending considerable resources to ensure the lawful placing of their products on the market. All interviewees stated that, depending on the company's size and available resources, the employment of an internal regulatory affairs department, collaboration with external legal specialists, or a combination of both is necessary to oversee and advise during different product development stages. Guidance documents from national safety agencies or EFSA were considered an informational source during product development but do not constitute a legally binding statute.

Finally, most interviewees expressed dissatisfaction with the lack of harmonization in the EU supplement market. The absence of a positive list of botanical and other bioactive ingredients, as well as maximum dosages for minerals and vitamins, was seen as risk factors for sanctions and a barrier for market entry and sales. Interviewees also indicated that, from the FBO perspective, the declared product purpose and advertisement claims significantly contribute to the delineate between pharmaceuticals and food supplements.

4.4 Discussion

Health claims are an integral part of the EU's agenda due to their role in guiding consumers towards healthier food consumption. FBOs can benefit from leveraging science-based claims for advertising and on-package labelling purposes. A harmonized approach to regulating their use could improve fair market conditions, stimulating further economic growth. As highlighted by the results from the doctrinal legal analysis, streamlined health claims evaluations and authorization procedures could serve the purpose of diminishing the fragmentation of EU food supplement regulation identified by previous research (Jost *et al.*, 2025).

The results from expert interviews with food supplement industry representatives highlighted the perspective of the private sector on the current state of EU health claims regulation. Presenting food supplements as health-focused to consumers was reported as an important aspect within marketing narratives and developing business growth. Reflecting the consumers' perception of supplements as a tool for positively influencing personal health, this marketing

approach extensively relies on a robust regulatory framework. However, during the expert interviews, companies reported difficulties due to missing harmonization efforts in this regard. Instead, FBOs must spend substantial financial and human resources to accommodate for complex regulatory conditions, preventing financial repercussions and other sanctions.

The difficulties in lawfully using health claims described by FBOs are in line with other research. Khedkar et al. (2017) and Bröring et al. (2017) highlighted that the introduction of Article 13(1) HCR did not foster innovation in the food sector, as financial costs and lack of transparency were considered major challenges by companies. Buttriss (2015) recommended to lower administrative costs and improving economic conditions, especially for SMEs, by providing greater wording flexibility and better clarification of health claim communication limits. The empirical findings of this study seem to support these hypotheses, as interview candidates indicated difficulties with health claims wordings or a preference for switching to pharmaceutical authorizations. Although the study focused on issues present at the German market, previous research highlighted that difficulties in complying with horizontal EU food information laws are also present in other EMS. For example, supplement advertisements in Spanish radio were found to endorse unauthorized claims (Muela-Molina *et al.*, 2021a, 2021b). In the Czech Republic, online advertisements for food supplements were also identified as often non-compliant with EU regulations and providing only low-quality information to consumers (Baudischova *et al.*, 2018).

Previously identified issues concerning the use of botanical and other bioactive ingredients in food supplements appear to extent into advertisement and labelling requirements. Noble (2017) described that the suspension of botanical claims assessments contributes to the fragmentation of botanical ingredient regulation at the EMS level. Lenssen et al. (2018) highlighted that inconsistencies and a lack of transparency in EFSA's claims assessment procedures have created legal uncertainties for FBOs. Other research also highlighted that companies require more in-depth information and clarity on how to fulfill criteria for conducting food and health studies in order to obtain health claims authorizations (González-Díaz *et al.*, 2018). De Boer (2021) examined the use of traditional use evidence, comparable to THMPs authorization procedures, as a potential basis for claim approval aligned with meet the Commission's Farm to Fork agenda of harmonized front-of-pack labelling. This corresponds with the expert interviews, where the marketing of botanical supplements was perceived as challenging, often requiring substantial legal consultation. Although the HCR permits the of use traditional claims, most interviewees stated to avoid them to reduce the risk of regulatory conflicts.

Empirical evidence on the use of health claims by food supplement businesses in the EU is limited, as the majority of comparable research in this field focused on consumer perceptions

and understanding of circulating health claims (Meijer *et al*, 2022). Doctrinal legal studies primarily analyzed regulatory framework conditions for using health claims in the EU (Gonzáléz-Díaz *et al*., 2018). Brandenburger & Birringer (2015) conducted an online survey comprising sixteen food and beverage enterprises, highlighting anticipated comparatively higher costs for SMEs. This study underscores the impact of the fragmented EU food supplements regulatory framework on FBOs, particularly by incomplete enforcement of the HCR. Doctrinal legal analysis confirmed its partial implementation in the EU, despite calls from the European Parliament and EMS. Empirical research emphasized the significance of health claims in supplement marketing strategies aimed to align their products with consumer expectations. As the CJEU clarified, the EC did not fulfill its obligations under Article 13(3) HCR to adopt, within the prescribed period, an exhaustive list of permitted health claims, and its communication concerning the suspension of suspension of the health claims assessment did not amount to a defined position within the meaning of EU primary law (European Court of Justice, 2017). Statements of German authorities on the stalled assessment of on-hold botanical claims further highlight the need for a harmonized regulatory framework (Bundesregierung, 2021).

As this study focused exclusively on stakeholders in the German market, the findings from both the empirical and doctrinal legal analyses should not be directly generalized, given the significant divergences in market structures, legal cultures, and regulatory frameworks across jurisdictions. In addition, the study is subject to limitations due to its relatively small sample size, encompassing companies of varying sizes, resources, and target consumer groups.

4.5 Conclusion

Regulation of food supplements in the EU remains a persistent challenge to both companies and authorities. Legal fragmentation and resulting legal uncertainties extent into health claims regulation, particularly affecting herbal product manufacturers, which face a heightened scrutiny potential sanctions by safety authorities due to institutional inactiveness of responsible EU entities, posing financial and reputational risks. Given the central role of health claims in marketing strategies of the German food supplement market, greater harmonization is needed to support EU internal market development. Future research should focus on obtaining empirical insights from private stakeholders participating in other EMS markets or engaged in cross-border trade within the Union.

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4.7 Annex

4.7.1 Supplementary Material 1

Investigating the Impact of EU Food Information Regulation on Food Supplement Marketing Strategies – A Case Study on the German Market

Questionnaire used for conducting semi-structured expert interviews

I. Company Role and Responsibilities:

1. **What is your role in the company?**

II. Marketing Strategy and Target Audience:

2. Which target groups does your company aim to address with the marketing of its supplements?
3. What are some examples of the kinds of health claims your company makes on the products?
4. How important is promoting or improving individual health for the advertising and sale of supplements?

III. Distribution:

5. Which distribution channels do you primarily use to reach customers?

IV. Regulatory Awareness:

6. To what extent is your company sensitized to the regulatory distinction between food and medicine?
7. How do you classify your supplements? (i.e. food, medicine etc)
8. If you classify the products as food, what factors or measures does your company take to ensure your product is food as opposed to medicine?
9. Are there any specific claims you avoid to ensure your products are not considered medicinal?

V. Legal Compliance:

10. What assistance, if any, does your company receive in reaching a decision about whether a product is medicinal or food before it is released? For instance, legal support or regulatory guidance.

4.7.2 Supplementary Material 2

Investigating the impact of EU food information regulation on food supplement marketing strategies – A case study on the German market

Themes and codes for deductive qualitative content analysis by Mayring

Category	Subcategory	Definition	Delineation
External Affairs	Customer Relation	Statements referring to engaging with or approaching consumers	Only refers to interactions between the company and consumers
	Commercialization	Statements referring to market access and sales channels	Does not refer to advertisement materials or products development procedures
	Product Advertisement	Statements referring to developing and creating product packaging	Refers to any advertisement materials which do not rely on health claims
	Authority Relationships	Statements referring to cooperation and collaboration with food safety authorities	Refers to dealing with affairs concerning authority activities, not regulations
Internal Affairs	Expert Function	Statements referring to the role the interview candidate takes within the respective organization	Includes only statements on the function of the interviewee
	Product Development	Statements referring to procedures or considerations necessary to place a food supplement on the German market	Refers to internal procedures concerning decisions on ingredients, dosages, and delineation with pharmaceuticals
	Health Claims	Statements referring to the use or development of nutritional health claims on food supplements	Refers only to health claims, not other advertisement claims
	Regulation	Statements referring to legal acts regulating the manufacturing and distribution of food supplements	Refers to all relevant legal acts and other regulatory acts but not activities from authorities

4.7.3 Supplementary Material 3

Investigating the impact of EU food information regulation on food supplement marketing strategies – A case study on the German market

Claims Category	Example
Specific Health Claim	Beta-glucans contribute to the maintenance of normal blood cholesterol levels
Unspecific Health Claim	Supports well-being
Functional Health Claim	Calcium is needed for the maintenance of normal bones
Cognitive Health Claim	Iron contributes to normal cognitive function
Botanical Health Claim	Allium sativum contributes to vascular health
Disease Reduction Claim	Plant sterols and plant stanol esters have been shown to lower/reduce blood cholesterol. High cholesterol is a risk factor in the development of coronary heart disease.
Children's Development Claim	Essential fatty acids are needed for normal growth and development of children.
Nutrition Claim	A claim that a food is energy-reduced, and any claim likely to have the same meaning for the consumer, may only be made where the energy value is reduced by at least 30 %, with an indication of the characteristic(s) which make(s) the food reduced in its total energy value.

Supplementary Material 3 Examples for different types of health claims eligible for use on food products in the European Union

Chapter 5
Could Pharmacopoeial Reference Standards Serve as a Platform to Enhance the Quality and Safety Control Systems of European Food Supplement Businesses?

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Abstract

Previous research has highlighted several quality-related concerns regarding food supplements available on the European market, which compromise their safe consumption. This study evaluates whether the adoption of the European Pharmacopoeia (Ph. Eur.) as a framework for improving supplement quality could enhance quality and safety control practices. The findings are derived from a comparative legal analysis of the Canadian and U.S. legal systems. The results suggest that its application in the Canadian market may serve as an illustration of the Brussels effect in practice. Simultaneously, the European Food Safety Authority (EFSA) already encourages EU Food Business Operators (FBOs) to utilise the Ph. Eur. when assessing food supplement ingredients. Nevertheless, careful consideration is necessary regarding the extent of regulatory compliance by FBOs to mitigate potential conflicts with existing EU legislation and to prevent delays in innovative developments within the supplement market.

Keywords: Food Supplements; Food Law; Food Safety; Pharmacopoeia; Food Quality

5.1 Introduction

Even though they may often resemble pharmaceutical products in appearance, under European Union (EU) law food supplements are classified as foodstuffs.[1] While legally defined as food products intended to supplement the normal diet, research shows that consumers often perceive these products as a low-risk means of maintaining or enhancing their health, rather than merely as sources of nutritional value.[2] This divergence gives rise to questions as to whether the existing regulatory framework is suitably designed to ensure effective oversight of the food supplement market, particularly with respect to market surveillance.[3] Given the credence nature of these products, consumers cannot independently ascertain whether food supplements possess the claimed nutritional and health-related properties, nor whether they are affected by potential deficiencies. One way of dealing with such shortcomings may be the introduction of more robust market surveillance mechanisms with the aim to empower consumers to make informed choices and to realise the free movement provisions under EU primary law.

[1] Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements [2002] OJ L 183/51. Member States, however, are free to categorise food supplements as pharmaceutical products in their country in case they meet the respective criteria of EU law.

[2] Valeria Catalani and others, 'The Market of Sport Supplement in the Digital Era: A netnographic Analysis of perceived Risks, Side-effects and other Safety Issues' (2021) 1 Emerging Trends in Drugs, Addictions, and Health 100014

[3] R. Warda, K. Purnhagen and M. Molitorisová, 'Has Mutual Recognition in the EU Failed? — A Legal-Empirical Analysis on the Example of Food Supplements Containing Botanicals and Other Bioactive Substances' (2024) 47(3) Journal of Consumer Policy 425

In EU food law, food quality and safety are distinct but interdependent concepts. Its horizontal legal framework constitutes a risk-based regulatory system, which defines the conditions for food safety under Article 14 of Regulation (EC) No 178/2002 (General Food Law), whereas the marketing of food which is injurious to human health or otherwise unfit for consumption is prohibited.[4] The General Food Law imposes an obligation on food business operators (FBOs) to ensure and verify that their products comply with the requirements of food law.[5] This regulatory framework applies by definition also to food supplements.[6] Several European food safety acts also relevant to food supplements, such as Regulation (EC) No 852/2004 (Food Hygiene Regulation), Regulation (EC) No 396/2005 (Food Pesticides Regulation), and Commission Regulation (EU) 2023/915 (Food Contamination Regulation), establish specific manufacturing standards and permissible limits.[7]

The term of food quality is not uniformly defined by EU law, instead it is indirectly addressed through sectoral legislation, such as Directive 2002/46/EC (Food Supplements Directive), consumer information rules, or voluntary quality schemes. However, as quality defects may evolve into relevant safety aspects, such as contaminations or compositional inconsistency, establishing food quality serves a pivotal role in maintaining food safety and food supply chain integrity.

Implementing an effective quality control system is critical for performing robust product analyses and for the periodic assessment of results to identify and address quality defects, such as galenic inconsistencies or contamination.[8] However, the EU's legal framework does not prescribe detailed quality control measures specific to the food supplement sector, leaving the development and implementation of such measures to individual FBOs. Since regulatory authorities typically evaluate the efficacy of quality control methods during inspections, this dynamic may, willingly or unwillingly, allow lower-quality products to enter the market.[9] This significance of this dynamic is further underscored by FBOs facing significant methodological challenges in developing effective quality control methods, particularly for complex products such as multi-herbal ingredient supplements.

