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

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Keywords: Seafood, RASSF, notifications, risk, control authority

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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.

Dear Editor,

Please find enclosed the manuscript entitled “**Seafood products notifications in the EU Rapid Alert System for Food and Feed (RASFF) database (2011-2015): data analysis for implementing effective official controls**” to be considered for publication in Food Control.

At the end of ‘70s, the Rapid Alert System for Food and Feed (RASFF) was put in place to support a close cooperation and communication between European Control Authorities and Member States in response to serious food and feed safety risks.

Since the RASFF was established, it has become increasingly efficient and effective, especially thanks to the IT development and internet-based means of data communication. Starting from June 2014, the RASFF is also supported by an interactive searchable database, the RASFF portal, that was set up in order to keep information as transparent as possible even to consumers and food business operators. The portal is a very consumer-friendly internet tool of public access and can provide whoever of interest with summary information about the most recent food and feed safety incidents.

Most of the notifications issued by the system involve foods of animal origin and, among these, seafood represents the first cause of alert. Thanks to their nutritional properties and an increasing consumers’ predilection for seafood, the consumption of fishery products has been growing over the years. Currently at EU level, citizens consume on average 25.1 Kg per capita of seafood annually, 8% more than in the last decade.

The need to cope with an ever-increasing demand for fisheries products has led to a considerable increase in their international trade in the last 20 years. However, globalization of the food supply chain has favored complexity and potential risks across the seafood production industry, making fishery products among the foodstuffs most prone to food safety issues.

Through the analysis of the RASFF portal, this study aimed at highlighting the most relevant noncompliance affecting seafood during the five-year period analyzed (2011-2015) and explore possible relationships between variables characterizing faulty 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.

At the same time this study can give positive impulses for a better implementation of the RASFF portal and its data collection, highlighting the gaps to be filled and the weaknesses to be consolidated.

The manuscript has not been published elsewhere nor is it being considered for publication elsewhere. All authors have approved this manuscript, agree to the order in which their names are listed, declare that no conflict of interests exists and disclose any commercial affiliation.

Yours sincerely,

Andrea Armani

Dear Editor,

we send you back the revised version of the manuscript entitled “**Seafood products notifications in the EU Rapid Alert System for Food and Feed (RASFF) database: data analysis during the period 2011-2015**”. The title has been changed and the manuscript modified taking into consideration the reviewers’ suggestions.

Reviewers' comments:

Reviewer #1: The paper provides an original overview of seafood related notifications in RASFF from 2011 to 2015. While the presented information is of interest to the reader and scientific community, the manuscript would benefit from shortening and a clear focus on essential and factual points.

The title of the manuscript mentions 'data analysis for implementing effective official controls' however an implementation of effective official controls is not a subject of the manuscript. It would seem for example appropriate to say 'data analysis of RASFF notifications for seafood products from 2011 to 2015' or similar.

The title has been modified as suggested.

Throughout the paper (including the highlights) the term 'faulty' product is used and should be replaced an appropriate term such as regulatory non-compliant product or similar.

Faulty product is a term that is commonly used by authors (Petroczi et al., 2010; Nepusz et al., 2008; Nepusz et al., 2012; Ene, 2012; Taylor et al., 2013) to identify products notified in the RASFF. However, the term “faulty” has been removed and substituted with more appropriate terms throughout the paper.

The introduction section is very long and partly not factual. It should be shortened. Reference is made to European Commission (2009) on several occasions and this should be updated.

The introduction has been shortened as requested. As regards the reference to the European Commission (2009), this is a booklet made by the EU Commission about The Rapid Alert System for Food and Feed of the European Union which illustrate the history of the RASFF and explain other aspects of this system. It can be considered still valid and current. In addition, the European commission from 2009 to date has not produced another booklet, more updated or complete than this mentioned.

Line 66: please remove the part of the sentence 'to damage Israeli economy'.

The sentence has been amended as requested.

Line 80: please reword 'thanks to' and specifically mention IT developments e.g. cloud based services etc.

The sentence has been modified accordingly

Lines 86 etc.: EC annual report: please include reference to the most recent report.

See previous answer about the reference to the European Commission (2009)

Line 108: the term 'risk' should be replaced by 'hazard' (RASFF is a hazard based)

Done.

Section Material and Methods

Section 2.1. the reference to European Commission (2009) should be updated to current state.

See previous answer about the reference to the European Commission (2009)

A paragraph explaining as to why the statistics tests were selected and considered suitable.

Statistical analyses were used considering that the reported notification proportions (for all the presented tables) alone would not have allowed the assessment of statistically significant and meaningful differences, Therefore, they allowed the highlight of important changes or variation across categories.

Section Results and Discussions

Table 1 needs to be clarified 'A'/B' etc.

Similar comment as above to Tables 2, 3, 4, 5, 6, 7.

Tables captions have been clarified.

It is not clear why statistical analysis was done with regards to the percentage of notifications from 2011 to 2015. Where is the added value? Please explain.

These analyses were performed on proportions of notification 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. This sentence has been added to M&M (line 130-134).

Text lines 211 - 216 seems very speculative and should be considered as to whether it adds value to the manuscript.

The text was deleted

Section 2.5 Notification basis and distribution status

The part 'distribution status' is reflected in the last paragraph of the section (lines 318 - 323) and seems to add little value. For clarity it should be considered whether it is adding value. Table 6 seems to add little value and can be considered to be omitted.

Section 3.5 has been shortened and focused on the results of the present study. Table 6 and Fig. 4 were cancelled but the brief information on the distribution status was maintained.

It is suggested to reword the title of section 3.6 to 'notifications per hazard category'.

Done.

Section 3.7 entitled 'risk decision' is very confusing and difficult to understand. It should be clarified or considered whether it adds value to the manuscript and reader and otherwise omitted.

Section 3.7 was shortened and combined with section 3.8

Section 3.8 referring to 'follow-up actions' could be shortened and possibly combined to a short concise section together with 3.7 if needed since both are concerned with risk management actions.

Section 3.8 was shortened and combined with section 3.7

Figures 1 to 6 are listed at the end of the manuscript however seem not to be referenced or integrated into the text. It is suggested to replace the tables by the figures where possible.

As requested by the journal's guidelines figures captions have been reported at the end of the manuscript while figures are uploaded separately. All the figures are recalled in the text (fig 1 line 166; fig. 2 line 274; fig. 3 line 330; fig.4 line 347; fig. 5 line 373)

Figure legends need to be more explanatory ensuring conclusive understanding of the content of each figure as self standing entity by the reader.

Figure legends was amended

Figure 4 on the distribution status is very packed with information, difficult to read and it seems to add not very much value and is therefore recommended to be omitted.

Figure 4 was cancelled.

Conclusion section:

There seem to be elements of discussion/speculations which are recommended to be omitted such as line 571 ..probably because there are no standard parameters...etc'.

This sentence was deleted

Line 576: please insert the word 'perceived' to that the sentence reads: 'The perceived lack of standardised parameters...'. It is recommended omit this sentence (line 576-578) unless there is a reference to the highlighted fact that there are no parameters. If this would be the case would be more appropriate to discuss in section 3.

The sentence was omitted

In general, the conclusion section could be shorter and more concise.

The conclusion section was shortened.

1 **Seafood products notifications in the EU Rapid Alert System for Food and Feed (RASFF)**
2 **database ~~(2011-2015): data analysis during the period 2011-2015 for implementing effective~~**
3 **~~official controls~~**

4
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24 **Abstract**

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

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45 **Keywords:** Seafood, RASSF, notifications, risk, control authority

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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 (Trevisani & Rosmini, 2008; Kleter et al., 2009; En-chen, 2010; Alemanno & Gabbi, 2016). Official control bodies represent a key element to ensure the correct ~~and effective~~ application of regulatory requirements ~~and. In this regard~~, 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; Pięłowski, 2015).

~~The origins of the RASFF date back to the end of '70s, when the Dutch and German CAs detected some consignments of oranges, coming from Israel that had been deliberately contaminated with mercury (European Commission, 2009) to damage Israeli economy. The "orange incident" provoked such a large-scale concern across Europe that Belgium, Denmark, France, Germany, Ireland, Italy, Luxembourg, the Netherlands and the United Kingdom set up a rapid alert system to inform each other in case of food safety incidents (European Commission, 2009).~~ 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

74 Regulation (EC) n. 178/2002 (the European General Food Law) while its implementing measures
75 are set in the Commission Regulation (EU) n. 16/2011.

