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Addition of selected cereal grains as non-dairy ingredients to dairy products: A microbiological risk assessment approach

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ABSTRACT

The addition of cereal grains to dairy products in the dairy industry has the potential to contaminate final products with pathogenic and spoilage microorganisms. In this study, the microbial risks involved in the addition of cereal grains to dairy products with low, intermediate, and high-water activity/moisture content were assessed using a semi-quantitative risk assessment method.

The results showed that the most critical microbiological hazard in the selected cereal grains is *Bacillus cereus* (*B. cereus*) due to its ability to form spores and persist in cereal grains. The addition of cereal grains to dairy products with high water activity/moisture content such as liquid breakfast products were found to pose the highest theoretical risk, and processing mitigations, such as UHT, would need to be implemented. The results of this study have identified some knowledge gaps in conducting risk assessments and have also provided background information about the microbial risks involved in the addition of cereal grains to dairy products.

1. Introduction

Cereal grains are often formulated into dairy products. The reasons for the addition of cereal grains to dairy products include increasing the nutritional value of the final product, novel development of new products which increases consumer interest, and production of functional foods. Liquid breakfast product is an example of a convenient food that combines non-dairy and dairy ingredients. In 2017, the global liquid breakfast product market was valued at approximately USD 302.06 billion and is estimated to generate around USD 448.23 billion by 2024, at a compound annual growth rate (CAGR) of around 5.8% between 2018 and 2024 (Zion market research, 2019).

There have been several food safety issues associated with cereal grains. The Centers for Disease Control and Prevention (CDC) in 2016 reported 383 foodborne outbreaks that involved grains and beans in the United States (CDC, 2018b). In the same year, contamination of cereal milled product (flour) by *Escherichia coli* (*E. coli*) O 121 caused 63 cases of food poisoning. There was another outbreak in New Zealand in 2008–2009 which was associated with *Salmonella* Typhimurium contamination in wheat flour leading to 67 cases of food poisoning (McCallum et al., 2013).

These are indicative of the potential risks which can arise from cereal grains. However, no studies have been conducted to assess the risks involved in the addition of cereal grains to dairy products with low, intermediate, and high-water activity/moisture content. Therefore, the purpose of this study was to conduct a risk assessment for the addition of cereal grains to dairy products. The outcome of this study will provide background information for the dairy industry to help manage the food safety risks associated with cereal grains when they are added to dairy products.

2. Materials and methods

2.1. Data collection

Data required in each risk assessment step was collected using specific databases including Web of Science and Google Scholar. The general search engine Google was used to search reports, publications, and regulatory data from government institutions and agencies (e.g., EFSA, FDA, CDC, FSANZ, MPI), relevant international organizations (e.g.,

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WHO, FAO/WHO, CAC, JECFA, IARC), and industry databases. Theses and dissertations were identified using Massey University Discover and ProQuest databases. The literature focused on articles and reports published in English.

A search strategy was applied, resulting in an initial set of search results which further were screened for their relevance in two stages by applying the evaluation criteria. The first screening was done by examining the title, abstracts, and keywords of each reference, resulting in a list of references which then go through the second screening by reading the full text.

Evaluation criteria used for screening the references were.

1) Relevant references with the purpose of the literature research included: (a) reviewing microbiological hazards in food including cereal grains (cereals, pseudo-cereals and grain legumes), and/or dairy; (b) describing risk analysis and risk assessment methods related to food safety and human health and/or; (c) explaining risk prioritisation or risk ranking application of food-related hazards to human health including drinking water.
2) References originating from international peer-reviewed journals or scientific articles and reports from notable government institutions and agencies as well as recognised international bodies.
3) Reference containing methods that were possibly applicable to the present study.

To better understand which specific pathogens were associated with cereal grain products and outbreaks as part of the exposure assessment, databases from three different countries (US, New Zealand, and Taiwan) were selected to have an overview of databases from both developed and developing countries. Foodborne outbreak data was collected from the National Outbreak Reporting System (NORS) for the US (CDC, 2018c), and annual reports for outbreaks in New Zealand and Taiwan. In NORS, search criteria for foods included cereal, cereal products, grains, beans, and legume. The annual summary of outbreaks in New Zealand classifies the foodborne outbreaks by causal agent and implicated vehicle/source. Implicated vehicles/sources used included rice and grains/beans. However, foodborne outbreaks by causal agent and implicated vehicle/source data were not explained in the annual outbreak summary before 2007 and after 2015. Due to the limited information available on foodborne disease outbreaks by causal agents and implicated vehicle/source data for Central Taiwan, this report shows only outbreaks from 1991 to 2000.

For exposure evaluation, the same approach described by Gilbert, Lake, Cressey, and King (2010) was used. New Zealand data was used as the source of information for the exposure assessment. New Zealand data from the 1997 NNS, 2002 Children's National Nutrition Survey (2002 CNNS) and the 2008/09 Adult Nutrition Survey (2008/09 ANS) were analysed. The number of participants aged 15 + years old was 4636 from the 1997 NNS and age 5–14 years old was 3275 children from the 2002 CNNS. The cereal grain consumption from the 1997 NNS was used because the information in 2008/09 is not available. Cereals may be added into a food serving as a major or minor ingredient, where major ingredient means the amount was more than 20% by weight. One or more cereals are a major ingredient in 17,528 servings from the 1997 NNS and in 14,490 servings from 2002 CNNS. Based on the New Zealand population of 4,965,538 (StatsNZ, 2019), the proportions based on the latest 2013 census i.e. adults (15+ years; 79.6%) and children (<15 years; 20.4%), were used in the calculation of total number of servings. The diet of children less than 5 years old was assumed to be similar to children aged 5–14 years.

2.2. Uncertainties, variabilities, and assumptions

There were several assumptions made at the outset this study: (1) Cereal grains are always subjected to control strategies such as heat treatment to reduce microbiological contamination before they are used; (2) Cereal grains are of good quality and harvested according to Good Agricultural Practice (GAP); (3) Cereal grains are manufactured under various standards for different countries guaranteeing their safety and quality. For example, in New Zealand, they are manufactured under the New Zealand Crop Quality Assurance Scheme (NZCQAS) issued by The Arable Food Industry Council (AFIC).

In conducting the hazard identification, assumptions were made regarding the state/form of cereal grains as well as utilisation of the available information. Cereal grains were in the form of whole grain and milled products including buckwaterwheat as whole grain cereals; millet as hulled cereals; barley as whole grain, pearled grain, grits, or flour; wheat as grits or flour; oats as flakes, rolled, or flour; corn (maize) as flour, grits, or meal; rice as flour; soybeans as flour (Baik, 2016; Daczkowska-Kozon, Bednarczyk, Biba, & Repich, 2009; Izydorczyk & Edney, 2017). In the absence of literature on particular cereal grains, the available information on the related types of cereal grains was used. For example, black soybeans used soybean data; brown rice and black glutinous rice used white rice data.

Variability and uncertainty within the cereal grain supply chain were identified. For instance, epidemiological data for pathogens in cereal grains was mostly related to cereal grains in their post-harvest stage (Berghofer, Hocking, Miskelly, & Jansson, 2003; Losio et al., 2017). However, this is only available for most common cereal grains such as wheat and oats. Factors recognised as having influence on the growth or survival of bacterial pathogens include differences in farming practices, different seasons (winter or spring) and variation in control measures to reduce microbial contamination of cereal grains (Beuchat et al., 2013; FAO/WHO, 2014; Finn, Condell, McClure, Amézquita, & Fanning, 2013; Podolak, Enache, Stone, Black, & Elliott, 2010; Richter, Dorneanu, Eskridge, & Rao, 1993).

Epidemiological data for pathogens in cereal grains was obtained from global data from countries such as Taiwan and the USA, with New Zealand data being minimal. Consumption data and serving estimations used the New Zealand data, although it is not up to date. The cereal consumption data was obtained from the 1997 National Nutrition Survey (1997 NNS) for New Zealand's adult population.

2.3. Samples

Selected cereal grains of interest in this present study are shown in Table 1. For the purpose of this study, cereal grains is a term used to represent three categories, i.e. cereals, pseudocereals, and grains legumes (pulses). These cereal grains were selected due to their popularity and high possibility to be used in developing more appealing dairy products (Bullerman & Bianchini, 2009; Koehler & Wieser, 2013; Wrigley, 2017b).

Table 1
List of selected cereal grains to be evaluated.

Category	Ingredient's name	Scientific name
Cereals	Barley	*Hordeum vulgare*
	Maize (Corn)	*Zea mays*
	Millet	*Pennisetum glaucum*
	Oats	*Avena sativa*
	Rye	*Secale cereal*
	Black glutinous rice	*Oryza sativa* var *glutinosa*
	Brown rice	*Oryza sativa*
	Wheat	*Triticum aestivum*
Pseudo-cereals	Buckwheat	*Fagopyrum esculentum*
Grain legumes (pulses)	Adzuki beans (red mung bean)	*Vigna angularis*
	Garden peas	*Pisum sativum*
	Hyacinth beans	*Lablab purpureus*
	Mung beans	*Vigna radiate*
	Soybeans	*Glycine max*
	Black soybeans	*Glycine* max (L) Merrit

2.4. Risk assessment methods

The microbiological risk assessment was conducted according to the Codex Committee on Food Hygiene Principles, and Guidelines for the Conduct of Microbiological Risk Assessment (CAC, 1999b) which consist of hazard identification, hazard characterisation, exposure assessment, and risk characterisation. This study employed a semi-quantitative approach that combines qualitative and quantitative inputs.

