



Proceeding Paper

Analyzing European Union Rapid Alert System (RASFF) Notifications of Emerging Marine and Freshwater Toxins from the Last Decade: Appearance Trends and Links with Occurrence Data and Risk Assessment Advancements [†]

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Abstract: The EU Rapid Alert System for Food and Feed (RASFF) is a tool for the rapid exchange of information on food and feed safety issues between EU member states and the European Commission, destined to notify food safety authorities about products posing a risk to human health. Emerging marine and freshwater toxins and their impact on human health and aquatic ecosystems have become a growing concern in the recent years. This is also reflected in the RASFF notifications shared by European countries during the last decade, with the occasional appearance of relevant records. In this work, RASFF notifications related to emerging marine and freshwater toxins from 2012 to date were retrospectively analyzed to discover the patterns of their appearance, as well as to explore their relationship with concurrent occurrence data and/or risk assessment advancements in the field. A total of fifteen notifications involving emerging marine and freshwater toxins were found, which included: ten on ciguatoxins in fish, three on tetrodotoxins in bivalve molluscs, one on microcystins in algae powder, and one on pinnatoxins in bivalve molluscs. This study contributes to a better understanding of the reasons behind the RASFF's provision of notifications on emerging toxins in EU countries.

Keywords: RASFF notifications; emerging toxins; marine toxins; freshwater toxins; risk assessment; ciguatoxins; tetrodotoxins; cyanotoxins; pinnatoxins



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1. Introduction

Marine and freshwater toxins (MFTs), also known as biotoxins, are natural compounds generated by algae and cyanobacteria that exist in marine, estuarine, and freshwater environments. These toxins can accumulate in different edible marine organisms, including fish, crabs, and shellfish, without causing them any harm or poisoning, but may constitute one of the most significant risks for human health following their entrance in the food chain through seafood consumption [1]. Certain toxin groups are already regulated at the European Union (EU) level, for which official monitoring systems are in place to ensure safe levels in seafood. However, the emergence of new, previously unknown toxin groups, or known ones spreading to new areas due to climate change and globalization, is gradually becoming a source of major concern for human health. These compounds are commonly referred to as “emerging toxins” and include groups such as cyclic imines (spirolides, gymnodimines, pinnatoxins), tetrodotoxins, ciguatoxins, and cyanotoxins. The occurrence of emerging toxins in aquatic food commodities, as well as the potential risks arising from consumers' exposure to these substances, have been under consideration by the European Food Safety Authority (EFSA) for more than one decade [2,3].

In order to enhance the level of food and feed safety for the benefit of consumers' protection, in 1979, the European Union established the Rapid Alert System for Food and

Feed (RASFF). This system now operates under the Regulation (EC) 178/2002, which lays down the “general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety” [4,5]. The RASFF foresees the collection, sharing between member states, and publication of notifications on health risks associated with food or animal feed, as well as the actions taken to safeguard consumers, such as withdrawing or recalling products from the market. Notifications are triggered by the issue identifier and disseminated to allow the withdrawal of the product from all markets or implementation of any required measures to protect consumers [6].

RASFF notifications are categorized into four distinct types: alerts, information for attention, border rejections, and news. Alert notifications are issued when a food or feed which presents a serious health risk is on the market, indicating that rapid action is required by other member states regarding the product’s distribution. Information notifications, on the other hand, are sent when the identified hazardous food or feed is placed on the market, but no rapid actions are required on behalf of other RASFF members. Border rejections refer to food and feed consignments being tested and rejected at the external EU borders upon detection of a health risk; these are disseminated to enable all border posts reinforce their controls and ensure that no re-entrance of the rejected product through another border post occurs. Any other information relevant to food and feed safety not communicated under one of the previous notification types, but judged as interesting for the official control authorities, is transmitted as “news” to the RASFF members [7].

RASFF notifications on MFTs are filed in the system under the “biotoxins (other)” hazard category; they occur occasionally, constituting on a yearly basis around 1–5% of seafood-related notifications [6,8,9], and are commonly associated with the product categories “bivalve molluscs and products thereof” and “fisheries and products thereof”. The first RASFF notification on marine toxins (MTs) appeared on the system as early as 1986 [6]. On the other hand, RASFF notifications on freshwater toxins (FTs) are scarce, with the oldest record referring to the presence of saxitoxin in 2003 in the freshwater snail *Pila polita* (ref. 2003.171), known also as the apple snail [6]. Nonetheless, the first ever RASFF alert relevant to an emerging biotoxin appeared much later, in 2009. This was notified by Italy, and referred to the presence of a potentially toxic fish species (*Lagocephalus* spp.) in frozen headless fish blocks from Spain (ref. 2009.0730), thus indicating the potential exposure of consumers to tetrodotoxin. All other existing notifications relevant to emerging biotoxins have been reported during the last decade, starting from 2012 [6,8], and are analyzed in detail within the context of the present study. To the best of our knowledge, so far, no other works have specifically dealt with the issue of RASFF notifications on MFTs, neither the regulated nor the emerging ones.

