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European alerting and monitoring data as inputs for the risk assessment of microbiological and chemical hazards in spices and herbs

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ABSTRACT

Food chains are susceptible to contaminations from food-borne hazards, including pathogens and chemical contaminants. An assessment of the potential product-hazard combinations can be supported by using multiple data sources. The objective of this study was to identify the main trends of food safety hazards in the European spice and herb chain, and then, evaluate how the data sources can be used during each step of a microbiological and a toxicological risk assessment. Thereafter, the possibilities and limitations of the selected data sources for the risk assessment of certain hazards in spices and herbs are examined. European governmental alerting and monitoring data and legislation were examined and evaluated for particular product-hazard combinations. Pathogenic microorganisms, particularly *Salmonella* spp. and pathogenic *Bacillus* spp., were identified as a potential concern in black pepper and dried herbs, while mycotoxins like aflatoxin (B_1) and ochratoxin A were a probable concern in chilies (including chili powder and cayenne), paprika, and nutmeg. Evaluating multiple, accessible, data sources can support several steps during the risk assessment process as seen for the hazard identification step. Therefore, identifying the potential spice and herb food safety hazards in the chain and other specific data can support risk assessors in compiling a comprehensive risk assessment.

1. Introduction

Spices and herbs have a traditional history of use in food preparation, cuisine, and medicine. Their popularity is related to their capacity to enhance flavoring in foods and their potential health benefits (e.g., as antimicrobials). Nevertheless, the spice and herb supply chain is vulnerable to deliberate, accidental, or natural chemical and microbial contaminations, while the cause is often difficult to determine (Federal Institute for Risk Assessment, 2016). Additionally, concerns associated with food of non-animal origin (FoNAO), such as spices and herbs, are recognized as potentially associated with large outbreaks like the 2011 VTEC (verotoxin-producing *Escherichia coli*) O104 outbreak, which resulted in a reported 3793 cases, 2353 hospitalizations, and 53 deaths (European Food Safety Authority, 2013). Since this outbreak, the European Food Safety Authority (EFSA) evaluated European Union (EU) zoonoses monitoring data between 2007 and 2011 to elucidate potential concerns related to FoNAO. These data indicated an increased risk originating from *Bacillus cereus* within spices and dried herbs such as curry, white pepper, turmeric (curcuma), and ground cumin with 343 human cases reported during this period (European Food Safety Authority, 2013). According to EU FoNAO consumption data in FoodEx, an EFSA food classification system, spice and dried powdered herb consumption is “very high” (European Food Safety Authority, 2013). Microbiological and chemical hazards in the spice and herb supply chain, such as those from pathogenic microorganisms and mycotoxin contaminations, have also been reported in literature and in open access databases. A hazard may result in a risk when the probability and/or severity of the adverse health effect, as a result of the hazard, increases. This may occur when measures to reduce the extent of a hazard in the food (chain) are not taken or when consumer consumption

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patterns (*i.e*. exposure) to a hazard increases. In order to investigate the extent of food chain contaminations, Kleter, Prandini, Filippi, and Marvin (2009) recommended the Rapid Alert System for Food and Feed (RASFF) database as a tool to identify hazards. The RASFF database may be a valuable source of information during the hazard identification step of a risk assessment. The RASFF database allows EU member states (MS), the European Commission (EC), and the EFSA to quickly exchange information on either direct or indirect risks to human and animal health in food and feed chains (European Commission, 2002). The EFSA is responsible for communicating such risks in the food chain. Nevertheless, acquiring data for a risk assessment can become problematic due to sample representativeness as well as under- and over-reporting in databases. On the other hand, by utilizing multiple databases alongside scientific literature, possible misinterpretations of the relevant hazards may be avoided. Therefore, potential data sources, besides RASFF, that can help to comprehensively identify and assess biological and chemical hazards within the spice and herb chains include the World Health Organization (WHO) databases, reports from European scientific agencies such as the EFSA and the European Centre for Disease Prevention and Control (ECDC), and data from EU MS national monitoring programs.

Currently, an analysis of alerting and monitoring databases and scientific literature to support the risk assessment of hazards in spices and herbs has not yet been performed. The objective of this study is to identify the main trends of food safety hazards in the EU spice and herb chains by investigating major, accessible governmental alerting and monitoring system data. After identifying the main hazards, the data are evaluated for their feasibility in microbiological and toxicological risk assessments, while the possibilities and limitations of the examined sources are elucidated.

2. Materials and methods

2.1. Data sources

For the objectives of this study, the RASFF database, EFSA and ECDC reports, and the WHO Global Environmental Monitoring System (GEMS)/Food contaminants database were identified as appropriate sources. These sources were selected based on the following criteria:

1. Accessibility (open access)
2. Subject (alerting or monitoring data for spices and herbs),
3. Data from the investigated years (2004–2014), and
4. Reputation of the publisher (e.g., highly-respected governmental bodies or research organizations).

Additionally, the Netherlands national monitoring database, KAP, serves as an example of MS data on mycotoxins that may be used for risk assessments. Criteria 2–4 were applicable for this source.

The EFSA and the RASFF are established in EC Regulation 178/2002/EC, also known as the General Food Law (GFL) (European Commission, 2002). The GFL aims to protect consumers by creating a framework to monitor, control, prevent, and manage food risks in the EU (European Commission, 2002). Another EU agency, the ECDC, identifies, assesses, and communicates current and emerging threats to human health from communicable diseases (European Centre for Disease Prevention and Control, 2016). The RASFF and the EFSA and ECDC annual reports provide relevant information regarding hazards in foods like spices and herbs. RASFF notifications were selected to determine biological and chemical hazards, while the EFSA and ECDC annual reports were utilized to substantiate biological hazards, namely pathogenic microorganisms, in spices and herbs.

Several WHO databases compile scientific information for experts and professionals. The WHO GEMS/Food contaminants database was selected to identify chemical hazards in spices and herbs. Similar WHO databases for biological hazards (e.g., pathogenic microorganisms) were not used, because the databases often contained parallel data that were retrieved from the EFSA and ECDC annual reports.

As an example of national monitoring data, the KAP program from the National Institute for Public Health and the Environment (2015) in the Netherlands was selected. The program monitors the quality of agricultural products, such as chemical hazards in spices and herbs. Similar information for biological hazards in Netherlands was not accessible.

Furthermore, EUR-Lex legal texts, information from the official websites of the EU, including the EFSA and the ECDC, alongside information from the Directorate-General for Health and Food Safety (DG SANTE) website were reviewed. For the literature review, Google Scholar, the bibliographic database Scopus, and, when appropriate, the search engines of the aforementioned websites were used. Keywords included spices, herbs, pathogens, outbreaks, zoonoses, mycotoxins, food safety, emerging hazards, and risk assessment.

2.2. RASFF database

In February 2014, the RASFF had products divided among the categories: food, feed, and food contact material. Product subcategories specified the product types, for example: eggs and egg products, meat and meat products, or herbs and spices. Hazards were also categorized into either their harmful effects on human health or their non-compliance to EU law. All 26 RASFF hazard categories were evaluated. RASFF notifications were divided into alerts, information (including attention and follow-up), border rejection, and news. A further explanation of these terms is available in Regulation (EU) No 16/2011. Additionally, these notification types were categorized by notification basis: official control on the market, border control (including consignment release, consignment detained, and consignment under customs), companies own check, food poisoning, consumer complaint, and monitoring of media. These notification subdivisions aimed to specify where the hazardous product was first indicated (e.g., on the market, at the border, or as an outbreak). The database also provided information about the country of origin, the country in which the hazard was notified, and the countries to which the product was distributed. However, the RASFF website asserts that the information concerning the country of origin may not represent the actual origin of the product; rather information that had been made available at the point of notification (European Commission, 2015b).

Generated data were exported to Excel and analyzed as described in Section 2.6. In addition to the frequency of notification (*i.e*. total notifications), total hazards were determined since a notification may cite multiple hazards within the same hazard category, with reference to another hazard category, and/or may report different levels of contamination. Thus, the difference between the total notifications (reported) and total hazards (calculated) was due to overlapping hazards and/or multiple analytical results within a notification (for one or more hazards). Based on the total notifications, top rated hazards categories were accessed to determine the frequency of reports by specific hazard (e.g., aflatoxin B_1, ochratoxin A) and re-evaluated to determine the total hazards.

2.3. European scientific agencies' reports

The DG SANTE, previously the DG SANCO, has provided annual reports that complement RASFF data regarding food poisoning cases. The reports summarize information including details regarding the number of notifications, the sources of contamination, the origin of the notifications, the products, and the countries involved (Rapid Alert System for Food and Feed, 2013). In addition, the number of people affected by the food poisoning cases was provided in the annual reports.

