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(Article begins on next page)

### Seafood products notifications in the EU Rapid Alert System for Food and Feed (RASFF) database: Data analysis during the period 2011-2015



<sup>a</sup>FishLab, Department of Veterinary Sciences, University of Pisa, Viale delle Piagge 2, 56124, Pisa, Italy

<sup>b</sup>Department of Agriculture, Forest and Food Science, University of Turin, Largo Braccini 2, 10095, Grugliasco, Torino, Italy

\*Corresponding author.

#### Abstract

Through the analysis of the EU Rapid Alert System for Food and Feed (RASFF) portal, this study aimed at highlighting the most relevant noncompliance affecting seafood and explore possible relationships between variables characterizing notified products. Trends in RASFF notifications can be useful to improve controls and audits of official authority and the safety management of fishery products from Food Business Operators. During the five-year period analyzed (2011-2015), 16304 original notifications were logged on the RASFF database, of which 16.6% (2713) involved seafood. Seafood notifications were issued in most of the cases by Italy (35.7%) and Spain (19.3%) that were also the countries with the highest number of notified products (15.37%), followed by Vietnam and Morocco. Notifications were mainly triggered during official control activities on the market (43%) and border checks (42.8%) and in the 39.3% of cases they were classified as serious. The first two reasons that led to notifications were non-compliant content of heavy metals (fish and cephalopods) and pathogenic microorganisms (bivalve molluscs). At border level, seafood was rejected in 37% of cases, especially (41.1%) because of poor temperature control, unsuitable transport conditions or fraudulent/absence of health certificate. Patterns emerged in this study give a and 'up-to-date' evidence of those that are current issues of the sector. However, even though the RASFF represent a useful "data mine" essential for risk assessment process, limitation arises since, despite the legal obligation for all members, regulatory non-compliant products are not always notified.

Keywords: Seafood; RAS<mark>SE</mark>F; Notifications; Risk; Control authority

# **1** Introduction

Over the years, the EU has sought to strengthen its food safety policy by reorganizing and enforcing official control activities within its territory and throughout the food chain (Alemanno & Gabbi, 2016; En-chen, 2010; Kleter, Prandini, Filippi, & Marvin, 2009; Trevisani & Rosmini, 2008). Official control bodies represent a key element to ensure the correct application of regulatory requirements and, it is of pivotal importance that their activities are well structured, organized and coordinated (Broberg, 2010; Iurato, 2017). At the Community level, Regulations (EC) n. 882/2004 and 854/2004 currently define principles and tools of official checks on food and animal feed, however starting from 14th December 2019 they will be repealed by the new Regulation (EU) 625/2017.

To support a close cooperation and communication between Control Authorities (CAs) of the Member States (MSs), EU has set up an alert network, the Rapid Alert System for Food and Feed (RASFF), involving all EU MSs, Iceland, Liechtenstein, Norway and Switzerland as well as the European Commission (EC) and the European Food Safety Authority (EFSA). The RASFF was put in place to provide CAs with an effective tool to exchange information rapidly and act coordinately in response to serious food and feed safety risks (Kleter et al., 2009; Pigłowski, 2015). The establishment of the RASFF was formalized through a Proposal for a Council Decision (COM/79/725 FINAL), followed by an Amended proposal in 1982 and the Council Decision 84/133/EEC in 1984. Currently, the RASFF legal basis are laid down in the Article 50 of the Regulation (EC) n. 178/2002 (the European General Food Law) while its At the beginning, the RASFF was used as a short-term surveillance and it only covered products destined for consumers (European Commission, 2009). Over the years it has undergone a deep change and nowadays it is even expanding on a global scale, working together with the International Network of Food Safety Authorities (INFOSAN), jointly managed by the Food and Agricultural Organization and the World Health Organization (European Commission, 2009). The RASFF has become increasingly efficient and effective, following the development of internet based IT tools (such as cloud based services and biga data management), which have sped up the exchange of information on food recall within the Community (European Commission, 2009). Since June 2014, the EC has also set up an interactive searchable database, the RASFF portal, to keep information as transparent as possible to consumers, Food Business Operators (FBOs) and CAs worldwide (European Commission, 2018). The RASFF portal is a consumer-friendly internet tool giving public access to summary information about the most recently transmitted notifications as well as allowing to search for information on any notification issued in the past.

Most of the notifications issued by the system involve foods of animal origin and, among these, seafood represents the first cause of alert (Parisi, Barone, & Sharma, 2016; Piglowski, 2015). The number of notified fishery products has considerably increased (+7.7%) since the RASFF was established (Parisi et al., 2016) and this is probably linked to their growing trade and consumption within the EU and worldwide (World Bank, 2013; EUMOFA, 2016; Chan et al., 2017. Currently, EU citizens consume on average 25.1 Kg per capita of seafood annually, 8% more than in the last decade. Therefore, the EU must necessarily import seafood from abroad. In 2016, the EU trade of seafood amounted to 14.1 million tones, for a value of 54.3 billion euros of which about 24.4 billion came from imported products (EUMOFA, 2017).

Given the importance of fishery products in the global and EU market and their primacy as the foodstuff of animal origin most affected by safety issues, this study aimed at carrying out an overall evaluation of data concerning non-compliant seafood notified through the RASFF, during the period 2011-2015 and, by exploring possible associations between variables, highlighting the main hazards affecting different product categories.