2. Methods

2.1. Data Sourcing and Preprocessing

Data were sourced from both the RASFF notifications pre-2021 and the 2021 public information dataset repositories [6], and the currently searchable “RASFF window” database, which contains the data from 2022 onwards [8]. Filtering using the relevant Microsoft Excel (Microsoft Corporation, Redmond, DC, USA) function was applied to the data up to the end of 2021 (downloadable in spreadsheet form), by initially selecting the hazard category “natural toxins (other)” and then filtering further within the fields “substance/finding” and “product category”, to exclude cases irrelevant to MFTs. A similar approach was adopted for the data after 2022, which were filtered through the online search menu of the database by first selecting the hazard category “biotoxin (other)” within the “Risk/Hazard category” field, and secondly restricting the results in regard to the product category (by selecting “bivalve molluscs and products thereof”, “fish and products thereof”, and “other food product/mixed”). Data were visually examined to exclude entries evidently unrelated to MFTs, while further crosschecks were also applied by searching the whole datasets for relevant keywords with wildcard symbols (where needed), such as “cigua*”, “poison*”, “toxin*”, etc., to retrieve potentially missed entries of interest. At the next step, all cases

that fitted within the context of emerging MFTs were selected and entered into an Excel spreadsheet containing the following variables: year, reference number, product category, product type, genus/species involved, notifying country, country of origin, notification classification, notification basis, relevant legislation/rationale for notification, and action taken. Notification details still available in the searchable database were also stored as pdf files to be further processed using a thematic analysis approach.

2.2. Data Analysis

The data entered in the spreadsheets were initially explored in Microsoft Excel to obtain frequencies of their nominal variables that were quantifiable. Available notification details (in spreadsheets and pdf files) were also uploaded to the qualitative analysis software Quirkos 2.4.1 CAQDAS (computer-assisted qualitative data analysis software) to allow for thematic analysis of the dataset in order to identify patterns and display the findings in a visually engaging representation (Figure S1). The quantitative data obtained (sums and % occurrence) for some of the variables were graphically plotted using Microsoft Excel (Version 2311).

3. Results and Discussion

3.1. Overall Results—Notification Numbers by Variable

The above-described search strategy yielded a total of 15 notifications relevant to emerging MFTs, of which ten were on the presence of ciguatoxins in fisheries, three were on tetrodotoxins in bivalve molluscs (oysters), one was on the presence of cyanotoxins (microcystins) in algae powder, and one was on pinnatoxins’ presence in bivalve molluscs (mussels). The overall results grouped by variable are summarized in Table 1, while some of the most interesting occurrence frequencies are presented in Figure 1.

Table 1. Details of the RASFF notifications relevant to emerging marine and freshwater toxins reported in the system in 2012–2022 (n = 15).

Variable	Toxin Group			
	Ciguatera/Ciguatoxins	Tetrodotoxins	Pinnatoxins	Microcystins (Cyanotoxins)
Number of notifications (year)	10 (of which: 1 (2012); 1 (2015); 5 (2016); 2 (2017); 1 (2019); 1 (2020))	3 (2016)	1 (2022)	1 (2020)
Notification(s) reference (year.number)	2012.1602; 2015.0088; 2016.0932; 2016.1152; 2016.1153; 2016.1155; 2017.0345; 2017.1112; 2019.0875; 2020.2254	2016.0845; 2016.1118; 2016.1119	2022.3934	2020.3019
Product category	Fish and products thereof (10)	Bivalve molluscs and products thereof (3)	Bivalve molluscs and products thereof (1)	Other food product/mixed (1)
Product type	Frozen fillets (4); wild origin, chilled (3); frozen, whole, gutted, and scaled (2); fresh fillets (1)	Live (3)	Fresh (1)	Klamath algae powder (1)
Genus/species involved	Red snapper: <i>Lutjanus</i> spp. (5) (of which <i>L. bohar</i> (1)); Kingfish: <i>Caranx</i> spp. (2); Barracuda: <i>Sphyraena</i> spp. (2) (of which <i>S. jello</i> (1) and <i>S. barracuda</i> (1)); Wahoo: <i>Acanthocybium solandri</i> (1)	Oysters (3)	Mussels (1)	<i>Aphanizomenon flos-aquae</i> (1)
Notifying country	France (7); Germany (2); Netherlands (1)	Netherlands (3)	Belgium (1)	Belgium (1)
Country of origin	India (6); Vietnam (2); Sri Lanka (1); Senegal (1)	Netherlands (3)	Netherlands (1)	USA (1)

