Risk Profiling Framework

Example Classifications (*extracts*)

Extracts comprising Example Classifications: 23 to 25, 27, 29 to 32

Prepared for

Department of Health and Ageing

by

Tom Ross and Lyndal Mellefont
Food Safety Centre, Tasmanian Institute of Agricultural Research,
University of Tasmania

Olivia McQuestin
Food Safety Centre, Tasmanian Institute of Agricultural Research, and
Department of Health and Human Services, Tasmania

Heather Haines
Department of Human Services, Victoria

and

Jim Smith
Infocus Management Group, Victoria

July, 2009
Introduction

In April, 2005 the Department of Health and Ageing, on behalf of the Food Regulation Standing Committee (FRSC), contracted the development of a Risk Profiling Tool for Australian Food Business Sectors.

The tool, which became known as the Risk Profiling Framework\(^1\) (RPF), was developed by a multi-disciplinary group from private enterprise, academia and government, who consulted with and whose work was overseen by, the FRSC Policy Working Group - Developing Options for Food Safety Management in Australia.

On March 19, 2007, FRSC endorsed the RPF. At its subsequent meeting in August 2007, FRSC asked the Food Safety Management Working Group to develop a list of key food business sectors and to scope the extent of work that would be required to assign risk priority classifications to those sectors. The Working Group established a Task Group to initiate the work.

The Task Group recommended that the list of key business sectors to be assigned priority classification by the RPF should be those that:

- were initially included in the RPF tables of example classifications and rated in the higher risk categories (i.e., P-1 or P-2);
- were additional to the RPF tables of example classifications but preliminarily described as P-1 or P-2 by the Task Group; and
- are potentially outside the scope of current Food Standards Australia New Zealand (FSANZ) proposals to develop primary production and processing standards for meat and meat products, and plants and plant products, for example, seed sprouts and packaged, fresh-cut fruits and vegetables.

The Task Group recommended a “four tier” format for the classification of businesses. The Task Group also recommended that the initial list of businesses would best be classified, according to their proposed four tier model, by an independent group of technical experts that would include scientists and representatives with broad industry experience.

The Food Safety Centre, Tasmanian Institute of Agricultural Research, University of Tasmania, was invited to convene a group to complete the required work. In collaboration with:

- Department of Health and Human Services, Tasmania
- Department of Human Services, Victoria, and
- Infocus Marketing Group, Victoria,

the group completed the task of classifying 32 business types nominated by the FRSC Food Safety Management Working Group using the RPF and presenting the classifications using the Task Group’s four tier model.

This report presents those classifications.

\(^1\) The Framework Tool is available for download from
Explanation of Priority Classifications

Priority 1 and Priority 2

Businesses that will, characteristically, handle 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.

---

2 **low risk foods**: those that are unlikely to contain pathogenic organisms and will not support their growth 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

3 **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 are fruits and vegetables, orange juice, canned foods, salami, vegetables stored in oil, peanut butter, shell eggs, milk-based confectionary and hard-frozen ice cream.
Full Example Classifications (extract):
Four Tier Model
23. **Retailers of: Bakery products, e.g. pastries with potentially hazardous fillings**

Layer 1:

<table>
<thead>
<tr>
<th>Food Business Type</th>
<th>Characterising Features</th>
<th>Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>23. Retailer of: Bakery products, e.g. pastries with potentially hazardous fillings</td>
<td>Medium or high risk food, ready-to-eat food, refrigerated storage, consumed cold, packaged product</td>
<td>P-2</td>
</tr>
</tbody>
</table>

Layer 2:

<table>
<thead>
<tr>
<th>23. Retailer of: Bakery products</th>
<th>FB1</th>
<th>FB2</th>
<th>FB3</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Retailer but not processor of high risk products</td>
<td>a (Y)</td>
<td>a (Y)</td>
<td>a (Y), b (N) ⇒ P-2</td>
</tr>
<tr>
<td>2. Retailer and processor of high risk products</td>
<td>See also Example Classification</td>
<td>16 Processor of: Ready to eat food II</td>
<td>a (Y), b (Y), c (Y), d (Y), e (N), f (N), g (Y) ⇒ P-1</td>
</tr>
</tbody>
</table>

Layer 3:

**Question 1**

FB1a. Yes.

The business description specifies that the products of concern require refrigerated storage which indicates that they are, by definition, potentially hazardous foods. Note that there is ample evidence that bakery products can harbour microbial hazards – see response to Question 3, below.

**Question 2**

FB2a. Yes.

The products handled by the business are described as medium or high risk. The Risk Profiling Framework documentation states that a business should be classified according to the highest risk product handled, or process undertaken, by the business. Thus, the answer to the question is based on the high risk foods.

**Question 3**

FB3a. Yes.

Hazard control actions include refrigeration, a technology which is virtually universally available in Australia, and control over the storage time of the products prior to consumption. The products handled are described as packaged, which suggests that cross-contamination is not likely and does not require active control.

FB3b.

*Background*

The literature is replete with reports of outbreaks related to bakery products, particularly those that include creams, custard, egg-based filling or glazes based on egg (e.g., 1-5, 8, 9, 13-19, reviews in 10-12). A large proportion of the outbreaks relate to *Salmonella* spp., but noroviruses have been involved in several outbreaks (1, 17) as have *Bacillus cereus*, and Hepatitis A (see 12). In food microbiology text books (e.g., 7, 20), *Staphylococcus aureus* is reported as a hazard in bakery products including cream or custard, e.g. vanilla slices, chocolate éclairs. This arises from older reports, possibly relating to outbreaks prior to the widespread use of refrigerated storage for such products; *S. aureus* is carried on
### 23. Retailer of: Bakery products

The skin of many people, without symptoms, and is readily transferred to foods. Its minimum growth temperature is relatively high (7 - 10°C), so that its growth, and the consequent hazard, is readily controlled by refrigeration. The risk from *Salmonella* in bakery products arises principally from the use in bakery products of raw egg preparations, e.g., for glazes. The products are often held unrefrigerated, allowing the growth of *Salmonella* that may be present in eggs to high levels, and increasing the probability of infection from (cross-)contaminated foods.

While bakeries and bakery products are frequently responsible for foodborne illness outbreaks, and were identified in the National Risk Validation Project (NRVP; 6) as high risk, most reports indicate that the cause of outbreaks is improper storage temperatures or poor hygienic practices in bakeries (6). The NRVP (6) was based on data up to 2000/2001, but there have been numerous bakery related outbreaks in Australia since that date, involving ~800 cases (summarised in 10). Several surveys (6, 10, 11) of the microbiological quality of bakery products found that poor hygiene and handling practices, and poor temperature control, were frequently observed and identified as contributing to outbreaks (and data from USA cited therein). From these reports, however, there is a strong suggestion that the principle causes of hazards are through cross-contamination, inappropriate storage temperatures, or inadequate cooking (e.g., meat-topped bread products), during the making of these products. For example, data from USA for bakery-related outbreaks (cited in 6) from 1973-1987 estimates that 73% of outbreaks involved improper holding temperatures, 53% involved cross-contamination from equipment, and 67% involved poor personal hygiene of food handlers.

**Question 3 (continued) – 1. Retailer but not processor of high risk products**

FB3b. No.

The businesses considered for this classification only handle packaged product. 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. Thus, in this case the main responsibility for food safety rests with the manufacturer, not the retailer. ⇒ P-2

**Question 3 (continued) – 2. Retailer and processor of high risk products**

(see also Example Classification 16 Processor of: Ready to eat food II)

FB3b. Yes.

As discussed above, numerous reports indicate poor hygienic practices and poor temperature control in bakeries as the main causes of foodborne outbreaks involving bakery products. As such, good hygiene – both personal and prevention of cross-contamination (e.g., from raw egg preparations) - and proper temperature control appear to be vital to assuring the food safety of bakery products that include fillings, etc. The products in the business description are nominated as ready-to-eat. As such there is no step after processing and packaging that can be expected to eliminate introduced pathogens, and the actions taken by the bakery will be critical to the final safety of the product, as consumed.

FB3e. Yes.

Recontamination after baking appears to be relatively common. In other circumstances, inadequate cooking has resulted in pathogen survival in ready-to-eat products. Some ingredients, e.g., cream, custard, egg-based ingredients are not heat-treated at all and can become contaminated with *S. aureus* (from food handlers due to extensive manual handling), noroviruses (from infected food handlers), or *Salmonella* from raw egg products commonly used in baking, and *B. cereus* as a common contaminant of flour, milk, and cream because it is a spore-forming organism and can survive pasteurisation and baking. Poor hygiene involving the use of piping bags has also been reported (19).

FB3d. Yes.

