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RESEARCH

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 is 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

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 EU (Warda et al., 2024). Enforcement mechanisms in EU food law have been characterised as employing a hybrid approach, seeking to integrate

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both public and private enforcement tools (Purnhagen & Molitorisová, 2022). Within this model, public enforcement mechanisms are designed to incentivise self-regulation by food business operators (FBOs) (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 and Yu (2021) investigated notification patterns of mycotoxin contamination of nut products. De 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 (De Leo et al., 2021). 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. Food supplements were identified as a primary cause of triggered RASFF notifications (Mikulec et al., 2023). Additionally, they were frequently associated with cases of food fraud reaching the EU market, as indicated by corresponding RASFF notifications (Pigłowski & Śmiechowska, 2024). An analysis of RASFF data by Eissa et al. (2024) further highlighted that food supplements were among the food categories most often affected by food additives and flavorings exceeding permissible limits. Other studies analysed the adulteration of supplements with pharmaceutical ingredients, as reported in the RASFF (Czepielewska et al., 2018). Kowalska and 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.

Methodology

The Method of Doctrinal Legal Analysis

In this study, doctrinal legal analysis was employed to systematically assess the primary legal sources relating to the regulation of food supplements at the EU level (Hutchinson, 2015). The analysis focused on identifying and interpreting relevant legislation and case law to determine underlying principles and norms of the governing legal system in this sector. Secondary materials such as institutional communications and peer-reviewed articles were included to contextualise doctrinal developments within the broader regulatory landscape (Hutchinson, 2015).

The Method of Secondary Data Analysis

The synthesis of doctrinal legal analysis with empirical research methods has been endorsed by legal scholarship to better reflect contextual nuances (Bhat, 2020; Hutchinson, 2015). In this study, we performed secondary data analysis to draw on a compilation of quantifiable publicly available data. Information on how the investigated aspects of the legal system governing food supplements in the EU operate in practice would otherwise be difficult to obtain (Greenhoot & Dowsett, 2012). Although a degree of data conversion was required to ensure careful interpretation the data set, secondary data analysis is a well-established research method in other fields such as epidemiology or public health (Greenhoot & Dowsett, 2012; Williams & Shepherd, 2015; Windle, 2010).

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).

Data Extraction

All notifications on food supplements are placed in the "dietetic foods, food supplements, and fortified foods" category of the RASFF Window (https://webgate.ec.europa.eu/rasff-window). Notifications of this category from 1 January 2022 until 31 December

2022 were obtained from the RASFF Window website via download in.xls format. Due to maintenance issues, prior notifications were inaccessible through the RASFF Window. Instead, RASFF notification data sets from 1 st January 2002 to 31 st December 2020, and 1 st January to 31 st December 2021 were obtained from the EU data portal (https://data.europa.eu/data/datasets/restored_rasff) under the search term "RASFF" via download in.xls format. In total, 5208 notifications were extracted on the 2nd May 2023. EU legislative texts were retrieved from the EUR-Lex database.

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.

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 predetermined 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. Notifications on unauthorized novel foods were separated into bioactive and botanical ingredients to account for their differing chemical complexity and toxicological profiles. Dosage-related alerts were divided into minerals

and vitamins and bioactive ingredients because the former have established nutritional reference values, whereas the latter vary in potency, composition, and effects.

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.

Inferential statistical analysis was applied to characterise trends in RASFF food supplements notifications and to explore their temporal alignment with the adoption of EU food safety legislation applicable to food supplements. Bivariate linear regression was used as the primary analytical approach to estimate growth rates of the total food supplement notifications and individual notification bases. The statistical significance of the estimated growth rates was assessed using one-sample *t*-tests of the regression slope coefficients, while overall model variability was evaluated using one-sample *F*-tests. R-squared (R^2) was calculated to test the strength of the relationship between time and notification counts. The level of significance was set as $\alpha = 0.05$ for all tests. For each group, regression analyses were conducted separately for 2003 to 2014 and 2015 to 2022 to descriptively characterise differences in trend dynamics across regulatory periods.