2.5. Risk matrix

In estimating the most critical microbiological risk in the selected cereals and grains, the likelihood and severity of the adverse effects which could occur for a given population was determined in the form of semi-quantitative risk assessment matrix (Blackmore et al., 2008; van der Fels-Klerx et al., 2018). Furthermore, in estimating the risk of cereal grains addition to dairy products, a qualitative measure of likelihood based on European Food Safety Authority (EFSA) terms was used to describe prevalence (EFSA, 2013, p. 248).

3. Results

3.1. Hazard identification and characterisation for cereal grains

Several researchers found cereal grains as the sources of foodborne pathogens and faecal micro-organisms such as *B. cereus, C. botulinum, C. perfringens, E. coli, Listeria monocytogenes (L. monocytogenes), Salmonella* spp., *Shigella* spp., and *Staphylococcus aureus (S. aureus)* (Berthold-Pluta, Pluta, Garbowska, & Stefańska, 2019; Bullerman & Bianchini, 2009; Forsythe, 2002; NZFSA, 2010b). The presence of faecal micro-organisms in grains such as coliforms and enterococci are used as indicators of improper sanitary handling and processing conditions (Bullerman & Bianchini, 2009). The hazard characterisation of these microorganisms are summarised in Table 2 and in detail in Appendix B.

3.2. Exposure assessment for cereal grains

3.2.1. Exposure model

Cereal grain contamination may originate from different sources such as soil, water, air, dust, insects, fertiliser, and animal faeces (Laca, Mousia, Díaz, Webb, & Pandiella, 2006). Contamination can occur at pre-harvest, harvest, and post-harvest processes. Pre-harvest contamination usually occurs during crop growth, while transport and storage are crucial contamination points for post-harvest (Li, Li, Luo, & Yoshizawa, 2002). Fig. 1 shows the potential sources and aspects of microbiological contamination throughout the cereal grains manufacturing chain (Brown, 2002a; Los, Ziuzina, & Bourke, 2018).

Significant contamination sources of enteric pathogens such as *Salmonella* and *E. coli* can come from the faecal matter of humans and animals pre-harvest. Two possible routes of contamination in cereal crops are direct exposure to pathogens contained in animal faeces and direct exposure to soil or dust that has been previously exposed to the animal faeces. Fortunately, cereal crops are covered with an outer casing that may shield the grain from contact with the animal faecal matter until harvest (Gilbert et al., 2010).

During harvesting, potential sources of contamination may come from inefficient pre-drying, contaminated equipment, unsanitary handling, and harvesting after rainfall (Los et al., 2018). Since harvested cereal grains usually contain high moisture, drying is needed to reach a moisture content between 10% and 14% (Alldrick, 2010; Los et al., 2018) equivalent to a_w <0.70. These moisture contents generate a hostile environment for mould growth. If the drying is insufficient, micro-organism growth will occur (Miskelly, Batey, & Suter, 2010).

Milling includes exclusion of debris and outer material, conditioning to regulate the moisture levels; exclusion of bran and/germ; and grinding into flour, grit, or meal (ICMSF, 1996b). Some end products of milling which can be used in the food industry include buckwheat as whole grain cereals, millet as hulled cereals, barley and wheat as grits, wheat as flour and germ, oats as flakes, and corn and semolina as meals (Daczkowska-Kozon et al., 2009). Milling and the environment influence the microbiological quality of cereal grains (Berghofer et al., 2003). Milling may reduce the microbiological contamination of cereal grains. Microbial contaminants are concentrated in the outer layer of grains. During the milling process from grain to flour, the outer layer of grain which may contain contaminants is detached. The inner endosperm contains fewer microorganisms. The inner endosperm then is crushed into refined flour that is relatively uncontaminated.

Milling may also be responsible for adding to the microbiological load of the flour. Conditioning grains may increase the bacterial, yeast and mould counts (Hocking, 2003). Accumulation of residue attached to the equipment in the milling plant may contribute to microbial contamination. Spore-forming bacteria such as *Bacillus* may reside in milling equipment, which can increase the microbial level in particular midstream products (Berghofer et al., 2003).

Salmonella is not commonly isolated from flour, while, *B. cereus* is

Table 2
Summary of microbiological hazard identification in selected cereal grains.

Ingredient name	Microbiological hazards	References
Cereals		
Barley	*Bacillus cereus*.	Daczkowska-Kozon et al. (2009), Forsythe (2002), Ok, Kim, Cho, Oh, and Chun (2009)
Corn (Maize)	Moulds, Yeasts, *Escherichia coli,* Coliform.	Sperber (2007)
Millet	*Bacillus cereus*.	Kimanya et al. (2003)
Oats	*Bacillus cereus*. *Salmonella* spp.	Rosenkvist and Hansen (1995) Sperber (2007)
Rye	*Bacillus cereus*.	Eglezos (2010), Rosenkvist and Hansen (1995)
Black glutinous rice	*Bacillus cereus*, *Cronobacter* spp. *(Enterobacter sakazakii)*.	Forsythe (2002), Lin and Beuchat (2007)
Brown rice	*Bacillus cereus*, *Cronobacter* spp. *(formerly Enterobacter sakazakii)*.	Forsythe (2002), Lin and Beuchat (2007)
Wheat	*Bacillus cereus*, Yeast, Mould. *Salmonella* Thypimurium, *Salmonella* Agona, *Salmonella* Mbandaka, *Escherichia coli* O157:H7, *Escherichia coli* O121, *Escherichia coli* O26, Coliform.	CDC (2016), Eglezos (2010), FDA (2017), Gamage et al. (2021), NZFSA (2010b)
Pseudocereal		
Buckwheat	Yeast, Mould, Coliforms, *Bacillus cereus*, *Staphylococcus aureus*.	Losio et al. (2017)
Grain legumes		
Adzuki beans (red mung bean)	*Staphylococcus* spp., *Escherichia coli*, *Salmonella* spp.	Neumayr and Krämer (1990) Yang et al. (2013)
Garden pea	Nonpathogenic *Escherichia coli*, *Salmonella* Typhimurium.	Saroj et al. (2006)
Hyacinth beans	*Escherichia coli, Salmonella* spp.	Yang et al. (2013)
Mung beans	*Salmonella* spp., *Salmonella enterica*, *Salmonella enteritidis*, *Escherichia coli* O157:H7, *Listeria monocytogenes*, Nonpathogenic *Escherichia coli, Salmonella* Typhimurium.	Ding and Fu (2016), Saroj et al. (2006), Trząskowska, Dai, Delaquis, and Wang (2018), Yang et al. (2013)
Soybeans	*Staphylococcus* spp., *Salmonella* spp., *Escherichia coli*.	Adepehin (2018), Yang et al. (2013)
Black Soybeans	*Staphylococcus* spp., *Salmonella* spp., *Escherichia coli*.	Adepehin (2018), Yang et al. (2013)

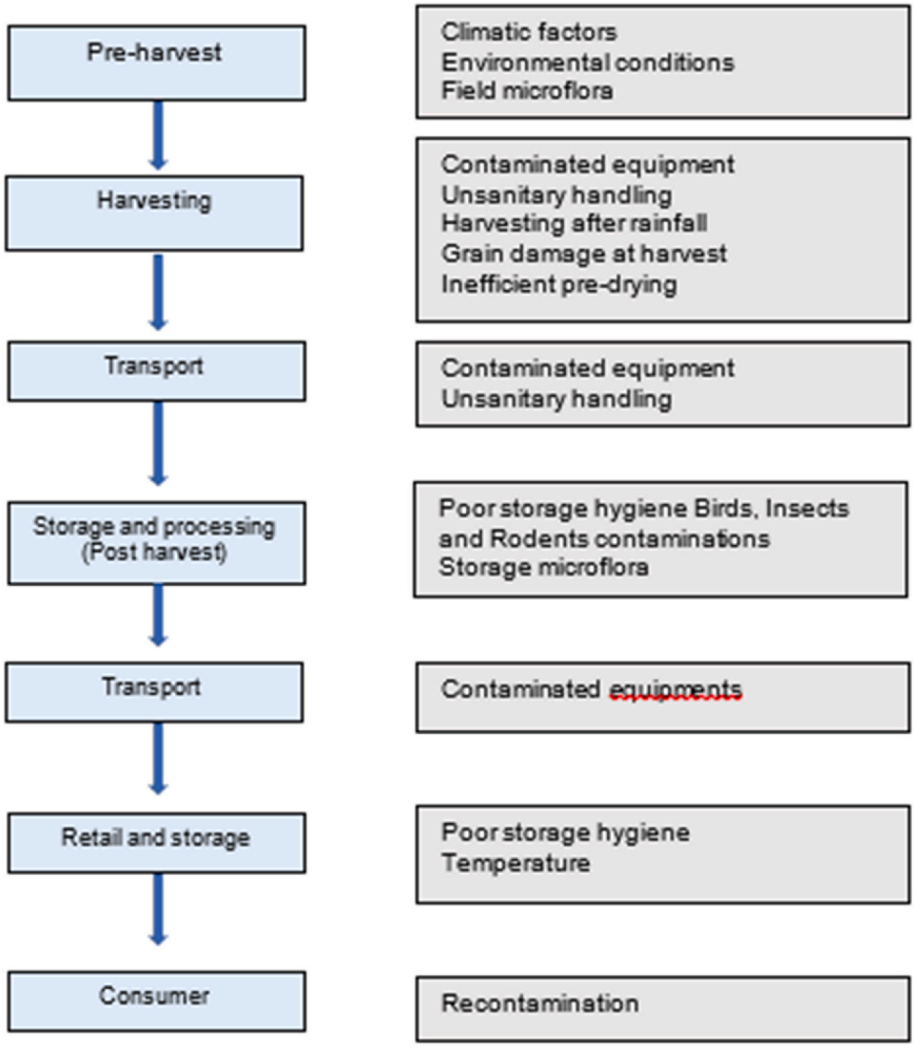

Fig. 1. Cereal grains supply chain and potential sources of microbiological contamination (references).

more common (Berghofer et al., 2003). A survey on the microbiological status of Australian wheat and the distribution of microorganisms in flour milling fractions and end products was conducted in 1997–1999. The study found that *B. cereus* was one of the most frequently detected microorganisms throughout the survey. *Salmonella* was not detected in the incoming wheat or end product. The ability of *B. cereus* to form spores that survive in harsh environments could be an explanation.