Table 1. Cont.

Variable	Toxin Group			
	Ciguatera/Ciguatoxins	Tetrodotoxins	Pinnatoxins	Microcystins (Cyanotoxins)
Notification classification	Alert (5); information for attention (5)	Alert (3)	Information for attention (1)	Alert (1)
Notification basis	Food poisoning (6); border control—consignment released (4)	Company’s own check (2); official control on the market (1)	Official control on the market (1)	Official control on the market (1)
Relevant legislation/rationale for notification ¹	Reg. 178/2002 requirements (4); national surveillance plan (4); reg. 178/2002 precautionary principle (3); reg. 178/2002, art. 14 (2a) (1)	National legislation (3); reg. 178/2002 precautionary principle (3)	Reg. 178/2002 requirements (1); risk evaluation (1)	National research project (1); risk evaluation (1)
Action taken ¹	Withdrawal from the market (4); recall from consumers (3); informing authorities (2); informing recipients (1); no action taken (1)	Withdrawal from the market (3)	No stock left (1)	Recall from consumers (1); public warning—press release (1)

¹ In some cases, more than one option was applicable, so the sum of individuals is higher than the total number of notifications.

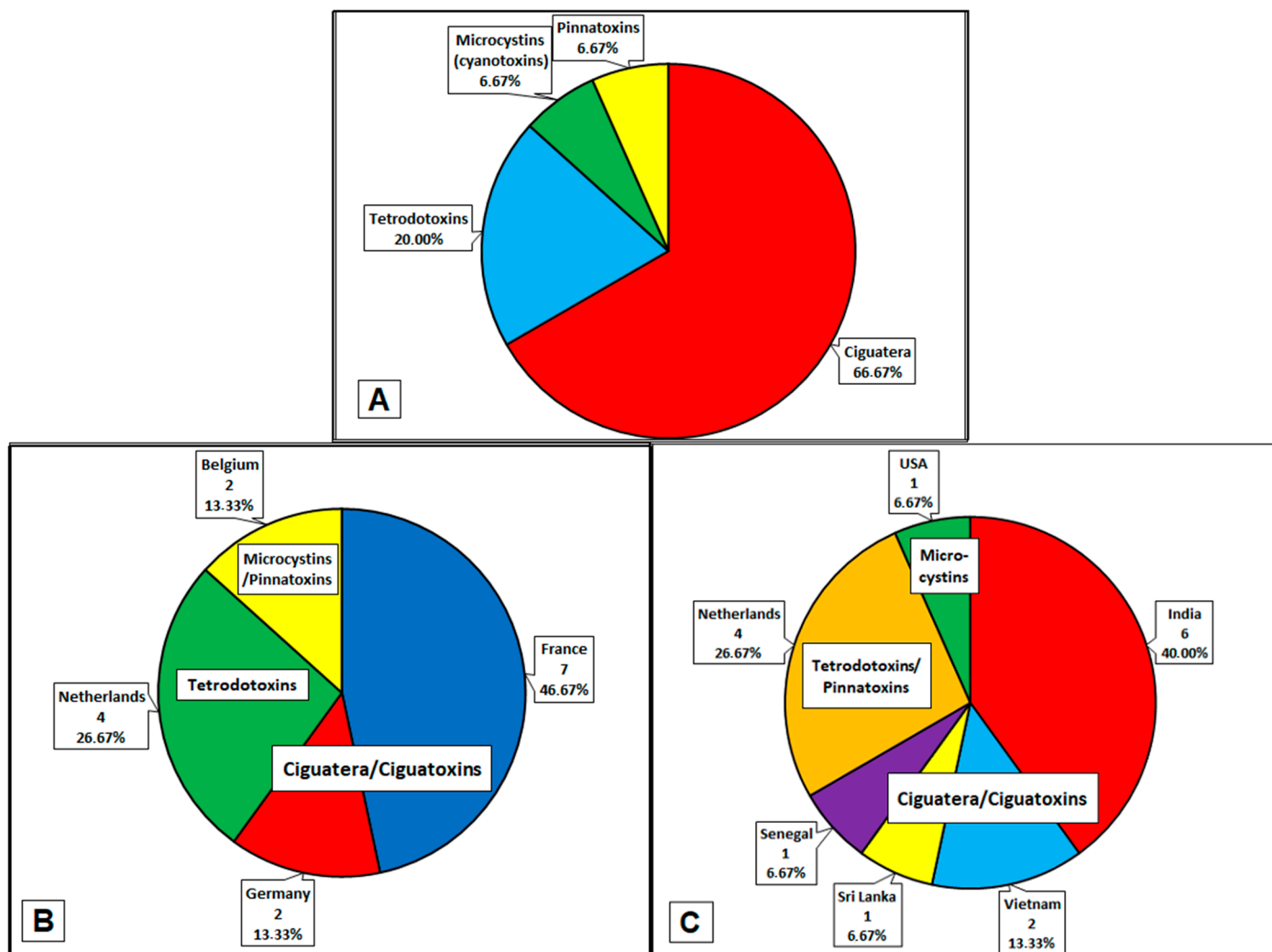


Figure 1. RASFF notifications associated with emerging marine and freshwater toxins according to: (A) the toxin involved; (B) the notifying country; and (C) the product origin.

3.2. Details on Individual Toxin Groups

3.2.1. Ciguatera–Ciguatoxins

The majority of the emerging MFT-related notifications (10/15) were associated with ciguatera fish poisoning (CFP) and/or the presence of ciguatoxins (CTXs) (Table 1). More than half (6/10) of them were connected to food poisoning incidents caused by fish of the genera *Lutjanus* and *Acanthocybium* sp. originating from India or Vietnam, whereas the remaining four were the outcome of border controls on *Caranx* and *Sphyræna* sp. fish imported from India, Sri Lanka, and Senegal. Most of the CFP/CTXs-related reports (7/10) were notified by France, some of which (4/7) were within the framework of a national surveillance plan, while CFP outbreaks were also reported in the RASFF by Germany (2/6) and the Netherlands (1/6).

