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

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Abstract

Background: Global food safety incidents are frequently reported and are on the rise. Although the increase in number of food safety incidents is impacted by improved surveillance and reporting systems and increased awareness from consumers, nevertheless the increase in food safety issues is a threat to public health and the economic costs of countries and businesses. Hence, identifying the root causes of contamination or recall is critically needed to understand the source of contamination in foodborne outbreaks and product recalls, thus helping food businesses to develop risk mitigating strategies.

Scope and Approach: This study aims to identify common contributory factors in food manufacturing 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, 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 information to identify possible root causes.

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. Undeclared allergens and cross contamination were identified as the top two recorded causes of food safety incidents/recalls. This review has further proposed the primary and secondary causes for undeclared allergens and cross contamination.

Conclusions: This study offers key insights into global food safety incidents according to food and drink categories, hazards and common contributory factors. Food manufacturers could use the identified primary and secondary causes as guidance for continuous improvement programmes to prevent food safety incidents.

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

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 causes.
- Primary and secondary causes for unidentified allergens and cross contamination were proposed.

Introduction

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

Recent foodborne disease outbreaks include *Listeria monocytogenes* in South Africa, which infected 1060 patients of whom 216 died. The outbreak was traced to a ready-to-eat (RTE) processed meat plant where the *Listeria* outbreak strain was identified in patient isolates, polony and the processing 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 undetermined (Whitworth, 2018). Another international listeriosis outbreak in the EU affected 47 patients and resulted in 9 fatalities between 2015 – 2018. Frozen corn was identified as the likely source of outbreak of *Listeria monocytogenes* serogroup IVb, but matching strains of *L. monocytogenes* were also found in other frozen vegetables (ECDC, 2018a; ECDC-EFSA, 2018). Further investigations were recommended to identify the source of contamination (ECDC, 2018b). These examples highlight the need to determine the root cause of the incidents and why the contamination occurred. Cross contamination of food and beverages can occur at all food processing stages. Nerin, Aznar and Carrizo (2016) reviewed the food processing steps that can contribute to food contamination such as external raw food contamination, during transportation, cleaning processes, heating, food packaging and during food storage. The various sources, routes and contributors of contamination were emphasised by Kase, Zhang and Chen (2017) who reported that 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 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.

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

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 official websites and five journal databases were reviewed from 2008 – 2018 (Table 1). Since the data were collated from governmental websites, this approach ensures data credibility. According to Potter et al. (2012), governmental organisations and their websites provide the most detailed and accurate records of food recalls. The sources were selected based on the quality of data available (where possible with root cause analysis) and their known previous use in desktop research for 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 October 2018. Journal articles were reviewed where possible to identify known or suspected causes of outbreaks or contamination. Journal databases i.e. Science Direct, Ingenta Connect, Emerald Insight, PubMed and Google Scholar were searched online from 2008 - 2018. Search terms included ‘foodborne outbreaks’, ‘food source’, ‘causes’, ‘investigation’, ‘root cause’, ‘contamination’, ‘microbiological’, ‘chemical’, ‘physical’, ‘food allergen’ and ‘food fraud’.

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.

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

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

Insert Table 1 here

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.

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

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

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

Insert Figures 1a and 1b here

Food safety incidents and/or recalls from 2008 – 2018

Insert Figure 2 here

There was a 50.2% rise in total numbers of reported food safety incidents in 2014 compared to 2013 (Figure 2). One of the reasons supporting the spike was a change in the reporting system of the

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

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

Food safety incidents and/or recalls according to hazards

Insert Figure 3 here

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 (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).

Allergens

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

Insert Figure 4 here

Microbiological hazards

The main microbiological hazards include *Listeria monocytogenes* (32.91%), *Salmonella* spp. (29.85%) and *E. coli* (17.86%) (Figure 5). *Listeria monocytogenes* was often reported in RTE meals (31%), cooked meat & fish (16.80%) and dairy & liquid eggs (14.47%). Fruits, vegetables and nuts (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%).

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

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

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 contaminate fresh produce at the pre-harvest stage (Matthews, Sapers, & Gerba, 2014; Jacobsen & Bech, 2012). The ability of *Salmonella* to withstand desiccation conditions and survive for long periods of time under low A_w 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).

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.

Insert Figure 5 here

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.

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

Insert Figure 6 here

Incoming material control (7.64%) is another cause for concern as a number of incidents/recalls were linked, a typical example being the 2008-09 Peanut Corporation of America (PCA) multistate *Salmonella* Typhimurium incident in the USA, where 714 people were affected (CDC, 2009). There were multiple causes at the PCA manufacturing site, including GMP failures and cross contamination and possibly processing issues. However, any supplier who initiates a product recall will trigger a series of product recalls by its customers (food manufacturers or retailers) and thus result in incoming material control incidents for those manufacturers. The process failure category (5.42%) includes specific causes such as process deviation, undercooking, temperature abuse during 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 as a cause in its own. Mislabelling occurred when manufacturers incorrectly labelled 'X' food product as 'Y' and there was no declaration of allergens for product 'X', or where incorrect use-by date or incorrect cooking instructions were applied to the product.

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.

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

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.

Undeclared allergens

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

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

Cross contamination

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

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

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

Root cause analysis of undeclared allergens and cross contamination

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

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

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

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

Limitations

This study is focused on reported food safety incidents, especially incidents where the contributory factors had been identified or suspected at processing facilities. Hence, there remains some discrepancy between the notifications of hazards (e.g. very few *Campylobacter* incidents) in comparison to regional reports of foodborne illnesses (e.g. Campylobacteriosis is the leading cause of foodborne illness in the EU). There are multiple official websites that could be reviewed such as those from Asia, South America and Africa. This study only includes official websites and journal articles presented in the English language. It is recommended that other official websites particularly those from Asia, South America and Africa are reviewed to determine the trend of global food safety incidents and factors leading to the incidents. The data from RASFF were not reviewed in depth, but future studies could analyse the trends and causative factors for these recalls. It is possible that RASFF is double counting some of the incidents in the 2932 data but this cannot be established 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 systematic review. As this form of review does not adhere to a specific guideline, the study did not include a quality assessment to determine inclusion/exclusion of data. However, official data from governmental websites provide the most accurate records of food recalls and incidents and quality of data is assured.

Conclusions

This study offers key insights into global food safety incidents according to food and drink categories, hazards and common contributory factors. Food incidents are recorded across all 18 BRC food and drink categories with the top three being raw fish, ready-to-eat meals and fruits, vegetables and nuts, making up 43% of the total 8914 incidents (including RASFF summary data). There has been a doubling of incidents recorded in these sources between 2008 and 2018 but the apparent jump in numbers in 2014 is likely due to a change in recording methodology. Incidents involve all four hazard categories (biological, chemical, physical, allergen) but majority are in allergens and microbiological categories. Cross contamination (microbiological) and undeclared allergens were the most 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 information, e.g. equipment design has several specific causes detailed; however, this still does not 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 environment. Similarly, it is difficult to identify the root cause of the problem i.e. how did the contaminated raw material contaminate the processing environment or how did the pre-harvest conditions contaminate the food products. Therefore, it is important to examine a range of incidents 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 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 will benefit food regulators and industry by providing guidance on areas of focus for the prevention of incidents.

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