The moisture content grains in storage are important from the food safety point of view. Usually, grains are stored at a moisture content of 12–14% (Zwer, 2017) or water activity lower than 0.60. For example, flour and maize meals have a critical moisture content of 12% or less. This is because the moisture content does not favour microbial growth including spoilage fungi.

Storage facilities need to avoid increasing the moisture content of the grains through exposure to water. Some possible routes of water exposure include high humidity, condensates from equipment, and improper cleaning procedures (Gilbert et al., 2010). Condensation on equipment may be caused by the heat that is generated during grinding and sifting.

The essential control measures for low moisture foods such as cereal grains include preventing contamination from occurring during harvest, post-harvest and processing by sound implementation of good agricultural practices (GAPs), good hygienic practices (GHPs), good manufacturing practices (GMPs), and hazard analysis and critical control point (HACCP) programs (Beuchat et al., 2013; FAO/WHO, 2014; Finn et al., 2013; Podolak et al., 2010).

3.2.2. *Outbreaks associated with cereal grain products*

Foodborne outbreaks associated with specific pathogens in cereal and grain products is presented in Table 3. Different pathogens have been reported to be associated with cereals from different locations.

Table 3
The occurrence of pathogens identified in cereal grain products.

Pathogens	Number of outbreaks			
	USA[a]	Taiwan[b]	New Zealand[c]	Total
Bacillus cereus	41	27	1	69
Clostridium botulinum	NS	NS	0	0
Clostridium perfringens	87	NS	12	99
Cronobacter spp.	0	NS	0	0
Escherichia coli enteropathogenic	NS	1	0	1
Escherichia coli O157:H7 (STEC)	4	NS	0	4
Listeria monocytogenes	0	NS	0	0
Salmonella spp.	26	0	4	30
Shigella spp.	1	NS	0	1
Staphylococcus aureus	14	25	1	40
Norovirus	NS	NS	18	18

NS: Not stated.

[a] The foodborne outbreaks in USA 1998–2015 (CDC, 2018b) associated with cereal, cereal: oat, cereal: puffed wheat, cereal: puffed rice, cereal: unspecified, dry cereal, grains, grains: other, unspecified grains, beans, and legume.

[b] Central Taiwan 1991–2000 on cereal products (Chang & Chen, 2003).

[c] New Zealand 2007–2015 on grains/beans and rice category (MOE, 2015).

From Table 3, it can be seen that the most common bacterial pathogen among cereal grains in New Zealand is *C. perfringens* (33.3%), followed by *Salmonella* (11.1%). *B. cereus* has also been implicated in many cereal grains related foodborne outbreaks in other parts of the world such as America and Taiwan (CDC, 2018b; Chang & Chen, 2003) and a microbiological problem in the dairy industry (Andersson, Ronner, & Granum, 1995; Montanhini, Montanhini, Pinto, & Bersot, 2013; Vasavada, Martin, Bienvenue, & Heidenreich, 2018).

The United States, central Taiwan and New Zealand show different pathogens that are related to cereal grains. Table 3 shows the number of cases in the United States, central Taiwan, and New Zealand where cereal grains associated with microorganisms have caused foodborne outbreaks. In the United States, the term cereal includes oat, puffed wheat, puffed rice, unspecified cereal, dry cereal, grains, other grains, unspecified grains, beans, and legume (CDC, 2018b). In New Zealand, the term cereal includes grains, beans, and rice (MOE, 2015). In central Taiwan, the term includes instant cereal products and the cereal mix (Chang & Chen, 2003; Fang, Chu, & Shih, 1997). The cereal grains terms in three countries are dissimilar to a certain extent; therefore, a direct comparison of data across countries should be carried out with some caution. There is a natural bias to data collection, which is often based on funding, outbreaks, and ability to culture and is not necessarily reflective of the prevalence that these pathogens might be present.

Epidemiological data for pathogens in cereal grains is needed in an exposure assessment. The prevalence of pathogenic micro-organisms in selected cereal grains, based on an international microbiological survey, showed that *Salmonella* and *B. cereus* are frequently found in cereal grain products (Berghofer et al., 2003; Sperber, 2007). Interestingly, there is a lack of studies on prevalence data of *C. botulinum*, *C. perfringens*, *L. monocytogenes* and *Shigella* in cereal grains (CDC, 2018b; Chang & Chen, 2003; MOE, 2015).

Although viruses, such as norovirus, have been associated with outbreaks related to grains/beans and rice, the majority of the outbreaks were associated with poor hygiene practices by food handlers in the facilities in which they occurred e.g., long-term care and childcare facilities (MPI, 2017a). Norovirus outbreaks were therefore not caused by the cereal grains themselves, and were not considered further for this risk assessment.

Table 4
New Zealand food balance sheets per capita supply in 2013.

Item	Food balance sheets kg/capita/year (%)
Total cereal consumption	**98.02 (100%)**
Wheat and products	76.91 (78.5%)
Rice (Milled Equivalent)	9.16 (9.3%)
Maize And Products	4.43 (4.5%)
Oats	3.29 (3.4%)
Cereals, other	3.82 (3.9%)
Barley and products	0.4 (0.4%)
Rye and products	0 (0%)
Pulses	**3.66 (100%)**
Beans	1.64 (44.8%)
Pulses, other and products	1.25 (34.2%)
Peas	0.77 (21.0%)

Adapted from (FAOSTAT, 2013).

3.2.3. Consumption data

Cereals are essential in the human diet in many cultures, including New Zealand (Olsson, Börjesson, Lundstedt, & Schnürer, 2000). The most recent available data from the Food and Agriculture Organisation of the United Nations (FAO) food balance sheets for New Zealand is 2013. A summary of food balance sheets for cereal and pulses is shown in Table 4 (FAOSTAT, 2013). Wheat and products are the most frequently consumed cereal (78.5%) followed by other cereals such as oats (3.4%) and barley (0.4%) in New Zealand. Pulses (3.66 kg/capita/year) are well below the total cereal consumption (98.02 kg/capita/year).

The available data for cereal consumption is from the 1997 National Nutrition Survey (1997 NNS) for New Zealand's adults (Table 5). This is similar to the data obtained from the FAO food balance sheets showing wheat flour consumption in New Zealand is very high compared with other cereals.

3.2.4. Exposure evaluation

The calculation for the annual average number of servings cereals is shown below for New Zealand as the representative country.

$$\begin{aligned} \textit{Annual number of servings (total population)} &= 4,965,538\ x\ ((0.204\ x\ 14,490/3,275) + (0.796\ x\ 17,529/4636))\ x\ 365 \\ &= 4,965,538\ x\ (0.903 + 3.009)\ x\ 365 \\ &= 7.1\ x\ 10^{9}\ \textit{servings} \end{aligned}$$

The result shows a very high number of servings, and this was posited as cereal grains serve as a staple part of New Zealanders' diet. The number of servings depicts the total number of cereal servings. Cereal grains which are consumed directly and their main processed products such as flour were assumed to have little contribution to these servings. However, this data did not allow food identification and practices such as eating raw cake batter. In 2008–2009, eating raw cake batter practice was associated with foodborne illness outbreaks in New Zealand and in the USA (CDC, 2009).

Overall, the exposure assessment showed that bacterial pathogen contamination may occur throughout the cereal grain manufacturing chain. Cereals and grains are highly consumed which reflects one of the staples of the diet of New Zealand. Fortunately, cereal grains are consumed mostly after cooking or heat treatment, which inactivates the pathogens. The probability of bacterial pathogen contamination in raw cereal grains in New Zealand is unknown. However, the prevalence of *B. cereus* in wheat flour in Australia was reported to be 93% with <1 spore/gram (Berghofer et al., 2003). The prevalence of *B. cereus* in raw material for bread (such as wheat, rye, and oats) in Denmark was reported to be 2%, whereas the Bacillus spore numbers surviving heat treatment at 100 °C for 10 min in wheat (grains, rolled, bran, wholemeal, flour) was 1.8–12.4 CFU/g, in rye (grains, rolled, bran, wholemeal) was 2.2–7.3 CFU/g, and in oats (grains, rolled, wholemeal) was 9.6–29.8 CFU/g (Rosenkvist & Hansen, 1995). Conversely, the two studies described above indicate that considerable variability by region/country is likely.

3.3. Risk characterisation for cereal grains – identifying the most critical microbial risk

Risk characterisation exemplifies the integration of the hazard identification, hazard characterisation and exposure assessment to provide a risk estimate. In order to identify the most critical pathogen in cereal grains, this risk assessment used the qualitative measure of consequence from the hazard characterisation and qualitative measures

Table 5
Consumption of cereal grains in New Zealand.