[4] Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety [2002] OJ L 31/1
[5] Ibid.
[6] Directive 2002/46/EC (n 1)
[7] Ariane Vettorazzi and others, 'European Regulatory Framework and Safety Assessment of Food-Related Bioactive Compounds' (2020) 12(3) Nutrients 613
[8] Richard Owusu-Apenten and Ernest Vieira, 'Food Safety Management, GMP & HACCP' in Richard Owusu-Apenten and Ernest R Vieira (eds), *Elementary Food Science* (Springer International Publishing 2023)
[9] Carlos A F Oliveira and others, 'Food Safety: Good Manufacturing Practices (GMP), Sanitation Standard Operating Procedures (SSOP), Hazard Analysis and Critical Control Point (HACCP)' in Jorge Barros-Velázquez (ed), *Antimicrobial Food Packaging* (Elsevier 2016)

Additionally, the range of enterprise sizes within the EU supplement market, from small and medium-sized enterprises (SMEs) to globally operating corporations, results in considerable disparities in financial and human resources. Although product quality is regarded as a key competitive factor among FBOs, the substantial effort required to develop and implement adequate quality control measures may place SMEs at a disadvantage compared to larger companies.[10] These variations affect FBOs' ability to establish robust quality control systems, whether independently or through third-party contractors.[11] [12] Addressing the resource allocation discrepancies between SMEs and larger enterprises in ensuring effective quality control could enhance consumer access to high-quality supplements across the EU, benefiting both public health and informed decision making.[13]

The United States of America (USA) and Canada have adopted a more nuanced approach to regulating food supplements by explicitly considering their pharmaceutical properties. Both countries have updated their pharmacopoeial compendia for supplements, aiming to enhance their quality and safety. Building on these developments, this article explores whether utilising the European Pharmacopoeia (Ph. Eur.) as a platform for improving food supplement quality could strengthen quality control practices among FBOs and regulatory authorities.

This study seeks to examine the potential benefits and risks associated with introducing pharmacopoeial reference standards in the EU supplement market by comparing the EU's legal framework, designed to support the production and sale of high-quality supplement products, with alternative regulatory approaches.

5.1.1 State of the art of the EU food supplements market regarding safety and quality control

The EU food supplements market has expanded from approximately €26 billion to nearly €32 billion between 2018 and 2020 and is projected to reach €48 billion by 2026.[14] This rapid growth highlights an increasing relevance of enhancing consumer access to safe and high-quality supplements.

[10] Noor Z Noor Hasnan and others, 'Analysis of the Most Frequent Nonconformance Aspects Related to Good Manufacturing Practices (GMP) Among Small and Medium Enterprises (SMEs) in the Food Industry and Their Main Factors' (2022) 141 Food Control 109205

[11] Keigo Sato, Kota Kodama and Shintaro Sengoku, 'Optimizing the Relationship Between Regulation and Innovation in Dietary Supplements: A Case Study of Food with Function Claims in Japan' (2023) 15(2) Nutrients

[12] Noor Hasnan and others (n 10)

[13] Irene B Murimi-Worstell and others, 'Association Between US Pharmacopeia (USP) Monograph Standards, Generic Entry and Prescription Drug Costs' (2019) 14(11) PloS one e0225109

[14] Statista, 'Value of the Dietary Supplements Market Worldwide in 2018 and 2020 With a Forecast to 2026, by Region (in Billion U.S. dollars)' (20 September 2021) <https://www.statista.com/statistics/1264459/region-global-dietary-supplement-market/> accessed 8 November 2024

Previous research has identified a range of persisting quality defects compromising the safe consumption of food supplements in the EU, with contamination being a primary concern. Among the most significant toxicological risks are the presence of heavy metals such as lead, arsenic, and chromium.[15] [16] Pesticide residues and metabolites have also been detected in botanical food supplements, likely originating from the agricultural treatment of plants and raw materials.[17] Notably, substances such as piperonyl butoxide, cyromazine, and chlorate, whose use is either strictly limited or prohibited in the EU due to safety concerns, have been found.[18] [19]Microbiological contamination poses an additional threat, with potentially human-pathogenic bacteria such as *Enterobacter* spp., *Salmonella* spp., and *Escherichia coli* confirmed in food supplements.[20] Identification of harmful mycotoxins produced by fungi, including ochratoxins, aflatoxins, and fumonisins, further exacerbate microbiological risks.[21] Moreover, frequent consumption of herbal supplements containing naturally occurring toxic compounds such as hepatotoxic pyrrolizidine alkaloids may lead to acute or short-term toxicity, as highlighted by the European Food Safety Agency (EFSA) in 2016.[22]

While the contamination issues documented in research may fall within the range of permitted daily doses and may not cause immediate toxic symptoms, the potential for frequent exposure to toxic substances and associated long-term health risks must be taken into account.[23] Beyond contamination, research has highlighted significant variability in ingredient quantities across supplements containing similar components, illustrating the broader problem of inconsistent galenic quality in EU food supplements.[24] Reflecting the prevalence of quality defects and their impact on product safety, food supplements have consistently ranked among the most frequently reported product categories in the European Commission's (EC) annual

[15] Piotr Rzymski and others, 'Essential and Toxic Elements in Commercial Microalgal Food Supplements' (2019) 31(6) Journal of Applied Phycology 3567
[16] Barbara Poniedziałek and others, 'Monitoring of Essential and Toxic Elements in Multi-Ingredient Food Supplements Produced in European Union' (2018) 13(1) Journal of Consumer Protection and Food Safety 41
[17] João G Costa and others, 'Contaminants: A Dark Side of Food Supplements?' (2019) 53(sup1) Free Radical Research 1113
[18] Renata Domingos Alves and others, 'Fast Determination of Four Polar Contaminants in Soy Nutraceutical Products by Liquid Chromatography Coupled to Tandem Mass Spectrometry' (2016) 408(28) Analytical and Bioanalytical Chemistry 8089
[19] Yang Chen and others, 'Determination of Multiresidue Pesticides in Botanical Dietary Supplements Using Gas Chromatography-Triple-Quadrupole Mass Spectrometry (GC-MS/MS)' (2016) 64(31) Journal of Agricultural and Food Chemistry 6125
[20] Magdalena Ratajczak and others, 'Quality of Dietary Supplements Containing Plant-Derived Ingredients Reconsidered by Microbiological Approach' (2020) 17(18) International Journal of Environmental Research and Public Health 6837
[21] Ibid.
[22] Helle K Knutsen and others, 'Risks for Human Health Related to the Presence of Pyrrolizidine Alkaloids in Honey, Tea, Herbal Infusions and Food Supplements' (2017) 15(7) EFS2 e04908
[23] Poniedziałek and others (n 16)
[24] Antonietta Stellavato and others, 'Comparative Analyses of Pharmaceuticals or Food Supplements Containing Chondroitin Sulfate: Are Their Bioactivities Equivalent?' (2019) 36(11) Advances in therapy 3221

Alert and Cooperation Network (ACN) reports, which track food product-related issues in the EU. [25] [26]

The increasing complexity and diversity of food supplements' compositions present a major challenge for developing laboratory methods capable of verifying the purity, identity, and quality of new ingredients or individual substances in mixtures.[27] Accurate identification and labelling of ingredients are especially critical for botanical supplements due to their potential toxicological impacts.[28] [29] However, developing effective quality control measures for singular ingredients within complex botanical mixtures is widely recognised as a difficult task.[30] [31] Furthermore, these quality control measures are often not publicly disclosed, as they remain proprietary to FBOs or third-party contractors, limiting transparency and collaboration in addressing these challenges.[32]

5.1.2 Consideration of pharmacopoeias as a remedy?

The current regulatory framework for food supplements in the EU places primary responsibility on FBOs, with a more limited role for competent authorities, to design and implement appropriate production and quality control procedures.[33] In contrast, jurisdictions outside the EU have adopted an alternative approach to enhancing the quality and safety of food supplements by providing the industry with scientifically validated production and quality control standards through pharmacopoeial codification.[34] In the USA, following debates over the regulatory status of certain botanical supplements and the subsequent enactment of the Dietary Supplements Health and Education Act (DSHEA) in 1994, the United States

[25] European Commission, 'Alert and Cooperation Network: 2022 Annual Report' (2022) <https://food.ec.europa.eu/document/download/499ffcf1-6c99-43ec-8905-5ff3e812eeb2_en?filename=acn_annual-report_2022.pdf> accessed 11 November 2024
[26] European Commission, 'Alert and Cooperation Network: 2023 Annual Report' (2023) <https://food.ec.europa.eu/document/download/911d49f2-b3ef-4752-8ea3-5f20dbbe9945_en?filename=acn_annual-report_2023.pdf> accessed 11 November 2024
[27] Gunawan Indrayanto, 'Regulation and Standardization of Herbal drugs: Current Status, Limitation, Challenge's and Future Prospective' (2024) 49 Profiles of Drug Substances, Excipients, and Related Methodology 153
[28] Anna R Bilia and Maria d C Costa, 'Medicinal Plants and Their Preparations in the European Market: Why Has the Harmonization Failed? The Cases of St. John's Wort, Valerian, Ginkgo, Ginseng, and Green Tea' (2021) 81 Phytomedicine: International Journal of Phytotherapy and Phytopharmacology 153421
[29] Hong You and others, 'Analytical Strategies to Determine the Labelling Accuracy and Economically-Motivated Adulteration of "Natural" Dietary Supplements in the Marketplace: Turmeric Case Study' (2022) 370 Food Chemistry 131007
[30] Indrayanto (n 27)
[31] Hongting Wang and others, 'Advancing Herbal Medicine: Enhancing Product Quality and Safety Through Robust Quality Control Practices' (2023) 14 Frontiers in Pharmacology 1265178
[32] Nandakumara Sarma and others, 'Pharmacopeial Standards for the Quality Control of Botanical Dietary Supplements in the United States' (2023) 20(3) Journal of Dietary Supplements 485
[33] Kai P Purnhagen and Alexandra Molitorisová, 'Public and Private Enforcement in European Union Food Law' (2022) 13(3) European Journal of Risk Regulation 464
[34] Sarma and others (n 32)

Pharmacopoeia (USP) was revised to incorporate supplement ingredients and preparations.[35] Additionally, the American Herbal Pharmacopoeia (AHP), which specialises in botanical supplements and ingredients, is accessible to supplement manufacturers.[36]

In Canada, food supplements have been regulated as natural health products (NHPs), a category of over-the-counter (OTC) drugs, since 2004.[37] However, there is no specific Canadian pharmacopoeia dedicated to natural health products.[38] Instead, authorities actively encourage FBOs to utilise validated production and laboratory quality control methods outlined in recognised pharmacopoeias, such as the Ph. Eur. or the USP.[39] [40]

Traditionally associated with the pharmaceutical industry, pharmacopoeias constitute public collections of monographs containing standardised guidelines for defining, identifying, preparing, and storing ingredients, raw materials, and formulations. They also include suitable methods for determining the quantity, purity, and quality of listed ingredients or galenic preparations.[41] With contributions from stakeholders, including academics, regulatory authorities, and industry representatives, the development of pharmacopoeial monographs often achieves a high level of methodological validation.[42] In this context, the Ph. Eur. has long been established as a common reference standard for quality assurance programs across the European pharmaceutical market.[43] Given the challenges FBOs face in implementing effective quality control, pharmacopoeial standards applicable to supplements could offer a low-threshold solution by providing uniform, validated reference standards for FBOs in the EU.

