RANKING OF LOW MOISTURE FOODS IN SUPPORT OF MICROBIOLOGICAL RISK MANAGEMENT

REPORT OF AN FAO/WHO CONSULTATION PROCESS

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ABBREVIATIONS

a_w	Water activity
CAC	Codex Alimentarius Commission
CCFH	Codex Committee on Food Hygiene
CFU	Colony forming unit
DALY	Disability adjusted life years
GAP	Good Agriculture Practices
GHP	Good Hygienic Practices
GMP	Good Manufacturing Practices
HACCP	Hazard Analysis and Critical Control Points
LMF	Low Moisture Food(s)
MCDA	Multi Criteria Decision Analysis

EXECUTIVE SUMMARY

Low moisture foods (LMF) are foods that are naturally low in moisture or are produced from higher moisture foods through drying or dehydration processes. The low water activity (a_w) of these foods contributes to a long shelf life and has for many years possibly led to the perception that these foods were not of concern from a microbiological food safety perspective. However, in recent years, a number of outbreaks of foodborne illnesses linked to LMF has illustrated that despite the fact that organisms cannot grow in these products, they do have the possibility to persist for long periods of time and depending on the organism can cause illness due to their low infectious dose (e.g. *Salmonella* in chocolate) or possible subsequent temperature abuse that allows the organism to grow (e.g. *Bacillus cereus* in rice). As a result, there has been global recognition of the need to more rigorously consider and manage the microbiological hazards associated with these products and in this context the Codex Alimentarius Commission agreed that a Codex Code of Hygienic Practice for Low Moisture Foods be developed.

Responding to a request from the Codex Committee on Food Hygiene (CCFH), the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO) have implemented a series of activities aimed at collating and analysing the available information on microbiological hazards related to LMF and then ranking the foods of greatest concern from a microbiological food safety perspective. Given the broad range of LMF that exist, a categorization of these products was made to facilitate the data collection and ranking exercises. At that stage some decisions were taken as to products to be excluded from this data collection and ranking process. These included powdered infant formula for infants and young children due to the extensive amount of work that had already been undertaken to address the microbiological safety of these products and the existence of Codex guidance in this area. In addition dry, cured and fermented meats (e.g. sausages, salami, jerky) were excluded due to the variability in water activity around these products which may or may not be below 0.85. The seven categories of LMF which were ultimately considered in the ranking process were 1; Cereals and grains; 2: Confections and Snacks; 3: Dried fruits and vegetables; 4: Dried protein products; 5: Nuts and nut products; 6: Seeds for consumption; and 7: Spices and dried aromatic herbs (including teas). Honey and preserves were excluded based on the information available from the scoping structured review indicating that the primary hazards of concern in relation to this category was *Clostridium botulinum* and the primary population of concern was infants.

The output of this work includes an extensive structured review of all publically available data on the illnesses linked to LMF and data on contamination of these products with a range of microbial hazards. Meta-analyses of the contamination data were also undertaken. This work fed into a multi criteria decision analysis process for ranking of LMF. In addition, the review summarized research on interventions targeted towards microbiological hazards in LMF, but it was found that the applicability of this evidence to commercial (real-life) conditions was limited.

The ranking model for the LMF categories described in this document was built up in a consultative manner between experts in the subject matter and in decision and risk analysis. Each of the food categories was evaluated against four criteria: burden of illness, production, consumption and international trade. This required the collection of additional data to ensure that, to the greatest extent possible, the scoring against each of the above mentioned criteria was based on the best available evidence. Where evidence was not readily available expert opinion was relied upon. The output of the ranking in descending order was as follows:

1. Cereals and grains;
2. Dried protein products;
3. Spices and dried herbs;
4. Nuts and nut products;
5. Confections and snacks;
6. Dried fruits and vegetables and
7. Seeds for consumption.

As the ranking process can be used as a learning tool, i.e. not to prescribe a solution but, instead, to explore the robustness of the findings and the consequences that uncertainties might cause on the ranking, a robustness analysis was undertaken, varying input parameters to test the sensitivity of results to their changes. In addition, a more detailed robustness analysis, concerning difference of priorities among the expert group (criteria weights) and uncertainties about the evidence available (impacts), was undertaken.

Cereals and Grains scored highly across all the criteria, especially for international trade and food consumption criteria. This is not surprising given the importance of the commodities and products in this category as staples in the global food supply. Dried protein products which were ranked second stood out in terms of burden of disease linked to these products. This was influenced by a couple of very large outbreaks associated with dried dairy products, which led to a high disability adjusted life year (DALY) calculation for this category. The analyses of sensitivity on weights show that the ranking is quite robust with either cereals and grains or dried protein products always being in the top position.

1. BACKGROUND

The burden of foodborne illness and the number of food recalls associated with microbial contamination of low-moisture foods (LMF) has risen in recent years (Beuchat et al., 2013; Dey et al., 2013; Finn et al., 2013; Podolak et al., 2010; Scott et al., 2009; Van Doren et al., 2013a; Vij, et al., 2006). LMF are naturally low in moisture or are produced from higher moisture foods through drying or dehydration processes. The low water activity (a_w) of these foods contributes to a long shelf life (Finn et al., 2013). Examples of LMF products include cereals, grains, confections (e.g. chocolate), powdered-protein products (e.g. dairy and egg powders), dried fruits and vegetables, honey, spices, seeds, nuts and nut-based products (e.g. peanut butter), among others (Beuchat et al., 2013; Finn et al., 2013; Podolak et al., 2010). LMF are generally perceived as safe by consumers, and many LMF are consumed as ready-to-eat products with no consumer-level pathogen reduction step such as cooking (Beuchat et al., 2011; Beuchat et al., 2013).

LMF are susceptible to contamination from a wide range of microbial hazards. Although most microbial hazards cannot grow in LMF due to the low a_w, many pathogens can survive and remain viable for months to years in these foods, posing potential risks to consumers (Beuchat et al., 2013; Finn et al., 2013; Podolak et al., 2010). It is difficult to reduce microbial hazard contamination of LMF by significant margins (e.g. >5 logs) and to non-detectable levels using traditional processing interventions such as heat treatments that are effectively applied to high moisture foods (Beuchat et al., 2013; Finn et al., 2013). The combination of low a_w with the high sugar and/or fat content of many LMF is believed to contribute to the enhanced survival and heat resistance of microbial hazards in these foods (Beuchat et al., 2013; Finn et al., 2013).

Many LMF products undergo specific pathogen reduction treatments to reduce potential hazards for consumers. For example, spices and seasonings are often treated with ethylene oxide, propylene oxide, steam treatment, or irradiation to reduce the risk of microbial contamination (Van Doren et al., 2013b). The most important control measures for LMF involve preventing contamination during harvest, post-harvest, and processing through implementation of good agricultural practices (GAPs), good manufacturing practices (GMPs), good hygienic practices (GHPs) and hazard analysis critical control point (HACCP) programs (Beuchat et al., 2013; Finn et al., 2013; Podolak et al., 2010). Process-based verification (e.g. audits) and microbial sampling of LMF products and food processing environments are also important strategies for industry to monitor food safety. However, surveillance of microbial hazards in LMF is not cost-effective due to the heterogeneous distribution of pathogens in LMF, diagnostic test limitations, and the very low average prevalence of microbial hazards in most LMF (Beuchat et al., 2013; Sperber, 2007).

In recognition of the increased global consumption of LMF and the growing risk to human health from these products, several regulatory authorities around the world have developed recommendations and guidelines for industry on how to prevent and manage potential risks of LMF product contamination from microbial hazards (Beuchat et al., 2011; European Food Safety Authority, 2013; Grocery Manufacturers Association, 2009; Scott et al., 2009; USFDA, 2013). Due to this increased momentum and a need for standardized and comprehensive international guidance in this area, the Codex Alimentarius Commission has approved the development of a Code of Practice for LMF (CAC, 2013a). The Codex Committee on Food Hygiene (CCFH) has initiated work on the development of this Code of Practice and in doing so also agreed on the need to request scientific advice on the following:

- The LMF, which should be considered as the highest priorities for the Committee and the associated microbiological hazards. The ranking process should include, but not be limited to, dried fruits and dehydrated fruits and vegetables, peanut butter, cereals, dry protein products (e.g. dried dairy products), confections (e.g. cocoa and chocolate), snacks (e.g. spiced chips), tree nuts, desiccated coconut, seeds for consumption, spices and dried aromatic plants.

- Information relevant to the risk management of the microbiological hazards associated with the identified range of LMF, with particular attention to the role of agricultural and handling/manufacturing practices in the introduction and control of hazards and the identification of the critical control points for mitigation of the risks associated with LMF. (CAC, 2012).

The 45th session of the CCFH reconfirmed its request to FAO/WHO and to extend the request to include teas. Following a preliminary report provided by FAO and WHO, the Committee also asked some clarification in terms of the source of dried protein products that had been associated with foodborne outbreaks. In addition, the Committee agreed that FAO/WHO could consider the following criteria in the ranking of LMF:

- Prevalence of contamination of the pathogen in the specified food;
- Dose-response relationship as estimated by expert knowledge of the behaviour and physiology of the specific pathogen;
- Frequency and severity of disease;
- Size and scope of production;
- Diversity and complexity of the production chain and industry;
- Potential for amplification of foodborne pathogens through the food chain;
- Potential for control;
- Extent of international trade and economic impact. (CAC, 2013b)

This report describes the approach that was taken to address this request and presents the results of that work. For purposes of transparency, as well as further development or future application of the approach, it also includes an overview of the extensive amount of data that was considered in undertaking this work.

2. OBJECTIVES AND APPROACH

Based on the request of the CCFH the objectives of this work were as follows:

- To undertake a scoping systematic review and analysis of the available knowledge on foodborne illness linked to LMF, microbial contamination of LMF and interventions available for the control of LMF.
- To develop and apply a multi-criteria decision analysis approach to rank LMF of greatest concern from a global microbiological food safety perspective.
- To provide a comprehensive report on the available information and ranking results for use by Codex and member countries.

Given the breath of the work, there were multiple steps involved. These are outlined in the subsequent sections. In addition a flow chart of the process is provided in Figure 2.1.

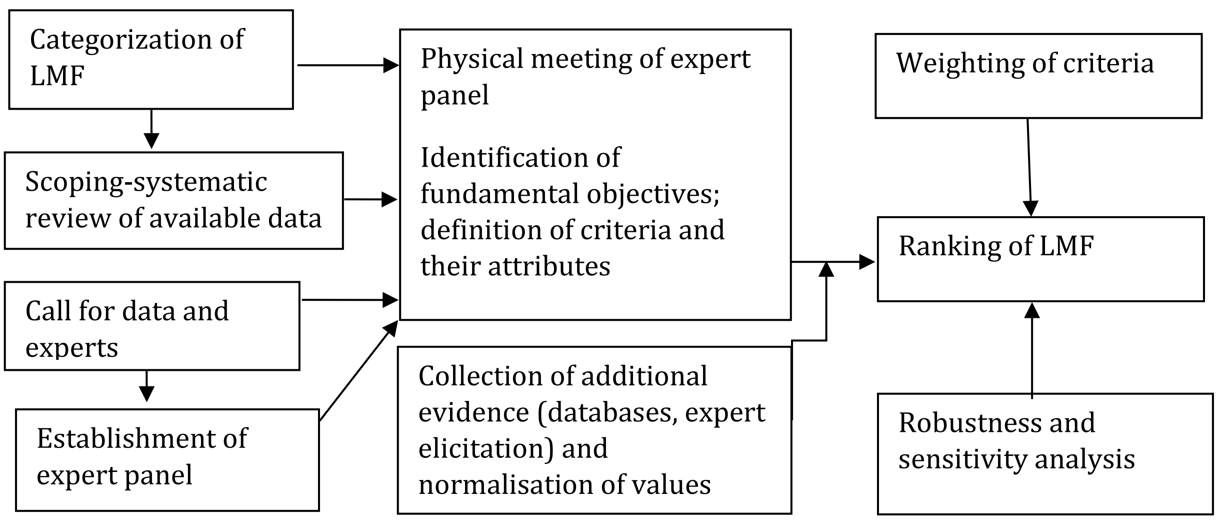

FIGURE 2.1. FLOW CHART OF THE STEPS INVOLVED IN THE DATA COLLECTION AND RANKING EXERCISE

2.1 IDENTIFICATION OF CATEGORIES OF LMF

For the purpose of this work LMF were defined as any food item that has a a_w level of less than 0.85. The request from CCFH outlined a range of LMF that should be considered in the ranking exercise. In order to facilitate data collection and analysis it was decided to group LMF into a number of categories. The initial categorization was developed by the FAO/WHO Secretariat and revised based on input from the leads of the Codex working group on LMF and selected experts. The list of categories is presented in Table 2.1. These categories were used as the basis for the scoping-systematic review that was subsequently undertaken (Appendix 1).

TABLE 2.1: CATEGORIZATION OF LMF

Category	Foods included
Cereals and Grains	whole and milled grains (wheat, barley maize, oats, rye, millet, sorghum, buckwheat) rice and rice products cereals and cereal products (e.g. breakfast cereals)
Confections and snacks	cocoa and chocolate products other confections/confectionery (e.g. marshmallows, candies) snacks (e.g. chips, crackers, biscuits) yeast
Dried fruits and vegetables	dried fruits (e.g. raisins, prunes, dates, mangos, apricots, desiccated coconut) dried vegetables (e.g. tomatoes, potatoes, carrots) dried/dehydrated mushrooms dried seaweed
Dried protein products	dried dairy products (e.g. milk/whey powders) dried egg products (e.g. egg powders) dried meat other than sausages/salamis/jerky (e.g. meat powders, gelatine, fish)
Honey and preserves	honey, jams, syrups (e.g. corn syrup)
Nuts and nut products	tree nuts (e.g. almonds, brazil nuts, cashews, hazelnuts, macadamia nuts, pecans, pine nuts, pistachios, walnuts) peanuts and peanut products (e.g. peanut butter, peanut spreads) mixed and unspecified nuts
Seeds for consumption	sesame seeds tahini (sesame seed paste) halva/helva (confection made from sesame paste/tahini) other and unspecified seeds (e.g. pumpkin seeds, sunflower seeds, poppy seeds, melon seeds, flax seeds, mixed/unspecified seeds for consumption)
Spices and dried herbs	fruit/seed-based (e.g. paprika, black/white/green/long pepper, aniseed, caraway, celery, coriander, dill seed, fennel, chervil, cumin, allspice, nutmeg/mace, cardamom, fenugreek, mustard) root-based (e.g. garlic, ginger, turmeric, galangal, onion) herb/leaf-based (e.g. oregano, marjoram, basil, bay leaf, mint, rosemary, parsley, sage, thyme, dill weed/leaves) bark/flower-based (e.g. cinnamon, cloves, saffron) mixed/unspecified (e.g. curry powder, garam masala, tandoori, herb mixes, other mixed/unspecified spices) tea (e.g. herbal, black teas)
Specialized nutritional products	lipid based nutrient supplements (ready to use therapeutic foods (RUTF) and ready to use supplementary foods (RUSF) dried/powdered nutrient supplements (blended powders including some of products listed above)

In the course of the work some modifications to the categories were made. Following the request of the 45th session of the CCFH in 2013, teas were added to the category on spices and dried herbs. Powdered formulae for infants and young children were not included in these categories as the hazards and risks associated with these products have been recently reviewed by FAO and WHO, and Codex has already developed a code of hygienic practice for these products (FAO/WHO 2004; 2006; 2008; CAC, 2008). In addition, the category of dried protein products was refined to exclude cured and fermented meat products, primarily due to the variability of the water activity associated with these products, depending on the recipe and production process. Thus, in terms of meat, only products with a consistently low aw <0.85 e.g. meat powders were summarised for this category. It was also clarified that oils intended for use in food were not considered in this exercise.

2.2 COLLECTION AND REVIEW OF KEY DATA

An overview of the microbiological hazards of concern in LMF was determined to be an important starting point and a structured knowledge synthesis of the global research evidence was commissioned. Specifically, a scoping review and systematic-review/meta-analysis was conducted to summarize: 1) the burden of illness due to microbial contamination of LMF; 2) the prevalence and concentration of selected microbial hazards in LMF; and 3) interventions to reduce microbial contamination of LMF. The review focused on the above mentioned categories of LMF and a selection of pathogenic microbiological hazards: *Bacillus cereus*, *Clostridium botulinum, Clostridium perfringens*, *Cronobacter* spp., pathogenic *Escherichia coli*, *Salmonella* spp., *Staphylococcus aureus*, and *Listeria monocytogenes*. For the purposes of data collection, the following indicator bacteria were also included: Enterobacteriaceae and generic *E. coli*.

The scoping –systematic review was conducted following standardized international principles while also utilizing a "rapid review" approach that employed some short cuts to accommodate limited time and resources (Anderson et al., 2008; Arksey & O'Malley, 2005; Ganann, Ciliska, & Thomas, 2010; Higgins & Green, 2011; Rajić & Young, 2013). Electronic bibliographic databases Scopus and Pubmed/Medline, Google search engine and reference lists of selected key relevant articles were searched using a reproducible search algorithm to identify potentially relevant citations. The scoping review stage was used to identify and characterize available research for all three objectives. Study characteristics were recorded for all relevant articles to describe the breadth and distribution of the current knowledge and to identify the main gaps in knowledge. Systematic review methods were used to extract more detailed data from relevant articles, including information on their methodological/reporting soundness. Meta-analysis was utilized to generate weighted estimates of the prevalence of selected microbial hazards in LMF categories where possible. A full overview of the methodology used and the outcome of this review, presented as an evidence "summary card" for each category of LMF, is described in Appendix 1.

This review was prepared in advance of the expert meeting and served as one of the key pieces of evidence to support the discussions which led to the development of the ranking model. This review was highly appreciated in terms of the comprehensive summaries it provided for each of the categories which could be used directly as information resources to support risk management decisions on specific categories of LMF. Feedback from the experts, both during and after the meeting, was used to finalize the review. Modifications included additional visual presentation of the contamination data for each category in the form of forest plots and additional description in terms of the strengths and the variability of the data sets.

The data presented in Appendix 1 was based on the available literature up to January 13, 2014. In the subsequent months a widely reported outbreak and recall linked to chia seeds unfolded in the USA and Canada (USFDA, 2014). It should also be noted that the scope of the review did not include statistics on LMF recalls. Data on recalls or refused import shipments is difficult to acquire, however it can be a useful indicator of trends. The most easily accessible data from recalls is available for the United States of America and the European Union. These data indicate that there have been recalls across all categories of LMF and while *Salmonella* spp. is the most common reason cited it is far from being the only reason for recalls (see summary data in Appendix 2).

2.3 SELECTION OF CATEGORIES FOR RANKING PURPOSES

During the expert workshop in May 2014 it was agreed that only seven categories would be considered for the purposes of ranking. These were 1; Cereals and grains; 2: Confections and Snacks; 3: Dried fruits and vegetables; 4: Dried protein products; 5: Nuts and nut products; 6: Seeds for consumption; and 7: Spices and dried herbs (including teas). Honey and preserves were excluded based on the information available from the scoping review indicating that the primary hazard of concern in relation to this category was *Clostridium botulinum* and the primary population of concern was infants. In addition, the options for risk management are limited and many countries already provide guidance advising that honey not be consumed by infants.

The expert group also considered special nutritional foods for malnourished populations which have recently been identified as potentially being contaminated with *Salmonella* and *Cronobacter* spp (FAO/WHO, in press). The expert meeting recommended at this point in time that these products not be included as a separate category for ranking purposes due to the limited data associated with these foods at the current time – the scoping review did not identify any information on these products in relation to illness and prevalence of microorganisms, thus the limited data is only available from the agencies which supply these foods to malnourished populations (FAO/WHO, in press). Furthermore, it was considered that there was no information to suggest that these were particularly different from other low moisture and therefore did not warrant a separate category based on consuming population rather than product characteristics. Thus while this category of products were not further considered in the ranking, it was recommended that CCFH make reference to these in the Codex Code of Hygienic Practice currently under development for LMF.

The expert group also clarified that those extensively used common ingredients which are low moisture in nature and are widely used in processed foods e.g. sugar, salt, were not included in this ranking exercise.

2.4 DEVELOPMENT OF RANKING APPROACH

In the development of a ranking approach for LMF in terms of microbiological food safety, the objective was to rank the LMF categories in a robust and transparent way, utilising the best expertise on the subject available and a sound methodology for the assessment of impacts and ranking of food categories.

There were a number of challenges to be overcome in the development of a ranking approach. These included the need for a global perspective in the assessment, the existence of multiple impacts of concern, the limited amount of evidence about some of these impacts, and the need to incorporate the expertise and opinions of the expert panel supporting the ranking process. These challenges led to the use of Multi-Criteria Decision Analysis (MCDA) and, more specifically, Multi-Attribute Value Theory as the conceptual framework (Keeney & Raiffa 1993; von Winterfeldt & Edwards 1986; Edwards, Miles & von Winterfeldt 2007) for the ranking model. This methodology is firmly based on decision theory (French 1989) and measurement theory (Krantz, et al., 1971). It is also well-rooted on behavioural decision research, regarding the elicitation of parameters for the evaluation model (von Winterfeldt, 1999). MCDA has been extensively used in health assessments and prioritizations worldwide, at international level (e.g. WHO) and national levels (e.g. the UK Department for Environment, Food & Rural Affairs (Defra), and the British National Health Service (NHS), among others).

The ranking model was developed and applied in an interactive manner (Franco & Montibeller 2011) by experts in decision and risk analysis and those on the microbiological safety of LMFs. The facilitated approach enabled experts to share information and opinions in a structured way and enhanced the joint understanding and the confidence on the results of the analysis. The evaluation model developed here is an example of the emergent field of Policy Analytics (Tsoukias, et al., 2013), with a focus on bridging the science to policy gap. The modelling process followed a top-down evaluation. The steps followed, as shown in Figure 2.2, were: (i) identification of the fundamental objectives, (ii) definition of evaluation criteria, (iii) definition of attributes, (iv) gathering of evidence for assessing the impacts of each LMF category on each attribute, (v) conversion to normalised impacts of every LMF category on each attribute, (vi) elicitation of priorities for impacts minimisation (criteria weights), (vii) prioritisation of the LMF categories, and (viii) development of a robustness analysis. The process itself and the theory behind it are described in more detail in Appendix 3. The development and application of the ranking model is presented in Chapter 3.

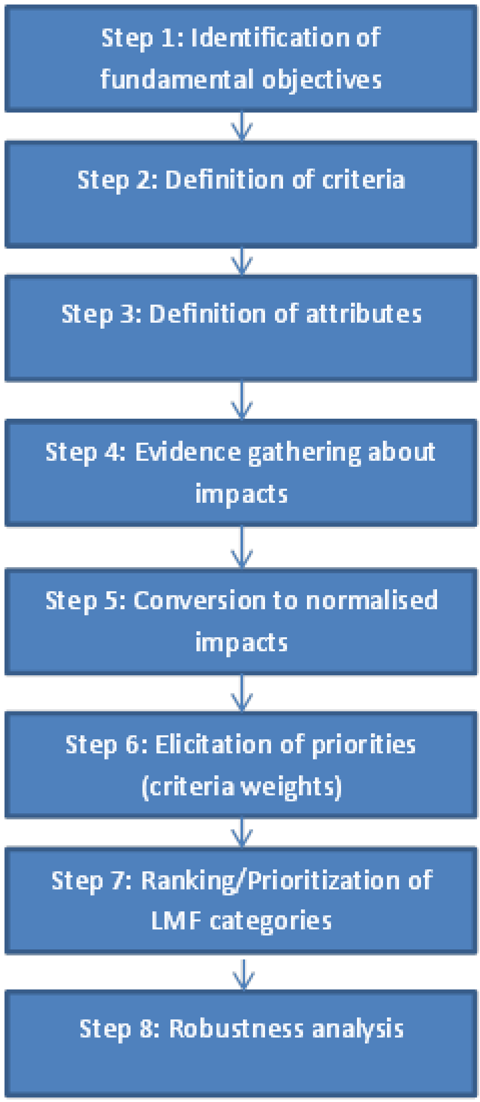

FIGURE 2.2. STEPS IN THE MULTI-CRITERIA PRIORITISATION OF LMF CATEGORIES.

3. DEVELOPMENT AND APPLICATION OF RANKING MODEL

This chapter provides the details of the inputs and the specific evidence that were used in the development and implementation of ranking model. The first step in this type of ranking is to identify the key and the fundamental objectives for the evaluation. While as noted earlier the key objective of this work was to rank LMF in terms of their microbiological food safety concerns in order to support the provision of management guidance by Codex, breaking this down in terms of what it means for countries was used as a first step, which then fed into the description of the criteria, their characterization (definition of their attributes) and ultimately the determination of their relative importance in terms of the weight assigned to each criterion. An overview of each of the steps is provided here with particular emphasis on the data that was used to inform the ranking. More technical details of the ranking approach can be found in Appendix 3.

3.1 STEP 1: IDENTIFICATION OF FUNDAMENTAL OBJECTIVES

The fundamental objectives were defined as International Trade, Burden of Disease, Vulnerabilities due to Food Consumption, and Vulnerabilities due to Food Production. These were defined by use of a means end network and more details are provided in Appendix 3 (Step 1).

3.2 STEP 2: DEFINITION OF EVALUATION CRITERIA

The four fundamental objectives identified in the means-end network - International Trade, Burden of Disease, Vulnerabilities due to Food Consumption, and Vulnerabilities due to Food Production were translated into four evaluation criteria, C1 to C4, and organised as a value tree (Belton & Stewart 2002), as shown in Figure 3.1.

Two evaluation criteria were decomposed into three sub-criteria. The criterion Vulnerabilities from Food Consumption (C3) was decomposed into Average Serving (C3.1), Proportion of Vulnerable Consumers (C3.2), and Potential for Consumer Mishandling (C3.3). The criterion Vulnerabilities from Food Production (C4) was decomposed into Increased Risk of Contamination (C4.1), Proportion without Kill Step (C4.2), and Prevalence of Pathogen (C4.3). These criteria must observe a strict set of properties, to enable a quantitative multi-criteria value model to be developed (See Appendix 3 - Step 2).

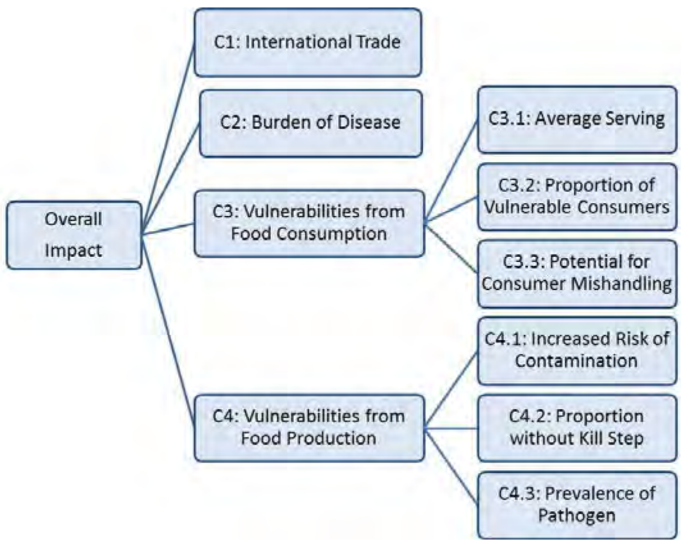

FIGURE3.1. VALUE TREE FOR THE PRIORITISATION OF LMF CATEGORIES

3.3 STEP 3: DEFINITION OF ATTRIBUTES

For each criterion located at the bottom level of the value tree, an associated attribute was specified (Table 3.1). This attribute is a performance indicator employed to measure the impact of each option being assessed on the fundamental objective being pursued.

TABLE3.1. CRITERIA, SUB-CRITERIA, AND ATTRIBUTES FOR THE EVALUATION OF LMF CATEGORIES.

Criteria	Sub-Criteria	Attribute	Source of information /evidence
C1: International Trade	-	Export value in US$ billions/year	FAOSTAT Trade data (http://faostat3.fao.org/)
C2: Burden of Disease	-	Total DALYs in outbreak cases from 1990 onwards	Systematic/scoping review (Appendix 1) and Published DALY data (Appendix 5)
C3: Vulnerabilities due to Food Consumption	C3.1: Average Serving	Average g/day	FAO/WHO Chronic Individual Food Consumption Database Summary Statistics (CIFOCOSS) (Appendix 6)
	C3.2: Proportion Vulnerable Consumers	Proportion (0-100%) consumed by vulnerable groups (toddlers and elderly)	FAO/WHO Chronic Individual Food Consumption Database Summary Statistics (CIFOCOSS) (Appendix 6)
	C3.3: Potential for Consumer Mishandling	Proportion (0-100%) of LMF products in a given category with an increased risk as a result of mishandling/poor practices at any time between final retail and consumption (see Appendix 7 for details)	Expert opinion
C4: Vulnerabilities due to Food Production	C4.1: Increased Risk of Contamination	Proportion (0-100%) of LMF products in a given category with an increased risk of contamination post kill step (see Appendix 7for details)	Expert opinion
	C4.2: Proportion without Kill Step	Proportion (0-100%) of LMF in a given category without a kill step prior to retail and distribution (see Appendix 7 for details)	Expert opinion
	C4.3: Prevalence of Pathogen	Probability that a LMF is contaminated at a level with any pathogens with the potential to cause illness in consumers[1]	Systematic/scoping review (Appendix 1)

[1] Levels of contamination: *Salmonella* = presence, *B. cereus*, *C. perfringens* and *S. aureus*, =>3log CFU/g, pathogenic *E. coli*, *Listeria* and *Cronobacter* were omitted from calculation due to lack of data,

3.4 STEP 4: EVIDENCE GATHERING ABOUT IMPACTS

Following the definition of the criteria and their attributes, an effort was made to collect the available data and evidence that would specifically support evaluation of the criteria against the attributes identified in Table 3.1. The primary sources of data and evidence used to evaluate each of the criteria are also indicated in Table 3.1. Whenever documented evidence was available it was employed, but for some attributes it was necessary to rely on expert judgments. In this case a clear protocol was developed to elicit such parameters, as described in Appendix 7. The sources and the rationale for each attribute are provided below.

C1: INTERNATIONAL TRADE

The data on the value of international trade was collated from FAOSTAT which was found to be the most comprehensive database with regard to LMF as for many categories the data were sufficiently disaggregated to distinguish LMF from other products. The data collated was the most recent available which was from 2011. There was however a number of challenges in terms of using this data and for most categories there are some key caveats which should be highlighted. In the case of cereal and grains it was recognized that not all of these commodities that enter the export market were intended for human consumption. Therefore, a correction factor was applied based on the FAO Food Balance sheets (available at http://faostat3.fao.org/browse/FB/*/E), which indicate from a global perspective the proportion of key commodities which are consumed as food. In relation to confections and snacks, it should be noted that there were limited data for snacks due to the difficulty in clearly defining these. Also with regard to seeds for human consumption, the export figures were also subjected to a correction factor to account for the proportion of seeds which are pressed for oil. An overview of the data and any modifications that had to be made are included in Appendix 4. The trade values for each LMF category are shown in Table 3.2.

TABLE 3.2. VALUES FOR INTERNATIONAL TRADE AND BURDEN OF DISEASE CRITERIA FOR EACH OF THE SEVEN LMF CATEGOREIS

		C1: International Trade	C2: Burden of Disease
Code	**Category Name**	**Export value [US$ billions/year]**	**Total DALYs based on outbreak cases from 1990 onwards**
Cat 1	Cereals and Grains	118.594	72.53
Cat 2	Confections and Snacks	58.124	60.26
Cat 3	Dried Fruits and Vegetables	15.211	32.78
Cat 4	Dried Protein Products	22.800	136.44
Cat 5	Nuts and Nut Products	20.338	118.51
Cat 6	Seeds for Consumption	1.150	18.42
Cat 7	Spices, Dried Herb and Tea	14.938	80.71

C2: BURDEN OF DISEASE

As part of the scoping review any publically available literature on the burden of illness was identified and synthesized for each category. This information was almost exclusively from outbreaks and is summarized in detail in Appendix 1. Total DALYs were calculated from the data on outbreaks since 1990. Across all LMF categories, outbreaks involving *B. cereus*, *Cl. botulinum, Cl. perfringens*, pathogenic *E. coli*, *Salmonella* spp. and *S. aureus* were captured. No outbreaks associated with generic *E. coli*, *Cronobacter* spp., *L. monocytogenes* or Enterobacteriaceae, were identified in the scoping review. The impacts are shown in Table 3.3. Details of the DALY calculations are shown in Appendix 5.

TABLE3.3. IMPACTS FOR THE BURDEN OF DISEASE CRITERION (C2)

C2: Burden of Disease		
Code	**Category Name**	**Total DALYs based on outbreak cases from 1990 onwards**
Cat 1	Cereals and Grains	72.53
Cat 2	Confections and Snacks	60.26
Cat 3	Dried Fruits and Vegetables	32.78
Cat 4	Dried Protein Products	136.44
Cat 5	Nuts and Nut Products	118.51
Cat 6	Seeds for Consumption	18.42
Cat 7	Spices, Dried Herb and Tea	80.71

C3: CONSUMPTION

As mentioned earlier the criterion related to consumption was decomposed to three sub criteria as it was not possible to find a single means of capturing the aspects that the experts determined needed to be considered here. Even when broken down however this was not an easy area for which to obtain data and so a mixture of information from databases and expert elicitation were used in the evaluation of these sub-criteria.

C3.1: AVERAGE SERVING

For the purpose of the exercise, the FAO/WHO Chronic Individual Food Consumption Database Summary Statistics (CIFOCOSS) was chosen as being the most reliable individual food consumption database available at the global level (See Appendix 6). It was noted that it was not possible to provide reliable estimates for the median and therefore for the standard deviation for some LMF categories (i.e. dried fruits and vegetables, dried protein products.) due to the low number of consumers reported in the surveys. The mean serving in grams per day for the average population as well as the amount consumed by those considered to be high consumers were therefore used for ranking purposes and are shown in Table 3.4. The detailed tables on consumption can be found in Appendix 6.

C3.2: VULNERABLE CONSUMERS

For the purposes of this work it was decided to use age as a proxy for vulnerability of consumers and so in this context vulnerable consumers are defined as infants and young children (0 – 35 months) and the elderly (>65 years). While this data is available from population statistics it was not possible to link such data to the LMF categories and therefore this would not distinguish those categories which may be more frequently consumed by the vulnerable population. Therefore, using the CIFOCOSS data that was presented in 3.1, the proportion of consumers that were infants and young children and the elderly was calculated for each category. The results are shown in Table 3.4 and details of the calculations are provided in Appendix 6.

C3.3: POTENTIAL FOR CONSUMER MISHANDLING

This variable is defined as the proportion (0-100%) of LMF products in a given category with an increased risk as a result of mishandling/poor practices at any time between final retail and consumption. It concerns those LMF products to which may become contaminated at high enough levels to affect human health if mishandling occurs (e.g. temperature abuse, etc.) there is addition or combining of ingredients after the kill-step, which would present an opportunity for contamination of the product. The inputs to the ranking model on this sub-criterion were based on expert opinion, where experts were asked to provide the most likely estimate for the variable for each LMF category. The median of these estimates as shown in Table 3.4 was used was used in the ranking. Further details of the expert elicitation process are provided in Appendix 7.

TABLE 3.4. VALUES FOR EACH OF THE SUB-CRITERIA USED TO DESCIRBE THE CRITERION ON VULNERABILITIES DUE TO FOOD CONSUMPTION.

C3.1 - Average Serving		C3.1 - Average Serving		C3.2 - Vulnerable Consumers	C3.3 - Consumer Mishandling
Code	Category Name	Mean [g/day]	High consumers Level (P95) [g/day]	Proportion (0-100%) consumed by vulnerable groups: toddlers and elderly	Proportion (0-100%) of LMF products in a given category with an increased risk as a result of mishandling/poor practices at any time between final retail and consumption
Cat 1	Cereals and Grains	185.0	537.5	14.9	20
Cat 2	Confections and Snacks	67.4	513.0	12.7	5
Cat 3	Dried Fruits and Vegetables	21.1	295.5	16.0	5

Cat 4	Dried Protein Products	1.1	40.0	33.5	25
Cat 5	Nuts and Nut Products	2.1	131.7	19.8	5
Cat 6	Seeds for Consumption	5.5	179.0	12.7	5
Cat 7	Spices, Dried Herb and Tea	4.4	49.1	13.9	15

C4: PRODUCTION

As mentioned earlier the criterion related to production was decomposed into three sub criteria as it was not possible to find a single means of capturing the issues that the experts determined needed to be considered here. The evidence for these sub criteria came from the structured scoping review (Appendix 1) and expert elicitation.

C4.1: INCREASED RISK OF CONTAMINATION

This variable is defined as the proportion (in terms of amount of product produced for human consumption) of LMF products in a given category with an increased risk of contamination post kill step. More specifically, this is defined as those LMF products to which there is addition or combining of ingredients after the kill-step which would present an opportunity for contamination of the product. Inputs on this were based on expert elicitation where experts were asked to provide the Most Likely (ML) estimate for the variable for each LMF category. The median of these estimates are shown in Table 3.5. Further details of the expert elicitation process are provided in Appendix 7.

C4.2: PROPORTION WITHOUT KILL STEP

This variable is defined as the proportion (0-100%) of LMF products in a given category without a kill step prior to retail and distribution. For the purposes of characterizing this parameter a kill step is defined as follows: a process applied to a food or food ingredient with the aim of minimizing public health hazards from pathogenic microorganisms. The process step would likely not inactivate all microorganisms present, but it should reduce the number of harmful ones to a level at which they do not constitute a significant health hazard.

Although not originally intended as a kill step, processes such as roasting or extrusion cooking of LMF may also contribute to reducing numbers of harmful microorganisms which might be present. Regardless of the origin of the process step, all the processes which are used as a kill step must be validated to ensure that they are delivering the intended effect. In the absence of validation, such processes should not be considered as a kill step. Examples of a kill step could include validated processes of: applying heat or other means of inactivation when the food or ingredient has a high water activity (e.g. cooking meat, pasteurizing liquids, etc.). Inputs on this were based on expert elicitation where experts were asked to provide the most likely estimate for the variable for each LMF category. The median of these estimates are shown in Table 3.5. Further details of the expert elicitation process are provided in Appendix 7.

C4.3: PREVALENCE OF PATHOGEN

The pathogen prevalence per category was estimated based average meta-analysis estimates from the scoping-systematic review. Based on the availability of data for all seven categories, and the degree of confidence in that data it was agreed to use data on the prevalence of *B. cereus*, *C. perfringens*, *S. aureus* and *Salmonella* spp. to calculate an estimation of prevalence of contamination for each category. However, one concern that had to be overcome in relation to this approach related to the toxin producing organisms and the fact that they are only of concern when they reach a threshold concentration and toxin production becomes a likely concern. A threshold of 3 log CFU/g was assumed for this exercise. For each category the proportion of positive samples in prevalence surveys that are likely to exceed a 3 log CFU/g threshold was estimated based on the available data. Once the corrected values for each of the pathogens were determined a minimum, maximum and mid value for the overall prevalence of pathogen contamination were determined for each category. This approach involved several round of expert discussion before being finalized in order to confirm that the approach was reasonable and the output was within what was expected. Further details are provided in Appendix 8 and the results are shown in Table 3.5.

TABLE 3.5. VALUES FOR EACH OF THE SUB-CRITERIA USED TO DESCRIBE THE CRITERION ON VULNERABILITIES DUE TO FOOD PRODUCTION

		C4.1 - Increased Risk of Contamination	C4.2 - Proportion Without Kill Step	C4.3 – Prevalence of Pathogens
Code	Category Name	**Proportion (0-100%) of LMF products in a given category with an increased risk of contamination post kill step**	**Proportion (0-100%) of LMF products in a given category not subject to a kill step (see definition below) prior to retail and distribution**	**Prevalence or probability of contamination**
Cat 1	Cereals and Grains	14.55	85	3.94
Cat 2	Confections and Snacks	40	20	2.21
Cat 3	Dried Fruits and Vegetables	10	70	4.84
Cat 4	Dried Protein Products	20	10	2.54
Cat 5	Nuts and Nut Products	10.5	50	0.78
Cat 6	Seeds for Consumption	10	75	2.07
Cat 7	Spices, Dried Herb and Tea	10	75	11.67

3.5 STEP 5: EVALUATION OF NORMALISED IMPACTS

The scale for measuring the normalised impact of each LMF category on every attribute was normalised between 0 (for the lowest impact) to 100 (for the highest impact). This is therefore a linear function, with the properties associated with multi-attribute value theory (Dyer & Sarin 1979). Tables 3.6 to 3.8 show the normalised impact for each attribute of the model.

TABLE3.6. NORMALISED IMPACTS FOR CRITERION C1: INTERNATIONAL TRADE AND CRITERION C2: BURDEN OF DISEASE.

		C1: International Trade		C2: Burden of Disease	
Code	**Category Name**	**Export value [US$ billions/year]**	**Normalised Impact (v_1) [Dis-Value]**	**Total DALYs in outbreak cases from 1990 to 2014**	**Normalised Impact (v_2) [Dis-Value]**
Cat 1	Cereals and Grains	118.594	100.0	72.53	45.9
Cat 2	Confections and Snacks	58.124	48.5	60.26	35.4
Cat 3	Dried Fruits and Vegetables	15.211	12.0	32.78	12.2
Cat 4	Dried Protein Products	22.800	18.4	136.44	100.0
Cat 5	Nuts and Nut Products	20.338	16.3	118.51	84.8
Cat 6	Seeds for Consumption	1.150	0.0	18.42	0.0
Cat 7	Spices, Dried Herb and Tea	14.938	11.7	80.71	52.8

TABLE 3.7. NORMALISED IMPACTS FOR THE CRITERION C3 CONSUMPTION

		C3.1: Average Serving		C3.2 - Vulnerable Consumers		C3.3 - Consumer Mishandling	
Code	**Category Name**	**Average g/day**	**Normalised Impact ($v_{3.1}$) [Dis-Value]**	**Proportion (0-100%) consumed by vulnerable groups: toddlers and elderly**	**Normalised Impact ($v_{3.2}$) [Dis-Value]**	**Proportion (0-100%) of LMF products in a given category with an increased risk as a result of mishandling/poor practices at any time between final retail and consumption**	**Normalised Impact ($v_{3.3}$) [Dis-Value]**
Cat 1	Cereals and Grains	185.0	100.0	14.9	10.6	20	75.0
Cat 2	Confections and Snacks	67.4	36.1	12.7	0.0	5	0.0
Cat 3	Dried Fruits and Vegetables	21.1	10.9	16.0	15.9	5	0.0
Cat 4	Dried Protein Products	1.1	0.0	33.5	100.0	25	100.0
Cat 5	Nuts and Nut Products	2.1	0.5	19.8	34.1	5	0.0
Cat 6	Seeds for Consumption	5.5	2.4	12.7	0.0	5	0.0
Cat 7	Spices, Dried Herb and Tea	4.4	1.8	13.9	5.8	15	50.0

TABLE 3.8. NORMALISED IMPACTS FOR CRITERION C4 .PRODUCTION

		C4.1 - Increased Risk of Contamination		C4.2 - Proportion Without Kill Step		C4.3 - Prevalence of Pathogens	
Code	**Category Name**	**Proportion (0-100%) of LMF products in a given category with an increased risk of contamination post kill step**	**Normalised Impact ($v_{4.1}$) [Dis-Value]**	**Proportion (0-100%) of LMF products in a given category not subject to a kill step (see definition below) prior to retail and distribution**	**Normalised Impact ($v_{4.2}$) [Dis-Value]**	**Presence of contamination ($\log_{10}$ cfu/g)**	**Normalised Impact ($v_{4.3}$) [Dis-Value]**
Cat 1	Cereals and Grains	14.55	15.2	85	100.0	3.94	29.0
Cat 2	Confections and Snacks	40	100.0	20	13.3	2.21	13.1
Cat 3	Dried Fruits and Vegetables	10	0.0	70	80.0	4.84	37.3
Cat 4	Dried Protein Products	20	33.3	10	0.0	2.54	16.2
Cat 5	Nuts and Nut Products	10.5	1.7	50	53.3	0.78	0.0
Cat 6	Seeds for Consumption	10	0.0	75	86.7	2.07	11.8
Cat 7	Spices, Dried Herb and Tea	10	0.0	75	86.7	11.67	100.0

3.6 STEP 6: ELICITATION OF CRITERIA WEIGHTS

The aggregation of multiple impacts into an overall impact requires the definition of priorities among the impacts considered. These priorities are represented by criteria weights in a multi-criteria model. It is important that proper elicitation procedures are employed for obtaining these parameters from experts, as they should consider not only the relative importance of the criteria but also the ranges of each attribute in such prioritisation[2] (Keeney & Raiffa 1993; Keeney 2002).

Several valid protocols are available and in this exercise the weights were elicited from the expert group using an adaption of the swing weighting method (see (von Winterfeldt & Edwards 1986)), which makes the assessments more concrete. Details of the protocol used are included in Appendix 3 (Step 6). The weights elicited for each of the criteria and sub-criteria are presented in Table 3.9. The swing weights define the level of importance to be applied to each of the criteria in the final ranking. The experts clearly identified Burden of disease as the most important criterion in the ranking exercise. There were some differences of opinions among experts, regarding the swing weights for the other three criteria. Ultimately, production was considered to be the second most important criterion, followed by consumption and finally international trade.

TABLE 3.9: OVERVIEW OF THE SWING WEIGHTS AND THEIR RANGES ASSIGNED TO EACH OF THE 4 MAIN CRITERIA THROUGH EXPERT ELICITATION.

Criteria	Swing weight	Range	Normalized value (%)	Range (%)
C1 International trade	45	[30, 60]	16.7	[11.8, 21.1]
C2 Burden of Disease	100	-	37	
C3 Consumption	50	[40, 65]	18.5	[15.4, 22.8]
C4 Production	75	[70,80]	27.8	[26.4, 29.1]

3.7 STEP 7: PRIORITISATION OF LMF CATEGORIES (RESULTS)

As the criteria are preferentially independent, i.e. the impacts of LMF categories can be assessed independently on every attribute (Keeney 1996; von Winterfeldt & Edwards 1986), a simple weighted sum could be used to aggregate the different normalised impacts onto a single overall impact.

The overall normalised impact (V) of a LMF category *a* is thus given by the following formula:

[2] The notion of direct importance of a criterion should be avoided in defining weights of evaluation criteria, as it can lead to the misleading definition of these parameters (von Nitzsch & Weber, 1993) and misrepresentation of priorities (Keeney, 2002).

$$V(a) = w_1 v_1(a) + w_2 v_2(a) + w_3 v_3(a) + w_4 v_4(a). \qquad \text{[Eq. 1]}$$

With:

$$w_1 + w_2 + w_3 + w_4 = 1.$$

The normalised aggregated impact (v_3) for Food Consumption is given by:

$$v_3(a) = w_{3\cdot1} v_{3.1}(a) + w_{3.2} v_{3.2}(a) + w_{3.3} v_{3.3}(a). \qquad \text{[Eq. 2]}$$

With:

$$w_{3\cdot1} + w_{3.2} + w_{3.3} = 1.$$

The normalised aggregated impact (v_4) for Food Production is given by:

$$v_4(a) = w_{4\cdot1} v_{4.1}(a) + w_{4.2} v_{4.2}(a) + w_{3.3} v_{4.3}(a). \qquad \text{[Eq. 3]}$$

With:

$$s_{4\cdot1} + w_{4.2} + w_{4.3} = 1.$$

Table 3.10 shows the impact from the three sub-criteria of Food Consumption (C3) and their aggregated impact for each LMF category, using Equation 2 above and the baseline weights elicited in the previous step of the analysis. This illustrates that based on consumption criteria alone, cereals and grains and dried protein products have a very similar high score and rank far ahead of the other categories based on this criterion.

TABLE 3.10. NORMALISED AGGREGATED IMPACT ON FOOD CONSUMPTION (C3) FOR EACH LMF CATEGORY

C3: Food Consumption					
		C3.1 - Average Serving	**C3.2 - Vulnerable Consumers**	**C3.3 - Consumer Mishandling**	**Impact Food Consumption**
Code	**Category Name**	[Dis-Value]	[Dis-Value]	[Dis-Value]	**[Dis-Value]**
Cat 1	Cereals and Grains	100.0	10.6	75.0	**57.9**
Cat 2	Confections and Snacks	36.1	0.0	0.0	**15.7**
Cat 3	Dried Fruits and Vegetables	10.9	15.9	0.0	**11.6**
Cat 4	Dried Protein Products	0.0	100.0	100.0	**56.5**
Cat 5	Nuts and Nut Products	0.5	34.1	0.0	**15.1**
Cat 6	Seeds for Consumption	2.4	0.0	0.0	**1.0**
Cat 7	Spices, Dried Herb and Tea	1.8	5.8	50.0	**9.8**
	Normalised Weights	$w_{3.1}$ = 43.5%	$w_{3.2}$ = 43.5%	$w_{3.3}$ =13.0%	

Table 3.11 shows the impact from the three sub-criteria of Food Production (C4) and their overall normalised impact for each LMF category, using Equation 3 above and the baseline weights elicited in the previous step of the analysis. Considering the production criterion alone, spices, dried herbs and teas rank highest, followed by cereals and grains and dried fruits and vegetables. Against this criterion, dried protein products rank much lower, which may be a reflection of the well-controlled conditions under which the dried protein products considered in this ranking are produced.

TABLE 3.11. NORMALISED IMPACT ON FOOD PRODUCTION (C4) FOR EACH LMF CATEGORY

C4: Vulnerability Food Production					
		C4.1 - Risk of Contamination	**C4.2 - Proportion Without Kill Step**	**C4.3 - Prevalence of Pathogens**	**Impact Food Production**
Code	**Category Name**	[Dis-Value]	[Dis-Value]	[Dis-Value]	**[Dis-Value]**
Cat 1	Cereals and Grains	15.2	100.0	29.0	**50.0**
Cat 2	Confections and Snacks	100.0	13.3	13.1	**29.7**
Cat 3	Dried Fruits and Vegetables	0.0	80.0	37.3	**44.4**
Cat 4	Dried Protein Products	33.3	0.0	16.2	**14.0**
Cat 5	Nuts and Nut Products	1.7	53.3	0.0	**18.1**
Cat 6	Seeds for Consumption	0.0	86.7	11.8	**34.5**
Cat 7	Spices, Dried Herb and Tea	0.0	86.7	100.0	**76.5**
	Normalised Weights	$w_{4.1}$ = 19.0%	$w_{4.2}$ = 33.3%	$w_{4.3}$ = 47.6%	

Table 3.12 shows the normalised impacts on the four main criteria and the overall normalised impact for each LMF category, using Equation 1 above and the baseline weights elicited in the previous step of the analysis. Category 1 (Cereals and Grains) has the highest score (V = 58.3), followed by Category 4 (Dried Protein Products, V = 54.5), and then Category 7 (Spices, Dried Herb and Tea, V = 44.6).

TABLE 3.12. OVERALL IMPACT FOR EACH LMF CATEGORY AND FINAL RANKING OF LMF CATEGORIE.

Code	Category Name	C1 - International Trade (v_1)	C2 - Burden of Disease (v_2)	C3 - Food Consumption (v_3)	C4 - Food Production (v_4)	Overall Impact (V) [dis-value]	Ranking order
Cat 1	Cereals and Grains	100.0	45.9	57.9	50.0	**58.3**	**1**
Cat 2	Confections and Snacks	48.5	35.4	15.7	29.7	**32.4**	**5**
Cat 3	Dried Fruits and Vegetables	12.0	12.2	11.6	44.4	**21.0**	**6**
Cat 4	Dried Protein Products	18.4	100.0	56.5	14.0	**54.5**	**2**
Cat 5	Nuts and Nut Products	16.3	84.8	15.1	18.1	**42.0**	**4**
Cat 6	Seeds for Consumption	0.0	0.0	1.0	34.5	**9.8**	**7**
Cat 7	Spices, Dried Herb and Tea	11.7	52.8	9.8	76.5	**44.6**	**3**
Normalised Weights		W_1 = 16.7%	W_2 = 37.0%	W_3 = 18.5%	W_4 = 27.8%		
						100.0%	

Figure 3.2 presents the contribution of each main criterion to the overall normalised impact of every LMF category. Notice that a large part of the overall score of Category 4 comes from its impact on the Burden of Disease criterion (v_2 = 37), while Category 1 has more distributed impacts on the four main criteria. Thus Figure 3.2 not only illustrates the overall ranking but the criterion which really drove the ranking result. Category 1 (Cereals and Grains) had quite high impacts for all criteria, especially for International Trade and Food Consumption criteria, compared to most of the other categories. This is not particularly surprising given that this category included the commodities and products which are considered as staple foods in most parts of the world. However, having said that, these aspects did not completely overshadow the other criteria. For category 4 (Dried Protein Products), burden of disease was the dominating driver of the high score, primarily due to a couple of very large outbreaks associated with dried dairy products, which equated to a high total DALY for this food category. For the third ranked category, category 7 (Spices, Dried Herbs and Tea), the Vulnerabilities of the Production and the Burden of Disease were the driving factors. Generally spices and dried herbs are produced without any steps to reduce or kill pathogens. In addition, it should be noted that most of the outbreaks involved *Salmonella*, which has a higher DALY than other common pathogens e.g. *B. cereus*. For category 5 (Nuts and Nut Products): burden of disease was also the key driver as

with spices and dried herbs, because there have been several moderate to large outbreaks of international concern (e.g. Roasted peanuts (2001) shipped globally from China).

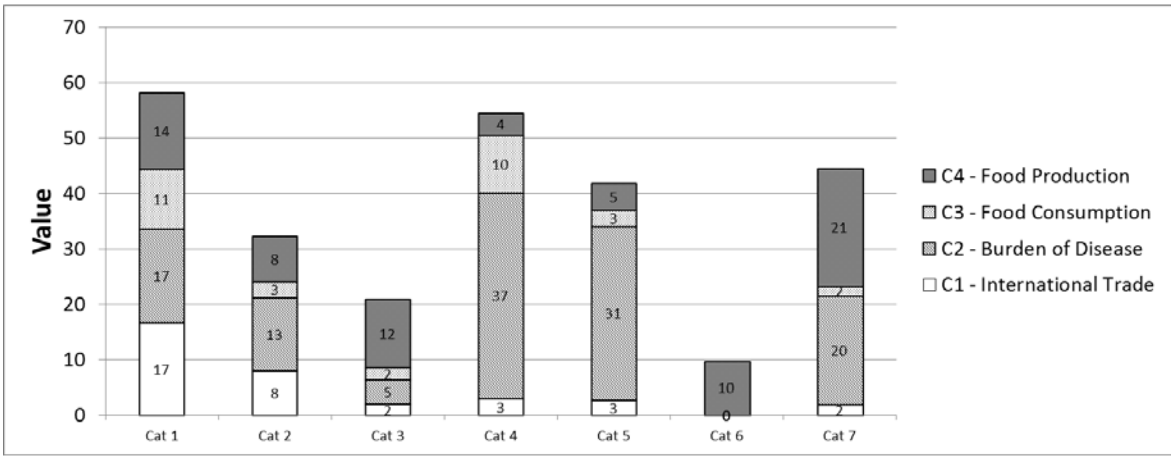

FIGURE3.2. OVERALL IMPACT LMF CATEGORIES

3.8 STEP 8: ROBUSTNESS ANALYSIS

It is important that the modelling process is used as a learning tool, i.e. not to prescribe a solution but, instead, to explore the robustness of the findings and the consequences that uncertainties might cause on the ranking (Roy 1993; Roy 2010).

An interactive robustness analysis was conducted with the experts during the ranking process by varying input parameters to test the sensitivity of results to their changes. This was done by using a spreadsheet-based decision support system developed during the project. In addition, a detailed backroom robustness analysis was conducted, concerning difference of priorities among the expert group (criteria weights) and uncertainties about the evidence available (impacts).

SENSITIVITY TO CRITERIA WEIGHTS – MAIN CRITERIA OF THE MODEL

As mentioned previously, the elicitation of weights from experts provided ranges of weights. In this section the consequences of varying weights on the ranking of LMF categories for the four main criteria of the model are analysed.

Figure 3.3 presents a sensitivity analysis of the overall impact of every LMF category as the weight of Criterion C1 (International Trade) is ranged from 0 to 100%. The baseline weight of this criterion in the model is w_1 = 16.7% and is indicated by the black vertical line. With this baseline weight, Category 1 has the highest overall score, followed by Category 4, then Category 7 as indicated in the figure. (Notice that the ranking of the categories with the baseline weights is the same for all the subsequent criteria analysed here.). As shown in Figure 3.3, if the weight of this criterion was further increased, to the right of the black vertical d line, Category 1's overall normalised impact would further increase – therefore more emphasis on International Trade would lead to the selection of Category 1. However, if the weight of this criterion were decreased, there is a point where Category 1 intersects with Category 4 (point ①: w'_1 = 12%). Any further reduction of weight beyond this point ① would lead to the selection of Category 4. Notice that the range provide by the experts (w_1 = [11.8%, 21.1%]) contemplates a lower-bound for this weight that is slightly below w'_1 = 12%, which indeed could lead to the selection of Cat 4.