It is noteworthy that despite the longstanding worldwide occurrence of CFP, RASFF notifications relevant to CFP/CTXs only started appearing in 2012, some years after the first CFP outbreaks were reported in European territories (2004 in the Canary Islands and 2008 in Madeira) and very soon after the publication of the relevant EFSA scientific opinion on emerging toxins of the ciguatera group in 2010, which highlighted numerous information gaps existing at that time [10]. Although all of these RASFF notifications concern fish and fish products imported from third countries (i.e., non-EU members), it is possible that the above circumstances resulted in increasing the competent authorities' awareness on the issue. At the same time, they have also triggered a more intense research interest on behalf of the relevant scientific community regarding the emergence of this toxin group in Europe. It is also notable that all CFP/CTXs-related RASFF notifications were reported by only three countries (France, Germany, the Netherlands), even though the products in question were distributed to many more EU member states. This indicates a possible under-ascertainment of the occurrence of CFP/CTXs in the EU and may camouflage the actual incidence ratio of such outbreaks [11]. In fact, CFP incidence in EU member states is indeed much higher. Data collected from numerous national or EU-level sources (including national public health surveillance systems, poisoning centers and food safety competent authorities, the EU Food-borne Outbreaks Reporting System (EU-FORS) of the EFSA, the Epidemic Intelligence Information System (EPIS FWD) of the European Centre for Disease Prevention and Control (ECDC), other alert systems (INFOSAN, IHR), etc.) within the framework of the EuroCigua project revealed that at least 34 CFP outbreaks occurred between 2012 and 2019 in Spain, Germany, France, and Portugal, which were related to 209 individual cases [12]. Evidently, only a small proportion of these outbreaks were notified through the RASFF, whereas the true incidence rate of CFP in the EU remains largely unknown [12].