76 At the beginning, the RASFF was used as a short-term surveillance and it only covered products
77 destined for consumers (European Commission, 2009). Over the years it has undergone a deep
78 change and nowadays it is even expanding on a global scale, working together with the
79 International Network of Food Safety Authorities (INFOSAN), jointly managed by the Food and
80 Agricultural Organization and the World Health Organization (European Commission, 2009). The
81 RASFF has become increasingly efficient and effective, following the development of internet
82 based IT tools (such as cloud based services and big data management) especially thanks to the IT
83 development and internet based means of data communication, which have sped up the exchange of
84 information on food recall within the Community (European Commission, 2009). ~~The RASFF~~
85 ~~network consists essentially of contact points in the European Commission (EC), EFSA and~~
86 ~~European Economic Area (EEA includes EU countries, Iceland, Liechtenstein and Norway),~~
87 ~~exchanging information through an online system (iRASFF), using specific templates and standard~~
88 ~~forms (Pigłowski, 2015).~~

89 ~~To give a profound insight into the activity of RASFF, the EC annually issues a report on the~~
90 ~~types of notifications, products, hazards and notifying countries that have been reported through the~~
91 ~~network in the previous year (Kleter et al., 2009; Pigłowski, 2015). Moreover, since June 2014,~~
92 the EC has also set up an interactive searchable database, the RASFF portal, to keep information as
93 transparent as possible to consumers, Food Business Operators (FBOs) and CAs worldwide
94 (European Commission, 2018). The RASFF portal is a consumer-friendly internet tool giving
95 public access to summary information about the most recently transmitted notifications as well as
96 allowing to search for information on any notification issued in the past.

97 Most of the notifications issued by the system involve foods of animal origin and, among these,
98 seafood represents the first cause of alert (Pigłowski, 2015; Parisi et al., 2016). The number of

99 notified fishery products has considerably increased (+7.7%) since the RASFF was established
100 (Parisi et al., 2016) and this is probably linked to their growing trade and consumption within the
101 EU and worldwide (World Bank, 2013; EUMOFA, 2016; Chan et al., 2017). ~~In fact, an increasing~~
102 ~~consumers' predilection for fish (Thurstan & Roberts, 2014; Pot et al., 2015; Chan et al., 2017), has~~
103 ~~avored the market of fishery products in the last 20 years.~~ Currently, EU citizens consume on
104 average 25.1 Kg per capita of seafood annually, 8% more than in the last decade. Therefore, the EU
105 must necessarily import seafood from abroad. In 2016, the EU trade of seafood amounted to 14.1
106 million tones, for a value of 54.3 billion euros of which about 24.4 billion came from imported
107 products (EUMOFA, 2017).

108 Given the importance of fishery products in the global and EU market and their primacy as the
109 foodstuff of animal origin most affected by safety issues, this study aimed at carrying out an overall
110 evaluation of data concerning non-compliant faulty seafood notified through the RASFF, during the
111 period 2011-2015 and, by exploring possible associations between variables, highlighting the main
112 risk hazards affecting the different products ~~category categories and better defining targeted and~~
113 ~~effective official control.~~

114 **2. Materials and Methods**

115 ***2.1 Data collection and analysis***

116 A RASFF notification that has never been notified to the EC is called 'original' notification
117 (European Commission, 2009). According to the seriousness of the identified risks and to the
118 distribution of the product on the market, the EC contact point classifies the original notification as
119 an alert, an information (for follow up or for attention) or a border rejection (European
120 Commission, 2009). For the purposes of this study, all notifications issued during the period
121 01/01/2011 - 31/12/2015 under the product categories "Bivalve molluscs and products thereof
122 (p.t.)", "Cephalopods and p.t.", "Crustaceans and p.t." and "Fish and fish products" were extracted
123 from the RASFF portal (European Commission, 2018). The search was performed by selecting one

124 or more items of the 6 main sections (Notification, Type, Date, Product, Hazard, Keywords) in
125 which the portal is divided. Data have been subsequently parsed into an Excel spreadsheet file and
126 the following attributes were analyzed for notifications pertaining to each product category: total
127 original notifications; type of notification, notifying country, country of origin, notifications basis
128 and distribution status, category of hazard, risk decision, action taken. Associations among
129 attributes were investigated using chi-square test for proportion comparison by using Epi Info®
130 version 7.2 for windows. Significance level was set to $p < 0,05$ for all comparisons. These analyses
131 were performed on proportions in order to compare and assess the differences even when calculated
132 on different samples sizes. The significance level was set to 0.05 instead of 0.1 even if multiple
133 proportions were compared, in order to minimize for the increase in type I error rate given the
134 unequal sample sizes.

135 **3. Results and Discussions**

136 ***3.1 Total number of original notifications***

137 During the period 2011-2015, a total of 16304 original notifications were logged on the RASFF
138 database, of which 16.6% (2713) involved seafood. However, it should be pointed out that RASFF
139 analysis may lead to an overestimation of notifications of food safety incidents, especially when the
140 non-compliance is detected after foodstuffs have been distributed on the markets of several MSs
141 (Kleter et al., 2009; Bouzebrak & Marvin 2016). In fact, the same faulty-non-compliant product
142 may be notified by more than one MS. Considering that information about product identity, such as
143 the name of the producer or the importer or the lot, is not available on the RASFF portal, it is
144 impossible to surely identify notifications resulting from the same food safety incident (Kleter et al.,
145 2009; Riviere et al., 2012; Bouzebrak & Marvin 2016). Conversely, in other cases, RASFF
146 notifications may underestimate issues as incidents may not always be notified to the EC (Taylor et
147 al., 2013; Pięłowski, 2017).

148 “Fish and fish products” was the product category with the highest number of notifications
 149 (1776; 65.5%), followed by “Bivalve mollusks and p.t.” (431; 15.8%), “Crustaceans and p.t.” (318;
 150 11.7%) and “Cephalopods and p.t.” (188; 7%). Probably, these differences are mostly linked to their
 151 relative quantities marketed at European level. In fact, fish and fish products is the most traded
 152 category (80.1% of EU seafood trade by volume), followed by bivalve mollusks (8.7%),
 153 crustaceans (7.1%) and cephalopods (4.1%) (EUMOFA, 2017) (see also Table 1). Statistical
 154 analyses revealed differences of proportion of notifications across years for all categories, but
 155 crustaceans and product thereof (p.t. in table).

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

156
 157 | **Table 1. Comparison across years of non compliances for each product category. ^SSuperscript letters identify**
 158 **significant differences across columns: identical letters indicate proportions which are not statistically different.**
 159 **The bold statistical values refer to the overall significance for each food category across years. N.s. indicates non**
 160 **significant differences across years**
 161

162 3.2 Type of notifications

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

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

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

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

176
 177 | **Table 2. Comparison across different product categories of RAFFS notification types.:** **S**superscript letters
 178 **identify significant differences across rows: identical letters indicate proportions which are not statistically**
 179 **different. The bold statistical values refer to the overall significance of each type of notification across species.**
 180 **N.s stands for non significant differences; p.t. indicates products thereof.**
 181

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

191 carried out only on a representative percentage of samples (European Commission, 2013) and this
 192 could result in a further concealment of non-conforming cases.

193 Alerts have been launched especially for products originating from inside the EU (95%) and
 194 during control on the market (68.5%). The fact that alerts mainly involve products originating from
 195 inside the EU is likely due to the fact that consignments imported from non-EU countries, when
 196 non-compliant, are halted at the port of entry (without entering the EU market), whereas products
 197 originating from within the EU are more easily moveable within the community borders (Kleter et
 198 al., 2009). In 50% of the alerts, the cause was the overcoming of the EU limits for
 199 pathogens/residues. For example, in most of the cases (81.4%), notifications concerning heavy
 200 metals have been classified as alerts (42.4%) or information (39%, of which 95.5% for attention and
 201 4.5% for follow up), because related non-compliances were revealed especially during official
 202 controls on the market (60.3%).

203 3.3 Notifying country

204 In previous studies wide variations in contributions to RASFF's notifications between EU MSs
 205 were found: Italy, Spain, France and Germany were the key reporting countries (Petroczi et al.,
 206 2010; Taylor et al., 2013; Leuschner et al., 2013; Pięłowski, 2017). The same pattern was
 207 confirmed by this study.