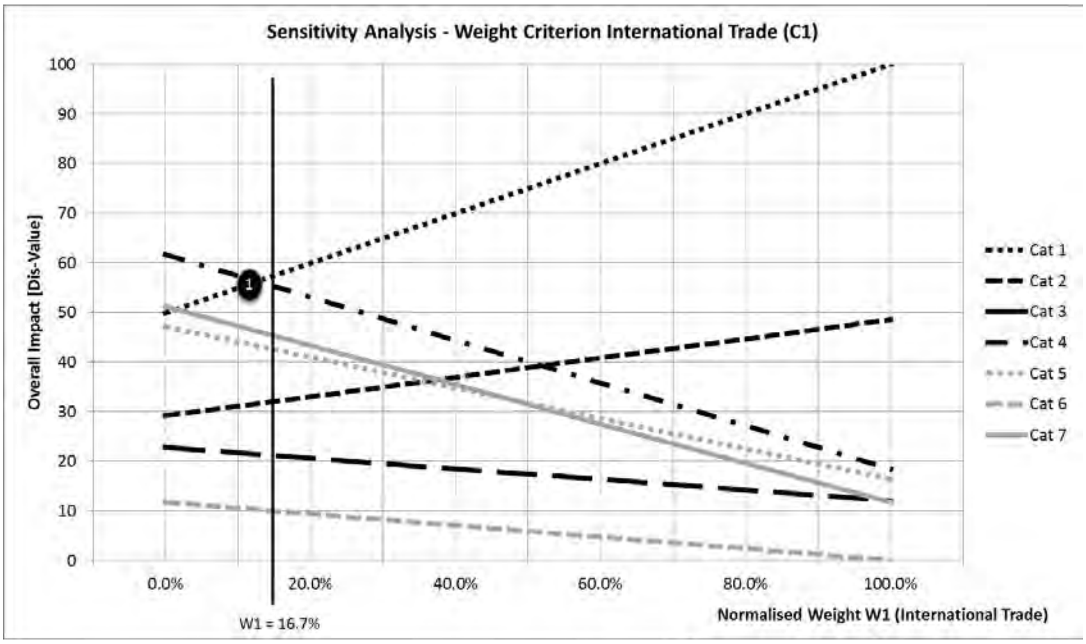

FIGURE 3.3. SENSITIVITY ANALYSIS FOR THE WEIGHT OF CRITERION C1 (INTERNATIONAL TRADE)

Figure 3.4 presents a sensitivity analysis of the overall normalised impact of every LMF category as the weight of Criterion C2 (Burden of Disease) is ranged from 0 to 100%. The baseline weight of this criterion in the model is w_2 = 37.0% and is indicated by the black vertical line. If the weight of this criterion were increased, to the right of the black vertical line, there is a point where Category 1 intersects with Category 4 (point ②: w'_2 = 41.4%). If the weight of this criterion were further increased beyond this point ②, Category 4 should rank higher. For any level below point ② Category 1 remains the highest in the rank. Notice that experts did not contemplate a further increase in this parameter during the elicitation of weights.

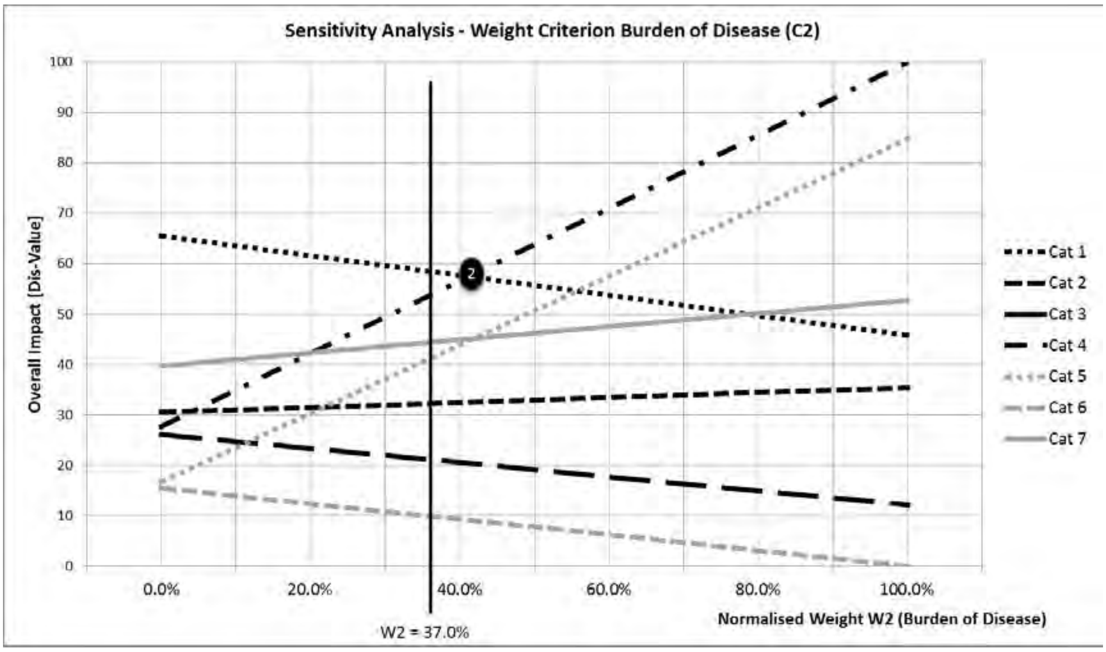

FIGURE 3.4. SENSITIVITY ANALYSIS FOR THE WEIGHT OF CRITERION C2 (BURDEN OF DISEASE)

Figure 3.5 presents a sensitivity analysis of the overall normalised impact of every LMF category as the weight of Criterion C3 (Food Consumption) is ranged from 0 to 100%. The baseline weight of this criterion in the model is w_3 = 18.5% and is indicated by the black vertical line. As the graph shows, whatever the priority (weight) placed on this criterion, the highest LMF category is always Category 1.

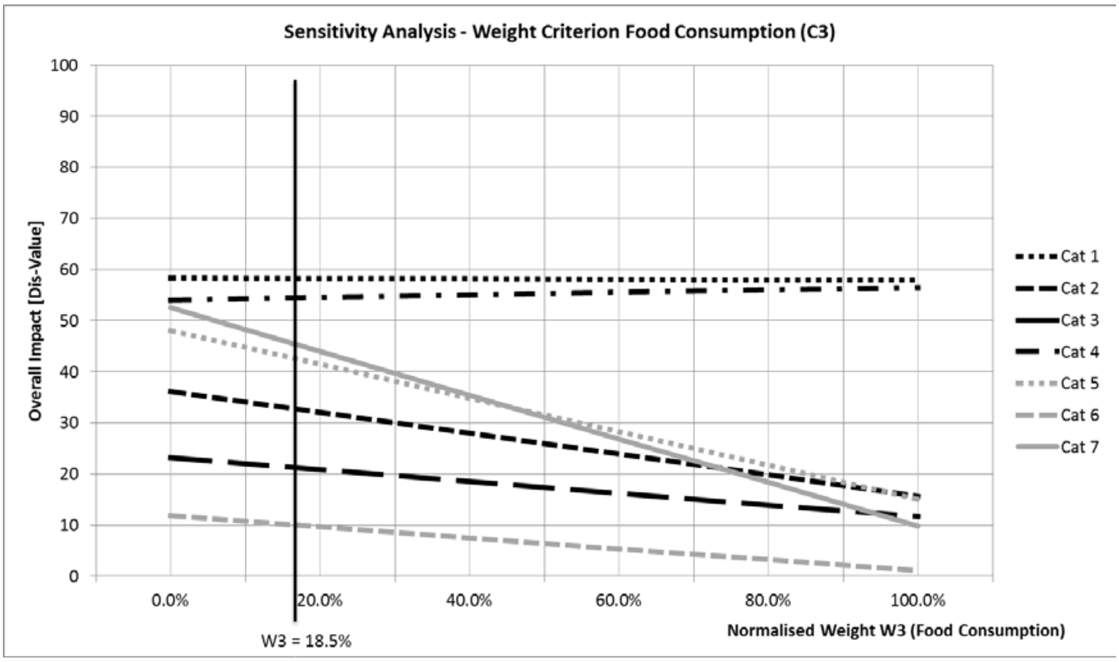

FIGURE 3.5. SENSITIVITY ANALYSIS FOR THE WEIGHT OF CRITERION C3 (FOOD CONSUMPTION)

Figure 3.6 presents a sensitivity analysis of the overall normalised impact of every LMF category as the weight of Criterion C4 (Food Production) is ranged from 0 to 100%. The baseline weight of this criterion in the model is w_2 = 27.8% and is indicated by the black vertical line. If the weight of this criterion were reduced to the left of the black vertical line, there is a point where Category 1 intersects Category 4 (point ③: w'_4 = 20.0%). For weights below this level, Category 4 should rank highest. On the other hand, if the weight of this criterion were increased, to the right of the vertical line, there is a point where Category 1 intersects with Category 7 (point ④: w''_4 = 52.0%). For weights above this level Category 7 should rank highest. Notice that the range of weights provide by the experts for this criterion (w_4 = [26.4%, 29.1%]) is within points ③ and ④, where Category 1 has the highest score.

These analyses of sensitivity on weights show that the ranking is quite robust to changes of priorities, with either Category 1 or Category 4 always being on the top position. There are no intersection points very near the baseline weights and, in all case except for Criterion 1 (Figure 3.3), there was not a range of weights provided by the experts that reached any intersection point. (For Criterion 1, the lower bound of the range provided by experts was only slightly below the intersection point ①.)

In addition to this analysis, the four graphs (Figure 3.3 to 3.6) can help in identifying the category to be selected if their priorities increase/decrease from the baseline weights suggested by the expert group during this ranking exercise.

The sensitivity analysis of the sub criteria for criterion 3 and 4 are presented in Appendix 3 (Step 8) with similar results. In addition an analysis of robustness considering the uncertainties about the evidence available particularly in those sub criteria which were based on expert opinion was undertaken as shown in Appendix 3.

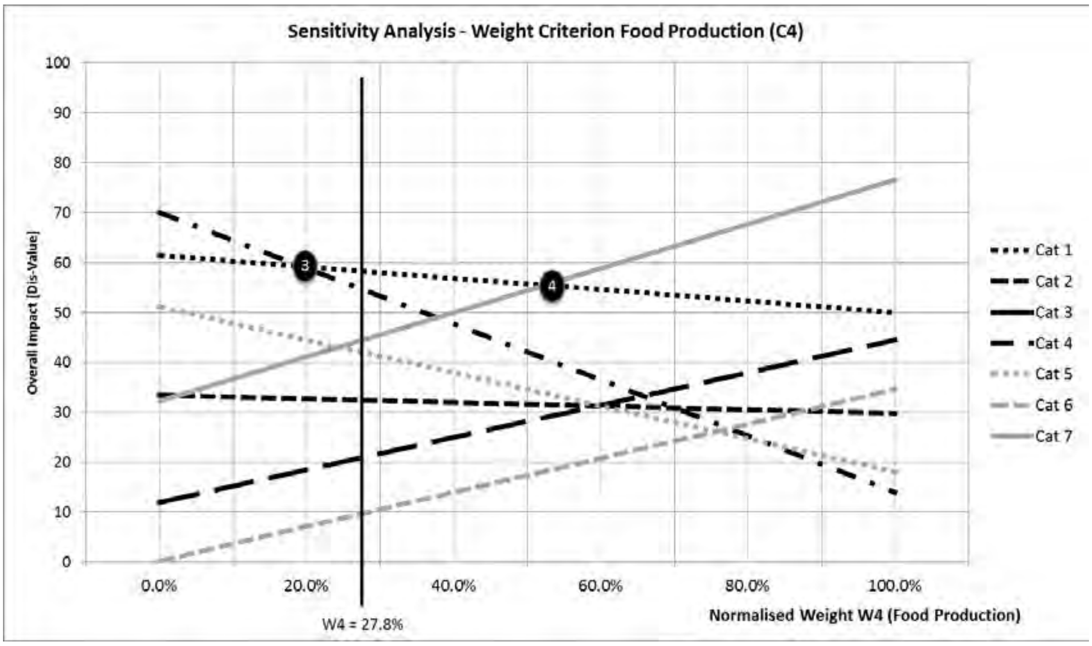

FIGURE3.6. SENSITIVITY ANALYSIS FOR THE WEIGHT OF CRITERION C4 (FOOD PRODUCTION)

5. DISCUSSION AND CONCLUSIONS

RANKING RESULTS

Cereals and Grains were in the first position in the ranking that was undertaken. It had quite high impacts for all criteria, especially for the International Trade and Food Consumption criteria, compared to most of the other categories. However it also ranked among the top categories for the other two criteria, Burden of illness and Food Production. This is a diverse group of products, which are consumed globally and subject to many different production and preparation practices. It includes staple commodities for much of the world and thus measures to control the microbiological hazards associated with this category will potentially have wide reaching impact in terms of consumer health protection.

Dried Protein Products was ranked second overall. Burden of Disease was the dominating driver of the high score, primarily due to a couple of very large outbreaks associated with dried dairy products which led the increase of DALYs for this food category. While there was some concern expressed by the experts that these outbreaks were having too large an impact on the ranking of this category, it was also acknowledged that, while in general many of the commodities in this category are produced under well controlled conditions, if something does go wrong, the potential impact is extensive. This is impacted by the wide distribution of the products considered in the ranking e.g. dried milk powder as well as other factors such as their extensive use as ingredients and the potential for them to be prepared in a way prior to consumption that is favourable for microbial growth.

Spices, dried herbs and teas ranked third overall. Food Production and Burden of Disease criteria were the driving factors. Despite the fact that these commodities are generally consumed in small amounts, there is ample opportunity for contamination during the production and processing stages. While they may be subjected to microbial inactivation treatments, these may not be suitable for or permitted for all possible commodities in this category, or if GAP/GMP/GHP have not been applied may not be adequate to reduce the contamination to levels which minimize the risk to consumer health. In addition, it should be noted that several large outbreaks of salmonellosis associated with the food category have been observed recently.

Nuts and nut products, which were ranked fourth, with Burden of Disease being once again the important driver. In this case also, there have been several outbreaks of international concern. For confections and snacks, there was a better distribution of impact across the criteria, although consumption was lowest here. For dried fruits and vegetables and seeds, production conditions had the greatest impact with limited or no impact from other criteria.

An extensive robustness analysis of the ranking results was conducted, considering both the criteria weights and the parameters where expert judgment was required. These analyses of sensitivity on weights showed that the ranking was quite robust to changes of priorities, with either Category 1 or Category 4 always being on the top positions - the latter would become the top ranked if the weight of burden of disease were further increased. Due to the large quantity of these two product categories relative to other categories, it is not surprising that these ranked highly, and in other words, improvements in these industries are likely to have a larger impact on public health compared to LMFs consumed in smaller portions and with lower frequency. There are no intersection points very near the baseline weights for any of the criteria except for Criterion 1. In the context of this sensitivity or robustness analysis the model was considered to be robust. The sensitivity or robustness analysis can also help in identifying the changes in the ranking if significant changes in weights, away from the baseline weights established by experts, were considered.

KNOWLEDGE SYNTHESIS AND DATA COLLECTION TO SUPPORT DECISION MAKING

Synthesis research methodologies such as systematic review offer transparent and replicable methods to identify critically appraise and synthesize the literature on a clearly formulated question (Young et al. 2014, Sargeant J. et al. 2014; Higgins and Green, 2011). Thus, synthesis research results provide a valuable means of underpinning evidence-informed policy making in food safety and public health because of the improved transparency and accountability they lend to the process (Rajić, Young & McEwen 2013). Meta-analysis is a statistical method to combine results from similar studies identified in a systematic review, which measure the same outcome, into an overall average estimate of effect (Young et al. 2014, Sargeant J. et al. 2014). This ranking process used evidence-informed inputs from a rapid scoping and systematic review that synthesized global evidence and presented meta-analytic summaries of the current knowledge of the microbial food safety (prevalence and concentration), burden of illness and effectiveness of interventions against microbial contamination of LMF.

Some of the key points in relation to data highlighted by this process include the following:

- There is significant variability in the quantity and quality of data for prevalence and concentration of selected bacteria in various LMF products. Some prevalence estimates were underpinned by >10 studies and represented surveys from around the world, whereas others may have only been underpinned by 2 small studies from remote regions. (e.g. *E. coli* O157:H7 in cereals and grains, which the experts decided to dismiss from the estimation of contamination)
- Meta-analytic summaries of prevalence data were computed where possible. Data related to important contamination thresholds for toxin producing bacteria and the proportion of contaminated samples likely to exceed the thresholds were extracted from the literature identified in the scoping study. However, the amount of data available for this additional and informative analysis was limited.
- Burden of illness data was almost exclusively related to outbreaks. It was the outbreak data that was used to calculate DALYs for each category as an indicator or relative measure of the potential burden of illness in each category. No primary data was available on sporadic cases of illness of LMF.
- Burden of illness data was considered by the experts to underrepresent what is likely occurring as many LMFs are components of mixed dishes and the likelihood of them being associated with illness is significantly lower than for other foods e.g. ground beef or eggs. However the outbreaks represent a signal that something has gone wrong and while these may be only a fraction of actual illness caused by LMF, the experts decided that this was the best information we have and that it should be used for the relative ranking between categories.
- Intervention studies identified from the literature were largely small challenge trials that used artificially inoculated samples and were conducted under laboratory conditions. These studies suffered from small sample size and potentially exaggerated effectiveness due to the challenge, most interventions were not commercialized or conducted under commercial conditions, and therefore the generalizability is limited. However many of the investigated interventions are already being implemented on a commercial scale in some LMF industries (e.g. nuts and spices), which means that there is a possibility that

these interventions based on experimental trials could not always eliminate hazards from LMF under commercial conditions. Therefore, prevention of cross-contamination and GHP/GMP/HACCP based control would be important to minimize hazards in LMF.

- There was also significant variability in the data for different categories of LMF, relevant to those criteria such as trade and consumption. For those LMF which are consumed in a state close to the primary commodity e.g. nuts, seeds, there were adequate data to allow characterization of the situation. However, for more complex products such as confections and snacks, or those categories such as cereals and grains where there are a very large number of potential products, a number of assumptions had to be made to enable use of the data. This highlights the challenge of reviewing such broad categories of products.

- LMF categories covered a diverse number of categories and products. The work that went into this report, summarizing the literature, gathering additional data and obtaining expert opinion very carefully tried to balance the complexity of the industries which produce the LMFs of interest with the desire to summarize by larger categories to get an appreciation for those categories where guidelines and improved production practices may have the largest impact on the quality of the food and public health. It is anticipated that some categories will need to be organized into sub-categories with related production processes to develop good production practices.

MCDA AS A RANKING APPROACH FOR FOOD SAFETY ISSUES

The MCDA process when professionally facilitated offers a clear transparent approach to ranking options. The experts were challenged to step outside of their particular area of expertise and consider LMF diversity on a global scale. The resulting ranking makes sense from this global perspective.

While the output of this ranking process was considered to be reasonable, the approach like others is still something that is reflective of the time it was undertaken, and the available data. If this exercise was repeated at a regional or global level, it is likely there would be some modification to the outcome. However from the global perspective, the MCDA approach facilitated the combination of quantitative and non-quantitative inputs on a range of criteria which are not always easy to combine.

The MCDA approach is not the same as a risk-based approach and this may provide a challenge for those working in the food safety area and are more familiar with the concept of risk.

This process has not highlighted LMFs where there is evidence and willingness for change within the production industry. This was outside of this project's scope, but would potentially be of interest when evaluating where influence and impact could happen easily and quickly within the industry.

CHALLENGES AND BENEFITS OF PROCESS

The use of synthesis methodology to provide evidence-based summaries of the global knowledge that was used to guide expert discussions, and as inputs (where appropriate) into the MCDA was a valuable addition to the process, especially with the diverse topic of LMF, where no expert necessarily had knowledge across all categories. The synthesis report (appendix 1) provided a basis for discussion and transparent list of the available evidence including outbreaks. Furthermore, it was recognized by the expert group that the output of the knowledge synthesis alone serves as a valuable resource in itself to inform risk managers on the issues and challenges associated with LMF.

The synthesis methodologies and the MCDA approaches require time and expertise to execute and they were new to most of the experts. As a result time was required during the consultation process to introduce the concepts and continually reiterate strengths and challenges with these methods. A major strength of the synthesis methodology is the transparency and inclusiveness. This was highlighted on several occasions during the consultation process where the content was challenged primarily for possible missing information (outbreaks primarily), however, the outbreak or article was on each occasion located in the synthesis documentation or an explanation of why it did not meet the inclusion criteria identified.

There were a number of challenges to be overcome in the development of a ranking approach. Firstly, there was the need for a global perspective in the assessment. Secondly, multiple impacts of concern existed. Thirdly, there was the limited amount of evidence about some of these impacts. Fourthly, there was the need to incorporate the expertise and opinions of the expert panel supporting the ranking process.

The evaluation model that was developed had several important features. Firstly, it was grounded on an appropriate decision frame that considered the nature of the impacts to be assessed. Secondly, it considered decision criteria and associated measurements (attributes) that fulfilled the required properties for a rigorous value assessment, and the unambiguous assessment of impacts. Thirdly, it represented criteria weights that were appropriately elicited using psychometrically valid procedures, and which fulfilled the required properties demanded by multi-attribute value theory. Finally, it was based on a robust methodology and was fit-for-purpose, given the evidence available and the defined criteria.

The modelling process that was developed had several benefits. Firstly, it organized the many conflicting criteria under consideration. Secondly, it clarified and adequately measured the impacts of each LMF category on the criteria considered, given the evidence available. Thirdly, it enabled the aggregation of partial impacts into an overall impact given the associated trade-offs, and thus an adequate ranking of LMF categories. Fourthly, it ensured a successful deployment of the evaluation model by involving key experts during the decision modelling process. Fifthly, it supported the sharing of information, opinions and perspectives among the experts, enabling a better understanding of the evaluation problem and learning about the evidence, impacts, priorities, and the final ranking.

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GLOSSARY

Attributes: The performances indices that enable the evaluation of the impact of every option on each criterion considered in a multi-criteria evaluation.

Decision Theory: A normative theory, based on mathematical axioms, that prescribes how rational decisions should be made.

Evaluation Criteria: The variables that decision makers/assessors want to consider when assessing options in decisions with conflicting objectives or multi-criteria evaluations.

Fundamental Objectives: The fundamental concerns that decision makers/assessors want to take into account in decisions with conflicting objectives or multi-criteria evaluations.

Impacts: The possible consequences that each option may generate on the criteria considered in the multi-criteria evaluation, given the evidence available.

Means-End Network of Objectives: A qualitative model that represent the means objectives available to decision/policy makers to achieve their fundamental and ultimate objectives.

Measurement Theory: A theory that defines how measurements should be made to assure the compatibility between stimuli (e.g. judgments) and responses (e.g normalised impacts).

Meta-Analysis: A statistical technique to obtain weighted estimates of effect, association or prevalence on data from multiple, similar primary research studies collected in a systematic review.

Multi-Attribute Value Theory: A multi-criteria methodology to support the assessment of the overall value of options by evaluating their partial value on every criterion for impacts that are deterministic.

Multi-Criteria Decision Analysis: A group of methodologies to support decision making when there are conflicting objectives to be achieved when evaluating and choosing options.

Multi-Criteria Value Model: An evaluation model which represents the evaluation criteria, the criteria weights, and the normalised impacts of the options, and enables the evaluation of the overall impact of each option under consideration.

Normalised Impacts: The re-scaled impacts of options being evaluated, on a 0-100 scale (where the option with the lowest impact is set as 0, the one with the highest impact as 100, and the other options scored proportionally to those two bounds of the scale). The unit of normalised impacts is dis-value (the higher the number, the highest is the concern about it).

Overall Normalised Impact: The normalised impact of every option being evaluated, on a 100-0 scale, which is obtained by aggregating all the normalised impacts from the criteria. The unit of overall normalised impacts is dis-value (the higher the number, the highest is the concern about it).

Preferential Independence: A logical property of the criteria that enables the assessor to evaluate the impacts of options on one criterion independently of their impacts on all the other criteria of the model.

Robustness Analysis: An analysis designed to explore the robustness of the ranking provided by a multi-criteria evaluation regarding the input parameters of the model (impacts and weights).

Sensitivity Analysis: An analysis designed to explore how sensitive to input parameters of the multi-criteria model the option with the highest overall impact is.

Rapid Review: A streamlined scoping or systematic review that uses some shortcuts or restrictions in the standardized review process to synthesize evidence about a given topic or question in short timelines and/or using limited resources to directly inform urgent decision-making.

Scoping Review: A structured and transparent method of knowledge synthesis used to identify, "map out" and describe the distribution and characteristics of a broad research or topic area.

Systematic Review: A structured and transparent method of knowledge synthesis that uses a clearly defined question to comprehensively search, assess, appraise, summarize and analyse the available research literature on a given topic or question.

Swing-weighting method: A valid elicitation protocol to elicit criteria weights for multi-criteria value models, by presenting the ranges of attributes associated with the evaluation criteria and asking decision makers to value such ranges.

RANKING OF LOW MOISTURE FOODS IN SUPPORT OF MICROBIOLOGICAL RISK MANAGEMENT

REPORT OF AN FAO/WHO CONSULTATION PROCESS

Preliminary Report

30th October

2014

PART II – APPENDIX 1

RAPID SCOPING AND SYSTEMATIC REVIEW-META-ANALYSIS OF RESEARCH KNOWLEDGE

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

2014

Microbial Hazards in Low-Moisture Foods: Rapid Scoping and Systematic Review-Meta-Analysis of Research Knowledge

Co-authors: Laboratory for Foodborne Zoonoses-Guelph, Public Health Agency of Canada, in collaboration with the Food and Agriculture Organization and World Health Organization of the United Nations

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Introduction and Objectives

The burden of foodborne illness and the number of food recalls associated with microbial hazard contamination of low-moisture foods (LMF) has risen in recent years (Beuchat et al., 2013; Dey, Mayo, Saville, Wolyniak, & Klontz, 2013; Finn, Condell, McClure, Amezquita, & Fanning, 2013; Podolak, Enache, Stone, Black, & Elliott, 2010; Scott et al., 2009; Van Doren et al., 2013; Vij, Ailes, Wolyniak, Angulo, & Klontz, 2006). LMF are naturally low in moisture or are produced from higher moisture foods through drying or dehydration processes. The low water activity (a_w) of these foods contributes to a long shelf life (Finn et al., 2013). Examples of LMF products include cereals, grains, confections (e.g. chocolate), powdered-protein products (e.g. dairy and egg powders), dried fruits and vegetables, honey, spices, seeds, nuts and nut-based products (e.g. peanut butter), among others (Beuchat et al., 2013; Finn et al., 2013; Podolak et al., 2010). LMF are generally perceived as safe by consumers, and many LMF are consumed as ready-to-eat products with no consumer-level pathogen reduction step such as cooking (Beuchat et al., 2011; Beuchat et al., 2013).

LMF are susceptible to contamination from a wide range of microbial hazards. Although most microbial hazards cannot grow in LMF due to the low a_w, many pathogens can survive and remain viable for months to years in these foods, posing potential risks to consumers (Beuchat et al., 2013; Finn et al., 2013; Podolak et al., 2010). It is difficult to reduce microbial hazard contamination of LMF by significant margins (e.g. >5 logs) and to non-detectable levels using traditional processing interventions such as heat treatments that are effectively applied to high moisture foods (Beuchat et al., 2013; Finn et al., 2013). The combination of low a_w with the high sugar and/or fat content of many LMF is believed to contribute to the enhanced survival and heat resistance of microbial hazards in these foods (Beuchat et al., 2013; Finn et al., 2013).

Many LMF products undergo specific pathogen reduction treatments to reduce potential hazards for consumers. For example, spices and seasonings are often treated with ethylene oxide, propylene oxide, steam treatment, or irradiation to reduce the risk of microbial contamination (Van Doren, Kleinmeier, Hammack, & Westerman, 2013). The most important control measures for LMF involve preventing cross-contamination during harvest, post-harvest, and processing through implementation of good agricultural and manufacturing practices and hazard analysis critical control point (HACCP) programs (Beuchat et al., 2013; Finn et al., 2013; Podolak et al., 2010). Process-based verification (e.g. audits) and microbial sampling of LMF products and food processing environments are also important strategies for industry to monitor food safety. However, surveillance of microbial hazards in LMF is not cost-effective due to the heterogeneous distribution of pathogens in LMF, diagnostic test limitations, and the very low average prevalence of microbial hazards in most LMF (Beuchat et al., 2013; Sperber, 2007).

In recognition of the increased global consumption of LMF and the growing risk to human health from these products, several agencies worldwide have developed recommendations and guidelines for industry on how to prevent and manage potential risks of LMF product contamination from microbial hazards (Beuchat et al., 2011; European Food Safety Authority, 2013; Grocery Manufacturers Association, 2009b; Scott et al., 2009; United States Food and Drug Administration, 2013). Due to this increased momentum and a need for standardized and comprehensive international guidance in this area, the Codex Alimentarius Committee on Food Hygiene has acted to create general guidelines on hygienic practices for LMF production and processing (Cahill and Kojima, personal communication). The Food and Agriculture Organization (FAO) and World Health Organization (WHO) Expert Meeting on Microbiological Risk Assessment (JEMRA) was tasked to review the current state of research knowledge on microbial hazards in LMF and to rank risks to human health and food safety. The results of these activities will be used to inform the new Codex Alimentarius guidelines.

Introduction and Objectives

This report summarizes the results of a structured and transparent scoping and systematic review – meta-analyses of three key aspects of the microbial food safety of LMF:

1) The burden of illness due to microbial contamination of LMF
2) The prevalence and concentration of microbial hazards in LMF
3) Interventions to reduce microbial contamination of LMF

Synthesized research findings for these three focus areas will be used as evidence-informed inputs along with additional supporting criteria in a comprehensive risk ranking process of microbial hazards in LMF. The results of the review and risk ranking process will be used to inform the new Codex Alimentarius guidelines for LMF.

Review Methods

Review Approach

The review followed standardized procedures for scoping and systematic reviews as outlined by internationally recommended guidelines (Anderson, Allen, Peckham, & Goodwin, 2008; Arksey & O'Malley, 2005; Higgins & Green, 2011; Rajić & Young, 2013). However, given the very broad review scope, large quantity of published research in this area, small review team, and a limited timeline of <4 months for producing results and a final report, some of the review steps were streamlined in accordance with the principles of structured “rapid reviews” to inform urgent decision-making (Ganann, Ciliska, & Thomas, 2010; Rajić & Young, 2013):

1) Only two bibliographic databases were searched for peer-reviewed literature. However, we implemented a very comprehensive search verification strategy (described below) and are confident that any literature potentially missed by the searches was captured during verification.
2) Only one reviewer conducted data extraction instead of the recommended two independent reviewers. This limitation could have resulted in some errors in the results, but we believe it would not have unduly affected the overall conclusions.

The review was built upon a preliminary and unpublished rapid scoping and systematic review of the same research questions conducted in 2013 (Rajić, Dysart and Cahill, unpublished data). The preliminary review was conducted by an external contractor and was used as a basis for development of the review protocol, questions, search, and forms as described in this review.

Review Protocol and Team

The review was conducted following a pre-specified protocol outlining each of the review steps as described in this report, including screening and extraction forms. The review team consisted of five professionals with diverse expertise and experience in microbiology, food safety, epidemiology, and knowledge synthesis, transfer, and exchange. Two professionals from the Public Health Agency of Canada conducted the review activities with oversight and coordination from three professionals from the FAO and WHO. The team convened via teleconference prior to initiating the review and exchanged correspondence regularly thereafter to discuss the protocol and all screening and extraction forms, to evaluate questions about review scope and eligibility criteria, to review the study progress and preliminary results, and to determine a strategy for summarizing and reporting results.

Review Questions

The review was conducted to answer the following three research questions:

1) What is the burden of illness in humans suspected or attributed to LMF contaminated with pathogenic bacteria?
2) What is the frequency of contamination (prevalence and concentration) of selected microbial hazards in LMF?
3) What are the potentially effective interventions (from primary production to the end of processing) to mitigate risks associated with contaminated LMF?

Definitions and Eligibility Criteria

The review scope was limited to the following nine selected microbial hazards: *Bacillus cereus*, *Clostridium botulinum*, *Clostridium perfringens*, *Cronobacter* spp. (formerly *Enterobacter sakazakii*), *Escherichia coli* (including generic *E. coli* and pathogenic strains), *Salmonella* spp., *Staphylococcus aureus*, *Listeria monocytogenes*, and Enterobacteriaceae. Other bacterial pathogens, indicator organisms, viruses, parasites, and fungi were excluded from the scope of this review. Note that unless otherwise specified, the term *E. coli* is used in this report to refer to both generic and pathogenic strains; in the summary cards, evidence on *E. coli* is divided into generic *E. coli* and specific pathogen strains (e.g. *E. coli* O157).

LMF were defined as any food product with a water activity (a_w) level of less than 0.85. Categories and sub-categories of LMF products were developed to facilitate data organization, summarization, and reporting. Eight major LMF product categories were used to structure this report:

1) Cereals and grains
2) Confections and snack
3) Dried fruits and vegetables
4) Dried protein products
5) Honey and preserves
6) Nuts and nut products
7) Seeds for consumption
8) Spices, dried herbs and tea

Results for the burden of illness, prevalence, and intervention information are reported in category-specific summary cards for each LMF product category. A full list of the sub-categories and example LMF products for each of these categories is shown in Appendix A, with additional details reported in the summary cards.

Composite LMF products with multiple ingredients were assigned to only one of the above categories according to where the product best fit (e.g. mixed cereal/grain products were classified under "cereals") or based on the primary ingredient of concern for contamination (e.g. halva/helva was classified under seeds for consumption as the contamined ingredient of concern is sesame seed paste).

Powdered infant formula was specifically excluded from the scope of this review because international Codex Alimentarius Commission guidelines for these products were recently updated based on a prior risk assessment (Codex Alimentarius Commission, 2008; WHO/FAO, 2004). Articles describing the validation of diagnostic tests for the detection of microbial hazards in LMF and those examining interventions at the consumer level (e.g. cooking) were also excluded.

For burden of illness information reported in this review, we defined an outbreak as two or more individuals with a similar illness resulting from consuming a common food product and with either an epidemiological or laboratory confirmation (Greig & Ravel, 2009). We also included case studies where only one reported case of illness occurred due to a confirmed or suspected contaminated LMF product (e.g. infant botulism cases due to honey consumption). Only primary research on burden of illness information was included; foodborne illness attribution studies using outbreak data and/or expert elicitation to attribute foodborne illness to specific food groups or commodities (usually not specific LMF products) were excluded (Havelaar et al., 2008; Batz et al., 2012; Painter et al., 2013).

Information on LMF recalls were not summarized in this scoping review. While the scoping review may have captured some of this information if published in peer-reviewed journals and indexed in the bibliographic databases included in the search, most would be contained only in food recall databases which were not searched in this review.

Search Strategy

The preliminary scoping and systematic review conducted in 2013 was used as a basis for development of a comprehensive search algorithm (Rajić, Dysart and Cahill, unpublished data). This prior review extracted keyword terms from 11-14 known relevant articles from each of the three research questions (burden of illness, prevalence, and intervention information), combined them into a search algorithm and pre-tested the algorithm in PubMed to achieve a highly specific search. In this review, we updated and refined this search algorithm through additional pre-testing in PubMed to improve the sensitivity of the search. The final algorithm contained combinations of keywords in three broad categories: LMF product terms, microbial hazards terms, and outcome terms (Appendix B). The search was implemented in two bibliographic databases (Scopus and PubMed/Medline) on January 13, 2014. There were no language or publication date restrictions on the search. Scopus coverage included 1823-2014 and PubMed coverage included 1946-2014 (coverage included “in press” articles).

The search was verified through multiple steps. Firstly, we reviewed the final reference list of 464 relevant articles identified in the preliminary scoping and systematic review (Rajić, Dysart and Cahill, unpublished data). The preliminary review included a web search in Google using the terms “low-moisture food”, “low-water activity food” and “dry food pathogens”, it included a search of the reference lists of eight review articles and reports relevant to the review questions (Beuchat et al., 2011; Beuchat et al., 2013; Grocery Manufacturers Association, 2009a, 2009b; Pan, Bingol, Brandl, & McHugh, 2012; Podolak et al., 2010; Scott et al., 2009; Zweifel & Stephan, 2012), and it included a hand search of the reference lists of all included, relevant articles in the review (Rajić, Dysart and Cahill, unpublished data). In this review, we conducted additional verification by reviewing the reference lists of eight additional articles relevant to the review questions (Austrian Institute of Technology & Austrian Agency for Health and Food Safety, 2013; Dey et al., 2013; Friedemann, 2007; Holck et al., 2011; Lehner & Stephan, 2004; Sperber, 2007; Van Doren et al., 2013a, 2013b), and through hand-searching the reference lists of relevant articles.

To identify additional grey literature sources of burden of illness (i.e. outbreak) information for LMF products, we searched a comprehensive database of international foodborne disease outbreak reports maintained at the Public Health Agency of Canada (Greig & Ravel, 2009). The database comprises >7900 outbreak reports from multiple sources: journal articles, newspapers, listservs, press releases, country line lists, and government and laboratory websites (Greig & Ravel, 2009). To search the database, all outbreaks implicating LMF products and the selected microbial hazards were queried and used to obtain all recorded information about the outbreak.

Relevance Screening

Screening of the titles and abstracts of all unique citations identified in the search was conducted using an *a priori* developed screening form (Appendix C). The form contained one yes/no question to determine the relevance of citations for the project as described above. If the title and abstract did not provide sufficient detail to determine the article’s relevance (e.g., “confectionary items”, “sweets”, “snacks”, may not refer to LMF), the article was automatically included at this stage for further evaluation.

Relevance Confirmation and Article Characterization

Full texts of all relevant citations were obtained and articles were reviewed using a relevance confirmation and article characterization form (Appendix D). This contained four questions: confirmation of relevance and research question of focus (burden of illness, prevalence, and/or interventions); article language; LMF product categories; and microbial hazards investigated. Only articles in English, French, and Spanish were included at this stage unless there was sufficient extractable data from an English abstract.

Results from this initial characterization were used to prioritize more detailed data extraction. In addition, after charting of these characterization results, the review team decided to exclude dried and/or fermented sausages, salamis, and jerky's from further extraction and summarization. This category of products was considered beyond the scope of this review given the large volume of research identified in this area and because we were not able to confirm the a_w of many of these products due to reporting limitations in the literature. In addition, at this stage we decided to exclude all articles that investigated the prevalence or concentration of microbial hazards in LMF published prior to 1990, as these were not considered relevant or reflective of the current state of evidence to inform the risk ranking process or Codex Alimenatarius standards.

Data Extraction

Data were extracted from each article confirmed as relevant using one of three specific data extraction forms developed for each research question of focus (burden of illness, prevalence, and interventions) (Appendix E). The burden of illness form contained 17 questions about: the source of the outbreak report; year; region/country; outbreak confirmation method (epidemiological or laboratory); specific LMF and microbial hazards implicated; the number of exposed persons, cases, hospitalizations, deaths, attack rate; and other outbreak details (e.g. microbial hazard concentration in the implicated LMF).

The prevalence form contained 21 total questions, including 10 general questions about the article details (e.g. publication year), study location, study design, and sampling methods. Prevalence and concentration data were confirmed to be sampled independent of an outbreak investigation. The 11 other questions were extracted for each LMF product and microbial hazard combination investigated: LMF category and product; microbial hazard; country of product origin; outcome (prevalence and/or concentration data); whether outcome data were sufficiently reported; laboratory methods; and quantitative prevalence and concentration data (e.g. sample size, number positive, mean values, measures of variability).

Similarly, the intervention form contained 20 total questions, with nine general questions about the article details (e.g. publication year), study location, study design, and whether the intervention was conducted under commercial conditions. The other 11 questions were extracted for each LMF product and microbial hazard combination: LMF category and product; microbial hazard; intervention type and details; whether the intervention was found to be effective; outcome type; laboratory methods; whether outcome data were sufficiently reported; and the sample size.

Data Analysis

Data for all three questions of interest (burden of illness, prevalence, and interventions) were summarized descriptively and reported in a tabular and narrative format. In addition, overall and LMF category-specific evidence charts were created to highlight cross-tabulations between combinations of the following variables: research question of focus; LMF categories investigated; and microbial hazards investigated. The evidence charts were created using bubble figure plots in Microsoft Excel, where each cross-tabulation value is represented by bubbles that are proportional in size to the total number of articles.

For prevalence data, we conducted meta-analysis on data subsets to obtain weighted average estimates of the prevalence of microbial hazards in LMF. Random-effects meta-analysis models were calculated for each LMF sub-category and microbial hazard combination with prevalence data from ≥2 articles and when at least one of the articles reported non-zero prevalence. The models were calculated using the DerSimonian and Laird method for random-effects (DerSimonian & Laird, 1986). In addition, we used a double arcsine transformation to stabilize the variance of the input data (Barendregt, Doi, Lee, Norman, & Vos, 2013; Freeman & Tukey, 1950). This transformation was necessary because the data subsets often contained low prevalence levels and a high proportion of zero values, and these situations can add undue weight to outlying prevalence values when using a standard log transformation (Barendregt et al., 2013; Fazel, Khosla, Doll, & Geddes, 2008). The unit of analysis was prevalence within trials, and in some cases there was more than one trial reported within an article. We did not account for the extra level of variation due to trials being clustered within articles as this was unlikely to have much consequence on the overall estimates.

Heterogeneity in the meta-analysis estimates was assessed using I^2, which measures the proportion of variation between trials that is due to heterogeneity rather than random error (Higgins, Thompson, Deeks, & Altman, 2003). The following values of I^2 were used to categorize the level of heterogeneity: ≤30% was considered low; 31-60% medium; and >60 high (Higgins & Green, 2011). Average estimates of effect were calculated and reported only if heterogeneity was low or moderate. When heterogeneity was high (i.e. >60%), we instead reported the median and range of the prevalence values within the data subset, as reporting meta-analytic average estimates may be misleading with so much variation (Higgins & Thompson, 2002).

Review Management

All citations identified in the search were entered into RefWorks (Thomson ResearchSoft, Philadelphia, PA) and duplicates were removed using the automatic function and manually. Unique citations were imported into the web-based, systematic review software program DistillerSR (Evidence Partners, Ottawa, ON) for relevance screening and article characterization. Data extraction and descriptive analysis were conducted using Microsoft Excel 2010 (Microsoft Corporation, Redmond, WA). Meta-analysis was conducted using the Excel add-in MetaXL (EpiGear International Pty Ltd., Wilston, Australia).

The forms used for relevance screening and article characterization were pre-tested on a selection of 30 abstracts and six articles, respectively. Reviewing proceeded only when consistent inclusion and exclusion agreement was achieved between pre-test reviewers (kappa >0.8). Relevance screening was conducted by two independent reviewers, and discrepancies or conflicts between reviewers were resolved by consensus. Article characterization and extraction were conducted by one reviewer.

Summary Cards

Results of this review are reported in eight “summary cards” representing the major categories of LMF products (Ruzante et al., 2010). The summary cards were developed to display the results of the review in a more useful and practical format to better meet the stakeholders’ needs. More specifically, the purpose of the summary cards is to highlight the key findings for each of the research questions of interest (burden of illness, prevalence, and intervention information) to better support future risk ranking, risk management, and decision-making on the microbial food safety of LMF products. Each summary card contains the following six sections:

1) LMF category description
2) Overall evidence summary
3) Burden of illness summary
4) Prevalence summary
5) Interventions summary
6) References

The LMF category description section briefly provides key definitions related to the LMF products, describes LMF product sub-categories used to summarize the information, and provides examples of specific, included LMF products.

The evidence summary section briefly highlights the amount of evidence included in the summary and describes an evidence chart showing the distribution of available research by research question focus and microbial hazards investigated.

The burden of illness, prevalence, and intervention sections each provide a short (<1 page) narrative summary of the available evidence and key descriptive characteristics and results. In addition, they also provide accompanying tables and figures that describe the evidence and results in more detail.

The burden of illness table lists all identified outbreaks stratified by LMF product (or sub-category) and causative microbial hazard. Quantitative data on the number of outbreaks reported and total cases, hospitalizations, and deaths is reported for each food product and microbial hazard combination. Also reported are the outbreak countries and years, reference publications, and any additional details (e.g. whether susceptible populations were affected, the attack rate, concentration of the microbial hazard in the LMF product).

The prevalence table shows the average or median prevalence estimates for each LMF sub-category and microbial hazard combination. For each cell in the table, three lines of data are shown.

The first shows the total number of observations (i.e. food product samples), the total number of individual trials (i.e. food product and microbial hazard combinations), and the total number of articles for each combination. In brackets beside these numbers is the percentage of all trials that did not identify any positive samples (i.e. the prevalence was 0%). This measure is provided as an indicator of how often trials identified any positive samples in that LMF sub-category/microbial hazard combination.

The second line of prevalence data shows either:

- An average estimate of the prevalence from a random-effects meta-analysis for that combination (with 95% confidence intervals in brackets), *or*
- The median prevalence value and the range (minimum and maximum values in brackets)

The third line in the prevalence table reports two indicators of the representativeness of the prevalence information:

1) Level of consistency in the prevalence data obtained from the heterogeneity measure I^2 during meta-analysis (classified as low, medium, or high), *and*
2) Risk of selection bias due to a non-representative sample (also classified as low, medium, or high)

Heterogeneity refers to the variability among studies summarized in a meta-analysis. In the context of this review, the variability in prevalence estimates between studies could be due to differences in study design, sampling and laboratory methodology, geographic location, and/or specific food products investigated, among many other factors. The extent of this variability was measured using the I^2 statistic, which indicates (on a scale from 0-100%) how different the studies are from each other than would be expected by chance (random error) alone. Heterogeneity rating definitions were as follows: low = I^2 0-30%; medium = 31-60%; high = >60%.

For meta-analysis estimates with high heterogeneity (i.e. I^2 >60%), it can be misleading to present and interpret average prevalence estimates because there is so much unexplained variation between studies. The main meta-analysis assumption is that studies are reasonably comparable and measuring the same effect estimate. High heterogeneity may indicate this assumption has been violated and studies should not be pooled. Therefore, only the median and range are provided for prevalence data if there was significant heterogeneity (i.e. I^2 was >60%) in the meta-analysis estimates. A superscript of ^{M} indicates that the prevalence values represent average estimates from meta-analysis, and a superscript of ^{R} indicates that the values represent the median and range.

Studies that conducted random or systematic sampling of LMF products were considered to be representative. Selection bias ratings were defined as follows: low = 0-30% of trials used a representative sample; medium = 31-60% of trials used a representative sample; low = >60% of trials used a representative sample.

The overall robustness of the meta-analysis prevalence estimates can be inferred from the heterogeneity and selection bias ratings. When heterogeneity is low and the risk of selection bias is low (i.e. the proportion of studies with a representative sample is high), we have confidence that the reported meta-analysis prevalence estimate is likely reflective of the true average prevalence value across a group of studies that were generalizable to their target commodity. When the opposite is true, heterogeneity is high and there is high risk of selection bias (i.e. few studies had a representative sample), we have little confidence in the meta-analysis overall prevalence estimate as it may be based on unrepresentative data and the variability in results is not explainable. This could mean that the outcome is truly highly variable, or that there are unmeasured context-specific influences affecting the reported prevalences (e.g. geography, time of sampling, study design and methods, etc.).

Note that in order to obtain a normal account of the prevalence and concentration of microbial hazards in LMF, we excluded we excluded any surveys conducted during an outbreak or associated with an outbreak investigation.

A forest plot figure describing the information captured in the prevalence table is shown following each prevalence table to graphically illustrate the meta-analysis results across all microbial hazard and LMF sub-categories. Note that microbial hazards were excluded from these figures if no positive samples were identified in the LMF category/summary card. Enterobacteriaceae prevalence results were also excluded from these figures.

The forest plot figures are meant to facilitate the interpretation of meta-analysis results within each LMF category and summary card. In these figures, the results of high heterogeneity meta-analyses are presented along with the median and range from the previous table. It was decided that this was the most informative way to convey the results for risk ranking and decision-making; however, we caution our readers that due to high unexplained heterogeneity, the overall estimates of prevalence in the forest plot figures should be interpreted with caution.

The intervention table shows all investigated interventions stratified by LMF sub-category and intervention type. For each LMF sub-category/intervention type combination, the table shows the specific interventions applied (including dose and duration, when available), the source publications for each specific intervention, the microbial hazards investigated, the study type, the total number of trials and articles, the percentage of trials with extractable data, and the percentage of trials that found the intervention was effective to reduce microbial hazards counts or prevalence.

In addition, for any LMF sub-category/intervention type combination with ≥2 articles, a sign test was calculated to determine if the number of trials finding a positive intervention effect was greater than what would be expected by chance alone. If the sign test was significant ($P < 0.05$), this was indicated by an asterisk (*) and bold text in the final column of the table.

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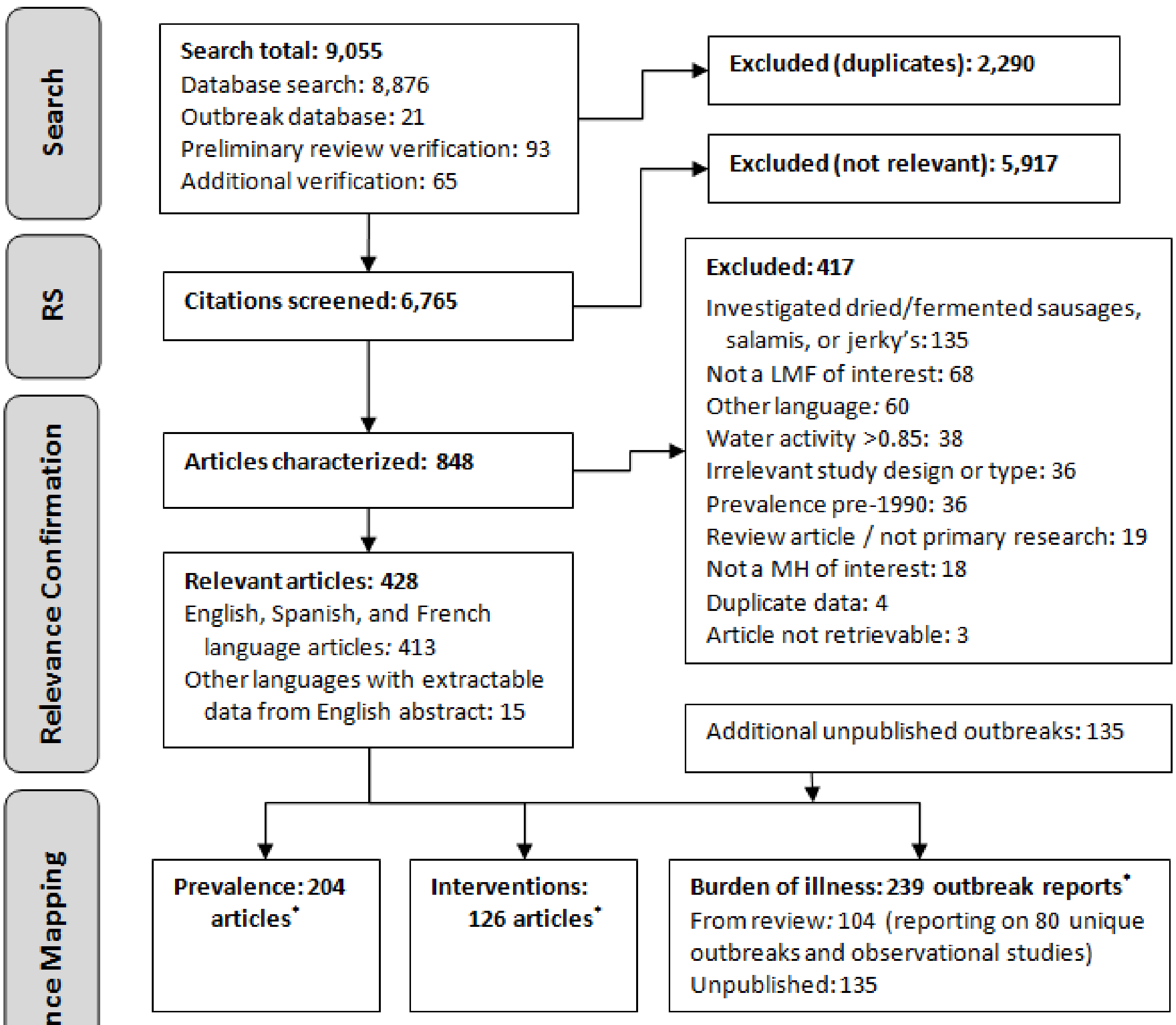
Review Evidence Summary

A flow chart of the review process and findings is shown in Figure 1. Overall, 6,765 citations were screened for relevance, 848 full articles were procured and characterized, and 428 were confirmed as relevant to the review scope. In addition, 135 unpublished outbreak reports involving LMF were also identified and summarized.

Figure 1: Review Flow Chart



RS = Relevance screening.
* NOTE: Some articles (n=8) contained data in more than one of the above categories. In addition, individual outbreak reports were sometimes reported in more than one article, so the total number of unique articles and outbreak reports was 537.

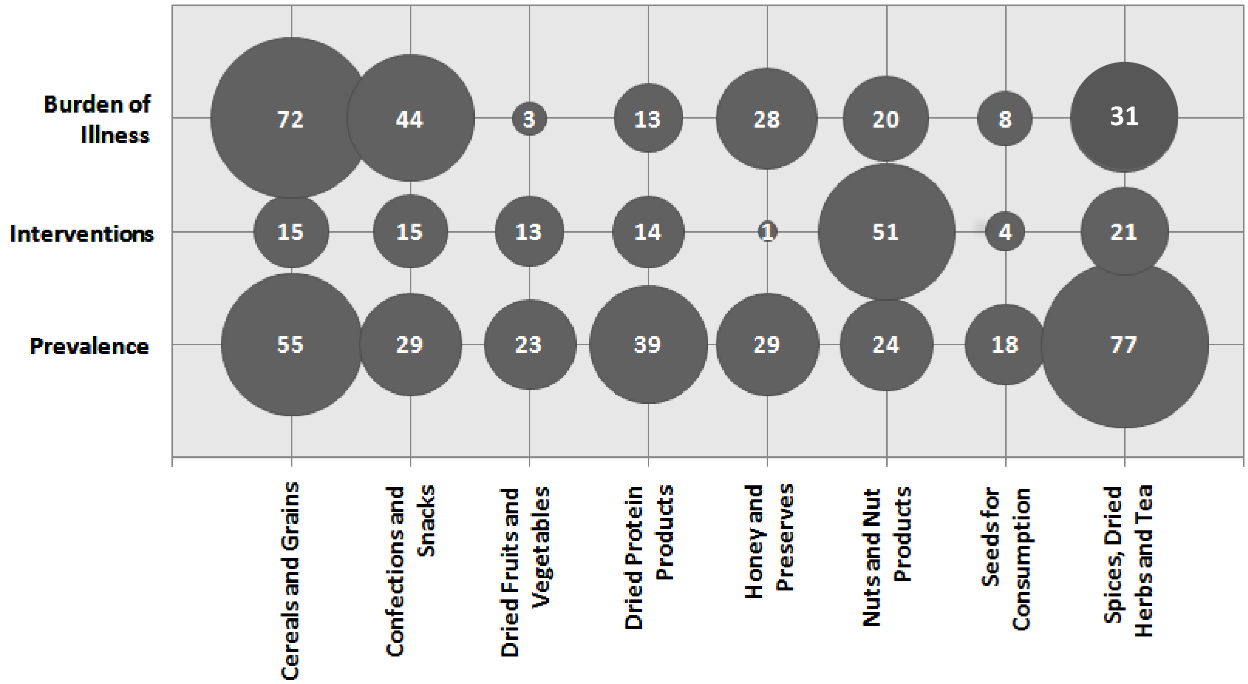
Among all unique articles and outbreak reports (n=537), the most commonly investigated LMF product categories were (Figure 2):

1) Cereals and grains (n=142)
2) Spices, dried herbs and tea (n=129), and
3) Nuts and nut products (n=95).

