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| 1 | Determining common | contributory factors in | food safety incidents | <ul> <li>a review of global of</li> </ul> | outbreaks |
|---|--------------------|-------------------------|-----------------------|---|-----------|
|   |                    |                         |                       |   |           |

and recalls 2008-2018

# 2

3

# 4 Abstract

- 5 Background: Global food safety incidents are frequently reported and are on the rise. Although the
- 6 increase in number of food safety incidents is impacted by improved surveillance and reporting
- 7 systems and increased awareness from consumers, nevertheless the increase in food safety issues is
- 8 a threat to public health and the economic costs of countries and businesses. Hence, identifying the
- 9 root causes of contamination or recall is critically needed to understand the source of contamination
- 10 in foodborne outbreaks and product recalls, thus helping food businesses to develop risk mitigating
- 11 strategies.
- 12
- 13 Scope and Approach: This study aims to identify common contributory factors in food manufacturing
- 14 incidents leading to potential food safety incidents (e.g. product withdrawals and recalls, food
- poisoning incidents and legal offences), and to near misses. This study reviews published food safety incidents and recalls collated from official websites (e.g. Center for Disease Control and Prevention,
- 17 Rapid Alert System for Food and Feed, Food Standards Australia New Zealand) and journal databases
- (e.g. Science Direct, PubMed). Ishikawa cause and effect analysis was used along with published
- 19 information to identify possible root causes.
- 20

21 Key Findings: The total specific food safety incidents and/or recalls with known or suspected causes

- found over the period 2008-2018 is 2932. Where possible, the contributory and root causes of incidents were identified, or literature evidence was used to determine the suspected cause.
- 24 Undeclared allergens and cross contamination were identified as the top two recorded causes of
- 25 food safety incidents/recalls. This review has further proposed the primary and secondary causes for
- 26 undeclared allergens and cross contamination.
- 27

28 Conclusions: This study offers key insights into global food safety incidents according to food and

- 29 drink categories, hazards and common contributory factors. Food manufacturers could use the
- identified primary and secondary causes as guidance for continuous improvement programmes toprevent food safety incidents.
- 32

33 **Keywords:** cross contamination; hazards; root cause analysis; undeclared allergens

34

# 35 Highlights

- Food safety incidents were frequently reported in raw fish and ready-to-eat meals.
- Incidents involve all 4 hazard categories (biological, chemical, physical, allergen).
- Cross contamination and undeclared allergens are the most frequently cited causes of incidents.
- Overall causes for incidents were reasonably detailed but there is limited information on root
- 40 causes.
- Primary and secondary causes for unidentified allergens and cross contamination were
- 42 proposed.
- 43

#### 44 Introduction

45 Food safety incidents are frequently reported in the food supply chain and numbers are on the rise. 46 A food safety incident occurs when the safety of the food has been compromised and actions are 47 required to protect consumers (FSA, 2019). Examples of food safety incidents include contamination 48 of food products such as the recent South African Listeria monocytogenes outbreak in polony (a local 49 cold meat) (Boatemaa et al., 2019) and deliberate adulteration of food and feed for economic gain 50 e.g. substituting beef with horsemeat (FSAI, 2013). Although the increase in number of food safety 51 incidents is impacted by improved surveillance and reporting systems and increased awareness from 52 consumers, nevertheless the increase in food safety issues is a cause for concern. Foodborne 53 diseases are prevalent globally and are major causes of morbidity and death. Recent estimates 54 revealed norovirus and Campylobacter as the most frequent causes of foodborne illness. Deaths 55 were attributed to non-typhoidal Salmonella enterica, Salmonella Typhi, Taenia solium, hepatitis A 56 virus and aflatoxin (WHO, 2015). Food safety issues often result in food recalls which are a threat to 57 economic cost of businesses and countries.

58

59 Recent foodborne disease outbreaks include Listeria monocytogenes in South Africa, which infected 60 1060 patients of whom 216 died. The outbreak was traced to a ready-to-eat (RTE) processed meat 61 plant where the Listeria outbreak strain was identified in patient isolates, polony and the processing 62 environment (Boatemaa et al., 2019). However, the source of contamination e.g. how the outbreak strain was introduced into the factory and how it was transferred to food products remain 63 64 undetermined (Whitworth, 2018). Another international listeriosis outbreak in the EU affected 47 65 patients and resulted in 9 fatalities between 2015 – 2018. Frozen corn was identified as the likely 66 source of outbreak of Listeria monocytogenes serogroup IVb, but matching strains of L. 67 monocytogenes were also found in other frozen vegetables (ECDC, 2018a; ECDC-EFSA, 2018). Further 68 investigations were recommended to identify the source of contamination (ECDC, 2018b). These 69 examples highlight the need to determine the root cause of the incidents and why the 70 contamination occurred. Cross contamination of food and beverages can occur at all food processing 71 stages. Nerin, Aznar and Carrizo (2016) reviewed the food processing steps that can contribute to 72 food contamination such as external raw food contamination, during transportation, cleaning 73 processes, heating, food packaging and during food storage. The various sources, routes and 74 contributors of contamination were emphasised by Kase, Zhang and Chen (2017) who reported that 75 contamination events leading to outbreaks could occur before, during and after food processing. Hence, identifying the causes of contamination or recall is critically needed to understand the 76 77 potential sources and routes of contamination of foodborne outbreaks and product recalls, and to

develop steps to mitigate their occurrence. To date, there remains limited data on contributory
factors associated with food safety incidents; thus further comprehensive review of reported food
safety incidents and recalls is needed.

81

82 Potter et al. (2012) conducted a review of product recalls in the agri-food industry in the USA, UK 83 and Ireland from 2004-2010. Official sites such as US Food and Drug Administration, US Department of Agriculture Food Safety and Inspection Service, UK Food Standards Agency and Food Safety 84 85 Authority of Ireland were used. Researchers found that operational hazards (including mislabelling, packaging defects, product contaminations, production defects, unauthorised ingredients, incorrect 86 87 ingredient level and food fraud) were the most frequent recall type (Potter, Murray, Lawson, & 88 Graham, 2012). The Rapid Alert System for Food and Feed (RASFF) System is also often reviewed and 89 analysed by researchers to determine, for example, allergen-related recalls (Padua, Moreira, 90 Moreira, de Vasconcelos, & Barros, 2019), food products contaminated with Listeria monocytogenes 91 (Luth, Boone, Kleta, & Al Dahouk, 2019), food product notifications' trends (D'Amico et al., 2018), 92 food safety issues (Djekic, Jankovic, & Rajkovic, 2017; Kleter, Prandini, Filippi, & Marvin, 2009) and 93 for prediction of food safety incidents (Bouzembrak & Marvin, 2019) and fraud (Bouzembrak, & 94 Marvin, 2016). Reviews of RASFF data carried out to date were topic-specific, e.g. focused on specific 95 food safety issues, food and drink categories or affected countries. There is little research that 96 examined the contributory factors and root causes of food safety incidents and lessons learned 97 (Kase et al., 2017). Thus, this study aims to identify common contributory factors in food 98 manufacturing incidents (e.g. incidents resulting in product withdrawals and recalls, food poisoning 99 incidents and legal offences) and near misses by reviewing published food safety incidents and 100 recalls collated from official websites and journal articles and, where possible, to identify the 101 contributory and root causes of the incidents. Where contributory causes are unavailable or 102 unclear from official sources, this study aims to use additional literature evidence to determine the 103 suspected causes, and to organise these in order to provide guidance on potential root causes.

104

#### 105 Approach

A systematic search and review of food recall and food safety incidents was conducted. A systematic
search and review process combines the strength of a critical review with a comprehensive search
process. It provides a more complete picture of a research topic such as 'what are the contributory
factors of food safety incidents' than a systematic review which is limited to randomised controlled
trials or intervention studies (Grant, & Booth, 2009). It does not adhere to a specific guideline,
hence this study did not include a quality assessment to determine inclusion/exclusion criteria. Nine

112 official websites and five journal databases were reviewed from 2008 – 2018 (Table 1). Since the 113 data were collated from governmental websites, this approach ensures data credibility. According to 114 Potter et al. (2012), governmental organisations and their websites provide the most detailed and 115 accurate records of food recalls. The sources were selected based on the quality of data available 116 (where possible with root cause analysis) and their known previous use in desktop research for 117 product recalls and incidents (Bouzembrak, & Marvin, 2016; Luth et al., 2019; Tähkäpää et al., 2015). Apart from Rapid Alert System for Food and Feed (RASFF), each site was reviewed from 2008 to 118 119 October 2018. Journal articles were reviewed where possible to identify known or suspected causes 120 of outbreaks or contamination. Journal databases i.e. Science Direct, Ingenta Connect, Emerald 121 Insight, PubMed and Google Scholar were searched online from 2008 - 2018. Search terms included 'foodborne outbreaks', 'food source', 'causes', 'investigation', 'root cause', 'contamination', 122 123 'microbiological', 'chemical', 'physical', 'food allergen' and 'food fraud'.