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

EU Country	Product category			
	Bivalve Mollusks and p.t.	Cephalopods and p.t.	Crustaceans and p.t.	Fish and fish products
Italy	17,56% ^A	6,92% ^A	6,40% ^A	69,11% ^A
Spain	12,81% ^B	7,44% ^A	7,23% ^A	32,44% ^B
France	24,22% ^C	0,52% ^B	2,48% ^B	17,05% ^C
Germany	12,60% ^B	0,62% ^B	3,82% ^{AB}	13,12% ^C
<i>chi square</i>	41,4	22,5	44,6	16,1
<i>p</i>	<0,001	<0,001	<0,001	0,001

210

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

215 |
216 |
217 | The present results configure Italy as the first MS for number of issued notifications, accounting for
218 | 35.7% of the total number, followed by Spain (19.3%), France (9.4%) and Germany (6.5%). These
219 | countries contribute for almost 70% of all notifications, whereas the remaining 30% is shared
220 | among 27 countries. During the period considered, no notification was directly launched by the
221 | Commission Services and, among non-EU countries, only Norway participated in reports with 33
222 | (1.2%) notifications. ~~Despite almost all food safety regulations in EU MSs rest on European law,~~
223 | ~~several differences, especially as regards responsibilities and tasks of official control bodies, can~~
224 | ~~still be observed. In some MSs, based on national policy and legislation, the mandate of CAs~~
225 | ~~includes risk communication and enforcement of food control, while in others it is limited to risk~~
226 | ~~assessment and scientific advice to the Government, likely resulting in less participation in the~~
227 | ~~RASFF network. Therefore, RASFF notifications reflect the activity of a MS's food and feed~~
228 | ~~enforcement action and variations in rates can be explained by different patterns of EU food law~~
229 | ~~implementation and official control activities in each MSs (Havinga, 2014). However, T~~the number
230 | of RASFF notifications per country can be ~~strictly~~ affected even by the volume of imports. MSs that
231 | trigger most of the notifications are usually those with the largest food trade (Petroczi et al., 2010)
232 | and highest transit of food matches, providing major ports for imports (Taylor et al., 2013). This is
233 | the case of Italy that is the MS with the highest volume of seafood import ~~(, which represents~~ 73.5%
234 | of the total incoming consignments at Italian BIPs) (Ministry of Health, 2013). This can also
235 | explain why Italy is the first MS by number of notifications for fishery products. Similarly, the
236 | Netherlands issues 2.9% of the notifications despite its small territory, ~~probably because of the~~
237 | ~~presence of major sea harbors or airports receiving large volumes of seafood from Extra-EU~~
238 | ~~countries (Petroczi et al., 2010). It is notable that s.~~ SSome countries, such as the UK, make relatively
239 | few entries to the RASFF database (4.3%) perhaps due to fewer checks or favorable findings in the

240 foodstuff selected for testing (Petroczi et al., 2010). ~~Additional reasons for low notifications might~~
 241 ~~be related to: static trading relationships, less import of food from outside of the EU, import from~~
 242 ~~countries that are less likely to transgress or import of food normally not noted in the RASFF~~
 243 ~~database (Taylor et al., 2013; Petroczi et al., 2010).~~

244 *3.4 Country of origin*

245 In the five-year period 2011-2015, 60% of the notifications were made on fishery products
 246 coming from 14 different countries, while the remaining 40% from 92. Notified fish originated from
 247 97 countries, crustaceans from 46, cephalopods from 29 and bivalve mollusks only from 27. These
 248 findings indicate that fish is imported in the EU from many more different countries than the other
 249 three product categories. On the contrary, the low number of countries from which notified bivalve
 250 mollusks came from is probably related to the strict regulations imposed by EU for this kind of
 251 products. In fact, only 16 third countries are authorized to export bivalves to the EU markets
 252 (Commission Decision 2006/766/EC and Commission Decision 2009/951/EU). ~~From Asia, only~~
 253 ~~Japan, the Republic of Korea, Thailand and Vietnam are currently qualified to export bivalves to the~~
 254 ~~European Community.~~ This contrasts with other seafood products, where approximately 100 third
 255 countries and territories have been approved to export their products to the EU. Almost all major
 256 seafood producing countries in Asia have been approved by the EU authorities.

257 Spain was the country affected by the highest number of notifications (accounting for 15.4% of
 258 the total), followed by Vietnam (9.9%) and Morocco (5.2%). It should be noted that 7.5% of the
 259 notified products originating from Spain were made with raw materials coming mainly (48.3%)
 260 from South America (Mexico 35.7%, Ecuador 21.4%, Brazil 14.3% and others 28.6%) and Asia
 261 (42.0%). However, the notification rate was not similar for each food category across countries, as
 262 showed by the statistical analyses performed (Table 4).

County	Product category			
	Bivalve Mollusks and p.t.	Cephalopods and p.t.	Crustaceans and p.t.	Fish and fish product

Spain	12,71% ^A	2,64% ^A	1,44% ^A	83,21% ^A
Vietnam	23,33% ^B	3,33% ^A	22,59% ^B	50,74% ^B
Morocco	2,13% ^C	9,93% ^B	2,84% ^A	85,11% ^A
<i>chi square</i>	35,7	14,8	101	100
<i>P</i>	<0,001	0,001	<0,001	<0,001

263
264 | **Table 4. Comparison across countries of notification by product category.** ~~S~~^S superscript letters identify
265 significant differences **across columns; identical letters indicate proportions which are not statistically different.**
266 The bold statistical values refer to the overall significance of each product category across countries. N.s stands
267 for non significant differences; p.t. indicates products thereof.

268
269 The EU countries with the highest number of notifications were Spain (15.4%), France (4.5%)
270 and Poland (3.4%) and as regards third countries Vietnam (9.9%), Morocco (5.2%) and China
271 (4.2%). However, these patterns vary, even considerably depending on the product category.
272 Notified bivalve molluscs were mainly from Vietnam, France and Italy; cephalopods from India,
273 New Zealand and Indonesia; crustaceans from Vietnam, India and Mozambique and fish from
274 Spain, Vietnam and Morocco (Fig. 2). Most of the countries with the highest number of
275 notifications per product category are also among the top world producers of that specific product
276 category (FAO, 2016) and/or the top extra-EU countries of origin by value and volume per product
277 category (EUMOFA, 2017).

278 | ~~It must be emphasized that t~~^The number of notifications issued to a Country can also be
279 influenced by the frequency with which foodstuffs coming from it are checked. This can be the case
280 of re-enforced checks (RECs) on third countries. According to the Council Directive 97/78/EC,
281 following a rapid alert issued under the RASFF or a serious/repeated infringement of EU veterinary
282 legislation, the next 10 consignments from the same establishment of origin (in the third country)
283 for which the notification is made, must undergo additional checks at BIPs. If the results for all 10
284 consignments are satisfactory RECs are stopped, otherwise a second, or at maximum a third, group
285 of 10 consecutive consignments begins (Council Directive 97/78/EC). ~~Therefore, with the increase~~
286 ~~in the frequency of checks, there may be a greater detection of non-compliance and consequently an~~

287 ~~increase in the number of notifications to the third country of origin, influencing estimates in favor~~
288 ~~of those countries whose goods are not or less subject to RECs.~~

289 **3.5 Notifications basis and distribution status**

290 ~~Notifications reported in the RASFF system can be launched following different and various~~
291 ~~control activities (official and non-official). On average, according to the EU Commission figures~~
292 ~~(European Commission, 2009), about 52% of RASFF notifications concern controls at the outer~~
293 ~~EEA borders at points of entry or BIPs. In most of the cases the consignment is not accepted for~~
294 ~~import (consignment detained). In some cases, CAs can decide to take samples for analysis and if~~
295 ~~the results are satisfactory, the consignment is forwarded to its destination under customs seals~~
296 ~~(consignment under customs). Otherwise, the consignment can be released without awaiting the~~
297 ~~analytical results. Then, in the case of unfavorable results, the product needs to be withdrawn from~~
298 ~~the market (consignment released). The second largest category of notifications is official controls~~
299 ~~on the internal market, accounting for 30% of the total RASFF notifications. To a lesser extent,~~
300 ~~notifications are triggered following company's own check (13%), consumers' complaint (3%) or~~
301 ~~food poisoning (2%) (European Commission, 2009).~~

302 ~~The above mentioned EU Commission figures are confirmed in the present study.~~ During the
303 period analyzed in this study, the notifications were triggered in most of the cases (85.8%) by
304 border checks or by official control activities on the market. In particular, during border control, the
305 consignment was detained in most of the cases (41.7%), while it was released (1.1%) or forwarded
306 to its destination under customs seals (0.04%) only occasionally.

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

Bases	Product category				chi square	p
	Bivalve Mollusks and p.t.	Cephalopods and p.t.	Crustaceans and p.t.	Fish and fish products		
A	44,32% ^A	18,60% ^B	21,34% ^B	48,01% ^A	96,6	<0,001

B	28,77% ^A	77,52% ^B	68,77% ^B	38,03% ^A	183	<0,001
C	10,90% ^A	3,10% ^B	6,32% ^{BC}	8,06% ^{AC}	18,4	<0,001
D	9,51% ^A	0,00% ^B	1,98% ^B	2,98% ^B	53	<0,001
E	0,46% ^A	0,78% ^A	1,58% ^A	2,79% ^B	10,6	0,01
F	6,03% ^A	0,00% ^B	0,06% ^B	0,00% ^B	108	<0,001
G	0,00% ^A	0,06% ^A	0,00% ^A	0,00% ^A		n.s

309

310 | **Table 5. Comparison of bases for notifications, across food categories.** ^sSuperscript letters identify ,
311 **significant differences across rows: identical letters indicate proportions which are not statistically different.** The
312 **bold statistical values refer to the overall significance of each notification base. N.s stands for non significant**
313 **differences; p.t. indicates products thereof. A: Official control at the market; B Border Control Consignment**
314 **detained; C: Company's own check; D: food poisoning; E: Consumer complaint; F: Border Control**
315 **Consignment released; G: Border Control consignments under customs**
316

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

331 | Regarding distribution status, the analysis showed that in most cases faulty-non-compliant
332 seafood considered were no distributed (23.2%) or not yet placed on the market (16.4%). These data
333 are evenly distributed within the product categories analyzed, with the exception of bivalve

334 molluscs where, in most cases (26.16%), the notified products were distributed to other member
 335 countries (Fig. 4).