5.2 Methodology

Through employing the functional method of comparative law, this study will examine the potential of the Ph. Eur. to serve as a platform for accelerating the development of quality control methods within the EU food supplement sector using the regulatory frameworks of the USA and Canada as case studies. The USA and Canada were selected as case studies as they already integrated pharmacopoeial standards into their regulatory systems, albeit to

[35] Darla D O'Dwyer and Sujatha Vegiraju, 'Navigating the Maze of Dietary Supplements' (2020) 35(3) Topics in Clinical Nutrition 248
[36] American Herbal Pharmacopoeia, 'About AHP Monographs' <https://herbal-ahp.org/about-ahp-monographs/> accessed 22 January 2025
[37] Natural Health Products Regulations, SOR 2003/196 (Can, 2003)
[38] Natural and Non-prescription Health Products Directorate, 'Compendium of Monographs: Version 3.0' (13 June 2014) <https://www.canada.ca/content/dam/hc-sc/migration/hc-sc/dhp-mps/alt_formats/pdf/consultation/natur/2013-08-compendium-eng.pdf> accessed 12 August 2024
[39] Natural and Non-prescription Health Products Directorate, 'Quality of Natural Health Products Guide' (1 May 2015) <https://www.canada.ca/content/dam/hc-sc/migration/hc-sc/dhp-mps/alt_formats/pdf/prodnatur/legislation/docs/eq-paq-eng.pdf> accessed 12 August 2024
[40] Sarma and others (n 32)
[41] O'Dwyer and Vegiraju (n 35)
[42] Sarma and others (n 32)
[43] Anne-Sophie Bouin and Michael Wierer, 'Quality Standards of the European Pharmacopoeia' (2014) 158 Pt B Journal of Ethnopharmacology 454

varying degrees, providing a broader perspective on the application of such standards in supplement regulation.[44] Moreover, the United States hosts the world's largest supplement market, whereas Canada has adopted a distinct regulatory approach to supplements.As EU food law must balance progressing the EU's internal market freedoms with ensuring a high level of consumer protection, this study also examines the legally binding nature of pharmacopoeias within these regulatory frameworks.[45] [46]

The functional method of comparative law provides an effective approach for identifying similarities and differences between legal frameworks governing a specific sector across different jurisdictions.[47] As described by previous research, comparative law can provide deep understanding and accelerate improvements of a legal system.[48] The functional method does not solely investigate the theoretical background of the studied legal frameworks provided by comprehensive law texts.[49] Instead, it also considers the effects created by these frameworks, thereby investigating different approaches to dealing with a comparable socio-legal problem.[50] Although there is no uniform definition of conducting functional legal comparison, it has been recognised as a suitable research method in the context of European law development.[51] In this study, we first examined and compared the corresponding legal frameworks defining and regulating the quality of food supplements in the observed countries. Second, we comparatively assessed the relevance of pharmacopoeial standards within the respective supplement markets. European legal texts were retrieved from N-Lex, US-American legal texts from the Federal Register. Canadian legislation was retrieved from the public Justice Laws Website maintained by the Canadian Department of Justice. To enhance the context of the studied legal texts, we included relevant grey literature, such as institutional statements, in the functional comparison.[52]

The comparison between the European Roman law-based legal culture against the Anglo-Saxon legal cultures of the USA and Canada is not subject of this research as the assessment

[44] Sarma and others (n 32)
[45] Federica Ronchetti, Laura Springer and Kai P Purnhagen, 'Pre-Market Authorisation' in Federica Ronchetti, Laura Springer and Kai P Purnhagen (eds), *The Regulatory Landscape in the EU for Dairy Products Derived from Precision Fermentation* (Springer Nature Switzerland 2024)
[46] Purnhagen and Molitorisová (n 33)
[47] Mark van Hoecke, 'Methodology of Comparative Legal Research' (2015) Law and Method 1-35
[48] Ibid.
[49] Ralf Michaels, 'The Functional Method of Comparative Law' in Mathias Reimann, Reinhard Zimmermann and Ralf Michaels (eds), *The Oxford Handbook of Comparative Law* (Oxford University Press 2006)
[50] Ibid.
[51] Jaakko Husa, 'Methodology of Comparative Law Today: From Paradoxes to Flexibility?' (2006) 58(4) Revue internationale de droit comparé 1095
[52] van Hoecke (n 47)

of different legal cultures primarily focuses on broad societal patterns and would exceed the scope of this study.[53] [54]

5.3 Results

5.3.1 Food supplement quality and safety framework conditions

5.3.1.1 Classification: Food or medicine

In the EU, supplements are regulated as foodstuff intended to supplement the regular diet with concentrates of vitamins, minerals, and other micronutrients such as botanicals, amino acids, and other bioactive substances via the Food Supplements Directive.[55] Food supplements must also be marketed in pharmaceutical-like single-dosed forms intended for oral ingestion, such as capsules, tablets, powders, or liquids.[56]

In the USA, the Federal Food, Drug, and Cosmetics Act (FD&C Act) stipulates comprehensive legal framework conditions for several product categories derived from the food and pharmaceuticals sector, defining basic terms and responsibilities.[57] In 1994, the FD&C Act was amended by the Supplements Act DSHEA.[58] Similarly to EU legislation, DSHEA Article 3 (21 United States Code (U.S.C.) Article 321(ff)) defines food supplements as foodstuff intended to supplement the diet, containing minerals, vitamins, botanicals, amino acids, or other dietary ingredients and does not include a substance considered as a drug, antibiotic, biological, or a substance under clinical investigation.[59]

In Canada, food supplements are categorised as NHPs, a type of OTC self-care products containing naturally occurring substances designed for personal health maintenance.[60] Since 2004, around 120,000 products have been licensed, of which around half have been placed on the Canadian market.[61] Substantiated in a generally assumed level of risk derived from their consumption, although lesser than other pharmaceutical preparations, the corresponding

[53] David Nelken, 'Comparative Legal Research and Legal Culture: Facts, Approaches, and Values' (2016) 12(1) Annual Review of Law and Social Science 45
[54] Ján Ivančík, 'Roman Principles – Foundations of the European Legal Culture and Their Position in the Changing World' (2021) Vilnius University Open Series 58
[55] Directive 2002/46/EC (n 1)
[56] Ibid.
[57] Josef A Brinckmann and others, '25 Years of DSHEA: Impact on Supply, Conservation and Sustainability, GACPs and Regulatory Compliance of Botanical Ingredients' in Ákos Máthé (ed), *Medicinal and Aromatic Plants of North America* (Springer International Publishing 2020)
[58] 'Dietary Supplement Health and Education Act of 1994, Pub L No 103-417, 108 Stat 4325 (US 1994)'
[59] Ibid.
[60] Health Canada, 'Self-Care Products and Health Canada' (30 January 2017) <https://www.canada.ca/content/dam/hc-sc/documents/services/publications/drugs-health-products/fs-eng.pdf> accessed 12 August 2024
[61] Health Canada, 'Proposed Fees for Natural Health Products (for Consultation)' (1 May 2023) <https://www.canada.ca/content/dam/hc-sc/documents/programs/consultation-proposed-fees-natural-health-products/overview/overview.pdf> accessed 11 November 2024

regulatory framework provided by the Natural Health Products Regulation (NHPR) was adopted in 2004.[62] NHPR Article 1 defines NHPs as preparations containing Schedule 1 ingredients, meaning botanicals or their parts, algae, bacteria, fungi, animal materials, or extracts and isolates derived from them.[63] NHPR Schedule 1 lists minerals, probiotics, enzymes, and certain vitamins as permitted ingredients.[64] Homoeopathic and traditional medicines, such as traditional Chinese medicine or ayurvedic medicines, and some cosmetics, such as certain sunscreens or toothpaste, also fall in the category of NHPs.[65] As of 2023, following the enactment of the Protecting Canadians from Unsafe Drugs Act (Vanessa's Law), the definition of therapeutic products in the Canadian Food and Drug Act (F&D Act) was revised to include NHPs.[66]

5.3.1.2 Baseline prerequisites for lawful market access

The eligibility of food supplements being placed on the market in the EU is generally regulated by the General Food Law and the Food Supplements Directive, stipulating that all foodstuff must be safe for human consumption, for which the FBO is responsible, and cannot be a medicinal product, cosmetic or medical device.[67] [68] In the USA, by stating that food is considered adulterated if it is injurious to human health, FD&C Act Section 402(a)(1) (21 U.S.C. Article 342(a)(1)) also places the responsibility of ensuring food safety upon the FBO.[69] Section 402(g)(1) (21 U.S.C. Article 342(g)(1)) further requires FBO to manufacture their products in accordance with the applicable Good Manufacturing Practices (GMP) regulations.[70] DSHEA Article 4 (21 U.S.C. Article 343) requires supplements to be safe for consumption.[71] However, it places the burden of proof that a product or ingredient is unsafe for it being considered injurious upon the responsible authority, meaning the Food and Drug Administration (FDA).[72]

Although NHPs are considered therapeutic products, the Canadian F&D Act only applies to them if specifically mentioned, as the NHPR is the primary legal act providing framework

[62] Natural Health Products Regulations SOR 2003/196 (n 37)
[63] Ibid.
[64] Ibid.
[65] Ibid.
[66] Health Canada, 'Guide to Authorities Under the Protecting Canadians from Unsafe Drugs Act (Vanessa's Law)' (1 August 2023) <https://www.canada.ca/content/dam/hc-sc/documents/services/drugs-health-products/medical-devices/application-information/guidance-documents/clinical-evidence-requirements-medical-devices/guide-authorities-protecting-canadians-unsafe-drugs-act-vanessas-law-eng.pdf> accessed 11 November 2024
[67] Regulation (EC) No 178/2002 (n 4)
[68] Evelyn Breitweg-Lehmann, Birgit Liebscher and Carolin Bendadani, 'Food Supplements: Definition and Classification' in Franz J Hock and Michael R Gralinski (eds), *Drug Discovery and Evaluation: Methods in Clinical Pharmacology* (Springer International Publishing 2020)
[69] Federal Food, Drug, and Cosmetics Act, Pub L No 75-717, 52 Stat 1040 (US, 1938)
[70] Ibid.
[71] (n 58)
[72] Ibid.

conditions.[73] However, the F&D Act stipulates that therapeutic products and foodstuffs must be safe for humans to consume (compare Section B.01.001, B.01.002., and C.01.016).

5.3.1.3 Technical regulations

While not directly aimed at supplements, horizontal technical specifications laid down in EU legislation concerning food quality and safety also apply to supplements as they fall under the definition of foodstuff.[74] Commission Regulation (EU) 2023/915 specifies maximum levels for food contaminants such as heavy metals, mycotoxins, pyrrolizidine alkaloids, polycyclic aromatic hydrocarbons (PAHs), dioxins, or polychlorinated biphenyls (PCBs).[75] Regulation (EC) No 396/2005 further regulates maximum pesticide residue levels, while Regulation (EC) No 2073/2005 specifies microbiological criteria for foodstuff.[76] [77] General requirements concerning product labelling, allergen declarations, and advertisement claims are laid down by Regulation (EU) No 1169/2011 (Food Information Regulation) and Regulation (EC) No 1924/2006 (Health Claims Regulation).

Pursuant to Regulation (EC) No 1925/2006, the general use of ingredients or substances in food may be prohibited or limited in the EU if placed in the annexes of the regulation, such as ephedra or red yeast rice extracts.[78] Positive Union lists on ingredients approved for use in supplements exist only for vitamins and minerals, which are placed in the annexes of the Food Supplement Directive.[79] The creation of a list of approved ingredients other than nutrients, namely botanicals or other bioactive substances, was abolished by the EC in 2008.[80] Instead, it was anticipated that the principle of mutual recognition, where a product lawfully sold in a Member State cannot be restricted from entering the market in another Member State, would contribute to harmonising this supplement category.[81] As this particular mode of governance has not been widely established in the supplement sector, the use of botanicals in the EU

[73] Natural Health Products Regulations SOR 2003/196 (n 37)
[74] Pia Noble, 'Nahrungsergänzungsmittel: Rechtliche Grundlagen, Abgrenzung zu Arzneimitteln, sonstige Fragestellungen' [Food Supplements: Legal Foundations, Distinction from Medicinal Products, Other Issues] (2017) 60(3) Bundesgesundheitsblatt, Gesundheitsforschung, Gesundheitsschutz 260
[75] Commission Regulation (EU) 2023/915 of 25 April 2023 on maximum levels for certain contaminants in food and repealing Regulation (EC) No 1881/2006 [2023] OJ L 119/103
[76] Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC [2005] OJ L 70/1
[77] Commission Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs [2005] OJ L 338/1
[78] Regulation (EC) No 1925/2006 of the European Parliament and of the Council of 20 December 2006 on the addition of vitamins and minerals and of certain other substances to foods [2006] OJ L 404/26
[79] Directive 2002/46/EC (n 1)
[80] European Commission, 'Report from the Commission to the Council and the European Parliament on the use of substances other than vitamins and minerals in food supplements' (2008) COM(2008) 824
[81] Pieter van Cleynenbreugel, 'Maximum Vitamin Amounts in Food Supplements: Towards Science-Based and Streamlined EU Mutual Recognition and Risk Assessment Procedures?' (2018) 9(1) European Journal of Risk Regulation 162

remains mostly regulated at the national level.[82] While the applicable legal framework sets technical conditions that food supplement production has to meet, it remains the responsibility of the FBO to develop quality control methods suitable for process monitoring.[83] Since no uniform codex containing validated methods is available, FBOs must develop and implement these themselves or commission a third-party contractor.[84] The appropriateness of the implemented measures is regularly inspected by food safety authorities, as the assessment of production and quality control systems is mandated by Article 9(1) of the Official Controls Regulation (Regulation (EU) 2017/625).[85]

Contrary, the quality of food supplements on the US market is further regulated by Chapter I, Subchapter B, Part 111 of Title 21 of the Code of Federal Regulation (21 CFR 111), which codifies current GMP (cGMP) rules applicable to manufacturing, packaging, labelling, and holding operations.[86] It contains detailed requirements that FBOs must meet regarding personnel and staff training, documentation, sanitary conditions, facility specifications, and equipment.[87] Subpart E specifically mandates steps quality control systems should incorporate, emphasizing the need for scientifically valid methods to continuously ensure defined identity, purity, composition and contamination limits.[88] However, manufacturers must only implement measures to identify reasonably expected contaminations and may rely on quality certificates provided by suppliers or third parties.[89]

In Canada, the NHPR sets out a comprehensive framework governing the manufacturing, distribution, and sale of NHPs. cGMP requirements are laid down in Part 3, and Article 43(1) makes compliance with them mandatory for selling, manufacturing, and distribution. While cGMP requirements are more generally described, stipulating the need for business operators to implement sufficient measures to assess purity, identity, quantity, and potency, describe testing methods and define their tolerance levels, emphasis is placed upon the responsibility of quality assurance staff Article 47 requires staff to be qualified for functional roles through sufficient training, education, or experience. Article 51 requires businesses to employ a trained quality assurance person responsible for approving every specification, material, method, procedure, or activity before manufacturing and selling NHPs. To assist manufacturers in their legal obligations, the Natural and Non-prescription Health Products Directorate (NNHPD) has