Cereal	Per cent consuming in 24- hours period (%)	Average daily consumption, all (g/day)	Average consumption, consumers only (g/day)	97.5th percentile consumption, consumers only (g/day)
Cereal grain fractions	98.3	127.3	129.5	370.1
Wheat flour	98.0	106.6	108.7	347.3
Rice, polished	20.4	10.2	50.0	213.8
Maize flour	23.0	3.2	14.1	68.2
Cereal brans, processed	13.6	0.9	6.7	49.9
Rye, wholemeal	23.5	2.3	9.9	27.1
Oats	22.5	5.9	26.1	99.3
Millet	2.1	0.1	6.0	27.9

'All' means the overall set of respondents, comprising people who did not report consuming cereals in the previous 24-h 'Consumers' means only to those who reported consumption of cereals in the previous 24-h.
From "Risk Profile: *Salmonella* in cereal grains," (Gilbert et al., 2010, p. 15).© 2010 by Institute of Environmental Science & Research Limited. In the public domain.

Table 6
Semi-quantitative risk assessment matrix result.

Likelihood	Consequences				
	Insignificant (1)	Minor (2)	Moderate (3)	Major (4)	Severe (5)
Almost certain (5)	Medium	High *C. perfringens*	High *B. cereus*	Very high	Very high
Likely (4)	Medium	Medium	High	High	Very high
Possible (3)	Low	Medium	Medium *S. aureus*	High	High
Unlikely (2)	Low	Medium	Medium	Medium *C. botulinum*	High *Cronobacter* spp. *E. coli (STEC)* *Salmonella* spp.
Rare (1)	Low	Low	Low	Medium *Shigella* spp.	Medium *L. monocytogenes*

of likelihood from the exposure assessment in the form of a score. The score obtained from the consequence and likelihood were multiplied to give the overall risk score. The risk score was then extrapolated to a semi-quantitative risk assessment matrix (Table 6) to be more understandable. The calculation of the score can be seen in Appendix A. *B. cereus* scored the highest and is regarded as high representing the pathogen of most critical risk in cereal grains. Other pathogens that are also high risk are *C. perfringens*, *Cronobacter* spp., *E. coli* (STEC) and *Salmonella*. Pathogens representing a medium risk are *S. aureus*, *C. botulinum*, *L. monocytogenes*, and *Shigella* spp.

3.4. Exposure assessment for addition of cereal grains added to dairy products

Based on the risk assessment matrix, *B. cereus* is the highest microbial risk in cereal grains. Therefore, the scenario used in this exposure assessment is cereal grains (Table 7) contaminated with *B. cereus* in addition to dairy product examples with different water activities (milk powder, Parmesan cheese and liquid breakfast product). Oats was the model cereal grain used. Milk powder represents low water activity, Parmesan cheese represents intermediate water activity, and liquid breakfast products represent high water activity. The milk powder and liquid breakfast products are based on commodities already available commercially, while Parmesan cheese with added grains is a hypothetical product. *B. cereus* is a spore-forming bacterium that is naturally present in the dairy farming environment, and in dairy products (Shaheen et al., 2006). *B. cereus* is also capable of attaching to dairy processing equipment (Shaheen, Svensson, Andersson, Christiansson, & Salkinoja-Salonen, 2010). The ability of *B. cereus* to attach and form biofilms on processing equipment means it can also contaminate cereal

Table 7
The prevalence summary of *B. cereus* in cereal grains.

Ingredient	Prevalence	Bacterial cell counts	References
Barley	High (21%)	NS	Park et al. (2009)
Corn (Maize)	Low (4.3%)	<4 log CFU/g	Losio et al. (2017)
Millet	NA		
Oats	Low (2%)	9.6–29.8 CFU/g	Rosenkvist and Hansen (1995)
Rye	Low (2%)	2.2–2.9 CFU/g	Rosenkvist and Hansen (1995)
Black glutinous rice	High (37%)	NS	Park et al. (2009)
Brown rice	High (37%)	NS	Park et al. (2009)
Wheat	Low to Extremely high (2%–94%)	<1 spore/g to 12.4 CFU/g	Berghofer et al. (2003)
Buckwheat	Medium (12.5%)	<4 log CFU/g	Losio et al. (2017)
Adzuki beans	NA		
Garden pea	NA		
Hyacinth beans	NA		
Mung beans	NA		
Soybeans	NA		
Black Soybeans	NA		

NA: Not available; NS: Not stated.

grains added to the processing lines since the characteristics of some cereal grains favour the growth of microorganisms.

3.4.1. Cereal addition to low water activity dairy products

Skim milk powder and non-fat milk powder are examples of low water activity dairy products (a_w<0.60) (Early, 1998b). As cereals do not go through a sterilisation process, they may contain *B. cereus* spores. Spores are persistent in dry foods such as cereals (Beuchat et al., 2013). As mentioned earlier, oats as a raw material may contain *Bacillus* spores 9.6–29.8 CFU/g, which is considered a low count (Rosenkvist & Hansen, 1995).

In milk powder, there are several possibilities for contamination with *B. cereus*: from manufacturing equipment, packaging line/faulty package, storage, distribution, and consumer use. Contamination during storage and distribution of milk powder shows variability in the prevalence of *B. cereus* ranging from of 10.3%–19.3% (Becker, Schaller, von Wiese, & Terplan, 1994; Reyes, Bastias, Gutiérrez, & Rodríguez, 2007) and similarly, the prevalence in powdered infant and young children formula was reported as 14.08% with >100 CFU/g (Li, Pei, Yang, & Li, 2014), meaning the likelihood of contamination can be classified as low. The addition of cereals contaminated with *B. cereus* to milk powder may add to the levels of *B. cereus* which may be naturally present from the milk source. In dry milk powder products itself, this is a low food safety risk as spores will not grow at low water activity (aw < 0.6). The food safety risk from these added *B. cereus* spores from cereal sources has the same food safety risks as spores already present in milk powder from milk. For example, it is well understood that temperature abuse of reconstituted milk powder, such as those for infants, can allow for germination and growth of *B. cereus* spores to levels that may constitute a toxin risk (Bursová, Necidová, & Haruštiaková, 2018).

3.4.2. Cereal addition to intermediate water activity dairy products

Intermediate water activity dairy products ($0.60 \leq a_w \geq 0.85$) include Parmesan cheese and salted butter (Schmidt & Fontana, 2008). The presence of salt and other intrinsic characteristics of Parmesan cheese (a_w of 0.69–0.73 and low pH < 4.5) suppress the growth of *B. cereus*. The likelihood of *B. cereus* spore contamination from cereals in Parmesan cheese is expected to be low (i.e. similar to milk powder, the addition of cereals contaminated with *B. cereus* to cheese may add to the levels of *B. cereus* naturally present from the milk source).

3.4.3. Cereal addition to high water activity dairy product

High water activity dairy products ($a_w > 0.85$ include milk, cream, cheddar cheese, unsalted butter, and yoghurt (Schmidt & Fontana, 2008). Liquid breakfast products, which is a combination of non-dairy such as cereal grains and a dairy ingredient such as milk has become common in the market. The high-water activity of such products is excellent for the growth of many microorganisms, including *B. cereus* (Jay, Loessner, & Golden, 2005). The likelihood of *B. cereus* spore contamination to be transferred from oats to liquid milk of a neutral pH is predicted to be high. High moisture dairy foods with a low pH (pH < 4.6), such as yoghurt, have intrinsic properties that can protect them from pathogen growth, including *B. cereus*.

3.4.4. Risk estimate summary

A summary of risk estimate (Table 8) showed that the risk estimate for oats as a raw material is low, but, contamination of products from

Table 8
Summary of risk estimation of oats addition to dairy products.

	Risk estimate			
	B. cereus in milk powder	*B. cereus* in Parmesan cheese	*B. cereus* in liquid breakfast product	References
The occurrence in raw material (cereal):	Low (2%)	Low (2%)	Low (2%)	Rosenkvist and Hansen (1995), Nicholson, Munakata, Horneck, Melosh, and Setlow (2000), Jaquette and Beuchat (1998)
The likelihood of contamination/growth in the dairy product:	Low (low a_w)	Low (intermediate a_w)	High (high a_w)	Early (1998a), Jay et al. (2005), Schmidt and Fontana (2008)
Effect of decontamination process (pasteurisation or UHT):	Complete inactivation	Complete inactivation	Complete inactivation	FSAI (2016), Schraft and Griffiths (2006)
The occurrence of toxin:	Rare (0–0.1%)	Rare (0–0.1%)	Rare (0–0.1%)	MPI (2015)
Contamination after pasteurisation or UHT process:				
- Manufacturing equipment:	High to very high (25.9%–56%)	High to very high (25.9%–56%)	High to very high (25.9%–56%)	Shaheen et al. (2010), Eneroth et al. (1998), Becker et al. (1994), Lin, Ren, Zhao, and Guo (2017), Champagne et al. (1994)
- Packaging line/faulty package	NA	NA	Very high (64%)	Eneroth et al. (1998)
- Storage and distribution	Medium to extremely high (10.3%–100%)	Medium to high (10.04%–14%)	Medium to extremely high (13%–100%)	Li et al. (2014), Champagne et al. (1994), Yibar et al. (2017)
- Consumer use	High to very high (45.9%–59%)	Very high (55%)	Medium to extremely high (13%–100%)	Reyes et al. (2007), Zeinab, Refaat, Abd El-Shakour, Mehanna, and Hassan (2015), Salustiano et al. (2009), Giffel, Beumer, Granum, and Rombouts (1997), Haughton, Garvey, and Rowan (2010)

NA: Not available.

manufacturing equipment and packaging plus the growth of any contaminants during storage and distribution may vary along with the potential for consumer abuse influence the risk estimate.