3.2.2. Tetrodotoxins

All three RASFF notifications on tetrodotoxins (TTXs) resulted from official market controls conducted in the Netherlands on oysters produced in the country itself (Table 1) and were founded on the national legislation adopted for tetrodotoxins in 2016, establishing any presence of TTX in live bivalve molluscs, starting from 20 µg/kg (the detection limit) [13], as a risk to public health according to the requirements of the EU legislation [4]. These measures stemmed from a national risk assessment following the pronounced research interest on the presence of TTXs in Europe starting from 2015 onwards, when TTXs were consecutively detected in bivalve molluscs from the UK, Greece, and the Netherlands [14–16]. Subsequently, in 2017, the relevant EFSA scientific opinion on the risks related to the presence of TTXs in marine bivalves and gastropods was adopted and published, introducing a proposed safe concentration of lower than 44 µg of TTX eq/kg of shellfish meat [17], after which no further RASFF notifications on TTXs were entered in the system.

3.2.3. Pinnatoxins

The single RASFF entry referring to the presence of pinnatoxins (PnTXs) in bivalve molluscs (fresh mussels) from the Netherlands was the outcome of an official market control

in Belgium in 2022. The detected concentration was 25.1 ± 12.6 μg PnTX-G/kg, and based on the risk evaluation of the French Agency for Food, Environmental, and Occupational Health and Safety (ANSES) regarding pinnatoxins-associated health risks, adopted in 2019, it was judged as a potential risk for children using the Belgian consumption data, considering the acute reference value of 0.13 μg PnTX-G/kg body weight and proposed safety limit of 23 μg PnTX-G/kg of shellfish [18,19]. Although the presence of PnTXs in shellfish is nowadays widespread at a worldwide level, it appears that, at least until quite recently, PnTXs were not recognized as hazardous for human health, mostly due to a lack of sufficient relevant epidemiological and toxicological data [20].

3.2.4. Cyanotoxins (Microcystins)

The RASFF notification from Belgium on the presence of high concentrations of microcystins (MCs) in a food supplement (Klamath algae powder) originating from the USA also pertained to an official market control, which was triggered through a national research project assessing the presence of cyanotoxins in algal food supplements on the Belgian market [21]. The Belgian national competent authorities (AFSCA—Agence Fédérale pour la Sécurité de la Chaîne Alimentaire) evaluated the risk as serious, indicating a long-term effect on human health, and issued a relevant public warning/press release to communicate the product's withdrawal from the market [22]. Results from the aforementioned research study indicated that MCs at concentrations ranging between 0.24 and 5.6 $\mu\text{g}/\text{g}$ total MCs were exclusively detected in products containing *Aphanizomenon flos-aquae* [21], as was the case for the algae powder in question. Levels within this range, in a worst case exposure scenario, exceed by far the Tolerable Daily Intake (TDI) of 0.04 $\mu\text{g}/\text{kg}_{\text{bw}}$ per day, established by the World Health Organization as a safe dose for lifetime ingestion [21,23].

3.3. General Considerations

By examining the details of all of the RASFF notifications relevant to emerging MFTs, a precautionary approach is evident in many of the cases regarding the legislative bases behind the actions of the competent authorities. Furthermore, studies conducted by the MFT scientific community have largely contributed towards a recognition of the potential risks involved, in order to guide authorities in taking appropriate action. It is, therefore, essential to foster close scientific dialogue between academia and public authorities in order to effectively manage the risks arising from MFTs and to safeguard consumer health. Furthermore, despite the fact that communicating serious direct or indirect risks to human health deriving from food or feed through notifying the RASFF is imposed on EU member states by legislation [4], oftentimes the information available through RASFF does not realistically represent the true incidence rates, as member states most probably prioritize the use of local reporting systems or other routes of information dissemination. In this context, the EU should take appropriate action to ensure that member states recognize the necessity of notifying all relevant issues through the RASFF, even if used in addition to their national systems. Moreover, adaptations to the current use and functionality of the RASFF promoting its linking with the tasks of the EFSA could also contribute towards strengthening the use of RASFF by member states.

4. Conclusions

The present study contributes to a better understanding of the main reasons behind RASFF notifications relevant to emerging toxins in EU countries, and highlights the importance of new occurrence data, sometimes originating from research studies, as well as of advancements in relevant risk assessments when interpreting the trends observed in RASFF reports. The necessity for further raising the EU national authorities' awareness on the risks derived from MFTs and for pursuing more coordinated actions at the EU level, through a more consistent use of the RASFF, to tackle their potential consequences on public health is imperative.

Supplementary Materials: The following supporting information can be downloaded at <https://www.mdpi.com/article/10.3390/IECT2023-14887/s1>: Figure S1: Quirkos 2.5.3 software: Developed hierarchies of themes and codes.

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Conflicts of Interest: The author declares no conflict of interest.

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