The most frequently investigated LMF products for prevalence, intervention, and burden of illness information were the following (Figure 2):

- Prevalence = Spices, dried herbs and tea (n=77)
- Interventions = Nuts and nut products (n=51)
- Burden of illness = Cereals and grains (n=72)

Figure 2: Evidence Chart: LMF Products Investigated by Research Focus

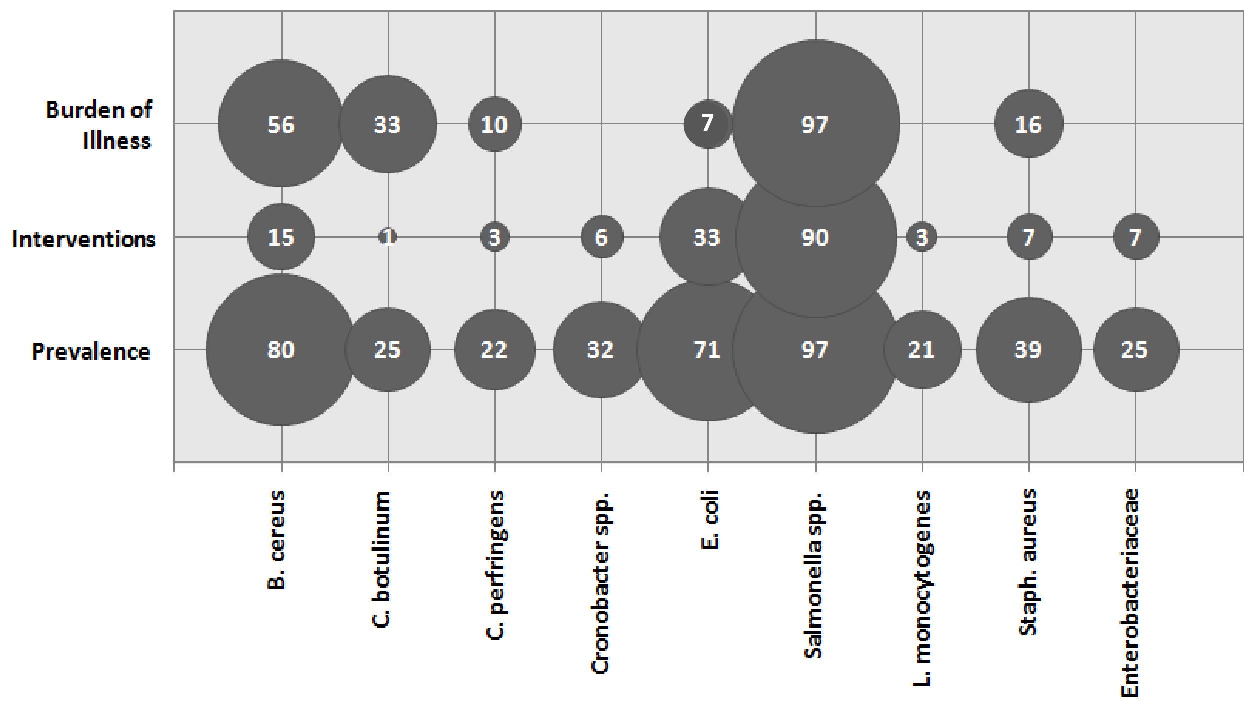


Across all unique articles and outbreak reports (n=537), the most commonly investigated microbial hazards were (Figure 3):

1) *Salmonella* spp. (n=278)
2) *B. cereus* (n=148)
3) *E. coli* (n=109)

The most frequently investigated microbial hazard for prevalence, intervention, and burden of illness information was *Salmonella* spp. (n=97, 90, and 97, respectively).

Figure 3: Evidence Chart: Microbial Hazards Investigated by Research Focus

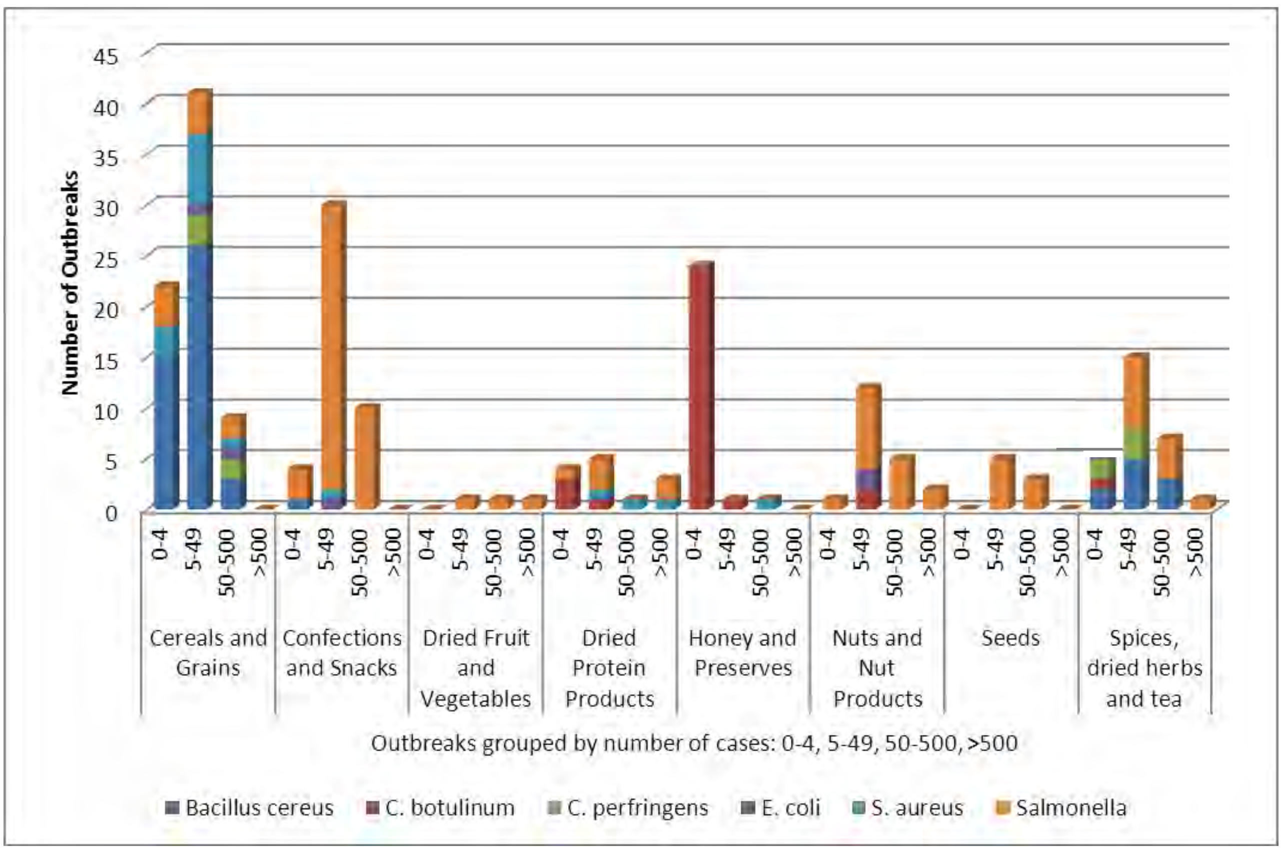


Burden of illness data was mainly informed by global outbreaks that have occurred since the 1950s to present. Table 1 below shows the overall proportion of burden of illness information captured in thie review stratified by the microbial hazards of focus. *Salmonella* spp. was the most frequent microbial hazard implicated in outbreaks and had the potential to cause large, widespread outbreaks. *B. cereus* outbreaks were mainly related to smaller outbreaks from rice and other cereal products. *S. aureus* caused some very large outbreaks due to contaminated powdered milk, thus overall a disproportionate number of cases is attributed to *S. aureus*. Figure 4 below shows the number and relative size of outbreaks in each category by implicated microbial hazard. There were no illnesses due to *L. monocytogenes* or *Cronobacter* spp. captured in this scoping review.

Table 1: Summary of the burden of illness related to LMF outbreaks attributed to select microbial hazards

% (count)	Outbreaks	Cases	Hospitalizations	Deaths
Salmonella spp.	44.9% (96)	43.8%(12415)	88.6% (895)	73.7% (14)
E. coli	2.3% (5)	1.2% (354)	3.3% (33)	5.3% (1)
B. cereus	25.7% (55)	3.7% (1057)	1.4% (14)	0% (0)
C. botulinum	15.0% (32)	0.3% (84)	6.0% (61)	21.1% (4)
C. perfringens	4.7% (10)	1.5% (432)	0% (0)	0% (0)
S. aureus	7.5% (16)	49.4% (14006)	0.7% (7)	0% (0)
L. monocytogenes	0% (0)	0% (0)	0% (0)	0% (0)
Cronobacter spp.	0% (0)	0% (0)	0% (0)	0% (0)
Enterobacteriaceae	0% (0)	0% (0)	0% (0)	0% (0)

Figure 4: The number of LMF outbreaks in each category, grouped by size of the outbreak (number of cases: 0-4, 5-49, 50-500, >500) and microbial hazard



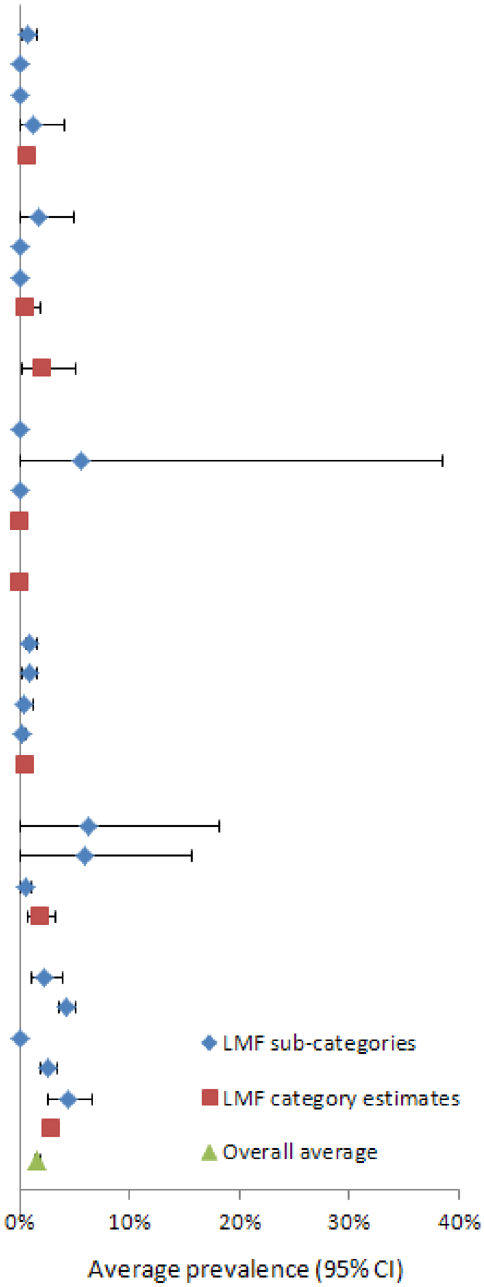
Prevalence and concentration data captured in this review provides an understanding of the frequency and level of contamination detected in different LMF products. Most categories had survey information for a range of microbial hazards and products. While the data may not be globally representative and does not demonstrate any changes over time, it does provide a baseline for the likely frequency of contamination. *Salmonella* spp. was implicated in the most number of outbreaks and accounted for 44% of disease across LMF categories. Similarly, S*almonella* contamination was relatively consistent across all LMF categories with an overall average prevalence of 1.6% (95% CI: 1.4 – 1.9), as shown in Figure 5 below. Other microbial hazards (e.g. *B. cereus*) were detected at more variable levels in LMF.

Intervention data captured in this review was mostly conducted under laboratory and non-commercial conditions, limiting its direct relevance and potential application to real-life conditions. Nevertheless, common themes from these studies across all LMF categories include the importance of preventing LMF contamination during harvest, post-harvest, and processing through implemention of good agricultural and manufacturing practices and hazard analysis critical control point (HACCP) food safety management systems. This is because many LMF products are eaten without a consumer-level kill step (e.g. cooking), and even under experiemental and laboratory conditions, many of the investigated processing interventions could not acheive full elimination of microbial hazards at practical doses and durations.

Figure 5: Avereage prevalence of *Salmonella* spp. across all LMF product categories

LMF category / sub-category	Average prevalence	Low 95% CI	High 95% CI	Hetero-geneity	Median (range)
Cereals and grains					
Milled grains	0.7	0.2	1.5	High	0 (0 - 46.2)
Other cereals	0.0	0.0	0.0	Low	-
Rice products	0.0	0.0	0.0	Low	-
Whole grains	1.3	0.0	4.1	Low	-
Overall	0.7	0.3	1.4	High	0 (0 - 46.2)
Confections and snacks					
Cocoa/chocolate	1.7	0.0	5.0	Med.	-
Other confections	0.0	0.0	0.0	Low	-
Snacks	0.0	0.0	0.0	Low	-
Overall	0.5	0.0	1.9	High	0 (0 - 4.6)
Dried fruits and vegetables					
Overall	2.0	0.2	5.2	High	0 (0 - 33.3)
Dried protein products					
Dried dairy	0.0	0.0	0.0	Low	-
Dried fish	5.6	0.0	38.5	High	10 (0 - 20)
Dried meat	0.0	0.0	0.0	Low	-
Overall	0.0	0.0	0.1	Low	0 (0 - 20)
Honey and preserves					
Overall	0.0	0.0	0.0	Low	-
Nut and nut products					
Almonds	0.9	0.5	1.5	High	0.4 (0 - 2.7)
Other tree nuts	0.8	0.3	1.6	High	0 (0 - 66.7)
Peanuts	0.5	0.0	1.2	High	0 (0 - 2.3)
Mixed nuts	0.2	0.0	0.5	Low	-
Overall	0.6	0.4	0.9	High	0 (0 - 66.7)
Seeds for consumption					
Sesame	6.2	0.0	18.2	High	6.5 (0 - 12.5)
Halva/helva	6.0	0.0	15.6	Med.	-
Other/unspecified	0.5	0.1	1.1	Med.	-
Overall	1.9	0.8	3.3	High	0.1 (0 - 16.7)
Spices and dried herbs					
Bark/flower	2.3	1.0	3.9	Low	-
Fruits/seed	4.3	3.6	5.0	Low	-
Herb	0.0	0.0	0.0	Low	-
Mixed/unspecified	2.6	1.9	3.4	High	0 (0 - 14)
Root	4.4	2.5	6.7	Low	-
Overall	3.0	2.6	3.4	Low	-
Overall	1.6	1.4	1.9	High	0 (0 - 66.7)

NOTE: The overall estimate for dried fruits and vegetables was based on data only from the dried fruits sub-category, and the overall estimate from honey and preserves was based on data only from the honey sub-category.



4Summary Card: Cereals and Grains

(Burden of Illness, Prevalence and Interventions)

Low-moisture food category description

Cereals and grains refer to gramineous crops harvested for dry grains and their food products (FAO, 1994). This includes wheat, barley, maize/corn, oats, rye, millet, sorghum, buckwheat, and rice, as well as their milled products (e.g. flours, starches) and use in further processed foods (e.g. dry baking mixes, breakfast cereals, pasta, noodles) (FAO, 1994).

For the purposes of summarizing prevalence information and conducting meta-analysis in this summary, cereals and grains were classified into the following categories: 1) dried whole grains other than rice; 2) raw rice and rice products (e.g. rice flour, rice noodles); 3) milled grains other than rice, including flours and starches; and 4) other dry cereals and cereal products, including breakfast cereals, cereal and baking mixes, and unspecified/mixed cereals. For the interventions summary, the milled grain category was combined with the other dry cereals and cereal products due to limited data availability.

Evidence summary

In total, 142 articles[1] and outbreak reports[2] were identified that investigated the burden of illness related to cereals and grains, the prevalence or concentration of selected microbial hazards in cereals and grains, and/or interventions to reduce contamination of microbial hazards in cereals and grains. The distribution of identified research stratified by microbial hazard investigated and research focus is shown in Appendix F: Summary Card Evidence Charts. *B. cereus* was the most frequently investigated microbial hazard in cereals and grains for burden of illness (n=44 outbreak reports), prevalence (n=34 articles), and intervention (n=8 articles) information.

Burden of illness

Burden of illness evidence related to cereal and grain products includes 72 outbreaks that affected 1835 individuals, including 98 hospitalizations and 0 deaths between 1975 and 2013. *B. cereus* was the cause of 44/72 outbreaks (31 due to rice) > *S. aureus* (11) > *Salmonella* (10) > *C. perfringens* (5) > pathogenic *E. coli* (2). Outbreaks occurred in the United States (26), Australia (6), New Zealand (1), Japan (1), and Europe (34): France (8), Belgium (5), Germany (4), Netherlands (4), Denmark (4), Austria (2), Finland (2), United Kingdom (2), Poland, Italy, Switzerland, Sweden and Norway. Where stated, the products in this category (but not necessarily the ingredients) originated from the same country as the outbreak.

Almost 58.5% of illnesses captured in this category are attributed to cooked rice and pasta dishes (53 outbreaks) and with the exception of one large rice cake outbreak (15% of illnesses), most outbreaks were small and isolated to an event or batch of food at a restaurant. Only 5 of these 53 outbreaks were

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[1] Articles refer to peer-reviewed journal publications as well as government and research agency reports.

[2] For burden of illness information, multiple articles often reported complementary and/or overlapping information on the same outbreak. In addition, outbreak data were supplemented from other literature sources, including line lists from various countries, news reports, or annual summaries of country outbreaks. Thus, to avoid counting the same outbreak more than once, the term 'outbreak report' is used instead of 'article' to count the total number of unique outbreaks.

captured in peer-reviewed publications, the remainder were from country line lists and reports with minimal information. Thirty-seven cooked rice outbreaks account for 28% of illnesses and were from several countries. Of these 31 were caused by *B. cereus* which had a median (range) 7 (2-103) of illnesses per outbreak followed by three *S. aureus* outbreaks 7 (2-50), a *C. perfringens* outbreak (23 cases) and a *Salmonella* outbreak (2 cases). Similarly, 16 outbreaks (3-5 per microbial hazard) involving pasta accounted for 31% of illnesses and had a median (range) for *B. cereus* 15 (2-50), *S. aureus* 5 (10-32), *C. perfringens* 40 (16-250) and *Salmonella* 10 (2-26). Most of these outbreaks were attributed to food handler or consumer mishandling of the product, mainly temperature abuse or slow cooling. Due to a lack of information, it was not always clear that the rice or pasta was the confirmed contaminated ingredient.

Considering the quantity of milled product that is consumed, there were virtually no outbreaks associated with flour; of the three captured here the median (range) of cases were 52 (35-67). This is likely because most of these products are cooked prior to consumption. Two out of three outbreaks associated with "flour" resulted in a product recall.

There were some larger and/or more widespread outbreaks that involved ready-to-eat products such as infant cereal (2), breakfast cereal (2) and commercially prepared rice cakes (1), which had a median (range) of 33 (2-278) cases. Contamination of these products occurred during manufacturing and there were recalls and implications for industry associated with these outbreaks.

Summary of globally reported outbreaks related to cereals and grains

Cereal or Grain Product (reference)	Microbial hazard(s)	Outbreaks/ cases[a]/ hospitalized/ deaths	Country (year)[b]	Comments: susceptible populations/ attack rate/ concentration of microbial hazard in the product
Toasted Oat Cereal Anon (1998)	*Salmonella* Agona	1/209/47/0	United States (1998)	47% cases were <10 years and 21% were >70 years.
Puffed Rice Cereal Russo (2013)	*Salmonella* Agona	1/33/12/0	United States (2008)	Product origin in this outbreak and the toasted oats outbreak is the same manufacturing plant.
Infant Cereal Rushdy (1998)	*B. cereus*	1/2/0/0	United Kingdom (2005)	Concentration in product was 103 spores/g (Infant threshold of emetic syndrome is 105/g.) Infants <12 months
Duc le (2005)	*Salmonella* Senftenberg	1/5/0/0	United Kingdom (1995)	Affected infants <12 months
Cereal products including rice and seeds/pulses (nuts, almonds) **EFSA (2013),** EU **(2012c),** **EU** (2012e**)**	*B. cereus*	5/46/12/0	France (2011)[E], France (2012)[E], Switzerland (2012)[E]	Cereal products, including rice and seeds/pulses (nuts, almonds), is a European Union reporting category. Specific products could not be verified.
EU (2009a), EFSA (2013)	*S. aureus*	2/11/1/0	France (2009, 2011)	
Bulgur EFSA (2013)	*B. cereus*	3/21/0/0	Finland (2010)[E], Denmark (2011)	Attributed to temperature abuse and slow cooling.
Buckwheat EU (2009c)	*B. cereus*	1/52/0/0	Poland (2009)	Temporary mass gathering.
Flour McCallum (2013)	*Salmonella* Typhimurium 42	1/67/12/0	New Zealand (2008)	Due to consumption of an uncooked baking mixture that contain the contaminated flour. Product from implicated batch was recalled.

ProMed (2013)	*E. coli* O121	1/35/7/0	United States (2013)[E]	Flour epidemiologically implicated in the frozen food recall.
Unspecified Grains CDC (*no date*)	*Salmonella* Lika	1/3/0/0	United States (2003)	
Rice Cake Nabae (2013)	*E. coli* (STEC)	1/142[C], 136[P]/ 0/0	Japan (2011)	Commercial product, contaminated during manufacturing.
Cooked Rice Ref[c]	*B. cereus*	31/382[C],44[P]/2/ 0	(Country year)[c]	16/29 are laboratory confirmed outbreaks. 3 outbreaks involved children < 6 years at a daycare/school. Most outbreaks were isolated to a home, catered event or a single batch at a restaurant. Temperature abuse was the most cited cause. The 1975 outbreak had cooked rice concentrations of 1.7 x 10^8 organisms/g and raw rice concentration: 100 organisms/g.
Kerouanton (2007), Ozfoodnet (2002), EFSA (2013)	*S. aureus*	3/52[C],7[P]/0/0	France (2001), Australia (2002), Portugal (2011)	The French outbreak *S. aureus* concentration was 2.9×10^4 CFU/g.
Ozfoodnet (2006)	*C. perfringens*	1/23[P]/0/0	Australia (2005)[E]	
Ozfoodnet (2011)	*Salmonella* Typhimurium 42.	1/2/2/0	Australia (2010)[E]	Daycare center outbreak
Cooked Pasta EU (2004), EU (2012b), CDC (*no date*)	*B. cereus*	3/17[C], 50[P]/0/0	Belgium (2004)[E], United States (2009), Germany (2012)	The German outbreak had *B. cereus* concentration of > 3 x 10^7 CFU/g.
Anon (2004), CDC (*no date*)	*C. perfringens*	4/330[C],16[P]/0/0	Australia (2004)[E], United States (2004, 2009, 2010)	
EU (2005c), CDC (*no date*)	*Salmonella* Enteritidis PT21, PT4, Anatum	4/44[C], 4[P]/2/0	Austria (2005)[E], United States (1996[E], 2004)	
EU (2009d), Kerouanton (2007), CDC (*no date*)	*S. aureus*	5/98/1/0	France (1988), United States (1995[E], 1999, 2008), Belgium (2009)	
Rice Noodles Ozfoodnet (2010)	*S. aureus*	1/3/0/0	Australia (2010)	*S. aureus* concentration > 2.5 x 10^7 organisms/g.

[a] Superscript [C] indicates confirmed cases, [P] indicates presumptive cases.
[b] Superscript [E] indicates the link between human cases and implicated product was epidemiological only, otherwise the link was laboratory confirmed.
[c] Reference (Country, Year): Raevuori 1976 (Finland 1975), Ozfoodnet 2002 (Australia, 2002),EU 2005a/EU 2010a/EU 2012a (Belgium 2005[E], 2010[E], 2012), EFSA 2013 (Denmark, 2011[E]), EFSA 2013 /EU 2012b (Germany 2011[E], 2012), Martinelli 2013 (Italy, 2012), EU 2009b (Netherlands, 2009[E]), EU 2005b (Norway, 2005[E]), EU 2012d (Denmark, 2012[E]), Tay 1982 (Singapore, 1981[E]), EFSA 2013 (Sweden, 2011[E]), Khodr 1994/CDC *no date* /ProMed 2011(United States 1993, 1995[E],1999[E],2000[E],2009[E], 2010[E], 2011[E])

Prevalence

A total of 55 studies containing 203 unique trials were identified that investigated the prevalence and/or concentration of one or more selected microbial hazards in cereals and grains. The median publication year was 2009 (range 1992-2014).

Seventy-five percent of studies were conducted in Asia/the Middle East (n=24) and Europe (n=17). Most studies (87%) sampled products during a specific or defined period of time, while two conducted sampling over multiple time points, and 5 reported on the results of systematic surveillance programmes. Over 80% of studies sampled products at retail (e.g. markets, grocery stores) and/or from mills. Only 15/55 (27%) studies specified the country(s) of product origin.

B. cereus was the most commonly investigated microbial hazard across all cereal and grain categories. It was found at highly variable prevalence levels, in some cases detected in all sampled products. Some studies found that a high proportion of *B. cereus* isolates from positive cereal and grain samples contained enterotoxin-producing genes (Lee et al., 2012; Samapundo et al., 2011).

Salmonella spp. was investigated extensively in flours, starches and other milled grains, with most observations coming from two large surveillance studies in the United States (Richter et al., 1993; Sperber, 2007). Most trials (77%) did not detect *Salmonella* spp. in any samples, and only one study found a high prevalence (46%) in a small and non-representative sample (n=13) in Colombia (Acosta et al., 2013).

Generic *E. coli* was detected at a variable and sometimes very high prevalence in cereals and grains, with a median prevalence of 12.4% in milled grains and 8.9% in other dry cereals and cereal products. Berghofer et al. (2003) found that incoming whole grains at mills in Australia had a lower prevalence of generic *E. coli* than milled end-products, suggesting that cross-contamination likely occurred during the milling process. *E. coli* O157:H7 was identified in only one study, in 4/15 samples of sorghum flour from South Africa (Kunene et al., 1999).

C. botulinum, C. perfringens, *L. monocytogenes* and *S. aureus* were investigated in only a few studies and were found at low to moderate prevalence levels. A very high prevalence of Enterobacteriaceae was identified in rice samples from South Korea in one study (Jung and Park, 2006).

Few studies reported extractable concentration data on levels of selected microbial hazards in cereals and grains (not shown in the table below).

In flours, starches and other milled grains, average concentrations of *B. cereus* ranged from 1.3 to 3.0 x 10^4 CFU/g and 0.3 to 30 MPN/g, and average concentrations of generic *E. coli* ranged from 1.9 to 23.5 MPN/g and 0.8 to 5.1 x 10^4 CFU/g (Aydin et al., 2009; Berghofer et al., 2003; Chitov et al., 2008; Eglezos, 2010; Fangio et al., 2010; Sengun and Karapinar, 2012; Victor et al., 2013).

In rice, four studies reported concentrations of *B. cereus* ranging from 36 to 7700 CFU/g and 16 to 210 MPN/g (Ankolekar et al., 2009; Chitov et al., 2008; Fangio et al., 2010; Sandra et al., 2012). Average concentrations of *B. cereus* in other dry cereals and cereal products ranged from 3 to 960 CFU/g and 3 to 200 MPN/g (Chitov et al., 2008; Fang et al., 1997; Kim et al., 2009; Lee et al., 2007, 2009, 2012; Rahimi et al., 2013).

In samples of a powdered cereal blend in South Korea, an average concentration of 15 CFU/g was identified for *C. perfringens* and a concentration range of 0.7 to 2.24 X 10^3 MPN/100g was identified for *Cronobacter* spp. (Lee et al., 2007). In wheat flour samples from Turkey, an average concentration of 1.3 to 1.6 CFU/g was identified for *C. perfringens*, with all samples below reported acceptable limit levels (10^4 CFU/g) for this pathogen (Aydin et al., 2009).

Prevalence of selected microbial hazards within cereal and grain categories

Each cell includes the number of observations/trials/studies contributing to the average or median prevalence estimate, the proportion of trials that did not find any positive samples and measures of heterogeneity and risk of selection bias. See the table footnotes for detailed explanations on each of these parameters.

	Cereals and Grains Number of observations/trials/studies (% trials with zero prevalence)[a] Meta-analysis prevalence (%) estimates (95% CI) OR prevalence median (range)[b] Heterogeneity rating / Risk of selection bias (low, medium or high)[c]			
Microbial hazard	**Whole grains**	**Flours, starches, and other milled grains**	**Rice and rice products**	**Other dry cereals and cereal products**
B. cereus	327/11/6 (27%) 26.8 (0 – 100)[R] High / High	1037/28/14 (54%) 0 (0 – 100)[R] High / High	546/10/9 (38%) 57.3 (17 – 100)[R] High / High	908/19/13 (21%) 41.7 (0 – 100)[R] High / High
C. botulinum	N/A	25/1/1 (0%) 16 N/A / High	N/A	N/A
C. perfringens	N/A	227/5/5 (80%) 0 (0 – 9.9)[R] High / High	8/2/1 (100%) 0 (0 – 0)[R] Low / High	44/2/2 (0%) 7.3 (1.2 – 17.2)[M] Low / High
***Cronobacter* spp.**	N/A	22/5/2 (60%) 11.3 (1.2 – 27.7)[M] Low / High	43/3/3 (33%) 0 (0 – 37.5)[R] High / High	894/12/11 (58%) 0 (0 – 45)[R] High / High
Generic *E. coli*	108/2/2 (50%) 1.3 (0 – 4.1)[M] Low / Low	4146/12/9 (17%) 12.4 (0 – 100)[R] High / Med.	N/A	266/5/5 (20%) 8.9 (0 – 68.2)[R] High / High
***E. coli* O157:H7**	N/A	25/4/2 (25%) 15.9 (4 – 32.7)[M] Low / High	8/2/1 (100%) 0 (0 – 0)[R] Low / High	100/1/1 (100%) 0 N/A / High
Enterobacteriaceae	N/A	N/A	47/2/1 (0%) 91.7 (83 – 100)[R] High / High	N/A
L. monocytogenes	N/A	102/3/3 (33%) 13.3 (0 – 18.5)[R] High / High	N/A	308/2/2 (50%) 0.7 (0.01 – 2)[M] Low / Med.
S. aureus	N/A	129/4/4 (50%) 3.3 (0 – 11.5)[R] High / High	2/1/1 (100%) 0 N/A / High	369/3/3 (33%) 6.3 (0 – 6.7)[R] High / Med.
***Salmonella* spp.**	108/2/2 (50%) 1.3 (0 – 4.1)[M] Low / Low	11040/22/12 (77%) 0 (0 – 46.2)[R] High / Med.	8/2/1 (100%) 0 (0 – 0)[R] Low / High	287/3/3 (100%) 0 (0 – 0)[R] Low / Med.

N/A = No data identified for this product-hazard combination. Med. = medium.

[a] Observations/trials/studies: The observations are the total number of samples for all studies included in the summarized category. The number of studies is the number of articles captured. In some cases, articles report data on multiple prevalence trials or sampling frames. While the observations for each trial are independent by time and sample, they are part of a larger study where the methods and investigators are the same. Thus, there is not full independence in these observations and we note this by acknowledging there are multiple trials within a study.

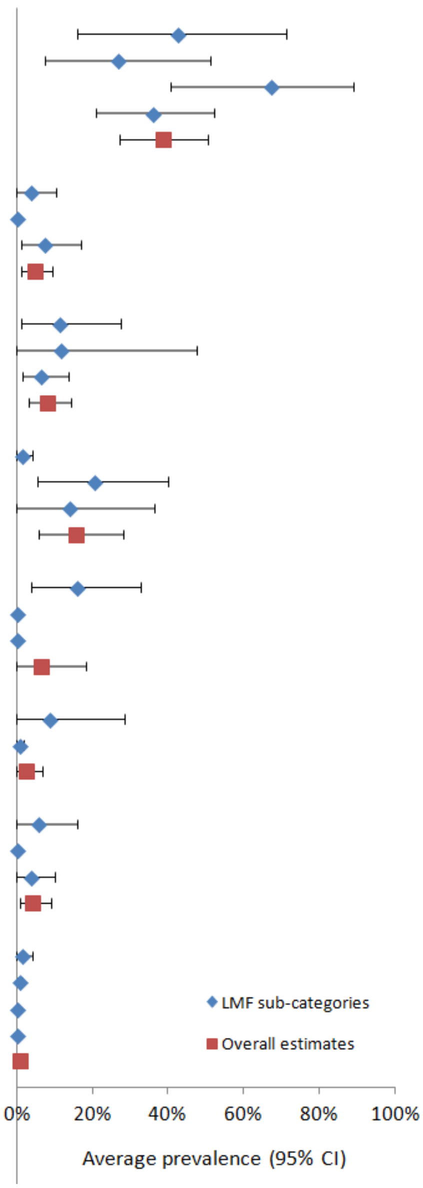
[b] Superscript [M] indicates an average prevalence estimate (and 95% confidence interval) from a random-effects meta-analysis. Meta-analysis estimates were calculated only if heterogeneity was low or medium (I^2 0-60%) and if at least one trial found a positive sample.

Superscript [R] indicates a median (and range) of trial prevalence estimates, calculated If heterogeneity was high (I^2 >60%). Ranges not provided when only one trial was identified.

[c] I^2 is a measure of the degree of heterogeneity between trials combined in the meta-analysis. Heterogeneity rating definitions: low = I^2 0-30%; medium = 31-60%; high = >60%.
Selection bias rating definitions: high = 0-30% of trials used a representative sample; medium = 31-60% of trials used a representative sample; low = >60% of trials used a representative sample. Studies that conducted random or systematic sampling were considered representative.
The overall robustness of the meta-analysis prevalence estimates can be inferred from the heterogeneity and selection bias ratings. Taking into consideration the number of studies in the meta-analysis, high confidence in the meta-analysis results can be inferred when heterogeneity is low and the risk of selection bias is low, and low confidence can be inferred when both are high, see the methods section (page 11) for more information.

Forest plot of the prevalence of selected microbial hazards within cereal and grain categories

Micobial hazard / LMF sub-category	Average prevalence	Low 95% CI	High 95% CI	No. obs./ trials/studies	Hetero-geneity	Selection bias	Median (range)
B. cereus							
Whole grains	42.6	16.1	71.2	327/11/6	High	High	26.8 (0 - 100)
Milled grains	26.7	7.4	51.4	1037/28/14	High	High	0 (0 - 100)
Rice/rice products	67.0	40.6	89.2	546/10/9	High	High	57.3 (17 - 100)
Other cereals	35.8	20.8	52.3	908/19/13	High	High	41.7 (0 - 100)
Overall	38.5	27.3	50.5		High		32.8 (0 - 100)
C. perfringens							
Milled grains	3.5	0.0	10.4	227/5/5	High	High	0 (0 - 9.9)
Rice/rice products	0.0	0.0	0.0	8/2/1	Low	High	-
Other cereals	7.3	1.2	17.2	44/2/2	Low	High	-
Overall	4.5	1.2	9.6		Med.		-
***Cronobacter* spp.**							
Milled grains	11.3	1.2	27.7	22/5/2	Low	High	-
Rice/rice products	11.7	0.0	47.7	43/3/3	High	High	0 (0 - 37.5)
Other cereals	6.4	1.5	13.9	894/12/11	High	High	0 (0 - 45)
Overall	8.0	3.2	14.5		High		0 (0 - 45)
Generic *E. coli*							
Whole grains	1.3	0.0	4.1	108/2/2	Low	Low	-
Milled grains	20.2	5.6	40.0	4146/12/9	High	Med.	12.4 (0 - 100)
Other cereals	13.8	0.0	36.4	266/5/5	High	High	8.9 (0 - 68.2)
Overall	15.5	6.0	28.1		High		8.9 (0 - 100)
***E. coli* 0157**							
Milled grains	15.9	4.0	32.7	25/4/2	Low	High	-
Rice/rice products	0.0	0.0	0.0	8/2/1	Low	High	-
Other cereals	0.0	0.0	0.0	100/1/1	N/A	High	-
Overall	6.4	0.0	18.3		High		0 (0 - 26.7)
L. monocytogenes							
Milled grains	8.7	0.0	28.5	102/3/3	High	High	13.3 (0 - 18.5)
Other cereals	0.7	0.0	2.0	308/2/2	Low	Med.	-
Overall	2.2	0.0	6.8		High		0.5 (0 - 18.5)
S. aureus							
Milled grains	5.7	0.0	16.2	129/4/4	High	High	3.3 (0 - 11.5)
Rice/rice products	0.0	0.0	0.0	2/1/1	N/A	High	-
Other cereals	3.7	0.0	10.2	369/3/3	High	Med.	6.3 (0 - 6.7)
Overall	4.0	0.9	9.0		High		3.1 (0 - 11.5)
***Salmonella* spp.**							
Whole grains	1.3	0.0	4.1	108/2/2	Low	Low	-
Milled grains	0.7	0.2	1.5	11040/22/12	High	Med.	0 (0 - 46.2)
Rice/rice products	0.0	0.0	0.0	8/2/1	Low	High	-
Other cereals	0.0	0.0	0.0	287/3/3	Low	Med.	-
Overall	0.7	0.3	1.4		High		0 (0 - 46.2)



CI = confidence interval; Med. = medium; No. obs. = number of total samples tested per category.
See the prevalence table for full explanations of all columns.
NOTE: *C. botulinum* evidence not shown in this figure because only one trial/study was identified.

Interventions

A total of 15 experimental studies (consisting of 104 unique trials) were identified evaluating the effects of various interventions to reduce contamination of microbial hazards in cereals and grains. The median publication year was 2003 (range 1973 – 2013). Most studies (>70%) were conducted in the United States (n=6) and Asia and the Middle East (n=5, four of which were in South Korea). Twelve of the 15 studies were challenge trials with artificially inoculated samples, one was a lab-based controlled trial, one included challenge and controlled trials, and one was a field-based controlled trial. Most trials were conducted under laboratory and non-commercial conditions, and most (84%) contained only three samples per intervention combination investigated.

The most common interventions were dry heat treatments, chemical treatments (various acid solutions), irradiation (including ionizing radiation and microwave radiation), and various combinations of these and other treatments. All interventions in rice and other grains were applied against *B. cereus*, with the exception of one controlled trial that evaluated the effect of irradiation on generic *E. coli* concentrations (Sarrías et al., 2003). In dry cereal mixes and flours, dry heat and microwave irradiation treatments were investigated against *Salmonella* spp. in several trials, modified storage conditions were investigated against the survival of *B. cereus*, *Cronobacter* spp., and *E. coli* O157:H7 (each in one to two studies), and fermentation with lactic acid bacteria was investigated against generic *E. coli* in one trial.

Nearly all trials found that the applied interventions were effective at reducing concentration levels of the investigated microbial hazards. However, for some interventions, the doses and/or duration of treatments required to achieve suitable log reductions in microbial concentration might negatively affect product quality or consumer acceptability (Mtenga et al., 2013; Park et al., 2009).

Almost all milled cereals (e.g. flours) are baked, fried or cooked prior to consumption (Sperber, 2007), reducing the risk of illness from microbial hazards such as *Salmonella*; but certain cereal products are ready-to-eat (e.g. breakfast cereals) and are usually consumed without further processing (Neil et al., 2012). In the case of *B. cereus*, typical cooking of frequently contaminated cereals and grains, such as rice and pasta, is not sufficient for complete destruction of spores, and mishandling during preparation (e.g. temperature abuse) may lead to foodborne illness in consumers (EFSA, 2005).

Control of the selected microbial hazards in cereals and grains should focus on implementation of good agricultural and manufacturing practices and hazard analysis critical control point (HACCP) food safety management systems (EFSA, 2005; Sperber, 2007). Additional interventions and treatments could be considered for higher risk products, such as those that are typically eaten without an additional “kill step” (Sperber, 2007).

Summary table of experimental studies evaluating the effects of interventions to reduce contamination of selected microbial hazards in cereals and grains

Food category	Intervention type	Intervention details (dose and/or duration, where available)	Source(s)[a]	Microbial hazard(s)	Study type[b]	No. trials/ studies	% of trials with extractable data	% of trials finding intervention is effective[c]
Dry cereal mixes and flours	Fermentation	Lactic acid bacteria (72 hr)	Kimmons (1999)[a]	Generic *E. coli*	C.T.	1/1	0	100
	Heat treatment	Dry heat (57-75°C; 10-150 min) Dry heat (43-60°C; 1-13 days) Dry heat (49°C; 0.5-24 hr)	Archer (1998) Bookwalter (1980) VanCauwenberge (1981)	*Salmonella* spp.	Ch.T.	11/3	0	100*
	Irradiation	Microwave (2450 MHz; 56.7-82.2°C; 3.9-10 min)	Bookwalter (1982)[a]	*Salmonella* spp.	Ch.T.	1/1	0	100
	Storage conditions	Increased temperature (5-45°C), increased a_w (0.27-0.78), decreased pH (5.6-6.7; 1-36 weeks)	Jaquette (1998)	*B. cereus*	Ch.T.	6/1	0	67
	Storage conditions	Increased temperature (4- 30°C), increased a_w (0.30-0.69; 1-12 months)	Lin (2007)	*Cronobacter* spp.	Ch.T.	6/1	17	83
	Storage conditions	Product storage in vacuum flasks (750ml)	Kimmons (1999)[a]	Generic *E. coli*	C.T.	1/1	0	100
	Storage conditions	Increased temperature (5-45°C), increased a_w (0.35-0.73), decreased pH (4.0-6.8; 1-24 weeks)	Deng (1998)	*E. coli* O157:H7	Ch.T.	3/1	0	67
Rice	Chemicals	Fermented ethanol (10-70%; 5-60 min) Supercritical carbon dioxide (36-44°C; 100-200 bar; 10-30 min) Fermented ethanol + supercritical CO_2 Sodium hypochlorite dip (100ppm; 25-60°C; 3-6 hr) Citric acid dip (1%; 25-60°C; 3-6 hr)	Kim (2013) Kim (2013) Kim (2013) Park (2009) Park (2009)	*B. cereus*	Ch.T.	15/2	13	100*
	Electrolyzed water	Acidic electrolyzed water (3-6 hr) Alkaline electrolyzed water (3-6 hr)	Park (2009)	*B. cereus*	Ch.T.	12/1	0	100

	Heat treatment	Dry heat (120°C; 1-3 hrs)	Houška (2007)	*B. cereus*	Ch.T.	2/1	100	100
	Irradiation	Electron beam (1.1-7.5 kGy)	Sarrías (2003)[a]	*B. cereus*, Generic *E. coli*	Ch.T.	2/1	100	100
	Irradiation	Gamma (1.5-30 kGy; 10 kGy/hr) Electron beam (1.1-7.5 kGy)	Mtenga (2013) Sarrías (2003)[a]	*B. cereus*	Ch.T.	4/2	25	75
	Multiple	Gamma irradiation (0.1-0.3 kGy) + sodium hypochlorite (10-1000 ppm; 2 min) + ultrasound (18 min) Citric acid dip + acidic and alkaline electrolyzed water (3-6 hr)	Ha (2012) Park (2009)	*B. cereus*	Ch.T.	13/2	7	100*
	Ozone	Gas (0.1-0.4 ppm; 1-7 hr)	Shah (2011)	*B. cereus*	C.T.	1/1	0	100
Other grains	Chemicals	Sodium hypochlorite dip (100ppm; 25-60°C; 3-6 hr) Citric acid dip (1%; 25-60°C; 3-6 hr)	Park (2009)	*B. cereus*	Ch.T.	8/1	0	100
	Electrolyzed water	Acidic electrolyzed water (3-6 hr) Alkaline electrolyzed water (3-6 hr)	Park (2009)	*B. cereus*	Ch.T.	8/1	0	100
	Multiple	Citric acid dip + acidic and alkaline electrolyzed water (3-6 hr)	Park (2009)	*B. cereus*	Ch.T.	8/1	0	100

[a] Indicates these studies were conducted under commercial conditions.
[b] Ch.T. = challenge trial; C.T. = controlled trial.
[c] Intervention categories marked with an asterisk (*) indicate that more trials found a positive intervention effect than would be expected by chance alone (sign test *P* value <0.05). Significance only calculated if more than one study was conducted per intervention/microbial hazard/study type combination.

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Summary Card: Confections and Snacks

(Burden of Illness, Prevalence and Interventions)

Low-moisture food category description

For the purposes of this summary, we refer to confections as sugar and sugar-based sweets such as fondants/creams, marshmallows, caramels/toffees, chewing gum, and chocolate and other cocoa-based products (e.g. cocoa and chocolate powders and mixes). We refer to snacks as savoury and ready-to-eat low-moisture foods such as chips and dried biscuits/crackers. We also include yeast in this summary, which can be used as a flavouring or additive to low-moisture foods.

For the purposes of summarizing prevalence and intervention information, confections and snacks were classified into the following categories: 1) cocoa and chocolate products; 2) other and unspecified confections and sweets; 3) snacks; and 4) yeast extract.

Evidence summary

In total, 87 articles[3] and outbreak reports[4] were identified that investigated the burden of illness, the prevalence or concentration of selected microbial hazards, and interventions to reduce contamination of microbial hazards in confections and snacks. The distribution of identified research stratified by microbial hazard investigated and research focus is shown in Appendix F: Summary Card Evidence Charts. *Salmonella* spp. was the most frequently investigated microbial hazard in confections and snacks for burden of illness (n=41 outbreak reports), prevalence (n=11 articles), and intervention (n=12 articles) information.

Burden of illness

Burden of illness evidence related to confections and snacks includes 44 outbreaks that affected 2547 individuals, including 151 hospitalizations and 0 deaths between 1955 and 2012. The median (range) outbreak size was 14 (3-439) cases, this varied by product type. For example, the size of chocolate outbreaks (n=9) caused by *Salmonella* was 119 (14-439) cases and accounted for 60.5% of all cases. *Salmonella* caused 93% of outbreaks and 99% of cases > *E. coli* O157:H7 (2.3%/0.4%), *B. cereus* (2.3%/0.2%), and *S. aureus* (2.3%/0.2%). Outbreaks occurred in Poland (23), United States (9), United Kingdom (6), Canada (4), Romania (2), Hungary, Sweden, Israel, Germany and Norway. There were several international outbreaks or outbreaks that implicated an imported product in this category, see the table below.

Most of the products in this category are ready-to-eat with the exception of cocoa powder and cake mix, which would usually undergo a further cooking step prior to consumption. Except for the Mexican wheat snack and some or all of the “sweet” outbreaks reported from Poland in 2011-2012, all outbreaks were

[3] Articles refer to peer-reviewed journal publications as well as government and research agency reports.

[4] For burden of illness information, multiple articles often reported complementary and/or overlapping information on the same outbreak. In addition, outbreak data were supplemented from other literature sources, including line lists from various countries, news reports, or annual summaries of country outbreaks. Thus, to avoid counting the same outbreak more than once, the term ‘outbreak report’ is used instead of ‘article’ to count the total number of unique outbreaks.

attributed to commercially prepared products. A high proportion (82%) of non-Polish outbreaks captured in this section were published in peer-reviewed sources.

Summary of globally reported outbreaks related to confections and miscellaneous snacks

Confection or Snack (reference)	Microbial hazard(s)	Outbreaks/ cases[a]/ hospitalized/ deaths	Country (year)[b]	Comments: susceptible populations/ attack rate/ concentration of microbial hazard in the product
Confections				
Chocolate Werber (2005), Harker (2013), Craven (1975), Gill (1981), Anon. (1986), Kapperud (1990), EU (2009), EU (2010)	*Salmonella* Oranienburg, Nima, Montevideo, Eastbourne, Napoli, Typhimurium, Enteritidis	9/1402[c], 143[P]/63/0	Germany, other EU states and Canada (2001), Canada (2001), Canada and United States (1973, 1985), United Kingdom (1982, 2006), Norway (1987), Hungary (2009), Romania (2010)	German chocolate concentration: 1.1 – 2.8/g Canadian chocolate concentration: 2.5/g Italian chocolate concentration: 3/g Belgium chocolate concentration: 4.3-24/100g Norwegian chocolate concentration: range 0-60 CFU/ 100g, 90% samples had <10 CFU/100g
EU (2010)	*S. aureus*	1/5/5/0	Romania (2010)[E]	
Sweets and Chocolate EU (2011), EU (2012)	*Salmonella* Enteritidis	23/232/79/0	Poland (2011[15E], 2012[3E])	"Sweets and Chocolate" is a European Union reporting category. Specific products could not be verified. If any of these are related, there has been no investigation to link them.
Chocolate covered brazil nuts Harker (2013)	*Salmonella* Schwarzengrund	1/90/0/0	United Kingdom (2006)	
Cocoa Powder Gastrin (1972)	*Salmonella* Durham	1/110/?/0	Sweden (1970)	Traced to a contaminated cocoa powder shipment (origin unknown)
Hot Chocolate Mix Nelms (1997)	*B. cereus*	1/4/0/0	United States (1994)	Concentration in hot chocolate was 170,000/g.
Cake Mix Zhang (2007)	*Salmonella* Typhimurium	1/26/0/0	United States (2009)	Cake mix was implicated in this ice cream outbreak. (No cooking step)
Marshmallow Lewis (1996)	*Salmonella* Enteritidis PT 4	1/36/0/0	United Kingdom (1995)	Concentration : 2.7 x 10^4/g of marshmallow Hypothesized to be due to using shelled eggs. Isolated to one bakery.
Yeast Joseph (1991), Kunz (1955), McCall (1966)	*Salmonella.* Oranienburg, Senftenberg, Montevideo, Manchester, Schwarzengrund	3/191[c], 130[P]/5/0	United States (1955, 1964), United Kingdom (1989)	1989 outbreak was a snack flavouring from which 66% of the cases were <5 years old. The 1955 and 1964 outbreaks occurred in medical settings and were due to contaminated supplemental food. The attack rate in these outbreaks across several institutions was 23-94.4%.
Snacks				
Peanut flavoured Kosher Snack Killalea (1996)	*Salmonella* Agona	1/160/0/0	United Kingdom, Israel and United States (1994)	Product of Israel. Mainly consumed by children 3-5 years old. Concentration in product 2-45 organisms/ 25g serving.
Mexican wheat snack CDC (*no date*)	*E. coli* O157:H7	1/11/4/0	United States (2010)	Prepared at home.
Tortilla chips CDC (*no date*)	*Salmonella* Enteritidis	1/7/0/0	United States (2010)	Served in a restaurant

[a] Superscript [C] indicates confirmed cases, [P] indicates presumptive cases.
[b] Superscript [E] indicates the link between human cases and implicated product was epidemiological only, otherwise the link was laboratory confirmed.

Prevalence

A total of 29 studies containing 108 unique trials were identified that investigated the prevalence and/or concentration of one or more selected microbial hazards in confections and snacks. The median publication year was 2009 (range 1992-2014).

Most studies (90%) were conducted in Europe (n=15) and Asia/the Middle East (n=11). Most studies (76%) sampled products during a specific or defined period of time, while two conducted sampling over multiple time points, and 5 reported on the results of systematic surveillance programmes. Nearly 80% of studies sampled products at retail (e.g. markets, grocery stores) and/or from manufacturing and processing facilities. Only 8/29 studies (28%) specified the country(s) of product origin.

Salmonella spp., *L. monocytogenes,* and *E. coli* were the most commonly investigated microbial hazards in the cocoa and chocolate, other/unspecified confections, and snack categories, respectively. A very low average prevalence of *Salmonella* spp. was identified in cocoa and chocolate (1.7%, 95% CI: 0.03 to 5.0), while it was not identified in other/unspecified confections and snacks. *L. monocytogenes* was identified at low prevalence levels in other/unspecified confections, and was not found in studies sampling cocoa/chocolate and snacks. A very low prevalence of generic *E. coli* was found in all categories except cocoa and chocolate, where one study identified 14/29 positive samples of dried and fermented cocoa beans in Brazil (Nascimento et al., 2010).

B. cereus and *Cronobacter* spp. were found at highly variable prevalence levels in confections and snacks. *S. aureus* was identified in only one small study (3/4) of Turkish delight samples (Akan and Sürücüoğlu, 2012). *C. botulinum* and Enterobacteriaceae were both investigated in one study each; a low to moderate prevalence of *C. botulinum* was found in sugar samples from Japan (Nakano et al., 1992), and Enterobacteriaceae was found in 5/25 samples of cocoa powder in the Netherlands (Lima et al., 2011).

C. perfringens and *E. coli* O157:H7 were not identified in any study.

Only one study investigated yeast (not shown in the table below); the authors did not isolate *B. cereus* from 4 samples in Denmark (Rosenkvist and Hansen, 1995).

Few studies reported extractable concentration data on levels of selected microbial hazards in confections and snacks (not shown in the table below).

Average (standard deviation) log CFU/g concentrations of *B. cereus* in chocolate (n=100 samples), chewing gum (100), taffy (50), other candies (300), and mixed snacks (150) in South Korea were identified as 0.17 (0.58), 0.06 (0.41), 0.02 (0.60), 0.07 (0.42), and 0.32 (0.82), respectively (Kim et al., 2013). The concentration of most of the *B. cereus* positive samples in this study was much lower than those typically associated with foodborne illness from this pathogen (EFSA, 2005; Kim et al., 2013). Higher average (standard deviation) CFU/g concentrations of *B. cereus*, at 1.25×10^3 (1.97×10^3), were identified in a study that sampled corn snacks (n=20) in Egypt (Zeid, 2009).

In other studies, a median concentration of 155 MPN/g was identified for 8/8 *B. cereus* positive samples in cereal bar snacks (Lee et al., 2009), a mean (standard deviation) of 33.7 (15.2) CFU/g was identified for *S. aureus* in 3/4 Turkish delight samples (Akan and Sürücüoğlu, 2012), and a concentration range of 0.9 to >3.0 log MPN/g was identified for generic *E. coli* in 14/29 dried and fermented cocoa bean samples (Nascimento et al., 2010).

Prevalence of selected microbial hazards within confection and snack categories

Each cell includes the number of observations/trials/studies contributing to the average or median prevalence estimate, the proportion of trials that did not find any positive samples and measures of heterogeneity and risk of selection bias. See the table footnotes for detailed explanations on each of these parameters.

	Confections and Snacks Number of observations/trials/studies (% trials with zero prevalence)[a] Meta-analysis prevalence (%) estimates (95% CI) OR prevalence median (range)[b] Heterogeneity rating / Risk of selection bias (low, medium or high)[c]		
Microbial hazard	**Cocoa and chocolate**	**Other and unspecified confections**	**Snacks**
B. cereus	106/2/2 (0%) 21.2 (9.0 – 33.3)[R] High / Med.	450/3/1 (0%) 3.1 (1.7 – 4.9)[M] Low / Low	192/5/5 (20%) 40 (0 – 70)[R] High / High
C. botulinum	N/A	103/5/1 (20%) 7.6 (1.1 – 18.1)[M] Med. / High	N/A
C. perfringens	100/1/1 (100%) 0 N/A / Low	450/3/1 (100%) 0 (0 – 0)[R] Low / Low	150/1/1 (100%) 0 N/A / Low
***Cronobacter* spp.**	47/3/2 (67%) 0 (0 – 29.7)[R] High / Med.	123/5/4 (60%) 5.8 (0.7 – 14.3)[M] Med. / High	33/3/3 (33%) 4.6 (0 – 100)[R] High / High
Generic *E. coli*	129/2/2 (50%) 24.1 (0 – 48.3)[R] High / Med.	454/4/2 (75%) 0.7 (0.1 – 1.8)[M] Low / Low	377/3/3 (67%) 0 (0 – 4.4)[R] High / Low
***E. coli* O157:H7**	100/1/1 (100%) 0 N/A / Low	450/3/1 (100%) 0 (0 – 0)[R] Low / Low	202/4/3 (100%) 0 (0 – 0)[R] Low / High
Enterobacteriaceae	25/1/1 (0%) 20 Low / High	N/A	N/A
L. monocytogenes	102/2/2 (100%) 0 (0 – 0)[R] Low / Med.	1685/11/4 (55%) 0 (0 – 16.7)[R] High / Low	164/3/3 (100%) 0 (0 – 0)[R] Low / Med.
S. aureus	100/1/1 (100%) 0 N/A / Low	454/4/2 (75%) 0 (0 – 75)[R] High / Low	160/2/2 (100%) 0 (0 – 0)[R] Low / Med.
***Salmonella* spp.**	254/5/4 (40%) 1.7 (0.03 – 5.0)[M] Med. / High	450/3/1 (100%) 0 (0 – 0)[R] Low / Low	166/4/4 (100%) 0 (0 – 0)[R] Low / Med.

N/A = No data identified for this product-hazard combination. Med. = medium.

[a] Observations/trials/studies: The observations are the total number of samples for all studies included in the summarized category. The number of studies is the number of articles captured. In some cases, articles report data on multiple prevalence trials or sampling frames. While the observations for each trial are independent by time and sample, they are part of a larger study where the methods and investigators are the same. Thus, there is not full independence in these observations and we note this by acknowledging there are multiple trials within a study.

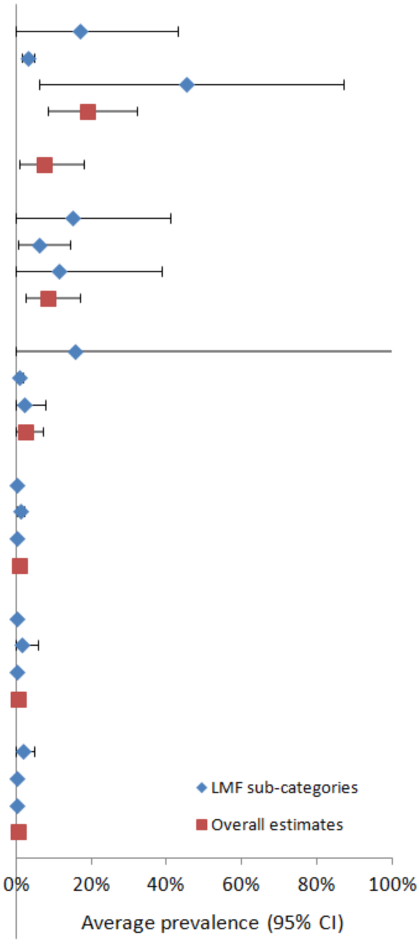
[b] Superscript [M] indicates an average prevalence estimate (and 95% confidence interval) from a random-effects meta-analysis. Meta-analysis estimates were calculated only if heterogeneity was low or medium (I^2 0-60%) and if at least one trial found a positive sample.