[82] Ibid.
[83] Regulation (EC) No 178/2002 (n 4)
[84] Sarma and others (n 32)
[85] Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products [2017] OJ L 95/1
[86] 21 CFR 111 - Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements (US, 2025)
[87] Ibid.
[88] Ibid.
[89] Ibid.

published a GMP guidance document, laying down specific steps ranging from sanitary conditions and formulation of standard operating procedures to effectively performing quality assurance activities.[90]

5.3.1.4 The role of food safety authorities

EFSA, on behalf of the EC, is the EU's authority responsible for safety assessments of food ingredients and providing guidance for FBOs. Following the adoption of the Food Supplements Directive, EFSA developed the list of minerals and vitamins and their chemical forms permitted for use in supplements.[91] Additionally, in the absence of respective legal statutes, EFSA published an overview of tolerable upper intake levels for nutrients.[92] Per Regulation (EC) No 1925/2006, EFSA carried out safety assessments for substances for which safety concerns were raised by Member States or the EC and subsequently banned or restricted, such as monacolins, ephedra, or yohimbe.[93] However, following a decentralised approach, enforcing compliance of FBOs with EU food law to ensure safety and quality through inspections or sanctions remains the responsibility of national competent authorities.[94]

Health Canada, being the Canadian Ministry of Health, and its subordinate NNHPD are the responsible authorities for regulating the use and sale of NHPs.[95] Via the introduction of Vanessa's Law, Health Canada is entitled to order recalls, enclose confidential business information, or mandate healthcare institutions to report adverse reactions.[96] The act aims to strengthen regulatory oversight of NHPs in response to an audit by the Commissioner of the Environment and Sustainable Development in 2021.[97] [98] Its report identified, among other issues, an inability of Health Canada to comprehensively enforce NHP safety and quality under the NHPR, e.g. successfully removing adulterated and contaminated products from the market.[99]

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[90] Natural and Non-prescription Health Products Directorate, 'Good Manufacturing Practices Guidance Document: Version 3.0' (11 June 2014) <https://www.canada.ca/content/dam/hc-sc/migration/hc-sc/dhp-mps/alt_formats/pdf/consultation/natur/gmp-bpf-eng.pdf> accessed 12 August 2024
[91] Directive 2002/46/EC (n 1)
[92] Dominique Turck and others, 'Guidance for Establishing and Applying Tolerable Upper Intake Levels for Vitamins and Essential Minerals: Draft for Internal Testing' (2022) 20(1) EFSA Journal e200102
[93] Regulation (EC) No 1925/2006 (n 78)
[94] Purnhagen and Molitorisová (n 33)
[95] Sarma and others (n 32)
[96] Health Canada, 'Guide to Authorities Under the Protecting Canadians from Unsafe Drugs Act (Vanessa's Law)' (n 6
[97] Ibid.
[98] Office of the Auditor General of Canada, 'Reports of the Commissioner of the Environment and Sustainable Development to the Parliament of Canada. Report 2: Natural Health Products - Health Canada' (2021) <https://open.canada.ca/data/dataset/4bfc8fde-63bf-4096-83f0-2a3daddbd372/resource/7b72ead3-75ee-40d3-81a4-c0b1bb8b34a3/download/parl_cesd_202104_02_e.pdf> accessed 11 November 2024
[99] Ibid.

In the USA, the FDA's authority to regulate the sale and manufacturing of food supplements is limited by DSHEA to sole post-market enforcement.[100] Therefore, unlawfully marketed products can only be removed from the market upon individually establishing that they are misbranded, adulterated, or hazardous.[101] In response to monitoring the sale of unlawfully sold or insufficiently produced supplements, the FDA has repeatedly issued warning letters to manufacturers.[102]

5.3.1.5 Notification procedures

As NHPs are considered therapeutic products under Canadian law, the NHPR prohibits their manufacturing, sale, and importing without a respective license.[103] Business operators are mandated by NHPR Part 1 to apply with the NNHPD for a product license prior to selling (compare Article 4(1)). Application requirements are also specified, whereas the names of ingredients and excipients and their potency, quantity, and purpose must be stated. After issuing a license, every NHP is assigned a number, which must be presented on the label. Amendments or changes to the permit needs approval from the authority or must be notified 60 days prior. NNHPD retains the authority to remove a product from the market upon the reasonable belief of unsafety and the business operator's inability to prove its safety sufficiently.[104] As of 2023, Canadian authorities receive around 10000 product applications annually.[105] NHPR Part 2 also mandates that every production site or storage site, in the case of imported NHPs, must be licensed by the NNHPD before manufacturing, packaging, labelling, or storing NHPs.[106] Site license applications further require the statement of an assigned quality assurance person that all used buildings, equipment, practices, and procedures comply with cGMP requirements. If a license is obtained by an FBO, it must be renewed periodically.

In the EU, FBOs intending to place a new product on the market are required by the Food Supplements Directive to notify the responsible national authority.[107] However, the design of the notification procedures is left to the individual European Member States and may range from a simple notification form to authorisation-like procedures.[108] As many botanical

[100] Aarika Nieto, 'Supplementing DSHEA One Step at a Time: The FDA's Modernization Plan' (2022) 70(1) DePaul Law Review 115
[101] Ibid.
[102] Jenna Tucker and others, 'Unapproved Pharmaceutical Ingredients Included in Dietary Supplements Associated with US Food and Drug Administration Warnings' (2018) 1(6) JAMA Network Open e183337
[103] Natural Health Products Regulations SOR 2003/196 (n 37)
[104] Ibid.
[105] Health Canada, 'Proposed Fees for Natural Health Products (for Consultation)' (n 61)
[106] Natural Health Products Regulations SOR 2003/196 (n 37)
[107] Directive 2002/46/EC (n 1)
[108] European Commission, 'Report from the Commission to the Council and the European Parliament on the use of substances other than vitamins and minerals in food supplements' (n 80)

ingredients, extracts, or preparations may be found in food or medicine, EU legislation allows the marketing of a majority of them as herbal medicinal products (HMPs) or food supplements.[109] [110] HMPs are defined as pharmaceuticals containing a botanical active ingredient by Directive 2001/83/EC (Medicinal Products Directive),thereby being regulated by medicinal products law in terms of efficacy, quality, and safety.[111] Botanical ingredients used in medical indications for at least 30 years can also be registered as Traditional Herbal Medicinal Products (THMPs) under the provisions of Article 16(a)(1) of the Medicinal Products Directive, which includes a simplified authorisation procedure, requiring proof of quality and safety, but not of efficacy.[112] Depending on commercial interests, such as authorisation procedures, development costs, or permitted advertisement claims, FBO may choose under which legal framework they register their product.[113] [114] The European Court of Justice (ECJ) established in its case *Commission v Germany* (C-319/05) that supplements containing botanical ingredients, which may be found in both food or pharmaceuticals, should be considered a supplement if their physiological effect and dosage are comparable to regular dietary consumption of this ingredient.[115]

5.3.1.6 New dietary ingredients

Following a debate on the legal status of botanical supplement ingredients, comparable to the EU borderline product issue, all supplement ingredients legally marketed in the USA before 1994 are considered safe without the need for pre-marketing approval from the FDA since the adoption of DSHEA.[116] Since then, only so-called new dietary ingredients (NDI), which were placed on the market after DSHEA was adopted, require pre-market approval from the FDA.[117] FBO intending to sell NDI supplements must notify the authority 75 days before market entry, during which the agency shall issue a decision based upon an individual safety assessment.[118] However, as stated by the FDA, the growing number of available supplements and FBOs pose

[109] Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use [2001] OJ L 311/67
[110] Vittorio Silano and others, 'Regulations Applicable to Plant Food Supplements and Related Products in the European Union' (2011) 2(12) Food & Function 710
[111] Directive 2001/83/EC (n 109)
[112] Ibid.
[113] Bilia and Costa (n 28)
[114] Silano and others (n 110)
[115] Case C-319/05 *Commission of the European Communities v Federal Republic of Germany* [2007] ECR I-09811 (Court of Justice of the European Union)
[116] Brinckmann and others (n 57)
[117] (n 58)
[118] Ibid.

a great regulatory challenge.[119] As estimated by the authority, several thousand NDI were not notified correctly prior to market entry, circumventing pre-market authorisation procedures.[120]

Comparable to the US-American regulation of NDI, the EU Regulation (EU) 2015/2283 (Novel Food Regulation) defines substances which have not significantly been consumed in the EU before 1997, are newly developed and innovative food products, or are foodstuff produced by using new technologies as novel foods.[121] Regarding supplements, these mainly concern new botanicals, certain bioactive micronutrients, or new analogues of permitted nutrients. Comparable to the USA, novel foods in the EU also require pre-market authorisation by the EC, contingent upon individual safety assessments by EFSA.[122] FBOs must detail scalable and reliable production procedures and provide a proof of safety in their application file.[123] EFSA published several guidance documents aimed at FBOs, detailing the required product information necessary for a sufficient safety assessment. Besides toxicological data, emphasis is placed on the description of production procedures and the provision of compositional data and stability. In its Guidance on the scientific requirements for an application for authorisation of a novel food in the context of Regulation (EU) 2015/2283 from 2024, EFSA explicitly states a preference for internationally recognised and validated methods such as provided by the Ph. Eur.[124] Another example of the use of Ph. Eur. quality control methods relevant to novel food safety assessment is the mention of Ph. Eur. methods for conducting dissociation studies.[125] Further, in its scientific opinion on assessing the safety of botanical ingredients in food supplements, EFSA advises FBOs to follow the Ph. Eur. nomenclature for the identification of botanicals.[126] To standardise manufacturing procedures of botanical supplements and set analytical specifications for characterising one or multiple ingredients, EFSA also recommends leveraging on validated Ph. Eur. methods.[127] However, the use of these methods is focused on the proof of safety of an ingredient or product, albeit there might be an overlap in determining a product's quality to demonstrate its safety. Therefore, supervising production

[119] Food and Drug Administration, 'Policy Regarding Certain New Dietary Ingredients and Dietary Supplements Subject to the Requirement for Pre-Market Notification: Guidance for Industry' (2022) <https://www.fda.gov/media/158369/download?attachment> accessed 12 August 2024
[120] Ibid.
[121] Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods 11 December [2015] OJ L 327/1
[122] Ibid.
[123] Ibid.
[124] Dominique Turck and others, 'Guidance on the Scientific Requirements for an Application for Authorisation of a Novel Food in the Context of Regulation (EU) 2015/2283' (2024) 22(9) EFSA Journal e8961
[125] Ibid.
[126] Dominique Turck and others, 'Guidance on the Preparation and Presentation of an Application for Authorisation of a Novel Food in the Context of Regulation (EU) 2015/2283' (2016) 14(11) EFSA Journal e04594
[127] Ibid.

procedures and quality control methods for food supplements containing novel food ingredients remain with the responsible national food safety authorities.

5.3.2 Pharmacopoeias: Ph. Eur., USP-NF, AHP, Compendium of Monographs

5.3.2.1 Pharmacopoeial compendia

The Ph. Eur. is the EU pharmacopoeia, codifying definitions of active pharmaceutical ingredients (APIs) and preparations thereof and validated analytical or production methods.[128] The European Directorate for the Quality of Medicines & Health Care (EDQM), a directorate of the Council of Europe, is the responsible agency for developing the Ph. Eur. and its monographs. In cooperation with the European Medicines Agency (EMA), national safety authorities, academic experts, and stakeholders from the pharmaceutical industries, the EDQM's Ph. Eur. Commission aims to continuously update and revise the Ph. Eur. monographs and general chapters.

In the USA, USP develops and publishes standards for ensuring the identity, purity, and strength of APIs, pharmaceutical preparations, excipients and food supplements, published as monographs in the USP-National Formulary (USP-NF).[129] Unlike EDQM, USP is a scientific non-profit organisation aiming to improve the quality of pharmaceuticals and food supplements and strengthen its supply chains by developing public reference standards.[130] It is governed by the USP Convention, which consists of 455 primarily US-American member organisations, ranging from healthcare professional associations, consumer organisations, manufacturer and trade associations, and academic or governmental entities.[131] The development of monographs is conducted by voluntary USP Expert Committees working together with FDA experts representing governmental liaisons.[132] The life cycle of monographs is also continuously updated by incorporating public comments from academia, industry, healthcare professionals, or governmental entities.[133] Additionally, the AHP non-profit organisation was founded in 1995, shortly after DSHEA was adopted. AHP provides several public monographs on botanical ingredients intended for use in herbal medicines or food supplements.

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[128] Bouin and Wierer (n 43)
[129] United States Pharmacopoeia, 'An Overview of USP Monographs' (2019) <https://www.usp.org/sites/default/files/usp/document/about/public-policy/monograph-basics.pdf> accessed 12 August 2024
[130] United States Pharmacopoeia, 'Annual Report 2022' (2023) <https://www.usp.org/sites/default/files/usp/document/about/annual-report/usp-annual-report-2022.pdf> accessed 12 August 2024
[131] United States Pharmacopoeia, 'USP Convention Members by Membership Category' (3 January 2023) <https://www.usp.org/sites/default/files/usp/document/convention/2024_Members-by-region.pdf> accessed 28 November 2024
[132] United States Pharmacopoeia, 'An Overview of USP Monographs' (n 129)
[133] Ibid.