124

Data collected included affected products, food and drink categories, type of food hazards, details of the incident (if provided), origin, distribution, number of injuries and deaths. Food safety hazards were divided into biological (e.g. microorganisms), chemical (e.g. natural toxins, antibiotics), physical (e.g. metal, plastics) and allergen (e.g. fish, egg, tree nuts) categories. Data were screened and triangulated with similar websites and research articles to ensure repeated records were not duplicated. Random search validation by the first and second author was also carried out to ensure accurate data were recorded.

132

133 Data were extracted and transferred to Microsoft Excel 2010 to create descriptive statistics and 134 frequency distributions. A Chord diagram was constructed using https://app.flourish.studio/ in 135 Figure S1 to visualise the inter-relationships between food and drink categories with hazards and 136 contributory factors. Food and drinks were divided into 18 categories according to the BRC Global 137 Standard for Food Safety (BRC, 2015) i.e. raw red meat (e.g. beef, veal, pork), raw poultry (e.g. 138 chicken, turkey, duck), raw prepared products (e.g. comminuted meat and fish products, ready-to-139 cook meat, vegetable prepared meals), raw fish (e.g. wet fish, molluscs, crustacea), fruit, vegetables 140 and nuts (e.g. herbs, unroasted nuts), prepared fruit, vegetables and nuts (e.g. semi-processed or 141 prepared foods, chips, frozen vegetables), dairy and liquid egg (e.g. milk, yogurt, and including non-142 dairy products such as soya milk), cooked meat and fish products (e.g. meat and fish pâté, hot 143 smoked fish, poached salmon), raw cured/and/or fermented meat and fish (e.g. salamis, air-dried 144 meats, dried fish), ready-to-eat meals (e.g. chilled foods, wraps, pizzas), cans and jars (e.g. beans, 145 soups, sauces), beverages (e.g. non-alcoholic drinks, concentrates, cordials), alcoholic drinks (e.g.

146 beers, wine, spirits, vinegar), bakery (e.g. breads, cakes, biscuits), dried foods (e.g. spices, rice, 147 pasta), confectionery (e.g. candies, chocolate, jellies), cereal and nuts (e.g. oats, muesli, roasted 148 nuts) and oils and fat (e.g. margarine, shortening, spreads). Fishbone diagrams (Ishikawa, 1990) 149 were used to organise and visualise the contributory factors and root cause analysis of the two main 150 reported causes of incidents and recalls. Ishikawa cause and effect analysis was used to identify 151 possible root causes by asking questions such as 'What happened?', 'When?', 'Where?', 'Why?' and 152 'How?' (Ishikawa, 1990; Wallace and Motarjemi, 2014). The Ishikawa diagram helps to illustrate the 153 sequence of events that leads to an incident. The incidents depend on many factors that can be 154 divided into groups such as materials, machinery, manpower, management, methods and 155 environment (Ishikawa, 1990). This tool has been utilised in food industry to analyse potential 156 hazards at all processing stages (Varzakas, 2016), in construction and manufacturing industries to 157 identify cause of accidents (Hola, Nowobilski, Szer & Szer, 2017) and in health facilities to improve 158 overall healthcare services (Colli et al., 2019). The possible root causes in this study were also 159 supplemented by literature searches.

160

161 Insert Table 1 here

162

#### 163 Findings and Discussion

The total food safety incidents and/or recalls with known or suspected causes reviewed is **n=2932**. This total is captured from the data sources shown in Table 1, except data from RASFF (RASFF data is summary reporting and does not give details of individual incidents so known/suspected causes are not available). The total number of incidents from RASFF (n=5982) is included in food and drink categories (Figure 1a) and in the year category (Figure 2) to give an overall picture of the scale of food incidents reporting.

170

#### 171 Food safety incidents and/or recalls according to food and drink categories

172

Raw fish has the highest number of reported food safety incidents/recalls in this timeframe. RASFF reported the highest number of notifications for raw fish including crustaceans, bivalve molluscs and cephalopods (n=1,411). These notifications included detection of foodborne pathogens (e.g. *Listeria monocytogenes, Salmonella* spp., *Vibrio parahaemolyticus, V. cholerae*, norovirus), presence of prohibited substances (e.g. chloramphenicol, nitrofuran), heavy metals (e.g. mercury, cadmium), undeclared or high sulphite content and other allergens and poor temperature control. D.Amico et al. (2018) conducted a comprehensive review of seafood notifications in RASFF that indicated the

180 main hazards associated with the notifications. Fish and fish products were identified as the product 181 category with the highest number of notifications, mainly due to non-compliant presence of 182 mercury, cadmium or both, as reported in Nepusz, Petroczi and Naughton (2009) and Piglowski 183 (2018). It is known that seafoods generally bioaccumulate heavy metal contaminants (Bonsignore et 184 al., 2018). Heavy metals including other chemical contaminants such as persistent organic pollutants 185 are often discharged into the marine environment via anthropogenic activities and then accumulate 186 in fish tissues (Traina et al., 2019). Other seafood notifications identified by D.Amico et al. (2018) 187 were caused by poor and inadequate controls such as poor temperature control and lack of hygiene, 188 contamination with pathogenic microorganisms, biotoxins and parasitic infestations.

189

190 Ready-to-eat meals recorded the second highest number of incidents/recalls. Some of the most 191 common hazards contributing to the incidents were Listeria monocytogenes, undeclared allergens 192 and contamination with extraneous materials. Other important categories in terms of number of 193 incidents/recalls were fruits, vegetables and nuts, where microbiological hazards such as Salmonella 194 spp. and *Escherichia coli* and chemical hazards such as chlorpyrifos and formetanate (insecticides) 195 and mycotoxins were some of the hazards commonly found. Our findings on Salmonella spp. in 196 fruits, vegetables and nuts were supported by Da Silva Felicio et al. (2015) who identified raw leafy 197 greens and Salmonella spp. as the top food/pathogen combination, followed by bulb and stem 198 vegetables/Salmonella spp. and tomatoes/Salmonella spp. in ready-to-eat unprocessed foods of 199 non-animal origin. When RASFF data were excluded from the food incidents reporting, a different 200 trend emerged. Ready-to-eat meals, raw prepared products and bakery were identified as the food 201 categories with the highest notifications (Figure 1b). The main contributory factors identified in the 202 top three food categories were undeclared allergens, cross contamination and GMP failures. This is 203 further discussed in the 'Food safety incidents / recalls according to known or suspected causes' 204 section.

205

206 Insert Figures 1a and 1b here

207

208 Food safety incidents and/or recalls from 2008 – 2018

209

210 Insert Figure 2 here

211

There was a 50.2% rise in total numbers of reported food safety incidents in 2014 compared to 2013

213 (Figure 2). One of the reasons supporting the spike was a change in the reporting system of the

6

214 Canadian Food Inspection Agency (CFIA). Archived food incidents were recorded from 2008 – 2011 215 (Jan – June), with no data published between the second half of 2011 – 2013. From 2014 onwards, 216 the reporting system was more structured with background information, number of illnesses and 217 related recalls. The improved reporting system from CFIA boosted the numbers from 2014 onwards. 218 Whilst this may not have been the only reason for the apparent jump in numbers between 2013-14, 219 it can be postulated that a smoother rise may have been seen if CFIA data had been published 220 between second half of 2011 and 2013, although this cannot be determined. Only 295 incidents / 221 recalls were noted in 2018 and this total does not include data from RASFF. For the period 2008-222 2017 there is an approximate doubling of the annual rate of incidents but some of this increase will 223 be due to the aforementioned change in reporting systems.

224

225 The rise in total incidents or recalls is also due to improved surveillance and reporting systems in 226 other countries and networks. For example, the Foodborne Diseases Active Surveillance Network 227 (FoodNet) is an active surveillance system that links 10 state and local health departments with the 228 Centers for Disease Control and Prevention (CDC). FoodNet actively collects data from local 229 physicians and clinical laboratories on the incidences of nine pathogens commonly transmitted 230 through food in the 10 US states covering approximately 15% of the US population (Crim et al., 2015; 231 FoodNet, 2018). Passive surveillance such as the National Notifiable Diseases Surveillance System 232 (NNDSS) also collects, analyses and summarises data on infectious and non-infectious conditions including foodborne outbreaks (McCabe-Sellers, & Beattie, 2004; NNDSS, 2018). Similarly, RASFF is 233 234 an open access tool initiated in 32 countries of the EU and European Economic Area (EEA) to provide 235 information on food safety issues among its members. RASFF notifications received from national 236 food safety authorities are verified by the European Commission and then shared efficiently 237 between its members. RASFF continues to evolve to improve its notifications and reporting system 238 to prevent food safety risks to consumers (Luth et al., 2019; RASFF, n.d.a). Shared collaborative 239 efforts in such regions to record and monitor food safety incidents have contributed to the increased 240 number of reported incidents and recalls.

241

## 242 Food safety incidents and/or recalls according to hazards

243 Insert Figure 3 here

244

Allergens (46.18%) are recorded as the top food safety hazard category, followed by microbiological

hazards (40.11%). Key physical hazards (9.31%) were plastic, metal and glass while chemical hazards

247 (2.25%) include biotoxins, unapproved ingredients, heavy metals and antibiotics. The 'other'

category (2.15%) includes hazards associated with packaging (e.g. loss of seal integrity, risk of
bursting), mislabelling and product tampering (Figure 3).