There is ample evidence (see references cited above) in the scientific literature and Australian and international epidemiological reports of outbreaks related to bakery products.

FB3e. No.

Bakeries and retailers of bakery products sell products to the general public.
23. Retailer of: Bakery products

FB3f. No.
The hazards identified usually cause mild, self-limiting, disease in otherwise healthy consumers.

FB3g. Yes.
The literature referred to above provides ample evidence that acute gastrointestinal illness can arise due to the levels of hazards present at consumption. ⇒ P-1

Layer 4:

23. Retailer of: Bakery products

References


### 23. Retailer of: Bakery products

salmonella/2005/01/22/1106334254944.html on 15 April, 2009.


24. Retailer of: Delicatessen products

Layer 1:

<table>
<thead>
<tr>
<th>Food Business Type</th>
<th>Characterising Features</th>
<th>Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>24. Retailer of: Delicatessen products</td>
<td>High risk, processed (heat and non-heat treatment), ready-to-eat food requiring refrigerated storage or reheating</td>
<td>P-2</td>
</tr>
</tbody>
</table>

Layer 2:

<table>
<thead>
<tr>
<th>24. Retailer of: Delicatessen products</th>
</tr>
</thead>
<tbody>
<tr>
<td>FB1</td>
</tr>
<tr>
<td>FB2</td>
</tr>
<tr>
<td>FB3</td>
</tr>
<tr>
<td>a (Y)</td>
</tr>
<tr>
<td>a (Y)</td>
</tr>
<tr>
<td>a (Y), b (Y), c (Y), d (N) ⇒ P-2</td>
</tr>
</tbody>
</table>

Layer 3

24. Retailer of: Delicatessen products

**Background**

Delicatessen is an Anglicisation of the German word ‘delikatesse’ meaning delicacies or fine foods. Traditionally, the kinds of foods would include 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, breads and high quality or specialist coffee, chocolates, herbs and spices, teas, honey, preserved fruit and jams, etc. and unusual foods from other countries and cultures.

In Europe, few delicatessen shops prepare or sell take-away foods but those products are characteristic of the delicatessen (or ‘deli’) in North American culture. In Australia, delicatessen businesses are usually more similar to the European style, than the North American style. However, while there are many independent traditional (European style) delicatessens in Australia, stores of the large national supermarket chains, as well as many independent small supermarket/grocers, now also include ‘delicatessen counters’ that offer a range of traditional delicatessen products. (The term ‘deli’ is also used to denote a small convenience store or milk bar in the states of Western Australia and South Australia and some such businesses use deli in their business name; the term “continental delicatessen” is sometimes used to distinguish businesses of the European style.)

In the grocer/supermarket businesses, these deli counters are often near displays of raw meat, poultry and fish, presumably due to the need for shop assistants to weigh out and wrap the products and the need for refrigerated display cases for customers to select from. In some cases, these businesses may also sell ready-to-eat mixed salads, hot foods (e.g., cooked chickens, quiches, other types of pies) or prepare and sell fresh sandwiches and filled rolls, etc. (5)

The businesses described are characterised by handling a wide range of ready-to-eat products that have been involved in foodborne disease outbreaks, e.g. cheese, processed meats, fermented meats, etc., many of which are ready-to-eat and require refrigerated storage, or are expected to be reheated before consumption.

In keeping with the business description the following ranking considers principally the risks associated function/operation of a delicatessen, i.e. weigh out/slice etc. and sell portions of delicatessen foods which as described above, but will not consider the risk of other types of products sold by some delicatessen operations. There are, however, possibly differences in risks from delicatessen foods due to handling of other, non-delicatessen, foods in some delicatessen businesses and these differences will be considered, as relevant, in the classification.

**Question 1**

FB1a. Yes.

Consistent with the description of the business, many of the foods sold by delicatessens require refrigeration, being the principle method of control of microbial growth in these products. Moreover, many are foods commonly involved in outbreaks such as fermented meats, cured ready-to-eat meats and soft cheeses. Thus, the products sold and handled are, by definition, potentially hazardous.

In keeping with the principles for application of the Risk Profiling Framework, delicatessen businesses
24. Retailer of: Delicatessen products

should be classified according to their highest risk product. It is expected that all delicatessen business sell at least one product that requires refrigeration to prevent pathogen growth, i.e., all sell potentially hazardous foods. *L. monocytogenes* is a relatively common contaminant of processed meats and has been involved in numerous outbreaks, including outbreaks in France related to cross-contamination in delicatessens (4).

**Question 2**

FB2a. Yes.

Growth of pathogenic microorganisms is possible in the many of the products sold by delicatessens, particularly cheeses and processed meats. Thus, by definition, the highest risk products are high risk.

**Question 3**

FB3a. Yes.

The National Risk Validation Project (3) identified three outbreaks in Australia considered to have been caused by cross-contamination in delicatessen businesses. Thus, prevention of recontamination of those foods is essential to maintain food safety. Sources of contamination include food handlers and food processing equipment, e.g., slicers, cutting boards/surfaces etc. Delicatessens are characterised by a high degree of handling of high risk products due to weighing out, slicing, etc., of bulk product into smaller, consumer-size, units.

As noted elsewhere in this report, many of the foods sold by delicatessens may occasionally still contain viable pathogens and, in the absence of refrigeration, those pathogens may be able to grow. This is particularly true for *L. monocytogenes* and *C. botulinum* in vacuum-packed processed meats, smoked fish, caviar, etc., or for *L. monocytogenes* in some soft cheeses. Thus, temperature control is required. The infrastructure for refrigeration is readily available and well established in the retail food industry. Some products rely on drying, or addition of salt or sugar for their stability. In very humid environments, if these products are left exposed to the atmosphere they may be able to absorb water, thereby raising the water activity sufficiently to allow growth of some microbes, including toxigenic moulds. Accordingly, some dried products will need special controls in very humid environments.

FB3b. 

**Background**

In traditional delicatessen businesses many of the foods will be shelf-stable, or mildly preserved (e.g. fermented or cured) and will limit, at least in part, microbial growth. Temperature control (refrigeration) is still required for many of these products. Due to the processing of these foods, few will contain viable vegetative pathogens, because most will have been eliminated during thermal processes (e.g., cooking of cured meats, pasteurisation of milk used in cheese making) or due to acid treatment in the case of fermented foods. Cold smoked fish is an exception, but is unlikely to be contaminated with Gram negative pathogens (e.g. *Salmonella, Escherichia coli, Campylobacter*) because these are not normally associated with fish and do not colonise fish processing plants. As indicated in other Example Classifications, the main hazards in these types of products are expected to be controlled by the producer of those foods with the exception of *L. monocytogenes* which can recontaminate some products after thermal processing, and *C. botulinum* which is not eliminated by heat. For these hazards, product formulation is a critical control but is under the control, and therefore the responsibility, of the manufacture. Such products will require temperature control, and this responsibility will be shared by all in the farm-to-fork chain, including delicatessen businesses, as appropriate.

The significance of cross-contamination will depend on the virulence of the pathogen, or the potential for growth on the product prior to consumption. For most foodborne infectious diseases, relatively high doses (of the order of millions of cells) are required to cause illness. Exceptions are viral agents such as Hepatitis A and norovirus, and enterohaemorrhagic *E. coli*. As stated above, it is assumed that most processed foods sold in delicatessens will have low likelihood of containing pathogens, with the exception of *L. monocytogenes* and *C. botulinum* (see Example Classification 17 Processors of: Seafood). Moreover, most foods would not be expected to contain disease causing levels of the
pathogen so as to be able to transfer sufficient cells of the pathogen to another food and to induce illness. Similarly, for packaged foods, cross-contamination is not expected to arise – cross contamination is primarily of concern when the contaminant comes into direct contact with the food that will be eaten.

C. botulinum levels associated with disease are of the order of millions of cells per gram. The organism is strictly anaerobic and, if introduced to another food due to product handling at a delicatessen, would not be expected to be able to grow in products because they would be exposed to air. As such cross-contamination with this organism is unlikely to cause risk to consumers.

In mildly-preserved fish, nematode larvae might be present, but cross-contamination would not increase risk (because the organisms cannot grow in foods) but merely transfer the risk from one food to another.

Enterohaemorrhagic E. coli (EHEC) could potentially be present in fermented meats but the responsibility for its absence lies with the manufacturer of the product. In general, normal temperature control would preclude growth of the organism on other products if cross-contamination did occur, i.e., risk would be transferred, not increased. Some consumers know not to feed fermented meats to small children (who are at heightened risk of serious illness from EHEC) and potential transfer from contaminated fermented meat to other products that could be consumed by young children should be avoided. The likelihood of such cross-contamination seems low given current regulations to assure safety of fermented meats (e.g., use of starter cultures, banning of ‘back-slopping’, assessment of processes, etc.).