# **2** Materials and methods

## 2.1 Data collection and analysis

A RASFF notification that has never been notified to the EC is called 'original' notification (European Commission, 2009). According to the seriousness of the identified risks and to the distribution of the product on the market, the EC contact point classifies the original notification as an alert, an information (for follow up or for attention) or a border rejection (European Commission, 2009). For the purposes of this study, all notifications issued during the period 01/01/2011-31/12/2015 under the product categories "Bivalve molluscs and products thereof (p.t.)", "Cephalopods and p.t.", "Crustaceans and p.t." and "Fish and fish products" were extracted from the RASFF portal (European Commission, 2018). The search was performed by selecting one or more items of the 6 main sections (Notification, Type, Date, Product, Hazard, Keywords) in which the portal is divided. Data have been subsequently parsed into an Excel spreadsheet file and the following attributes were analyzed for notifications pertaining to each product category: total original notifications; type of notification, notifying country, country of origin, notifications basis and distribution status, category of hazard, risk decision, action taken. Associations among attributes were investigated using chi-square test for proportion comparison by using Epi Info<sup>®</sup> version 7.2 for windows. Significance level was set to p < 0,05 for all comparisons. These analyses were performed on proportions in order to compare and assess the differences even when calculated on different samples sizes. The significance level was set to 0.05 instead of 0.1 even if multiple proportions were compared, in order to minimize for the increase in type I error rate given the unequal sample sizes.

## **3 Results and discussions**

## 3.1 Total number of original notifications

During the period 2011-2015, a total of 16304 original notifications were logged on the RASFF database, of which 16.6% (2713) involved seafood. However, it should be pointed out that RASFF analysis may lead to an overestimation of notifications of food safety incidents, especially when the non-compliance is detected after foodstuffs have been distributed on the markets of several MSs (Bouzembrak & Marvin, 2016; Kleter et al., 2009). In fact, the same non-compliant product may be notified by more than one MS. Considering that information about product identity, such as the name of the producer or the importer or the lot, is not available on the RASFF portal, it is impossible to surely identify notifications resulting from the same food safety incident (Bouzembrak & Marvin, 2016; Kleter et al., 2009; Riviere, Buckley, & Committee on Strengthening Core Elements of Regulatory Systems in Developing Countries, 2012). Conversely, in other cases, RASFF notifications may underestimate issues as incidents may not always be notified to the EC (Piglowski, 2017; Taylor, Petróczi, Nepusz, & Naughton, 2013).

"Fish and fish products" was the product category with the highest number of notifications (1776; 65.5%), followed by "Bivalve mollusks and p.t." (431; 15.8%), "Crustaceans and p.t." (318; 11.7%) and "Cephalopods and p.t." (188; 7%). Probably, these differences are mostly linked to their relative quantities marketed at European level. In fact, fish and fish products is the most traded category (80.1% of EU seafood trade by volume), followed by bivalve mollusks (8.7%), crustaceans (7.1%) and cephalopods (4.1%) (EUMOFA, 2017) (see also Table 1). Statistical analyses revealed differences of proportion of notifications across years for all categories, but crustaceans and product thereof (p.t. in table).

 Table 1 Comparison across years of non compliances for each product category. Superscript letters identify significant differences across columns: identical letters indicate proportions which are not statistically

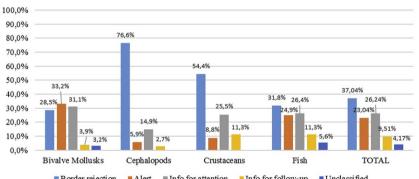
different. The bold statistical values refer to the overall significance for each food category across years. N.s. indicates non significant differences across years.

### alt-text: Table 1

	Product Category						
Year	Fish and fish products	Bivalve mollusks and p.t.	Crustaceans and p.t.	Cephalopods and p.t.			
2011	68,42% <sup>A</sup>	9,82% <sup>A</sup>	10,67% <sup>A</sup>	11,10% <sup>A</sup>			
2012	69,49% <sup>A</sup>	10,17% <sup>AC</sup>	11,3% <sup>A</sup>	9,04% <sup>A</sup>			
2013	61,1% <sup>B</sup>	24,17% <sup>B</sup>	10,41% <sup>A</sup>	4,32% <sup>B</sup>			
2014	59,67% <sup>B</sup>	23,23% <sup>B</sup>	13,20% <sup>A</sup>	3,90% <sup>B</sup>			
2015	68,06% <sup>A</sup>	13,89% <sup>c</sup>	13,66% <sup>A</sup>	4,40% <sup>B</sup>			
chi square	20	<u>81,5</u>	ne	<u>39,9</u>			
<u>P</u>	< <u>0,001</u>	<0,001	n.s.	< <u>0,001</u>			

## **3.2 Type of notifications**

Of the 2713 notifications referring to seafood, 37.0% were Border rejections (the most represented in cephalopods, crustaceans and fish), 26.2% Info for attention, 23.0% Alerts (the most represented in bivalve mollusks), 9.6% Info for follow-up and 4.2% was not classified/reported (Fig. 1). These percentages are not homogeneously distributed over the most representative hazard categories (see section 3.6).



Border rejection Alert Info for attention Info for follow-up Unclassified

Fig. 1 Type of notifications reported by the RASFF portal for seafood products between 2011 and 2015 subdivided per product category.

alt-text: Fig. 1

Table 2 shows the distribution of proportions of each RAFFS type of notification across food category and the significant differences associated. All classified types of notification were statistically different across product categories.

 Table 2 Comparison across different product categories of RAFFS notification types. Superscript letters identify significant differences across rows: identical letters indicate proportions which are not statistically different. The bold statistical values refer to the overall significance of each type of notification across species. N.s stands for non significant differences; p.t. indicates products thereof.

 alt-text: Table 2

Product category

Type of notification	Bivalve Mollusks	Cephalopods	Crustaceans	Fish	chi square	<mark>p</mark>
	and p.t.	and p.t.	and p.t.	and fish products		
Border rejection	28,54% <sup>A</sup>	76,60% <sup>B</sup>	54,40% <sup>B</sup>	31,81% <sup>A</sup>	<mark>78,2</mark>	<0,001
Alert	33,18% <sup>A</sup>	5,85% <sup>B</sup>	8,81% <sup>B</sup>	24,94% <sup>c</sup>	<mark>65,2</mark>	<0,001
Info for attention	31,09% <sup>A</sup>	14,89% <sup>B</sup>	25,47% <sup>A</sup>	26,41% <sup>A</sup>	11	<mark>0,01</mark>
Info for follow-up	3,94% <sup>A</sup>	2,66% <sup>A</sup>	11,32% <sup>B</sup>	11,26% <sup>B</sup>	28,7	<0,001
Unclassified	3,25%	0,00%	0,00%	5,57%	<mark>n.s</mark>	

In general, border rejection notifications have been issued especially (41.1%) because of poor or insufficient controls (which is the third hazard category by number of notifications), such as poor temperature control, unsuitable transport conditions or fraudulent/absence of health certificate. Only a small fraction (6%) of border rejections were due to heavy metals, which is the first hazard category by number of notifications (see section 3.6).