Superscript [R] indicates a median (and range) of trial prevalence estimates, calculated If heterogeneity was high (I^2 >60%). Ranges not provided when only one trial was identified.

[c] I^2 is a measure of the degree of heterogeneity between trials combined in the meta-analysis. Heterogeneity rating definitions: low = I^2 0-30%; medium = 31-60%; high = >60%.
Selection bias rating definitions: high = 0-30% of trials used a representative sample; medium = 31-60% of trials used a representative sample; low = >60% of trials used a representative sample. Studies that conducted random or systematic sampling were considered representative.
The overall robustness of the meta-analysis prevalence estimates can be inferred from the heterogeneity and selection bias ratings. Taking into consideration the number of studies in the meta-analysis, high confidence in the meta-analysis results can be inferred when heterogeneity is low and the risk of selection bias is low, and low confidence can be inferred when both are high, see the methods section (page 11) for more information.

Forest plot of the prevalence of selected microbial hazards within confection and snack categories

Micobial hazard / LMF sub-category	Average prevalence	Low 95% CI	High 95% CI	No. obs./ trials/studies	Hetero-geneity	Selection bias	Median (range)
B. cereus							
Cocoa and chocolate	16.6	0.0	43.1	106/2/2	High	Med.	21.2 (9.0 – 33.3)
Other confections	3.1	1.7	4.9	450/3/1	Low	Low	-
Snacks	44.9	6.2	87.1	192/5/5	High	High	40 (0 – 70)
Overall	19.0	8.6	32.2		High		9 (0 – 100)
C. botulinum							
Overall	7.6	1.1	18.1	103/5/1	Med.	High	-
***Cronobacter* spp.**							
Cocoa and chocolate	14.9	0.0	41.0	47/3/2	High	Med.	0 (0 – 29.7)
Other confections	5.8	0.7	14.3	123/5/4	Med.	High	-
Snacks	11.2	0.0	38.7	33/3/3	High	High	4.6 (0 – 100)
Overall	8.5	2.6	17.1		High		0 (0 – 100)
Generic *E. coli*							
Cocoa and chocolate	15.5	0.0	100.0	129/2/2	High	Med.	24.1 (0 – 48.3)
Other confections	0.7	0.1	1.8	454/4/2	Low	Low	-
Snacks	2.0	0.0	7.8	377/3/3	High	Low	0 (0 – 4.4)
Overall	2.5	0.1	7.2		High		0 (0 – 42.3)
L. monocytogenes							
Cocoa and chocolate	0.0	0.0	0.0	102/2/2	Low	Med.	-
Other confections	1.0	0.2	2.2	1685/11/4	High	Low	0 (0 – 16.7)
Snacks	0.0	0.0	0.0	164/3/3	Low	Med.	-
Overall	0.8	0.3	1.7		Med.		-
S. aureus							
Cocoa and chocolate	0.0	0.0	0.0	100/1/1	N/A	Low	-
Other confections	1.4	0.0	5.9	454/4/2	High	Low	0 (0 – 75)
Snacks	0.0	0.0	0.0	160/2/2	Low	Med.	-
Overall	0.5	0.0	1.9		High		0 (0 – 75)
***Salmonella* spp.**							
Cocoa and chocolate	1.7	0.0	5.0	254/5/4	Med.	High	-
Other confections	0.0	0.0	0.0	450/3/1	Low	Low	-
Snacks	0.0	0.0	0.0	166/4/4	Low	Med.	-
Overall	0.6	0.1	1.4		Low		-



CI = confidence interval; Med. = medium; No. obs. = number of total samples tested per category.
See the prevalence table for full explanations of all columns.
NOTE: *C. perfringens* and *E. coli* 0157 evidence not shown in this figure because no positive samples were identified in these categories. *C. botulinum* evidenceis based on data from only the other confections sub-category.

Interventions

A total of 15 experimental studies (consisting of 41 unique trials) were identified evaluating the effects of various interventions to reduce contamination of microbial hazards in confections and snacks. The median publication year was 2000 (range 1968 to 2013). Studies were conducted in the United States (n=7), Brazil (2), Switzerland (2), Canada, Egypt, Spain, and the United Kingdom. Thirteen of the 15 studies were challenge trials with artificially inoculated samples, and two were lab-based controlled trials. None of the studies were conducted under commercial conditions, and most included only a small number of samples (e.g. 2-4 replicates per intervention combination) or did not report their sample size.

The most commonly investigated interventions were various heat treatments to reduce contamination of *Salmonella* spp. in cocoa and chocolate. All investigated trials found that heat treatment is effective against *Salmonella* spp. in these products (more than would be expected by chance alone). However, high doses and/or durations were often required for complete elimination of this pathogen (Lee et al., 1989; Nascimento et al., 2012).

Two studies investigating the efficacy of conching (the last heat treatment step in chocolate making) found that it reduces *Salmonella* contamination but is not effective to fully eliminate high doses of *Salmonella* from chocolate (Krapf and Gantenbein-Demarchi, 2010; Nascimento et al., 2012). These findings emphasize the importance of ensuring that good agricultural and manufacturing practices and hazard analysis critical control point (HACCP) food safety management systems are implemented during cocoa harvesting and pre-processing (Krapf and Gantenbein-Demarchi, 2010; Nascimento et al., 2013). The National Confectioners Association Chocolate Council recommends that chocolate manufacturers design their roasting process to achieve a validated 4-5 log reduction of *Salmonella* spp. (NCACC, 2011).

A limited number of studies investigated interventions against other pathogens and in other confections/sweets, snacks and yeast.

Summary table of experimental studies evaluating the effects of interventions to reduce contamination of selected microbial hazards in confections and snacks

Food category	Intervention type	Intervention details (dose and/or duration, where available)	Source(s)	Microbial hazard(s)	Study type[a]	No. trials/ studies	% of trials with extractable data	% of trials finding intervention is effective[b]
Cocoa / chocolate	Drying	25-35°C; 60-80% RH; 6-7 days	Nascimento (2013)	*Salmonella* spp.	Ch.T.	1/1	100	0
	Fermentation	25-35°C; 60-80% RH; 7 days	Nascimento (2013)	*Salmonella* spp.	Ch.T.	1/1	0	0
	Heat treatment	Dry heat (57-90°C; 1-1050 min) Dry heat (54-100°C; 1-600 min) Dry heat (71°C; 0.5-20 hr) Dry heat (71°C; 2-24 hr) Conching (50-90°C; 0.5-23 hr) Hot oil dip (100°C; 15 min) Roasting (110-140°C; 10-50 min) Conching (50-70°C; 180-1440 min)	Goepfert (1968) Barrile (1970a) Barrile (1970b) Lee (1989) Krapf (2010) Izurieta (2012) Nascimento (2012) Nascimento (2012)	*Salmonella* spp.	Ch.T.	20/7	50	**100***
	Irradiation	Gamma (5-10 kGy)	Bonvehí (2000)	Enterobacteriaceae	C.T.	1/1	100	100
	Irradiation	Ultraviolet (19×10^3 erg cm^2/s; 0.5-10 min)	Lee (1989)	*Salmonella* spp.	Ch.T.	1/1	0	100
	Storage conditions	Increased temperature (10-38°C; 1-366 days)	Baylis (2004)	Pathogenic *E. coli* strains	Ch.T.	1/1	100	100
	Storage conditions	Increased a_w (0.43-0.75; 2 days to 14 weeks)	Juven (1984)	*Salmonella* spp.	Ch.T.	2/1	0	100
	Ultrasound	160 kHz; 42°C; 10-30 min	Lee (1989)	*Salmonella* spp.	Ch.T.	1/1	0	100
Other confections	Heat treatment	Hot water dip (65-70°C; 20 min)	Nummer (2012)	*Salmonella* spp.	Ch.T.	1/1	0	100
	Modified packaging	Air (oxygen 0.5-20%) vs. vacuum (1-27 weeks)	Christian (1973)	*Salmonella* spp., *S. aureus*	Ch.T.	4/1	0	100
	Storage conditions	Increased temperature (10-38°C; 4 hr to 367 days)	Baylis (2004)	Pathogenic *E. coli* strains	Ch.T.	2/1	100	100
	Storage conditions	Increased a_w (0.11-0.53; 1-27 weeks)	Christian (1973)	*Salmonella* spp., *S. aureus*	Ch.T.	4/1	0	100
Snacks	Irradiation	Gamma (1-10 kGy; 5.6 kGy/hr)	Zeid (2009)	*B. cereus*	C.T.	1/1	100	100
Yeast	Spray drying	225°C	Miller (1972)	*Salmonella* spp.	Ch.T.	1/1	0	100

[a] Ch.T. = challenge trial; C.T. = controlled trial.
[b] Intervention categories marked with an asterisk (*) indicate that more trials found a positive intervention effect than would be expected by chance alone (sign test *P* value <0.05). Significance only calculated if more than one study was conducted per intervention/microbial hazard/study type combination.

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Summary Card: Dried Fruits and Vegetables

(Burden of Illness, Prevalence and Interventions)

Low-moisture food category description

This summary covers dried and dehydrated fruits and vegetables, as well as dried seaweed and mushrooms. Examples of dried fruits included raisins, prunes, dates, dried mangos, dried apricots, desiccated coconut, and fruit powders. Examples of dried vegetables included sun-dried vegetables (e.g. tomatoes, okra), vegetable powders and mixes (e.g. dry soup mixes), dehydrated vegetables (e.g. potato flakes, carrot slices), and vegetable flours (e.g. potato starch, yam flour). We also included dried legumes and legume flours in the dried vegetable category. For the purposes of summarizing prevalence and intervention information, data were collapsed across four categories: 1) dried/dehydrated fruits; 2) dried/dehydrated vegetables; 3) dried/dehydrated mushrooms; and 4) dried seaweed.

Evidence summary

In total, 39 articles[5] and outbreak reports[6] were identified that investigated the burden of illness, the prevalence or concentration of selected microbial hazards, and interventions to reduce contamination of microbial hazards in dried fruits and vegetables. The distribution of identified research stratified by microbial hazard investigated and research focus is shown in A Appendix F: Summary Card Evidence Charts. *Salmonella* spp. was the most frequently investigated microbial hazard in dried fruits and vegetables for burden of illness (n=3 outbreak reports), prevalence (n=12 articles), and intervention (n=8 articles) information.

Burden of illness

Burden of illness evidence related to dried fruits and vegetables includes 3 reported outbreaks between 1953 and 2004. *Salmonella* was implicated in all outbreaks affecting 719 individuals (median 50, range 18-651), including 247 hospitalizations and 1 death. The dried fruit and vegetable outbreaks are shown in the summary table below and were reported from Australia, the United Kingdom, and Greece.

Summary table of globally reported outbreaks on dried fruits and vegetables

Dried fruit or vegetable category/ specific source *(reference)*	Microbial hazard(s)	Outbreaks/ cases/ hospitalized / deaths[a]	Country (year)[b]	Comments: susceptible populations/ attack rate/ concentration of microbial hazard in the product
Desiccated coconut (Ward 1999, Wilson 1953)	*Salmonella* Typhi, Senftenberg Java phage type Dundee	2/68/7/0	Australia (1953), United Kingdom (1998)	Retail desiccated coconut.
Raisins & chickpea powder (Mellou 2014)	*Salmonella* Enteritidis (9:g,m:-)	1/651/247/1	Greece (2004)	Contaminated kolliva served at 8 funerals. Raisins and chickpea powder =confirmed contaminated ingredient. Attack rate >70%

[5] Articles refer to peer-reviewed journal publications as well as government and research agency reports.
[6] For burden of illness information, multiple articles often reported complementary and/or overlapping information on the same outbreak. In addition, outbreak data were supplemented from other literature sources, including line lists from various countries, news reports, or annual summaries of country outbreaks. Thus, to avoid counting the same outbreak more than once, the term 'outbreak report' is used instead of 'article' to count the total number of unique outbreaks.

[a] Superscript [C] indicates confirmed cases, [P] indicates presumptive cases.
[b] Superscript [E] indicates the link between human cases and implicated product was epidemiological only, otherwise the link was laboratory confirmed.

Most of these outbreaks were small and isolated to one batch of a retail product. The Kolliva outbreak from Greece was largely caused by temperature abuse and the source of the contamination was confirmed to be raisins and chickpea powder.

Prevalence

A total of 23 studies containing 64 unique trials were identified that investigated the prevalence and/or concentration of one or more selected microbial hazards in dried fruits and vegetables. The median publication year was 2008 (range 1992-2014).

Most studies (70%) were conducted in Europe (n=9) and Asia/the Middle East (n=7) > Africa (4) > Brazil (2) > New Zealand (1). Most studies (78%) sampled products during a specific or defined period of time, while two conducted sampling over multiple time points, and three reported on the results of systematic surveillance programmes. Over 80% of studies sampled products at retail (e.g. markets, grocery stores) and/or from imports, and four sampled from processing facilities. Only 9/23 studies (39%) specified the country(s) of product origin.

Most studies investigated *Salmonella* spp. and/or generic *E. coli* in dried fruits, and *B. cereus* and/or *Cronobacter* spp. in dried vegetables. *Salmonella* spp. was detected at a very low prevalence in dried fruits (median 0%), with the exception of one study that found a prevalence of 33% (6/20) in raisin samples in India (Sharma et al., 2008). Generic *E. coli* and *S. aureus* were not identified in dried fruits, but they were detected in 1/16 and 4/16 samples, respectively, of sun-dried okra from Nigeria (Arise et al., 2012). *B. cereus* and *Cronobacter* spp. were identified at highly variable prevalence levels in dried fruits and vegetables, with *B. cereus* prevalence approaching or at 100% in several trials. Enterobacteriaceae were investigated in a small number of total samples (n=37) of dried fruit in two studies, with an average prevalence of 7.8% (95% CI: 1.1 to 18.6).

One study investigated *C. botulinum* in dried mushrooms (not shown in the table below); the authors did not isolate *C. botulinum* spores from 48 samples in China (Malakar et al., 2013). No prevalence studies were identified investigating dried seaweed.

C. perfringens and *L. monocytogenes* were not identified in any study.

Few studies reported extractable concentration data on levels of selected microbial hazards in dried fruits and vegetables (not shown in the table below).

Average (standard deviation) concentrations of Enterobacteriaceae and *Salmonella* spp. in 2/20 and 6/20 positive samples of raisins in India were 15 (7.1) and 8.5×10^3 (2.0×10^4) CFU/g, respectively (Sharma et al., 2008). Concentrations of *Salmonella* spp. in raisins (1/3 samples) and prunes (1/3 samples) from South Africa were 10 and 40 CFU/g, respectively (Witthuhn et al., 2005). Concentrations of *B. cereus* in positive samples (37/50) of dehydrated potato flakes from New Zealand ranged from 10 to 370 CFU/g, with only 8 samples >100 CFU/g (Turner et al., 2006).

Prevalence of selected microbial hazards within dried fruit and vegetable categories

Each cell includes the number of observations/trials/studies contributing to the average or median prevalence estimate, the proportion of trials that did not find any positive samples and measures of heterogeneity and risk of selection bias. See the table footnotes for detailed explanations on each of these parameters.

	Dried Fruits and Vegetables Number of observations/trials/studies (% trials with zero prevalence)[a] Meta-analysis prevalence (%) estimates (95% CI) OR prevalence median (range)[b] Heterogeneity rating / Risk of selection bias (low, medium or high)[c]	
Microbial hazard	**Dried/dehydrated fruits**	**Dried/dehydrated vegetables**
B. cereus	556/2/2 (0%) 50.2 (0 – 100)[R] High / Med.	230/6/4 (0%) 98 (13 – 100)[R] High / High
C. perfringens	1/1/1 (100%) 0 N/A / High	N/A
***Cronobacter* spp.**	10/1/1 (0%) 10 N/A / High	114/6/4 (33%) 9.8 (0 – 60)[R] High / Med.
Generic *E. coli*	822/8/4 (100%) 0 (0 – 0)[R] Low / High	16/1/1 (0%) 6.3 N/A / High
Enterobacteriaceae	37/6/2 (83%) 7.8 (1.1 – 18.6)[M] Low / High	N/A
L. monocytogenes	555/1/1 (100%) 0 N/A / Low	N/A
S. aureus	766/3/3 (100%) 0 (0 – 0)[R] Low / Low	16/1/1 (0%) 25 N/A / High
***Salmonella* spp.**	1150/14/10 (71%) 0 (0 – 33.3)[R] High / Med.	N/A

N/A = No data identified for this product-hazard combination. Med. = medium.

[a] Observations/trials/studies: The observations are the total number of samples for all studies included in the summarized category. The number of studies is the number of articles captured. In some cases, articles report data on multiple prevalence trials or sampling frames. While the observations for each trial are independent by time and sample, they are part of a larger study where the methods and investigators are the same. Thus, there is not full independence in these observations and we note this by acknowledging there are multiple trials within a study.

[b] Superscript [M] indicates an average prevalence estimate (and 95% confidence interval) from a random-effects meta-analysis. Meta-analysis estimates were calculated only if heterogeneity was low or medium (I^2 0-60%) and if at least one trial found a positive sample.

Superscript [R] indicates a median (and range) of trial prevalence estimates, calculated If heterogeneity was high (I^2 >60%). Ranges not provided when only one trial was identified.

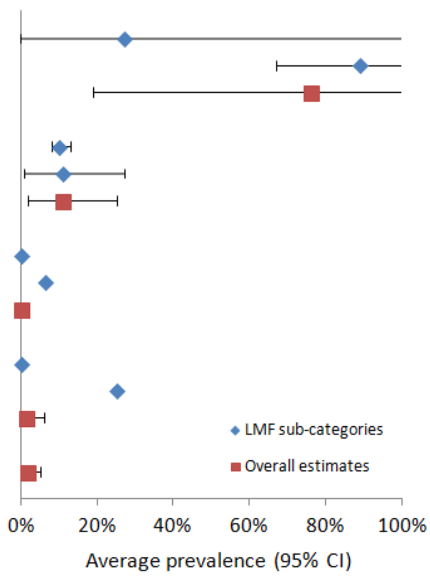
[c] I^2 is a measure of the degree of heterogeneity between trials combined in the meta-analysis. Heterogeneity rating definitions: low = I^2 0-30%; medium = 31-60%; high = >60%.

Selection bias rating definitions: high = 0-30% of trials used a representative sample; medium = 31-60% of trials used a representative sample; low = >60% of trials used a representative sample. Studies that conducted random or systematic sampling were considered representative.

The overall robustness of the meta-analysis prevalence estimates can be inferred from the heterogeneity and selection bias ratings. Taking into consideration the number of studies in the meta-analysis, high confidence in the meta-analysis results can be inferred when heterogeneity is low and the risk of selection bias is low, and low confidence can be inferred when both are high, see the methods section (page 11) for more information.

Forest plot of the prevalence of selected microbial hazards within dried fruit and vegetable categories

Micobial hazard / LMF sub-category	Average prevalence	Low 95% CI	High 95% CI	No. obs./ trials/studies	Hetero-geneity	Selection bias	Median (range)
B. cereus							
Dried fruits	27.1	0.0	100.0	556/2/2	High	Med.	50.2 (0 – 100)
Dried vegetables	88.6	67.0	100.0	230/6/4	High	High	98 (13 – 100)
Overall	76.3	19.0	100.0		High		98 (0.4 – 100)
***Cronobacter* spp.**							
Dried fruits	10.0	-	-	10/1/1	N/A	High	-
Dried vegetables	10.8	0.9	27.2	114/6/4	High	Med.	9.8 (0 – 60)
Overall	11.1	2.0	25.1		High		0.1 (0 – 60)
Generic *E. coli*							
Dried fruits	0.0	0.0	0.0	822/8/4	Low	High	-
Dried vegetables	6.3	-	-	16/1/1	N/A	High	-
Overall	0.2	0.0	0.9		Low		-
S. aureus							
Dried fruits	0.0	0.0	0.0	766/3/3	Low	Low	-
Dried vegetables	25.0	-	-	16/1/1	N/A	High	-
Overall	1.7	0.0	6.1		High		0 (0 – 25)
***Salmonella* spp.**							
Overall	2.0	0.2	5.2	1150/14/10	High		0 (0 – 33.3)



CI = confidence interval; Med. = medium; No. obs. = number of total samples tested per category.
See the prevalence table for full explanations of all columns.
NOTE: *C. perfringens* and *L. monocytogenes* evidence not shown in this figure because no positive samples were identified in these categories. *Salmonella* spp. evidence is based on data from only the dried fruits sub-category.

Interventions

A total of 13 experimental studies (consisting of 44 unique trials) were identified evaluating the effects of various interventions to reduce contamination of microbial hazards in dried fruits and vegetables. The median publication year was 2005 (range 1973 to 2011). Studies were conducted in the United States (n=10), Turkey (1), Thailand (1) and South Korea (1). All studies were challenge trials with artificially inoculated samples. None of the studies were conducted under commercial conditions, and most included only a small number of samples (2-10 replicates per intervention combination).

The most commonly investigated interventions were various chemical dips and heat treatments applied to fruits and vegetables to reduce contamination of *Salmonella* spp. and *E. coli* prior to drying with home-type dehydrators. Nearly all pre-drying treatments were found to be more effective at reducing levels of microbial hazard contamination on the final dried product compared to drying without any pre-treatment; however, in some cases these pre-treatments were not superior to dipping products in sterile water (Derrickson-Tharrington, 2005; Yoon et al., 2004).

One study found that irradiation is effective to reduce contamination of *E. coli*, *S. aureus*, and *Salmonella* spp. on dried seaweed (Jo et al., 2005), and one study found that gaseous ozone can effectively reduce *B. cereus* and generic *E. coli* contamination of dried figs (Akbas and Ozdemir, 2008). Other studies investigated modified storage conditions and packaging on *Salmonella* spp., pathogenic *E. coli*, and *S. aureus* survival in various dried fruits and vegetables (Christian and Stewart, 1973; Deng et al., 1998; Park and Beuchat, 2000).

Summary table of experimental studies evaluating the effects of interventions to reduce contamination of selected microbial hazards in dried fruits and vegetables

Food category	Intervention type	Intervention details (dose and/or duration, where available)	Source(s)	Microbial hazard(s)	No. trials/ studies	% of trials with extractable data	% of trials finding intervention is effective[a]
Dried fruits	Pre-drying (57.2-62.8°C; 6 hr) chemical dips	Ascorbic acid (2.8-3.4%; 10-15 min) Citric acid (1.7%; 10 min) Lemon juice (50%; 10 min) Lemon juice with preservatives (50%; 10 min)	Burnham (2001)/ Derrickson (2005) Derrickson (2005) Derrickson (2005) Derrickson (2005) Derrickson (2005)	*E. coli* O157:H7	5/2	83	100
	Pre-drying (60°C; 6 hr) chemical dips	Ascorbic acid dip (3.4%; 25°C; 10 min) Citric acid (0.21%; 10 min) Sodium metabisulfite (4.18%; 10 min)	DiPersio (2003)	*Salmonella* spp.	3/1	100	100
	Pre-drying (57.2-62.8°C; 6 hr) heat treatment	Steam blanching (88°C; 3 min)	Burnham (2001)	*E. coli* O157:H7	1/1	0	0
	Ozone	Gas (0.1-1 ppm; 70% RH; 60-360 min)	Akbas (2008)	*B. cereus*	2/1	0	100
	Ozone	Gas (0.1-1 ppm; 70% RH; 60-360 min)	Akbas (2008)	Generic *E. coli*	1/1	0	100
	Storage conditions	Increased temperature (5-37°C; 1-19 weeks)	Deng (1998)	*E. coli* O157:H7	2/1	0	100
Dried vegetables	Drying	Hot air (50-70°C; 0-16 hr) Low-pressure superheated steam and vacuum (10 kPa; 50-70°C; 0-16 hr)	Phungamngoen (2011)	*Salmonella* spp.	3/1	0	100
	Heat treatment	Dry heat (80°C; 15 min)	DiPersio (2005a)	*Salmonella* spp.	1/1	0	0
	Pre-drying (60°C; 6 hr) chemical dips	Ascorbic acid (3.4%; 10 min) Sodium chloride (3.23%; 25°C; 5 min) Citric acid (0.105-0.21%; 88°C; 4 min)	Yoon (2004) DiPersio (2005a) DiPersio (2005b, 2007)/Yoon (2004)	*Salmonella* spp.	7/4	57	**100***
	Pre-drying (60°C; 6 hr) heat treatment	Water blanching (88°C; 3-4 min) Steam blanching (88°C; 3-10 min)	DiPersio (2005a,b, 2007) DiPersio (2005a,b, 2007)/Yoon (2004)	*Salmonella* spp.	7/4	43	86
	Modified packaging	Air (oxygen 0.5-20%) vs. vacuum (1-27 weeks)	Christian (1973)	*Salmonella* spp., *S. aureus*	2/1	0	100

	Multiple pre-drying (60°C; 6 hr) treatments	Steam blanching (88°C; 3 min) + ascorbic acid dip (3.4%; 10 min)	Yoon (2004)	*Salmonella* spp.	2/1	100	100
	Storage conditions	Increased temperature (4-37°C), increased a_w (0.26-0.78), decreased pH (4.1-6.7; 1-33 weeks)	Park (2000)	*E. coli* O157:H7	3/1	0	67
	Storage conditions	Increased a_w (0.11-0.53; 1-27 weeks)	Christian (1973)	*Salmonella* spp., *S. aureus*	2/1	0	100
Dried seaweed	Irradiation	Gamma (1-3 kGy; 10 kGy/hr)	Jo (2005)	Generic *E. coli*, *S. aureus*, *Salmonella* spp.	3/1	100	100

[a] Intervention categories marked with an asterisk (*) indicate that more trials found a positive intervention effect than would be expected by chance alone (sign test *P* value <0.05). Significance only calculated if more than one study was conducted per intervention/microbial hazard/study type combination.

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Summary Card: Dried Protein Products

(Burden of Illness, Prevalence and Interventions)

Low-moisture food category description

This summary covers dried protein products. For the purposes of summarizing prevalence and intervention information, data were collapsed across four categories: 1) dairy products (e.g. milk, whey, and milk-product powders); 2) egg products (e.g. egg powders); 3) fish/seafood products (e.g. dried fish, fish meal/flour); and 4) meat products other than sausages, salamis, and jerky's (e.g. gelatin, meat powders). Although the search included terms for dry protiens of plant origin (e.g. soy powder), no evidence on these products was identified in this scoping review.

Specifically excluded from this summary are dried and/or fermented sausages, salamis, and jerky's, which can have a low water activity (i.e. a_w <0.85). However, they were excluded due to the vast amount of literature identified in this area and reporting limitations (the water activity of products in most studies could not be confirmed). Also excluded is powdered infant formula, which was considered beyond the scope of this review.

Evidence summary

In total, 66 articles[7] and outbreak reports[8] were identified that investigated the burden of illness, the prevalence or concentration of selected microbial hazards, and interventions to reduce contamination of microbial hazards in dried protein products. The distribution of identified research stratified by microbial hazard investigated and research focus is shown in Appendix F: Summary Card Evidence Charts. *Salmonella* spp. was the most frequently investigated microbial hazard in dried protein products for burden of illness (n=6 outbreak reports) and intervention (n=10 articles) information, while *Cronobacter* spp. was the most commonly investigated microbial hazard in prevalence studies (n=20 articles).

Burden of illness

Burden of illness evidence related to dried protein products included 13 outbreaks, 6 attributed to powdered milk and 7 attributed to dried fish. There were no outbreaks related to dry vegetable proteins such as soy powders. Outbreaks occurred in the United States (2), Ukraine (2), Japan (2), Trinidad, France, Singapore, Canada, Russia, and Germany. There was a lot of variation in the size of the outbreaks captured in each category. Hospitalizations and deaths were only reported from dried fish outbreaks involving *C. botulinum*.

The 6 powdered milk outbreaks 1965-2006 were caused by *Salmonella* in 3 outbreaks affecting 3078 individuals (median 49, range 29- 3000) and *S. aureus* in the remaining 3 outbreaks affecting 13606 individuals (median 150, range 36-13420). The large outbreak in this category was from Japan, they

[7] Articles refer to peer-reviewed journal publications as well as government and research agency reports.
[8] For burden of illness information, multiple articles often reported complementary and/or overlapping information on the same outbreak. In addition, outbreak data were supplemented from other literature sources, including line lists from various countries, news reports, or annual summaries of country outbreaks. Thus, to avoid counting the same outbreak more than once, the term 'outbreak report' is used instead of 'article' to count the total number of unique outbreaks.

were not able to culture *S. aureus* from the powdered milk; however staphylococcal enterotoxin A was detectable at high enough concentrations to cause illness.

The seven outbreaks attributed to commercial dried fish products included 3 due to *Salmonella* that affected 1540 individuals (median 33, range 2-1505). The remaining 4 outbreaks were caused by *C. botulinum* contamination and affected 16 people, including 14 hospitalizations and one death. The median outbreak size was 4 (range 3-6).

Summary table of globally reported outbreaks on dried protein products

Dried protein category/ specific source *(reference)*	Microbial hazard(s)	Outbreaks/ cases/ hospitalized / deaths[a]	Country (year)[b]	Comments: susceptible populations/ attack rate/ concentration of microbial hazard in the product
Milk Protein				
Powdered Milk (Collins 1968, Weissman 1977, Asoa 2003)	*Salmonella* Worthington, Newbrunswick, Derby	3/3078/0/0	United States (1965), Trinidad (1973), France (2005)	Children <4 years comprised 89% of cases in the Trinidad outbreak. The outbreak in France was mainly in hospitalized patients.
(InVS 2005, Clark 2007, Doyle 2008)	*S. aureus*	3/ 4949[C], 8657[P]/0/0	Japan (2000), China (2004), United States (2006)[E]	Most cases were from the large outbreak in Japan; viable *S. aureus* was not cultured in this outbreak, but the staphylococcal enterotoxin A concentration mean was 7.28 (range 1.4–26.2) ng/g
Fish/Seafood Protein				
Dried Anchovy (Ling 2002, Anon 2005)	*Salmonella* Typhimurium DT104	2/35/0/0	Singapore (2000), Canada (2005)	Singapore outbreak mainly involved infants and toddlers.
Cuttlefish Chips (Miyakawa 2006)	*Salmonella* Oranienburg and Chester	1/1505/0/0	Japan (1999)	Largely affected infants and toddlers.
Commercial Dried Fish (Peck 2003, Eriksen 2006)	*C. botulinum*	4/14[C], 2[P]/14/1	Ukraine (2004[E], 2005[E]), Russia (2004)[E], Germany (2003)	Commercially produced dried fish snack.

[a] Superscript [C] indicates confirmed cases, [P] indicates presumptive cases.
[b] Superscript [E] indicates the link between human cases and implicated product was epidemiological only, otherwise the link was laboratory confirmed.

Prevalence

A total of 39 studies containing 90 unique trials were identified that investigated the prevalence and/or concentration of one or more selected microbial hazards in dried protein products. The median publication year was 2010 (range 1995-2014). Most studies (72%) were conducted in Europe (n=18) and Asia/the Middle East (n=10) > Africa (6) > Latin/South America (4) > Australia (1). Most studies (74%) sampled products during a specific or defined period of time, while four conducted sampling over multiple time points, and six reported on the results of systematic surveillance programmes. Nearly 80% of studies sampled products at retail stores or markets (n=24) and from processing facilities (n=7). Only 13/39 studies (33%) specified the country(s) of product origin.

Most studies investigated *Cronobacter* spp. in dried dairy products, which was found at a low average prevalence of 4.5% (95% CI 3 to 6.2%). Enterobacteriaceae were also found at a low median prevalence

(3.3%) in dried dairy products. In a study of 813 milk powder samples that were presumptive positive for Enterobacteriaceae (not shown in the table below), *Cronobacter* spp. was found at a higher prevalence of 17% (Jacobs et al., 2011).

B. cereus was found at highly variable prevalence levels (ranging from 0 to 60%) in dried dairy products. *C. botulinum* was found in 3/26 milk powder samples in one study (Carlin, 2004), and *L. monocytogenes* was not identified from 100 milk powder samples in one study (Rodas-Suarez et al., 2013).

Salmonella spp. was not isolated from dried dairy products or gelatin in any study. However, 1/61 batch samples of gelatin were found to be non-compliant with *Salmonella* criteria in European Union Regulation 2073/2005 in the 2008 summary surveillance report (EFSA/ECDC, 2010).

In a study of 8 samples of gelatin, *Cronobacter* spp. was isolated from one sample and generic *E. coli* was not found (de la Rosa et al., 1995).

Dried fish and seafood products were investigated in only two studies (not shown in the table below). In a representative study of 100 dried fish and seafood products in South Korea, *B. cereus*, generic *E. coli,* and *L. monocytogenes* were found in 13, 1, and 1 samples, respectively, while *C. perfringens, E. coli* O157:H7, *S. aureus*, and *Salmonella* spp. was not identified (Kim et al., 2013). In another study in Zambia, *Salmonella* spp. was isolated from 1/5 dried minnow samples (Jermini et al., 1997).

No studies were identified that investigated microbial hazards in egg or meat powders.

Few studies reported extractable concentration data on levels of selected microbial hazards in dried protein products (not shown in the table below).

Average (standard deviation) concentrations of *B. cereus* in 29/65 and 2/35 positive samples of milk powder in Egypt were 630 (140) and 380 (200) CFU/g in two different brands, respectively (Deeb et al., 2010). Average concentrations of *B. cereus* in 175/381 positive samples of various milk powder products in Chile ranged from 6.4 to 5.96 x 10^3 MPN/g (Reyes et al., 2007).

In 13/100 positive samples of dried fish and seafood products from South Korea, average (standard deviation) concentrations of *B. cereus* were 0.28 (0.74) log CFU/g (Kim et al., 2013).

Interventions

A total of 14 experimental studies (consisting of 62 unique trials) were identified evaluating the effects of various interventions to reduce contamination of microbial hazards in dried protein products. The median publication year was 1991 (range 1968 to 2013). Studies were conducted in the United States (n=9), Turkey (2), Hungary (1), Jordan (1), and South Africa (1). All studies were challenge trials with artificially inoculated samples. None of the studies were conducted under commercial conditions, and most included only a small number of samples (2-10 replicates per intervention combination) or did not report their sample size.

The most commonly investigated interventions applied to dried protein products were various heat and drying treatments, chemical additives, and modified storage conditions. Interventions were applied again *Salmonella* spp., pathogenic *E. coli*, *Cronobacter* spp., and *S. aureus* in dried dairy products, *Salmonella* spp. in dried egg and fish/seafood products, and pathogenic *E. coli* in dried meat products.

With the exception of chemical additives, most studies found that the investigated interventions were effective to reduce levels of microbial hazard contamination on the final dried products. However, in some cases, although treatments reduced levels of contamination, they did not always fully eliminate microbial hazards from dried protein products (LiCari and Potter, 1970a; Torlak and Sert, 2013).

Prevalence of selected microbial hazards within dried protein product categories

Each cell includes the number of observations/trials/studies contributing to the average or median prevalence estimate, the proportion of trials that did not find any positive samples and measures of heterogeneity and risk of selection bias. See the table footnotes for detailed explanations on each of these parameters.

	Dried Protein Products Number of observations/trials/studies (% trials with zero prevalence)[a] Meta-analysis prevalence (%) estimates (95% CI) OR prevalence median (range)[b] Heterogeneity rating / Risk of selection bias (low, medium or high)[c]	
Microbial hazard	**Dried dairy products**	**Gelatin**
B. cereus	632/7/7 (14%) 44.4 (0 – 60)[R] High / Med.	N/A
C. botulinum	26/1/1 (0%) 11.5 N/A / High	N/A
***Cronobacter* spp.**	2714/29/17 (45%) 4.5 (3.0 – 6.2)[M] Med. / High	8/1/1 (0%) 12.5 N/A / High
Generic *E. coli*	N/A	8/1/1 (0%) 0 N/A / High
Enterobacteriaceae	2288/4/2 (50%) 3.3 (0 – 7.1)[R] High / Med.	N/A
L. monocytogenes	100/1/1 (100%) 0 N/A / Low	N/A
***Salmonella* spp.**	4505/7/6 (100%) 0 (0 – 0)[R] Low / Low	565/6/5 (100%) 0 (0 – 0)[R] Low / Low

N/A = No data identified for this product-hazard combination. Med. = medium.

[a] Observations/trials/studies: The observations are the total number of samples for all studies included in the summarized category. The number of studies is the number of articles captured. In some cases, articles report data on multiple prevalence trials or sampling frames. While the observations for each trial are independent by time and sample, they are part of a larger study where the methods and investigators are the same. Thus, there is not full independence in these observations and we note this by acknowledging there are multiple trials within a study.

[b] Superscript [M] indicates an average prevalence estimate (and 95% confidence interval) from a random-effects meta-analysis. Meta-analysis estimates were calculated only if heterogeneity was low or medium (I^2 0-60%) and if at least one trial found a positive sample.

Superscript [R] indicates a median (and range) of trial prevalence estimates, calculated If heterogeneity was high (I^2 >60%). Ranges not provided when only one trial was identified.

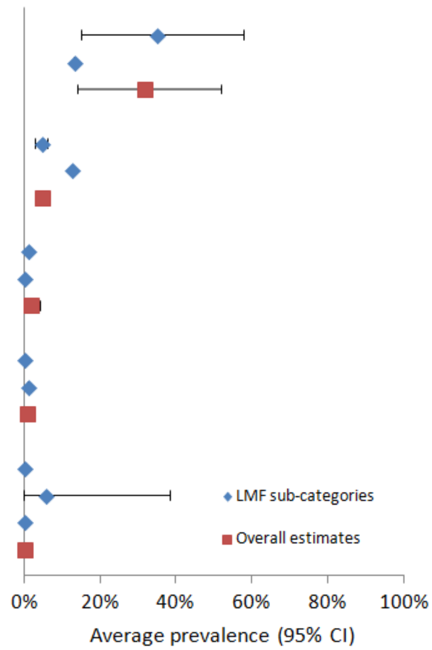
[c] I^2 is a measure of the degree of heterogeneity between trials combined in the meta-analysis. Heterogeneity rating definitions: low = I^2 0-30%; medium = 31-60%; high = >60%.

Selection bias rating definitions: high = 0-30% of trials used a representative sample; medium = 31-60% of trials used a representative sample; low = >60% of trials used a representative sample. Studies that conducted random or systematic sampling were considered representative.

The overall robustness of the meta-analysis prevalence estimates can be inferred from the heterogeneity and selection bias ratings. Taking into consideration the number of studies in the meta-analysis, high confidence in the meta-analysis results can be inferred when heterogeneity is low and the risk of selection bias is low, and low confidence can be inferred when both are high, see the methods section (page 11) for more information.

Forest plot of the prevalence of selected microbial hazards within dried protein product categories

Micobial hazard / LMF sub-category	Average prevalence	Low 95% CI	High 95% CI	No. obs./ trials/studies	Hetero-geneity	Selection bias	Median (range)
B. cereus							
Dried dairy products	35.0	14.9	57.9	632/7/7	High	Med.	44.4 (0 – 60)
Dried fish products	13.0	-	-	100/1/1	N/A	Low	-
Overall	31.5	14.2	51.7		High		38.9 (0 – 60)
***Cronobacter* spp.**							
Dried dairy products	4.5	3.0	6.2	2714/29/17	Med.	High	-
Gelatine	12.5	-	-	8/1/1	N/A	High	-
Overall	4.6	3.1	6.4		Med.		-
Generic *E. coli*							
Dried fish products	1.0	-	-	100/1/1	N/A	Low	-
Gelatine	0.0	-	-	8/1/1	N/A	High	-
Overall	1.5	0.0	4.3		Low		-
L. monocytogenes							
Dried dairy products	0.0	-	-	100/1/1	N/A	Low	-
Dried fish products	1.0	-	-	100/1/1	N/A	Low	-
Overall	0.7	0.0	2.1		Low		-
***Salmonella* spp.**							
Dried dairy products	0.0	0.0	0.0	4505/7/6	Low	Low	-
Dried fish products	5.6	0.0	38.5	105/2/2	High	Med.	10 (0 – 20)
Gelatine	0.0	0.0	0.0	565/6/5	Low	Low	-
Overall	0.0	0.0	0.1		Low		0 (0 – 20)



CI = confidence interval; Med. = medium; No. obs. = number of total samples tested per category.
See the prevalence table for full explanations of all columns.
NOTE: *C. botulinum* evidence not shown in this figure as only one trial was identified in this category.

Summary table of experimental studies evaluating the effects of interventions to reduce contamination of selected microbial hazards in dried protein products

Food category	Intervention type	Intervention details (dose and/or duration, where available)	Source(s)	Microbial hazard(s)	No. trials/ studies	% of trials with extractable data	% of trials finding intervention is effective[a]
Dried dairy	Chemical additives	Diethylpyrocarbonate (0.1%), potassium sorbate (500 ppm), sodium benzoate (0.2%), whey (1-10%; 0-3 months)	McDonough (1968)	*Salmonella* spp.	4/1	0	0
	Heat treatment	Hot water (60-100°C; 10 min)	Osaili (2009)	*Cronobacter* spp.	3/1	100	100
	Heat treatment	Dry heat (110°C; 1-5 min) Dry heat (60-115.5°C; 15 min to 10 hr) Hot air heated though oil bath (87.7-148.8°C; 3-6 min)	LiCari (1970a) McDonough (1968) McDonough (1968)	*Salmonella* spp.	6/2	0	**100***
	Modified packaging	Air (oxygen 0.5-20%) vs. vacuum (1-27 weeks)	Christian (1973)	*Salmonella* spp., *S. aureus*	2/1	0	100
	Ozone	Gas (2.8-5.3 mg/L; 30-120 min)	Torlak (2013)	Cronobacter spp.	2/1	0	100
	Spray drying	165-225°C	Miller (1972)	Pathogenic *E. coli* (multiple strains)	1/1	0	100
	Spray drying	32.2-226.7°C; 5.3-8.8 kg/cm^2; 3 sec 165-225°C	LiCari (1970a) Miller (1972)	*Salmonella* spp.	8/2	0	**100***
	Storage conditions	Increased temp. (5-37°C; 1-19 weeks)	Deng (1998)	*E. coli* O157:H7	3/1	0	100
	Storage conditions	Increased temp. (25-55°C; 1-8 weeks) Increased temp. (4.4-50°C; 1-15 weeks) Increased a_w (0.43-0.75; 2 days-14 weeks) Increased a_w (0.11-0.53; 1-27 weeks)	LiCari (1970b) McDonough (1968) Juven (1984) Christian (1973)	*Salmonella* spp.	6/4	0	**100***
	Storage conditions	Increased a_w (0.11-0.53; 1-27 weeks)	Christian (1973)	*S. aureus*	1/1	0	100
Dried eggs	Heat treatment	Dry heat (54-82°C; 1 hr to 7 days) Dry heat (50-55°C; 6-24 hr)	Jung (1999) Németh (2011)	*Salmonella* spp.	2/2	50	100
	Spray drying	225°C	Miller (1972)	*Salmonella* spp.	3/1	0	100

	Storage conditions	Increased temp. (13 and 37°C) and A_w (0.30-0.37 vs. 0.52-0.61; 1-8 weeks)	Jung (1999)	*Salmonella* spp.	2/1	0	100
Dried fish	Chemical additives	Acetic (0.2%), butyric (0.5%), formic (0.5%), and propionic (0.5%) acids (13-82 days) Ethoxyquin (400 mg/kg; 10-212 days) Fish oil (8%) and oxidized fish oil (10%; 10-200 days) Stearic acid (10%; 20-220 days) Free unsaturated fatty acids (10%; 10-120 days)	Lamprecht (1974)	*Salmonella* spp.	13/1	0	54
	Modified packaging	Oxygen vs. air atmosphere (20-30°C; 26-207 days)	Lamprecht (1974)	*Salmonella* spp.	1/1	0	100
	Salting and drying	Salting (30-80%) and drying (4°C; 1-70 days)	Mol (2010)	*Salmonella* spp.	1/1	100	100
Dried meat powders	Chemical additives	Sodium chloride (0.5-20%; 1-8 weeks)	Ryu (1999)	*E. coli* O157:H7	1/1	0	100
	Storage conditions	Increased temp. (5-7°C; 1-19 weeks) Increased temp. (5-25°C; 1-8 weeks) Increased A_w (0.34-0.68; 1-8 weeks)	Deng (1998) Ryu (1999) Ryu (1999)	*E. coli* O157:H7	3/2	0	100

[a] Intervention categories marked with an asterisk (*) indicate that more trials found a positive intervention effect than would be expected by chance alone (sign test *P* value <0.05). Significance only calculated if more than one study was conducted per intervention/microbial hazard/study type combination.

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Summary Card: Honey and Preserves

(Burden of Illness, Prevalence and Interventions)

Low-moisture food category description

This summary primarily covers honey, a natural sweet produced by honeybees from the nectar of plants (FAO, 2002). It also includes syrups (e.g. corn, table) and preserves (e.g. jam).

Evidence summary

In total, 57 articles[9] and outbreak reports[10] were identified that investigated the burden of illness, the prevalence or concentration of selected microbial hazards, and interventions to reduce contamination of microbial hazards in honey and preserves. The distribution of identified research stratified by microbial hazard investigated and research focus is shown in Appendix F: Summary Card Evidence Charts. *C. botulinum* was the most frequently investigated microbial hazard in honey and preserves for burden of illness (n=27 outbreak reports and articles), prevalence (n=21 articles), and intervention (n=1 article) information.

Burden of illness

Burden of illness evidence includes 1 outbreak, 2 case control studies and 25 case reports or case series reported between 1976 and 2013. *S. aureus* was implicated in one outbreak involving a maple-bacon jam. *C. botulinum* was associated with honey in all case reports and the two case control studies on infant botulism (Midura, 1979; Spika, 1989). Honey was the only food that tested positive for *C. botulinum* in all but one case report, Saraiva et al. (2012) reported chamomile fed to the infant also tested positive for *C. botulinum* B toxins. In some studies soil and vacuum cleaner dust from case households also tested positive. Globally, recommendations not to feed honey to infants less than 12 months old have been adopted since the late 1970's.

Summary table of globally reported case reports and outbreaks on honey and preserves

Preserve or honey category/ specific source *(reference)*	Microbial hazard(s)	Outbreaks/ cases/ hospitalized/ deaths[a]	Country (year)[b]	Comments: susceptible populations/ attack rate/ concentration of microbial hazard in the product
Maple-bacon Jam (Giovani 2013)	*S. aureus*	1/79[C], 144[P]/5/0	Canada (2013)	Temperature abuse was suspected. Served by a fair food vendor.
Honey (Abdulla 2012, Anon 2009, Arriagada 2009, Balslev 1997, Centorbi 1999, Fenicia 1993,	*C. botulinum*	25/17[C],22[P]/39/1	Japan (1986, 1989), Italy (1991), United States (1994[E]), Argentina (1995[E], 1999), Denmark (1996, 2000), Mucia (1996[E]),	All were infant botulism case reports of infants <12 months. 100% were hospitalized cases with hospitalizations lasting 3 days to 7.5 months. All cases were

[9] Articles refer to peer-reviewed journal publications as well as government and research agency reports.

[10] For burden of illness information, multiple articles often reported complementary and/or overlapping information on the same outbreak. In addition, outbreak data were supplemented from other literature sources, including line lists from various countries, news reports, or annual summaries of country outbreaks. Thus, to avoid counting the same outbreak more than once, the term ‘outbreak report’ is used instead of ‘article’ to count the total number of unique outbreaks.

Hoarau 2012, Jung 2001, King 2010, Kothare 1995, Mueller-Bunke 2000, Nabeya 1989. Noda 1988, Puig de Centorbi 1998, Ramroop 2012, Saraiva 2012, Smith 2010, Thomasse 2005, Torres Tortosa 1986, Toyoguchi 1991, van der Vorst 2006, Wolters 2000, Yanay 2004, Marler 2014)	Norway (1998[E]), Netherlands (2000[E] 2004[E]), Arabian Gulf (2005), France (2009[E]), Chile (2008[E]), United Kingdom (2009, 2010, 2012, 2013[E]), Israel (2004[E]), Germany (2000[E]), Portugal (2012)	confirmed to be *C. botulinum* type A or B.

[a] Superscript [C] indicates confirmed cases, [P] indicates presumptive cases.
[b] Superscript [E] indicates the link between human cases and implicated product was epidemiological only, otherwise the link was laboratory confirmed.

Prevalence

A total of 29 studies containing 47 unique trials were identified that investigated the prevalence and/or concentration of one or more selected microbial hazards in honey and preserves. The median publication year was 2003 (range 1990-2013). Most studies were conducted in either Brazil or Argentina (38%) > Asia/the Middle East (28%) > Europe (28%) > the United States (3.5%) and South Africa (3.5%). Nearly all studies (97%) sampled products during a specific or defined period of time, while one conducted sampling over multiple time points. Most studies sampled products from apiaries (38%) and/or at retail stores and markets (38%). Most studies (69%) specified the country(s) of product origin.

C. botulinum was the most commonly investigated microbial hazard in honey and preserves. In honey, it was found at a low median prevalence of 3.4% (95% CI 0 to 24%). The highest prevalence (24%) was found in honey extracted from honeycombs in apiaries in Finland (Nevas et al., 2006). *C. botulinum* was found at a very low median prevalence of 0.2% (95% CI 0 to 0.7%) in corn and other syrups in two studies; only 1/16 samples of corn syrup from one study in Japan were positive (Nakano et al., 1992).

B. cereus was identified in honey at highly variable prevalence levels, ranging from 23 to 78%. *C. perfringens* was identified at a low prevalence in honey in one study: from 7/116 samples in France (Delmas et al., 1994).

Cronobacter spp., generic *E. coli*, *E. coli* O157:H7, *L. monocytogenes*, *S. aureus*, and *Salmonella* spp. were not identified in any study.

No prevalence studies were identified for preserves (e.g. jams).

Few studies reported extractable concentration data on levels of selected microbial hazards in honey (not shown in the table below).

Average concentrations of *C. botulinum* in positive honey samples ranged with 36 to 60 spores/g in two studies (De Centorbi et al., 1997; Nakano and Sakaguchi, 1991), and were 38 spores/kg in a study from Finland (Nevas et al., 2002). In a study that found three positive samples in Argentina, two samples contained <1000 spores/kg, while one contained 15000/kg and was associated with a case of infant botulism (Monetto et al., 1999). *B. cereus* concentrations in honey ranged from 100 to 10000 spores/kg in two studies (Monetto et al., 1999; Piana et al., 1991).

Prevalence of selected microbial hazards in honey and preserves

Each cell includes the number of observations/trials/studies contributing to the average or median prevalence estimate, the proportion of trials that did not find any positive samples and measures of heterogeneity and risk of selection bias. See the table footnotes for detailed explanations on each of these parameters.

	Honey and Preserves Number of observations/trials/studies (% trials with zero prevalence)[a] Meta-analysis prevalence (%) estimates (95% CI) OR prevalence median (range)[b] Heterogeneity rating / Risk of selection bias (low, medium or high)[c]	
Microbial hazard	**Honey**	**Syrups**
B. cereus	698/6/6 (0%) 33.2 (22.9 – 77.8)[R] High / High	N/A
C. botulinum	2197/20/19 (20%) 3.4 (0 – 23.9)[R] High / Med.	741/4/2 (75%) 0.2 (0 – 0.7)[M] Med. / Low
C. perfringens	166/2/2 (50%) 3.0 (0 – 6.0)[R] High / Med.	N/A
***Cronobacter* spp.**	30/1/1 (100%) 0 N/A / High	N/A
Generic *E. coli*	71/2/2 (100%) 0 (0 – 0)[R] Low / High	N/A
***E. coli* O157:H7**	30/1/1 (100%) 0 N/A / High	N/A
L. monocytogenes	30/1/1 (100%) 0 N/A / High	N/A
S. aureus	30/1/1 (100%) 0 N/A / High	N/A
***Salmonella* spp.**	604/9/9 (100%) 0 (0 – 0)[R] Low / High	N/A

N/A = No data identified for this product-hazard combination. Med. = medium.

[a] Observations/trials/studies: The observations are the total number of samples for all studies included in the summarized category. The number of studies is the number of articles captured. In some cases, articles report data on multiple prevalence trials or sampling frames. While the observations for each trial are independent by time and sample, they are part of a larger study where the methods and investigators are the same. Thus, there is not full independence in these observations and we note this by acknowledging there are multiple trials within a study.

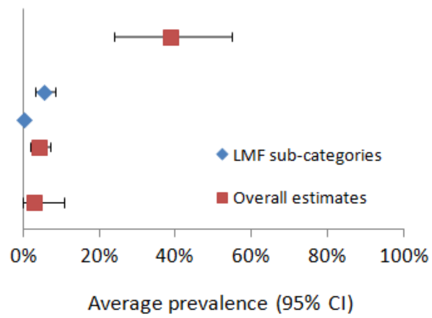
[b] Superscript [M] indicates an average prevalence estimate (and 95% confidence interval) from a random-effects meta-analysis. Meta-analysis estimates were calculated only if heterogeneity was low or medium (I^2 0-60%) and if at least one trial found a positive sample.
Superscript [R] indicates a median (and range) of trial prevalence estimates, calculated If heterogeneity was high (I^2 >60%). Ranges not provided when only one trial was identified.

[c] I^2 is a measure of the degree of heterogeneity between trials combined in the meta-analysis. Heterogeneity rating definitions: low = I^2 0-30%; medium = 31-60%; high = >60%.
Selection bias rating definitions: high = 0-30% of trials used a representative sample; medium = 31-60% of trials used a representative sample; low = >60% of trials used a representative sample. Studies that conducted random or systematic sampling were considered representative.

The overall robustness of the meta-analysis prevalence estimates can be inferred from the heterogeneity and selection bias ratings. Taking into consideration the number of studies in the meta-analysis, high confidence in the meta-analysis results can be inferred when heterogeneity is low and the risk of selection bias is low, and low confidence can be inferred when both are high, see the methods section (page 11) for more information.

Forest plot of the prevalence of selected microbial hazards in honey and preserves

Micobial hazard / LMF sub-category	Average prevalence	Low 95% CI	High 95% CI	No. obs./ trials/studies	Hetero-geneity	Selection bias	Median (range)
B. cereus							
Overall	38.9	24.1	54.7	698/6/6	High	High	33.2 (22.9 – 77.8)
C. botulinum							
Honey	5.5	3.1	8.4	2197/20/19	High	Med.	3.4 (0 – 23.9)
Syrups	0.2	0.0	0.7	741/4/2	Med.	Low	-
Overall	4.2	2.0	7.1		High		2.9 (0 – 23.9)
C. perfringens							
Overall	2.9	0.0	10.6	166/2/2	High	Med.	3.0 (0 – 6.0)



CI = confidence interval; Med. = medium; No. obs. = number of total samples tested per category.
See the prevalence table for full explanations of all columns.
NOTE: *E. coli, L. monocytogenes, S. aureus,* and *Salmonella* spp. evidence not shown in this figure because no positive samples were identified in these categories. *B. cereus* and *C. perfringens* evidence is based on data from only the honey sub-category.

Interventions

Only 1 experimental study (consisting of 1 unique trial) was identified evaluating the effects of interventions to reduce contamination of microbial hazards in honey. The study investigated the effect of gamma irradiation (6-25 kGy; 125 Gy/min) to reduce contamination of *C. botulinum* spores in honey (Postmes et al., 1995). The authors found that a large dose (25kGy) was needed to fully eliminate *C. botulinum* spores, which could affect the honey's sensory quality (Postmes et al., 1995). The study was conducted in the Netherlands, was a challenge trial with artificially inoculated samples, was conducted under laboratory and non-commercial conditions, did not include extractable data, and included only 6 samples per intervention combination.

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Summary Card: Nuts and Nut Products

(Burden of Illness, Prevalence and Interventions)

Low-moisture food category description

This summary covers edible nuts and nut products, which are defined as the dried, hard-shelled fruits, kernals or seeds of trees, shrubs or other plants (FAO, 1995). We define two major categories of nuts in this summary: 1) tree nuts and 2) peanuts. Peanuts, or groundnuts (*Arachis hypogaea*), refer to the edible seeds of a plant in the legume family (FAO, 1995). Tree nuts refer to all other nuts included in this summary, including true nuts in the botanical sense (e.g. hazelnuts/filberts) and other dried, hard-shelled fruits and seeds commonly referred to as culinary nuts (e.g. almonds, Brazil nuts, cashews, pecans, pistachios, pine nuts, walnuts).

For the purposes of conducting meta-analysis of prevalence estimates, data were collapsed across four nut categories: 1) almonds; 2) other tree nuts (consisting of Brazil nuts, cashews, hazelnuts, macadamia nuts, pecans, pine nuts, pistachios, and walnuts); 3) peanuts; and 4) mixed/unspecified nuts. For the interventions summary, these categories were further collapsed into 1) all tree nuts (including almonds) and 2) peanut butters/spreads. The difference in peanut categories is because no prevalence studies were identified that investigated peanut butters/spreads, while intervention studies in peanut products only investigated the latter and none evaluated raw peanuts.