336 Considering the different food categories, the frequency of the distribution status varies
 337 significantly across products categories, for almost all the distribution options (Table 6).

Distribution Status	Product category				chi-square	P
	Bivalve Mollusks and p.t.	Cephalopods and p.t.	Crustaceans and p.t.	Fish and fish products		
Distribution on the market	0,23% ^A	0,53% ^A	0,31% ^A	0,56% ^A	n.s.	
Distribution restricted to N.C.	10,42% ^A	11,17% ^A	18,24% ^B	17,29% ^B	16,7	0,001
Distribution to other M.C.	26,16% ^A	3,19% ^B	11,01% ^C	13,01% ^C	72,4	<0,001
Distribution to third countries	0,93% ^A	0,00% ^A	0,00% ^A	0,63% ^A	n.s.	
Information not (yet) available	5,09% ^A	4,26% ^A	5,66% ^A	11,49% ^B	23,9	<0,001
No distribution	9,72% ^A	56,91% ^B	26,73% ^C	22,35% ^C	167	<0,001
No distribution from N.C.	5,09% ^B	1,06% ^A	2,83% ^A	6,53% ^B	15,3	0,002
No stock left	0,00% ^A	0,53% ^A	0,31% ^A	0,45% ^A	n.s.	
Product no longer on the market	17,36% ^A	1,06% ^B	2,52% ^B	9,01% ^C	67,5	<0,001
Travel under custom seals	0,00% ^A	0,00% ^A	0,00% ^A	0,11% ^A	n.s.	
Product already consumed	3,24% ^A	0,53% ^B	0,63% ^B	1,30% ^B	16,2	0,001
Product not placed on the market	19,44% ^A	20,74% ^A	30,50% ^B	12,73% ^C	150	<0,001
Product past best before date	0,46% ^A	0,00% ^A	0,00% ^A	1,24% ^A	n.s.	
Product past use-by date	1,85% ^A	0,00% ^A	1,26% ^A	3,32% ^B	11,8	0,008

338
 339 **Table 6. Comparison of Distribution status across food categories: superscript letters identify significant**
 340 **differences across rows; identical letters indicate proportions which are not statistically different. The bold**
 341 **statistical values refer to the overall significance of each status. Across product categories. N.s stands for non**
 342 **significant differences; p.t. indicates products thereof.**
 343

344 **3.6 Notifications per hazard category Category of hazard**

345 The overall analysis of the category of hazard in seafood products revealed that the top three
 346 hazards were heavy metals (21%), pathogenic microorganisms (20%), and poor or insufficient
 347 controls (15%) (Fig. 54). Heavy metals represent the fourth most often notified hazard category in
 348 the RASFF from 1980–2016 and fish and fish products are the category most affected by the
 349 presence of heavy metal among all the food product categories (European Commission, 2017,
 350 Piglowsky, 2018). In addition to these, other frequently encountered hazards were parasitic
 351 infestations (7%), biocontaminants (7%) and residues of veterinary medicinal products (6%). In
 352 agreement with the results reported by other surveys on RASFF (Kleter et al., 2009; Tähkäpää et al.,
 353 2015; Bouzembrak & Marvin, 2016), cases of seafood notifications due to adulterations or frauds
 354 are very limited (2% of the total). However, in the light of the data on seafood adulteration reported
 355 in literature, it seems to be an underestimation (Guardone et al., 2017). The fact that frauds are
 356 poorly reported in the RASFF is probably due to the fact that they are generally considered as a
 357 commercial problem rather than a health issue. Thus, they are often not communicated to the
 358 network. In addition, the most frequent fraudulent practice, consisting in the replacement of
 359 valuable seafood species with products of lower value, cannot be detected by using only visual
 360 inspection. However, according to the new Regulation (EU) 625/2017, official controls activities
 361 aimed at identifying fraudulent or deceptive practices will become more relevant and EU reference
 362 centres for the authenticity and integrity of the agri-food chain will be designated.

363 Category of hazards are not uniformly distributed in the product categories: statistical analyses
 364 showed significant differences in proportion of all hazards across product categories (Table 76).

Hazard category	Product category				chi square	p
	Bivalve Mollusks and p.t.	Cehalopods and p.t.	Crustaceans and p.t.	Fish and fish products		
Heavy metals	2,97% ^A	28,42% ^B	4,53% ^A	26,37% ^B	178	<0,001
Pathogenic microorganism	65,07% ^A	7,89% ^B	10,03% ^B	11,51% ^B	705	<0,001
Poor or insufficient controls	5,71% ^A	34,21% ^B	25,89% ^B	13,54% ^C	114	<0,001

Parasitic infestation	0,00% ^A	11,05% ^B	0,00% ^A	10,09% ^B	82,4	<0,001
Biocontaminants	0,00% ^A	0,00% ^A	0,00% ^A	10,2% ^B	103	<0,001
Residues of vet medical products	0,23% ^A	1,58% ^{AB}	32,69% ^C	3,45% ^B	438	<0,001
Organoleptic aspects	4,34% ^A	5,26% ^A	0,65% ^B	4.17% ^A	10,3	0,02
Food additives and flavouring	1,37% ^A	2,11% ^A	19,42% ^B	1,92% ^A	232	<0,001
Biotoxins	14,84% ^A	0,00% ^B	0,00% ^B	0,33% ^B	313	<0,001

365

366 | **Table 76. Comparison of hazard distribution across food categories: superscript lettes identify significant**
367 **differences across rows: identical letters indicate proportions which are not statistically different. The bold**
368 **statistical values refer to the overall significance of each hazard category across products.**
369

370 In fact, while in fish products a wide range of hazards was responsible of the notifications, in the
371 other product categories most part of the notifications was due to fewer categories of hazard. For
372 example, in bivalves one hazard was responsible for 65% of the notifications observed. Results,
373 detailed in (Table 1SM) and summarized in (Fig. 56), will be described in the following sections.

374 *3.6.1 Category of hazard in fish and fish products.* Fish and fish products were mainly (26.4%)
375 notified because of non-compliant presence of heavy metals such as mercury (94%), cadmium (5%)
376 or both (1%), as also highlighted by Pięłowski (2017 and 2018). Products affected by this issue
377 were mainly from Spain (39.1%) and Vietnam (10.3%). This product category also resulted
378 particularly affected by poor or insufficient controls (13.5%), pathogenic microorganisms (11.5%),
379 bio contaminants (10.2%) and parasitic infestations (10.1%). As regards poor or insufficient
380 controls, notifications were manly triggered against products coming from Morocco (8.8%),
381 Senegal (7.6%), United States (7.6%) and China (7.2%) and because of poor temperature control
382 (84.6%) and poor hygienic state (8.1%). Faulty-Non-compliant products due to pathogenic
383 microorganisms were in 89.0% of the cases contaminated by *L. monocytogenes*. They were mostly
384 (91.3%) from EU Member States and in particular from Poland (39.7%), Denmark (25.0%), Spain
385 (17.0%) and Norway (11.0%). This is probably because at EU level most of the fish products are
386 traded as fresh/chilled and this makes them more subjected to bacterial contamination and growth

387 (especially of *L. monocytogenes* which grows even at refrigeration temperatures) respect to frozen
388 products, which, on the contrary, come especially from third countries. In addition, the above
389 mentioned countries are big producers of smoked salmon; Poland for example produces around
390 34% of the smoked salmon produced in the EU, largely processing fresh farmed salmon from
391 Norway (EUMOFA, 2016; Doyle A., 2016, <http://www.eurofish.dk>). Smoked salmon was shown to
392 be the food product most affected by *L. monocytogenes* among all the food products included in the
393 RASFF analysis (European Commission, 2017), data confirmed in the present study. In fact, 73.8%
394 of all notifications issued for the presence of this pathogenic microorganism involved smoked
395 salmon coming mainly from Poland (52.8%) and Denmark (17.3%).