This is probably because at Border Inspection Posts (BIPs), the control of temperature and documentation is easier and more frequently conducted than that of other hazards, like heavy metals or pathogenic microorganisms (second hazard category by number of notifications), which require laboratory analysis to be revealed. However, as regards the verification of documents accompanying goods, a recent study performed together with the BIP of Livorno-Pisa, highlighted how, also in this kind of control, laboratory analyses are essential to reveal some kind of shortcomings (Guardone et al., 2017). A focused analysis using molecular tools allowed to highlight a higher level of label non-conformities with respect to a previous survey of the EC (European Commission, 2018a). Furthermore, at BIPs, laboratory controls on incoming goods are carried out only on a representative percentage of samples (European Commission, 2013) and this could result in a further concealment of non-conforming cases.

Alerts have been launched especially for products originating from inside the EU (95%) and during control on the market (68.5%). The fact that alerts mainly involve products originating from inside the EU is likely due to the fact that consignments imported from non-EU countries, when non-compliant, are halted at the port of entry (without entering the EU market), whereas products originating from within the EU are more easily moveable within the community borders (Kleter et al., 2009). In 50% of the alerts, the cause was the overcoming of the EU limits for pathogens/residues. For example, in most of the cases (81.4%), notifications concerning heavy metals have been classified as alerts (42.4%) or information (39%, of which 95.5% for attention and 4.5% for follow up), because related non-compliances were revealed especially during official controls on the market (60.3%).

## **3.3 Notifying country**

In previous studies wide variations in contributions to RASFF's notifications between EU MSs were found: Italy, Spain, France and Germany were the key reporting countries (Leuschner, Hristova, Robinson, & Hugas, 2013; Petroczi, Taylor, Nepusz, & Naughton, 2010; Pigłowski, 2017; Taylor et al., 2013). The same pattern was confirmed by this study.

Table 3 shows significant differences among countries in reporting rate for each product category.

 Table 3 Comparison across countries of frequency of notification by product category. Superscript letters identify significant differences across columns: identical letters indicate proportions which are not statistically different. The bold statistical values refer to the overall significance of each food category across countries. N.s stands for non significant differences; p.t. indicates products thereof.

lt-text: Table 3
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	Product category						
EU Country	Bivalve Mollusks	Cephalopods	Crustaceans	Fish			
	and p.t.	and p.t.	and p.t.	and fish products			
Italy	17,56% <sup>A</sup>	6,92% <sup>A</sup>	6,40% <sup>A</sup>	69,11% <sup>A</sup>			
Spain	12,81% <sup>B</sup>	7,44% <sup>A</sup>	7,23% <sup>A</sup>	32,44% <sup>B</sup>			
France	24,22% <sup>c</sup>	0,52% <sup>B</sup>	2,48% <sup>B</sup>	17,05% <sup>c</sup>			
Germany	12,60% <sup>B</sup>	0,62% <sup>B</sup>	3,82% <sup>AB</sup>	13,12% <sup>c</sup>			
<mark>chi square</mark>	41,4	22,5	44,6	16,1			

-	10 001	-0.001	-0.001	0001
D	< 0.001	<0.001	< 0.001	0001
<b>4</b>	-0,001			0001

The present results configure Italy as the first MS for number of issued notifications, accounting for 35.7% of the total number, followed by Spain (19.3%), France (9.4%) and Germany (6.5%). These countries contribute for almost 70% of all notifications, whereas the remaining 30% is shared among 27 countries. During the period considered, no notification was directly launched by the Commission Services and, among non-EU countries, only Norway participated in reports with 33 (1.2%) notifications. However, the number of RASFF notifications per country can be affected even by the volume of imports. MSs that trigger most of the notifications are usually those with the largest food trade (Petroczi et al., 2010) and highest transit of food matches, providing major ports for imports (Taylor et al., 2013). This is the case of Italy that is the MS with the highest volume of seafood import (73.5% of the total incoming consignments at Italian BIPs) (Ministry of Health, 2013). This can also explain why Italy is the first MS by number of notifications for fishery products. Similarly, the Netherlands issues 2.9% of the notifications despite its small territory. Some countries, such as the UK, make relatively few entries to the RASFF database (4.3%) perhaps due to fewer checks or favorable findings in the foodstuff selected for testing (Petroczi et al., 2010).

## **3.4 Country of origin**

In the five-year period 2011-2015, 60% of the notifications were made on fishery products coming from 14 different countries, while the remaining 40% from 92. Notified fish originated from 97 countries, crustaceans from 46, cephalopods from 29 and bivalve mollusks only from 27. These findings indicate that fish is imported in the EU from many more different countries than the other three product categories. On the contrary, the low number of countries from which notified bivalve mollusks came from is probably related to the strict regulations imposed by EU for this kind of products. In fact, only 16 third countries are authorized to export bivalves to the EU markets (Commission Decision 2006/766/EC; Commission Decision 2009/951/EU). This contrasts with other seafood products, where approximately 100 third countries and territories have been approved to export their products to the EU. Almost all major seafood producing countries in Asia have been approved by the EU authorities.

Spain was the country affected by the highest number of notifications (accounting for 15.4% of the total), followed by Vietnam (9.9%) and Morocco (5.2%). It should be noted that 7.5% of the notified products originating from Spain were made with raw materials coming mainly (48.3%) from South America (Mexico 35.7%, Ecuador 21.4%, Brazil 14.3% and others 28.6%) and Asia (42.0%). However, the notification rate was not similar for each food category across countries, as showed by the statistical analyses performed (Table 4).