Evidence summary

In total, 95 articles and outbreak reports were identified that investigated the burden of illness related to nuts, prevalence or concentration of selected microbial hazards in nuts, and/or interventions to reduce contamination of microbial hazards in nuts. The distribution of identified research stratified by microbial hazard investigated and research focus is shown in Appendix F: Summary Card Evidence Charts. *Salmonella* spp. was the most frequently investigated microbial hazard in nuts for burden of illness (n=16 articles and outbreak reports), prevalence (n=19), and intervention (n=46 articles) information.

Burden of illness

Burden of illness evidence related to nuts and nut products (mainly peanut butter) includes 20 outbreaks that affected 2241 individuals, including 318 hospitalizations and 13 deaths between 1986 and 2013. *Salmonella* spp. accounted for 97% of illnesses associated with nuts and nut products **>** *E. coli O157:H7* 1.3% **>** *C. botulinum* 0.7%. Few countries have reported outbreaks associated with nuts (4 involved multiple countries): United States (11) > Canada (6) > Australia (4) > Sweden (2) > United Kingdom (1), Taiwan (1). The origin of the product implicated in the outbreaks was local (13), imported (5) from United States, China, Turkey and India and unknown (2).

Six contaminated peanut butter outbreaks were mainly from North America with one exception from Australia. This group accounted for 73% of the cases, 5 outbreaks (1619 cases) due to *Salmonella* and 1 outbreak (5 cases) due to *C. botulinum*. The outbreak size, median (range), from contaminated peanut butter was 75 (5-715). Conversely, there were 14 outbreaks associated with various nuts including: almonds (4), cashews (2), hazelnuts (1), peanuts (4), pine nuts (1), pistachios (2), and walnuts (1) that caused 27% of all illness median (range) 23 (1-168) cases per outbreak. Sixteen outbreaks (564 cases) were caused by *Salmonella*, 2 (30 cases) by *E. coli* O157:H7 and 1 (23 cases) by *C. botulinum*.

Summary of globally reported outbreaks related to nuts and nut products

Nut or Nut Product (reference)	Microbial hazard(s)	Outbreaks/ cases[a]/ hospitalized/ deaths	Country (year)[b]	Comments: susceptible populations/ attack rate/ concentration of microbial hazard in the product
Almonds (Isaacs 2005, Keady 2004, Muller 2007, efoodalert 2012)	*Salmonella (*Enteritidis PT30, PT9+ & NST3+ and Typhimurium*)*	4/219[C]. 47[P]/14/1	United States & Canada (2001 & 2004[E])' Sweden (2006)[E], Australia (2012)	Raw almonds implicated (3) and unknown (1). Trace back to California (3), Australia (1), California started pasteurization in 2007. Almonds were laboratory confirmed only in 2001 & 2012.
Cashew (EFSA 2013)	*Salmonella* Poona	1/16/0/0	Sweden (2011)[E]	Epidemiological evidence only
Cashew and Peanut mix (OzFoodNet 2010)	*Salmonella* Typhimurium DT170	1/19[P]/0/0	Australia (2010)[E]	The nut mixture tested positive for S. *Typhimurium*.
Peanuts (Kirk 2004, Harris 2014)	*Salmonella* Stanley, Newport and Thompson	2/211/0/0	Australia, Canada & United Kingdom (2001), United States (2006)	Flavoured and roasted in shell peanuts from China (2001). Concentration <0.03 -2 organisms/g. Boiled peanuts from fair vendor implicated in (2006).
(Chou 1988)	*C. botulinum*	1/11[C], 12[P]/3/2	Taiwan (1986)	Canned, unsalted peanuts in water. *C. botulinum* confirmed in one batch.
Peanut Butter (Scheil 1998, Lawyer 2004, Sheth 2011, Cavallaro 2011, MacDonald 2013)	*Salmonella* Mbandaka, Group B, Tennessee, Typhimurium, Bredeney	5/1556[C], 63[P]/272/9	Australia (1996), United States (2004[E], 2007, 2009, 2012)	The 1996 outbreak implicated contaminated roasted peanuts 3 cfu/g. 2004, small restaurant associated outbreak. 2007 and 2009 had >700 cases each. Recalls occurred in 2007, 2009 & 2012.
(Sheppard 2012)	*C. botulinum*	1/5/5/0	Canada (2006-8)	
Pine Nuts (CDC, 2011)	*Salmonella* Enteritidis	1/43/2/0	United States (2011)	Pine nuts from Turkey were recalled.
Pistachios (CDC, 2009) (FDA, 2014)	*Salmonella* Montevideo, Newport, and Senftenberg	2/9/0/0	United States (2009) United States (2013)	Products were identified as contaminated by the FDA and recalled. Only one case had a matching PFGE pattern (2009) and 8 were identified in 2013.
Hazelnuts (Miller, 2012)	*E. coli* O157:H7	1/16/12/0	United States & Canada (2011)	In shell hazelnuts implicated, contamination on-farm suspected.
Walnuts (PHAC, 2011)	*E. coli* O157:H7	1/14/10/1	Canada (2011)	Contaminated walnuts from the United States were implicated.

[a] Superscript [C] indicates confirmed cases, [P] indicates presumptive cases.
[b] Superscript [E] indicates the link between human cases and implicated product was epidemiological only, otherwise the link was laboratory confirmed.

Prevalence

A total of 24 studies containing 192 unique trials were identified that investigated the prevalence and/or concentration of selected microbial hazards in nuts and nut products. The median publication year was 2010 (range 1995 to 2014).

More than half of the studies (n=13/24) were conducted in Europe, while four were conducted in the United States, three in Asia and the Middle East, two in Australia, and two in South America. Most studies (58%) sampled products during a specific or defined period of time, while 6 conducted sampling over multiple years or time points, and 4 reported on the results of surveillance programmes. Studies primarily sampled products at retail grocery stores and markets (50%), and from processing plants (42%). Half of the studies (n=12) specified the country(s) of product origin.

Overall, most trials did not identify any of the selected microbial hazards in nuts or nut products. When microbial hazards were found, the prevalence was generally low (with the exception of *B. cereus* and Enterobacteriaceae in tree nuts in a limited number of samples and trials).

Salmonella spp. was the most commonly investigated microbial hazard across all nuts categories, followed by generic *E. coli* and *E. coli* O157:H7*.* The prevalence of *Salmonella* spp. was largely heterogeneous in the almonds, other tree nuts, and peanuts categories, while the average prevalence in mixed/unspecified nuts was 0.2% (95% CI: 0 to 0.5). In the former categories, *Salmonella* spp. median prevalence estimates were all <1%. Average generic *E. coli* prevalence estimates were also very low (<1%) across all nut categories. Only one study found positive samples of *E. coli* O157:H7, identified in 3 of 10162 samples of raw, shelled runner peanuts from United States processing facilities (Miksch et al., 2013).

L. monocytogenes was identified only in two studies and trials: from 1/1 walnut sample in Saudi Arabia (Alwakee and Nasser, 2011), and from 2/43 ready-to-eat mixed nuts in Australia (Eglezos, 2010). *C. perfringens* and *S. aureus* were not isolated from nuts or nut products in any study.

Concentration information for positive microbial hazard samples was reported in only a few studies (not shown in the table below). Two studies from the United States found *Salmonella* concentrations ranging from 0.003 to 2.4 MPN/g in peanuts (Calhoun et al., 2013; Miksch et al., 2013) and 0.013 to 0.023 MPN/g in almonds (Danyluk et al., 2007; Bansal et al., 2010). Retail samples from the United Kingdom reported *Salmonella* spp. concentrations of 0.09, 0.23 and <0.01 MPN/g in two positive Brazil nut samples and a mixed nut sample, respectively (Little, 2010).

For generic *E. coli*, Little et al. (2009) found a concentration of 3.6 MPN/g in two positive retail samples of roasted Brazil nuts and walnuts in the United Kingdom, and they found a concentration of 4 MPN/g in a positive sample of roasted almonds. Generic *E. coli* concentrations ranging from 0.4 to 0.9 MPN/g were found in almonds in the United States that were also *Salmonella* positive (Bansal, 2010).

Prevalence of selected microbial hazards within nut categories

Each cell includes the number of observations/trials/studies contributing to the average or median prevalence estimate, the proportion of trials that did not find any positive samples and measures of heterogeneity and risk of selection bias. See the table footnotes for detailed explanations on each of these parameters.

	Nuts and Nut Products Number of observations/trials/studies (% trials with zero prevalence)[a] Meta-analysis prevalence (%) estimates (95% CI) OR prevalence median (range)[b] Heterogeneity rating / Risk of selection bias (low, medium or high)[c]			
Microbial hazard	**Almonds**	**Other tree nuts**	**Peanuts**	**Mixed/unspecified nuts**
B. cereus	33/2/2 (50%) 9.6 (1.5 – 22.4)[M] Low / High	64/8/4 (88%) 6.4 (1.6 – 13.8)[M] Low / High	11/2/2 (100%) 0 (0 – 0)[R] Low / High	N/A
C. perfringens	N/A	2/1/1 (100%) 0 N/A / High	2/1/1 (100%) 0 N/A / High	N/A
***Cronobacter* spp.**	N/A	N/A	N/A	2/1/1 (0%) 100 N/A / Low
Generic *E. coli*	3261/6/6 (33%) 0.7 (0 – 4.8)[R] High / Low	2957/23/5 (42%) 0.8 (0.5 – 1.2)[M] Low / Low	1170/4/4 (75%) 0.1 (0 – 0.4)[M] Low / Low	435/3/3 (67%) 0.6 (0.04 – 1.6)[M] Low / Low
***E. coli* O157:H7**	15/1/1 (100%) 0 n/a / High	51/6/2 (100%) 0 (0 – 0)[R] Low / High	10184/4/3 (75%) 0.03 (0.004 – 0.08)[M] Low / High	16/1/1 (100%) 0 n/a / High
Enterobacteriaceae	30/1/1 (0%) 10 N/A / High	N/A	N/A	N/A
L. monocytogenes	45/2/2 (100%) 0 (0 – 0)[R] Low / Med.	147/8/2 (88%) 1.4 (0 – 4.4)[M] Low / Med.	350/2/2 (100%) 0 (0 – 0)[R] Low / Med.	43/1/1 (0%) 4.7 N/A / High
S. aureus	30/1/1 (100%) 0 N/A / High	29/5/2 (100%) 0 (0 – 0)[R] Low / High	4/2/1 (100%) 0 (0 – 0)[R] Low / High	N/A
***Salmonella* spp.**	13774/8/7 (50%) 0.4 (0 – 2.7)[R] High / Low	3051/36/9 (81%) 0 (0 – 67)[R] High / Low	12287/9/8 (78%) 0 (0 – 2.3)[R] High / Low	114/7/5 (86%) 0.2 (0 – 0.5)[M] Low / Low

N/A = No data identified for this product-hazard combination. Med. = medium.

[a] Observations/trials/studies: The observations are the total number of samples for all studies included in the summarized category. The number of studies is the number of articles captured. In some cases, articles report data on multiple prevalence trials or sampling frames. While the observations for each trial are independent by time and sample, they are part of a larger study where the methods and investigators are the same. Thus, there is not full independence in these observations and we note this by acknowledging there are multiple trials within a study.

[b] Superscript [M] indicates an average prevalence estimate (and 95% confidence interval) from a random-effects meta-analysis. Meta-analysis estimates were calculated only if heterogeneity was low or medium (I^2 0-60%) and if at least one trial found a positive sample.

Superscript [R] indicates a median (and range) of trial prevalence estimates, calculated If heterogeneity was high (I^2 >60%). Ranges not provided when only one trial was identified.

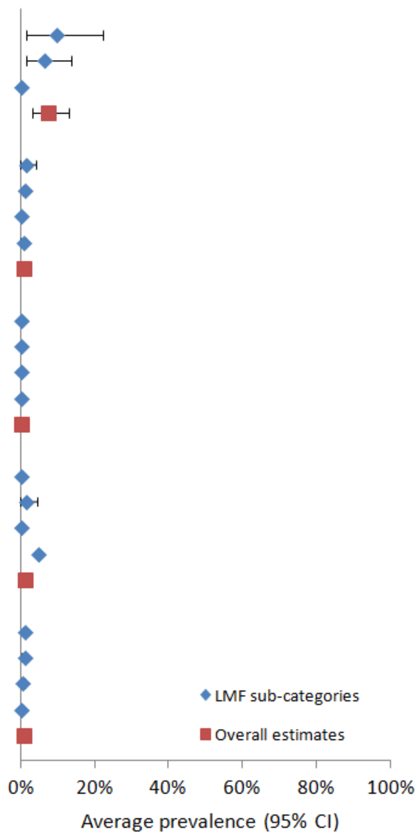
[c] I^2 is a measure of the degree of heterogeneity between trials combined in the meta-analysis. Heterogeneity rating definitions: low = I^2 0-30%; medium = 31-60%; high = >60%.

Selection bias rating definitions: high = 0-30% of trials used a representative sample; medium = 31-60% of trials used a representative sample; low = >60% of trials used a representative sample. Studies that conducted random or systematic sampling were considered representative.

The overall robustness of the meta-analysis prevalence estimates can be inferred from the heterogeneity and selection bias ratings. Taking into consideration the number of studies in the meta-analysis, high confidence in the meta-analysis results can be inferred when heterogeneity is low and the risk of selection bias is low, and low confidence can be inferred when both are high, see the methods section (page 11) for more information.

Forest plot of the prevalence of selected microbial hazards within nut categories

Micobial hazard / LMF sub-category	Average prevalence	Low 95% CI	High 95% CI	No. obs./ trials/studies	Hetero-geneity	Selection bias	Median (range)
B. cereus							
Almonds	9.6	1.5	22.4	33/2/2	Low	High	-
Other tree nuts	6.4	1.6	13.8	64/8/4	Low	High	-
Peanuts	0.0	0.0	0.0	11/2/2	Low	High	-
Overall	7.3	3.1	12.9		Low		-
Generic *E. coli*							
Almonds	1.3	0.0	4.3	3261/6/6	High	Low	0.7 (0 – 4.8)
Other tree nuts	0.8	0.5	1.2	2957/23/5	Low	Low	-
Peanuts	0.1	0.0	0.4	1170/4/4	Low	Low	-
Mixed/unspecified nuts	0.6	0.0	1.6	435/3/3	Low	Low	-
Overall	0.8	0.3	1.4		High		0 (0 – 4.8)
***E. coli* 0157**							
Almonds	0.0	-	-	15/1/1	N/A	High	-
Other tree nuts	0.0	0.0	0.0	51/6/2	Low	High	-
Peanuts	0.0	0.0	0.1	10184/4/3	Low	High	-
Mixed/unspecified nuts	0.0	-	-	16/1/1	N/A	High	-
Overall	0.0	0.0	0.1		Low		-
L. monocytogenes							
Almonds	0.0	0.0	0.0	45/2/2	Low	Med.	-
Other tree nuts	1.4	0.0	4.4	147/8/2	Low	Med.	-
Peanuts	0.0	0.0	0.0	350/2/2	Low	Med.	-
Mixed/unspecified nuts	4.7	-	-	43/1/1	N/A	High	-
Overall	0.9	0.0	2.9		Med.		-
***Salmonella* spp.**							
Almonds	0.9	0.5	1.5	13774/8/7	High	Low	0.4 (0 – 2.7)
Other tree nuts	0.8	0.3	1.6	3051/36/9	High	Low	0 (0 – 66.7)
Peanuts	0.5	0.0	1.2	12287/9/8	High	Low	0 (0 – 2.3)
Mixed/unspecified nuts	0.2	0.0	0.5	114/7/5	Low	Low	-
Overall	0.6	0.4	0.9		High		0 (0 – 66.7)



CI = confidence interval; Med. = medium; No. obs. = number of total samples tested per category.
See the prevalence table for full explanations of all columns.
NOTE: *C. perfringens* and *S. aureus* evidence not shown in this figure because no positive samples were identified in these categories. *Cronobacter* spp. evidence is not shown in this figure because only one trial/study was identified.

Interventions

A total of 51 experimental studies (consisting of 265 unique trials) were identified evaluating the effects of various interventions and processing conditions to reduce contamination of microbial hazards in nuts and nut products. More than half (55%) of the studies were published since 2010, which was the median publication year (publication range 1969 to 2014). The majority of studies (84%) were conducted in North America (USA). All studies were challenge trials with artificially inoculated samples. Most studies were conducted under laboratory and non-commercial conditions (although many of the interventions investigated are used in the commercial nut industry), and most studies used a small sample size (e.g. 2-20 samples per intervention combination).

Of the 265 trials, 84% investigated tree nuts and 16% investigated peanut butter and spreads. Most of the tree nut trials (82%) investigated pecans (92 trials) and almonds (90 trials). Most trials investigated *Salmonella* spp. (83%) and *E. coli* (14%), with only 7 and 3 investigating *L. monocytogenes* and *B. cereus*, respectively.

The majority of trials found that the applied interventions were effective to reduce microbial hazard concentrations in nuts and nut products, and for several intervention categories the number of trials finding a positive intervention effect was greater than we would expect by chance alone. However, in many cases these reductions were only minimal (e.g. <1-5 log CFU/g) and did not decrease microbial hazard counts to non-detectable levels. For some interventions, treatment efficacies may be limited due to natural nut proteins and fats acting as a protective barrier (Shachar and Yaron, 2006; Grasso et al., 2010).

The most common interventions were various types of heat (e.g. hot air, water and oil) and chemical treatments (e.g. acid solutions and fumigations). While some interventions were found to be very effective, the doses and/or duration of treatment required to achieve suitable reductions in microbial hazard concentrations may also negatively affect the sensory quality (e.g. taste and texture) of nuts and nut products (Beuchat and Mann, 2011b; Prakash et al., 2010).

Since 2007, all almonds produced in California, United States, and marketed in North America must undergo a mandatory pasteurization step necessary to achieve a 5-log reduction in *Salmonella* spp., which could include roasting, blanching, steam treatments, or propylene oxide treatment (Almond Board of California, 2012).

Due to the difficulties in reliabily reducing levels of microbial hazards on nuts and nut products without unduly affecting their quality, emphasis in the industry should be placed on preventing contamination during harvesting and processing (e.g. shelling) operations (Beuchat et al., 2013).

Summary table of experimental studies evaluating the effects of interventions to reduce contamination of selected microbial hazards in nuts and nut products

Nut category	Intervention type	Intervention details (dose and/or duration, where available)	Study reference IDs[a,b]	Microbial hazard(s)	No. trials/ studies	% of trials with extractable data	% of trials finding intervention is effective[c]
Tree nuts	Chemicals	Methyl bromide gas (32-96 mg/L; 4-8 hr) Propylene oxide gas (40-800 ppm; 20-37°C; 4-16 hr)	3893 6749	*E. coli* (H-23 and K-12)	2/2	0	100
	Chemicals	Sodium hypochlorite spray (25-50 ppm; 15 min) Peroxyacetic acid spray (80-120 ppm; 15 min) Acidified sodium chlorite spray (450-1013 ppm; 15 min) Sodium hypochlorite dip (30,000 ppm; 2 min) Sodium dodecyl sulfate dip (0.05%; 2-20 min) Chlorinated water dip (200-1000 µg/ml; 1-20 min) Lactic acid dip (0.5-2%; 2-20 min) Levulinic acid dip (0.5-2%; 2-20 min) Mixed peroxyacid sanitizer (40-80 µg/ml; 2-20 min) Lactic acid/sodium dodecyl sulfate dip (2-20 min) Levulinic acid/sodium dodecyl sulfate dip (2-20 min) Chlorinated water dip (100-400 µg/ml; 1 min to 24 hr) Acidic electrolyzed water (mild to strong; 10 s) Propylene oxide gas (0.5 kg/m^3; 4 hr) Methyl bromide gas (16-96 mg/L; 4-8 hr) Acetic acid spray (5-15%; 1-40 min) Citric acid spray (5-15%; 1-40 min) Acidified sodium chlorite spray (≤400 ppm; 1-40 min) Peroxyacetic acid spray (80-500 ppm; 1-40 min)	22 22 22 62 140/279 140/279 140/279 140/279 140/279 140/279 140/279 729 1129 1950[a] 3893 5657 5657 5657 5657	*Salmonella* spp.	68/9	28	**97***
	Drying	Ambient temperature; 24 hr Ambient temperature; 72 hr Ambient temperature; 7 days	62 356 496	*E. coli* O157:H7, *L. monocytogenes*	5/3	20	100
	Drying	Ambient temperature; 24 hr Ambient temperature; 72 hr Ambient temperature; 7 days 15-37°C; 24 hr	62 356 496 1833	*Salmonella* spp.	7/4	43	**100***
	Heat treatment	Hot water dip (Boiling; 0.25-6 min) Hot oil dip (100-150°C; 0.25-6 min)	4039	Generic *E. coli*	2/1	0	100

	Heat treatment	Hot water dip (70-80°C; 80-90 s) Hot oil dip (121°C; 0.5-2 min) Hot oil dip (110-138°C; 0.5-42 min) Dry air (60-170°C; 5-20 min) Steam pasteurization (121-204°C; 0-90% Mv; 1-1206 s) Hot water dip (75-95°C; 5-20 min) Hot oil dip (93-127°C; 0.5-4 min) Steam pasteurization (143 kPa; 95°C; 5-65 s) Steam pasteurization (121-232°C; 5-90% Mv; 1-1800 s) Hot water bath (85-89°C; 20-40 s) Dry heat (55-60°C; 1-4 days) Hot water dip (60-99°C; 1-6 min) Hot oil dip (100°C; 15-30 min) Hot water dip (60-88°C; 0.5-12 min) Steam pasteurization (93°C; 5-65 s) Steam pasteurization (99°C)	230 511 615 615 728 729 904 995 1109 1129 1129 3953 4542 4548 5639 6621[a]	*Salmonella* spp.	40/14	58	**95***
	High-hydrostatic pressure	414 and 483 Mpa; 50°C; 1.5-6 min 50000-70000 psi; 25-55°C; 5-10 min	1384 5616	*Salmonella* spp.	8/2	0	88
	Irradiation	X-ray (0.3-5.5 kGy; 20 Gy/s) Catalytic infrared (70 s) Catalytic infrared (3000-5458 W/m^2; 74-113°C; 20-45 s) Gamma (1-3 kGy)	536 1129 1372 4953	*Salmonella* spp.	12/4	8	58
	Multiple	Electron beam radiation (0.2-0.8 kGy) + modified atmosphere packaging (vacuum, nitrogen and oxygen)	4085	Generic *E. coli*	3/1	100	100
	Multiple	Intermittent vacuum and ambient atmospheric pressure (16-983 mbar; 5-20 min) + chemical dips (see above) Hot water bath (75-95°C; 5-20 min) + chlorinated water dip (200 µg/ml; 1 min) Catalytic infrared-radiation (70 s) + Superheated steam (115°C; 20-120 s) Catalytic infrared-radiation (70 s) + dry heat (60°C; 1-4 days) Catalytic infrared-radiation + hot water bath (85-89°C; 20-40 s) Catalytic infrared-radiation + ozone dip (5 ppm; 10 s) Catalytic infrared-radiation + acidic electrolyzed water (mild to strong; 10 s)	140 729 975 1129 1129 1129 1129	*Salmonella* spp.	27/8	44	**100***

		High-hydrostatic pressure (414 and 483 Mpa; 50°C; 6 min) + Dry heat (55-115°C; 5-25 min) Electron beam radiation (0.2-0.8 kGy) + modified atmosphere packaging (vacuum, nitrogen and oxygen) Citric acid spray (10%; 20 min) + shelling and storage (24°C; 1-7 days) Citric acid spray + deionized water rinse (50 mL/25 g), air-drying (25°C; 2 hr) and storage (24°C; 1-7 days) Chlorine dioxide gas (5-10 mg/L; 80-90% RH; 10-30 min) + vacuum-atmospheric pressure (20kpa-80kPa)	1384 4085 5657 5657 6712				
	Non-thermal/cold plasma	549 W; 47 kHz; 10-20 s 16-25 kV; 1000-2500 Hz; 10-30 s	479 1512	*E. coli* (generic and pathogenic)	6/2	0	**100***
	Non-thermal/cold plasma	549 W; 47 kHz; 10-20 s	479	*Salmonella* spp.	3/1	0	100
	Nut extracts	Shuck, shell, pith, shell-pith (1-5 min)	279	*Salmonella* spp.	8/1	0	75
	Ozone	Gas (0.1-1 ppm; 60-360 min)	5615	*B. cereus*, Generic *E. coli*	3/1	0	100
	Ozone	Dip (5 ppm; 10 s)	1129	*Salmonella* spp.	1/1	0	0
	Storage conditions	Increased temperature (-19 to 24°C; 1-365 days) Increased temperature (-7 to 30°C; 1-24 weeks) Increased temperature (5-37°C; 1-19 weeks)	356 6749 6628	*E. coli* (generic and pathogenic)	4/3	0	100
	Storage conditions	Increased temperature (-19 to 24°C; 1-365 days)	356	*L. monocytogenes*	2/1	0	100
	Storage conditions	Increased temperature (4°C to ambient; 21-1143 days) Increased temperature (-19 to 24°C; 1-365 days) Increased temperature (-20 to 23°C; 1-364 days) Increased temperature (4 and 23°C; 1-48 weeks) Increased temperature (-20 to 37°C; 2-78 weeks) Increased temperature (-20 to 35°C; 7-171 days) Increased temperature (-18 to 21°C; 2-32 weeks)	62 356 496 511 903 1762 3953	*Salmonella* spp.	12/7	17	**100***
	Vacuum-atmospheric pressure	33 cm; 6 min	3953	*Salmonella* spp.	1/1	0	0
Peanut butter/ spreads	Heat treatment	Hot water dip (72 and 90°C; 10-60 min)	602	*E. coli* O157:H7	4/1	100	100
	Heat treatment	Hot water dip (72 and 90°C; 10-60 min) Hot water dip (71-90°C; 2.5-50 min)	602 1110	*Salmonella* spp.	7/3	100	86

		Hot water dip (70-90°C; 5-50 min)	1708				
	High-hydrostatic pressure	400-600 MPa; 4-18 min 600 Mpa; 45°C; 5 min	522 710	*Salmonella* spp.	4/2	50	50
	Irradiation	Radio-frequency (27.12 MHz; 10-90 s)	182	*E. coli* O157:H7	2/1	100	100
	Irradiation	Gamma (1-3 kGy) Radio-frequency (27.12 MHz; 10-90 s) Electron beam (0.5-3.1 kGy) Electron beam (0.5-3.1 kGy)	10 182 706 1017	*Salmonella* spp.	9/4	100	**100***
	Storage conditions	Increased temperature (4 and 25°C; 1-4 weeks) Increased temperature (4 and 25°C; 1-15 weeks)	602 6758	*E. coli* O157:H7	5/2	0	100
	Storage conditions	Increased temperature (4 and 25°C; 1-4 weeks) Increased temperature (5 and 21°C; 1-24 weeks) Increased temperature (4 and 25°C; 1-15 weeks)	602 2586 6758	*Salmonella* spp.	12/3	58	**100***

[a] Indicates these studies were conducted under commercial conditions.
[b] DistillerSR reference ID number. Refer to citation list at the end of this summary for full citation of each reference matched to the reference ID.
[c] Intervention categories marked with an asterisk (*) indicate that more trials found a positive intervention effect than would be expected by chance alone (sign test *P* value <0.05).

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Summary Card: Seeds for Consumption

(Burden of Illness, Prevalence and Interventions)

Low-moisture food category description

This summary covers seeds for consumption, which includes dried sunflower seeds, pumpkin seeds, melon seeds, poppy seeds, flax seeds, sesame seeds and sesame products, and other edible seeds. Specific sesame seed products covered in this summary include tahini (sesame paste), which is produced from roasted and milled sesame seeds, and halva/helva, which is a confectionery produced from mixing tahini, sugar, glucose syrup, and other ingredients (Brockmann et al., 2004; Kotzekidou, 1998). Excluded from this summary are other seeds traditionally referred to as nuts (e.g., almonds, pecans, etc., which are covered in a separate summary) and sprouted seeds (FAO, 1995).

For the purposes of summarizing prevalence and intervention information, seeds were classified into the following categories: 1) sesame seeds; 2) tahini; 3) halva/helva; and 4) other/unspecified seeds for consumption.

Evidence summary

In total, 28 articles[11] and outbreak reports[12] were identified that investigated the burden of illness, the prevalence or concentration of selected microbial hazards, and interventions to reduce contamination of microbial hazards in seeds. The distribution of identified research stratified by microbial hazard investigated and research focus is shown in Appendix F: Summary Card Evidence Charts. *Salmonella* spp. was the most frequently investigated microbial hazard in seeds for burden of illness (n=8 outbreak reports), prevalence (n=14 articles), and intervention (n=3 articles) information.

Burden of illness

Burden of illness evidence related to seeds includes 8 reported outbreaks between 1995 and 2013; all outbreaks were related to seed-based products and not ready-to-eat retail seeds. *Salmonella* was implicated all outbreaks that affected 376 individuals (median 23, range 13-137), including 4 hospitalizations and 1 death. Seed outbreaks are shown in the summary table below and were reported from the United States (3), Australia (3), New Zealand (2), Germany, Norway and Sweden.

The outbreaks notably had small numbers of confirmed cases; however, all sesame outbreaks (except 1995 as details could not be verified) resulted in large product recalls. In Australia and New Zealand 2003, the recalls extended to many sesame-based products and triggered recalls in Canada and the United Kingdom. The United States as another example reported recalls associated with outbreaks in 2011 and 2013, and there were tahini recalls due to *Salmonella* contamination reported in 2007 and 2009 with no associated illness.

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[11] Articles refer to peer-reviewed journal publications as well as government and research agency reports.

[12] For burden of illness information, multiple articles often reported complementary and/or overlapping information on the same outbreak. In addition, outbreak data were supplemented from other literature sources, including line lists from various countries, news reports, or annual summaries of country outbreaks. Thus, to avoid counting the same outbreak more than once, the term 'outbreak report' is used instead of 'article' to count the total number of unique outbreaks.

Summary table of globally reported outbreaks on seeds

Seed category/ specific spice *(source)*	Microbial hazard(s)	Outbreaks/ cases/ hospitalized / deaths[a]	Country (year)[b]	Comments: susceptible populations/ attack rate/ concentration of microbial hazard in the product
Sesame Seeds Unicomb (2005), Anon (2003), Anon (2011), Anon (2013), Aavitsland (2001), Brockmann (2001), De Jong (2001), Little (2001), O'Grady (2001)	*Salmonella* Montevideo, Bovismorbifican, Brandenburgs, Mbandaka, Maastricht, Typhimurium DT104, Senftenberg, Oranienburg	7/327[P], 11[C]/1/1	Australia (2002, 2003), New Zealand (2003, 2012), United States (1995[E], 2011, 2013),Norway, Sweden and Australia (2001)	Sesame seeds or products were imported from Egypt, Lebanon and Turkey. Implicated product usually tahini and helva although some recalls involved more products not linked to human illness. Testing and product recalls occurred in all outbreaks except 1995 in the outbreak country and in other countries with no reported illness in 2001, 2003 & 2011.
Hemp Seeds Stocker (2011)	*Salmonella* Montevideo	1/4[C], 34[P]/3/0	Germany (2010)	The contaminated product was an herbal diet supplement. The supplement and hemp flour at the mill tested positive.

[a] Superscript [C] indicates confirmed cases, [p] indicates presumptive cases.
[b] Superscript [E] indicates the link between human cases and implicated product was epidemiological only, otherwise the link was laboratory confirmed.

Prevalence

A total of 18 studies containing 86 unique trials were identified that investigated the prevalence and/or concentration of one or more selected microbial hazards in edible seeds, which were summarized in the following categories: sesame seeds, halva/helva, and other/unspecified seeds. The median publication year was 2010 (range 1995-2014). Most studies were conducted in Europe (67%) > Asia/the Middle East (22%) > the United States (11%). Most studies (61%) sampled products during a specific or defined period of time, while 7 reported on the results of systematic surveillance programmes. More than 60% of studies sampled products at retail (e.g. markets, grocery stores), while two sampled from manufacturing and processing facilities and two from imported products. Only 4/18 studies (22%) specified the country(s) of product origin.

Salmonella spp. was the most commonly investigated microbial hazard across all seed categories. It was found at a low average prevalence in other (alfalfa, flax, hemp, karela, melon, poppy, pumpkin, and sunflower) and mixed/unspecified seeds (0.5%) and halva/helva (6.0%), and a low median prevalence in sesame seeds (6.5%). An average prevalence of 9.1 (95% CI: 8.2-10.0) was identified for generic *E. coli* in poppy and unspecified seeds in two studies, respectively, with nearly all observations coming from a retail survey of unspecified seeds for consumption in the United Kingdom (Willis et al., 2009). Only one study conducted in Germany sampled sesame products other than seeds and halva/helva (not shown in the table below), finding *Salmonella* spp. in 1/12 samples of tahini (produced in Turkey) and 0/6 samples of sesame cereal (Brockmann et al., 2004).

B. cereus was identified at an average prevalence of 7.0 (95% CI: 0.4 to 18.9) in other seeds for consumption (flax, karela, poppy, pumpkin, sunflower) in three studies, while *Cronobacter* spp. was identified at highly variable (9-67%) prevalence levels across three trials in two studies of poppy, pumpkin, and sesame seeds, respectively. Enterobacteriaceae was found in only one study, in 6/6 samples of retail poppy seeds from India (Banerjee et al., 2003).

C. perfringens, *E. coli* O157:H7, *L. monocytogenes*, and *S. aureus* were not identified in any study.

Few studies reported extractable concentration data on levels of selected microbial hazards in seeds and seed products (not shown in the table below). Average concentrations of *Salmonella* spp. in halva from Turkey ranged with 3.8 to 87 CFU/g, with minimum and maximum values ranging from <10 to 850 CFU/g (Sengun et al., 2005). In another study of halva from Greek manufacturing plants, average concentrations of Enterobacteriaceae and *S. aureus* ranged from <10-30 CFU/g and 70-80 CFU/g, respectively (Kotzekidou, 1998).

Prevalence of selected microbial hazards within seed categories

Each cell includes the number of observations/trials/studies contributing to the average or median prevalence estimate, the proportion of trials that did not find any positive samples and measures of heterogeneity and risk of selection bias. See the table footnotes for detailed explanations on each of these parameters.

	Seeds Number of observations/trials/studies (% trials with zero prevalence)[a] Meta-analysis prevalence (%) estimates (95% CI) OR prevalence median (range)[b] Heterogeneity rating / Risk of selection bias (low, medium or high)[c]		
Microbial hazard	**Sesame seeds**	**Halva/helva**	**Other/unspecified seeds[d]**
B. cereus	4/1/1 (100%) 0 N/A / High	N/A	30/6/3 (83%) 7.0 (0.4 – 18.9)[M] Low / High
C. perfringens	N/A	N/A	6/1/1 (100%) 0 N/A / Low
***Cronobacter* spp.**	12/1/1 (0%) 67 N/A / High	N/A	22/2/1 (0%) 27.3 (9.1 – 45.5)[R] High / High
Generic *E. coli*	1/1/1 (100%) 0 N/A / High	N/A	3741/2/2 (50%) 9.1 (8.2 – 10.0)[M] Low / Low
***E. coli* O157:H7**	N/A	N/A	66/4/1 (100%) 0 (0 – 0)[R] Low / High
Enterobacteriaceae	N/A	63/1/1 (100%) 0 N/A / High	6/1/1 (0%) 100 N/A / Low
L. monocytogenes	N/A	N/A	15/3/1 (100%) 0 (0 – 0)[R] Low / High
S. aureus	N/A	69/2/2 (100%) 0 (0 – 0)[R] Low / High	6/1/1 (100%) 0 N/A / Low
***Salmonella* spp.**	965/4/4 (25%) 6.5 (0 – 12.5)[R] High / Med.	97/3/2 (67%) 6.0 (0 – 15.6)[M] Med. / High	3509/15/5 (53%) 0.5 (0.1 – 1.1)[M] Med. / Low

N/A = No data identified for this product-hazard combination. Med. = medium.

[a] Observations/trials/studies: The observations are the total number of samples for all studies included in the summarized category. The number of studies is the number of articles captured. In some cases, articles report data on multiple prevalence trials or sampling frames. While the observations for each trial are independent by time and sample, they are part of a larger study where the methods and investigators are the same. Thus, there is not full independence in these observations and we note this by acknowledging there are multiple trials within a study.

[b] Superscript [M] indicates an average prevalence estimate (and 95% confidence interval) from a random-effects meta-analysis. Meta-analysis estimates were calculated only if heterogeneity was low or medium (I^2 0-60%) and if at least one trial found a positive sample.

Superscript [R] indicates a median (and range) of trial prevalence estimates, calculated If heterogeneity was high (I^2 >60%). Ranges not provided when only one trial was identified.

[c] I^2 is a measure of the degree of heterogeneity between trials combined in the meta-analysis. Heterogeneity rating definitions: low = I^2 0-30%; medium = 31-60%; high = >60%.

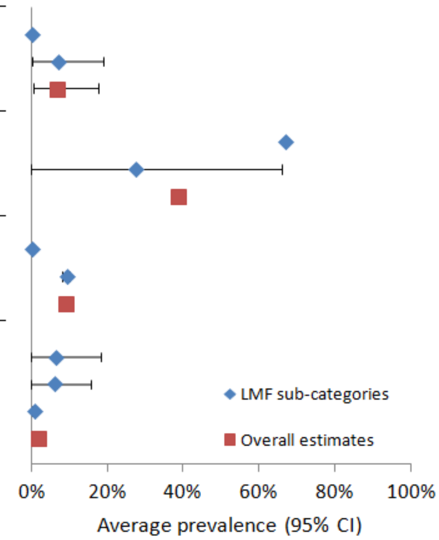
Selection bias rating definitions: high = 0-30% of trials used a representative sample; medium = 31-60% of trials used a representative sample; low = >60% of trials used a representative sample. Studies that conducted random or systematic sampling were considered representative.

The overall robustness of the meta-analysis prevalence estimates can be inferred from the heterogeneity and selection bias ratings. Taking into consideration the number of studies in the meta-analysis, high confidence in the meta-analysis results can be inferred when heterogeneity is low and the risk of selection bias is low, and low confidence can be inferred when both are high, see the methods section (page 11) for more information.

[d] "Other" seeds included the following for each microbial hazard: *B. cereus* (flax, karela, poppy, pumpkin, sunflower); *C. perfingens* , Enterobacteriaceae, and *S. aureus* (poppy); *Cronobacter* spp. (poppy, pumpkin); *E. coli* (poppy, mixed/unspecified); *E. coli* O157:H7 (melon, pumpkin, sunflower, watermelon); *L. monocytogenes* (karela, pumpkin, sunflower); *Salmonella* spp. (alfalfa, flax, hemp, karela, melon, poppy, pumpkin, sunflower, mixed/unspecified).

Forest plot of the prevalence of selected microbial hazards within seed categories

Micobial hazard / LMF sub-category	Average prevalence	Low 95% CI	High 95% CI	No. obs./ trials/studies	Hetero-geneity	Selection bias	Median (range)
B. cereus							
Sesame seeds	0.0	-	-	4/1/1	N/A	High	-
Other/unspecified seeds	7.0	0.4	18.9	30/6/3	Low	High	-
Overall	6.7	0.5	17.6		Low		-
***Cronobacter* spp.**							
Sesame seeds	66.7	-	-	12/1/1	N/A	High	-
Other/unspecified seeds	7.0	0.3	18.9	22/2/1	High	High	27.3 (9.1 – 45.5)
Overall	38.6	7.5	75.1		High		45.5 (9.1 – 66.7)
Generic *E. coli*							
Sesame seeds	0.0	-	-	1/1/1	N/A	High	-
Other/unspecified seeds	9.1	8.2	10.0	3741/2/2	Low	Low	-
Overall	9.1	8.2	10.0		Low		-
***Salmonella* spp.**							
Sesame seeds	6.2	0.0	18.2	965/4/4	High	Med.	6.5 (0 – 12.5)
Halva/helva	6.0	0.0	15.6	97/3/2	Med.	High	-
Other/unspecified seeds	0.5	0.1	1.1	3509/15/5	Med.	Low	-
Overall	1.9	0.8	3.3		High		0.1 (0 – 16.7)



CI = confidence interval; Med. = medium; No. obs. = number of total samples tested per category.
See the prevalence table for full explanations of all columns.
NOTE: *C. perfringens*, *E. coli* 0157, *L. monocytogenes*, and *S. aureus* evidence is not shown in this figure because no positive samples were identified in these categories.

Interventions

A total of only 4 experimental studies (consisting of 8 unique trials) were identified evaluating the effects of various interventions to reduce contamination of microbial hazards in seeds: specifically, sesame seeds or their products tahini and halva/helva. The median publication year was 2009 (range 1998 to 2013). The studies were conducted in Turkey (n=2), Greece and Jordan. All studies reported on challenge trials with artificially inoculated samples, while one also included a controlled trial. None of the studies were conducted under commercial conditions, and they all included only a small number of samples (2-6 replicates per intervention combination).

Two studies each investigated the effect of various storage and packaging conditions on Enterobacteriaceae, *E. coli* O157:H7, *S. aureus*, and *Salmonella* spp. in halva/helva and tahini paste. Microbial hazards were reduced but not completely eliminated during storage at higher temperatures and at higher levels of initial contamination. One study found that roasting sesame seeds for 60 min can reduce *Salmonella* counts by >5 logs, but these roasting conditions could affect consumer acceptability of the final product (Torlak et al., 2013).

Given the potential for microbial hazards to survive sesame seed processing and storage, and for subsequent cross-contamination, good agricultural and manufacturing practices and hazard analysis critical control point (HACCP) food safety management systems should be implemented during sesame seed harvesting and throughout the production process (Al-Nabulsi et al., 2013; Torlak et al., 2013).

Summary table of experimental studies evaluating the effects of interventions to reduce contamination of selected microbial hazards in seeds

Food category	Intervention type	Intervention details (dose and/or duration)	Source(s)	Microbial hazard(s)	Study type[a]	No. trials/ studies	% of trials with extractable data	% of trials finding intervention is effective
Halva/ helva	Modified packaging	Vacuum vs. air-sealed (6 days to 8 months)	Kotzekidou (1998)	Enterobac-teriaceae	C.T.	1/1	0	100
	Modified packaging	Vacuum vs. air-sealed (6 days to 8 months)	Kotzekidou (1998)	*Salmonella* spp.	Ch.T.	1/1	100	100
	Storage conditions	Increased temperature (6-20°C; 6 days to 8 months)	Kotzekidou (1998)	Enterobac-teriaceae	C.T.	1/1	0	100
	Storage conditions	4 and 20°C; 1-9 months	Sengun (2005)	*S. aureus*	Ch.T.	1/1	0	100
	Storage conditions	Increased temperature (6-20°C; 6 days to 8 months)	Kotzekidou (1998)	*Salmonella* spp.	Ch.T.	1/1	100	100
Sesame seeds	Heat treatment	Roasting (110-150°C; 10-60 min)	Torlak (2013)	*Salmonella* spp.	Ch.T.	1/1	0	100
Tahini	Storage conditions	Increased temperature (10-37°C; 1-28 days)	Al-Nabulsi (2013)	*E. coli* O157:H7	Ch.T.	1/1	100	100
	Storage conditions	Increased temperature (4 and 22°C; 1-16 weeks)	Torlak (2013)	*Salmonella* spp.	Ch.T.	1/1	0	100

[a] Ch.T. = challenge trial; C.T. = controlled trial.

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Summary Card: Spices, Dried Herbs and Tea

(Burden of Illness, Prevalence and Interventions)

Low-moisture food category description

Spices are dried parts of fruits, seeds, bark, roots, leaves, or flowers of plants and herbs (EFSA, 2013; US FDA, 2013). They are often ground, crushed, or otherwise processed and used for seasoning, flavouring, and/or preserving foods (EFSA, 2013; US FDA, 2013). For the purposes of this summary, and due to their similar nature, spices (including dried herbs) have been combined with tea – an aromatic beverage prepared by mixing hot water with dried leaves of the tea plant and/or other dried herbs such as chamomile.

To facilitate summary and interpretation of this large area of research, "spices" have been grouped into hierarchical categories based primarily on the part of the plant from which they originated (Sagoo et al., 2009; US FDA, 2013; Van Doren et al., 2013a). Categories were also created for mixed/unspecified spices and dried herbs, and for tea (Appendix G: Spice Classification Table).

Evidence summary

In total, 129 articles[13] and outbreak reports[14] were identified that investigated the burden of illness related to spices, the prevalence or contamination of selected microbial hazards in spices, and/or interventions to reduce contamination of microbial hazards in spices. The distribution of identified research stratified by microbial hazard investigated and research focus is shown in Appendix F: Summary Card Evidence Charts. *Salmonella* spp. was the most frequently investigated microbial hazard in spices for burden of illness (n=13 articles and outbreak reports), prevalence (n=42 articles), and intervention (n=12 articles) information.

Burden of illness

Burden of illness evidence related to spices includes 28 reported outbreaks and non-outbreak burden of illness information in 1 cohort study and 2 case-control studies. Outbreaks affected 2228 individuals, including 134 hospitalizations and 2 deaths between 1973 and 2012. Outbreaks were generally small: median 20 (range 1-1000); however, they can be very large. Spice outbreaks, shown in the summary table below, were reported from Demark (9), the United States (4), Finland (3), the United Kingdom (2), Germany, Norway, Canada, France, Hungary and Belgium. Several outbreaks occurred where the spice was added to the food product after the final pathogen reduction step. Spice outbreaks are likely significantly under-reported as they are usually consumed in mixed ingredient foods and in small amounts.

Salmonella spp. accounted for 77% of illnesses associated with spices **>** *B. cereus* 19.7% **>** *C. perferingens* 2.8% **>** *C. botulinum* 0.04%. A case-control study examining source association with *Salmonella* Enteritidis cases (n=719) in Germany found the consumption of dried herbs was associated with infection; OR 1.4 (95% CI: 1.04-1.73) (Ziehm et al., 2013).

[13] Articles refer to peer-reviewed journal publications as well as government and research agency reports.
[14] For burden of illness information, multiple articles often reported complementary and/or overlapping information on the same outbreak. In addition, outbreak data were supplemented from other literature sources, including line lists from various countries, news reports, or annual summaries of country outbreaks. Thus, to avoid counting the same outbreak more than once, the term 'outbreak report' is used instead of 'article' to count the total number of unique outbreaks.

Ten of the 28 outbreaks (1973-2012) implicated black or white pepper as the contaminated ingredient. Other spices were implicated in 1 or 2 outbreaks each.

All outbreaks associated with tea were in infants less than 18 months old in Germany, Serbia and Portugal and are detailed in the summary table below. One case-control study implicated tea in association with *B. cereus* infection in child cancer patients (El Saleeby et al., 2004). In contrast, a cohort study of Mexican infants from 0-1 year old (n=98) found that herbal tea was protective against diarrhea; hazard ratio 0.11 (95% CI: 0.067 to 0.62) (Long et al., 1994).

Summary table of globally reported outbreaks on spices

Spice category/ specific spice *(source)*	Microbial hazard(s)	Outbreaks/ cases/ hospitalized/ deaths[a]	Country (year)[b]	Comments: susceptible populations/ attack rate/ concentration of microbial hazard in the product
Bark/flowers				
Cinnamon *(EU, no date)*	*B. cereus*	1/30[c]/0/0	Denmark (2011)	Concentration: 5000 organisms/g.
Root				
Turmeric *(EFSA, 2013)*	*B. cereus*	2/23[c]/0/0	Finland (2011)	
Fruit/seed				
Cumin *(EFSA, 2013)*	*B. cereus* *C. perfringens* *Salmonella* Caracas	1/3[c]/0/0	Finland (2011)	Concentration: *B. cereus* 16 000 CFU/g, C. perfringens 180 CFU/g and S. Caracas presence/25 g.
***Capsicum* spp.**				
Dried chilies *(EU, no date)*	*C. perfringens*	1/3[c]/0/0	Denmark (2011)	
Red Pepper *(EU, no date)*	*C. perfringens*	1/37[c]/0/0	Denmark (2011)	
Paprika *(Anon., no date)*	*B. cereus*	1/48[c]/0/0	Denmark (2009)	
(Lehmacher, 1995)	*Salmonella* Saintpaul, Rubislaw, Javiana (94 serovars isolated)	1/1000[c]/0/0	Germany (1993)	Implicated paprika on potato chips. Attack rate= 1/1000. Mostly affected children <14 years old. Concentrations: chips 0.04-11 MPN/g; paprika 2.5 MPN/g; spice mixture 0.04-0.4MPN/g.
Piper nigrum				
Black pepper ***(EU, no date; EU, 2012a)***	*C. perfringens*	2/19[c]/0/0	Denmark (2011)	Concentration 330 mill. / g of pepper.
(EFSA, 2013; Van Doren, 2013b)	*B. cereus*	2/164[c]/0/0	Denmark (2010[E] & 2011)	
(Gieraltowski, 2013; Gustavsen , 1984; Little, 2003; Van Doren, 2013b)	*Salmonella* Weltevreden, Oranienburg, Enteritidis PT4, Montevideo, Seftenberg & Rissen	6/521[c]/94/2	Canada (1973), Norway (1981), United Kingdom (1996), United States (2009, 2009, 2008)	Black pepper originated from India, Brazil [0.1 to >2.4 MPN/g], Vietnam & China. White pepper from Vietnam. Red pepper from India implicated in 2 outbreaks with black pepper.
Mixed spices				

Garlic salt & black pepper mix *(Raevuori, 1976)*	*B. cereus*	1/18[c]/0/0	Finland (1975)	Attack rate 50%, Concentration: garlic salt 100 organisms/g, white pepper 4500 organisms/g.
BBQ spices *(EU, no date)*	*C. perfringens*	1/4[c]/0/0	Denmark (2011)	
Seasoning mix *(Sotir, 2009)*	*Salmonella* Wandsworth & Typhimurium	1/87[c]/8/0	United States (2007)	Seasoning applied to commercial puffed vegetable coated ready-to-eat snack after final pathogen reduction step.
Spice blend *(Van Doren, 2013b)*	*B. cereus*	1/146[c]/0/0	France (2007)	Outbreak in school children.
(EU 2012b)	*Salmonella* Enteritidis	1/41/6/0	Hungary (2012)	EU category of herbs and spices.
Curry powder *(Van Doren, 2013b)*	*Salmonella* Braenderup	1/20[c]/1/0	United Kingdom (2002)	Spice originated from India.
(EU, 2010)	*B. cereus*	1/7[c]/0/0	Belgium (2009)	

[a] Superscipt [C] indicates confirmed cases, [P] indicates presumptive cases.
[b] Superscript [E] indicates the link between human cases and implicated product was epidemiological only, otherwise the link was laboratory confirmed.

Summary of globally reported outbreaks related to tea

Tea category/ specific tea	Microbial hazard(s)	Outbreaks/ cases[a]/ hospitalized/ deaths	Country (year)[b]	Comments: susceptible populations/ attack rate/ concentration of microbial hazard in the product
Tea				
Chamomile tea (Saraiva, 2012)	*C. botulinum*	1/1[c]/0/0	Portugal (2009)	Case of infant botulism, both honey and chamomile tested positive.
Anise seed in tea *(Koch, 2005)*	*Salmonella*	1/42[c]/21/0	Germany (2002)	Cases, infants <13 months. Anise seed (*Pimpinella anisum*) from Turkey. Concentration: 0.036 MPN/g.
Fennel seed in tea (Ilic, 2010)	*Salmonella*	1/14[c]/4/0	Serbia (2007)	Cases, infants <12 months. Fennel seed (*Foeniculum vulgare*)

[a] Superscript [C] indicates confirmed cases, [P] indicates presumptive cases.
[b] Superscript [E] indicates the link between human cases and implicated product was epidemiological only, otherwise the link was laboratory confirmed.

Prevalence

A total of 77 studies containing 1,275 unique trials were identified that investigated the prevalence and/or concentration of one or more selected microbial hazards in spices. The median publication year was 2009 (range 1991-2014).

Most studies (>69%) were conducted in Europe (n=32) and Asia/the Middle East (n=21). Most studies (84%) sampled products during a specific or defined period of time, while 2 conducted sampling over multiple time points, and 10 reported on the results of systematic surveillance programmes. Studies primarily sampled products at retail (e.g. markets, grocery stores) and/or from manufacturing plants (75%). Only 8 studies specified the country(s) of product origin, while 12 studies sampled products produced in the country where the study was conducted.

Salmonella spp. was the most commonly investigated microbial hazard across most spice categories. Both *Salmonella* and *S. aureus* were infrequently isolated from most trials; in many cases only one or a few trials found positive results for these pathogens. However, the prevalence estimates and ranges shown in the summary table indicate the potential for high contamination if appropriate good production and manufacturing practices are not followed (ASTA, 2011; US FDA, 2013). A summary of United States FDA spice recalls (1970-2003) recorded 17 recalls all due to *Salmonella* contamination in spices and dried herbs (Vij et al., 2006). Generic *E. coli* was also infrequently found in prevalence trials except in the mixed/unspecified spice category, where it was found in 75% of trials with a median prevalence of 11% and range of 0-33%.

B. cereus, *C. perfringens*, *Cronobacter* spp. and Enterobacteriaceae were found at variable and wide-ranging prevalence levels across most spice categories. When meta-analysis was possible for these hazards, average prevalence estimates ranged from 6% (95% CI: 3-7%) for *C. perfringens* in dried herbs to 37% (95% CI: 29-45%) for Enterobacteriaceae in fruit/seed spices. Some trials found very high prevalence levels (approaching 100%) for certain hazard/spice combinations. While most trials that investigated *C. perfringens* used a representative sample (i.e. samples were randomly or systematically selected), the opposite was true for *Cronobacter* spp., as the latter trials tended to sample multiple low-moisture and other food products and spices comprised only a small and non-representative category.

Comparatively little research was identified in teas. Three studies from Argentina found a low to moderate prevalence of *C. botulinum* in tea (Bianco et al., 2008, 2009; De Jong et al., 2003), while the prevalence of other microbial hazards (e.g. *Cronobacter* spp. and generic *E. coli*) varied widely across difference studies.

E. coli O157:H7 and *L. monocytogenes* were not isolated from spices or teas in any study.

Only three studies were identified that reported extractable concentration (CFU or MPN) data for Enterobacteriaceae (Witkowska et al., 2011) and generic *E. coli* (Koohy-Kamaly-Dehkordy et al., 2013), respectively, in various spices, and *C. botulinum* in tea (De Jong et al., 2003), with an associated measure of variability (e.g. confidence interval and/or standard deviation). These data are summarized in a table below.

There were 34 studies that measured concentration data for selected microbial hazards in spices, but these trials were excluded from this summary because they did not have appropriate extractable data. Required extractable data included a mean concentration value, a measure of variability, and the sample size. In addition, 8 studies reported the prevalence of selected microbial hazards in spice shipments or batch samples (data not shown in the table below). A list of these studies can be found in Appendix H: Articles reporting non-extractable concentration data and prevalence in batch samples for spices, dried herbs and tea.

The data reinforces that many spices can be contaminated, sometimes at a very high prevalence, with various microbial hazards.

Prevalence of selected microbial hazards within spice categories

Each cell includes the number of observations/trials/studies contributing to the average or median prevalence estimate, the proportion of trials that did not find any positive samples and measures of heterogeneity and risk of selection bias. See the table footnotes for detailed explanations on each of these parameters.