396 All fish products (100%) notified under the hazard category biocontaminants contained
397 histamine levels that did not comply with European limits (Commission Regulation (EC) No
398 2073/2005 and its amendment Regulation (EC) No 1441/2007). However, over the five-year period
399 considered, notifications for histamine were unexpectedly low (10.2% of the total of Fish and fish
400 products notifications) if considering that histamine poisoning is the most common fish poisoning
401 in the EU and outbreaks are subject to mandatory notification (ANSES, 2012; Tortorella et al.,
402 2014). From 2011 to 2015, RASFF counts 190 notifications due to histamine of which 55.7%
403 concerned Tuna (especially chilled 37.7% or frozen 21.7%), 25.8% Sardines (especially canned
404 47% or frozen 18%), 8.4% Anchovies and 5.8% Mackerels. These data can be compared with the
405 results of the study of Leuschner et al., 2013 on the presence of biogenic amines between 1979 and
406 2010. An increasing trend was observed by the authors over time, as total RASFF notifications for
407 biogenic amines were 7 from 1979 to 1994, 35 from 1995 to 2001, 88 from 2002 to 2005 and
408 finally 227 from 2006 to 2010. However, in this last period of time (2006-2010) 209 out of the 227
409 notifications were issued for fish and fish products, while the remaining 18 were related to fish
410 sauce (11), soy sauce (6) and grated cheese (1). Thus, the number of notifications found in the
411 present study (190) appears only slightly lower than the number reported by Leuschner et al. (2013)

412 for the last period of time they analyzed. The species involved were substantially the same. These
413 data are also confirmed by a recent systematic review (Colombo et al., 2017).

414 Histamine notifications found in this study originated from products from Spain (25%), Morocco
415 (19%) and Asian Countries (Thailand 7%, Vietnam 5.7%, India 4.7%, Indonesia 4.2%). They were
416 mainly classified as information for attention (51.0%) and triggered during border control (37.9%),
417 official control on the market (23.2%), food poisoning (20.5%), company's own check (16.3%) and
418 consumer complaint (2.1%) with a significant difference in the action taken (see section 3.8). It
419 should be noted that in the case of histamine, company's own checks and food poisoning have had a
420 greater role as basis notification than the overall average found in this study (8.12% and 3.88%,
421 respectively) and the reasons are easily understandable. In fact, as already mentioned above,
422 histamine outbreaks must be notified systematically, and this increases the RASFF notifications
423 triggered by food poisoning. Moreover, sampling plans and testing for histamine is a routine
424 regulatory surveillance for fish processor, importer or distributor worldwide (FAO, 2012; James et
425 al., 2013) and this makes any non-compliance more easily and frequently detectable in this context.

426 The parasite most involved in fish products' notifications was reported as *Anisakis* spp. (84.2%),
427 followed by unspecified nematodes (8.7%). In 4.9% of the cases the parasites were not identified.
428 Notified products because of *Anisakis* spp. were mainly from Morocco (22.5%), Spain (27%) and
429 France (13%) and involved in particular chilled (63%) or frozen (22,7%) hake (*Merluccius* spp.
430 23.2%), mackerel (*Scomber* spp. 19.3%), monkfish (*Lophius* spp. 16.1%), anchovies (*Engraulis*
431 spp., 9.0%) and silver scabbardfish (*Lepidopus caudatus*, 8.3%). All these species are known to be
432 hosts of *Anisakis* spp. (Levsen et al., 2017). Unidentified nematodes were detected especially in
433 chilled (53.8%), frozen (19.2%) or canned (12.5%) monkfish (20%), cod (*Gadus* spp., 13,3%), hake
434 (13,3%) and mackerel (13,3%) which in most of cases (80%) were from EU countries (France
435 46,8%, Polonia 20%, Denmark 6,6% and Spain 6,6%). Notified products were mainly fresh and
436 chilled, but also frozen, smoked, salted, marinated and in oil, thus probably involving also dead

437 larvae. Other notifications reported *Pseudoterranova* spp. (1.1%) and unspecified tapeworms
438 (0.5%). Finally, one notification (0.5%) regarded swordfish fillets because of the presence of
439 *Pennella*, which, although not dangerous for human health, can make products unfit for
440 consumption (Guardone et al., 2018).

441 *3.6.2 Category of hazard in bivalve mollusks.* The most frequent category of hazard in bivalve
442 mollusks was that of pathogenic microorganisms accounting for 65.1% of the notifications,
443 followed by biotoxins (14.8%) and poor or insufficient controls (5.7%). Among the pathogenic
444 microorganisms, the most represented were *E. coli* (49.1%) and Norovirus (34.4%), followed by
445 *Salmonella* spp. (14.4%). Interestingly, while *E. coli* and *Salmonella* spp. represent food safety
446 criteria (Regulation CE 2073/2005), Norovirus are not contemplated in the aforesaid Regulation,
447 even though the opinion issued by the Scientific Committee on Veterinary Measures relating to
448 Public Health (SCVPH) on Norwalk-like viruses (NLVs, noroviruses) on 30-31 January 2002,
449 reported that the conventional faecal indicators are unreliable for demonstrating the presence or
450 absence of NLVs in live bivalve molluscs. It follows that, while CAs and FBOs must check live
451 bivalve mollusks for the presence of *E. coli* and *Salmonella* spp., tests for the presence of NLVs are
452 not required. Therefore, the identification of NLVs as zoonotic agents responsible for the infection
453 have been probably performed after the outbreaks on the EU territory. This hypothesis is supported
454 by the results of this study showing that notifications due to food poisoning were mainly
455 attributable to bivalve mollusks or fish consumption (section 3.5). In agreement, the category
456 including norovirus and bacterial toxins (other than *Clostridium botulinum*) was most frequently
457 reported in ‘Canteen or Catering to Workplace, school, hospital’ and in ‘Restaurants, pubs, street
458 vendors and take away’ (EFSA & ECDC, 2017).

459 Bivalve products affected by pathogenic microorganisms originated particularly from Vietnam
460 (18.3%), France (14.8%), Italy (14.4%) and Spain (4%), which are also among the world's largest
461 producers of mollusks (FAO, 2016). In France, in particular, an increasing trend in the number of

462 intoxication outbreaks by calicivirus (including norovirus) was recently observed (EFSA & ECDC,
463 2017), which may probably arise also from the circulation of both new and/re-emergent strains of
464 norovirus in the country (Bidalot et al., 2017).

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

471 As concerns the poor or insufficient controls category, non-conforming products were mainly
472 traded by third countries, such as Chile (28%), Thailand (12%) and Vietnam (12%), and most of the
473 them (72%) were notified because of poor temperature control (56%) and poor hygienic state
474 (16%). Moreover, bivalve mollusks were deemed as non-compliant because they came from a non-
475 classified production area or were unpurified in 16% and 4% of the cases, respectively. This could
476 be related to the fact that importing countries enforce strict regulations on live, fresh and frozen
477 bivalves which many exporting developing countries are unable to meet (Regulation CE 2073/2005
478 and further amendments).

479 *3.6.3 Category of hazard in crustaceans.* In crustaceans, the main hazards reported were:
480 residues of veterinary medicines (32.7%), poor or insufficient controls (25.9%), presence of
481 additives/flavorings (19.4%) and pathogenic microorganisms (10%).

482 Among the residues of veterinary drugs, the most commonly substances found were Nitrofurantoin
483 metabolites (45%), Tetracycline (28%) and Chloramphenicol (19%). In 77.2% of cases, products
484 originated from Asia (India 39.6%, Vietnam 37.6% and China 12.9%). As regards nitrofurantoin
485 metabolites, the number of notifications is in line with data from the preceding years (Karunsagar,
486 2017). In fact, after a study showed that semicarbazides (SEM), the metabolite most frequently

487 involved in the past in persisting alerts, can be found naturally in the shell of crustaceans, only the
488 edible part was tested and the number of alerts has dropped significantly (Van Poucke et al., 2011).
489 Tetracyclines are broad-spectrum antibiotics widely used in aquaculture, frequently in enriched
490 commercial shrimp feeds (Gräslund & Bengtsson, 2001). Our data support the importance to pay
491 attention to their use and fate in aquaculture (Liu et al., 2017). For what concerns chloramphenicol,
492 the rejection of a high number of crustacean imports into the EU due to a zero tolerance policy, lead
493 the EC to published a decision introducing a minimum required performance limit (MRPL)
494 or/reference point for action (RPA) for chloramphenicol (0.3 mg/kg) (Commission Decision of 11
495 January 2005). Despite this, chloramphenicol still represents the third residue category.

496 Poor or insufficient controls in notified crustaceans were mainly due to poor temperature control
497 (90.0%) and, to a lesser extent, to unsuitable organoleptic characteristics (5.0%), poor hygienic state
498 (3.8%) and improper production (1.3%). Faulty-Regulatory non-compliant products were traded
499 especially by Mozambique (32.9%).

500 The non-compliant presence of additives/flavorings was largely determined by too high
501 content/undeclared sulphites (83%) followed by undeclared citric acid (E 330) (7%), unauthorized
502 use of colorants (3%) or sodium aluminum phosphate (3%) and too high content of benzoic acid (E
503 210) (3%) in products originating from different countries (among the most represented are Tunisia
504 14.5%, Croatia 12.9%, Ecuador 12.9%). Sulphites are used as the main inhibitors of melanosis;
505 however, are frequently linked to allergic reactions and asthmatic attacks in humans (Gonçalves &
506 de Oliveira, 2016).

507 Crustaceans notified because of pathogenic microorganisms were almost all (92.6%)
508 shrimps/prawns (55,5% frozen, 14,8% cooked and 11,1% frozen cooked) coming from Vietnam
509 (48.1%) and Netherland (11.1%) and containing *Salmonella* spp. (29.6%), *L. monocytogenes* (26%),
510 *Vibrio* spp (22.2%) or combination *Salmonella* spp./*Vibrio* spp. (22.2%).