 Table 4 Comparison across countries of notification by product category. Superscript letters identify significant differences across columns: identical letters indicate proportions which are not statistically different.

 The bold statistical values refer to the overall significance of each product category across countries. N.s stands for non significant differences; p.t. indicates products thereof.

alt-text: Table 4

	Product category						
County	Bivalve Mollusks	Cephalopods	Crustaceans	Fish			
	and p.t.	and p.t.	and p.t.	and fish product			
Spain	12,71% <sup>A</sup>	2,64% <sup>A</sup>	1,44% <sup>A</sup>	83,21% <sup>A</sup>			
Vietnam	23,33% <sup>B</sup>	3,33% <sup>A</sup>	22,59% <sup>B</sup>	50,74% <sup>B</sup>			
Morocco	2,13% <sup>c</sup>	9,93% <sup>B</sup>	2,84% <sup>A</sup>	85,11% <sup>A</sup>			
chi square	<mark>35,7</mark>	<b>14,8</b>	<b>101</b>	100			
<u>P</u>	<0,001	0001	<mark>&lt;0,001</mark>	<0,001			

The EU countries with the highest number of notifications were Spain (15.4%), France (4.5%) and Poland (3.4%) and as regards third countries Vietnam (9.9%), Morocco (5.2%) and China (4.2%). However, these patterns vary, even considerably depending on the product category. Notified bivalve molluscs were mainly from Vietnam, France and Italy; cephalopods from India, New Zealand and Indonesia; crustaceans from Vietnam, India and Mozambique and fish from Spain, Vietnam and Morocco (Fig. 2). Most of the countries with the highest number of notifications per product category are also among the top world producers of that specific product category (FAO, 2016) and/or the top extra-EU countries of origin by value and volume per product category (EUMOFA, 2017).

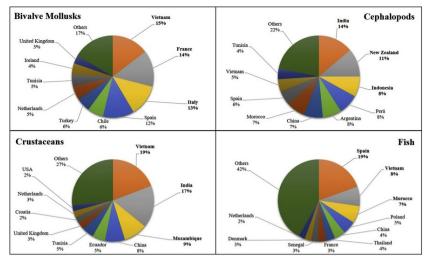


Fig. 2 Countries of origin of seafood products reported by the RASFF portal between 2011 and 2015 subdivided per product category.

#### alt-text: Fig. 2

The number of notifications issued to a Country can also be influenced by the frequency with which foodstuffs coming from it are checked. This can be the case of re-enforced checks (RECs) on third countries. According to the Council Directive 97/78/EC, following a rapid alert issued under the RASFF or a serious/repeated infringement of EU veterinary legislation, the next 10 consignments from the same establishment of origin (in the third country) for which the notification is made, must undergo additional checks at BIPs. If the results for all 10 consignments are satisfactory RECs are stopped, otherwise a second, or at maximum a third, group of 10 consecutive consignments begins (Council Directive 97/78/EC).

## 3.5 Notifications basis and distribution status

During the period analyzed in this study, the notifications were triggered in most of the cases (85.8%) by border checks or by official control activities on the market. In particular, during border control, the consignment was detained in most of the cases (41.7%), while it was released (1.1%) or forwarded to its destination under customs seals (0.04%) only occasionally.

Interestingly the frequency of bases of notification were statistically different across products (Table 5).

**Table 5** Comparison of bases for notifications, across food categories. Superscript letters identify, significant differences across rows: identical letters indicate proportions which are not statistically different. The boldstatistical values refer to the overall significance of each notification base. N.s stands for non significant differences; p.t. indicates products thereof. A: Official control at the market; B Border Control Consignmentdetained; C: Company's own chieck; D: food poisoning; E: Consumer complaint; F: Border Control Consignment released; G: Border Control consignments under customs.

alt-text: Table 5

Bases	Bivalve Mollusks	Cephalopods	Crustaceans	Fish	chi square	p
	and p.t.	and p.t.	and p.t.	and fish products		
А	44,32% <sup>A</sup>	18,60% <sup>B</sup>	21,34% <sup>B</sup>	48,01% <sup>A</sup>	<mark>96,6</mark>	<0,001
В	28,77% <sup>A</sup>	77,52% <sup>B</sup>	68,77% <sup>B</sup>	38,03% <sup>A</sup>	<mark>183</mark>	<mark>&lt;0,001</mark>
С	10,90% <sup>A</sup>	3,10% <sup>B</sup>	6,32% <sup>BC</sup>	8,06% <sup>AC</sup>	<mark>18,4</mark>	<mark>&lt;0,001</mark>
D	9,51% <sup>A</sup>	0,00% <sup>B</sup>	1,98% <sup>B</sup>	2,98% <sup>B</sup>	<mark>53</mark>	<mark>&lt;0,001</mark>

E	0,46% <sup>A</sup>	0,78% <sup>A</sup>	1,58% <sup>A</sup>	2,79% <sup>B</sup>	<mark>10,6</mark>	0,01
F	6,03% <sup>A</sup>	0,00% <sup>B</sup>	0,06% <sup>B</sup>	0,00% <sup>B</sup>	<b>108</b>	<mark>&lt;0,001</mark>
G	0,00% <sup>A</sup>	0,06% <sup>A</sup>	0,00% <sup>A</sup>	0,00% <sup>A</sup>	n.s	

The high percentage of official control on the market seems to be mainly related to imported consignments, as self-reports by MSs are relatively rare in the RASFF database. Therefore, if market notifications are classified correctly by the reporting country, they must be made on products coming from other countries (EU, EEA or outside). To a lesser extent (14.1%), the notifications were issued by companies during their own check, in case of food poisoning (mainly attributable to bivalve mollusks or fish consumption) or consumers' complaint, especially regarding fish. This lower percentage is presumably because in this context, isolated and localized episodes that remain within the involved MS in most of the cases are not reported to the RASFF network. Moreover, as also suggested by Petroczi et al. (2010), MSs not always correctly identify the basis for the notification and "company's own check" or "consumer complaint" categories are often included in "official market control". Basis notification patterns vary according to the product categories. In particular, with regard to bivalve mollusks and fish, notifications were initiated mainly after official market inspections, while for cephalopods and crustaceans following border controls (Fig. 3).