A range of contaminants could be introduced by food handlers. These include gastrointestinal pathogens (including viral agents) and Staphylococcus aureus from food handlers that are passive carriers or have minor skin infections. In the former case it would be assumed that relatively low numbers of S. aureus would be transferred to foods. For S. aureus food poisoning to occur, levels of S. aureus typically must exceed 10^8 cfu.g^-1. Thus, growth to these levels would have to occur. Growth of S. aureus on foods is readily controlled by normal refrigeration. Disease could arise, however, if high levels are transferred, e.g., from an active skin infection.

In short, the consequences of cross-contamination from contaminated foods to uncontaminated foods in delicatessens might be expected to be minor, except where raw meats are also handled and sold. Rather, in traditional delicatessens, cross-contamination leading to illness is also likely to arise from infected food handlers or from L. monocytogenes becoming established in equipment and being transferred in high numbers to ready-to-eat foods. L. monocytogenes is unusually capable of becoming established in food processing facilities.

Conversely, in delicatessens that also handle raw product, the potential for illness arising from cross-contamination from raw to processed product is much greater. This is because raw meat, poultry and fish could contain low infectious dose pathogens such as EHEC, or high levels of other pathogens, such as Campylobacter or Salmonella potentially present on raw chicken. While the potential for their growth is limited by formulation of many delicatessen products, and normal storage conditions, there is potential for transfer of sufficient cells to cause disease unless rigorous attention is paid to minimisation of cross-contamination between raw products and ready-to-eat delicatessen products via surfaces, equipment, utensils, aerosols (splashing/drips) and food handlers themselves

FB3b. Yes.

In these cases the formulation of the products sold, and usual storage conditions, argue against serious consequences of cross-contamination by other foods sold. The foods are expected to have been processed to provide adequate levels of safety so that cross-contamination from other foods is unlikely, and, if it does occur, to not result in increased risk. Some products, however, rely on temperature control for protection against the potential presence of C. botulinum or L. monocytogenes. Current regulations place responsibility for absence of L. monocytogenes in at-risk foods with manufacturers. C. botulinum continues to be a rare contaminant in Australian-produced foods.

Infected food handlers or poor hygiene leading to niches for L. monocytogenes growth and transfer to uncontaminated product, represent a more credible risk.

For delicatessen businesses handling raw meats, fish and poultry, the probability and consequences of
24. Retailer of: Delicatessen products

cross-contamination are expected to be considerably higher.

Thus, prevention of recontamination is critical to the safety of the product sold by the business.

FB3c. Yes.

As discussed above, prevention of recontamination of ready-to-eat foods sold by delicatessens could occur. The National Risk Validation Project (NRVP, 3) identified at least three outbreaks (two small but one involving ~150 cases) in Australia from delicatessens and in which cross-contamination was implicated as the causative factor. ACT Health (1) conducted a survey into food handling practices in delicatessens and reported that, of ~40 premises visited, 17 (42%) had practices that could result in cross-contamination from raw to cooked products. Despite this, in 85% of cases, samples of cooked products taken from those premises when tested showed good microbiological results and no evidence of cross-contamination, suggesting that transfer of organisms is not a guaranteed outcome despite poor handling practices.

FB3d. No.

The NRVP (3) identified three outbreaks due to failures in delicatessens in Australia, and international reports support that delicatessens can be a cause of foodborne disease outbreaks. The NRVP also presented data from USA for outbreaks related to delis/café’s/restaurants. From USA data, there are of the order of 200 outbreaks per year in USA due to that category of businesses. Closer examination of the available USA data (2) suggests that most of those incidents relate to food service activities that are a more usual part of the American style ‘deli’, as noted in the ‘Background’, above. Accordingly, it is concluded that delicatessens, in the sense used in Australia, are not currently frequent sources of outbreaks or severe human illness. ⇒ P-2

Layer 4:

24. Retailer of Delicatessen products

References


25. Retailers of: Perishable, ready-to-eat, packaged food, e.g. packaged, fresh-cut fruits and vegetables

Layer 1:

<table>
<thead>
<tr>
<th>Food Business Type</th>
<th>Characterising Features</th>
<th>Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>25. Retailer of: Perishable, ready-to-eat, packaged food, e.g. packaged, fresh-cut fruit and vegetables</td>
<td>Medium or high risk, ready-to-eat food, refrigerated storage, consumed cold, packaged product</td>
<td>P-2</td>
</tr>
</tbody>
</table>

Layer 2:

| 25. Retailers of: Perishable, ready-to-eat, packaged food |
| FB1 | FB2 | FB3 |
| 1. High risk product | a (Y) | a (Y) | a (Y), b (Y), c (N) ⇒ P-2 |
| 2. Medium risk product only | a (Y) | a (N), b (N), c (N), d (Y), e (N) ⇒ P-3 | Not applicable |

Layer 3:

25. Retailers of: Perishable, ready-to-eat, packaged food

**Question 1**

FB1a. Yes.
Perishable, ready-to-eat, packaged foods are potentially hazardous. Storage at low temperature is necessary to minimise the growth of pathogens that may be present on the food and to prevent the formation of toxins.

**Question 2 – 1. High risk product**

FB2a. Yes.
Some perishable, ready-to-eat, packaged foods are considered high risk. These foods may contain pathogenic microorganisms and support their growth. Examples include fresh-cut fruits and vegetables and packaged sandwiches or pastries that contain meat, poultry or egg.

For example, fresh-cut fruits and vegetables have been recognised as high risk foods in Australia, based on international epidemiology data (FSA & Minter Ellison Consulting 2002). Although pathogens will not grow on the uninjured outer surface of fresh fruits or vegetables, cutting fresh produce can transfer pathogenic microorganisms, if present, from the surface to the internal tissues, where growth can occur (2).

**Question 2 – 2. Medium risk product only**

FB2a. No.
The businesses referred to here do not retail any high risk products. Foods retailed will be unlikely to contain pathogenic microorganisms due to food type or processing but will support the formation of toxins or growth of pathogenic microorganisms. An example is pasteurised milk products.

FB2b. No.
The business sector does not undertake processes that would introduce chemical contaminants to the product.

FB2c. No.
The business sector does not engage in unreliable hazard reduction processes according to the definition in the Risk Profiling Framework (RPF).
### 25. Retailers of: Perishable, ready-to-eat, packaged food

**FB2d. Yes.**
The products are medium risk as they are unlikely to contain pathogenic microorganisms due to prior processing of the food.

**FB2e. No.**
The business sector neither produces nor serves the product. ⇒ P-3

### Question 3 – 1. High risk product

**FB3a. Yes.**
Storing perishable, ready-to-eat, packaged foods under refrigerated conditions and ensuring packaging is clean and undamaged on receipt and during storage and display are control actions for retailers of these products.

**FB3b. Yes.**
Some pathogens potentially present in raw materials are not reliably eliminated during processing of some perishable, ready-to-eat, packaged foods (see Example Classification 15 Processors of: Ready-to-eat foods I). Refrigeration throughout the distribution chain, including at retail level, is an essential part of the product’s safety. Refrigeration inhibits the proliferation of pathogenic microorganisms that may have contaminated the food, such as *Escherichia coli* and *Salmonella* spp. Temperature abuse at the retail level has contributed to outbreaks of salmonellosis from ready-to-eat food in Australia (reviewed by 1). For these reasons, the answer to this question is ‘Yes’. It is noted, however, that other food businesses (i.e. processors of these products) are also responsible for safety.

It is noted that retailers of perishable, ready-to-eat, packaged foods do not have essential responsibility for ensuring that the product is not a vehicle of *Listeria monocytogenes* infection. The business sector should maintain good refrigeration. However, even with good refrigeration, the retailer cannot ensure a safe product if the food is contaminated with *L. monocytogenes* and the food supports growth of this pathogen. The critical control of this hazard would be prevention of contamination at the processing plant.

**FB3c. No.**
Cold temperature storage of packaged food is recognised as a reliable critical control action within the RPF. ⇒ P-2

Layer 4:  

### 25. Retailers of: Perishable, ready-to-eat, packaged food

**References**


27. Retailers of: Seafood products

Layer 1:

<table>
<thead>
<tr>
<th>Food Business Type</th>
<th>Characterising Features</th>
<th>Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>27. Retailers of: Seafood products</td>
<td>High risk, processed (raw and heat treated food), refrigerated storage</td>
<td>P-2</td>
</tr>
</tbody>
</table>

Layer 2:

<table>
<thead>
<tr>
<th>27. Retailers of: Seafood products</th>
<th>FB1</th>
<th>FB2</th>
<th>FB3</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>a (Y)</td>
<td>a (Y)</td>
<td>a (Y), b (Y), c (Y), d (N) ⇒ P-2</td>
</tr>
</tbody>
</table>

Layer 3:

27. Retailers of: Seafood products

For a detailed discussion of hazards in processed seafood, and supporting documentation, see Example Classification 17 Processor of: Seafood.

