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Supporting document 2

Risk profile for Australian food service and related food retail businesses – P1053

Executive summary

Foodborne illness associated with food service sectors are reported to account for approximately two-thirds of all reported foodborne illness outbreaks (Astridge et al. 2011). The general trend of the annual number of foodborne outbreaks and the number of people ill associated with the food service industry is reported to have steadily increased from 2001 to 2016 (Osterberger 2018). Food safety management for these sectors is considered a priority for the food regulatory system and is included in [Australia's National Foodborne Illness Reduction Strategy 2018-2021+](#)¹ under the sector based initiative: food service.

The objectives of this assessment were to review classifications of Australian food service and related food retail business sectors on the basis of food safety risk using the National Risk Profiling Framework, including the consideration of recent OzFoodNet data on foodborne outbreaks associated with food prepared in these businesses. The assessment also aimed to determine if certain characteristic food handling activities undertaken by these business sectors could be categorised on the basis of food safety risks.

Data from the OzFoodNet Outbreak Register relevant to foodborne and probable foodborne outbreaks from food prepared in Australian food service and related food retail business sectors were reviewed. The total number of foodborne and probable foodborne outbreaks in Australia for 2010 – 2017 was 1,257, resulting in 19,497 persons reported ill, 1,914 of these people were hospitalised, and 56 fatalities were reported. The majority of these outbreaks were associated with food prepared in Australian food service and related food retail settings that were considered in this assessment.

Salmonella spp. and egg related foodborne outbreaks from food prepared in food service or retail businesses were responsible for the largest number of outbreaks, people ill, and people hospitalised where a hazard or food commodity could be identified. As such, raw eggs can be considered a high risk potentially hazardous food (PHF) when handled by these businesses. However, for a large number of foodborne outbreaks in Australia, the causative hazard or implicated food commodity was unidentified.

The major contaminating, bacterial growth, and microbial survival factors identified by OzFoodNet as contributing to foodborne outbreaks in food service and related retail

¹ On 29 June 2018 the Australia and New Zealand Ministerial Forum on Food Regulation (the Forum) endorsed Australia's Foodborne Illness Reduction Strategy 2018-2021+.

businesses from 2013 - 2017 were diverse. Ingestion of contaminated raw products, cross contamination from raw ingredients, inadequate cleaning of equipment, insufficient cooking, foods left at room or warm temperature, inadequate refrigeration, delay between preparation and consumption, insufficient time/temperature during cooking, and inadequate or failed disinfection were all frequently reported.

The outbreak data indicates that the controls required for maintaining food safety at various points during food preparation and service by the in-scope business sectors are not adequately implemented, and foodborne outbreaks associated with these sectors contribute significantly to the burden of foodborne illness in Australia.

In 2011, the Department of Health and Ageing finalised the assignment of risk priority classifications to the business types that were identified by Ministers for the scope of Proposal P1053 and for which they consider food safety management could be improved. The business sector classifications were reviewed on the basis of food safety risk using the National Risk Profiling Framework (the Framework) that provides a four-tier model of classification (Priority 1 - Priority 4). The following priority risk classifications were assigned following the review:

- Food service: commercial catering (P1) (Activity 1)
- Food service: eating establishments - RTE prepared in advance (P1) (Activity 1)
- Food service: RTE food is prepared express order – some high risk food components are raw (P1) (Activity 2)
- Food service: RTE food is prepared express order – all high risk food components are cooked (P2) (Activity 2)
- Retailer and manufacturer: bakery products (P1) (Activity 1)
- Retailer: bakery products (P2) (Activity 3)
- Retailer: processed delicatessen products (P2) (Activity 3)
- Retailer: processed seafood products (P2) (Activity 3)
- Retailer: High risk perishable pre-packaged food (P2) (Activity 4)

However, not all jurisdictions use the Framework to classify businesses. Therefore, four characteristic handling activities identified for the business sectors by the Implementation Subcommittee for Food Regulation (ISFR) Working Group, to provide an alternate way of identifying priority businesses, were grouped into three categories on the basis of food safety risk. This categorisation was based on the number of critical food safety controls required, and the proportion of Australian foodborne outbreaks and associated people ill represented by the food service or related food retail businesses most likely to undertake the handling activity.

Category 1 included: Food Handling Activity 1 - *process high risk potentially hazardous food in advance of serving the ready-to-eat food to the consumer*, and Food Handling Activity 2 - *process potentially hazardous food and serve as ready-to-eat food to the consumer in a time period which does not adversely affect the microbiological safety of the food*. The handling activities have common critical controls that need to be consistently implemented, along with general principles for food hygiene, by the associated business sectors that undertake that handling activity as their highest risk activity.

The categories developed by FSANZ provide a food safety risk profile of the key food business sectors and their characteristic handling activities that can be used to inform risk management options.

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1 Introduction

Foodborne illnesses associated with food service sectors are reported to account for approximately two-thirds of all reported foodborne illness outbreaks in Australia (Astridge et al. 2011). For this reason, food safety management for these sectors is considered a priority for the food regulatory system and is included in [Australia's National Foodborne Illness Reduction Strategy 2018-2021+](#)² under the sector based initiative: food service.

This document seeks to profile risks to public health and safety associated with Australian food service and related food retail businesses. FSANZ uses a number of tools to assess risks to public health and safety, including risk profiling³, quantitative and qualitative risk assessments⁴ and scientific evaluations. The application of these tools to the assessment of the risks to public health and safety is dependent on the purpose of the assessment and on the availability, quality and quantity of relevant data.

In 2011, the Department of Health and Ageing finalised the assignment of risk priority classifications to eight food service and food retail business types by an independent team of food safety experts using the science-based National Risk Profiling Framework (the Framework) that provides a four-tier model of classification, between Priority 1 and Priority 4, based on food safety risks (DoHA 2007; Ross et al. 2009). The eight identified food service and food retail business sectors were all assigned classifications in the two highest risk categories (Priority 1 and 2).

Profiling the risks to public health and safety associated with these sectors is part of FSANZ's risk analysis⁵ approach to assessing which businesses should be subject to certain mandatory regulatory measures, if enacted. However, while the Framework priority risk classifications have been used in previous work undertaken by the Implementation Sub Committee for Food Regulation (ISFR) and are used by a number of jurisdictions to classify in-scope businesses, not all jurisdictions use the Framework. As such, during the progression of P1053 it was identified that there needed to be an alternate way to identify priority businesses. To this end, the key characteristics of the in scope businesses and classification examples described by Ross et al. (2009) were discussed with the ISFR WG, and were translated into four food handling activities. The four food handling activities as agreed with the ISFR WG were:

- *Activity 1: process potentially hazardous food in advance of serving the ready-to-eat food to the consumer*
- *Activity 2: process potentially hazardous food and serve as ready-to-eat food to the consumer in a time period which does not adversely affect the microbiological safety of the food*
- *Activity 3: serve unpackaged potentially hazardous food as ready-to-eat food for retail*
- *Activity 4: serve packaged potentially hazardous food as ready-to-eat food. The food is packaged prior to receipt by the food business for retail*

As part of the evidence base for P1053, the risks to public health and safety were profiled for

² On 29 June 2018 the Australia and New Zealand Ministerial Forum on Food Regulation (the Forum) endorsed Australia's Foodborne Illness Reduction Strategy 2018-2021+.

³ Risk profiling is defined by FAO/WHO as 'the process of describing a food safety problem and its context, in order to identify those elements of the hazard or risk relevant to various risk management decisions'.

⁴ Risk assessment is a scientific process undertaken to characterise the risk to public health and safety posed by foodborne hazards associated with a food commodity.

⁵ Risk analysis is comprised of three interrelated components: risk assessment, risk management and risk communication.

the priority food service and related food retail businesses engaged in the different food handling activities. The profiling considered the best available evidence from OzFoodNet to present the epidemiology of foodborne outbreaks associated with Australian food service and related food retail business sectors; reviewed the classifications of these business sectors using the Framework; and also considered if the food handling activities identified by the ISFR WG could be prioritised on the basis of food safety risks.

The outcomes of this assessment will contribute to risk management decisions and assessing if improvements can be made within food service and related retail sectors to strengthen the food regulatory system and reduce foodborne illness.

2 Risk assessment questions and scope

The objectives of this assessment were to:

- (i) review the classifications of the eight Australian food service and related food retail business sectors identified by Food Ministers on the basis of food safety risk using the Framework, including the consideration of recent OzFoodNet data regarding foodborne outbreaks associated with food prepared in these businesses; and
- (ii) determine if the characteristic food handling activities identified by the ISFR WG for these business sectors can also be classified on the basis of food safety risks.

The assessment brings together the best available data regarding foodborne outbreaks, and describes the hazards and the controls that are required within those food business sectors to ensure food safety.

The following risk assessment questions were developed in discussion with risk managers:

1. What evidence is there regarding the frequency, type, and severity of hazards (*i.e.*, aetiological agents), and contributing factors, involved in outbreaks associated with food service and related retail businesses engaged in different food handling activities?
2. What potential hazards/risk factors are associated with different food handling activities of food service and related retail businesses, and what controls are required for food safety?

The data collated for the risk assessment questions were used to review the classification of Australian food service and related food retail business sectors using the Framework, and, additionally, to group the handling activities identified by the ISFR WG into priority groups of handling activities on the basis of food safety risk. The prioritising of handling activities included consideration of the number of controls required for food safety, and the proportion of foodborne outbreaks associated with the food service or food retail business sectors that are characterised by that handling activity.

In this assessment the following definitions regarding food businesses and handling activities apply:

- **‘Potentially Hazardous Food (PHF)’ definition from Std 3.2.2**

PHF means food that has to be kept at certain temperatures to minimise the growth of any pathogenic microorganisms that may be present in the food or to prevent the formation of toxins in the food.

- **‘Ready-to-eat food (RTE)’ definition from Std 3.2.2**

Ready-to-eat food means food that is ordinarily consumed in the same state as that in which it is sold and does not include nuts in the shell and whole, raw fruits and vegetables that are intended for hulling, peeling or washing by the consumer.

- **‘Handle’ definition from Std 3.1.1**

Handling of food includes the making, manufacturing, producing, collecting, extracting, processing, storing, transporting, delivering, preparing, treating, preserving, packing, cooking, thawing, serving or displaying of food.

- **‘Process’ definition from Std 3.2.2**

Process in relation to food, means activity conducted to prepare food for sale including chopping, cooking, drying, fermenting, heating, pasteurising, thawing and washing, or a combination of these activities.

The ISFR WG provided input into the development of a definition for '**retailer**' to be used in this assessment:

Retailer is a food business which sells food direct to the public that is

- a) not processed on the food premises other than being sliced and/or weighed (e.g. delicatessen products); repacked; or reheated and hot-held (e.g. RTE cooked foods); and*
- b) the food is generally not intended to be consumed on the food premises.*

3 Foodborne outbreaks associated with Australian food service and related food retail businesses 2010 – 2017

3.1 Introduction

The Communicable Disease Network Australia and OzFoodNet monitor incidents and outbreaks of foodborne disease which can lead to the detection of an unsafe food product or unsafe food practice. The OzFoodNet Outbreak Register contains data on reported outbreaks of gastrointestinal disease in Australia since 2001, with foodborne and suspected foodborne outbreaks defined as two or more cases of illness associated with a common food.

Data were retrieved from the OzFoodNet Outbreak Register with the aim of describing the frequency, type, and severity of hazards (*i.e.*, aetiological agents), and contamination factors, involved in foodborne or probable foodborne outbreaks (hereafter referred to as ‘foodborne outbreaks’) associated with Australian food service and related food retail businesses.

The OzFoodNet Outbreak Register only includes outbreaks reported to, and investigated by, OzFoodNet sites in states and territories. The data presented in this assessment therefore only represents a proportion of the total outbreaks occurring in the community, resulting in under-representation of the true burden of illness associated with foodborne disease outbreaks within Australia. The number of hospitalisations and deaths are also likely to under-represent the true burden as the number of hospitalised cases may only represent those cases who are interviewed, and as deaths are not routinely followed up for foodborne diseases and may only represent those deaths that were known at the time of investigation. The number of outbreaks and cases of illness reported by OzFoodNet may differ over time as investigations are finalised, reported and reviewed.

3.2 Methods

Data were obtained for 2010 – 2012 from the OzFoodNet annual reports available online (OzFoodNet Working Group, 2012; 2015; 2018). Additional data were also requested by FSANZ from OzFoodNet for 2013 – 2017, and were retrieved from the OzFoodNet Outbreak Register on 22/10/2020 (OzFoodNet, 2020).

The information fields provided by OzFoodNet for each outbreak from 2010 – 2017 included; year; state or territory; month; setting prepared; aetiological agent responsible; number (no.) ill; no. hospitalised; no. fatalities; evidence; epidemiological study; responsible food vehicles; and food commodity.

To describe the epidemiology of foodborne outbreaks across the variety of different food service or food retail businesses in Australia a number of different settings described in the OzFoodNet Outbreak Register were considered in scope for this assessment. It should be noted, however, that the settings used by OzFoodNet do not directly correspond to the classification of businesses in the Framework.

In this assessment, “food service and related food retail businesses” includes the settings identified in the “vulnerable populations food service settings”, “priority food service or retail settings”, and the “additional food service or retail settings”.

The ‘vulnerable populations food service settings’ category includes the OzFoodNet settings

'aged care', 'child care', and 'hospital'. These settings are intended to reflect those that apply to Standard 3.3.1 – Food safety programs for food service to vulnerable persons. However, the setting descriptions used by OzFoodNet do not completely match the descriptions of vulnerable population food business described in Standard 3.3.1. As such, businesses that need to adhere to Standard 3.3.1 may also be represented in other settings described by OzFoodNet such as 'institutions'.

The 'priority food service and retail settings' category includes the OzFoodNet settings 'restaurant', 'commercial caterer', 'take-away', 'bakery', 'national franchised fast food restaurants', 'fair or festival or mobile service', and 'grocery stores and delicatessens'. These settings are intended to reflect the majority of the in scope P1 and P2 businesses including catering, eating establishments, retailer and/or manufacturers of bakery products, and retailers processed delicatessen products. Notably, the P2 businesses including retailers of processed seafood products and retailers of perishable pre-packaged food do not have relevant settings descriptors in Outbreak Register.

The 'additional food service and retail settings' category includes 'camp', 'church or monastery', 'correctional facility', 'cruise or airline', 'institution', 'military', 'mining camp', and 'school' settings. These are reported in this assessment to provide additional information regarding foodborne outbreaks for settings that may have similar food handling characteristics to the priority food service and retail settings.

Only the OzFoodNet data obtained from 2013 – 2017 reported the categories of major contamination factors along with major bacterial growth, and microbial survival factors that contributed to outbreaks. As such, only the data from 2013 – 2017 were used to identify which of these factors were most often associated with foodborne outbreaks. Up to two factors can be reported for each category in the OzFoodNet Outbreak Register. It was important in this assessment to understand the burden of illness potentially associated with individual factors. To this end, if two factors were reported in an outbreak these were separated for analysis and each factor was allocated the same values for number of persons ill to provide a conservative estimate for each factor. However, it should be noted that it is not possible to accurately proportion the burden of illness to individual factors. There are different levels of evidence used when OzFoodNet attributes contamination, microbial survival, and bacterial growth factors but the level of evidence associated with the attributions of different factors was not requested nor supplied for this review.

The data were analysed using Prism9 Graph-pad and Microsoft Excel. Frequencies of outbreak characteristics were calculated including outcomes (number of persons ill, hospitalisation, fatalities); food service or food retail business settings where food was prepared; reported agent responsible; the food commodity; contamination factors; microbial survival factors; and bacterial growth factors.

3.3 Results

3.3.1 Australian food service and related food retail foodborne outbreaks from 2010 - 2017

The total number of all foodborne outbreaks in Australia from 2010 – 2017 was 1,257, the associated number of people ill was 19,497; of these, 1,914 people were hospitalised, and 56 fatalities were reported.

The number of foodborne outbreaks, people reported ill, people reported hospitalised, and fatalities associated with food prepared by food service and related food retail settings from 2010 – 2017 are summarised in Table 1. A total of 970 foodborne outbreaks were associated with these settings that resulted in 15,286 people being reported ill, 1,371 of these people being hospitalised, and 34 fatalities.

Foodborne outbreaks in priority food service and retail settings accounted for 63.9% (803/1,257) of all foodborne outbreaks, 64.6% (12,598/19,497) of the total people ill, 63.9% (1,224/1,914) of hospitalisations, and 17.9% (10/56) of fatalities from 2010 – 2017.

Table 1. The number of foodborne outbreaks, people reported ill, people reported hospitalised, and fatalities associated with food prepared in Australian food service and related food retail settings reported from 2010-2017.

Settings	No. of outbreaks	No. ill	No. hospitalised	No. fatalities
Vulnerable populations food service settings	113	1,377	80	24
Priority food service and retail settings	803	12,598	1,224	10
Additional food service and retail settings	54	1,311	67	0
Total	970	15,286	1,371	34

Of the 970 reported foodborne outbreaks from food service and related food retail settings, NSW (34.85%) followed by Victoria (23.40%), Queensland (12.27%), and Western Australia (10.31%) accounted for the largest proportion, with all other states or territories accounting for < 10% (Table 2). Food prepared in restaurant settings accounted for the largest proportion of outbreaks and persons ill in all states and territories (data not shown).

The number of foodborne outbreaks, people ill, hospitalised, and fatalities associated with food prepared in different Australian food service and related food retail settings from 2010 – 2017 are summarised in

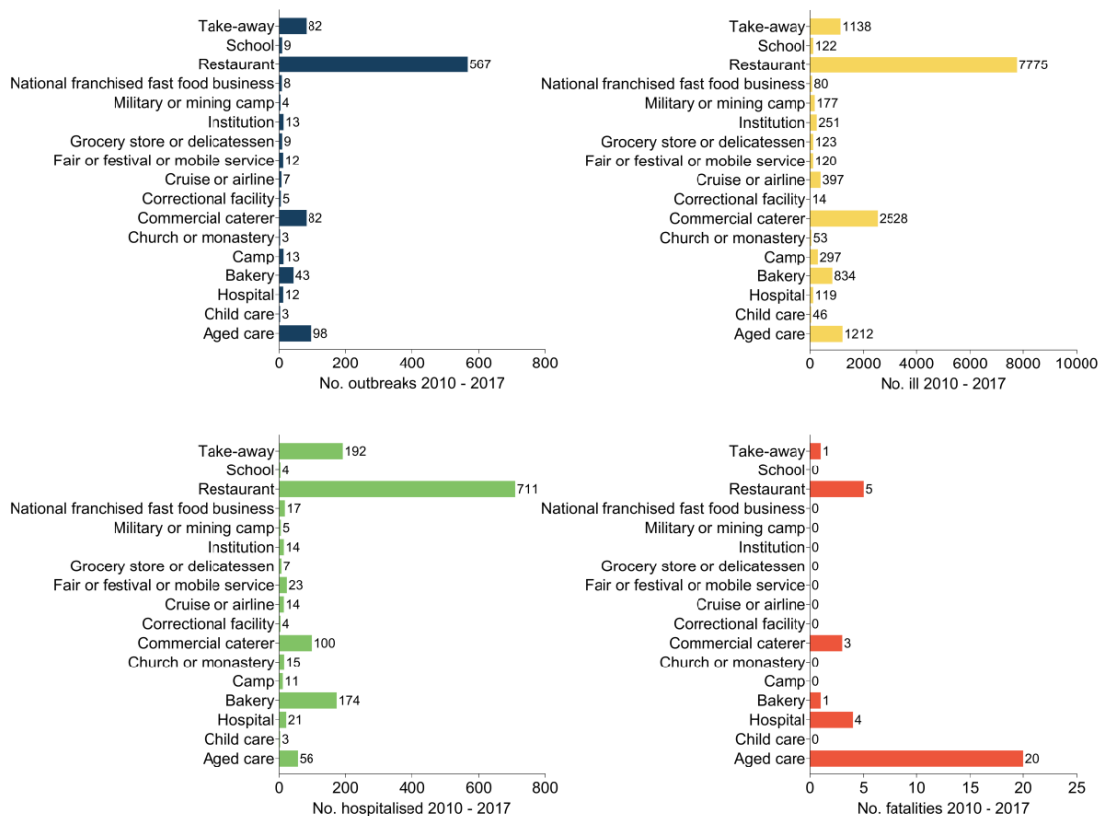


Figure 1. At the national level, foodborne outbreaks were most frequently associated with food prepared in restaurants which represented 58.5% (567/970) of foodborne outbreaks associated with the food service and food retail settings considered in this review, followed by aged care (10.1%), take-away (8.5%), commercial caterer (8.5%), additional food service and retail settings (5.6%)⁶, bakery (4.4%), fair or festival or mobile service (1.2%), grocery stores and delicatessens (0.9%), and national franchised fast food restaurants (0.8%) settings.

Table 2. The number of foodborne outbreaks, people reported ill, people reported hospitalised, and fatalities associated with food prepared in Australian food service and food retail settings reported from 2010–2017 by state or territory.

State or territory	No. outbreaks	No. ill	No. hospitalised	No. fatalities
ACT	39	904	82	3
MJOI*	3	352	3	0
NSW	338	4,585	337	5
NT	38	388	12	0
Qld	119	2,112	251	5
SA	83	1,263	206	3
Tas	23	534	18	0
Vic	227	3,770	337	15
WA	100	1,378	125	3
Total	970	15,286	1,371	34

*MJOI = multijurisdictional incident

Outbreaks associated with restaurants were also associated with the highest proportion of

⁶ The 'Additional settings' category includes 'camp', 'church or monastery', 'correctional facility', 'cruise or airline', 'institution', 'military', 'mining camp', and 'school' settings.

the 15,286 people ill (50.9%), and 1,371 hospitalised (51.9%). The highest proportion of the 34 fatalities were associated with foodborne outbreaks from food prepared in aged care (58.8%), restaurant (14.7%), hospital (11.8%), and commercial caterer (8.8%) settings (

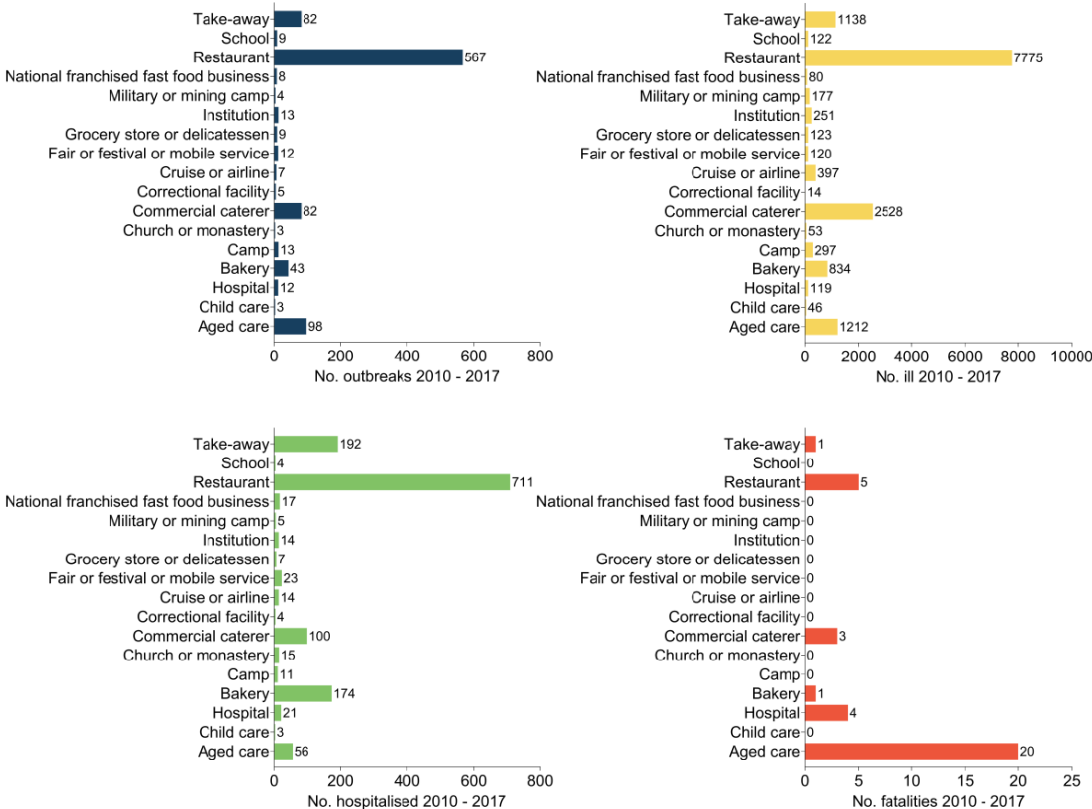


Figure 1). The high proportion of fatalities in aged care and hospital settings may reflect the increased susceptibility of the consumers in these settings to foodborne illness (NSW Food Authority, 2017).

While food prepared in commercial caterer settings was associated with more people reported ill (2,528) than takeaways (1,138) or bakeries (834), a higher number of people reported requiring hospitalisation in outbreaks associated with bakeries (174) and takeaways (192) compared with commercial caterer settings (100). This could in part be due to the differences in the severity of illness generally associated with the hazards that differ across these settings (See section 3.3.2), though a number of factors can influence the severity of illness associated with foodborne outbreaks (ICMSF 2018; Gibney et al., 2014).

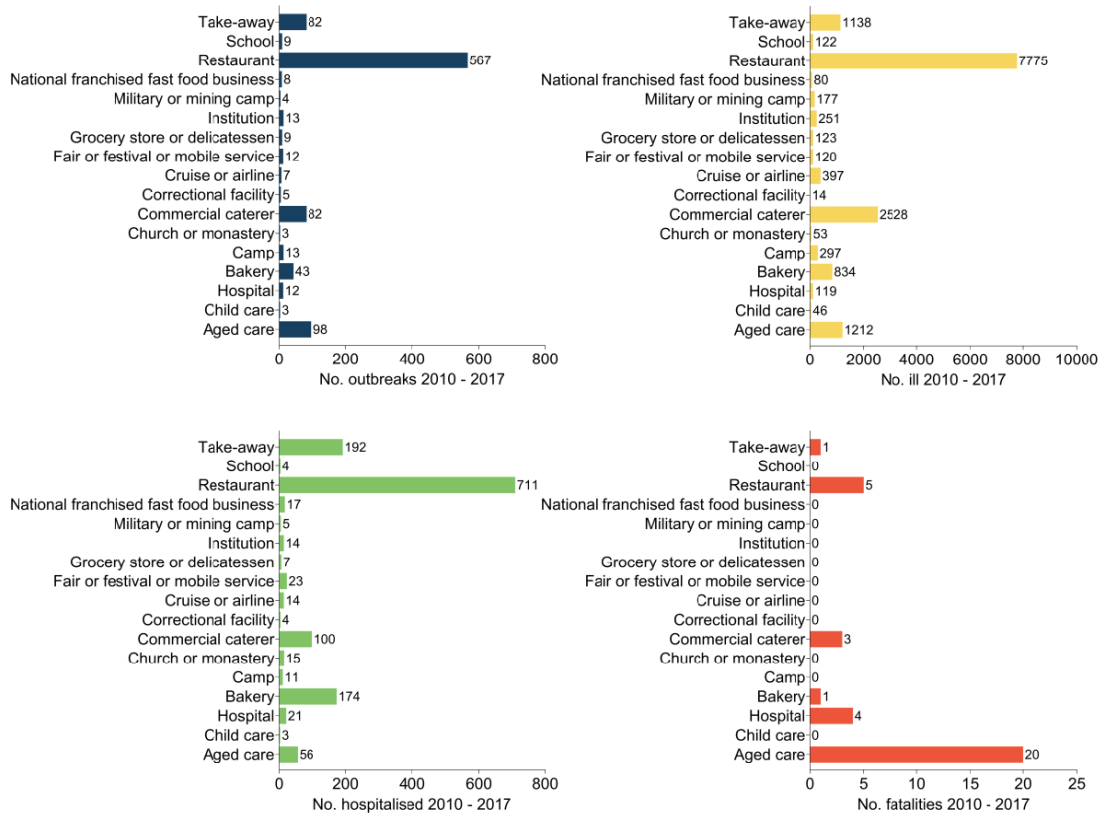


Figure 1. The number of foodborne outbreaks, people reported ill, people hospitalised, and fatalities associated with food prepared in Australian food service and food retail settings from 2010 – 2017.

3.3.2 Hazards (aetiological agents) responsible for foodborne outbreaks from food prepared in Australian food service and food retail settings 2010-2017

Hazards responsible

The number of foodborne outbreaks, people reported ill, hospitalised, and fatalities associated with food prepared in Australian food service and food retail settings from 2010 – 2017 that were attributed to different hazards (*i.e.*, aetiological agents) are summarised in Figure 2.

The most frequently reported hazard responsible for 46.4% (450/970) of foodborne outbreaks in Australian food service and food retail settings was *Salmonella* spp., followed by outbreaks caused by unknown hazards (31.2%), norovirus (8.3%), *Clostridium perfringens* (5.1%), and *Campylobacter* spp. (5.0%) (Figure 2). The majority of the *Salmonella* spp. outbreaks were attributed to *Salmonella* Typhimurium (91%, 410/450).

Similarly, foodborne outbreaks caused by *Salmonella* spp. resulted in the highest proportion of the 15,286 people reported ill (50.39%), followed by unknown hazards (23.0%), norovirus (14.3%), *C. perfringens* (4.1%), and *Campylobacter* spp. (3.6%) (Figure 2).

Salmonella spp. caused the largest proportion of the 1,371 reported hospitalisation (88.3%), followed by norovirus (3.4%), unknown hazards (2.7%), and *Campylobacter* spp. (1.9%)

(Figure 2).

Salmonella spp. also caused the largest proportion of the 34 fatalities (76.5%), followed by *C. perfringens* (5.9%), *Campylobacter* spp. (5.9%), *Amanita phalloides* (5.9%), *L. monocytogenes* (2.9%), and *Staphylococcus aureus* (2.9%) (Figure 2).

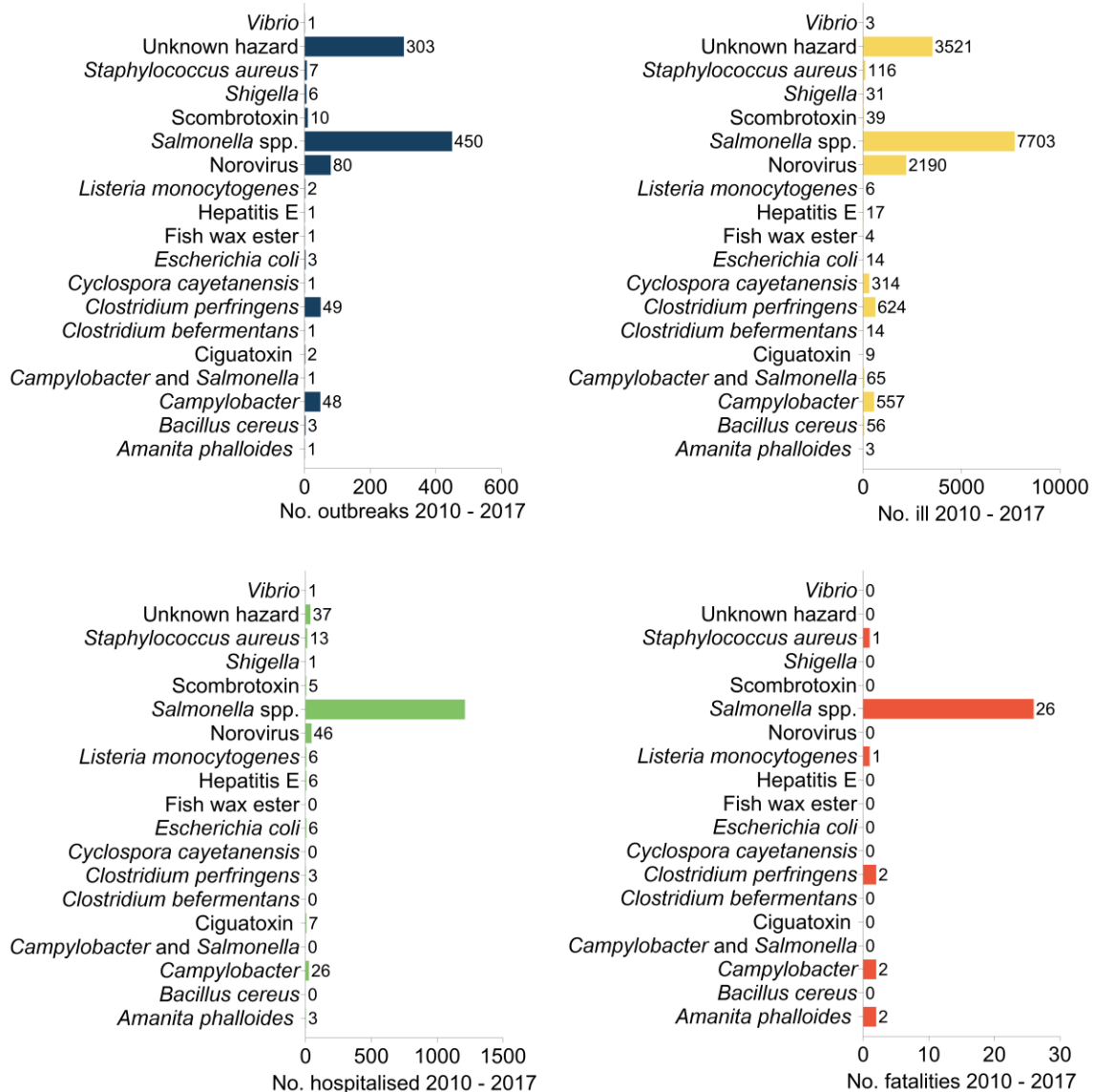


Figure 2. The number of foodborne outbreaks, people ill, people hospitalised, and fatalities associated with food prepared in Australian food service and food retail settings reported from 2010 – 2017 that were attributed to different hazards (i.e., aetiological agents).

Hazards responsible for foodborne outbreaks in different Australian food service and related food retail settings

The proportion of foodborne outbreaks and the proportion of people reported ill associated with foodborne outbreaks caused by different hazards in different Australian food service and related food retail settings from 2010 – 2017 are summarised in Figure 3.

Foodborne outbreaks from food prepared in restaurant, commercial caterer, takeaway, and the additional settings had the greatest diversity of hazards reported with 16, 9, 7, and 7 different hazards reported for each setting respectively.

Salmonella spp. were responsible for the highest proportion of foodborne outbreaks in restaurant (46.7% of 567), take-away (59.8% of 82), bakery (90.7% of 43), fair or festival or mobile service (83.3% of 12), grocery store or delicatessen (44.4% of 9, equal to the proportion of unknown hazards), and the additional food service (57.4% of 54) settings. For many of these food service settings the second most common hazards were unknown hazards (restaurant 34.0%, take-away 31.7%, bakery 4.7%, and the additional food service 16.8%).

Unknown hazards were responsible for the highest proportion of foodborne outbreaks in commercial caterer settings (35.4% of 82, followed by *Salmonella* (24.9%), and norovirus (22.0%)), and national franchised fast food business settings (50.0% of 8, followed by *Salmonella* spp. (37.5%)).

The 113 foodborne outbreaks from food prepared in vulnerable population settings were attributed in similar proportions to unknown hazards (31.9%), *C. perfringens* (29.2%), and *Salmonella* serovars (27.4%)(data not shown).

Salmonella spp. were responsible for the greatest proportion of people reported ill in almost all settings considered in this assessment (restaurant (50.8% of 7775), commercial caterer (34.8% of 2528), take-away (81.6% of 1138), bakery (95.4% of 834), national franchised fast food business settings (73.8% of 80), fair or festival or mobile service (91.67% of 120), grocery store or delicatessen (56.9% of 123), and additional food service settings (39.9% of 1311)). The vulnerable populations setting was the exception (*C. perfringens* (28.9% of 1377), followed by *Salmonella* (27.9%), and unknown hazards (25.2%), data not shown).

Similarly, *Salmonella* spp. were also responsible for greater than 75% of people hospitalised in all settings including the vulnerable populations setting (restaurant (86.36% of 711), commercial caterer (79.0% of 100), take-away (94.3% of 192), bakery (98.9% of 174), national franchised fast food business settings (94.1% of 17), fair or festival or mobile service (100% of 23), grocery store or delicatessen (100% of 7), additional food service (86.6% of 67), vulnerable populations (76.25% of 80)).

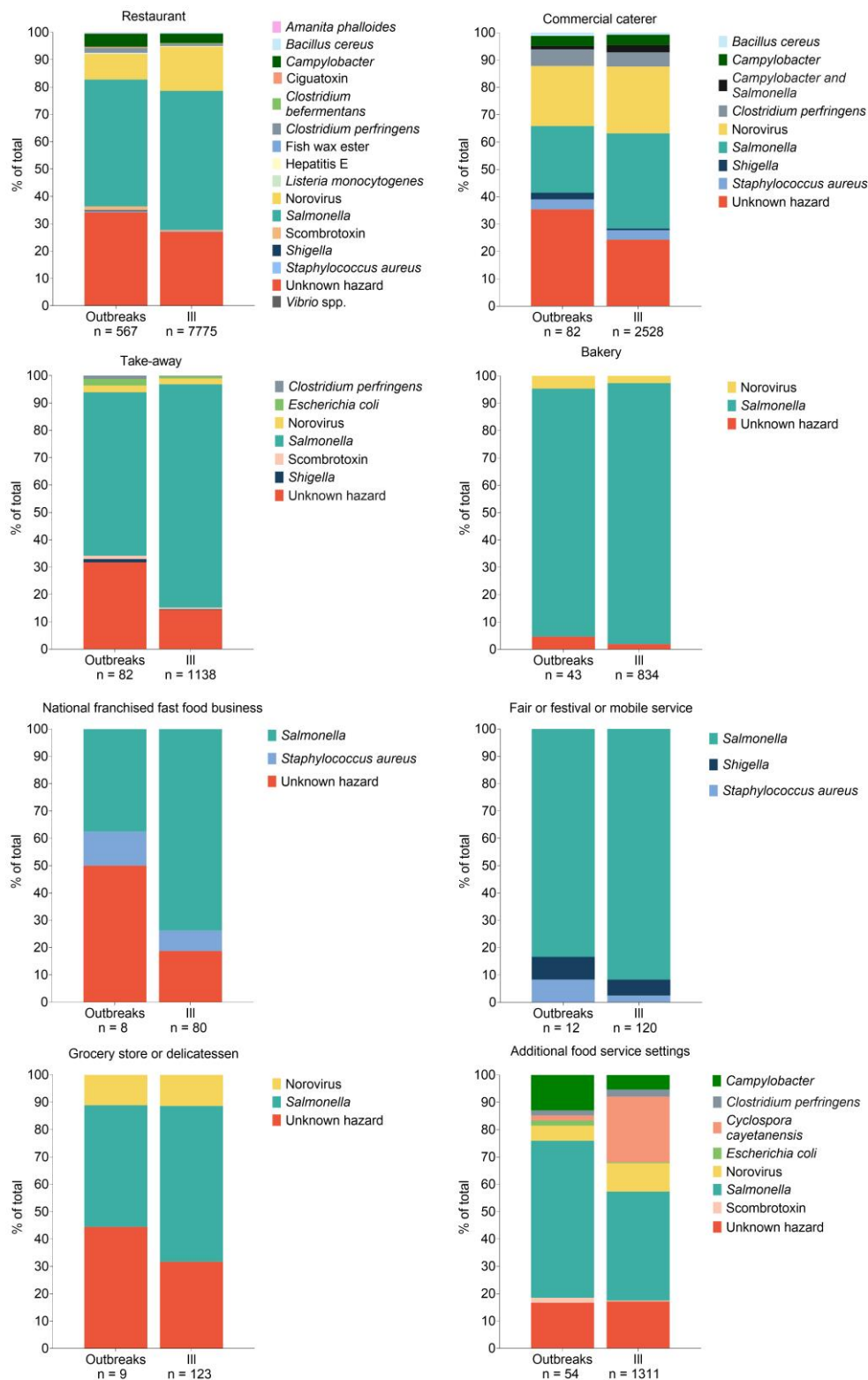


Figure 3. The proportion of foodborne outbreaks and the proportion of people reported ill attributed to different hazards and associated with different Australian food service and food retail settings from 2010 – 2017.

3.3.3 The commodity of food most likely to be responsible for foodborne outbreaks associated with Australian food service and food retail settings 2010-2017

Responsible food commodities

The number of foodborne outbreaks, people reported ill, people reported hospitalised, and fatalities associated with food prepared in Australian food service and food retail settings from 2010 – 2017 that were attributed to different food commodities are summarised in Figure 4. The food commodity⁷, rather than the food vehicle data, is summarised due to the vast diversity of reported food vehicles likely to be responsible for foodborne outbreaks.

The food commodity most likely responsible for the largest proportion of the 970 foodborne outbreaks in Australian food service and food retail settings were: unattributed to a commodity (58.9%), eggs (21.3%), > 1 commodity (6.2%), poultry (5.7%), and fish (2.0%). In this assessment, 205 (99.0%) of the 207 egg related outbreaks were attributed to *Salmonella* spp. (data not shown).

Foodborne outbreaks most likely caused by unattributed commodities affected the highest proportion (50.8%) of the total 15,286 people reported ill, followed by eggs (30.1%), > 1 commodity (8.0%), and poultry (5.6%).

Eggs were most likely responsible for the largest proportion of the 1,371 reported hospitalisations (49.2%), followed by unattributed commodities (31.7%), > 1 commodity (8.7%), and poultry (4.5%).

Unattributed commodities were associated with the largest proportion of the 34 fatalities (64.7%), followed by eggs (14.7%), poultry (8.8%), fungi (5.9%), > 1 commodity (2.9%), and fish, beef, vine-stalks (2.9%).

⁷ For example, 'Vietnamese sandwich' may be reported as the responsible food vehicle, however, if the contaminated ingredient was identified as raw egg used in mayonnaise, egg would be subsequently identified as the responsible commodity.



Figure 4. The number of foodborne outbreaks, people ill, people hospitalised and fatalities associated with food prepared in Australian food service and food retail settings reported from 2010 – 2017 that were attributed to different food commodities (D,E,G, OS, FN = Dairy, eggs, grains-beans, oils-sugars, fruits-nuts).

Responsible food commodities for foodborne outbreaks in different Australian food service and related food retail settings

The proportion of foodborne outbreaks, people reported ill, and people reported hospitalised most likely caused by different food commodities and associated with different Australian food service and related food retail settings from 2010 – 2017 are summarised in Figure 5.

Foodborne outbreaks from food prepared in restaurant, takeaway, commercial caterer and the additional settings had the greatest diversity of food commodities reported with 21, 11, 9, and 9 respectively.

For the majority of settings, the responsible food commodity was not attributed for the largest proportion of foodborne outbreaks (restaurant (55.38% of 567), commercial caterer (64.6% of 82), take-away (45.1% of 82), national franchised fast food business settings (62.5% of 8), fair or festival or mobile service (50.0% of 12), grocery store or delicatessen (44.4% of 9), additional food service settings (63.0% of 54)), and vulnerable populations (90.27% of 113) settings. The exception was bakery settings where 41.9% of 43 foodborne outbreaks were attributed to eggs, followed by 37.2% not attributed to a food commodity.

Eggs were attributed to the second largest proportion of foodborne outbreaks in restaurant (25.75%), takeaway (26.8%), fair or festival or mobile service (16.7%), national franchised fast food business settings (12.5%, equal to milk and poultry), additional food service settings (14.8%), and vulnerable population (4.4%) settings.

For seven of the nine settings, eggs were attributed to the largest or second largest proportion of people ill (restaurant (not attributed: 49.1% of 7775, eggs: 35.5%), commercial caterer (not attributed: 50.4% of 2528, eggs: 21.16%), take-away (eggs: 41.0% of 1138, not attributed: 25.57%), bakery (eggs: 56.4% of 834, not attributed: 17.87%), national franchised fast food business settings (eggs: 60.0% of 80, not attributed: 27.5%), additional food service settings (not attributed: 70.4% of 1311, eggs: 14.9%), vulnerable populations (not attributed: 88.1% of 1377, eggs: 7.0%)).

For seven of the nine settings, eggs were also attributed to the largest or second largest proportion of people reported hospitalised as a result of foodborne outbreaks from restaurant (eggs: 59.4% of 711, not attributed: 30.0%), commercial caterer (not attributed: 57.0% of 100, eggs: 27.0%), take-away (eggs: 41.7% of 192, not attributed: 23.5%), bakery (eggs: 57.5% of 174, >1 food: 13.8%), national franchised fast food business settings (eggs: 82.4% of 17, not attributed/milk/poultry: 5.9%), additional food service settings (not attributed: 34.3% of 67, eggs: 25.4%), and vulnerable population settings (not attributed: 78.8% of 80, eggs: 15.0%).

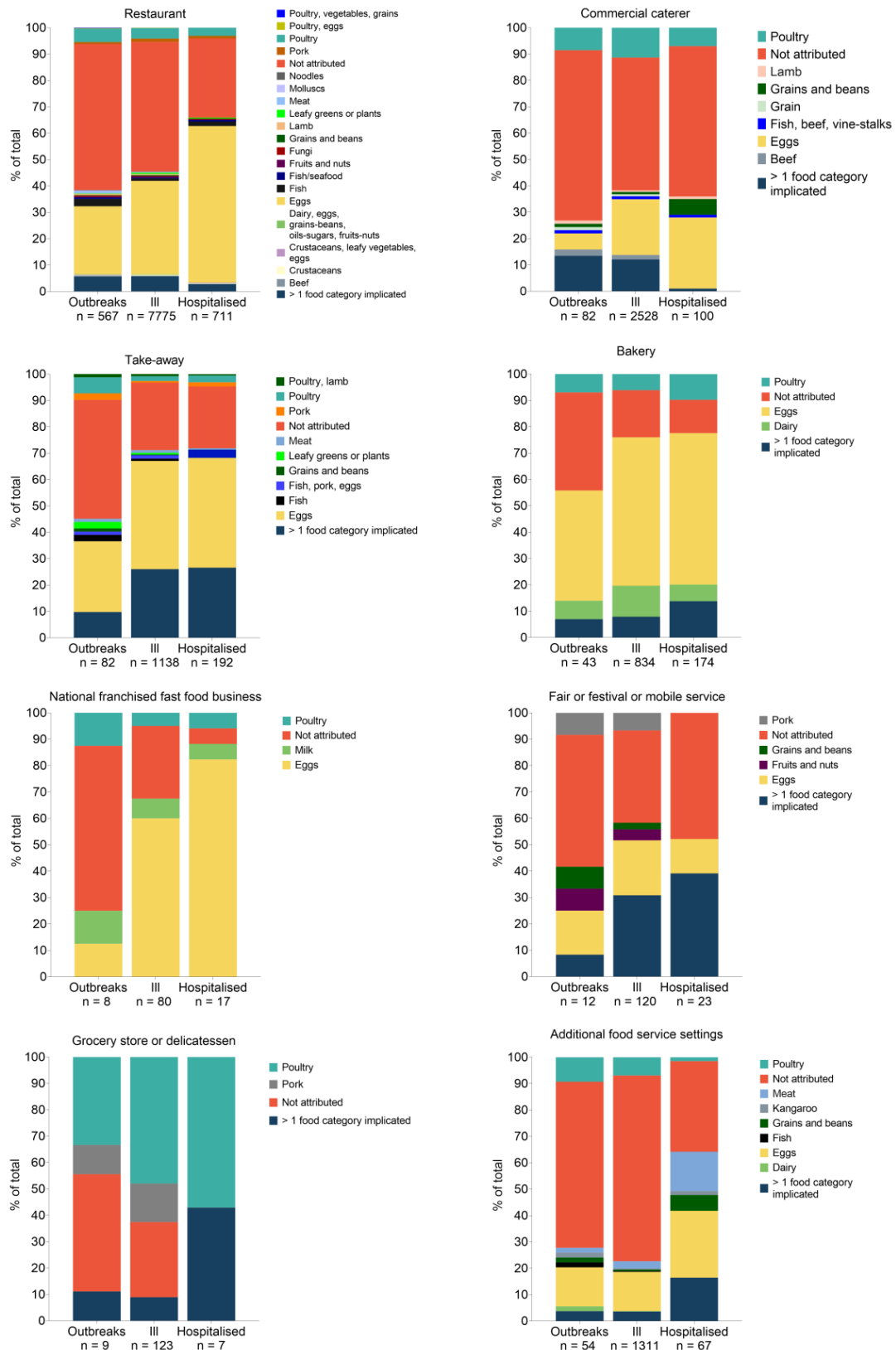


Figure 5. The proportion of foodborne outbreaks, people reported ill, and of people reported hospitalised attributed to different food commodities and associated with different Australian food service and related food retail settings from 2010 – 2017.

3.3.4 The major contributing contamination factors of food that led to the foodborne outbreaks 2013 - 2017

Major contamination factors

The number of foodborne outbreaks and people reported ill associated with food prepared in Australian food service and related food retail settings from 2013 – 2017 where individual contamination factors⁸ were reported are summarised in Figure 6.

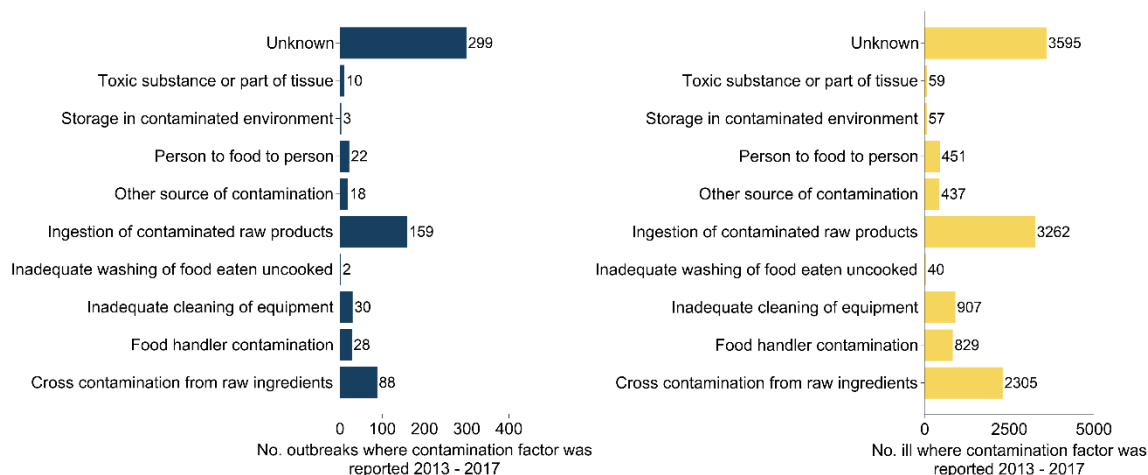


Figure 6. The number of foodborne outbreaks and people reported ill associated with food prepared in Australian food service and food retail settings reported from 2013 – 2017 where individual contamination factors were reported.

Overall, 10 different contamination factors were reported. The most frequently reported contamination factors that contributed to foodborne outbreaks in Australian food service and food retail settings from 2013 – 2017 were unknown contamination factors (299 outbreaks), ingestion of contaminated raw products (159 outbreaks), cross contamination from raw ingredients (88 outbreaks), inadequate cleaning of equipment (30 outbreaks), food handler contamination (28 outbreaks), and person to food to person (22 outbreaks). The remaining contamination factors were reported in <20 outbreaks.

The contamination factors associated with the largest number of people ill were unknown contamination factors (3,595 people ill), ingestion of contaminated raw products (3,262 people ill), cross contamination from raw ingredients (2,305 people ill), inadequate cleaning of equipment (907 people ill), and food handler contamination (829 people ill). The remaining contamination factors were associated with < 500 people ill.

Major contamination factors for foodborne outbreaks in different Australian food service and related food retail settings 2013-2017

The proportion of the number of foodborne outbreaks and people reported ill that were reported against individual contamination factors and associated with different Australian

⁸ As discussed previously, because in some cases two contamination factors were reported for a single foodborne outbreak these were separated for analysis and each contamination factor was allocated the same values for number of persons ill. As such, the total number of persons ill may be greater than those reported by OzFoodNet for 2013 – 2017.

food service and related food retail settings from 2013 – 2017 are summarised in *Figure 7*.

The greatest diversity of contamination factors were reported in foodborne outbreaks associated with food prepared in restaurants (10 factors), commercial caterer (8 factors), take-away (8 factors), and additional food service (7 factors) settings.

Unknown contamination factors were most frequently reported in six of the nine food service settings: restaurant (45.2% of 416 outbreaks), commercial caterer (48.2% of 54 outbreaks), take-away (34.0% of 53 outbreaks), grocery store or delicatessen (85.7% of 7 outbreaks), additional food service settings (48.65% of 37 outbreaks), and vulnerable population (76.1% of 46 outbreaks) settings. Ingestion of contaminated raw product was the most frequently reported factor contributing to foodborne outbreaks in bakery (41.2% of 34), and fair or festival or mobile service (37.5% of 8) settings.

Ingestion of contaminated raw product, food handler contamination, or cross-contamination from raw ingredients were the second most frequently reported contamination factors in the following settings. Ingestion of contaminated raw product: restaurant (26.0%), additional food service (27.0%), and vulnerable population (10.9%) settings. food handler contamination: commercial caterer (18.5%), grocery store or delicatessen (14.3%), and fair or festival or mobile service (12.5%). cross-contamination from raw ingredients: takeaway (26.4%), and bakery (35.3%) settings.

Unknown contamination factors, ingestion of raw product, cross contamination of ingredients, and inadequate cleaning of equipment were each reported in relation to national franchised fast food (all 25.0% of 4 outbreaks) settings.

The contamination factors that were associated with the largest proportion of people ill included unknown contamination factors (restaurant 45.2% of 6,321, grocery store and delicatessens 83.8% of 68, additional food service settings 35.4% of 978, vulnerable populations 73.7% of 647), ingestion of contaminated raw product (caterer 27.8% of 2,249, national fast food franchise 73.9% of 65, fair or festival or mobile service 46.8% of 62), and cross-contamination from raw ingredients (takeaway 38.6% of 865, bakery 47.9% of 687).

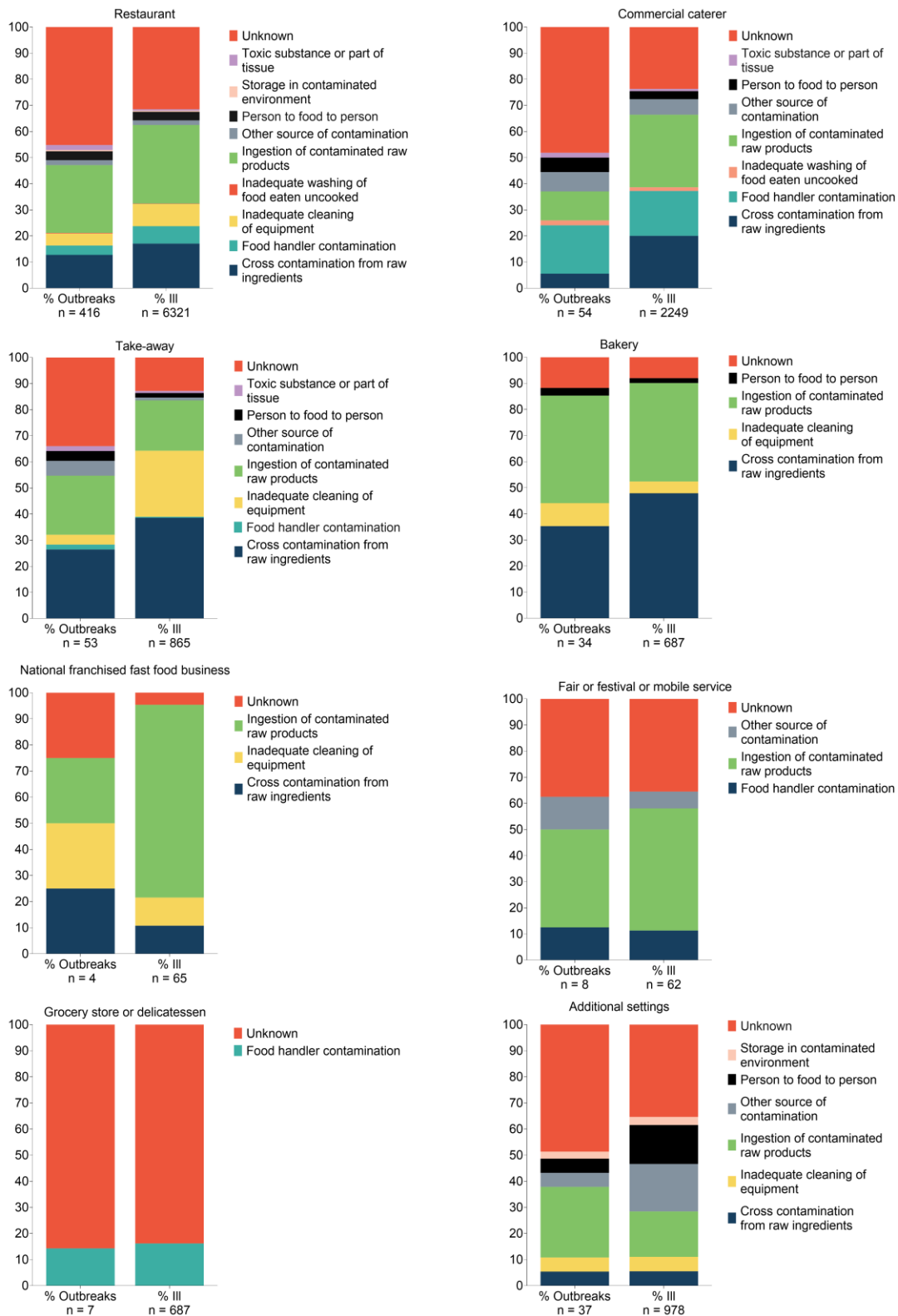


Figure 7. The proportion of foodborne outbreaks and people reported ill associated with food prepared in Australian food service and food retail settings reported from 2013 – 2017 that were attributed to individual contamination factors.

3.3.5 The major contributing bacterial growth factors that led to the foodborne

outbreaks 2013-2017

Major contributing bacterial growth factors

The number of foodborne outbreaks, and people reported ill associated with food prepared in Australian food service and related food retail settings from 2013 – 2017 where different bacterial growth factors⁹ were reported are summarised in Figure 8.

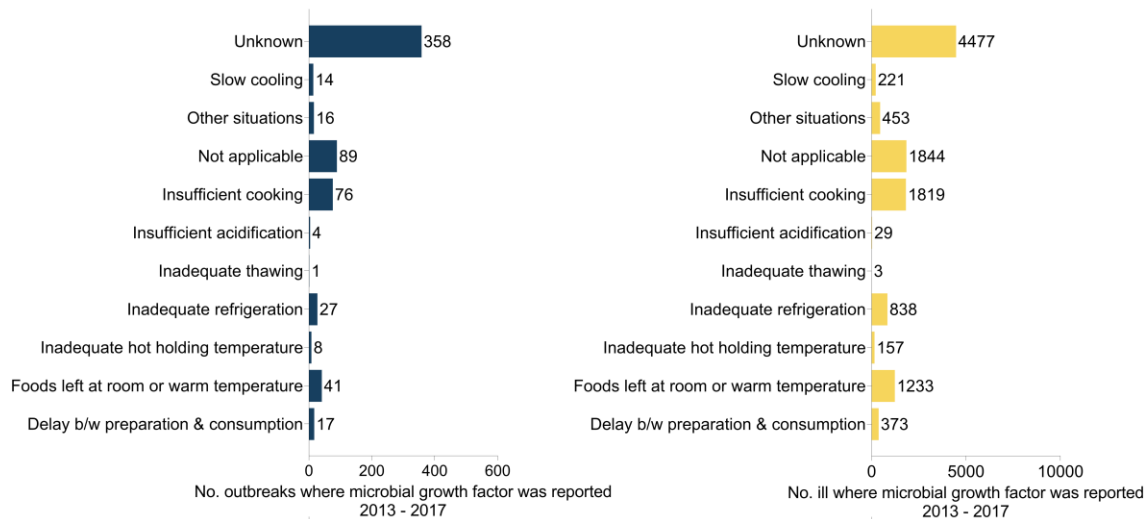


Figure 8. The number of foodborne outbreaks, and people reported ill associated with food prepared in Australian food service and food retail settings reported from 2013 – 2017 where different bacterial growth factors were reported.

Overall, 11 different factors were reported. The most frequently reported major contributing factor for bacterial growth or toxin production in the food vehicle that led to foodborne outbreaks in Australian food service and food retail settings 2013 – 2017 were unknown factors (358 outbreaks), not applicable to the outbreak (89), insufficient cooking (76), foods left at room temperature (41), and inadequate refrigeration (27).

The bacterial growth factors reported against the highest proportion of people ill during these foodborne outbreaks were unknown contamination factors (4,477 people ill), not applicable to the outbreak (1,844 people ill), insufficient cooking (1,819 people ill), food left at room or warm temperature (1,233 people ill), and inadequate refrigeration (838 people ill).

Major contributing bacterial growth factors in different Australian food service and related food retail settings 2013-2017

The proportion of foodborne outbreaks and people reported ill associated with food prepared in Australian food service and food retail settings reported from 2013 – 2017 where bacterial growth factors were reported are summarised in Figure 9.

⁹ As discussed previously, because in some cases two factors were reported for a single foodborne outbreak these were separated for analysis and each contamination factor was allocated the same values for number of persons ill. As such, the total number of persons ill may be greater than those reported by OzFoodNet for 2013 – 2017.



Figure 9. The proportion of foodborne outbreaks and people reported ill associated with food prepared in Australian food service and food retail settings reported from 2013 – 2017 where individual bacterial growth factors were reported.

The greatest diversity of contributing factors for bacterial growth or toxin production in the food vehicle that led to outbreaks was reported for restaurant (10), take-away (10),

commercial caterer (7), and bakery (6) settings.

Unknown factors were reported most frequently in foodborne outbreaks in all settings ranging from 36 – 85.7%. The exception was national franchised fast food business settings where insufficient cooking was reported most frequently (66.7% of 3) and the remainder were unknown bacterial growth factors. Excluding instances of bacterial growth factors being reported as not applicable to certain outbreaks, the next most frequently reported bacterial growth factor was insufficient cooking for seven of the nine other settings (restaurant 12.3% of 407, commercial caterer 9.8% of 61, take-away 7.4% of 54, fair or festival of mobile service 12.5% of 8, additional food service settings 18.2% of 33, and vulnerable population (6.5% of 46). For bakery settings, the next most common bacterial growth factors were inadequate refrigeration 18.8% and inadequate cooking 15.6% (n = 32). Grocery store or delicatessen settings only reported unknown or inapplicable bacterial growth factors.

For the majority of settings, unknown bacterial growth factors were reported against the largest proportion of people ill (vulnerable populations 54.0% of 628, bakery 39.1% of 698, additional settings 39.0% of 778, commercial caterer 28.8 of 2431, fair or festival of mobile service 87.1% of 62, grocery store or delicatessens 73.5% of 68, restaurant 42.3% of 6,034). The exceptions was national franchised fast food (insufficient cooking 94.8% of 58) and takeaway (foods left at room or warm temperature 35.7% of 690) settings.

3.3.6 The major contributing microbial survival factors that led to the foodborne outbreaks 2013-2017

Major contributing microbial survival factors

The number of foodborne outbreaks, and people reported ill associated with food prepared in Australian food service and food retail settings from 2013 – 2017 that were attributed to individual microbial survival factors¹⁰ are summarised in Figure 10.

Overall, 8 different factors were reported. The most frequently reported major contributing microbial survival factors that led to the foodborne outbreaks in Australian food service and related food retail settings from 2013 – 2017 were unknown factors (361 outbreaks), insufficient time/temperature during cooking (95 outbreaks), outbreaks where microbial survival factors were not applicable (73), other process failures (34), and inadequate or failed disinfection (31).

The microbial survival factors reported against the highest number of people ill associated with foodborne outbreaks were unknown factors (4,980 people ill), insufficient time/temperature during cooking (1,984 people ill), not applicable (1,489 people ill), and inadequate or failed disinfection (667 people ill).

¹⁰ As discussed previously, because in some cases two factors were reported for a single foodborne outbreak these were separated for analysis and each contamination factor was allocated the same values for number of persons ill. As such, the total number of persons ill may be greater than those reported by OzFoodNet for 2013 – 2017.

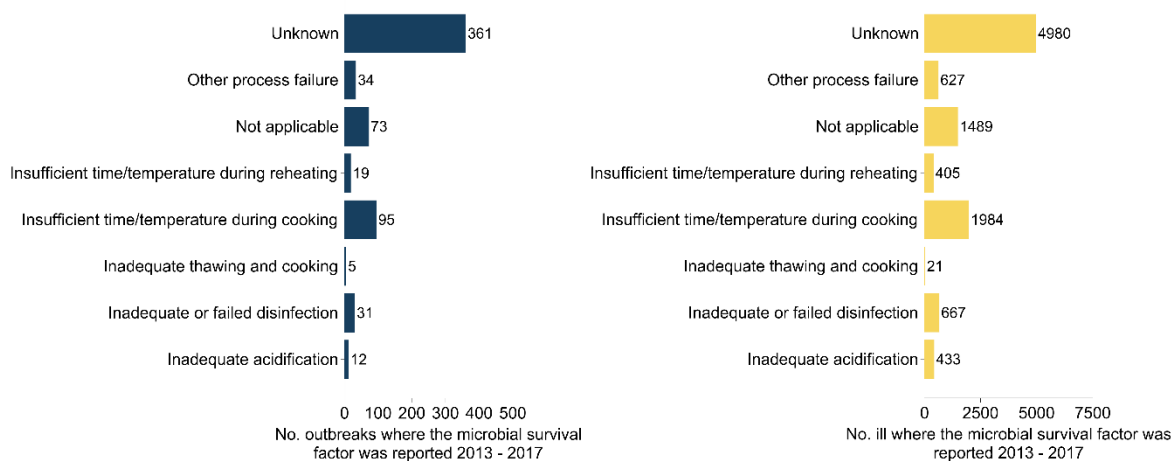


Figure 10. The number of foodborne outbreaks, and number of people reported ill associated with food prepared in Australian food service and food retail settings reported from 2013 – 2017 where microbial survival factors were reported.

Major contributing microbial survival factors in different Australian food service and related food retail settings 2013-2017

The proportion of foodborne outbreaks and people reported ill associated with food prepared in Australian food service and food retail settings reported from 2013 – 2017 where individual microbial survival factors were reported are summarised in Figure 11.

The greatest diversity of contributing factors for microbial survival in the food vehicle that led to outbreaks were reported for restaurant (8), take-away (8), commercial caterer (6), and bakery (6) settings.

Unknown microbial survival factors were reported in the highest proportion in all settings ranging from 45.2 – 100%. Excluding instances of microbial survival factors being reported as not applicable to certain outbreaks, the next most frequently reported microbial survival factor that contributed to foodborne outbreaks was insufficient cooking for six of the nine other settings (restaurant 17.4% of 397 outbreaks, commercial caterer 13.2% of 53 outbreaks, bakery 12.9% of 31 outbreaks, fair or festival of mobile service 12.5% of 8 outbreaks, additional food service settings 20.6% of 33 outbreaks, and vulnerable population 8.9% of 46 outbreaks). Grocery store or delicatessen settings were only associated with unknown microbial survival factors. Inadequate or failed disinfection was reported in 11.5% of 52 take-away related outbreaks.

Unknown microbial survival factors were reported against the largest proportion of people ill for the majority of settings, ranging from 35.6% to 100%. The exceptions were takeaway (inadequate or failed disinfection 38.3% of 666) and national franchised fast food (other process failure 82.8% of 58).

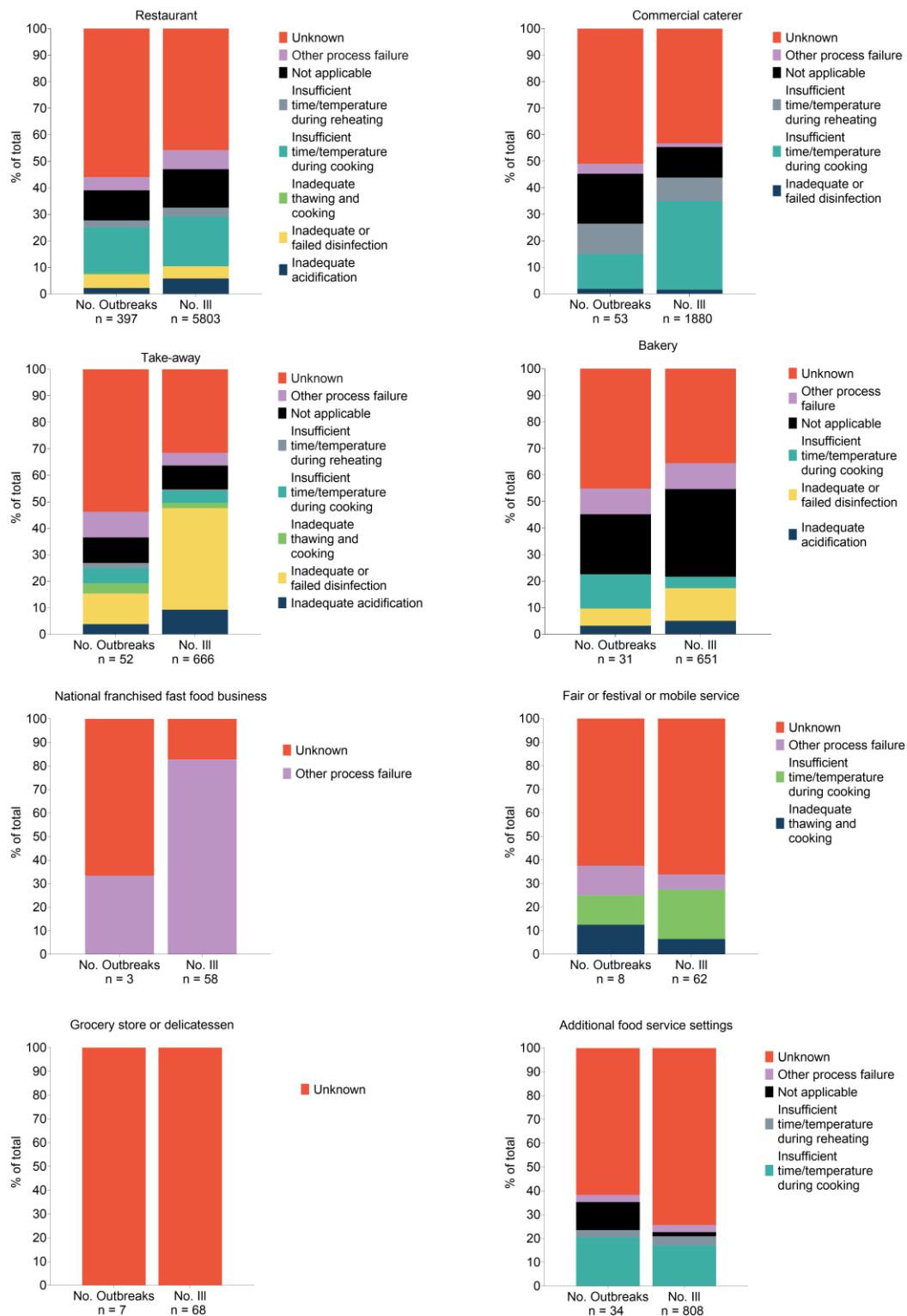


Figure 11. The proportion of foodborne outbreaks and people reported ill associated with food prepared in Australian food service and food retail settings reported from 2013 – 2017 where microbial survival factors were reported.

3.4 Summary of key findings

The total number of foodborne and probable foodborne outbreaks in Australia for 2010 – 2017 was 1,257, resulting in 19,497 persons reported ill; 1,914 of these people were hospitalised, and 56 fatalities were reported.

Of these, 970 foodborne outbreaks were associated with food prepared in the Australian food service and related food retail settings that were considered in this assessment. The 970 outbreaks resulted in 15,286 people being reported ill, 1,371 of these people being hospitalised, and 34 fatalities. NSW (34.85%) followed by Victoria (23.40%), Queensland (12.27%), and Western Australia (10.31%) accounted for the largest proportion of these outbreaks. Osterberger (2018) noted that, overall, the general trend of the annual number of foodborne outbreaks and the number of people ill associated with the food service industry has been steadily increasing in Australia from 2001 to 2016.

It is apparent that the vast majority of identified foodborne outbreaks in Australia are associated with food prepared in Australian food service and related food retail settings that were considered in this assessment, with food prepared in restaurant settings accounting for the largest proportion of all the settings:

1. Restaurant 45.1% (567/1,257)
2. Aged care 7.8% (98/1,257)
3. Commercial caterer 6.5% (82/1,257)
4. Take-away 6.5% (82/1,257)
5. Bakery 3.4% (43/1,257)

These results are similar to those reported for Australia from 2001 – 2009 where food prepared in restaurants also accounted for 40.0% of the total foodborne outbreaks (409/1,025) (Astridge et al. 2011).

Within the Australian food service and related food retail settings, foodborne outbreaks from food prepared in restaurant settings were associated with the highest proportion of people ill and hospitalised, and food prepared in aged care facilities was associated with the highest proportion of fatalities;

- Restaurant settings were associated with the highest proportion of the 15,286 people ill (50.9%), and 1,371 hospitalised (51.9%).
- The highest proportion of the 34 fatalities were associated with foodborne outbreaks from food prepared in aged care (58.8%) settings. The high proportion of fatalities in aged care setting may reflect the high susceptibility of the consumers in these settings to foodborne illness (NSW Food Authority, 2017).

The most frequently reported hazard responsible for foodborne outbreaks in Australian food service and food retail settings during 2010 – 2017 was *Salmonella* spp. (46.4%, 450/970) with the majority of these being *S. Typhimurium* serovars (91%, 410/450). However, the responsible hazard was not able to be identified in a large number of foodborne outbreaks in Australian food service and related food retail settings during 2010 - 2017 (31.2%). *Salmonella* spp. also caused the largest proportion of reported hospitalisations (88.3%), and the largest proportion of fatalities (76.5%).

A recent analysis of *Salmonella enterica* outbreaks in Australia identified an increasing trend in outbreaks from this hazard from 2001 to 2016, and highlighted the need for continued identification of responsible food vehicles, contributing factors to outbreaks, and the need to implement controls to reduce illnesses (Ford et al. 2018).

Salmonella spp. were responsible for the highest proportion of outbreaks in all individual Australian food service and food retail settings, where a responsible hazard was reported, except the vulnerable population setting (*C. perfringens* 29.2% and *Salmonella* 27.4% of 113 outbreaks).

Salmonella spp. were responsible for the greatest proportion of people reported ill (range 34.8% to 95.4%) in almost all settings considered in this assessment. The vulnerable populations food service setting was the only exception where *C. perfringens* was attributed to the highest proportion (28.9%).

The majority of the *Salmonella* outbreaks were attributed to eggs (45.5%, 205/450) or were not attributed to a food commodity (41.5%, 187/450). Eggs are a food commodity of high concern as they were implicated in a large proportion of the foodborne outbreaks, people ill, and hospitalisations where a responsible commodity was identified:

- an implicated food commodity was not attributed in 58.9% of the 970 food service outbreaks
- eggs were attributed to the next highest proportion of outbreaks (21.3%, 207/970)
- unattributed commodities affected the highest proportion (50.8%) of the total 15,2856 people reported ill, followed by eggs (30.1%)
- eggs were attributed to the largest proportion of the 1,371 reported hospitalisations (49.2%), followed by unattributed commodities (31.7%)
- unattributed commodities were associated with the largest proportion of the 34 fatalities (64.7%), followed by eggs (14.7%).

Eggs were attributed to the largest proportion of foodborne outbreaks and people reported ill, where a responsible food commodity could be identified, in the majority of settings considered in this assessment.

As such, raw eggs handled by Australian food service and related food retail business sectors represent a high risk product, because eggs were associated with a large proportion of the foodborne outbreaks, people ill, and hospitalisations in foodborne outbreaks where a responsible commodity has been identified between 2010 - 2017. Similar conclusions were reached in other studies that identified that eggs and egg-containing foods were the most common cause of outbreaks in Australia over the period 2001–2016, caused significant morbidity in the population, and recommended additional control measures are required for Australian food service and related food retail business sectors particularly around the preparation of foods containing raw or lightly cooked eggs (Ford et al. 2018; Moffat et al. 2016). In this assessment, 205 (99.0%) of the 207 egg related outbreaks from food prepared in Australian food service and related food retail business sectors were attributed to *Salmonella* spp.

The most frequently reported contamination factors that contributed to foodborne outbreaks in Australian food service and food retail settings 2013 – 2017 in descending order were:

1. unknown contamination factors
2. ingestion of contaminated raw products
3. cross contamination from raw ingredients
4. inadequate cleaning of equipment
5. food handler contamination, and
6. person to food to person contamination.

The most frequently reported bacterial growth factors that contributed to foodborne outbreaks in Australian food service and food retail settings during 2013-2017 were:

1. unknown factors
2. insufficient cooking

3. foods left at room temperature, and
4. inadequate refrigeration.

The most frequently reported microbial survival factors that contributed to foodborne outbreaks in Australian food service and food retail settings 2013-2017 were:

1. unknown factors
2. insufficient time/temperature during cooking, and
3. inadequate or failed disinfection.

As *Salmonella* was associated with the highest proportion of Australian food service and related food retail business sector foodborne outbreaks and also accounted for 99% of egg related outbreaks that was identified as a high risk food for these businesses, it is of interest to identify the major contaminating, bacterial growth, and microbial survival factors contributing to outbreaks caused by this pathogen. Ingestion of contaminated raw products, cross contamination from raw ingredients, and inadequate cleaning of equipment were the most frequently reported contamination factors. Numerous bacterial growth factors were frequently reported including insufficient cooking, foods left at room or warm temperature, inadequate refrigeration, and delay between preparation & consumption. Key microbial survival factors were insufficient time/temperature during cooking, inadequate or failed disinfection, and inadequate acidification.

There was a larger diversity of contamination, bacterial growth or microbial survival factors reported to contribute to outbreaks for food prepared in restaurant, commercial caterer or take-way settings, compared to the other settings.

These results indicate that the controls required for food safety are failing at various points during food preparation and service. There is, however, considerable uncertainty in identifying the food commodities and contributing factors that may contribute significantly to the burden of foodborne illness due to the large proportion of foodborne outbreaks where these factors are not identified due to the inherent difficulties in identifying contributing factors described below. Regardless, the interventions targeted to these business sectors that are required to reduce foodborne illness need to be multi-faceted and aimed at developing robust food safety awareness and knowledge of appropriate interventions during food handling through receipt, processing, storage and service of food to consumers.

Data limitations

As mentioned, there are challenges in attributing the cause of outbreaks to specific parts of the supply chain using only OzFoodNet data. For example, Moffat et al. (2016) identified that 61% (102/166) of egg-related outbreaks during 2001–2010 were associated with food prepared by food service sectors (e.g., restaurants and caterers), while 28% occurred in the setting of private residences. In a significant number (~20%) of cases, additional information from traceback investigations by jurisdictions identified the outbreak strain on the farm which produced the eggs¹¹.

Food vehicles or commodities responsible for foodborne illness are generally determined through epidemiological and/or microbiological associations in outbreak investigations. Critical in this process is the ability to identify an outbreak through the existing surveillance

¹¹ “[T]race back investigations were conducted for 106 (64%) of the 166 outbreaks, with 72 (68%) of these investigations identifying a specific farm from which the implicated eggs had been produced. For these farms, 63 (88%) were inspected and testing undertaken. 51% of the tested farms had phage types or multilocus variable number of tandem repeats analysis patterns detected in the farm environment, on eggs or both, that were indistinguishable from *Salmonella* recovered from outbreak cases.” (Moffat et al., 2016)

system to enable an investigation to then proceed. There are, however, challenges associated with identifying and attributing illness to a particular food vehicle or commodity, including:

- Food recall biases when gathering food consumption histories (compounded by pathogens with long incubation periods, e.g. hepatitis A)
- Time delays in recognition or notification of an outbreak, including:
 - the time taken for infected persons to seek medical treatment
 - obtaining stool samples
 - laboratory confirmation of the presence of pathogenic organisms
 - notification to public health authorities, and
 - identification and subsequent investigation of the outbreak
- Inability to trace food products to their source
- Reluctance of individuals to participate in investigations
- Long exposure windows for specific pathogens (e.g. *L. monocytogenes*)
- Inability to obtain food samples for analysis
- A lack of precision in, or suitable methods for, sample analysis and pathogen identification (e.g. it is difficult to obtain confirmatory microbiological evidence of hepatitis A in foodstuff due to the variable distribution of the virus on the food and level of virus and as the level of the virus in food may be below the level that can be detected while still having the potential to result in illness)
- Immune status of the exposed population
- Food attribution in dishes with multiple food items
- The potential for variation in categorising features of outbreaks depending on investigator interpretation and circumstances.

Therefore, it is important to recognise that outbreak data are likely to only represent a small proportion of actual cases of foodborne illness, due to the reasons given above and as many people do not always seek medical attention for mild forms of gastroenteritis, medical practitioners do not always collect specimens for analysis, and not all foodborne illnesses require notification to health authorities¹² (Gibbons et al. 2014).

¹² A list of Australian national notifiable diseases is available at:
<https://www1.health.gov.au/internet/main/publishing.nsf/Content/cdna-casedefinitions.htm#s>

4 Review of Australian food service and related food retail business sector classifications using the National Risk Profiling Framework

4.1 Introduction

To address the second risk assessment question, the in scope business classifications were reviewed using the National Risk Profiling Framework (the Framework)(DoHA 2007). The Framework was originally designed to provide a nationally agreed approach for government to classify business types on the basis of food safety risk. The Framework reflects a science-based and transparent approach, reflecting risks inherent to the product/process, the potential of controlling the risks, as well as a measure of the association of the risk with past foodborne illness outbreak information (Ross et al. 2009).

The NPRF comprises a series of decision trees that require consideration of the nature of the potential risk that might exist or arise from products sold by a business sector and the reliability of existing risk management actions, whether there are steps that are susceptible to introduction of hazards, or processes that are critical to the safety of the product at the time it is consumed (Ross et al. 2009). Essentially, the NPRF asks three key questions consisting of a number of sub questions, which must be answered sequentially:

1. Could the business sector introduce a hazard to the food, or fail to control the level of a hazard that could be present?
2. Does the business sector need to take action(s) to eliminate, reduce or control a hazard critical to the safety of product at the time of consumption?
3. Will/could the presence of the hazard lead to “severe” public health consequences?

The outcomes of the decision tree lead to four priority categories. The Framework uses the following definitions for P1, P2, P3, and P4 classifications of food service and retail businesses:

Priority 1 and Priority 2: Businesses that will, characteristically, handle ‘high risk’ foods that support the growth of pathogenic microorganisms and where such pathogens are present or could, from experience or literature reports, be expected to be present. Their handling of food will, characteristically, also involve at least one step at which control actions must be implemented to ensure the safety of the food.

Priority 1 businesses are further characterised by known risk-increasing factors, such as potential for inadequate/incorrect temperature control (e.g. reheating or hot-holding of food), a consumer base that includes predominantly immuno-compromised populations, the scale of production/service and other factors identified in the National Risk Validation Project (FSA & ME, 2002).

Priority 3: Businesses that will only handle ‘low risk’ or ‘medium risk’ foods.

Priority 4: Businesses that will normally handle only low risk foods, and would be extremely unlikely to introduce microbial, physical or chemical hazards to the foods they sell or handle.

Essential to the determination of the priority classifications is the definition of high risk, medium risk and low risk foods. The definitions used in the Framework are as follows:

High risk foods: foods that may contain pathogenic microorganisms and will support formation of toxins or growth of pathogenic microorganisms. Examples include raw meat, poultry and fish, unpasteurised milk, oysters, tofu, fresh filled pasta, meat pies, frankfurts, cooked rice and lasagne. Using the Framework, business sectors that handle high risk foods will always be classified as Priority 1 or 2.

Medium risk foods: those that:

- may contain harmful natural toxins or chemicals introduced at steps earlier in the food supply chain, or that:
- may contain pathogenic microorganisms but will not normally support the formation of toxins or growth of pathogenic microorganisms due to food characteristics; or,
- are unlikely to contain pathogenic microorganisms due to food type or processing but may support the formation of toxins or growth of pathogenic microorganisms.

Examples include fresh fruits and vegetables, orange juice, pasteurised milk, canned foods, salami, vegetables stored in oil, peanut butter, eggs in the shell, milk-based confectionary and hard-frozen ice cream.

Low risk foods: those that are unlikely to contain pathogenic organisms and will not support their growth (see also ‘potentially hazardous foods’) and are unlikely to contain harmful chemicals or foreign matter. Examples are grains and cereals, bread, carbonated beverages, sugar-based confectionary, dried fruit, alcohol and fats and oils.

These definitions are based on FSANZ definitions that are no longer current (ANZFA, 2001). However, whereas FSANZ’s definitions were based on risk under current risk management controls, particularly in relation to the probability of a pathogen being present, the Framework definitions are based on the inherent potential for pathogen outgrowth and survival, with probability of contamination considered separately (DoHA 2007).

Currently, there are no definitions of high, medium, or low risk foods provided by FSANZ. However, the current definition and interpretive advice for determining potentially hazardous foods provides some indication of how these risk classifications can be considered in the context of Chapter 3.

In Standard 3.2.2 potentially hazardous food is defined as food that has to be kept at certain temperatures to minimise the growth of any pathogenic microorganisms that may be present in the food or to prevent the formation of toxins in the food. As such this is synonymous with high risk foods as defined above. High risk foods can be considered potentially hazardous foods.

As indicate in by FSANZ (2016) in Appendix 1 of “Safe Food Australia: A Guide to the Food Safety Standards”, if a food does not contain pathogens, or does not support the growth of a pathogen or toxin production, then the food is not potentially hazardous. As such, low risk foods as defined above are not considered potentially hazardous foods. This includes foods that have been processed in a certain way; for example if a food contains certain additives or has been commercially sterilised.

However, medium risk foods cannot be identified solely considering the current guidance for potentially hazardous foods. Medium risk foods as defined above include foods that are unlikely to contain pathogenic microorganisms due to food type or processing but may support the formation of toxins or growth of pathogenic microorganisms. This is intended to capture potentially hazardous foods where preparation and packaging of the product manage the risk to a consistently acceptable level. Thus, in such cases potentially hazardous foods,

such as pasteurised milk, have been classified as medium risk foods because they are unlikely to contain pathogens. Similarly, whole fruits and vegetables are not generally considered potentially hazardous foods, however, because they may contain pathogenic organisms but will not generally support their growth due to the food characteristics they are considered medium risk foods by definition in the Framework. Therefore medium risk foods can be both potentially hazardous and non-potentially hazardous foods.

If a medium risk food is the highest risk food that a business handles the Framework will classify these business as Priority 3 *unless* any of the following are true:

- chemical contaminants could be present at levels that could cause acute illness
- the food produced by the sector involves a potentially unreliable hazard reduction process
- the business produces or serves sufficient units or servings to pose an unacceptable risk.

Further guidance for determining if a food is high risk or potentially hazardous is provided in the Framework (DoHA 2007) and for the latter by FSANZ (2016).

The scope of Proposal P1053 includes the eight business sectors identified by Ministers in which they consider food safety management could be improved. These business sectors have previously been assigned Priority 1 (P1) and Priority 2 (P2) classification using the NPRF (DoHA 2007; Ross et al. 2009) (Table 3).

Table 3. Proposed handling activities and associated priority classified business sectors.

Sector classification or descriptor (Ross et al., 2009)	Characteristic food handling activity
P1 Food service: catering	Activity 1: process potentially hazardous food in advance of serving the ready-to-eat food to the consumer
P1 and P2 Food service: eating establishments	Activity 1: process potentially hazardous food in advance of serving the ready-to-eat food to the consumer Activity 2: process potentially hazardous food and serve as ready-to-eat food to the consumer in a time period which does not adversely affect the microbiological safety of the food
P1 Retailer and manufacturer: bakery products	Activity 1: process potentially hazardous food in advance of serving the ready-to-eat food to the consumer
P2 Retailer: bakery products	Activity 3: serve unpackaged potentially hazardous food as ready-to-eat food for retail
P2 Retailer: processed seafood products	Activity 3: serve unpackaged potentially hazardous food as ready-to-eat food for retail
P2 Retailer: processed delicatessen products	Activity 3: serve unpackaged potentially hazardous food as ready-to-eat food for retail
P2 Retailer: perishable pre-packaged food	Activity 4: serve packaged potentially hazardous food as ready-to-eat food. The food is packaged prior to receipt by the food business for retail

However, because not all jurisdictions use the Framework, the ISFR WG identified four handling activities that were proposed to provide an alternate way to identify priority

businesses. The in scope businesses and classification examples described by Ross et al. (2009) were discussed with ISFR WG, and were translated into four food handling activities:

Activity 1: process potentially hazardous food in advance of serving the ready-to-eat food to the consumer

Activity 2: process potentially hazardous food and serve as ready-to-eat food to the consumer in a time period which does not adversely affect the microbiological safety of the food

Activity 3: serve unpackaged potentially hazardous food as ready-to-eat food for retail

Activity 4: serve packaged potentially hazardous food as ready-to-eat food. The food is packaged prior to receipt by the food business for retail

The Framework classifications are proposed to be used in conjunction with identification of characteristic food handling activities for the application of any potential new recommended requirements (Table 3). Therefore, the handling activities are also proposed to be indicative of potential food safety risks.

Therefore this assessment considered the hazards and controls both from the perspective of the food handling activities and also the food business sector. However, as indicated in the Framework (DoHA 2007), “No categorisation based on a ‘class’ of product, business type, or handling activities will be completely appropriate to every product or business in that category. Rather, the aim is to provide an objective means to appropriately classify the risk presented by most of the businesses producing, or handling, a particular product type. Users should recognise that individual circumstances could affect the risk category.” This is also true of the proposed categorisations of the handling activities in this assessment.

The review of the classifications of the in-scope business sectors was undertaken against the questions in the decision tree of the Framework (Figure 12). It should be noted that much of the background information provided by Ross et al. (2009) is still relevant to the classified businesses. The assessment of the best available evidence regarding foodborne outbreaks in Australia in Section 3 provided additional evidence to be considered in the review.

The following sections present the rationale used to answer the questions from the Framework (see Figure 12) and to review the classifications of the different priority businesses. To allow for ease of interpretation and understanding of the Framework process, footnotes are provided that contain information regarding definitions and guidance from the Framework for specific questions. However, the Framework (DoHA 2007) should be referred to for a detailed explanation of its intended use and for additional information. Classification of business sectors using the Framework relies on the user integrating a high level understanding of food safety issues, and approaches to their management, along with documented evidence of the potential for hazards to cause illness or re-contaminate foods. As such, the Framework is not intended for general use by food businesses but for governments to classify business types on the basis of food safety risk.

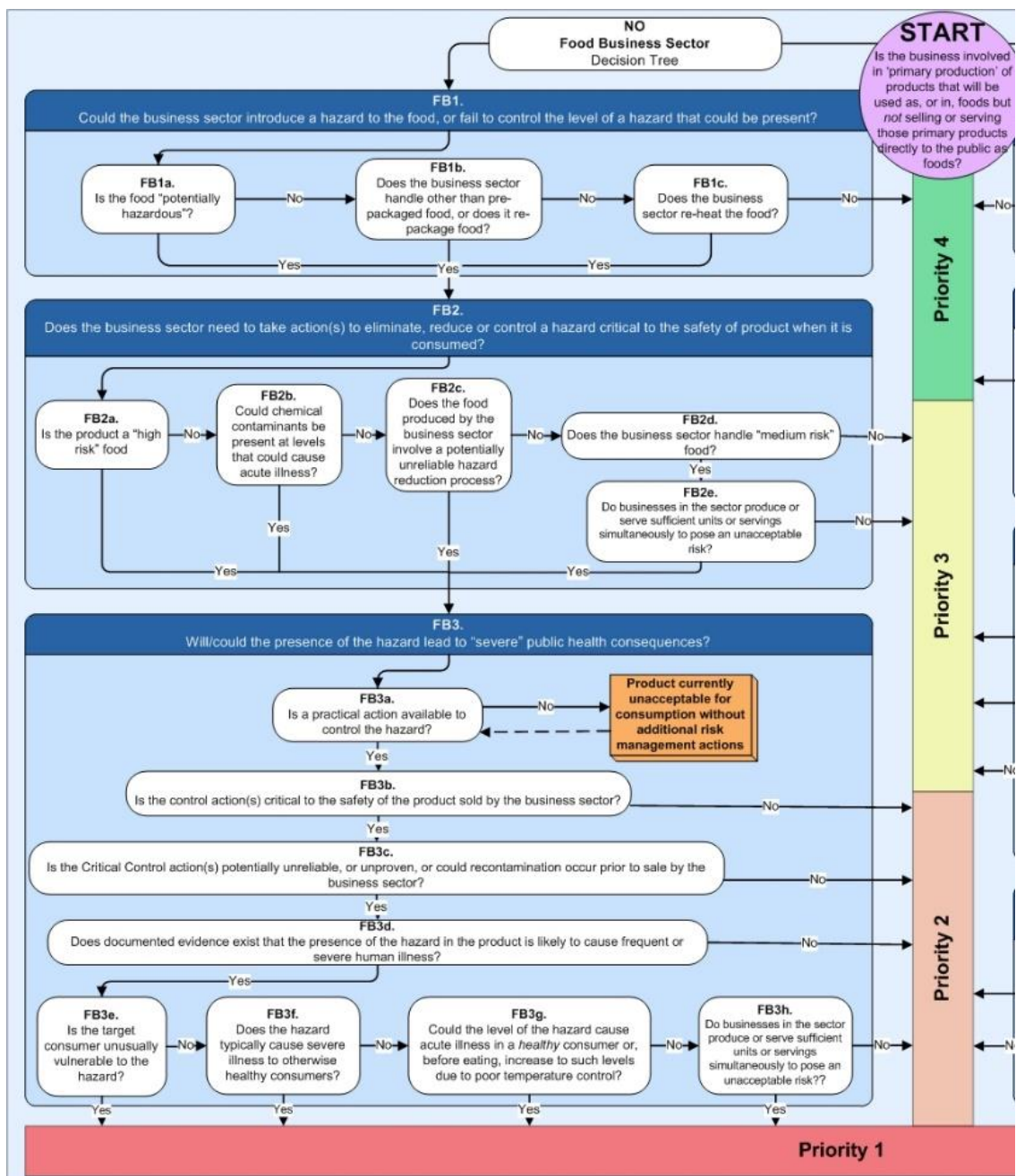


Figure 12. The National Risk Profiling Framework food business sector decision tree. Reproduced from DoHA (2007).

4.2 Businesses characterised by Activity 1: Food service or retail businesses that process potentially hazardous food in advance of serving the ready-to-eat food to the consumer

The in-scope businesses identified by the ISFR WG to be characterised by the handling activity of processing potentially hazardous food in advance of serving the RTE food to consumers are:

- On-site and off-site caterers, e.g. catering that occurs at events such as the Melbourne cup, catering by a food business off site in an office building, catering for weddings in a restaurant, catering for weddings offsite
- Food service for RTE food prepared in advance (e.g., takeaway or that hot-hold RTE food and restaurants that pre-prepare RTE food, sushi, restaurants that also provides takeaway or serves hot-held dishes, a restaurant that pre-prepares hollandaise sauce for service, restaurant that pre-prepares desserts in advance, restaurant that pre-prepares pasta in advance.
- Processors that retail bakery products containing PHF, e.g., custard containing pastry

Additional food service businesses previously classified as P1 that are likely to undertake this handling activity include boarding schools and correctional facilities (DoHA 2007).

Q1a. Is the food “potentially hazardous”? Yes. The food service or catering businesses described above have the common characteristics of handling of high risk¹³ PHF that must be kept at a certain temperatures to minimise the growth of pathogenic microorganism that may be present in the food. The processing of food in advance of serving the RTE food to the consumer is a significant handling activity because this provides an extended time between processing and consumption, compared to if the food was consumed directly after processing, during which bacterial growth or contamination may occur. Therefore, additional refrigeration (<5°C), hot holding (>60°C), or storage at some other temperature (if the food business can demonstrate that another practice it uses is safe) for a period of time to limit the potential growth of microorganisms is required following processing.

Q2a. Is the product a “high risk” food? Yes. These food service or catering businesses are also characterised by processing and serving high risk¹⁴ potentially hazardous foods. The foods processed by these food businesses are expected to include at least one high risk food such as seafood, raw meat, poultry, and eggs. These are foods that are more likely to contain microbial pathogens, are able to support the growth of microbial pathogens, and the processing of these high risk foods can lead to the recontamination of other cooked or raw foods (Ross et al. 2009).

As such, these businesses could introduce a hazard to the food, or fail to control the level of the hazard that could be present. These businesses need to take actions to eliminate, reduce, or control a hazard critical to the safety of the product when it is consumed.

¹³ While businesses that handle high risk foods are immediately placed into Priority 1 or 2, a high volume producer of medium risk foods may represent a risk to public health unless adequate and reliable controls are in place.

¹⁴ High risk foods: food that may contain pathogenic microorganisms and will support formation of toxins or growth of pathogenic microorganisms (see ‘potentially hazardous foods’). Examples include raw meat, poultry and fish, unpasteurised milk, oysters, tofu, fresh filled pasta, meat pies, frankfurts, cooked rice and lasagne. Using the Framework, business sectors that handle high risk foods will always be classified as Priority 1 or 2.

Q3a. Is a practical action available to control the hazard? Yes. Practical control¹⁵ actions are available and required during both food processing, storage, and service to limit microbial contamination, recontamination, growth and survival.

Q3b. Is the control action critical to the safety of the product sold by the business sector¹⁶? Yes. The control actions implemented by the food service or catering businesses engaged in these handling activities can be critical to the safety of the food sold. Food businesses that process RTE food in advance must have controls in place during food receipt, preparation, storage (before and after processing), and service to minimise the growth of pathogenic microorganisms that were already in the raw product and to reduce the potential for the cross-contamination to other cooked or raw foods. The hazards and risk factors associated with these food business handling activities and the controls are discussed below:

- Adequate storage of PHF at appropriate temperatures before processing is a critical control action for these food businesses. This will ensure that the potential growth of any pathogenic organisms already present in the food is limited, and that the quality of food is maintained. Raw high risk foods may contain pathogenic microorganisms that are not able to be eliminated during primary production and, therefore, food businesses have shared responsibility for their control (Ross et al., 2009). *Salmonella* is a pathogen of concern often associated with raw eggs and poultry (Chousalkar & Roberts 2012; Ford et al., 2018), raw seafood is associated with a number of potential hazards including both enteric pathogens and chemical hazards (Sumner & Ross 2002; Elbashir et al., 2018), raw meats are associated with a number of enteric pathogens including *E. coli*, *Campylobacter*, and *C. perfringens* (Phillips et al., 2008; Tesson et al., 2020). Heat-resistant toxins that are not destroyed by cooking can be formed in food due to uncontrolled bacterial growth (e.g. staphylococcal enterotoxin, cereulide, and histamine), thus, appropriate storage is critical for their control (May et al., 2016).
- Adequate cooking or reheating is a critical control action for these food businesses to ensure that non-spore-forming pathogens such as *Salmonella*, *L. monocytogenes*, *Vibrio spp.*, and *Campylobacter* are effectively inactivated if present in raw product. The combination of cooking temperature and time must be sufficient to reduce pathogens associated with that food to safe levels. However, cooking will not eliminate all spore-forming bacteria such as *C. perfringens* and *B. cereus* (Smelt & Brul, 2014). Therefore, adequate cooling and subsequent storage is also required to limit the potential for growth of these organisms.
- Adequate cooling of cooked foods is a critical control action for these food businesses. Spore-forming organisms such as *C. perfringens* and *B. cereus* can survive the cooking process and may grow during cooling or storage if the cooling rate is inadequate (Coorey et al., 2018). If these organisms proliferate in cooked

¹⁵ This question is principally intended to identify foods or processes for which a practical strategy (i.e. technologically and economically feasible), or combination of strategies, is available to control the hazard in the product made, sold or handled by the business sector. "Control" is used in the sense used in the HACCP approach, i.e. an action taken to prevent, reduce to an acceptable level, or eliminate a food safety hazard. Thus, 'control' does not always mean reduction or elimination of a hazard, but can include prevention of worsening of a hazard (e.g. refrigeration) as well as hazard reduction or elimination.

¹⁶ The intent of this question is to identify business sectors that, while handling a medium or high risk food, do not have essential responsibility for the safety of the product at the point of consumption. The inference of a 'NO' answer is that processes undertaken by another business sector(s) in the food supply chain are the most important in assuring the safety of the product at the time of consumption.

foods they may grow quickly to infectious levels or produce toxins able to cause illness in consumers. This can result in an increased potential for cross-contamination to other raw or cooked foods prepared by the business. Therefore prevention of recontamination must also be controlled by these businesses.

- Minimising cross-contamination and re-contamination are also critical control actions for these food businesses. Re-contamination can occur due to cross-contamination from raw foods, from cooked foods containing spore formers, infected food handlers, and unclean surfaces and equipment. Hazards associated with infected food handlers include both bacteria and viruses such as *Staphylococcus aureus*, *Shigella*, hepatitis A and E viruses, and norovirus that can be carried both symptomatically and asymptotically (Michaels et al., 2004; Hardstaff et al., 2018). The likelihood of re-contamination to processed food via a food handler from raw meat, poultry, eggs, and fish are greater for these businesses, compared to business that do not process raw foods, because the raw products have a higher likelihood of containing infectious doses of pathogens (Ross et al., 2009). Furthermore, the risk of foodborne-illness increases if food is re-contaminated and then subsequently stored at inadequate temperatures that allow bacterial growth.
- Adequate storage of RTE food processed in advance at appropriate temperatures either <5°C or >60°C before service to the consumer is also a critical control action for these food businesses. The prevention of growth of microbial pathogens that may be present in RTE foods is primarily achieved through adequate temperature storage prior to service, and subsequent storage of RTE foods at inadequate time and temperatures allowing growth of pathogenic microorganisms (Ross et al. 2009). As a general rule, the total time that a RTE PHF can be kept at temperatures between 5°C and 60°C is 4 hours (FSANZ 2016). After this time the food needs to be discarded.

Q3c. Are the Critical Control actions potentially unreliable, or unproven, or could recontamination occur prior to sale by the business sector? Yes. Some of these critical control actions have been reported to be unreliably¹⁷ applied and the potential for recontamination of processed RTE food prior to sale during food handling has been documented.

- The storage of food at appropriate temperatures both prior to and after processing is not considered unreliable by definition in the Framework. However, food being left at room or warm temperature and inadequate refrigeration were reported as major contributing factors for bacterial growth or toxin production in a food that led to 66 foodborne outbreaks in Australia from 2013 – 2017 from food prepared in bakery, commercial caterer, restaurant, or take-away settings that are likely to prepare some RTE food in advance of serving to consumers (

¹⁷ Food service or business sectors that rely on processes that do not achieve high levels of hazard reduction (e.g. fermentation, chlorine washes, vegetables acidified and stored in oil), or where evidence indicates that recontamination with hazards is common, or where the process can occasionally fail, without that failure being detected prior to release of the product for sale are considered 'unreliable'.

- Table 4) (OzFoodNet, 2020).

Table 4. The number of foodborne outbreaks (2013-2017) where food being left at room or warm temperature and inadequate refrigeration were reported as major contributing factors of bacterial growth in from food prepared in bakery, commercial caterer, restaurant, or take-away settings (OzFoodNet, 2020).

The setting where the food was prepared, bacterial growth factor, and associated hazards.	Number of outbreaks where factor was reported
Bakery	
Foods left at room or warm temperature	3
<i>Salmonella</i>	3
Inadequate refrigeration	6
<i>Salmonella</i>	6
Commercial caterer	
Foods left at room or warm temperature	6
<i>Bacillus cereus</i>	1
<i>Clostridium perfringens</i>	2
<i>Salmonella</i>	3
Inadequate refrigeration	4
<i>Clostridium perfringens</i>	2
<i>Salmonella</i>	1
Unknown	1
Restaurant	
Foods left at room or warm temperature	26
<i>Clostridium perfringens</i>	2
<i>Salmonella</i>	15
Scombrototoxin (Histamine fish poisoning)	1
<i>Staphylococcus aureus</i>	1
Unknown	7
Inadequate refrigeration	14
<i>Salmonella</i>	10
Scombrototoxin (Histamine fish poisoning)	2
<i>Staphylococcus aureus</i>	1
Unknown	1
Take-away	
Foods left at room or warm temperature	4
<i>Salmonella</i>	3
Unknown	1
Inadequate refrigeration	3
<i>Salmonella</i>	3
Total	66

- Adequate cooking is also is considered reliable by definition in the Framework. Nonetheless, insufficient cooking was reported as a major contributing factor for bacterial growth or toxin production in the food that led to 65 foodborne outbreaks in Australia from 2013 – 2017 from food prepared in bakery, commercial caterer, restaurant, or take-away settings (

- Table 5) (OzFoodNet, 2020). Similarly, insufficient time/temperature was reported as a major contributing factor to microbial survival that led to 83 foodborne outbreaks during 2013 – 2017 for the same food preparation settings (Table 6) (OzFoodNet, 2020).

Table 5. The number of foodborne outbreaks (2013-2017) where insufficient cooking was reported as a major contributing factor of bacterial growth in food prepared in bakery, commercial caterer, restaurant, or take-away settings (OzFoodNet, 2020).

The setting where the food was prepared, bacterial growth factor, and associated hazards.	Number of outbreaks where factor was reported
Bakery	
Insufficient cooking	5
<i>Salmonella</i>	5
Commercial caterer	
Insufficient cooking	6
<i>Campylobacter</i>	2
<i>Salmonella</i>	3
Unknown	1
Restaurant	
Insufficient cooking	50
<i>Campylobacter</i>	5
Norovirus	1
<i>Salmonella</i>	41
Unknown	3
Take-away	
Insufficient cooking	4
<i>Clostridium perfringens</i>	1
<i>Salmonella</i>	2
Unknown	1
Grand Total	65

Table 6. The number of foodborne outbreaks (2013-2017) where insufficient time/temperature during cooking was reported as a major contributing factor of microbial survival in food prepared in bakery, commercial caterer, restaurant, or take-away settings (OzFoodNet, 2020).

The setting where the food was prepared, microbial survival factor, and associated hazards.	Number of outbreaks where factor was reported
Bakery	
Insufficient time/temperature during cooking	4
<i>Salmonella</i>	4
Commercial caterer	
Insufficient time/temperature during cooking	7
<i>Campylobacter</i>	3
<i>Salmonella</i>	3
Unknown	1
Restaurant	
Insufficient time/temperature during cooking	69
<i>Campylobacter</i>	11
<i>Clostridium befermentans</i>	1
Hepatitis E	1
<i>Salmonella</i>	54
Unknown	2
Take-away	
Insufficient time/temperature during cooking	3
<i>Escherichia coli</i>	1
<i>Salmonella</i>	2
Grand Total	83

- The slow cooling of cooked foods has also been reported as a major contributing factor for bacterial growth or toxin production in a food that led to 12 foodborne outbreaks associated with restaurants and commercial caterers during 2013 – 2017 (Table 7) (OzFoodNet, 2020). Furthermore, the insufficient time/temperature during the reheating of foods prepared in restaurants, commercial caterers, and take-away settings has also been reported to have contributed to the microbial survival of pathogens in food that led to 17 outbreaks in restaurant, commercial caterer, and takeaway settings (Table 8)(OzFoodNet, 2020).

Table 7. The number of foodborne outbreaks (2013-2017) where slow cooling during cooking was reported as a major contributing factor of bacterial growth or toxin production in food prepared in bakery, commercial caterer, restaurant, or take-away settings (OzFoodNet, 2020).

The setting where the food was prepared, bacterial growth factor, and associated hazards.	Number of outbreaks where factor was reported
Commercial caterer	
Slow cooling	5
<i>Bacillus cereus</i>	1
<i>Clostridium perfringens</i>	1
Unknown	3
Restaurant	
Slow cooling	7
<i>Clostridium befermentans</i>	1
<i>Clostridium perfringens</i>	1
<i>Salmonella</i>	1
Unknown	4
Grand Total	12

Table 8. The number of foodborne outbreaks (2013-2017) where insufficient time/temperature during reheating was reported as a major contributing factor of microbial survival in food prepared in bakery, commercial caterer, restaurant, or take-away settings (OzFoodNet, 2020).

The setting where the food was prepared, microbial survival factor, and associated hazards	Number of outbreaks where factor was reported
Commercial caterer	
Insufficient time/temperature during reheating	6
<i>Clostridium perfringens</i>	3
<i>Salmonella</i>	1
Unknown	2
Restaurant	
Insufficient time/temperature during reheating	10
<i>Clostridium perfringens</i>	1
<i>Salmonella</i>	3
Unknown	6
Take-away	
Insufficient time/temperature during reheating	1
<i>Clostridium perfringens</i>	1
Grand Total	17

- Cross-contamination and re-contamination can occur during the handling activities undertaken by these food businesses. The cross-contamination of food from raw ingredients and the inadequate cleaning of equipment have also been frequently cited as a major contamination factor likely to have led to foodborne outbreaks in food businesses that are likely to prepare RTE food in advance (Table 9) (OzFoodNet, 2020). A food handler with an infectious illness who prepared or handled food has been reported as a major contamination factor likely to be responsible for foodborne outbreaks in these food businesses (Table 9) (OzFoodNet, 2020).

Table 9. The number of foodborne outbreaks (2013-2017) where cross-contamination of food from raw ingredients, the inadequate cleaning of equipment, or food handler contamination was reported as a major contributing factor for contamination of food prepared in bakery, commercial caterer, restaurant, or take-away settings (OzFoodNet, 2020).

The setting where the food was prepared, contamination factor, and associated hazards	Number of outbreaks where factor was reported
Bakery	
Cross contamination from raw ingredients	12
<i>Salmonella</i>	12
Inadequate cleaning of equipment	3
<i>Salmonella</i>	3
Commercial caterer	
Cross contamination from raw ingredients	3
<i>Salmonella</i>	3
Food handler contamination	10
Norovirus	7
<i>Shigella</i>	1
Unknown	2
Restaurant	
Cross contamination from raw ingredients	53
<i>Campylobacter</i>	3
<i>Salmonella</i>	47
Unknown	3
Food handler contamination	15
Norovirus	10
<i>Shigella</i>	1
Unknown	4
Inadequate cleaning of equipment	19
<i>Salmonella</i>	17
Unknown	2
Take-away	
Cross contamination from raw ingredients	14
<i>Escherichia coli</i>	2
<i>Salmonella</i>	11
Unknown	1
Food handler contamination	1
<i>Shigella</i>	1
Inadequate cleaning of equipment	2
<i>Salmonella</i>	2
Grand Total	132

- The inadequate hot holding of food prepared in advance or delays between preparation and consumption has also been reported as a major bacterial growth factor contributing to foodborne outbreaks in food businesses likely to prepare RTE food in advance (Table 10)(OzFoodNet, 2020).

Table 10. The number of foodborne outbreaks (2013-2017) where inadequate hot holding of food prepared in advance or delays between preparation and consumption were reported as a major contributing factor for bacterial growth in food prepared in bakery, commercial caterer, restaurant, or take-away settings (OzFoodNet, 2020).

The setting where the food was prepared, bacterial growth factor, and associated hazards	Number of outbreaks where factor was reported
Commercial caterer	
Inadequate hot holding temperature	4
<i>Clostridium perfringens</i>	1
Unknown	3
Restaurant	
Delay between preparation & consumption	14
<i>Salmonella</i>	9
Unknown	5
Inadequate hot holding temperature	1
<i>Salmonella</i>	1
Take-away	
Delay between preparation & consumption	2
<i>Salmonella</i>	1
Unknown	1
Inadequate hot holding temperature	2
<i>Clostridium perfringens</i>	1
Unknown	1
Grand Total	23

Q3d. Does documented evidence exist that the presence of the hazard in the product is likely to cause frequent or severe human illness? Yes. There is documented evidence¹⁸ that foodborne outbreaks have been attributed to food prepared by food businesses that are likely to process potentially hazardous food in advance of serving the ready-to-eat food to the consumer. As reviewed by Ross et al., (2009) and in Section 3 of this report (Table 11), there is evidence of frequent foodborne outbreaks from food prepared in these food service or retail settings that are likely to undertake the handling activity.

Table 11. Number of foodborne outbreaks, persons ill, persons hospitalised, and fatalities from food prepared in settings likely to prepare RTE PHF in advance (2010-2017) (see Section 3).

Setting where food was prepared	No. outbreaks	No. ill	No. hospitalised	No. fatalities
Bakery	43	834	174	1
Commercial caterer	82	2,528	100	3
Restaurant	567	7,775	711	5

¹⁸ Many foods could contain many different hazards. To facilitate assignment of an appropriate Priority Risk classification, this question is included to differentiate credible risks from improbable risks. "Documented evidence" is taken to include evidence that the hazard in the product, or an analogous hazard in an analogous product, has caused foodborne illness.

Q3e. Is the target consumer unusually vulnerable to the hazard? No. The target consumers¹⁹ of these businesses are the general public.

Q.3f. Does the hazard typically cause severe illness to consumers? No. The types of hazards²⁰ that are reported to cause foodborne outbreaks in these settings are not generally considered to be severe hazards²¹ that cause life threatening illness or chronic sequelae in the average healthy consumer as defined by the ICMSF (2018). As indicated in Section 3 and in Tables 4 – 10 above, the hazards most frequently reported in (e.g. *Salmonella*, norovirus, *Campylobacter*, *C. perfringens*) generally cause self-limiting illness that is not normally life threatening in healthy consumers and are considered moderate²² or serious²³ hazards.

E. coli O157:H7 has been reported as the cause of a foodborne outbreak in a takeaway setting during 2013 - 2017 and is generally considered a severe hazard. However, outbreaks from this pathogen in these settings are relatively rare.

Q3g. Could the level of the hazard cause acute illness in a healthy consumer or, before eating, increase to such levels due to poor temperature control? Yes. As indicated by Ross et al. (2009) It is likely that large enough amounts of hazards can be transferred to food that could cause illness in the average consumer²⁴ or that lower levels of hazards could increase as a result of poor temperature control. The evidence provided above regarding foodborne outbreaks in these food service or retail sectors indicate that large enough amounts of pathogens are likely to have been transferred to food both from infected food handlers, contaminated raw products, and that low levels of pathogens on products may have been treated in such ways that the level of pathogens increase to a levels that had a high likelihood of causing illness (Section 3 and in Tables 4 – 10 above).

The review of the priority classification of these businesses based on the evidence above indicates that those businesses that are characterised by undertaking handling activity 1 -

¹⁹ If the population served by the business sector includes a high proportion of very young children (e.g. ≤4 y.o), elderly (e.g > 70 y.o.) or other people known to have reduced immunity (e.g pregnant women, liver disease, HIV, transplant recipients, cancer patients receiving chemo- or radiotherapy etc) risk is increased due to the susceptibility of these consumers to food borne illness.

²⁰ Hazard severity can depend on the inherent nature of the hazard, and the dose ingested. As such, when evaluating hazard severity, the usual disease symptoms associated with a recognisable case of the illness should be the basis of the hazard severity assessment. The usual symptoms could change, for example, if the risk to a specific susceptible population were being assessed.

²¹ ICMSF (2018) describes severe illness as “causing life threatening illness or substantial chronic sequelae or causing an illness of long duration”.

²² ICMSF (2018) describes moderate hazards as not usually life threatening (i.e. usually no sequelae, illness normally of short duration, symptoms are self-limiting but can cause severe discomfort).

²³ ICMSF (2018) describes serious hazards as causing incapacitating but not usually life threatening illness; sequelae rare, and of intermediate duration.

²⁴ This question is intended to further identify business sectors that may present a high risk because they undertake processes or produce foods that are susceptible to temperature abuse that could lead to significant pathogen growth (e.g. slow reheating, protracted cooling, or ‘hot holding’ of foods prior to sale or service, inadequate refrigeration of raw foods), i.e. processes for which temperature is the principal means of assuring safety. In the case of psychrotrophic pathogens in long shelf life refrigerated foods, even proper temperature control will not eliminate or control the hazard, i.e. temperature control is not the principal risk management action. Additionally, the question is intended to identify business sectors that employ processes that are susceptible to recontamination of the product, or susceptible to failure to eliminate hazards present at levels that could cause acute illness (e.g. toxins, low infectious dose pathogens such as enterohaemorrhagic *Escherichia coli*). If the business sector produces or serves foods that could be contaminated at levels that could lead to acute illness, or foods that could be contaminated and during normal handling allow hazard levels to increase to those that could cause acute illness if temperature is not properly controlled, answer “YES”.

process potentially hazardous food in advance of serving the ready-to-eat food to the consumer - are classified as Priority 1 businesses.

4.3 Businesses characterised by Activity 2: Food service or retail businesses that process and serve PHF RTE to consumers for immediate consumption

The in-scope businesses identified by the ISFR WG to be characterised by the handling activity to process potentially hazardous food and serve as ready-to-eat food to the consumer in a time period which does not adversely affect the microbiological safety of the food – is intended to capture businesses that process food upon order for immediate consumption – and includes:

- Food service for express order (e.g. eating establishments or takeaway businesses that do not prepare food in advance)

In this classification, Ross et al. (2009) considered that *all* meal components are cooked or prepared fresh for individual orders, with little opportunity for contamination or extensive bacterial growth.

Q1a. Is the food “potentially hazardous”? Yes. The food service businesses described above have the common characteristic of handling of high risk²⁵ potentially hazardous food that have to be kept at a certain temperatures to minimise the growth of pathogenic microorganism that may be present in the food. In contrast to those businesses undertaking Activity 1, these businesses do not process or store RTE in advance of serving of RTE food to the consumer and instead process food upon order for immediate consumption.

Q2a. Is the product a “high risk” food? Yes. These food service or catering businesses are also characterised by processing and serving high risk²⁶ potentially hazardous foods. The foods processed by these food businesses are expected to include at least one high risk food such as seafood, raw meat, poultry, and eggs. These are foods that are more likely to contain microbial pathogens, are able to support the growth of microbial pathogens, and the processing of these high risk foods can lead to the recontamination of other cooked or raw foods (Ross et al. 2009).

As such, these businesses could introduce a hazard to the food, or fail to control the level of the hazard that could be present. These businesses need to take actions to eliminate, reduce, or control a hazard critical to the safety of the product when it is consumed.

Q3a. Is a practical action available to control the hazard? Yes. Practical control²⁷ actions are available and required during receipt, storage, food processing, and service to limit microbial contamination, recontamination, growth and survival.

²⁵ While businesses that handle high risk foods are immediately placed into Priority 1 or 2, a high volume producer of medium risk foods may represent a risk to public health unless adequate and reliable controls are in place.

²⁶ High risk foods: food that may contain pathogenic microorganisms and will support formation of toxins or growth of pathogenic microorganisms (see ‘potentially hazardous foods’). Examples include raw meat, poultry and fish, unpasteurised milk, oysters, tofu, fresh filled pasta, meat pies, frankfurts, cooked rice and lasagne. Using the Framework, business sectors that handle high risk foods will always be classified as Priority 1 or 2.

²⁷ This question is principally intended to identify foods or processes for which a practical strategy (i.e. technologically and economically feasible), or combination of strategies, is available to control the hazard in the product made, sold or handled by the business sector. “Control” is used in the sense

Q3b. Is the control action critical to the safety of the product sold by the business sector? Yes. The control actions implemented by food service businesses engaged in this handling activity can be critical²⁸ to the safety of the food sold. Food businesses that process PHF upon order for immediate consumption must have controls in place during food preparation, storage, and service to minimise the growth of pathogenic microorganisms that were already in the raw product or that may potentially cross-contaminate food. These controls include:

- Adequate storage of PHF at appropriate temperatures before processing is a critical control action for these food businesses. The discussion of controls for adequate storage in Q3b in Section 4.2 is equally relevant for food businesses that process PHF upon order for immediate consumption.
- Adequate cooking is a critical control action for these food businesses to ensure that non-spore-forming pathogens such as *Salmonella*, *L. monocytogenes*, *Vibrio spp.*, and *Campylobacter* are effectively inactivated if present in raw product. The discussion of controls for adequate cooking in Q3b in Section 4.2 is equally relevant for food businesses that process PHF upon order for immediate consumption.
- Minimising cross-contamination and re-contamination are also a critical control action for these food businesses. The discussion of controls for minimising cross-contamination and re-contamination in Q3b in Section 4.2 is equally relevant for food businesses that process PHF upon order for immediate consumption.
- RTE PHF food prepared for express order must be served within a time frame that does not affect the microbiological safety of the food. As a general rule, the total time that a RTE PHF can be kept at temperatures between 5°C and 60°C is 4 hours (FSANZ 2016). After this time the food needs to be discarded.

Q3c. Are the Critical Control actions potentially unreliable, or unproven, or could recontamination occur prior to sale by the business sector? Yes. Some of these critical control actions have been reported to be unreliably²⁹ applied and the potential for recontamination of processed PHF prior to sale has been reported.

- The storage of food at appropriate temperatures both prior to and after processing is not considered unreliable by definition in the RPF. The OzFoodNet outbreak register does not report foodborne outbreaks against the same business or priority categories outlined in the Framework. As such, it is assumed for the purpose of this risk classification that take-away and national franchised food business settings in the OzFoodNet outbreak register are most likely to represent at least some businesses that process high risk PHF upon order for immediate consumption. However, it is not

used in the HACCP approach, i.e. an action taken to prevent, reduce to an acceptable level, or eliminate a food safety hazard. Thus, 'control' does not always mean reduction or elimination of a hazard, but can include prevention of worsening of a hazard (e.g. refrigeration) as well as hazard reduction or elimination.

²⁸ The intent of this question is to identify business sectors that, while handling a medium or high risk food, do not have essential responsibility for the safety of the product at the point of consumption. The inference of a 'NO' answer is that processes undertaken by another business sector(s) in the food supply chain are the most important in assuring the safety of the product at the time of consumption.

²⁹ Food service or business sectors that rely on processes that do not achieve high levels of hazard reduction (e.g. fermentation, chlorine washes, vegetables acidified and stored in oil), or where evidence indicates that recontamination with hazards is common, or where the process can occasionally fail, without that failure being detected prior to release of the product for sale are considered 'unreliable'.

possible, with the data available, to distinguish between businesses that process PHF in advance or upon order for immediate consumption. Inadequate refrigeration and foods left at room or warm temperature were reported as major contributing factors to bacterial growth that led to foodborne outbreaks in 4 and 3 outbreaks respectively from food prepared in take-away settings during 2013 – 2017 (OzFoodNet 2020). These factors were not reported in outbreaks attributed to food prepared in national franchised food business settings during the same time frame (Table 12).

Table 12. The number of foodborne outbreaks (2013-2017) where food being left at room or warm temperature and inadequate refrigeration were reported as major contributing factors of bacterial growth in food prepared in Take-away or National Franchised Food Business settings (OzFoodNet, 2020).

The setting where the food was prepared, bacterial growth factor, and associated hazards.	Number of outbreaks where factor was reported
Take-away	
Foods left at room or warm temperature	4
<i>Salmonella</i>	3
Unknown	1
Inadequate refrigeration	3
<i>Salmonella</i>	3
Grand Total	7

- Insufficient cooking (Table 13) and insufficient time/temperature during cooking (Table 14) were reported as major contributing factors to bacterial growth or survival in 6 and 3 foodborne outbreaks respectively from food prepared in food businesses where some businesses are assumed to process PHF upon order for immediate consumption (OzFoodNet 2020).

Table 13. The number of foodborne outbreaks (2013-2017) where insufficient cooking of food was reported as a major contributing factor to bacterial growth in food prepared in Take-away or National Franchised Food Business settings (OzFoodNet, 2020).

The setting where the food was prepared, bacterial growth factor, and associated hazards.	Number of outbreaks where factor was reported	No. ill potentially associated with factor
National franchised fast food		
Insufficient cooking	2	55
<i>Salmonella</i>	2	55
Take-away		
Insufficient cooking	4	67
<i>Clostridium perfringens</i>	1	3
<i>Salmonella</i>	2	34
Unknown	1	30
Grand Total	6	122

Table 14. The number of foodborne outbreaks (2013-2017) where insufficient time/temperature during cooking was reported as a major contributing factor to microbial survival in food prepared in take-away or national franchised food business settings (OzFoodNet, 2020).

The setting where the food was prepared, microbial survival factor, and associated hazards.	Number of outbreaks where factor was reported
Take-away	
Insufficient time/temperature during cooking	3
<i>Escherichia coli</i>	1
<i>Salmonella</i>	2
Grand Total	3

- Cross-contamination and re-contamination can occur during the handling activities undertaken by these food businesses. The cross-contamination of food from raw ingredients and the inadequate cleaning of equipment have also been cited as a major contamination factor likely to have led to foodborne outbreaks in these food businesses (Table 15). A food handler with an infectious illness who prepared or handled food has been less frequently reported as a major contamination factor likely to be responsible for foodborne outbreaks in these food businesses (Table 15) (OzFoodNet 2020).

Table 15. The number of foodborne outbreaks (2013-2017) where cross-contamination of food from raw ingredients, the inadequate cleaning of equipment, or food handler contamination was reported as a major contributing factor for contamination of food prepared in take-away or national franchised fast food settings (OzFoodNet, 2020).

The setting where the food was prepared, microbial contamination factor, and associated hazards.	Number of outbreaks where factor was reported
National franchised fast food	
Cross contamination from raw ingredients	1
<i>Salmonella</i>	1
Inadequate cleaning of equipment	1
<i>Salmonella</i>	1
Take-away	
Cross contamination from raw ingredients	14
<i>Escherichia coli</i>	2
<i>Salmonella</i>	11
Unknown	1
Food handler contamination	1
<i>Shigella</i>	1
Inadequate cleaning of equipment	2
<i>Salmonella</i>	2
Grand Total	19

Q3d. Does documented evidence exist that the presence of the hazard in the product is likely to cause frequent or severe human illness? Yes. There is documented evidence³⁰ that foodborne outbreaks have been attributed to food prepared by food businesses that are likely to process PHF upon order for immediate consumption (see Section 3) and are summarised in Table 16 (OzFoodNet 2020). However, it is not possible to determine what proportion of take-away or national franchised fast food business are undertaking the specific handling activities. It is therefore assumed for the purpose of this assessment that some of these businesses are undertaking the specified handling activities.

Table 16. Table 17. Number of foodborne outbreaks, persons ill, persons hospitalised,

³⁰ Many foods could contain many different hazards. To facilitate assignment of an appropriate Priority Risk classification, this question is included to differentiate credible risks from improbable risks. "Documented evidence" is taken to include evidence that the hazard in the product, or an analogous hazard in an analogous product, has caused foodborne illness.

and fatalities from food prepared in settings likely to prepare RTE PHF upon order for immediate consumption (2010-2017) (see Section 3).

Setting where food was prepared	No. outbreaks	No. ill	No. hospitalised	No. fatalities
National franchised fast food business	8	80	17	0
Take-away	82	1138	192	1

Q3e. Is the target consumer unusually vulnerable to the hazard? No. The target consumers³¹ of these businesses are the general public.

Does the hazard typically cause severe illness to consumers? No. The types of hazards³² that are reported to cause foodborne outbreaks in these settings are not generally considered to be severe hazards³³ that cause life threatening illness or chronic sequelae in the average healthy consumer as defined by the ICMSF (2018). As indicated in Section 3 and in Tables 4 – 15 above, the hazards most frequently reported in (e.g. *Salmonella*, norovirus, *S. aureus*) generally cause self-limiting illness that is not normally life threatening in healthy consumers and are considered moderate³⁴ or serious³⁵ hazards.

Q3g. Could the level of the hazard cause acute illness in a healthy consumer or, before eating, increase to such levels due to poor temperature control? No. For the businesses that process PHF upon order for immediate consumption there is likely to be insufficient time for food containing low numbers of pathogens to grow to levels that are likely to cause illness in healthy consumers between processing and consumption.

However, in determining if it is likely that large enough amounts of hazards can be transferred to food that could cause illness in the average consumer³⁶, this is dependent upon whether the high risk food components are raw or cooked.

³¹ If the population served by the business sector includes a high proportion of very young children (e.g. ≤4 y.o), elderly (e.g > 70 y.o.) or other people known to have reduced immunity (e.g pregnant women, liver disease, HIV, transplant recipients, cancer patients receiving chemo- or radiotherapy etc) risk is increased due to the susceptibility of these consumers to food borne illness.

³² Hazard severity can depend on the inherent nature of the hazard, and the dose ingested. As such, when evaluating hazard severity, the usual disease symptoms associated with a recognisable case of the illness should be the basis of the hazard severity assessment. The usual symptoms could change, for example, if the risk to a specific susceptible population were being assessed.

³³ ICMSF (2018) describes severe illness as “causing life threatening illness or substantial chronic sequelae or causing an illness of long duration”.

³⁴ ICMSF (2018) describes moderate hazards as not usually life threatening (i.e. usually no sequelae, illness normally of short duration, symptoms are self-limiting but can cause severe discomfort).

³⁵ ICMSF (2018) describes serious hazards as causing incapacitating but not usually life threatening illness; sequelae rare, and of intermediate duration.

³⁶ This question is intended to further identify business sectors that may present a high risk because they undertake processes or produce foods that are susceptible to temperature abuse that could lead to significant pathogen growth (e.g. slow reheating, protracted cooling, or ‘hot holding’ of foods prior to sale or service, inadequate refrigeration of raw foods), i.e. processes for which temperature is the principal means of assuring safety. In the case of psychrotrophic pathogens in long shelf life refrigerated foods, even proper temperature control will not eliminate or control the hazard, i.e. temperature control is not the principal risk management action. Additionally, the question is intended to identify business sectors that employ processes that are susceptible to recontamination of the product, or susceptible to failure to eliminate hazards present at levels that could cause acute illness (e.g. toxins, low infectious dose pathogens such as enterohaemorrhagic *Escherichia coli*). If the business sector produces or serves foods that could be contaminated at levels that could lead to acute illness, or foods that could be contaminated and during normal handling allow hazard levels to increase to those that could cause acute illness if temperature is not properly controlled, answer “YES”.

Where the high risk food components are cooked sufficiently before consumption, the microbial pathogens should be reduced below levels that would cause illness in healthy consumers.

However, it should be noted that if raw or lightly cooked high risk food components, such as eggs or seafood, are prepared upon order for immediate consumption, these businesses would be classified as P1 businesses. This is because the answer to Q3g would be 'yes' because raw or lightly cooked high risk foods, such as eggs and seafood, have a higher likelihood of containing infectious doses of microorganisms and the evidence regarding foodborne outbreaks in these food service or retail sectors indicate that large enough amounts of pathogens have been transferred to food both from infected food handlers or contaminated raw products (Ross et al., 2009).

Q3h. Do businesses in the sector produce or serve sufficient units or servings simultaneously to pose an unacceptable risk? No. For food businesses that process high risk food for individual orders for immediate consumption, and where all high risk components are cooked prior to consumption, it is not considered that business would serve sufficient servings simultaneously to pose an unacceptable risk under the definitions of the RPF (Ross et al., 2009).

The review of the priority classification of these businesses indicates that those businesses characterised by undertaking handling activity 2 - process potentially hazardous food and serve as ready-to-eat food to the consumer in a time period which does not adversely affect the microbiological safety of the food where all raw high risk food components are cooked adequately – were classified as Priority 2 businesses.

Food businesses that process potentially hazardous food and serve as ready-to-eat food to the consumer in a time period which does not adversely affect the microbiological safety of the food where high risk food components are raw or lightly cooked were classified as Priority 1 businesses.

4.4 Businesses characterised by Activity 3: Food retail businesses that serve unpackaged potentially hazardous food as ready-to-eat food for retail

The in-scope businesses identified by the ISFR WG to be characterised by the handling activity of serving unpackaged potentially hazardous food that is not processed by the food business and sold as ready-to-eat food for retail include:

- Retailer: bakery products (unpackaged)
- Retailer: processed seafood products (unpackaged)
- Retailer: processed delicatessen products (unpackaged)

In this classification, it is assumed that the main functions of these businesses is to weigh out, slice, or sell portions of already processed PHF high risk foods.

Q1a. Is the food “potentially hazardous”? Yes. These retail food businesses are characterised by the handling of unpackaged PHF that have to be kept at a certain temperature to minimise the growth of pathogenic microorganism that may be present in the food.

Q2a. Is the product a “high risk” food? Yes. The foods served by these food businesses are likely to include high risk foods such as raw seafood, raw meat, raw poultry, fermented meats, soft cheeses, egg containing bakery products and RTE salads. These foods may contain microbial pathogens, are able to support the growth of microbial pathogens (Ross et al., 2009). Furthermore, as food is unpackaged and handled, recontamination or cross contamination may occur.

As such, these businesses could introduce a hazard to the food, or fail to control the level of the hazard that could be present. These businesses need to take actions to eliminate, reduce, or control a hazard critical to the safety of the product when it is consumed.

Q3a. Is a practical action available to control the hazard? Yes. Practical control³⁷ actions are available and required during both food storage, handling, and service to limit microbial contamination, recontamination, growth and survival.

Q3b. Is the control action critical to the safety of the product sold by the business sector? Yes. The control actions implemented by food retail business that do not process but handle and serve unpackaged potentially hazardous food for retail can be critical³⁸ to the safety of the food sold. These food retail businesses must have controls in place during food handling and storage to minimise the growth of pathogenic microorganisms that were already in the processed product or that may potentially cross-contaminate or re-contaminate food.

³⁷ This question is principally intended to identify foods or processes for which a practical strategy (i.e. technologically and economically feasible), or combination of strategies, is available to control the hazard in the product made, sold or handled by the business sector. “Control” is used in the sense used in the HACCP approach, i.e. an action taken to prevent, reduce to an acceptable level, or eliminate a food safety hazard. Thus, ‘control’ does not always mean reduction or elimination of a hazard, but can include prevention of worsening of a hazard (e.g. refrigeration) as well as hazard reduction or elimination.

³⁸ The intent of this question is to identify business sectors that, while handling a medium or high risk food, do not have essential responsibility for the safety of the product at the point of consumption. The inference of a ‘NO’ answer is that processes undertaken by another business sector(s) in the food supply chain are the most important in assuring the safety of the product at the time of consumption.

- Adequate storage of PHF at appropriate temperatures is a critical control action for these food retail businesses. This will ensure that the potential growth of any pathogenic organisms already present in the food is limited, and the quality of food maintained.

Bakery products include creams, custard, egg-based filling or glazes based on egg are frequently reported to harbour pathogens that have led to foodborne outbreak (Ross et al. 2009; Moffatt et al. 2016). *Salmonella* is frequently associated with outbreaks from bakery products (see Section 3), but other pathogens such as *B. cereus*, *S. aureus*, and norovirus have been reported to contaminate bakery products in Australia (Figure 13) (Ross et al. 2009).

Delicatessens can handle a large variety of foods including cured and processed meats such as ham, pâté, fermented products such as cheese and salami, smoked fish and meats, caviar, pickled fish, pickled vegetables, olives, and breads. Many of these products may occasionally contain viable pathogens (Churchill et al., 2019; Ross et al., 2009). Soft cheeses and smoked fish require adequate temperature control to limit the growth of *L. monocytogenes* that has been associated with outbreaks of foodborne illness from these products (Ross et al., 2009). Vacuum packed products also require refrigeration to prevent or limit growth of *L. monocytogenes* and *C. botulinum*, and also rely on product formulation by processors to reduce pH and water activity to limit the potential for growth (Ross et al., 2009; Rasetti-Escargueil et al., 2020). Some products rely on drying, or addition of salt or sugar for their stability and thus require specialised storage to reduce absorption of water and potential pathogen growth.

Seafood retailers may handle a variety of products that could be both cooked and raw. Raw seafood may be contaminated by various bacterial pathogens, including *Vibrio* spp., the growth of which must be controlled by refrigeration (Huss et al., 2000; Ross et al., 2009; Sumner et al., 2014; Elbashir et al., 2018). Furthermore, histamine fish poisoning (or Scombrototoxin poisoning) is a type of food poisoning caused by elevated levels of histamine being present in the fish as a result of bacterial growth from storage at insufficient temperatures (Knoppe et al., 2014). In contrast, ciguatera toxin will be present in the fish at the time of catch, and the levels are not affected by temperature storage.

- If reheating of food occurs in any of these settings, adequate reheating and subsequent hot holding is a required for these food businesses to ensure that non-spore-forming pathogens such as *Salmonella*, *L. monocytogenes*, *Vibrio species*, *Campylobacter* are effectively inactivated if present in the product. However, as it is assumed that these business are reheating foods cooked and processed previously by another business, these hazards should already be controlled if cooking was effective and is therefore not considered a critical control action. However, cooking will not eliminate all spore-forming bacteria such as *C. perfringens* and *B. cereus*. Therefore, adequate hot-holding is also required to limit their potential for growth and toxin production.
- Minimising cross-contamination and re-contamination are also critical control actions for these food businesses. Re-contamination can occur due to cross-contamination from raw foods, cooked foods containing spores, infected food handlers, and unclean surfaces and equipment. Hazards associated with infected food handlers include both bacteria and viruses such as *Staphylococcus aureus*, *Shigella*, hepatitis A and E viruses, and norovirus that can be carried both symptomatically and asymptotically (Michaels et al., 2004; Hardstaff et al., 2018).

Delicatessens and seafood retailers are characterised by a high degree of handling of high risk products due to weighing out, slicing, and re-portioning with various equipment leading to a high likelihood of cross or re-contamination if food is contaminated or a food handler infected.

Q3c. Are the Critical Control actions potentially unreliable, or unproven, or could recontamination occur prior to sale by the business sector? Yes. Some of these critical control actions have been reported to be unreliably³⁹ applied and the potential for recontamination of processed PHF prior to sale has been reported.

- The storage of food at appropriate temperatures both prior to and after processing is not considered unreliable⁴⁰ by definition in the RPF. However, if unpackaged food that is contaminated at processing or re-contaminated by retailers is not stored appropriately hazards may increase to levels that could cause illness in consumers.

Although it is not possible to determine exactly which Australian outbreaks that were reported during 2010 – 2017 were attributed to retailers (not producers of unpackaged bakery products), there are a large variety of bakery products that are likely to be available for retail sale that have been implicated in foodborne outbreaks. For example, cakes, custard filled products, eclairs with cream, sandwiches and rolls are all food vehicles that have been implicated in foodborne outbreaks in Australia (OzFoodNet Working Group, 2012; 2015; 2018; OzFoodNet, 2020). Furthermore, inadequate refrigeration and food being left at room temperature have been reported as major contributing factors for bacterial growth or toxin production in the food that led to nine Australian foodborne outbreaks respectively in bakery settings during 2013 – 2017 (see

³⁹ Food service or business sectors that rely on processes that do not achieve high levels of hazard reduction (e.g. fermentation, chlorine washes, vegetables acidified and stored in oil), or where evidence indicates that recontamination with hazards is common, or where the process can occasionally fail, without that failure being detected prior to release of the product for sale are considered 'unreliable'.

⁴⁰ Definition from RPF

Table 4).

Foodborne outbreaks attributed to the improper storage of food sold by retail delicatessens were not identified in the outbreak data provided to FSANZ for outbreaks occurring in Australia during 2010 – 2017. However, a 2017 - 2018 investigations of retail delis found a cluster of eight listeriosis cases in NSW were attributed to RTE deli meats sold through retail delicatessens (NSW DPI 2018) and were associated with a number of positive environmental swabs for *L. monocytogenes* or *Listeria* spp.. A food sample that was positive for >1500 CFU/g of *L. monocytogenes* was also associated with temperature control issues during storage of the food.

Limited evidence is available regarding Australian foodborne outbreaks that occur from food prepared or sold by seafood retail businesses. However, two outbreaks of histamine poisoning were reported between 2010 – 2013 from seafood prepared in a retail settings (Knobe et al., 2014). Although the contributing factors for these outbreaks were not identified, the most important contributing factor to histamine poisoning is considered to be improper refrigeration which enables bacterial growth.

- Cross contamination and re-contamination can occur during the handling activities undertaken by these food retail businesses.

During 2013 – 2017, the major contributing factors for contamination of a food vehicle that led to foodborne outbreaks from food prepared in bakery settings included 12 outbreaks citing cross-contamination from raw ingredients, and 3 citing the inadequate cleaning of equipment (see Table 9).

The number of outbreaks where cross-contamination of food from raw ingredients, inadequate cleaning of equipment, or food handler contamination was reported as a major contributing factor for contamination of food prepared in grocery store or delicatessen settings are summarised in Table 18. Of these, two *Salmonella* outbreaks were reported to be the result of cross-contamination of cold roast chicken, and an ill food handler contaminating food was reported to be the main contributing contamination factor in a *Salmonella* outbreak attributed to contaminated deli meats. As previously mentioned, a number of Australian delicatessen businesses returned positive environmental and food contact surface swabs for *L. monocytogenes* or *Listeria* spp. (NSW DPI 2018).

Table 18. The number of foodborne outbreaks (2013-2017) where cross-contamination of food from raw ingredients, the inadequate cleaning of equipment, or food handler contamination was reported as a major contributing factor for contamination of food prepared in grocery store or delicatessen settings (OzFoodNet, 2020).

The setting where the food was prepared, contamination factor, and associated hazards	Number of outbreaks where factor was reported
Grocery store or delicatessen	
Cross contamination from raw ingredients	2
<i>Salmonella</i>	2
Food handler contamination	1
<i>Salmonella</i>	1
Unknown	6
Norovirus	1
<i>Salmonella</i>	1
Unknown	4
Grand Total	9

Limited evidence is available regarding Australian foodborne outbreaks that occur from food prepared or sold by seafood retail businesses. However, as a variety of pathogens can potentially contaminate seafood and potentially high levels of handling, there is the possibility for cross-contamination and also re-contamination via infected food handlers.

Q3d. Does documented evidence exist that the presence of the hazard in the product is likely to cause frequent or severe human illness? No. There is not documented evidence of frequent or severe foodborne outbreaks that have been attributed to food handled by food retail businesses that serve unpackaged potentially hazardous food as ready-to-eat food for retail.

There are a relatively large number of foodborne outbreaks that are reported to occur from food prepared in bakery settings (43 outbreaks were reported in Australia between 2010 and 2017, see Section 3). However, it is not possible to determine from the OzFoodNet data if an outbreak occurred in a bakery setting that was a producer and retailer or only a retailer of unpackaged bakery products. On further inspection of the OzFoodNet data, it appears that the majority of outbreaks were attributed to handling practices that are more common for food service and food processors, or the use of contaminated ingredients when food was processed, rather than temperature abuse or food handler contamination at retail. As such it can be assumed that outbreaks are less likely to occur as a result of handling by bakeries that only sell unpackaged product for retail compared to those bakery business that process bakery products.

A relatively small number of foodborne outbreaks (nine foodborne outbreaks where attributed to food prepared in grocery or delicatessen settings during 2010 - 2017) have been attributed to delicatessens in Australia (see Section 3). As such, there is little evidence of frequent or severe illness from foods sold by delicatessens that were due to a lack of control by retailers.

As mentioned above, two outbreaks of histamine poisoning were reported between 2010 – 2013 from seafood prepared in a retail settings (Knope et al., 2014). Although the contributing factors for these outbreaks were not identified, improper refrigeration can enable bacterial growth. While there are a number of reports of foodborne outbreaks involving seafood from chemical hazards during 2010 – 2017 (data not shown), the majority of these were associated with eating fish contaminated with ciguatoxins which are produced by dinoflagellates eaten by the fish. Ciguatoxins are present in the fish at the time of catch and do not generally increase as a result of handling by retailers. As such, there is little evidence of frequent or severe illness from seafood due to inadequate food safety controls by retailers.

The review of the priority classifications for these businesses indicates that those businesses characterised by handling activity 3 - serve unpackaged potentially hazardous food as ready-to-eat food for retail that is not processed by the food retail business - were classified as Priority 2 businesses.

4.5 Businesses characterised by Activity 4: Food retail businesses that handle but do not process packaged PHF that is sold as packaged RTE food to the consumer

The in-scope businesses identified by the ISFR WG to be characterised by the handling activity of the sale of packaged RTE PHF where the food is packaged prior to receipt by the food business for retail and provided packaged to the consumer include:

- retailers of RTE perishable, packaged foods (e.g. sandwiches)

Q1a. Is the food “potentially hazardous”? Yes. The food retail businesses described above have the common characteristic of handling of high risk⁴¹ or medium risk packaged potentially hazardous food that has to be kept at a certain temperature to minimise the growth of pathogenic microorganisms that may be present in the food.

Q2a. Is the product a “high risk” food? Yes. These food retail businesses are also characterised by serving potentially hazardous foods. However, the risk associated with products considered to be medium risk, such as pasteurised milk products, will be less than for that of products containing high risk foods such as fresh-cut fruits and vegetables and packaged sandwiches or pastries that contain meat, poultry or egg (Ross et al., 2009).

If a food retail business only handles packaged perishable food that is considered a medium risk food that is unlikely to contain pathogenic microorganisms due to prior processing of the food, and that food is not likely to contain a significant amount of a chemical hazard, not exposed to unreliable hazard reduction processes, and not opened and served to the consumer, then that business would be considered a P3 business.

However, for those businesses that handle packaged high risk food, these businesses could fail to control the level of the hazard that may be present. These businesses need to take actions to control a hazard critical to the safety of the product when it is consumed.

Q3a. Is a practical action available to control the hazard? Yes. Practical control⁴² actions are available and required during food handling to limit bacterial growth and survival.

Q3b. Is the control action critical to the safety of the product sold by the business sector? No. The control actions implemented by a food business that sell packaged potentially hazardous foods for retail sale are not considered to be critical to the safety of the food sold. As stated in Ross et al. (2009), while temperature control by the retailer will assist to minimise the risk, the risk only exists if poor handling (hygiene) or inadequate cooking has occurred by the processor, therefore, in this case the main responsibility for food safety rests with the manufacturer.

⁴¹ While businesses that handle high risk foods are immediately placed into Priority 1 or 2, a high volume producer of medium risk foods may represent a risk to public health unless adequate and reliable controls are in place.

⁴² This question is principally intended to identify foods or processes for which a practical strategy (i.e. technologically and economically feasible), or combination of strategies, is available to control the hazard in the product made, sold or handled by the business sector. “Control” is used in the sense used in the HACCP approach, i.e. an action taken to prevent, reduce to an acceptable level, or eliminate a food safety hazard. Thus, ‘control’ does not always mean reduction or elimination of a hazard, but can include prevention of worsening of a hazard (e.g. refrigeration) as well as hazard reduction or elimination.

The review of the priority classification of these businesses based on the evidence above indicates that those businesses characterised by handling activity 4 - serve packaged potentially hazardous food as ready-to-eat food to the consumer where the food is packaged prior to receipt by the food business – were classified as Priority 2 businesses.

4.6 Review of business priority classifications summary

The review of the priority classifications for the in scope businesses using the Framework required the consideration of the potential hazards/risk factors that are associated with different food handling activities of food service and related retail businesses, the controls required for food safety, and other information including the availability of documented evidence that the presence of a hazard in food could cause frequent or severe human illness.

A summary of the reclassification of the priority businesses and associated handling activities is provided in Table 19. It should be noted that much of the background information provided by Ross et al. (2009) is still relevant to the classified businesses.

Table 19. Priority classifications for food service and related food retail business sectors using the Framework and their associated handling activities.

Business sector	Handling activity	Priority Classification 2021
Food service: commercial catering	Activity 1	P1
Food service: eating establishments - RTE prepared in advance	Activity 1	P1
Food service: RTE food is prepared express order – some high risk food components are raw	Activity 2	P1
Food service: RTE food is prepared express order – all high risk food components are cooked	Activity 2	P2
Retailer and manufacturer: bakery products	Activity 1	P1
Retailer: bakery products	Activity 3	P2
Retailer: processed delicatessen products	Activity 3	P2
Retailer: processed seafood products	Activity 3	P2
Retailer: high risk perishable pre-packaged food	Activity 4	P2

5 Categorisation of handling activities

The final objective of this report was to assign the handling activities identified by the ISFR

WG into categories on the basis of food safety risk.

It is necessary for the categorisation of these handling activities that it is specified that high risk potentially hazardous food is the highest risk food handled. This is because if a business only handles a medium risk food, then the Framework may classify that business as a P2 or P3 business depending on the answer to other subsequent questions. As such, the following amended definitions are provided for this process:

Handling activity 1: process high risk potentially hazardous food in advance of serving the ready-to-eat food to the consumer

Handling activity 2: process and serve high risk potentially hazardous food as ready-to-eat food to the consumer in a time period which does not adversely affect the microbiological safety of the food (either all RTE high risk components cooked or some RTE high risk components are raw)

Handling activity 3: serve unpackaged high risk potentially hazardous food for retail

Handling activity 4: serve packaged high risk potentially hazardous food as ready-to-eat food. The food is packaged prior to receipt by the food business for retail and sold to the consumer packaged.

These activities were categorised based on the number of food safety controls required, and the proportion of Australian foodborne outbreaks and associated people ill represented by the food service or related food retail businesses most likely to undertake the handling activity.

For those businesses that were identified to undertake handling activity 1, there were five controls indicated to be critical to the safety of food (see Section 4.2):

- Adequate storage of PHF at appropriate temperatures before processing
- Adequate cooking or reheating
- Adequate cooling of cooked foods
- Minimising cross-contamination and re-contamination
- Adequate storage at appropriate temperatures of RTE food processed in advance before service to the consumer

For those businesses undertaking handling activity 2, there were three controls indicated to be critical to the safety of food (see Section 4.3):

- Adequate storage of PHF at appropriate temperatures before processing
- Adequate cooking
- Minimising cross-contamination and re-contamination

For those businesses undertaking handling activity 3, there were two controls indicated to be critical to the safety of food (see Section 4.4):

- Adequate storage of PHF at appropriate temperatures
- Minimising cross-contamination and re-contamination

For those businesses undertaking handling activity 4, there was one control indicated to be required for the safety of food (see Section 4.5):

- Adequate storage of PHF at appropriate temperatures is required for food safety.

There are a greater number of controls required to manage those scenarios which may lead to microorganisms being present, increasing, transferred, or introduced to food handled by (in decreasing order) Activity 1 > Activity 2 > Activity 3 > Activity 4. Furthermore, the majority of P1 businesses and those business sectors that are responsible for the largest number of

foodborne outbreaks and persons ill in Australia during 2010 – 2017 (see section 3.3 and 4) are represented by Activity 1 or Activity 2 (i.e., restaurants, commercial caterers, takeaways, bakeries) and those P2 businesses that are less often attributed to frequent or severe foodborne outbreaks are represented in Activity 3 (i.e., delicatessen and seafood retailers) and Activity 4 represents only businesses that retail packaged high risk products for which there is little evidence of frequent foodborne outbreaks related to businesses undertaking this handling activity.

Additionally, handling activity 1 and 2 require similar critical controls and knowledge to ensure food safety. For example, although the Framework only identified three critical controls for Activity 2, even if a business is only preparing food for express order, an understanding of the importance of time and temperature in reducing microbial growth following the preparation of RTE food is still required. Business are required to understand *why* the preparation of high risk food RTE food for express order can reduce the risk of microbial growth and contamination, compared to if high risk RTE food is prepared in advance of serving to consumers. If these businesses are unaware of why ‘time and temperature’ controls following preparation of RTE food are critical to safety, there could be a higher likelihood that RTE food may be mishandled prior to service to consumers allowing for microbial growth. As such, it is the application of all the critical controls relevant to handling activity 1 by businesses undertaking handling activity 2 that reduce the likelihood that high risk RTE food processed by the business would be mishandled prior to service to consumers

In summary, the risk categorisation of the handling activities undertaken by food service and related food retail businesses based on the number of controls critical to food safety, proportion of Australian foodborne outbreaks and associated people ill represented by the food service or related food retail businesses most likely to undertake the handling activity, are summarised in

Table 20. Category 1 is the highest risk category and 3 the lowest.

The handling activity categories have common associated critical controls that need to be consistently implemented, along with general principles for food hygiene, by the associated business sectors that undertake that handling activity to ensure food safety.

Table 20. Risk categories for handling activities.

Handling activity category	Handling activities	Associated priority business sectors
<p><u>Category 1</u></p> <p>Those handling activities that require the greatest number of controls critical to the safety of food prepared by the business, and that are most likely to be undertaken by business sectors that represent a high proportion of Australian foodborne outbreaks.</p>	<p>Handling activity 1: process high risk potentially hazardous food in advance of serving the ready-to-eat food to the consumer.</p> <p>Handling activity 2: process and serve high risk potentially hazardous food as ready-to-eat food to the consumer in a time period which does not adversely affect the microbiological safety of the food.</p>	<p>Food service: commercial catering</p> <p>Food service: eating establishments - RTE prepared in advance</p> <p>Food service: RTE food is prepared express order – some high risk food components are raw</p> <p>Food service: RTE food is prepared express order – all high risk food components are cooked</p> <p>Retailer and manufacturer:</p>

		bakery products
<p><u>Category 2</u></p> <p>Those handling activities that require fewer controls critical to the safety of food prepared by the business compared to Category 1 handling activities; and that are most likely to be undertaken by business sectors that represent a relatively lower proportion of Australian foodborne outbreaks compared to Category 1 handling activities</p>	<p>Handling activity 3: serve unpackaged high risk potentially hazardous food as ready-to-eat food for retail.</p>	<p>Retailer: bakery products</p> <p>Retailer: processed delicatessen products</p> <p>Retailer: processed seafood products</p>
<p><u>Category 3</u></p> <p>Those handling activities that require fewer controls critical to the safety of food prepared by the business compared to Category 2 handling activities; and that are most likely to be undertaken by business sectors for which there is little evidence of associated foodborne illness in Australia.</p>	<p>Handling activity 4: serve packaged high risk potentially hazardous food as ready-to-eat food. The food is packaged prior to receipt by the food business for retail and sold to the consumer packaged.</p>	<p>Retailer: High risk perishable pre-packaged food</p>

6 Conclusions

The objectives of this assessment were to (i) review the classifications of the eight Australian food service and related food retail business sectors by Ministers on the basis of food safety risk using the Framework including the consideration of recent OzFoodNet data regarding foodborne outbreaks associated with food prepared in these businesses; and (ii) determine if the characteristic food handling activities identified by the ISFR WG for these business sectors can also be classified on the basis of food safety risks.

The total number of foodborne outbreaks in Australia for 2010 – 2017 was 1257, resulting in 19497 persons reported ill, 1914 of these people were hospitalised, and 56 fatalities were reported. The vast majority of these outbreaks are associated with food prepared in Australian food service and related food retail settings that were considered in this assessment, with food prepared in restaurant settings accounting for the largest proportion (45.1% (567/1257)) of foodborne outbreaks in Australia. It has been reported that outbreaks associated with the food service industry is reported to have increased steadily from 2001 to 2016 (Osterberger 2018).

The most frequently reported hazard responsible for foodborne outbreaks, largest proportion of people ill and hospitalised for food prepared in Australian food service and food retail settings during 2010 – 2017 was *Salmonella* spp. However, for a large number of foodborne outbreaks in Australia the causative agent is unidentified. Furthermore, the majority of the *Salmonella* spp. outbreaks were attributed to eggs (45.5%, 205/450) or were not attributed to a food commodity (41.5%, 187/450).

Raw eggs can be considered a high risk PHF when handled by Australian food service and related food retail business sectors as eggs were associated with the largest proportion of the foodborne outbreaks, people ill, and hospitalisations due to foodborne outbreaks where a responsible commodity was identified. However, a large proportion of foodborne outbreaks were not able to be attributed to a specific food commodity. In this assessment, of the 207 egg related outbreaks Australian food service and related food retail business sectors, 205 (99.0%) of those were attributed to *Salmonella* spp..

The major contaminating, bacterial growth, and microbial survival factors contributing to these outbreaks caused by *Salmonella* spp. are diverse. Ingestion of contaminated raw products, cross contamination from raw ingredients, and inadequate cleaning of equipment were the most frequently reported contamination factors. Numerous bacterial growth factors were frequently reported including insufficient cooking, foods left at room or warm temperature, inadequate refrigeration, and delay between preparation & consumption. Key microbial survival factors were insufficient time/temperature during cooking, inadequate or failed disinfection, and inadequate acidification.

There was a larger diversity of these contamination, bacterial growth or microbial survival factors reported to contribute to outbreaks for food prepared in restaurant, commercial caterer or take-way settings, compared to other settings. These results suggest that there are failings in the controls that are required for food safety at various points during food preparation and service undertaken by Australian food service and related food retail business sectors.

To further assist in the identification of priority business sectors and handling activities that contribute to the burden of illness in Australia, the review of priority classifications of Australian food service and related food retail business sectors on the basis of food safety risk using updated epidemiological data was undertaken using the using the National Risk Profiling Framework. The Framework was designed to provide a nationally agreed approach

for government to classify business types on the basis of food safety risk. Its use is science-based and transparent, reflecting risks inherent to the product/process, the potential of controlling the risks, as well as a measure of the association of the risk with past foodborne illness outbreak information. Much of the background information provided by Ross et al. (2009) is still relevant to the classified businesses, and following the assessment of additional evidence the following priority risk classifications were assigned as an outcome of the review:

- Food service: commercial catering (P1) (Activity 1)
- Food service: eating establishments - RTE prepared in advance (P1) (Activity 1)
- Food service: RTE food is prepared express order – some high risk food components are raw (P1) (Activity 2)
- Food service: RTE food is prepared express order – all high risk food components are cooked (P2) (Activity 2)
- Retailer and manufacturer: bakery products (P1) (Activity 1)
- Retailer: bakery products (P2) (Activity 3)
- Retailer: processed delicatessen products (P2) (Activity 3)
- Retailer: processed seafood products (P2) (Activity 3)
- Retailer: High risk perishable pre-packaged food (P2) (Activity 4)

Additionally, the handling activities identified above by the Implementation Subcommittee for Food Regulation (ISFR) Working Group were grouped into three categories on the basis of food safety risk. This categorisation reflects the number of controls critical to the safety of food prepared by the business, and the proportion of Australian foodborne outbreaks and people ill associated with the businesses characterised as most likely to undertake the food handling activity.

Category 1:

Those handling activities that require the greatest number of controls critical to the safety of food prepared by the business, and that are most likely to be undertaken by business sectors that represent a high proportion of Australian foodborne outbreaks include:

- Handling activity 1: process high risk potentially hazardous food in advance of serving the ready-to-eat food to the consumer.
- Handling activity 2: process and serve high risk potentially hazardous food as ready-to-eat food to the consumer in a time period which does not adversely affect the microbiological safety of the food.

For those businesses that were identified to undertake handling activity 1 and handling activity 2, there were five controls indicated to be critical to the safety of food:

- Adequate storage of PHF at appropriate temperatures before processing
- Adequate cooking or reheating
- Adequate cooling of cooked foods
- Minimising cross-contamination and re-contamination
- Adequate storage at appropriate temperatures of RTE food processed before service to the consumer

Category 2:

Those handling activities that require fewer controls critical to the safety of food prepared by the business compared to Category 1 handling activities; and that are most likely to be undertaken by business sectors that represent a relatively lower proportion of Australian

foodborne outbreaks compared to Category 1 handling activities include:

- Handling activity 3: serve unpackaged high risk potentially hazardous food as ready-to-eat food for retail.

For those business undertaking handling activity 3, there were two controls indicated to be critical to the safety of food:

- Adequate storage of PHF at appropriate temperatures
- Minimising cross-contamination and re-contamination

Category 3:

Those handling activities that require fewer controls critical to the safety of food prepared by the business compared to Category 2 handling activities; and that are most likely to be undertaken by business sectors for which there is little evidence of associated foodborne illness in Australia include:

- Handling activity 4: serve packaged high risk potentially hazardous food as ready-to-eat food. The food is packaged prior to receipt by the food business for retail and sold to the consumer packaged.

For those businesses undertaking handling activity 4, there was one control indicated to be required for the safety of food:

- Adequate storage of PHF at appropriate temperatures is required for food safety.

The categories provide a food safety risk profile of the key food business sectors and their characteristic handling activities that can be used to inform risk management options.

7 Data gaps, limitations and suggestions for further work

The identified data gaps and limitations in this assessment are summarised below.

- A large proportion of foodborne outbreaks in Australia do not have a reported responsible hazard, attributed food vehicles or commodities, or identified major contributing contamination factors. As such, while proportions of known outbreaks have been attributed to particular business sectors and risk factors in this report, there is uncertainty as to the true proportion of Australian foodborne these factors represent.
- The OzFoodNet outbreak data are likely to only represent a small proportion of actual cases of foodborne illness, as many people do not always seek medical attention for mild forms of gastroenteritis, medical practitioners do not always collect specimens for analysis, and not all foodborne illnesses require notification to health authorities (Gibbons et al. 2014).
- It is not always possible for OzFoodNet to determine to what extent an outbreak, or the severity of an outbreak, particularly those involving eggs, is the result of factors at the food service level. For example, the role of temperature abuse or infectious dose of a pathogen present at the time of receipt of eggs by the food service or related food retail business is unknown. As such, in some cases there is uncertainty regarding the contribution of primary production and processing factors to these foodborne outbreaks. Analysis of additional jurisdictional trace-back investigation data associated with foodborne outbreaks investigated by OzFoodNet would be required to provide a more accurate attribution of risk.
- The OzFoodNet outbreak register does not report foodborne outbreaks against the same business or priority classifications as outlined in the Framework or as described by states and territories.
- Not all states and territories use the Framework to classify priority business sectors. Moreover, food service and food retail businesses are becoming more diverse in their handling activities and may now undertake a number of services from a single business. As such, the need for an updated or adapted Framework should be assessed with consultation with jurisdictions.
- One of the key decision pathways of the Framework is the determination of high risk, medium risk, and low risk foods. If the Framework is to be applied consistently, a national data base defining and compiling these foods could be developed⁴³.
- The Framework is not intended to be a substitute for food safety risk assessment. Food safety risk encompasses the probability of a hazard being present in a food and the severity of the any consequences. The true food safety risk is based on many factors which can vary in time, location, and circumstances specific to individual businesses within a sector.

⁴³ For example, the FDA is currently working on defining a list of high risk foods: <https://www.fda.gov/media/124152/download>

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