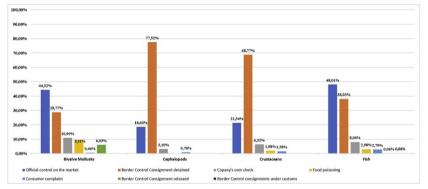


Fig. 3 Notification basis for seafood products reported by the RASFF portal between 2011 and 2015 subdivided per product category.

alt-text: Fig. 3

Regarding distribution status, the analysis showed that in most cases non-compliant seafood considered were no distributed (23.2%) or not yet placed on the market (16.4%). These data are evenly distributed within the product categories analyzed, with the exception of bivalve molluscs where, in most cases (26.16%), the notified products were distributed to other member countries.

Considering the different food categories, the frequency of the distribution status varies significantly across products categories, for almost all the distribution options.

## 3.6 Notifications per hazard category

The overall analysis of the category of hazard in seafood products revealed that the top three hazards were heavy metals (21%), pathogenic microorganisms (20%), and poor or insufficient controls (15%) (Fig. 4). Heavy metals represent the fourth most often notified hazard category in the RASFF from 1980-2016 and fish and fish products are the category most affected by the presence of heavy metal among all the food product categories (European Commission, 2017, Piglowski, 2018). In addition to these, other frequently encountered hazards were parasitic infestations (7%), biocontaminants (7%) and residues of veterinary medicinal products (6%). In agreement with the results reported by other surveys on RASFF (Bouzembrak & Marvin, 2016; Kleter et al., 2009; Tähkäpää, Maijala, Korkeala, & Nevas, 2015), cases of seafood notifications due to adulterations or frauds are very limited (2% of the total). However, in the light of the data on seafood adulteration reported in literature, it seems to be an underestimation (Guardone et al., 2017). The fact that frauds are poorly reported in the RASFF is probably due to the fact that they are generally considered as a commercial problem rather than a health issue. Thus, they are often not communicated to the network. In addition, the most frequent fraudulent practice, consisting in the replacement of valuable seafood species with products of lower value, cannot be detected by using only visual inspection. However, according to the new Regulation (EU) 625/2017, official controls activities aimed at identifying fraudulent or deceptive practices will become more relevant and EU reference centres for the authenticity and integrity of the agri-food chain will be designated.

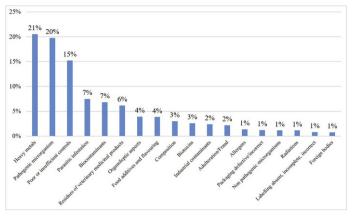


Fig. 4 Categories of hazard of seafood products notifications reported by the RASFF portal between 2011 and 2015.

#### alt-text: Fig. 4

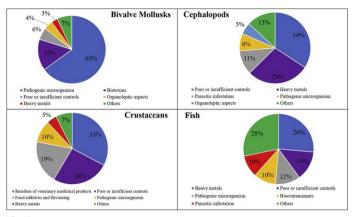
Category of hazards are not uniformly distributed in the product categories: statistical analyses showed significant differences in proportion of all hazards across product categories (Table 6).

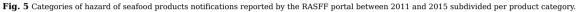
 Table 6 Comparison of hazard distribution across food categories: superscript lettes identify significant differences across rows: identical letters indicate proportions which are not statistically different. The bold statistical values refer to the overall significance of each hazard category across products.

### alt-text: Table 6

		Product category				
Hazard category	Bivalve Mollusks	Cehalopods	Crustaceans	Fish	chi square	p
	and p.t.	and p.t.	and p.t.	and fish products		
Heavy metals	2,97% <sup>A</sup>	28,42% <sup>B</sup>	4,53% <sup>A</sup>	26,37% <sup>B</sup>	<mark>178</mark>	<0,001
Pathogenic microrganism	65,07% <sup>A</sup>	7,89% <sup>B</sup>	10,03% <sup>B</sup>	11,51% <sup>B</sup>	<mark>705</mark>	<0,001
Poor or insufficient controls	5,71% <sup>A</sup>	34,21% <sup>B</sup>	25,89% <sup>B</sup>	13,54% <sup>c</sup>	114	<0,001
Parasitic infestation	0,00% <sup>A</sup>	11,05% <sup>B</sup>	0,00% <sup>A</sup>	10,09% <sup>B</sup>	<mark>82,4</mark>	<0,001
Biocontaminants	0,00% <sup>A</sup>	0,00% <sup>A</sup>	0,00% <sup>A</sup>	10,2% <sup>B</sup>	<b>103</b>	<mark>&lt;0,001</mark>
Residues of vet medical products	0,23% <sup>A</sup>	1,58% <sup>AB</sup>	32,69% <sup>c</sup>	3,45% <sup>B</sup>	<mark>438</mark>	<mark>&lt;0,001</mark>
Organoleptic aspects	4,34% <sup>A</sup>	5,26% <sup>A</sup>	0,65% <sup>B</sup>	4.17% <sup>A</sup>	10,3	<mark>0,02</mark>
Food additives and flavouring	1,37% <sup>A</sup>	2,11% <sup>A</sup>	19,42% <sup>B</sup>	1,92% <sup>A</sup>	232	<mark>&lt;0,001</mark>
Biotoxins	14,84% <sup>A</sup>	0,00% <sup>B</sup>	0,00% <sup>B</sup>	0,33% <sup>B</sup>	313	<0,001

In fact, while in fish products a wide range of hazards was responsible of the notifications, in the other product categories most part of the notifications was due to fewer categories of hazard. For example, in bivalves one hazard was responsible for 65% of the notifications observed. Results, detailed in (Table 1SM) and summarized in (Fig. 5), will be described in the following sections.