Question 1

FB1a. Yes.
Some of the products sold require refrigeration to extend shelf life and minimize pathogen growth and are therefore, by definition, ‘potentially hazardous’ foods. According to the instructions for use of the Risk Profiling Framework, a business will be classified according to the highest risk product that it handles.

Question 2

FB2a. Yes.
Some raw, mildly processed, products would be expected to harbour pathogens (see Example Classification 17 Processor of: Seafood for details and explanation).

Question 3

FB3a. Yes.
The business could introduce hazards to the food, or increase the levels of hazards already present, unless foods are properly stored (i.e. refrigerated) and (re-)contamination from raw products, food handlers, or due to poor premises hygiene, is prevented. Good hygiene and correct refrigeration are within the control of the seafood retailer. The discussion of cross-contamination, and its consequences (see Example Classification 24 Retailer of: Delicatessen products), in the context of delicatessens is relevant to seafood retailers selling both cooked, mildly processed and raw seafood products, i.e., the food safety hazards posed by these businesses are analogous.

FB3b. Yes.
As noted above, there are similarities in food safety risks posed by retailers of seafood and delicatessens that handle raw foods as part of their product range and the discussion of cross-contamination, and its consequences (see Example Classification 24 Retailer of: Delicatessen products) is relevant to this business also.

For seafood retailers there is a possibility of contamination of unpackaged ready-to-eat foods (e.g. cooked prawns) from pathogens that may be present on raw fish products. Similarly, as discussed in Example Classification 17 Processor of: Seafood, some pathogens potentially present in raw materials are not reliably eliminated by the process, so that refrigeration throughout the distribution chain is an essential part of the product’s safety. For these reasons, the answer to this question is ‘yes’.

FB3c. Yes.
As discussed above, prevention of recontamination of ready-to-eat seafood, particularly cooked, unpackaged prawns, sold by seafood retailers could occur.
27. Retailers of: Seafood products

FB3d. No
The National Risk Validation Project (1) identified two outbreaks (involving 28 cases) related to seafood purchased at retail. The contributing factor in those cases was food from an unsafe source, i.e., not cross-contamination or temperature mishandling. One incident involved 27 people with *Vibrio* infections due to imported prawns that were labelled as cooked, when they were, in fact, raw. There are many reports of chemical hazards (namely ciguatera and, to a lesser extent, scombrototoxicosis) related to seafood purchased at retail but these mostly relate to raw finfish. Moreover, ciguatera toxin will be present in the fish at the time of catch, and will not change thereafter. As such, there is little that a seafood retailer can do to manage the hazard, other than to avoid sale of species known to be susceptible to ciguatera contamination. As such, there appears to be little evidence of frequent or severe illness from processed seafood that were due to lack of control by retailers. ⇒ P-2

Layer 4:

27. Retailers of: Seafood products

References

29. Food service: On-site catering activity but will not be subject to the proposed Catering Standard due to event size and frequency, e.g. eating establishments that hold either small (50 or less people) or infrequent (12 or less/year) catering events.

Layer 1:

<table>
<thead>
<tr>
<th>Food Service:</th>
<th>Characterising Features</th>
<th>Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>29. Food service: On-site catering activity but will not be subject to the proposed Catering Standard due to event size and frequency, e.g. eating establishments that hold either small (50 or less people) or infrequent (12 or less/year) catering events</td>
<td>High risk, processed (heat treatment), pre-prepared ready-to-eat food, refrigerated storage, reheating or hot-holding</td>
<td>P-1</td>
</tr>
</tbody>
</table>

Layer 2:

<table>
<thead>
<tr>
<th>29. Food service: On-site catering activity but will not be subject to the proposed Catering Standard due to event size and frequency</th>
<th>FB1</th>
<th>FB2</th>
<th>FB3</th>
</tr>
</thead>
<tbody>
<tr>
<td>a (Y)</td>
<td>a (Y)</td>
<td>a (Y), b (Y), c (Y), d (Y), e (N), f (Y) ⇒ P-1 OR a (Y), b (Y), c (Y), d (Y), e (N), f (N), g (Y) ⇒ P-1</td>
<td></td>
</tr>
</tbody>
</table>

Layer 3:

<table>
<thead>
<tr>
<th>29. Food service: On-site catering activity but will not be subject to the proposed Catering Standard due to event size and frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>Question 1</td>
</tr>
<tr>
<td>FB1a. Yes.</td>
</tr>
<tr>
<td>Section 3.2.2.1 of the Food Standards Code defines potentially hazardous foods as those that have to be kept at a certain temperature to minimise the growth of any pathogenic organisms that may be present. This could include refrigeration (e.g. &lt;5°C), hot-holding (e.g. &gt; 60°C) or storage at some other temperature for a defined period of time that limits potential microbial growth to acceptably low levels.</td>
</tr>
<tr>
<td>According to the business description, at least some of the foods handled by these businesses require refrigeration or hot-holding. As discussed below, these foods may contain pathogens and will not include preservative systems because they are prepared to be consumed soon after preparation or rely on refrigeration or hot-holding to minimise microbial growth, i.e., they will support pathogen growth and/or toxin production.</td>
</tr>
<tr>
<td>Although some foods handled and served by the business sector may not be potentially hazardous, the principles for application of the Risk Profiling Framework (RPF) require that businesses are classified according to their highest risk product or process. It is expected that all caterers handle at least one food that requires refrigeration or hot-holding to prevent pathogen growth and toxin formation, i.e., all businesses fitting the description would handle potentially hazardous foods.</td>
</tr>
</tbody>
</table>

| Question 2 |
| FB2a. Yes. |
| From the business description given, foods included in this category are high risk because pathogenic microorganisms, if present, could grow due to the nature of the food (e.g. high nutrient value, high water activity and neutral pH or slight acidity). For example, raw meat, poultry and fish are all classified as high risk foods. It is highly likely that all catering businesses included under the current classification handle raw meat, poultry, eggs and/or fish. Recontamination of cooked foods with pathogens is commonly identified as a cause of foodborne disease outbreaks involving food service |
29. **Food service: On-site catering activity but will not be subject to the proposed Catering Standard due to event size and frequency**

Businesses (see FB3c, below) and many cooked products retain high water activity, neutral to slightly acidic pH and high nutrient content and can support pathogen growth unless prevented by high, or low, temperature.

**Question 3**

FB3a. Yes.

Control actions used by caterers during food preparation and service aim to limit microbial contamination and, if it occurs (or has occurred at previous stages in the food chain), to reduce contamination or minimise survival and growth. Control actions include proper stock control, prevention of recontamination by good food handling practices and adequate temperature control (during cooking and cold- and hot-temperature storage).

FB3b. Yes.

Control actions employed by the business can be critical to safety of the product sold.

Food businesses that prepare ready-to-eat food in advance must ensure that the growth of any pathogenic microorganisms that may be present, either in raw material or from recontamination of cooked food, is minimised between preparation and service. Additionally, spore-forming bacteria such as *Clostridium perfringens* and *Bacillus cereus* can survive cooking but grow during cooling of the food or during storage if time/temperature control is inadequate. Both organisms are common causes of foodborne illness from food service operations, including commercial caterers (2, Appendix 1). Thus, minimising the likelihood of cross-contamination is another critical control action for the food business. In food service prevention of microbial growth is primarily achieved by temperature control. Storage of food under temperature control (see FB1a, above) is critical for safety of the final product.

Proper cooking is often also critical for safe food. For example, raw meat, poultry and fish can contain pathogenic microorganisms in sufficient numbers to cause illness in consumers. Although relevant business sectors prior in the food chain will have employed control actions to minimise contamination and growth, the major control action for the risk associated with the pathogens in raw meat, poultry, eggs and fish is adequate cooking of the food.

FB3c. Yes.

Temperature control during cooking and storage of food prior to service is not considered potentially unreliable within the definitions of the RPF. Nonetheless, in food service operations, inadequate temperature control is often cited as a cause of foodborne disease outbreaks (2, Appendix 1). Possible reasons for this are discussed in Appendix 1. Inadequate time/temperature control exacerbates the consequence of recontamination of food prior to service of the food by the business sector, and is another factor frequently cited (see 2) as a cause of foodborne disease outbreaks from catering operations. Recontamination can arise from cross-contamination with raw foods, from infected food handlers or from unclean work surfaces and utensils that harbour pathogens.