Between 2006 and 2015, the EFSA and the ECDC published ten summaries related to trends and sources of zoonoses, zoonotic agents, and antimicrobial resistance and foodborne outbreaks; these are based on data from 2004 until 2013 and are further referred to as EU summary reports (European Food Safety Authority & European Centre for Disease Prevention and Control, 2005, 2006, 2007, 2009, 2010, 2011, 2012, 2013, 2014, 2015). The EU summary reports covered the prevalence of pathogens in spices and herbs in addition to outbreaks of foodborne illnesses. These reports provided information on the prevalence such as number of samples taken, positive samples, sample size, sample unit, general product category, issuing country, sampling frame (place of sampling), sample weight, information on species (serotypes where applicable), *etc*. The annual reports also provided information on foodborne outbreaks from 2009 until 2013, such as causative agent species (serotypes where applicable), outbreak type (general or unknown), factor of outbreak (e.g., storage time/temperature abuse, inadequate heat treatment), *etc*.

2.4. WHO GEMS/Food contaminants database

Data extracted from the WHO GEMS/Food contaminants database were based on the following criteria: WHO European Region, all contaminations, food category herbs, spices, and condiments, and all food names. Generated data were exported to Excel and analyzed as described in Section 2.6. Additionally, contaminant names were parsed based on their subject name (e.g., type of mycotoxin), year, result value, result text, unit names, the limit of detection (LOD), and when available in EU legislation, the maximum level (ML).

2.5. Netherlands national monitoring database

The Netherlands Food and Consumer Product Safety Authority (NVWA) has collected annual monitoring and survey data for the presence of contaminants in food and feed. This information, alongside similar private monitoring data, has been compiled in the KAP database. As an example of national monitoring data for a chemical hazard in spices and herbs, mycotoxin monitoring data of various spices and herbs were investigated and were available from 2004 until 2006 and from 2009 until 2011. Generated data were exported to Excel and analyzed as described in Section 2.6. Similar to the WHO GEMS/Food contaminants database, contaminant names were parsed based on their subject name (e.g., type of mycotoxin), year, result value, result text, unit names, the LOD, and when available in EU legislation, the ML.

2.6. Data analysis

The RASFF database, the EU summary reports, and the WHO GEMS/Food contaminants database were obtained from the public domain of alerting and monitoring systems that addressed the 28 EU MS and the European Free Trade Association (EFTA) countries (Iceland, Sweden, Liechtenstein, and Norway), while use of the Netherlands national monitoring database was approved by the National Institute for Public Health and the Environment (RIVM). Data were collected from the period between 01/01/2004 and 01/01/2014 concerning spices and herbs, unless indicated otherwise. These data were divided into columns that followed similar descriptions as in the databases and evaluated in Microsoft Office Excel 2010 spreadsheets (Microsoft Corporation, Redmond, WA).

Data were classified according to the hazard category (e.g., pathogenic microorganisms, mycotoxins, contaminants) and sorted based on the following information: chronology of the number of notifications per quarter or per year, possible relationships between hazards categories and spice or herb products, and, when available, possible relationships between hazards categories and the country of origin. Additionally, when the selected source contributed information concerning the concentration, occurrence, and/or information on human cases, this was included for each of these hazard categories. Hazards with the highest number of notifications within each hazard category (*i.e.* top rated hazards) were further analyzed. When more than one data source contributed data to a top rated hazard, then the data were allocated to the steps of a risk assessment: hazard identification, hazard characterization, exposure assessment, and risk characterization.

Since the RASFF database serves as "an effective tool to exchange information about measures taken responding to serious risks detected in relation to food or feed," (Rapid Alert System for Food and Feed, 2015) total notifications and total reports are referred to interchangeably. Similarly, this is the case for total hazards and total reports per top rated hazard. On the other hand, the WHO GEMS/Food contaminants database and the KAP database reported both the total notifications, indicating the frequency of all reported samples, and the total reports, indicating the frequency of, for example values above the LOD and values, when available in EU legislation and the database, above the ML. In the end, total notifications or total reports were indicated per hazard category respective to the database or annual report. Data uncertainty was reported as a confidence interval (CI) of the sampling results with a 95% CI calculated by using binomial distributions (Clopper & Pearson, 1934; Van Doren et al., 2013).

3. Results and discussion

Biological and chemical hazards in spices and herbs are determined by using the aforementioned databases and annual reports alongside scientific literature and legislation. Data are then evaluated for their feasibility to support the microbiological and toxicological risk assessments of certain hazards in spices and herbs.

3.1. Biological hazards

3.1.1. RASFF database

Table 1 provides an overview of reports within the "herbs and spices" product category concerning the notification type and the hazard category frequency between 01/01/2004 and 01/01/2014. There were 1831 total notifications. The three top rated hazards were mycotoxins, pathogenic microorganisms, and composition.

3.1.1.1. Pathogenic microorganisms. Table 1 indicates 425 total notifications for pathogenic microorganisms. From these total notifications, 500 total hazards were determined (Table 2). Of these total hazards, the following spices and herbs were identified frequently: basil (20%), coriander (7%), and black pepper (7%). The remaining spices and herbs were reported at less than 7% (data not shown). Table 2 outlines the frequencies, percentages, and the levels of the hazards notified. Many "pathogenic microorganism" notifications included hazards such as coliforms, *Enterobacteriaceae*, sulfite reducing anaerobes, and fungi. The reported levels were microorganism dependent and either were not applicable (N/A), present in 25 g, or ranged from 10^1 colony forming units (CFU)/g to 10^8 CFU/g.

Based on the total reports per specific hazard, the most reported was *Salmonella* spp., of which the most reported products were

Table 1
RASFF reports within the herbs and spices product category between 01/01/2004 and 01/01/2014.

Category	Number of reports
	Frequency (*Percentage*)
Total	1831 (100)
Notification type	
Alert	448 (24)
Border rejection	534 (29)
Information	710 (39)
Information for attention	112 (6)
Information for follow-up	27 (1)
Hazard categories	
Adulteration/Fraud	13 (<1)
Allergens	8 (<1)
Biotoxins (other)	2 (<1)
Chemical contamination (other)	1 (<1)
Composition[a]	416 (23)
Food additives and flavorings	93 (5)
Foreign bodies	31 (2)
GMO/novel food	6 (<1)
Heavy metals	9 (<1)
Industrial contaminants	4 (<1)
Labelling absent/incomplete/incorrect	4 (<1)
Mycotoxins[a]	501 (27)
Non-pathogenic microorganisms	61 (3)
Not determined/other	1 (<1)
Organoleptic aspects	21 (1)
Packaging aspects	1 (<1)
Pathogenic microorganisms[a]	425 (23)
Pesticide residues	198 (11)
Poor or insufficient controls	8 (<1)
Radiation	28 (2)

[a] Indicates a top rated hazard.

Table 2
Microorganisms as reported in the hazard category pathogenic microorganisms in RASFF between 01/01/2004 and 01/01/2014.

Category	Number of reports	
	Levels (*CFU/g*)	*Frequency* (*Percentage*)
Total		500 (100)
Specific Hazards		
Aerobic Plate Counts[a]	2.5×10^5	1 (<1)
Aspergillus spp.[b]	5×10^5	3 (<1)
Bacillus spp.	1×10^3–3×10^8	41 (8)
Campylobacter spp.	Presence in 25 g	1 (<1)
Clostridium spp.	2×10^2–3×10^3	7 (1)
Coliforms	70–3×10^5	2 (<1)
Enterobacteriaceae[a]	4×10^3–4×10^4	6 (1)
Escherichia coli	10–3×10^5	61 (12)
Fungi[a]	3×10^3–6×10^4	6 (1)
Salmonella spp.	Presence in 25 g	369 (74)
Shigella spp.	N/A[c]	1 (<1)
Staphylococcus aureus	3×10^4	1 (<1)
Sulfite reducing anaerobes[a]	2×10^3	1 (<1)

[a] Overlaps with the RASFF hazard category non-pathogenic microorganisms.
[b] Only one notification had this level reported.
[c] N/A: not applicable.

basil (18%), coriander (9%), black pepper (8%), and peppermint (5%). *E. coli* was also frequently reported, of which the most reported products were basil (46%), mint (18%), peppermint (8%), and coriander (7%). *Bacillus* spp. were mainly reported in chili products (15%) and curry products (12%) (data not shown).