alt-text: Fig. 5

### 3.6.1 Category of hazard in fish and fish products

Fish and fish products were mainly (26.4%) notified because of non-compliant presence of heavy metals such as mercury (94%), cadmium (5%) or both (1%), as also highlighted by Pigtowski (2017 and 2018). Products affected by this issue were mainly from Spain (39.1%) and Vietnam (10.3%). This product category also resulted particularly affected by poor or insufficient controls (13.5%), pathogenic microorganisms (11.5%), bio contaminants (10.2%) and parasitic infestations (10.1%). As regards poor or insufficient controls, notifications were manly triggered against products coming from Morocco (8.8%), Senegal (7.6%), United States (7.6%) and China (7.2%) and because of poor temperature control (84.6%) and poor hygienic state (8.1%). Non - compliant products due to pathogenic microorganisms were in 89.0% of the cases contaminated by *L. monocytogenes*. They were mostly (91.3%) from EU Member States MSs and in particular from Poland (39.7%), Denmark (25.0%), Spain (17.0%) and Norway (11.0%). This is probably because at EU level most of the fish products are traded as fresh/chilled and this makes them more subjected to bacterial contamination and growth (especially of *L. monocytogenes* which grows even at refrigeration temperatures) respect to frozen products, which, on the contrary, come especially from third countries. In addition, the above mentioned countries are big producers of smoked salmon; Poland for example produces around 34% of the smoked salmon produced in the EU, largely processing fresh farmed salmon from Norway (EUMOFA, 2016; Doyle, 2016; http://www.eurofish.dk). Smoked salmon was shown to be the food product most affected by *L. monocytogenes* among all the food products included in the RASFF analysis (European Commission, 2017)<sup>\*</sup>, These data are confirmed in the present study. In fact, 73.8% of all notifications issued for the presence of this pathogenic microorganism involved smoked salmon coming mainly from Poland (52.8%) and Denmark (17.3%).

All fish products (100%) notified under the hazard category biocontaminants contained histamine levels that did not comply with European limits (Commission Regulation (EC) No 2073/2005 and its amendment Regulation (EC) No 1441/2007). However, over the five-year period considered, notifications for histamine were unexpectedly low (10.2% of the total of Fish and fish products notifications) if considering that histamine poisoning is the most common fish poisoning in the EU and outbreaks are subject to mandatory notification (Anses, 2012; Tortorella et al., 2014). From 2011 to 2015, RASFF counts 190 notifications due to histamine of which 55.7% concerned Tuna (especially chilled 37.7% or frozen 21.7%), 25.8% Sardines (especially canned 47% or frozen 18%), 8.4% Anchovies and 5.8% Mackerels. These data can be compared with the results of the study of Leuschner et al., 2013 on the presence of biogenic amines between 1979 and 2010. An increasing trend was observed by the authors over time, as total RASFF notifications for biogenic amines were 7 from 1979 to 1994, 35 from 1995 to 2001, 88 from 2002 to 2005 and finally 227 from 2006 to 2010. However, in this last period of time (2006-2010) 209 out of the 227 notifications were issued for fish and fish products, while the remaining 18 were related to fish sauce (11), soy sauce (6) and grated cheese (1). Thus, the number of notifications found in the present study (190) appears only slightly lower that the number reported by Leuschner et al. (2013) for the last period of time they analyzed. The species involved were substantially the same. These data are also confirmed by a recent systematic review (Colombo, Cattaneo, Confalonieri, & Bernardi, 2017).

Histamine notifications found in this study originated from products from Spain (25%), Morocco (19%) and Asian Countries (Thailand 7%, Vietnam 5.7%, India 4.7%, Indonesia 4.2%). They were mainly classified as information for attention (51.0%) and triggered during border control (37.9%), official control on the market (23.2%), food poisoning (20.5%), company's own check (16.3%) and consumer complaint (2.1%) with a significant difference in the action taken (see section 3.8). It should be noted that in the case of histamine, company's own checks and food poisoning have had a greater role as basis notification than the overall average found in this study (8.12% and 3.88%, respectively) and the reasons are easily understandable. In fact, as already mentioned above, histamine outbreaks must be notified systematically, and this increases the RASFF notifications triggered by food poisoning. Moreover, sampling plans and testing for histamine is a routine regulatory surveillance for fish processor, importer or distributor worldwide (FAO, 2012; James, Derrick, Purnell, & James, 2013) and this makes any non-compliance more easily and frequently detectable in this context.

The parasite most involved in fish products' notifications was reported as Anisakis spp. (84.2%), followed by unspecified nematodes (8.7%). In 4.9% of the cases the parasites were not identified. Notified products because of Anisakis spp. were

mainly from Morocco (22.5%), Spain (27%) and France (13%) and involved in particular chilled (63%) or frozen (22,7%) hake (*Merluccius* spp. 23.2%), mackerel (*Scomber* spp. 19.3%), monkfish (*Lophius* spp. 16.1%), anchovies (*Engraulis* spp., 9.0%) and silver scabbardfish (*Lepidopus caudatus*, 8.3%). All these species are known to be hosts of *Anisakis* spp. (Levsen et al., 2017). Unidentified nematodes were detected especially in chilled (53.8%), frozen (19.2%) or canned (12.5%) monkfish (20%), cod (*Gadus* spp., 13,3%), hake (13,3%) and mackerel (13,3%) which in most of cases (80%) were from EU countries (France 46,8%, Polonia 20%, Denmark 6,6% and Spain 6,6%). Notified products were mainly fresh and chilled, but also frozen, smoked, salted, marinated and in oil, thus probably involving also dead larvae. Other notifications reported *Pseudoterranova* spp. (1.1%) and unspecified tapeworms (0.5%). Finally, one notification (0.5%) regarded swordfish fillets because of the presence of *Pennella*, which, although not dangerous for human health, can make products unfit for consumption (Guardone et al., 2018).