As a supplementary analysis, interrupted time series analysis (ITSA) was conducted to formally test whether the transition between the two periods was associated with statistically identifiable changes in notification levels or trends. Segmented regression models were fitted to estimate the pre-transition slope, immediate level change, and post-transition slope modification. The transition point was defined as the boundary between the regulatory expansion phase (2003–2014) and the subsequent consolidation phase (from 2015 onwards). Durbin-Watson-statistics were applied to assess potential autocorrelation and verify model assumptions. Given certain limitations such as the gradual implementation of EU food safety laws, potential delays of regulatory effects being visible in the RASFF database, and heterogeneity in national enforcement practices, ITSA was considered primarily as a robustness check for abrupt structural changes rather than as the main analytical framework.

Potential outliers in the data set were identified for 2014 ($n = 391$) and 2021 (company check $n = 102$), which deviated from the overall linear trend. Outlier detection used a 95% confidence band around the bilinear regression model, with values outside this interval flagged as extreme values. To maintain model stability, these values were replaced with the mean response value calculated using one-way ANOVA. This proportional adjustment aligns with standard practices in secondary data analysis when extreme values potentially influence regression estimates. 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, 2018).

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; De 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.

Results

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 (Commission of the European Communities, 2000). 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, 2004), health claims (Regulation (EC) No 1924/2006, 2006), restricted ingredients (Regulation (EC) No 1925/2006, 2006), novel foods (Regulation (EU) 2015/2283, 2015), food additives (Regulation (EC) No 1333/2008, 2008), or limits for pesticide residues (Regulation (EC) No 396/2005, 2005) and contaminants (Commission Regulation (EC) No 1881/2006, 2006; Regulation (EU) 2023/915, 2023). 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 RASFF was established after adopting the GFL in 2002 (Regulation (EC) No 178/2002, 2002). Stakeholders of the EU food supplement market, including authorities, food companies, and consumers, may notify their NCP 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 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" (Article 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 (Article 19 (3,4) GFL) and the judiciary (Federal Court of Justice, 2024) likewise stipulate such a "principle of cooperation" in food law enforcement (*Bundesgerichtshof – 3rd Civil Senate, III ZR 24/23*, 2024; Regulation (EC) No 178/2002, 2002). 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-related issues,generally involving non-compliance of perceived limited individual impact, 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 EU's 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).

Secondary Data Analysis of RASFF Notifications

RASFF Notifications by Stakeholders

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.

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

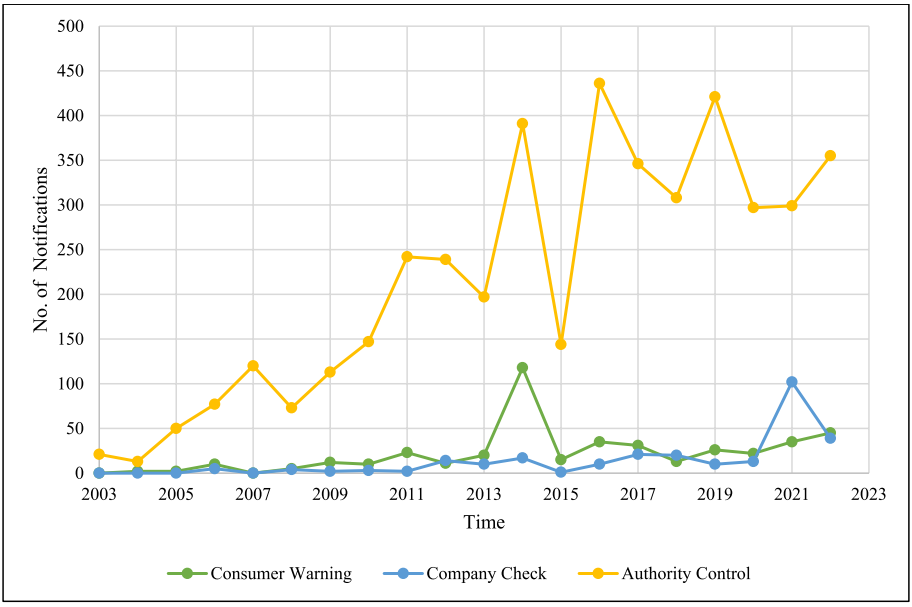

Fig. 1 Distribution of food supplement notifications from 2003 to 2022 by consumer warning, company check, and authority control

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

	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

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.