250

#### 251 Allergens

252

253 Most incidents / recalls were due to undeclared allergens especially milk (24.37%), multiple 254 allergens (23.93%) and wheat/gluten (9.97%) (Figure 4). Bakery (20.30%), confectionery (17.27%), 255 and dried foods (13.94%) were reported as the most common food categories associated with 256 undeclared milk while RTE meals (26.85%), bakery (21.60%) and raw prepared products (12.93%) 257 contain the highest frequency of multiple undeclared allergens. These findings support Gendel and 258 Zhu (2013) who reported that food allergen labelling problems are the most common cause of 259 recalls for US FDA regulated food products. Milk was the most frequently undeclared allergen and 260 bakery products were the main food products recalled (Gendel & Zhu, 2013). Bedford, Yu, Wang, 261 Garber and Jackson (2017) tested a selection of dark chocolate bars for undeclared milk and found 262 87% of the chocolate products (n=23) with an advisory statement (e.g. may contain) for milk 263 contained milk at more than 100 ppm whilst more than half were above 1000 ppm. Fifteen percent 264 of the chocolates with dairy-free or lactose-free statement and 25% of vegan chocolate were also 265 tested positive for milk. Bedford et al. (2017) further supports our findings that milk was the most 266 frequently undeclared allergen. In RASFF, cereals and bakery products were the most reported food 267 categories and milk, cereals containing gluten and eggs were the main allergens in allergen-related 268 recalls between 2011 – 2017. The notifications were mostly triggered by a 'company's own check' 269 (company notifying an outcome as a result of their own testing or quality assurance measures) and 270 'official control on the market' (official control on the European Economic Area internal market, e.g. 271 official samples tested by government bodies) (Padua et al., 2019; RASFF, n.d.b). There was also a 272 distinct increase in notifications between 2014 and 2015 and this may be related to the 273 implementation of Regulation (EU) No 1169/2011 on provision of food information to consumers in 274 December 2014 (Padua et al., 2019; Regulation EU No. 1169/2011) which has particular relevance 275 for accurate food allergen labelling. Similarly, in microbial notifications in RASFF, the practice of 276 making food manufacturers accountable for the detection and notification of contaminated 277 products can help to reduce the number of contaminated food products entering the market (Luth 278 et al., 2019). 279 Insert Figure 4 here

280

#### 281 Microbiological hazards

282

283 The main microbiological hazards include *Listeria monocytogenes* (32.91%), *Salmonella* spp.

284 (29.85%) and E. coli (17.86%) (Figure 5). Listeria monocytogenes was often reported in RTE meals

285 (31%), cooked meat & fish (16.80%) and dairy & liquid eggs (14.47%). Fruits, vegetables and nuts

- 286 (18.23%) and dried foods (16.24%) were associated with *Salmonella* spp. while *E. coli* were found in
- raw prepared products (34.29%) and raw red meat (31.43%).

288

289 L. monocytogenes is environmentally ubiquitous and can survive and grow in hostile conditions such 290 as refrigeration temperature, low pH and high salt concentration. Certain RTE foods such as 291 delicatessen meats, poultry products, seafood and dairy products are high-risk vehicles for L. 292 monocytogenes as these foods tend to be chilled and provide a suitable environment for L. 293 monocytogenes to grow (Gandhi & Chikindas, 2007; Swaminathan, Cabanes, Zhang, & Cossart, 294 2007). Listeriosis outbreaks in the EU were linked to seafood, dairy, meat and vegetable products 295 (EFSA, 2015). A recent report by Luth et al. (2019) found that the majority of L. monocytogenes 296 notifications in Germany from 2001 – 2015 were associated with milk (especially soft cheese), fish 297 and meat products. However, listeriosis outbreaks were recently associated with unconventional 298 food vehicles such as fresh produce (e.g. celery, cantaloupe, mung bean sprouts, stone fruits, 299 caramel apples) and ice cream in the US (Buchanan, Gorris, Hayman, Jackson, & Whiting, 2017). 300

301 Fresh produce, nuts and dried foods have been linked to microbiological outbreaks in many parts of 302 the world (Julien-Javaux, Gerard, Campagnoli, & Zuber, 2019; Russo et al., 2013; Werber et al., 303 2005). A review of US FDA recalls between 2002 – 2011 found that nuts and edible seeds, seafood 304 and spices were commonly recalled due to microbiological contamination especially Salmonella 305 (Dey, Mayo, Saville, Wolyniak, & Klontz, 2013). Another review carried out between 2012 – 2017 in 306 US for the fresh fruits and vegetables product category reported that the most common reason for 307 recalls was the presence (or possible presence) of *L. monocytogenes* and *Salmonella* spp. 308 (Paramithiotis, Drosinos and Skandamis, 2017).

309

310 Salmonella spp. and other pathogenic bacteria are often found in livestock, pets, wild animals,

animal manure and contaminated irrigation water, making it more likely that the organism will

312 contaminate fresh produce at the pre-harvest stage (Matthews, Sapers, & Gerba, 2014; Jacobsen &

313 Bech, 2012). The ability of *Salmonella* to withstand desiccation conditions and survive for long

periods of time under low A<sub>w</sub> conditions (Lambertini et al., 2016) make this a pathogen of concern in

low water activity foods such as chocolate (Werber et al., 2005), peanut butter (Sheth et al., 2011),
nuts (Uesugi, Danyluk, & Harris, 2006) and spices (Keller, VanDoren, Grasso, & Halik, 2013).

*E. coli* is a naturally occurring bacteria found in the gastrointestinal tract of cattle. During slaughter
and processing, cross contamination of the originally sterile muscle tissues occurs, resulting in
contaminated beef and beef products (Cassin, Lammerding, Todd, Ross, & McColl, 1998; Yang,
Wang, He, & Tran, 2018). Pathogenic *E. coli* is a major cause of outbreaks and is often associated
with consumption of raw or undercooked, contaminated beef (CDC, 2018a; Gaulin, Ramsay, Catford,
& Bekal, 2015; Yahata et al., 2015).

324

It is interesting to note that there were very few *Campylobacter* incidents (with known/suspected
causes) reported in most of the databases. Campylobacteriosis remains the most commonly
reported zoonosis and foodborne illness in the EU (EFSA, 2018; Lake et al., 2019). Similarly, it is a
leading cause of foodborne illness in the US (CDC, 2018b). Previous source attribution studies
identified chicken and poultry meat as major risk factors for *Campylobacter* infections (Batz et al.,
2012; Domingues et al., 2012; Ravel et al 2017). Note that Figure 5 excludes data from RASFF which
covers the Europe region.

332

333 Insert Figure 5 here

334

#### **Food safety incidents / recalls according to known or suspected causes**

2932 specific food safety incidents/recalls (not including RASFF summary data) were recorded in
Figure 6. Each incident was reviewed to identify (where possible) the cause of the food safety
incident or recall. Where causes were given, a qualitative viewing of the data allowed further detail
on contributing factors to be listed. In addition, some of the causes (with no contributing factor
identified) were cross-referenced with scholarly and research articles to identify plausible specific
sources of contamination.

342

Undeclared allergens (40.45%) were the highest recorded cause of food safety incidents/recalls.
Cross contamination (28.58%) of food products with microbiological hazards (especially cross
contamination from farm for fresh produce and raw milk, cross contamination of raw meat during
slaughter or from processing site and cross contamination from the processing environment in raw
prepared products and RTE meals) was the second highest reported cause of incidents. GMP failures
(9.17%) include insanitary design, lack of maintenance and equipment failure (leading to

349 contamination), ineffective segregation of raw and finished products, improper cleaning practices350 and lack of monitoring of sanitation conditions and staff hygiene.

351

352 Insert Figure 6 here

353

354 Incoming material control (7.64%) is another cause for concern as a number of incidents/recalls 355 were linked, a typical example being the 2008-09 Peanut Corporation of America (PCA) multistate 356 Salmonella Typhimurium incident in the USA, where 714 people were affected (CDC, 2009). There 357 were multiple causes at the PCA manufacturing site, including GMP failures and cross contamination 358 and possibly processing issues. However, any supplier who initiates a product recall will trigger a 359 series of product recalls by its customers (food manufacturers or retailers) and thus result in 360 incoming material control incidents for those manufacturers. The process failure category (5.42%) 361 includes specific causes such as process deviation, undercooking, temperature abuse during 362 processing and swelling and bursting of packaging materials (due to microbial growth). Mislabelling (4.23%) was identified as one of the contributing factors for undeclared allergens but was also listed 363 364 as a cause in its own. Mislabelling occurred when manufacturers incorrectly labelled 'X' food product 365 as 'Y' and there was no declaration of allergens for product 'X', or where incorrect use-by date or 366 incorrect cooking instructions were applied to the product.