The three most notified pathogens in RASFF are chronologically depicted in Fig. 1. Although there is a large scatter, there is no apparent trend over time. *Salmonella* spp. were reported each quarter from 2004 until 2014. Based on the total hazards for *Salmonella* spp., Thailand (44%) and Vietnam (14%) were reported most frequently. From the 54 countries reported in RASFF, 45 of them notified *Salmonella* spp. at least once. Based on the total hazards for *E. coli*, Thailand (46%) and Vietnam (37%) were also reported frequently, while similarly for *B. cereus*, India (34%) was reported most frequently. Other countries were also reported, e.g., Turkey, Germany, but to a lesser extent (data not shown). Given the RASFF disclaimer, country of origin data should be carefully interpreted.

3.1.1.2. Food poisoning cases. From 2004 until 2007, food poisoning cases were mentioned in the category consumer complaints. These notifications also included undesirable chemicals, wrongful compositions of a food supplement, or deficient labelling (e.g., not mentioning an allergenic substance). Since 2008, the RASFF reports poisoning and outbreak cases; the herb and spice notifications for these cases are outlined in the next paragraph. The term “food poisoning” is used to cover incidents which affect more than one consumer from the same source of illness. This includes human cases caused by pathogenic bacteria or viruses and by toxic substances (Rapid Alert System for Food and Feed, 2009; 2014). A foodborne outbreak includes two or more people that have the same symptoms that can be traced back to the same source of the disease (Rapid Alert System for Food and Feed, 2013). When an outbreak involves one or more countries, it can be referred to as national or multinational outbreaks, respectively.

In 2008, *Bacillus pumilus* (51,000 CFU/g) in frozen ginger processed in Norway, with raw material from Thailand, affected 1 person (Rapid Alert System for Food and Feed, 2009). In 2011, *Shigella sonnei* in fresh basil (*Ocimum basilicum*) from Israel, via the Netherlands, affected 46 persons (Rapid Alert System for Food and Feed, 2011). Also in 2011, *B. cereus* (16,000 CFU/g), *Clostridium perfringens* (180 CFU/g) and *Salmonella* Caracas (presence/25g) in ground cumin from the United Kingdom affected 3 persons (Rapid Alert System for Food and Feed, 2011). The aforementioned cases were reported in the hazard category pathogenic microorganisms. In 2013, toxic herbal extracts in marshmallow (*Althea officinalis*) from Bulgaria, via Germany, affected 3 persons (Rapid Alert System for Food and Feed, 2014). Details were reported in the hazard category biotoxins. The RASFF database had not indicated how these were classified as food poisonings or how many people were affected by the contaminated product. The persons affected are reported in the RASFF annual reports, yet are based on information provided at the time of the original notification and do not necessarily include the total number affected (Rapid Alert System for Food and Feed, 2014).

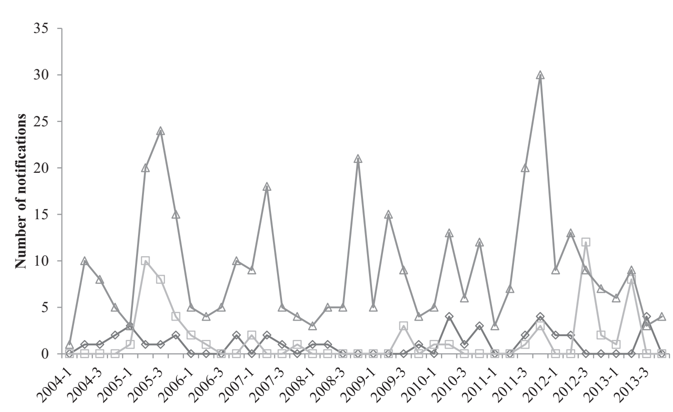

Fig. 1. Chronology of RASFF notifications for *Bacillus* spp. (◊), *E. coli* (□), and *Salmonella* spp. (△) in the product category herbs and spices.

3.1.2. European scientific agencies

3.1.2.1. Prevalence of pathogenic microorganisms. The EC adopted directive 2003/99/EC to monitor zoonoses and zoonotic agents in the EU/EFTA countries. This directive still provides rules for monitoring zoonoses, zoonotic agents, and related antimicrobial resistance. The directive also covers rules on epidemiological investigations of foodborne outbreaks and the exchange of information related to zoonoses and zoonotic agents (European Parliament & Council of the European Union, 2003). As a result of this directive, the EFSA and ECDC provide the EU summary reports, which illustrate trends in zoonotic prevalence, outbreaks, and foodborne illnesses. These results originate from a general EU surveillance program 'Monitoring of zoonoses and zoonotic agents,' which monitors zoonoses, antimicrobial resistance, and foodborne illnesses. These reports have not covered border investigations of imports; rather they mainly covered controls within the EU market, either at the industry or retailer, and focused on pathogens with antimicrobial resistant strains. Hence, data on pathogen prevalence in spices and herbs were provided under a general category, while further information on a specific spice or herb which was implicated was not available. Table 3 depicts the key results from the EU summary reports with respect to pathogen prevalence in spices and herbs.

3.1.2.2. Reported foodborne outbreaks. Since 2009, the EU summary reports provide information on foodborne outbreaks, which are defined as: "an incidence, observed under given circumstances, of two or more human cases of the same disease and/or infection, or a situation in which the observed number of human cases exceeds the expected number and where the cases are linked, or are probably linked, to the same food source" (European Parliament & Council of the European Union, 2003). The reports covered cases from 2006 until 2013 and provided detailed information such as the number of people affected and the food source implicated (European Food Safety Authority & European Centre for Disease Prevention and Control, 2011, 2012, 2013, 2014, 2015). Human cases reported between 2006 and 2013 are depicted in Fig. 2.

Between 2006 and 2013, there were nine foodborne outbreaks reported as a result of *B. cereus* intoxications from spices and herbs with around 350 people affected and nine outbreaks from *Salmonella* spp. with around 400 people affected. Although only three outbreaks concerned *E. coli*, pathogenic *E. coli* had the highest numbers of human cases reported with more than 500 people affected. In the aforementioned outbreaks, no deaths were reported.

In 2006, there was one outbreak with 260 people affected. In 2007, there were three outbreaks of which one was an outbreak

Table 3
Microorganisms reported in EU summary reports with the total number of spice and herb samples, prevalence, and the 95% confidence interval (CI) from 2004 until 2013.

Year	Microorganism	Total samples	Prevalence	95% CI (low-high)
2004	*Campylobacter* spp.	1	0	0–1
	L. monocytogenes	16	0	0–0.2
2005	*L. monocytogenes*	17	0	0–0.2
	Salmonella spp.	565	0.018	0.0085–0.032
2006	*L. monocytogenes*	62	0	0–0.1
	Salmonella spp.	192	0.052	0.025–0.094
2007	*Campylobacter* spp.[a]	5172	0	0–0.001
	L. monocytogenes	16	0	0–0.2
	Salmonella spp.[a]	5172	0.0046	0.003–0.007
2008	*Campylobacter* spp.	323	0	0–0.01
	L. monocytogenes	38	0	0–0.09
	Salmonella spp.	3781	0.020	0.015–0.025
2009	*Campylobacter* spp.	4	0	0–0.6
	L. monocytogenes	15	0	0–0.2
	Salmonella spp.	1349	0.001	0.0002–0.005
2010	*L. monocytogenes*	30	0.03	0.0008–0.2
	Salmonella spp.	1468	0.015	0.0094–0.023
	S. aureus (MRSA)	15	0	0–0.2
2011	*Campylobacter* spp.[a]	209	0.005	0.0001–0.03
	E. coli (VTEC)[a]	209	0	0–0.02
	L. monocytogenes	278	0.01	0.004–0.4
	Salmonella spp.	1809	0.0072	0.004–0.01
	S. aureus (MRSA)[a]	209	0	0–0.02
2012	*Campylobacter* spp.[a]	296	0	0–0.01
	E. coli (VTEC)[a]	296	0	0–0.01
	L. monocytogenes	286	0.03	0.01–0.06
	Salmonella spp.	2517	0.017	0.012–0.022
	S. aureus (MRSA)[a]	296	0	0–0.01
2013	*Campylobacter* spp.	45	0	0–0.08
	E. coli (VTEC)	851	0.004	0.001–0.01
	L. monocytogenes	1611	0.001	0.0002–0.004
	Salmonella spp.	5390	0.0093	0.0069–0.012
2004–2013	*Campylobacter* spp.	6050	0.0002	0–0.001
	E. coli (VTEC)	1356	0.002	0.0005–0.006
	L. monocytogenes	2369	0.0068	0.0039–0.011
	Salmonella spp.	22,243	0.0111	0.00977–0.0126
	S. aureus (MRSA)	520	0	0–0.007

[a] Pathogens investigated/detected within a year originate from the same total samples.