	Spice Category Number of observations/trials/studies (% trials with zero prevalence)[a] Meta-analysis prevalence (%) estimates (95% CI) OR prevalence median (range)[b] Heterogeneity rating / Risk of selection bias (low, medium or high)[c]					
Microbial hazard	**Bark/flower**	**Fruit/seed**	**Herbs**	**Mixed**	**Root**	**Tea**
B. cereus	154/12/5 (50%) 1.9 (0 – 60)[R] High / Med.	1001/76/9 (42%) 11.7 (0 – 85.7)[R] High / Low	207/20/5 (60%) 0 (0 – 75)[R] High / Med.	4468/20/14 (10%) 26.9 (0 – 68.8)[R] High / Low	142/15/5 (40%) 20.2 (10.0 – 32.6)[M] Med. / Low	1/1/1 (100%) 0 n/a / High
C. botulinum	N/a	N/a	N/a	65/1/1 (100%) 0 n/a / High	N/a	423/3/3 (0%) 7.5 (1.5 – 26.1)[R] High / High
C. perfringens	114/9/4 (67%) 0 (0 – 46.8)[R] High / Low	324/76/49 (69%) 10.3 (7.3 – 13.6)[M] Low / Low	196/12/5 (67%) 6.0 (3.1 – 9.7)[M] Low / Low	3889/11/6 (45%) 1.4 (0 – 32.7)[R] High / Low	107/9/3 (78%) 15.0 (8.9 – 22.3)[M] Low / Low	N/a
***Cronobacter* spp.**	19/4/3 (75%) 12.4 (0 – 34.3)[M] Low / High	83/18/3 (22%) 34.8 (20.3 – 50.8)[M] Med. / High	51/6/3 (50%) 18.8 (7.3 – 33.1)[M] Low / High	341/13/11 (23%) 26.9 (0 – 73.3)[R] High / High	17/4/2 (25%) 35.3 (14.8 – 58.7)[M] Low / High	209/22/6 (27%) 34.4 (0 – 75)[R] High / High
Generic *E. coli*	179/11/7 (82%) 4.2 (1.7 – 7.6)[M] Low / Med.	826/57/9 (72%) 10.2 (7.3 – 13.6)[M] Med. / Med.	118/18/6 (83%) 0 (0 – 70.6)[R] High / High	3045/8/6 (25%) 11.2 (0 – 33.3)[R] High / Med.	176/11/5 (75%) 0 (0 – 35.4)[R] High / Low	68/7/5 (57%) 0 (0 – 66.7)[R] High / High
***E. coli* O157:H7**	16/2/2 (100%) 0 (0 – 0)[R] Low / High	209/12/3 (100%) 0 (0 – 0)[R] Low / High	32/2/2 (100%) 0 (0 – 0)[R] Low / High	2/1/1 (100%) 0 n/a / High	4/2/1 (100%) 0 (0 – 0)[R] Low / High	22/1/1 (100%) 0 n/a / High
Enterobact-eriaceae	127/11/5 (77%) 0 (0 – 80)[R] High / Med.	256/51/5 (43%) 36.6 (28.6 – 44.9)[M] Med. / Med.	28/12/3 (67%) 24.7 (11.4 – 40.9)[M] Low / High	129/4/3 (25%) 35.1 (27.1 – 43.5)[M] Low / High	35/8/3 (75%) 9.7 (2.0 – 21.4)[M] Low / Low	1/1/1 (0%) 100 n/a / High
L. mono-cytogenes	17/5/2 (100%) 0 (0 – 0)[R] Low / High	141/27/3 (100%) 0 (0 – 0)[R] Low / High	68/17/2 (100%) 0 (0 – 0)[R] Low / High	174/6/4 (100%) 0 (0 – 0)[R] Low / Med.	32/7/2 (100%) 0 (0 – 0)[R] Low / High	N/a
S. aureus	195/16/8 (94%) 2.6 (0.8 – 5.3)[M] Low / Med.	914/89/10 (92%) 5.6 (4.2 – 7.1)[M] Low / Low	255/25/7 (96%) 2.4 (0.9 – 4.7)[M] Low / Med.	132/9/4 (78%) 2.8 (0.6 – 6.4)[M] Low / Med.	144/16/6 (81%) 10.6 (6.2 – 16.1)[M] Low / Med.	89/5/2 (100%) 0 (0 – 0)[R] Low / Low
***Salmonella* spp.**	306/26/13 (96%) 1.8 (0.6 – 3.6)[M] Low / Med.	2832/160/20 (87%) 2.3 (1.0 – 3.9)[M] Low / Med.	503/52/12 (100%) 0 (0 – 0)[R] Low / High	18315/47/17 (60%) 0 (0 – 14)[R] High / Low	367/26/11 (88%) 4.4 (2.5 – 6.7)[M] Low / Med.	138/8/3 (88%) 3.1 (0 – 8)[M] Med. / Low

N/a = No data identified for this product-hazard combination. Med. = medium.

[a] Observations/trials/studies: The observations are the total number of samples for all studies included in the summarized category. The number of studies is the number of articles captured. In some cases, articles report data on multiple prevalence trials or sampling frames. While the observations for each trial are independent by time and sample, they are part of a larger study where the methods and investigators are the same. Thus, there is not full independence in these observations and we note this by acknowledging there are multiple trials within a study.

[b] Superscript [M] indicates an average prevalence estimate (and 95% confidence interval) from a random-effects meta-analysis. Meta-analysis estimates were calculated only if heterogeneity was low or medium (I^2 0-60%) and if at least one trial found a positive sample.

Superscript [R] indicates a median (and range) of trial prevalence estimates, calculated If heterogeneity was high (I^2 >60%). Ranges not provided when only one trial was identified.

[c] I^2 is a measure of the degree of heterogeneity between trials combined in the meta-analysis. Heterogeneity rating definitions: low = I^2 0-30%; medium = 31-60%; high = >60%.
Selection bias rating definitions: high = 0-30% of trials used a representative sample; medium = 31-60% of trials used a representative sample; low = >60% of trials used a representative sample. Studies that conducted random or systematic sampling were considered representative.
The overall robustness of the meta-analysis prevalence estimates can be inferred from the heterogeneity and selection bias ratings. Taking into consideration the number of studies in the meta-analysis, high confidence in the meta-analysis results can be inferred when heterogeneity is low and the risk of selection bias is low, and low confidence can be inferred when both are high, see the methods section (page 11) for more information.

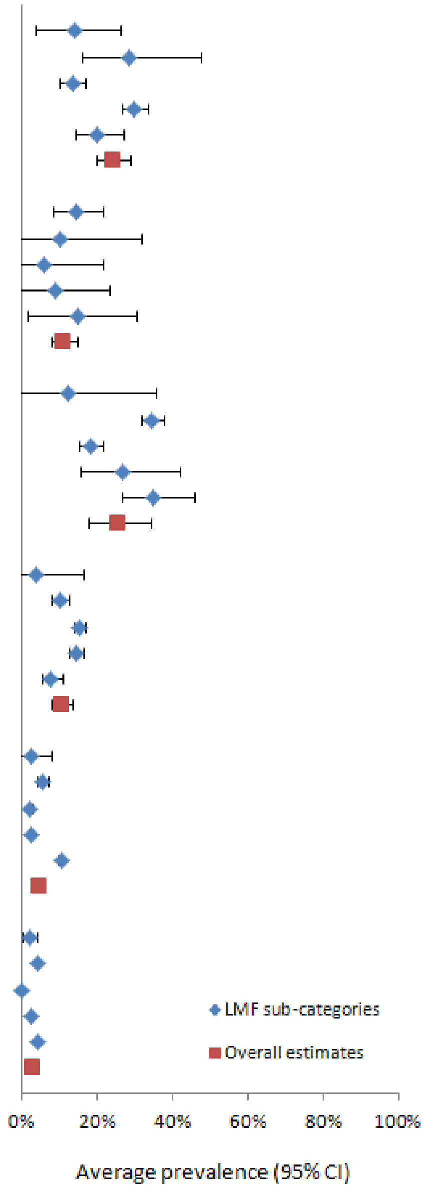
Summary of studies reporting the concentration of selected microbial hazards in spices and tea with an associated measure of variability

Specific spice	Microbial hazard	Concentration (SD or 95% CI)	No. of observations	Units	Source
Spices					
Basil	Enterobacteriaceae	4.01 (0.15)	6	log CFU/g	Witkowska et al., 2011[a]
Black pepper powder	Generic *E. coli*	5.8 (32.8)	55	MPN/g	Koohy-Kamaly-Dehkordy et al., 2013[b,c]
Caraway	Generic *E. coli*	157.6 (598.1)	16	MPN/g	Koohy-Kamaly-Dehkordy et al., 2013
Celery	Enterobacteriaceae	4.06 (0.13)	6	log CFU/g	Witkowska et al., 2011
Coriander	Enterobacteriaceae	3.19 (0.25)	6	log CFU/g	Witkowska et al., 2011
Cow parsnip	Generic *E. coli*	38.5 (173.8)	40	MPN/g	Koohy-Kamaly-Dehkordy et al., 2013
Cumin	Enterobacteriaceae	3.08 (0.24)	6	log CFU/g	Witkowska et al., 2011
Curry powder	Generic *E. coli*	14.9 (79.9)	33	MPN/g	Koohy-Kamaly-Dehkordy et al., 2013
Fennel	Enterobacteriaceae	4.50 (0.24)	6	log CFU/g	Witkowska et al., 2011
Garlic	Generic *E. coli*	2.4 (13.3)	31	MPN/g	Koohy-Kamaly-Dehkordy et al., 2013
Garlic	Enterobacteriaceae	1.86 (0.43)	6	log CFU/g	Witkowska et al., 2011
Parsley	Enterobacteriaceae	3.32 (0.81)	6	log CFU/g	Witkowska et al., 2011
Red pepper powder	Generic *E. coli*	5.1 (22.9)	45	MPN/g	Koohy-Kamaly-Dehkordy et al., 2013
Turmeric	Generic *E. coli*	7.1 (35.0)	48	MPN/g	Koohy-Kamaly-Dehkordy et al., 2013
Tea					
Chamomile	*C. botulinum*	0.31 (0.09, 1.03)	23	Spores/g	De Jong et al., 2003

SD = standard deviation; CI = confidence intervals.
[a] Study also sampled the following spices but did not isolate Enterobacteriaceae from any of the samples: aniseed, bay leaves, black pepper powder, cayenne pepper, cinnamon, cloves, coriander, dill, French onion, ginger, mace, marjoram, mustard, nutmeg, onion powder, oregano, paprika, pimento, rosemary, sage, thyme, turmeric, and white pepper powder.
[b] Study also sampled the following spices but did not isolate E. coli from any of the samples: cinnamon and sumac.
[c] Study used a representative (i.e. randomly or systematically selected) sample.

Forest plot of the prevalence of selected microbial hazards within spice categories

Micobial hazard / LMF sub-category	Average prevalence	Low 95% CI	High 95% CI	No. obs./ trials/studies	Hetero-geneity	Selection bias	Median (range)
B. cereus							
Bark/flower	14.2	4.7	27.3	154/12/5	High	Med.	1.9 (0 – 60)
Fruit/seed	28.8	20.4	38.1	1001/76/9	High	Low	11.7 (0 – 85.7)
Dried herbs	13.6	5.0	25.1	207/20/5	High	Med.	0 (0 – 75)
Mixed/unspecified	29.9	20.2	40.6	4468/20/14	High	Low	26.9 (0 – 68.8)
Root	20.2	10.0	32.6	142/15/5	Med.	Low	-
Overall	24.5	20.1	29.2		High		11.7 (0 – 100)
C. perfringens							
Bark/flower	14.6	2.1	33.7	114/9/4	High	Low	0 (0 – 46.8)
Fruit/seed	10.3	7.3	13.7	324/76/49	Low	Low	-
Dried herbs	6.0	3.1	9.7	196/12/5	Low	Low	-
Mixed/unspecified	9.1	3.6	16.4	3889/11/6	High	Low	1.4 (0 – 32.7)
Root	15.0	8.9	22.3	107/9/3	Low	Low	-
Overall	11.4	8.3	14.9		High		0 (0 – 50)
***Cronobacter* spp.**							
Bark/flower	12.5	0.0	34.3	19/4/3	Low	High	-
Fruit/seed	34.8	20.3	50.8	83/18/3	Med.	High	-
Dried herbs	18.6	7.3	33.1	51/6/3	Low	High	-
Mixed/unspecified	27.0	13.6	42.7	341/13/11	High	High	26.9 (0 – 73.3)
Root	35.3	14.8	58.7	17/4/2	Low	High	-
Overall	25.8	17.9	34.7		High		22.6 (0 – 100)
Generic *E. coli*							
Bark/flower	4.2	1.7	7.6	179/11/7	Low	Med.	-
Fruit/seed	10.2	7.3	13.6	826/57/9	Med.	Med.	-
Dried herbs	15.6	4.6	30.9	118/18/6	High	High	0 (0 – 70.6)
Mixed/unspecified	14.6	6.3	25.3	3045/8/6	High	Med.	11.2 (0 – 33.3)
Root	7.8	0.5	20.3	176/11/5	High	Low	0 (0 – 35.4)
Overall	10.7	8.0	13.7		High		0 (0 – 70.6)
S. aureus							
Bark/flower	2.6	0.8	5.3	195/16/8	Low	Med.	-
Fruit/seed	5.6	4.2	7.2	914/89/10	Low	Low	-
Dried herbs	2.4	0.9	4.7	255/25/7	Low	Med.	-
Mixed/unspecified	2.8	0.5	6.3	132/9/4	Low	Med.	-
Root	10.6	6.2	16.1	144/16/6	Low	Med.	-
Overall	4.9	3.9	5.9		Low		-
***Salmonella* spp.**							
Bark/flower	2.3	1.0	3.9	306/26/13	Low	Med.	-
Fruit/seed	4.3	3.6	5.0	2832/160/20	Low	Med.	-
Dried herbs	0.0	0.0	0.0	503/52/12	Low	High	-
Mixed/unspecified	2.6	1.9	3.4	18315/47/17	High	Low	0 (0 – 14)
Root	4.4	2.5	6.7	367/26/11	Low	Med.	-
Overall	3.0	2.6	3.4		Low		-



CI = confidence interval; Med. = medium; No. obs. = number of total samples tested per category.
See the prevalence table for full explanations of all columns.
NOTE: The tea sub-category was excluded from this figure. *C. botulinum*, *E. coli* 0157, and *L. monocytogenes* evidence is not shown because no positive samples were identified in these categories.

Interventions

A total of 20 experimental studies (consisting of 66 unique trials) and one summary of surveillance data were identified evaluating the effects of various interventions to reduce contamination of microbial hazards in spices and tea. The median publication year was 2011 (range 1984 – 2014). Half (50%) of the studies were conducted in Asia and the Middle East (with four studies each in South Korea and Turkey). Twelve of the experimental studies were challenge trials with artificially inoculated samples, 8 were controlled trials and one was a quasi-experiment (measuring changes in contamination before and after an applied intervention). All studies except the quasi-experiment were conducted under laboratory and non-commercial conditions.

The most common interventions were heat treatments, chemical treatments, and irradiation (including ionizing radiation and non-ionizing such as UV and microwave). Most of these interventions are commonly applied in the spice industry (ASTA, 2011; US FDA, 2013). However, it is not a requirement for exporting countries to indicate if a pathogen reduction intervention has been applied. One study that summarized US FDA surveillance data (not shown in the table below) analyzed imported spice shipments and found that spices labelled as “treated” had a lower *Salmonella* prevalence compared to spice shipments that were untreated or of unknown treatment status (3% compared to 6.8%), although the difference was not statistically significant (Van Doren et al., 2013a).

Nearly all trials found that the applied interventions were effective. The interventions were applied against various microbial hazards, including *Salmonella* spp. (n=9 studies) > *E. coli* (9) > Enterobacteriaceae (4) > *B. cereus* (3) > *C. perfringens* (3) > *Cronobacter spp*. (2). The vast majority of trials (>70%) were applied to black (*Piper* spp.) or red (*Capsicum* spp.) pepper.

Many trials did not report data on intervention efficacy in an extractable format, and typical sample sizes were small (e.g. 2-4 replicate samples per intervention combination).

Summary table of experimental studies evaluating the effects of interventions to reduce contamination of selected microbial hazards in spices, dried herbs and tea

Spice category	Intervention category	Intervention details (dose and/or duration, where available)	Source(s)[a]	Microbial hazard(s)	Study type[b]	No. trials/ studies	% of trials with extractable data	% of trials finding intervention is effective[c]
Bark/ flower	Chemicals	Polyethylene packaging with silver nano-particles (up to 300ppm)	Hamid Sales (2012)	*C. perfringens* Generic *E. coli*, Entero-bacteriaceae	C.T.	1/1	0	100
	Irradiation	Gamma (1 to 4 kGy)	Hamid Sales (2012)	*C. perfringens* Generic *E. coli*, Entero-bacteriaceae	C.T.	1/1	0	100
Fruit/ seed	Chemicals	Cold plasma with nitrogen, nitrogen-oxygen, helium, and helium-oxygen gases (300-900 W; 267-26680 Pa; 4-20 min)	Kim (2014)	*B. cereus*	Ch.T.	1/1	0	0
	Chemicals	Ethylene oxide gas (70 kg/48m^3; 24 hr)	Pafumi (1984)	*B. cereus, C. perfringens*, *Salmonella* spp., Generic *E. coli*	C.T.	3/1	0	100
	Chemicals	Phosphine gas (3-6 g/m^3; 24-72 hr)	Castro (2011)	*Salmonella* spp.	Ch.T.	1/1	0	100
	Changes to storage parameters	Increased temperature (25-35°C; 0-120 days) Increased humidity (<40-97%; 0-120 days) Increased temperature (5-35°C; 0-15 days) Increased Aw (0.66 to 0.94; 0-15 days)	Keller (2013) Keller (2013) Ristori (2007) Ristori (2007)	*Salmonella* spp.	Ch.T.	4/2	50	100
	Desiccation	Desiccation (58°C; 50 min)	Ijabadeniyi (2013)	*Cronobacter* spp.	Ch.T.	2/1	100	100
	Heat treatment	Hot water dip (70-90°C; 10-60 min)	Kim (2014)	*B. cereus*	Ch.T.	1/1	0	100
	Heat treatment	Pasteurization (72°C; 15 s)	Ijabadeniyi (2013)	*Cronobacter* spp.	Ch.T.	2/1	0	0
	Irradiation	Far-infrared (300-350°C; 1.88-5.88 min) Far-infrared + UV-C radiation (10.5	Erdogdu (2013)	*B. cereus*	C.T.	2/1	100	100

		mW/cm^2; 2 hr)						
	Irradiation	Gamma (5-10 kGy) Microwave (2450 ± 50 MHz; 20-75 s)	Emam (1995)	*C. perfringens.*	C.T.	2/1	0	100
	Irradiation	Gamma (2 to 5 kGy; 6-30 min) Radio-frequency (27.12 MHz; 57-79°C; 40-50 s) Near-infrared (500 W; 50-75°C; 1-5 min) UV-C (16 W; 50-75°C; 1-5 min) Near-infrared + UV-C	Song (2014) Kim (2012) Ha (2013) Ha (2013) Ha (2013)	*E. coli* O157:H7, *Salmonella* spp.	Ch.T.	7/3	71	**100***
	Irradiation	Gamma (5-10 kGy) Microwave (2450 ± 50 MHz; 20-75 s) UV-C (10.5 mW/cm^2; 2 hr) Far-infrared (650 W; 300-350°C; 1.88-5.88 min) + UV-C	Emam (1995) Emam (1995) Erdogdu (2013) Erdogdu (2013)	Generic *E. coli*	C.T.	4/2	50	100
	Irradiation	Electron beam (2.4-12.5 kGy) Microwave (2450 ± 50 MHz; 50-150 s)	Nieto (2000) Aydin (2006)	Entero-bacteriaceae	C.T.	2/2	100	100
	Mincing	Grinding in cutter (1.5 min) and mincing in corundum mill	Schweiggert (2005)[a]	Generic *E. coli*	Quasi.	1/1	0	100
	Multiple	Cold plasma + hot water treatment (70-90°C; 10-60 min)	Kim (2014)	*B. cereus*	Ch.T.	1/1	0	100
	Ozone	0.1-1.0 ppm; 30-360 min	Emer (2008)	Generic *E. coli*	Ch.T.	1/1	100	100
Herbs	Ozone	2.8 and 5.3 mg/L; 30-120 min	Torlak (2013)	*Salmonella* spp.	Ch.T.	1/1	0	100
Mixed	Irradiation	Gamma (5 kGy)	Kiss (1990)	Entero-bacteriaceae	C.T.	1/1	0	100
Tea	Heat treatment	Hot water (50-70°C; 10 min)	Al-Nabulsi (2009)	*Cronobacter* spp.	C.T.	3/1	0	100
	Heat treatment	Hot water (60-65°C; 5 min)	Zhao (1997)	*Salmonella* spp.	C.T.	2/1	0	100
	Multiple	Bovine lactoferrin (1-10 mg/mL) + hot water (50-70°C; 10 min)	Al-Nabulsi (2009)	*Cronobacter* spp.	C.T.	3/1	0	100

[a] Indicates these studies were conducted under commercial conditions.
[b] Ch.T. = challenge trial; C.T. = controlled trial; Quasi. = quasi-experiment (e.g. before and after study)
[c] Intervention categories marked with an asterisk (*) indicate that more trials found a positive intervention effect than would be expected by chance alone (sign test *P* value <0.05).

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Microbial Hazards in Low-Moisture Foods:
Rapid Scoping and Systematic Review-Meta-Analysis of Research Knowledge

Appendices

Appendix A: LMF Product Categories and Sub-Categories

LMF Categories / Sub-Categories	Examples of included food products
Cereals and grains	
Whole grains other than rice	Wheat, barley, maize/corn, oats, rye, millet, sorghum, buckwheat
Rice and rice products	Rice, rice noodles
Milled grains	Milled grain products (e.g. flours, starches)
Other dry cereals and cereal products	Breakfast cereals, cereal and baking mixes, unspecified/mixed cereals
Confections and snacks	
Cocoa and chocolate products	Dried cocoa beans, cocoa powder, chocolate, cocoa and chocolate-based products (e.g. hot chocolate mix)
Other and unspecified confections	Fondants/creams, marshmallows, caramels/toffees, candies, chewing gum, other/unspecified confections and sweets
Snacks	Savoury snacks (e.g. chips, crackers, biscuits)
Yeast	Yeast extract (as LMF additive or flavouring)
Dried fruits and vegetables	
Dried fruits	Raisins, prunes, dates, dried mangos, dried apricots, desiccated coconut, fruit powders
Dried vegetables	Dried vegetables (e.g. tomatoes), vegetable powders and mixes (e.g. dry soup mixes), dehydrated vegetables (e.g. potato flakes, carrot slices), vegetable flours (e.g. potato starch), dried legumes
Dried mushrooms	Dried/dehydrated mushrooms

Dried seaweed	Dried seaweed
Dried protein products	
Dried dairy products	Milk/whey powders, other dairy powders (e.g. cheese), milk-based powders and mixes
Dried egg products	Egg powders
Dried fish/seafood products	Dried fish and seafood, fish flour/meal
Dried meats other than sausages/ salamis/jerky	Meat powders, gelatin
Honey and preserves	
Honey	Honey
Preserves	Jams, syrups (e.g. corn syrup)
Nuts and nut products	
Almonds	Almonds
Other tree nuts	Brazil nuts, cashews, hazelnuts/filberts, macadamia nuts, pecans, pine nuts, pistachios, and walnuts
Peanuts and peanut products	Peanuts, peanut butter, other peanut products (e.g. peanut spreads)
Mixed and unspecified nuts	Mixed/unspecified nuts
Seeds for consumption	
Sesame seeds	Sesame seeds
Tahini	Tahini (sesame seed paste)
Halva/helva	Halva/helva (confection made from sesame paste/tahini)
Other and unspecified seeds	Pumpkin seeds, sunflower seeds, poppy seeds, melon seeds, flax seeds, mixed/unspecified seeds for consumption (does not include sprouted seeds)
Spices and dried aromatic plants	
Spices- fruit/seed-based	*Capsicum* spp. (paprika, cayenne pepper, chili peppers, other hot and sweet dried capsicum peppers) *Piper* spp. (black, white, green, long pepper) Apiaceae (aniseed, caraway, celery, coriander, dill seed, fennel, chervil, cumin) Allspice, nutmeg/mace, other (e.g. cardamom, fungreek, mustard, sumac)

Spices- root-based	Garlic, ginger, turmeric, other (e.g. galangal, onion, asafoetida)
Spices- herb/leaf-based	*Origanum* spp. (e.g. oregano, marjoram), basil, bay leaf, other (e.g. mint, rosemary, parsley, sage, thyme, dill weed/leaves
Spices- bark/flower-based	Cinnamon, cloves, saffron, other (e.g. geranium, safflower)
Spices- mixed/ unspecified	Curry powder, Indian spices (e.g. garam masala, tandoori), herb mixes (e.g. Herbs de province, other/unspecified), other mixed/unspecified spices
Tea	Herbal (e.g. chamomile, spearmint, peppermint, linden flower, hibiscus), other/unspecified (e.g. black, green, rooibos)

Appendix B: Final Search Algorithm

Category	Terms
Hazards	"bacillus cereus" OR "clostridium botulinum" OR "clostridium perfringens" OR "cronobacter" OR "enterobacter sakazakii" OR "enterobacteriaceae" OR "escherichia coli" OR "e. coli" OR "salmonella" OR "staphylococcus aureus" OR "listeria monocytogenes"
LMF	("low-moisture food" OR "low-moisture foods" OR "low moisture foods" OR "low moisture food") OR ("dried fruit" OR "dried fruits" OR "dehydrated fruit" OR "dehydrated fruits" OR "raisin" OR "raisins" OR "dried vegetables" OR "dried vegetable" OR "dehydrated vegetables" OR "dehydrated vegetable" OR "preserved vegetable" OR "preserved vegetables" OR "preserved fruit" OR "preserved fruits" OR "desiccated coconut") OR ("peanut" OR "peanut butter" OR "peanuts" OR "nut" OR "nuts" OR walnut OR walnuts OR pecan OR pecans OR almond OR almonds OR hazelnut OR hazelnuts OR pistachio OR pistachios OR "pine nut" OR "pine nuts" OR cashew OR cashews OR "mixed nuts" OR chestnut OR chestnuts OR "sesame seed" OR "sesame seeds" OR "sunflower seed" OR "sunflower seeds" OR "poppy seed" OR "poppy seeds" OR "edible seed" OR "edible seeds" OR "tahini") OR (cereals OR cereal OR oats OR granola OR flour OR buckwheat OR millet OR rye OR wheat OR maize OR corn OR rice) OR ("dry milk" OR "dehydrated milk" OR "whey protein" OR "powdered milk" OR "milk powder" OR "rice protein" OR "soy protein" OR "dry protein" OR "dry sausage" OR "dry cured sausage" OR " cured sausage" OR "jerky" OR "fermented sausage" OR "egg powder" OR "beef powder" OR "fermented seafood" OR "meat powder") OR (confection OR confections OR confectionery OR candies OR candy OR sweets OR chocolate OR cocoa OR marshmallow OR halva) OR (snack OR "potato chips") OR (spice OR "dried herb" OR "dried herbs" OR "dehydrated herb" OR "dehydrated herbs" OR basil OR "curry" OR "ginger" OR coriander OR pepper OR "chili powder" OR turmeric OR paprika OR cardamom OR nutmeg OR allspice OR aniseed OR "bay leaves" OR caraway OR cinnamon OR chive OR chives OR clove OR cloves OR cumin OR dill OR fennel OR fenugreek OR galanga OR marjoram OR mustard OR oregano OR parsley OR peppermint OR rosemary OR sage OR spearmint OR tarragona OR thyme OR vanilla OR annatto OR saffron) OR (tea OR teas) OR (honey OR jam OR jams OR jelly OR syrup)
Outcome	illness OR illnesses OR case OR cases OR outbreak OR recall OR recalls OR prevalence OR frequency OR detection OR surveillance OR contamination OR intervention OR inactivate OR treatment OR pasteurisation OR disinfect OR hygiene OR haccp OR "hazard analysis"

	OR "agricultural practices" OR "manufacturing practices"

Search notes:

- Each category of terms was combined with the AND operator
- The Scopus search was conducted in the Title/Abstract/Keywords
- The PubMed search was conducted in the Title/Abstract
- There were no language or date restrictions on the search

Appendix C: Relevance Screening Form

Question	Options	Definitions/additional notes
1. Does the citation describe research investigating or discussing the prevalence, cases/outbreaks of human illness, or interventions for any relevant microbial hazards in low moisture foods?	☐ Yes ☐ No	Low moisture foods (LMF) – for the purposes of this study, refers to as any food item that has a water activity (a_w) level <0.85. Categories of LMF for inclusion: dehydrated/dried fruit and vegetables, cereals, dry protein products (**excluding infant milk formula**), confections, snacks, tree nuts, peanuts/peanut butter, seeds for consumption, spices and dried aromatic plants, lipid-based supplementary foods, and preserves (e.g. jams, honey). If a product is suspected of being a LMF (e.g. "dry fermented sausage") and the a_w level is not explicitly stated in the study, the study should be included. Microbiological hazards (MH) – for the purposes of this study, refers to Bacillus cereus, Clostridium botulinum, Clostridium perfringens, Cronobacter spp. (formally, Enterobacter sakazakii), Escherichia coli, Salmonella spp., Staphylococcus aureus, and Listeria monocytogenes, Enterobacteriaceae Include citations that do not provide sufficient detail to determine the article's relevancy (e.g., "confectionary items", "snacks", "sausages" may not refer LMFs). Exclude • Articles describing the validation of tests/tools for the detection of MHs in LMFs. • Reviews (non-primary research) • Consumer-level interventions (e.g. cooking)

Appendix D: Relevance Confirmation and Article Characterization Form

Question	Comments
1. Does the article describe research investigating or discussing the prevalence/risk factors, cases/outbreaks of human illness, or interventions for any relevant microbial hazards in low moisture foods? ☐ Prevalence or risk factors ☐ Cases/outbreaks ☐ Interventions ☐ None of the above, specify: ○ Not a LMF of interest ○ Not a microbial hazard of interest ○ A_w is >0.85 ○ Other, specify:_____________	Low moisture foods (LMF) – for the purposes of this study, refers to as any food item that has a water activity (a_w) level <0.85. Categories of LMF for inclusion: dehydrated/dried fruit and vegetables, cereals, dry protein products (**excluding infant milk formula**), confections, snacks, tree nuts, peanuts/peanut butter, seeds for consumption, spices and dried aromatic plants, lipid-based supplementary foods, and preserves (e.g. jams, honey). If a product is suspected of being a LMF (e.g. "dry fermented sausage") and the a_w level is not explicitly stated in the study, the study should be included. Microbiological hazards (MH) – for the purposes of this study, refers to Bacillus cereus, Clostridium botulinum, Clostridium perfringens, Cronobacter spp. (formally, Enterobacter sakazakii), Escherichia coli, Salmonella spp., Staphylococcus aureus, Listeria monocytogenes, and Enterobacteriaceae **NOTE:** Articles investigating "semi-dry" sausages without mention of a_w values should be considered a_w >0.85 and excluded.
2. Is the article written in English, French, or Spanish? ☐ Yes ☐ No, but abstract contains extractable data; specify article language:_________ ☐ No, none-English abstract or non-extractable data in abstract; specify language:_________	
3. What LMFs were investigated or discussed? ☐ Dried or dehydrated fruit and/or vegetables ☐ Nuts and nut products ○ Tree nuts ○ Peanuts and peanut-based products ☐ Cereals/grains ○ Whole and dried cereals/grains, and	

products thereof ○ Rice ☐ Dried protein products ○ Dried/fermented sausages/salamis ○ Dried meats/meat products other than sausages/salamis ○ Dried dairy products ○ Dried egg products ○ Dried fish/seafood products ☐ Confections ☐ Snacks ☐ Seeds for consumption ☐ Spices / dried aromatic plants / teas ☐ Lipid-based supplementary foods	
4. What microbial hazards were investigated or discussed? ☐ Bacillus cereus ☐ Clostridium botulinum ☐ Clostridium perfringens ☐ Cronobacter spp. (Enterobacter sakazakii) ☐ Escherichia coli ☐ Salmonella spp. ☐ Listeria monocytogenes ☐ Staphylococcus aureus ☐ Enterobacteriaceae	

Appendix E: Data Extraction Forms

Burden of illness extraction form

Question	Comments
1. Outbreak Ref: ☐ Outbreak database #: ☐ Distiller REFID: ☐ Source of info:	
2. What type of document is the article? ☐ Journal article ☐ Research report ☐ Conference proceedings ☐ Non-peer reviewed data from line listing, government report or other source ☐ Other:____________	Non-peer reviewed data from line listing, government report or other source (e.g. ProMed, Eurosurveillance, newspapers)
3. When did the outbreak occur? ☐ Enter year:___________	
4. Where did the outbreak occur? *Please specify exact country in separate column* ☐ Africa ☐ Asia ☐ Australia/New Zealand ☐ Europe ☐ North America ☐ Latin America/Caribbean ☐ Other:_____________ ☐ Not stated	
5. Specify exact country where outbreak occurred	
6. From what region did the implicated product originate? ☐ Africa ☐ Asia ☐ Australia/New Zealand ☐ Europe ☐ North America ☐ Latin America/Caribbean ☐ Other:_____________ ☐ Not stated ☐ N/A – same as outbreak location	

7. Specify exact country of origin	
8. How was the outbreak source confirmed? ☐ Laboratory ☐ Epidemiologically ☐ Other:______________	**Lab confirmed source** **Epi association to source**
9. What LMF product category was implicated?	
10. What specific product was implicated?	
11. Epidemiological association with the implicated product (if provided): *Paste in OR (and 95%CI)*	
12. What microbial hazard was implicated?	
13. What was the specific bacteria species/serovar?	
14. Extract quantitative outcomes ☐ No. presumed cases: ☐ No. confirmed cases: ☐ No. hospitalizations: ☐ No. deaths: ☐ No. exposed (if provided) ☐ Attack rate (if provided)	
15. How were the cases confirmed to be part of the outbreak? a. Laboratory b. Epidemiologically c. Other:______________	**Lab confirmed to be part of the outbreak** **Epi association to outbreak**
16. If provided, what was the concentration of the hazard in the implicated product (specify units)?	
17. Additional Comments.	

Prevalence extraction form

Question	Comments
1. REFID: ______	
2. What type of document is the article? ☐ Journal article ☐ Research report ☐ Conference proceedings ☐ Other:_____________	
3. First author's last name: Enter name:____________	
4. When was the article published? ☐ Enter year:____________	
5. When was the study conducted? ☐ Enter month/year to month/year:_________ ☐ Not reported	
6. Where was the study conducted? ☐ Africa ☐ Asia ☐ Australia/New Zealand ☐ Europe ☐ North America ☐ Latin America/Caribbean ☐ Other:______________ ☐ Not stated	
7. Specify exact country where study was conducted	
8. What was the study design? ☐ Prevalence survey ☐ Longitudinal prevalence ☐ Surveillance ☐ Challenge trial (ChT) ☐ Controlled trial (CT) ☐ Quasi-experiment (QE) ☐ Cohort study ☐ Case-control study (C-C) ☐ Cross-sectional study (XS) ☐ Case report or series ☐ Outbreak report/investigation ☐ Other, please specify:	Prevalence survey: A study that measures, and may describe (e.g. concentration), the degree of contamination of a LMF by one or more MH at a particular point in time. It does not investigate risk factors for contamination. Longitudinal prevalence: A study that measures, and may describe (e.g., concentration), the degree of contamination of a LMF by one or more MH over two or more time intervals. Samples may either be at the level of the location (e.g., supermarkets; processing facilities) or the product (e.g. a set of 10 dry-fermented sausages sampled three times over several weeks). It does not investigate risk factors for contamination.

	Surveillance: A system that continuously gathers, analyzes, and interprets data about diseases (or contamination of certain LMFs) and disseminates conclusions of the analyses to relevant organizations in a timely manner. Challenge trial: An experiment where LMF are artificially challenged or exposed to the MH for the purpose of characterizing the MH in the LMF. Controlled trial: An experiment where an intervention is applied to contaminated LMF or relevant environment(s) (e.g. processing facilities) for the purpose of reducing or eliminating the MH. Quasi-experimental: An experiment where an intervention is applied to contaminated LMF or relevant environment(s) (e.g. processing facilities) in a non-randomized fashion for the purpose of reducing or elimination the MH (e.g. Before and after trial) Cohort study: An observational study where multiple measurements of a sample population of LMF or affected persons or relevant environment(s) (e.g. processing facilities) are obtained over two or more time periods to identify risk factors for contamination with one or more MH. Can be either retrospective or prospective. Case-control study: An observational study where contaminated LMFs or affected persons or relevant environments (e.g. processing facilities) are matched with non-contaminated LMFs, affected persons or relevant environments, respectively, to identify risk factors for contamination with MH or vehicles of MHs. Cross-sectional study: An observational study where LMFs, or relevant environment(s) (e.g. processing facilities) are sampled for the purpose of identifying or characterizing the degree of contamination, as well as potential risk factors for contamination of one or more MH. Case report or series: A descriptive study that tracks affected persons with a foodborne disease for the purpose of identifying the

	aetiological agent (MH), vehicle of transmission (LMF) and source/point of contamination. Includes preliminary assessment that includes qualitative/quantitative questionnaires of affected persons, collection of clinical specimens, collection of food and environmental samples, but does not include further epidemiological investigation (e.g. case-controls).
9. Where was the sampling conducted? ☐ Farm ☐ Processing plant ☐ Retail/markets ☐ Ready-to-eat ☐ Import/export ☐ Research/lab facility ☐ Other:______________ ☐ Not reported	Farm: Location of commercial production/harvesting of LMF (e.g., farm, almond orchard, etc). (I.e., products that will later be sold to consumers). Commercial processing plant: Location of processing and/or packaging of LMF (e.g., dry sausage processing facility, facilities to process fresh spices and herbs into LMF products). Retail: Any location where consumers can purchase LMF (e.g., local grocery stores, supermarkets, farmer's markets, butcher's shops). Ready-to-eat: Locations that serve/offer LMF and products containing LMF that can be immediately consumed. (e.g., restaurants, delicatessens, cafeterias, buffets, etc.) Import/Export: LMF are sampled immediately before they leave the country of production or immediately after they enter the country of sale. Research/laboratory facility: Articles that report on a study sampling products in a laboratory setting.
10. Was the LMF product sampling representative of the larger/target population? ☐ Yes ☐ No	
Quantitative DE section – complete multiple rows for each study as appropriate for each product/hazard combination	
11. What LMF product category was measured?	

<table>
<tr><td>12. What specific product was measured?</td><td></td></tr>
<tr><td>13. What microbial hazard was measured?</td><td></td></tr>
<tr><td>14. What was the specific bacteria species/serovar?</td><td></td></tr>
<tr><td>15. From what region did the samples originate?
☐ Africa
☐ Asia
☐ Australia/New Zealand
☐ Europe
☐ North America
☐ Latin America/Caribbean
☐ Other:_____________
☐ Multiple
☐ Not stated
☐ N/A – same as study location</td><td></td></tr>
<tr><td>16. Specify exact country of origin</td><td></td></tr>
<tr><td>17. How was the outcome reported? Check al l that apply
☐ Prevalence
☐ Concentration (e.g. MPN or CFU counts)</td><td></td></tr>
<tr><td>18. Is raw/unadjusted data or measures of association/effect provided?
☐ Yes, for all outcomes
☐ Yes, for some outcomes, specify:_______
☐ No, specify reason:______________</td><td>Yes:
For prevalence data, the following data must be reported
• Numerator and denominator, or
• proportion + EITHER numerator or denominator
For measures of association/effect:
• OR/RR/IR/RD reported and its measure of variability (SE, SD, CI) or P-value is provided
For continuous measures:
• Mean value, sample size, and SD
• Mean value and SE/CIs

<u>Examples of no:</u>
a. Graphical data only
b. No reporting of raw results
c. Just median
d. Only p-value
e. Only denominator
f. Only numerator</td></tr>
<tr><td>19. What lab method was used to identify the microbial hazard?</td><td></td></tr>
</table>

☐ Culture ☐ PCR ☐ Other:________________	
20. Extract quantitative prevalence and concentration outcomes (each in a separate column) *Prevalence* ☐ Number positive ☐ Sample size *Concentration* ☐ Mean value ☐ Sample size ☐ SD ☐ SE ☐ Lower CI ☐ Upper CI ☐ Units (e.g. MPN, CFU):_______________	
21. Other comments:	

Interventions extraction form

Question	Comments
1. REFID:	
2. What type of document is the article? ☐ Journal article ☐ Research report ☐ Conference proceedings ☐ Other:____________	
3. First author's last name: Enter name:___________	
4. When was the article published? ☐ Enter year:___________	
5. When was the study conducted? ☐ Enter month/year to month/year:___ ☐ Not reported	
6. Where was the study conducted? ☐ Africa ☐ Asia ☐ Australia/New Zealand ☐ Europe ☐ North America ☐ Latin America/Caribbean ☐ Multiple ☐ Other:_____________ ☐ Not stated	
7. Specify exact country	
8. What was the study design? ☐ Prevalence survey ☐ Longitudinal prevalence ☐ Surveillance ☐ Challenge trial (ChT) ☐ Controlled trial (CT) ☐ Quasi-experiment (QE) ☐ Cohort study ☐ Case-control study (C-C) ☐ Cross-sectional study (XS) ☐ Case report or series ☐ Outbreak report/investigation ☐ Other, please specify:	Prevalence survey: A study that measures, and may describe (e.g. concentration), the degree of contamination of a LMF by one or more MH at a particular point in time. It does not investigate risk factors for contamination. Longitudinal prevalence: A study that measures, and may describe (e.g., concentration), the degree of contamination of a LMF by one or more MH over two or more time intervals. Samples may either be at the level of the location (e.g., supermarkets; processing facilities) or the product (e.g. a set of 10 dry-fermented sausages sampled three times over several weeks). It does not investigate risk factors for contamination.

	Surveillance: A system that continuously gathers, analyzes, and interprets data about diseases (or contamination of certain LMFs) and disseminates conclusions of the analyses to relevant organizations in a timely manner. Challenge trial: An experiment where LMF are artificially challenged or exposed to the MH for the purpose of characterizing the MH in the LMF. Controlled trial: An experiment where an intervention is applied to contaminated LMF or relevant environment(s) (e.g. processing facilities) for the purpose of reducing or eliminating the MH. Quasi-experimental: An experiment where an intervention is applied to contaminated LMF or relevant environment(s) (e.g. processing facilities) in a non-randomized fashion for the purpose of reducing or elimination the MH (e.g. Before and after trial) Cohort study: An observational study where multiple measurements of a sample population of LMF or affected persons or relevant environment(s) (e.g. processing facilities) are obtained over two or more time periods to identify risk factors for contamination with one or more MH. Can be either retrospective or prospective. Case-control study: An observational study where contaminated LMFs or affected persons or relevant environments (e.g. processing facilities) are matched with non-contaminated LMFs, affected persons or relevant environments, respectively, to identify risk factors for contamination with MH or vehicles of MHs. Cross-sectional study: An observational study where LMFs, or relevant environment(s) (e.g. processing facilities) are sampled for the purpose of identifying or characterizing the degree of contamination, as well as potential risk factors for contamination of one or more MH. Case report or series: A descriptive study that tracks affected persons with a foodborne disease for the purpose of identifying the aetiological agent (MH), vehicle of transmission (LMF) and source/point of contamination. Includes preliminary assessment that includes

	qualitative/quantitative questionnaires of affected persons, collection of clinical specimens, collection of food and environmental samples, but does not include further epidemiological investigation (e.g. case-controls).
9. Was the intervention conducted under field conditions? ☐ Yes ☐ No, laboratory-based under simulated commercial conditions ☐ No, laboratory-based not simulated conditions	Simulated conditions should be applicable or potentially applicable for implementation in a real-world setting.
Enter the following section on a separate row for each product/MH combination	
10. What LMF product category was investigated?	
11. What specific products were investigated?	
12. What microbial hazard was investigated?	
13. What was the specific bacteria species/serovar?	
14. What intervention(s) was investigated? *(For each category specify the exact intervention and dose/duration if available)* ☐ Change in storage conditions: ○ pH ○ a_w ○ Temperature ☐ Starter culture ☐ Inactivation/lethality step: ○ Heat treatment ○ High-hydrostatic pressure ○ Irradiation ○ Ozone ○ Chemical(s):______ ○ Other:_____ ☐ Other:_________	
15. At what level in the food chain is the intervention designed to be applied? ☐ Farm ☐ Processing plant	<u>Farm:</u> Location of commercial production/harvesting of LMF (e.g., farm, almond orchard, etc). (I.e., products that will later be sold to consumers).

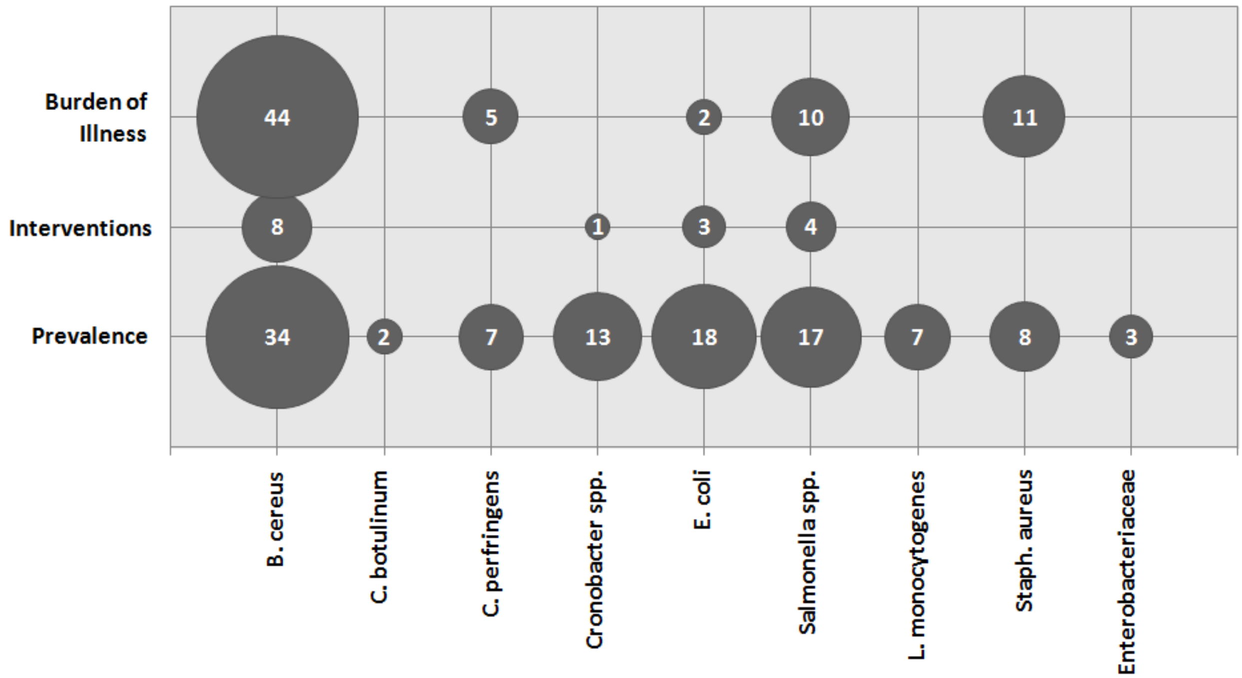
☐ Storage ☐ Retail ☐ Ready-to-eat ☐ Other:_____________	Commercial processing plant: Location of processing and/or packaging of LMF (e.g., dry sausage processing facility, facilities to process fresh spices and herbs into LMF products). Retail: Any location where consumers can purchase LMF (e.g., local grocery stores, supermarkets, farmer's markets, butcher's shops). Ready-to-eat: Locations that serve/offer LMF and products containing LMF that can be immediately consumed. (e.g., restaurants, delicatessens, cafeterias, buffets, etc.)
16. For this LMF/ microbial hazard/intervention combination, was there a significant effect? ☐ Significant ($P<0.05$) ☐ Non-significant ($P\geq0.05$) ☐ No differences assessed	Significant: Differences to the microbial levels in the product were significantly impacted by this intervention. Non-significant: There was no significant difference in the microbial hazard reported.
17. For this LMF/ microbial hazard/intervention combination, what was the direction of effect (regardless of significance)? ☐ Treatment effective ☐ Treatment not effective ☐ Not measured	
18. How was the outcome reported? *Check all that apply* ☐ Prevalence ☐ Concentration (e.g. MPN or CFU counts) ☐ D value ☐ Other:______________	
19. What lab method was used to identify the microbial hazards? ☐ Culture ☐ PCR ☐ Other:_______________	
20. Is raw/unadjusted data or measures of association/effect provided? ☐ Yes, for all outcomes ☐ Yes, for some outcomes, specify:________ ☐ No, specify reason:______________	**Yes:** For prevalence data, the following data must be reported • Numerator ***and*** denominator, ***or*** • proportion + EITHER numerator or denominator For measures of association/effect: • OR/RR/IR/RD reported ***and*** its measure of variability (SE, SD, CI) *or* P-value is provided

	For continuous measures: • Mean value, sample size, and SD • Mean value and SE/CIs <u>Examples of no:</u> a. Graphical data only b. No reporting of raw results c. Just median d. Only p-value e. Only denominator f. Only numerator
21. What was the sample size?	
22. Additional comments:	

Appendix F: Summary Card Evidence Charts

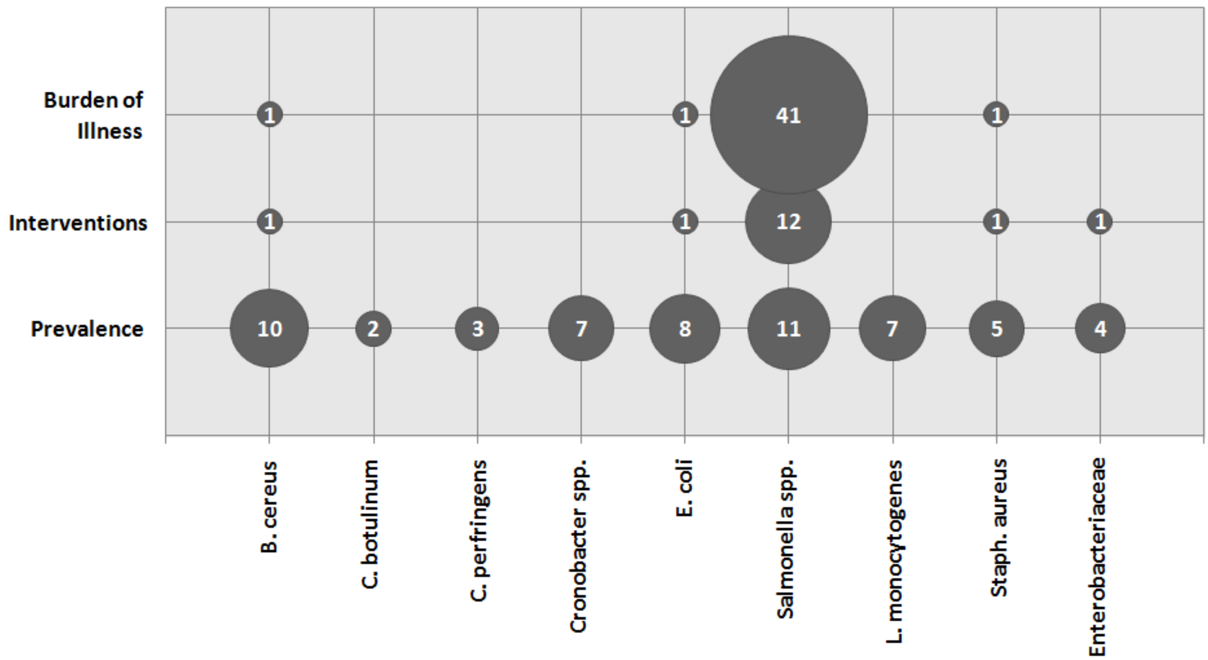
Cereals and Grains

Bubble size is proportional to the total number of articles and reports (Total N=142).



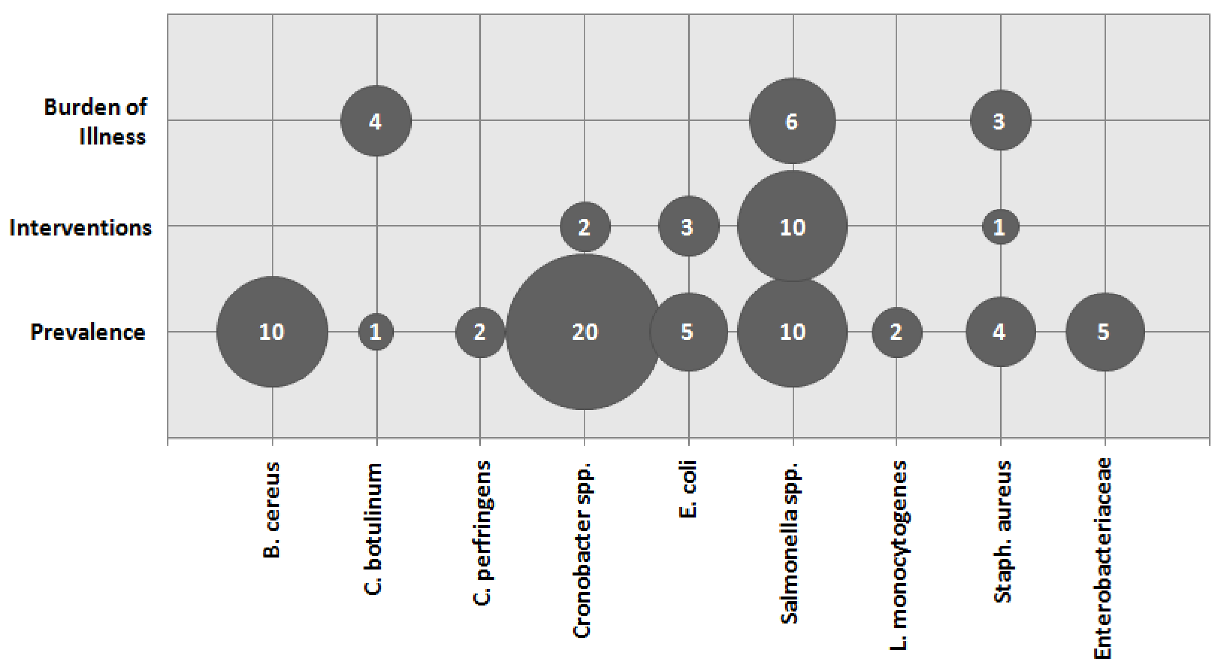
Confections and Snacks

Bubble size is proportional to the total number of articles and reports (Total N=87).



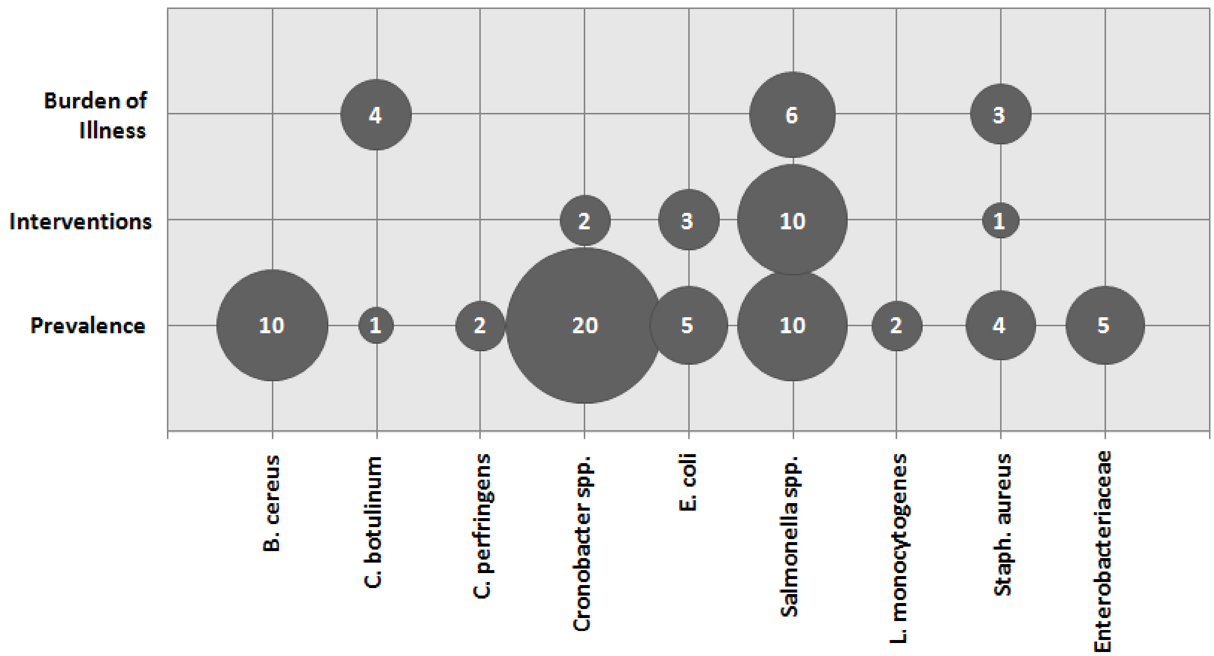
Dried Fruits and Vegetables

Bubble size is proportional to the total number of articles and reports (Total N=39).



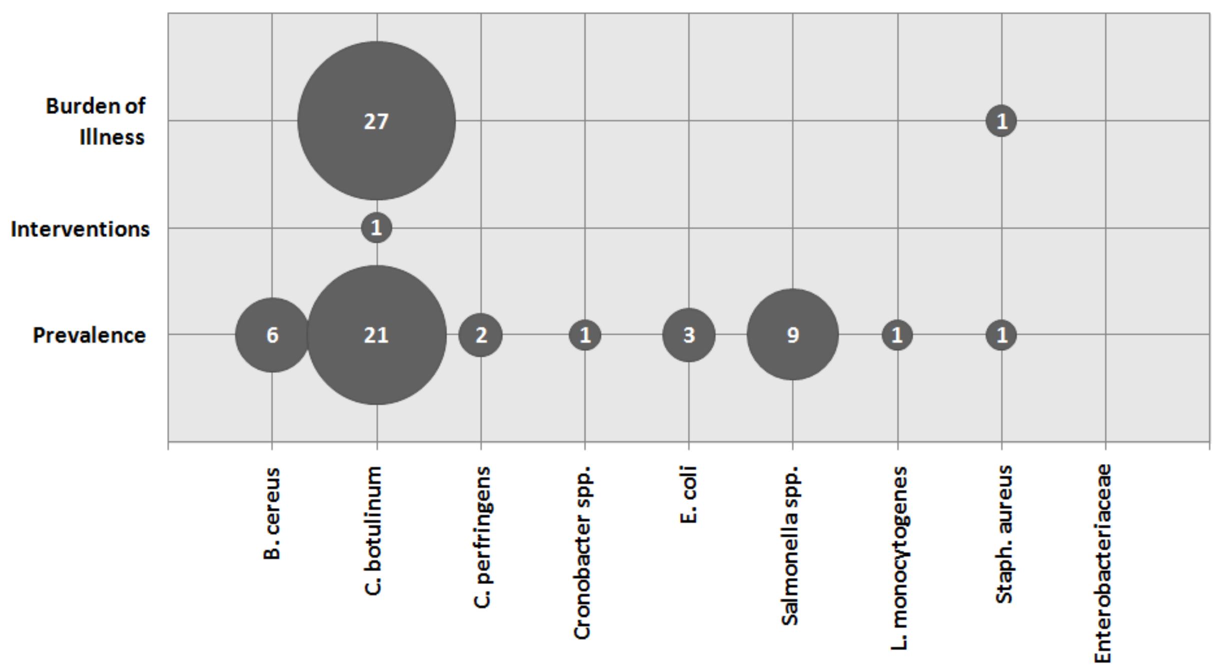
Dried Protein Products

Bubble size is proportional to the total number of articles and reports (Total N=66).