Unlike the EU and the USA, the quality of NHPs and other types of therapeutic products are not defined by a national pharmacopoeia in Canada.[134] Instead, the NNHPD provides the Compendium of Monographs, explicitly pertaining to single or multiple NHP ingredients and specific so-called product monographs.[135] Compendial monographs set out the proper common and scientific name, administration route, recommended use, dosage, preparation method, current risk information, and duration of use.[136] However, unlike the Ph. Eur. or USP, they do not detail methods for verification of quality, purity, or identity. All monographs are publicly available through the Natural Health Products Ingredient Database and may function as references for which efficacy, quality, and safety have been demonstrated during license application procedures.[137] [138] [139]

5.3.2.2 Monographs

The Ph. Eur.'s general part contains detailed information on analytical methods for physicochemical and microbiological testing, standard procedures for assays involving biological materials, and descriptions of preparing, using, and calibrating reference standards for these methods.[140] An additional list of reagents for use in analytical methods and assays, detailing their preparation and standardisation, is also provided.[141] A chapter on pharmaceutical technology describes preparation and testing methods, including guidelines on their respective performance and specifications for primary contact materials and dosage forms such as tablets, capsules, or injections.[142] The specific part contains a collection of monographs which define and characterise natural, synthetic, semi-synthetic, biological, or microbiological API.[143] Each API monograph contains information and reference values for analytical identification, purity, and stability methods.[144] Monographs on excipients and bulking agents for pharmaceutical use can be found in the general part.[145]

Like the Ph. Eur. monographs, USP-NF monographs define quality aspects of a substance or preparation, such as identity, purity, strength, composition, or pharmacodynamic aspects and

[134] Sarma and others (n 32)
[135] Natural and Non-prescription Health Products Directorate, 'Compendium of Monographs' (n 38)
[136] Ibid.
[137] Natural and Non-prescription Health Products Directorate, 'Natural Health Products Ingredients Database: Listing of Single Ingredient Monographs' (2024) <https://webprod.hc-sc.gc.ca/nhpid-bdipsn/monosReq?monotype=single> accessed 12 August 2024
[138] Natural and Non-prescription Health Products Directorate, 'Natural Health Products Ingredients Database: Listing of Product Monographs' (2024) <https://webprod.hc-sc.gc.ca/nhpid-bdipsn/monosReq?monotype=product> accessed 12 August 2024
[139] Natural and Non-prescription Health Products Directorate, 'Compendium of Monographs' (n 38)
[140] European Directorate for the Quality of Medicines & Healthcare, 'European Pharmacopoeia' (2020)
[141] Ibid.
[142] Ibid.
[143] Ibid.
[144] Ibid.
[145] Ibid.

provide validated testing methods and acceptance levels for these criteria.[146] Besides monographs, the USP-NF also contains general chapters, which provide manufacturers with information on validated production and testing procedures.[147] Additionally, USP-NF provides material references as standards for reagents and apparatus to be used in conjunction with the general chapters and monographs.[148] AHP monographs outline quality control methods required to assess the identity, purity, and quality solely of botanical preparations and raw ingredients. Additionally, they also encompass reviews on traditional use and current scientific-based knowledge.

As quality assurance methods are not described by NHP monographs, the NNHPD provides an additional quality control guideline to FBOs, detailing validated control procedures, analytical methods, and corresponding specifications.[149] Moreover, the NNHPD specifically references methods and procedures described by other international pharmacopoeias such as USP-NF or Ph. Eur.[150] Against the background of a Canadian national pharmacopoeia being unavailable, the NNHPD generally accepts and supports FBOs in leveraging specifications and methods published in certain other international pharmacopoeias to effectively ensure the quality of NHPs and food supplements.[151]

5.3.2.3 Compendial legal character

As the legal framework conditions for pharmaceuticals are more restrictive, based on a generally higher assumed risk for consumers arising from consumption thereof, Article 8(3)(h) of the European Medicinal Products Directive stipulates that APIs and preparations thereof must comply with specifications laid down in the Ph. Eur. to obtain a marketing authorisation.[152] [153] [154] Mandating the summary of product characteristics and the production process to comply with the pharmacopoeia, the legally binding character of the Ph. Eur. in the EU pharmaceutical sector is further strengthened by Article 11 and 23.[155] Although pharmacopoeial monographs may concern ingredients or formulations identically used in food supplements, such as minerals, vitamins, botanical preparations, or essential oils, the Ph. Eur. exclusively applies to

[146] United States Pharmacopoeia, 'Combined Index to USP 43 and NF 38, Volume 1-5' <https://www.uspnf.com/sites/default/files/usp_pdf/EN/USPNF/usp-nf-commentary/usp-43-nf-38-index.pdf> accessed 12 August 2024
[147] Ibid.
[148] Ibid.
[149] Natural and Non-prescription Health Products Directorate, 'Quality of Natural Health Products Guide' (n 39)
[150] Ibid.
[151] Ibid.
[152] Bilia and Costa (n 28)
[153] Directive 2001/83/EC (n 109)
[154] Ibid.
[155] Ibid.

medicinal products.[156] [157] FBOs manufacturing supplements containing ingredients also referenced in the Ph. Eur. could choose to adhere to pharmacopoeial reference standards voluntarily. However, previous research has identified great differences in quality between herbal medicinal products and food supplements containing similar ingredients on the EU market.[158]

The USP-NF is legally recognised as the official compendium of the USA by Section 201(j) of the FD&C Act (21 U.S.C. Article 321(j)).[159] Section 501(b) FD&C Act (21 U.S.C. Article 351(b)) stipulates that pharmaceuticals which do not comply with USP standards are deemed to be adulterated, thereby making adherence mandatory for business operators.[160] Regarding food supplements, the USP-NF is also recognised by Section 403(s) FD&C Act (21 U.S.C. Article 343(s)) as an official compendium, but only deeming them misbranded if they state to comply with a compendial standard but fail to do so.[161] [162] Therefore, compliance with the USP-NF remains voluntary in the supplement sector.[163] However, cGMP rules applicable to food supplement production laid down in 21 CFR 111 emphasise the implementation of scientifically valid methods.[164] To clarify the term of validation, the FDA stated in their final rule on the cGMP code in 2007 that while the authority recognises the significance of compendial standards such as USP or AHP, a specific compendium shall not be listed as a source of validated methods.[165] Instead, it should remain the responsibility of the FBO to validate applied production and quality control methods, regardless of whether they are compendial or not.[166]

5.3.2.4 Limitations of pharmacopoeial methods in quality assurance

Despite methods and procedures described by the Ph. Eur. are considered validated and sufficient for meeting their analytical purposes, previous research identified cases in which they could not deliver desired analytical results compared to other non-pharmacopoeial methods.[167] This was partly attributed to Ph. Eur. materials not always corresponding with the

[156] European Directorate for the Quality of Medicines & Healthcare (n 140)
[157] Bilia and Costa (n 28)
[158] Ibid.
[159] Federal Food, Drug, and Cosmetics Act (n 69)
[160] Ibid.
[161] Ibid.
[162] Brinckmann and others (n 57)
[163] Ibid.
[164] 21 CFR 111 - Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements (n 86)
[165] Food and Drug Administration, 'Current Good Manufacturing Practice - Dietary Supplements; Manufacturing, Packaging, Labelling, or Holding Operations; Final Rule: Federal Register 72, Volume 121' (25 June 2007) <https://www.govinfo.gov/content/pkg/FR-2007-06-25/pdf/FR-2007-06-25.pdf> accessed 10 August 2024
[166] Ibid.
[167] Anna Bogni and others, 'Tetrabutylammonium HPLC Analysis: Shortcomings in the Ph. Eur. Method' (2020) 63(4) Journal of Labelled Compounds and Radiopharmaceuticals 203

latest materials practically in use. Additionally, research has identified a shortcoming of Ph. Eur. development regarding the adoption of innovative laboratory methods, such as the characterisation of different nanoparticles or DNA-based analytical methods pertaining to identifying herbal ingredients individually or in multi-ingredient compositions.[168] [169]

In the USA, where FBOs are voluntarily subjected to USP standards, only few seek official USP verification. Compared to around 80000 supplements available on the US market, as of 2024, only a small number of around 100 products are certified with the USP label.[170] [171] Additionally, despite issuing warning letters from the FDA to FBOs regarding the detection of insufficient food supplement quality, research has identified an increasing trend of supplements adulterated with pharmaceuticals sold in the USA.[172] In Canada, the regulatory requirements to manufacture and sell food supplements are higher than in the EU and USA due to them being considered a subset of therapeutic products. However, in the 2021 audit report, the Commissioner of the Environment and Sustainable Development also emphasised that Health Canada failed to enforce compliance with NHPR and GMP regulations due to a lack of routine inspections of production sites between 2017 and 2020.[173] The limited monitoring of license holders led to non-compliance of FBOs, e.g. selling of unlicensed products, unauthorised manufacturing activities, or product mislabeling.[174] This was partly found to be due to the high numbers of registered products on the market and pending license applications affecting Health Canada's ability to enforce NHP regulations.[175]

5.4 Discussion

The EU's regulatory framework governing food supplements faces multiple challenges to ensure access to products of sufficient quality and safety.[176] Previous research has identified a wide range of quality issues impairing the safe consumption of food supplements available in the EU.[177] Additionally, the extent to which they are present in food supplements remains

[168] Arnaud Pallotta and others, 'Quality Control of Gold Nanoparticles as Pharmaceutical Ingredients' (2019) 569 International Journal of Pharmaceutics 118583
[169] Karthikeyan Mahima and others, 'Advancements and Future Prospective of DNA Barcodes in the Herbal Drug Industry' (2022) 13 Frontiers in Pharmacology 947512
[170] United States Pharmacopoeia, 'USP Verified Products' <https://www.quality-supplements.org/usp_verified_products> accessed 14 August 2024
[171] Food and Drug Administration, 'Policy Regarding Certain New Dietary Ingredients and Dietary Supplements Subject to the Requirement for Pre-Market Notification: Guidance for Industry' (n 119)
[172] Pieter A Cohen and others, 'Nine Prohibited Stimulants Found in Sports and Weight Loss Supplements: Deterenol, Phenpromethamine (Vonedrine), Oxilofrine, Octodrine, Beta-Methylphenylethylamine (BMPEA), 1,3-Dimethylamylamine (1,3-DMAA), 1,4-Dimethylamylamine (1,4-DMAA), 1,3-Dimethylbutylamine (1,3-DMBA) and Higenamine' (2021) 59(11) Clinical Toxicology 975
[173] Office of the Auditor General of Canada (n 98)
[174] Ibid.
[175] Ibid.
[176] Mona Abdel-Tawab, 'Do We Need Plant Food Supplements? A Critical Examination of Quality, Safety, Efficacy, and Necessity for a New Regulatory Framework' (2018) 84(6-07) Planta Medica 372
[177] Costa and others (n 17)

uncertain, and it has been estimated that only 1 % of adverse effects are reported.[178] Consumers cannot generally assess and differentiate the quality of supplements nominally containing the same ingredients.[179] Instead, they have to rely on efficacy and quality claims made by FBOs and trust that the stated quality complies with technical specifications in EU regulations.[180] [181] However, as product quality can be considered a factor driving competition in a free market, the lack of opportunity for consumers to independently assess supplement quality could represent a distorting factor for the EU internal market.[182] Furthermore, against the background of the continuously expanding supplement market, it could be considered an incentive to reduce adequate quality assurance due to financial or other interests despite the risk of punitive actions or sanctions from regulatory authorities.[183]

The regulation of the EU supplement market has been described as fragmented by previous research due to missing harmonisation in certain aspects, such as permission of herbal and bioactive ingredients or dosages, resulting in differing national regulatory approaches.[184] Additionally, the enforcement practices of responsible safety authorities vary greatly between Member States. These have not been fully mitigated despite certain Union-level governance efforts, e.g. via mutual recognition procedures.[185] [186] Since harmonisation efforts in the EU aim to strengthen consumer protection and establish the internal market, a single set of quality rules generally recognised for reference purposes may reduce regulatory fragmentation. The Ph. Eur. has long been established in the pharmaceutical sector, and its uniform quality standards benefit the industry and consumers alike. Manufacturers and third-party contractors gained public access to effective, validated methods for analytical testing to ensure reliable product quality management in accordance with the requirements set by the applicable legislation. Despite singular incidents, patients generally benefit from the exclusion of low-quality therapeutic products from the EU market via the mandatory adherence to Ph. Eur.