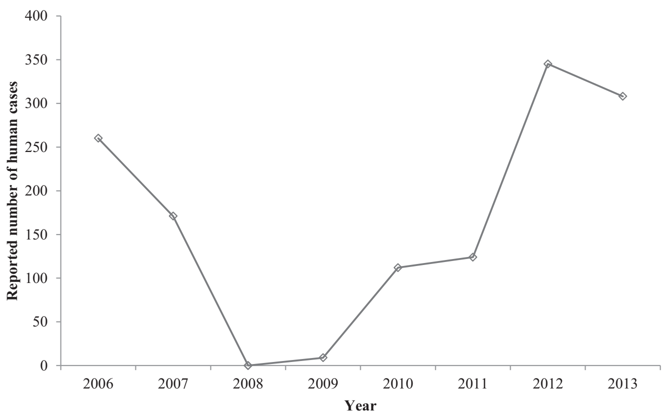

Fig. 2. Reported number of human cases from 2006 until 2013 in the EU summary reports concerning spices and herbs contaminated with pathogenic microorganisms.

that affected 145 people. In 2008, no outbreaks were reported, while in 2009, one outbreak was reported. In 2012, enterotoxigenic *E. coli* (ETEC) in chives from Norway affected 300 people. Also in 2012, there were two more outbreaks reported: one from *Salmonella* spp., which affected 41 people, and one from ETEC, which affected four people. In 2013, one outbreak with *Salmonella* spp. in fresh curry leaves from the UK affected more than 250 people.

3.2. Chemical hazards

3.2.1. RASFF database

3.2.1.1. Mycotoxins. Table 1 indicates 501 notifications for the hazard category mycotoxins. From these notifications, 1024 total hazards were determined of which the most frequently reported were aflatoxins (90%, with aflatoxin B_1 (49%) and non-specified aflatoxins (41%)), and ochratoxin A (10%) (Table 4). Non-specified aflatoxins were frequently reported together with aflatoxin B_1; 98% of the total non-specified aflatoxin notifications, of which 26% of these overlapping notifications occurred in 2010. Aflatoxins can be reported as B_1, as a total value, or a non-specific value within a notification. Additionally, a notification may have multiple analytical results reported. Furthermore, ochratoxin A was reported together with aflatoxin B_1 (20%) and with non-specific aflatoxins (12%), each based on total ochratoxin A notifications. The frequency by which aflatoxin B_1 was reported with non-specified aflatoxins and ochratoxin A was 2%, based on the total aflatoxin B_1 notifications.

The most reported products for aflatoxin B_1 were chilies (45%), nutmeg (18%), and paprika (10%), while for non-specified aflatoxins these same products were most frequently reported at 45%, 18%, and 9%, respectively. Ochratoxin A was mainly reported in paprika and chilies at 53% and 17%, respectively, and to a lesser extent in pepper (7%) and nutmeg (7%) (data not shown). For chilies, nutmeg, and paprika, in addition to other products reported for these mycotoxins, there were several product forms (e.g., ground, powder, crushed, dried, whole) reported in RASFF; however, all of these forms are reported according to the spice or herb (e.g., ground chilies and chili powder are both chilies).

Mycotoxin reports, in particular for aflatoxins in spices and herbs, had peak notifications during 2010 (Fig. 3). The substantial increase in notified hazards may be due to the Regulation (EC) No 669/2009 implementing Regulation (EC) No 882/2004 regarding the increased level of official controls on imports of certain feed and food of non-animal origin and amending Decision 2006/504/EC, which entered into force on the 25th of January 2010. This regulation imposed control measures for some products from certain countries with respect to the presence of aflatoxins (Rapid Alert System for Food and Feed, 2011). For spices from India, the control frequency was set at 50% during most of 2010 and 2011; however, in 2012, this control decreased to 20% for spices from India due to the decreased number of aflatoxin notifications between 2010 and 2011 (Rapid Alert System for Food and Feed, 2011). On the other hand, the increase may also be related to changes in prevalence or as a result of amendments to Regulation (EC) No 1881/2006. As expected, several notifications of aflatoxin B_1, 59% of the total aflatoxin B_1 notifications, and aflatoxin (non-specified), 60% of the total aflatoxin (non-specified) notifications, were reported to come from India (data not shown). Given the RASFF disclaimer, country of origin data should be interpreted carefully. Besides the reported origin, sometimes additional information can help to trace the route of the product such as the location of raw materials, manufacturing, packaging, processing, dispatch, and where the product has passed "via."

In order to control the presence of certain contaminants in foodstuffs, Commission Regulation (EC) No 1881/2006 sets MLs for aflatoxins and ochratoxin A in particular for spices. Commission Regulation (EU) No 165/2010 amends Regulation 1881/2006 with respect to MLs in aflatoxins for particular foodstuffs. The current ML for aflatoxin B_1 is 5.0 µg/kg and for the sum of aflatoxins (B_1, B_2, G_1, and G_2) is 10.0 µg/kg (European Commission, 2006, 2010b). These MLs are for the following species of spices: *Capsicum* spp. (dried fruits thereof, whole or ground, including chilies, chili powder, cayenne and paprika); *Piper* spp. (fruits thereof, including white

Table 4
Specific hazards as reported in the hazard category mycotoxins in RASFF between 01/01/2004 and 01/01/2014.

Category	Number of reports *Frequency (Percentage)*
Total	1024 (100)
Specific Hazards	
Aflatoxin B_1 [a]	497 (49)
Aflatoxins (non-specified) [a]	419 (41)
Ochratoxin A [a]	101 (10)
Salmonella Aequatoria [b]	1 (<1)
Sudan I [b]	3 (<1)
Sudan IV [b]	2 (<1)
Triazophos [b]	1 (<1)

[a] Indicates a top rated specific hazard.
[b] Indicates a non-mycotoxin hazard. This occurs since multiple hazards are reported within a single notification.

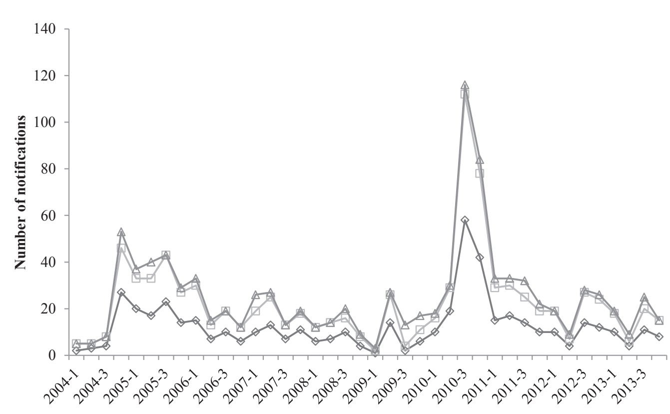

Fig. 3. Chronology of RASFF notifications for top rated specific mycotoxin hazards, aflatoxin B_1 (◊), aflatoxins (non-specified) (□), and ochratoxin A (△) in the product category herbs and spices.

and black pepper); *Myristica fragrans* (nutmeg); *Zingiber officinale* (ginger); *Curcuma longa* (turmeric), and mixtures of spices containing one or more of the abovementioned spices (European Commission, 2006, 2010b). More recently, Commission Regulation (EU) 2015/1137 also amended Regulation 1881/2006 with respect to MLs for ochratoxin A in particular for *Capsicum* spp. The current MLs for ochratoxin A depend on the spice or herb form. For *Capsicum* spp. (dried fruits thereof, whole or ground, including chilies, chili powder, cayenne and paprika), the ML is 20 μg/kg (European Commission, 2015a). However for spices, including dried spices, *Piper* spp. (fruits thereof, including white and black pepper), *Myristica fragrans* (nutmeg), *Zingiber officinale* (ginger), *Curcuma longa* (turmeric), as well as the mixtures of spices containing one of the abovementioned spices, the ML is 15 μg/kg (European Commission, 2006, 2010a, 2015a). For licorice root used as an ingredient for herbal infusions, there is a ML of 20 μg/kg (European Commission, 2006, 2012).

3.2.1.2. Composition. Table 1 indicates 416 notifications for the hazard category composition. From these notifications, 747 total hazards were determined of which the most frequently reported was Sudan I (50%), Sudan IV (30%), and Para Red (9%) (Table A1). Sudan IV was frequently reported with Sudan I; 87% of the total Sudan IV notifications, of which 43% of these overlapping notifications occurred in 2004. Also, Para Red was often reported with Sudan I, 52% of the total Para Red notifications, of which 76% of these overlapping notifications occurred in 2005. The most reported products for Sudan I were chilies (24%), spice mixtures (22%), and paprika (17%). For Sudan IV, these same products were most frequently reported at 27%, 20%, and 16%, respectively. Para Red was mainly reported in spice mixtures (56%), seasonings (19%), and to a lesser extent in spices (8%) (data not shown).