367

Product formulation (1.64%) also contributed to undeclared allergens. Changes in an ingredient
formulation by the supplier or manufacturer without a corresponding change in the finished product
label was the major cause noted in this category. Packaging deformity, integrity issues and caps
popping off unexpectedly were some of the causes identified under packaging control (0.78%). Food
fraud (0.55%) includes illegal sales of recalled or unsafe products and stolen goods.

373

374 Equipment design (0.51%) has been categorised on its own due to the identification of causes 375 carried out in some incidents. Equipment design failures were caused by broken or dislodged metal 376 or plastic pieces from processing machines, conveyor belts, guiding rods and reels used to move the 377 belt. Natural contaminants (0.44%) are naturally occurring chemicals found in food products such as 378 cyanide, marine biotoxins and heavy metals in fish. Needles, nails, medications (pain relief tablets), 379 unknown powder and a battery were some of the hazards found in malicious/tampering (0.27%) 380 attack of food products. There were four incidents of unknown causes (0.31%), e.g. 'a taint'; 381 however, the lack of information prevented the identification of a plausible cause for each of the

382 four examples in this category.

11

383

Undeclared allergens and cross contamination affected a diverse range of food and drink categories
(Figure S1). The remainder of this study will focus on these two main causative factors as most food
and drink categories were affected by them.

387

### 388 Undeclared allergens

389 Most incidents / recalls associated with allergens were listed as undeclared allergens. This is still a 390 vague description of the cause although some manufacturers further identified the issue as not 391 declaring the allergen in English or the allergen was declared in uncommon terms. For example, a 392 manufacturer declared cashews with a French term 'anacardes' that is not commonly recognised in 393 Canada (CFIA, 2008). Ingredient statement omission is another factor particularly when the 394 ingredients used are less conspicuous such as icing (that contains egg) in a cereal based product 395 (CFIA, 2010), glaze (that contains wheat) used in nuts (USDA FSIS, 2017) or if food products 396 containing multiple small packs of ingredients e.g. seasoning ingredients were left off the ingredients 397 list (USDA FSIS, 2016). Errors in a newly designed label where an incorrect ingredient statement was 398 used reiterate the need for verification of new labelling artwork (FSN, 2014).

399

400 Bucchini, Guzzon, Poms and Senyuva (2016) agreed that 'not indicated on the label' as a generic 401 explanation of cause and does not indicate why the failure occurred. However, the authors did find 402 that a small percentage of the products were recalled due to unintended presence of allergen as a 403 result of cross contact. In the US, the use of wrong package or label was identified as the most 404 frequent problem leading to food allergen recalls (Gendel & Zhu, 2013). Other problems that caused 405 the allergen recalls were also identified and categorised. For example, computer error (e.g. use of 406 wrong computer file leading to labelling error), cross contact (e.g. ineffective cleaning between 407 products with different allergens), in process error (e.g. unfinished product added to another 408 product without the allergen), ingredient mislabelled (e.g. ingredient used to manufacture the 409 product did not declare the presence of an allergen) and knowledge (e.g. manufacturer unaware of 410 allergen labelling requirements) (Gendel & Zhu, 2013). Although one could summarise that the 411 major factors for undeclared allergens were ingredient statement omissions and errors, cross 412 contact from food processing equipment and errors caused by ingredient suppliers or food 413 processing staff (Vierk, Falci, Wolyniak, & Klontz, 2002), the root causes for the omission, cross 414 contact, errors by suppliers and unclear supply chain information transfer remain unknown.

415

#### 416 Cross contamination

417 Cross contamination, especially from microbiological hazards, could be further classified into cross 418 contamination at pre-harvest and processing stages. There were more extensive reports provided 419 for cross contamination incidents especially if the contamination resulted in microbiological 420 outbreaks. However, publication of the findings of traceback investigations is still limited. 421 Investigators were able to trace Salmonella Saintpaul in agricultural water and raw produce on a 422 Mexican farm and jalapeño peppers in Texas (Behravesh et al., 2011) while Escherichia coli O157:H7 423 in bagged spinach was linked to wild boars, cattle and irrigation water (Gelting, Baloch, Zarate-424 Bermudez, & Selman, 2011). In the listeriosis outbreak associated with cantaloupes, McCollum et al. 425 (2013) traced Listeria back to environmental and product samples in the packaging facility but 426 environmental samples from growing fields were negative. Some of the key factors identified as the 427 most likely cause of contamination of cantaloupes with Listeria monocytogenes were contamination 428 from a truck used to transport waste culled cantaloupes to a cattle farm. The truck was found 429 parked next to the packing facility and could have introduced contamination into the facility. Facility 430 design that allowed stagnant water to accumulate on the packing facility floor and inadequate good 431 manufacturing practices (GMP) may also have contributed to the contamination (McCollum et al., 432 2013; US FDA, 2011).

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434 To date, there has been an increase in foodborne disease outbreaks associated with consumption of 435 raw and/or minimally processed fruits and vegetables. Recent outbreaks include E. coli O157:H7 in 436 romaine lettuce (CDC, 2019c) and alfalfa sprouts (CDC, 2016), E. coli O157:H7 in mixed salad leaves 437 (PHE, 2016) and Salmonella Hvittingfoss on rock melons (Flynn, 2016). Sources and established 438 contamination routes of pathogens include agricultural inputs such as contaminated irrigation 439 water, inadequately composted manure, contaminated water used in reconstituted pesticides, soil, 440 livestock, wild animals (including insects) and the ability of microorganisms to colonise and persist in 441 fresh produce (Alegbeleye, Singleton, & Sant'Ana, 2018; Verhaelen, Bouwknegt, Rutjes, & Husman, 442 2013; Wasala, Talley, DeSliva, Fletcher, & Wayadande, 2013; Erikson et al., 2019).

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*Listeria monocytogenes* remains a major challenge for ready-to-eat food, cooked meat and fish
products, and dairy processors. The ability of *L. monocytogenes* to survive cold temperatures and its
capability to form biofilms as a survival strategy improves its chances of colonising and persisting in
food processing environments (Pang, Wong, Chung, & Yuk, 2019). The colonisation and persistence
of *L. monocytogenes* in food processing plants have been well established in dairy (Melero et al.,
2019), meat and poultry (Berrang, Meinersmann, Frank, & Ladely, 2010), fish (Di Ciccio et al., 2012;
Rotariu, Thomas, Goodburn, Hutchinson, & Strachan, 2014) and ready-to-eat foods processing

451 facilities (Henriques, da Gama, & Fraqueza, 2014). In most colonisation incidences, raw product is an 452 important source of the organism (Berrang et al., 2010; Di Ciccio, et al., 2012; Zuber et al., 2019). 453 Although raw material is an important source of contamination, Di Ciccio et al. (2012) found that 454 contamination of processed food such as smoked salmon occurred mainly during processing rather 455 than from raw materials. GMP failures, equipment design and lack of hygienic measures contribute 456 to the spread and prevalence of *L. monocytogenes* throughout food processing plants. Harbourage 457 sites play a role in the persistence of L. monocytogenes as cleaning and sanitising agents are unable 458 to reach sheltered processing areas due unhygienic design of equipment and premises or unhygienic 459 or damaged material (Carpentier & Cerf, 2011). Lack of hygienic barriers and uncontrolled personnel 460 flow (Melero et al., 2019), spread of contamination by mobile food transport elements (e.g. trolleys, 461 conveyors, forklift trucks) and ineffective hygiene measurements in food contact environments 462 (Muhterem-Uyar et al., 2015), poor food handling after processing (Henriques et al., 2014), 463 inadequate refrigeration temperature and condensation drip from chills on products (Rotariu et al., 464 2014) are examples of poor GMP and hygienic measures that led to the persistence and 465 contamination of food products. Further root cause analyses were carried out to identify how the 466 failures could have occurred.

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#### 469 Root cause analysis of undeclared allergens and cross contamination

470 Fishbone diagrams, also known as cause and effect diagrams, or Ishikawa analysis (Ishikawa, 1990) 471 are a problem solving tool in determining root causes of issues. The technique was used to illustrate 472 the root cause analysis (RCA) of undeclared allergens (Figure S2) and cross contamination (Figure 473 S3), where the skeletons represent the different major causal factor categories and primary and 474 secondary causes are organised under these categories. The fishbone diagram is a useful way of 475 organising information, especially when presented with a complex situation (e.g. multiple potential 476 causes) to understand the relationships between the cause and effect (Motarjemi & Wallace, 2014) 477 and these are often constructed by brainstorming possible causes of a given problem. In this study, 478 the diagrams were developed by grouping the contributory factors identified in the review of official 479 databases and journal articles under appropriate major causal factor categories. Primary causes 480 came from review of official databases and journal articles while secondary causes were derived 481 from literature searches and the Ishikawa cause and effect analysis. 482

Figure S2 shows the cause and effect for undeclared allergens and is grouped into four categories of
process, packaging, people and place (environment). In addition to primary causes, secondary causes

485 are portrayed, and this can assist food manufacturers to work back to the root cause. For example, 486 presence of allergens could be due to carry over or cross contact from processing equipment. The 487 cross contact could have occurred due to poor equipment design (e.g. allowing allergen residue to 488 accumulate), ineffective cleaning and sanitation (e.g. inadequate removal of allergen residue) and/or 489 limited product scheduling (e.g. production of allergen containing food followed by non-allergen 490 containing food products on shared equipment) (Dzwolak et al., 2017; Gojkovic et al., 2015; Shoji & Obata, 2010). Latent and active failures relating to management of people is essential in root cause 491 492 analysis. Behind any process and control measure, there are staff who have to implement the 493 process / measures or to verify that the measures have been implemented correctly. For example, 494 during labelling of food products, steps are carried out to label and package the product and there 495 are verification steps to ensure that correct labelling / packaging and products are used. Failures to 496 perform such tasks are known as active failures since the (lack of / incorrect) actions have a direct 497 impact on the safety of the products (Motarjemi & Wallace, 2014). In RCA, investigators should dig 498 deeper and understand the conditions contributing to ineffective cleaning or mislabelling. For 499 example, why was the cleaning inadequate? Are the staff adequately trained? Is sufficient time and 500 resources provided for cleaning? A working environment that leads to non-compliances are latent 501 conditions that arise from management decisions and culture (Motarjemi & Wallace, 2014).