[178] Colin W Binns, Mi K Lee and Andy H Lee, 'Problems and Prospects: Public Health Regulation of Dietary Supplements' (2018) 39 Annual Review of Public Health 403
[179] Heather Boon and Natalie Bozinovski, 'A Systematic Narrative Review of the Evidence for Labeling of Natural Health Products and Dietary Supplements' (2019) 25(8) Journal of Alternative and Complementary Medicine 777
[180] Ibid.
[181] C. Muela-Molina, S. Perelló-Oliver and A. García-Arranz, 'Health-Related Claims in Food Supplements Endorsements: A Content Analysis from the Perspective of EU regulation' (2021) 190 Public Health 168
[182] Ariel Ezrachi and Maurice E Stucke, 'The Curious Case of Competition and Quality' (2015) 3(2) Journal of Antitrust Enforcement 227
[183] Júlia Toropilová and Pavel Bystrický, 'Why HACCP Might Sometimes Become Weak or Even Fail' (2015) 5 Procedia Food Science 296
[184] Warda, Purnhagen and Molitorisová (n 3)
[185] Ibid.
[186] Stephen Weatherill, 'The Principle of Mutual Recognition: It Doesn't Work Because It Doesn't Exist' (2018) 43 European Law Review 224

standards. As food supplements and pharmaceuticals share galenic forms and properties, the Ph. Eur. could potentially offer comparable opportunities for the supplement market.[187] [188]

The American and Canadian regulatory systems illustrate that it is possible to include pharmacopoeial compendia in food supplement regulation to improve the quality and safety by strengthening quality control practices.[189][190] Additionally, the factual implementation of the Ph. Eur. in the Canadian NHP sector could be considered as an example of the Brussels effect, whereas EU legislation is adopted or impacts comparable legal frameworks in third countries outside the EU. [191] Despite not being recognised as an official supplement compendium in the EU , EFSA already references the Ph. Eur. in its ingredient safety assessments and encourages FBOs to leverage validated pharmacopoeial methods.[192]

However, the results of this study demonstrate obstacles encountered by Canadian and USA authorities in implementing pharmacopoeial reference standards in the respective supplement markets, illustrated by the emergence of quality issues comparable to those identified in the EU.[193] [194] In the USA, the adulteration of supplements with APIs, usually found in prescription drugs or doping substances, remains a persisting issue in particular.[195] [196] This has primarily been attributed to DSHEA placing the burden of proof of a product hazard or manufacturing sites and procedures not being cGMP-compliant upon the FDA.[197] [198] Regarding NDI, for which pre-market approval is required, the FDA has stated that thousands of unapproved supplements containing such ingredients are available on the market.[199] This, further illustrated by the FDA repeatedly issuing warning letters to manufacturers, could highlight that

[187] Bouin and Wierer (n 43)
[188] Laura Righetti, Chiara Dall'Asta and Renato Bruni, 'Risk Assessment of RYR Food Supplements: Perception vs. Reality' (2021) 8 Frontiers in Nutrition 792529
[189] Sarma and others (n 32)
[190] Wang and others (n 31)
[191] Anu Bradford, 'Exporting Standards: The Externalization of the EU's Regulatory Power via Markets' (2015) 42 International Review of Law and Economics 158
[192] Dominique Turck and others, 'Guidance on Scientific principles and Data Requirements for the Safety and Relative Bioavailability Assessment of New Micronutrient Sources' (2024) 22(9) EFSA Journal e8946
[193] Gerry Schwalfenberg, Ilia Rodushkin and Stephen J Genuis, 'Heavy Metal Contamination of Prenatal Vitamins' (2018) 5 Toxicology Reports 390
[194] Andrew M Abe, Darren J Hein and Philip J Gregory, 'Regulatory Alerts for Dietary Supplements in Canada and the United States, 2005-13' (2015) 72(11) American Journal of Health-System Pharmacy 966
[195] Rahul S Pawar and Erich Grundel, 'Overview of Regulation of Dietary Supplements in the USA and Issues of Adulteration with Phenethylamines (PEAs)' (2017) 9(3) Drug Testing and Analysis 500
[196] Tucker and others (n 102)
[197] John P Swann, 'The History of Efforts to Regulate Dietary Supplements in the USA' (2016) 8(3-4) Drug Testing and Analysis 271
[198] Ranjani R Starr, 'Too Little, Too Late: Ineffective Regulation of Dietary Supplements in the United States' (2015) 105(3) American Journal of Public Health 478
[199] Food and Drug Administration, 'Current Good Manufacturing Practice - Dietary supplements; Manufacturing, Packaging, Labelling, or Holding Operations; Final Rule' (n 165)

manufacturers tend not to comply with the applicable legal provisions of DSHEA.[200] [201] Against the background of a legal framework considered to shield the private sector from extensive regulatory oversight, FBOs manufacturing supplements generally seem to refrain from adopting pharmacopoeial standards.[202] Although the low number of USP-verified food supplements does not necessarily indicate that FBOs do not apply these standards, there appears to be little incentive to seek compliance with the USP-NF officially.[203]

In contrast, the Canadian legal framework conditions governing supplements impose a stricter regime on FBOs for manufacturing and selling NHPs.[204] However, authorities allow for a flexible approach while keeping high-quality validated reference standards, whereas FBOs may choose their preferred pharmacopoeia or develop a comparable method or procedure by themselves.[205] [206] Previous research found that the Canadian NHP industry has welcomed the approach, as although some FBOs followed this approach before the introduction of the NHPR in 2004, its introduction advanced equal conditions in the NHP market regarding efforts for implementing comprehensive quality assurance programs.[207] The acceptance of the introduction of higher quality and safety requirements via NHPR has been described as being promoted through close communication of Canadian authorities with stakeholders such as industry associations or healthcare professionals during its development.[208] Despite its introduction is generally being considered an improvement of food supplement regulation in Canada, it also increased the regulatory and financial burden on FBOs.[209] [210] Aligning with observations from other food categories such as the EU novel food sector, streamlining the NHP regulatory conditions has been found to increase the risk of lowering innovation in this sector.[211] [212] SMEs could be especially affected, as they require more resources to market

[200] Starr (n 198)
[201] Hellen A Oketch-Rabah and others, 'Challenges and Opportunities for Improving the Safety Assessment of Botanical Dietary Supplements: A United States Pharmacopeia Perspective' (2018) 104(3) Clinical Pharmacology and Therapeutics 426
[202] Ibid.
[203] Sarma and others (n 32)
[204] Jeremy Y Ng, Minji Kim and Ayush Suri, 'Exploration of Facilitators and Barriers to the Regulatory Frameworks of Dietary and Herbal Supplements: A Scoping Review' (2022) 15(1) Journal of Pharmaceutical Policy and Practice 55
[205] Natural and Non-prescription Health Products Directorate, 'Quality of Natural Health Products Guide' (n 39)
[206] Alysyn Smith, Sumedha Jogalekar and Adam Gibson, 'Regulation of Natural Health Products in Canada' (2014) 158 Pt B Journal of Ethnopharmacology 507
[207] Rishma Walji and Mary Wiktorowicz, 'Governance of Natural Health Products Regulation: An Iterative Process' (2013) 111(1) Health Policy 86
[208] Ibid.
[209] Ibid.
[210] Smith, Jogalekar and Gibson (n 206)
[211] Walji and Wiktorowicz (n 207)
[212] Alessandro Monaco and Kai Purnhagen, 'Risk Triggers as Innovation Triggers? Risk Analysis and Innovation´s Promotion under the Novel Food Regulation.' (2022) 17(3) European Food and Feed Law Review 219

innovative or niche products lawfully.[213] For Canadian authorities, the regulatory burden to enforce safety and quality provisions of the NHPR has also increased.[214] In this regard, previous research has identified a lack of regulatory oversight by provincial health ministries due to unmet personnel requirements.[215] Additionally, the reliance on the NHP industry to provide correct testing methods and results for products and manufacturing sites has also been found to be a potential weak point of the Canadian NHP regulation.[216] This seems to be acknowledged by Canadian authorities, as the report on Health Canada's ability to supervise and enforce applicable NHP regulations appears to be challenged by a high number of products, license applications, and manufacturing sites.[217] Additionally, while Canadian sellers, importers, and distributors are obligated to comply with the NHPR, selling and importing non-compliant supplements via internet trade has been identified as a possibility to circumvent implemented higher regulatory requirements.[218] Therefore, amending the Ph. Eur. to include food supplements and the extent of its legally binding character in this sector must be considered carefully.

EU primary law mandates that interventions with the EU's free movement of goods, including foodstuff, should not be more restrictive than necessary and justified in balancing other fundamental rights such as the protection of consumer health. Within the EU's risk-based legal framework governing products intended for use in humans, food supplements being considered as food nominally constitute a lower risk as compared to pharmaceuticals. Mandating FBOs and to adhere to Ph. Eur. quality standards, originally intended to ensure safety and quality of a product category for which a higher risk has been established, could conflict with EU law. However, leaving it to the FBOs' discretion to adhere to pharmacopoeial standards could lead to a comparable situation like in the USA, where FBOs are reluctant to apply them to their manufacturing operations to decrease production costs and increase profit margins.[219] [220] Contrary, as discussed by previous research and observed from our study on the Canadian NHP regulatory framework, mandatory compliance to augmented safety legislation could increase the regulatory burden of administrative procedures for authorities and industry in the EU.[221] As the adoption of Vanessa's Law in Canada demonstrated, food

[213] Ibid.
[214] Walji and Wiktorowicz (n 207)
[215] Kyle T Ganson, Eliana Sinicropi and Jason M Nagata, 'Assessing Canadian Regulation of Muscle-Building Supplements: Identifying Gaps and Recommendations for Improvement to Protect the Health and Well-Being of Young People' (2023) 11(3) Performance Enhancement & Health 100255
[216] Ibid.
[217] Office of the Auditor General of Canada (n 98)
[218] Ganson, Sinicropi and Nagata (n 215)
[219] David P Carter, Tyler A Scott and Nadia Mahallati, 'Balancing Barriers to Entry and Administrative Burden in Voluntary Regulation' (2018) 1(3) Perspectives on Public Management and Governance 207
[220] Brinckmann and others (n 57)
[221] Monaco and Purnhagen (n 212)

safety authorities require sufficient resources and a robust legal mandate to enforce such regulations. The decentralised enforcement landscape across the Union may form another obstacle to effectively implementing this approach.

Another aspect that should be considered is the development of pharmacopoeial validated methods, as the development of analytical methods suitable for ingredient or product quality control is rapidly advancing. Although pharmacopoeias such as the Ph. Eur. or USP-NF are constantly reevaluated by the responsible committees, concerns have been raised by research whether new and innovative methods, e.g. genetic fingerprinting of herbal ingredients or identification of nano-particles, are insufficiently integrated.[222] [223] Missing suitable reference standards despite a potential mandatory adherence could lead to a regulatory gap, creating legal uncertainty, especially in the field of innovative products, underscoring the effect of additional regulatory burden on consumers' access to new products. However, in this regard, the Canadian NHP framework, providing the opportunity for FBO to leverage non-pharmacopoeial methods if they are considered a suitable quality control method nonetheless, could be considered.

In conclusion, the Ph. Eur. could serve as a platform to generally improve quality control practices of food supplement FBOs, based on its already existing overlap with this product category. Additionally, while EFSA promotes the use of pharmacopoeial validated methods in the supplement and novel food sector, Canada has officially encouraged the use of the Ph. Eur. for supplement quality standards. However, if considered in the EU, careful considerations such as the extent of legal adherence by FBO, an increased need for resources for both industry and authorities, and the potential effects on innovations on the market must be made.

This study is subject to several limitations considering the methodological approach of functional comparative legal analysis. While extensive literature research was performed, insights derived from empirical research, such as expert interviews, are missing. As empirical methods can contribute to support findings derived from comparative legal analysis, data on stakeholders, such as FBOs or authorities illustrating their perception of pharmacopoeial references to supplements, could have been a valuable addition. However, it would have exceeded the scope of this research. Additionally, the studied legal systems differ significantly, as the EU is governed by a multi-leveled structure consisting of horizontal technical regulations and different food law enforcement structures on national levels. Canada and the USA have implemented national regulatory systems, independent from an additional comparable supra-national legal framework. Further, while supplements are considered foodstuff in the EU and the USA, they are regulated as therapeutic products in Canada. This has major implications

[222] Pallotta and others (n 168)
[223] Mahima and others (n 169)

for legal quality and safety requirements, which can not necessarily be met by EU and US food law.

5.5 Conclusion

Pharmacopoeial reference standards and monographs offer considerable potential to strengthen food supplement quality control practices. Although traditionally applied in the pharmaceutical sector, pharmacopoeial standards have long been extended to food supplements in major markets outside the EU. This study demonstrates, however, that both the scope of their application and the degree of industry adherence vary substantially.

Integrating food supplements into the Ph. Eur. could enhance consumer access to high-quality products while reducing barriers for SMEs to implement effective product quality control measures. Nonetheless, legislators should appropriately calibrate the extent to which the use of pharmacopoeial references is mandated. Minimal mandatory requirements risk discouraging the private sector from adoption for economic reasons. Conversely, overly stringent requirements could impose additional regulatory burdens on both the industry and authorities, potentially hindering the entry of innovative food products into the EU market.

Future research should therefore focus on empirical research to highlight the perspectives of the EU industry on proportionate strategies, that enhance the safety and quality control practices in the food supplement sector without impeding innovation or market access.

5.6 Declarations

Competing interests: The authors declare none.

The authors declare that no funding was received for conducting this study.

Chapter 6
Conclusion and General Discussion

6.1 Introduction

This dissertation enhances the understanding how the fragmented regulatory system governing food supplements interact with each other and exert an impact on product quality. Additionally, it explores how quality codification could serve as a regulatory measure to enhance food supplement quality beyond the stagnating institutional efforts to implement and enforce previously adopted food safety laws.

First, the transposition of legal fragmentation pertain to EU food supplement governance into regulatory enforcement practices of national food safety authorities and the relevance of the principle of mutual recognition in safety assessment proceedings to them is assessed. As a second step, using RASFF data base analysis as a case study, the engagements of public and private stakeholders of reporting quality defects serving as an indicator for participation in food risk communication is investigated. Third, the significance of health claims for consumer engagements and product development by food supplement manufacturers against the background of regulatory fragmentation is addressed. Finally, a functional approach of food supplement quality enhancement through reference standard codification using comparative analysis with other jurisdictions is discussed.