A range of contaminants can be introduced by food handlers. These include gastrointestinal pathogens (including bacteria and viral agents) and *Staphylococcus aureus* from food handlers that are passive carriers or have minor skin infections. In the former case it would be assumed that relatively low numbers of *S. aureus* would be transferred to foods. For *S. aureus* food poisoning to occur, levels of *S. aureus* typically must exceed $10^6$ CFU g$^{-1}$ (5). Thus, to achieve such levels, growth would usually have to occur. Most strains of *S. aureus* cannot grow below ~7°C (3) so that growth on foods is readily controlled by normal refrigeration. Disease could also arise, however, without growth if very high levels are transferred, e.g., from an active skin infection.

Importantly, because caterers handle raw meat, poultry, eggs and fish, the potential for illness arising from cross-contamination from raw to processed product is much greater. This is because raw meat, poultry and fish could contain low infectious dose pathogens such as pathogenic *Escherichia coli*, or high levels of other pathogens, such as *Campylobacter* or *Salmonella*, e.g., potentially present on raw chicken. While the survival of these pathogens is reduced to safe levels by cooking (and potential for their growth is limited by correct storage conditions), there is potential for transfer of sufficient cells to cooked food to cause disease unless rigorous attention is paid to prevent cross-contamination between...
29. Food service: On-site catering activity but will not be subject to the proposed Catering Standard due to event size and frequency

Raw products and ready-to-eat foods via surfaces, equipment, utensils, aerosols (splashing/drips) and food handlers themselves.

FB3d. Yes.

As reported in the National Risk Validation Project (NRVP; 1) there is ample documented evidence of frequent foodborne disease outbreaks that are attributed to food service operations, both within Australia and internationally, including on-site catering operations. The NRVP (1) indicated that ~2/3 of foodborne disease outbreaks in Australia were due to commercial food preparers. The NRVP (1) was completed and the outcomes published in 2002. To determine whether the situation in Australia has changed, OzFoodNet Quarterly reports from October 2005 to September 2008 were examined and outbreaks relating to restaurants, caterers and 'take-aways' summarised. This information is presented in Appendix 1. There were 349 foodborne disease outbreaks reported in that period, of which 57% involved food service businesses. Eleven per cent were caused by commercial caterers. Outbreaks typically involved 10 – 30 people but in some cases affected hundreds. From the data obtained, “food service” appears to remain a significant source of foodborne disease outbreaks in Australia.

FB3e. No.

Service is to the general public.

FB3f. Yes

Enterohaemorrhagic E. coli can cause outbreaks of severe illness in healthy people and has often been linked to restaurants, e.g. (1, 4); however, it has not been associated with this business sector in Australia. ⇒ P-1

Alternative Decision Pathway

Typically, the hazards most commonly associated with foods served by the business sector (i.e., Campylobacter, Salmonella spp., C. perfringens, B. cereus, norovirus) do not cause severe illness (as defined in the RPF) in otherwise healthy consumers but, rather, usually cause mild, self-limiting diarrhoeal and emetic illness. Therefore, if Enterohaemorrhagic E. coli is not considered a likely contaminant, the answer to FB3f would be 'no' and the following decision pathway applies:

FB3g. Yes.

As discussed above (see FB3c), large numbers of pathogenic microorganisms can be transferred to prepared foods and, if proper temperature control is not maintained, pathogenic microorganisms can, and have, increased to sufficient levels to cause acute disease in healthy consumers. As noted above, poor temperature control and cross contamination of cooked foods with pathogens are frequently implicated in outbreaks of foodborne disease, including those involving catering operations. ⇒ P-1

Layer 4:

29. Food service: On-site catering activity but will not be subject to the proposed Catering Standard due to event size and frequency

References


29. Food service: On-site catering activity but will not be subject to the proposed Catering Standard due to event size and frequency

30. **Food service: Off-site catering activity but will not be subject to proposed Catering Standard due to frequency**

Layer 1:

<table>
<thead>
<tr>
<th>Food Service</th>
<th>Characterising Features</th>
<th>Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>30. Food service: Off-site catering activity but will not be subject to the proposed Catering Standard due to frequency</td>
<td>High risk, processed (heat treatment), pre-prepared ready-to-eat food, transported to another location, refrigerated storage, hot-holding or reheating before serving</td>
<td>P-I</td>
</tr>
</tbody>
</table>

Layer 2:

<table>
<thead>
<tr>
<th>30. Food service: Off-site catering activity but will not be subject to the proposed Catering Standard due to frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>FB1</strong></td>
</tr>
<tr>
<td>a (Y)</td>
</tr>
</tbody>
</table>

Layer 3:

<table>
<thead>
<tr>
<th>30. Food service: Off-site catering activity but will not be subject to the proposed Catering Standard due to frequency</th>
</tr>
</thead>
</table>

Much of the discussion and information presented in Example Classification 29: Food service: On-site caterers is equally relevant to this business sector and readers are referred to that Example for more detailed information and supporting documentation.

---

**Question 1**

FB1a. Yes.
The business handles foods that require refrigeration. These foods may contain pathogens and will support pathogen growth or the formation of toxins. Although some foods handled and served by the business sector may not be potentially hazardous, the principles for application of the Risk Profiling Framework (RPF) require that businesses are classified according to their highest risk product. It is expected that all caterers handle at least one food that requires refrigeration to prevent pathogen growth and toxin formation, i.e., all handle potentially hazardous foods.

---

**Question 2**

FB2a. Yes.
From the description of the business given, foods handled by businesses in this category are high risk foods, i.e., pathogenic microorganisms, if present, could grow due to the nature of the food (e.g. high nutrient value, high water activity and neutral pH or slight acidity). For example, raw meat, poultry and fish are all classified as high risk foods. It is highly likely that all catering businesses included under the current classification handle raw meat, poultry and/or fish. Additionally, recontamination of cooked foods with pathogens is commonly identified as a cause of foodborne disease outbreaks involving food service businesses and many cooked products retain high water activity, neutral to slightly acidic pH and high nutrient content and can support pathogen growth unless prevented by high, or low, temperature.

---

**Question 3**

FB3a. Yes.
Control actions used by caterers during food preparation and service aim to limit microbial contamination and, if it occurs (or has occurred at previous stages in the food chain), to reduce contamination or to minimise pathogen growth and survival. Control actions include proper stock
30. Food service: Off-site catering activity but will not be subject to the proposed Catering Standard due to frequency

<table>
<thead>
<tr>
<th>FB3b</th>
<th>Yes.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Control actions employed by the business are critical to safety of the product sold.</td>
<td></td>
</tr>
</tbody>
</table>

Food businesses that prepare ready-to-eat food in advance must ensure that the growth of any pathogenic microorganisms that may be present, either in raw material or from recontamination of cooked food, is minimised between preparation and service. Additionally, spore-forming bacteria such as *Clostridium perfringens* and *Bacillus cereus* can survive cooking but grow during cooling of the food or during storage if time/temperature control is inadequate. Both organisms are common causes of foodborne illness from food service operations, including commercial caterers (1, Appendix 1). Thus, minimising the likelihood of cross-contamination is another critical control action for the food business. In food service prevention of microbial growth is primarily achieved by temperature control. Off-site caterers should use additional control actions to prevent cross-contamination occurring during food transportation (e.g. packaging of food to prevent contact with other food types, either directly or through spillage during transport, etc.).

Proper cooking is often also critical for safe food. For example, raw meat, poultry, eggs and fish can contain pathogenic microorganisms in sufficient numbers to cause illness in consumers. Although relevant business sectors prior in the food chain will have employed control actions to minimise contamination and growth, the major control action for the risk associated with the pathogens in raw meat, poultry, eggs and fish is adequate cooking of the food.

Storage of food under temperature control (i.e. below 5°C or above 60°C) is also critical for the safety of the final product. Food businesses that prepare ready-to-eat food in advance must ensure that the growth of any pathogenic microorganisms that may be present in the food is minimised. This is primarily achieved by temperature control. For caterers that engage in off-site food preparation, time/temperature control is the principal means of minimising microbial growth during transportation.