502

503 The causes for cross contamination are divided into five categories i.e. pre-harvest, processing, 504 product, people and place (environment) (Figure S3). Similarly, by applying RCA of the causes, one 505 could evaluate the conditions leading to the incidents. For example, why and how did the cross 506 contamination from food contact surfaces to food product occur? Why were the food contact 507 surfaces contaminated? Did the food handlers cause and/or spread the contamination? As described 508 in the RCA scenario for undeclared allergens, this often leads back to identification of active and 509 latent failures. Failure of food handlers to clean food contact surfaces adequately is an example of 510 active failure. This may be caused by latent failures i.e. the working conditions such as unhygienic 511 equipment design and lack of hygiene barriers or measurements that led to ineffective cleaning and 512 sanitation practices. Latent failures may not have an immediate impact on food safety but create 513 gaps in the food safety management systems and opportunities for active failures and incidents 514 (Motarjemi & Wallace, 2014). In fact, a combination of active and latent failures often leads to food 515 safety incidents. For example, the culmination of active and latent failures such as an insufficient 516 feedback mechanism, failure of regulators and industrial departments to collect samples, lack of 517 supervision from the Ministry of Health and distributors and retailers making wrong judgements and 518 selling unsafe dairy products led to the melamine in milk incident in 2008 (Song, Yu, & Lv, 2018).

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- 519 Root cause analysis is a practical and useful tool in identifying the actual cause of the incident. Once
- 520 the root cause is identified, corrective and preventative measures can be implemented to prevent
- 521 similar incidents from recurring. Thus, food manufacturers could use these Fishbone diagrams
- 522 (Figures S2 and S3) as guidance on areas to target in continuous improvement programmes to
- 523 prevent incidents associated with undeclared allergens and cross contamination.
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#### 525 Limitations

526 This study is focused on reported food safety incidents, especially incidents where the contributory 527 factors had been identified or suspected at processing facilities. Hence, there remains some 528 discrepancy between the notifications of hazards (e.g. very few Campylobacter incidents) in 529 comparison to regional reports of foodborne illnesses (e.g. Campylobacteriosis is the leading cause 530 of foodborne illness in the EU). There are multiple official websites that could be reviewed such as 531 those from Asia, South America and Africa. This study only includes official websites and journal 532 articles presented in the English language. It is recommended that other official websites particularly 533 those from Asia, South America and Africa are reviewed to determine the trend of global food safety 534 incidents and factors leading to the incidents. The data from RASFF were not reviewed in depth, but 535 future studies could analyse the trends and causative factors for these recalls. It is possible that 536 RASFF is double counting some of the incidents in the 2932 data but this cannot be established 537 without line by line check and this was not possible in the current study. This study is also based on a systematic search and review process and is not as exhaustive compared to the gold standard 538 539 systematic review. As this form of review does not adhere to a specific guideline, the study did not 540 include a quality assessment to determine inclusion/exclusion of data. However, official data from 541 governmental websites provide the most accurate records of food recalls and incidents and quality 542 of data is assured.

543

#### 544 Conclusions

545 This study offers key insights into global food safety incidents according to food and drink categories, 546 hazards and common contributory factors. Food incidents are recorded across all 18 BRC food and 547 drink categories with the top three being raw fish, ready-to-eat meals and fruits, vegetables and 548 nuts, making up 43% of the total 8914 incidents (including RASFF summary data). There has been a 549 doubling of incidents recorded in these sources between 2008 and 2018 but the apparent jump in 550 numbers in 2014 is likely due to a change in recording methodology. Incidents involve all four hazard 551 categories (biological, chemical, physical, allergen) but majority are in allergens and microbiological 552 categories. Cross contamination (microbiological) and undeclared allergens were the most

- 553 frequently cited causes of specific incidents, making up 69% of the total. In incidents where overall
- causes were recorded, these were reasonably well detailed (n = 2932 incidents). However there is
- still very limited information recorded on the root causes. Some categories have slightly better
- 556 information, e.g. equipment design has several specific causes detailed; however, this still does not
- 557 get to the root cause of the problem, i.e. we still don't know the reasoning behind the plastic pieces,
- etc., gaining access to the products. Microbiological outbreaks are often investigated in detail to
- determine the implicated food and sources of contamination e.g. raw materials and/or processing
- 560 environment. Similarly, it is difficult to identify the root cause of the problem i.e. how did the
- 561 contaminated raw material contaminate the processing environment or how did the pre-harvest
- 562 conditions contaminate the food products. Therefore, it is important to examine a range of incidents
- 563 in depth from a qualitative perspective in order to try to close this data gap that is essential to
- identify the root causes of the food safety incidents. One of the main contributions and novel
- 565 findings of this review is the identification of the primary and secondary causes for undeclared
- allergens and cross contamination. Trend analysis of product notifications and root cause analysis
- 567 will benefit food regulators and industry by providing guidance on areas of focus for the prevention
- 568 of incidents.
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## 575 References

- Alegbeleye, O. O., Singleton, I., & Sant'Ana, A. S. (2018). Sources and contamination routes of
  microbial pathogens to fresh produce during field cultivation: A review. *Food Microbiology*, *73*, 177208.
- Batz M. B., Hoffmann, S., & Morris, J. G. Jr. (2012). Ranking the disease burden of 14 pathogens in
  food sources in the United States using attribution data from outbreak investigations and expert
  elicitation. *Journal of Food Protection*, *75*(7), 1278-1291.
- 584
- Bedford, B., Yu, Y., Wang, X., Garber, E. A. E., & Jackson, L. S. (2017). A limited survey of dark
  chocolate bars obtained in the United States for undeclared milk and peanut allergens. *Journal of Food Protection, 80*(4), 692-702.
- 588
- Behravesh, C. B., Mody, R. K., Jungk, J., Gaul, L., Redd, J. T., Chen, S. et al. (2011). 2008 outbreak of *Salmonella* Saintpaul infections associated with raw produce. *New England Journal of Medicine, 364,*918-927.
- 592
- 593 Berrang, M. E., Meinersmann, R. J., Frank, J. F., & Ladely, S. R. (2010). Colonization of a newly
- 594 constructed commercial chicken further processing plant with Listeria monocytogenes. *Journal of*
- 595 *Food Protection, 73*(2), 286-291.