This final chapter discusses how the underlying research questions have been addressed by the conducted research. Key academic and practical contributions to the field of EU food supplement regulation are laid down, while acknowledging statutory limitations and outlining recommendations for future research. Lastly, the chapter provides an outlook on possible future directions of food supplement regulation in the EU.

6.2 Answering the research questions

The research conducted for this dissertation was guided by the following general research question:

> *How do interacting regulatory dysfunctions within the EU's risk-based regulatory framework affect food supplement quality, and to what extent could pharmacopoeial reference standards serve as a corrective mechanism?*

The first three chapters identified different aspects of regulatory dysfunctions and their impact on food supplement quality, laying down the interactive character of non-harmonised aspects of the EU's food supplement legal framework conditions. Chapter 2 illustrated the divergence of food law enforcement practices concerning botanical and other bioactive supplement ingredients in the absence of effectively harmonising EU law provisions. Chapter 3 highlighted the imbalance between the public and private sector concerning risk communication on food supplement quality issues. Chapter 4 examined the impact of the unattained harmonisation of

health-claims regulation on economic practices by food supplement manufacturers. Finally, Chapter 5 discussed the potential of amending the Ph. Eur. to include food supplement reference standards as a mean to alleviate stagnation of the evolvement of food supplement quality regulation. In the following sections, the answers to the research sub-questions are discussed.

1. *To what level does the fragmentation of regulatory approaches governing food supplement ingredients extend on the Member State level?*

Aligning with previous research, the research results presented in Chapter 2 demonstrate that the incomplete implementation of provisions concerning the safety evaluation and permission status of botanical and other bioactive ingredients of the Food Supplements Directive has led to divergent regulatory systems at the EMS level (Bilia & Costa, 2021). These national approaches can be broadly distinguished into more complex law-based regulatory approaches and more flexible, guideline-based approaches, the latter providing greater latitude to business operators.

While legal scholarship has primarily focussed on examining the structural legal framework conditions governing food supplements (Anadón et al., 2021), the empirical insights obtained in this study highlighted how regulatory fragmentation is reflected by the enforcement practices of competent authorities. Significant differences were observed in preferences for data bases used in risk-based safety assessments of non-harmonised ingredients and in how potential borderline issues are addressed. These empirical findings reflect broader, long-term developments in the EU's regulatory approach to food supplements. For example, in 2009, EFSA published its guidance on safety assessments of botanical ingredients and preparations and its first compendium on toxicologically concerning botanical ingredients (European Food Safety Agency, 2009; European Food Safety Agency & EFSA Scientific Committee, 2009). Although these resources were explicitly intended for use by regulatory authorities, interview respondents from EMS authorities stated a preference for national databases and recommendations from other national agencies over those of other EMS, EU institutions, or third countries. The legal implementation of botanical positive lists into national law by certain EMS, following the BELFRIT initiative, underscores the preference for national legally-binding measures and regulatory approaches over non-legally binding EU guidance documents (Cousyn et al., 2013; Klaus & Gherardini, 2014; Silano et al., 2011).

Despite the EC's assumption, articulated in its report to the European Parliament and Council of the European Union from 2008, whereas adopted secondary Union law shall provide indirect harmonisation of the EU food supplement market and regulatory framework (European Commission, 2008), the study revealed the limitation of this approach. The doctrinal legal analysis highlighted that the restriction of potentially hazardous food ingredients at the Union

level, although permitted by Article 8 of Regulation (EC) No 1925/2006, has only been applied to only a few substances (Regulation (EC) No 1925/2006, 2006). The limited use of Article 8 corresponds with recent calls from national food safety authorities for joint efforts to expand and accelerate the implementation of Article 8 procedures (Heads of Food Safety Agencies, 2024).

This study also examined how public food safety authorities perceive the application of mutual recognition procedures within their respective jurisdictions. The empirical findings suggest that the procedure is rarely applied in the studied EMS and holds limited relevance for national authorities. Data suggesting that other EMS were not considered as particular suitable reference member states for conducting the procedure further support Jan's hypothesis that mutual recognition is dependent on the acceptance by EMS and is unlikely to function as governance method due to low levels of trust between EMS (Jan, 2021).

The acceptance of mutual recognition principle for harmonising the EU food supplement market is challenged at the EMS level (Jan, 2018; van Cleynenbreugel, 2018). The doctrinal analysis findings further highlighted that EMS favour advancing regulatory harmonisation through multilateral initiatives, such as the BELFRIT project or the Federal List of Substances mutually used by German and Austrian authorities, rather than solely relying on the current EU framework under the Food Supplements Directive and the principle of mutual recognition.

2. *What roles do public and private stakeholders play in risk communication within the food supplement sector under the EU's hybrid food law enforcement mechanism?*

Risk communication constitutes a central element of the EU's risk-based approach to regulate and ensure food safety as established by the GFL (Christodoulou et al., 2021). However, as recognised by Regulation (EU) 2019/1381 (Transparency Regulation) its effectiveness relies on transparency and the timeliness of relevant safety-related information shared by both public and private stakeholders (Christodoulou et al., 2021; Vrbos et al., 2022). Since the complete exclusion of food-related incidents across the food production and distribution chain is unattainable, companies must adhere to national, EU, and international standards for food hygiene, quality, and safety, including the rigorous implementation of HACCP and GMP-compliant quality control measures (Oliveira et al., 2016). These control procedures should be applied consistently to effectively identify and manage occurring product quality defects (King & Bedale, 2018). Pre-market quality controls asses product batches prior to release, while post-market controls are conducted after the product has entered the market. When a defect is identified through post-market surveillance, the public or private entity which detected it is obligated to promptly report it through appropriate communication channels (Regulation (EC) No 178/2002, 2002; Garcia Martinez et al., 2013).

This part of the dissertation investigated how actively both the public and private stakeholders of the EU food supplement market engage with risk communication mechanisms under the hybrid food safety enforcement model, using RASFF notifications on post-market issues as a case study. Under this model competent authorities are responsible for conducting official controls and inspections, whereas private actors are obligated to perform internal quality controls and notify authorities if non-compliant products have entered the market (Regulation (EC) No 178/2002, 2002; Garcia Martinez et al., 2013).

The statistical analysis demonstrated that, throughout the observation period RASFF notifications originating from quality controls by private companies were consistently fewer than those triggered by authority controls, which is consistent with findings from RASFF analyses in other food categories. Moreover, the low increase of company-related notifications suggests a persistent imbalance in stakeholder engagements with risk communication processes. These findings are further supported by analysis results, showing that while the frequency of authority-control related notifications correlated with the adoption of EU food safety regulations, industry-led notifications remained less affected. The limited number and marginal growth of company-related notifications point to significant shortcomings of participation in risk communication by the private sector.

Although previous studies identified a range of quality issues present at the EU supplement market, such as mislabelling, the unauthorised addition of non-permitted ingredients, contamination with toxins (e.g. heavy metals, pesticides), to adulteration with pharmaceuticals (Costa et al., 2019; Czepielewska et al., 2018; Petroczi et al., 2011; Pigłowski, 2018), this study not only addressed the scale of these issues but also found that the majority of these risks is primarily reported by the public sector. The identified prevalence of authority-control related notifications, particularly in categories considered a high risk to consumer health such as the adulteration with pharmaceuticals, underscores an imbalance within the overall risk communication framework.

The limited engagement of the private food supplement sector in risk communication may reflect broader issues within the EU's hybrid food law enforcement model. One key challenge is that private entities may exhibit a form of rational apathy in reporting issues in the food supply chain, weighing the perceived costs of non-compliance against the potential benefits of avoiding sanctions (Korzycka & Wojciechowski, 2014; K. Purnhagen & Molitorisová, 2022). The effective interaction between private stakeholders and regulatory bodies in communicating identified risks in the supply chain is not only considered essential for transparency but also risk analysis (Baba & Esfandiari, 2023). However, although sanctions theoretically incentivize legal compliance due to potential severe financial or reputational losses, their impact hinges upon the regularity and robustness of risk-based controls by authorities (Korzycka &

Wojciechowski, 2014; Purnhagen & Molitorisová, 2022). In the food supplement sector, this problem might be exacerbated as food safety agencies are faced with a proliferation of available products, expanding manufacturer networks, and cross-border internet sales (Bilia, 2015; Bonnet et al., 2024; Wróbel-Harmas et al., 2014). Supporting this, Wróbel et al. (2022) found that on the Polish market, a number of products registered as non-compliant before have been re-notified, thereby circumventing effective oversight (Wróbel-Harmas et al., 2014).

Additionally, enforcement capacities vary across EMS due to different levels of institutional resources, socio-legal cultures, or regulatory priorities (Corini et al., 2017; Safjan et al., 2008; Weber, 2013). For instance, the study results showed that RASFF notifications are disproportionately concentrated on comparatively well-resourced EMS such as Germany. The identified regional disparity of risk communication across the EU raises further concerns of the impact of regulatory dysfunctionalities on consumer protection.

In conclusion, the findings reveal that risk communication in the EU's food supplement sector, representing an essential part of its risk-based regulatory approach, suffers from structural weaknesses. Limited private sector engagement and structural fragmentation at the EMS level against a wide range of serious persisting quality issues, many of which pose substantial risks to food supplement regulation and food supply chain integrity, negatively affect the EU's risk-based regulatory approach. The divergence observed between the roles envisioned by the regulatory framework and patterns of stakeholder engagements suggest that risk communication responsibilities in the food supplement sector are not being exercised in a consistent manner.

3. *How does fragmentation within the EU's food information framework impact the marketing and product development practices of food supplement manufacturers?*

This section of the dissertation investigated how food-related health claims influence the marketing and product development practices of food supplement businesses in the context of the regulatory fragmentation characterizing the implementation of the EU Health Claims Regulation.

Food information in the EU operates under the assumption that consumers lack the knowledge of nutritional properties of food products. As the right to food information is regarded as a fundamental consumer right, the EU's food information framework seeks to ensure that consumers receive science-based and accurate food information through FBOs, non-governmental organisations, and public authorities to enable informed dietary choices. As food supplements are increasingly perceived by consumers as tools for individual health optimisation, reflecting consumer trends of individualized nutrition, FBOs recognise the commercial benefits of aligning their market strategies with these trends. Thus, a streamlined

and predictable regulatory framework for health claims is critical, not only to protect consumers from misleading product claims but also to facilitate cross-border trade and the proper functioning of the internal market.

The doctrinal analysis highlights that the implementation of the EU's Health Claims Regulation remains significantly fragmented. One key issue concerns the scientific assessment of botanical health claims by the EC and EFSA. Both institutions have maintained a restrictive interpretation of Article 13(1) of the Health Claims Regulation and relevant provisions of the GFL, primarily accepting human clinical trials as sufficient data for evidence-based substantiation of health claims. However, this strict requirement creates a particular challenge to the assessment of botanical claims, for which such data is often unavailable.

Previous research has identified this regulatory stagnation as a concern for the regulation of food supplements, particular in relation to non-harmonised botanical ingredients, which are increasingly popular with European consumers (Garcia-Alvarez et al., 2014; Noble, 2017; Puścion-Jakubik, Bielecka, et al., 2021). Furthermore, the EC's asserted in its 2008 report to the European Parliament and the Council that the implementation of the Health Claims Regulation would contribute to alleviating regulatory fragmentation of so-called "other ingredients", including botanicals (European Commission, 2008). However, recently several EMS and the European Parliament urged the EC to finalise its safety assessments under Article 13(1), illustrating the continuing gap between envisioned regulatory standards and actual legal implementation (Bundesregierung, 2021; European Parliament, 2024; Lebensmittelverband Deutschland e.V., 2021). While the EC has reaffirmed its commitment to further action during its REFIT initiative in 2020, the European Parliament's 2024 report expresses continued concern about the lack of progress (European Commission, 2020; European Parliament, 2024).

In legal scholarship and literature, the potential of accepting evidence for safety and efficacy based on traditional use for botanical ingredients which have already been authorised as THMPs under Article 16(a) of the EU Medicines Directive has been discussed (Boer, 2021; Kušar & Pravst, 2022; Lenssen et al., 2019). Although such an approach could address current data gaps, its compatibility with modern consumer consumption habits and possible emerging safety considerations presents barriers to integrating it into the current framework (Kušar & Pravst, 2022; Lenssen et al., 2022).

Empirical findings from interview with industry stakeholders highlighted that FBOs have adopted divergent strategies for using health claims, often related to company size and associated risk resilience. Nonetheless, all participants emphasized that the incomplete implementation of the Health Claims Regulation constitutes a major barrier to market access.

Companies face uncertainty over the permissibility of specific claims, inflexibility claim wording, and inconsistent interpretation of provisions across EMS.

These challenges were considered to increase the risk of regulatory violations by FBOs, including the classification of products as unauthorised medicines under the Medicines Directive, leading to punitive actions from food safety authorities such as financial sanctions or product recalls. Such enforcement risks carry significant administrative, legal, economic, and reputational costs. These findings align with other research, indicating that the current state of the Health Claims Regulation contributes to legal uncertainty for the private sector, discourages product innovation, and perpetuates regulatory fragmentation at the EMS level.

Although health claims play a critical role within the broader EU's food information framework, in particular by empowering consumers to make responsible dietary choices and providing fair competition and advertisement conditions, FBOs are disproportionately affected by the lack of a harmonized and transparent approval process. Additionally, regulatory goals of consumer protection are undermined by permitting the exposure to unsubstantiated claims. Unless the Commission addresses the structural barriers to completing claims safety assessments, especially for botanicals, the EU will continue to face a fragmented regulatory landscape governing food supplements.