Chronologically, the trends in notifications reported for compositional hazards have been decreasing (Fig. A1). Sudan dyes are classified into group 3 “Not classifiable as to its carcinogenicity to humans” as reported by the International Agency for Research on Cancer (1987). In 2003, the EC adopted Decision 2003/460/EC on the emergency measures regarding the presence of Sudan I in chili and chili products (European Commission, 2003). With this decision, Sudan dyes became illegal to use in foodstuffs and, therefore, are notified through RASFF. In 2005, EFSA provided a scientific opinion for Sudan family dyes indicating strong evidence for both genotoxicity and carcinogenicity (European Food Safety Authority (EFSA), 2005). Products imported to the EU must comply with such EU laws, which are presently still enforced. Since 2005, the notification frequency has drastically decreased and in 2013 there were no reports. Furthermore, the chronological trend observed may be the result of the increased regulation of Sudan dyes in exporting/producing countries (e.g., third countries).

According to the 2012 RASFF annual report, illegal dyes were still reported, yet at a lower frequency. Hence, the Decision 2005/402/EC that required an analytical report for Sudan dyes with imported batches of chili, curry, curcuma, or palm red oil was repealed in 2010 and replaced with a prescribed 20% sampling at import as established by Regulation (EC) No 669/2009. Nevertheless, Sudan dyes were removed from this list during the second trimester of 2012 (Rapid Alert System for Food and Feed, 2013). Furthermore, some cases of Sudan I and Para Red still originate from within the EU. For example, Germany notified 8% of the total Sudan I notifications and 33% of the total Para Red notifications. With respect to non-EU countries, Turkey reported 17% and India reported 16% of the total Sudan I notifications. Similarly, Turkey reported 19% and India reported 16% of the total Sudan IV notifications. Russia reported 45% of the total Para Red notifications (data not shown). Given the RASFF disclaimer, country of origin data should be carefully interpreted.

3.2.2. WHO GEMS/Food contaminants database

3.2.2.1. Mycotoxins. In the WHO GEMS/Food contaminants database, several major groups of mycotoxins were notified including aflatoxin, ochratoxin, ergot alkaloids, patulin, and fusarium (data not shown). Aflatoxins were notified as six separate forms: aflatoxin (total), aflatoxin B_1, aflatoxin B_1 and B_2, aflatoxin B_2, aflatoxin G_1, and aflatoxin G_2. In comparison to the total notifications for all contaminants (n = 36,165), the most notified mycotoxins were aflatoxins (61%), which included the total samples notified for the six aforementioned aflatoxin forms, and ochratoxin A (13%) (Table 5). Similarly, in comparison to the total values above the LOD for all contaminants (n = 16,569), aflatoxins (47%) and ochratoxin A (19%) were reported most frequently (Table 5). Total notifications for the aforementioned mycotoxins peaked in 2011, while the 95% CI for total reports, either values above the LOD or ML, increased in 2012.

Based on the sum of total notifications for aforementioned mycotoxins, Germany notified mycotoxins most frequently at 58%. Similarly for total values above the LOD and ML, Germany reported frequently with 57% and 45%, respectively. The second most notifying and reporting country, based on the WHO European Region filter, was Finland with 8% of the total notifications, 21% of the values above the LOD, and 24% of the values above the ML, each based on total sum per respective category (data not shown).

3.2.2.2. Heavy metals. In the WHO GEMS/Food contaminants database, heavy metals notified included arsenic (inorganic), arsenic (total), cadmium, lead, and mercury. In comparison to the total notifications for all contaminants (n = 36,135), these heavy metals were notified frequently (24%) as total arsenic (6%), cadmium (8%), lead (8%), and mercury (2%). Inorganic arsenic was also notified, yet at frequency of less than 1% (Table A2). In comparison to the total values above the LOD for all contaminants (n = 16,569), heavy metals were reported frequently (34%) of which lead (12%), cadmium (12%), arsenic (total) (8%), and mercury (2%) were reported. Inorganic arsenic was also reported, yet at frequency of less than 1% (Table A2).

Commission Regulation (EC) No 1881/2006 sets a ML for cadmium of 0.2 mg/kg wet weight in fresh herbs (European Commission, 2006). However, MLs of aforementioned heavy metals in other herb forms or spices are not set. In general, reported notifications for heavy metals have a decreasing trend; however, there was an upward trend in 2011 for arsenic (total) and lead (Table A2). Total reports of cadmium above the ML (assumed for all herbs, spices, and condiments) only occurred in 2004.

Germany (29%), Italy (23%), and Slovakia (19%) notified heavy metals most frequently based on the sum of total notifications for aforementioned heavy metals. Similarly, Germany (29%), Italy (26%), and Slovakia (20%) reported most frequently based on the sum of total values above the LOD for aforementioned heavy metals. However, Germany (96%) reported most frequently, based on the sum of total values above the ML for cadmium (data not shown).

3.2.3. Netherlands national monitoring database (KAP)

3.2.3.1. Mycotoxins. In the KAP database, several groups of mycotoxins were notified such as aflatoxins, ochratoxins, fumonisins, *etc.* (data not shown) of which aflatoxin B_1 and ochratoxin A were most frequently reported. There were 569 and 353 total notifications for aflatoxin B_1 and ochratoxin A, respectively. Total values above the LOD and the ML were 435 and 111 reports, respectively, for aflatoxin B_1, while for ochratoxin A these were 299 and 92, respectively (Table 6).

Notifications for aflatoxin B_1 in spices (including mixed), herbs (including blended), and seasonings decreased over time since 2004. For ochratoxin A, there appears to be no distinct trend (Table 6). In general, total notifications and values above the LOD,

Table 5
WHO GEMS/Food contaminants database notifications (total samples), prevalence with values > the limit of detection (LOD) and values > maximum level (ML), in addition to the 95% confidence interval (CI) within the herb, spices and condiments food category for selected mycotoxins between 01/01/2004 and 01/01/2014.

Year	Contaminant	Total samples	Values > LOD[a]	95% CI (low-high)[b]	Values > ML[a,b,c]	95% CI (low-high)[b]
2004	Aflatoxin (total)	0	undefined	N/A	undefined	N/A
	Aflatoxin B_1	12	0	0–0.3	0	0–0.3
	Aflatoxin B_1 & B_2	0	undefined	N/A	N/A	N/A
	Aflatoxin B_2	1	0	0–1	N/A	N/A
	Aflatoxin G_1	1	0	0–1	N/A	N/A
	Aflatoxin G_2	0	undefined	N/A	N/A	N/A
	Ochratoxin A	7	0	0–0.4	0	0–0.4
2005	Aflatoxin (total)	0	undefined	N/A	undefined	N/A
	Aflatoxin B_1	7	0	0–0.4	0	0–0.4
	Aflatoxin B_1 & B_2	0	undefined	N/A	N/A	N/A
	Aflatoxin B_2	41	0	0–0.09	N/A	N/A
	Aflatoxin G_1	0	undefined	N/A	N/A	N/A
	Aflatoxin G_2	0	undefined	N/A	N/A	N/A
	Ochratoxin A	45	0	0–0.08	0	0–0.08
2006	Aflatoxin (total)	0	undefined	N/A	undefined	N/A
	Aflatoxin B_1	0	undefined	N/A	undefined	N/A
	Aflatoxin B_1 & B_2	0	undefined	N/A	N/A	N/A
	Aflatoxin B_2	0	undefined	N/A	N/A	N/A
	Aflatoxin G_1	0	undefined	N/A	N/A	N/A
	Aflatoxin G_2	0	undefined	N/A	N/A	N/A
	Ochratoxin A	0	undefined	N/A	undefined	N/A
2007	Aflatoxin (total)	263	0.605	0.543–0.664	0.004	0–0.02
	Aflatoxin B_1	550	0.576	0.534–0.618	0.022	0.011–0.038
	Aflatoxin B_1& B_2	263	0.605	0.543–0.664	N/A	N/A
	Aflatoxin B_2	547	0.247	0.211–0.285	N/A	N/A
	Aflatoxin G_1	547	0.234	0.199–0.272	N/A	N/A
	Aflatoxin G_2	547	0.055	0.037–0.077	N/A	N/A
	Ochratoxin A	598	0.662	0.623–0.700	0.087	0.066–0.11
2008	Aflatoxin (total)	286	0.500	0.441–0.559	0.003	0–0.02
	Aflatoxin B_1	609	0.540	0.500–0.580	0.01	0.006–0.03
	Aflatoxin B_1 & B_2	236	0.39	0.33–0.46	N/A	N/A
	Aflatoxin B_2	526	0.247	0.211–0.286	N/A	N/A
	Aflatoxin G_1	528	0.320	0.280–0.362	N/A	N/A
	Aflatoxin G_2	536	0.17	0.14–0.21	N/A	N/A
	Ochratoxin A	935	0.686	0.655–0.715	0.061	0.046–0.078
2009	Aflatoxin (total)	277	0.560	0.499–0.619	0.03	0.01–0.06
	Aflatoxin B_1	362	0.528	0.475–0.580	0.028	0.013–0.050
	Aflatoxin B_1 & B_2	195	0.45	0.38–0.52	N/A	N/A
	Aflatoxin B_2	292	0.33	0.28–0.39	N/A	N/A
	Aflatoxin G_1	293	0.32	0.26–0.37	N/A	N/A
	Aflatoxin G_2	291	0.24	0.19–0.29	N/A	N/A
	Ochratoxin A	443	0.605	0.558–0.651	0.072	0.05–0.10
2010	Aflatoxin (total)	614	0.588	0.548–0.627	0.018	0.009–0.032
	Aflatoxin B_1	740	0.562	0.526–0.598	0.045	0.031–0.062
	Aflatoxin B_1& B_2	457	0.488	0.441–0.535	N/A	N/A
	Aflatoxin B_2	569	0.320	0.282–0.360	N/A	N/A
	Aflatoxin G_1	569	0.295	0.258–0.335	N/A	N/A
	Aflatoxin G_2	570	0.223	0.189–0.259	N/A	N/A
	Ochratoxin A	535	0.677	0.635–0.716	0.14	0.11–0.17
2011	Aflatoxin (total)	851	0.532	0.498–0.566	0.038	0.026–0.053
	Aflatoxin B_1	1228	0.529	0.501–0.558	0.050	0.038–0.063
	Aflatoxin B_1& B_2	679	0.527	0.489–0.565	N/A	N/A
	Aflatoxin B_2	1137	0.221	0.197–0.246	N/A	N/A
	Aflatoxin G_1	1132	0.166	0.145–0.189	N/A	N/A
	Aflatoxin G_2	1126	0.109	0.0916–0.129	N/A	N/A
	Ochratoxin A	1056	0.682	0.653–0.710	0.0985	0.0812–0.118
2012	Aflatoxin (total)	770	0.448	0.413–0.484	0.11	0.088–0.13
	Aflatoxin B_1	982	0.425	0.393–0.456	0.098	0.080–0.12
	Aflatoxin B_1& B_2	119	0.32	0.24–0.41	N/A	N/A
	Aflatoxin B_2	869	0.143	0.12–0.168	N/A	N/A
	Aflatoxin G_1	872	0.163	0.139–0.189	N/A	N/A
	Aflatoxin G_2	868	0.11	0.089–0.13	N/A	N/A
	Ochratoxin A	1012	0.610	0.579–0.640	0.114	0.0947–0.135
2013	Aflatoxin (total)	137	0.69	0.60–0.76	0.03	0.008–0.07
	Aflatoxin B_1	155	0.729	0.652–0.797	0.04	0.01–0.08
	Aflatoxin B_1 & B_2	31	0.2	0.07–0.4	N/A	N/A
	Aflatoxin B_2	151	0.56	0.47–0.64	N/A	N/A
	Aflatoxin G_1	151	0.61	0.53–0.69	N/A	N/A

Table 5 (*continued*)

Year	Contaminant	Total samples	Values > LOD[a]	95% CI (low-high)[b]	Values > ML[a,b,c]	95% CI (low-high)[b]
	Aflatoxin G_2	151	0.56	0.48–0.64	N/A	N/A
	Ochratoxin A	116	0.64	0.54–0.73	0.13	0.074–0.20
2004–2013	Aflatoxin (total)	3198	0.5347	0.5172–0.5521	0.0441	0.0372–0.0518
	Aflatoxin B_1	4645	0.5238	0.5093–0.5382	0.0487	0.0426–0.0552
	Aflatoxin B_1 & B_2	1980	0.487	0.465–0.509	N/A	N/A
	Aflatoxin B_2	4133	0.2424	0.2294–0.2558	N/A	N/A
	Aflatoxin G_1	4093	0.239	0.226–0.253	N/A	N/A
	Aflatoxin G_2	4089	0.152	0.141–0.164	N/A	N/A
	Ochratoxin A	4747	0.6484	0.6346–0.6620	0.0946	0.0864–0.103
2004–2013	Selected mycotoxins	26,885	0.40134	0.39547–0.40723	0.0304	0.0300–0.0342
	Other contaminants	9250	0.6248	0.6148–0.6346	N/A	N/A
	Total contaminants	36,165	0.45853	0.45300–0.46330	N/A	N/A

[a] Undefined: value cannot be divided by zero.
[b] N/A: not applicable.
[c] MLs are based on Commission Regulation (EC) No 1881/2006. Due to regulation amendments, the following MLs were utilized for all spices and herbs, mixtures, or products thereof: aflatoxin B_1 (5.0 μg/kg), the sum (total) of aflatoxin B_1, B_2, G_1, and G_2 (10.0 μg/kg), and ochratoxin A (15 μg/kg).

for both aflatoxin B_1 and ochratoxin A, respectively, coincide more closely after 2005. Monitoring reports for 2007, 2008, 2012, and 2013 were not stored in the KAP database. From 2005 to 2006, the upper 95% CI for the prevalence of values above the ML (based on Regulation 1881/2006), shifted upward for both aflatoxin B_1 and ochratoxin A. Even though the MLs were generalized for all herbs and spices, this shift resulted from both an increase in prevalence as well as the reduced sample size between these years (Table 6).

The percentage of occurrence by product type was also determined (data not shown). Monitoring data for aflatoxin B_1 indicated the most reported values above the LOD and the ML in paprika (26% and 19%), white pepper (16% and 14%), and nutmeg (13% and 30%). Other products reported less frequently included chili powder/cayenne (11% and 8%) and turmeric (10% and 8%), each of which are based on total sum per respective category. Monitoring data for ochratoxin A indicated the most reported products as paprika (42% and 51%) and chili powder/cayenne (18% and 15%), while nutmeg (6% and 12%) was found less frequently, each of which are based on total values above the LOD the ML, respectively.

With respect to the origin, the most frequent total notifications, values above LOD and values above the ML for aflatoxin B_1 were from India (27%, 31%, and 26%), unknown (31%, 30%, and 31%), and from Indonesia (9%, 9%, and 19%), respectively, of which each percentage is based on the total sum per respective category (data not shown). Similarly for ochratoxin A, these were unknown in origin (40%, 37%, and 34%), from India (22%, 24%, and 27%), from the Netherlands (11%, 13%, and 16%), and to a lesser extent from Turkey (8%, 9%, and 7%), respectively (data not shown). Similar to the RASFF disclaimer, care should be taken when evaluating the country of origin.

3.3. Relevance of data for the risk assessment of spices and herbs in the EU

3.3.1. What is a risk assessment?

The general principles of risk assessments, as defined by Codex Alimentarius, indicate that risk assessments should be conducted with a transparent and structured approach. This approach includes four elements: hazard identification, hazard characterization, exposure assessment, and risk characterization (Codex Alimentarius Commission, 2015). These elements are applicable to a Microbiological Risk Assessment (MRA) and a Toxicological Risk Assessment (TRA), yet sometimes during the TRA, the hazard identification and hazard characterization steps are combined and referred to as the hazard assessment. Furthermore, an MRA and a TRA have some more intricate differences. For example, a TRA focuses more on the long term rather than acute exposure. Other

Table 6
KAP database notifications (total samples), prevalence with values > the limit of detection (LOD) and values > maximum level (ML), in addition to the 95% confidence interval (CI) within herbs and spices for aflatoxin B_1 and ochratoxin A from 2004 until 2006 and 2009 until 2011.