- 596
- Boatemaa, S., Barney, M., Drimie, S., Harper, J., Korsten, L., & Pereira, L. (2019). Awakening from the
  listeriosis crisis: Food safety challenges, practices and governance in the food retail sector in South
  Africa. *Food Control, 104*, 333-342.
  Bonsignore, M., Manta, D. S., Mirto, S., Quinci, E. M., Ape, F., Montalto, V., Gristina, M., Traina, A.
- and Sprovieri, M. (2018). Bioaccumulation of heavy metals in fish, crustaceans, molluscs and
   echinoderms from the Tuscany coast. *Ecotoxicology and Environmental Safety*, *162*, 554-562.
- Bouzembrak, Y. & Marvin, H. J. P. (2016). Prediction of food fraud type using data from Rapid Alert
  System for Food and Feed (RASFF) and Bayesian network modelling. *Food Control, 61,* 180–187.
- 607
  608 Bouzembrak, Y. & Marvin, H. J. P. (2019). Impact of drivers of change, including climatic factors, on
  609 the occurrence of chemical food safety hazards in fruits and vegetables: A Bayesian Network
  610 approach. *Food Control*, *97*, 67-76.
- 611
- BRC (2015). Food safety. A global view 2015. London: BRC Global Standards, pp. 1-48. Available at:
   https://www.brcglobalstandards.com/media/9393/food-safety-a-global-view-2015.pdf [Accessed 14]
- 614 February 2019].
- 615
- Bucchini, L., Guzzon, A., Poms, R., & Senyuva, H. (2016). Analysis and critical comparison of food
  allergen recalls from the European Union, USA, Canada, Hong Kong, Australia and New Zealand. *Food Additives & Contaminants: Part A, 33*(5), 760-771.
- 619
- Buchanan, R. L., Gorris, L. B. M., Hayman, M. M., Jackson, T. C., & Whiting, R. C. (2017). A review of
  Listeria monocytogenes: An update on outbreaks, virulence, dose-response, ecology, and risk
  assessments. Food Control, 75, 1-13.
- 623
- 624 CAC (Codex Alimentarius Commission) (2003). Hazard Analysis and Critical Control Point (HACCP)
- System and Guidelines for its application. Codex Alimentarius Commission Food Hygiene Basic Texts
   (Revision 4). Available at: http://www.codexalimentarius.org [Accessed 23 May 2019]
- 627 Carpentier, B. & Cerf, O. (2011). Review Persistene of *Listeria monocytogenes* in food industry 628 equipment and premises. *International Journal of Food Microbiology*, *145*(1), 1-8.
- 629
- Cassin, M. H., Lammerding, A. M., Todd, E. C. D., Ross, W., & McColl, R. S. (1998). Quantitative risk
  assessment for *Escherichia coli* O157:H7 in ground beef hamburgers. *International Journal of Food Microbiology*, 41(1), 21-44.
- 633
- 634 CDC (2009). Multistate Outbreak of *Salmonella* Typhimurium Infections Linked to Peanut Butter,
   635 2008-2009 (FINAL UPDATE). Available at: <u>https://www.cdc.gov/salmonella/2009/peanut-butter-</u>
   636 2008-2009.html
- 637
- 638 CDC (2016). Escherichia coli O157 infections linked to Jack & The Green sprouts alfalfa sprouts.
  639 Available at: https://www.cdc.gov/ecoli/2016/o157-02-16/index.html [Accessed 22 February 2019]
- 639 640
- 641 CDC (2018a). Outbreak of E. coli infections linked to ground beef. Available at:
  - 642 https://www.cdc.gov/ecoli/2018/o26-09-18/index.html [Accessed 20 February 2019]
  - 643
  - 644 CDC (2018b). FoodNet 2018 preliminary data. Available at:
  - 645 <u>https://www.cdc.gov/foodnet/reports/prelim-data-intro-2018.html</u> [Accessed 23 May 2019]

646 647 CDC (2019a). Morbidity and Mortality Weekly Report. Available at: 648 https://www.cdc.gov/mmwr/mmwr\_wk/wk\_pvol.html [Accessed 8 February 2019] 649 CDC (2019b). List of selected multistate foodborne outbreak investigations. Available at: 650 651 https://www.cdc.gov/foodsafety/outbreaks/multistate-outbreaks/outbreaks-list.html [Accessed 8 652 February 2019] 653 654 CDC (2019c). Outbreak of E. coli infections linked to romaine lettuce. Available at: https://www.cdc.gov/ecoli/2018/o157h7-11-18/index.html [Accessed 22 February 2019] 655 656 657 CFIA (2008). Allergy alert. Presence of cashews in some Berni brand pesto. Canadian Food Inspection 658 Agency. Available at: http://epe.lac-bac.gc.ca/100/206/301/cfia-acia/2011-09-659 21/www.inspection.gc.ca/english/corpaffr/recarapp/2008/20080522e.shtml [Accessed 20 February 660 2019] 661 662 CFIA (2008). Allergy alert. Undeclared egg in Kellogg's Rice Krispies treats holiday village kits sold at 663 Michaels stores. Canadian Food Inspection Agency. Available at: http://epe.lac-664 bac.gc.ca/100/206/301/cfia-acia/2011-09-665 21/www.inspection.gc.ca/english/corpaffr/recarapp/2010/20101223e.shtml [Accessed 20 February 666 2019] 667 668 CFIA (2019). Complete listing of all recalls and allergy alerts. Canadian Food Inspection Agency. 669 Available at: http://www.inspection.gc.ca/about-the-cfia/newsroom/food-recall-670 warnings/complete-listing/eng/1351519587174/1351519588221?ay=2014&fr=0&fc=0&fd=0&ft=1 671 [Accessed 8 February 2019] 672 673 Colli, L. F. M., da Silva, L. C. R., de Sousa, V. P., de Padula, M., & Cabral, L. M. (2019). Evaluation of 674 the effectiveness of the notification process in the area of health products. Health Policy and 675 Technology, 8(2), 105-110. 676 677 Crim, S. M., Griffin, P. M., Tauxe, R., Marder, E. P., Gilliss, D., Cronquist, A. B. et al. (2015). 678 Preliminary incidence and trends of infection with pathogens transmitted commonly through food -679 Foodborne Diseases Active Surveillance Network, 10 US sites, 2006-2014. MMWR Morbidity and 680 Mortality Weekly Report, 64(18), 495-499. 681 682 Domingues, A. R., Pires, S. M., Halasa, T., & Hald, T. (2012). Source attribution of human 683 campylobacteriosis using a meta-analysis of case-control studies of sporadic infections. Epidemiology 684 & Infection, 140(6), 970-981. 685 686 D.'Amico, P., Nucera, D., Guardone, L., Mariotti, M., Nuvoloni, R., & Armani, A. (2018). Seafood 687 products notifications in the EU Rapid Alert System for Food and Feed (RASFF) database: Data analysis during the period 2011-2015. Food Control, 93, 241-250. 688 689 690 Da Silva Felicio, M. T., Hald, T., Liebana, E., Allende, A., Hugas, M., Nguyen-The, C., Johannessen, G. 691 S., Niskanen, T., Uyttendaele, M., & McLauchlin, J. (2015). Risk ranking of pathogens in ready-to-eat 692 unprocessed foods of non-animal origin (FoNAO) in the EU: Initial evaluation using outbreak data 693 (2007-2011). International Journal of Food Microbiology, 195, 9-19. 694

695 Dey, M., Mayo, J. A., Saville, D., Wolyniak, C., & Klontz, K. C. (2013). Recalls of foods due to 696 microbiological contamination classified by the US Food and Drug Administration, fiscal years 2003 697 through 2011. Journal of Food Protection, 76(6), 932-938. 698 699 Di Ciccio, P., Meloni, D., Festino, A. R., Conter, M., Zanardi, E., Ghidini, S. et al. (2012). Longitudinal 700 study on the sources of Listeria monocytogenes contamination in cold-smoked salmon and its 701 processing environment in Italy. International Journal of Food Microbiology, 158(1), 79-84. 702 703 Djekic, I., Jankovic, D., & Rajkovic, A. (2017). Analysis of foreign bodies present in European food 704 usign data from Rapid Alert System for Food and Feed (RASFF). Food Control, 79, 143-149 705 706 Dzwolak, W. (2017). Assessment of food allergen management in small food facilities. Food Control, 707 73, 323-331. 708 709 ECDC (2018a). Rapid risk assessment: Multi-country outbreak of Listeria monocytogenes serogroup 710 IVb, multi-locus sequence type 6, infections linked to frozen corn and possibly to other frozen 711 vegetables. European Centre for Disease Prevention and Control. Available at: 712 https://ecdc.europa.eu/en/publications-data/rapid-risk-assessment-multi-country-outbreak-listeria-713 monocytogenes-serogroup-ivb [Accessed 8 February 2019] 714 715 ECDC (2018b). Frozen corn likely source of ongoing Listeria monocytogenes outbreak. European 716 Centre for Disease Prevention and Control. Available at: https://ecdc.europa.eu/en/news-717 events/frozen-corn-likely-source-ongoing-listeria-monocytogenes-outbreak [Accessed 8 February 718 2019] 719 720 ECDC (2019). Publications and data. European Centre for Disease Prevention and Control. Available 721 at: https://ecdc.europa.eu/en/publications-data [Accessed 8 February 2019] 722 723 ECDC-EFSA (2018). Multi-country outbreak of Listeria monocytogenes serogroup IVb, multi-locus 724 sequence type 6, infections probably linked to frozen corn. Joint ECDC-EFSA Rapid Outbreak 725 Assessment. Available at: https://ecdc.europa.eu/sites/portal/files/documents/22-02-2018-RRA-726 Listeria-Finland.pdf [Accessed 8 February 2019] 727 728 EFSA (2015). The European Union summary report on trends and sources of zoonoses, zoonotic 729 agents and foodborne outbreaks in 2013. EFSA Journal, 13(1), DOI: 10.2903/j.efsa.2015.3991 730 731 EFSA (2018). The European Union summary report on trends and sources of zoonoses, zoonotic 732 agents and foodborne outbreaks in 2017. EFSA Journal, 16(12), DOI: 10.2903/j.efsa.2018.5500 733 734 Erikson, M. C., Liao, J.-Y., Payton, A. S., Cook, P. W., Den Bakker, H. C., Bautista, J., & Perez, J. C. D. 735 (2019). Pre-harvest internalization and surface survival of Salmonella and Escherichia coli O157:H7 736 sprayed onto different lettuce cultivars under field and growth conditions. International Journal of 737 Food Microbiology, 291, 197-204. 738 739 Flynn, D. (2016). How did Salmonella Hvittingfoss get on Aussie rock melons? Food Safety News. 740 Available at: https://www.foodsafetynews.com/2016/08/130219/#.WA6FuotMqUk [Accessed 22 741 February 2019] 742 743 FoodNet (2018). Foodborne Diseases Active Surveillance Network. Centers for Disease Control and 744 Prevention. Available at: https://www.cdc.gov/foodnet/index.html [Accessed 15 February 2019] 745