4. Discussion

4.1. Microbiological risk assessment of selected cereal grains

The risk assessment matrix was useful for identifying the most critical risks for microbiological hazards in selected cereal grains. The most critical microbiological hazard in the selected cereal grains is *Bacillus cereus* (*B. cereus*). *B. cereus* was the highest for both criteria (i.e. number of outbreaks and prevalence) in assessing the likelihood of a microbial hazard. The findings are in agreement with studies by Alldrick, 2017; Brown, 2000. According to Alldrick, 2017; Brown, 2000, the most significant indigenous bacteria in cereal products are *Bacillus* spp. which includes *B. cereus*. They attributed this to the ability of *Bacillus* spores to activate after cooking (thermal shocks) followed by slow cooling and storage at room temperature causing outgrowth in the cooled cooked product.

B. cereus is among the microorganisms that persist in low moisture conditions (MOE, 2015). Spores of this bacterium survive dry conditions and antimicrobial treatments providing a food safety risk (MPI, 2015). The result from the present study shows that, although the prevalence of *B. cereus* is high (up to 94%), the microbial load is relatively low (up to 29.8 CFU/g). However, this bacterium can cause sickness due to possible temperature abuse that allows the microorganism to grow. A good example is *B. cereus* in cooked rice (FAO/WHO, 2014; Gilbert et al., 2010).

To assess the consequences of microbial hazards, a modified version of the ICMSF classification was used (ICMSF, 2018). This led to the categories 'insignificant', 'minor', 'moderate', 'major' and 'severe' being used. In spite of *B. cereus* scoring the highest microbial hazard, the severity of its consequences scored below *C. botulinum*, *Cronobacter* spp., *E. coli STEC* and *L. monocytogenes*. This is because the symptoms associated with other pathogenic bacteria such as *C. botulinum* (cause infant botulism which can result in paralysis of the respiratory muscles, legs and trunk), *Cronobacter (*causes death in infants less than 6 months old with mortality rate among neonates up to 70%), *E. coli* O157:H7 (STEC) (which can lead to Haemolytic-uremic syndrome (HUS) in children which is characterised through renal failure and its consequences) and *L. monocytogenes* (a life threatening disease which can lead to abortion in pregnant women) are more severe than *B. cereus* (which causes diarrhoea and death is rare) (ICMSF, 2018). It is important to note that, to date, none of these pathogens mentioned above have been associated with cereal grain related foodborne outbreaks in New Zealand.

Heat treatment is the common risk mitigation for the microbiological safety of cereal grains (Gilbert et al., 2010). Although heat treatment can eliminate most micro-organisms, it may induce spore germination (Alldrick, 2017; Lake, Hudson, & Cressey, 2004). To avoid the spore germination after heat treatment, alternatives to heat treatment can be used. These alternatives include cold plasma, high hydrostatic pressure, ultrasonication, use of chemicals (fermented ethanol or supercritical carbon dioxide or sodium hypochlorite dip or citric acid dip), irradiation (microwave, gamma, or electron beam) and combination other of treatments that have shown their effectiveness in reducing the contamination of *B. cereus*, *Salmonella*, *E. coli* and *S. aureus* in cereal grains (FAO/WHO, 2014; Los et al., 2018). Not all countries allow the use of gamma irradiation for food products. For example, Australia and New Zealand approve irradiation using gamma rays to a limited range of commodities such as herbs and spices, herbal infusions, and some fruits (e.g. blueberry, raspberry, persimmons) and vegetables (e.g. tomato, capsicum) (FSANZ, 2017a).

A risk ranking method using a risk-based control approach is useful for prioritizing hazards in food combinations (Van Asselt, Sterrenburg, Noordam, & Van der Fels-Klerx, 2012). The risk assessment matrix is one example of a risk-based control approach (Van Asselt et al., 2012), unlike other approaches such as multi-criteria decision analysis (MCDA). Recently, the MCDA approach was used to rank low moisture foods of greatest concern based on the microbiological food safety perspective by FAO/WHO (2014). Criteria used were international trade, burden of disease, vulnerabilities due to food consumption and vulnerabilities to food production. However, the MCDA was not used in this risk assessment because the method is not a risk-based approach and criteria used are more applicable to policy makers (including government and international agencies) (Baltussen & Niessen, 2006) whereas the use of a risk assessment matrix has wider context and may be suitable for assessing the risks in food product development for the food industry.

The risk matrix provides a visualisation of the consequences and likelihood of occurrence of a hazard. To assess the likelihood of a microbial hazard, the prevalence of the hazard in a food and the number of outbreaks were used. The number of outbreaks criteria was taken to represent the burden of illness. The data from three different countries including Taiwan, New Zealand and the United States were used depending on the available data in the literature from 1991 to 2015. One limitation is the unavailability of data from the countries used in the time period assessed. For example, for Taiwan, data from 1991 to 2000 was available to be used whilst data from 1998 to 2015 was available to be used for the United States. A high number of outbreaks of *B. cereus* food poisoning associated with cereal grains has been shown in the US and Taiwan but not in New Zealand. A possible explanation for this might be that illness caused by *B. cereus* is not a notifiable disease in New Zealand (Lake et al., 2004).

The use of outbreak data in assessing the likelihood/probability may not represent the true burden of illness. Batz et al. (2005) reveals that outbreak data may contain inherent bias. Outbreaks that are large, have short incubation period, produce serious illness and involve food premises e.g. restaurants, tend to be investigated and reported. On the other hand, sicknesses caused by pathogens that are difficult to identify or do not often cause a large outbreak are underreported, hence understated. Another way to describe the burden of illness is by using Disability Adjusted Life Years (DALY) (McKenna, Michaud, Murray, & Marks, 2005). The DALY approach requires abundant data including the quantitative estimates of incidents, disease burden and the costs for a country in a specific time frame and these data are often limited (Mangen et al., 2015). In 2011, New Zealand adopted the US model to estimate the numbers of cases of illness, hospitalisations, and deaths due to foodborne agents (Cressey & Lake, 2011). However, the authors claimed that the model is under development (Cressey & Lake, 2011).

This study was unable to perform a comprehensive exposure evaluation. The exposure evaluation results did not indicate the form/state of cereal products (food identification) and practices such as eating raw cake batter. It is important to note that cereal grains are not often consumed directly in the form of grains (e.g. wheat grains) or their main processed product (i.e. flour). Instead, cereal grains are usually consumed in the form of secondary processed products including bread, biscuits, cakes, and pasta. These secondary processed products involve heat-treatment or drying that will kill many micro-organisms (Alldrick, 2017).

4.2. Microbial risk assessment of selected cereal addition to dairy products

Cereal grains (oats) contaminated by *B. cereus* incorporated into high water activity dairy products such as milk pose a high theoretical risk to the safety of dairy products. Conversely, low and intermediate moisture dairy products pose a low theoretical risk. Although *B. cereus* is unlikely to grow in the low and intermediate moisture dairy products, its spores, if they exist in raw material, can survive throughout the manufacturing process and may be present in the final product. This result supports the hypothesis that the addition of non-dairy origin ingredients to dairy products may pose microbiological risks depending on product's

characteristics such as water activity.

The addition of *B. cereus* contaminated cereal grains to dairy products contaminated with *B. cereus* can exacerbate the risk already present from *B. cereus* that may naturally be found in milk. It is crucial for the dairy industry to ensure that cereal grains from suppliers comply with microbiological criteria for such ingredients.

Microbiological quality of raw material (cereal grains and milk) used in dairy products is paramount (FSANZ, 2006). This is because bacteria and fungi are capable of producing toxins or causing invasive illness especially when they exist in high numbers in raw material. For some toxin producing microorganisms, heat treatment will inactivate the vegetative forms of the microorganisms however many toxins are heat stable and survive heat treatment. The only acceptable solution is to control the microbiological quality of cereal grain ingredients.

From the exposure assessment, the number of bacterial spores is low in the raw material. However, the prevalence shows that *B. cereus* spores are frequently reported in the dairy processing and manufacturing plant (Becker et al., 1994; Eneroth, Christiansson, Brendehaug, & Molin, 1998; Shaheen et al., 2010). Milk after pasteurisation and UHT has been found to contain *B. cereus* spores. However, their presence in UHT products would suggest faulty operations in the processing plant (Fernandes, 2009). This indicates the importance of maintaining suitable holding times and appropriate temperature for heat treatment in the dairy industry. Moreover, the ability of *B. cereus* to form spores as well as grow in a temperature range (30–37 °C) (MPI, 2015) make it possible for this bacterium to thrive before and after pasteurisation and in the final product until consumption. Some *B. cereus* strains can grow up to 55 °C while others can grow as low as 4–5 °C (Ehling-Schulz, Fricker, & Scherer, 2004; Lake et al., 2004).

Bacterial spores can be activated by several factors such as low pH, availability of nutrients and sublethal heat (Lake et al., 2004). *B. cereus* and its spores occur naturally in most raw foods (Jay et al., 2005), including dry foods, dried herbs, and spices (MPI, 2015). The microbial load of *B. cereus* in raw material is relatively low (<100 spores/g or mL) (Heyndrickx, 2011) and it is impractical to eliminate low numbers of spores from foods. Therefore, Lake et al. (2004) suggests preventing spore germination and growth to high numbers that threaten food safety.