Year	Mycotoxin	Total samples	Values > LOD	95% CI [low-high]	Values > ML[a]	95% CI [low-high]
2004	Aflatoxin B_1	168	0.607	0.529–0.681	0.17	0.12–0.24
	Ochratoxin A	35	0.57	0.39–0.74	0.1	0.03–0.30
2005	Aflatoxin B_1	151	0.58	0.50–0.66	0.06	0.03–0.1
	Ochratoxin A	70	0.47	0.35–0.59	0.06	0.02–0.1
2006	Aflatoxin B_1	62	0.92	0.82–0.97	0.21	0.12–0.33
	Ochratoxin A	34	0.94	0.80–0.99	0.32	0.17–0.51
2009	Aflatoxin B_1	61	1.0	0.94–1.0	0.31	0.20–0.44
	Ochratoxin A	79	1.0	0.95–1.0	0.43	0.32–0.55
2010	Aflatoxin B_1	59	1.0	0.94–1.0	0.36	0.24–0.49
	Ochratoxin A	71	1.0	0.95–1.0	0.30	0.19–0.42
2011	Aflatoxin B_1	68	1.0	0.95–1.0	0.29	0.19–0.42
	Ochratoxin A	64	1.0	0.94–1.0	0.28	0.18–0.41
2004–2006; 2009–2011	Aflatoxin B_1	569	0.764	0.727–0.799	0.195	0.163–0.230
	Ochratoxin A	353	0.847	0.805–0.883	0.261	0.216–0.310

[a] MLs are based on Commission Regulation (EC) No 1881/2006. Due to regulation amendments, the following MLs were utilized for all spices and herbs, mixtures, and products thereof: aflatoxin B_1 (5.0 μg/kg) and ochratoxin A (15 μg/kg).

differences include the use of *in vitro* model data, animal based toxicity studies, or molecular biological 'omics' techniques during the hazard identification step for the TRA and the use of bacterial growth/survival models and epidemiological studies during an MRA. Nevertheless, the data used for both types of risk assessments should be unbiased and such that uncertainty or variability in the risk estimate can be determined, while data and data collection systems should be of sufficient quality and precision that uncertainty in the risk estimate can be minimized (Codex Alimentarius Commission, 2015).

3.3.2. Data on microbiological hazards for Microbiological Risk Assessment (MRA)

For microbiological hazards, the RASFF database can provide information on pathogenic species, associated products, and levels of microorganisms. When certain organisms and levels are reported, the information can be used in parts of the MRA such as the hazard identification and hazard characterization steps; however, these data should be interpreted carefully since data from monitoring systems are often based on targeted actions rather than on random sampling. Therefore, if a certain hazard food combination is not reported, it does not necessarily mean that it is an improbable combination, rather that the combination might not have been investigated or previously considered.

The EU summary reports can also provide data on pathogenic species, prevalence, and associated products. These data can largely fluctuate due to the differences in prevalence, but also due to varying attention for specific organisms, substances, or food commodities. The function of each monitoring system may vary, but, in principal, is based on guidelines set by the EU or national authorities. Data on the pathogen prevalence in spices and herbs from the EU summary reports can be used for the hazard identification and exposure assessment steps. These reports also provide information on the outbreak frequency associated with the consumption of spices and herbs, the number of people affected, and the particular food that was implicated. From these data, *Salmonella* spp. and pathogenic *Bacillus* spp. are the most relevant hazards in black pepper and dried herbs, whereas for fresh herbs the most relevant hazard was pathogenic *E. coli*. Data on human cases can contribute to hazard characterization and exposure assessment steps, while prevalence data can provide an estimation of initial counts.

Although, all the data collected from all the investigated sources may be biased or sometimes limited to the scope of the monitoring and alerting systems, these data can contribute to hazard identification, hazard characterization, and exposure assessment steps. An example of how these data can contribute to an MRA is presented with *Salmonella* spp. and *B. cereus* in pepper.

Based on the total reports per specific hazard in the RASFF hazard category "pathogenic microorganisms," the most reported organism was *Salmonella* of which black pepper was reported (8%). Similarly in the EU summary reports, *Salmonella* spp. were the most important pathogens in spices and herbs (14% prevalence), which was particularly the case for black pepper. The EU summary reports also indicated two *B. cereus*-pepper related outbreaks, which resulted in 164 cases and no hospitalizations. The cause was attributed to inadequate heating/chilling treatments. This information supports the hazard identification step indicating that *Salmonella* spp. and *B. cereus* are a potential concern in pepper and, to a certain extent, supports the hazard characterization step for *B. cereus* given the foodborne outbreak data.

The RASFF and EU summary reports sometimes provide information relevant for hazard characterization, as aforementioned, and exposure assessment. However, the outbreaks reported in RASFF had no data regarding *Salmonella* spp. or *B. cereus*-pepper outbreaks. Furthermore, the EU summary reports did not indicate the dose that initiated the *B. cereus*-pepper outbreaks, because they were based on descriptive epidemiological evidence. Even though some outbreaks reported that the agent was identified with analytical epidemiological evidence - implying that the level of ingested microorganisms was determined - the amount of the causative agent was not indicated. In this instance, the outbreak reports can partly contribute to hazard characterization, yet not to the exposure assessment of *Salmonella* spp. and *B. cereus* in pepper.

3.3.3. Data on chemical hazards for Toxicological Risk Assessment (TRA)

Similarly for chemical hazards, the RASFF database can provide information on chemical agents of concern, associated products, and traceability aspects such as the route of entry into or within the EU. During a TRA, the potential agents of concern and associated products can support the hazard identification step, while the traceability aspects can support the exposure assessment step. As aforementioned, RASFF data on hazard product combinations should be interpreted carefully as monitoring efforts may target specific, previously known, hazard-product combinations, yet in a more bias manner since these alerts can be based on previous notifications.

The WHO database provides corresponding data and information on sampling plans for a reporting MS. For example, the potential agents of concern and associated products can support hazard identification, while the monitoring data can support exposure assessment. Unfortunately, the WHO database notifications are often generally categorized under spices or sauces and condiments; thus, a transparent product is difficult to determine. In general, from the RASFF and WHO databases, aflatoxins and ochratoxin A appear to be relevant hazards especially in spices.

The KAP database is an example of a national MS database. This data can be used in a similar fashion for a TRA as the WHO database; however, a TRA specific to the Dutch situation would be applicable. Furthermore in the KAP database, the product type is more clearly stated in comparison to the product descriptions made available in the WHO GEMS/Food contaminants database. Therefore, identifying a chemical agent of concern and a specific spice or herb product, *i.e.* a hazard-product combination, is possible. KAP data on aflatoxin B_1 indicated spices of concern such as chilies (including chili powder/cayenne), paprika, nutmeg, pepper (white), and possibly turmeric. Similarly for ochratoxin A, spices of concern include paprika, chilies (including chili powder and cayenne), and possibly nutmeg and pepper.

Data from these sources may be biased and sometimes limited to the scope of the alerting or monitoring database. Nevertheless, this data can contribute to hazard identification and partly to exposure assessment during a TRA. An example of how these data sources can contribute to a TRA are presented with aflatoxin B_1 and ochratoxin A in paprika.

Based on the total reports per specific hazard in the RASFF hazard category "mycotoxins," aflatoxin B_1 and ochratoxin A were most reported of which paprika was notified 10% and 53%, respectively. Similarly in the WHO database, aflatoxin B_1 and ochratoxin A were each notified 13% with 52% and 47% of these notifications occurring above the LOD, respectively. From the KAP database, aflatoxin B_1 values above the LOD and the ML were 26% and 19%, respectively, for paprika. Similarly, ochratoxin A values were 42% and 51%. This information supports the hazard identification step indicating that aflatoxin B_1 and ochratoxin A are a potential concern in paprika.

The RASFF, WHO GEMS/Food contaminants, and KAP databases sometimes provide exposure assessment information like traceability aspects or monitoring plans. In RASFF, several notifications of aflatoxin B_1, 59% of the total aflatoxin B_1 notifications, were from India. Based on the total ochratoxin A notifications, 24% and 21% were from Peru and India, respectively. Despite the RASFF country of origin disclaimer, this information provides an idea about traceability aspects like the source and magnitude of the hazard exposure and potentially that of the notified country. Additionally, this information can help to set policies on imports and exports of a certain product in order to prevent heightened exposure (e.g., the control frequencies of spices from India) (European Commission, 2009). The WHO GEMS/Food contaminants database provides a general comparison of national monitoring plans between MS for mycotoxins and confirms the unsafety in the herb, spice and condiment commodities. For example, Germany notified 45% of the total mycotoxin values above the ML, with 11% from aflatoxin B_1 and 29% from ochratoxin A. Similar to RASFF, the KAP database origin data should be carefully utilized. For both mycotoxins, paprika was generally unknown in origin. Values above the LOD and ML were 43% and 38%, respectively for aflatoxin B_1 and 45% and 38%, respectively for ochratoxin A. Each percentage was based on the total LOD or ML for paprika. In this instance, these data can partly contribute to exposure assessment for aflatoxin B_1 and ochratoxin A in paprika.

3.4. Possibilities and limitations

An overview of how the selected data sources can be incorporated into the risk assessment of identified hazards in spices and herbs in the EU alongside the strengths of weaknesses of these sources are depicted in Table 7.