746 FSA (n.d.). Alerts. Food Standards Agency. Available at: https://www.food.gov.uk/news-747 alerts/search/alerts [Accessed 8 February 2019] 748 749 FSAI (2013). FSAI survey finds horse DNA on some beef burger products. Food Safety Authority of 750 Ireland. Available at: https://www.fsai.ie/details.aspx?id=11878 [Accessed 24 October 2019] 751 752 FSANZ (2019). Food recalls. Available at: 753 http://www.foodstandards.gov.au/industry/foodrecalls/recalls/Pages/default.aspx [Accessed 8 754 February 2019] 755 756 FSN (2014). ND firm recalls beef franks for misbranding, undeclared allergen. Food Safety News. 757 Available at: https://www.foodsafetynews.com/2014/01/nd-firm-recalls-beef-franks-for-758 misbranding-undeclared-allergen/#more-83320 [Accessed 20 February 2019] 759 760 Gandhi, M., & Chikindas, M. L. (2007). Listeria: A foodborne pathogen that knows how to survive. 761 International Journal of Food Microbiology, 113(1), 1-15. 762 Gaulin, C., Ramsay, D., Catford, A., & Bekal, S. (2015). Escherichia coli O157:H7 outbreak associated 763 764 with the consumption of beef and veal tartares in the Province of Quebec, Canada in 2013. 765 Foodborne Pathogen and Disease, 12(7), 612-618. 766 767 Gelting, R., Baloch, M. A., Zarate-Bermudez, M. A., & Selman, C. (2011). Irrigation water issues 768 potentially related to the 2006 multistate E. coli O157:H7 outbreak associated with spinach. 769 Agricultural Water Management, 98(9), 1395-1402. 770 771 Gendel, S. M., & Zhu, J. (2013). Analysis of U.S. Food and Drug Administration food allergen recalls 772 after implementation of the Food Allergen Labeling and Consumer Protection Act. Journal of Food 773 Protection, 76(11), 1933-1938. 774 775 Gojkovic, V., Marjanovic-Balaban, Z., Vukic, M., Grujic, R., & Novakovic, B. (2015). Allergen 776 management system in the food production. Journal of Hygienic Engineering and Design, 12, 76-84. 777 778 Grant, M. J., & Booth, A. (2009). A typology of reviews: an analysis of 14 review types and associated 779 methodologies. Health Information and Libraries Journal, 26, 91-108. 780 781 Henriques, A. R., de Gama, L. T., & Fraqueza, M. J. (2014). Assessing Listeria monocytogenes 782 presence in Portuguese ready-to-eat meat processing industries based on hygienic and safety audit. 783 Food Research International, 63(Part A), 81-88. 784 785 Hola, B., Nowobilski, T., Szer, I., & Szer, J. (2017). Identification of factors affecting the accident rate 786 in the construction industry. Procedia Engineering, 208, 35-42. 787 788 Ishikawa, K. (1990). Introduction to Quality Control, Productivity Press, New York. 789 790 Jacobsen, C. S. & Bech, T. B. (2012). Soil survival of Salmonella and transfer to freshwater and fresh 791 produce. Food Research International, 45(2), 557-566. 792 793 Julien-Javaux, F., Gerard, C., Campagnoli, M., & Zuber, S. (in press). Strategies for the safety 794 management of fresh produce from farm to fork. Current Opinion in Food Science. DOI: 795 10.1016/j.cofs.2019.01.004 796

797 Kase, J. A., Zhang, G., & Chen, Y. (2017). Recent foodborne outbreaks in the United States linked to 798 atypical vehicles – lessons learned. Current Opinion in Food Science, 18, 56-63. 799 800 Keller, S. E., VanDoren, J. M., Grasso, E. M., & Halik, L. A. (2013). Growth and survival of Salmonella 801 in ground black pepper (Piper nigrum). Food Microbiology, 34(1), 182-188. 802 803 Kleter, G. A., Prandini, A., Filippi, L., & Marvin, H. J. P. (2009). Identification of potentially emerging 804 food safety issues by analysis of reports published by the European Community's Rapid Alert System 805 for Food and Feed (RASFF) during a four-year period. Food and Chemical Toxicology, 47(5), 932-950. 806 807 Lake, I. R., Colon-Gonzalez, F. J., Takkinen, J., Rossi, M., Sudre, B., Gomes Dias, J. et al. (2019). 808 Exploring Campylobacter seasonality across Europe using the European Surveillance System (TESSy), 809 2008 to 2016. Eurosurveillance, 24(13), pii=1800028. 810 811 Lambertini, E., Mishra, A., Guo, M., Co, H., Buchanan, R. L., & Pradhan, A. K. (2016). Modeling the 812 long-term kinetics of Salmonella survival on dry pet food. Food Microbiology, 58, 1-6. 813 814 Luth, S., Boone, I., Kleta, S., & Al Dahouk, S. (2019). Analysis of RASFF notifications on food products 815 contaminated with Listeria monocytogenes reveals options for improvement in the rapid alert 816 system for food and feed. Food Control, 96, 479-487. 817 818 Matthews, K. R., Sapers, G. M., & Gerba, C. P. (2014). The Produce Contamination Problems: Causes 819 and Solutions. Amsterdam: Academic Press, pp. 1–469. 820 821 McCabe-Sellers, B. J., Beattie, S. E. (2004). Food safety: Emerging trends in foodborne illness 822 surveillance and prevention. Journal of the American Dietetic Association, 104(11), 1708-1717. 823 824 McCollum, J. T., Cronquist, A. B., Silk, B. J., Jackson, K. S., O'Connor, K. A., Cosgrove, S. et al. (2013). 825 Multistate outbreak of listeriosis associated with cantaloupe. New England Journal of Medicine, 369, 944-953. 826 827 828 Melero, B., Stessl, B., Manso, B., Wagner, M., Esteban-Carbonero, O. J., Hernandez, M., Rovira, J., & 829 Rodriguez-Lazaro, D. (2019). Listeria monocytogenes colonization in a newly established processing 830 facility. International Journal of Food Microbiology, 289, 64-71. 831 832 Motarjemi, Y., & Wallace, C. A. (2014). Food safety assurance systems: Root cause analysis of 833 incidents. Y. Motarjemi, G. Moy & E. Todd (Eds.). Encyclopedia of Food Safety, Volume 4. San Diego: 834 Academic Press, 331-339. 835 836 Muhterem-Uyar, M., Dalmasso, M., Bolocan, A. S., Hernandez, M., Kapetanakou, A. E., Kuchta, T. et 837 al. (2015). Environmental sampling for Listeria monocytogenes control in food processing facilities 838 reveals three contamination scenarios. Food Control, 51, 94-107. 839 840 Nerin, C., Aznar, M., & Carrizo, D. (2016). Food contamination during food process. Trends in Food 841 Science & Technolohy, 48, 63-68. 842 843 Nepusz, T., Petroczi, A., & Naughton, D. P. (2009). Food alert patterns for metal contamination 844 analyses in seafoods: Longitudinal and geographical perspectives. Environment International, 35(7), 1030-1033. 845 846