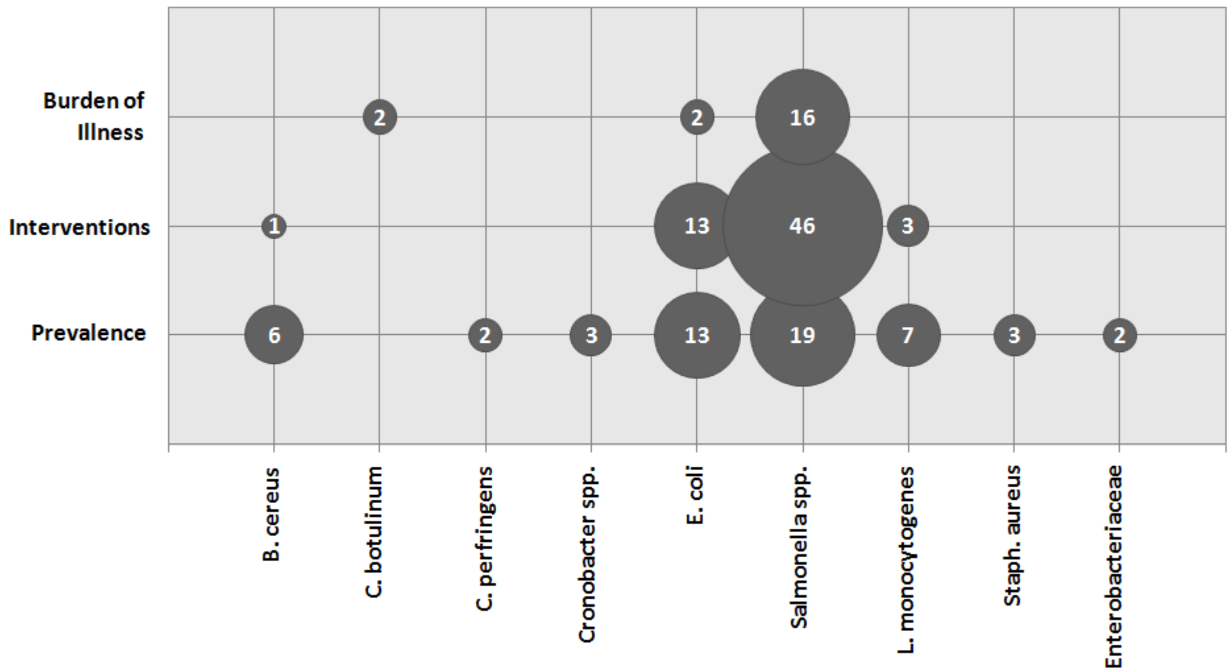
Honey and Preserves

Bubble size is proportional to the total number of articles and reports (Total N=58).



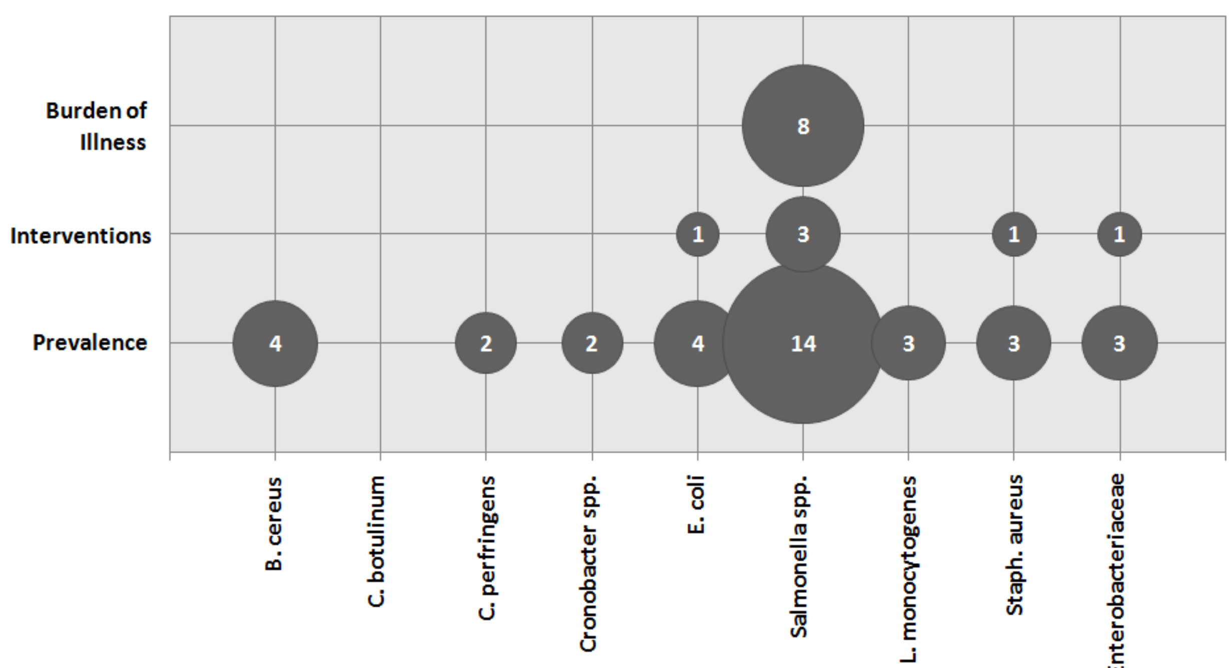
Nuts and Nut Products

Bubble size is proportional to the total number of articles and reports (Total N=95).



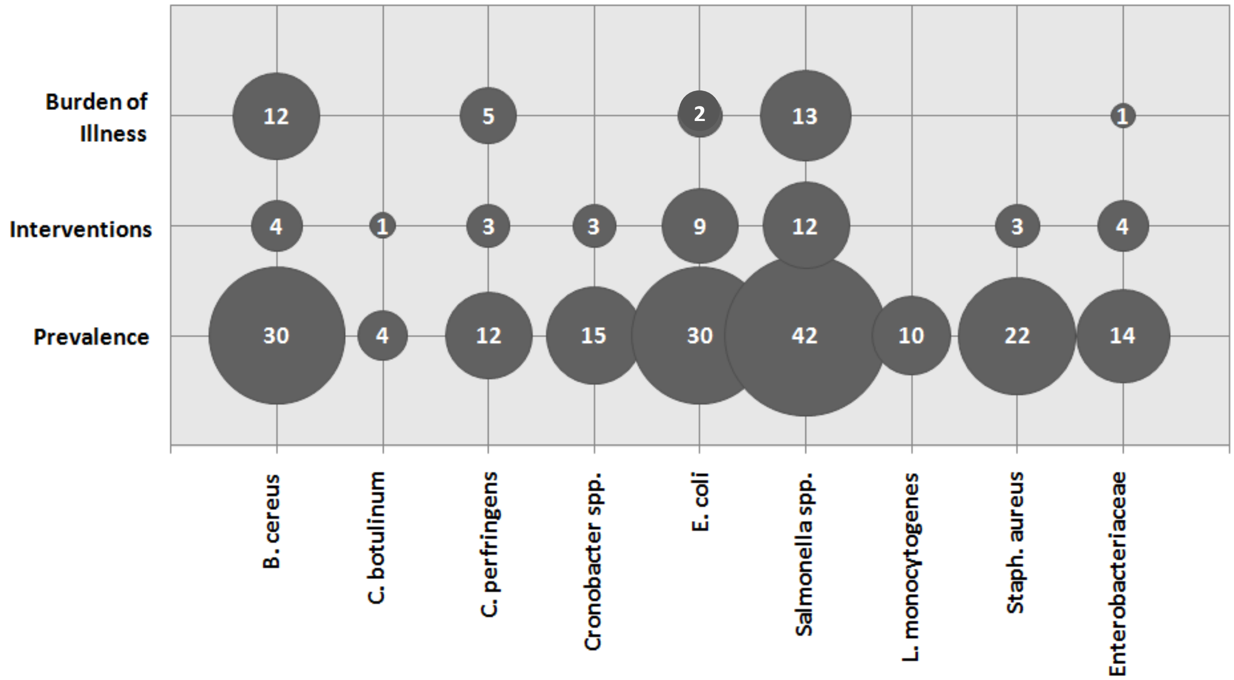
Seeds for Consumption

Bubble size is proportional to the total number of articles and reports (Total N=28).



Spices, Dried Herbs and Tea

Bubble size is proportional to the total number of articles and reports (Total N=129).



Appendix G: Spice Classification Table

Category	Product subcategory[a]	Specific products/notes
Fruit/seed	*Capsicum* spp.	Paprika, cayenne pepper, chili peppers, other hot and sweet dried capsicum peppers
	Piper spp.	Black, white, green, long pepper
	Apiaceae	Family of aromatic plants including: aniseed, caraway, celery, coriander, dill seed, fennel, chervil
	Allspice	
	Cumin	Also part of Apiaceae family but separated due to large amount of prevalence data available
	Nutmeg/mace	
	Other	Cardamom, fungreek, mustard, sumac, star anise, ajmud, Bishop's weed/ajowan, Juniper
Root	Garlic	
	Ginger	
	Turmeric	
	Other	Galangal, onion, asafoetida
Herbs/leaves	*Origanum* spp.	Oregano and marjoram
	Basil	
	Bay leaf	
	Other	Mint, rosemary, parsley, sage, thyme, dill weed/leaves, African spider herb
Bark/flower	Cinnamon	
	Cloves	
	Saffron	
	Other	Geranium, safflower
Mixes/ unspecified	Curry powder	
	Indian spices	Garam masala, tandoori
	Herb mixes	Herbs de province, other/unspecified
	Unspecified/mixed spices	
Teas	Herbal	Chamomile, spearmint, peppermint, lemon balm, linden flower, common nettle, St. John's wart, hibiscus, Jews mallow
	Other/unspecified	Black, green, rooibos

[a] NOTE: Raw data has been classified to this level, but prevalence summaries (and meta-analyses) presented in subsequent sections are at the category level.

Appendix H: Articles Reporting Non-extractable Concentration Data and Prevalence in Batch Samples for Spices, Dried Herbs and Tea

Articles reporting non-extractable concentration data for selected microbial hazards in spices

Spices/teas investigated	Microbial hazards investigated	Sources
Aniseed, basil, black pepper, caraway, celery, coriander, cumin, dill, fennel, geranium, marjoram, parsley, saffron, tea	*E. coli, S. aureus, Salmonella* spp.	Abou (2008)
Ajmud, allspice, aniseed, asafoetida, black pepper, Bishop's weed, caraway, cardamom, chili powder, cloves, coriander, cumin, fenugreek, garlic, ginger, mustard, tejpat, turmeric	*B. cereus, E. coli,* Enterobacteriaceae, *S. aureus, Salmonella* spp.	Banerjee (2003)
Allspice, black pepper, cinnamon, cumin, red pepper	Enterobacteriaceae	Beki (2008)
Unspecified/mixed spices and herbs	Enterobacteriaceae	Baumgartner (2009)
Tea - herbal	*C. botulinum*	Bianco (2008)
Tea - herbal	*C. botulinum*	Bianco (2009)
Bay leaves, black pepper powder, chili powder, cloves, curry powder, garlic, ginger, paprika, white pepper	*C. perfringens, E. coli, S. aureus, Salmonella* spp.	Candlish (2001)
Unspecified/mixed spices and herbs	*C. botulinum*	Carlin (2004)
Red pepper	*B. cereus*	Choo (2007)
Tea - herbal	*E. coli*	Cioanca (2011)
Saffron	*B. cereus, C. perfringens, E. coli,* Enterobacteriaceae, *S. aureus, Salmonella* spp.	Cosano (2009)
Unspecified/mixed spices and herbs	*B. cereus*	Daelman (2013)
Caraway, chili powder, cloves, coriander, cumin, fennel, fenugreek, garam masala, ginger, mustard, nutmeg, mixed spices, sumac, tandoori, turmeric	*B. cereus, C. perfringens*	Department of Health, State Government of Victoria, Australia (2007)
Unspecified/mixed spices and herbs	*E. coli*	Dogan-Halkman (2003)
Black pepper	*B. cereus, E. coli, S. aureus, Salmonella* spp.	Erdogdu (2013)
Tea - black	*B. cereus, E. coli,* Enterobacteriaceae, *S. aureus, Salmonella* spp.	Favet (1992)
Black pepper powder, white pepper	*B. cereus, Cronobacter* spp., *E.*	Freire (2002)

	coli, S. aureus	
Allspice, black pepper powder, coriander, cumin, ginger, red pepper, white pepper	*B. cereus, E. coli, S. aureus*	Hampikyan (2009)
Black pepper powder, cinnamon, chili powder, masala	*S. aureus*	Ijabadeniyi (2013)
Unspecified/mixed spices and herbs	Enterobacteriaceae, *Cronobacter* spp	Iverson (2004)
Red pepper	*B. cereus*, Enterobacteriaceae	Jeong (2010)
Black pepper, cumin, peppermint, red pepper, thyme	*B. cereus, E. coli, S. aureus, Salmonella* spp.	Kahraman (2009)
Unspecified/mixed spices and herbs	Enterobacteriaceae	Kandhai (2010)
Saffron	*E. coli, S. aureus*	Khazaei (2011)
Allspice, aniseed, basil, black pepper, caraway, cardamom, cayenne pepper, chervil, chili powder, Chinese five spice, cinnamon, cloves, coriander, curcuma, curry powder, dill, fennel, ginger, green pepper powder, Herbs de provence, Juniper, marjoram, mint, nutmeg, oregano, paprika, Peruvian pepper, rosemary, saffron, sage, mixed spices, sumac, tandoori, thyme, white pepper	Enterobacteriaceae	Kneifel (1994)
Unspecified/mixed spices and herbs	*B. cereus, Salmonella* spp.	Little (2003)
Red pepper	*B. cereus*	Oh (2012)
Unspecified/mixed spices and herbs	*C. perfringens, E. coli*	Osmar Aguilera (2005)
Unspecified/mixed spices and herbs	*E. coli*	Rampersad (1999)
Bay leaves, black pepper powder, cumin, garlic, oregano	*C. perfringens*	Rodriguez-Romo (1998)
Unspecified/mixed spices and herbs	*B. cereus*	Rusul (1995)
Unspecified/mixed spices and herbs	*B. cereus, C. perfringens, S. aureus*	Sheth (2000)
Bay leaves, black pepper powder, cayenne pepper, cumin, dill, mint, oregano, white pepper	Enterobacteriaceae	Sospedra (2010)
Unspecified/mixed spices and herbs	*B. cereus*	Te Giffel (1996)

Articles reporting the prevalence of selected microbial hazards in batch/shipment samples of spices

Spices/teas investigated	Microbial hazards investigated	Sources
Unspecified/mixed spices and herbs	*Salmonella spp.*	EFSA/ECDC (2010)
Unspecified/mixed spices and herbs	*Salmonella spp.*	EFSA/ECDC (2011)
Unspecified/mixed spices and herbs	*Salmonella spp.*	EFSA/ECDC (2012)
Unspecified/mixed spices and herbs	*L. monocytogenes*	EFSA/ECDC (2013)
Unspecified/mixed spices and herbs	*B. cereus, C. perfringens, Salmonella* spp.	Food Safety Authority of Ireland (2005)
Black pepper powder, cinnamon, cumin, oregano	*Salmonella* spp.	Rodriguez (1991)
Unspecified/mixed spices and herbs	*B. cereus, C. perfringens, E. coli*	Sagoo (2009)
Capsicum spp.	*Salmonella* spp.	Van Doren (2013)

RANKING OF LOW MOISTURE FOODS IN SUPPORT OF MICROBIOLOGICAL RISK MANAGEMENT

REPORT OF AN FAO/WHO CONSULTATION PROCESS

Preliminary Report

30th October

2014

PART III – APPENDICES 2-8

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

2014

APPENDIX 2: SUMMARY OF RECALL DATA ON LOW MOISTURE FOODS

Table A2.1: EU-RASFF- Recall /border rejections of LMF as a result of contamination with microbiological hazards (2010 to June 2014) (EU, 2014)

Product category	Microbial hazard	Recall-rejection frequency / year				
		2010	2011	2012	2013	2014
Cereal and Grains	*Salmonella* spp.	-	-	1[1]	1[2]	-
	L. monocytogenes	-	-	-	1 [3]	-
	Bacillus cereus	-	1 [4]	-	-	-
	Cronobacter sakazakii	-	-	1[5]	-	-
Confections and Snacks[6]	*Salmonella* spp.	1	-	1	1	1
Dried Fruits and Vegetables	*Salmonella* spp.[7]	-	1	1	2	4
	L. monocytogenes[8]	-	-	-	1	1
	Bacillus spp.	-	-	-	1	-
	B. cereus[9]	-	-	2	2	-
Dried Protein products	*Salmonella* spp.[10]	1	1	-	3	1
	Salmonella spp. + *Cronobacter sakazakii*[11]			1		
	L. monocytogenes[12]	-	-	-	1	-

[1]Linked to organic bread meal mix
[2] Linked to muesli with nuts
[3] Linked to pasta tortellini so unclear if pasta or filling
[4] Linked to couscous
[5] Linked to rice cereal for children
[6] Products included mini marshmallow, maltodextrin, galacto-oligosacaride and chocolate bar with coconut
[7] Three recalls linked with dried black mushrooms, 1 with dried sliced mushroom, 1 with chlorella algae powder, 1 dried chlorella algae, 1 dehydrated red onions and 1 moringa powder
[8] Both recalls linked enoki mushrooms
[9] Recalls were linked to dried mushrooms, dried mulberries and dates.
[10] Five recalls were linked to dry sausages, and the other two were skimmed milk powder, and soy protein product
[11] Recall was associated with dried infant formulae

Nut and Nut Products	*Salmonella* spp[13].	5	3	9	4	1
	B. cereus + *Enterococcus*[14]				1	
	Faecal Streptococci[14]	-	-	6	-	-
Spices Dried Herbs and Tea[15]	*Salmonella* spp.	3	14	21	14	9
	Bacillus cereus	-	4	2	3	3
	Escherichia coli	-	-	-	1	1
	C. perfringens + *B. cereus* + *Salmonella*	-	1	-	-	-
	Enterobacteriaceae	-	1	-	1	-
Seeds for Consumption	*Salmonella* spp[16].	1	2	11	9	6
	B. cereus + *Salmonella* + Enterobacteriaceae	-	1	-	-	-
Honey and Preserves	-	-	-	-	-	-

Table A2.2: US FDA Recalls (USA market) of LMF from 2009 up to June 2014 related to microbial hazards (USFDA, 2014a)

Product category	**Microbial hazard**	**Recall frequency / year**					
		2009	**2010**	**2011**	**2012**	**2013**	**2014**
Cereal and	*Salmonella* spp[17].	-	2	1		2	-

[12] Recall associated with dried sausage
[13] 11 recalls were for pine nuts, 9 for coconut flour/desiccated coconut and 2 for hazelnuts.
[14] Implicated product was coconut flour/desiccated coconut
[15] Recalls mainly linked to of cumin, curry, oregano, black pepper, spice mix, ginger powder and basil.
[16] 26 of these recalls were for sesame seeds and Tahini

Grains	*L. monocytogenes*[18]	-	-	-	2	-	-
Confections and Snacks	*Salmonella* spp.[19]	4	12	1	17		1
	Bacillus cereus[20]	-	-	1	-		-
	C. botulinum[21]	-	-	2	-		-
	S. aureus[22]		1				
	L. monocytogenes	-	-		-	1	-
Dried Fruits / Vegetables	*Salmonella* spp[23].	-	1	-	1	-	-
Dried Protein products	*Salmonella* spp.[24]	5	5	2	3	-	-
	C. botulinum[25]	-	2	-	-	-	-
Nut and Nut Products	*Salmonella* spp.[26]	485	6	5	20	3	
	E. coli 0157:H7[27]	-	-	1	-	-	-
	L. monocytogenes[28]	-	-	-	-	-	3
Spices, Dried Herbs, Tea	*Salmonella* spp.	5	20	2	5	1	7
Seeds for	*Salmonella* spp.[29]	-	2	-	1	2	3

[17] Recalls were for cereal, baking mix and soybean flour
[18] Recalls were associated with popcorn and cake
[19] Recalls were linked to a range of products included snack mix, candy and bars containing peanut or peanut butter; corn chips, cookies, snack crackers
[20] Recall of cookies
[21] Recall of black bean tortilla
[22] Recall of gingerbread houses
[23] Recalls of vegetable soup mix and prune concentrate dietary supplement
[24] Recalls were of nonfat milk powder, prebiotic formula powder, kids powder dietary supplements, powdered protein products, whey protein isolate, instant beef soup mix, gravy mix, protein bistro box
[25] Recalls of dried fish and dried seafood products
[26] Almost all of the recalls were due to peanuts and pistachios contaminated with *Salmonella* spp. Many companies recalled related products containing the suspected peanut or pistachios.
[27] Hazelnuts and mixed nuts
[28] Walnuts

Consumption							
Honey and Preserves	-	-	-	-	-	-	-

Table A2.3: US FDA Import Refusals of LMF as a result of microbial contamination frequency (USA) from 2012 up to 2014. Note that product is the most routinely sampled and tested for *Salmonella* spp.. Sampling for other microbes is determined by the product's risk category (USFDA, 2014b).

Product category	**Microbial hazard**	**Refusal frequency (%) / year**		
		2012	2013	**2014**
Cereal and Grains[30]	*Salmonella* spp.	10	4	1
Confections and Snacks	*Salmonella* spp.	25	20	11
Dried Fruits / Vegetables[31]	*Salmonella* spp.	5	4	1
Dried Protein products	-	-	-	-
Nut and Nut Products	*Salmonella* spp.	4	14	3
	Vibrio cholerae[32]	1	2	-
	Listeria +*Salmonella* +*V. cholerae*[32]	-	1	-
Spices, Dried Herbs, Tea	*Salmonella* spp.	226	229	80

29 Recalled products included chia seed powder, sesame seeds and tahini sesame paste

30 Products recalled included products included instant noodles, barley flour, mixed cereal, soybean flour, grain, oat flakes, bread rolls.

31 Products recalled products included dried tomatoes, dried spinach, dried berry, dried fungus and vegetables

32 Linked to Coconut

Seeds for Consumption[33]	*Salmonella* spp.	17	13	7
Honey and Preserves	-	-	-	-

REFERENCES

EU [European Union]. 2014. Food and Feed Safety Alerts. Available at http://ec.europa.eu/food/safety/rasff/index_en.htm

USFDA. 2014a. Recalls, Market Withdrawels and Safety Alerts. Available at http://www.fda.gov/Safety/Recalls/

USFDA. 2014b. Import Refusals. Available at http://www.fda.gov/forindustry/importprogram/importrefusals/default.htm

[33] Products recalled included sesame seeds, sesame seed paste, pumpkin seeds, melon seeds, and lotus seed.

APPENDIX 3 – TECHNICAL DETAILS OF THE MCDA RANKING APPROACH

STEP 1: IDENTIFICATION OF FUNDAMENTAL OBJECTIVES

The first step in the identification of fundamental objectives was the development, of a means-end network of objectives (Keeney 1996; Montibeller & Belton 2006). This helped the experts to consider the links between means available to mitigate risks (bottom of the diagram in Figure A3.1) and ends that policy makers are pursuing (top of the diagram in Figure A3.1), as well as the links between the former and the latter. For example, according to the diagram, knowing the pathogen of concern, leads to knowledge on the root of contamination, which leads to knowledge on how to control exposure, which is a means to minimise the burden of disease and, therefore increase the confidence in the health system (an ultimate objective). The objectives on the top, with only in-arrows, are ultimate objectives to be achieved by an adequate management of LMF risks, which are reducing the cost of the health systems, confidence in the health system and perceived safety of food, reducing costs to the food industry and improving countries' economies. As can be seen in Figure A3.1 below, four fundamental objectives in terms of achieving these have been identified. These are minimizing the burden of foodborne disease, facilitating international trade and several descriptors relating to production and consumption of the food.

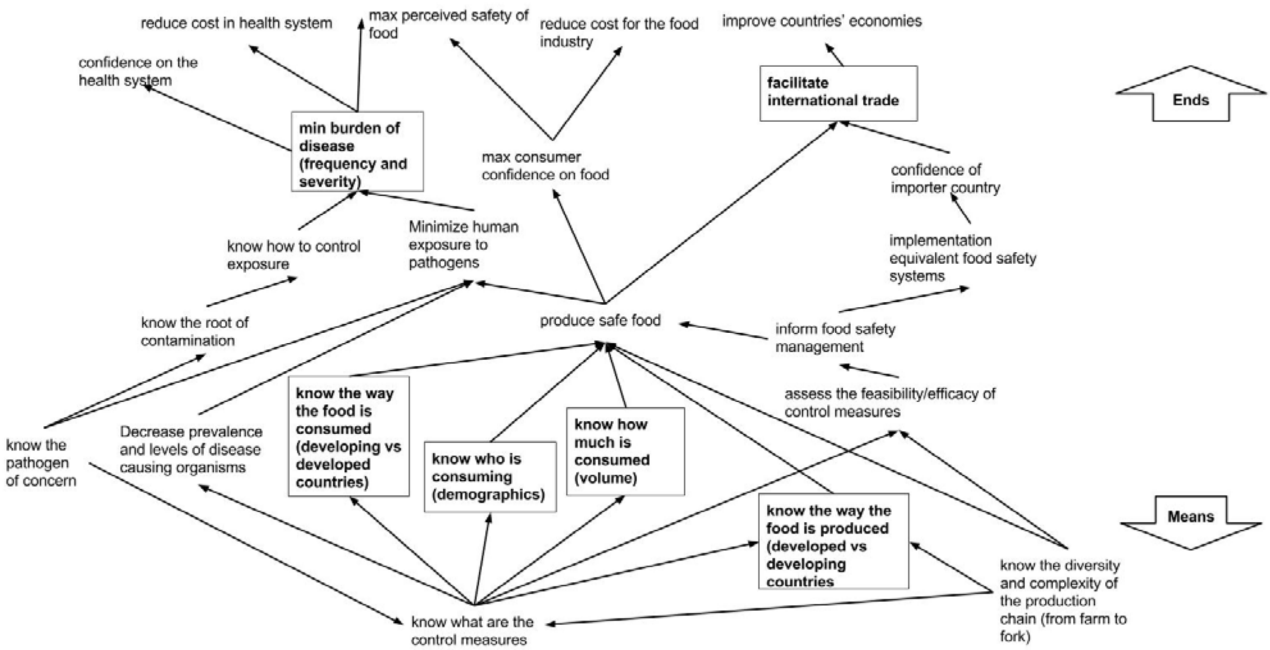


FIGURE A3.1. MEANS-END NETWORK OF OBJECTIVES FOR MANAGING LMF RISKS.

STEP 2: DEFINITION OF EVALUATION CRITERIA

The evaluation criteria associated with the fundamental objectives must observe a strict set of properties, to enable a quantitative multi-criteria value model to be built up (Keeney 1996; Belton & Stewart 2002; Franco & Montibeller 2011), which were checked in this step of the project:

- *Essential and Complete*. They should consider all the fundamental objectives involved in the evaluation.
- *Understandable*. They should have a clear meaning for all the members of the expert group involved in the evaluation.
- *Operational*. It should be possible to gather evidence about the options being assessed.
- *Non-redundant*. They should not measure the same concern twice.
- *Concise*. It should be the smallest number of objectives required for the analysis.
- *Preferentially independent*. If it is possible to measure the performance of options on one criterion disregarding their performance on all other criteria, then a simple weighted sum can be used to aggregate the impacts.

STEP 3: DEFINITION OF ATTRIBUTES

There were two types of attributes employed in this ranking exercise:

- *Natural attributes*: they measure directly the concern expressed by the objective, are of general use and have a common interpretation (e.g US$ billion/year of trade for assessing the fundamental objective International Trade).
- Proxy attributes: they measure indirectly the concern expressed by the fundamental objective, by assessing the degree of achievement of its associated means objective (e.g. proportion without a kill step to assess the vulnerability of a LMF category to contamination during food production).

Whenever available natural attributes were used, as they reduce the ambiguity of the assessment and measure directly the concern expressed by the fundamental objective (Keeney & Gregory 2005). Proxy attributes were carefully selected or developed to assess as directly as possible the impact of concern.

STEP 4: EVIDENCE GATHERING ABOUT IMPACTS

Details of data and evidence collection and use are provided in Appendices 4 to 7.

STEP 5: EVALUATION OF NORMALISED IMPACTS

The scale for measuring the normalised impact of each LMF category on every attribute was normalised between 0 (for the lowest impact) to 100 (for the highest impact). This is therefore a linear function, with the properties associated with multi-attribute value theory (Dyer & Sarin 1979).

STEP 6: ELICITATION OF CRITERIA WEIGHTS

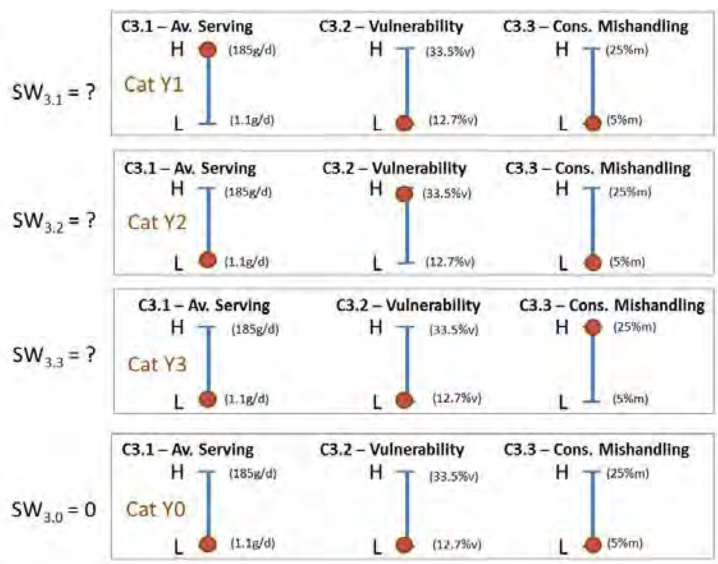
Elicitation of the Weights for Sub-Criteria under Food Consumption (C3)

The experts were presented with a set of hypothetical LMF categories (notice that these categories might not exist in practice) as shown in Figure A3.2, considering the lower and upper bound of each attribute. For example, the hypothetical LMF category Y1 has the highest (H) level on the Average Serving sub-criteria (C3.1) and the lowest (L) level on all the other criteria. The LMF category Y0 has all impacts at the lowest level.

The hypothetical LMF category with all impacts at the lowest level (Y0) receives a score of zero (swing weight $SW_{3.0} = 0$)**.** Participants were asked to identify among the other hypothetical LMF categories (Y1, Y2, or Y3) which one had the most serious impact. Two categories were selected by them – Y1 and Y2 – and thus received a score of 100 (baseline swing weights): $SW_{3.1} = 100$; $SW_{3.2} = 100$. The baseline swing weight of the next category (Y3) was defined within these two extreme anchors by the group as $SW_{3.3} = 30$.

These baseline swing weights (SW's) are then normalised into baseline weights (w's) so they sum up 1 as follows: $w_{31} = SW_{31}/\sum SW_{3i} = 100/230 = 43.5\%$; $w_{32} = SW_{32}/\sum SW_{3i} = 100/230 = 43.5\%$; $w_{33} = SW_{33}/\sum SW_{3i} = 30/230 = 13.0\%$.

There were some differences of opinions among experts in their individual estimates, with the ranges defined as: $SW_{3.1} = [70,100]$; $SW_{3.2} = [70,100]$; $SW_{3.3} = [30,70]$. For the normalised weights the equivalent ranges were therefore: $w_{31} = [35.0\%,43.5\%]$; $w_{32} = [35.0\%,43.5\%]$; $w_{33} = [13.0\%, 25.9\%]$. The ranges are obtained when a certain SW is altered (e.g. $SW_{3.1}$ is changed from 100 to 70) keeping the other SWs (e.g. $SW_{3.2}$ and $SW_{3.3}$) constant.



SW	(range)	Normalized value(%)	(range)
100	(70, 100)	43.5	(35.0, 43.5)
100	(70, 100)	43.5	(35.0, 43.5)
30	(30-70)	13.0	(13.0, 25.9)
0	-	-	-

FIGURE A3.2. HYPOTHETICAL LMF CATEGORIES FOR THE ELICITATION OF WEIGHTS FOR THE SUB-CRITERIA UNDER C3.

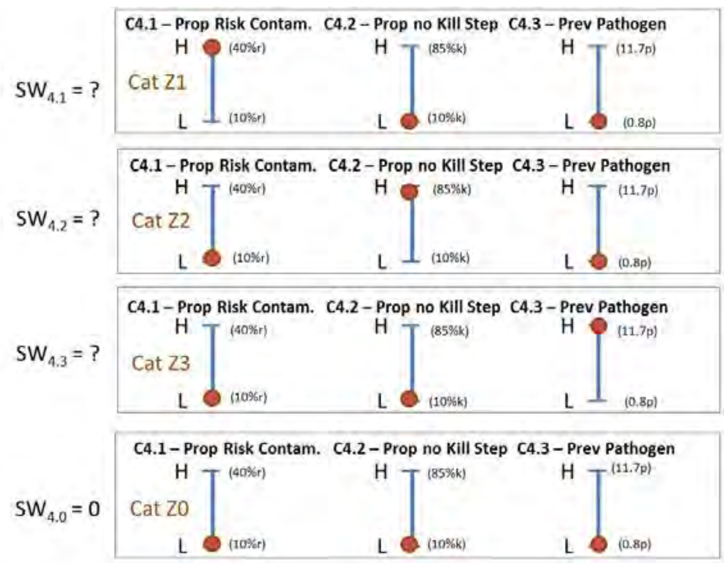
Elicitation of the Weights for Sub-Criteria under Food Production (C4)

The same procedure detailed above was employed for eliciting the weights for the sub-criteria under the Food Production Criterion (C4). The experts were presented with a set of hypothetical LMF categories as shown in Figure A3.3, considering the lower and upper bound of each attribute.

The hypothetical LMF category Z0 received a swing weight of zero ($SW_{4.0} = 0$). The experts were asked to identify among the other hypothetical LMF categories (Z1, Z2, or Z3) which one has the most serious impact. The category Z3 was selected and thus the baseline swing weight set as $SW_{4.3} = 100$. The second most serious category was, according to the group, Z2 and the baseline swing weight was defined by the experts as $SW_{4.2} = 70$. The third most serious category was Z1 with the baseline swing weight defined by the group as $SW_{4.1} = 40$.

These baseline swing weights were then normalised into baseline weights so they sum up 1 as follows: $w_{41} = SW_{41}/\sum SW_{4i} = 40/210 = 19.0\%$; $w_{42} = SW_{42}/\sum SW_{4i} = 70/210 = 33.3\%$; $w_{43} = SW_{43}/\sum SW_{4i} = 100/210 = 47.6\%$.

There were some differences of opinions among experts, regarding the swings for the first and second sub-criterion with the ranges defined as: $SW_{4.1} = [30, 50]$; $SW_{4.2} = [60, 80]$. For the normalised weights the equivalent ranges were therefore: $w_{4.1} = [15.0\%, 22.7\%]$; $w_{4.2} = [30.0\%, 36.4\%]$.



SW	(range)	Normalized value(%)	(range)
40	(30, 50)	19.0	(14.0, 22.7)
70	(60, 80)	33.3	(30.0, 36.4)
100	-	47.6	-
0	-	-	-

FIGURE A3.3. HYPOTHETICAL LMF CATEGORIES FOR THE ELICITATION OF WEIGHTS FOR THE SUB-CRITERIA UNDER C4.

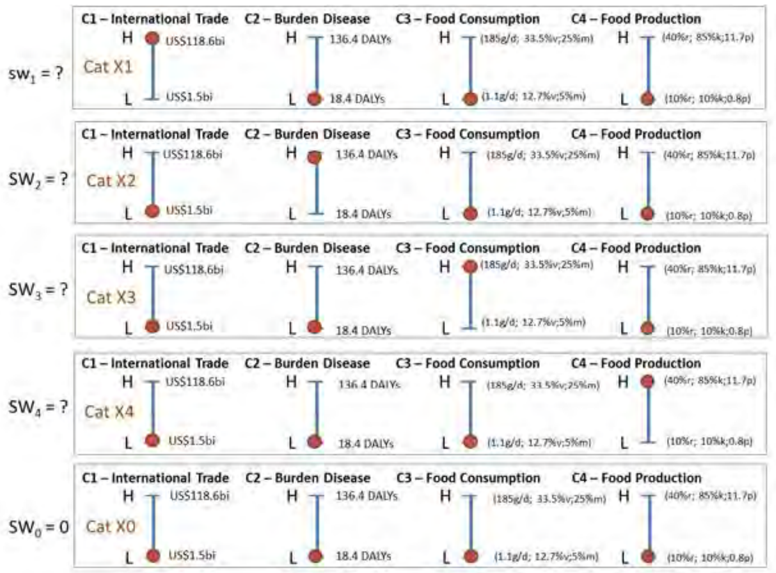
ELICITATION OF THE WEIGHTS FOR THE MAIN CRITERIA

The same procedure was employed for eliciting the weights for the four main criteria of the model. The experts were presented with a set of hypothetical LMF category as shown in Figure A3.4, considering the lower and upper bound of each attribute.

The hypothetical LMF category X0 received a swing weight of zero ($SW_0 = 0$). Participants were asked to identify among the other hypothetical LMF categories (X1, X2, X3, or X4) which one had the most serious impact. Category X2 was selected by the experts and thus the baseline swing weight set as $SW_2 = 100$. The second most serious category according to them was X4 and the baseline swing weight was defined by the experts as $SW_4 = 75$. The third most serious category was X3 with the baseline swing weight defined by them as $SW_3 = 50$. The fourth most serious category was X1 with the baseline swing weight of $SW_1 = 45$ by the group.

These baseline swing weights were then normalised into baseline weights: $w_1 = SW_1/\sum SW_i = 45/270 = 16.7\%$; $w_2 = SW_2/\sum SW_i = 100/270 = 37.0\%$; $w_3 = SW_3/\sum SW_i = 50/270 = 18.5\%$; $w_4 = SW_4/\sum SW_i = 75/270 = 27.8\%$.

There were some differences of opinions among experts, regarding the swings for the first, third and fourth criteria, with the ranges defined as: $SW_1 = [30, 60]$; $SW_3 = [40, 65]$; $SW_4 = [70, 80]$. For the normalised weights the equivalent ranges were therefore: $w_1 = [11.8\%, 21.1\%]$; $w_3 = [15.4\%, 22.8\%]$; $w_4 = [26.4\%, 29.1\%]$.



SW	(range)	Normalized value(%)	(range)
45	(30, 60)	16.7	(11.8, 21.1)
100	-	37.0	-
50	(40, 65)	18.5	(15.4, 22.8)
75	(70, 80)	27.8	(26.4, 29.1)
0	-	-	-

FIGURE A3.4. HYPOTHETICAL LMF CATEGORIES FOR THE ELICITATION OF WEIGHTS FOR MAIN CRITERIA.

STEP 8 ROBUSTNESS ANALYSIS

SENSITIVITY TO CRITERIA WEIGHTS – SUB-CRITERIA OF THE MODEL

We first analyse the three sub-criteria that decompose Criterion C3 (Food Consumption), followed by the three sub-criteria that decompose Criterion C4 (Food Production). We start with the former sub-criteria.

Figure A3.5 presents a sensitivity analysis of the overall normalised impact of every LMF category as the weight of Criterion C3.1 (Average Serving) is ranged from 0 to 100%. The baseline weight of this criterion in the model is $w_{3.1} = 43.5$ % as indicated by the red vertical dashed line. If the weight of this criterion were further increased, to the right of the red vertical dashed line, Cat 1's overall normalised impact would further increase. However, if the weight of this criterion were decreased, there is a point where Cat 1 intersects with Cat 4 (point ⑤: $w'_{3.1}$ = 31.0%). Any further reduction of weight beyond this point ⑤ should lead to the selection of Cat 4. Notice that the range of weights provide by the experts for this criterion (w_{31} = [35.0%,43.5%]) is above point ⑤, thus maintaining Cat 1 as the highest scored category.

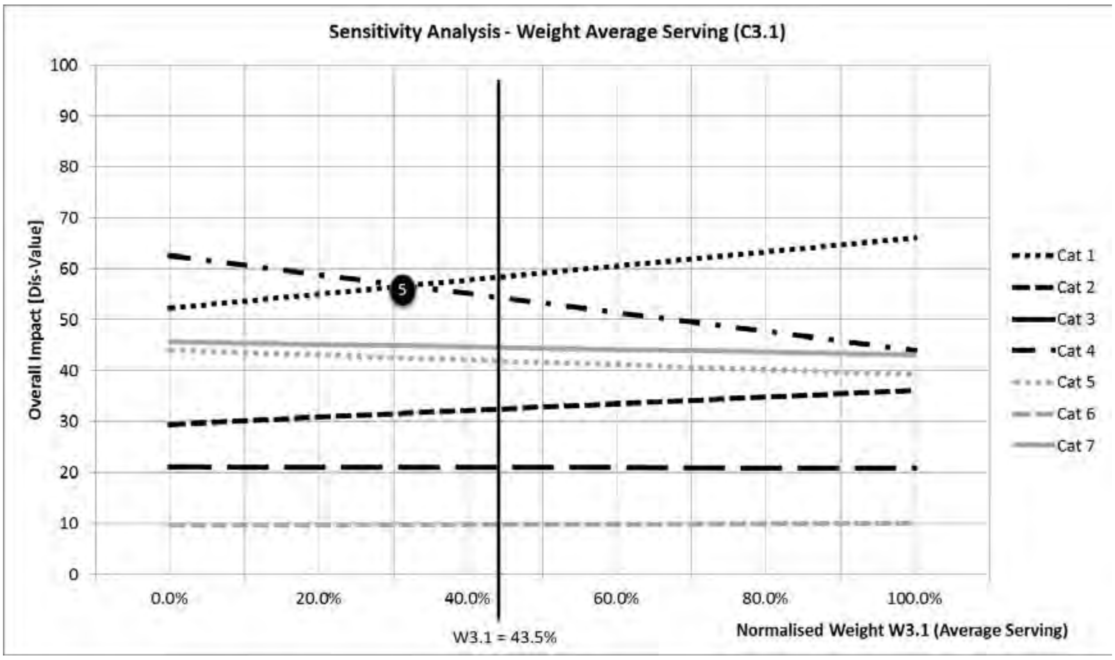


FIGURE A3.5. SENSITIVITY ANALYSIS FOR THE WEIGHT OF CRITERION C3.1 (AVERAGE SERVING).

Figure A3.6 presents a sensitivity analysis of the overall normalised impact of every LMF category as the weight of Sub-Criterion C3.2 (Vulnerability of Consumers) is ranged from 0 to 100%. The baseline weight of this criterion in the model is $w_{3.2}$ = 43.5% and is indicated by the red vertical dashed line. If the weight of this criterion were increased, to the right of the red vertical dashed line, there is a point where Cat 1 intersects with Cat 4 (point ⑥: $w'_{3.2}$ = 55.8%). If the weight of this criterion were further increased beyond this point ⑥, Cat 4 should be selected. For any level below point ⑥, Cat 1 remains the highest in the rank. Notice that the range of weights provide by the experts for this criterion (w_{32} = [35.0%,43.5%]) is below point ⑥, thus maintaining Cat 1 as the highest scored category.

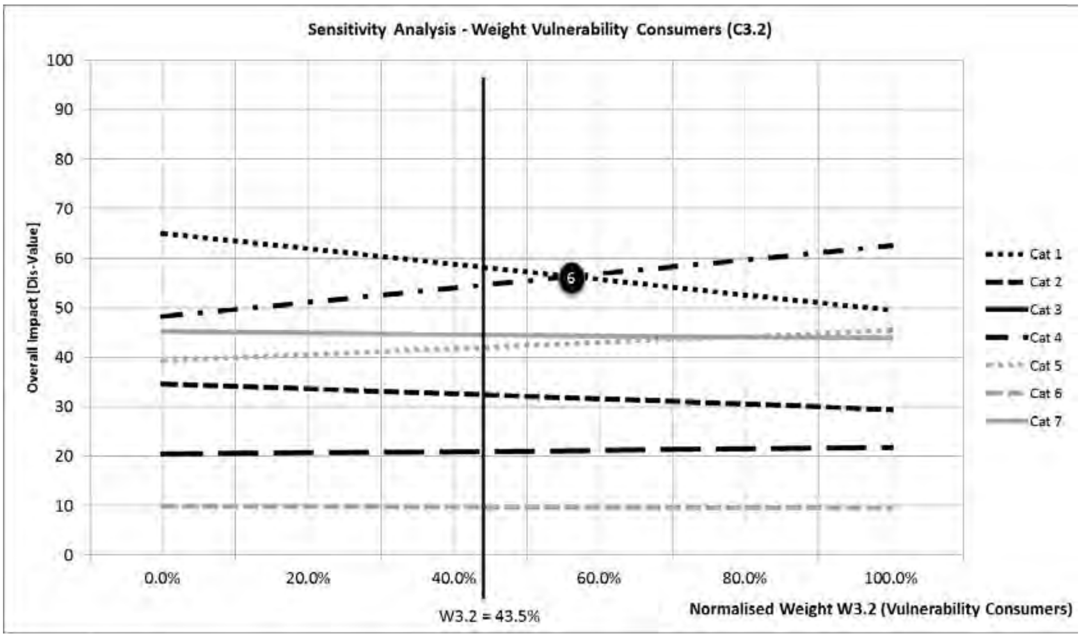


FIGURE A3.6. SENSITIVITY ANALYSIS FOR THE WEIGHT OF CRITERION C3.2 (VULNERABILITY CONSUMERS).

Figure A3.7 presents a sensitivity analysis of the overall normalised impact of every LMF category as the weight of Sub-Criterion C3.3 (Consumer Mishandling) is ranged from 0 to 100%. The baseline weight of this criterion in the model is $w_{3.3}$ = 13.0% and is indicated by the red vertical dashed line. If the weight of this criterion were increased, to the right of the red vertical dashed line, there is a point where Cat 1 intersects with Cat 4 (point ⑦: $w'_{3.3}$ = 69.2%). If the weight of this criterion were further increased beyond this point ⑦, Cat 4 should be selected. For any level below point ⑦, Cat 1 remains the highest in the rank. Notice that the range of weights provided by the experts for this criterion (w_{33} = [13.0%, 25.9%]) is below point⑦, thus maintaining Cat 1 as the highest scored category.

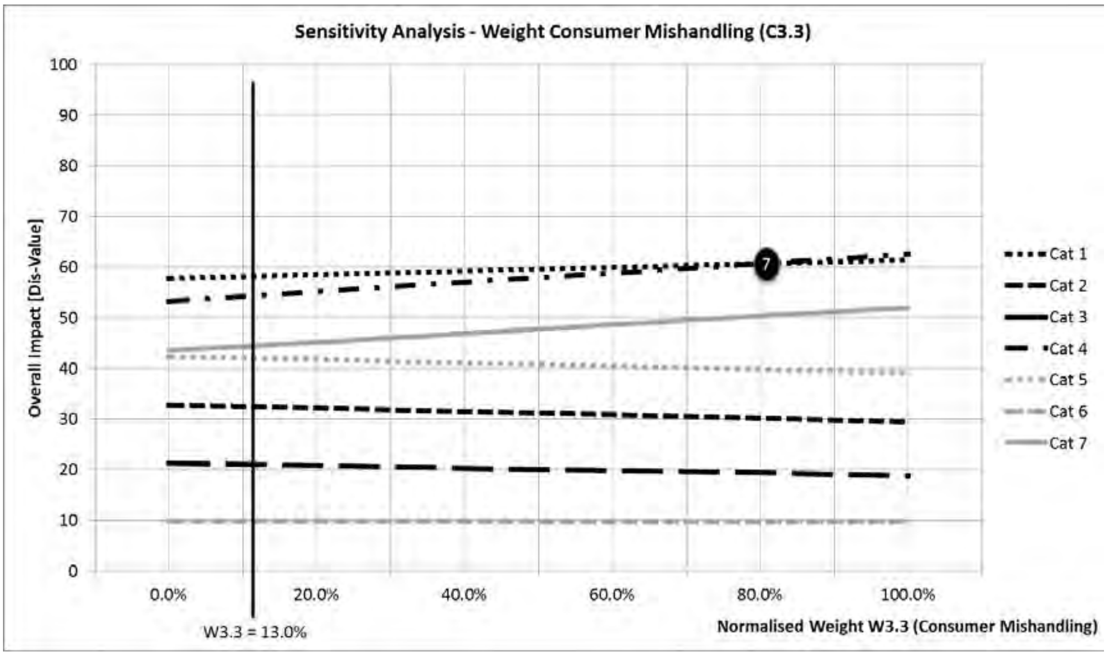


FIGURE A3.7. SENSITIVITY ANALYSIS FOR THE WEIGHT OF CRITERION C3.3 (CONSUMER MISHANDLING).

We will now analyse the three sub-criteria that decompose Criterion C4 (Food Production).

Figure A3.8 presents a sensitivity analysis of the overall normalised impact of every LMF category as the weight of Sub-Criterion C4.1 (Risk of Contamination) is ranged from 0 to 100%. The baseline weight of this criterion in the model is $w_{4.1}$ = 19.0% and is indicated by the red vertical dashed line. If the weight of this criterion were increased, to the right of the red vertical dashed line, there is a point where Cat 1 intersects with Cat 4 (point ⑧: $w'_{4.1}$ = 42.3%). If the weight of this criterion were further increased beyond this point ⑧, Cat 4 should be selected. For any level below point ⑧, Cat 1 remains the highest in the rank. Notice that the range of weights provided by the experts for this criterion (w_{41} = [15.0%, 22.7%] is below point ⑧, thus maintaining Cat 1 as the highest scored category.

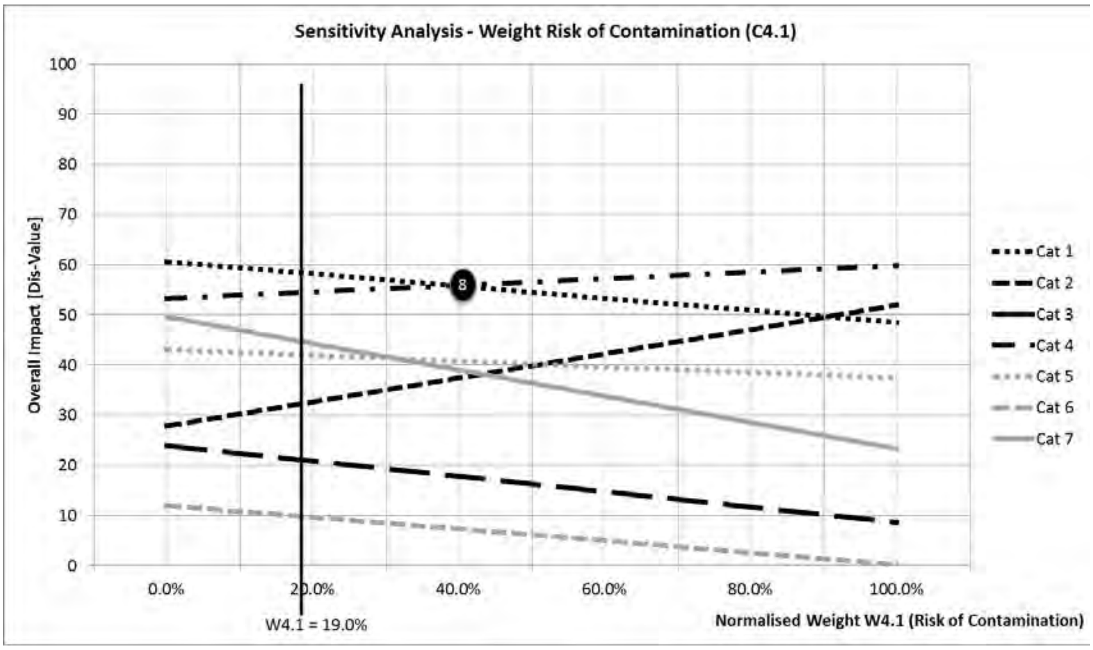


FIGURE A3.8. SENSITIVITY ANALYSIS FOR THE WEIGHT OF CRITERION C4.1 (RISK OF CONTAMINATION).

Figure A3.9 presents a sensitivity analysis of the overall normalised impact of every LMF category as the weight of Criterion C4.2 (Proportion without Kill Step) is ranged from 0 to 100%. The baseline weight of this criterion in the model is $w_{4.2}$ = 33.3 % as indicated by the red vertical dashed line. If the weight of this criterion were further increased, to the right of the red vertical dashed line, Cat 1's overall normalised impact would further increase. However, if the weight of this criterion were decreased, there is a point where Cat 1 intersects with Cat 4 (point ⑨: $w'_{4.2}$ = 19.2%). Any further reduction of weight beyond this point ⑨ should lead to the selection of Cat 4. Notice that the range of weights provide by the experts for this criterion (w_{42} = [30.0%, 36.4%]) is above point ⑨, thus maintaining Cat 1 as the highest scored category.

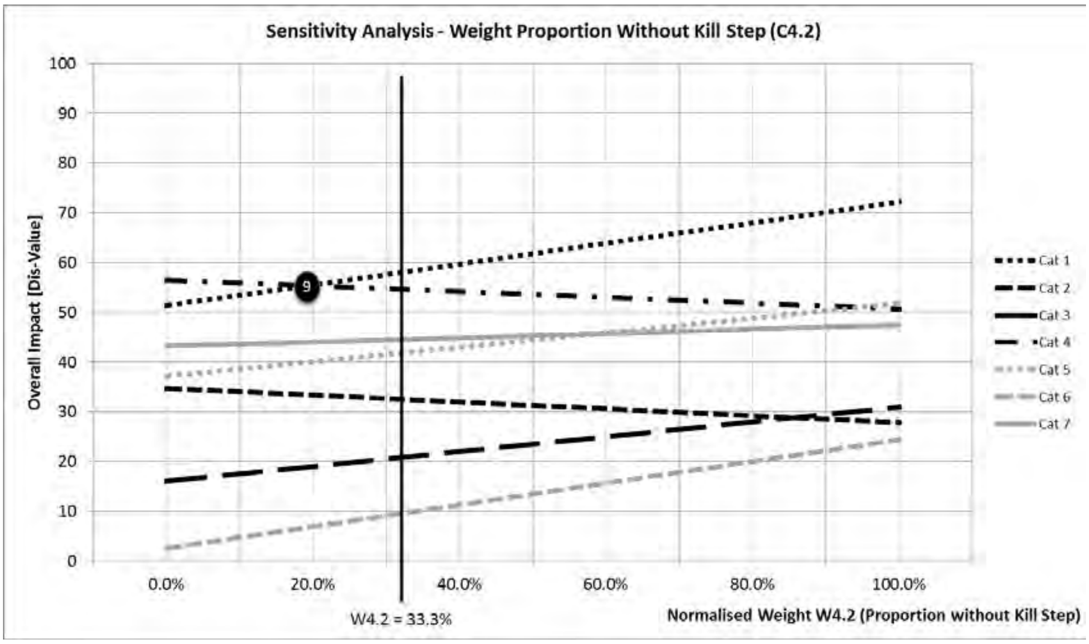


FIGURE A3.9. SENSITIVITY ANALYSIS FOR THE WEIGHT OF CRITERION C4.2 (PROPORTION WITHOUT KILL STEP).

Finally, Figure A3.10 presents a sensitivity analysis of the overall normalised impact of every LMF category as the weight of Sub-Criterion C4.3 (Presence of Pathogen) is ranged from 0 to 100%. The baseline weight of this criterion in the model is $w_{4.3}$ = 47.6% and is indicated by the red vertical dashed line. If the weight of this criterion were increased, to the right of the red vertical dashed line, there is a point where Cat 1 intersects with Cat 4 (point ⑩: $w'_{4.3}$ = 76.9%). If the weight of this criterion were further increased beyond this point ⑩, Cat 4 should be selected. For any level below point ⑩, Cat 1 remains the highest in the rank. Notice that experts did not contemplate a further increase on this parameter during the elicitation of weights.