<table>
<thead>
<tr>
<th>FB3c</th>
<th>Yes.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Temperature control during cooking and storage of food prior to service is not considered potentially unreliable within the definitions of the RPF. Nonetheless, in food service operations, inadequate temperature control is often cited as a cause of foodborne disease outbreaks (1, Appendix 1). Possible reasons for this are discussed in Appendix 1. Inadequate time/temperature control exacerbates the consequence of recontamination of food prior to service of the food by the business sector, and is another factor frequently cited (see 1) as a cause of foodborne disease outbreaks from catering operations. Recontamination can arise from cross-contamination with raw foods, from infected food handlers or from unclean work surfaces and utensils that harbour pathogens. The significance of cross-contamination is identical for on-site and off-site caterers, except that the latter business must consider specific issues associated with the transportation of prepared food and, in some cases, the extended time between food preparation and service.</td>
<td></td>
</tr>
</tbody>
</table>

A range of contaminants could be introduced by food handlers. These include gastrointestinal pathogens (including viral agents) and *Staphylococcus aureus* from food handlers that are passive carriers or have minor skin infections. In the former case it would be assumed that relatively low numbers of *S. aureus* would be transferred to foods. For *S. aureus* food poisoning to occur, levels of *S. aureus* typically must exceed 100,000 cells per gram. Thus, growth to these levels would have to occur. Growth of *S. aureus* on foods is readily controlled by normal refrigeration. Disease could arise, however, if high levels are transferred, e.g., from an active skin infection.

Importantly, because caterers handle raw meat, poultry and fish, the potential for illness arising from cross-contamination from raw to processed product is much greater. This is because raw meat, poultry and fish could contain low infectious dose pathogens such as pathogenic *Escherichia coli*, or high...
30. Food service: Off-site catering activity but will not be subject to the proposed Catering Standard due to frequency

Levels of other pathogens, such as *Campylobacter* present on raw chicken or *Salmonella* potentially present in raw chicken and eggs. While the survival of these pathogens is reduced to safe levels by the process of cooking (and potential for their growth is limited by temperature-controlled storage conditions), there is potential for transfer of sufficient cells to cause disease unless scrupulous attention is paid to prevent cross-contamination between raw products and ready-to-eat foods via surfaces, equipment, utensils, aerosols (splashing/drips) and food handlers themselves.

FB3d. Yes.

Foodborne disease outbreaks due to catering operations are frequently reported (see Example Classification 29 Food service: On-site caterers; ref. 1; Appendix 1). This information is presented in Appendix 1. Three hundred and forty-nine foodborne disease outbreaks were reported to OzFoodNet quarterly reports from October 2005 to September 2008 of which 57% involved food service businesses, and 11% were caused by commercial caterers.

FB3e. No.

Service is to the general public.

FB3f. Yes

Enterohaemorrhagic *E. coli* can cause outbreaks of severe illness in healthy people and has often been linked to restaurants, e.g. (1, 4); however, it has not been associated with this business sector in Australia. ⇒ P-1

*Alternative Decision Pathway*

Typically, the hazards most commonly associated with foods served by the business sector (i.e., *Campylobacter*, *Salmonella* spp., *C. perfringens*, *B. cereus*, norovirus) do not cause severe illness (as defined in the RPF) in otherwise healthy consumers but, rather, usually cause mild, self-limiting diarrhoeal and emetic illness. Therefore, if Enterohaemorrhagic *E. coli* is not considered a likely contaminant, the answer to FB3f would be ‘no’ and the following decision pathway applies:

FB3g. Yes.

As discussed above (see FB3c), large numbers of pathogenic microorganisms can be transferred to prepared foods, although poor temperature control leading to pathogen growth is more likely. If proper temperature control is not maintained, pathogenic microorganisms can, and have, increased to sufficient levels to cause acute disease in healthy consumers. As noted above, poor temperature control and cross contamination of cooked foods with pathogens are frequently implicated in outbreaks of foodborne disease, including those involving catering operations. Temperature control during transportation may be more prone to failure than on-site refrigeration, or hot-holding equipment, and is an additional risk factor for this business sector, compared to on-site catering. ⇒ P-1

Layer 4:

30. Food service: Off-site catering activity but will not be subject to the proposed Catering Standard due to frequency

References

This page left blank deliberately.
31. **Food service: Food is prepared express order, e.g. eating establishments or take-aways that do not prepare food in advance**

Layer 1:

<table>
<thead>
<tr>
<th>Food Service:</th>
<th>Characterising Features</th>
<th>Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>31. Food service: Food is prepared express order, e.g. eating establishments or take-aways that do not prepare food in advance</td>
<td>High risk, processed (heat treatment), direct cook-serve operation, anticipated for immediate consumption</td>
<td>P-2</td>
</tr>
</tbody>
</table>

Layer 2:

<table>
<thead>
<tr>
<th>31. Food service: Food is prepared express order</th>
<th>FB1</th>
<th>FB2</th>
<th>FB3</th>
</tr>
</thead>
<tbody>
<tr>
<td>a (Y)</td>
<td>a (Y)</td>
<td>a (Y), b (Y), c (Y), d (Y), e (N), f (N), g (N), h (N) =&gt; P-2</td>
<td></td>
</tr>
</tbody>
</table>

Layer 3:

<table>
<thead>
<tr>
<th>31. Food service: Food is prepared express order</th>
</tr>
</thead>
<tbody>
<tr>
<td>Much of the discussion and information presented in Example Classification 29 Food service: On-site catering is equally relevant to this business sector and readers are referred to that Example Classification for additional detail and supporting information.</td>
</tr>
</tbody>
</table>

**Question 1**

FB1a. Yes.

Food businesses in this sector prepare and serve foods that are potentially hazardous. These foods may contain pathogens and will support pathogen growth or the formation of toxins prior to preparation for sale (i.e., cooking). While cooking would be expected to eliminate vegetative pathogens and viruses, if growth had occurred prior to cooking, toxins (e.g., staphylococcal enterotoxin, histamine, etc.) could be present and would survive cooking and be capable of causing illness. Equally, ingestion of high doses of endospores of some pathogenic bacteria (e.g., *Bacillus cereus*, *Clostridium perfringens*) would survive cooking and be able to cause gastrointestinal illness.

Although some foods handled and served by the business sector may not require temperature control, the principles for application of the Risk Profiling Framework (RPF) require that businesses are classified according to their highest risk product. It is expected that each business will handle at least one food that requires temperature control to prevent pathogen growth and toxin formation, i.e., all handle potentially hazardous foods.

**Question 2**

FB2a. Yes.

From the business description given, the food business handles high risk foods. These foods may contain pathogenic microorganisms and will support formation of toxins or microbial growth. For example, raw meat, poultry and fish are all classified as high risk foods and it is likely that many eating establishments and take-away businesses handle these types of food. Food businesses that do not handle raw meat, poultry, eggs and/or fish (e.g., a take-away that only prepares pre-cooked hamburgers) could be excluded from this Example Classification unless they handle other high risk foods (e.g., cooked rice, fresh-cut fruits or vegetables, etc.).

**Question 3**

FB3a. Yes.

The food business can employ control actions to limit microbial contamination and, if it occurs (or has occurred at previous stages in the food chain), to reduce microbial contamination or to further minimise growth and survival. Control actions include proper stock control, good handling practices and...
Risk Profiling Framework for Australian Food Business Sectors: Example Classifications

31. Food service: Food is prepared express order

adequate temperature control (during cooking and storage of food before preparation).

FB3b. Yes.
The business sector handles high risk foods. These may contain pathogenic microorganisms at levels that are sufficient to cause illness in healthy consumers. It is critical that the business employs controls to limit microbial proliferation prior to cooking (see FB1a, above) and a hazard reduction process to reduce the pathogen load in some high risk foods (e.g. raw meat, poultry and fish). This is principally achieved by cooking. Refrigerated storage (below 5°C) of food prior to preparation may be critical to product safety. If uncooked foods are part of the meal, (e.g. salads on hamburgers) actions to minimise cross-contamination from raw meats and eggs to these components during food preparation may also be critical for the safety of meals produced by the food business. Cross-contamination is commonly cited as a cause of foodborne disease outbreaks linked to take-away businesses in Australia (1).

FB3c. Yes.
Temperature control during cooking and storage of food is not considered potentially unreliable within the definitions of the RPF (but see Appendix 1). However, inadequate cooking is occasionally implicated in foodborne disease outbreaks, and recontamination of food can occur during food preparation. Within this business sector, cross-contamination between foods and from food handlers is frequently implicated in outbreaks (1), though the consequences of this are expected to be less than in other food service businesses because the food is cooked immediately prior to consumption which should greatly reduce the levels of any pathogens present. Note that inadequate cooking of hamburger patties was a relatively common cause of foodborne disease infection in USA due to cultural preferences for relatively rare cooking of hamburger patties. This preference does not seem to be as strong in Australia, and the lessons learnt from USA outbreaks in the 1980s have meant that large hamburger take-away businesses more thoroughly cook meat patties.

A range of contaminants could be introduced by food handlers. These include gastrointestinal pathogens (including viral agents) and *Staphylococcus aureus* from food handlers that are passive carriers or have minor skin infections. In the former case it is likely that insufficient numbers of *S. aureus* would be transferred to foods to cause human illness. Further, growth of *S. aureus* to disease-causing levels would be unlikely because the food is for immediate consumption. Disease could arise, however, if high levels are transferred, e.g., from an active skin infection. Many strains of *S. aureus* produce emetic enterotoxins (i.e., that induce vomiting) and are heat stable, i.e., that survive normal cooking.