3.4.1. RASFF

RASFF sometimes provides background information on a hazard (e.g., concerning traceability, levels of contamination, and the presence of positive samples). However, only some RASFF notifications differentiate *B. cereus* strains; these strains can cause either diarrheal or emetic syndromes, yet each one has different dose responses (Stenfors Arnesen, Fagerlund, & Granum, 2008). Szeitz-Szabó and Szabó (2007) also recognize the resourcefulness of RASFF data for risk assessment purposes and propose that the availability of supplementary data such as the ratio of total/tested/positive lots for mycotoxins could be used for risk assessments. Also, RASFF tries to acknowledge food poisoning cases such as the agent, the dose of the agent in the food, the food implicated, and how many persons had been affected. In an EFSA technical report from the working group on emerging risks, data from regulatory sources, the main example being RASFF data, are considered one of four types of data inputs when trying to identify reliable data and information sources for emerging risks (European Food Safety Authority, 2009). Furthermore, RASFF has been recognized as an essential, up-to-date system, which is consulted more frequently by stakeholders when forming food safety opinions concerning fresh produce than reports from international organizations, legislative documents, national reports, or informal contact exchanges, respectively (Van Boxstael et al., 2013).

On the other hand, RASFF data does not always specify the pathogenic species of microorganisms such as *Bacillus* spp., or the severity of chemical agents (e.g., genotoxic, carcinogenic, mutagenic). Additionally, cases of food poisoning, according to the RASFF definition, are very limited and have mainly pertained to biological

Table 7
Overview of the possibilities and limitations of selected data sources for the risk assessment of herbs and spices within the EU.

Source	RA[a]	RA Step[b]	Data type	Possibilities	Limitations
RASFF portal database and annual reports	MRA	HI, HC	Associated products Reported hazards	• Able to identify the relationship between hazards and products	• Biased information • Details on hazards are inconsistently reported
		HI, EA	Level of hazards	• High number of data available	• Product type may be misinterpreted
		EA	Prevalence	• Publically accessible	
	TRA	HI	Associated products Reported hazards	• Sometimes hazard levels are reported	
		EA	Traceability aspects		
EFSA/ECDC annual reports	MRA	HI	Associated products Reported hazards	• Explicit information on microbial identity	• Annual reports (2012 and 2013) are under revision
		HC	Foodborne outbreaks Number of cases Product implicated	• High number of data available • Publically accessible • Sometimes detailed information on hazard levels are reported	• Biased information • Data not harmonized among member states – interpret reports with care.
		EA	Level of hazards Prevalence	• Specified "strong-evidence" and "weak-evidence" outbreaks	• Data not necessarily derived from statistically designed sampling plans • Product type may be misinterpreted
WHO GEMS/Food contaminants database	TRA	HI	Associated products Reported hazards	• Able to identify important hazards in a general product category	• Biased information • Details on hazard levels are sometimes limited
		EA	Monitoring plans	• Provides insight into a member state's monitoring priorities • Publically accessible	• Product type may be misinterpreted • Reporting is inconsistent and monitoring can also depend on a member state's objectives • Specific relationship between hazards and products difficult to identify
Netherlands national monitoring database KAP	TRA	HI	Associated products Reported hazards	• Able to identify the relationship between hazards and products	• Biased information • Data inconsistently monitored over the years
		HI, EA	Levels of hazards	• Details on sampling plans and sometimes on hazards	• Improved methods in detection and policy changes are not reported alongside data
		EA	Monitoring plans Traceability aspects	• High number of data available • Specific data for a member state	• Not publically accessible • Specific data for a member state

[a] RA: Risk Assessment; MRA: Microbiological Risk Assessment; TRA: Toxicological Risk Assessment.
[b] HI: Hazard Identification; HC: Hazard Characterization; EA: Exposure Assessment.

hazards. In some instances, RASFF notifications, e.g., food poisoning cases can provide data on reported outbreaks which can mainly be used to obtain (or estimate) the necessary parameters of dose response models of microorganisms, which can cause severe or serious effects.

Although prevalence data are sometimes available, these data have to be used with care since microorganisms, including mycotoxins, within foods, and especially dried matrixes, are heterogeneously distributed (Jongenburger, Reij, Boer, Zwietering, & Gorris, 2012); consequently, appropriate sampling, milling, and homogenization of food samples are critical to obtaining reliable analytical results (Köppen et al., 2010). Although notification reporting and interpretation is the responsibility of each MS, hazard overlapping can instigate over-reporting. The overlap in notifications for product categories poses a limitation as to which hazards need to be identified. Hazards may be inconsistently sampled and/or reported as notifications can be based on what was monitored and detected, which in turn may influence subsequent, and possibly more frequent, monitoring and notifications. Hence, when evaluating the food safety concern for a certain product, the hazard may be overestimated. Furthermore, data which accompanies RASFF notifications are not always consistent regarding relevant information on the hazards identified. In many cases, editing mistakes occur (e.g., products and hazards are misspelled), categories are misrepresented (e.g., non-pathogens in the category pathogenic microorganisms), or relevant information for early identification may be unintentionally omitted (e.g., since it does not pose a concern for a MS). Also, certain organisms, agents, and commodities are barely investigated. Thus, underreporting may very well occur.

Despite the limitations of RASFF data to be used for risk assessments, the data can be used, alongside other supplemental information such as the anticipated health and trade impacts, as inputs for identifying emerging, or re-emerging, hazards (Kleter & Marvin, 2009; Marvin, Kleter, Prandini, Dekkers, & Bolton, 2009) and to help define the scope for risk ranking approaches that aim to prioritize food and feed related concerns (EFSA Panel on Biological Hazards, 2015; van der Fels-Klerx et al., 2015). Nevertheless, the data reported in the RASFF portal should be utilized carefully as the alerted information may be seen as biased since notifications can influence further reporting. In general, RASFF provides information that can be used for hazard identification and exposure assessment, and sometimes along with the annual reports, information for hazard characterization.

3.4.2. European scientific agencies

As for European scientific agencies like the EFSA and the ECDC, quantitative data on prevalence can be retrieved from the reports on monitoring zoonoses and zoonotic agents. The calculated CI showed the level of uncertainty, but not the likelihood of the hazard occurrence in the final product. Although the EU summary reports provide more detailed information regarding foodborne outbreaks associated with spice and herb consumption in the EU, the reports omit the doses responsible for the outbreaks. Furthermore, patterns of consumption of spices and herbs in the EU and EFTA countries could not be retrieved from the investigated EU sources. Prevalence data from these reports also included some bias, which is dependent on the manner in which a competent authority reports this data. For example, while some countries consistently provide data on spices and herbs each year, other countries have not (data not shown). In general, the EU summary reports provide information that can be used for hazard identification, hazard characterization, and exposure assessment.

3.4.3. WHO GEMS/Food contaminants and KAP databases

Databases like the WHO GEMS/Food contaminants database and national monitoring data provide quantitative data on the concentration of contaminants in spices and herbs. Data from these sources can, to a certain extent, support an exposure assessment since an exposure level of a substance can be quantified; however, the incidence and severity of an effect remains less apparent. Therefore, additional data like food questionnaires, production volume data, environmental monitoring data, bioaccumulation data, exposures routes, or uptakes of agents can help to make the risk assessment holistic. However, such information is not always available or accessible. On the other hand, when monitoring data are available, e.g., KAP, these data can help to identify other hazards and quantify the exposure. For example, national monitoring data can be used for trend analyses e.g., by identifying product-hazard combination tendencies, and as input for national risk assessments.

Overall, these sources can support hazard identification. Additionally, the source, type, magnitude and duration of contact with a certain agent may be elucidated (*i.e.* exposure assessment); however, the incidence and severity of the effect is less acknowledged with these data sources.

4. Conclusions

This study represents a detailed investigation of data from alerting and monitoring databases and scientific literature to be used for the risk assessment of microbiological and chemical hazards in spices and herbs. Biological hazards, in particular pathogenic microorganisms such as *Salmonella* spp. and pathogenic *Bacillus* spp., are potentially a concern in black pepper and dried herbs. Chemical hazards, in particular mycotoxins such as aflatoxins (B_1) and ochratoxin A, are potentially a concern in chilies (chili powder and cayenne), paprika, and nutmeg. All investigated data sources can be used for hazard identification in spices and herbs. Even though these investigated sources provide additional information required for hazard characterization and/or exposure assessment steps, these investigated sources do not provide all the necessary data to complete a risk assessment. Thus, other open data sources that can help complete the risk characterization step should be investigated in order to complete a comprehensive risk assessment on spices and herbs. Nonetheless, the aforementioned data sources can provide relatively consistent information on a fundamental step during a risk assessment: hazard identification.

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Appendix A. Supplementary data

Supplementary data related to this article can be found at http://dx.doi.org/10.1016/j.foodcont.2016.04.010.

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