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1 **Determining common contributory factors in food safety incidents – a review of global outbreaks**  
2 **and recalls 2008-2018**

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  
15 poisoning incidents and legal offences), and to near misses. This study reviews published food safety  
16 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  
18 (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  
22 found over the period 2008-2018 is 2932. Where possible, the contributory and root causes of  
23 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  
30 identified primary and secondary causes as guidance for continuous improvement programmes to  
31 prevent food safety incidents.

32  
33 **Keywords:** cross contamination; hazards; root cause analysis; undeclared allergens

34  
35 **Highlights**

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

#### 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) (Boatema 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 (Boatema et al., 2019). However, the source of contamination e.g. how the outbreak  
63 strain was introduced into the factory and how it was transferred to food products remain  
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.  
76 Hence, identifying the causes of contamination or recall is critically needed to understand the  
77 potential sources and routes of contamination of foodborne outbreaks and product recalls, and to

78 develop steps to mitigate their occurrence. To date, there remains limited data on contributory  
79 factors associated with food safety incidents; thus further comprehensive review of reported food  
80 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  
84 of Agriculture Food Safety and Inspection Service, UK Food Standards Agency and Food Safety  
85 Authority of Ireland were used. Researchers found that operational hazards (including mislabelling,  
86 packaging defects, product contaminations, production defects, unauthorised ingredients, incorrect  
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**

106 A systematic search and review of food recall and food safety incidents was conducted. A systematic  
107 search and review process combines the strength of a critical review with a comprehensive search  
108 process. It provides a more complete picture of a research topic such as 'what are the contributory  
109 factors of food safety incidents' than a systematic review which is limited to randomised controlled  
110 trials or intervention studies (Grant, & Booth, 2009). It does not adhere to a specific guideline,  
111 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; Tähkää et al., 2015).  
118 Apart from Rapid Alert System for Food and Feed (RASFF), each site was reviewed from 2008 to  
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  
122 'foodborne outbreaks', 'food source', 'causes', 'investigation', 'root cause', 'contamination',  
123 'microbiological', 'chemical', 'physical', 'food allergen' and 'food fraud'.

124

125 Data collected included affected products, food and drink categories, type of food hazards, details of  
126 the incident (if provided), origin, distribution, number of injuries and deaths. Food safety hazards  
127 were divided into biological (e.g. microorganisms), chemical (e.g. natural toxins, antibiotics), physical  
128 (e.g. metal, plastics) and allergen (e.g. fish, egg, tree nuts) categories. Data were screened and  
129 triangulated with similar websites and research articles to ensure repeated records were not  
130 duplicated. Random search validation by the first and second author was also carried out to ensure  
131 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**

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

170

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

172

173 Raw fish has the highest number of reported food safety incidents/recalls in this timeframe. RASFF  
174 reported the highest number of notifications for raw fish including crustaceans, bivalve molluscs and  
175 cephalopods (n=1,411). These notifications included detection of foodborne pathogens (e.g. *Listeria*  
176 *monocytogenes*, *Salmonella* spp., *Vibrio parahaemolyticus*, *V. cholerae*, norovirus), presence of  
177 prohibited substances (e.g. chloramphenicol, nitrofurantoin), heavy metals (e.g. mercury, cadmium),  
178 undeclared or high sulphite content and other allergens and poor temperature control. D.Amico et  
179 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

212 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

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  
233 including foodborne outbreaks (McCabe-Sellers, & Beattie, 2004; NNDSS, 2018). Similarly, RASFF is  
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

245 Allergens (46.18%) are recorded as the top food safety hazard category, followed by microbiological  
246 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'



248 category (2.15%) includes hazards associated with packaging (e.g. loss of seal integrity, risk of  
249 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  
287 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,  
311 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  
314 periods of time under low  $A_w$  conditions (Lambertini et al., 2016) make this a pathogen of concern in

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

317

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

324

325 It is interesting to note that there were very few *Campylobacter* incidents (with known/suspected  
326 causes) reported in most of the databases. Campylobacteriosis remains the most commonly  
327 reported zoonosis and foodborne illness in the EU (EFSA, 2018; Lake et al., 2019). Similarly, it is a  
328 leading cause of foodborne illness in the US (CDC, 2018b). Previous source attribution studies  
329 identified chicken and poultry meat as major risk factors for *Campylobacter* infections (Batz et al.,  
330 2012; Domingues et al., 2012; Ravel et al 2017). Note that Figure 5 excludes data from RASFF which  
331 covers the Europe region.

332

333 Insert Figure 5 here

334

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

336 2932 specific food safety incidents/recalls (not including RASFF summary data) were recorded in  
337 Figure 6. Each incident was reviewed to identify (where possible) the cause of the food safety  
338 incident or recall. Where causes were given, a qualitative viewing of the data allowed further detail  
339 on contributing factors to be listed. In addition, some of the causes (with no contributing factor  
340 identified) were cross-referenced with scholarly and research articles to identify plausible specific  
341 sources of contamination.

342

343 Undeclared allergens (40.45%) were the highest recorded cause of food safety incidents/recalls.  
344 Cross contamination (28.58%) of food products with microbiological hazards (especially cross  
345 contamination from farm for fresh produce and raw milk, cross contamination of raw meat during  
346 slaughter or from processing site and cross contamination from the processing environment in raw  
347 prepared products and RTE meals) was the second highest reported cause of incidents. GMP failures  
348 (9.17%) include insanitary design, lack of maintenance and equipment failure (leading to

349 contamination), ineffective segregation of raw and finished products, improper cleaning practices  
350 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  
363 (4.23%) was identified as one of the contributing factors for undeclared allergens but was also listed  
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

368 Product formulation (1.64%) also contributed to undeclared allergens. Changes in an ingredient  
369 formulation by the supplier or manufacturer without a corresponding change in the finished product  
370 label was the major cause noted in this category. Packaging deformity, integrity issues and caps  
371 popping off unexpectedly were some of the causes identified under packaging control (0.78%). Food  
372 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.

383

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

433

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, Bouwknecht, Rutjes, & Husman,  
442 2013; Wasala, Talley, DeSilva, Fletcher, & Wayadande, 2013; Erikson et al., 2019).

443

444 *Listeria monocytogenes* remains a major challenge for ready-to-eat food, cooked meat and fish  
445 products, and dairy processors. The ability of *L. monocytogenes* to survive cold temperatures and its  
446 capability to form biofilms as a survival strategy improves its chances of colonising and persisting in  
447 food processing environments (Pang, Wong, Chung, & Yuk, 2019). The colonisation and persistence  
448 of *L. monocytogenes* in food processing plants have been well established in dairy (Melero et al.,  
449 2019), meat and poultry (Berrang, Meinersmann, Frank, & Ladely, 2010), fish (Di Ciccio et al., 2012;  
450 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.

467

468

#### 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

483 Figure S2 shows the cause and effect for undeclared allergens and is grouped into four categories of  
484 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 &  
491 Obata, 2010). Latent and active failures relating to management of people is essential in root cause  
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).



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.

524

### 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  
538 systematic search and review process and is not as exhaustive compared to the gold standard  
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  
554 causes were recorded, these were reasonably well detailed (n = 2932 incidents). However there is  
555 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,  
558 etc., gaining access to the products. Microbiological outbreaks are often investigated in detail to  
559 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  
564 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  
566 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.

569

570

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574

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