Importantly, because caterers handle high risk foods that may be contaminated with disease-causing levels of pathogenic microorganisms, the potential for illness arising from cross-contamination from raw to processed product is much greater. Hazards of particular concern are pathogenic *Escherichia coli*, *Campylobacter* and *Salmonella*. While the survival of these pathogens is reduced to safe levels by the process of cooking, there is potential for transfer of sufficient cells to cause disease to components of the meals that are not heat-treated. Thus, scrupulous attention must be paid to minimise cross-contamination between raw products and ready-to-eat foods via surfaces, equipment, utensils, aerosols (splashing/drips) and food handlers themselves. Inadequate cooking of meals is rarely nominated as a cause of foodborne illness outbreaks (1) in food service but, given the available data, it is not possible to state whether this is a particular risk in businesses preparing food to express order.

FB3d. Yes.
Take-aways and restaurants are responsible for a high proportion of foodborne disease outbreaks in Australia, though it is not possible to state what proportion of these are due to express order operations. Erring on the side of caution, ‘yes’ was selected as the correct response to this question.

FB3e. No.
Sale is to the general public.

FB3f. No.
Typically, the hazards most commonly associated with foods served by the business sector (i.e. *Campylobacter*, *Salmonella* spp., norovirus and *Clostridium perfringens* (see Appendix 1)) do not cause severe illness in otherwise healthy consumers.
31. **Food service: Food is prepared express order**

FB3g. No.
The food business prepares food upon order, which will be immediately consumed. It is unlikely that vegetative pathogenic microorganisms, if present, will survive cooking at levels sufficient to cause disease at the time of consumption. This is particularly true where all ingredients in the final food product are cooked, because total pathogen numbers will be reduced by the heat treatment. In foods where low numbers of pathogenic microorganisms are present, there is not adequate time between cooking and consumption for growth to occur.

FB3h. No.
As meals are prepared for individual orders and cooked prior to consumption, the business would not serve sufficient servings simultaneously to pose an unacceptable risk under the definitions of the RPF unless some ingredients used:

- were prepared in advance, and
- were contaminated with low-dose pathogens or had been temperature-abused allowing extensive growth of pathogens, and
- did not receive a microbicidal heat treatment as part of the meal preparation process.

In this case, a succession of customers might be affected by a common source of contamination. However, in this classification it is assumed that all meal components are cooked or prepared fresh, with little opportunity for contamination or extensive microbial growth. ⇒ P-2

Layer 4:

31. **Food service: Food is prepared express order**

**References**

This page deliberately left blank.
32. **Food service: Ready-to-eat food prepared in advance, e.g. take-aways that hot-hold ready-to-eat food, restaurants that pre-prepare ready-to-eat food**

Layer 1:

<table>
<thead>
<tr>
<th>Food Service:</th>
<th>Characterising Features</th>
<th>Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>32. Food service: Ready-to-eat food is prepared in advance, e.g. take-aways that hot-hold ready-to-eat food, restaurants that pre-prepare ready-to-eat food</td>
<td>High risk, processed (heat treatment), time delay before serving (hot or cold holding)</td>
<td>P-1</td>
</tr>
</tbody>
</table>

Layer 2:

<table>
<thead>
<tr>
<th>32. Food service: Ready-to-eat food is prepared in advance</th>
<th>FB1</th>
<th>FB2</th>
<th>FB3</th>
</tr>
</thead>
<tbody>
<tr>
<td>a (Y)</td>
<td>a (Y)</td>
<td>a (Y), b (Y), c (Y), d (Y), e (N), f (N), g (Y) ⇒ P-1</td>
<td></td>
</tr>
</tbody>
</table>

Layer 3:

<table>
<thead>
<tr>
<th>32. Food service: Ready-to-eat food is prepared in advance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Much of the discussion and information presented in Example Classification 29 Food service: On-site catering is equally relevant to this business sector and readers are referred to that Example Classification for additional detail and supporting information.</td>
</tr>
</tbody>
</table>

**Question 1**

FB1a. Yes.

The food businesses prepare and serve foods that are potentially hazardous. These foods may contain pathogens and will support pathogen growth or the formation of toxins. Although some foods handled and served by the business sector may not require refrigeration or hot-holding, the principles for application of the Risk Profiling Framework (RPF) require that businesses are classified according to their highest risk product. It is expected that each business will handle at least one food that requires temperature control to prevent pathogen growth and toxin formation, i.e., all handle potentially hazardous foods.

**Question 2**

FB2a. Yes.

By the description given, the food business handles high risk foods. These foods may contain pathogenic microorganisms and will support formation of toxins or growth of pathogenic microorganisms. For example, raw meat, poultry and fish are all classified as high risk foods and it is likely that many eating establishment and take-away businesses handle these types of food. Any food businesses that do not handle high risk foods are not considered under the current Example Classification.

**Question 3**

FB3a. Yes.

Control actions used during food preparation and service aim to limit microbial contamination and, if it occurs (or has occurred at previous stages in the food chain), to reduce contamination or, at least, to minimise growth and survival. Control actions include proper stock control, good handling practices and adequate temperature control (during cooking and cold- and hot-temperature storage).

FB3b. Yes.

The business sector handles high risk foods. These may contain pathogenic microorganisms at levels that are sufficient to cause illness in healthy consumers. It is critical that the business employs a hazard reduction process to reduce the pathogen load in some high risk foods (e.g. raw meat, poultry and fish). This is principally achieved by cooking. Refrigerated storage (below 5°C) of food prior to and after
### 32. Food service: Ready-to-eat food is prepared in advance

Preparation may also be critical to product safety. For other foods, hot-holding (> 60°C) will be a more appropriate critical control action. Minimising the likelihood of cross-contamination during food preparation is another critical control action for the food business.

**FB3c.** Yes.

Temperature control during cooking and storage of food is not considered potentially unreliable within the definitions of the RPF, except that hot-holding of foods supporting *Clostridium perfringens* growth has been associated with foodborne illness (1, 3, Appendix 1).

Temperature control during cooking and storage of food prior to service is not considered potentially unreliable within the definitions of the RPF. Nonetheless, in food service operations, inadequate temperature control is often cited as a cause of foodborne disease outbreaks (1, Appendix 1). Possible reasons for this are discussed in Appendix 1. Inadequate time/temperature control exacerbates the consequence of recontamination of food prior to service of the food by the business sector, and is another factor frequently cited (see 1) as a cause of foodborne disease outbreaks from catering operations. Recontamination can arise from cross-contamination with raw foods, from infected food handlers or from unclean work surfaces and utensils that harbour pathogens.

A range of contaminants can be introduced by food handlers. These include gastrointestinal pathogens (including bacteria and viral agents) and *Staphylococcus aureus* from food handlers that are passive carriers or have minor skin infections. In the former case it would be assumed that relatively low numbers of *S. aureus* would be transferred to foods. For *S. aureus* food poisoning to occur, levels of *S. aureus* typically must exceed $10^6$ cfu.g$^{-1}$ (4). Thus, to achieve such levels growth would usually have to occur. Most strains of *S. aureus* cannot grow below ~7°C (2) so that growth on foods is readily controlled by normal refrigeration. Disease could also arise, however, without growth if very high levels are transferred, e.g., from an active skin infection.

Importantly, because caterers handle raw meat, poultry, eggs and fish, the potential for illness arising from cross-contamination from raw to processed product is much greater. This is because raw meat, poultry and fish could contain low infectious dose pathogens such as pathogenic *Escherichia coli*, or high levels of other pathogens, such as *Campylobacter* or *Salmonella*, e.g., potentially present on raw chicken. While the survival of these pathogens is reduced to safe levels by cooking (and potential for their growth is limited by correct storage conditions), there is potential for transfer of sufficient cells to cooked food to cause disease unless rigorous attention is paid to prevent cross-contamination between raw products and ready-to-eat foods via surfaces, equipment, utensils, aerosols (splashing/drips) and food handlers themselves.

**FB3d.** Yes.

As reported in the National Risk Validation Project (NRVP; 1) there is ample documented evidence of frequent foodborne disease outbreaks that are attributed to food service operations, both within Australia and internationally, including restaurants and take-aways. The NRVP (1) was completed and the outcomes published in 2002. To determine whether the situation in Australia has changed, OzFoodNet Quarterly reports from October 2005 to September 2008 were examined and outbreaks relating to restaurants, caterers and take-aways summarised. This information is presented in Appendix 1. There were 349 foodborne disease outbreaks reported in that period, of which 57% involved food service businesses and 46% were caused by restaurants and ‘take-aways’. Outbreaks typically involved 10 - 30 people but in some cases affected hundreds.