### 3.6.2 Category of hazard in bivalve mollusks

The most frequent category of hazard in bivalve mollusks was that of pathogenic microorganisms accounting for 65.1% of the notifications, followed by biotoxins (14.8%) and poor or insufficient controls (5.7%). Among the pathogenic microorganisms, the most represented were *E. coli* (49.1%) and Norovirus (34.4%), followed by *Salmonella* spp. (14.4%). Interestingly, while *E. coli* and *Salmonella* spp. represent food safety criteria (Regulation CE 2073/2005), Norovirus are not contemplated in the aforesaid Regulation, even though the opinion issued by the Scientific Committee on Veterinary Measures relating to Public Health (SCVPH) on Norwalk-like viruses (NLVs, noroviruses) on 30–31 January 2002, reported that the conventional faecal indicators are unreliable for demonstrating the presence of NLVs in live bivalve molluscs. It follows that, while CAs and FBOs must check live bivalve mollusks for the presence of *E. coli* and *Salmonella* spp., tests for the presence of NLVs are not required. Therefore, the identification of NLVs as zoonotic agents responsible for the infection have been probably performed after the outbreaks on the EU territory. This hypothesis is supported by the results of this study showing that notifications due to food poisoning were mainly attributable to bivalve mollusks or fish consumption (section 3.5). In agreement, the category including norovirus and bacterial toxins (other than *Clostridium botulinum*) was most frequently reported in 'Canteen or Catering to Workplace, school, hospital' and in 'Restaurants, pubs, street vendors and take away' (EFSA & ECDC, 2017).

Bivalve products affected by pathogenic microorganisms originated particularly from Vietnam (18.3%), France (14.8%), Italy (14.4%) and Spain (4%), which are also among the world's largest producers of mollusks (FAO, 2016). In France, in particular, an increasing trend in the number of intoxication outbreaks by calicivirus (including norovirus) was recently observed (EFSA & ECDC, 2017), which may probably arise also from the circulation of both new and/re-emergent strains of norovirus in the country (Bidalot, Thery, Kaplon, De Rougemont, & Ambert-Balay, 2017).

As regards notifications for biotoxins, 63% of the cases were attributable to Diarrhoeic Shellfish Poisoning (DSP) toxins, followed by Paralytic Shellfish Poisoning (PSP) toxins (14%), Amnesic Shellfish Poisoning (ASP) toxins (11%), Yessotoxin (YTX) (6%) and Azaspiracid Shellfish Poisoning (AZP) toxins (6%). All non-compliant products were from EU Member States, in particular Spain (21.5%), France (16.9%), Italy (16.9%) and the United Kingdom (16.9%) that are among the most important producers of bivalve in Europe (Rees, 2010).

As concerns the poor or insufficient controls category, non-conforming products were mainly traded by third countries, such as Chile (28%), Thailand (12%) and Vietnam (12%), and most of the them (72%) were notified because of poor temperature control (56%) and poor hygienic state (16%). Moreover, bivalve mollusks were deemed as non-compliant because they came from a non-classified production area or were unpurified in 16% and 4% of the cases, respectively. This could be related to the fact that importing countries enforce strict regulations on live, fresh and frozen bivalves which many exporting developing countries are unable to meet (Regulation CE 2073/2005 and further amendments).

### 3.6.3 Category of hazard in crustaceans

In crustaceans, the main hazards reported were: residues of veterinary medicines (32.7%), poor or insufficient controls (25.9%), presence of additives/flavorings (19.4%) and pathogenic microorganisms (10%).

Among the residues of veterinary drugs, the most commonly substances found were Nitrofuran metabolites (45%), Tetracycline (28%) and Chloramphenicol (19%). In 77.2% of cases, products originated from Asia (India 39.6%, Vietnam 37.6% and China 12.9%). As regards nitrofuran metabolites, the number of notifications is in line with data from the preceding years (Karunasagar, 2017). In fact, after a study showed that semicarbazides (SEM), the metabolite most frequently involved in the past in persisting alerts, can be found naturally in the shell of crustaceans, only the edible part was tested and the number of alerts has dropped significantly (Van Poucke et al., 2011). Tetracyclines are broad-spectrum antibiotics widely used in aquaculture, frequently in enriched commercial shrimp feeds (Gräslund & Bengtsson, 2001). Our data support the importance to pay attention to their use and fate in aquaculture (Liu, Steele, & Meng, 2017). For what concerns chloramphenicol (0.3 mg/kg) (Commission Decision of 11 January 2005). Despite this, chloramphenicol still represents the third residue category.

Poor or insufficient controls in notified crustaceans were mainly due to poor temperature control (90.0%) and, to a lesser extent, to unsuitable organoleptic characteristics (5.0%), poor hygienic state (3.8%) and improper production (1.3%). Regulatory non-compliant products were traded especially by Mozambique (32.9%).

The non-compliant presence of additives/flavorings was largely determined by too high content/undeclared sulphites (83%) followed by undeclared citric acid (E 330) (7%), unauthorized use of colorants (3%) or sodium aluminum phosphate (3%) and too high content of benzoic acid (E 210) (3%) in products originating from different countries (among the most represented are Tunisia 14.5%, Croatia 12.9%). Sulphites are used as the main inhibitors of melanosis; however, are

frequently linked to allergic reactions and asthmatic attacks in humans (Gonçalves & de Oliveira, 2016).

Crustaceans notified because of pathogenic microorganisms were almost all (92.6%) shrimps/prawns (55,5% frozen, 14,8% cooked and 11,1% frozen cooked) coming from Vietnam (48.1%) and Netherland (11.1%) and containing *Salmonella* spp. (29.6%), *L. monocytogenes* (26%), *Vibrio* spp (22.2%) or combination *Salmonella* spp./*Vibrio* spp. (22.2%).

### 3.6.4 Category of hazard in cephalopods

In cephalopods, most of the notifications (62.6%) were due to poor or insufficient controls (34.2%; 86% poor temperature control and 14% poor hygienic state) and heavy metals (28.4%; 100% for cadmium content beyond the limits), detected mainly in products from Perù (20.3%) and India (29.6%) respectively. The presence of cadmium in cephalopods is in agreement with the data of Piglowski (2018).