511 3.6.4 *Category of hazard in cephalopods.* In cephalopods, most of the notifications (62.6%) were
 512 due to poor or insufficient controls (34.2%; 86% poor temperature control and 14% poor hygienic
 513 state) and heavy metals (28.4%; 100% for cadmium content beyond the limits), detected mainly in
 514 products from Peru (20.3%) and India (29.6%) respectively. The presence of cadmium in
 515 cephalopods is in agreement with the data of Piglowsky (2018).

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

524 **3.7 Risk decision and actions taken by official control authorities or food**
 525 **operators/industries**

526 As regards the risk decision, 39.3% of the total notifications ~~analyzed~~ was classified as serious,
 527 19.2% as not serious and 41.5% was not classified (undecided), ~~with different patterns according to~~
 528 ~~the product category (Table 8).~~ As shown in ~~the Table 87, the difference in proportions of decisions~~
 529 ~~were~~ statistically significant ~~differences were observed~~ across product categories.

Risk decision	Bivalve Mollusks and p.t.	Cephalopods and p.t.	Crustaceans and p.t.	Fish and fish products	chi square	p
Not serious	8,12% ^A	21,81% ^B	39,94% ^C	17,91% ^B	124,98	<0,001
Serious	66,13% ^A	17,55% ^B	21,70% ^B	38,29% ^C	209.11	<0,001
Undecided	25,75%	60,64%	38,37%	43,81%		N.D.

531 **Table 87. Comparison across different product categories of risk decision types.:** **S**superscript letters identify
 532 **significant differences across rows: identical letters indicate proportions which are not statistically different.** The
 533 **statistical values refer to the overall significance of each decision across product categories.** N.D. stands for not
 534 **done.**
 535

536 In bivalve mollusks serious-risk notifications were prevalent, whereas in the case of crustaceans
537 the majority of the notifications were non-serious. In both the remaining product categories,
538 notifications were mostly undecided. Remarkably, there is no evident correlation between the risk
539 decision and the hazard category ~~as, analyzing data, since~~ a same hazard can be classified either as
540 serious, not serious or not classified at all, as already highlighted by Pięłowski (2017). This is the
541 case for example of mercury in fishery products and cadmium in cephalopods. ~~For example, taking~~
542 ~~into account the cases of mercury in fishery products and cadmium in cephalopods, notifications~~
543 ~~were classified as serious (71.5% and 53.7% respectively), not serious (2.5% and 1.8%~~
544 ~~respectively) or undecided (26% and 44.5% respectively) regardless of the levels detected. A~~
545 similar case occurred for ~~This is also the case of~~ *Listeria monocytogenes* in fishery products and
546 *Escherichia coli* in bivalve mollusks ~~bivalve, that were classified as serious (38.5% and 79.2%~~
547 ~~respectively), not serious (6.4% and 2.1% respectively) or undecided (55.1% and 18.7%~~
548 ~~respectively) without taking into account the bacterial charge. These discrepancies are probably due~~
549 to the fact that, ~~at the time of notification,~~ notifying authorities take into account also other factors,
550 such as the distribution status. In fact, a non-compliant product not yet distributed on the market has
551 significantly lower risk compared to another that is instead on the market (and in particular at retail
552 sale). In addition, in the absence of a specific procedure and/or standard provisions for
553 categorization, CAs often prefer to not define the risk. However, the fact that the same hazards can
554 be interpreted differently and that there are no standardized indicators (such as specific bacterial
555 charge or limit values) to formulate an objective risk decision, represents a serious ~~limits~~ for all
556 RASFF members and can also affect risk communication between them.

557 3.8 Actions undertaken by official control authorities or food operators/industries

558 ~~The action taken is the last step of the entire RASFF process and it represents the response from~~
559 ~~control authorities to non-compliances. When speaking of foods and feed products on the market,~~
560 ~~the most important actions are surely withdrawn and recall (Parisi et al., 2016).~~ In this study, the

561 most common (22.2%) action taken was the withdrawn of products from the market, especially
562 because of the presence pathogenic microorganism (27.4%), heavy metals (25.8%), histamine
563 (8.1%) and residues of veterinary medicinal products (3.9%).

564 In 16.8% of the cases non-compliant seafood were returned (mainly due to poor or insufficient
565 controls 49.9% or pathogenic microorganism 28.8%), 12.8% destroyed (especially because of
566 heavy metals 20% or poor or insufficient controls 18.8%) and 11.9% unauthorized to enter the EU
567 market. Official detention and product recall were performed in 7.3% and 5.9% of cases
568 respectively, while no action was taken in 4.4%. Actions were most commonly taken for the fish
569 and fish products category (65%) and this can be explained by the quantity of these products
570 imported to the EU, ~~compared to the other categories~~. In 23.4% of the cases fish and fish products
571 were withdrawn from the market, 14.6% destroyed and 13.7% re-dispatched. As regards bivalve
572 mollusks, in most cases (30.3%), the control authority set the withdrawal from the market and, to a
573 lesser extent, re-dispatch (14.9%) and destruction (11.6%). Cephalopods and crustaceans were
574 mainly re-dispatched (39.7% and 23% respectively) or unauthorized to import (24.1% and 21.4%
575 respectively).

576 **Conclusions**

577 The RASFF system represents a data source commonly used by scientists for various purposes,
578 such as studying historical trends, evaluating emerging food safety hazard and predicting future
579 risks. ~~Moreover, RASFF notifications may be a valuable source of information during the hazard
580 identification step of a risk assessment (Banach et al., 2016).~~ However, it is necessary to point out
581 that data retrieved only from the RASFF portal may be influenced by ~~some limits of the systems. In
582 particular, registration of information related to faulty products does not seem to be homogeneous,
583 probably because there are no standard parameters that allow uniform classification of RASFF
584 notifications. Moreover, data logged in the portal seems to depend on~~ many factors: (i) periodic
585 changes (~~based on~~ the attention of different countries to various problems); (ii) subjective

586 perception of those who issue notifications (as in the case of risk decision); (iii) the issuance of
587 multiple notifications or omissions of reports (with consequent over-under estimation); (iv) the
588 types and frequency of controls carried out at the border posts. ~~The perceived lack of standardize~~
589 ~~parameters also affects the risk decision, sometimes even leading to different interpretations of the~~
590 ~~same hazard and hampering the risk decision.~~ Despite ~~these~~ this shortcomings, the analysis of data
591 from the RASFF portal represents a useful tool to obtain an overview and a valuable 'real-life' and
592 'up-to-date' evidence of the (past and present) issues affecting global and EU fish sector and a
593 valuable source of information during the hazard identification step of a risk assessment. ~~and~~
594 ~~therefore a valuable tool for implementing official controls.~~ Finally, ~~p~~Patterns emerged during this
595 study suggest that the attention of EU official control bodies, FBOs and consumers should be
596 placed not only on seafood from third countries but also on those manufactured at the Community
597 level, especially for chemical and microbiological hazards. In this light, it needs to be considered
598 that an increasing number of products declared to originate from a EU country are produced with
599 raw materials coming from third countries.

600 **Figure captions**

601 **Figure 1.** Type of notifications reported by the RASFF portal for seafood products between
602 2011-2015 subdivided per product category ~~(2011-2015).~~

603 **Figure 2.** Countries of origin of seafood products reported by the RASFF portal between 2011-
604 2015 subdivided per product category ~~notified product per product category (2011-2015).~~

605 **Figure 3.** Notification basis for seafood products reported by the RASFF portal between 2011-
606 2015 subdivided according to the ~~per~~ product category ~~(2011-2015).~~

607 ~~**Figure 4.** Distribution status of notified products in relation to the product category (2011-2015).~~

608 **Figure 45.** ~~Overall~~ Categories of hazard of seafood products notifications reported by the
609 RASFF portal between 2011-2015 ~~involved in the notifications (2011-2015).~~

610 **Figure 56. Categories of hazard of seafood products notifications reported by the RASFF portal**
611 **between 2011-2015 subdivided per product category** ~~Category of hazard per product category~~
612 ~~(2011-2015).~~