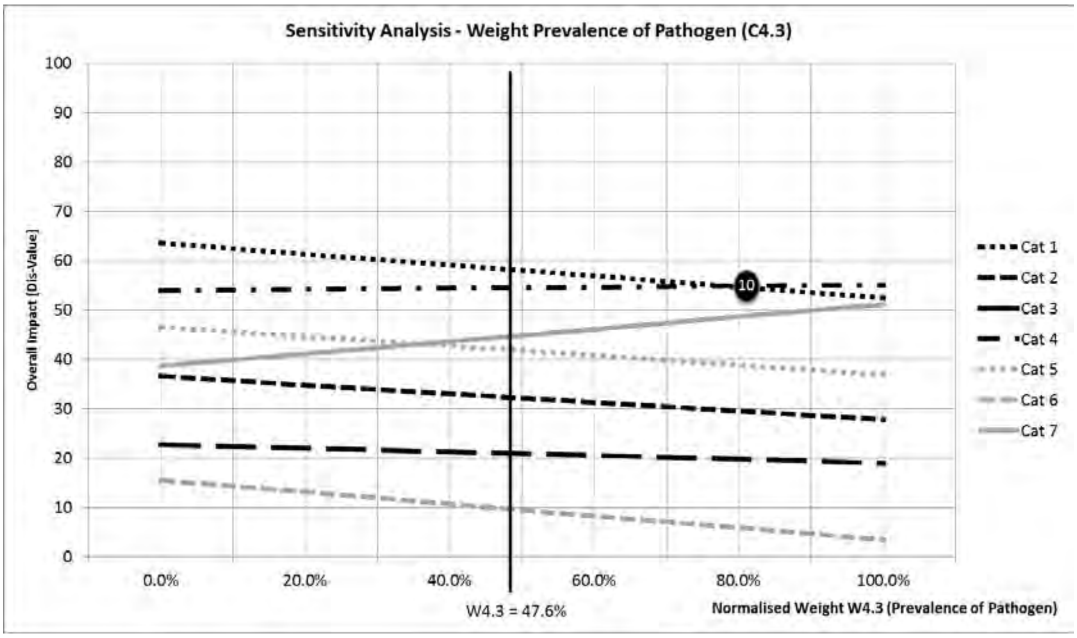


FIGURE A3.10. SENSITIVITY ANALYSIS FOR THE WEIGHT OF CRITERION C4.3 (PREVALENCE OF PATHOGEN).

These analyses of sensitivity on weights show that the ranking is quite robust to changes of priorities, with either Cat 1 or Cat 4 always being on the top position. There are no intersection points very near the baseline weights and, in all case except for Criterion 1 (Figure 3.3 of the main report), there was not a range of weights provided by the experts that reached any intersection point. (For Criterion 1, the lower bound of the range provided by experts was only slightly below the intersection point ①.)

In addition to this analysis, the four graphs for the main criteria (from Figure 3.3 to Figure 3.6 of the main report) can help the policy makers in identifying the category to be selected if their priorities increase/decrease from the baseline weights suggested by the expert group during the project.

SENSITIVITY TO THE ESTIMATION OF IMPACTS

An analysis of robustness considering the uncertainties about the evidence available (impacts), which was used to calculate the normalised impacts of each LMF category was also considered. (As a simplifying assumption, we are considering throughout this analysis that the criteria weights remain fixed, as the baseline weights, despite the changes in the ranges of the attributes.)

Three criteria were expert derived estimates given the lack of available data and the extensive expertise of the group. We have considered the consequence of different estimates of Most Likely (ML) values across the expert group.

For Criterion C3.3 (Consumer Mishandling) we considered the experts' baseline estimates used in the results (Table 3.4 of the main report) as well as their lower ML and upper ML estimates (Table A7.1 of Appendix 7), and calculated the overall normalised impact with these three set of inputs, as shown in Figure A3.11. The ranking for the three sets of estimates remains the same in the three set of inputs, with Cat 1 followed by Cat 4 in each case .

For Criterion C4.1 (Risk of Contamination) the experts' baseline estimates used in the results (Table 3.5 of the main report) as well as their lower ML and upper ML estimates were considered (Table A7.2 of Appendix 7), and the overall normalised impact with these three set of inputs calculated, as shown in Table A3.12. The ranking for the three sets of estimates remains the same for the baseline and upper estimates, with Cat 1 followed by Cat 4. However, the overall normalised impact of Cat 4 is slightly higher than Cat 1 when using the lower estimates.

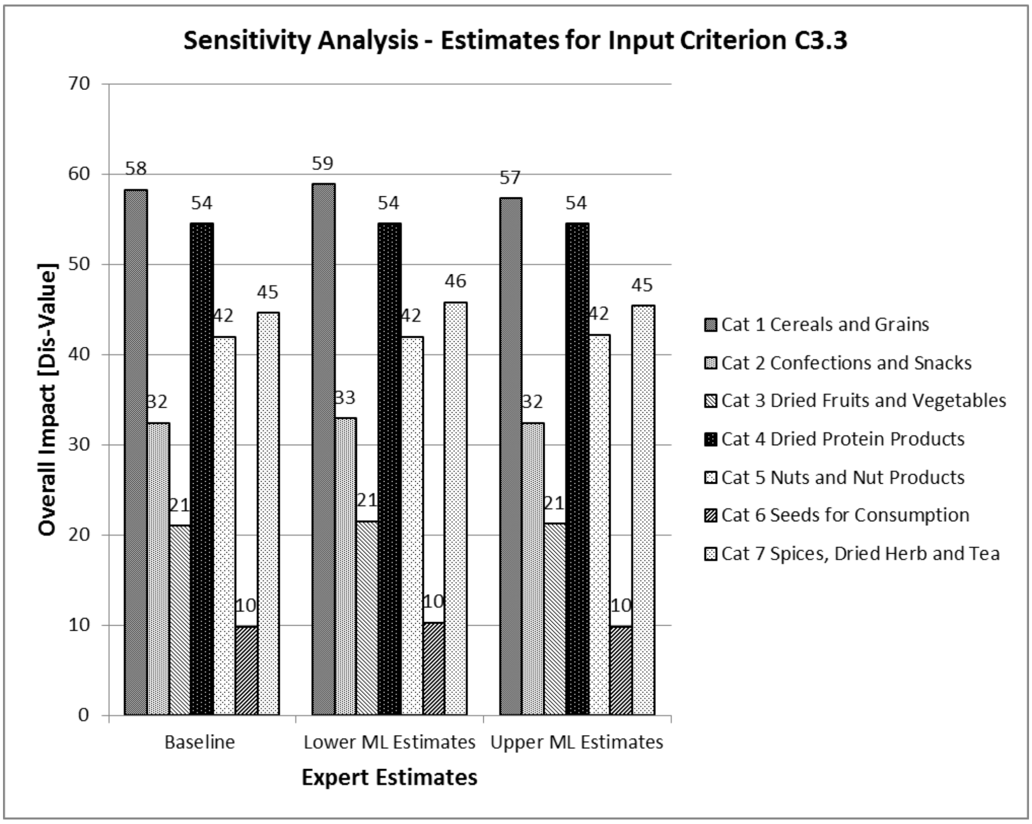


FIGURE A3.11. SENSITIVITY ANALYSIS FOR THE INPUT ESTIMATES – CRITERION C3.3.

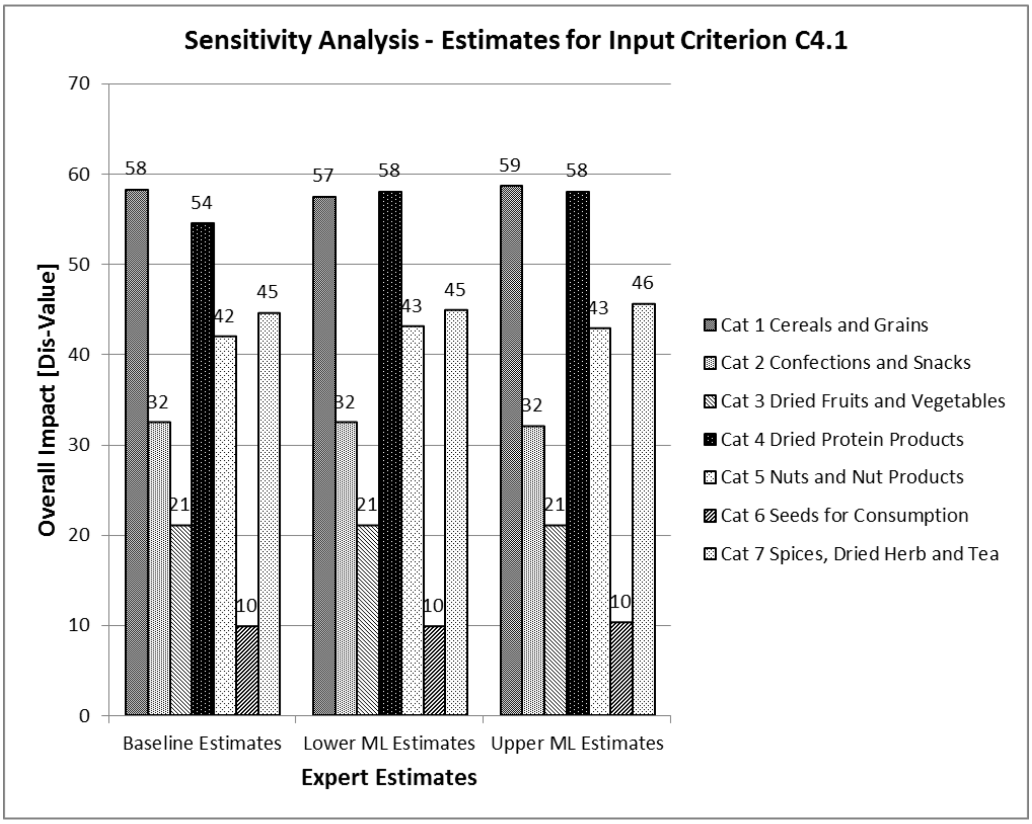


FIGURE A3.12. SENSITIVITY ANALYSIS FOR THE INPUT ESTIMATES – CRITERION C4.1.

For Criterion C4.2 (Proportion without a Kill Step) the experts' baseline estimates used in the results (Table 3.5 of the main report) as well as their lower ML and upper ML estimates were considered (Table A7.3 of Appendix 7), and calculated the overall normalised impact with these three set of inputs, as shown in Figure A3.13. The ranking for the three sets of estimates remains the same for the baseline and upper estimates, with Cat 1 followed by Cat 4. However, the overall normalised impact of Cat 4 is the same as Cat 1 when using the lower estimates.

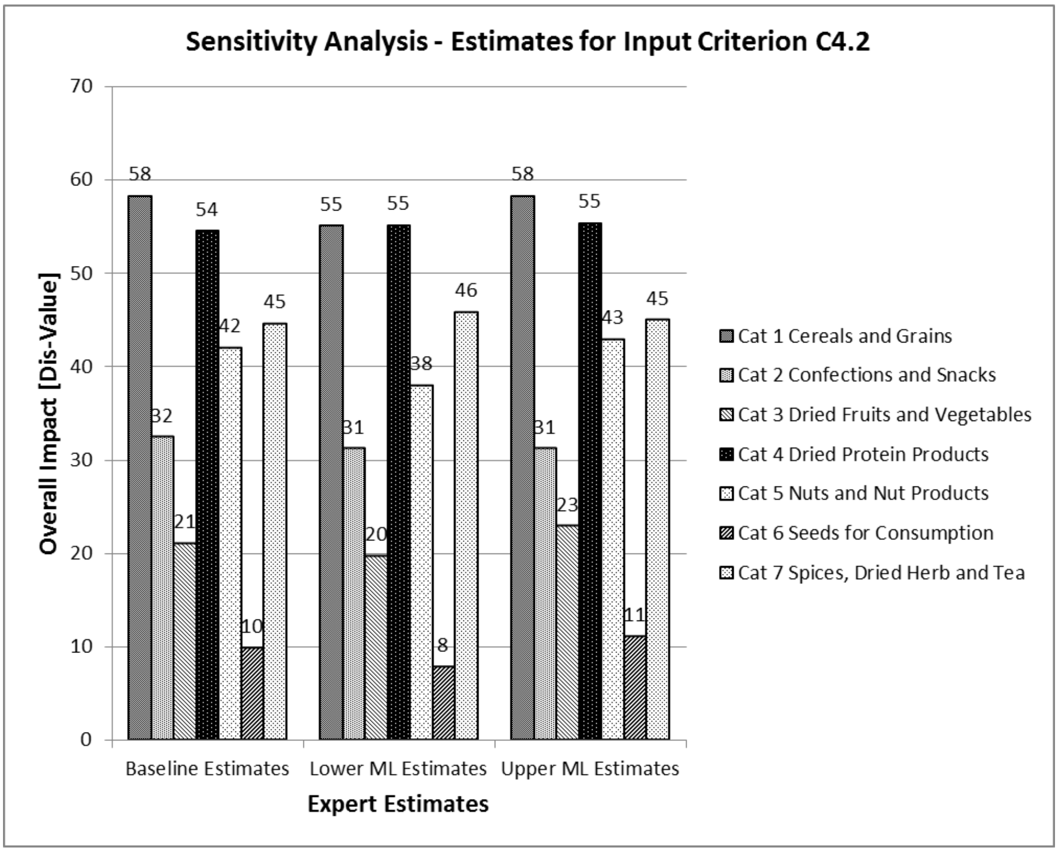


FIGURE A3.13. SENSITIVITY ANALYSIS FOR THE INPUT ESTIMATES – CRITERION C4.2.

Finally, the three set of estimates together, for the Sub-Criteria C3.3, C4.1, and C4.2 we considered. The experts' baseline estimates for these three sub-criteria as well as their lower ML and upper ML estimates were employed, and the overall normalised impact with these three set of inputs calculated, as shown in Figure A3.14. Category Cat 4 is higher than Cat 1 for the lower estimates, and the former is also slightly higher than the latter for the upper estimates. This is mainly due to a wider range of estimates among experts for Cat 4 when compared with Cat 1.

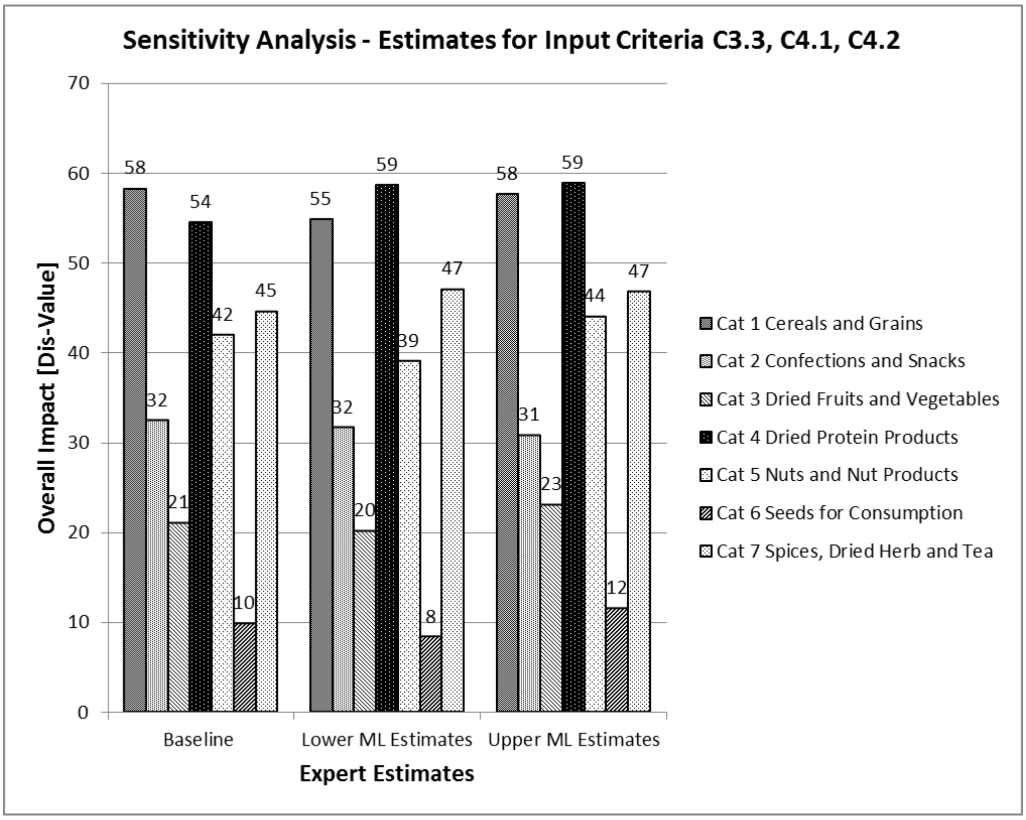


FIGURE A3.14. SENSITIVITY ANALYSIS FOR THE INPUT ESTIMATES – CRITERIA C3.3, C4.1, AND C4.2.

Another sensitivity analysis that we conducted was on the estimates for Criterion C3.1 (Average Serving). The baseline estimates employed the mean values to calculate overall normalised impact, which we now compared with the overall results for high volume consumers (P95) (Table 3.4 of the main report). As Table A3.15 shows, there is no change of ranking if the latter estimates were used. The much wider range of normalised impacts if these estimates (high volume consumers) were employed would tend to further increase the weight of this criterion, above its baseline value ($w_{3.1}$ = 43.5%). However, as analysed in Figure A3.5, an increase of its weight would not change the ranking – with Cat 1 remaining the one with the highest score. The ranking is therefore very robust to the two sets of estimates available for C3.1.

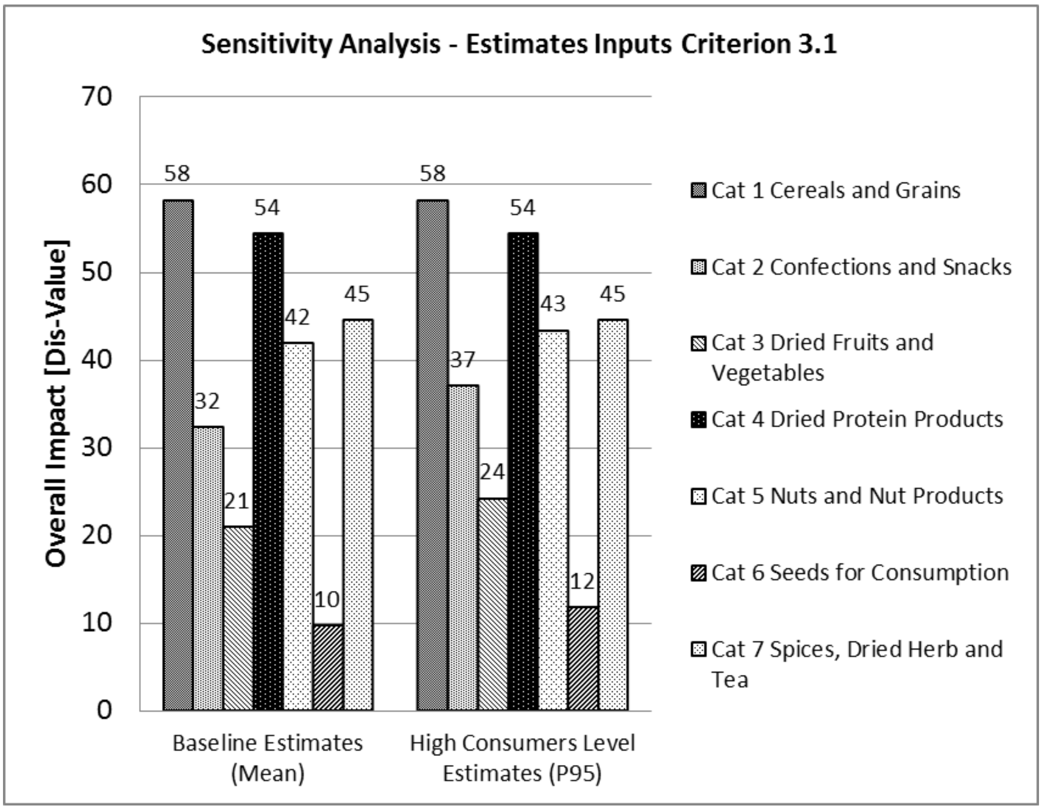


FIGURE A3.15. SENSITIVITY ANALYSIS FOR THE INPUT ESTIMATES – CRITERION C3.1.

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APPENDIX 4: TRADE DATA

TABLE A4.1: EXPORT VALUE IN US DOLLARS OF EACH OF THE CATEGORIES OF LMF FOR BASED ON THE DATA AVAILABLE FOR 2011 IN FAOSTAT.

Category	Export value in US dollars in 2011 (x1000)	Comments/Limitations
Cereals and Grains	**118,594,636**	
Sub-categories		
Unprocessed cereals	42,678,253	Amount adjusted to account for proportion of grains going for human consumption
Partly processed cereals	34,317,536	
Cereal based products	41,598,847	
Confections and snacks	**58,124,835**	
Sub-categories		
Chocolate and cocoa	42,465,315	
Non-chocolate confectionary	9,677,740	
Snacks	5,981,780	Very limited data available, may be partly included in other categories (cereals and grains, dried vegetables but not possible to segregate out)
Dried Fruits and Vegetables	**15,211,735**	
Sub categories		
Dried fruits	5,033,350	
Dried Vegetables	10,178,385	includes vegetable flours
Dried Protein products	**22,800,655**	
Sub categories		
Dried meat products	n/a	Data aggregated with all preserved meats and not possible to disaggregate. Proportion meeting definition for this work considered minimal
Dried dairy products	21,729,252	
Dried egg products	305,936	
Dried vegetable protein products	765,467	Based on an assumption that 2% of total soybean production is consumed by

		humans in foods .
Dried fish products	n/a	Data aggregated with all preserved fish and not possible to disaggregate. Proportion meeting definition of this work considered minimal
Nut and nut products	**20,338,654**	
Sub categories		
Tree nuts	17,964,125	
Ground nuts	2,374,529	Includes peanut butter
Seeds for consumption	**1,150,471**	As many oils used for oil production figure adjusted to account for this - Based on available data 10% assumed to be for direct human consumption
Spices, Dried herbs and teas	**14,938,847**	
Sub categories		
Spices and dried herbs	7,150,458	
Teas	7,788,389	

Data source: FAOSTAT. Available at http://faostat3.fao.org/browse/T/TP/E

Accessed June 2014

APPENDIX 5: CALCULATION OF DALYS

TABLE A5.1: CALCULATION OF THE DALY FOR EACH OF THE MICROORGANISMS UNDER CONSIDERATION BASED ON DALY PER 1000 CASES OF ILLNESS IN THE NETHERLAND (HAVELAAR ET AL., 2012) AND CASES OF ILLNESS PER ORGANISM AND PER LMF CATEGORY IDENTIFIED IN THE STRUCTURED SCOPING REVIEW (APPENDIX 1).

		Cereals and Grains		**Confections and Snacks**		**Dried Fruit and Vegetables**		**Dried Protein Products**	
DALY for each pathogen	Pathogens	CASES	TOTAL DALY	CASES	TOTAL DALY	CASES	TOTAL DALY	CASES	TOTAL DALY
0.143	*E. coli*	313	44.759	11	1.573		0		0
0.049	*Salmonella*	257	12.593	1448	70.952	669	32.781	1589	77.861
1.45	*Clostridium botulinum*		0		0		0	16	23.2
0.0023	*Bacillus cereus*	577	1.3271	4	0.0092		0		0
0.0032	*Clostridium perfringens*	369	1.1808		0		0		0
0.0026	*Staphylococcus aureus*	152	0.3952		0		0	13606	35.3756
	TOTAL	1668.0	60.3	1463.0	72.5	669.0	32.8	15211.0	136.4

		Nuts and nut products		**Seeds for consumption**		**Spices, dried herbs and teas**	
DALY for each pathogen	Pathogens	CASES	TOTAL DALY	CASES	TOTAL DALY	CASES	TOTAL DALY
0.143	*E. coli*	30	4.29		0	4	0.572
0.049	*Salmonella*	2183	106.967	376	18.424	1582	77.518
1.45	*Clostridium botulinum*	5	7.25		0	1	1.45
0.0023	*Bacillus cereus*		0		0	421	0.9683
0.0032	*Clostridium perfringens*		0		0	63	0.2016
0.0026	*Staphylococcus aureus*		0		0		0
	TOTAL	2218.0	118.5	376.0	18.4	2071.0	80.7

TABLE A5.2: TOTAL DALY FOR EACH OF THE CATEGORIES OF LMF TAKING INTO CONSIDERATION ALL OF THE MICROORGANISMS UNDER CONSIDERATION.

SUMMARY	**Average DALY**	**Total cases**	Total DALY
Cereals and Grains	0.0361	1668	**60.3**
Confections and Snacks	0.0496	1463	**72.5**
Dried Fruit and Vegetables	0.0490	669	**32.8**
Dried Protein Products	0.0090	15211	**136.4**
Nuts and Nut Products	0.0534	2218	**118.5**
Seeds	0.0490	376	**18.4**
Spices, dried herbs and tea	0.0390	2071	**80.7**

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APPENDIX 6: CONSUMPTION DATA

The FAO/WHO Chronic Individual Food Consumption Database Summary Statistics (CIFOCOSS) is a preliminary concise global food consumption database, which will soon be published on FAO/WHO websites and contains summary daily intake statistics (i.e. 5th, 50th, 75th, 95th, 97.5th…) for different populations groups (i.e. toddlers, children, adolescents, adults, elderly and general population) based upon 34 food consumption surveys from at least two days of consumption conducted in 23 countries from the last 10 years (Australia, Belgium, Brazil, Bulgaria, China, Cyprus, Czech Republic, Denmark, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Japan, Latvia, Netherlands, South Korea, Spain, Sweden, Thailand, United Kingdom).

This database provides summary statistics parameters of daily food consumed by population expressed at the lowest food classification level, i.e. food item level 3 (example of wheat flour classified in the broad food categories cereals and grains at level 1, appendix 1). Considering the need of the ranking exercise, it was agreed to express the consumption data at the broad food category level 1 with at least the following statistics parameters (mean whole population, median whole population, standard deviation, the 95 percentiles of consumers, the number of subjects and the % of consumers). As the raw data at the individual level was not available internally within FAO/WHO due to the format of CIFOCOSS, it was agreed that the estimates of the 95th percentile of consumers be calculated using the same guidelines as those used by JECFA (WHO, 2009.) The approach used for estimating high percentiles of exposure from all contribution food sources is based on the assumption that an individual might be a high level consumer of one food category only, and would be an average consumer of all the remaining food groups. The method consists simply of adding the highest level of exposure from one food category (calculated for high consumers only at the P95) to the mean exposure values for the remaining categories (calculated for the whole population with consumers and non-consumers).

Moreover, in order to provide the best description of the intakes distributions for the seven categories the standard deviation (SD) was estimated assuming a log-normal distribution. First the error factor is calculated. For a lognormal distribution, it is defined as the ratio of the 95th percentile to the median. Then mathematical relationships between the mean, the error factor and the standard deviation of the underlying normal distribution (sigma) defined by the following equations are used:

- error factor=P95/median
- sigma = LOG(error factor) / 1.645
- SD=mean * SQR(EXP(sigma ^ 2) - 1)

It was noted that it was not possible to provide reliable estimates for the median and therefore for the standard deviation for some low-moisture broad food categories (i.e dried fruits and vegetables, dried protein products..) due to the low number of consumers reported in the surveys. The mean serving in grams per day for the average population as well as the amount consumed by those considered to be high consumers are based on the tables provided below.

I. AVERAGE SERVING

Table 1 gives a description of different population groups considered for the description of the consumption from the low-moisture broad food category as they have been reported by data providers to WHO/FAO and as they have been used by the expert consultation group to report the description of the consumption from the low-moisture broad food category.

TABLE A6.1. FOOD CONSUMPTION SURVEYS CONSIDERED FOR THE CALCULATION OF CONSUMPTION DATA OF LMF.

Population	Age range	Countries with food consumption surveys covering more than one day
Toddlers	from 12 up to and including 35 months of age	Belgium, Bulgaria, China*, Finland, Germany, Italy, Japan*, Netherlands, South Korea*, Spain
Children	from 36 months up to and including 9 years of age	Australia, Belgium, Bulgaria, Czech Republic, Denmark, Finland, France, Germany, Greece, Italy, Latvia, Netherlands, Spain, Sweden
Adolescents	from 10 up to and including 17 years of age	Australia, Belgium, Cyprus, Czech Republic, Denmark, France, Germany, Italy, Latvia, Netherlands, Spain, Sweden
Adults	from 18 up to and including 64 years of age	Belgium, Czech Republic, Denmark, Finland, France, Germany, Hungary, Ireland, Italy, Latvia, Netherlands, Spain, Sweden, United Kingdom
The elderly	from 65 years of age and older	Belgium, Denmark, Finland, France, Germany, Hungary, Italy
General population	From 24 months up to over 65 years of age	Australia, Belgium, Brazil, Bulgaria, China, Czech Republic, Denmark, Finland, France, Germany, Greece, Italy, Japan, Latvia, Netherlands, South Korea, Spain, Sweden, Thailand

*age range for those countries was up to 72 months

Table 2 summarises the range estimates of daily consumption of low moisture broad food categories at global level per population groups considered by the expert working group (in g/person)

TABLE A6.2. DAILY CONSUMPTION OF LMF PER POPULATION GROUPS

	Toddlers (1-3 years)*	Children (3-9 years)	Adolescents (10-17 years)	Adults (18-64 years)	Elderly (>65 years)	General population (all population groups, 2 ->65 years)$
Cereals and grains						
Number of subjects	4432	8405	9870	29807	4056	184417
% of consumers	90	95	93	93	95	93
Mean whole population (g/day)	123	147	196	193	182	185
Median whole population(g/day)	66	96	128	121	111	116
SD	166,7	92,8	130,5	140,1	112,4	217,8
High consumers Level (P95) (g/day)	353,1	249,4	345,8	353,1	284,0	537,5
High consumers Level (P95) – % of population (approximate)	4.5%	4.8%	4.65%	4.65%	4.75%	4.7%
Confections and snacks						
Number of subjects	4432	8405	9870	29807	4056	184417
% of consumers	66	89	82	69	57	72
Mean whole population (g/day)	27.4	63	79	57	35	52.0
Median whole population(g/day)	16	41	34	32	12	30
SD	63.4	184.1	273.6	272.9	467.6	224.7
High consumers Level (P95) (g/day)	147	486	476	592	502	513
High consumers Level (P95) – % of population (approximate)	3.3	4.5	4.1	3.5	2.9	3.6
Dried fruits and vegetables						
Number of subjects	4432	8405	9870	29807	4056	184417
% of consumers	33	30	33	33	37	36

Mean whole population (g/day)	15.6	12.9	14.2	16.9	19.7	21.1
Median whole population(g/day)	0.0	0.0	0.0	0.0	0.0	0.0
SD	-	-	-	-	-	-
High consumers Level (P95) (g/day)	171.8	221.6	190.3	294.3	283.8	295.5
High consumers Level (P95) – % of population (approximate)	1.65	1.5	1.65	1.65	1.85	1.8
Dried protein products						
Number of subjects	3283	3579	2753	28187	3766	160024
% of consumers	35	13	14	8	11	15
Mean whole population (g/day)	2.9	0.1	0.1	0.3	0.2	1.1
Median whole population(g/day)	0.0	0.0	0.0	0.0	0.0	0.0
SD	-	-	-	-	-	-
High consumers Level (P95) (g/day)	20.6	2.9	5.2	29.9	26.7	40.0
High consumers Level (P95) – % of population (approximate)	1.75	0.65	0.7	0.4	0.55	0.75
Honey and preserves						
Number of subjects	4432	8405	9870	29807	4056	184417
% of consumers	52	70	66	73	77	66
Mean whole population (g/day)	8.2	15.4	20.4	17.6	16.5	15.5
Median whole population(g/day)	0.1	5.5	4.4	5.1	12.2	5.0
SD	-	64.1	-	-	32.7	-
High consumers Level (P95) (g/day)	49.8	90.6	152.4	123.0	97.5	141.3
High consumers Level (P95) – % of population (approximate)	2.6	3.5	3.3	3.65	3.85	3.3
Nuts and nut products						
Number of subjects	3778	8405	9870	29807	4056	183763
% of consumers	19	10	11	11	14	14

Mean whole population (g/day)	1.3	1.4	2.2	2.8	1.7	2.1
Median whole population(g/day)	0.0	0.0	0.0	0.0	0.0	0.0
SD	-	-	-	-	-	-
High consumers Level (P95) (g/day)	24.2	74.4	139.2	143.0	88.4	131.7
High consumers Level (P95) – % of population (approximate)	0.95	0.5	0.55	0.55	0.7	0.7
Seeds for consumption						
Number of subjects	4361	8405	9567	29807	4056	181332
% of consumers	17	25	30	35	37	30
Mean whole population (g/day)	2.3	4.0	6.0	6.7	9.7	5.5
Median whole population(g/day)	0.0	0.0	0.0	0.0	0.0	0.0
SD	-	-	-	-	-	-
High consumers Level (P95) (g/day)	79.4	85.0	161.2	151.6	188.0	179.0
High consumers Level (P95) – % of population (approximate)	0.85	1.25	1.5	1.75	1.85	1.5
Spices, dried herbs and tea						
Number of subjects	4379	8405	9870	29807	4056	184364
% of consumers	59	61	69	81	80	69
Mean whole population (g/day)	1.5	2.0	3.6	7.0	6.8	4.4
Median whole population(g/day)	0.02	0.1	0.1	0.7	2.4	0.1
SD	-	-	-	-	19.9	-
High consumers Level (P95) (g/day)	7.6	20.1	42.0	45.9	28.9	49.1
High consumers Level (P95) – % of population (approximate)	2.95	3.05	3.45	4.05	4	3.45

High consumers Level (P95): Estimates based on the added highest P95 consumers food group + the mean consumption value for the remaining food group from whole population.

*China, Japan and south of Korean are included with age up to 72 months

$: consumption figures also includes intakes from Asian countries which were reported only at the general population group

(-) could not be estimated due to the low number of consumers

(0.0) means that there is <50% of consumers

II. VULNERABLE CONSUMERS

The proportion of vulnerable consumers was calculated, for each category, by considering the % of total consumers that were consuming a given LMF category in the surveys against the % of vulnerable consumers (toddlers and elderly) as shown in Table 3.

TABLE A6.3. PROPORTION OF VULNERABLE CONSUMERS (TODDLERS AND ELDERLY)

	Toddlers (1-3 years)*	Children (3-9 years)	Adolescents (10-17 years)	Adults (18-64 years)	Elderly (>65 years)	Proportion Vulnerable (Toddlers + Elderly)
Cereals and grains						
Number of subjects	4432	8405	9870	29807	4056	
% of consumers	90	95	93	93	95	
Consumers	3988.8	7984.75	9179.1	27720.51	3853.2	
Proportion	7.60%	15.10%	17.40%	52.60%	7.30%	14.90%
Confections and snacks						
Number of subjects	4432	8405	9870	29807	4056	
% of consumers	66	89	82	69	57	
Consumers	2925.12	7480.45	8093.4	20566.83	2311.92	
Proportion	7.10%	18.10%	19.60%	49.70%	5.60%	12.70%
Dried fruits and vegetables						
Number of subjects	4432	8405	9870	29807	4056	
% of consumers	33	30	33	33	37	
Consumers	1462.56	2521.5	3257.1	9836.31	1500.72	
Proportion	7.90%	13.60%	17.50%	52.90%	8.10%	16.00%
Dried protein products						
Number of subjects	3283	3579	2753	28187	3766	
% of consumers	35	13	14	8	11	
Consumers	1149.05	465.27	385.42	2254.96	414.26	
Proportion	24.60%	10.00%	8.30%	48.30%	8.90%	33.50%
Nuts and nut products						
Number of subjects	3778	8405	9870	29807	4056	
% of consumers	19	10	11	11	14	
Consumers	717.82	840.5	1085.7	3278.77	567.84	
Proportion	11.10%	12.90%	16.70%	50.50%	8.70%	19.80%
Seeds for consumption						
Number of subjects	4361	8405	9567	29807	4056	
% of consumers	17	25	30	35	37	
Consumers	741.37	2101.25	2870.1	10432.45	1500.72	
Proportion	4.20%	11.90%	16.30%	59.10%	8.50%	12.70%
Spices, dried herbs and tea						
Number of subjects	4379	8405	9870	29807	4056	

% of consumers	59	61	69	81	80	
Consumers	2583.61	5127.05	6810.3	24143.67	3244.8	
Proportion	6.20%	12.20%	16.30%	57.60%	7.70%	13.90%

* Data of three countries (China, Japan and the Republic of Korea) are included with age up to 72 months.

TABLE A6.4. THE TYPES OF LOW-MOISTURE FOODS INCLUDED IN EACH MAJOR FOOD CATEGORY FOR THE PURPOSES OF COMPILING THE DATA ON CONSUMPTION

Cereals and grains	**Confection and snacks**	**Dried fruits and vegetables**	**Dried protein products**	**Nuts and nut products**	**Seeds for consumption**	**Spices, dried herbs and tea #**
Banana cake	Bullets or lollipop	Apple, dried	Cured (including salted) and dried non-heat treated processed meat, poultry, and game products in whole pieces or cuts	Almonds	Anise seed	Angelica (leaves)
Barley	Cakes, cookies and pies (e.g., fruit-filled or custard types)	Apricot, dried	Egg products and processed eggs	Brazil nut	Borage seed	Basil
Barley bran, processed	Cakes, cookies and pies (e.g., fruit-filled or custard types), nes	Banana, dried	Milk powder and cream powder (plain)	Cashew nut	Caraway seed	Basil, dry
Barley bran, unprocessed	Chocolate cake	Beans, except broad bean and soya bean	Smoked, dried, fermented, and/or salted fish and fish products, including mollusks, crustaceans, and echinoderms	Chestnuts	Coriander seed	Bay leaves, dry
Barley flour and grits	Cocoa beverage (water-based)	Blackberries, dried	Smoked, dried, fermented, and/or salted fish and fish products, including mollusks, crustaceans, and echinoderms, nes	Coconut	Cumin seed	Camomile or Chamomile (Herb tea)
Bread crumbs	Cocoa butter	Blueberries, dried		Hazelnuts	Fennel seed	Cardamom

Breakfast cereals, including rolled oats	Cocoa mass	Broad bean		Macadamia nuts	Green bean (green pods and immature seeds)	Celery leaves
Buckwheat	Cocoa powder	Chick-pea		Peanut	Linseed	Chives, dry
Buckwheat flour	Gum	Cranberry, dried		Peanut oil and butter	Melon seed	Cilantro, leaves, dry
Bulgur wheat	Honey	Currants, dried		Pecan	Mustard seed	Cilantro/coriander leaves
Cake Corn	Other cocoa products (incl. chocolate), nes	Date, dried		Pine nuts	Peas, Shelled (succulent seeds)	Cinnamon bark (incl. cinnamon, chinese bark)
Cake manioc	Popcorn	Dates, dried or dried and candied		Pistachio nuts	Perilla seeds	Cloves, buds
Canjiquinha	Potato crisps	Dried fruit		Processed nuts, including coated nuts and nut mixtures (with e.g., dried fruit)	Poppy seed	Dill weed raw
Carrot cake	Snacks - potato, cereal, flour or starch based (from roots and tubers, pulses and legumes)	Dried grape		Sweet peanut	Pumpkin seed	Dried herbs for herbal tea, nes
Cassava flour	Snacks - potato, cereal, flour or starch based (from roots and tubers, pulses and legumes), nes	Dried tomato		Tree nuts processed, nes	Sesame seed	Edible flowers, nes
Cellopane noodles	Snacks, nes	Fig, dried		Tree nuts, nes	Soya bean (immature seeds)	Galangal, rhizome
Cereal-based composite food	Sugar beet	Goji Berry, Dried		Walnuts	Sunflower seed	Ginger, rhizomes
Cereal-based	Sugar cane	Green bean (green				Ginseng

composite food, nes		pods and immature seeds)				
Cereals grains, nes	Sugar cane molasse	Haricot bean (dry) [Navy bean (dry)]				Green tea
Chocolate cake	Sugar cane, nes	Kidney bean (dry)				Herbs, nes
Corn Bread	Sugar products and confectionaries, nes	Lentil				Hops, dry
Cornmeal cake	Sugar, nes	Lima bean (dry) [Butter bean, Sieva bean]				Lemon verbena (dry leaves)
Flours, nes	Sweet corn, dried	Lima bean (young pods and/or immature beans)				Lemongrass
Gingerbread	Sweet Potato Cake	Mango, dried				Liquorice, roots
Hominy / mugunzá	Yeast only	Mangoes, dried				Mace
Instant noodles		Mixed dried fruits, dried				Marjoram, dry
Job's tears		Mushrooms and fungi				Maté (dry leaves) (Herb tea)
Maize		Mushrooms preserved				Mate beverage
Maize flour		Mushrooms, dried				Mints
Maize meal		Okra				Mints, dry
Millet		Papaya, dried				Native mint
Millet flour		Pear, dried				Nutmeg
Oat bran, unprocessed		Peas				Parsley
Oatmeal		Peas, Shelled (succulent seeds)				Parsley, dried
Oats		Pigeon pea				Pepper (black, white)
Orange cake		Podded pea (young				Pimento, fruit

		pods)[Mangetout, Sugar pea]				
Other processed products (excl. for infant), nes		Prunes, dried				Rooibos leaves dry
Popcorn		Pulses processed, nes				Rosemary
Porridge		Pulses , nes				Rosemary, dry
Quinoa		Pulses, oilseed and treenuts-based composite food				Saffron
Rice (excl. Wild)		Raisins, dried				Sage and related salvia species
Rice (excl. Wild), nes		Raspberries, Red, Black, dried				Sage, dry
Rice bran, unprocessed		Seaweed, nes				Salt
Rice cake		Soya bean				Tarragon
Rice flour		Soya bean (immature seeds)				Tea and mate beverages, nes
Rice pastas and noodles and like products		Strawberry, dried				Tea infused, beverage
Rice pastas and noodles and like products, nes		Sultanas, dried				Tea, dried leaves
Rye		Tomato, dried				Thyme
Rye bread		Vine fruits (currants, raisins and sultanas), dried				Thyme, dry
Rye flour						Turmeric, root
Sorghum						Vanilla beans

Soy Flour						Vietnamese mint
Sweet corn, dried						
Sweet Potato Cake						
Tapioca cake						
Tapioca flour						
Triticale						
Wheat						
Wheat bran, processed						
Wheat flour						
Wheat germ						
Wheat pastas and noodles and like products						
Wheat pastas and noodles and like, nes products						
Wheat white bread						
Wheat wholemeal bread						
Wild rice						
Yam cake						

A dilution factor of 20 was applied to beverage reported as consumed in order to obtain the consumption of herbs or tea expressed as dry matter (i.e tea infused)

Nes=-not specified elsewhere

References

WHO, (2009). 2009: Principles and methods for the risk assessment of chemicals in food, Environmental Health Criteria (EHC) 240. (IPCS).

APPENDIX 7: ELICITATION SURVEY AND RESULTS

Objectives

The purpose of this survey is to elicit information on three parameters relevant to the ranking of LMF. Questions 1 and 2 below are relevant to the definition of the criterion on Production. The production criterion has been characterized by three variables a) the prevalence of pathogens in the specific categories of LMF b) the proportion of foods in a category subject to a kill step and c) the proportion of foods in the categories to which ingredients are added after the kill step. Inputs for b and c are dependent on expert judgement and questions 1 and 2 below relate to these. Question 3 is relevant to the definition of the criterion on consumption and aims to capture the impact of mishandling by the food handler or consumer after the retail stage.

Questions and guidance to the experts in the elicitation process

1. Proportion (in terms of amount of product produced[34]) of low moisture food products in a given category subject to a kill step (see definition below) prior to retail and distribution

For the purposes of characterizing this parameter a kill step is defined as follows: a process applied to a food or food ingredient with the aim of minimizing public health hazards from pathogenic microorganisms. The process step would likely not inactivate all microorganisms present, but it should reduce the number of harmful ones to a level at which they do not constitute a significant health hazard. Although not originally intended as a kill step, processes such as roasting or extrusion cooking of LMF may also contribute to reducing numbers of harmful microorganisms which might be present. Regardless of the origin of the process step, all the processes which are used as a kill step must be validated to ensure that they are delivering the intended effect. In the absence of validation such processes should not be considered as a specific kill step. Examples of a kill step could include validated processes of: applying heat or other means of inactivation when the food or ingredient has a high water activity (e.g. cooking meat, pasteurizing liquids etc. before drying), increasing the water activity and applying heat (steam pasteurization of nuts, spices etc. sometimes combined with roasting), applying dry heat [to lower water activity foods or food ingredients] (validated roasting, baking, toasting etc.), applying other inactivation methods such as: UV, infrared, pulsed light, chemicals, irradiation etc.

2. Proportion (in terms of amount of product produced[34]) of low moisture food products in a given category with an increased risk of contamination post kill step

This is defined as those low moisture food products to which there is addition or combining of ingredients after the kill step which would present an opportunity for contamination of the product.

[34] produced for human consumption

3. Proportion (of the product which is sold for human consumption[35]) of low moisture food products in a given category with an increased risk as a result of mishandling/poor practices at any time between final retail and consumption

For the purposes of characterizing this parameter please note the following:
- the increased risk is only related to an increase in the intrinsic microbial population
- the potential for cross-contamination or contamination from extrinsic sources is not considered

Important notes

Values are requested for the most likely (median) proportion of food in a given category that may be subject to a kill step, post kill step contamination or poor practices during food preparation that would lead to an increased risk.
The proportion can be expressed as % i.e. a number between 1 and 100.
The minimum proportion and the maximum proportion of food within each of these categories should also be provided.
The three values provided do not have to add up to 100.
Values should be provided at the category level taking into account the range of products within each category.
Data on global production of each of the categories is limited and only available at the raw commodity level so this could not be provided. However the values of the different categories and where feasible sub categories within those categories are provided in a separate spread sheet for use as appropriate.

[35] For ease of completion this can also be considered in terms of the amount of product produced for human consumption

Answer sheet

Category	1. Proportion (0-100%) of low moisture food products in a given category subject to a kill step (see definition below) prior to retail and distribution			2. Proportion (0-100%) of low moisture food products in a given category with an increased risk of contamination post kill step			3. Proportion (0-100%)of low moisture food products in a given category with an increased risk as a result of mishandling/poor practices at any time between final retail and consumption		
	Most likely	Minimum	Maximum	Most likely	Minimum	Maximum	Most likely	Minimum	Maximum
Cereals and Grain									
Confections and Snacks									
Dried fruits and vegetables									
Dried Protein Products									
Nuts and nut products									
Seeds for consumption									
Spices, dried herbs and teas									

Cereals and Grain
This category includes wheat, barley, maize/corn, oats, rye, millet, sorghum, buckwheat, and rice, as well as their milled products (e.g. flours, starches) and further processed foods based on cereals and grains (e.g. dry baking mixes, breakfast cereals, pasta, noodles)

Confections and Snacks

This category includes sugar and sugar-based sweets such as fondants/creams, marshmallows, caramels/toffees, chewing gum, and chocolate and other cocoa-based products (e.g. cocoa and chocolate powders and mixes), savoury and ready-to-eat low-moisture foods such as chips and dried biscuits/crackers. Yeast is also included as a flavouring or additive to low-moisture foods

Dried Protein Products
This category includes dried dairy products (e.g. milk, whey, and milk-product powders); 2) dried egg products (e.g. egg powders); 3) dried fish/seafood products (e.g. dried fish, fish meal/flour); and 4) dried meat products other than sausages, salamis, and jerky's (e.g. gelatin, meat powders) and dried protiens of plant origin (e.g. soy powder).

Nuts and nut products

This category includes edible nuts and nut products, which are defined as the dried, hard-shelled fruits, kernals or seeds of trees, shrubs or other plants (FAO, 1995). It included 2 categories - 1) tree nuts (e.g. almonds, Brazil nuts, cashews, pecans, pistachios, pine nuts, walnuts) and 2) ground nuts or peanuts.

Seeds for consumption
This category includes dried sunflower seeds, pumpkin seeds, melon seeds, poppy seeds, flax seeds, sesame seeds and sesame products, and other edible seeds. Specific sesame seed products are also included here - tahini (sesame paste), which is produced from roasted and milled sesame seeds, and halva/helva, which is a confectionery produced from mixing tahini, sugar, glucose syrup, and other ingredients

Dried fruits and vegetables
This category included dried and dehydrated fruits and vegetables, as well as dried seaweed and mushrooms. Examples of dried fruits included raisins, prunes, dates, dried mangos, dried apricots, desiccated coconut, and fruit powders. Examples of dried vegetables included sun-dried vegetables (e.g. tomatoes, okra), vegetable powders and mixes (e.g. dry soup mixes), dehydrated vegetables (e.g. potato flakes, carrot slices), and vegetable flours (e.g. potato starch, yam flour). We also included dried legumes and legume flours in the dried vegetable category. For the purposes of summarizing prevalence and intervention information, data were collapsed across four categories: 1) dried/dehydrated fruits; 2) dried/dehydrated vegetables; 3) dried/dehydrated mushrooms; and 4) dried

Spices, dried herbs and teas
Spices are dried parts of fruits, seeds, bark, roots, leaves, or flowers of plants and herbs which are are often ground, crushed, or otherwise processed and used for seasoning, flavouring, and/or preserving foods.

FIGURE A7.1 ELICITATION SURVEY SPREADSHEET

RESULTS OF THE ELICITATION PROCESS

The most likely values provided by each of the experts for each of the three questions are provided below. The median values of these were used in the ranking exercise.

1. Proportion (in terms of amount of product produced[36]) of low moisture food products in a given category subject to a kill step (see definition below) prior to retail and distribution

TABLEA7.1. EXPERT ESTIMATES FOR CRITERION 4.2 PROPORTION WITHOUT A KILL STEP (MOST LIKELY VALUES).

Food Category	Expert 1	Expert 2	Expert 3	Expert 4	Expert 5	Lower Estimate	Upper Estimate	Median	Average	SD
Confections and Snacks	5	35	20	20	3	3	35	20	16.6	13
Dried fruits and vegetables	90	70	70	80	50	50	90	70	72	14.8
Dried Protein Products	15	40	10	10	8	8	40	10	16.6	13.3
Nuts and nut products	10	70	50	60	30	10	70	50	44	24.1
Seeds for consumption	50	75	70	75	90	50	90	75	72	14.4
Spices, dried herbs and teas	75	80	75	75	85	75	85	75	78	4.5

2. Proportion (in terms of amount of product produced[36]) of low moisture food products in a given category with an increased risk of contamination post kill step

TABLE A7.2. EXPERT ESTIMATES FOR CRITERION 4.1 INCREASED RISK OF CONTAMINATION (MOST LIKELY VALUES).

Food Category	Expert 1	Expert 2	Expert 3	Expert 4	Expert 5	Lower Estimate	Upper Estimate	Median	Average	SD
Confections and Snacks	40	15	10	40	70	10	70	40	35	24
Dried fruits and vegetables	1	20	10	10	1.5	1	20	10	8.5	7.8
Dried Protein Products	10	25	20	10	73.6	10	73.6	20	27.72	26.5
Nuts and nut products	3	30	25	10	10.5	3	30	10.5	15.7	11.3
Seeds for consumption	1	20	25	10	9	1	25	10	13	9.5
Spices, dried herbs and teas	10	30	15	5	1.5	1.5	30	10	12.3	11.1

[36] produced for human consumption

3. Proportion (of the product which is sold for human consumption[37]) of low moisture food products in a given category with an increased risk as a result of mishandling/poor practices at any time between final retail and consumption

TABLEA7.3. EXPERT ESTIMATES FOR CRITERION 3.3 CONSUMER MISHANDLING (MOST LIKELY VALUES).

Food Category	Expert 1	Expert 2	Expert 3	Expert 4	Expert 5	Lower Estimate	Upper Estimate	Median	Average	SD
Cereals and Grain	10	30	20	5	30	5	30	20	19	11.4
Confections and Snacks	1	8	10	5	2	1	10	5	5.2	3.8
Dried fruits and vegetables	1	15	15	5	5	1	15	5	8.2	6.4
Dried Protein Products	70	25	20	5	70	5	70	25	38	30.1
Nuts and nut products	0	15	10	5	1	0	15	5	6.2	6.3
Seeds for consumption	1	10	10	5	1	1	10	5	5.4	4.5
Spices, dried herbs and teas	60	15	20	5	10	5	60	15	22	22

[37] For ease of completion this can also be considered in terms of the amount of product produced for human consumption

APPENDIX 8: CALCULATION OF PREVALENCE

There was a strong desire during the consultation process to base the inputs to the ranking on available evidence where possible. In this context there was much discussion on how the data on prevalence collected during the knowledge synthesis could be used. There were some concerns about the representativeness of the data and in some cases the limited number of studies that had been undertaken. As a result it was decided to consider the data for a selected number of pathogens only where there were the greatest number of studies and so there could be more confidence in the data. Details of the organisms considered, the reported prevalence data and the corrected prevalence data are provided in Table A8.1. The correction factors and their basis applied to toxin producers within each of the categories are presented in Table A8.2.

TABLE A8.1. OVERVIEW OF PREVALENCE DATA FROM KNOWLEDGE SYNTHESIS AND AFTER APPLICATION OF CORRECTION FACTORS TO ACCOUNT FOR LEVELS ABOVE A CERTAIN THRESHOLD OF TOXIN PRODUCERS BEFORE A RISK OF ILLNESS EXISTS.

	Expert Judgement	Prevalence from knowledge synthesis	Prevalence of pathogen contamination above specified thresholds (Prevalence (%) from KS * correction factors in the table below (Table A8.2))
Cereals and Grains			
B. cereus		38.5	3.47
C. Perfringens		4.5	0.05
S. aureus		4.0	0.21
Salmonella spp		0.7	0.70
Overall- middle	**5.5**	**9.5**	**3.94**
min			**3.47**
max			**4.42**
Confections and Snacks			
B. cereus		19	1.90
C. Perfringens		0	0.00
S. aureus		0.5	0.03
Salmonella spp		0.6	0.60
Overall- middle	**0.2**	**4.02**	**2.21**
min			**1.90**
max			**2.53**
Dried Fruits and Vegetables			
B. cereus		76.3	3.82
C. Perfringens		0	0.00

S. aureus		1.7	0.05
Salmonella spp		2.0	2.00
Overall- middle	**4.8**	**20.0**	**4.84**
min			**3.82**
max			**5.86**
Dried Protein Products			
B. cereus		31.5	2.52
Salmonella spp		0.03	0.03
Overall- middle	**0.1**	**0.6**	**2.54**
min			**2.52**
max			**2.55**
Nuts and Nut Products			
B. cereus		7.3	0.37
C. Perfringens		0	0.00
S. aureus		0	0.00
Salmonella spp		0.6	0.60
Overall- middle	**1.2**	**1.6**	**0.78**
min			**0.60**
max			**0.97**
Seeds for Consumption	all data relates to sesame seed and sesame seed products		
B. cereus		6.7	0.34

C. Perfringens		0	0.00
S. aureus		0	0.00
Salmonella spp		1.9	1.90
Overall- middle	**2**	**1.7**	**2.07**
min			**1.90**
max			**2.24**
Spices, Dried Herbs and Tea			
B. cereus		24.5	9.56
C. Perfringens		11.4	0.11
S. aureus		4.9	1.12
Salmonella spp		3	3.00
Overall- middle	**7**	**8.76**	**11.67**
min			**9.56**
max			**13.79**

TABLE A8.2. OVERVIEW OF CORRECTION FACTORS APPLIED TO TOXIN PRODUCERS IN EACH OF THE CATEGORIES TO ACCOUNT FOR THE NEED TO REACH A THRESHOLD BEFORE THE POSSIBILITY TO CAUSE ILLNESS EXISTS

Toxin Producers Correction Factors	Proportion of positive samples in prevalence surveys that are likely to exceed a 3 log CFU/g threshold*. *Prevalence in the tables above have been adjusted by these values in right most column.*		
	B. cereus[1]	*S. aureus*[2]	*C. perfringens*[3]
Cereals and Grains	9.0%	5.3%	1.0%
Confections and Snacks	10.0%	5.8%	1.0%
Dried Fruits and Veg	5.0%	2.9%	1.0%
Dried Protein	8.0%	4.7%	1.0%
Nuts	5.0%	2.9%	1.0%
Seed	5.0%	2.9%	1.0%
Spices	39.0%	22.8%	1.0%

* 3 log CFU/g was considered by the experts and the literature on this topic to be a conservative cut-off for contamination with toxin producing bacteria above a safe threshold.

[1] B. cereus literature was used to support variable correction factors for different categories. Nuts and seeds lacked direct evidence and so the correction for dried fruits and vegetables was used as the most appropriate category.

[2] S. aureus literature only supported a correction factor for spices and herbs. Thus the relative corrections for B. cereus (other categories compared to spices) were used to estimate variable corrections for S. aureus as the experts agreed that this was the most logical behaviour for *S. aureus*.

[3] *C. perfringens* literature indicated that these toxin levels were rarely detected above the threshold and this was consistent across several food categories, so the experts agreed that a single, low correction was to be used across all categories of *C. perfringens*.