In 11.1% of the cases, products were notified for the presence of parasites, mainly of *Anisakis* spp. in frozen squids (*Nototodarus* spp.) from New Zealand (95.2%). The presence of anisakids in several species of cephalopods of commercial value is known (Serracca et al., 2013) and, sarting from 2011, a preventive freezing treatment is required also for cephalopod products (Regulation EC No. 1276/2011). Hweve, few data on the presence of *Anisakis* spp. in *Nototodarus* spp. are available in the literature (Wharton, Hassall, & Aalders, 1999). Although in this case, the squids were frozen and thus larvae were inactivated, dead parasites are an increasing reason to consider products unfit for consumption (Bilska-Zając et al., 2016; Guardone et al., 2018).

## 3.7 Risk decision and actions taken

As regards the risk decision, 39.3% of the total notifications was classified as serious, 19.2% as not serious and 41.5% was not classified (undecided). As shown in Table 7, statistically significant differences were observed across product categories.

 Table 7 Comparison across different product categories of risk decision types. Superscript letters identify significant differences across rows: identical letters indicate proportions which are not statistically different.

 The statistical values refer to the overall significance of each decision across product categories. N.D. stands for not done.

#### alt-text: Table 7

Risk decision	Bivalve Mollusks	Cephalopods	Crustaceans	Fish	chi square	
	and p.t.	and p.t.	and p.t.	and fish products	Ciii Square	<u>v</u>
Not serious	8,12% <sup>A</sup>	21,81% <sup>B</sup>	39,94% <sup>c</sup>	17,91% <sup>B</sup>	124,98	<0,001
Serious	66,13% <sup>A</sup>	17,55% <sup>B</sup>	21,70% <sup>B</sup>	38,29% <sup>c</sup>	<mark>209.11</mark>	<mark>&lt;0,001</mark>
Undecided	25,75%	60,64%	38,37%	43,81%	N.D.	

In bivalve mollusks serious-risk notifications were prevalent, whereas in the case of crustaceans the majority of the notifications were non-serious. In both the remaining product categories, notifications were mostly undecided. Remarkably, there is no evident correlation between the risk decision and the hazard category since a same hazard can be classified either as serious, not serious or not classified at all, as already highlighted by Pigłowski (2017). This is the case for example of mercury in fishery products and cadmium in cephalopods. A similar case occurred for *Listeria monocytogenes* in fishery products and *Escherichia coli* in bivalve mollusks. These discrepancies are probably due to the fact that notifying authorities take into account also other factors, such as the distribution status. In fact, a non-compliant product not yet distributed on the market has significantly lower risk compared to another that is instead on the market (and in particular at retail sale). In addition, in the absence of a specific procedure and/or standard provisions for categorization, CAs often prefer to not define the risk. However, the fact that the same hazards can be interpreted differently and that there are no standardized indicators (such as specific bacterial charge or limit values) to formulate an objective risk decision, represents a serious limit for all RASFF members and can also affect risk communication between them.

In this study, the most common (22.2%) action taken was the withdrawn of products from the market, especially because of the presence pathogenic microorganism (27.4%), heavy metals (25.8%), histamine (8.1%) and residues of veterinary medicinal products (3.9%).

In 16.8% of the cases non-compliant seafood were returned (mainly due to poor or insufficient controls 49.9% or pathogenic microorganism 28.8%), 12.8% destroyed (especially because of heavy metals 20% or poor or insufficient controls 18.8%) and 11.9% unauthorized to enter the EU market. Official detention and product recall were performed in 7.3% and 5.9% of cases respectively, while no action was taken in 4.4%. Actions were most commonly taken for the fish and fish products category (65%) and this can be explained by the quantity of these products imported to the EU. In 23.4% of the cases fish and fish products were withdrawn from the market, 14.6%

destroyed and 13.7% re-dispatched. As regards bivalve mollusks, in most cases (30.3%), the control authority set the withdrawal from the market and, to a lesser extent, re-dispatch (14.9%) and destruction (11.6%). Cephalopods and crustaceans were mainly re-dispatched (39.7% and 23% respectively) or unauthorized to import (24.1% and 21.4% respectively).

# **4** Conclusions

The RASFF system represents a data source commonly used by scientists for various purposes, such as studying historical trends, evaluating emerging food safety hazard and predicting future risks. However, it is necessary to point out that data retrieved only from the RASFF portal may be influenced by many factors: (i) periodic changes in the attention of different countries to various problems; (ii) subjective perception of those who issue notifications (as in the case of risk decision); (iii) the issuance of multiple notifications or omissions of reports (with consequent over-under estimation); (iv) the types and frequency of controls carried out at the border posts. Despite this, the analysis of data from the RASFF portal represents a useful tool to obtain an overview and a valuable 'real-life' and 'up-to-date' evidence of the (past and present) issues affecting global and EU fish sector and a valuable source of information during the hazard identification step of a risk assessment. Patterns emerged during this study suggest that the attention of EU official control bodies, FBOs and consumers should be placed not only on seafood from third countries but also on those manufactured at the Community level, especially for chemical and microbiological hazards. In this light, it needs to be considered that an increasing number of products declared to originate from a EU country are produced with raw materials coming from third countries.

# Appendix A. Supplementary data

Supplementary data related to this article can be found at https://doi.org/10.1016/j.foodcont.2018.06.018.

# **Uncited reference**

<del>Banach et al., 2016.</del>

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# Appendix A. Supplementary data

The following is the supplementary data related to this article:

Multimedia Component 1

Multimedia component 1

alt-text: Multimedia component  ${\bf 1}$ 

#### Highlights

- From 2011 to 2015, the 16.6% of all RASFF notifications involved seafood.
- Spain was the country affected by the highest number of faulty products.
- Notifications were mainly triggered during official controls at borders and markets.
- The hazard category with the highest number of notifications was "Heavy metals".
- The withdrawal of faulty seafood from the market was the most common action taken.

## **Queries and Answers**

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