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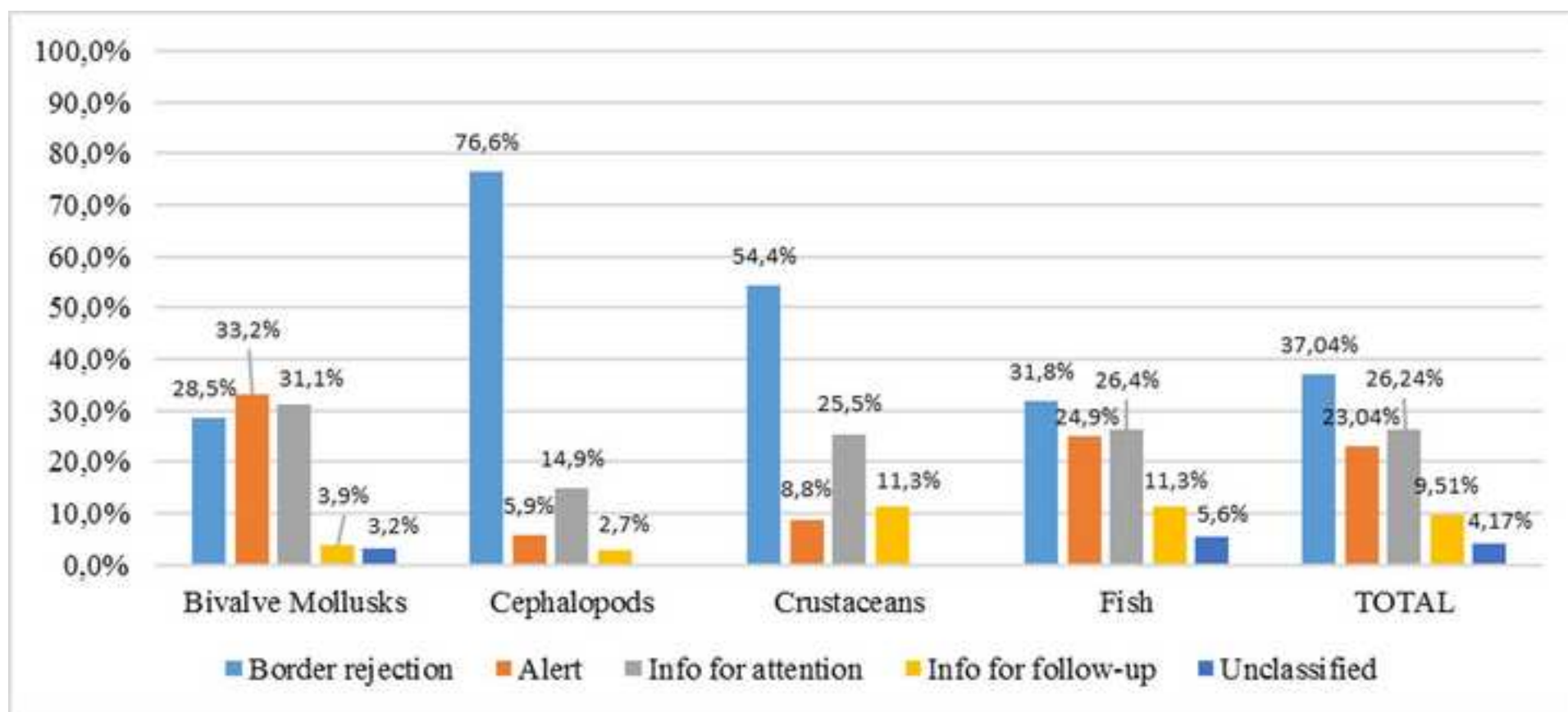
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Highlights