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

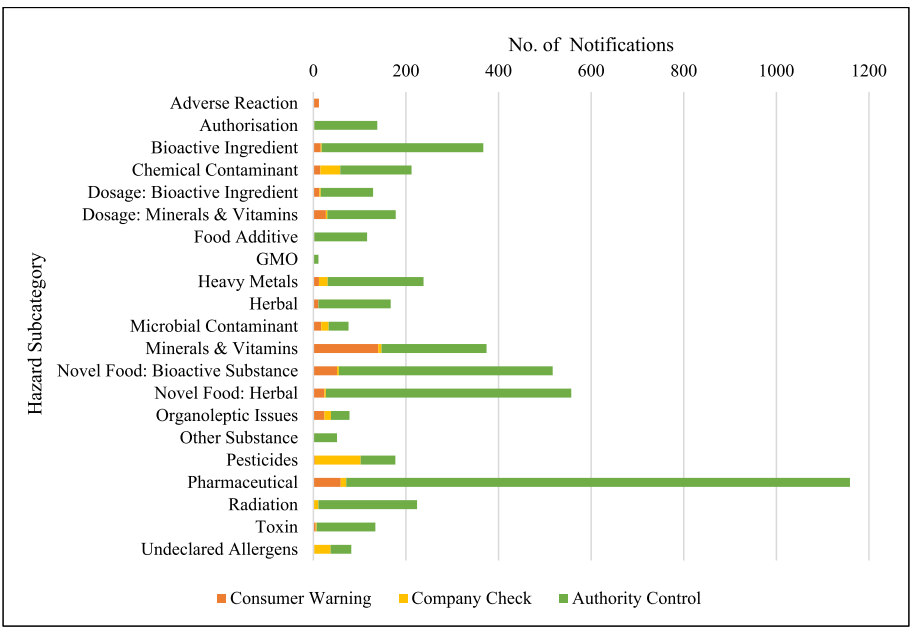

Fig. 2 Distribution of total supplement RASFF notifications across hazard categories per notification basis from 2003 to 2022

complaints, and only 12 were first reported by companies. Underscoring the risk of unintentional consumption of undeclared active pharmaceutical 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 ($n=128$).

After pharmaceutical adulteration, the addition of unauthorised novel food ingredients to supplements was the most prevalent issue. Figure 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.

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. An overview of registered countries of origin associated with triggered RASFF notifications on detected pharmaceutical adulterants is provided in Supplementary Material 5. 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

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

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

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).

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.

Temporal trends in RASFF food supplement notifications were analysed using bilinear regression analysis as descriptive primary approach for total notifications and each individual stakeholder group. ITSA was applied to test for potential structural changes between the two defined time periods. Results of the bilinear trend analysis are illustrated in Fig. 3, while formal tests of level and slope changes are reported separately in Table 5.

Bilinear Regression Analysis

The first indicator of food supplement notification trends temporarily aligned with the regulatory expansion (2003—2014) and the consolidation period (2015—2022) can be

Table 3 Number of food supplements RASFF notifications per stakeholder

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

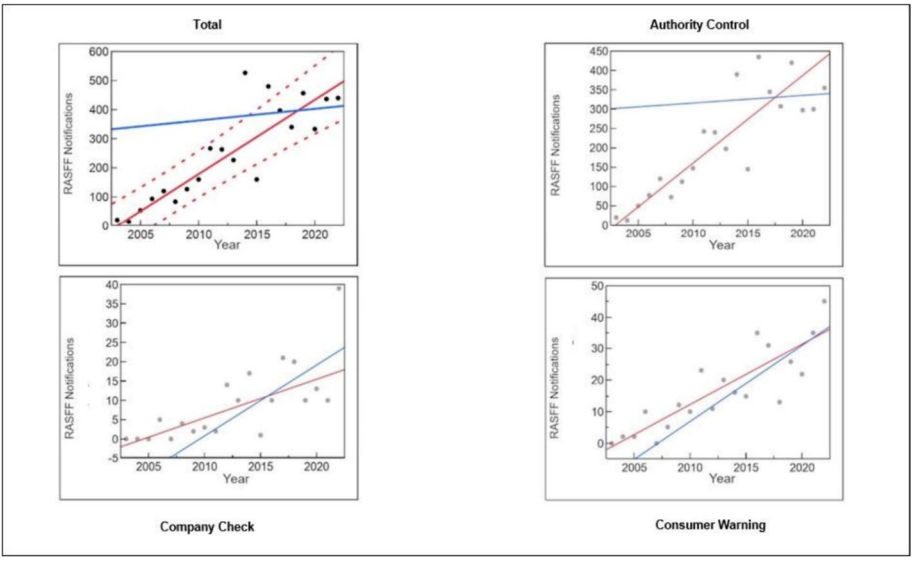

Fig. 3 Descriptive bilinear trends in annual RASFF food supplement notifications (dots) across the study periods 2003–2014 (red line) and 2015–2022 (blue line)

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 consistent with a saturation-like pattern 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, suggesting that a plateau may be 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.