Addition of non-dairy ingredients contaminated with bacterial spores to dairy products that are nutrient dense could lead to spore germination. Pasteurisation is the main method for microbiological control and in the dairy industry with high-temperature short time (HTST) treatment at 72 °C for 15 s as the standard pasteurisation conditions (Bylund, 2015). While this will not inactivate spores it will inactivate the vegetative cells that have resulted from spore germination. The holding time during heat treatment is a critical control point for ingredients added before heat treatment (Fernandes, 2009).

There is also the possibility of contamination after pasteurisation with contamination originating from the manufacturing equipment, packaging line, storage, distribution, and consumer use (Becker et al., 1994; Li et al., 2014; Salustiano et al., 2009; Yibar, Cetinkaya, Soyutemiz, & Yaman, 2017). There is some variability in the prevalence of post pasteurisation contamination depending on the conditions in the manufacturing plant and the country in which the studies were undertaken.

The prevalence of contamination at the consumer level reflects the importance of risk communication to educate the consumer regarding proper food safety behaviour. For example: preparation, storage and handling of reconstituted milk should be properly done by diluting the milk powder in warm or cool water that has been previously boiled, consuming milk right after each preparation, and storing reconstituted milk at <5 °C. Many foods need to be completely reheated before consumption; rapid and efficient cooling of cooked foods is needed for storage (Setlow & Johnson, 1997; Turck, 2012).

Regardless of the high incidence of *B. cereus* in milk, very few *B. cereus* associated foodborne outbreaks have been reported. Currently, there is no evidence of dairy product contamination with *B. cereus* as a concern to public health in New Zealand as *B. cereus* has not been associated with any foodborne outbreak related to dairy in New Zealand from 2007 to 2015. This may be due to several factors such as their presence in low number (10^2/g to 10^3/g) or the presence of competitive microflora in dairy products and unfavourable growth conditions which do not allow them to grow to high numbers that can reach the dose of food safety concern (10^5-10^8/g) (Champagne et al., 1994; Granum & Lund, 1997; Spanu, 2016). One of the characteristics of *B. cereus* is that it is a poor competitor, allowing other spoilage microorganisms to overgrow and spoil dairy products before *B. cereus* becomes a risk. Spoiled dairy products marked with sour or off-flavours prevent people from consuming the contaminated products.

There is limited information about risk assessment of non-dairy ingredient addition to dairy products. Nonetheless, many products that combine non-dairy ingredients with dairy ingredients are sold worldwide. This supports the importance of conducting a risk assessment to get an overview of safety in these products. The present study was unable to provide a risk estimate of microbial and chemical hazards for New Zealand due to unavailability of local information. Hence, this risk assessment gives a general idea on the global scale of non-dairy ingredient addition to dairy products. Some of the references regarding dairy products contamination with *B. cereus* were documented more than ten years ago which may be not be relevant anymore due to improvements in dairy processing.

5. Conclusions

The most critical microbiological hazard in the selected cereal grains is *Bacillus cereus*. This bacterium is a microorganism that persists in low moisture conditions in products such as cereal grains. Spores of this bacterium survive in both dry conditions and antimicrobial treatments providing a food safety risk. Therefore, it is recommended to prevent spore germination and prevent multiplication of bacterial cells.

The addition of cereal grains to dairy products poses a theoretical microbial risk. Oats contaminated with *Bacillus cereus* added to milk powder or Parmesan cheese were found to pose a low theoretical risk, whereas their addition to liquid cereal was found to be a high theoretical risk (mitigated by UHT processing). Microbial risks are also mitigated by selecting cereal grains with a low microbial loading and high quality.

There are some disadvantages in the use of the risk matrix tool. Risk matrices are predicted to be less accurate than other techniques which use a quantitative approach by considering concentration data and dose-response relationships or toxicological reference values (Elmontsri, 2013; van der Fels-Klerx et al., 2018). Another limitation of using a risk matrix is the subjectivity of the consequence levels. The risk matrix may be a blunt tool and often requires a number of value judgements to be made, which have the potential to bias the assessment. Nevertheless, the risk matrix can be used as a preliminary step in the prioritisation of risk (Cressey, 2019, May 31). Note that the risk matrix may result in different pathogens other than *B. cereus* as a priority if there is new data available for criteria used to determine the likelihood. Other pathogens that may be a concern include *Clostridium perfringens (C. perfringens)*, *Cronobacter* spp., *Salmonella* spp., and Shiga toxin-producing *E. coli (STEC)*.

The present study highlights the significance of *B. cereus* contamination in cereal grains and dairy products. Complete removal of this bacterium through decontamination processes is not possible. The food industry must apply proper handling and storage of cereal grains as well as dairy products to prevent the proliferation of *B. cereus* to levels that can cause foodborne illness. It is, therefore, recommended to carry a quantitative risk assessment as well after addressing the knowledge gaps.

The present study provides a foundation for future work. This study was able to identify knowledge gaps for future work in microbiological risk assessment. There is lack of studies on prevalence data for pathogens such as *C. botulinum*, *C. perfringens*, *L. monocytogenes* and *Shigella*

spp. in the selected cereal grains in New Zealand, including those which are domestically produced or imported. In order to improve the exposure assessment, predictive modelling is needed for a real overview on the level of *B. cereus* from the farm to fork. Information regarding consumption frequency and serving sizes of any dairy products with added cereal grains is also required.

CRediT authorship contribution statement

Fitry Fatima: Writing – review & editing, Writing – original draft, Formal analysis, Data curation. **Indra Pramularsih:** Methodology, Investigation, Data curation. **Emmanuel O. Kyere:** Supervision, Methodology, Formal analysis. **Denise Lindsay:** Writing – original draft, Resources, Project administration, Funding acquisition, Conceptualization. **Grant Abernethy:** Writing – original draft, Supervision, Formal analysis. **Simone Laing:** Writing – original draft, Validation, Supervision, Resources, Formal analysis. **Steve Flint:** Writing – review & editing, Writing – original draft, Supervision, Project administration.

Declaration of competing interest

We declare no conflict of interest in the content of this manuscript "Microbiological risk assessments of the addition of selected cereal grains as non-dairy ingredients go dairy products".

Data availability

Data will be made available on request.

Appendix A. Risk characterisation of microbiological risk assessment

The consequence levels for microbiological hazards that were used in the research were insignificant (1), minor (2), moderate (3), major (4) and severe (5). Five levels of consequences and their qualitative descriptions are shown in Table 9.

Table 9
Qualitative description of consequence

Consequence level	Score	Description
Severe	5	Severe hazard for vulnerable population (category III·B based on ICMSF): Life-threatening, substantial chronic sequelae, long duration.
Major	4	Severe hazard for the general population (category III.A based on ICMSF): Life-threatening, substantial chronic sequelae, long duration.
Moderate	3	Serious hazard (category II based on ICMSF): Incapacitating but not life-threatening, sequelae infrequent, moderate duration.
Minor	2	Moderate category (category I based on ICMSF): Not usually life-threatening, no sequelae, usually short duration, symptoms are self-limiting, can be severe discomfort.
Insignificant	1	Not significant.

Adapted from (ICMSF, 2018; FAO/WHO, 2009b).

The risk levels identified for the likelihood of occurrence were rare (1), unlikely (2), possible (3), likely (4), and almost certain (5). The five likelihood levels and their qualitative descriptions are presented in 10.

Table 10
Semi-quantitative description of likelihood

Likelihood level	Score	Description	No. of outbreaks	Prevalence
Almost Certain	5	is expected to occur in most circumstances	>60	>85%
Likely	4	Will probably occur in most circumstances	41–60	50–85%
Possible	3	Might occur or would occur at some time	21–40	21–49%
Unlikely	2	Could occur at some time	11–20	1–20%
Rare	1	May occur only in exceptional circumstances	0–10	<1%

Adapted from (FAO/WHO, 2009b, p. 34) and (Popov et al., 2016).

Risk is a quantification of the probability/likelihood of an uncertain future event and severity of consequence which can be defined in the following equation:

$$\text{Risk (R)} = \text{Severity (S)} \times \text{Likelihood (L)}$$

Table 11
Risk characterisation calculation

Microbiological hazards	Severity of illness	Consequence score (C)	Exposure assessment $\frac{\text{Outbreaks} + \text{Prevalence}}{2}$	Likelihood score (L)	Risk Score (R = C × L)
Bacillus cereus	Moderate	3	(5 + 5)/2	5	15
Clostridium botulinum	Severe	5	(1 + 2)2	1.5	7.5
Clostridium perfringens	Moderate	3	(5 + 2)/2	3.5	10.5
Cronobacter spp.	Severe	5	(1 + 3)/2	2	10
Escherichia coli O157:H7 (STEC)	Major	4	(1 + 4)/2	2.5	10
Listeria monocytogenes	Severe	5	(1 + 1)/2	1	5
Salmonella spp.	Major	4	(3 + 2)/2	2.5	10
Shigella spp.	Major	4	(1 + 1)/2	1	4
Staphylococcus aureus	Moderate	3	(3 + 3)/2	3	9

Appendix B. Hazard characterisation of microbiological risk assessment

1. *Bacillus cereus*

Bacillus cereus (*B. cereus*) is a Gram-positive, facultative aerobic, spore-forming organism which is extensively spread in nature, thus is readily isolated from soil, dust, vegetation, cereal produces, water, air and sediment (FSAI, 2016; MPI, 2015). *B. cereus* and its spores occur naturally in most raw foods (Jay et al., 2005), including dry foods, dried herbs, and spices (MPI, 2015). According to Glasset et al. (2016), food-borne outbreaks by *B. cereus* in France from 2007 to 2014 were associated with vegetables and starchy foods such as rice.