- 847 NNDSS (2018). National Notifiable Diseases Surveillance System. Centers for Disease Control and 848 Prevention. Available at: https://www.cdc.gov/foodnet/index.html [Accessed 15 February 2019] 849 850 Padua, I., Moreira, A., Moreira, P., de Vasconcelos, F. M., & Barros, R. (2019). Impact of the 851 regulation (EU) 1169/2011: Allergen-related recalls in the rapid alert system for food and feed 852 (RASFF) portal. Food Control, 98, 389-398. 853 854 Pang, X., Wong, C., Chung, H.-J., & Yuk, H.-G-. (2019). Biofilm formation of Listeria monocytogenes 855 and its resistance to quarternary ammonium compounds in a simulated salmon processing 856 environment. Food Control, 98, 200-208. 857 858 Paramithiotis, S., Drosinos, E. H., & Skandamis, P. N. (2017). Food recalls and warnings due to the 859 presence of foodborne pathogens – a focus on fresh fruits, vegetables, dairy and eggs. Current 860 Opinion in Food Science, 18, 71-75. 861 862 PHE, Public Health England (2016). E. coli O157 national outbreak update. Available at: 863 https://www.gov.uk/government/news/update-as-e-coli-o157-investigation-continues [Accessed 22 864 February 2019] 865 866 Piglowski, M. (2018). Heavy metals in notifications of Rapid Alert System for Food and Feed. 867 International Journal of Environment Research and Public Health, 15(2), 365. DOI: 868 10.3390/ijerph15020365 869 870 Potter, A., Murray, J., Lawson, B. & Graham, S. (2012). Trends in product recalls within the agri-food 871 industry: Empirical evidence from the USA, UK and the Republic of Ireland. Trends in Food Science & 872 Technology, 28(2), 77-86. 873 874 RASFF (n.d.a). RASFF – Food and feed safety alerts. European Commission. Available at: 875 https://ec.europa.eu/food/safety/rasff\_en [Accessed 15 February 2019] 876 877 RASFF (n.d.b). RASFF portal. European Commission. Available at: 878 https://ec.europa.eu/food/safety/rasff/portal\_en [Accessed 18 February 2019] 879 880 RASFF (2015). The Rapid Alert System for Food and Feed 2015 Annual Report. Available at: 881 https://ec.europa.eu/food/sites/food/files/safety/docs/rasff\_annual\_report\_2015.pdf [Accessed 8 882 February 2019] 883 884 RASFF (2017). The Rapid Alert System for Food and Feed 2017 Annual Report. Available at: 885 https://ec.europa.eu/food/sites/food/files/safety/docs/rasff\_annual\_report\_2017.pdf [Accessed 8 886 February 2019] 887 888 Ravel, A., Hurst, M., Petrica, N., David, J., Mutschall, S. K., Pintar, K., Taboada, E. N., & Pollari, F. 889 (2017). Source attribution of human campylobacteriosis at the point of exposure by combining 890 comparative exposure assessment and subtype comparison based on comparative genomic 891 fingerprinting. PLoS ONE, 12(8), e0183790. 892 893 Regulation (EU) No. 1169/2011 (2011). Regulation (EU) No 1169/2011 of the European Parliament 894 and of the Council of 25 October 2011. Available at: https://eur-lex.europa.eu/legal-895 content/EN/TXT/PDF/?uri=CELEX:32011R1169&from=EN [Accessed 18 February 2019] 896
  - 23

897 Rotariu, O., Thomas, J. I., Goodburn, K. E., Hutchinson, M. L., & Strachan, N. C. (2014). Smoked 898 salmon industry practices and their association with Listeria monocytogenes. Food Control, 35(1), 899 284-292. 900 901 Russo, E. T., Biggerstaff, G., Hoekstra, M., Meyer, S., Patel, N., Miller, B. et al. (2013). A recurrent, 902 multistate outbreak of Salmonella serotype Agona infections associated with dry, unsweetened 903 cereal consumption, United States, 2008. Journal of Food Protection, 76(2), 227-230. 904 905 Sheth, A. N., Hoekstra, M., Patel, N., Ewald, G., Lord, C., Clarke, C. et al. (2011). A national outbreak 906 of Salmonella serotype Tennessee infections from contaminated peanut butter: A new food vehicle 907 for salmonellosis in the United States. Clinical Infectious Diseases, 53(4), 356-362. 908 909 Shoji, M., & Obata, T. (2010). Manufacturing a biscuit that does not use milk, eggs, or soybeans. In, 910 Allergen Management in the Food Industry. J. I. Boye & S. B. Godefroy (Eds.). New Jersey: John Wiley 911 & Sons, pp. 393-419. 912 913 Song, Y.-H., Yu, H.-Q., & Lv, W. (2018). Risk analysis of dairy safety incidents in China. Food Control, 914 *92,* 63-71. 915 916 Swaminathan, B., Cabanes, D., Zhang, W., & Cossart, P. (2007). Listeria monocytogenes. In, Food Microbiolog: Fundamentals and Frontiers. M. P. Doyle, & L. R. Beuchat (Eds.). 3rd Edition. Washington 917 918 D.C.: ASM Press, pp. 457-491. 919 920 Tähkäpää, S., Maijala, R., Korkeala, H. & Nevas, M. 2015. Patterns of food frauds and adulterations 921 reported in the EU rapid alert system for food and feed and in Finland. Food Control, 47, 175–184. 922 923 Traina, A., Bono, G., Bonsignore, M., Falco, F., Giuga, M., Quinci, E. M., Vitale, S., & Sprovieri, M. 924 (2019). Heavy metals concentrations in some commercially key species from Sicilian coasts 925 (Mediterranean Sea): Potential human health risk estimation. Ecotoxicology and Environmental 926 Safety, 168, 466-478. 927 928 Uesugi. A. R., Danyluk, M. D., & Harris, L. J. (2006). Survival of Salmonella Enteritidis phage type 30 929 on inoculated almonds stored at -20, 4, 23, and 35°C. Journal of Food Protection, 69(8), 1851-1857. 930 931 US FDA (2011). Environmental assessment: Factors potentially contributing to the contamination of 932 fresh whole cantaloupe implicated in a multi-state outbreak of listeriosis. US Food and Drug 933 Administration. Available at: http://calcitrusquality.org/wp-content/uploads/FDA-Jensen-Farms-934 Environmental-Assessment-Final-Report.pdf [Accessed 22 February 2019] 935 936 USDA FSIS (2016). Boyle's Famous Corned Beef Co. recalls beef products due to misbranding and 937 undeclared allergen. US Department of Agriculture, Food Safety and Inspection Service. Available at: 938 https://www.fsis.usda.gov/wps/portal/fsis/topics/recalls-and-public-health-alerts/recall-case-939 archive/archive/2015/recall-143-2015-release [Accessed 20 February 2019] 940 941 USDA FSIS (2017). Mibo fresh food recalls turkey salad products due to misbranding and undeclared 942 allergens. US Department of Agriculture, Food Safety and Inspection Service. Available at: 943 https://www.fsis.usda.gov/wps/portal/fsis/topics/recalls-and-public-health-alerts/recall-case-944 archive/archive/2017/recall-034-2017-release [Accessed 20 February 2019] 945

946 USDA FSIS (2018). Recall case archive. US Department of Agriculture, Food Safety and Inspection 947 Service. Available at: https://www.fsis.usda.gov/wps/portal/fsis/topics/recalls-and-public-health-948 alerts/recall-case-archive [Accessed 8 February 2019] 949 950 USFDA (2018a). Archive for recalls, market withdrawals and safety alerts. US Food and Drug 951 Administration. Available at: https://www.fda.gov/Safety/Recalls/ArchiveRecalls/default.htm 952 [Accessed 8 February 2019] 953 954 USFDA (2018b). Outbreaks of foodborne illness. US Food and Drug Administration. Available at: 955 https://www.fda.gov/Food/RecallsOutbreaksEmergencies/Outbreaks/default.htm [Accessed 8 956 February 2019] 957 958 Varzakas, T. (2016). HACCP and ISO22000: Risk assessment in conjunction with other food safety 959 tools such as FMEA, Ishikawa diagrams and Pareto. B. Caballero, P. M. Finglas & F. Toldra (Eds). In, 960 Encyclopedia of Food and Health, , 295-302. 961 962 Verhaelen, K., Bouwknegt, M., Rutjes, S. A., & Husman, A. M. R. (2013). Persistence of human 963 norovirus in reconstituted pesticides – Pesticide application as a possible source of viruses in fresh 964 produce chains. International Journal of Food Microbiology, 160(3), 323-328. 965 966 Vierk, K., Falci, K., Wolyniak, C., & Klontz, K. C. (2002). Recalls of foods containing undeclared 967 allergens reported to the US Food and Drug Administration, fiscal year 1999. Journal of Allergy and 968 *Clinical Immunology, 109, 1022-1026.* 969 Wasala, L., Talley, J. L., DeSilva, U., Fletcher, J., & Wayadande, A. (2013). Transfer of Escherichia coli 970 O157:H7 o spinach by house flies, Musa domestica (Diptera: Muscidae). Phytopathology, 103(4), 971 373-380. 972 973 Werber, D., Dreesman, J., Feil, F., van Treeck, U., Fell, G., Ethelberg, S. et al. (2005). International 974 outbreak of Salmonella Oranienburg due to German chocolate. BMC Infectious Disases, 5(7), DOI: 975 10.1186/1471-2334-5-7 976 977 Whitworth, J. (2018). South Africa declares end to largest ever Listeria outbreak. Food Safety News. 978 Available at: https://www.foodsafetynews.com/2018/09/south-africa-declares-end-to-largest-ever-979 listeria-outbreak/ [Accessed 8 February 2019] 980 981 WHO (2015). WHO estimates of the global burden of foodborne diseases. Foodborne diseases 982 burden epidemiology reference group 2007-2015, World Health Organization. Available at: 983 https://www.who.int/foodsafety/publications/foodborne disease/fergreport/en/ [Accessed 8 984 February 2019] 985 986 Yahata, Y., Misaki, T., Ishida, Y., Nagira, M., Watahiki, M., Isobe, J. et al. (2015). Epidemiological 987 analysis of a large enterohaemorrhagic Escherichia coli O111 outbreak in Japan associated with 988 haemolytic uraemic syndrome and acute encephalopathy. Epidemiology and Infection, 143(13), 989 2721-2732. 990 991 Yang, X., Wang, H., He, A., & Tran, F. (2018). Biofilm formation and susceptibility to biocides of 992 recurring and transient Escherichia coli isolated from meat fabrication equipment. Food Control, 90, 993 205-211. 994