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

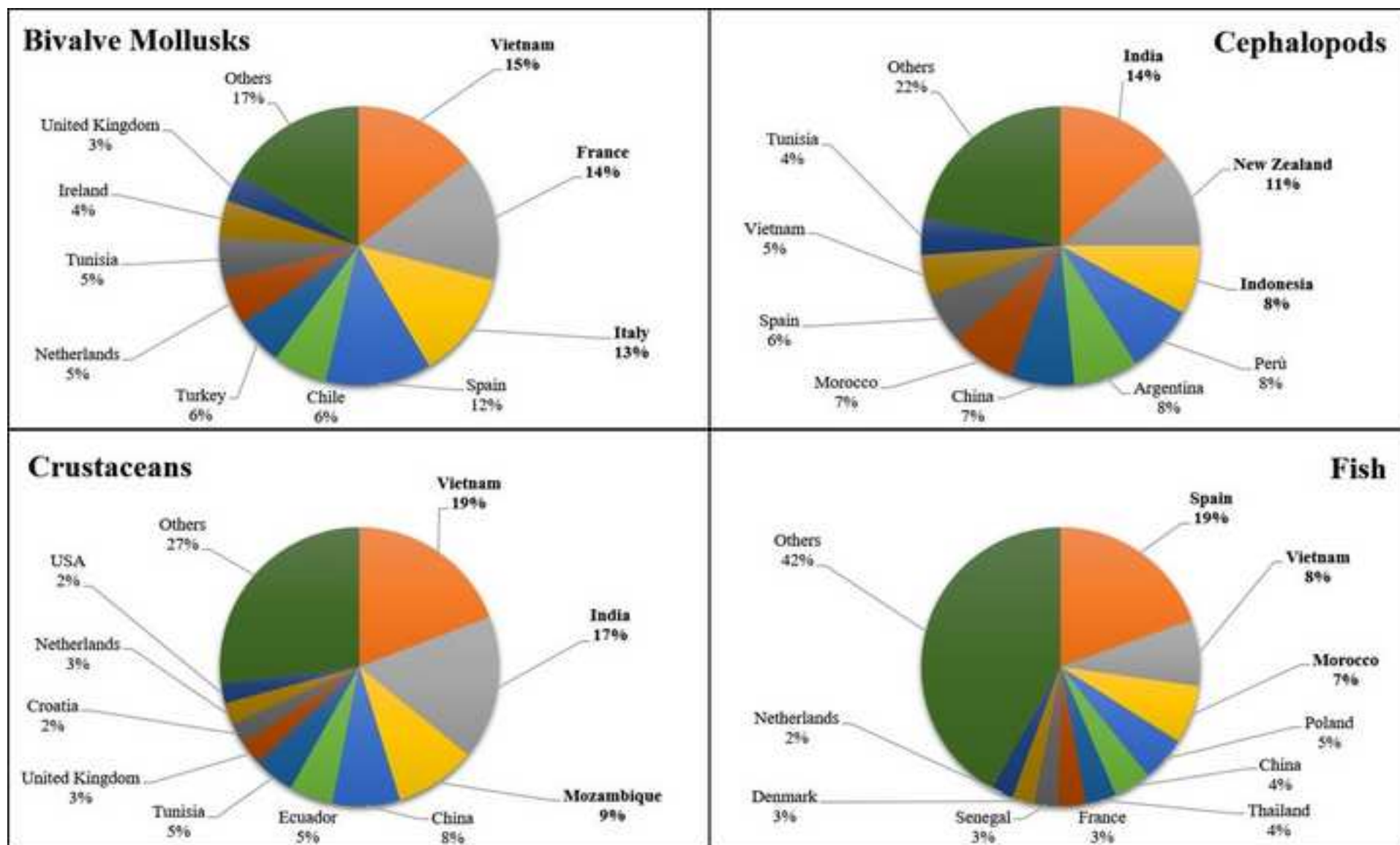
Figure

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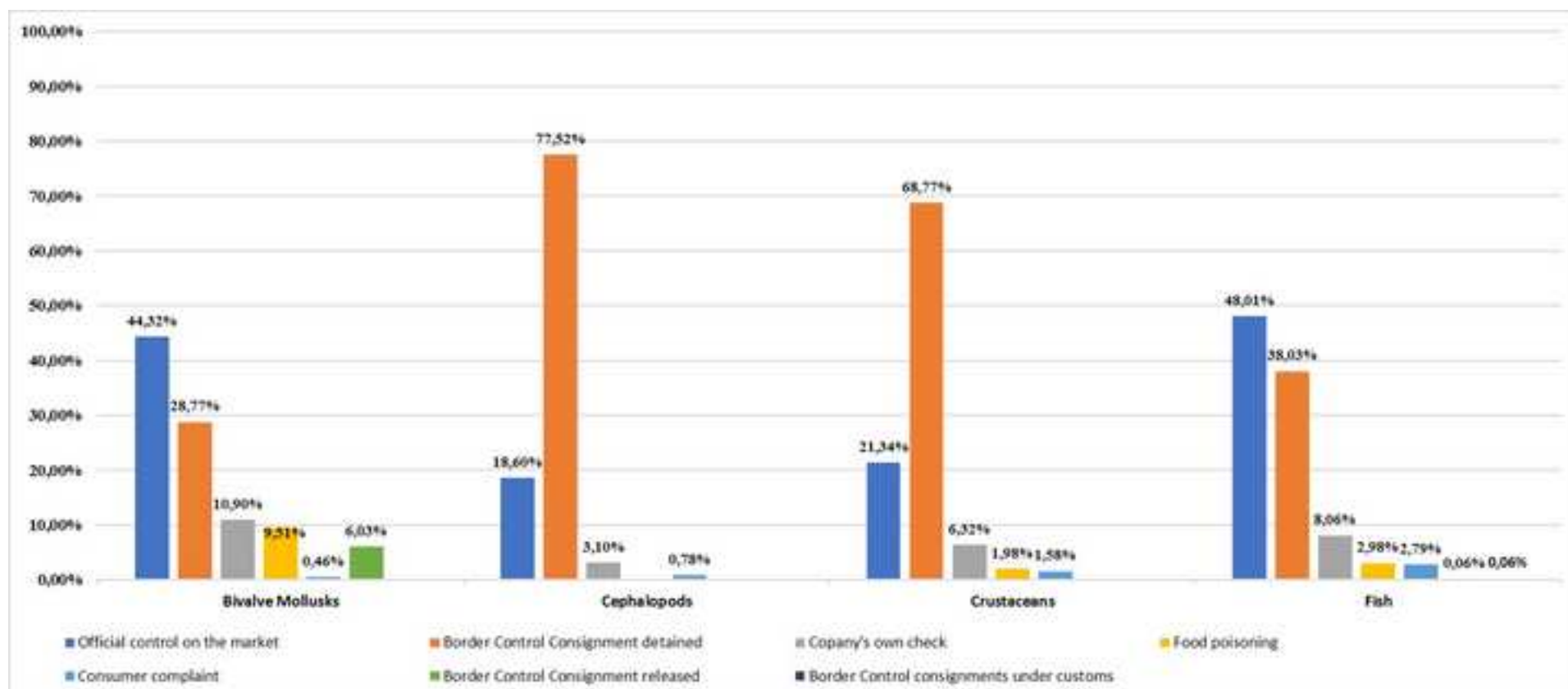
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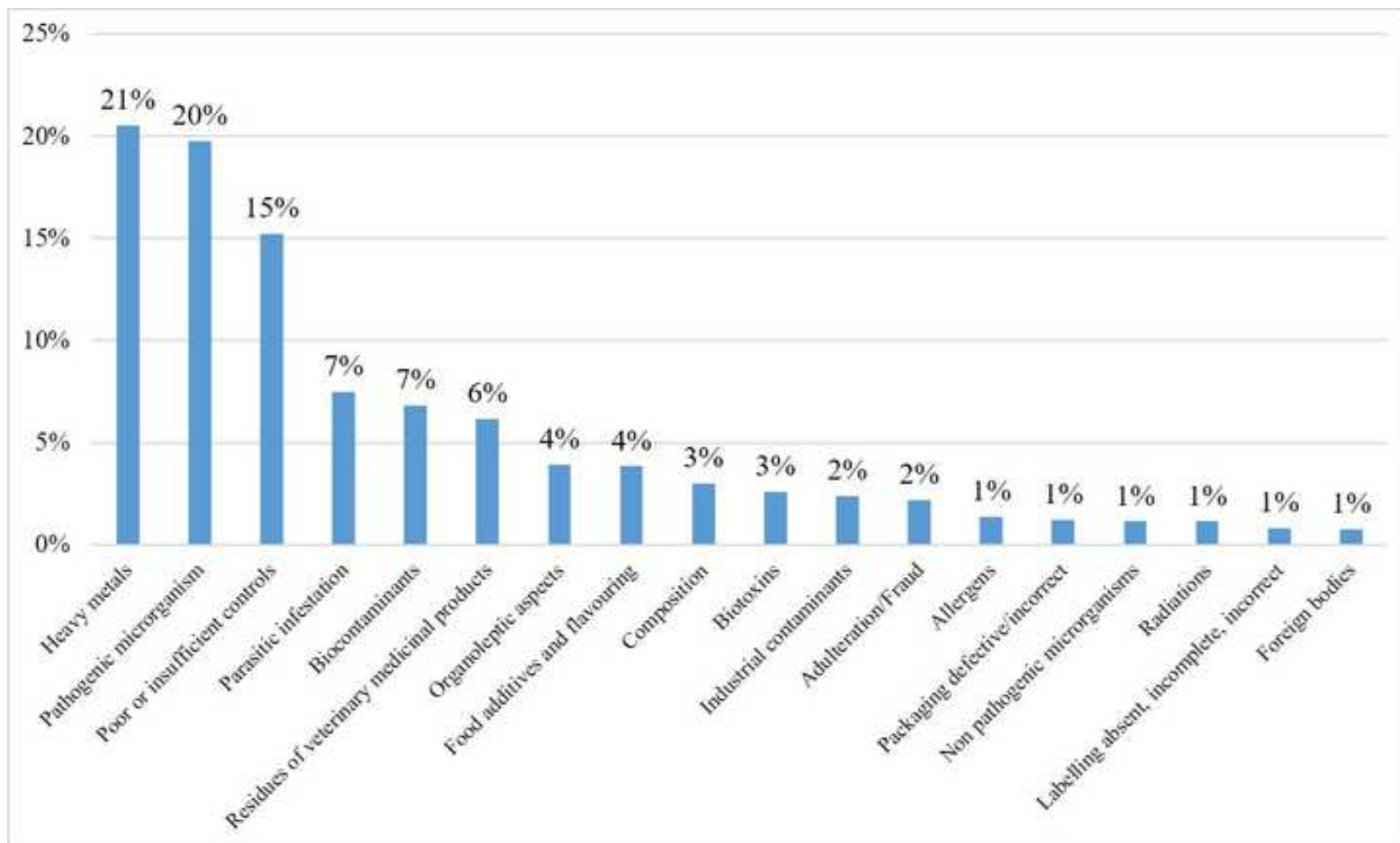
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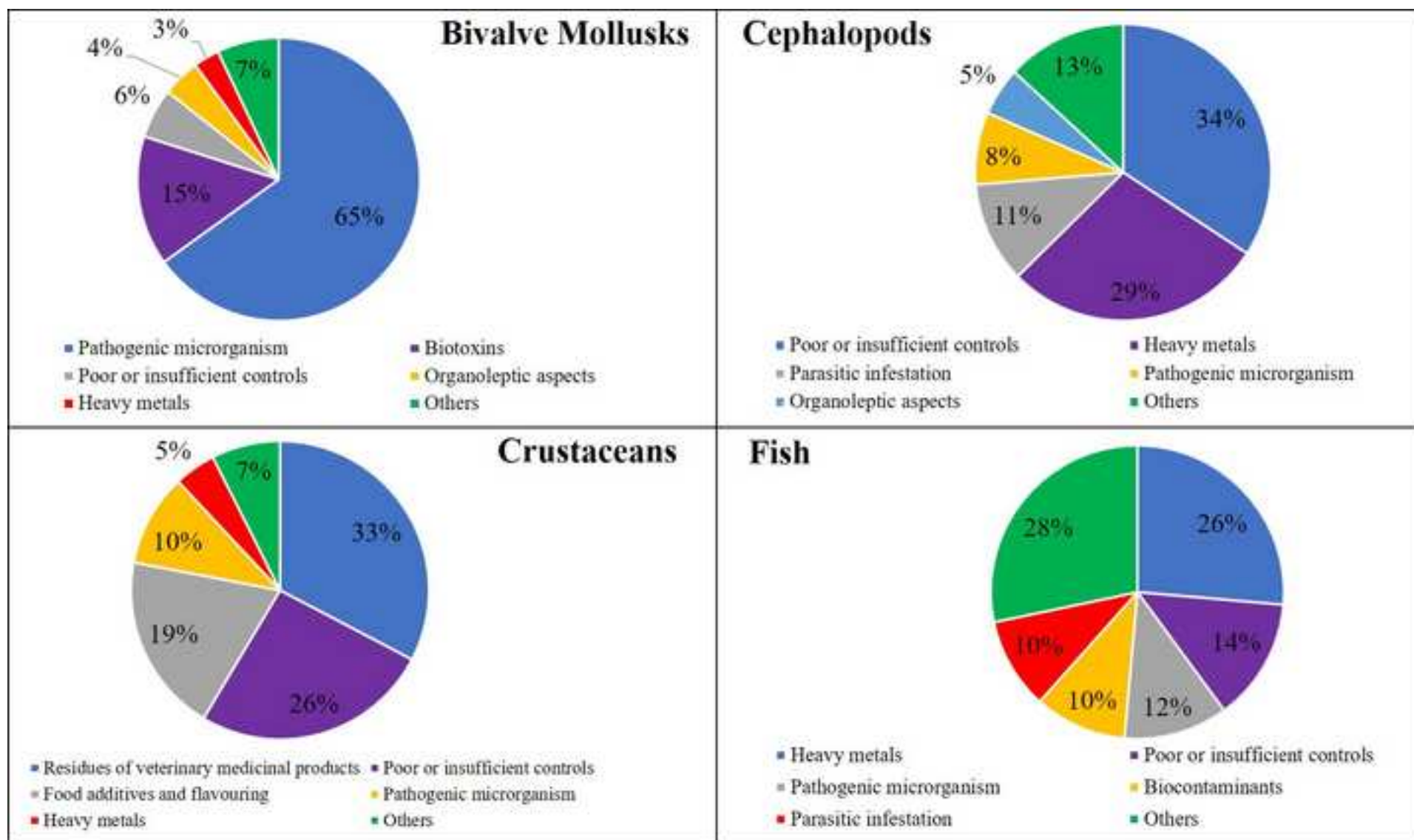
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Figure

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e-component

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