1.1. Bacterial growth

B. cereus can grow in the pH range of 4.5–9.5 with an optimum pH 6 to 7. It requires a minimum water activity between 0.93 and 0.95 in the presence of NaCl and water activity of 0.93 with glycerol. The microorganism can grow at temperatures of 4–55 °C and optimum 30–37 °C, while the emetic strains need a minimum temperature of 10 °C (Ehling-Schulz et al., 2004). *B. cereus* is capable of producing toxin at temperatures of 10–40 °C and with maximum toxin production at 20–25 °C (MPI, 2015).

1.2. Disease characteristic

B. cereus causes two types of foodborne illness, diarrhoeal or emetic syndromes (MPI, 2015). The emetic syndrome occurs because of emetic toxins (cereulide) ingestion that is formed when the vegetative cell count exceeds 10^5 CFU/g. Importantly, the toxins are highly stable (minimum 2 months at 4 °C), heat resistance (90 min at 126 °C), pH resistant ($2 \leq$ pH ≤ 11) and unaffected to proteolytic enzymes (IDF, 2016). Symptoms of an emetic syndrome include vomiting, nausea, malaise and is sometimes followed by diarrhoea, appearing within 6 h after consumption of food contaminated with the pre-formed toxin (Rajkovic, 2014). Emetic syndrome symptoms are similar to illness caused by *Staphylococcus aureus* (Glasset et al., 2016). Duration of sickness is 6–24 h.

Diarrhoeal syndrome arises due to ingestion of bacterial cells that further create enterotoxins in the small intestine. Symptoms such as occasional nausea, abdominal pain, and watery diarrhoea generally appear within 8–16 h (FSAI, 2016). The infection happens when the concentrations of *B. cereus* surpass 10^6 CFU/g in the food and adequate amounts of the enterotoxins are formed. The enterotoxins are heat-labile and sensitive to acid conditions or proteolysis (MPI, 2015).

1.3. Dose-response

Diarrhoeal syndromes are often linked to *B. cereus* counts of 10^5 to 10^8 cells or spores (Granum & Lund, 1997). Before toxins are detected in the food, a large number of viable cells (10^5 to 10^8/g) is required. A very low emetic toxin level in the range of 0.01–1.28 μg/g was associated with an outbreak in Japan (Agata et al., 2002). Another measure of emetic toxin level of 8 μg/kg body weight has been proposed as the intoxication dose (Paananen et al., 2002). The diarrhoeal syndrome is often associated with meat, vegetables, milk and milk products (Pexara & Govaris, 2010). Emetic intoxication is often linked with the consumption of raw starchy foods such as rice, noodles, pasta, pastries, and potatoes (Pexara & Govaris, 2010). Cooked or fried rice is involved in 95% of emetic cases. Lesson learned from the food poisoning cases associated with cereal-based products is not to let the foods cool down slowly and not to store in the range of 10–50 °C as this causes the spores to germinate and multiply up to level enough to cause illness (MPI, 2015).

2. *Clostridium botulinum*

Clostridium botulinum (*C. botulinum*) is a Gram-positive, anaerobic bacterium which is commonly found in soil and marine sediment. *C. botulinum* can contaminate crops cultivated in or on the soil (MRI, 2017c). It typically exists in the form of dormant spores, but, once it gets into a favourable condition, the spores propagate into active bacteria and produce toxins. Vegetative cells of *C. botulinum* and sometimes C. butyricum and C. baratii bacteria produce a toxin which is known as Botulinal neurotoxin (BoNT) (CDC, 2017). There are seven types of toxin (A through G), which are believed to be the most potent toxins known, including A, B, E and F types which cause botulism in humans.

2.1. Bacterial growth

C. botulinum can grow at temperatures of 10 °C–48 °C, with optimum 35–40 °C. Group I which produces of toxins A, B and F grow at pH 4.6 and water activity of 0.94 in 10% NaCl. Similarly, group II which produce toxins B, E and F grow at pH of 5 and water activity of 0.97 in 5% NaCl (MRI, 2017c).

2.2. Disease characteristic

Foodborne botulism is a severe intoxication caused by ingestion of foods contain BoNT. Botulism was formerly associated with the consumption of preserved low acid and low oxygen foods such as canned foods. BoNT affects the central nervous system and can cause breathing difficulties, muscular paralysis, and even death due to respiratory failure. There are five clinical classifications of human botulism: foodborne botulism; wound botulism; adult infectious botulism; infant botulism; and other types of intoxication such as botulinum toxin injection (WHO, 1999).

Symptoms of botulism include nausea, diarrhoea, vomiting, and paralysis of the eyes, mouth, throat and eventually, muscles within 12–36 h after consumption. *C. botulism* can grow and produces toxins in the intestines of babies and causes infant botulism with symptoms of constipation, fatigue, floppiness and breathing difficulties (MPI, 2017c).

Nowadays, the rate of dying from botulism is lower because of the development of antitoxins and modern medical care. It has reduced from 50/100 to <5/100 people dying with botulism. However, some patients still die because of infections or other problems caused by being paralysed for several weeks or months. Patients that survive from botulism still have fatigue and breathing difficulties for years and may require therapy (CDC, 2017).

2.3. Dose-response

The dose for type A and B toxins to cause death in human are estimated between 0.1 and 1.0 μg (ICMSF, 1996a) while the dose for types E and F toxins are roughly 10 μg (Bell & Kyriakides, 2000).

3. *Cronobacter spp.*

Cronobacter, previously known as *Enterobacter sakazakii* (*E. sakazakii*), is a Gram-negative, facultative anaerobic, rod-shaped, non-sporulating pathogenic bacterium which can cause foodborne sickness, mainly to infants and immunocompromised adults. This bacterium can cause meningitis, bacteraemia and necrotising enterocolitis (FDA, 2012a). *E. sakazakii* was reclassified into *Cronobacter* genus which comprises of six species: *Cronobacter sakazakii*; *C. malonaticus*; *C. turicensis, C. muytjensii* and *C. dublinensis*. Cronobacter have been isolated from environments such as domestic environments, manufacturing plants, foods (e.g. Powdered Infant Formula (PIF), fermented bread and cheese) (FSAI, 2011a).

3.1. *Bacterial growth*

Cronobacter spp. can grow at temperatures of 6–45 °C with an optimum temperature 37–43 °C. Generation time at 22 °C is 37–44 min (FSAI, 2011a).

3.2. *Disease characteristic*

The infection generally has a case-fatality rate ranging from 10 to 80%. New born infants are at risk, with infants older than 6 months hardly affected. Premature or low birth weight infants have higher case fatality rates. The highest mortality was reported in healthy term infants who suffered septicaemia. In infants, symptoms occur in a few days. The disease in adults is not common and food sources usually have not been determined (FDA, 2012a).

Symptoms are frequently severe and may include poor feeding response, jaundice, irritability, seizures, and fluctuation of body temperature, brain abscess, developmental delay and hydrocephalus. Duration of symptoms varies from 2 to 8 weeks. Death may occur within a few hours to several days after sepsis (FDA, 2012a).

3.3. *Dose-response*

The infectious dose of *Cronobacter* has not been determined. However, scientists estimated the dose might be similar to *E. coli* O157:H7 i.e. 10 to 100 micro-organisms (FDA, 2012a; FSAI, 2011a).

4. *Escherichia coli O157: H7*

Escherichia coli (E. *coli*) is a Gram-negative bacterium that naturally inhabit the gastrointestinal tract of humans and other warm-blooded animals. Most *E. coli* strains are not likely to cause harm, but some forms can cause severe disease. Shiga toxin-producing *E. coli* (STEC), also known as verocytotoxigenic *E. coli* (VTEC), are virulent and is responsible for the majority of human illness (NZFSA, 2017b).

4.1. *Bacterial growth*

E. coli can grow at temperatures of 7–8 °C to 46 °C with an optimum temperature of 37 °C. They grows at pH of 4.4–9.0 with optimum pH of 6–7. *E. coli* require a minimum water activity of 0.95 and optimum growth is observed at 0.99 (NZFSA, 2017b).

4.2. *Disease characteristic*

STEC attacks the gut and then produces a toxin that causes infection. STEC infection is characterised by mild or severe diarrhoea and abdominal pain that occurs 3–9 days (with a mean of 4 days) after ingestion. Infants under four years and older people above 65 years are at risk as they can acquire a fatal condition such as acute kidney disease (NZFSA, 2001a).

This disease has severe forms, such as haemorrhagic colitis (HC), haemolytic uremic syndrome (HUS), and thrombocytopenic purpura (TTP). HC symptoms are severe stomach pain, bloody diarrhoea, vomiting. HUS took place after HC and resulted in renal dysfunction, seizures, coma and death. HUS generally affects children and occurs in approximately 10% of children infected by *E. coli* O157: H7. Fortunately, the fatality rate can be reduced to less than 10% if the appropriate care is given (NZFSA, 2001a).

TTP is a form of HUS that commonly happens in the elderly. TTP symptoms are HUS symptoms and also the loss of platelets, seizures, and stroke. Duration of illness is two to nine days. Hospitality rate is one-third of cases. Long-term effects of HUS are problems related to kidney, hypertension and neurological deficiency. The death rate in the USA is less than 5% and around 1% for New Zealand (NZFSA, 2001a).

4.3. *Dose-response*

The dose of 0.3–0.4 cells/g has been associated with outbreaks. The amount of cells needed to produce a 50% probability of disease has been predicted at 5.9×10^5 CFU/g (NZFSA, 2001a).

4. *Listeria monocytogenes*

Listeria monocytogenes (L. monocytogenes) is naturally found in soil and water (NZFSA, 2001b).

5.1. *Bacterial growth*

L. monocytogenes can grow at temperatures of 1.5–45 °C with an optimum at a temperature of 37 °C. It can grow at the pH range of 4.4–9.4 with optimum pH at 7. This pathogen requires water activity of 0.92 to grow in 11.5% NaCl solution (NZFSA, 2001b).

5.2. *Disease characteristic*

L. monocytogenes can cause two kinds of disease, i.e. the invasive (listeriosis) and a non-invasive (febrile gastroenteritis). The invasive usually occurs in susceptible groups, while, the non-invasive disease can occur to the general population due to ingestion of a high number of *L. monocytogenes* cells ($>10^5$ cells/g) (MPI, 2017b).

Listeriosis and febrile gastroenteritis have similar symptoms. Febrile gastroenteritis disease is gastroenteritis related to mild 'flu-like' symptoms (such as a headache and fever) and other symptoms of non-invasive illness including muscle pain, diarrhoea and less common for vomiting and abdominal pain with a duration of 11 h to 7 days (MPI, 2017b). Symptoms of listeriosis include diarrhoea, vomiting, fever, headache, septicaemia,

meningitis, and spontaneous abortion in pregnant women. Duration of listeriosis is one to 90 days, and hospitalisation rate is high (92%).

Listeriosis rarely occurs but is potentially life-threatening. Compared to salmonellosis and campylobacteriosis; listeriosis has a high death rate (approximately 30%) especially for the immune-weakened people such as newborn babies, pregnant women, older adults and immunocompromised people. In pregnancy, *Listeria* infection has mild symptoms, but it can cause miscarriage, premature birth or severe disease in a newborn child (MPI, 2017b).

5.3. Dose-response

Estimated dose to cause illness for invasive disease is estimated to be lower (100–1000 cells) than non-invasive disease ($>10^5$ cells/g) (MPI, 2017b).

6. Salmonella spp

Salmonella are a Gram-negative, non-spore former, rod-shaped bacteria under the family Enterobacteriaceae. *Salmonella* are extensively distributed in nature. They inhabits the gastrointestinal tract of humans and animals such as cattle, pets and wildlife. In addition, and may be found in the sediment of pond-water. *Salmonella* may contaminate the soil, water, meat, food processing equipment, hands, and utensils (FDA, 2012b).

There are two species of non-typhoid Salmonellae, i.e. *Salmonella enterica* and *Salmonella bongori* (García & Heredia, 2009). *Salmonella enterica* has six subspecies (enterica, arizonae, salamae, houtanae, diarizonae, and indica), where the most significant subspecies is *S. enterica* subspecies *enterica* because it can cause foodborne disease (Lawley et al., 2008).

Salmonella may contaminate cereals through animal or human faecal material. Post-harvest contamination by rodents and birds may occur when the storage is insufficiently maintained. Insufficient storage means that storage facilities do not have a program to prevent rodent and bird to enter the storage room and defecate there. Cereals and their milled products have A dairy product with aw activity that suppresses the growth of *Salmonella*, but, it encourages the heat resistance of Salmonella. (Gilbert et al., 2010; NZFSA, 2001c).

6.1. Bacterial growth

Salmonella is a mesophilic bacterium which means that it can multiply at a temperature of 4–15 °C with optimum growth at 35–37 °C (García & Heredia, 2009; NZFSA, 2001c). Moreover, it can grow in the pH range of 3.6–9.5 with the optimum pH of 7–7.5. It requires water activity of 0.94 and maximum growth with water activity above 0.99. Nevertheless, *Salmonella* can survive in dehydrated environments for months (NZFSA, 2001c).

6.2. Disease characteristic

Non-typhoid Salmonellae cause a foodborne illness known as salmonellosis. It is a gastrointestinal disease with symptoms such as diarrhoea, nausea, vomiting, abdominal cramps and fever that could last 1–7 days. The incubation period for salmonellosis is 6–48 h, but commonly 12–36 h (Lawley et al., 2008). The susceptible group consists of older people, infants, and people with the weakened immune system may develop septicaemia and reactive arthritis in the long term (NZFSA, 2001c). The hospitalisation rate is predicted at 22.1%. Mortality rate of non-typhoid *Salmonella* is estimated at 0.8% and the rate could be higher for the elderly (Lawley et al., 2008; NZFSA, 2001c).

6.3. Dose-response

The dose of non-typhoid *Salmonella* required to cause illness are varies, and many factors are involved such as individual susceptibility, type of food and serotype. Ingestion of food containing 10–100 *Salmonella* cells can cause sickness in the elderly or young. The infective dose at low attack rates is between 4 and 45 cells, while at a high attack rate is generally in the range of 10^5 to 10^6 cells (Gilbert et al., 2010; NZFSA, 2001c).

The risk of contaminated cereal grains causing human salmonellosis is considered as low. An outbreak associated with flour suggests that it is likely to impact large numbers of people although is caused by unusual consumer behaviour such as consumption of uncooked home baking materials (Gilbert et al., 2010).

7. Shigella spp.

Shigella spp. comprises four species: *S. dysenteriae*, *S. boydii*, *S. flexneri*, and *S. sonnei* (ECDC, 2017).

7.1. Bacterial growth

Shigella spp. can grow at temperatures of 6–7 °C to 45–47 °C. They require a water activity at 0.96 (Duckworth, 2012). This microorganism can grow at a minimum pH of 4.8–5.0 in 3.8–5.2% NaCl solution, pH of 5.5 in the presence of 300–700 mg/L $NaNO_2$, and maximum pH of 9.3 in 5.2% NaCl solution (NZFSA, 2001d).

7.2. Disease characteristic

Shigella spp. can cause an illness called bacillary dysentery or shigellosis (FDA, 2012c). It has an incubation period of 12 h to four days. Shigellosis is a gastrointestinal infection described as diarrhoea where faeces contain mucus and sometimes blood coupled with fatigue, fever, abdominal pain, and malaise. In three days, the illness may develop to a colonic phase that is characterised by intense cramps with repeated and painful bowel movements that continue to happen for 3–14 days.

Shigella may cause severe disease in infants, older people, or immunocompromised people including cancer, diabetes, HIV/AIDS, and kidney failure disease patients (CDC, 2010). No toxin is produced in foods. Septicaemia is a severe bloodstream infection that may happen to individuals with a weakened immune system (NZFSA, 2001d).

7.3. Dose-response

The dose required to cause infection is estimated at 10–100 cells (NZFSA, 2001d).

8. Staphylococcus aureus

Staphylococcus aureus (*S. aureus*) is an abundant micro-organism present on the skin and mucous membranes of humans and also most warm-blooded animals such as cows (NZFSA, 2001c). It is usually found in foods of animal origin, for example, raw milk and raw meat. *S. aureus* rarely causes food poisoning in raw food, except for milk obtained from a mastitis cow.

8.1. Bacterial growth

S. aureus can grow at temperature of 6–48 °C with an optimum of 37 °C. It requires pH 4.2 to grow and maximum 9.3 with optimum growth at a neutral pH (7.0–7.5). 0.1% acetic acid solution of (pH 5.1) inhibits *S. aureus* from growing. *S. aureus* is unaffected by drying. It may grow in the food with a water activity of 0.85 and produce enterotoxins although its optimum water activity is 0.99. It is resistant to NaCl, as it grows at a NaCl level of 7–10% and up to 25% (NZFSA, 2001c).

8.2. Disease characteristic

S. aureus can produce staphylococcal enterotoxins (SEs) that cause staphylococcal food poisoning (NZFSA, 2001c). The toxin is produced when the concentration of the enterotoxigenic strains exceeds 10^5 CFU/g. It is hard to remove SEs from foods once it is formed as they are resistant to heat, irradiation, and freezing. Due to its heat resistant property, SEs can survive commercial pasteurisation and even the canned food sterilisation process. To date, 16 types of SE have been recognised, they are A, B, C1, C2, C3, D, E, G, H, I, J, K, L, M, N and O. There are several factors affecting the formation of SEs, for instance, water activity, pH, temperature, redox potential, and antimicrobial constituents such as starter culture in the fermentation of milk products are able to prevent the growth of *S. aureus* and thus, SE production.

Staphylococcal food poisoning (SFP) occurs due to the ingestion of the SEs (NZFSA, 2001c). The human strains of *S. aureus* generating SE (A) and SE (D), with the majority of strains generating only SE (A) are the primary cause of SFP. Symptoms include diarrhoea, nausea, vomiting, and abdominal pains that generally appear 1–7 h after ingestion. The quantity of toxin to make people sick depends on the vulnerability of the person. Epidemiological studies revealed that food poisoning could be caused by a tiny amount (1 μg) of SE. Collapse may happen in severe cases, but the recovery is within two days (FSAI, 2011b).

8.3. Dose-response

Toxins are produced when the number of *S. aureus* exceed 10^5 per gram. The dose of the toxin to cause the symptoms of illness is less than 1.0 μg (NZFSA, 2001c).

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