Interrupted Time Series Analysis

As a supplementary analysis, ITSA was conducted to formally test whether the transition between the two defined time periods was associated with statistically identifiable abrupt changes in notification levels or trends. Across all stakeholder groups, ITSA identified a statistically significant increasing pre-transition trend. However, no statistically significant immediate level changes or post-transition slope changes were observed. Residual diagnostics did not reveal meaningful autocorrelation. All calculated ITSA results are presented in Table 5.

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, De 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 (D'Amico et al., 2018). Considering that nearly a third of all observed notifications were flagged as alert signals further underscores the risk

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

	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 5 Interrupted time series analysis (ITSA) of RASFF food supplement notifications across stakeholder groups. Estimates include pre-transition trends (β_1), immediate level changes (β_2), post-transition slope changes (β_3), and residual autocorrelation diagnostics

	Pre-transition trend β1	p (β1)	Level change β2	p (β2)	Slope change β3	p (β3)	Durbin–Watson	p (DW)
Total	34.9	< 0.01	− 62.5	0.44	− 15.3	0.31	3.05	0.97
Authority Control	28.0	< 0.01	− 8.86	0.90	− 18.9	0.14	2.99	0.96
Consumer Warning	1.99	0.004	− 3.44	0.62	0.34	0.79	2.14	0.34
Company Check	1.28	0.027	− 9.31	0.14	1.72	0.14	1.76	0.09

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 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 temporarily conincides 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). Similar increases in RASFF notification activities following the adoption of food safety laws have been reported for orther food categories (De Leo et al., 2021; Pádua et al., 2019). Nogales et al. (2023) likewise described higher notification frequencies in regulatory environments characterised by stricter food policies.

The identified R^2 value of 0.88 for total notifications and $R^2 = 0.86$ for authority controls during the first observation period indicate that notification counts followed a predicatble pattern, suggesting that time was a strong descriptor of notification dynamics in the context of the expansion of the EU's food safety regulatory framework. However, the reported R^2 values for the subgroup of company checks ($R^2 = 0.53$) and consumer complaints ($R^2 = 0.63$) indicate greater variability, suggesting that factors other than time may have influenced notification behaviours of these groups.

From 2015 to 2022, notification dynamics shifted towards a phase characterised by relative stabilisation at a higher absolute level, with attenuated annual changes. While the bilinear regression analysis results illustrate this descriptive transition between time periods, ITSA did not identify statistically significant level of slope changes indicative of an abrupt structural break. Accordingly, the observed stabilisation should be interpreted as a gradual consolidation phase rather than as evidence of direct regulatory impact. Potential underlying biases must be acknowledged, including heterogeneous Member State engagement with RASFF and differences in categorization practices. As mentioned, authorities do not necessarily report every detected issue to the RASFF, which could have influenced the data analysis (De 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. Overall, the findings should be interpreted as descriptive temporal associations rather than as evidence of direct measurable regulatory effects.

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, whereas FBOs report only a few issues simply due to a generally high compliance level (Lorenzen et al., 2021). However, the findings indicating thatauthority controls contribute to the majority of reported 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 Sect. "RASFF Notifications", using the RASFF database is subject to several limitations, such as miscategorisation of issues or different regional activity levels.

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 food 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 coincides with authorities reporting 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 EU 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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Data Availability Analytical results obtained by this research are provided in the text or in the Supplementary Materials 1–5. Further details on analytical steps are available from the authors only upon reasonable request. The compiled data set used for this analysis is available in the Open Science Framework repository: https://doi.org/10.17605/OSF.IO/NF6KV.

Declarations

Competing interests Kai Purnhagen is a member of the editorial board of the Journal of Consumer Policy. The author(s) declared no other potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

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