4. *How could uniform quality standards for food supplements be sustainably integrated in the European Union without impeding internal market dynamics and innovation?*

In this last chapter, the dissertation investigates whether quality standards laid down by the Ph. Eur. could be integrated into the EU's regulatory framework for food supplements. The preceding chapters analysed how regulatory dysfunctionalities interact with each other and have affected product quality, enforcement practices, and commercial activities. Given that the most straightforward solution to resolve the identified dysfunctionalities, namely, the widespread availability of high-quality scientific data on safety and efficacy of a broad range of ingredients, is unlikely to be achieved due to high costs for the private sector and inherent methodological difficulties, this chapter explores alternative mechanisms to strengthen food supplement quality in the EU.

The study explored several key aspects of how pharmacopoeial quality standards could apply to the EU food supplement sector. First, the Ph. Eur. includes monographs of a wide array of dual-use substances, ingredients used both in food or pharmaceuticals products. It also codifies methods for manufacturing and quality control, reference values, and product characteristics that correspond to galenic forms used in food supplements. Second, the analysis revealed that the Ph. Eur. already serves as a reference standard for food

supplements in jurisdictions outside the EU, reflecting the “Brussel’s Effect”. It is also frequently accepted by EFSA in food safety assessments for other product categories.

However, drawing on the comparison with the regulatory systems of the United States of America (USA) and Canada as a case study, the analysis also illustrated the difficulties in integrating pharmacopoeial standards into food supplement regulation. In the USA, voluntary compliance with the USP has resulted in low uptake among producers. Although comparable product quality could be achieved through alternative methods, the increasing numbers of food law violations registered by the Food and Drug Administration (FDA) suggests that, when granted enough regulatory flexibility, FBOs may prioritise economic efficiency over implementing robust quality control methods.

In contrast, Canada’s approach of regulating food supplements as a subset of pharmaceuticals, termed “natural health products”, has demonstrated improvements in product quality through mandating adherence to the Ph. Eur., USP, or other internationally recognized pharmacopoeias. Although stakeholders have welcomed streamlining competition conditions, both private and public stakeholders have raised concerns about the increased administrative burden, enforcement costs, and personnel demands.

Within the current EU regulatory framework, voluntary adherence public Ph. Eur. quality standards by FBOs is already possible. However, as demonstrated by previous research and the results presented in Chapter 3, numerous quality issues persist in the EU food supplement market. Similar to the US market, commercial interests of FBOs potentially conflict with a commitment to voluntary higher quality control costs. Canada’s model shows that improved quality and safety outcomes are possible under a more stringent regime, but risks creating significant barriers for market access and innovation in the supplement sector. Especially smaller companies lacking sufficient resources to comply with elevated requirements are potentially affected.

The call for introducing a new regulatory category encompassing food supplements, HMPs, and THMPs, often referred to as “nutraceuticals”, has been proposed before (Domínguez Díaz et al., 2020). However, the implementation of such a new category would require a major policy shift by the EU institutions, EMS, and industry stakeholders. Additionally, the effectiveness of such a new system in achieving fundamental policy goals of protecting consumer health and facilitating the functioning of the free market is uncertain.

Rather than establishing a new product category, the EU should explore incentive-based approaches to encourage FBOs to adopt more rigorous quality control practices. The could include promoting the use of uniform, codified standards such as those contained in the Ph. Eur. Recognising the pharmaceutical sector’s need for stricter safety and quality regulations,

substantiated in the product category's higher risk, amending the Ph. Eur. to accommodate more flexible specifications tailored to food supplements may offer a balanced approach.

6.3 Contributions

The dissertation contributes to academic scholarship through doctrinal and comparative legal analysis on the EU regulatory system governing food supplements. By incorporating qualitative empirical analysis methods, based on expert interviews and secondary data base analysis, the interdisciplinary approach provides practical insights on the perspective of public and private stakeholders and quality issues present in the food supplement sector. The key contributions delivered by this dissertation can be summarised as follows.

6.3.1 Academic contributions

This dissertation contributes to theoretical discussions on how the access to high-quality food supplements can be enhanced by analysing the interplay between different aspects of regulatory inconsistencies within the EU regulatory framework.

While previous research has primarily addressed dysfunctional aspects of the EU food supplements regulatory system individually, this study systematically maps out the interaction among key issues, e.g. the missing harmonisation of botanical ingredients and the limited effectiveness of the mutual recognition principle. By demonstrating how the identified regulatory dysfunctionalities reinforce each other and exacerbate the risk of low-quality supplements reaching the market, the dissertation adds to the ongoing scholarly debate on the need for a more robust legal system governing food supplements.

The study further explores the potential of amending established pharmacopoeial reference standards to include food supplements. Drawing on conceptual parallels with pharmaceuticals, it suggests that pharmacopoeial standards could offer a publicly accessible, low-threshold regulatory mechanism with the potential to support non-legislative harmonisation in the EU. By exploring this non-binding functional instrument, the dissertation contributes to broader debates on soft law and adaptive governance in EU food safety law.

Bridging gaps in quality control and legal certainty through uniform, codified standards may offer a pragmatic regulatory alternative within the current fragmented legal landscape, aligned with the principles of risk-based regulation.

6.3.2 Practical contributions

While the dissertation engages with theoretical considerations regarding the dysfunctionalities of the EU's risk-based regulatory approach pertaining to food supplements, it additionally contributes empirical evidence that inform the prospect development of the studied legal

system. Through the analysis of stakeholder perspectives relevant to the EU food supplement market, the research elucidates how the interplay between regulatory inconsistencies influences both public and private sector enforcement and economic practices.

First, the examination of revealed significant divergences in enforcement practices of national food safety agencies, illustrating the EU's fragmented legal landscape for food supplements. Additionally, these observations reinforce prior critiques concerning the limited capacity of Regulation (EU) 2019/515 as a separate mode of product governance to ensure coherency between national legal systems in this sector. Accordingly, the findings offer policymakers nuanced insights into persisting regulatory shortcomings and potential trajectories for future policy evolution.

Second, the empirical findings highlight that the evolving shift in consumer perception, whereby the consumption of food supplements is not merely considered as a tool for augmenting the regular diet but as an instrument for health enhancements, has been reflected in the business strategies of FBOs. Moreover, the study identified the increased administrative burden from regulatory fragmentation as a barrier to market access and innovation for manufacturers and distributors. While individual stakeholder experiences might be subject to a certain degree of negative bias, they nonetheless provide valuable insights into the ways legal frameworks influence economic decision-making in the private food supplement sector.

Finally, the dissertation emphasizes the value of incorporating empirical analysis methodologies into legal scholarship. Such an approach facilitates not only the identification of normative gaps or systemic inefficiencies of the observed legal system but also a clearer understanding of how law provisions are enforced in practice.

6.4 Limitations

Although methodological limitations of the research have been addressed in each chapter, other limitations affecting the general theoretical framework of this dissertation must be addressed.

First, the research relies on empirical analysis methods to highlight and explore identified regulatory gaps within the EU food supplement legal framework conditions. However, data derived from interviews with stakeholders such as policymakers or private company representatives, is inherently subjective as the interview candidates are influenced by their personal beliefs and experiences. While qualitative empirical research methods aim towards minimising the influence of such external factors on the generated data sets and subsequent analysis, it is not possible to fully eliminate it. Therefore, establishing definitive causal conclusions between stakeholder behaviours and the applicable regulatory landscape remains

difficult. In conclusion, the generalizability of the obtained empirical research results should be considered carefully, especially since only a portion of EMS were included in the analysis.

Second, although the investigated aspects of food supplement regulation and quality entail an impact on financial and human resources of both the public and private sector, an in-depth economic cost-benefit analysis is missing. This would be beneficial in order to address market dynamics under the current regulatory regime and potential consequences of amending pharmacopoeial reference standards to food supplements to the EU market.

Finally, this analysis encompasses the empirical investigation of perspectives from the public and private sector on the EU food supplement regulatory system. Although capturing the viewpoints of regulators and food companies is integral to understanding and developing food quality mechanisms, the perspective of consumers is largely missing in this dissertation. In this regard, considerations derived from empirical analysis of perceptions or expectations expressed by consumers or consumer protection organisations on the current state of EU food supplement regulation and quality could have further benefit the research.

6.5 Recommendations

The stagnation surrounding efforts of fully implementing critical aspects of food supplement regulation in the EU is unlikely to be resolved in the near future. This is largely due to a persistent fundamental issue: the lack of sufficient and high-quality scientific data.

Future research investigating options for improving food supplement quality and safety should consider the limitation of the fragmented legal system, which has proven only partially effective in achieving its stated objectives of consumer protection and ensuring fair market conditions.

As the food supplement market is continuously growing, in particular the distribution and use of non-harmonised botanical ingredients, researchers and policymakers should explore alternatives to the current approach on food supplements governance under the adopted risk-based regulatory paradigm such as traditional use evidence.

While this dissertation has contributed to the discussion around expanding pharmacopoeial codices to food supplements, additional more targeted research approaches on this regulatory aspect are required. One potential for future exploration is the adaption of the traditional use clause from the EU Medicines Directive for the food supplements sector. Likewise, the use of traditional health claims warrants further investigation. Comparative legal analyses of legislative models outside the EU following other regulatory approaches could also offer valuable insights.

6.6 Conclusion

While the regulatory fragmentation of the EU's legal system governing food supplements has been described before, this dissertation focusses on the interplay between individual aspects creating issues for public and private stakeholder and ultimately exert an impact on the quality of products available on the market.

The administrative inertia of the EC and EFSA has been criticized by the private sector, other EU and national institutions, and academic scholarship. Although the risk-based approach and its focus on high-quality safety is justified through comprehensive EU food law provisions and CJEU decisions, and has further demonstrated its effectiveness in other sectors such as the EU medicines market, a regulatory gap has emerged for food supplements, contradicting the EU's goals of protecting consumers and progressing the free internal market.

As the reasons for the unavailability of the data required for upholding the current regulatory approach are well-known, primarily founded in high-costs and scientific complexity of conducting clinical studies by FBOs, it is highly unlikely the situation will change in the near future. Meanwhile, consumers continue to be exposed to the risk of consuming low-quality supplements, characterised by mislabelling, unlawfully added ingredients, non-assessed traditional health-claims and potentially misleading practices. Against the background of an increasing importance of the EU food supplement market, the EU needs a regulatory framework which provides clarity and legal certainty to both food safety authorities and manufacturers.

While the adoption of nutraceutical legal frameworks, considering the overlap between food supplements, nutritional health benefits, and herbal medicinal properties has been suggested by prior research, other jurisdictions have adopted more innovative approaches to adequately address the importance of food supplement quality and safety. In the EU a regulatory system has emerged, requiring proofs of safety efficacy for botanical ingredients and botanical health-claims comparable to medicinal products while setting narrow conditions and limits on the use of efficacy related statements. Meanwhile, it is possible to market similar product formulations as traditional herbal medicinal products, allowing for more advanced medical claims without proof of efficacy.

The EU should adopt a more flexible approach when it comes to the quality of required safety data, considering safety demonstrated under the traditional use clause of the Medicines Directive and codified in ESCOP or HMPC monographs, or indicated in pre-clinical or in vitro studies suggesting relative safety, until more data becomes available. Although this could represent a deviation from the precautionary principle dominant in regulating uncertainty surrounding a range of food products such as novel foods, traditional use as a safety metric is already in use in the absence of concluding EFSA safety assessments in the case of botanical health-claims. Pharmacopoeial reference standards could serve as a regulatory measure to

further streamline and harmonise quality aspects. The already established use of the Ph. Eur. in various aspects of food quality and safety assessments by EFSA and its use in the Canadian food supplement sector, exemplifying the Brussels Effect, underscores the potential of pharmacopoeial reference standards discussed in this dissertation.

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About the author

Roman Warda was born in Cologne, Germany, on 30th October 1995. Starting in 2014, he enrolled in the pharmacy degree program at the Philipps-University of Marburg, Germany. During his studies, he participated in international exchange programs, including ERASMUS at the Université de Poitiers, France, and SEP (Student Exchange Program for pharmacy students) to Prague, Czech Republic. These experiences exposed him to diverse approaches to pharmaceutical care and practices across Europe.

Internships in the pharmaceutical industry and the university's Faculty of Pharmaceutical Technology sparked his interest in manufacturing and quality control practices within the pharmaceutical sector. His passion for regulatory affairs was further shaped during his practical pharmacist training following graduation, where he worked in the EU OTC drug division of a pharmaceutical company. This experience intensified his interest in regulatory issues concerning food supplements and medicinal products at the EU level.

Driven by a keen focus on the intersection between the food supplement and pharmaceutical sector, Roman Warda pursued his PhD research focusing on the dynamics of the EU regulatory framework governing food supplements. His work examined how these issues interactively affect product quality and explored the potential for codified quality reference standards across the EU.

Alongside his academic endeavours, he continued working as a pharmacist in various settings in Lübeck and Hamburg, Germany. This hands-on experience allowed him to deepen his understanding of needs and expectations expressed by consumers and patients, particularly concerning OTC drugs and food supplements.

List of publications

2024

Warda, R., Purnhagen, K., & Molitorisová, M. (2024). Has mutual recognition in the EU failed? – A legal-empirical analysis on the example of food supplements containing botanicals and other bioactive substances. *Journal of Consumer Policy*, *47(*4*)*, 425-443.

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