**FB3e.** No.

Service is to the general public.

**FB3f.** No.

Typically, the hazards most commonly associated with foods served by the restaurants and take-aways in Australia (i.e., *Clostridium perfringens, Campylobacter, Salmonella* spp. and norovirus (see Appendix 1)) do not cause severe illness in otherwise healthy consumers but usually cause mild, self-limiting, diarrhoeal or emetic illness.

**FB3g.** Yes.
### 32. Food service: Ready-to-eat food is prepared in advance

As discussed above (see FB3c), large numbers of pathogenic microorganisms can be transferred to prepared foods, although poor temperature control leading to pathogen growth is more likely. If proper temperature control is not maintained, pathogenic microorganisms can, and have, increased to sufficient levels to cause acute disease in healthy consumers. ⇒ P-1

#### References


This page left blank deliberately.
Appendix 1: Foodborne outbreaks associated with Food Service Businesses: triennium to September 2008

The Final Report of the National Risk Validation Project (NRVP; 1) was presented in 2002, and based on data available at that time. The report presented an analysis of OzFoodNet data which revealed that about two thirds of Australian foodborne disease outbreaks are associated with eating establishments and catering operations (Table 6, National Risk Validation Report, 2002). Since that time there have been many initiatives to reduce the incidence of foodborne illness in Australia, so that it is possible that the contribution of food service business to the overall foodborne disease burden in Australia has altered since the NRVP (1) was completed.

To assess this possibility, an analysis of OzFoodNet quarterly reports from October 2005 to September 2008 (i.e., three years) were collated, summarised and analysed. (The reports are presented in the publication Communicable Diseases Intelligence copies of which are available for download from http://www.health.gov.au/internet/main/publishing.nsf/Content/cda-pubs-cdi-cdiintro.htm. Communicable Diseases Intelligence is a quarterly publication of the Surveillance Branch, Office of Health Protection, Australian Government Department of Health and Ageing).

In that triennium, 349 foodborne disease outbreaks were reported in Australia and, of these, 38.7% were attributed to restaurants and 10.6% to commercial caterers. Takeaway establishments accounted for 7.7% of outbreaks.

In many reported outbreaks the food source or aetiological agent was unknown. However, where the agents associated with outbreaks from foodservice businesses were identified (either by confirmed microbiology or by descriptive evidence implicating the suspected vehicle or suggesting foodborne transmission) they were collated. A summary of the data is presented in the Table A1, below. More detailed information is presented in Table A2, overleaf.

Table A1. Summary of Australian foodborne disease outbreak data involving food service businesses for the triennium to September 2008 (Data from OzFoodNet quarterly reports)

<table>
<thead>
<tr>
<th></th>
<th>Take-aways (Example Classification 32)</th>
<th>Restaurants (Example Classification 31)</th>
<th>Commercial caterer (Example Classification 29)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unknown</td>
<td>51.9% (n = 27)</td>
<td>43.7% (n = 135)</td>
<td>37.8% (n = 37)</td>
</tr>
<tr>
<td>Salmonella</td>
<td>25.9%</td>
<td>32.6%</td>
<td>16.2%</td>
</tr>
<tr>
<td>Campylobacter</td>
<td>11.1%</td>
<td>1.5%</td>
<td>5.4%</td>
</tr>
<tr>
<td>C. perfringens</td>
<td>7.4%</td>
<td>2.2%</td>
<td>16.2%</td>
</tr>
<tr>
<td>Norovirus</td>
<td>14.8%</td>
<td>3.0%</td>
<td>18.9%</td>
</tr>
<tr>
<td>Histamine</td>
<td>0.7%</td>
<td>0.7%</td>
<td></td>
</tr>
<tr>
<td>Hepatitis</td>
<td></td>
<td>0.7%</td>
<td></td>
</tr>
<tr>
<td>S. aureus</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>B. cereus</td>
<td></td>
<td></td>
<td>5.4%*</td>
</tr>
<tr>
<td>Ciguatoxin</td>
<td>3.7%</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* Occasionally B. cereus and C. perfringens were both identified as the agent

Possible Reasons for the Relatively High Association of Food Service with Foodborne Disease Outbreaks and Application of the Risk Profiling Framework.

During the use of the Risk Profiling Framework (RPF) for classification of the example business types included in this report it was noted that, while adequate knowledge and mechanisms of control do exist to be able to make food service a safe operation, the high incidence of outbreaks suggested that a theoretical response to question FB3c did not accurately reflect reality. In particular, the RPF does not consider the reliability of implementation of appropriate food safety measures for different businesses, whether due to human behaviour or practical feasibility.

Thus, whereas strategies for safe preparation of foods in food service are available, the epidemiological evidence suggests that they not working. Assuming that human nature (and the willingness to implement and execute appropriate food safety measures) is equal for people in all types of business, the apparently
disproportionate representation of food service businesses in foodborne disease outbreaks suggests that that measures are ineffective or impractical, rather than that they are deliberately ignored.

The reasons may lie in the great diversity of tasks undertaken in most food service operations compared to food processing operations, where there is greater opportunity for automation and cost-effectiveness for systems approaches, i.e., due to economies of scale. The greater dependence on manual operations, the diversity of meals prepared and food handling tasks that have to be undertaken, the equipment required, and time constraints in many food service environments, conceivably make it impractical to monitor times and temperatures etc., and make it harder to avoid cross-contamination etc., than in industrial scale processes where dedicated equipment and functional separation of tasks can be achieved. (Nonetheless, there no doubt remain aspects of food service where food safety improvement could be easily achieved).

Given the above, a slightly different interpretation of Question FB3c, which asks about ‘potentially unreliable’ inactivation processes, and the potential for cross-contamination, may need to be applied for food service: namely that normal food safety measures such as refrigerated storage are potentially unreliable in the context of food service operations, and that recontamination is potentially more likely in food service operations compared to industrial scale food processing operations, or businesses that undertake a dedicated production of one product, per ‘production line’, at a time.

Table A2. Details of Australian foodborne disease outbreak data involving food service businesses Oct 2005 to September 2008 (Data from OzFoodNet quarterly reports)

<table>
<thead>
<tr>
<th>Total Outbreaks</th>
<th>340</th>
<th>36</th>
<th>26</th>
<th>22</th>
<th>34</th>
<th>39</th>
<th>34</th>
<th>36</th>
<th>27</th>
<th>29</th>
<th>25</th>
<th>17</th>
</tr>
</thead>
<tbody>
<tr>
<td>Takeaways</td>
<td>27.0</td>
<td>7.7</td>
<td>4</td>
<td>4</td>
<td>4</td>
<td>0</td>
<td>5</td>
<td>3</td>
<td>5</td>
<td>2</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Restaurant</td>
<td>135.</td>
<td>38.7</td>
<td>11</td>
<td>9</td>
<td>8</td>
<td>9</td>
<td>16</td>
<td>16</td>
<td>13</td>
<td>7</td>
<td>12</td>
<td>13</td>
</tr>
<tr>
<td>Commercial Caterer</td>
<td>37.0</td>
<td>10.6</td>
<td>2</td>
<td>0</td>
<td>4</td>
<td>3</td>
<td>3</td>
<td>2</td>
<td>2</td>
<td>6</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>Outbreaks due to food service businesses</td>
<td>199.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

| Analysis of Causative Organisms | 27.0 | |
| Takeaway | Salmonella | 7.0 | 25.9 |
| | Norovirus | 0.0 | 0.0 |
| | Campylobacter | 3.0 | 11.1 |
| | Clostridium perfringens | 2.0 | 7.4 |
| | UNKNOW | 14.0 | 51.9 |
| | Bocillus cereus | 0.0 | 0.0 |
| | Ciguatoxin | 1.0 | 3.7 |
| Restaurant | Salmonella | 44.0 | 32.6 |
| | Norovirus | 20.0 | 14.8 |
| | Campylobacter | 2.0 | 1.5 |
| | Clostridium perfringens | 3.0 | 2.2 |
| | UNKNOW | 59.0 | 43.7 |
| | Histamine | 4.0 | 3.0 |
| | Hepatitis | 1.0 | 0.7 |
| | Staphylococcus aureus | 1.0 | 0.7 |
| | Scombroid | 1.0 | 0.7 |
| Commercial Caterer | Salmonella | 6.0 | 16.2 |
| | Norovirus | 7.0 | 18.9 |
| | Campylobacter | 2.0 | 5.4 |
| | Clostridium perfringens | 6.0 | 16.2 |
| | UNKNOW | 14.0 | 37.6 |
| | Bocillus cereus | 2.0 | 5.4 |

Reference: