final report

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Prepared by:	AProf. Marta Hernandez-Jover Mrs. Fiona Culley AProf. Jane Heller Prof. Michael Ward Charles Sturt University University of Sydney
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Meat and Livestock Australia Limited
Locked Bag 1961
NORTH SYDNEY NSW 2059

Review of food safety and market access risks in red meat supply chains

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Abstract

The current project has conducted a review and an update of the 2002 industry food safety risk profile, to identify the direction and priorities for future research. The first step of the project was to conduct a hazard characterization, which involved a review of literature and data on foodborne outbreaks, pathogen surveillance and product recalls, and an expert elicitation process with 15 Australian food safety experts. This process identified the Hazard:Product:Process combinations to be considered and the likelihood of contamination at the point of consumption. These likelihood ratings were then combined with hazard severity ratings to qualitatively estimate the relative risk posed by each combination. Combinations with a moderate to high risk were included in the semi-quantitative risk profiling using Risk Ranger v2, the semi-quantitative risk profiling tool identified as the most suitable for the purpose of the project. The Risk Ranger tool provides a risk ranking (RR), ranging from 0 (no risk) to 100 (every member of the population eats a meal that contains a lethal dose of the hazard every day). STEC *E.coli* O157 (RR 35-39) and *Salmonella* spp. (RR 33-37) in undercooked hamburgers and *Listeria monocytogenes* in ready-to-eat products (RR 35-38) resulted in the highest risk, with this risk being moderate. The model predicted 11–32 annual cases due to STEC *E.coli* O157 and 28–90 due to *Salmonella* spp. under different undercooking scenarios. Fifteen annual cases were estimated due to *Listeria monocytogenes*. This study provides an updated food safety risk profile for the red meat industry which, considering the available information, suggests red meat products in Australia do not pose a high food safety risk.

Executive summary

In 2002, a food safety risk profile was developed for the Australian red meat industry. It included raw and processed meat products of cattle, sheep and goats and considered microbiological, chemical and physical hazards (Pointon et al. 2006). The 2002 risk profiling exercise categorized combinations of hazard:meat products according to the food safety risk posed to humans after exposure to such hazards. The risk rating exercise concluded that the combinations posing the highest risk were meals contaminated with *C. perfringens* distributed by caterers working without effective HACCP plans; kebabs cross-contaminated with *Salmonella* from drip trays or undercooked; and, meals served at home cross-contaminated with *Salmonella*. Apart from causing ill health, foodborne disease outbreaks have the potential to seriously reduce profit margins for the producers of those foods involved, as well as reduce consumer confidence, a critical factor in maintaining business continuity. To anticipate hazards to human health and wellbeing and the threats posed to business, dynamic risk assessment methodologies are needed. Investment in such methodologies and studies is minor compared to the potential cost of foodborne outbreaks and loss of consumer confidence.

The current project has been conducted in response to the need, identified by the red meat industry, to review and update the 2002 risk profile using up-to-date assessment methods and to identify the direction for future research to assess and address those hazards or threats that pose the highest risk to the industry in terms of public health and market access. Therefore, the objectives of the current project were to: 1) Review current and new food safety issues affecting the Australian red meat industry; 2) Review currently available risk assessment tools, focusing on semi-quantitative methods, that could be suitable for the profiling and assessment of food safety and market access risks affecting the Australian red meat industry; 3) Conduct a risk profile of the identified food safety risks, using the most suitable risk profiling methods; and, 4) Provide an updated food safety risk profile for the red meat industry and recommendations.

To achieve the first objective of this project, the first step was to conduct a hazard characterization, to identify Product:Process:Hazard combinations posing a food safety or market access risk, to be considered in this risk profiling exercise. For this characterization, an iterative approach with several steps was used to gather the required information. Initially, a review of literature and available data on foodborne outbreaks, pathogen surveillance and product recalls and a consultation with processing stakeholders, identified the hazards. Information gathered in this step was subsequently presented for comment in an expert elicitation process with 15 Australian food safety experts. An expert elicitation workshop was conducted to identify current Product:Process:Hazard combinations and the likelihood of contamination of the product at point of consumption. Severity ratings for each hazard were derived using the International Commission on Microbiological Specifications for Foods (ICMSF 2002) as the main reference. These ratings were then combined with the expert likelihood scores for each Product:Process:Hazard combination, using a risk matrix, to qualitatively estimate the relative risk posed by each combination.

To identify those combinations to be included in the semi-quantitative risk profiling, the obtained relative risk ranking of the Product:Process:Hazard combinations was presented to, and discussed with, the project Steering Committee. As agreed upon by the Steering Committee, the high and moderate relative risk combinations were assessed using a qualitative risk rating approach (Sumner et al. 2005), as a means of further validating and prioritising the combinations. Estimates from this qualitative risk rating approach resulted in a risk category equal or lower to those estimated by experts, with significant agreement observed. Those combinations with a moderate to high qualitative risk estimate were selected for the semi-quantitative risk profiling.

These combinations were:

1. Packaged, cooked, ready to heat (vacuum, modified atmosphere packaging etc.) – *L. monocytogenes*
2. Unpackaged, cooked, ready to eat – *L. monocytogenes*
3. Cured meat (packaged for retail): Dry cured, sliced; Wet-cured, cooked and sliced – *L. monocytogenes*
4. Non-GMP UCFM – *Salmonella* spp., STEC
5. Offal (commonly undercooked) – *Salmonella* spp., STEC
6. Outside in (commonly served undercooked) – *Salmonella* spp., STEC
7. Roast - served warm (sliced primal) – *C. perfringens*
8. Uncooked comminuted meat – *Salmonella* spp., STEC, *Campylobacter*
9. Undercooked comminuted meat – *Salmonella* spp., STEC
10. Uncooked Primal – STEC
11. Vacuum-packed and undercooked primal – *C. botulinum, L. monocytogenes*
12. Dry-aged meat – Mycotoxins *(Rhizopus, Mucor)*
13. Undercooked lamb rolled roast or primal – *Toxoplasma gondii*

A literature review was undertaken to identify available risk assessment and ranking tools used for food safety issues, and assess their suitability for ranking contaminants in the context of risk profiling the red meat industry in Australia. A more detailed assessment of the FDA-iRISK®2.0 (U.S. Food and Drug Administration), P^3ARRT, Risk Ranger v2, and tools used by the European Food Safety Authority (EFSA - EFoNAO-RRT) was conducted because these tools were deemed to be the most suitable for the purposes of this project. This assessment identified Risk Ranger v2 as the most suitable tool.

Risk Ranger v2 is a semi-quantitative risk profiling tool that allows an estimation of the public health risk of hazard:product combinations and a ranking of this risk. This tool was developed in Microsoft Excel, using standard mathematical and logical functions and requires the selection of qualitative statements or provide quantitative data in relation to the criteria included in the model. The tool then converts the qualitative inputs into numerical values used for the estimation and ranking of the risk (RR). The risk is assessed from 0 to 100, with 0 meaning no risk posed by the hazard:product combination and 100 being the worst case scenario – every member of the population would eat a meal that contains a lethal dose of the hazard every day. Risk Ranger v2 uses eleven criteria describing the hazard severity, population susceptibility, consumption patterns and probability of the product containing an infectious dose. Information sources used to identify relevant data (including pathogen prevalence and concentration, production statistics and consumption patterns) to include in the semi-quantitative risk profiling process included a review of the literature, communication with market research companies and commercial businesses involved in the industry, and consultation with the project Steering Committee.

The combinations which resulted in the highest risk ranking involved undercooked hamburgers and STEC *E.coli* O157 (RR 35 to 39) and *Salmonella* spp. (RR 33 to 37), and *Listeria monocytogenes* in packaged and unpackaged ready-to-eat products (RR 35 to 38). These risk rankings are considered to be moderate. The model predicted 11–32 annual cases due to STEC *E.coli* O157, 28–90 due to *Salmonella* spp. and 15 due to *Listeria monocytogenes* among the general population. The range obtained for undercooked hamburgers is dependent on the level of undercooking, with the highest risk within the scenario assuming a cooking level causing 50% pathogen reduction. Although the predicted cases for *Salmonella* spp. are higher than for the other hazards, Salmonellosis in most people causes only a mild illness, characterised by gastrointestinal disease which resolves without treatment in less than seven days. In contrast, Listeriosis can have serious health consequences and a high case fatality rate (up to 50%) if a systemic infection occurs. For STEC *E.coli* O157, the severity of the illness was considered similar to *L. monocytogenes* in this assessment, with most infections resulting in bloody diarrhoea (haemorrhagic colitis) and cramping, but with recovery usually within a week. However, a small proportion of patients (generally less than 5%) will suffer more serious outcomes, such as haemolytic uraemic syndrome (HUS) or consequent death (1-4% of HUS cases). While 70% of HUS cases recover completely, the remainder suffer a range of long-term sequelae (CDC 2014, Rivas et al. 2014).

The combination involving *Toxoplasma gondii* in undercooked lamb resulted in a similar risk ranking (RR 38) among the general population, with a substantial number of infections predicted (n = 631). However, previous studies suggest that in most cases exposure in immunocompetent people would not cause clinical illness (Scallan et al. 2011). In contrast, when the population considered for this combination was only pregnant women, who are more susceptible to infection and would suffer a more severe illness, the risk ranking was high (RR 49), with an annual prediction of 142 congenital infections.

For those combinations involving *Clostridium perfringens* and *Campylobacter* spp. the estimated risk ranking was lower. *C. perfringens* in roast beef and lamb among the general population resulted in risk ranking of 27-28, with one to two cases predicted per year. In most cases, this hazard causes mild symptoms, with profuse diarrhoea and abdominal cramps that subside in 24h. The risk ranking increased when only an elderly population was considered (RR 36-40), with 5 and 20 cases predicted per year for lamb and beef, respectively. The increase in risk ranking and predicted cases among the elderly population is due to the higher susceptibility and the increased severity of illness. Fatal cases caused by *C. perfringens* are rare and usually occur among the elderly population, where the pathogen can cause necrotising small-bowel disease. *Campylobacter* in undercooked comminuted meat had an estimated risk ranking of 22 to 26, depending on the level of undercooking, with a prediction of up to one case per year. The illness is mild and characterised by an inflammatory process that causes diarrhoea, and this is more common in infants.

Results from this risk profiling exercise indicate that using data available, none of the combinations resulted in a high risk for the general population, and when compared to the 2002 risk profiling results, there has not been an increase in food safety risks posed by the red meat industry. Some combinations were found to pose a lower risk due to improved food safety measures and hygiene practices.

The final step of the project was to conduct a reality check, in which the predicted cases obtained for each hazard were compared with actual outbreak data available from OzFoodNet. OzFoodNet data on outbreaks attributed to red meat and the number of illnesses associated with these outbreaks from 2005 to 2014 were used because no more recent data were available. This reality check suggests the predictions obtained are similar to the actual cases reported. However, it is important to consider that the predicted cases for each of the hazards do not include all potential products that could be contaminated with these hazards, but only the combinations included in the assessment. Nevertheless these combinations were those identified as posing the highest risk and as such other products are likely to have a minor contribution to the overall food safety risk posed by the beef, sheep or goat meats.

The outputs generated from the semi-quantitative risk profiling should be interpreted considering the level of uncertainty in the input parameters used for each of the combinations and the assumptions used. There are a significant number of variables across the supply chain continuum that impact upon the chosen input parameters, and as such, on the resultant risk ranking outputs. These sets of variables, relevant to each stage of the chain, determine the prevalence of a hazard at each processing point and subsequently, in the final product.

This project identified data gaps that have an impact on the ability to accurately assess the food safety risk posed by red meat products. A set of prioritized recommendations were developed and are described below.

1. There is a lack of information on consumption patterns and consumer exposure to particular red meat products.

   Recommendations:
   - Conduct additional market research into the types of cuts used for dishes (e.g. types of cuts used for homemade UCFM, and proportion of red meat) and the frequency of consumption of the meals using these cuts.
     - Prioritise the above for Hazard:Product:Process combinations with the highest risk ranking and those with insufficient data to conduct the semi-quantitative risk profiling including undercooked comminuted meat products, retail deli meats and undercooked primal products (cryovaced, sous-vide, rolled, tenderised). If regulatory bodies deem dry-aged meat and vacuum-packed or modified atmosphere packaged product to be of risk then data needs to be collected to allow for a risk appraisal.

2. There is lack of accurate information on the prevalence of pathogen contamination of red meat products and the concentration of the pathogen in contaminated products.

   Recommendations:
   - Conduct review of prevalence of contamination and concentration data on a regular basis (e.g. every 5 years)
   - Obtain data that reflects Australia's current hygiene practices at different levels of the supply chain:
     - At the abattoir
     - Prior to distribution from the processing plant
     - Retail
       - Prioritise the above for Hazard:Product:Process combinations with the highest risk ranking and with the highest uncertainty and sample cuts / products in these combinations. These combinations include *Listeria monocytogenes* in both unpackaged and packaged, cooked, ready-to-eat meat products, and *Toxoplasma gondii* in undercooked lamb (chilled, rolled or primal cut).

3. There is a delay in the OzFoodNet reporting timeframes, with available outbreak data being delayed at least two years.

   Recommendation:
   - Provide support, in unison with fellow industry bodies and regulatory jurisdictions, for the increased funding for the OzFoodNet group, to allow for more timely food outbreak surveillance reporting.

4. There is a need to conduct ongoing reviews of the risk profiling given the changes in consumption patterns, cuisine trends, advances in methods of pathogen monitoring and trade agreements.

   Recommendation:
   - Repeat risk ranking exercise regularly (e.g. at least every 8 years or a time frame that reflects change in practice)

In addition to the recommendations in relation to increasing the understanding of the risk posed by microbiological hazards, it is also important that physical and chemical contaminant violations continue to be monitored to ensure compliance and rectify any recurring issues. To support this compliance, monitoring the potential changes in the management practices of red meat species (including farmed and rangeland goats) in relation to chemical exposure through feed and anaphylaxis measures is recommended, given violations of maximum residue limits occur intermittently in this sector. Furthermore, given some of the combinations posing the highest food safety risk are those involving uncooked and undercooked products, it is recommended to continue the use of consumer education campaigns on the use of appropriate food safety practices in food preparation. Finally, given the red meat industry's importance in a global context, its performance against international benchmarks in social responsibility (e.g. its contribution to the prevention of antimicrobial resistance, environmental sustainability, animal welfare standards) should be evaluated periodically to support ongoing confidence in Australian product.

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1 Background

In 2002, a food safety risk profile was developed for the Australian red meat industry, including raw and processed meat products of cattle, sheep and goats and considering microbiological, chemical and physical hazards (Pointon et al. 2006). In 2016, Meat and Livestock Australia (MLA) and the Australian Meat Processing Corporation (AMPC), both representative bodies of the Australian red meat industry, identified the need to review and update the risk profile conducted in 2002, using up-to-date assessment methods and identify the direction for future research to assess and address those hazards or threats that pose the highest risk to the industry in terms of public health and market access.

2 Project objectives

Project Objectives:

1. Review current and new technical food safety issues affecting the Australian red meat industry that need to be addressed to maximize the national and international market access opportunities
2. Review currently available risk assessment tools, focusing on semi-quantitative methods, that could be suitable for the profiling and assessment of food safety and market access risks affecting the Australian red meat industry
3. Conduct a risk profile of the identified technical food safety risks with sufficient quantitative information, using two to three different semi-quantitative risk assessment methods and provide a comparison of results obtained
4. Provide an updated food safety risk profile for the red meat industry and recommendations

3 Methodology

3.1 Methodology for the review of current and new food safety and/or market access issues affecting the Australian red meat industry

The following sections outline the methodology used for gathering and consolidating the required information to guide and inform the appraisal of food safety and market access issues, the selection of final Product:Process:Hazard combinations of most concern, and the tools to be used to rank the combinations. Prior to the start of the project a Steering Committee was formed and included the following Australian food safety experts: Dr Trish Desmarchelier, Dr Andrew Pointon and Prof. Martyn Kirk.

An iterative approach was employed to gain the necessary information for this review. As each stage informed the next, a stepped process was used. This process is presented in summary below and a detailed overview of each of the steps undertaken within the review is presented in **Appendix A.**

Step 1: The literature was reviewed and relevant stakeholders consulted to identify hazards that pose, or are interpreted to pose, a food safety or market access risk in the current beef, sheep or goat supply chain environment. The stakeholder consultation included a face to face semi-structured interview with Quality Assurance or export staff within key red meat processing/exporting organisations (the semi-structured interview outline is presented in **Appendix B**). The aim of this step was to identify hazards so that they could be presented for comment in the expert-elicitation process (Step 2).

Step 2: An expert elicitation process, via a workshop consisting of 15 Australian food safety 'experts', was performed to gather qualitative data to ground-truth the findings of the literature review (Step 1). Their expert opinion contributed towards identifying current Product:Process:Hazard combinations and the likelihood of contamination of a food serving at point of consumption (whereby the dose of the hazard is sufficient to cause disease).

Step 3*:* The experts' likelihood estimates were reviewed and the list of Product:Process:Hazard combinations to be considered in the qualitative estimation of risk (Step 5) were finalised during this step.

Step 4*:* Severity ratings (human health) were derived for the hazards identified in Step 1 and 2. A subsequent allocation of health severity ratings for each Product:Process:Hazard combination (identified in Step 3) was performed. A qualitative trade risk appraisal was undertaken by DAWR and AMIC representatives.

Step 5: In this step a qualitative estimation (and prioritisation) of the relative level of risk was performed, using a risk matrix paradigm to combine the likelihood (Step 3) and the severity (Step 4) of illness estimates, for each of the Product:Process:Hazard (Step 3) combinations.

3.2 Methodology for the review of currently available risk assessment tools used for risk ranking of food safety issues

In conjunction with a broader review of potentially relevant tools, MLA suggested the review of three methods in particular: FDA-iRISK®2.0 (U.S. Food and Drug Administration), Risk Ranger version 2.0, and tools used by the European Food Safety Authority (EFSA). A literature review was undertaken using Primo and Ovid database platforms with subsequent use of Scopus and Web of Science citation databases and a defined search protocol that included the years 2013-2017 and the categories of public health, risk assessment, risk prioritisation, risk ranking, food safety, health impact, nutritional hazards and pathogen; with a 'peer-reviewed' overlay. The year 2013 start date for the search was chosen as that was the end-point for the search protocol used by Fels-Klerx et al. (2016). The relevant journal articles were saved into Endnote.

In addition, papers from authors with particular experience in this field (e.g. Evers and Chardon) were also sought for review and assessed for relevance. The final method of identifying appropriate risk assessments for evaluation was the search for existing systems being used in USA and Europe and the existence of any reviews of those systems. The outcome of the search identified a document produced by The European Food Safety Authority (EFSA) that comprehensively discusses the various traits of the quantitative and semi-quantitative assessment, ranking and ranking tools prevailing at the time. The project, about which the report was written, sought to identify the best methods for the EFSA BIOHAZ Panel to use for the purpose of risk ranking of biological hazards taking into account performance and data requirements, uncertainty and variability. This document forms the primary source of information for the tabulated cross-comparison of the various methods under review for this project. The comparison incorporated inclusions (outputs), advantages (including ease of use) and disadvantages, and a column dedicated to improvements.

3.3 Methodology for the qualitative and semi-quantitative ranking of risk

The following sections outline the methodology used for conducting the qualitative assessment of risk, the selection of the Product:Process:Hazard combinations for the semi-quantitative risk ranking and the risk ranking process.

3.3.1 Qualitative assessment of the risk

The steps taken to validate the relative ranking of the Product:Process:Hazard combinations arising from the expert elicitation process, and identify those combination to include in the semi-quantitative assessment are as follows.

Step 1: **Review of Milestone 3 outputs.** The project Steering Committee, in a face to face meeting (6^{th} September 2017), were asked to provide comment on the prioritised Product:Process:Hazard combinations generated from the expert elicitation process. The outcome of this process was a qualitative estimation of the relative level of risk of each combination (presented in Milestone 3). The committee were also asked to discuss what risk-ranking tools would be most suitable for attempting to rank the prioritised combinations.

Step 2: As agreed upon by the Steering Committee, the high and moderate relative risk combinations were assessed using a qualitative risk rating approach as a means of validating and further prioritising the combinations to be evaluated/ranked using Risk Ranger Version 2.0 (v2) (and any other suitable risk ranking tools). This approach had been used in the previous risk ranking exercise (MLA PRMS.038c, 2003). The qualitative risk rating approach was developed from work produced by Food Science Australia (2000) and ICMSF (2002) with input from a subject expert (M. Cole). This approach was published by Sumner et al. (2005).

The qualitative risk rating approach considered the following criteria to qualitative estimate the risk of the Product:Process:Hazard combinations:

1. Severity of the hazard: In this matrix, the severity of the hazards is classified according to the International Commission of the Microbiological Specifications of Food (ICMSF 2002: M Cole pers. comm. and FSA 2000), and the following severity levels are used:

    IA. Severe hazard for general population, life threatening or substantial chronic sequelae or long duration. *(Severe)*

    IB. Severe hazard for restricted populations, life threatening or substantial chronic sequelae or long duration. *(Severe)*

    II. High hazard; incapacitating but not life threatening; sequelae rare; moderate duration. *(Serious)*

    III. Moderate, not usually life threatening; no sequelae; normally short duration; symptoms are self limiting; can be severe discomfort. *(Moderate)*

2. Occurrence risk (low, medium or high)
3. Growth in product required to cause disease (Yes / No)
4. Effect of production, process and/or handing on the concentration of the hazard in product (Increase / Decrease / No effect)
5. Presence of consumer terminal step (Yes / No)
6. Epidemiological link (Yes / No)

7. Other factors affecting the significance of the hazard

A more detailed description of these criteria is provided in the previous risk ranking final project report (MLA PRMS.038c; pp. 65).

Step 3: The steering committee were sent the outcomes of the qualitative estimation and validation process, with a list of the prioritised combinations, via email and asked to provide comment upon its content. As a result of the commentary, one new product was added for review ('dry-aged' meat), due to it being a product with increasing presence in the market place. Those combinations with a moderate to high qualitative risk estimate were selected for the semi-quantitative assessment.

3.3.2 Risk ranking

As previously described, in conjunction with a broader review of potentially relevant tools, the review focused on assessing the suitability of the FDA-iRISK®2.0 (U.S. Food and Drug Administration), Risk Ranger v2, and tools used by the European Food Safety Authority (EFSA). These tools were assessed as to their suitability for ranking contaminants in the context of risk profiling the red meat industry in Australia. Due to the paucity of quantitative data, ease of use and project timelines, Risk Ranger v2, a semi-quantitative tool, was chosen as the best means to generate risk rankings. The evaluation of the other methods is provided in the results section of this report.

Risk Ranger Version 2

Risk Ranger v2 is a semi-quantitative risk assessment tool that allows an estimation of the public health risk of hazard:product combinations and a ranking of this risk. The tool was accessed from the Centre of Food Safety & Innovation webpage (http://www.foodsafetycentre.com.au/riskranger.php). It was developed in Microsoft Excel, using standard mathematical and logical functions and requires the selection of qualitative statements or provide quantitative data in relation to the criteria included in the model. The tool then converts the qualitative inputs into numerical values, which are then used for the estimation and ranking of the risk. The risk is assessed from 0 to 100, with 0 meaning no risk posed by the hazard:product combination and 100 being the worst case scenario, meaning that every member of the population would eat a meal that contains a lethal dose of the hazard every day. The lower end of the scale (negligible probability) was arbitrarily chosen as a probability of mild foodborne illness of less than or equal to one case per 10 billion people per 100 years. The risk posed by this lower end scenario is 2.75×10^{-18} times that of the scenario of the upper end of the scale, meaning that the range of risk extends over 17.56 orders of magnitude and as such an increment in six units of risk in Risk Ranger outcome, corresponds to approximately a factor of 10 difference in the absolute risk estimate. More details on Risk Ranger are provided in the previous risk profiling final project report (MLA PRMS.038c, 2003) and in Ross and Sumner (2002).

Risk Ranger v2 uses the following criteria or input parameters in relation to the severity of the hazard and population susceptibility and the probability of the product containing an infectious dose:

1. Hazard severity:

   SEVERE hazard - causes death to most victims
   MODERATE hazard - requires medical intervention in most cases
   MILD hazard - sometimes requires medical attention
   MINOR hazard - patient rarely seeks medical attention

2. Susceptibility of the consumer (how susceptible is the population of interest?):

GENERAL - all members of the population
SLIGHT - e.g. infants, aged
VERY - e.g. neonates, very young, diabetes, cancer, alcoholic etc
EXTREME - e.g. AIDS, transplants recipients, etc.

3. Frequency of consumption:

   daily
   weekly
   monthly
   a few times per year
   OTHER

4. Proportion of population consuming the product (%):

   All (100%)
   Most (75%)
   Some (25%)
   Very few (5%)

5. Size of population of interest (size of consuming population):

   Australia
   ACT
   New South Wales
   Northern Territory
   Queensland
   South Australia
   Tasmania
   Victoria
   Western Australia
   OTHER

   In relation to this criteria the following assumptions were considered in the current assessment:

- The total population of Australia according to the 2016 Census was 24,210,809 people (1st June 2016).

- *Proportionate allocation of persons within published age brackets:* The age of 5 months was chosen as the lower limit of the 'general' consuming populationas 5 months is the age that children typically commence eating solid foods (including meat (finely chopped or minced), primarily in a pureed form (Australian Government Department of Health 2011). Children usually eat solid food (including finely chopped/minced meat) from approximately 5 months of age. Where an estimate of persons 5 months or greater was required then the Australian Bureau of Statistics 0-1 years age bracket was subdivided into an average number of persons per monthly age and multiplied by the appropriate proportion to represent the number of persons 5 months or greater. This figure was then added to the total population 1 year plus. (ABS 2017)

- *Non red meat-eating population:* The figure of 11.2% (over the age of 18) has been nominated as a non-meat eating class. While Roy Morgan's research indicated an "all or almost all vegetarian diet", the assumption was made for the purpose of this project that the diet excluded red meat. Between 2012 and 2016, the number of Australian adults whose diet is all or almost all vegetarian has risen from 1.7 million people (or 9.7% of the population) to almost 2.1 million (11.2%), the latest findings from Roy Morgan Research reveal. (Roy Morgan Research 2016).

- *Total population over the age of 5 months, exclusive of non-meat eating proportion of the population over the age of 18*: 22,002,599 persons.

- *Estimation of number of pregnant women in the year 2016*: The estimation was derived from the number of live births in 2016 (311,104), in addition to peri-natal deaths over 20 weeks gestation (2424), plus the estimated miscarriages (before 20 weeks gestation) which is suggested at 1 in 5 enduring pregnancies (62,706). This resulted in a combined total of 376,234. The estimate of meat-eating pregnant women, based on the "*non red meat-eating population"* notes above, gives a total of 334,096 persons. With estimations of 30% seropositivity for Toxoplasma gondii across the general population, then it is assumed that there would be approximately 263,364 initially seronegative pregnant women and 217,773 who had live births within the general population, and 233,867 seronegative pregnant women in the red meat-eating population.

- *Estimation of number of the elderly in the year 2016*. The World Health Organisation (WHO, 2002) define the elderly as 65 years and older. In terms of Australian 2016 population statistics this number equated to 3,673,511 (16.7% of the general population). While life expectancy is increasing 65 years continues to be the benchmark of the definition of 'elderly'. Life expectancy has been increasing, as has healthy life expectancy (the number of years of good health that a person can expect to live at any given age - considering age-associated mortality, morbidity, and functional health status). Allocation of a biological age would be more apt, as the ageing process is not homogenous across populations.

6. Proportion of raw product contaminated (%)/ probability of contamination of raw product per serving:

   Rare (1 in a 1000)
   Infrequent (1 per cent)
   Sometimes (10 per cent)
   Common (50 per cent)
   All (100 per cent)
   OTHER

7. Effect of process on the hazard:

   The process RELIABLY ELIMINATES hazards
   The process USUALLY (99% of cases) ELIMINATES hazards
   The process SLIGHTLY (50% of cases) REDUCES hazards
   The process has NO EFFECT on the hazards
   The process INCREASES (10 x) the hazards
   The process GREATLY INCREASES (1000 x) the hazards
   OTHER

8. Potential for recontamination after processing/ post-processing contamination rate (%)

   NO
   YES - minor (1% frequency)
   YES - major (50% frequency)
   OTHER

9. Effectiveness of post-processing control system/ post-processing control

   WELL CONTROLLED - reliable, effective, systems in place (no increase in pathogens)
   CONTROLLED - mostly reliable systems in place (3-fold increase)
   NOT CONTROLLED - no systems, untrained staff (10 -fold increase)
   GROSS ABUSE OCCURS - (e.g.1000-fold increase)
   NOT RELEVANT - level of risk agent does not change

10. Increase in the post-processing contamination level that would cause infection or intoxication (infectious or toxic dose) to the average consumer

    None
    slight (10 fold increase)
    moderate (100-fold increase)
    significant (10,000-fold increase)
    OTHER

    While the serving size was nominated in Risk Ranger V.2 as 100g, our calculations were based on 65g to 100g,depending on the product, and to account for the varied age of the considered consumer (5 months of age plus) and because it approximates serving sizes in recipes and is documented in Australia's Healthy Eating Guide (NHMRC, 2015).

11. Effect of preparation of meal before eating.

    Meal Preparation RELIABLY ELIMINATES hazards
    Meal Preparation USUALLY ELIMINATES (99%) hazards
    Meal Preparation SLIGHTLY REDUCES (50%) hazards
    Meal Preparation has NO EFFECT on the hazards
    OTHER

    Meat and Livestock Australia stipulations for approximate internal temperature and degree of cooking/'doneness' are:
    For roasts: Rare 60°C, Medium 65-70°C, and Well done 75°C / Rare – 55-60°C, Medium Rare 55-60°C, Medium 60-65°C, Medium Well 70-75°C, and Well done 75°C.
    For steaks: Rare 55-60°C, Medium Rare 60-65°C, Medium 65-75°C, Medium Well Done 70°C, Well Done 75°C*

* www.beefandlamb.com.au
www.beefandlamb.com.au/files/.../ApracticalguidetocookingAusbeefandlamb.pdf (2007)

Estimation of input values

Information sources used to identify relevant data (including pathogen prevalence and concentration, production statistics and consumption patterns) to include in the semi-quantitative risk profiling process included a review of the literature, as well as communication with market research companies and commercial businesses involved in the industry.

Literature review:
A variety of literature sources were used, including:

- MLA's past report depository
- Department of Agriculture and Water Resources
- The Australian Bureau of Statistics
- Australian Bureau of Agricultural and Resource Economics and Sciences
- Charles Sturt University Library Primo database search engine, which led to the identification of appropriate peer-reviewed journal articles and books
- Internet browser located documents (e.g. Google) and additional internet searches to supplement the above data collection, where information was not readily available.

Consultation:
Consultation with industry stakeholders including Australian red meat industry bodies, food regulatory bodies and commercial business entities (e.g. the Australian Meat Industry Council, PrimeSafe, RetailWorld and IBISWorld market research) was used as an alternative approach to source appropriate information. Such communication brought the access to specific datasets, as well as clarification of current market trends with respect to the use and of red meat in a domestic product manufacturing context as well as data interpretation.

4 Results

4.1 Review of current and new food safety or market access issues affecting the Australian red meat industry

4.1.1 Review of available information in an Australian food safety context

One of the terms of reference for the project was to understand and identify a) the current food safety risk around existing products as well as 'novel' products that have emerged as a result of food processing innovation or cuisine innovation (new products or new uses of product); and b) food safety *associated* risks/concerns i.e. those contaminants or attributes that are perceived to contribute to, or manifest in, a food safety risk as judged by the customer or consumer. Risk can be either inherent to the red meat raw material, resulting from the production system and primary processing, or developed within secondary processing, tertiary processing, home or food service environments, transport and storage or exacerbated with packaging or cooking terminal steps (undercooking or overcooking). While issues may arise within the supply chain the focus of the project was on the consumption end-point, i.e. the stage of the supply chain that has a direct influence whether illness results from ingestion.

The information gathered included:

1. Foodborne outbreaks associated with red meat from 2010 to 2014 (Table 1). A summary of these foodborne outbreaks by aetiology is provided in Table 2. The majority of outbreaks were associated with *Clostridium perfringens* and *Salmonella* spp., with a significant proportion of

outbreaks having unknown aetiology. The most common food (red meat-associated) vehicles linked to *C. perfringens* were roast meat or curries; however, a range of food vehicles were identified for *Salmonella* spp., including kebabs, burgers and offal. The roast meat entries did not stipulate the presence or absence of gravies, which is also a recognised source of *C. perfringens*.

2. Causes of food recalls (Table 3). Most of the food recalls relate to the presence of foreign matter or in relation to potential microbiological contamination, the most common pathogen being *Listeria monocytogenes*.
3. Annual notifications (from all sources) of significant microbiological pathogens, including Shiga toxin-producing *Escherichia coli* and Haemolytic Uraemic Syndrome (STEC and HUS - Fig. 1), *Salmonella* spp. (Fig. 2), *Campylobacter* (Fig. 3), *Clostridium botulinum* (Fig. 4) and *Listeria monocytogenes* (Fig. 5).
4. ESAM data from Australian abattoirs (Figs 6 to 9).
5. Residue violations from the Australian National Residue Survey (Tables 4 to 6).

Table 1. List of foodborne outbreaks (associated with red meat products/dishes containing red meat products) for the period, 2005-2014 (OzFoodNet, 2017)

Year	Aetiology	Food vehicle	Setting preparation/consumption	Ill	Hospitalised	Died[A]	1°/2° Growth factor	Contamin'n factors 1°/2°	Other characteristics	Compelling evidence
2005	*Listeria monocytogenes*	RTE Silverside-corned beef (ready-to-eat)	Hospital/Hospital	5	5	3[B]	Other situations/ Inadequate or failed disinfection	Cross-contamination from raw ingredients/ Inadequate cleaning of equipment		TRUE
2005	*Clostridium perfringens*	Braised Steak & Gravy	Aged care/Aged care	36	-	-	Slow cooling/ Insufficient time/ temperature during reheating	Not applicable	PCR for cpe gene was positive and chromosomally carried for both food and case isolates. FB strains	FALSE
2005	*Clostridium perfringens*	Beef Rendang	Restaurant/ Restaurant	3	-	-	Slow cooling	Not applicable		FALSE
2005	*Clostridium perfringens*	Chicken and / or lamb guvec	Restaurant/ Restaurant	14	-	-	Foods left at room or warm temperature/Slow cooling/ Insufficient time-temperature during reheating	Not applicable		FALSE
2005	*Unknown*	Veal rolls or red curry	Commercial Caterer/ Commercial Caterer	40	-	-	Unknown	Unknown		FALSE
2005	Unknown	Suspected beef steak	Restaurant/ Restaurant	2	-	-	Inadequate refrigeration	Cross-contamination from raw ingredients/ Storage in contaminated environment		TRUE
2005	Unknown	Suspected Big Mac beef burger	Restaurant/ Restaurant	2	-	-	Unknown	Ingestion of contaminated raw ingredients/ Cross-contamination from raw ingredients		FALSE
2005	*Salmonella* Typhimurium 197	Lambs liver	Private Residence/ Private Residence	43	13	-	Unknown/ Inadequate thawing and cooking	Ingestion of contaminated raw ingredients		FALSE
2005	Unknown	Lamb, beef	Restaurant/ Restaurant	5	-	-	Insufficient cooking/ Insufficient time-temperature during cooking	Cross-contamination from raw ingredients		FALSE

Year	Aetiology	Food vehicle	Setting preparation/consumption	Ill	Hospitalised	Died[A]	1°/2° Growth factor	Contamin'n factors 1°/2°	Other characteristics	Compelling evidence
2005	Unknown	Roast beef and gravy	Take-away, Private Residence/Private Residence	4	-	-	Unknown	Cross-contamination from raw ingredients		TRUE
2005	*Salmonella* Typhimurium 135a	Hamburgers; mayonnaise (homemade)	Restaurant/ Restaurant	11	1	-	Delay between preparation & consumption/ Insufficient cooking/ Insufficient time-temperature during cooking	Ingestion of contaminated raw ingredients/ Cross-contamination from raw ingredients		TRUE
2005	Unknown	Beef casserole	Commercial Caterer, Private Residence/ Private Residence	13	-	-	Unknown	Unknown		FALSE
2005	Unknown	Suspected roasted meats served hot from carvery	Restaurant/ Restaurant	5	-	-	Unknown	Unknown		TRUE
2006	*Salmonella* Montevideo	Plain hamburger; egg	Take-away/ Private residence	3	3	-	Unknown/ Other process failure	Cross-contamination from raw ingredients/ Food handler contamination		FALSE
2006	*Salmonella* Typhimurium 170	Beef or chicken burgers/eggs?	Take-away/Unknown	4	2	-	Unknown/ Inadequate thawing and cooking	Cross-contamination from raw ingredients		FALSE
2006	Unknown	Various Indian dishes - rice, beef madras, butter chicken, lamb rogan josh, vegetable curry	Restaurant/ Restaurant	24	-	-	Inadequate refrigeration	Unknown		TRUE
2006	*Salmonella* Typhimurium 170	Suspect Beef or Chicken Hamburger with salad, cheese, bacon	Take-away/Other[†]	4	1	-	Unknown	Unknown		TRUE
2006	*Clostridium perfringens*	Chicken & Lamb Guvec	Restaurant/ Restaurant	13	Unknown	-	Foods left at room or warm temperature/ Insufficient time-temperature during reheating	Other source of contamination		FALSE
2006	Unknown	Query oysters, lobsters, prawns, rainbow trout, icecream, sashimi, crab, mussels, beef curry	Restaurant/ Restaurant	13	-	-	Unknown	Unknown		TRUE
2007	*Salmonella* Typhimurium	100% beef patties	Private residence/Private Residence	8	2	-	Insufficient cooking	Ingestion of contaminated raw products/		FALSE

[†] Assumed the same entry as in 2006 OzFoodNet Annual report: Camp, 3 ill including 1 hospitalised; suspect chicken/beef hamburger cross-contaminated with eggs

Year	Aetiology	Food vehicle	Setting preparation/consumption	Ill	Hospitalised	Died[A]	1°/2° Growth factor	Contamin'n factors 1°/2°	Other characteristics	Compelling evidence
								Cross-contamination from raw ingredients		
2007	Unknown	Raw capsicum, onions, fresh herbs, chicken and/or beef	Restaurant/ Restaurant	14	-	-	Insufficient cooking/Modified atmosphere packaging, insufficient time-temperature during cooking	Cross-contamination from raw ingredients/ Storage in contaminated environment		FALSE
2007	Unknown	Suspected beef or lamb kebab	Take-away/ Restaurant	4	-	-	Foods left at room or warm temperature	Unknown		FALSE
2007	Unknown	Chicken stirfry or Massaman beef	Restaurant/ Restaurant	9	-	-	Inadequate refrigeration	Unknown	Massaman beef, although no micro-organisms present, revealed high Standard Plate Count	TRUE
2007	*Campylobacter*	Meat kebab (Species?)	Take-away/Other	2	1	-	Unknown	Unknown		TRUE
2007	*Unknown*	Meat curry suspected (Species?)	Take-away/Private residence	17	-	-	Foods left at room or warm temperature/ Slow cooling// Insufficient time-temperature during reheating	Not applicable		TRUE
2008	*Clostridium perfringens*	Suspected savoury mince	Institution/Institution	15	-	-	Slow cooling/ Insufficient time-temperature during reheating	Not applicable		TRUE
2008	Unknown	Multiple meat based foods (reported as lamb tenderloin and gravy or roast pork or chicken cacciatore in 2008 OzFoodNet Annual Report))	Restaurant/ Restaurant	41	-	-	Unknown	Unknown		FALSE
2008	Unknown	Rice, naan, butter chicken and lamb sabjwala	Restaurant/ Restaurant	3	-	-	Slow cooling/ Inadequate or failed disinfection	Cross-contamination from raw ingredients/ Inadequate cleaning of equipment		FALSE
2008	*Norwalk-like virus (Norovirus reported in OzFoodNet*	Deli meat & salad dish	Commercial caterer/ Institution	56	-	-	Not applicable	Person to food to person		FALSE

Year	Aetiology	Food vehicle	Setting preparation/consumption	Ill	Hospitalised	Died[A]	1°/2° Growth factor	Contamin'n factors 1°/2°	Other characteristics	Compelling evidence
	Annual Report, 2008)									
2008	*Salmonella* Typhimurium U290	Most likely "chilli beef"	Restaurant/ Restaurant	7	-	-	Foods left at room or warm temperature/ Insufficient time-temperature during cooking	Cross-contamination from raw ingredients/ Inadequate cleaning of equipment		FALSE
2008	Unknown	Stir fry beef with dried hot chilli and peanut from UBUD restaurant	Restaurant/ Restaurant	4	-	-	Unknown	Unknown		FALSE
2008	*Salmonella* Typhimurium 126	Cabanossi and pepperoni sausages	Grocery Store, Delicatessen, Other/Other	2	1	-	Unknown	Unknown		FALSE
2008	*Salmonella* Typhimurium 9	Suspect steak; suspect fried rice	Restaurant/ Restaurant	11	3	-	Unknown	Cross-contamination from raw ingredients		FALSE
2008	Unknown	? Lamb kebab	Take-away/ Unknown	5	-	-	Unknown	Unknown		FALSE
2008	Unknown	Barramundi, lamb, salad	Restaurant/ Restaurant	5	1	-	Unknown	Unknown	No samples taken	FALSE
2008	*B cereus and C. perfringens*	Curry pumpkin, Curry Chicken, Rice with Lamb	Commercial Caterer/ Commercial Caterer	75	-	-	Inadequate hot holding temperature/ Foods left at room or warm temperature/ Insufficient time-temperature during cooking	Storage in contaminated environment/ Other source of contamination		FALSE
2009	*Salmonella* Stanley	Unknown, probably assorted salads, wraps and burgers	Take-away/Unknown	32	7	-	Unknown	Food handler contamination		TRUE
2009	*Salmonella* Typhimurium 170	Unknown - possibly bacon & beef burgers	National franchised fast food	3	1	-	Foods left at room or warm temperature	Unknown		FALSE
2009	*Campylobacter*	Unknown - suspected Hickory Steak with Chips and Salad	Restaurant/ Restaurant	4	-	-	Unknown	Unknown		TRUE
2009	Unknown	Unknown - foods consumed by cases and non-cases were chicken, lamb, beef, and rice (alignment with Unknown, 5 ill, suspected lasagne, chicken Caesar salad?, OzFoodNet Annual Report 2009)	Restaurant/ Restaurant	4	-	-	Unknown	Unknown		FALSE

Year	Aetiology	Food vehicle	Setting preparation/consumption	Ill	Hospitalised	Died[A]	1°/2° Growth factor	Contamin'n factors 1°/2°	Other characteristics	Compelling evidence
2009	Unknown	Stews and curries	Restaurant/ Restaurant	10	-	-	Unknown	Unknown		TRUE
2010	*Bacillus cereus*	Rice (and /or beef curry)	Restaurant/Restaurant	24	-	-	Unknown	Unknown	Commodity nominated as grains/beans in OzFoodNet Annual Report 2010	TRUE
2010	*Listeria monocytogenes*	Cold Meat	Unknown/Community	6	6	4	Unknown	Unknown		FALSE
2010	Unknown	Assorted pizzas (beef, cheese, chicken)	Take-Away/Private Residence	3	-	-	Unknown/ Unknown	Unknown		TRUE
2010	Unknown	Suspect Mongolian lamb or fried rice	Take-Away/Private Residence	2	-	-	Unknown/ Unknown	Unknown		FALSE
2010	Unknown	Probably chicken or beef	Restaurant/ Restaurant	3	-	-	Not applicable	Unknown		FALSE
2010	Unknown	Possibly lamb, beef & chicken skewers and an assortment of vegetables.	Restaurant/ Restaurant	4	-	-	Unknown	Unknown		FALSE
2010	Unknown	Suspected beef pie	Restaurant/ Restaurant	4	-	-	Unknown			FALSE
2010	*Salmonella* Typhimurium 9	Passionfruit Cheesecake; meat pies	Bakery/Other	19	2	-	Insufficient cooking	Ingestion of contaminated raw products	Pers. comm.: almost certainly egg based. Perhaps egg glaze on pie post cooking.	FALSE
2010	*Clostridium perfringens*	Roti Curry Lamb	Restaurant/ Restaurant	4	-	-	Foods left at room or warm temperature/Slow cooling	Not applicable		FALSE
2010	*Campylobacter*	Steak with chicken liver paté	Restaurant/ Restaurant	18	2	-	Unknown	Unknown		FALSE
2011	*Clostridium perfringens*	Roast Beef	Commercial Caterer/ Commercial Caterer	41	-	-	Delay b/w preparation & consumption	Not applicable		FALSE
2011	*Clostridium perfringens*	Roast beef suspected	Private Caterer/ Community	17	-	-	Delay b/w preparation & consumption/ Inadequate refrigeration	Not applicable		TRUE
2011	*Salmonella* Typhimurium	Kebabs (PT 197, poultry, lamb association in OzFoodNet Annual Report 2011)	Take-Away/ Community	9	1	-	Inadequate thawing	Other source of contamination/ Inadequate cleaning of equipment		FALSE

Year	Aetiology	Food vehicle	Setting preparation/consumption	Ill	Hospitalised	Died[A]	1°/2° Growth factor	Contamin'n factors 1°/2°	Other characteristics	Compelling evidence
2011	Unknown	Suspect lamb curry	Commercial Caterer/ (Fair/Festival/Mobile service)	16	-	-	Unknown/ Unknown	Unknown/ Unknown		FALSE
2011	*Salmonella* Typhimurium 9	Beef kebab with onion, lettuce, tomato, cheese, BBQ & garlic sauce	Take-Away/ Community	5	2	-	Not applicable	Cross-contamination from raw ingredients		TRUE
2011	Unknown	Beef rendang or pork satay	Restaurant/ Restaurant	7	-	-	Foods left at room or warm temperature	Not applicable		TRUE
2012	*Salmonella* Newport	Kebabs	Restaurant/ Restaurant	10	-	-	Unknown	Unknown		TRUE
2012	*Salmonella* Typhimurium 9	Doner kebab	Fair/Festival/ Mobile service/ (Fair/Festival/Mobile service)	10	3	-	Unknown	Cross-contamination from raw ingredients		TRUE
2012	Unknown	Lamb salad	Commercial Caterer/ Function	16	1	-	Unknown/ Unknown	Unknown	3 samples tested were negative for bacteria and norovirus EIA, 1/3 was negative for STEC.	FALSE
2012	*Clostridium perfringens*	Roast beef (buffet)	Restaurant/ Restaurant	13	-	-	Inadequate hot holding temperature	Unknown	Enterotoxin A	TRUE
2012	*Clostridium perfringens*	Lamb Curry	Restaurant/ Restaurant	7	-	-	Foods left at room or warm temperature/ Inadequate refrigeration	Not applicable	Biotype A	FALSE
2013	*Listeria monocytogenes*	Pre-prepared frozen meals[C]	Commercially Manufactured	4	4	-	?	?		
2013	*Shigella sonnei* biotype a	Curried Meat - Unspecified Meat	Private Residence/ Private Residence	5	1	-	Not applicable	Food handler contamination		TRUE
2013	Unknown	Beef, chicken, bean and rice dishes	Private Residence/ (Fair/Festival/Mobile service)	6	-	-	Inadequate hot holding temperature	Unknown		FALSE
2013	Unknown	Hamburger with salad	Take-Away/ Private Residence	6	-	-	Unknown	Unknown		FALSE
2013	Unknown	Beef and Guinness pie	Restaurant/ Restaurant	4	-	-	Unknown	Unknown		FALSE
2013	Unknown	Beef taco	Restaurant/ Restaurant	4	-	-	Foods left at room or warm temperature/ Delay b/w preparation & consumption	Unknown		TRUE
2014	*Salmonella* Typhimurium	Lamb shanks or salad	Restaurant/ Restaurant	5	-	-	Insufficient cooking/ Unknown	Cross-contamination from raw ingredients/ Ingestion of	PFGE type 0001	FALSE

Year	Aetiology	Food vehicle	Setting preparation/consumption	Ill	Hospitalised	Died[A]	1°/2° Growth factor	Contamin'n factors 1°/2°	Other characteristics	Compelling evidence
								contaminated raw products		
2014	Unknown	Roast meats (turkey, pork, beef)	Commercial Caterer	13	-	-	Slow cooling/ Insufficient cooking	Unknown/ Not applicable	Incubation, duration, symptoms consistent with Clostridium perfringens	FALSE
2014	*Salmonella* Typhimurium	Beef burger	Restaurant/ Restaurant	4	-	-	Unknown	Unknown		TRUE
2014	*Salmonella* Typhimurium	Multiple foods, including sliced deli meats	Bakery/ Private Residence	12	7	-	Inadequate refrigeration	Cross-contamination from raw ingredients/ Inadequate cleaning of equipment	Two open food samples (sliced silverside and sliced roast beef) were positive for *S.* Typhimurium with a MLVA profile identical to the confirmed cases	FALSE
2014	*Salmonella* Chester	Offal stew (lamb intestine, tripe, liver and kidney)	Private Residence/ Other	3	1	-	Foods left at room or warm temperature	Ingestion of contaminated raw products		TRUE
2014	*Salmonella* Chester	Offal (lamb intestine)	Private Residence/ Other	6	3	-	Foods left at room or warm temperature	Ingestion of contaminated raw products		TRUE
2014	*Salmonella* Singapore	Beef Wraps	Restaurant/ Restaurant	15	-	-	Unknown	Cross-contamination from raw ingredients		TRUE
2014	*Salmonella* Typhimurium 44	Beef appetiser or Frittata	Private Residence/ School	10	-	-	Unknown	Cross-contamination from raw ingredients		FALSE
2014	Norovirus	Thai Beef Salad	Commercial Caterer/ Commercial Caterer	53	1	-	Not applicable	Food handler contamination		FALSE
2014	Norovirus	Lamb, lettuce and tomato	Commercial Caterer/ Private Residence	19	1	-	Not applicable	Unknown		FALSE

Notes: Transmission is foodborne or suspected foodborne. Factors of uncertainty: unknown agents and unknown vehicles which can't be attributed to red meat; some dishes contain multiple commodities e.g. vitamised food in aged care; OzFoodNet annual reports only published until 2011; terminology captured in OzFoodNet data request may not have captured all red meat vehicles e.g. vehicle nominated as silverside not beef silverside; meat species vehicle not specified e.g. vehicle nominated generically, e.g. burger, schnitzel (not beef, chicken, veal etc).

Changes made to the data by OzFoodNet for their annual reports may not always be incorporated into state and territory surveillance systems. Similarly, state and territory data may be updated at a later time following the publication of the OzFoodNet annual report and these changes will not be reflected in the OzFoodNet data. Small differences in numbers may hence result between OzFoodNet data and the datasets maintained by the individual states and territories. In addition there may be may influence the serotypes across the different states and territories that may influence the serotype data each year before their

A. Includes foetal deaths

B. Referenced by Givney (2006) in T. Ross et al. (2009)

C. Referenced in Communicable Diseases Network Australia - CDNA (2016)

Glossary

Bakery: Venue which prepares and sells baked bread, pasty and sweet products.

Compelling Evidence: Compelling supportive information was obtained from epidemiological investigation to implicate the food vehicle.

Commercial caterer: Includes wedding receptions or any function where a caterer prepares food for a specific group. Includes commercial catering for airlines.

Community: Outbreak occurs within the community where there is no defined setting.

Fair/festival/mobile service: Fair, festival, markets or other temporary or mobile services.
Foodborne: An incident where two or more persons experience a similar illness after consuming a common food or meal and epidemiological analyses implicate the meal or food as the source of illness.
Function: Non-commercial catered event, e.g. privately catered event in a community setting.
Private residence: Private residences.
Restaurants: Restaurant or café. Includes food served in hotels, meals eaten sitting down (includes food courts).
School: School, preschool, kindergarten, boarding school.
Suspected Foodborne: An incident where two or more persons experience a similar illness after consuming a common food or meal and a specific meal or food is suspected, but person-to-person transmission cannot be ruled out.
Take-away. Includes milk bars, fast food outlets where food is not eaten at the venue.
Unknown: Setting or Factor is not known.

Table 2. Summary of pathogens, by aetiology, implicated with red meat-associated outbreaks (2005-2014) (OzFoodNet, 2017; OzFoodNet Annual Reports; MLA Report V.RBP.0020 Milestone 3, Part 2; Review of the Post-mortem Inspection and Disposition Schedules of the Australian Standard 4696, 2016)

Year	Aetiology	Incidence of Pathogen	Food vehicle	Setting preparation/consumption
2008	*B. cereus and C. perfringens*	2	Curry pumpkin, Curry Chicken, Rice with Lamb	Commercial Caterer/Commercial Caterer
2010	*Bacillus cereus*		Rice (and/or beef curry)	Restaurant/Restaurant
2007	*Campylobacter*	3	Meat kebab (Species unknown)	Take-away/Other
2009	*Campylobacter*		Unknown - suspected Hickory Steak with Chips and Salad	Restaurant/ Restaurant
2010	*Campylobacter*		Steak with chicken liver paté	Restaurant/Restaurant
2005	*Clostridium perfringens*	11	Braised Steak & Gravy	Aged care/Aged care
2005	*Clostridium perfringens*		Beef Rendang	Restaurant/Restaurant
2005	*Clostridium perfringens*		Chicken and / or Lamb guvec	Restaurant/Restaurant
2006	*Clostridium perfringens*		Chicken & Lamb guvec	Restaurant/Restaurant
2008	*Clostridium perfringens*		Suspected savoury mince	Institution/Institution
2008	*Clostridium perfringens*		Curry Pumpkin, Curry Chicken, Rice with Lamb (as above)	Commercial Caterer/Commercial Caterer
2010	*Clostridium perfringens*		Roti curry lamb	Restaurant/Restaurant
2011	*Clostridium perfringens*		Roast beef	Commercial Caterer/Commercial Caterer
2011	*Clostridium perfringens*		Roast beef suspected	Private Caterer/Community
2012	*Clostridium perfringens*		Roast beef	Restaurant/Restaurant
2012	*Clostridium perfringens*		Lamb curry	Restaurant/Restaurant
2005	*Listeria monocytogenes*	2	Silverside-corned beef	Hospital/Hospital
2010	*Listeria monocytogenes*		Commercially manufactured cold meat	Unknown/Community
2014	Norovirus	2	Thai Beef Salad	Commercial Caterer/Commercial Caterer
2014	Norovirus		Lamb, lettuce and tomato	Commercial Caterer/Private Residence
2008	*Norwalk-like virus*	1	Deli meat & salad dish	Commercial caterer/Institution
2014	*Salmonella* Chester	23	Offal stew (lamb intestine, tripe, liver and kidney)	Private Residence/Other
2014	*Salmonella* Chester		Offal (lamb intestine)	Private Residence/Other
2006	*Salmonella* Montevideo		Plain hamburger; egg	Take-away/Private residence
2012	*Salmonella* Newport		Kebabs	Restaurant/Restaurant
2014	*Salmonella* Singapore		Beef wraps	Restaurant/Restaurant
2009	*Salmonella* Stanley		Unknown, probably assorted salads, wraps and burgers	Take-away/Unknown
2007	*Salmonella* Typhimurium		100% beef patties	Private residence/Private Residence
2011	*Salmonella* Typhimurium		Kebabs	Take-Away/Community
2014	*Salmonella* Typhimurium		Lamb shanks or salad	Restaurant/Restaurant
2014	*Salmonella* Typhimurium		Beef burger	Restaurant/Restaurant
2014	*Salmonella* Typhimurium		Multiple foods, including sliced deli meats	Bakery/ Private Residence (Two open food samples -sliced silverside and sliced roast beef were positive for *S.*

Year	Aetiology	Incidence of Pathogen	Food vehicle	Setting preparation/consumption
				Typhimurium with a MLVA profile identical to the confirmed cases)
2008	*Salmonella* Typhimurium 126		Cabanossi and pepperoni sausages	Grocery Store, Delicatessen, Other/Other
2005	*Salmonella* Typhimurium 135*a*		Hamburgers; mayonnaise (homemade)	Restaurant/Restaurant
2006	*Salmonella* Typhimurium 170		Beef or chicken burgers/eggs?	Take-away/Unknown
2006	*Salmonella* Typhimurium 170		Suspect Beef or Chicken Hamburger with salad, cheese, bacon	Take-away/Other
2009	*Salmonella* Typhimurium 170		Unknown - possibly bacon & beef burgers	National franchised fast food
2005	*Salmonella* Typhimurium 197		Lambs liver	Private residence/Private Residence
2014	*Salmonella* Typhimurium 44		Beef appetiser or Frittata	Private Residence/School
2008	*Salmonella* Typhimurium 9		Suspect steak; suspect fried rice	Restaurant/Restaurant
2010	*Salmonella* Typhimurium 9		Passionfruit cheesecake; meat pies	Bakery/Other
2011	*Salmonella* Typhimurium 9		Beef kebab with onion, lettuce, tomato, cheese, BBQ & garlic sauce	Take-Away/Community
2012	*Salmonella* Typhimurium 9		Doner kebab	Fair/Festival/Mobile service/(Fair/Festival/Mobile service)
2008	*Salmonella* Typhimurium U290		Most likely "chilli beef"	Restaurant/Restaurant
2013	*Shigella sonnei* biotype a*	1	Curried meat - Unspecified Meat	Private Residence/Private Residence
2005	Unknown	33	Veal rolls or red curry	Commercial Caterer/Commercial Caterer
2005	Unknown		Suspected beef steak	Restaurant/Restaurant
2005	Unknown		Suspected Big Mac beef burger	Restaurant/Restaurant
2005	Unknown		Lamb, beef	Restaurant/Restaurant
2005	Unknown		Roast beef and gravy	Take-away, Private Residence/Private Residence
2005	Unknown		Beef casserole	Commercial Caterer, Private Residence/Private Residence
2005	Unknown		Suspected roasted meats served hot from carvery	Restaurant/Restaurant
2006	Unknown		Various Indian dishes - rice, beef madras, butter chicken, lamb rogan josh, vegetable curry	Restaurant/Restaurant
2006	Unknown		Query oysters, lobsters, prawns, rainbow trout, icecream, sashimi, crab, mussels, beef curry	Restaurant/Restaurant
2007	Unknown		Raw capsicum, onions, fresh herbs, chicken and/or beef	Restaurant/Restaurant
2007	Unknown		Suspected beef or lamb kebab	Take-away/ Restaurant
2007	Unknown		Chicken stirfry or Massaman beef	Restaurant/Restaurant
2007	Unknown		Meat curry suspected (Species?)	Take-away/Private residence
2008	Unknown		Multiple meat based foods	Restaurant/Restaurant
2008	Unknown		Rice, naan, butter chicken and lamb sabjwala	Restaurant/Restaurant
2008	Unknown		Stir fry beef with dried hot chilli and peanut from UBUD restaurant	Restaurant/Restaurant
2008	Unknown		? Lamb kebab	Take-away/ Unknown
2008	Unknown		Barramundi, lamb, salad	Restaurant/ Restaurant
2009	Unknown		Unknown - foods consumed by cases and non-cases were chicken, lamb, beef, and rice	Restaurant/Restaurant
2009	Unknown		Stews and curries	Restaurant/Restaurant

Year	Aetiology	Incidence of Pathogen	Food vehicle	Setting preparation/consumption
2010	Unknown		Assorted pizzas (beef, cheese, chicken)	Take-Away/Private Residence
2010	Unknown		Suspect Mongolian lamb or fried rice	Take-Away/Private Residence
2010	Unknown		Probably chicken or beef	Restaurant/Restaurant
2010	Unknown		Possibly lamb, beef & chicken skewers and an assortment of vegetables	Restaurant/Restaurant
2010	Unknown		Suspected beef pie	Restaurant/Restaurant
2011	Unknown		Suspect lamb curry	Commercial Caterer/ (Fair/Festival/Mobile service)
2011	Unknown		Beef rendang or pork satay	Restaurant/Restaurant
2012	Unknown		Lamb salad	Commercial Caterer/Function
2013	Unknown		Beef, chicken, bean and rice dishes	Private Residence/(Fair/Festival/Mobile service)
2013	Unknown		Hamburger with salad	Take-Away/Private Residence
2013	Unknown		Beef and Guinness pie	Restaurant/Restaurant
2013	Unknown		Beef taco	Restaurant/Restaurant
2014	Unknown		Roast meats (turkey, pork, beef)	Commercial Caterer
Not present in collated OzFoodNet response to red meat-associated outbreak data request (2017)				
2006	*Clostridium perfringens*		Lamb korma	Cases: 6, Takeaway. Source: OzFoodNet Annual Report 2006
2006	*Clostridium perfringens*		Suspected beef/ lamb component of doner kebab	Cases: 4, Takeaway. Source: OzFoodNet Annual Report 2006
2007	*Clostridium perfringens*		Roast beef dish	Cases: 4. Source: MLA Report V.RBP.0020 Milestone 3, Part 2
2009	*Clostridium perfringens*		Unknown, suspected roast beef, vegetables and gravy	Cases: 4, Restaurant. Source: OzFoodNet Annual Report 2009
2006	*Salmonella* Anatum		Beef burger with bacon and egg	Cases: 5, Restaurant. Source: OzFoodNet Annual Report 2006
2006	*Salmonella* Typhimurium 135		Silverside	Cases: 4, Private Residence. Source: OzFoodNet Annual Report 2006
2006	*Salmonella* Zanzibar		Suspected lamb hotpot, lamb cutlets, hommus, baba ghanoush dip	Cases: 3. Source: MLA Report V.RBP.0020 Milestone 3, Part 2 Cases: 3, 1 hospitalised, Food vehicle unknown. Source: OzFoodNet Annual Report 2006
2005	*Staphylococcus aureus*		Rice, beef and black-bean sauce	Cases: 5. Source: MLA Report V.RBP.0020 Milestone 3, Part 2 (2016)
2005	*Staphylococcus aureus*		Roast beef, pork, chips, gravy	Cases: 2. Source: MLA Report V.RBP.0020 Milestone 3, Part 2 (2016)
2005	Suspected *Staphylococcus* toxin		Suspected lamb dish	Cases: 10. Source: MLA Report V.RBP.0020 Milestone 3, Part 2 (2016)
2011	Unknown		Burgers, schnitzels, chips and salad	Cases: 6, Restaurant. Source: OzFoodNet Annual Report 2011
2014	*Escherichia coli*		Kebab	Gastroenteritis among 3 diners who had eaten from the same takeaway kebab store. Elevated levels of *E. coli* were found in multiple samples of tabouli. Suspected that foods eaten had been either cross contaminated or contained pathogenic *E. coli*, with parsley used in the tabouli being a likely source. (OzFoodNet quarterly report, 1 January to 31 March 2014)

Notes: as per Table 1

Table 3. Recall notifications (isolations) associated with beef, sheepmeat or goatmeat products, 2010-2016

Product	Date	Contaminant
Ballyhigh Pty Ltd Carey Bros Meats brand — Paunch (Lamb Stomach)	21-Nov-16	Potential microbial contamination.
GD Mitchell Enterprises Pty Ltd — Lite n' Easy Traditional Favourites Chargrilled Steak (two varieties)	9-Nov-16	Presence of foreign matter (metal).
Woolworths Limited — Australian pork, lamb and beef mince	17-Oct-16	Potential contamination with metal fragments.
Linke's Central Meat Store — Linke's Garlic Mettwurst, Linke's Plain Mettwurst, Linke's Brandy Mettwurst, Linke's Pepperoni	30-Sep-16	Routine food safety checks being unable to verify the safety of the manufacturing process for these products.
Mrs Mac's Pty Ltd — Bakewell 12 Party Pies	19-Jun-15	Potential foreign object (metal).
Mondo Doro Smallgoods—Mondo Doro Chorizo Hot & Chorizo Mild *(unknown if beef was an ingredient)*	22-Dec-14	Possible *Salmonella* contamination
Tibaldi Australasia Pty Ltd—ALDI Berg Strassburg and ALDI Berg Skinless Hotdogs	1-Dec-14	Microbial contamination
Woolworths Ltd—Homebrand Beef Mince Regular 500g	26-Sep-14	Small fragments of blue food grade plastic
Kalleske Meats—Garlic Metwurst [Beef (50%), Pork (45%)]	18-Aug-14	*E.coli* contamination
Simply Fresh Food Company—Mama Chow Beef Bulgogi Gyoza	25-Jun-14	Presence of foreign matter (clear/white plastic)
Coles Supermarkets Limited—Coles Thick Beef Burger 500g	7-Feb-14	Undeclared allergen (gluten)
Coles—Coles Corned Beef Silverside	27-Nov-13	Undeclared sulphites
Patties Foods Ltd—Four 'N Twenty Aussie Pastie 175g	12-Sep-13	Containing hard plastic
General Mills Australia Pty Ltd—Pasta Master Fresh Lasagne 1.3kg	10-Sep-13	Potential presence of foreign matter (metal).
Pendle Ham and Bacon—Corned Beef (sliced, packaged)	12-Jun-13	*Listeria monocytogenes* contamination.
Melbourne Kosher Butchers—Chicken and Veal Wurst, sliced, vacuum-packed, 200g	14-Mar-13	*Listeria monocytogenes* contamination
Patties Foods Ltd—Four 'N Twenty Angus Beef Potato Pies (4 Pack)	26-Oct-12	Potential foreign matter contamination
Marsh Butcheries—Chorizo Sausages, vacuum-sealed packet available in varying sizes between 350g-400g	1-Jun-12	*Listeria Monocytogenes* contamination
Backa Australia—Chabi *(similar product to salami, unknown if beef included)*	23-Jan-12	Microbial (*Staphylococcus*) contamination.
Woolworths Ltd—Woolworths Australian Beef Mince Premium	28-Jul-11	Foreign matter contamination – soft plastic pieces.
Hunsa Smallgoods—Hunza Chorizo, clear plastic pack, 225g *(contained beef)*	6-Jun-11	*Listeria Monocytogene*s contamination
Sara Lee Australia Pty Ltd—Beef Lasagne	2-Jun-11	Foreign matter – metal, plastic and cloth contamination.
Enrico's Kitchen Pty Ltd—Frozen pizza and pasta products (*beef products included but a mixture of meat products*)	2-Jun-11	Foreign matter – metal, plastic and cloth contamination.
Patties Foods Ltd—Four 'n Twenty Meat Pies	8-Apr-11	Potential Foreign matter contamination – (plastic)
Pacific Trading International Pty Ltd—Gourmet Plus Beef Tomato Cevap – Skinless Sausage	9-Feb-11	Unknown microbial contamination leading to early spoilage of product (product not meeting best before date.)
Solomon Kosher Butcher Pty Ltd—Premium beef mince (diet beef mince - sold loose)	18-Jun-10	Foreign matter – rubber washing-up glove
Borgo Smallgoods Co—Friulano Salame, Lismore Salame and Casalingo Salame (*contained beef)*	31-May-10	*Salmonella Bovismorbificans contamination*
Woolworths Limited—Woolworths label Minced Heart Smart Beef	2-Mar-10	Foreign matter – Plastic pieces

Source: https://www.productsafety.gov.au/recalls
Search criteria: Meat, Seafood and Deli and Chilled and Frozen

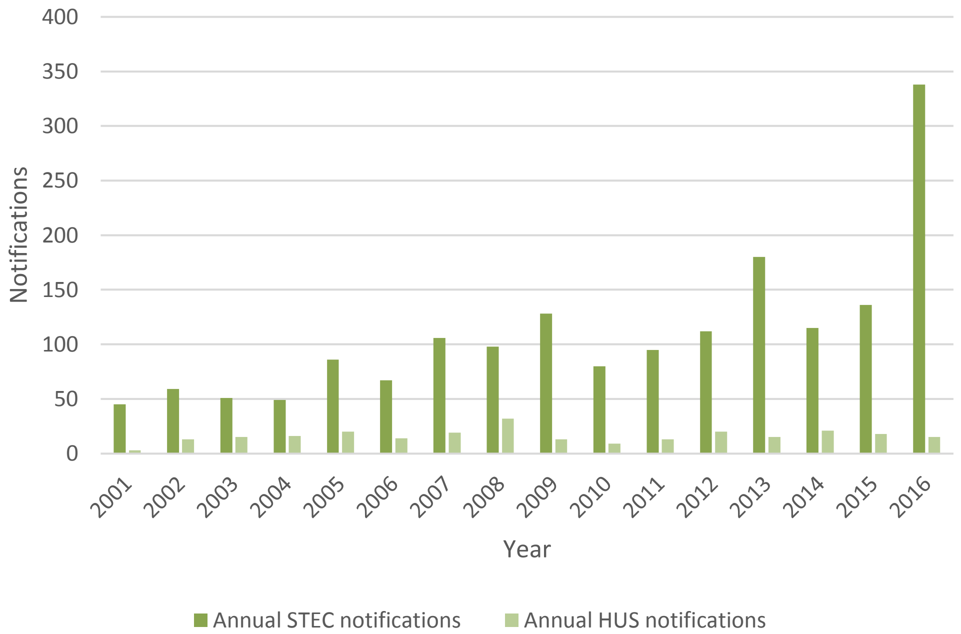

Fig. 1. Number of notifications of STEC and HUS, Australia, for the period 2001-2016 (Aust Government Department of Health NNDSS, 2017)

Although there appears to be an increasing trend of notifications between 2001 and 2015, more recent significant increases in STEC notifications relate to the methods and frequency of testing. Currently, all stool samples collected in hospitals are being screened for STECs. In addition, recent immigrants may have had stool samples analysed for STECS as part of their health check. In relation to the testing method, STEC PCR tests have become more prevalent, and have been (officially) acceptable under the national case definition from 1 July 2016. In April 2016, South Australia Pathology switched to testing every stool received with an STEC PCR. As a consequence of increased surveillance measures, increasing numbers of low pathogenicity STECs are being detected although cases may have mild or no symptoms.

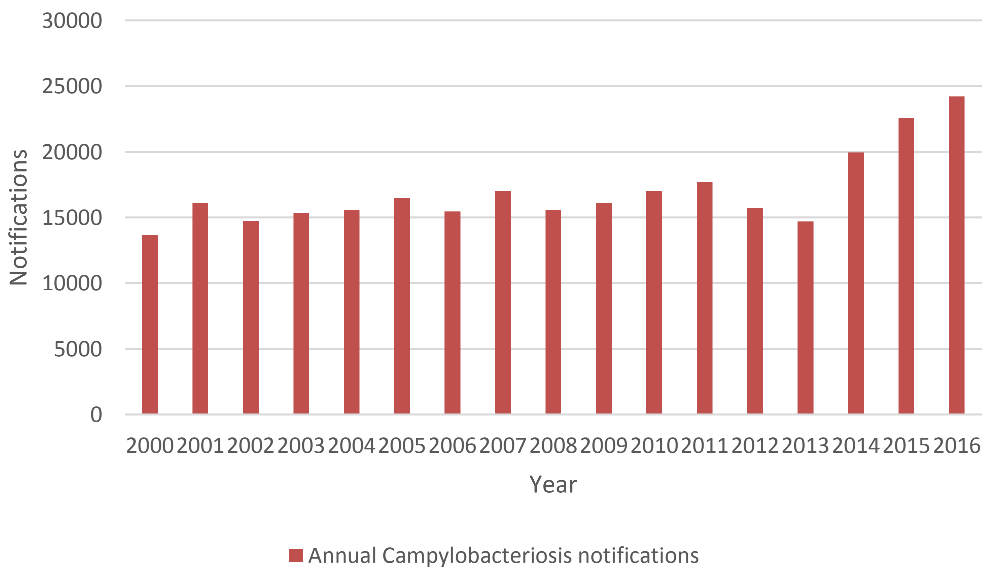

Fig. 2. Number of Campylobacteriosis notifications, Australia, for the period 2000-2016 (Aust Government Department of Health NNDSS, 2017) *(Notes: Campylobacteriosis: for the years 2000- 2005 not reported for NSW because it was only notifiable as a foodborne disease or source of gastroenteritis in an institutional setting)*

Recorded cases of Campylobacteriosis (together with *Shigella*) increased greatly from late 2013 due to the introduction of enteric multiplex PCR panels. According to OzFoodNet, *Campylobacter* and *Shigella* are notoriously difficult to culture and PCR panels are identifying many cases that would not normally have been notified. It is also suspected that General Practitioners prefer the PCR panels due to the more rapid turnaround and much greater likelihood of a diagnosis and have therefore increased their testing rate (OzFoodNet 2017).

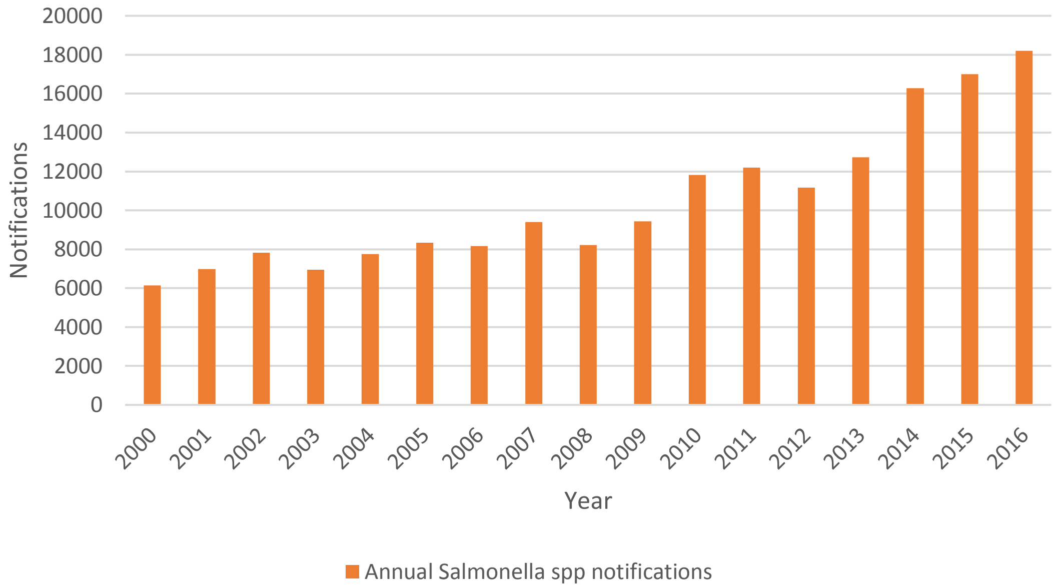

Fig. 3. Number of Salmonellosis notifications, Australia, for the period 2000-2016 (Aust Government Department of Health NNDSS, 2017) (Notes: Salmonellosis: AUS - 2001 - 2008 *Excludes notifications of typhoid)*

The number of notifications of Salmonellosis has been increasing since 2000, with a notable increase since 2011. The addition of typhoid to the notification database does not change the trend line as there are few cases of this disease. *Salmonella* Typhimurium (STm), which makes up 40-50% of national notifications, increased nationally until 2015. This increase was predominantly associated with the consumption of raw or undercooked eggs. In 2016, STm began to decrease in most states but there were 3 large primary produce multi-jurisdictional *Salmonella* outbreaks which increased total numbers. STm is now at record levels in Western Australia. The reasons for this are still under investigation. While not the primary cause, the PCR effect is considered a factor (OzFoodNet 2017).

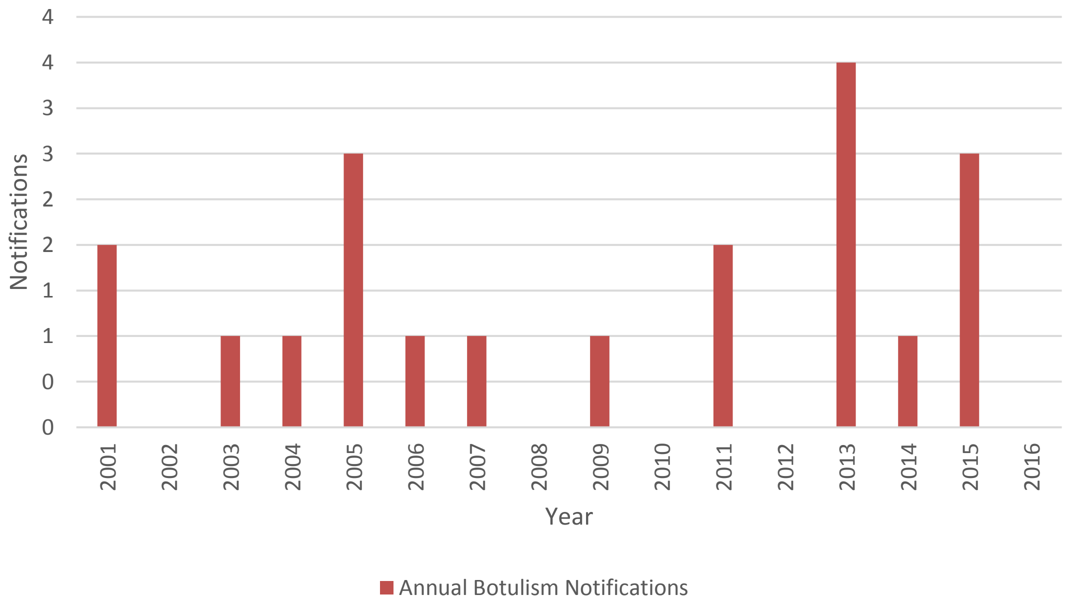

Fig. 4. Number of Botulism notifications, Australia, for the period 2001-2016 (Aust Government Department of Health NNDSS, 2017)

Annual botulism notifications have remained low over the designated time period. Botulism occurrence is sporadic and usually associated with infants (unknown environmental exposure, or honey) or resulting from unsafe food preparation, such as 'home' salami making (OzFoodNet 2017).

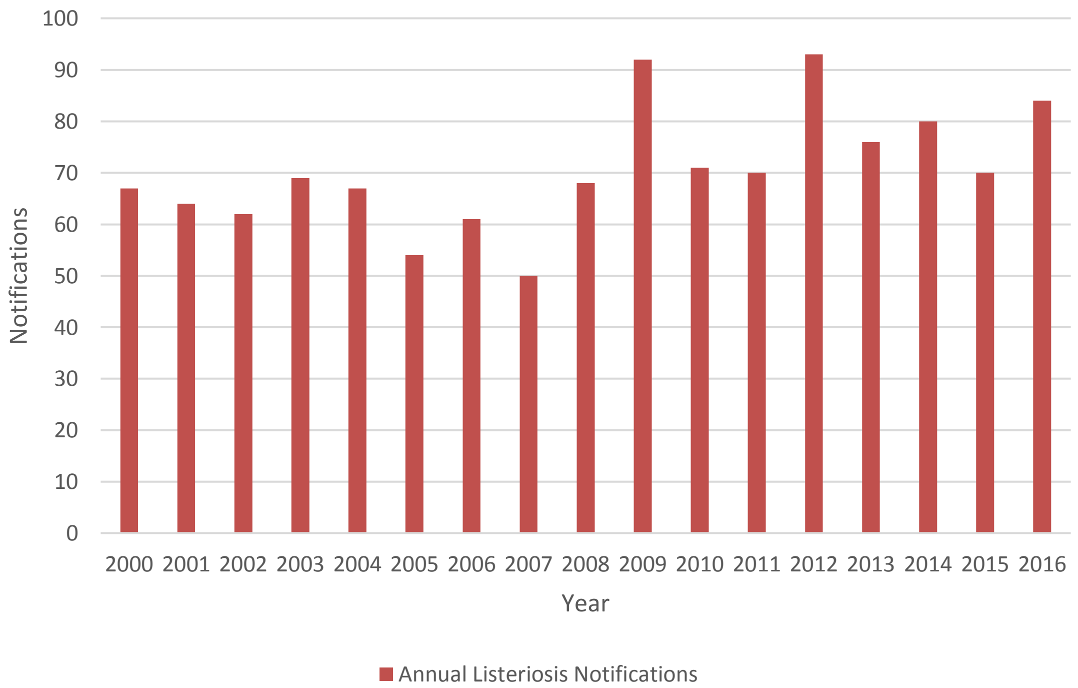

Fig. 5. Number of Listeriosis notifications, Australia, for the period 2000-2016 (Aust Government Department of Health NNDSS, 2017)

The number of listeriosis notifications has shown a very slight upward trend between 2000 and 2016.

As shown in Fig. 6 sheep, lamb and goat (skin off and skin on) counts have been consistently higher than their bovine counterparts since 2012, however the mean $\log_{10}$ counts (cfu/cm^2) have been lower than 0.5 for all, with the exception of one Goat Skin On entry that occurred in January 2012. Overall, the level of *E.coli* on carcases is considered to be low and similar to that reported in previous time periods, such as by Meat and Livestock Australian in 2011 (MLA 2011).The prevalence of *Salmonella* positive carcasses between 2012 and 2016 was negligible or extremely low for beef and sheep, respectively (Fig. 7). Similarly for *E.coli* these results align with results from previous time periods. Goat Skin On had the highest carcase *Salmonella* proportion positive in most recordings taken between January 2012 and July 2012 and with a significant variability between recordings, from 5% to over 30%. Goat Skin Off also exhibited higher levels of proportion positive, in general, than the other species, with an approximate range between 2% and 15%.

In relation to TVC counts (Fig. 8), the mean $\log_{10}$ for beef and sheep carcasses reported for the 2012 to 2016 time period was similar to that reported for the 2007 to 2011 time period (MLA 2011). The highest TVC counts across the designated time period were generally recorded for Goat Skin On followed by Goat Skin Off. The lowest TVC counts were recorded for beef carcasses.

Fig. 9 shows the proportion of STEC positive samples in grinding beef for each month from 2011 to 2016 (total number of confirmed positives divided by total number of samples collected from all establishments). The data points on the STEC graph represent total confirmed positives for a particular month from all establishments. While O157 STEC and estimated non-O157 STEC proportions have varied across the nominated time period, apart from an outlier recording of approximately 0.93%, all scores were less than 0.62% between January 2011 and November 2016. Over the past year there were approximately 1,500 samples tested per month, and currently there are 50 US/Canada listed meat establishments in Australia.

In beef processing, faecal contamination of hides is recognized as the significant source of contamination by enteric pathogens such as *E. coli* and *Salmonella*. However, many variables exist that impact upon the prevalence of pathogenic bacteria. Differences can occur between carcass sampling location, age classes, feedlots, seasons, and production or feeding systems.

"In Australia, the application of Good Agricultural Practice, Good Hygienic Practice and HACCP principles, have resulted in a very low prevalence of *Salmonella* and indicator microorganisms in both manufacturing beef (beef intended for grinding) and primals" (Jenson et al. 2017, p4). The *Salmonella* serotypes found in the survey of faecal samples undertaken by Jenson *et al*. were generally consistent with those previously found in studies of faeces of Australian cattle at slaughter. *Salmonella* Typhimurium was the most common serotype found with *S. Virchow*, *S.* Chailey, and *S.* Dublin found infrequently. *S.* Typhimurium and *S. Virchow* have consistently been amongst the five most highly reported foodborne serotypes isolated from humans in Australia since 2011 (NNDSS 2017, OzFoodNet 2017). The report also stated there is little evidence of beef being implicated to a significant degree in foodborne illness in Australia. Analysis of the Australian public health surveillance outbreak register indicates this statement also applies to sheep and goat meat.

In a 2014 study by Mellor and Barlow, reporting on the prevalence of pathogenic STEC (pSTEC) and *Salmonella*, *E. coli* and Enterococcus from beef cattle groups slaughtered at Australian export registered abattoirs, results indicated that *E. coli* O157 remained the dominant pSTEC in Australian cattle. *E. coli* O26 and *E. coli* O111 were the only other pSTEC serogroups identified. The isolation of pSTEC serogroups O45, O103, O121 and O145 (the remaining 'Big 6' serovars by U.S. standards) did not occur from any sample and is consistent with previous investigations suggesting that detections of these serogroups are extremely rare in Australian cattle (due to not being present, uncommon or present in levels too low to detect in Australian cattle). The study reported a higher prevalence of pSTEC in younger animal than adult animals with the highest prevalence observed in veal calves (which may thus represent a potentially high risk animal class with respect to pSTEC). The animal classes most likely to yield a pSTEC isolate, in order of prevalence, were veal (12.7%), young beef (9.8%), young dairy (7.0%), adult beef (5.1%) and adult dairy (3.9%). When animals were grouped into two classes (young and adult) significantly higher levels of *E. coli* O157 and non-O157 pSTEC serotypes were observed in younger animals. The study also revealed that dairy cattle faecal samples were shown to be significantly more likely to harbor *Salmonella* than samples from beef cattle or veal calves.

Of note was that the three pSTEC serotypes isolated from cattle in this study (O157, O26 and O111) were also the most common Australian clinical serotypes. The lack of pSTEC serotypes O45, O103, O121 and O145 was also strongly supported by human epidemiological data suggesting that these four serotypes are either not isolated or infrequently isolated from humans in Australia. After reviewing the results of other researchers the authors concluded that "Australian *E. coli* O157 isolates appear to have remained stable over time. Despite the fact that isolates were recovered from a large geographic spread of cattle, limited diversity of lineages and SBI genotypes were identified. This finding suggests that *E. coli* O157 are highly conserved within cattle populations across Australia" (Mellor and Barlow 2014 p32).

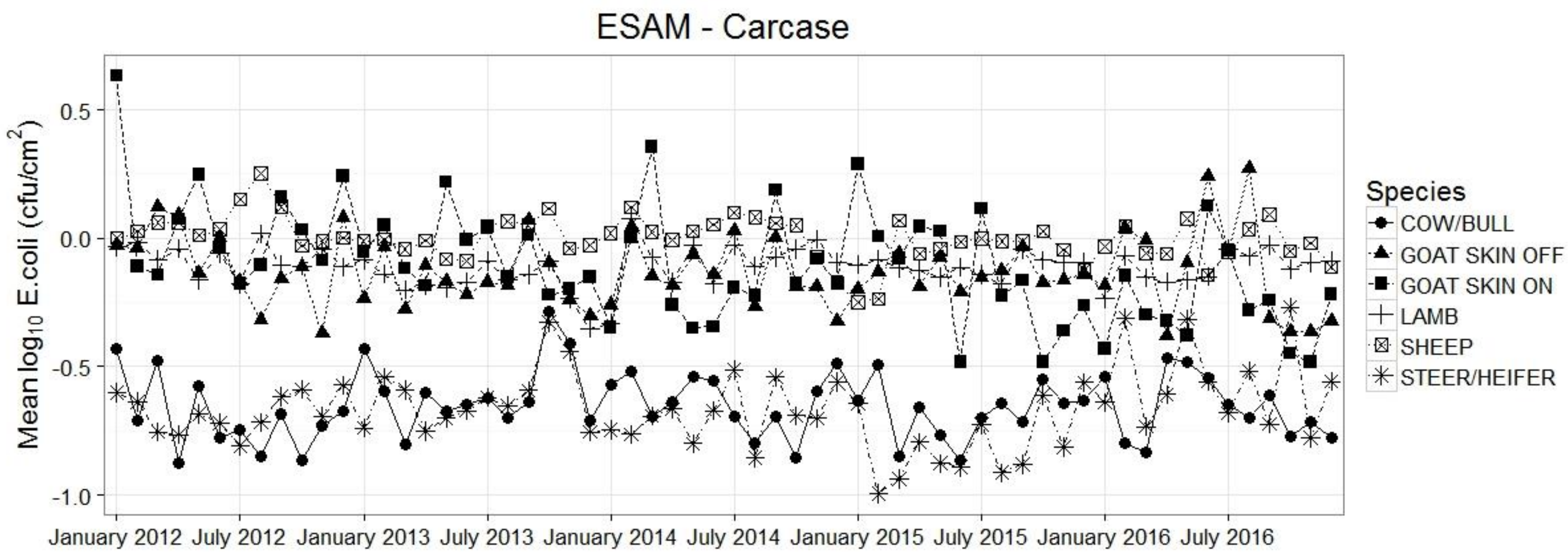

Fig. 6. ESAM Data for *E. coli*, for the period 2012-2016 (Department of Agriculture and Water Resources, 2017)

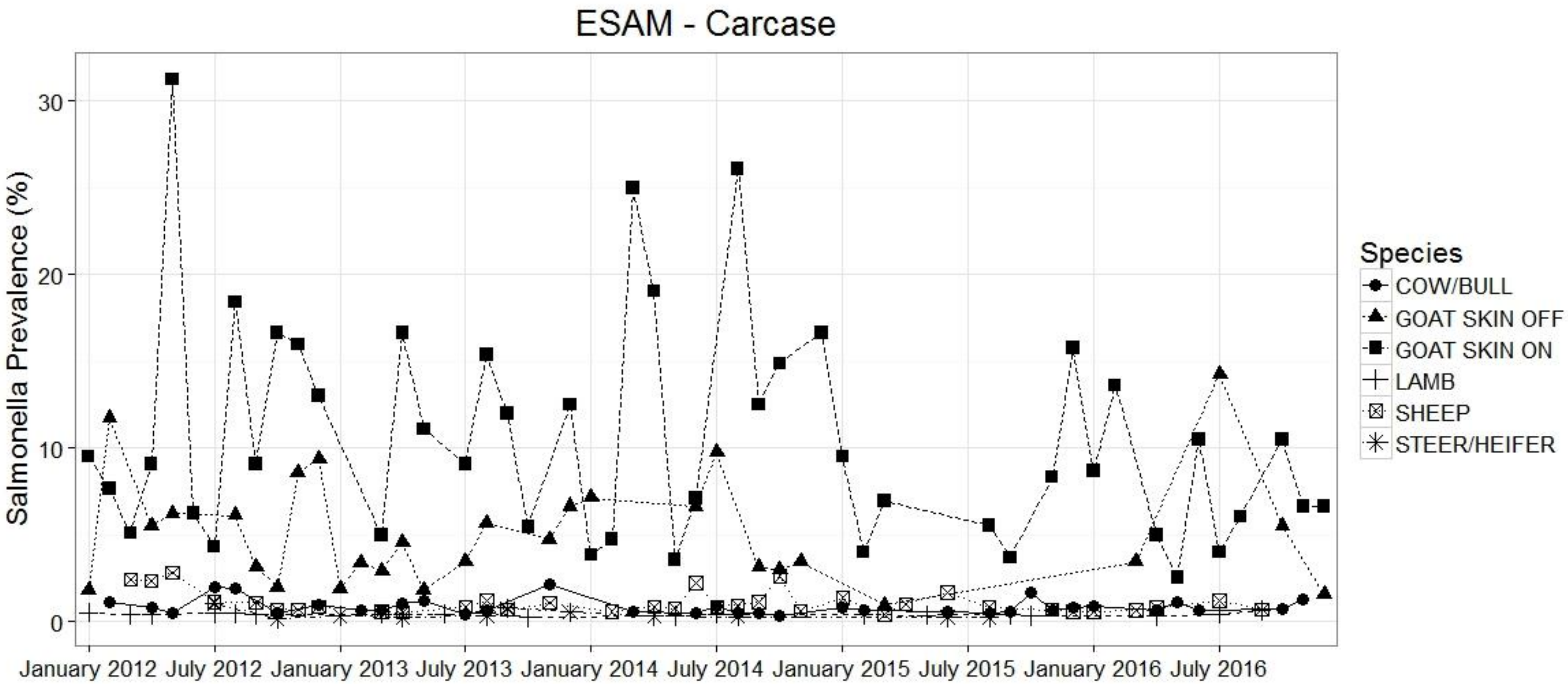

Fig. 7. ESAM Data for *Salmonella* for the period 2012-2016 (Department of Agriculture and Water Resources, 2017)

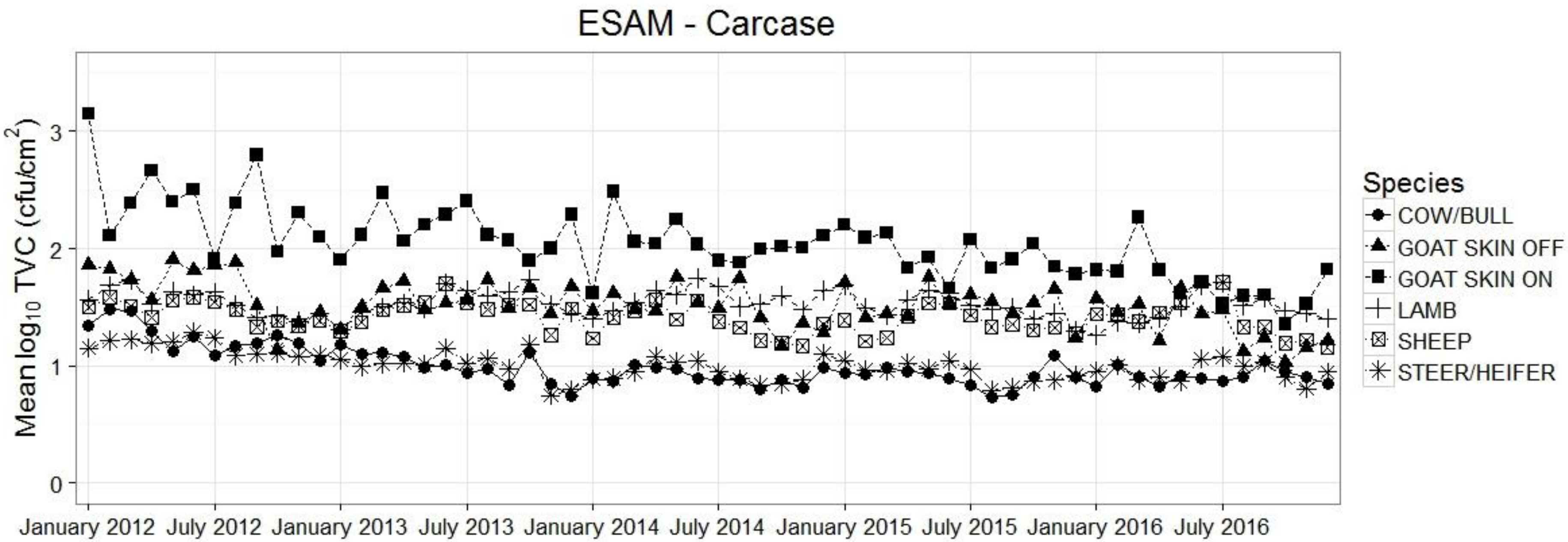

Fig. 8. ESAM Data for TVC (2012-2016) (Department of Agriculture and Water Resources, 2017)

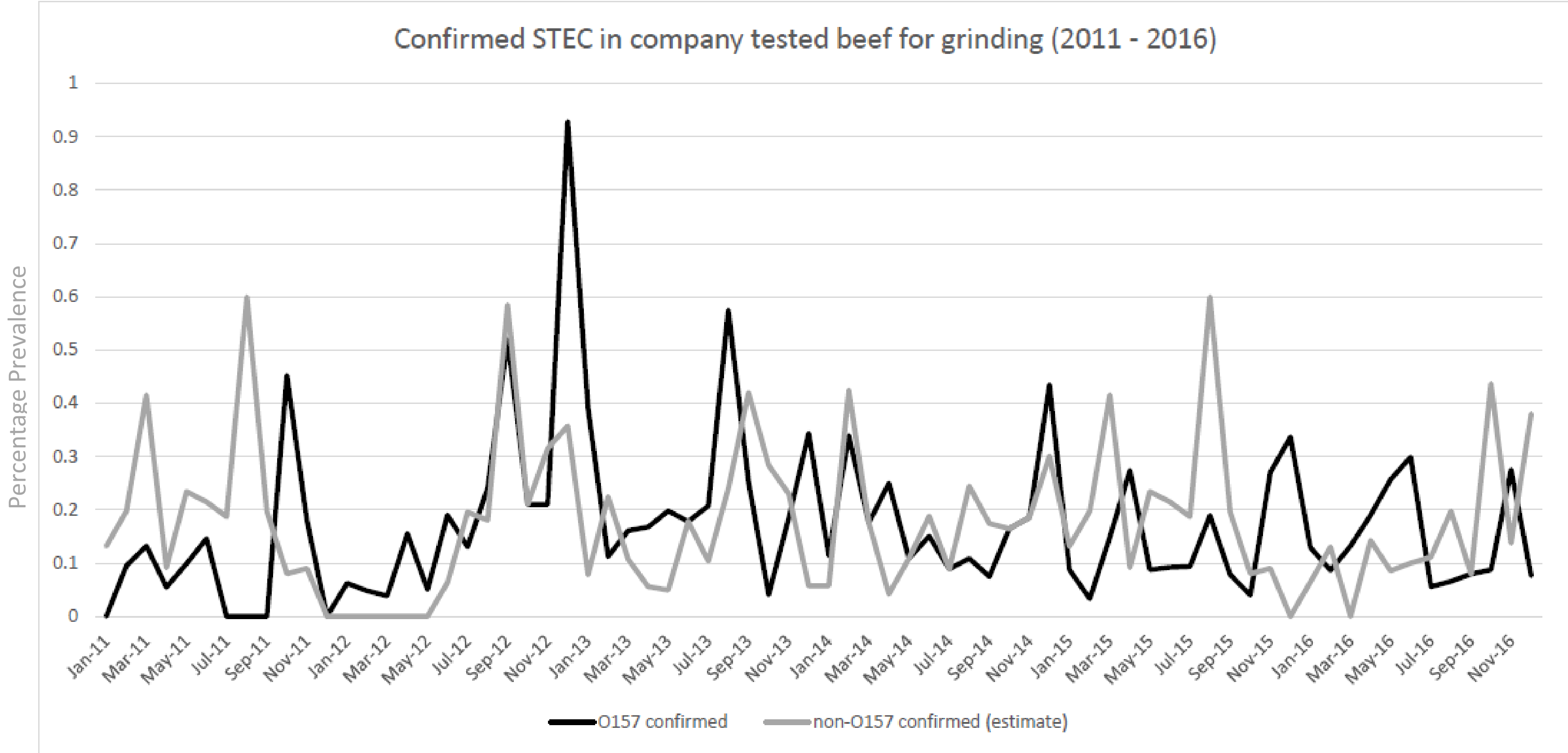

Fig. 9. Confirmed and estimated STEC in company-tested beef for grinding (2011-2016): Percentage Prevalence (Department of Agriculture and Water Resources, 2017) (Notes: incomplete dataset for non-O157 STEC therefore percentage positive may be an underestimation)

Table 4 displays the number of residue violations for each species, against Australian Standards, per annum between January 2011 and December 2016.

- In the 2011-2012 calendar year beef had 4 violations overall for either an anthelmintic, an anticoccidial or an antibiotic, and 2 in 2013-2014 for an insecticide, an antibiotic and a cadmium violation in offal. In 2013-2014 there was a heavy metal non-compliance for lead in offal (liver).
- Sheep products also had a range of violations with heavy metals in various offal samples being above the Australian Standard in each year considered, an insecticide was above limit in 2013-2014, an insecticide and an antibiotic in 2014-2015 and 3 insecticide violations in 2015-2016.
- Rangeland goats are normally not treated with medicines or parasite treatments so it is unusual to detect a violation for one of these products, as occurred in 2013-2014. Because of the extensive (free-range) management system typically used in the goat meat trade, many products are not tested. Changes in monitoring regimens need to reflect any changes to the norm in the extensive management system whereby the risk of exceeding residue limits could rise with increased product use.
- While no limit is set for mercury, it was detected in a number of samples across all 3 species.

Table 5 shows the compliance rate 1 July 2011 to 30 June 2016. There were 111 samples above the Australian Standard for beef, 129 for sheep and 4 for goat (the number of samples tested was considerably less than for the other species). Table 6 provides information on differences between Australian standards and import standards in our export destinations.

Table 4. MRL violations captured in the Australian National Residue Survey for beef, sheep and goat species, 2011-2016.

					2011-12			2012-13			2013-14			2014-15			2015-16		
	Chemical	Matrix	LOR (mg/kg)	Aust. Std	No. of samples tested	No. of samples > LOR ≤ Aust. Std	No. of samples > Aust. Std	No. of samples tested	No. of samples > LOR ≤ Aust. Std	No. of samples > Aust. Std	No. of samples tested	No. of samples > LOR ≤ Aust. Std	No. of samples > Aust. Std	No. of samples tested	No. of samples > LOR ≤ Aust. Std	No. of samples > Aust. Std	No. of samples tested	No. of samples > LOR ≤ Aust. Std	No. of samples > Aust. Std
BEEF																			
INSECTICIDES: BENZOYL UREAS	**chlorfluazuron**	Fat	0.01	1							1		**1**						
ANTHELMINTICS: MACROCYCLIC LACTONES	**ivermectin**	Fat	0.005	0.04	330		**1**												
ANTICOCCIDIALS	**lasalocid**	Liver	0.01	0.7	332		**1**												
ANTIBIOTICS: TETRACYCLINES	**oxytetracycline**	Kidney	0.1	0.6							970		**1**						
ANTIBIOTICS: SULFONAMIDES	**sulfadiazine**	Kidney	0.05	0.1	970		**1**												
ANTIBIOTICS: SULFONAMIDES	**sulfadimidine**	Kidney	0.05	0.1	970		**1**												
HEAVY METALS	**cadmium**	Liver	0.01	**1.25**	**336**	**242**	**0**	**331**	**243**	**0**	**331**	**280**	**1**	**330**	**266**	**0**	**331**	**35**	**0**
	lead	Liver	0.01	**0.5**	**336**	**98**	**0**	**331**	**108**	**0**	**331**	**124**	**0**	**330**	**158**	**1**	**331**	**112**	**0**
	mercury	Liver	0.01	**No Limit**	**336**	**10**	**n/a**	**331**	**5**	**n/a**	**0**	**0**	**n/a**	**330**	**0**	**n/a**	**331**	**4**	**n/a**
SHEEP																			
ANTIBIOTICS: PHENICOLS	**chloramphenicol**	Muscle	0.0003	Not Set							330	0	**1**						
INSECTICIDES: INSECT GROWTH REGULATOR, NOT BENZOYL UREAS, ORGANOCHLORINES,	**fipronil**	Fat	0.02	0.1				791	0	**1**							754	0	**1**

ORGANOPHOSPHATES, CARBAMATES OR PYRETHROIDS																		
INSECTICIDES: OTHER, NOT BENZOYL UREAS, ORGANOCHLORINES, ORGANOPHOSPHATES, CARBAMATES OR PYRETHROIDS	**melamine**	Kidney	0.025	Not Set							330	0	**1**				331	0	**2**
HEAVY METALS	**cadmium**	Liver	**0.01**	**1.25**	**332**	**300**	**11**	**330**	**299**	**5**	**331**	**305**	**10**	**330**	**304**	**6**	**331**	**297**	**3**
	lead	Liver	**0.01**	**0.5**	**332**	**180**	**3**	**330**	**232**	**2**	**331**	**236**	**1**	**330**	**262**	**2**	**331**	**232**	**2**
	mercury	Liver	**0.01**	**No Limit**	**332**	**11**	**n/a**	**330**	**23**	**n/a**	**331**	**34**	**n/a**	**330**	**0**	**n/a**	**331**	**16**	**n/a**
GOAT																		
ANTHELMINTICS: MACROCYCLIC LACTONES	**moxidectin**	Fat	0.005	Not Set							100	0	**1**						
HEAVY METALS	**cadmium**	Liver	0.01	**No Limit**	**50**	**34**	**n/a**	**51**	**36**	**n/a**	**50**	**31**	**n/a**	**50**	**0**	**n/a**	**50**	**38**	**n/a**
	lead	Liver	0.01	**No Limit**	**50**	**7**	**n/a**	**51**	**18**	**n/a**	**50**	**14**	**n/a**	**50**	**0**	**n/a**	**50**	**19**	**n/a**
	mercury	Liver	0.01	**No Limit**	**50**	**1**	**n/a**	**51**	**3**	**n/a**	**50**	**1**	**n/a**	**50**	**0**	**n/a**	**50**	**2**	**n/a**

Source: Australian Government Department of Agriculture and Water Resources, NRS, 2017

Notes:

LOR = Limit of reporting; Aust. Std = Australian Standard

Not set - No Australian Standard has been set for the chemical in the edible matrix and any detection is a contravention of the Australia New Zealand Food Standards Code.

No Limit - No Australian Standard applicable for the contaminant. The 'as low as reasonably achievable' principle applies. Detections at low levels are allowable.

Not defined - Standards are not defined in urine and faeces.

n/a - Australian Standard does not apply. No limit set or defined.

Table 5. MRL Compliance Rate - Australia (1/7/2011-30/06/2016)

Product	Number of samples tested	No. of samples >Aust std	Compliance rate %
Beef	**24524**	**111**	**99.55**
Ovine	**20348**	**129**	**99.37**
Goat	**997**	**4**	**99.60**

Source: Australian Government Department of Agriculture and Water Resources, NRS, 2017

Table 6. Example table indicating where differentials can occur between Australian standards and import standards in our export destinations.

Note: Importing countries may have MRLs that have a lower limits than the Australian Standard or may have limits where Australia has no set or defined limit.

Analyte	Matrix	ASEAN	Australia	Canada	China	Codex	EU	GCC	Hong Kong	India	Indonesia	Japan	Malaysia	North Korea	Russia	Singapore	South Africa	South Korea	Taiwan	Thailand	United States	Vietnam
Cadmium	**Liver**	Not Set	1.25	No Limit	0.5	Not Set	0.5	Not Set	Not Set	Not Set	0.5	No Limit	1	Not Set	0.3	0.2	2	No Limit	Not Set	Not Set	No Limit	Not Set

Source: Australian Government Department of Agriculture and Water Resources, NRS, 2017
Notes:
Pink shading denotes where an importing country MRL is lower than the Australian standard, or an MRL has not been set as per the definition below.
Not set - No Standard has been set for the chemical in the edible matrix and any detection is a contravention of the relevant Food Standards Code.
No Limit - No Standard applicable for the contaminant. The 'as low as reasonably achievable' principle applies.

4.1.2 Outputs of the expert elicitation

The tables below (Tables 7 to 9) detail the qualitatively ranked risks arising from the risk matrix combination of the likelihood parameters and the health severity measures as outlined in the methodology (**Appendix A**). A full list of the Product:Process:Hazard combinations arising from the expert elicitation is shown in **Appendix C**.

The common issues associated with qualitative expert elicitations should be considered when interpreting outputs of the process. Firstly, it is difficult to define scales without ambiguity, as arbitrary differentiation can exist within rating scales. While in this scenario the categories of probability/likelihood were assigned limits, and based on mathematical formulations, they were very broad and nomination of an ordinal score was based on an assessor's experiential judgement (best guess) in the absence of suitable quantitative data. In addition, with any hazard setting there may be many variables with which to contend. Experts needed to make judgements, and to allow transparency of the reasoning behind their decision-making they were requested to make comment regarding the origin of those judgements. Some of the responders made no changes to the issued set of likelihoods (arising from the workshop), or comments, which suggests they were either time poor, had a lack of confidence or a lack of knowledge to adequately rate likelihood. Likelihood ratings can be derived from two sources of thinking, either 1. the likelihood of the product actually being consumed, and 2. the likelihood - if it was consumed - of carrying an infective dose based on epidemiology and other factors. Inherently, in a group elicitation setting, there will be variation in opinion, core knowledge and level of risk adversity. The latter two variables have not been accounted for/weighted in this process.

To control the volume of information generated during the process some generic categories of products (such as offal) and contaminants were specified, i.e. chemicals, mycotoxins and physical contamination. Hence a generic rating was used for those classes despite the variation that may exist with the likelihood or severity categorisation associated with each constituent contaminant. As the list of Hazard:Product:Processes were largely mimicked from beef to sheep and goat meats, some combinations seemingly not commonplace to a particular species have still been recorded (e.g. packaged, cooked, ready-to-eat goat meat). Commentary surrounding likelihood choices were provided by the experts and are available upon request.

Table 7 shows the results of the risk ratings for beef for a general population. Tables 8 and 9 show the cross-comparisons between species for the 'High' and 'Moderate' risk categories. These two tables also provide information on the differences in combinations between species. Detailed information on risk rankings for sheep and goat meat, as well as for restricted (immunocompromised) populations for the three species, is shown in **Appendix D**. For the general population the 'High' risk categories centred around STECs in a variety of food vehicles, including comminuted meat (uncooked and undercooked), fusion-style primal cuts (beef only), offals, shelf-stable meat (beef only), UCFM and paté. *L. monocytogenes* for ready-to-eat packaged product also featured in this risk category. Unusual entries, due to being only cited for goat meat, STECS in Uncooked primal (e.g. carpaccio) and *Salmonella* spp. in uncooked comminuted goat meat were also rated as 'High'. The predominance of STECs as a risk is not directly reflected in the available foodborne outbreak data, however, there were many unknown aetiologies within these investigation data. While the dataset is dated, communication with OzFoodNet suggests that STECs as a source of foodborne outbreaks has not caused additional concern since subsequent data has been collected. Moderate risk combinations -while similar across species - show some variation, as seen in Table 9.

In relation to the risk to restricted or immunocompromised populations, the significant change in severity of ingesting an infective dose result in an increased risk for a number of combinations, which are then elevated to the 'High' risk category (compared to lower risk ranking in the general population). In particular, differences in risk are identified for *Salmonella* spp., *C. difficile* (particularly for those persons undergoing antibiotic therapy), *L. monocytogenes*, *C. perfringens*, and *Mycobacterium paratuberculosis.* The cross-comparison between beef, sheep and goat is also shown in **Appendix D**. Significant additions to the 'Moderate' risk group were *C. difficile, S. aureus* and *Toxoplasma gondii* combinations*,* as well as an additional *C. perfringens* combination.

Table 7. Qualitative risk estimates for Beef Hazard:Product:Process combinations for the general population generated from the expert elicitation

Likelihood x Severity (Qualitative Estimates)	Hazard	Product	Process	Minimum Likelihood Estimate	Severity
High	*L. monocytogenes*	Cooked, ready to eat	Packaged (vacuum, MAP etc)	3	2
	STEC	Comminuted meat	Uncooked	2	1
	STEC	Comminuted meat	Undercooked	3	1
	STEC	Primal	Outside in (commonly served undercooked)	2	1
	STEC	Offal (commonly undercooked)		3	1
	STEC	Paté		2	1
	STEC	Shelf-stable meat		3	1
	STEC	UCFM	Prepared, under Good Manufacturing Practice	3	1
	STEC	UCFM	Preparation, not under GMP	2	1
Moderate	*Campylobacter*	Comminuted meat	Uncooked	4	2
	Campylobacter	Paté		4	2
	C. botulinum	Primal	Vacuum packed and appropriate cooking	4	1
	C. botulinum	Primal	Vacuum packed and undercooked	4	1
	C. perfringens	Primal	Roast - served warm	2	3
	Chemical Contamination- residues above international MRL	Comminuted meat	Uncooked	4	2
	Chemical Contamination- residues above international MRL	Cured meat		4	2
	Chemical Contamination- residues above international MRL	Primal	Aged	4	2
	Cryptosporidium	Comminuted meat	Uncooked	4	2
	Cryptosporidium	Comminuted meat	Undercooked	4	2
	Cryptosporidium	Offal (commonly undercooked)		4	2

	L. monocytogenes	Cooked, ready to eat	Unpackaged	3	2
	L. monocytogenes	Cured meat		3	2
	L. monocytogenes	Primal	Vacuum packed and *undercooked*	4	2
	L. monocytogenes	Paté		3	2
	Mycobacterium paratuberculosis	Offal (commonly undercooked)		3	2
	Mycotoxins (Aflatoxin)	Offal (commonly undercooked)		4	1
	Mycotoxins (Aflatoxin)	Primal	Sous vide (appropriate cooking method)	4	1
	Salmonella spp.	Comminuted meat	Uncooked	3	2
	Salmonella spp.	Comminuted meat	Undercooked	4	2
	Salmonella spp.	Primal	Outside in (commonly served undercooked)	4	2
	Salmonella spp.	Primal	Uncooked (e.g. carpaccio)	4	2
	Salmonella spp.	Offal (commonly undercooked)		3	2
	Salmonella spp.	Paté		3	2
	Salmonella spp.	Shelf-stable meat		3	2
	Salmonella spp.	UCFM	Preparation, not under GMP	3	2
	Salmonella spp.	UCFM	Prepared, under Good Manufacturing Practice	3	2
	STEC	Primal	Uncooked	4	1
Low	*C. difficile*	Offal (commonly undercooked)		3	3
	S. aureus	UCFM	Preparation, not under GMP	3	3
Very Low	*C. difficile*	Comminuted meat	Cooked	4	3
	C. difficile	Comminuted meat	Undercooked	4	3
	C. difficile	Primal	Undercooked	4	3
	C. difficile	Primal	Aged	4	3
	C. difficile	Primal	Cooked	4	3
	C. difficile	Primal	Outside in (commonly served undercooked)	4	3
	C. difficile	Primal	Roast - served warm	4	3

	C. difficile	Primal	Uncooked	4	3
	C. difficile	Primal	Vacuum packed and appropriate cooking	4	3
	C. difficile	Primal	Vacuum packed and *undercooked*	4	3
	C. perfringens	Cooked, ready to eat	Unpackaged	4	3
	Cys. bovis	Comminuted meat	Uncooked	4	3
	Cys. bovis	Comminuted meat	Undercooked	4	4
	Cys. bovis	Offal (commonly undercooked)		4	4
	Mycotoxins (Mycotoxins (Other - Fumonisins, Ochrotoxin A, Trichothecane toxins, Zearlenone)	Primal	Sous vide (appropriate cooking method)	4	3
	Mycotoxins (Mycotoxins (Other - Fumonisins, Ochrotoxin A, Trichothecane toxins, Zearlenone)	Offal (commonly undercooked)		4	3
	Physical Contamination	Comminuted meat	Uncooked	4	3
	Physical Contamination	Comminuted meat	Undercooked	4	3
	S. aureus	Shelf-stable meat		4	3
	Toxoplasma gondii	Primal	Uncooked	4	3
	Toxoplasma gondii	Primal	Undercooked	4	3
	Toxoplasma gondii	Primal	Cooked	4	3
	Toxoplasma gondii	Primal	Vacuum packed and *undercooked*	4	3

Table 8. Cross-comparison between species of 'high' rated risk hazard:product:process combinations for a 'general' population generated from the expert elicitation (refer to Appendix C for tabulated risk for each species)

Hazard	Product:Process	Beef	Sheep	Goat
L. monocytogenes	Packaged, cooked, ready to eat (vacuum, MAP etc.)	✓	✓	✓
Salmonella spp.	Uncooked, comminuted meat	✗ (moderate)	✗ (moderate)	✓
STEC	Uncooked comminuted meat	✓	✓	✓
STEC	Undercooked comminuted meat	✓	✓	✓
STEC	Uncooked primal	✗ (moderate)	✗ (moderate)	✓
STEC	Offal (commonly undercooked)	✓	✓	✓
STEC	Outside in (commonly served undercooked)	✓	✗ (moderate)	✗ (moderate)
STEC	Paté	✓	✓	✗ (not rated*)
STEC	Shelf-stable meat	✓	✗ (moderate)	✗ (moderate)
STEC	GMP UCFM	✓	✓	✓
STEC	Non-GMP UCFM	✓	✓	✓

Notes: *Not rated as considered of negligible occurrence in global cuisine.

Table 9. Cross-comparison between species of 'moderate' rated risk hazard:product:process combinations for a 'general' population (refer to Appendix C for tabulated risk for each species)

Hazard	Product:Process	Beef	Sheep	Goat
Campylobacter	Uncooked comminuted meat	✓	✗ (negligible likelihood**)	✗ (negligible likelihood**)
Campylobacter	Paté	✓	✓	✗ (not rated*)
C. botulinum	Vacuum packed and appropriate cooking of primal products	✓	✓	✓
C. botulinum	Vacuum packed and undercooked primal products	✓	✓	✓
C. perfringens	Roast - served warm (primal)	✓	✓	✓
Chemical Contamination-residues above international MRL	Uncooked comminuted meat	✓	✓	✓
Chemical Contamination-residues above international MRL	Cured meat	✓	✓	✓
Chemical Contamination-residues above international MRL	Aged primal	✓	✗ (negligible likelihood**)	✗ (negligible likelihood**)
Cryptosporidium	Uncooked comminuted meat	✓	✓	✓
Cryptosporidium	Undercooked comminuted meat	✓	✓	✓

Cryptosporidium	Offal (commonly undercooked)	✓	✓	✓
L. monocytogenes	Unpackaged, cooked, ready to eat	✓	✓	✓
L. monocytogenes	Cured meat	✓	✓	✓
L. monocytogenes	Vacuum packed and undercooked primal	✓	✓	✗ (negligible likelihood**)
L. monocytogenes	Paté	✓	✓	✓
Mycobacterium paratuberculosis	Offal (commonly undercooked)	✓	✓	✓
Mycotoxins (Aflatoxin)	Offal (commonly undercooked)	✓	✓	✓
Mycotoxins (Aflatoxin)	Outside in (commonly served undercooked)	✓	✗ (negligible likelihood**)	✗ (negligible likelihood**)
Mycotoxins (Aflatoxin)	Primal cooked sous vide (appropriate cooking method)	✓	✓	✓
Salmonella spp.	Uncooked comminuted meat	✓	✓	✗ (high)
Salmonella spp.	Undercooked comminuted meat	✓	✓	✓
Salmonella spp.	Outside in (commonly served undercooked)	✓	✓	✓
Salmonella sppspp.	Uncooked primal	✓	✓	✓
Salmonella spp.	Offal (commonly undercooked)	✓	✓	✓
Salmonella spp.	Paté	✓	✓	✓
Salmonella spp.	Shelf-stable meat	✓	✓	✓
Salmonella spp.	Non-GMP UCFM	✓	✓	✓
Salmonella spp.	GMP UCFM	✓	✓	✓
STEC	Uncooked primal	✓	✓	✗ (high)
STEC	Shelf-stable meat	✗ (high)	✓	✓
STEC	Outside in (commonly served undercooked)	✗ (high)	✓	✓

Notes:
* Not rated as considered of negligible occurrence in global cuisine.
** Considered of negligible likelihood by expert panel

4.1.3 Review of market access issues and estimation of risk

Risk Ranking of prioritised trade severity issues

Table 10, presented below, depicts the qualitative relative trade risk ranking for particular contaminants (as determined by representatives of the Export Standards Branch in DAWR and AMIC). The designated scoring system used for the risk ranking was 1 to 10, with 1 being low risk and a score of 10 being high risk. Consolidated scores from five directors in the Export Standards Branch, DAWR were averaged, and those scores were agreed upon by the AMIC technical representative. The average scores were then presented to the research team. It was reported that the scores given below take into account the likelihood and potential cost (severity) of incidents. An example was cited regarding potential cost, i.e. that an issue in the Chinese market can be very expensive for an individual abattoir through trade suspension and have flow-on effects to the Australian red meat industry as a whole.

The scores in the table imply that all of the assigned contaminants are of low risk. Where all chemical contaminants were broadly grouped into a single entity of ‘chemical contamination- residues above international MRL' in the risk rating tables (Tables 7 to 9 and **Appendix D**) this classification was segmented for the trade risk appraisal and each resultant category assigned an individual rating (e.g. banned chemicals, persistent chemicals, approved chemicals). When Table 10 is used as an overlay on the qualitative food safety rankings, it reinforces the relative level of risk that STEC, *Salmonella* and 'higher than the MRL' chemical contaminants pose to the industry (i.e. that they are of potentially greater risk than other forms of contamination). The absence of transmissible spongiform encephalopathies indicates they are of negligible risk in the current biosecurity environment.

Table 10. Risk ranking of prioritised trade severity issues according to representatives of the Australian Meat Industry Council (AMIC) and the Department of Agriculture and Water Resources (DAWR)

Contaminant	Average Risk (Range)	Comment
Banned chemicals (e.g. HGPs, beta-agonists, chloramphenicol)	**3.6** (2 for by-products -5)	If detected by importing country may lead to increased testing, suspension trade, imposition of program to regain access.
Contaminants (Pb, Cd, Hg, dioxins etc.)	**3.6** (2-6)	Initially may result in intensified sampling. Repeat detections may result in suspensions. Note China suspended on single detection.
STEC	**2.8** (2-4)	Concern for some important markets, detection may result in product recall and intensified sampling. Repeated detections may lead to suspension of trade.
Salmonella	**2.6** (2-3)	Concern for most markets, low prevalence.
Approved AgVet chemicals not banned by importing country (e.g. antibiotics, parasiticides, crop chemicals)	**2.2** (2-3)	Initially, may result in intensified sampling. Repeated detections may lead to suspension of trade. While NRS data suggests low prevalence nationally, some chemicals have a high regional prevalence and therefore there is a high risk of repeated detection. Can be large number of animals involved, esp. with crop chemicals.
Other microbiological contaminants e.g. coliforms, APC	**1.2** (1-2)	Concern for Russia, detection may result in product recall and intensified sampling. Repeated detections may lead to suspension of trade.
AMR	**1.2** (1-2)	No international standards, no precedents for trade incident other than *Salmonella* DT104 some years ago.
Physical contamination	**1.2** (1-2)	Mostly handled commercially. Issues: seeds on sheep carcases, gun shot in beef. Past issue with gunshot and Korea.
Intentional adulteration	**1.2** (1-2)	Considered unlikely but could be high consequence, e.g. NZ had threat of milk powder contamination with 1080.
Anthrax	**1** (1, but outlier 4 for by-products)	Adequate controls, issue mainly with wool, hides.

<u>Outcomes of the review: Key aspects to consider in relation to market access</u>

The detailed outcomes of the literature review and consultations in relation to market access issues are presented in **Appendix E**. Below are the key aspects to consider, many of which have a direct relationship with food safety:

Trade agreements

Entry into a market may be altered, in the longer term, through government to government access negotiations and trade reform or abruptly through food safety concerns. Trade agreements (multilateral, regional or bilateral) at the government level facilitate trade access, however restrictions underpinning such entry can impinge on the financial benefits of the trade deal (from the exporter's perspective).

Tariff and non-tariff trade barriers

Impediments to trade are imposed in many forms and many of Australia's overseas markets are subject to some form of entry barrier. Tariffs and quotas are the most common border protection measures.

Free trade agreements (FTA)

The reduction or elimination of tariffs as well as improvements to other trade restrictive measures through FTA's has been of great benefit to the red meat industry. However once formalised, there are still lag periods and no restrictions on what other barriers may be presented to either leverage other trade deals or protect domestic industries.

Appropriate Level of Protection (ALOP)

Under WTO law, each member state's sovereign right to choose its own level of regulation is called the 'appropriate level of protection' (ALOP) or 'acceptable risk' which may or may not be based on an international standard (e.g. Sanitary and Phytosanitary Measures Agreement). Protectionism and non-technical trade barriers, being disguised as technical trade barriers, can originate therefore limiting market access despite the caveat of minimisation of trade effects on the exporting country. The ability to achieve the importing country stipulations can come at a cost therefore impacting on competitiveness. For example: sampling regimens, shelf-life requirements, product labelling.

Biosecurity

Regaining market access after it is lost due a biosecurity incursion is a very costly exercise, both from a time and economic perspective.

Business to business

Processors/exporters are looking more and more towards a heightened value proposition and more niche opportunities to counteract Australia's higher cost of production (Australian Meat Processing sector, 2017). New markets need to be researched in terms of desired attributes (credence, quality or integrity) accessed, developed and maintained in an already competitive environment. Resilient business relationships are more likely to overcome any infringements to customer confidence in a product or brand should an unforeseen problem occur.

Supply Limitations and Climatic Pressures – effects on the value chain

The industry remains constrained by several fundamental aspects stemming from inconsistent supply and quality. Over recent years, a major barrier to market access has been the limitation to supply due to drought and the consequent cost of production. In conjunction, there is competition from the live animal export trade in all three species. Not being able to fulfil a market request by volume or specification due to decreased stock levels opens up access for the competition to secure the contract. Economic pressures, higher costs of production and decreased animal health status can all be on the continuum toward consequent food safety implications. The ability of the supply chain to innovate and mitigate potential challenges to efficiency of supply will enhance market access and help to address 'social licence to operate' concerns with infirm stock.

Non-compliances and Maximum Residue Limit violations

Non-compliances can have a severe impact on market access, ranging from trade suspensions to impingements on customer trust. Irrespective of the low numbers of Australian non-compliances (with respect to MRLs) or the possible source of contamination (e.g. not adhering to withholding periods, age of stock, soil or feed) levels of detection above that considered safe for human consumption could therefore lead to serious repercussions for trade and the reputation of red meat. Land and stock management, functional record keeping, an appreciation of food safety and communication with processors are imperative to keep specific (violating) stock out of the food chain. For examples see Table 4 'Risk Ranking of prioritised trade severity issues' in the Methodology section of the Milestone Report.

Consumer trends: attitudes and behaviour

Consumer demands must be considered to ensure continued access, both in market entry and trade growth, to ensure the sustainability of agri-food chains. An AMPC report stated that one of the 8 key trends impacting the industry was 'increasing global standards of environmental protection, food safety and animal welfare' (AMPC 2016 p8). Other, less tangible, credence[‡] drivers relating to ethics and social responsibility (ESR) or perceived health attributes can also impinge on consumer purchasing behaviour. While 'willingness to pay' motivations may not be always apparent in the purchase of branded product (purchase behaviour disparity is evident), these values are often reported in the literature as important to purchase decisions, as is the perceived quality of the product.

Social licence to operate

Along with animal welfare, reduced use of antibiotics, effects of intensive farming practices on stock and the environment, carbon neutrality and sustainable practices (in terms of resource use and emissions) through chain are all factors considered within an industry's social licence to operate. Keeping a watching brief on which elements are having the greatest impact on purchasing behaviour, and responding to them via research into innovation, targets, frameworks and marketing, is key to market access.

Animal welfare/well-being and the consumer

The animal-welfare friendly driver resonates globally amongst various consumer segments and is a key subcategory of an industry's social licence to operate. While animal welfare features as a consumer trend and/or expectation, the link between animal welfare and food safety is recognised and continues to be investigated to increase knowledge around the determinants of the elements and strength of that connection, and the consequent impacts of varying levels of physiological stress.

Health drivers

The place of red meat in a healthy diet is subject to conjecture – from one perspective red meat benefits from the push for higher protein-based diets and the burgeoning protein snack market due to its nutritional density and taste, yet the association with colonic cancers and gastrointestinal inflammation pathways has a negative impact (is red meat actually safe to eat?). Direct red meat replacement with more 'credence-fulfilling' alternatives (such as lab-grown meat or texture-identical vegetable-based products) or the removal of red meat from the diet (or a stance on the continuum in between) is a real challenge to red meat access.

Preservative and salt use

[‡] Food attributes that cannot be readily observed by consumers but that may add value to the product.

Consumers are also seeking less preservative use, predominantly from synthetic/artificial sources, but also from salt-derived sources (e.g. smallgoods) to reduce their overall salt intake, which again has been linked to health impacts.

Antibiotic-free and hormone-free production systems

Antibiotic-free and hormone-free are two other product attributes that are becoming more prominent in the market. Irrespective of their health impact (e.g. as endocrine disruptors) consumer perception determines their importance through shopping spend.

Potential risks associated with red meat consumption

One of the most consistent epidemiological associations between diet and human disease risk is the impact of red meat consumption (beef, pork, and lamb, particularly in processed forms[§]). While risk estimates vary, associations are reported with all-cause mortality, colorectal and other carcinomas, atherosclerotic cardiovascular disease, type II diabetes, and possibly other inflammatory processes. New hypotheses have been postulated specific to red meat, including (1) infectious agents (viruses) in beef (*Bos taurus* in particular) and (2) metabolic incorporation Neu5Gc into the tissues of red meat consumers.

Chemicals, such as Persistent Chemical Contaminants, heavy metals, or toxins (such as mycotoxins) have been recorded within red meat tissue (offal and/or muscle). Levels have exceeded maximum residue limits (where limits exist) in various circumstances so these contaminants, having the potential to enter the red meat supply chain and impact health, warrant due consideration as per Table 3 in the Milestone Report.

The generation of chemicals as a result of the method of cooking (style, temperature and duration) has been noted by various authors. Such contaminants include heterocyclic amines (HCAs) and polycyclic aromatic hydrocarbons (PAHs) and acrylamide.

Increased pathogen virulence and antimicrobial resistance

There is an increasing demand for less antibiotic use in production systems to maintain the effectiveness of available antibiotics. An estimated 25000 human deaths per annum in the EU occur due to AMR infections (EFSA, 2016) or 700,000 deaths per year globally (European Commission Heath and Food Safety 2017). This means the red meat industry needs to consider alternatives to maintaining animal health.

Convenience

Convenience for the consumer (ways to: cook product, attain product, and to package or bundle product) is a driver of many product innovations. However the time-poor consumer may display riskier ‘short-cut’ behaviours and be more willing to chance food safety for the sake of less effort. With the increased number of inputs (and critical control points) associated with tertiary processing the risk to food safety inherently increases.

Cost

Cost factors (compared to other protein sources) are an ongoing market access challenge domestically and internationally. While perceptions around the relative cost (to nutritional value) of meat might be misguided the issue also creates a challenge to increasing market share/access. Value of the Australian dollar is the primary determinant for our trading terms.

Cool chain and chain of custody failures

New methods of food delivery being trialled may pose a food safety risk whereby the reliance on technology, or persons not fully appreciative of the risk cool chain breakdowns carry, may prove

[§] Refers to meat that has been transformed through salting, curing, fermentation, smoking or other processes to enhance flavour or improve preservation.

detrimental. In association with product delivery to premises or homes, the chain of custody (or who bears ownership or responsibility for the product) can become nebulous. This is particularly evident with home-delivery (e.g. products being left in warm conditions, favourable to bacterial growth). In addition, the market environment may pose a risk whereby vendor storage conditions and monitoring may be sub-optimal. Inappropriate placement of temperature monitoring probes in storage facilities and transport vehicles (thereby generating misleading information) tends to be an ongoing issue.

Innovations in processing

Manufacturing Processes

While automation and machination can be used to increase efficiency (DEXA), convenience (mobile abattoirs) and enhance food quality (e.g. the use of blade or needle tenderisers) pathogen colonisation may also increase if good hygiene practices are not followed and biofilms, that form a protective matrix, are allowed to form. It is hoped that future technologies will aid in managing foodborne illness. Such technologies include biotracing, 'omic technologies and other methods of monitoring pathogen behaviour (including gene expression) *in situ* on food surfaces and on implements and preparation surfaces (with respect to contact area and topography).

Packaging techniques

To be truly viable the development of multi-functional packaging (e.g. packaging with biodegradable, active and intelligent functions) or other innovations such as edible coatings/films or nanomaterial packaging, need to maintain or extend key product characteristics yet still meet retailer and consumer's packaging expectations in terms of sustainability and as a communiqué (AMPC 2015). . These characteristics may include quality (comprising various attributes such as colour, texture, etc.), food safety and shelf-life (through management of micro-environmental conditions/atmosphere and provision of an effective barriers to physical, chemical or biological contamination and be leak-proof) Chemical migration from packaging is still under review for various technologies.

Maintenance of quality associations with brand Australia

The risk to Australian product integrity with respect to re-branding of non-Australian product as Australian, the potential for contamination during the cutting / packing process of primals overseas or the slaughter of live animals in overseas destinations is a market concern, especially in terms of reputation. Extending traceability measures beyond Australian borders is an important consideration for the red meat industry.

Recurring issues that pose a risk

There are several issues that have historically posed a risk to red meat food safety and quality and therefore market access. These are:

- Human resource management, whereby staff strikes impact on throughput and food safety in chain elements leading to the processing plant (such as time in lairage) and beyond (e.g. distribution of product) and shelf-life can therefore be affected.
- General business pressure causing human error, such as the requirement for increased throughput leading to increased chances of a food-safety incident occurring.
- Stock entering the chain within withholding periods or presenting with elevated chemical levels from recent exposure or a result of compounding effects from recurrent exposure.
- Pre-slaughter cattle cleanliness affected by season, stress, transport and distance to market.
- Consumer behaviour in terms of care in food preparation and storage. Research suggests that 30% of foodborne illness is caused by cross-contamination in the home (Jakobsen and Verran 2011). Other factors include not cooling cooked foods appropriately or not defrosting appropriately. Consumer expectations can be that presented product has no potential for contamination (sterile).

Food safety risk associated with emerging food industry trends
Review of literature, and discussion with industry personnel, led to the compilation of the following products being noted as of potential future concern, as a result of changing food habits and cuisine as well as processing technologies. Not all products are supported by foodborne outbreak data or associated with violations in the National Residue Survey. However, it is felt a level of risk inherently resides with most products from the perspective of the expert consultation participants (as indicated by the resulting risk categories in Table 7 of this report and those presented in **Appendix D**), feedback from the international market team within MLA, and confirmed by the existence of research reports examining such topics.

Products/processes of concern, as a result of changing food preparation or 12cuisine habits, and processing technologies:

- Offals:
  - green runners (the intestinal runners left after stripping of ingesta – used for casings)
  - Kidney
  - Heart
  - Liver
- Needle/blade tenderised products – biofilms
- Jerky (also known as non-fermented dried meat protein snacks)
- Ready-to-heat meat products (e.g. sous vide, meal kits)

Restaurant or Consumer cuisine / preparation trends:

- dry-aging (restaurant or home)
- Fermentation of meat products (in the restaurant or at home)
- Consumption of home-made sausages (time/temperature)
- Consumption of raw Australian product (overseas) e.g. carpaccio/steak tartare/filet américain/kibbeh
- Consumption of raw product (domestic) e.g. carpaccio/steak tartare/filet américain/kibbeh
- Reduced cooking times to achieve rare product
- Preparation of bone broth (time and temperature control for safety)
- Cross-contamination in food preparation (e.g. consumers not exercising care)
- The presence of antimicrobial-resistant organisms
- Antibiotic-free production systems
- Reduced use of preservatives (synthetic or other) e.g. lowering salt content of processed goods
- Residue violations in red meat products (chemical)
- Residue violations in red meat products (antibiotic)
- Preparation and cooking practices in mobile food service/retail situations e.g. farmers markets (including slaughter methods and delivery methods to buyers), festivals, fairs, food trucks/pop-up restaurants and similar (time/temperature storage, display, cooking)
- Home delivery practices of meat or meat containing products – retail or food service (time and temperature control for safety)
- Exported meat being used beyond recommended expiry dates / washed in local (contaminated) water.

Industry and Government suggested initiatives to enhance food safety and market access
The following points have been compiled from discussions with industry and government:

<u>Improving transparency, traceability and integration along the supply chain</u>

- Enhancing the value to the NLIS by using its capability to help keep Australia's red meat industry ahead of the competition:

  - by including HGP status (to reduce risk of an adverse event)
  - As a supply chain integration tool along the supply chain by producers updating their stock status or to flag an exposure (to reduce risk of an adverse event) as needed and processors providing feedback on carcass attributes.
  - Consideration of scanning stock as they exit the farm for traceability and transparency (of stock movements) purposes and to reduce the risk of an adverse event.
  - Improved integration of NLIS into livestock management, including for disease and residues (linking of state databases on livestock disease status of PICs to NLIS with access for state and federal regulators).
- Getting farmers/producers to better identify themselves as a food (safety) business, and the repercussions to them and the businesses they supply if something goes wrong. Ultimately their market is the consumer also, both in terms of human health and the eating experience.

<u>Regulation and systems auditing</u>

- Systems implemented are made as user friendly/easy to use as possible to avoid disincentives for compliance (especially NLIS).
- Nationally consistent rules and regulations on off-label use and veterinary prescribing rights.
- Nationally consistent livestock feed standards and legislation.
- A strengthened LPA program would be beneficial, especially with respect to record keeping of chemical use {i.e. the ability to verify that withholding periods (WHPs) and export slaughter intervals (ESIs) have been observed if selling for slaughter, or information on chemical or prophylactic use is transferred with animals so buyers can ensure that WHPs and ESIs have been complied with}.
- LPA audits could be made more random (less forewarning) or increased in frequency, as a means to reduce risk.
- Regulatory bodies to persist with follow up of ‘repeat offenders’ who are still to sell into the market but carry high inherent risk.

<u>Meeting consumer expectations</u>

Enhancing the LPA system by adding in a welfare module was a change desired by the processing sector. However, the value of such a system is ultimately decided by customers/clients in terms of whether it meets their consumer’s expectations and from a producer/transporter/processor/auditing point of view, whether meeting those expectations is economically sound and achievable. It is hoped that the design of the system has incorporated all sectors of the supply/value chain in collaboration to create a baseline set of standards, so all parties have the opportunity to ‘own’ the measures, and that the requirements are truly representative of more general consumer sentiment (as opposed to activists). Specific areas of focus are:

- Chain member’s ability to assess suitability, and preparation, of stock for transport to a saleyard or abattoir.
- Chain member skill in transporter selection.
- Truck condition etc. which has a big impact on the welfare process.
- Ensuring the land transport guidelines are seamless from prior to when stock board the truck to when they are offloading. It is imperative that MLA’s fit to load information should be integrated into the LPA requirements.
- Information held by government parties on the types of issues abattoirs are identifying in delivered livestock be considered and worked into any module supporting documentation.
- Integrating the Sustainability framework in a similar way.
- Fast-tracking of research into alternative measures (and the economics of them) considered more humane, to meet consumer expectations (e.g. alternative practices to castration, hot branding and de-horning).

Trade agreements

- To decrease the risk of third party Halal certifiers (of Australian premises) not meeting importing country regulations, due consideration be given to the Federal government employing a Muslim certifier as a tool to instil confidence in importing nations as well as ascribe more accountability in trade suspension events.
- Stronger negotiation skills needed at a Federal level to ensure action is on behalf of the exporters rather than the importing nation, to help with efficiencies of supply.
- Where breakthroughs are made in shelf-life negotiations, the ability of smaller exporters supplying to those new specifications should be analysed, as a risk-management tool.

Ahead of the game

- Understanding what qualifying document might be required to take advantage of new trading terms and having systems (and collaborations) already in place e.g. establishment of shelf-life trials or residue trials.

Maintaining or gaining access to markets

- Skin-on goats to the EU – revisiting/renegotiating trading (including quota) terms to allow skin-on access.
- More accredited plant access to China to allow goat meat export.
- Ensuring education program of US inspectors, with respect to skin pigmentation issues (vs being a microbiological issue) in the US, is continuing in a positive direction.

4.2 Qualitative assessment of the risk

The outcomes of the qualitative assessment conducted to validate the expert elicitation estimates, including the input from the Steering Committee, are presented in Table 11. Only those Product:Process:Hazard combinations that resulted in a Moderate to High risk estimate in the expert elicitation were included in this validation process. The last column of Table 11 provides the expert elicitation estimates for comparison purposes. All estimates using the qualitative risk assessment approach resulted in a risk category equal or lower to those estimated by experts, with significant agreement observed. From the results of these validation process, none of the combinations resulted in a risk higher than Moderate. Those combinations with a Moderate risk result were selected to be considered in the semi-quantitative risk profiling. Despite receiving a low ranking in the qualitative validation process after its addition, dry-aged meat was also included as a prospective product to be reviewed due to it being a product with increasing presence in the market place. In addition, after consultation with the Steering Committee and MLA's Food Safety Risk panel, *Toxoplasma gondii* in undercooked lamb rolled roast or primal was also included in the risk profiling process. These combinations were:

1. Packaged, cooked, ready to heat (vacuum, MAP etc.) *L. monocytogenes*
2. Unpackaged, cooked, ready to eat – *L. monocytogenes*
3. Cured meat (packaged for retail): Dry cured, sliced; Wet-cured, cooked and sliced- *L. monocytogenes*
4. Non-GMP UCFM – *Salmonella* spp., STEC
5. Offal (commonly undercooked) – *Salmonella* spp., STEC
6. Outside in (commonly served undercooked)- *Salmonella* spp., STEC
7. Roast - served warm (sliced primal) – *C. perfringens*
8. Uncooked comminuted meat –*Salmonella* spp., STEC, *Campylobacter*
9. Undercooked comminuted meat - *Salmonella* spp., STEC
10. Uncooked Primal – STEC
11. Vacuum-packed and undercooked primal – *C. botulinum, L. monocytogenes*
12. Dry-aged meat – *Mycotoxins (Rhizopus, Mucor)*
13. Undercooked lamb rolled roast or primal – *Toxoplasma gondii*

A description of the products is provided in Table 12 and a more detailed description of the Product:Process:Hazard combinations is provided in the following sections.

Table 11. Qualitative assessment of the relative risk posed by the Product:Process:Hazard combinations to validate the expert elicitation estimates. Only combinations with a 'High' and 'Moderate' relative risk ratings arising from the expert elicitation have been included (adapted from FSA 2000, MLA 2003, Pointon 2017) *(Highlighted in grey are those combinations to be considered in the semi-quantitative assessment*)

	Product/Process[A]	Nominated Hazard	Severity (general pop'n / immuno-compromised pop'n)[B]	Occurrence risk (Australia 2005-2014)[C]	Growth in product required to cause disease	Production / process / handling ↑↓→hazard	Consumer terminal step	Epi link (world-wide?)[D]	Comments / other factors affecting significance	Risk rating	Estimates from the Expert elicitation (general pop'n / immuno-compromised pop'n)[B]
1	Primal	Chemical Contamination-residues above international MRL	Serious/Serious Trade – Moderate to Severe	Low	No	→	Yes (but no effect on hazard)	Yes (No in Australia 2010-2014)	Persistent compounds. Effect dependent on consumer's prior baseline levels. Mild if considering only one eating occasion. Higher risk with offals[E]	Low	Moderate
2	Cured meat	Chemical Contamination-residues above international MRL	Serious/Serious Trade – Low due to low trade volume/value	Low	No	→	Yes (but no effect on hazard)	Yes (No in Australia 2010-2014)	Undeclared allergen issue but regulations in place. CCP plan required for commercial manufacture	Low	Moderate
3	Cured meat (packaged for retail): Dry cured, sliced; Wet-cured, cooked and sliced. (note: this product/process was further refined to become "packaged, cooked, ready-to-eat" meat products)	*L. monocytogenes*	Serious/Severe	Low	Yes	↓ in processing ↑ in storage and handling or → during handling (retail)	No	Yes	e.g. pastrami, sliced corned meat CCP plan required for commercial manufacture.	Moderate	Moderate
4	Unpackaged, cooked, ready to eat, sliced (e.g. luncheon meats in deli cabinet)	*L. monocytogenes*	Serious/Severe	Low	Yes	↓ in processing. ↑ in storage and handling or → during handling (retail)	No	Yes (Yes in Australia 2010-2014)	e.g. roast beef CCP plan required for commercial manufacture and preparation at retail.	Moderate	Moderate
5	Packaged, cooked, ready to heat (vacuum, MAP etc.)	*L. monocytogenes*	Serious/Severe	Low	Yes	↓ in processing ↑ in storage and handling or → during handling (retail)	Yes (if packaging instruction followed)	Yes	Industry CCP code of practice required for commercial manufacture	Low – Moderate (moderate if instruction not followed)	High
6	GMP UCFM	*Salmonella* spp.	Serious/Severe	Low	Yes	↓	No	Yes	e.g. salami CCP plan required for manufacture.	Low	Moderate

	Product/Process[A]	Nominated Hazard	Severity (general pop'n / immuno-compromised pop'n)[B]	Occurrence risk (Australia 2005-2014)[C]	Growth in product required to cause disease	Production / process / handling ↑↓→hazard	Consumer terminal step	Epi link (world-wide?)[D]	Comments / other factors affecting significance	Risk rating	Estimates from the Expert elicitation (general pop'n / immuno-compromised pop'n)[B]
7	GMP UCFM	STEC	Severe/Severe	Low	No	↓	No	Yes	e.g. salami CCP plan required for manufacture.	Low	High
8	Non-GMP UCFM (Uncooked Comminuted Fermented Meat)	*Salmonella* spp.	Serious/Severe	Low	Yes	↑	No	Yes (No in Australia 2010-2014)	e.g. homemade salami	Moderate	Moderate
9	Non-GMP UCFM	STEC	Severe/Severe	Low	No	↑	No	Yes (No in Australia 2010-2014)	e.g. homemade salami	Moderate	High
10	Offal - commonly undercooked	*Cryptosporidium*	Serious/Severe	Low	No	→	No (partial)	Yes	70 C for at least 2 mins,>74°C reheating to destroy oocysts	Low	Moderate
11	Offal - commonly undercooked	*Mycobacterium paratuberculosis*	Serious/Severe	Low	No		Yes	Yes?	Negligible based on prior MLA risk assessment	Low	Moderate
12	Offal - commonly undercooked	Mycotoxins (Aflatoxin)	Severe/Severe	Low	No	→	Yes	Yes	160°C required	Low	Moderate
13	Offal - commonly undercooked	*Salmonella* spp.	Serious/Severe	Medium	Yes	→ ↑	Yes	Yes (Yes in Australia 2010-2014)	Insufficient cooking	Moderate	Moderate
14	Offal - commonly undercooked	STEC	Severe/Severe	Low	No	→↑	Yes	Yes	Insufficient cooking	Moderate	High
15	Outside in (commonly served undercooked)	Mycotoxins (Aflatoxin)	Severe/Severe	Low	No	→↓	Yes	Yes	160°C required	Low	Moderate
16	Outside in (commonly served undercooked)	*Salmonella* spp.	Serious/Severe	Medium	Yes	→↑	Yes	Yes (Yes in Australia 2010-2014)	e.g. kebabs, fusion CCP plan required for preparation.	Moderate	Moderate
17	Outside in (commonly served undercooked)	STEC	Severe/Severe	Low	No	→↑	Yes	Yes	e.g. kebabs, fusion Insufficient cooking CCP plan required for preparation.	Moderate	High: Beef/ Moderate: Sheep, Goat
18	Paté	*Campylobacter*	Serious/Severe	Low	No	→↑	Yes (if homemade) No (if commercial product in a distribution chain where	Beef, sheep goat unknown Yes to poultry	Insufficient cooking Low infective dose	Low	Moderate

	Product/Process[A]	Nominated Hazard	Severity (general pop'n / immuno-compromised pop'n)[B]	Occurrence risk (Australia 2005-2014)[C]	Growth in product required to cause disease	Production / process / handling ↑↓→hazard	Consumer terminal step	Epi link (world-wide?)[D]	Comments / other factors affecting significance	Risk rating	Estimates from the Expert elicitation (general pop'n / immuno-compromised pop'n)[B]
							cooking step prior)				
19	Paté	*L. monocytogenes*	Serious/Severe	Low	Yes	→↑	Yes (if homemade) No (if commercial product in a distribution chain where cooking step prior)	Yes?	Insufficient cooking	Low	Moderate
20	Paté	*Salmonella* spp.	Serious/Severe	Low	Yes	→↑	Yes (if homemade) No (if commercial product in a distribution chain where cooking step prior)	Yes?	Insufficient cooking	Low	Moderate
21	Paté	STEC	Severe/Severe	Low	Yes/No	→↑	Yes (if homemade) No (if commercial product in a distribution chain where cooking step prior)	Yes?	Insufficient cooking, No known epidemiological link in Australia Low infective dose for 0157:H7	Low	High
22	Primal cooked sous vide (appropriate cooking method)	Mycotoxins (Aflatoxin)	Severe/Severe	Low	No	→	Yes	?	Unlikely to be in muscle. Appropriate cooking	Low	Moderate
23	Roast - served warm (sliced, cooked primal) – food service	*C. perfringens*	Serious/Severe	Medium	Yes	↑	No	Yes	e.g. bain-marie Time / temperature (environment / sauces also a source) CCP plan required for preparation in commercial premises	Moderate	Moderate
24	Shelf-stable meat	*Salmonella* spp.	Serious/Severe	Low	Yes	↓	No	Yes	e.g. jerky establishment with CCPs	Low	Moderate
25	Shelf-stable meat	STEC	Severe/Severe	Low	No	↓	No	Yes		Low	Moderate/High
26	Uncooked comminuted meat	*Campylobacter*	Serious/Severe	Low	Yes	→	No	Yes		Moderate	Moderate
27	Uncooked comminuted meat	Chemical Contamination-residues above international MRL	Serious/Serious Trade - Moderate	Low	No	→	No	Yes	Based on NRS data, likelihood low. Offals carry higher risk.	Low	Moderate

	Product/Process[A]	Nominated Hazard	Severity (general pop'n / immuno-compromised pop'n)[B]	Occurrence risk (Australia 2005-2014)[C]	Growth in product required to cause disease	Production / process / handling ↑↓→hazard	Consumer terminal step	Epi link (world-wide?)[D]	Comments / other factors affecting significance	Risk rating	Estimates from the Expert elicitation (general pop'n / immuno-compromised pop'n)[B]
28	Uncooked comminuted meat	*Cryptosporidium*	Serious/Severe	Low	No	→	No	Yes		Low	Moderate
29	Uncooked comminuted meat	*Salmonella* spp.	Serious/Severe	Low	Yes	→	No	Yes	Addition of lemon juice may have an effect on reducing pathogen count	Moderate	Moderate/High
30	Uncooked comminuted meat	STEC	Severe/Severe	Low	No	→	No	Yes	Addition of lemon juice may have an effect on reducing pathogen count	Moderate	High
31	Undercooked comminuted meat	*Cryptosporidium*	Serious/Severe	Low	No	↓→	Yes (only partial)	Yes	Some loss of viability has been shown in acid conditions below pH 4.0 (foodsafetywatch.org). Infective dose dependent on virulence. Greatest associations with water-borne illness and faecal oral route with respect to young animals (e.g calves)	Low	Moderate
32	Undercooked comminuted meat	*Salmonella* spp.	Serious/Severe	Low	Yes	↓→	Yes (only partial)	Yes	Low initial levels, growth required. Perhaps reduced with some cooking, however product centre does not receive sufficient heat treatment to inactivate pathogens e.g. hamburger patties	Moderate	Moderate
33	Undercooked comminuted meat	STEC	Severe/Severe	Low	No	↓→	Yes (only partial)	Yes	Few cells required. As above, e.g. hamburger patties	Moderate	High
34	Uncooked primal	*Salmonella* spp.	Serious/Severe	Low	Yes	→	No	Yes	Low initial levels in Aust, growth required, low consumption of carpaccio. Lower potential of contamination	Low	Moderate

	Product/Process[A]	Nominated Hazard	Severity (general pop'n / immuno-compromised pop'n)[B]	Occurrence risk (Australia 2005-2014)[C]	Growth in product required to cause disease	Production / process / handling ↑↓→hazard	Consumer terminal step	Epi link (world-wide?)[D]	Comments / other factors affecting significance	Risk rating	Estimates from the Expert elicitation (general pop'n / immuno-compromised pop'n)[B]
									compared to fresh mince		
35	Uncooked primal	STEC	Severe/Severe	Low	No	→	No	Yes/ No if carpaccio	Few cells required.	Moderate	Moderate/High
36	Vacuum-packed and appropriate cooking of primal (sous vide product could also be considered in this category due to nature of packaging)	*C. botulinum*	Severe/Severe	Low	Yes	↓	Yes	Yes	Toxin neutralisation- Heating food to a typical cooking temperature of 80°C for 30 minutes or 100°C for 10 minutes can greatly reduce the risk of foodborne illness (UF/IFAS 2017).[F]	Low	Moderate
37	Vacuum-packed and undercooked primal (sous vide product could also be considered in this category due to nature of packaging)	*C. botulinum*	Severe/Severe	Low	Yes	→↑	Yes	Yes	Insufficient cooking, (to neutralise toxin and/or kill spores) Anaerobic environment.	Moderate	Moderate
38	Vacuum-packed and undercooked primal (sous vide product could also be considered in this category due to nature of packaging)	*L. monocytogenes*	Serious/Severe	Low	Yes	↑	Yes	Yes	Insufficient cooking, dependent on baseline and handling. Anaerobic environment.	Moderate	Moderate
39	Dry-aged primal	Mycotoxins (Rhizopus, Mucor)	Severe (Immuno-compromised) Moderate? (General)	Low	Yes	↓	Yes	? tbc	Outer layer of product removed before cooking. Banned from production in Vic.	Low	Not included in risk ranking as was considered negligible in the likelihood rating process, although some experts identified as a data gap

Notes:

A. A detailed description of products is provided in Table 12 of this report.

B. Severity is classified, where relevant, into a health and/or trade rating. Severity (of health effects) is based on descriptors in section 3.3.2 of this report and trade effects derived from Table 10;

C. ICMSF approach does not take product volume into account, though 'Occurrence risk' reflects a combination of the amount of product and likely combination.

D. Epidemiological

E. Vulnerability to effect of chemical load is dependent on factors such as historical ingestion of persistent chemicals, age (e.g. blood-brain barrier development, ingestion concentration/body weight), physiology/ability of the consumer to rid from or assimilate chemicals within their body.

F. If toxin present in the surrounding liquor, then it is likely to be in a quantity sufficient to cause illness. The chance of spores on meat surface is likely to be low. Animals with clinical botulism are normally condemned and do not enter the food chain. (MLA Food Safety Risk Panel, pers. comm.)
“Botulinum endospores, which are very resistant to a number of environmental stresses, such as heat and high acid, can become activated in anaerobic environments, low acidity (pH > 4.6), high moisture content, and in temperatures ranging from 4°C to 121°C (Sobel et al. 2004). Temperatures in the range of 115°C to 121°C are needed in order to kill spores (USDA 2015). While the botulinum spores can survive in boiling water, the toxin can be destroyed at high temperatures (heat labile). Heating food to a typical cooking temperature of 80°C for 30 minutes or 100°C for 10 minutes before consumption can greatly reduce the risk of foodborne illness.” (WHO 2000 in University of Florida IFAS 2017)

Table 12. A description of the Product:Process combinations used in the risk profiling exercise.

Product:Process	Description
Comminuted meat	Minced or ground meat *Example: steak tartare (raw- however suggested preparation is by chopping a primal cut finely), hamburgers, meatballs/kofta, sausages.*
Cooking level	- **Raw**: No heat treatment - **Undercooked**: Heated but not to a temperature/time regimen that ensures pathogens or toxins will not cause disease in the consumer (immunocompromised or general populations) - **Appropriate cooking**: Heated to a temperature/time regimen that ensures pathogens or toxins will not cause disease in the consumer (immunocompromised or general populations). This is generally considered to be 72 degrees Celsius however with some pathogens/spores/chemicals this temperature may not be sufficient to inactivate them. - **Rare**: According to the Australian Butchers Guild, for a product to be determined as rare requires an internal temperature of 55-60 degrees Celsius.
Cured	Curing is a food preservation and/or flavouring process, through ageing, drying, canning, salting, brining or smoking. It can be achieved through either wet (brine baths/injections) or dry methods (addition of combinations of salt, nitrates, nitrites, or sugar) *Example:* Corned meat (primal for cooking or RTE, sliced), pastrami.
GMP	Product manufactured under the application of Good Manufacturing Process code guidelines as stipulated, and enforced, by relevant regulatory authorities.
Non-GMP	Products not prepared in certified premises or under guidance by a Good Manufacturing Process code (as above). Commonly referred to as homemade.
Offal	Viscera/organs (e.g. brain, lungs, uterus, heart, kidney, liver); intestines (e.g. tripe, casings) or muscle tissue (e.g. skirt, tongue) or other by-products used for culinary use.
Outside In	Non-intact products, whereby the manufacturing or culinary processes used to create them generate the potential for contaminants on meat surfaces to become encapsulated internally, either mechanically or through rolling, layering, fusing or pressing pieces together such as primal cuts, slices, chunks or cubes. Such products could be also described as reconstituted, restructured or re-formed. *Example: 'fusion' products[**] (fused/'glued' by edible products such as the enzyme transglutaminase, needle or blade tenderised primal cuts, rolled roasts, kebabs (doner or shish), satay sticks.*
Packaged, cooked, ready-to-eat (RTE)	Meat portions (slices) that have been cooked and require no further cooking by the consumer before consumption. Could be vacuum packed or packaged with modified atmosphere packaging.
Packaged, cooked, ready-to-heat	Meat portions that have been cooked and require further cooking (as designated on packaging) by the consumer before consumption. Often accompanied by other products such as vegetables, sauces, and a carbohydrate source such as pasta or rice. Could be vacuum packed or packaged with modified atmosphere packaging. *Example: convenience meal packs*
Primal	A cut of meat whereby the external surface has not been incorporated internally (intact). Cooking level applies (see Comminuted meat) *Example: roasts (muscle portion or bone-in), loin muscle, steak.*

[**] Defined in FSANZ (2016) - raw meat joined or formed into the semblance of a cut of meat. For the labelling provisions, for a food that consists of raw meat that has been formed or joined in the semblance of a cut of meat, whether coated or not, using a binding system without the application of heat, the following information is required: (a) a declaration that the food consists of meat that is formed or joined; and (b) in conjunction with that information, cooking instructions that would result in microbiological safety of the food being achieved.

Shelf-stable	Non-fermented dried meat products, not requiring refrigeration (as opposed to UCFM below) *Example: jerky, biltong*
Sous vide	Method of cooking in which food is vacuum-sealed in a plastic pouch and placed in a water bath or steam environment for longer than normal cooking times (usually 1 to 7 hours) at an accurately regulated temperature much lower than normally used for cooking (typically around 55 to 60 C for meat). The intent is to cook the item evenly, ensuring that the inside is properly cooked without overcooking the outside, and to retain moisture. However undercooking (and extended storage) has the potential to cause illness.
UCFM	Uncooked Comminuted Fermented Meat *Example: salami*
Vacuum-packed	Cryovaced *Example:* shrink-wrapped cooked corn meat available at retail premises or used in food-service; primal cut bagged for export or domestic use (shelf-life extension)

4.3 Semi-quantitative risk ranking

In this section, the outcomes of the semi-quantitative estimation of the public health risk of Hazard:Product:Process combinations and the risk ranking of these combinations are presented. Table 13 provides an overview of the risk rankings generated by Risk Ranger, together with a qualitative description of the uncertainty around these risk rankings, and a comparison with the expert opinion estimates, and the qualitative risk ratings obtained in previous stages of this project and the risk rankings obtained at the 2003 risk profiling exercise. Table 14 provides a list of the combinations ordered by risk ranking. Tables 18 to 33 present the outputs of Risk Ranger and input parameters used for each of the Risk Ranger criteria, with a description of the input and assumptions, and the data sources used to estimate these inputs.

The semi-quantitative risk ranking for the following Hazard:Product:Process combinations was not estimated due to a lack of sufficient data to support estimation of input parameters. The main data gap was the prevalence of contamination of the products with the hazards.

- Offal (commonly undercooked) – *Salmonella* spp., STEC
- Vacuum-packed and undercooked primal – *C. botulinum*
- Dry-aged meat – Mycotoxins (*Rhizopus, Mucor*)

The combinations which resulted in the highest risk ranking involved undercooked hamburgers and STEC *E.coli* O157 (RR 35 to 39) and *Salmonella* spp. (RR 33 to 37) and *Listeria monocytogenes* in packaged and unpackaged ready-to-eat products (RR 35 to 38). These risk rankings are considered to be moderate. The model predicted 11–32 annual cases due to STEC *E.coli* O157, 28–90 due to *Salmonella* spp. and 15 due to *Listeria monocytogenes* among the general population. The range obtained for undercooked hamburgers is dependent on the level of undercooking, with the highest risk resulting in the scenario that assumed a cooking level causing 50% pathogen reduction. Although the predicted cases for *Salmonella* spp. are higher than for the other hazards, salmonellosis in most people causes a mild illness, characterised by a gastrointestinal process which resolves without treatment in less than seven days. In contrast, Listeriosis can have serious health consequences and a high case fatality rate (up to 50%) if a systemic infection occurs. For STEC *E.coli* O157, the severity of the illness was considered similar to *L. monocytogenes* in this assessment, with most infections resulting in bloody diarrhoea (haemorrhagic colitis) and cramping, but with recovery usually within a week. However, a small proportion of patients (generally less than 5%) will suffer more serious outcomes, such as haemolytic uraemic syndrome (HUS) or consequent death (1-4% of HUS cases). While 70% of HUS cases recover completely, the remainder suffer a range of long-term sequelae.

The combination involving *Toxoplasma gondii* in undercooked lamb resulted in a similar risk ranking (RR 38) among the general population, with a substantial number of infections predicted (n = 631). However, previous studies suggest that in most cases exposure in immunocompetent people would not cause clinical illness (Scallan et al. 2011). In contrast, when the population considered for this combination was only pregnant women, who are more susceptible to infection and would suffer a more severe illness, the risk ranking was high (RR 49) with an annual prediction of 142 congenital infections.

For those combinations involving *Clostridium perfringens* and *Campylobacter* spp. the estimated risk ranking was lower. *C. perfringens* in roast beef and lamb among the general population resulted in risk ranking of 27-28, with one to two cases predicted per year. In most cases, this hazard causes mild symptoms, with profuse diarrhoea and abdominal cramps that subside in 24h. The risk ranking increased when only elderly population were considered (RR 36-40), with 5 and 20 cases predicted per year for lamb and beef, respectively. The increase in risk ranking and predicted cases among the elderly population is due to the higher susceptibility and the increased severity of illness. Fatal cases caused by *C. perfringens* are rare and usually occur among the elderly population, where the pathogen can cause necrotising small-bowel disease. *Campylobacter* in undercooked comminuted meat had an estimated risk ranking of 22 to 26, depending on the level of undercooking, with a prediction of up to one case per year. The illness is mild and characterised by an inflammatory process that causes diarrhoea, and this is more common in infants.

Results from this risk profiling exercise indicate that using data available, none of the combinations resulted in a high risk for the general population, and when compared to the 2003 risk profiling results, there has not been an increase on food safety risks posed by the red meat industry, with some combinations posing a lower risk due to improved food safety measures and hygiene practices. The sections below provide a detailed description of the risk ranking estimation for each combination and section 4.4. provides an interpretation of the results in the context of current available data of outbreaks and illnesses due to each of the hazards included in this assessment.

The outputs of the semi-quantitative risk profiling using Risk Ranger v2 should be interpreted considering the level of uncertainty in the input parameters used for each of the combinations. There are many variables across the supply chain continuum that impact upon the chosen input parameters, and as such, on the resulting risk ranking outputs obtained. These sets of variables, relevant to each stage of the chain, determine the prevalence of a hazard at each processing point and subsequently, in the final product. Some of the key variables that contribute to this diversity are:

- farming systems (including age of turnoff) and climate (impacting on general health and well-being of the animal)
- transport management and duration (animal well-being)
- processing facilities with varying hygiene indexes (contamination prevalence)
- modes of carcase breakdown, handling, packaging and storage (risk of contamination)
- cool chain integrity/capability to wholesale, foodservice, retail and home and consequent storage regimen (pathogen growth)

In addition, products may then be exposed to environmentally ubiquitous pathogens (during preparation and cooking), cross-contamination and/or used in a variety of dishes whereby red meat may only be a small component of the final meal thereby creating uncertainty as to the source of contamination. Furthermore, conditions surrounding preparation and cooking vary considerably in manufacturing or the home and within product categories such as ‘outside-in’ or ‘ready-to-heat’ meals that were used to create a collective ranking for a group of individual products with related features. All of these factors, may contribute to the final microbial ecology of the product to be consumed.

Some of the assumptions used when estimating input parameters might have an impact on the accuracy of the risk ranking obtained, for example assuming that the cool chain is maintained (mentioned above), using data arising from reports that may not be ultimately specific to the product or estimating daily consumption from survey data captured over a two day period only. To reflect Australia’s high hygiene standard and give a more appropriate appraisal, Australian data has been used whenever possible. In general however, because of the number of assumptions for each product and the paucity of current prevalence, concentration (CFU/g) data, consumption patterns (amount and frequency) and well-defined international infective dose information, a considerable degree of uncertainty exists for each risk ranking.

The potential variability in product is difficult to incorporate in risk profiling models that are deterministic and semi-quantitative, such as Risk Ranger. However, it is important to stress that a risk profiling exercise is the first step in categorising the risk, to inform subsequent decision making in prioritising activities or resource allocation, and does not aim to accurately estimate the risk.

Table 13. A summary of risk rankings for the Hazard:Product:Process combinations obtained using Risk Ranger v2 (http://www.foodsafetycentre.com.au/riskranger.php) for a 'general' population.

Hazard:Product:Process Combination	Risk Ranking[A]	Uncertainty (estimate and reasons)	Expert estimate	Qualitative risk rating	Risk Ranking 2003
Listeria monocytogenes		*Moderate*			
• Packaged cooked ready-to-eat meat products (Table 18)	35 (Medium)	• Difficult to attribute proportion of contamination that may arise from red meat as opposed to pork or chicken mechanically deboned meat (MDM) in products such as Strasburg • Specific pathogen concentration data on RTE red meat lacking	Moderate	Moderate	36 (for Deli meats in general) (Medium)
• Unpackaged, cooked, ready-to-eat meat products (Table 19)	38 (Medium)	*Moderate* (as above)	Moderate	Moderate	As above
• Packaged, cooked, ready-to-heat meat products (Table 20)	17 (Low)	*Low* • Lack of prevalence and concentration data at retail • Difficult to attribute risk to red meat element as mixed dishes • Multiple forms of ready to heat products	High	Moderate	Not done
• Vacuum packed and undercooked primals (Table 21)	0	*Moderate* • Concentration of contamination data lacking • Production volume ,storage types and times and end-use data very limited	Moderate	Moderate	Not done
Clostridium perfringens		*Moderate*			
• Roast served warm (sliced, cooked primal) in food service (Table 22)	Beef: 28 (Medium) Lamb: 27 (Medium)	• Difficult to account for the range of handling practices in food service • Australian prevalence and concentration data lacking	Moderate	Moderate	46 (High)
Escherichia coli O157					
• Uncooked primals (e.g. steak tartare, carpaccio) (Table 23)	34 (Medium)	*Low* • Difficult to estimate consumption patterns and account for varied preparation practices	High	Moderate	Not done
• 'Outside in' products: 1. Doner kebabs (Table 24)	32 to 38 [B] (Medium)	*Low* • Difficult to account for the range of handling practices • Difficult to predict inactivation levels for degrees of undercooking	High	Moderate	Not done
• 'Outside in' products: 2. Rolled or blade/needle tenderised roasts (Table 25)	35 (Medium)	*Low* • Difficult to account for the range of products and handling practices • Difficult to predict inactivation levels for degrees of undercooking	High	Moderate	Not done
• Undercooked and uncooked comminuted meat products (e.g. undercooked hamburgers, mince) (Table 26)	Undercooked[C]: 35 to 39 (Medium) Uncooked: 34 (Medium)	*Low* • Hard to provide an overall account for the range of products • Degree of inactivation unknown for various cooking levels	High High	Moderate Moderate	Not done Not done

Hazard:Product:Process Combination	Risk Ranking[A]	Uncertainty (estimate and reasons)	Expert estimate	Qualitative risk rating	Risk Ranking 2003
• Non GMP UCFM products (e.g. homemade salami) (Table 27)	25 (Low)	*Low* • Difficult to estimate the proportion of consumption • Unknown degree of compliance to artisan 'tested' methods regarding process inputs and the process itself	High	Moderate	33 (Medium)
Salmonella spp.					
• Undercooked and uncooked comminuted meat products (e.g. undercooked hamburgers, mince) (Table 28)	Undercooked[C]: 33 to 37 (Medium) Uncooked: 32 (Medium)	*Low* • Range of infective doses that are required to cause illness • Degree of inactivation unknown for various heating levels • Difficult to provide an overall account for the range of products	Moderate High	Moderate Moderate	Not done
• 'Outside in' products: 1. Doner kebabs (Table 29)	28 to 34 [B] (Medium)	*Moderate* • Difficult to account for the range of handling practices • Concentration data at foodservice lacking & speculative • Difficult to predict inactivation levels for degrees of undercooking	Moderate	Moderate	40 (kebabs) (High)
• 'Outside in' products: 2. Rolled or blade/needle tenderised roasts (Table 30)	31 (Medium)	*Moderate* • Difficult to account for the range of products and handling practices • Concentration data at retail/foodservice lacking & speculative • Difficult to predict inactivation levels for degrees of undercooking	Moderate	Moderate	Not done
• Non GMP UCFM products (e.g. homemade salami) (Table 31)	21 (Low)	*Low* • Difficult to estimate the proportion of consumption • Unknown degree of compliance to artisan 'tested' methods regarding process inputs and process controls	Moderate	Moderate	33 (Medium)
Campylobacter spp. • Undercooked and uncooked comminuted meat products (e.g. undercooked hamburgers, mince) (Table 32)	Undercooked[C]: 22 to 26 (Low/Medium) Uncooked: 21(Low)	*Moderate* • Data lacking for pathogen prevalence and concentrations • Large variation in reported infective dose	Negligible Moderate	Not assessed Moderate	Not done
Toxoplasma gondii • Undercooked lamb rolled roast or primal (Table 33)	38 (Medium)	*Moderate* • Difficult to estimate the proportion of consumption • Data lacking for parasite prevalence, concentrations and infective dose for humans. • Difficult to predict inactivation levels for degrees of undercooking	Very Low	Not assessed	Not done

A. Arbitrary aggregation of Risk Ranger ratings are: Low (25 or less), Medium (26–40), High (>40). Note that an increment in six units of risk in Risk Ranger outcome, corresponds to approximately a factor of 10 difference in the absolute risk estimate (Ross and Sumner, 2002).
B. Two scenarios considered for kebabs, with and without final heat flashing.
C. The two rankings provided for undercooked products reflect two levels of cooking (meal preparation reduces 50% or 90% of the hazard).

Table 14. Ordered risk rankings for the Hazard:Product:Process combinations obtained using Risk Ranger v2

Hazard:Product:Process Combination	**Current Risk Ranking**	**Order of Ranking**
Escherichia coli undercooked† comminuted meat products (e.g. undercooked hamburgers, mince; 50% reduction) (Table 26)	39	**1**
Listeria monocytogenes Unpackaged, cooked, ready-to-eat meat products (Table 19)	38	**2**
Toxoplasma gondii Undercooked lamb (chilled, rolled or primal cut) (Table 33)	38	**2**
Salmonella spp. undercooked comminuted meat products (e.g. undercooked hamburgers, mince; 50% reduction) (Table 28)	37	**3**
Escherichia coli undercooked comminuted meat products (e.g. undercooked hamburgers, mince; 90% reduction) (Table 26)	35	**4**
Listeria monocytogenes Packaged, cooked, ready-to-eat meat products (Table 18)	35	**4**
Escherichia coli 'Outside in' products -2. Rolled or blade/needle tenderised roasts (Table 25)	35	**4**
Escherichia coli uncooked primals (e.g. steak tartare, carpaccio) (Table 23)	34	**5**
Escherichia coli uncooked comminuted meat products (e.g. undercooked hamburgers, mince) (Table 26)	34	**5**
Salmonella spp. undercooked comminuted meat products (e.g. undercooked hamburgers, mince; 90% reduction) (Table 28)	33	**6**
Escherichia coli 'Outside in' products – 1. Kebab (Table 24)	32 to 38	**7**
Salmonella spp. uncooked comminuted meat products (e.g. undercooked hamburgers, mince) (Table 28)	32	**7**
Salmonella spp. 'Outside in' products – 2. Rolled or blade/needle tenderised roasts) (Table 30)	31	**8**
Salmonella spp. 'Outside in' products -1. Kebabs (Table 29)	28 to 34	**9**
Clostridium perfringens Beef roast served warm (sliced, cooked primal) in food service (Table 22)	28	**9**
Clostridium perfringens Lamb roast served warm (sliced, cooked primal) in food service (Table 22)	27	**10**
Campylobacter spp. undercooked comminuted meat products (e.g. undercooked hamburgers, mince; 50% reduction) (Table 32)	26	**10**
Escherichia coli Non GMP UCFM products (e.g. homemade salami) (Table 27)	25	**11**
Campylobacter spp. undercooked comminuted meat products (e.g. undercooked hamburgers, mince; 90% reduction) (Table 32)	22	**12**
Campylobacter spp. uncooked comminuted meat products (e.g. undercooked hamburgers, mince) (Table 32)	21	**13**
Salmonella spp. Non GMP UCFM products (e.g. home-made salami) (Table 31)	21	**13**
Listeria monocytogenes Packaged, cooked, ready to heat meat products (Table 20)	17	**14**
Listeria monocytogenes Vacuum packed and undercooked primals (Table 21)	0	**15**

Notes: The two rankings provided for undercooked products reflect two levels of cooking (meal preparation reduces 50 or 90% of the hazard).

4.3.1 Detailed description of risk rankings

This section presents a detailed description of the input parameters used to estimate the risk ranking and predicted cases per annum for each of the Hazard:Product:Process combinations included in the risk profiling exercise, ordered by the hazard of concern.

4.3.1.1 *Listeria monocytogenes* in packaged, cooked, ready-to-eat (packaged for retail) meat products (e.g. deli or luncheon meats with a focus on red meat products such as roast beef)

Description of product and processing (roast beef): A primal goes from the abattoir to a manufacturing plant, where it is cooked, sliced and packaged. The raw product is the primal and the processing involves injection of lactate and/or diacetate, cooking, slicing and packaging for display on a retail shelf.

The risk associated with red meat products in smallgoods needs to be considered in context. Due to cost factors, where possible, the majority of meat to be used in smallgoods manufacture will be imported pork or chicken MDM (mechanically deboned meat). “Pork represents anywhere from 60-80% of the smallgoods industry’s meat input of which 60% comes from imported pig meat” (Australian Industry Skill Council 2017). As such, the risk that can be attributed to red meat in smallgoods items of variable meat origin can be difficult to quantify due to the fluctuating contribution the red meat category makes. Smallgoods manufacture (domestic and export) is a growth category. IbisWorld estimated that the annual growth rate of the cured meat and smallgoods manufacturing industry was 3.5% between 2012 and 2017, with further growth forecasted at 2.1% for the period 2017-2022 (IbisWorld 2016). The 2015 volume and market share data is presented in Table 15 below.

Table 15. Smallgoods Segment Volume and Market Share (2015)

Product	Volume (tonnes) (2015)	Volume market share (%) of category (2015)
Processed/Formed Knobs	11913.4	8.4
Other	1621.4	1.1
Continental Sausages	9769.4	6.9
Frankfurts/Saveloys	14836.1	10.5
Salami	6499.7	4.6
Ham	46732.2	33
Bacon	42688.7	30.1
Poultry	7632.3	5.4

Source: Retail World Annual Report 2015

Notes: Volume and market share data sourced by DB Media solely from manufacturers. Total intake of combined entries of ‘Frankfurts and saveloys, saturated fat content >5 g/100g’ and ‘Sausages, frankfurts and saveloys, saturated fat content <=5 g/100g’

Question 1. Hazard Severity

Listeria monocytogenes (listeria) is an environmentally ubiquitous organism. While foodborne listeriosis is relatively rare, it can have serious health consequences and is associated with relatively high fatality rates of 20-30% (FAO/WHO 2004). Invasive listeriosis (whereby the bacteria has spread from the intestines to the blood, causing bloodstream infection, or to the central nervous system, causing meningitis) is characterised by a high case fatality rate of 24 to 52% among non-pregnant adults despite adequate antimicrobial treatment. Based on the above, “MODERATE hazard - requires medical intervention in most cases” was chosen as the response to Question 1, for a general population. This assessment concurs with the same designation in MLA report PRMS.038c (2003).

Question 2. How susceptible is the population of interest
For the current assessment, the answer selected for Question 2 was "GENERAL - all members of the population". Population sub-groups known to have greater susceptibility were not differentiated. Populations susceptible to invasive listeriosis are those with a severe or underlying disease or condition such as immunosuppression (by disease or treatment), HIV/AIDS, cancer, transplant; or pregnant women; unborn or newly delivered infants; and the elderly (65 years or older). Also at greater risk are those that may have impaired immune systems because of chronic conditions such as heart disease, diabetes, asthma, alcohol dependency, liver cirrhosis, kidney failure or ulcerative colitis (inflammatory bowel disease) (Food Standards Australia New Zealand - FSANZ 2013) or potentially, those undertaking medical treatments (such as the use of gastric acid/proton-pump inhibitors; Europeans Food Safety Authority - EFSA 2018) for specific illnesses.

Question 3. Frequency of consumption
The frequency of consumption was nominated as 'daily' to align with the data from the Australian Health Survey (Australian Bureau of Statistics - ABS 2014) which states the proportion of persons consuming processed meats on any given day.

Question 4. Proportion of population consuming the product
Results from the 2011-2012 24-hour dietary recall dataset within the Australian Health Survey (ABS, 2014) indicate that, on any given day, processed meat was consumed by approximately 22% of the population, with ham the most popular processed meat being consumed by 12% of people. Sausages were consumed by 7% of the population, while lamb and bacon were each consumed by 5% of people (see Table 16). Excluding ham leaves 10% consuming other processed meat products. On the assumption that half of the smallgoods product is either purchased loose or packaged then the figure for packaged smallgoods is closer to 5%.

Table 16. Australian Health Survey Results 2011-2012: Proportion of persons (%) consuming foods (24-hour dietary recall)

Food Group	Males	Females	Persons
Sausages, frankfurts and saveloys	8.7	5.7	7.2
Sausage, saturated fat content >5 g/100g	7.7	5.0	6.3
Frankfurts and saveloys, saturated fat content >5 g/100g	0.6	0.2	0.4
Sausages, frankfurts and saveloys, saturated fat content <=5 g/100g	0.4	0.5	0.5
Processed Meats:	24.4	20.0	22.2
Bacon	5.9	4.4	5.2
Ham	13.3	11.1	12.2
Fermented, comminuted meats (e.g. Salami)	2.1	1.8	2.0
Processed delicatessen meat, mammalian	3.1	2.5	2.8
Processed delicatessen meat, poultry	1.3	0.9	1.1
Processed meat, commercially sterile (includes canned meats)	0.7	0.3	0.5
Dried meats	0.1	0.0	0.0

Source: Table 4.3 43640DO004_20112012 Australian Health Survey: Nutrition First Results, Foods and Nutrients, 2011–12 (2014)
Notes: The 24-hour dietary recall collected a list of all foods, beverages and supplements consumed the previous day from midnight to midnight, and the amount consumed. For more information, see the 24-hour Dietary Recall of the AHS: Users' Guide, 2011-13 (cat. no. 4363.0.55.001).

As discussed in MLA Report PRMS.038c the consumption patterns differ by product type between consumers (age and gender), as do serving sizes. Commentary made in that report suggest that the differences in consumption patterns/amounts by age, gender or geographic region are relatively minor (much less than ten-fold) and contribute relatively little to differences in risk.

Question 5. Total population

The Australian non-vegetarian population is estimated as 22,002,599 (ABS Census data 2016, Roy Morgan Research 2016) with persons being over the age of 5 months. See Section 3.3.2 Risk Profiling for further explanation on the derivation of the 'total population'. Vegetarianism was only considered for persons 18 years of age and above (11.2% of the population) (Roy Morgan Research 2016).

Question 6. Probability of contamination of raw product per serving

Ross et al. (2009) suggested a contamination rate of 4.77% (~4.8%) at the point of production for processed (deli) meats. Using this same statistic in the absence of any more current data, it was therefore assumed that contamination of raw product occurs "Sometimes". Previously reported Australian data sourced for the last project (MLA 2003), indicated a (similar) weighted mean level of approximately 6% of raw meat used for smallgoods manufacture had detectable levels of *L. monocytogenes*.

Question 7. Effect of processing on the hazard

During processing it is assumed that lactate and/or diacetate are injected into the raw product as a tenderising and food safety measure. Australian smallgoods manufacturing guidelines suggest a 6D cooking process (the process which reduces the listeria bacterial count from 1,000,000 to <1, a 6 log reduction) as a general principle of food hygiene to control *L. monocytogenes* in RTE foods [FSANZ (2014, 2016); MLA (2015), NSW Food Authority (2015)]. As such, the effect of processing on hazard has been estimated to cause a reduction to a level of 0.000001. See Appendix F for time temperature regimens to achieve a 6 log reduction.

Question 8. Post-processing contamination rate

While part of the processing eliminates most of the hazard (e.g. cooking, lactate), there is the potential for recontamination during slicing and packaging before distribution. The available data on Listeria contamination levels in Australian smallgoods at production, indicates that 15% of smallgoods at retail were contaminated with the pathogen (MLA Report PRMS.012 2004). However, it was not specified if the products considered were with or without packaging. After expert consultation with the MLA Food Safety Risk Panel, the post-processing contamination rate for this specific product was assumed to be 3%.

Question 9. Post-processing control

In refrigerated, low oxygen conditions listeria populations are still able to grow. MLA Report PRMS.038c suggests that 'up to 3 logs of growth is likely to occur between production and consumption in all vacuum-packed, processed meat products, except fermented meats' (p36). However, given the product has been treated with lactate and/or diacetate, this exercise assumed the level of growth will be minimal and the 'controlled' option was selected, allowing for a 3-fold increase.

Question 10. Increase required to cause infection/intoxication

While the infective dose is believed to vary with the pathogen strain and susceptibility of the host as well as the food matrix involved, the ID_{50} used in this study was $1x10^{10}$ (based on advice from MLA's Food Safety Risk Panel 2018, Sim et al. 2002 in FSANZ 2013). The weighted average contamination levels of *L. monocytogenes* on contaminated processed meats at production from Western Australian data was 52 CFU/g (Ross et al. 2009), which is very low compared to the infective dose. Assuming the serving size is between 65 and 100g, a multiplication factor of 1 x 10^7 would be required to cause infection. Typical serving sizes are presented in Table 17.

Question 11. Effects of preparation before eating on hazard
As the products are ready-to-eat there is no terminal cooking step considered in this scenario and growth/multiplication can occur until maximum growth levels are achieved or consumption takes place.

Table 17. Summary statistics for the ranges of values characterising distributions of RTE meat servings sizes consumed in Australia

Product Category	Range of estimates of serving sizes (g)		
	Minimum	**Range of averages**	**Maximum**
Processed meats	15	28 – 58	84
Cooked sausages, such as frankfurters, saveloys	42	63 – 108	140
Pâté and meat paste	7	40 – 56	140

Source: Ross et al. (2009)

Risk Ranger v2 outputs:
Table 18 provides information on the input parameters used and the Risk Ranger v2 outputs generated. A risk ranking of 35, classified as Medium, was obtained with a prediction of 3.6 cases per year. The daily probability of illness per person within the population of interest was estimated to be 9 x 10^{-9}.

Table 18. Risk ranking summary for *Listeria monocytogenes* in packaged, cooked, ready-to-eat (packaged for retail) meat products (*Description of the estimation of input parameters in 4.3.1.1*)

Criteria	Estimation	Sources
1. Hazard severity	Moderate	MLA PRMS.038c (2003)
2. Population susceptibility	General	
3. Frequency consumption	Daily	Australian Bureau of Statistics 4364.0.55.007 (2014)
4. Proportion consuming (%)	5%	Australian Bureau of Statistics 4364.0.55.007 (2014)
5. Total population	22,002,599 (meat-eating persons > 5 months of age)	Australian Bureau of Statistics 3101.0 (2017), Roy Morgan Research (2016)
6. Proportion of raw product contaminated (%)	4.8%	Ross et al. (2009)
7. Effect of processing on hazard	0.000001	MLA Food Safety Risk Panel estimate (2018) FSANZ (2014, 2016) MLA (2015), NSW Food Authority (2015)
8. Post processing contamination rate/potential for recontamination (%)	3%	MLA Food Safety Risk Panel estimate (February 2018) MLA PRMS.012 (2004) p
9. Post processing control	Controlled (mostly reliable systems in place, 3-fold increase	USDA (2012) MLA PRMS.012 (2004) p5 MLA Food Safety Risk Panel (2018)
10. Increase required to cause infection/intoxication	1 x 10^7	Ross et al. (2009) MLA A.MFS.0092 (2006) Sim et al. 2002 in FSANZ (2013) MLA Food Safety Risk Panel estimate (2018) based on FAO (2004), Smith et al. (2003, 2008), Willliams et al. (2009), Pouillot et al. (2011), Goulet et al. (2012)
11. Effects of preparation before eating on hazard	No effect on hazard	
Predicted cases per annum Risk Ranking	3.6 35	

4.3.1.2 *Listeria monocytogenes* in unpackaged, cooked, ready-to-eat meat products (e.g. deli or luncheon meats with a focus on red meat products such as roast beef)

Description of product and processing (roast beef): A primal goes from the abattoir to a manufacturing plant, where it is cooked. The raw product is the primal and the processing involves injection of lactate and/or diacetate and cooking and packaging for distribution. Slicing occurs at retail level.

Question 1. Hazard Severity
As described in 4.3.1.1.

Question 2. How susceptible is the population of interest
As described in 4.3.1.1.

Question 3. Frequency of consumption
As described in 4.3.1.1.

Question 4. Proportion of population consuming the product
Results from the 2011-2012 24-hour dietary recall dataset within the Australian Health Survey (ABS 2014) indicate that, on any given day, processed meat was consumed by 22% of the population, with ham the most popular processed meat being consumed by 12% of people. Sausages were consumed by 7% of the population, while lamb and bacon were each consumed by 5% of people. Excluding ham leaves 10% consuming other processed meat products. Assuming that half of the smallgoods product is either purchased loose or packaged then the estimate for unpackaged smallgoods is closer to 5%. While unpackaged red meat products may include roast beef, pastrami, corned meat or other products (which each undergo different curing techniques) for the purpose of the ranking exercise roast beef only is considered in this scenario. See Table 16.

Question 5. Total population
As described in 4.3.1.1.

Question 6. Probability of contamination of raw product per serving
As described in 4.3.1.1.

Question 7. Effect of processing on the hazard
As described in 4.3.1.1.

Question 8. Post-processing contamination rate
While part of the processing eliminates most of the hazard (e.g. cooking, lactate), there is the potential for recontamination after cooking. The available data on Listeria contamination levels in Australian smallgoods at production, indicates that 15% of smallgoods at retail where contaminated with the pathogen (MLA Report PRMS.012 2004). However, it was not specified if the products considered were with or without packaging. After expert consultation with the MLA Food Safety Risk Panel, the post-processing contamination rate for this specific product was estimated to be 10%.

Question 9. Post-processing control
The chosen entry for control post processing was 'Controlled – mostly reliable systems in place (3-fold increase)'. While product is packaged during storage and transit to retail outlets and conditions may still allow the generation of pathogen populations (in refrigerated, low oxygen conditions listeria populations are still able to grow), inevitably the product is sliced and expected to be consumed within the short-term (e.g. 3 days). Although the use of lactate and/or other acids will reduce the level of growth to a minimal level, the reliability of the systems in place may be inadequate with the potential

for recontamination and non-ideal storage conditions in each handling setting i.e. food service, delicatessens or the home. In comparison, packaged product is not re-handled (e.g. chub slicing) when it reaches retail, but is displayed only.

Question 10. Increase required to cause infection/intoxication
As described in 4.3.1.1.

Question 11. Effects of preparation before eating on hazard
As the products are ready-to-eat there is no terminal cooking step considered in this scenario and growth/multiplication can occur until consumption takes place.

Risk Ranger v2 outputs:
Table 19 provides information on the input parameters used and the Risk Ranger v2 outputs generated. A risk ranking of 38, classified as Medium, was obtained with a prediction of 12 cases per year. The daily probability of illness per person within the population of interest was estimated to be 3×10^{-8}.

Table 19. Risk ranking summary for *Listeria monocytogenes* in unpackaged, cooked, ready-to-eat meat products (e.g. deli or luncheon meats with a focus on red meat products such as roast beef) (*Description of the estimation of input parameters can be found in 4.3.1.2*)

Criteria	Estimation	Sources
1. Hazard severity	Moderate	MLA PRMS.038c (2003)
2. Population susceptibility	General	
3. Frequency consumption	Daily	Australian Bureau of Statistics 4364.0.55.007 (2014)
4. Proportion consuming (%)	5%	Australian Bureau of Statistics 4364.0.55.007 (2014)
5. Total population	22,002,599 (meat-eating persons > 5 months of age)	Australian Bureau of Statistics 3101.0 (2017), Roy Morgan Research (2016)
6. Proportion of raw product contaminated (%)	4.8%	Ross et al. (2009)
7. Effect of processing on hazard	0.000001	FSANZ (2014, 2016); MLA (2015), NSW Food Authority (2015)
8. Post processing contamination rate/potential for recontamination (%)	10%	MLA Food Safety Risk Panel (2018) MLA PRMS.012 (2004) p5
9. Post processing control	Controlled (mostly reliable systems in place, 3-fold increase	MLA Food Safety Risk Panel (2018)
10. Increase required to cause infection/intoxication	1×10^7	Ross et al. (2009) MLA A.MFS.0092 (2006) Sim et al. 2002 in FSANZ (2013) MLA Food Safety Risk Panel estimate (2018) based on FAO (2004), Smith et al. (2003, 2008), Willliams et al. (2009), Pouillot et al. (2011), Goulet et al. (2012)
11. Effects of preparation before eating on hazard	No effect on hazard	
Predicted cases per annum Risk Ranking	12 38	

*https://www.foodstandards.gov.au/publications/Documents/Safe%20Food%20Australia/Appendix%203%20-%20Limits%20for%20food%20processes.pdf; https://www.mla.com.au/globalassets/mla-corporate/research

4.3.1.3 *Listeria monocytogenes* in packaged, cooked, ready-to-heat (vacuum, MAP etc) meat products (e.g. convenience meals in retail or food service)

Description of product and processing: This classification, i.e. ready-to-heat/heat and eat convenience meals, covers a wide range of products which have multiple meat sources (including beef or lamb) and multiple ingredients (e.g. carbohydrate sources such as rice or pasta, added vegetables and sauces) which could also be the source of pathogen loading. Examples include pre-prepared lasagnes, Indian or Thai dishes. The raw product is the primal and processing involves a cooking step (most likely a sous vide process), followed by refrigeration, in a manufacturing setting.

Question 1. Hazard Severity
As described in 4.3.1.1.

Question 2. How susceptible is the population of interest
As described in 4.3.1.1.

Question 3. Frequency of consumption
The frequency of consumption was nominated as weekly by 75% of the population, assuming 75% of the general population will choose a convenience food as a meal option every week.

Question 4. Proportion of population consuming the product
The proportion of the population was nominated as 75% of the general population.

As discussed in PRMS.038c the consumption patterns differ by product type between consumers (age and gender), as do serving sizes. Commentary made in that report suggest that the differences in consumption patterns/amounts by age, gender or geographic region are relatively minor (much less than ten-fold) and contribute relatively little to differences in risk.

Question 5. Total population
As described in 4.3.1.1.

Question 6. Probability of contamination of raw product per serving
Phillips et al. (2012a, 2013, 2014) documented *L. monocytogenes* contamination rates of 0.1% for beef primals and for lamb: 0% for boneless samples and 0.2% leg samples. These cuts were chosen as the most similar to that of that used in the creation of a convenience meal (e.g. a curry). The probability of contamination of raw product was assumed to be 0.1% as an average estimate of the data listed above.

Calculations of concentrations were based on beef primals testing at 1 CFU/cm^2 (MLA A.MFS.0092 2006). An assumption was made that this figure equates to a concentration of 2 CFU/g. Communication with DAWR staff regarding conversions of MPN/cm^2 to CFU/g suggest calculations are made on the premise that sample surface slices have a surface area of 10cm^2 on average and approximate 5g in weight (Australian Government Department of Agriculture and Water Resources - DAWR 2017). The beef primals data of 1 CFU/cm^2 would equate to 10CFU in 10cm^2 in a 5 gram surface slice therefore 2 CFU per gram.

Question 7. Effect of processing on the hazard
Australian manufacturing guidelines suggest a 6D process (the process which reduces the listeria bacterial count from 1,000,000 to <1, a 6 log reduction) as a general principle of food hygiene to control *L. monocytogenes* in RTE foods [FSANZ (2014, 2016); MLA (2015), NSW Food Authority (2015)]. It is assumed that manufacturing premises are attempting to adhere to good manufacturing practice

and employing hazard control procedures. As such, the effect of processing on hazard has been estimated to cause a reduction to a level of 0.000001 at most.

Question 8. Post-processing contamination rate

It was considered that there was the potential for recontamination after processing and not all packaging will be properly sealed. A 1% recontamination rate was used.

Question 9. Post-processing control

The chosen entry for control post processing was 'controlled – mostly reliable systems in place (3-fold increase)'. The post-processing control was chosen as 'controlled', as opposed to 'well-controlled' to account for potential mismanagement of cold storage on the path to home storage.

Question 10. Increase required to cause infection/intoxication

While the infective dose is believed to vary with the strain and susceptibility of the host as well as the food matrix involved, the ID_{50} assumed in this study was $1x10^{10}$ (based on advice from MLA's Food Safety Risk Panel 2018, Sim et al. 2002 in FSANZ 2013). A recontamination concentration of 2 CFU/g (arbitrary figure) would equate to 130 CFU/65g serving. To then reach an infective dose a multiplication factor of $1x10^{8}$ would be required.

Question 11. Effects of preparation before eating on hazard

'Meal Preparation usually eliminates (99%) the hazard'. In most cases consumers will abide with the labelled cooking instructions, however there will be instances whereby some consumers will not. In addition, if the pathogen loading was excessive and the product not heated through properly, issues may occur (hence a 99% reduction as opposed to a 100% hazard reduction).

Risk Ranger v2 outputs:

Table 20 provides information on the input parameters used and the Risk Ranger outputs generated. A risk ranking of 17, classified as Low, was obtained with a prediction of 2.6×10^{-3} cases per year. The daily probability of illness per person within the population of interest was estimated to be 4.3×10^{-13}.

Table 20. Risk ranking summary for *Listeria monocytogenes* in packaged, cooked, ready-to-heat (e.g. vacuum, MAP) meat products (e.g. convenience meals) (*Description of the estimation of input parameters 4.3.1.3*)

Criteria	Estimation	Sources
1. Hazard severity	Moderate	MLA PRMS.038c (2003)
2. Population susceptibility	General	
3. Frequency consumption	Weekly	
4. Proportion consuming (%)	75%	
5. Total population	22,002,599 (meat-eating persons > 5 months of age)	Australian Bureau of Statistics 3101.0 (2017), Roy Morgan Research (2016)
6. Proportion of raw product contaminated (%)	Beef primals: 0.1% Lamb: 0% boneless samples; 0.2% leg samples	Phillips et al. (2012a, 2013, 2014) DAWR (2017) MLA A.MFS.0092 (2006)
7. Effect of processing on hazard	0.000001	FSANZ (2014, 2016); MLA (2015), NSW Food Authority (2015)
8. Post processing contamination rate/potential for recontamination (%)	1%	MLA Food Safety Risk Panel estimate (2018)
9. Post processing control	Controlled – mostly reliable systems in place (3-fold increase)	
10. Increase required to cause infection/intoxication	1×10^8	Sim et al. 2002 in FSANZ (2013) MLA Food Safety Risk Panel estimate (2018) based on FAO (2004), Smith et al. (2003, 2008), Willliams et al. (2009), Pouillot et al. (2011), Goulet et al. (2012)
11. Effects of preparation before eating on hazard	Meal Preparation usually eliminates (99%) the hazard	
Predicted cases per annum	2.6×10^{-3}	
Risk Ranking	17	

4.3.1.4 *Listeria monocytogenes* in Sous vide

Description of product and processing: Sous vide is a product resulting from a method of cooking in which a primal (raw product) is vacuum-sealed in a plastic pouch and placed in a water bath or steam environment for longer than normal cooking times (usually 1 to 7 hours) at an accurately regulated temperature much lower than normally used for cooking (typically around 55 to 60 C for meat). The processing phase is the vacuum packing and the cooking. The vacuum-packed product is then rapidly cooled, placed in chilled storage, distributed, before again being placed in refrigerated storage once it reaches the food service establishment. It is then reheated for consumption. The method of preparation and storage of sous-vide product has historically been of concern to regulators (NSW Government Food Authority 2015) due to the combination of sustained low cooking temperatures, storage under vacuum and re-heating applications.

Question 1. Hazard Severity
As described in 4.3.1.1.

Question 2. How susceptible is the population of interest
As described in 4.3.1.1.

Question 3. Frequency of consumption
The frequency of consumption (sous vide red meat in food service) was nominated as 'every 56 days/8 weeks' (100g serving). For the food service industry (including institutional and event catering) sous vide product is a convenient option, e.g. shanks, ribs, roasts, steaks or other portions, due to eating quality, shelf-life and kitchen through-put considerations. Estimated serving production per week for red meat (beef/veal/lamb/mutton) was 140000 serves/week with 60,000 each from Ribs and Roasts and Bidvest, and 20,000 from Creative Food Solutions. In combination with Question 4, a frequency of consumption was derived.

Question 4. Proportion of population consuming the product
The proportion of the population was nominated as 5% being the lowest allocation available. As discussed in PRMS.038c the consumption patterns differ by product type between consumers (age and gender), as do serving sizes. Commentary made in that report suggest that the differences in consumption patterns/amounts by age, gender or geographic region are relatively minor (much less than ten-fold) and contribute relatively little to differences in risk.

Question 5. Total population
As described in 4.3.1.1.

Question 6. Probability of contamination of raw product per serving
Phillips et al. (2012a, 2013, 2014) documented *L. monocytogenes* contamination rates of 0.1% for beef primals and for lamb: 0% for boneless samples and 0.2% leg samples. These cuts were chosen as the most similar to what might be used for sous vide food service catering purposes. The probability of contamination of raw product was assumed to be 0.1% as an average estimate of the data listed above.

Calculations of concentrations were based on beef primals testing at 1 CFU/cm^2 (MLA A.MFS.0092 2006). An assumption was made that this estimate would correlate to a concentration of 2 CFU/g. Communication with DAWR staff regarding conversions of MPN/cm^2 to CFU/g suggest calculations are made on the premise that sample surface slices have a surface area of 10cm^2 on average and approximate 5g in weight (DAWR 2017). The beef primals data of 1 CFU/cm^2 would equate to 10CFU in 10cm^2 in a 5 gram surface slice therefore 2 CFU per gram.

Question 7. Effect of processing on the hazard
Processing refers to vacuum packaging and cooking steps. Given Listeria is sensitive to heat, cooking will reduce the number of Listeria 1,000,000-fold, known as the 6D process [FSANZ (2014, 2016); MLA (2015), NSW Food Authority (2015)]. It is assumed that manufacturing premises are attempting to adhere to good manufacturing practice and employing hazard control procedures. As such, the effect of processing on the hazard has been estimated to cause a reduction to a level of 0.000001, at most.

Question 8. Post-processing contamination rate
It was considered that there was 'no' potential for recontamination after processing. It is assumed that further contamination does not occur as the integrity of seals and packaging are maintained.

Question 9. Post-processing control
The chosen entry for control post processing was 'controlled – mostly reliable systems in place (3-fold increase)'. The post-processing control was chosen as 'controlled', as opposed to 'well-controlled' to account for potential mismanagement of cold storage and length of storage.

Question 10. Increase required to cause infection/intoxication
While the infective dose is believed to vary with the strain and susceptibility of the host as well as the food matrix involved, the ID_{50} assumed in this study was $1x10^{10}$ (based on advice from MLA's Food Safety Risk Panel 2018, Sim et al. 2002 in FSANZ 2013). Given the processing has reduced the level of contamination to practically zero and there is no potential for recontamination, it is assumed that the product will have negligible level of contamination. As such, to then reach an infective dose a multiplication factor of $1x10^{10}$ would be required.

Question 11. Effects of preparation before eating on hazard
'Meal Preparation usually eliminates (99%) the hazard'. Normal preparation would involve a cooking step that would eliminate all hazards. However in the case of sous vide the re-heating step may not be sufficient to inactivate all pathogens. In addition, if the pathogen loading was excessive due to problems post-processing (above) and the product not heated through properly, issues may occur (hence a 99% reduction as opposed to a 100% hazard reduction).

Risk Ranger v2 outputs:
Table 21 provides information on the input parameters used and the Risk Ranger v2 outputs generated. Corresponding to the input parameters used, the risk posed by this combination is negligible, with a risk ranking of 0, and a prediction of 2×10^{-14} cases per year. The daily probability of illness per person within the population of interest was estimated to be negligible (5×10^{-23}).

Table 21. Risk ranking summary for *Listeria monocytogenes*, in red meat products used for sous vide to supply food service channels (*Description of the estimation of input parameters in 4.3.1.4*)

Criteria	Estimation	Sources
1. Hazard severity	Moderate	MLA PRMS.038c (2003)
2. Population susceptibility	General	Australian Bureau of Statistics 3101.0 (2017), Roy Morgan Research (2016)
3. Frequency consumption	Every 8 weeks or 6 x/annum	
4. Proportion consuming (%)	5%	Industry consultation (2018)
5. Total population	22,002,599 (meat-eating persons > 5 months of age)	Australian Bureau of Statistics 3101.0 (2017), Roy Morgan Research (2016)
6. Proportion of raw product contaminated (%)	Beef primals: 0.1% Lamb: 0% boneless samples; 0.2% leg samples	Phillips et al. (2012a, 2013, 2014)
7. Effect of processing on hazard	0.000001	FSANZ (2014, 2016); MLA (2015), NSW Food Authority (2015)
8. Post processing contamination rate/potential for recontamination (%)	Nil	
9. Post processing control	Controlled – mostly reliable systems in place (3-fold increase)	
10. Increase required to cause infection/intoxication	1×10^{10}	Sim et al. 2002 in FSANZ (2013) MLA Risk Management Panel estimate (February 2018) based on FAO (2004), Smith et al. (2003, 2008), Willliams et al. (2009), Pouillot et al. (2011), Goulet et al. (2012) DAWR (2017) MLA A.MFS.0092 (2006)
11. Effects of preparation before eating on hazard	Meal Preparation usually eliminates (99%) the hazard	
Predicted cases per annum Risk Ranking	2.2×10^{-14} 0	

4.3.1.5 *Clostridium perfringens* in roasts – served warm (sliced, cooked primal) in food service

Description of product and processing: The raw product is the primal, which may be rolled. It is distributed to a food service destination. In this scenario, processing commences with the initial cooking of the product, before it is perhaps cooled before being sliced and reheated in a bain-marie. This product may present in aged care institutions as well as in other food service channels such as restaurants, cafes or institutional or event catering.

Clostridium perfringens can reside in two forms – vegetative cells and spores. Illness is caused when a large number of vegetative cells are ingested. The vegetative cells form spores within the body's environmental conditions. During sporulation, a heat-sensitive enterotoxin is produced in the gastrointestinal tract.

With respect to food contamination, spores in the meat product can withstand cooking temperatures. The heating process activates spores while slow cooling promotes germination and multiplication. If the food does not receive adequate reheating (i.e.to temperatures that will kill the vegetative cells) or the cooked food is held between 4.4 °C and 60 °C for an extended period *C. perfringens* enters the gastro-intestinal tract and sporulates.

- Critical control point failures include temperature abuse, undercooking, inadequate cooling, poor reheating and improper hot holding. The effect of injectables or additives (such as salts, phosphates, nitrate) that may be present in the meat has not been assessed.
- The effect of germination-outgrowth-lag phases has not been assessed.
- The effect of pH has not been assessed.

Two scenarios were run for this combination, one for the general population and one for the elderly (>65 years of age). See Section 3.3.2 for a definition of 'elderly'.

Question 1. Hazard Severity
Based on Report PRMS.038c (2003) *C. perfringens* was considered a "MILD hazard – sometimes requires medical intervention" for a general population, aligning with the 'mild' iteration found in Risk Ranger.

For the elderly (>65 years of age), *C. perfringens* was considered a "MODERATE hazard" due the potential for weakened immune systems in this age group.

Question 2. How susceptible is the population of interest
For assessment of the general population, the answer selected for Question 2 was "GENERAL - all members of the population".

The 'elderly' population sub-group was chosen for assessment as this group is, as a general assumption, known to have greater susceptibility and are, due to historical influences, more likely to partake in roast meal dishes. An assumption is made that roast meat dishes are more frequently served in aged care facilities and in institutional sites than in other food service settings. The 'slight' option was selected.

Question 3. Frequency of consumption
For the general population the frequency of consumption was nominated as 'few times per year' for beef and twice per year for lamb. Results from a 24-hour dietary recall of food, beverages and dietary supplements (Australian Health Survey: Nutrition First Results – Food and Nutrients, 2011-12) suggest an aggregated average consumption of 17.1g/day of beef with gravy, sauce or vegetables and 5.4 g/day of lamb or mutton dishes with gravy, sauce or vegetables. The assumption that roast beef eaten at a ratio of ~3:1 to roast lamb/mutton (due to cost or preference) is supported by the data above. For the elderly population consumption was assumed to be more frequent, as it was considered by the MLA Food Safety Risk Panel that most people within this subgroup of the population would eat a roast meal in food service more frequently that younger people within the general population. As such, consumption of beef roast was estimated at monthly and lamb roast as a few times per year.

Question 4. Proportion of population consuming the product
For the general population, the proportion was nominated as 25% based on the assumption that is the fraction of the population who choose beef or lamb roast meal option during their visits to a food service establishment/restaurant. A higher proportion of population consuming this product was estimated among the elderly population (75%).

As discussed in PRMS.038c the consumption patterns differ by product type between consumers (age and gender), as do serving sizes.

Question 5. Total population
For general population as described in 4.3.1.1 and for elderly population (>65 years), as described in 3.3.2. In summary it was estimated to be 3,673,511 (16.7% of the general population). The option 'slight' is used in relation to susceptibility, which automatically considers 20% of the population.

Question 6. Probability of contamination of raw product per serving
An assumption was made that the probability of contamination of raw product was 10% (as there is no Australian data available to determine a local probability) with a prevalence of 1 cell/gram. Furthermore it is assumed that every cell has a spore. In MLA report PRMS.038c (2003) 10% was assumed with a prevalence relating to 1/g (or 100/100g serve).

International data was sourced in an attempt to derive an informed estimate:
- The ICMSF (2005). Beef and sheep carcass prevalence of <200 CFU/100cm^2 (2 CFU/cm^2, ~4 CFU/g based on DAWR (2017) calculations explained in Section *Listeria monocytogenes* in vacuum packed and undercooked primals, Question 10.)
- Miwaa (1998): 2% prevalence of enterotoxigenic *C. perfringens* in beef samples (<10^2 MPN/100 g) and total *C. perfringens* in 16% of beef samples (<10^2–4.3×10^2 MPN/100g).
- Huffman (2002): 3% Prevalence for US steer/heifer (45 CFU/g or cm^2 - units not distinguished) and 8% bull/cow (47 CFU/g or cm^2) carcasses.

Based on the above data, which ranged from 3% to 16% for total *C. perfringens*, an arbitrary 10% estimate was selected for the risk profiling exercise.

Question 7. Effect of processing on the hazard
It was considered that the process reduces the hazard significantly – equivalent to a 6D process [FSANZ (2014, 2016); MLA (2015), NSW Food Authority (2015)]. In this scenario, the process commences with the initial cooking of the product in a commercial kitchen, before it is perhaps cooled, stored, sliced, had condiments added (such as gravy) and reheated in a bain-marie. When considering rolled roasts, not all vegetative cells may be killed if the internal temperature is not sufficiently high enough (a 6D process did not occur). During testing in phosphate buffered saline, bacterial spores were found to be sensitive to temperatures higher than 95°C and vegetative cells sensitive to temperatures just over 45°C (RIVM, 2009). The heating process can cause sporulation to occur (Austin 2003).

"Cooking of foods can also heat shock C. perfringens spores, since germination activation of C. perfringens spores can occur at temperatures between 60 and 80°C (Walker 1975). After heat shock, germination and outgrowth of spores and C. perfringens vegetative growth are likely to occur in cooked foods if the rate and extent of cooling are not sufficient or if the processed foods are temperature abused. The abuse may occur during transportation, distribution, storage, or handling in supermarkets, or during preparation of foods by consumers which includes low-temperature—long-time cooking of foods as well as scenarios in which foods are kept on warming trays before final heating or reheating." (Juneja et al. 2010).

Question 8. Post-processing contamination rate
There is potential for some contamination to occur after cooking, due to cross-contamination between chopping boards, knives and other surfaces in commercial kitchens. This was nominated at 1 percent after discussion with the MLA Food Safety Risk Panel (2018).

Question 9. Post-processing control
The chosen entry for control post processing was 'well controlled – reliable, effective systems in place (no increase in pathogen)'. For meat where the pathogen has not been inactivated prior, inadequate cooling regimens and/or placement in a bain-marie where 'safe' temperatures are not reached or maintained, an environment for growth might be provided. An assumption has been made that most establishments would follow the relevant regulatory guidelines.

Question 10. Increase required to cause infection/intoxication
Symptoms are caused by ingestion of large numbers (> 10^6) of vegetative cells or >10^6 spores/gram (10^8 in a 100g serve) (Sim et al. 2002 in FSANZ, 2013). Toxin production in the digestive tract (or in vitro) is associated with sporulation (United States Food and Drug Administration - FDA 2012). Phillips et al. (2008) reported that *C. perfringens* was not recovered from any ground beef samples and recovered from 1 (1.1%) of the 92 samples of retail cubed lamb (at 30 CFU/g). No other data exists relevant to this project. It was suggested during personal communication with J Sumner (MLA Food Safety Risk Panel 2018) that concentration from pork samples in Kalinowski (2003; ~66 CFU/g) be used in the absence of other data. Therefore, assuming a 65 to 100 g serving size, 6,600 CFU/serving would require a 10^5 fold increase to reach an infective dose.

Question 11. Effects of preparation before eating on hazard
"No effect on the hazard" was chosen, because in this scenario, the 'processing step' included the preparation steps to make the meat cut ready for consumption (e.g. cooking, cooling, slicing, adding condiments (e.g. gravy), reheating/maintaining heat). No further product manipulation occurs.

Risk Ranger v2 outputs:
Table 22 provides information on the input parameters used and the Risk Ranger v2 outputs obtained. Corresponding to the input parameters used, the risk ranking for this combination for the general population is estimated to be 27 and 28 for lamb and beef roast (Medium), respectively. The predicted cases are 1.1 for the consumption of lamb roasts and 1.6 for the consumption of beef roasts. The daily probability of illness per person within the general population was estimated to be very similar for both lamb and beef roast consumption, 5 to 8 x 10^{-10}.

For the elderly population, considering this subgroup to be 20% of the general population and five times more susceptible, the risk ranking is estimated to be 36 for lamb and 40 for beef. The model predicts 5 cases due to the consumption of lamb roasts and 20 due to the consumption of beef roasts among the elderly population. As a result, the probability of illness per day increases by a factor of 10 to 100 (1.6 x 10^{-8} for beef; 4.1 x 10^{-9} for lamb). The increase in risk ranking and predicted cases among the elderly population is due to the higher susceptibility to this hazard within this subgroup of the population and the increased severity of illness, in conjunction with the higher consumption rate of these products.

Table 22. Risk ranking summary for *Clostridium perfringens* in roasts – served warm (sliced, cooked primal) in food service (*Description of the estimation of input parameters in 4.3.1.5*)

Criteria	Estimation (General population)	Estimation (Susceptible population)	Sources
1. Hazard severity	Mild	Moderate	MLA PRMS.038c (2003)
2. Population susceptibility	General	Slight	
3. Frequency consumption	Beef: Few times per year Lamb: Twice per year	Beef: Monthly Lamb: Few times per year	Australian Bureau of Statistics 4364.0.55.007 (2014)
4. Proportion consuming (%)	25%	75%	
5. Total population	22,002,599 (meat-eating persons > 5 months of age)	22,002,599 (meat-eating persons > 5 months of age). Software assumes 20% of population has a slight susceptibility (e.g. infants, aged)	Australian Bureau of Statistics 3101.0 (2017), Roy Morgan Research (2016)
6. Proportion of raw product contaminated (%)	10%	10%	MLA PRMS.038c (2003) ICMSF (2005) Miwaa (1998) Huffman (2002)
7. Effect of processing on hazard	0.000001	0.000001	FSANZ (2014, 2016); MLA (2015), NSW Food Authority (2015) Austin (2003)
8. Post processing contamination rate/potential for recontamination (%)	1%	1%	MLA Food Safety Risk Panel estimate (February 2018)
9. Post processing control	Well controlled – reliable, effective, systems in place (no increase in pathogen)	Well controlled – reliable, effective, systems in place (no increase in pathogen)	Juneja et al. (2010)
10. Increase required to cause infection/intoxication	10^5	10^5	Sim et al. (2002) in FSANZ (2013) MLA Food Safety Risk Panel (2018)
11. Effects of preparation before eating on hazard	No effect on hazard	No effect on hazard	
Predicted cases per annum Risk Ranking	Beef: 1.6 ; Lamb: 1.1 Beef: 28; Lamb: 27	Beef: 20; Lamb: 5 Beef: 40; Lamb: 36	

4.3.1.6 STEC *Escherichia coli* in uncooked primals (e.g. steak tartare, carpaccio)

Description of product and processing: The raw product is the primal, and the process involves slicing or manually mincing a primal cut to create a raw meat dish. The primal may be par-frozen to allow for ease of cutting.

Only *E.coli* 0157 was considered in this scenario. Different strains of *E.coli* exhibit different virulence and show large variations in the infective dose. The Joint FAO/WHO Core Expert Group Meeting on VTEC/STEC (2016) describe STEC pathogenicity as highly complex. There is no single trait of an STEC that can be used to assess the public health risk of its presence in the food chain; rather, a combination of criteria such as virulence and phenotypic properties and regional historical knowledge are required together with knowledge of the isolation context.

As data is more readily available for *E.coli O157* prevalence and concentration, in conjunction with the pathogen exhibiting the lowest of infective dose, it was chosen for the case studies. Examples of deliberately uncooked primals include steak tartare and carpaccio (and regional variants of these cuisines).

Assumptions:

- these products are made traditionally i.e. from primal cuts, as opposed to packaged mince as in the context of steak tartare.
- although an artisan preparation technique, the use of lemon juice or other acid-based condiment has not been considered in the effects of preparation on the hazard load.
- the contribution of raw egg in the pathogen load of steak tartare has not been analysed.

Question 1. Hazard Severity
E.coli O157 was considered as "Moderate– requires medical intervention in most cases" for a general population, aligning with the severity reported in PRMS.038c (2003).

Question 2. How susceptible is the population of interest
For the current assessment, the answer selected for Question 2 was "GENERAL - all members of the population". Population sub-groups known to have greater susceptibility were not differentiated.

Question 3. Frequency of consumption
The speculated frequency of consumption was nominated as "once per annum/365 days between servings" (65g serving) for a raw beef dish.

Question 4. Proportion of population consuming the product
The proportion was nominated as 5% based on the assumption that is only a small fraction of the population who are choosing raw meat as a meal option during a visit to a food service setting (i.e. venue, restaurant, catering) or in the home.

As discussed in PRMS.038c the consumption patterns differ by product type between consumers (age and gender), as do serving sizes. Commentary made in that report suggest that the differences in consumption patterns/amounts by age, gender or geographic region are relatively minor (much less than ten-fold) and contribute relatively little to differences in risk.

Question 5. Total population
As described in 4.3.1.1.

Question 6. Probability of contamination of raw product per serving
Under guidance by the MLA Food Safety Risk Panel (2018) the probability was nominated at 0.18% arising from data on beef trim in MLA Report V.MFS.0403 (2017).

Question 7. Effect of processing on the hazard
The process was deemed to have 'no effect' on the hazard. Primals destined for carpaccio would usually be held at low temperatures prior to distribution. It is not expected that processing would alter the inherent pathogen load. Consultation with industry (2017) suggest that holding product at <4^{o}C is a processing standard. However coming out of most chiller tunnels, temperatures are between 0-2^{o}C with chilled storage also held at these temperatures. Thus load out temperatures are usually around 2^{o}C.

Question 8. Post-processing contamination rate
An assumption was made that the cool chain is maintained and there is no further handling until food preparation that may cause further contamination.

Question 9. Post-processing control
This parameter was designated as "well controlled – reliable, effective, systems in place (no increase in pathogens)". As above the assumption was made that the cool chain is maintained.

Question 10. Increase required to cause infection/intoxication
The ID_{50} infective dose is considered to be 3,000 CFU/serving (Cassin et al. 1998, WHO 2011). There is currently no available data on initial CFU concentrations per gram, therefore an assumption of 1 CFU/serving initial loading was made. To reach an infective dose a multiplication factor of only 10^3 is required.

Question 11. Effects of preparation before eating on hazard
"No effect on the hazard" was chosen because the product is eaten raw without any cooking step. As mentioned the variable use of acidic condiments in carpaccio, in relation to the effects on pathogen loading, was not incorporated, nor was the presence of raw egg in steak tartare preparations.

Risk Ranger v2 outputs:
Table 23 provides information on the input parameters used and the Risk Ranger v2 outputs obtained for this combination. Corresponding to the input parameters used, the risk ranking for this combination is estimated to be 34 (Medium), with 2 predicted cases per year. The daily probability of illness per person within the general population was estimated to be 5×10^{-9}.

Table 23. Risk ranking summary for STEC *Escherichia coli* in uncooked primals (e.g. steak tartare, carpaccio) (*Description of the estimation of input parameters in 4.3.1.6*)

Criteria	Estimation	Sources
1. Hazard severity	Moderate	MLA PRMS.038c (2003)
2. Population susceptibility	General	
3. Frequency consumption	Once / annum	
4. Proportion consuming (%)	5%	
5. Total population	22,002,599 (meat-eating persons > 5 months of age)	Australian Bureau of Statistics 3101.0 (2017), Roy Morgan Research (2016)
6. Proportion of raw product contaminated (%)	0.18%	MLA AMPC Report V.MFS.0403 (2017) Figure suggested by MLA Food Safety Risk Panel (2018)
7. Effect of processing on hazard	The process has no effect on the hazard	Industry consultation (2017)
8. Post processing contamination rate/potential for recontamination (%)	Nil	
9. Post processing control	Well controlled – reliable, effective, systems in place (no increase in pathogens)	
10. Increase required to cause infection/intoxication	10^3	Cassin et al. (1998), WHO (2011)
11. Effects of preparation before eating on hazard	No effect on hazard	
Predicted cases per annum Risk Ranking	2 34	

4.3.1.7 STEC *Escherichia coli* in 'outside in' products: 1. Doner kebabs

Description of product and processing: The raw product is meat trim and the process involves a cone of meat pieces being compacted together and grilled on a vertical, rotating spit whereby the shaved meat is wrapped in flat bread with salad/ vegetables and dips. Prior to adding the meat onto the flat bread base it is suggested in Australian food safety guidelines that a final flash fry take place to help ensure any microbiological load is limited.

'Outside In' definition: Non-intact products, whereby the manufacturing or culinary processes used to create them generate the potential for contaminants on meat surfaces to become encapsulated internally, either mechanically or through rolling, layering, fusing or pressing pieces together such as primal cuts, slices, chunks or cubes. Such products could be also described as reconstituted, restructured or re-formed. Example products include 'fusion' products (fused/'glued' by edible products such as the enzyme transglutaminase), needle or blade tenderised primal roasts, rolled roasts, kebabs (doner or shish), satay sticks. As this is a category with many variations in cuisine, two products were selected to perform the risk ranking as indicative scenarios. 1. Doner Kebabs and 2. Rolled roasts or needle/blade tenderised roasts.

Question 1. Hazard Severity
As described in 4.3.1.6.

Question 2. How susceptible is the population of interest
As described in 4.3.1.6.

Question 3. Frequency of consumption
The speculated frequency of consumption of doner kebabs (or regional variants based on grilled meat on a vertical, rotating spit whereby the shaved meat is wrapped in flat bread with salad/ vegetables and dips) was nominated as "weekly" (65g serving) (MLA Food Safety Risk Panel 2018).

Question 4. Proportion of population consuming the product
For roasts, the proportion was nominated as 5% based on speculative assumptions. For kebabs, the 5% estimation was derived from anecdotal information reported by journalist Lucy Kippist (2013) and then extrapolated to estimate more current total kebab consumption per annum. 190,000 kebabs per annum in 2013 was multiplied by a growth factor of 20% over 3 years, to align with population growth (to 2016, see Question 5.) and growth in popularity of the category. Dividing the total annual number of kebabs consumed by the total population x 100 gives a percentage of the population consuming one kebab per annum. Dividing by 2 then gives the proportion consuming 2 kebabs per annum. It was estimated that the market share of each species was: 65% beef, 15% chicken, 10% lamb, with 10% of kebab purchases being vegetarian (aligning with estimates of vegetarianism amongst Australian consumers). Focussing on beef and lamb (in combination) approximately 75% of kebabs are red meat. Therefore 75% of those eating kebabs will be sourcing red meat-based kebabs, resulting in 3.6% eating a red meat kebab twice per year (correlating to the 'very few' 5% input parameter).

As discussed in PRMS.038c the consumption patterns differ by product type between consumers (age and gender), as do serving sizes. Commentary made in that report suggest that the differences in consumption patterns/amounts by age, gender or geographic region are relatively minor (much less than ten-fold) and contribute relatively little to differences in risk.

Question 5. Total population
As described in 4.3.1.1.

Question 6. Probability of contamination of raw product per serving
As described in 4.3.1.6.

Question 7. Effect of processing on the hazard
Kebab: First cooking step (as a processing step). The process (of cooking) usually (99% of cases) eliminates hazards (MLA PRMS.038c 2003).

Question 8. Post-processing contamination rate
Kebab: YES (minor, 1% frequency). This assumption is somewhat speculative, based on MLA Report PRMS.038c (2003). However it should be noted that there have been improvements in critical control point identification/management and food safety planning since this time.

Question 9. Post-processing control
Scenario 1: Well Controlled – reliable, effective, systems in place (no increase in pathogens). Assumed the cold chain is maintained to inhibit pathogen growth. *E.coli* does not grow at temperatures <7^{o}C but can survive in chilled and frozen food. Optimum temperatures for growth are 35-40^{o}C. In this scenario flash heating is assumed.

Scenario 2: Not controlled – no systems, untrained staff (10-fold increase) -No final flash-frying. While the cold chain may have been maintained as in Scenario 1, the recommended guideline of flash frying the meat shavings before serving is not undertaken.

The incorporation of guidelines on flash heating is assumed in most cases. Improvements in kebab food safety has been noted by the NSW Government Food Authority in past surveys. *"In a 2008 survey, the NSW Food Authority found 94% of the kebabs it surveyed were of good quality – or safe to eat. The results showed a slight improvement in standards since the previous survey in 2004. Then 89% of the kebabs surveyed were considered acceptable."* (SBS 2009).

It is further assumed that improvements have continued, with no outbreaks attributed by OzFoodNet to *E.coli* in lamb or beef kebabs between 2005 and 2014, however there were 2 kebab entries with unknown aetiology (2007 and 2008). There were 4 associations between *Salmonella* spp. and kebabs but with no attribution to particular ingredients.

Question 10. Increase required to cause infection/intoxication
As described in 5.3.2.1.6.

Question 11. Effects of preparation before eating on hazard
There is no further meal preparation for kebabs.

Risk Ranger v2 outputs:
Table 24 provides information on the input parameters used and the Risk Ranger v2 outputs obtained for this combination. According to the input parameters used, the risk ranking for this combination is estimated to be 32 to 38 (Medium) depending on the use of a final heat flashing during the process of preparing the kebab. The cases predicted range from 1 to 10 per year. The daily probability of illness per person within the general population was estimated to be between 2.6×10^{-9} to 2.6×10^{-8}.

Table 24. Risk ranking summary for STEC *Escherichia coli* O157 in 'outside in' products – 1. Doner kebabs (*Description of the estimation of input parameters in 4.3.1.7*)

Criteria	Estimation	Sources
1. Hazard severity	Moderate	MLA PRMS.038c (2003)
2. Population susceptibility	General	
3. Frequency consumption	Weekly	Kippist (2013)
4. Proportion consuming (%)	5%	
5. Total population	22,002,599 (meat-eating persons > 5 months of age)	Australian Bureau of Statistics 3101.0 (2017) Roy Morgan Research (2016)
6. Proportion of raw product contaminated (%)	0.18%	MLA AMPC Report V.MFS.0403 (2017) Figure suggested by MLA Food Safety Risk Panel (2018)
7. Effect of processing on hazard	First cooking step (as a processing step). The process usually (99% of cases) eliminates hazards	Industry communication (2017) MLA PRMS.038C (2003)
8. Post processing contamination rate/potential for recontamination (%)	Nil	MLA PRMS.038C (2003)
9. Post processing control	Scenario 1: Well Controlled – reliable, effective, systems in place (no increase in: pathogens) Scenario 2: Not controlled – no systems, untrained stall (10-fold increase) (No final flash-frying)	FSANZ (2016)
10. Increase required to cause infection/intoxication	10^3	Cassin et al. (1998), WHO (2011)
11. Effects of preparation before eating on hazard	Meal preparation has no effect on the hazard	 MLA PRMS.038C (2003)
Predicted cases per annum Risk Ranking	Scenario 1: 1; Scenario 2:10 Scenario 1: 32; Scenario 2: 38	

4.3.1.8 STEC *Escherichia coli* in 'outside in' products: 2. Rolled or blade/needle tenderised roasts

Description of product and processing: The raw product is the primal, and the process involves the primal being tenderised by blade or needle, or rolled in such a manner that external surface contamination becomes internalised in the new 'form'. In this scenario, it is assumed that some of these products are consumed undercooked.

'Outside In' products have been described in the previous section (5.3.2.1.7). Needle/blade tenderised product has increased in popularity and has caused illness (and recalls) internationally in the past, specifically in the U.S and Canada. From 2000 to May 2016 the U.S. Centers for Disease Control and Prevention (CDC) recorded 6 outbreaks attributed to mechanically tenderised beef products prepared in restaurants or in the home[††].

The contribution of marinades or other injections in this products in this scenario has not been analysed.

Question 1. Hazard Severity
As described in 5.3.2.1.6.

Question 2. How susceptible is the population of interest
As described in 5.3.2.1.6.

Question 3. Frequency of consumption
The speculated frequency of consumption of rolled or tenderised roasts was nominated as "a few (3) times per annum" (65-100g serving). When considering the consumption of roasts in relation to *C.perfringens* it was estimated that a total of 2 roast servings/annum (of beef) were consumed. For the purpose of this report it was considered that in half of these consumption events that the product had undergone a tenderisation process. Because of the fat content of lamb increasing tenderness, it was concluded that this product did not require tenderisation. Consumption of lamb rolled roasts was estimated at once per annum, giving 3 'outside in' red meat roast eating occasions per annum.

Question 4. Proportion of population consuming the product
For roasts, the proportion was nominated as 25% based on speculative assumptions. As discussed in PRMS.038c the consumption patterns differ by product type between consumers (age and gender), as do serving sizes. Commentary made in that report suggest that the differences in consumption patterns/amounts by age, gender or geographic region are relatively minor (much less than ten-fold) and contribute relatively little to differences in risk.

Question 5. Total population
As described in 4.3.1.1.

Question 6. Probability of contamination of raw product per serving

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[††] https://www.fsis.usda.gov/wps/portal/fsis/topics/food-safety-education/get-answers/food-safety-fact-sheets/food-labeling/MTB/mechanically-tenderized-beef (verifed 8 Feburary 2018)
http://www.foodauthority.nsw.gov.au/_Documents/scienceandtechnical/meat_food_safety_scheme_risk_assessment.pdf (verifed 8 Feburary 2018)
http://www.foodsafetynews.com/2014/08/canada-requires-labels-for-mechanically-tenderized-beef/#.Wnunt6iWaUk (verifed 8 Feburary 2018)
http://www.inspection.gc.ca/about-the-cfia/newsroom/food-recall-warnings/complete-listing/2017-05-11/eng/1494547407074/1494547409709 (verifed 8 Feburary 2018)
http://www.inspection.gc.ca/about-the-cfia/newsroom/food-recall-warnings/complete-listing/2017-10-17/eng/1508283692898/1508283695906 (verifed 8 Feburary 2018)

As described in 4.3.1.6.

Question 7. Effect of processing on the hazard
Rolled or blade/needle tenderised roasts: The process was deemed to have 'no effect' on the hazard. Primals are usually held at low temperatures prior to distribution; <4.0°C is a processing standard. However coming out of most chiller tunnels temperatures are between 0-2°C with chilled storage also held at these temperatures. Thus load out temperatures are usually around 2°C. It is therefore not expected that processing would alter the inherent pathogen load due to temperature factors.

Question 8. Post-processing contamination rate
Rolled or blade/needle tenderised roasts: Nil. An assumption was made that the cool chain is maintained and there is no further handling until the point food preparation that may cause further contamination.

Question 9. Post-processing control
This parameter was designated as "well controlled – reliable, effective, systems in place (no increase in pathogens)". It was assumed the cold chain would be maintained thus inhibiting pathogen growth. *E.coli* does not grow at temperatures <7°C but can survive in chilled and frozen food. Optimum temperatures for growth are 35-40°C (FSANZ 2016).

Question 10. Increase required to cause infection/intoxication
As described in 4.3.1.6.

Question 11. Effects of preparation before eating on hazard
Rolled or blade/needle tenderised roasts: 90% reduction. No data was available on cooking regimens of rolled roast and consequent reduction on pathogen loads. It is assumed that a proportion of this product is consumed undercooked and this scenario considers 90% inactivation of pathogens. Most contamination of tenderised product is in the top 1cm, with 3 to 4% being in the centre (Desmarchelier 2013). Retail packaged product is issued with cooking instructions to ensure full inactivation.

Risk Ranger v2 outputs:
Table 25 provides information on the input parameters used and the Risk Ranger outputs obtained for this combination. A risk ranking estimate of 35 (Medium) was obtained with 3 predicted cases per year. The daily probability of illness per person within the general population was estimated to be 1.5×10^{-9}.

Table 25. Risk ranking summary for STEC *Escherichia coli* in 'outside in' products – 2. Rolled or blade/needle tenderised roasts (Description of the estimation of input parameters in 4.3.1.8)

Criteria	Estimation	Sources
1. Hazard severity	Moderate	MLA PRMS.038c (2003)
2. Population susceptibility	General	
3. Frequency consumption	Few times per year	Australian Bureau of Statistics 4364.0.55.007 (2014) (see *C.perfringens* in roasts table)
4. Proportion consuming (%)	25%	
5. Total population	22,002,599 (meat-eating persons > 5 months of age)	Australian Bureau of Statistics 3101.0 (2017) Roy Morgan Research (2016)
6. Proportion of raw product contaminated (%)	0.18%	MLA AMPC Report V.MFS.0403 (2017) Figure suggested by MLA Food Safety Risk Panel (2018)
7. Effect of processing on hazard	The process has no effect on the hazard	Industry communication (2017) MLA PRMS.038C (2003)
8. Post processing contamination rate/potential for recontamination (%)	Nil	MLA PRMS.038C (2003)
9. Post processing control	Well Controlled – reliable, effective, systems in place (no increase in pathogens)	FSANZ (2016)
10. Increase required to cause infection/intoxication	10^3	Cassin et al. (1998), WHO (2011)
11. Effects of preparation before eating on hazard	Rolled or blade/needle tenderised roasts: 90% reduction	MLA PRMS.038C (2003)
Predicted cases per annum	3	
Risk Ranking	35	

4.3.1.9 STEC *Escherichia coli* O157 in undercooked and uncooked comminuted meat products (e.g. mince, undercooked hamburgers)

Description of product and processing: The raw product is comminuted meat and the process involves forming comminuted meat into a shape, then applying heat to varying degrees which is reflected by the Undercooked or Uncooked scenarios which pertain predominantly to the centre of the form.

A comparison between uncooked and undercooked comminuted meat product was performed in this analysis. Minced meat encompasses this category and is used as a base for a number of dishes. Hamburgers form a subset of the grouping with undercooked hamburgers having become an increasing popular cuisine and of concern to food regulators. Where minced product is formed in a pattie or other shape, the meat in the middle may be uncooked with only superficial layers reaching appropriate temperatures to kill pathogens.

Two scenarios were run for this combination, one for the general population and one for the elderly population (>65 years of age).

Question 1. Hazard Severity
For the general population as described in 4.3.1.6. For elderly population it was considered to be a 'Severe hazard – causes death to most victims', due to this subgroup of the population having a weakened immune system.

Question 2. How susceptible is the population of interest
General population as described in 4.3.1.6. Elderly population was identified as having a 'slight' susceptibility.

Question 3. Frequency of consumption
Undercooked: The speculated frequency of the consumption of undercooked mince was nominated as 3 times per annum (a few times a year).

Uncooked: The speculated frequency of the consumption of uncooked mince was nominated as "1 time per annum/365 days between servings".

Serving sizes assumed to be 65g. Generic mince consumption was reported in the 2011 – 2012 Nutrition and Physical Activity Survey (part of the 2011 – 2013 Australian Health Survey [‡‡]). Consumption patterns of beef (excluding mixed foods that contain beef and beef products) was detailed. In the survey, consumption could be divided into minced meat, whole muscle cuts and offal. Nine percent of children (aged 2 – 16 years), 7% of adults (aged 17 – 69 years) and 9% of people aged 70 and above reported consumption of minced meat.

Question 4. Proportion of population consuming the product
For undercooked product, the proportion was nominated as 25% based on speculative assumptions.
For uncooked product, the proportion was nominated as 5% based on speculative assumptions.
As discussed in PRMS.038c the consumption patterns differ by product type between consumers (age and gender), as do serving sizes. Commentary made in that report suggest that the differences in consumption patterns/amounts by age, gender or geographic region are relatively minor (much less than ten-fold) and contribute relatively little to differences in risk.

[‡‡] http://www.foodstandards.gov.au/consumer/importedfoods/Documents/Beef%20and%20Salmonella.pdf

Question 5. Total population
General population as described in 4.3.1.1. and an elderly population as described in 3.3.2.

Question 6. Probability of contamination of raw product per serving
As described in 4.3.1.6.

Question 7. Effect of processing on the hazard
Processing was deemed to have 'no effect' on the hazard. While comminuted product can increase the pathogen load, it is not expected that further processing would alter the inherent pathogen load. Product leaves the processing premises at less than 4°C (a processing standard). Note: The freezing of product (not considered in this generic scenario) would have the effect of reducing the pathogen load if temperatures were low enough and of suitable duration (MLA Report A.MFS.0097 2007).

Question 8. Post-processing contamination rate
Nil. An assumption was made that the cool chain is maintained and there is no further handling until the point food preparation that may cause further contamination.

Question 9. Post-processing control
This parameter was designated as "well controlled – reliable, effective, systems in place (no increase in pathogens)". It was assumed the cold chain would be maintained thus inhibiting pathogen growth. *E.coli* does not grow at temperatures <7°C but can survive in chilled and frozen food. Optimum temperatures for growth are 35-40°C (FSANZ 2016).

Question 10. Increase required to cause infection/intoxication
As described in 4.3.1.6.

Question 11. Effects of preparation before eating on hazard
There is no relevant data on cooking regimens of comminuted meat products and consequent reduction rates in pathogen load. There are many factors to consider when contemplating heat inactivation of bacteria which makes ranking the risk of a particular product more uncertain. When approaching the boundary for heat inactivation, bacterial strain type, the nature of the heated food, and other environmental factors have greater effects in relation to bacterial survival or death (Advisory Committee on the Microbiological Safety of Food - ACMSF 2014). Heat resistance is dependent on strain; physiological state, growth phase (stationary phase cells are more heat resistant) and growth conditions (cells in anaerobic conditions are more heat resistant); storage conditions (bacteria that have been stored frozen are more heat resistant than those stored at refrigerator or cold room temperatures); salt content, pH, fat content and other parameters of the matrix in which heating was performed; and greater following heat shock (this has implications for the speed at which cooking temperatures are reached) (ACMSF 2007). With respect to matrix parameters and storage conditions in beef burger patties, it has been reported that commercial processing and product formulation have profound effects on the heat resistance of *E. coli* O157:H7, with variation seen between burgers processed in line with commercial practice (i.e. tempered and stored frozen) than in burgers made with fresh ('unprocessed') meat (commercial patties had lower heat resistance values). Furthermore values in 'quality' processed burgers (100% beef) were significantly lower than in 'economy' processed products (70% beef, 30% soya, onion, etc.) [Byrne et al. 2002 in ACMSF 2007]. Blackman et al. (2005) comment that oxidative compounds, such as iron salts, ADP and ascorbic acid which are naturally present in meat and meat-based products, also have an effect on the thermal resistance of *E. coli* O157:H7 strains with oxidative stress modulating resistance both upwards and downwards according to the level of stress (ACMSF 2007).

Assumptions have been made to generate comparisons. For Undercooked product two scenarios were posed. The first scenario defines that meal preparation slightly reduces (50%) hazards. The second scenario presents a 90% reduction of hazards. For uncooked product meal preparation has no effect on the hazard because no cooking step is applied.

Risk Ranger v2 outputs:
Table 26 provides information on the input parameters used and the Risk Ranger outputs obtained for both the general and susceptible population (elderly >65 y of age). For the general population, the risk ranking for undercooked product ranged from 35 to 39 depending on the level of cooking (90 to 50% reduction), with 3 to 15 predicted cases per year. For uncooked product, the risk ranking is estimated to be 34 with 2 predicted cases per year. The lower risk ranking for uncooked product is due to the lower consumption of this product. The daily probability of illness per person within the general population was estimated to be very similar for undercooked and uncooked product, ranging from 1.5 to 7.4×10^{-9}.

For the elderly population, considering this subgroup to be 20% of the general population and five times more susceptible than the general population, the risk ranking is estimated to be 46 to 50 for undercooked product (90 to 50% pathogen reduction due to cooking) and 45 for uncooked product. The predicted cases among the elderly population were 3 to 15 for consumption of undercooked product and 2 for uncooked product. The probability of illness per day increases by a factor of 10 to 2.5×10^{-8}. Similarly to the *Clostridium perfringens* combination, the increase in risk ranking and predicted cases among the elderly population is due to the higher susceptibility to this hazard within this subgroup of the population and the increased severity of illness. In this case the same consumption was assumed for both, the general and the elderly population.

Table 26. Risk ranking summary for STEC *Escherichia coli* in undercooked and uncooked comminuted meat products (e.g. mince, undercooked hamburgers) (*Description of the estimation of input parameters in 4.3.1.9*)

Criteria	Estimation (General population)	Estimation (Susceptible population)	Sources
1. Hazard severity	Moderate	Severe	MLA PRMS.038c (2003)
2. Population susceptibility	General	Slight	
3. Frequency consumption	***Undercooked***: 3 times/y (few times a year) ***Uncooked***: once/y	***Undercooked***: 3 times/y (few times a year) ***Uncooked***: once/y	
4. Proportion consuming (%)	***Undercooked***: 25% ***Uncooked***: 5%	***Undercooked***: 25% ***Uncooked***: 5%	
5. Total population	22,002,599 (meat-eating persons > 5 months of age)	22,002,599 (meat-eating persons > 5 months of age). Software assumes 20% of the population have a slight susceptibility	Australian Bureau of Statistics 3101.0 (2017), Roy Morgan Research (2016)
6. Proportion of raw product contaminated (%)	0.18%	0.18%	MLA AMPC Report V.MFS.0403 (2017) Figure suggested by MLA Food Safety Risk Panel (2018)
7. Effect of processing on hazard	The process has no effect on the hazard	The process has no effect on the hazard	MLA A.MFS.0097 (2007)
8. Post processing contamination rate/potential for recontamination (%)	Nil	Nil	
9. Post processing control	Well controlled – reliable, effective, systems in place (no increase in pathogens)	Well controlled – reliable, effective, systems in place (no increase in pathogens)	FSANZ (2016)
10. Increase required to cause infection/intoxication	10^3	10^3	Cassin et al. (1998), WHO (2011)
11. Effects of preparation before eating on hazard	***Undercooked***: Scenario 1: Meal preparation slightly reduces (50%) hazards Scenario 2: 90% reduction of hazards ***Uncooked***: Meal preparation has no effect on the hazard	***Undercooked***: Scenario 1: Meal preparation slightly reduces (50%) hazards Scenario 2: 90% reduction of hazards ***Uncooked***: Meal preparation has no effect on the hazard	
Predicted cases per annum	***Undercooked***: Scenario 1: 15; Scenario 2: 3 ***Uncooked***: 2	***Undercooked***: Scenario 1: 15; Scenario 2: 3 ***Uncooked***: 2	
Risk Ranking	***Undercooked***: Scenario 1: 39; Scenario 2: 35 ***Uncooked***: 34	***Undercooked***: Scenario 1: 50; Scenario 2: 46 ***Uncooked***: 45	

4.3.1.10 STEC *Escherichia coli* in non GMP UCFM products (e.g. homemade salami)

Description of product and processing: Uncooked Comminuted Fermented Meat (UCFM). It is assumed that the artisan practice of mincing meat and trim for salami preparation is undertaken. The raw product may be trim and/or primal pieces (the percentage of meat to fat, and type of fat, is an important quality consideration) along with other additives and flavourings. The process involves fermentation and maturation/drying (sometimes a smoking step is also involved). There is no cooking step.

> *"There are a large number of fermented meat products made from chopped, comminuted meat, with or without additives. Raw meat, most often pork or beef, is chopped into small pieces in a silent bowl cutter at low speed to produce a course emulsion. Water is added for lubrication. A starter culture of certain bacteria is added to the mixture. The mixture may have added various other ingredients before being filled into casings and placed in a warm room with high humidity. Other non-meat ingredients usually include sodium chloride, sometimes nitrate or nitrites and occasionally a small amount of sugar, plus various spices or seasonings. Variables in the production of fermented meats include:*
>
> - *type of meat;*
> - *amount of fat added;*
> - *starter culture used;*
> - *curing mix composition and concentration;*
> - *fermentation time and temperature;*
> - *maturation time and temperature;*
> - *sausage diameter;*
> - *final pH, final water activity; and*
> - *recommended storage temperatures." (FSANZ 2003)*

An intensified media focus on food through popular food shows, growing awareness of sustainability, and concern about the health/ingredients has led to a considerable growth in the artisan food sector, both in retail and home cuisine. Several outbreaks of EHEC, globally, have been linked to dry-fermented sausages (Paton et al. 1996; Schimmer et al. 2008; Tilden et al. 1996 in McLeod et al. 2016). McLeod et al. further comment that enterohaemorrhagic *E. coli* (EHEC), and other pathogens, "*exhibit strategies (through adaptation) to survive stresses intended to control their growth. When tolerance to a particular stress has been induced, the pathogen may display enhanced resistance to the original stress as well as to other stresses. E. coli is more acid tolerant than many other enteric pathogens and may survive well in different acidic foods (Besser et al. 1993; Guraya et al. 1998; Miller and Kaspar 1994; Zhao et al. 1993). In addition, enhanced survival of acid adapted cells in comparison with non-adapted has been demonstrated in products such as apple cider and dry salami (Leyer et al. 1995), in French fermented raw meat sausage (Montet et al. 2009a), and in Camembert cheese (Montet et al. 2009b)*".

Question 1. Hazard Severity
As described in 4.3.1.6.

Question 2. How susceptible is the population of interest
As described in 4.3.1.6.

Question 3. Frequency of consumption
The frequency of consumption of artisan/homemade salami was speculative at once per annum. While artisan cooking has increased in popularity, it is assumed that the effort required in home curing of product inhibits its production. Serving sizes assumed to be 65g.

Question 4. Proportion of population consuming the product
The proportion consuming the product was again speculative, nominated as “very few: 5%” due to being the lowest parameter input. It assumed that only a low proportion of people engage in salami-making with only a small distribution reach.

As discussed in PRMS.038c the consumption patterns differ by product type between consumers (age and gender), as do serving sizes. Commentary made in that report suggest that the differences in consumption patterns/amounts by age, gender or geographic region are relatively minor (much less than ten-fold) and contribute relatively little to differences in risk.

Question 5. Total population
As described in 4.3.1.6.

Question 6. Probability of contamination of raw product per serving
It is assumed that if households are engaging in salami-making they would take the artisan approach of mincing trim/primal pieces for salami preparation.

Under guidance by the MLA Food Safety Risk Panel (2018) the probability was nominated at 0.18% based on data on beef trim in MLA Report V.MFS.0403 (2017).

Question 7. Effect of processing on the hazard
Processing was deemed to usually (99% of cases) eliminate hazards. “Inactivation of E.coli during fermentation and maturation of UCFM, a reduction in EHEC during the UCFM process by 2 log (99%) was assumed” (MLA PRMS.038c 2003, p41).

Question 8. Post-processing contamination rate
Nil. It was assumed there was no potential for recontamination post-processing.

Question 9. Post-processing control
This parameter was designated as “controlled – mostly reliable systems in place (3-fold increase)”. Concerns regarding environmental control of curing meats and consequent storage prevented a “well controlled” response.

Question 10. Increase required to cause infection/intoxication
As described in 4.3.1.6.

Question 11. Effects of preparation before eating on hazard
It is assumed that “meal preparation has no effect on the hazards” due to most artisan UCFM being eaten without a cooking step involved.

Risk Ranger v2 outputs:
Table 27 provides information on the input parameters used and the Risk Ranger outputs obtained for this combination. A risk ranking estimate of 25 (Low) was obtained with 5.9×10^{-2} predicted cases per year. The daily probability of illness per person within the general population was estimated to be 1.5×10^{-10}.

Table 27. Risk ranking summary for STEC *Escherichia coli* O157 in non GMP UCFM products (e.g. homemade salami) (*Description of the estimation of input parameters in 4.3.1.10*)

Criteria	Estimation	Sources
1. Hazard severity	Moderate	MLA PRMS.038c (2003)
2. Population susceptibility	General	
3. Frequency consumption	Once/y	
4. Proportion consuming (%)	5%	
5. Total population	22,002,599 (meat-eating persons > 5 months of age)	Australian Bureau of Statistics 3101.0 (2017), Roy Morgan Research (2016)
6. Proportion of raw product contaminated (%)	0.18%	MLA AMPC Report V.MFS.0403 (2017) Figure suggested by MLA Food Safety Risk Panel (2018)
7. Effect of processing on hazard	The process usually (99% of cases) eliminates hazards	MLA PRMS.038c (2003) p41
8. Post processing contamination rate/potential for recontamination (%)	Nil	
9. Post processing control	Controlled – mostly reliable systems in place (3-fold increase)	FSANZ (2016)
10. Increase required to cause infection/intoxication	10^3	Cassin et al. (1998), WHO (2011)
11. Effects of preparation before eating on hazard	Meal Preparation has NO EFFECT on the hazards	
Predicted cases per annum Risk Ranking	5.9×10^{-2} 25	

4.3.1.11 *Salmonella* spp. in undercooked and uncooked comminuted meat products (e.g. mince, undercooked hamburgers)

Description of product and processing: The raw product is comminuted meat and the process involves forming comminuted meat into a shape, then applying heat to varying degrees which is reflected by the Undercooked or Uncooked scenarios which pertain predominantly to the centre of the form. More detailed description of the scenarios used for this product has been provided in section 4.3.1.9.

Question 1. Hazard Severity
Salmonella was considered a "Mild– sometimes requires medical intervention" for a general population, aligning with the severity reported in PRMS.038c (2003).

Question 2. How susceptible is the population of interest
For the current assessment, the answer selected for Question 2 was "GENERAL - all members of the population". Population sub-groups known to have greater susceptibility were not differentiated.

Question 3. Frequency of consumption
Undercooked: The speculated frequency of the consumption of undercooked mince was nominated as 3 times per annum (a few times a year).

Uncooked: The speculated frequency of the consumption of uncooked mince was nominated as "1 time per annum/365 days between servings".

Serving sizes assumed to be 65g. Generic mince consumption was reported in the 2011 – 2012 Nutrition and Physical Activity Survey (part of the 2011 – 2013 Australian Health Survey[§§]). Consumption patterns of beef (excluding mixed foods that contain beef and beef products) was detailed. In the survey, consumption could be divided into minced meat, whole muscle cuts and offal. Nine percent of children (aged 2 – 16 years), 7% of adults (aged 17 – 69 years) and 9% of people aged 70 and above reported consumption of minced meat.

Question 4. Proportion of population consuming the product
For undercooked product, the proportion was nominated as 25% based on speculative assumptions.
For uncooked product, the proportion was nominated as 5% based on speculative assumptions.

As discussed in PRMS.038c the consumption patterns differ by product type between consumers (age and gender), as do serving sizes. Commentary made in that report suggest that the differences in consumption patterns/amounts by age, gender or geographic region are relatively minor (much less than ten-fold) and contribute relatively little to differences in risk.

Question 5. Total population
As described in 4.3.1.1.

Question 6. Probability of contamination of raw product per serving
For *Salmonella* spp. the probability was nominated at 0.7% (with a concentration of <0.3 MPN (most probable number/g) from survey data collected by Symbio on manufacturing beef reported in MLA Report VMFS.0335 (2014).

[§§] http://www.foodstandards.gov.au/consumer/importedfoods/Documents/Beef%20and%20Salmonella.pdf

Question 7. Effect of processing on the hazard
Processing was deemed to have 'no effect' on the hazard. While comminuting product can increase the pathogen load, it is not expected that further processing would alter the inherent pathogen load. Product leaves the processing premises at less than 4^{o}C (a processing standard). Note: The freezing of product (not considered in this generic scenario) would have the effect of reducing the pathogen load if temperatures were low enough and of suitable duration (MLA Report A.MFS.0097 2007).

Question 8. Post-processing contamination rate
Nil. An assumption was made that the cool chain is maintained and there is no further handling until the point in food preparation that may cause further contamination.

Question 9. Post-processing control
This parameter was designated as "well controlled – reliable, effective, systems in place (no increase in pathogens)". It was assumed the cold chain would be maintained thus inhibiting pathogen growth. The optimal growth temperature for *Salmonella* is 35-43^{o}C. Most serotypes do not grow at temperatures below 7^{o}C. (FSANZ 2016).

Question 10. Increase required to cause infection/intoxication
The particular food matrix and strain of *Salmonella* spp. influences the dose of *Salmonella* spp. required for illness. As few as one to 100 cells have been reported to cause illness, however, in most cases substantially more cells are required for illness to occur (FDA, ICMSF 1996 cited in FSANZ 2017). Investigation of salmonellosis outbreaks has estimated dose ranges of <10–10^9 organisms (depending on the food, FSANZ 2013). The ID_{50} infective dose was designated as 10^4 CFU/serving (FAO/WHO, 2002) due to the reliability of the source. A concentration of 0.3 CFU/g (based on <3 MPN/g in MLA VMFS.0335 2014) correlates to 19.5 CFU/65g serving. Therefore a multiplication factor of approximately 10^3 was required to reach an infective dose.

Question 11. Effects of preparation before eating on hazard
There is no relevant data on cooking regimens of comminuted meat products and consequent reduction rates in the pathogen load. Assumptions have been made to generate comparisons. For Undercooked product two scenarios were posed. The first scenario defines that meal preparation slightly reduces (50%) hazards. The second scenario presents a 90% reduction of hazards.

For Uncooked product meal preparation has no effect on the hazard because no cooking step is applied.

Risk Ranger v2 outputs:
Table 28 provides information on the input parameters used and the Risk Ranger outputs obtained for both undercooked and uncooked product consumed by the general population. For this population, the risk ranking for undercooked product ranged from 33 to 37 depending on the level of cooking (90 to 50% reduction), with 12 to 58 predicted cases per year. For uncooked product, the risk ranking is estimated to be 32 with 7.7 predicted cases per year. The lower risk ranking for uncooked product is due to the lower consumption of this product. The daily probability of illness per person within the general population was estimated to be 5.8×10^{-9} to 2.9×10^{-8} for undercooked product and 1.9×10^{-8} for uncooked product.

Table 28. Risk ranking summary for *Salmonella* spp. in undercooked and uncooked comminuted meat products (e.g. mince, undercooked hamburgers) (*Description of the estimation of input parameters in 4.3.1.11*)

Criteria	Estimation	Sources
1. Hazard severity	Mild	MLA PRMS.038c (2003)
2. Population susceptibility	General	
3. Frequency consumption	***Undercooked***: 3 times/y ***Uncooked***: once/y	
4. Proportion consuming (%)	***Undercooked***: 25% ***Uncooked***: 5%	Australian Bureau of Statistics 43640DO004_20112012 (2014)
5. Total population	22,002,599 (meat-eating persons > 5 months of age)	Australian Bureau of Statistics 3101.0 (2017), Roy Morgan Research (2016)
6. Proportion of raw product contaminated (%)	0.7%	MLA VMFS.0335 (2014) *Salmonella* in Bovine lymph nodes survey; Symbio, MLA 2014 (Manufacturing beef)
7. Effect of processing on hazard	The process has no effect on the hazard	A.MFS.0097 (2007
8. Post processing contamination rate/potential for recontamination (%)	Nil	
9. Post processing control	Well controlled – reliable, effective, systems in place (no increase in pathogens)	FSANZ (2016)
10. Increase required to cause infection/intoxication	10^3	MLA PRMS.038c (2003) Leggett et al. (2012) FSANZ (2013) FDA; ICMSF (1996) in FSANZ (2017) FAO/WHO (2002)
11. Effects of preparation before eating on hazard	***Undercooked***: Scenario 1: Meal preparation slightly reduces (50%) hazards Scenario 2: 90% reduction of hazards ***Uncooked***: Meal preparation has no effect on the hazard	
Predicted cases per annum Risk Ranking	***Undercooked***: Scenario 1: 58; Scenario 2: 11.6 ***Uncooked***: 7.7 ***Undercooked***: Scenario 1: 37; Scenario 2: 33 ***Uncooked***: 32	

4.3.1.12 *Salmonella* spp. in 'outside in' products: 1. Doner kebabs

The description of product and processing has been presented in section 4.3.1.7.

Question 1. Hazard Severity
As described in 4.3.1.11.

Question 2. How susceptible is the population of interest
As described in 4.3.1.11.

Question 3. Frequency of consumption
The speculated frequency of consumption of doner kebabs (or regional variants based on grilled meat on a vertical, rotating spit whereby the shaved meat is wrapped in flat bread with salad / vegetables and dips) was nominated as "weekly" (65g serving).

Question 4. Proportion of population consuming the product
For kebabs, the 5% estimation was derived from anecdotal information reported by journalist Lucy Kippist (2013) and then extrapolated to estimate more current total kebab consumption per annum. 190,000 kebabs per annum in 2013 was multiplied by a growth factor of 20% over 3 years, to align with population growth (to 2016, see Question 5.) and growth in popularity of the category. Dividing the total annual number of kebabs consumed by the total population x 100 gives a percentage of the population consuming one kebab per annum. Dividing by 2 then gives the proportion consuming 2 kebabs per annum. It was estimated that the market share of each species was: 65% beef, 15% chicken, 10% lamb, with 10% of kebab purchases being vegetarian (aligning with estimates of vegetarianism amongst Australian consumers). Focussing on beef and lamb (in combination) approximately 75% of kebabs are red meat. Therefore 75% of those eating kebabs will be sourcing red meat-based kebabs, resulting in 3.6% eating a red meat kebab twice per year (correlating to the 'very few' 5% input parameter).

As discussed in PRMS.038c the consumption patterns differ by product type between consumers (age and gender), as do serving sizes. Commentary made in that report suggest that the differences in consumption patterns/amounts by age, gender or geographic region are relatively minor (much less than ten-fold) and contribute relatively little to differences in risk.

Question 5. Total population
As described in 4.3.1.1.

Question 6. Probability of contamination of raw product per serving
Salmonella spp. probability was set at 0.34%, the prevalence on beef carcases at the end of processing as reported in MLA Report V.MFS.0332 (2017).

Question 7. Effect of processing on the hazard
Kebab: First cooking step (as a processing step). The process (of cooking) usually (99% of cases) eliminates hazards (MLA PRMS.038c 2003).

Question 8. Post-processing contamination rate
Kebab: Nil.

Question 9. Post-processing control
Scenario 1: Well Controlled – reliable, effective, systems in place (no increase in: pathogens). This parameter was designated as "well controlled – reliable, effective, systems in place (no increase in

pathogens)". It was assumed the cold chain would be maintained thus inhibiting pathogen growth. The optimal growth temperature for *Salmonella* is 35-43^{o}C. Most serotypes do not grow at temperatures below 7^{o}C (FSANZ 2016).

Scenario 2: Not controlled – no systems, untrained staff (10-fold increase) (No final flash-frying).

Question 10. Increase required to cause infection/intoxication
The particular food matrix and strain of *Salmonella* spp. influences the level of *Salmonella* spp. required for illness. As few as one to 100 cells have been reported to cause illness, however in most cases substantially more cells are required for illness to occur (FDA; ICMSF 1996 cited in FSANZ 2017). Investigation of salmonellosis outbreaks has estimated dose ranges of <10–10^9 organisms (depending on the food, FSANZ 2013). The ID_{50} infective dose was designated as 10^4 CFU/serving (FAO/WHO, 2002) due to the reliability of the source. A concentration of 0.3 CFU/g (based on <3 MPN/g in MLA VMFS.0335, 2014) correlates to 19.5 CFU/65g serving. Therefore a multiplication factor of approximately 10^3 was required to reach an infective dose.

Question 11. Effects of preparation before eating on hazard
Kebab: Meal preparation has no effect on the hazard.

Risk Ranger v2 outputs:
Table 29 provides information on the input parameters used and the Risk Ranger outputs obtained for this combination. A risk ranking estimate of 28 to 34 was obtained, depending on the implementation of the final heat flashing during the last stages of kebab production, with 2 to 19.5 predicted cases per year. The daily probability of illness per person within the general population was estimated to be between 4.8 x 10^{-8} to 4.8 x 10^{-9}.

Table 29. Risk ranking summary for *Salmonella* spp. in 'outside in' products – 1. Kebabs (*Description of the estimation of input parameters in 4.3.1.12*)

Criteria	Estimation	Sources
1. Hazard severity	Mild	MLA PRMS.038c (2003)
2. Population susceptibility	General	
3. Frequency consumption	Weekly	
4. Proportion consuming (%)	5%	Australian Bureau of Statistics
5. Total population	22,002,599 (meat-eating persons > 5 months of age)	Australian Bureau of Statistics 3101.0 (2017), Roy Morgan Research (2016)
6. Proportion of raw product contaminated (%)	0.34%	MLA Report V.MFS.0332 (2017) Beef and veal baseline survey 2016 – Final report
7. Effect of processing on hazard	First cooking step. The process usually (99% of cases) eliminates hazards	Industry communication (2017)
8. Post processing contamination rate/potential for recontamination (%)	Nil	
9. Post processing control	Scenario 1: Well Controlled – reliable, effective, systems in place (no increase in: pathogens) Scenario 2: Not controlled – no systems, untrained stall (10-fold increase) (No final flashing)	FSANZ (2016)
10. Increase required to cause infection/intoxication	10^3	MLA PRMS.038c (2003) Leggett et al. (2012) FSANZ (2013) FDA; ICMSF (1996) in FSANZ (2017) FAO/WHO (2002)
11. Effects of preparation before eating on hazard	Meal preparation has no effect on the hazard	
Predicted cases per annum Risk Ranking	Scenario 1: 2; Scenario 2: 19.5 Scenario 1: 28; Scenario 2: 34	

4.3.1.13 *Salmonella* spp. in 'outside in' products: 2. Rolled or blade/needle tenderised roasts

The description of product and processing has been presented in section 4.3.1.8.

Question 1. Hazard Severity
As described in 4.3.1.11.

Question 2. How susceptible is the population of interest
As described in 4.3.1.11.

Question 3. Frequency of consumption
The speculated frequency of consumption of rolled or tenderised roasts was nominated as "a few (3) times per annum" (65-100g serving). When considering the consumption of roasts in relation to *C.perfringens* it was estimated that a total of 2 roast servings/annum (of beef) were consumed. For the purpose of this report it was considered that in half of these consumption events the product had undergone a tenderisation process. Because of the fat content of lamb increasing tenderness, it was concluded that this product did not require tenderisation. Consumption of lamb rolled roasts was estimated at once per annum, giving 3 'outside in' red meat roast eating occasions per annum.

Question 4. Proportion of population consuming the product
For roasts, the proportion was nominated as 25% based on speculative assumptions.

As discussed in PRMS.038c the consumption patterns differ by product type between consumers (age and gender), as do serving sizes. Commentary made in that report suggest that the differences in consumption patterns/amounts by age, gender or geographic region are relatively minor (much less than ten-fold) and contribute relatively little to differences in risk.

Question 5. Total population
As described in 4.3.1.1.

Question 6. Probability of contamination of raw product per serving
As described in 4.3.1.12.

Question 7. Effect of processing on the hazard
Rolled or blade/needle tenderised roasts: The process was deemed to have 'no effect' on the hazard. Primals are usually held at low temperatures prior to distribution; <4.0^{o}C is a processing standard. However coming out of most chiller tunnels temperatures are between 0-2^{o}C with chilled storage also held at these temperatures. Thus load out temperatures are usually around 2^{o}C. It is therefore not expected that processing would alter the inherent pathogen load due to temperature factors.

Question 8. Post-processing contamination rate
Rolled or blade/needle tenderised roasts: Nil. An assumption was made that the cool chain is maintained and there is no further handling until the point of food preparation that may cause further contamination.

Question 9. Post-processing control
This parameter was designated as "well controlled – reliable, effective, systems in place (no increase in pathogens)". It was assumed the cold chain would be maintained thus inhibiting pathogen growth. The optimal growth temperature for *Salmonella* is 35-43^{o}C. Most serotypes do not grow at temperatures below 7^{o}C (FSANZ 2016).

Question 10. Increase required to cause infection/intoxication
As described in 4.3.1.11.

Question 11. Effects of preparation before eating on hazard
Rolled or blade/needle tenderised roasts: 90% reduction. No data on cooking regimens of rolled roast and consequent reduction on pathogen loads. It is assumed that a proportion of this product is consumed undercooked and this scenario considers 90% inactivation of pathogens. Most contamination of tenderised product is in the top 1cm, with 3 to 4% being in the centre (Desmarchelier 2013). Retail packaged product is issued with cooking instructions to ensure full inactivation.

Risk Ranger v2 outputs:
Table 30 provides information on the input parameters used and the Risk Ranger outputs derived for this combination. A risk ranking estimate of 31 was obtained, with 5.6 predicted cases per year. The daily probability of illness per person within the general population was estimated to be 2.8 x 10^{-9}.

Table 30. Risk ranking summary for *Salmonella* spp. in 'outside in' products -2. Rolled or blade/needle tenderised roasts *(Description of the estimation of input parameters in 4.3.1.13)*

Criteria	Estimation	Sources
1. Hazard severity	Mild	MLA PRMS.038c (2003)
2. Population susceptibility	General	
3. Frequency consumption	Few times per year	
4. Proportion consuming (%)	25%	
5. Total population	22,002,599 (meat-eating persons > 5 months of age)	Australian Bureau of Statistics 3101.0 (2017), Roy Morgan Research (2016)
6. Proportion of raw product contaminated (%)	0.34%	MLA Report V.MFS.0332 (2017) Beef and veal baseline survey 2016 – Final report
7. Effect of processing on hazard	The process has no effect on the hazard	Industry communication (2017)
8. Post processing contamination rate/potential for recontamination (%)	Nil	
9. Post processing control	Well controlled - reliable, effective, systems in place (no increase in pathogens)	FSANZ (2016)
10. Increase required to cause infection/intoxication	10^3	MLA PRMS.038c (2003) Leggett et al. (2012) FSANZ (2013) FDA; ICMSF (1996) in FSANZ (2017) FAO/WHO (2002)
11. Effects of preparation before eating on hazard	90% reduction	MLA PRMS.038c (2003)
Predicted cases per annum Risk Ranking	5.6 31	

4.3.1.14 *Salmonella* spp. in non GMP UCFM products (e.g. homemade salami)

The description of product and processing has been presented in section 4.3.1.10.

Question 1. Hazard Severity
As described in 4.3.1.11.

Question 2. How susceptible is the population of interest
As described in 4.3.1.11.

Question 3. Frequency of consumption
The frequency of consumption of artisan/homemade salami was speculative at once per annum. While artisan cooking has increased in popularity, it is assumed that the effort required in home curing of product inhibits its production. Serving size assumed to be 65g.

Question 4. Proportion of population consuming the product
The proportion consuming the product was again speculative, nominated as “very few: 5%” due to being the lowest parameter input. It assumed that only a low proportion of people engage in salami-making with only a small distribution reach.

As discussed in PRMS.038c the consumption patterns differ by product type between consumers (age and gender), as do serving sizes. Commentary made in that report suggest that the differences in consumption patterns/amounts by age, gender or geographic region are relatively minor (much less than ten-fold) and contribute relatively little to differences in risk.

Question 5. Total population
As described in 4.3.1.1.

Question 6. Probability of contamination of raw product per serving
It is assumed that if households are engaging in salami-making they would take the artisan approach of mincing trim/primals for salami preparation. *Salmonella* spp. probability was set at 0.34%, the prevalence on beef carcases at the end of processing as reported in MLA Report V.MFS.0332 (2017).

Question 7. Effect of processing on the hazard
Processing was deemed to usually (99% of cases) eliminate hazards. As with *E.coli* discussed above, it is assumed that when the rate of the fermentation and maturation process and storage conditions are suitable (as per traditional or regulatory jurisdiction guidelines), then hazards should usually be eliminated (MLA Report PRMS.038c 2003).

Question 8. Post-processing contamination rate
Nil. It was assumed there was no potential for recontamination post-processing.

Question 9. Post-processing control
This parameter was designated as “controlled – mostly reliable systems in place (3-fold increase)”. Concerns regarding environmental control of curing meats and consequent storage prevented a “well controlled” response.

Question 10. Increase required to cause infection/intoxication
As described in 4.3.1.11.

Question 11. Effects of preparation before eating on hazard

It is assumed that “meal preparation has no effect on the hazards” due to most artisan UCFM being eaten without a cooking step involved.

Risk Ranger v2 outputs:

Table 31 provides information on the input parameters used and the Risk Ranger outputs obtained for this combination. A risk ranking estimate of 21 was obtained, considered Low, with 1.1×10^{-1} predicted cases per year. The daily probability of illness per person within the general population was estimated to be 2.8×10^{-10}.

Table 31. Risk ranking summary for *Salmonella* spp. in non GMP UCFM products (e.g. homemade salami) (*Description of the estimation of input parameters in 4.3.1.14*)

Criteria	Estimation	Sources
1. Hazard severity	Mild	MLA PRMS.038c (2003)
2. Population susceptibility	General	
3. Frequency consumption	once / y	
4. Proportion consuming (%)	5%	
5. Total population	22,002,599 (meat-eating persons > 5 months of age)	Australian Bureau of Statistics 3101.0 (2017), Roy Morgan Research (2016)
6. Proportion of raw product contaminated (%)	0.34%	MLA Report V.MFS.0332 (2017) Beef and veal baseline survey 2016 – Final report
7. Effect of processing on hazard	The process usually (99% of cases) eliminates hazards	MLA PRMS.038C (2003)
8. Post processing contamination rate/potential for recontamination (%)	Nil	
9. Post processing control	Controlled – mostly reliable systems in place (3-fold increase)	FSANZ (2016)
10. Increase required to cause infection/intoxication	10^3	MLA PRMS.038c (2003) Leggett et al. (2012) FSANZ (2013) FDA; ICMSF (1996) in FSANZ (2017) FAO/WHO (2002)
11. Effects of preparation before eating on hazard	Meal Preparation has NO EFFECT on the hazards	
Predicted cases per annum Risk Ranking	1.1×10^{-1} 21	

4.3.1.15 *Campylobacter* spp. in undercooked and uncooked comminuted meat products (e.g. undercooked hamburgers, mince)

The description of product and processing is presented in section 4.3.1.9.

Question 1. Hazard Severity
Campylobacter was considered a "Mild– sometimes requires medical intervention" for a general population, aligning with the severity reported in PRMS.038c (2003).

Question 2. How susceptible is the population of interest
For the current assessment, the answer selected for Question 2 was "GENERAL - all members of the population". Population sub-groups known to have greater susceptibility were not differentiated.

Question 3. Frequency of consumption
Undercooked: The speculated frequency of the consumption of undercooked mince was nominated as 3 times per annum (a few times a year).

Uncooked: The speculated frequency of the consumption of uncooked mince was nominated as "1 time per annum/365 days between servings".

Serving sizes assumed to be 65g.

Question 4. Proportion of population consuming the product
For undercooked product, the proportion was nominated as 25% based on speculative assumptions.
For uncooked product, the proportion was nominated as 5% based on speculative assumptions.
As discussed in PRMS.038c the consumption patterns differ by product type between consumers (age and gender), as do serving sizes. Commentary made in that report suggest that the differences in consumption patterns/amounts by age, gender or geographic region are relatively minor (much less than ten-fold) and contribute relatively little to differences in risk.

Question 5. Total population
As described in 4.3.1.1.

Question 6. Probability of contamination of raw product per serving
An assumption of 1 in 10,000 was made for the purpose of this assessment. Campylobacter was not recovered from any samples in either of the recent surveys conducted - Phillips et al. 2008 regarding retail ground beef, or the industry's fourth national abattoir study 2011 (MLA 2012).

Question 7. Effect of processing on the hazard
Processing was deemed to have 'no effect' on the hazard. While comminuting product can increase the pathogen load, it is not expected that further processing would alter the inherent pathogen load. Product leaves the processing premises at less than 4^{o}C (a processing standard). Note: The freezing of product (not considered in this generic scenario) would have the effect of reducing the pathogen load if temperatures were low enough and of suitable duration (MLA Report A.MFS.0097 2007).

Question 8. Post-processing contamination rate
Nil. An assumption was made that the cool chain is maintained and there is no further handling until the point of food preparation that may cause further contamination.

Question 9. Post-processing control

This parameter was designated as "well controlled – reliable, effective, systems in place (no increase in pathogens)". Although unable to grow below 30°C, *Campylobacter* spp. survive at temperatures as low as 4°C under moist conditions (FSANZ 2013).

Question 10. Increase required to cause infection/intoxication

The ID_{50} was designated as 897 CFU (Evers & Chardon 2010). With a concentration of 1.1 CFU/g (Abley et al. 2012, based on US data in the absence of Australian data) correlating to 110 CFU/100g serving, an approximate multiplication factor of 10 was required to reach an infective dose.

Question 11. Effects of preparation before eating on hazard

There is no relevant data on cooking regimens of comminuted meat products and consequent reduction rates in the pathogen load. Assumptions have been made to generate comparisons. For Undercooked product two scenarios were posed. The first scenario defines that meal preparation slightly reduces (50%) hazards. The second scenario presents a 90% reduction of hazards. For Uncooked product meal preparation has no effect on the hazard because no cooking step is applied.

Risk Ranger v2 outputs:

Table 32 provides information on the input parameters used and the Risk Ranger outputs obtained for this combination. A risk ranking estimate of 22 to 26 was obtained for undercooked products, depending on the level of cooking (90 to 50% pathogen reduction) and 21 for uncooked product. These risk rankings are considered to be low. The predicted cases per year were 0.16 (90% reduction) to 0.8 (50% reduction) for undercooked product and 0.11 for uncooked product. The daily probability of illness per person within the general population was estimated to be 4.1×10^{-10} (90% reduction) and 8.2×10^{-11} (50% reduction) for undercooked product and 2.7×10^{-10} for uncooked product.

Table 32. Risk ranking summary for *Campylobacter* spp. in undercooked and uncooked comminuted meat products (e.g. undercooked hamburgers, mince) (*Description of the estimation of input parameters in 4.3.1.15*)

Criteria	Estimation	Sources
1. Hazard severity	Mild	MLA PRMS.038c (2003)
2. Population susceptibility	General	Australian Bureau of Statistics 3101.0 (2017)
3. Frequency consumption	***Undercooked***: 3 times / y (few times a year) ***Uncooked***: once / y	
4. Proportion consuming (%)	***Undercooked***: 25% ***Uncooked***: 5%	Australian Bureau of Statistics 43640DO004_20112012 (2014)
5. Total population	22,002,599 (meat-eating persons > 5 months of age)	Australian Bureau of Statistics 3101.0 (2017), Roy Morgan Research (2016)
6. Proportion of raw product contaminated (%)	1 in 10,000 (Assumption)	
7. Effect of processing on hazard	The process has no effect on the hazard	FSANZ (2013)
8. Post processing contamination rate (%)	Nil	
9. Post processing control	Well controlled – reliable, effective, systems in place (no increase in pathogens)	FSANZ (2013)
10. Increase required to cause infection/intoxication	10	Evers & Chardon (2010) FSANZ (2013, 2016). Teunis et al. (2005), Tribble et al. (2010) Abley et al. (2012)
11. Effects of preparation before eating on hazard	***Undercooked***: Scenario 1: Meal preparation slightly reduces (50%) hazards Scenario 2: 90% reduction of hazards ***Uncooked***: Meal preparation has no effect on the hazard	
Predicted cases per annum	***Undercooked***: Scenario 1: 0.8; Scenario 2 : 0.16 ***Uncooked***: 0.11	
Risk Ranking	***Undercooked***: Scenario 1: 26; Scenario 2: 22 ***Uncooked***: 21	

4.3.1.16 *Toxoplasma gondii* in undercooked lamb ('outside in' rolled roast or primal cut)

Description of product and processing: The raw product is the primal which has either being rolled in such a manner that external surfaces become internalised in the new 'form' or presented as a whole muscle portion. It is then cooked (to varying degrees in various settings) before being carved (if required) and served.

'Outside In' definition: Non-intact products, whereby the manufacturing or culinary processes used to create them generate the potential for contaminants on meat surfaces to become encapsulated internally, either mechanically or through rolling, layering, fusing or pressing pieces together such as primal cuts, slices, chunks or cubes. Such products could be also described as reconstituted, restructured or re-formed. Example products include 'fusion' products (fused/'glued' by edible products such as the enzyme transglutaminase), needle or blade tenderised primal roasts, rolled roasts, kebabs (doner or shish), satay sticks. The contribution of marinades or other injections has not been analysed.

Two scenarios were run for this combination, one for the general population and one for pregnant women, given the difference in the severity of the illness due to this hazard in these two populations.

Question 1. Hazard Severity
For the general population it was assumed that patients rarely seek medical attention and the option 'MINOR HAZARD' was chosen.

For the pregnant, non-seropositive population, 'SEVERE HAZARD' was chosen, with the hazard causing congenital infection, which can cause loss of vision, mental retardation or intrauterine death and abortion (Australian Institute of Food Science and Technology Incorporated – AIFST 2003). Moderate to serious illness developing later in life may affect substantial numbers of those infected in late pregnancy (MLA Panel-in-confidence 2008). While the timing of exposure during gestation is relevant in a clinical context, the variation of the severity of the outcome relating to this particular aspect has not been considered.

Singh (2016) summarised findings from a literature review of relevant studies on *T. gondii* exposure during pregnancy as follows:

- Infection of the mother before pregnancy rarely, if ever, results in birth of a congenitally infected child
- Half of the women who acquire *T. gondii* infection during pregnancy do not transmit the parasite to their fetus [Lopes et al. (2007) suggest a figure of 61% who do not transmit]
- T. *gondii* is transmitted more frequently during the latter part of gestation, but the disease is more severe if infection is acquired during the first and second trimesters

Question 2. How susceptible is the population of interest
Two populations were considered in this scenario – those who were sero-negative in the general population and those who were both sero-negative and pregnant. The latter was identified as 'very susceptible".

Despite a large proportion of the population being seropositive for *T. gondii*, scientific literature indicates that the seroprevalence is decreasing in several countries including France, Belgium, the United Kingdom and the US (Rosso et al. 2008 in FSANZ 2014).

Question 3. Frequency of consumption
The speculated frequency of consumption of lamb roasts was nominated as “1 time per annum/365 days between servings” for both populations.

Question 4. Proportion of population consuming the product
For roasts, the proportion was nominated as 5% based on speculative assumptions.
As discussed in PRMS.038c the consumption patterns differ by product type between consumers (age and gender), as do serving sizes. Commentary made in that report suggest that the differences in consumption patterns/amounts by age, gender or geographic region are relatively minor (much less than ten-fold) and contribute relatively little to differences in risk.

Question 5. Total population
The Australian non-vegetarian population is estimated as 22,002,599 (ABS Census data 2016, Roy Morgan Research 2016) with persons being over the age of 5 months. See Section 5.2.2 Risk Profiling for further explanation on the derivation of the ‘total population’. Vegetarianism was only considered for persons 18 years of age and above (11.2% of the population) (Roy Morgan Research 2016).

It has been cited that 30-40% of the population are seropositive. This proportion of the population, having already been infected and therefore likely not at risk of re-infection, was subtracted from the total non-vegetarian ‘general’ population over the age of five months, and the population considered was 15,401,819 (70% of the general population based on 30% seropositivity).

The assumption of 30% seropositivity in the estimated pregnant population (as described in 5.2.2) generates an estimated ‘vulnerable’ pregnant population of 233,867 persons or 1.5% of the total estimated red-meat eating ‘general’ population over the age of 5 months. However, it is suggested that women who contract a Toxoplasma infection with a sufficient time lapse prior to pregnancy generally do not pass on the infection to the foetus and that approximately half of the women who acquire *T. gondii* infection during pregnancy do not transmit the parasite (Singh 2016, Ruiz et al. 2007, Many and Koren 2006, Dupuoy-Camet 1997). Therefore 3% was chosen in the model as the lowest possible percentage allowed.

Question 6. Probability of contamination of raw product per serving
A seropositivity estimate of 16.4% of lambs was presented in MLA Report A.MFS.0129 (2008). It was assumed that viable cysts are present in muscle tissue of 50% of seropositive animals. The relationship between seropositivity and prevalence of viable cysts in lambs has not been documented (Guo et al. 2015). In this scenario contamination of raw product was considered to be 8.2%.

Question 7. Effect of processing on the hazard
The process was deemed to have ‘no effect’ on the hazard. The risk status of meat after processing remains the same as at farm level (Guo et al. 2015).

Question 8. Post-processing contamination rate
Nil. It is assumed no further contamination occurs.

Question 9. Post-processing control
This parameter was designated as “well controlled – reliable, effective, systems in place (no increase in pathogens)”. Commercial freezing can inactivate cysts (-20^{o}C for 4hrs) but common refrigeration temperatures do not (Guo et al. 2015). It was assumed product is stored and transported chilled but not commercially frozen.

Question 10. Increase required to cause infection/intoxication

- Guo et al. (2015): "The actual concentration of *T. gondii* tissue cysts in meat is largely unknown but has been estimated to be a low concentration (less than or equal 1 cyst in 50 or 100g of meat) in naturally infected animals"
- EFSA (2016): "A tissue cyst may contain a few to hundreds of bradyzoites depending on the age of the cyst".
- Warnekulasuriya et al. (1998): $<10^4$ organism infective dose rate resulting from extrapolation from animal studies (Remington et al. 1995).
- Mie et al. (2008): UK study $>5x10^3$ trophozoites/g sufficient to cause infection from consumption of a 'typical' serving of cured meat.

An assumption is made that the ingestion of a viable cyst, with some tachyzoite replication, can result in consequent human infection. Based on the above research a determination was made that a 10-fold increase is required to reach an infective dose.

Question 11. Effects of preparation before eating on hazard

Proper cooking methods should reliably eliminate the hazard (internal temp. ≥67°C: Dubey, 2004 in FSANZ, 2014). However, when considering roasts, not all bradyzoites may be killed if the internal temperature is not high enough. Critical limit core temperatures suggested by the MLA Food Safety Risk Panel (2008) are 55°C or higher for at least 20 mins, 61°C for 3.6 mins and 67°C for 3 secs. As the scenario describes an 'undercooked' product, then the assumption was made that 90% of pathogens were inactivated.

Risk Ranger v2 outputs:

Table 33 provides information on the input parameters used and the Risk Ranger outputs obtained for both the general population and pregnant women. For the general population, the risk ranking was estimated to be 38, with 631 predicted cases per year. The daily probability of illness per person within the general population was estimated to be 2.3×10^{-6}. However, given this is a hazard with minor severity, those affected would rarely seek medical attention.

For pregnant women, considering this subgroup to be 3% of the general population and 30 times more susceptible than the general population, the risk ranking is estimated to be 49 (High), with 568 predicted cases. The probability of illness per day increases by a factor of 10 to 6.75×10^{-5}. The severity of the infection, and the higher susceptibility to this hazard, among this population are the reasons for the risk ranking increase. Although these are a significant number of cases, the severity of the infection depends on the timing of exposure, with approximately half of the women infected with *T. gondii* during pregnancy not transmitting the parasite to their foetus. In addition, the 3% used is an overestimation of the proportion of pregnant and susceptible women in the country, as previously explained, and as such, the predicted cases will be overestimated. Further reality checks deliver a figure of approximately 142 clinical cases as described in section 4.4 below.

Table 33. Risk ranking summary for *Toxoplasma gondii* in undercooked lamb (rolled roast or primal cut) (*Description of the estimation of input parameters in 4.3.1.16*)

Criteria	Estimation (General population)	Estimation (Pregnant women)	Sources
1. Hazard severity	Minor	Moderate	
2. Population susceptibility	General	Very susceptible	
3. Frequency consumption	Once a year	Once a year	Australian Bureau of Statistics 4364.0.55.007 (2014) MLA Sheep Fast Facts (2017) ABARES (2017)
4. Proportion consuming (%)	5%	5%	
5. Total population	15,401,819 (meat-eating persons > 5 months of age)	Software assumes 3% of the population are very susceptible, however the vulnerable population approximates 1.5% (see above in Section 4.3.1.16)	Johnson (1992) and Sfameni et al. (1986) in Mie et al. (2008) Australian Bureau of Statistics 3101.0 (2017), Roy Morgan Research (2016)
6. Proportion of raw product contaminated (%)	8.2%	8.2%	MLA Report A.MFS.0129 (2008) Guo et al. (2015)
7. Effect of processing on hazard	Nil	Nil	Guo et al. (2015)
8. Post processing contamination rate/potential for recontamination (%)	Nil	Nil	
9. Post processing control	Well controlled – reliable, effective, systems in place (no increase in pathogen))	Well controlled – reliable, effective, systems in place (no increase in pathogen))	Guo et al. (2015)
10. Increase required to cause infection/intoxication	10-fold increase	10-fold increase	Guo et al. (2015) Opsteegh et al. (EFSA 2016) Mie et al. (2008) Warnekulasuriya et al. (1998)
11. Effects of preparation before eating on hazard	90% reduction	90% reduction	Dubey (2004) in FSANZ (2014) MLA Food Safety Risk Panel-in-confidence (2008) Guo et al. (2015)
Predicted cases per annum Risk Ranking	631 38	568 49	

**T. gondii* primarily exists in three forms: oocysts, tachyzoites, and bradyzoites. When oocysts are ingested they develop into tachyzoites, the rapidly multiplying trophozoite form of *T. gondii*. When tachyzoites localize in muscle tissues or the central nervous system they convert to bradyzoites (the slow reproductive tissue cyst stage). Ingestion of cysts in contaminated meat is also a source of infection, as bradyzoites transform back into tachyzoites upon entering a new host. https://web.stanford.edu/group/parasites/ParaSites2006/Toxoplasmosis/lifecycle.html (verified 1 Mar 2018)

4.4 Interpretation of Risk Ranking results

OzFoodNet data on outbreaks attributed to red meat and the number of illnesses associated with these outbreaks from 2005 to 2014 was used to conduct a reality check on the predicted cases obtained from the risk profiling exercise. No additional current data was available. To be able to compare the risk ranking results with the actual outbreaks data notified it must be noted that reported outbreaks require at least 2 incidences of illness and the risk ranking prediction estimates individual cases instead of outbreaks. Outbreaks therefore are not reflective of the total number of individual cases, nor are individual cases reflective of outbreaks. The tables below provide a comparison between OzFoodNet outbreaks (associated with red meat) surveillance information from 2005 to 2014 and the predicted cases per annum estimated through the risk ranking exercise using Risk Ranger v2 (RR). In addition, the 2016 National Notifiable Diseases Surveillance System (NNDSS) annual notifications for each hazard (from all sources) and the estimated number of domestically acquired illnesses that are foodborne (based on NNDSS data and Kirk *et al*. (2014) are also discussed. The estimated annual number of domestically acquired illnesses that are foodborne is calculated by the following formula (Kirk et al. 2014):

> Annual number of domestically acquired illnesses that are foodborne = Yearly observed laboratory confirmed cases (NNDSS, 2016) X Population adjustment multiplier (applied as needed for non-notifiable cases) X Domestically acquired multiplier (%) X Underreporting multiplier

While the result can be useful for more realistic comparisons when considering aetiologies from across all food classes and all meat species, it is difficult to obtain the proportion attributable to red meat products from this estimate.

Overall, this reality check suggests the predictions obtained are similar to the yearly average (from the 10 year review period) of actual cases reported. However, it is important to consider that the predicted cases for each of hazard do not include all potential products that could be contaminated with these hazards, but only the combinations included in the assessment. Nevertheless these combinations were those identified by experts as posing the highest risk and as such, other products are likely to have a minor contribution to the food safety risk. The reality check for each of the hazards considered in this assessment is presented below.

Listeria monocytogenes

Invasive listeriosis is an uncommon disease, even though exposure to *L. monocytogenes* in food is probably relatively common. In Australia, the five year mean for the period 2011-2015 was 78 invasive cases per year, with a notification rate of 0.3 per 100 000 population (CDNA 2016). The 2016 NNDSS annual notifications were 84 with an estimated annual number of domestically acquired illnesses that are foodborne (any source), accounting for underreporting, of 165.

During the period 2005-2014, there were two confirmed listeriosis outbreaks (2005 and 2010). The 2005 case implicated one of the red meat species under consideration, and involved corned beef silverside, in a hospital setting. This event resulted in 5 hospitalisations and 3 deaths (5 illnesses, Givney 2006 in Ross et al 2009). The 2010 outbreak involved 'cold meat[***] 'in a community setting[†††].

[***] The OzFoodNet 2010 Annual Report indicated that there was 'microbiological confirmation of aetiology in vehicle and cases'. Meat type however was not known.

[†††] Community: Outbreak occurs within the community where there is no defined setting (OzFoodNet definition).

The contamination resulted in 4 deaths and 6 hospitalisations (6 illnesses). However investigation of this case could not differentiate whether the source was ruminant or monogastric.

Outbreaks and sporadic cases of listeriosis are predominately associated with ready-to-eat foods – a large, heterogeneous category of food that can be subdivided in many different ways and vary from country to country according to local eating habits; availability and integrity of the chill chain; and regulations specifying, for example, the maximum temperature at retail level (FAO/WHO 2004).

Of the 28 recall notifications (isolations) possibly linked with beef, sheepmeat or goatmeat products, between 2010 and 2016, 4 (14%) were associated with listeria – corned beef (sliced, packaged), chorizo (vacuum-sealed packet 350-400g), chorizo (clear plastic pack, 225g), and chicken and veal wurst (sliced, vacuum-packed, 200g) (Australian Competition and Consumer Association 2017).

The risk ranking estimated approximately 15 cases per annum. Considering that OzFoodNet data only report outbreaks (two or more cases of the same illness with a common source), instead of individual cases, we consider the prediction to be realistic, with unpackaged ready-to-eat products posing the highest risk, most likely due to the probability of recontamination after processing.

Table 34. A comparison between OzFoodNet reported outbreak data with Risk Ranger v2 predicted cases for *Listeria monocytogenes*

OzFoodNet Surveillance Outbreaks associated with red meat (2005-2014)	Illnesses from Red-meat associated outbreaks in 10 year period (2005-2014)	Average number of red-meat associated illnesses/annum (from 10 yr OzFoodNet data)	RR Predicted cases per annum
2 (deli style meats)	10	1	• *Listeria monocytogenes* in packaged, cooked, ready-to-eat (packaged for retail) meat products: **3.6** • *Listeria monocytogenes* in unpackaged, cooked, ready-to-eat meat products (e.g. deli or luncheon meats with a focus on red meat products such as roast beef): **12** • *Listeria monocytogenes* in packaged, cooked, ready-to-heat (vacuum, MAP etc) meat products (e.g. convenience meals in retail or food service): **2.6×10^{-3}** • *Listeria monocytogenes* in Sous vide: **2.2×10^{-14}** • Total cases per annum: **15 to 16 cases**

Clostridium perfringens

Clostridium perfringens can reside in two forms – vegetative cells and spores. Illness is caused when a large number of vegetative cells are ingested. The vegetative cells sporulate under the body's environmental conditions. During sporulation, a heat-sensitive enterotoxin is produced in the gastrointestinal tract. These spores can withstand cooking temperatures, and germinate in cooler conditions. Consequently the germinated cells multiply. If the food does not receive adequate reheating (i.e.to temperatures that will kill the vegetative cells), *C. perfringens* enters the gastro-intestinal tract and enterotoxins are synthesized. The cooking/heating process causes spores to germinate. "The resulting vegetative cells will grow to large numbers during the post-cooking cooling period ("stabilization"), particularly if the cooked food is held between 4°C and 60°C for an extensive period." (USDA, 2012). As such, temperature abuse is a common cause of *C. perfringens* illness. Condiments, such as gravy, are a known source of *C. perfringens* spores. Since sauces are often served with roast meals it is difficult to determine if red meat is the sole source of contamination. In addition, cross contamination can occur in kitchen settings (commercial or private) contributing more uncertainty.

During the period 2005-2014, there were 11 red-meat associated *C. perfringens* outbreaks. Six of these outbreaks were associated with restaurant preparation and consumption, 2 with commercial caterers, one with a private caterer in a community setting, and 1 each for both aged care and institutional preparation and consumption. With respect to the scenario presented in this report, there were 2 events with roast beef as a food vehicle (2011, 2012) and 1 suspected roast beef vehicle (2011) associated with catering (commercial and private) and a restaurant. Sheepmeat dishes with a *C. perfringens* aetiology were predominantly associated with curries and kebabs and not with roast meat dishes. Of meals causing illness with unknown aetiologies 3 nominate roast meat/s as the food vehicle, one of which had characteristics consistent with *C. perfringens*. *C. perfringens* is not a notifiable disease and as such there is not record of notifications within the NNDSS.

There were no recalls associated with *C.perfringens* and the red meats under consideration between 2010 and 2016.

The risk ranking estimated approximately 3 cases per annum for the general population. When considering higher susceptibility among a subgroup of the population, the estimated number of cases increases to 25 per annum. A similar number of cases is reported by OzFoodNet, with an average of 7 cases per annum for the 2005-2014 time period.

Table 35. A comparison between OzFoodNet reported outbreak data with Risk Ranger v2 predicted cases for *Clostridium perfringens*

OzFoodNet Surveillance Outbreaks associated with red meat (2005-2014)	Illnesses from Red-meat associated outbreaks in 10 year period (2005-2014)	Average number of red-meat associated illnesses/annum (from 10 yr OzFoodNet data)	RR Predicted cases per annum
11, including 2 roast beef food vehicle incidences (2011, 2012) and 1 suspected roast beef incident (2011).	71 (for roast meat)	7 (for roast meat)	• *Clostridium perfringens* in roasts – served warm (sliced, cooked primal) in food: ○ Beef: **1.6** (general population); **20** (susceptible population) ○ Lamb: **1.1** (general population); **5** (susceptible population) • Total: **3** (general population); **25** (susceptible population)

STEC *Escherichia coli* O157

The reported incidence for STEC in 2016 was 1.4 cases per 100 000 people (340 cases, being of both non-foodborne and foodborne origin). The number of notifications in 2016 was significantly higher than previous years (2-3 times higher). The previous 5 year mean (2011-2015) was 0.6 cases per 100,000 population per year (range 0.4-0.8) (FSANZ 2017). The prior 10 year mean (2000-2010) was 0.4 cases per 100,000 population per year with an overall annual rate of notified HUS being 0.07 per 100,000 population per year (Vally et al. 2012). Data specifically relating to serotype O157 is described by Vally et al. (2012), whereby the average notification rate between 2001 and 2009 was 0.12 cases per 100,000 per year. The majority of infections that are serotyped have been found to be O157 strains (followed by O111 and O26 respectively). *E. coli* O157 accounted for 58.8% of STEC infections that underwent serotype testing (71.2% tested) between 2001 and 2009. In 2011, it accounted for 38% of cases, followed by O111 (17%; FSANZ 2013).

There were no red meat-related *E. coli* outbreaks between 2005 and 2014 and only 1 recall associated with *E. coli* [2014 - garlic mettwurst comprising beef (50%) and pork (45%)] during the period 2010 to 2016 (Australian Competition and Consumer Association 2017).

The risk ranking estimated approximately 11 to 32 cases per annum depending on the scenarios considered. These scenarios only account for some possible red meat meal products. The NNDSS reports approximately 120 to 340 cases per annum from all sources and includes notifications from people previously infected prior to entering Australia. Therefore, the predicted cases could align with the actual cases. No outbreaks caused by *E. coli* are reported by OzFoodNet in association with red-meat, however, as previously mentioned, only outbreaks with two or more cases are recorded. Undercooked hamburgers, with a 50% pathogen reduction rate, are posing the highest risk for *E. coli* O157.

Table 36. A comparison between OzFoodNet reported outbreak data with Risk Ranger predicted cases for STEC *Escherichia coli* O157

OzFoodNet Surveillance Outbreaks associated with red meat (2005-2014)	Illnesses from Red-meat associated outbreaks in 10 year period (2005-2014)	Average number of red-meat associated illnesses/annum (from 10 yr OzFoodNet data)	RR Predicted cases per annum

Nil	0	0	• STEC *Escherichia coli* O157 in uncooked primals (e.g. steak tartare, carpaccio): **2**
			• STEC *Escherichia coli* O157 in Doner kebabs:
			  o Scenario 1: Well Controlled – no increase in: pathogens: **1**
			  o Scenario 2: Not controlled – 10-fold increase (No final flash-frying): **10**
			• STEC *Escherichia coli* O157 in Rolled or blade/needle tenderised roasts: **3**
			• STEC *Escherichia coli* O157 in undercooked (50% reduction): **15**
			• STEC *Escherichia coli* O157 in undercooked (90% reduction): **3**
			• STEC *Escherichia coli* O157 in uncooked: **2**
			• STEC *Escherichia coli* O157 in non GMP UCFM products (e.g. homemade salami): **5.9×10^{-2}**
			• Total: Minimum of approximately **11** cases; Maximum of approximately **32** cases

***Salmonella* spp.**

The reported incidence rate in 2016 for *Salmonella* was 76.1 cases per 100,000 population (an increase from the previous 5 year mean of 59.9, range of 49.2-71.5 cases per 100,000 population) which includes both foodborne and non-foodborne cases (FSANZ 2017). Based on NNDSS data for 2016, the estimated annual number of domestically acquired illnesses that are foodborne was 77,982. *S.* Typhimurium was the most common *Salmonella* serovar identified in Australia in 2011 (48% of cases) with a large range of other serovars accounting for the remaining cases (FSANZ 2017).

There were 23 outbreaks (between 2005 and 2010) associated with *Salmonella* spp. in beef and lamb dishes, 17 of which had *S.* Typhimurium aetiology, causing 241 illnesses. A range of dishes were presented as the food vehicle; beef predominated as the meat ingredient versus lamb (there were no incidences associated with goat meat). However, many dishes also included other ingredients, such as egg, chicken or salad.

There were 8 associations between *Salmonella* spp. and burgers across the specified time period, including species *S.* Montevideo, *S.* Stanley and *S.* Typhimurium. Insufficient cooking, cross contamination from raw ingredients and food handler contamination (or a combination of these factors) were stated as causes. The settings were a mix of restaurants, takeaways and a private residence. Of note is that, in all but two instances, other ingredients such as salad, cheese, bacon, chicken, eggs or (homemade) mayonnaise were mentioned.

There were 4 associations between *Salmonella* spp. and kebabs (but with no attribution to particular ingredients, 3 with *S.* Typhimurium aetiology and 1 with *S.* Newport aetiology) between 2005 and 2014 and 2 kebab entries with unknown aetiology (2007 and 2008) as reported by OzFoodNet (2017). Improvements in kebab food safety has been noted by the NSW Government Food Authority in past surveys. *"In a 2008 survey, the NSW Food Authority found 94% of the kebabs it surveyed were of good quality – or safe to eat. The results showed a slight improvement in standards since the previous survey in 2004. Then 89% of the kebabs surveyed were considered acceptable."* (SBS, 2009). It is assumed that improvements have continued leading to further reductions in illnesses.

There were 3 *Salmonella* outbreaks associated with offal prepared in a private residence (one in 2005 – *S.* Typhimurium 197, and two in 2014 – *S.* Chester)

Between 2010 and 2016 there were 2 recalls associated with *Salmonella* species. One was for *Salmonella bovismorbificans* in salami (that had beef as one of the listed ingredients) and the other was only declared as 'possible *Salmonella'* contamination, however it could not be determined whether the product contained a red meat product.

The risk ranking estimated approximately 28 to 90 cases per annum depending on the scenarios considered. Similar to *E. coli*, these scenarios do not account for all possible red meat products that may be consumed. The NNDSS data reports over 77,000 cases per annum from all sources, of which the main sources are likely to be products of poultry origin. A total of 24 illness associated with red meat outbreaks were reported by OzFoodNet. Considering these only include those instances associated with an outbreak event, the predicted cases seem to align with the 10-year average of reported *Salmonella* cases associated with red meat meals. Undercooked hamburgers with a 50% reduction rate are posing the highest risk for this pathogen.

Table 37. A comparison between OzFoodNet reported outbreak data with Risk Ranger predicted cases for *Salmonella* spp.

OzFoodNet Surveillance Outbreaks associated with red meat (2005-2014)	Illnesses from Red-meat associated outbreaks in 10 year period (2005-2014)	Average number of red-meat associated illnesses/annum (from 10 yr OzFoodNet data)	RR Predicted cases per annum

23	241	24	• *Salmonella* spp. in undercooked comminuted meat products (50% reduction): **58**
			• *Salmonella* spp. in undercooked comminuted meat products (90% reduction): **11.6**
			• *Salmonella* spp. in uncooked comminuted meat products: **7.7**
			• *Salmonella* spp. in Doner kebabs
			  o Scenario 1: Well Controlled – reliable - no increase in: pathogens: **2**
			  o Scenario 2: Not controlled – 10-fold increase (No final flash-frying): **19.5**
			• *Salmonella* spp. in Rolled or blade/needle tenderised roasts: **5.6**
			• *Salmonella* spp. *in non GMP UCFM products (e.g. homemade salami):* **1.1×10^{-1}**
			• Total: Minimum of approximately **28** cases; Maximum of approximately **90** cases

Campylobacter

In New South Wales, Campylobacter spp. became notifiable in 2017. As reported in FSANZ (2017) the reported incidence rate in 2016 (excluding New South Wales) was 146.7 cases per 100,000 population, which includes both foodborne and non-foodborne cases. This was a large increase from the previous five year mean of 115.2 cases per 100,000 population per year (ranging from 93.4 – 139 cases per 100,000 population per year). Based on NNDSS 2016 data, the estimated annual number of domestically acquired illnesses that are foodborne (accounting for underreporting) is over 18,000 cases.

There were 3 red meat related outbreaks in Australia between 2005 and 2010, causing 24 illnesses, all from food service establishments, but with no direct aetiology linking the outbreak to red meat. The first (2007) had a kebab as the food vehicle but with a meat base of which the species was not known. The second outbreak (2009) related to steak and chips and salad and the third outbreak to steak with chicken liver paté in 2010. Considering the historical association between chicken liver paté and *Campylobacter* it seems unlikely that the steak would have been the source of infection. Based on Table 38 and the total number of notifications, it appears that, even had there been a direct link between *Campylobacter* outbreaks and red meat, that red meat species would be a very small contributor to the *Campylobacter* disease burden in Australia. The predicted number of cases generated by Risk Ranger v2 for products considered at higher risk of causing illness (based on the Expert Elicitation process and by MLA's Food Safety Risk Panel) also suggests red meat's contribution to the disease burden is very low and aligns with the reported cases.

Table 38. A comparison between OzFoodNet reported outbreak data with Risk Ranger predicted cases for *Campylobacter*

OzFoodNet Surveillance Outbreaks associated with red meat (2005-2014)	Illnesses from Red-meat associated outbreaks in 10 year period (2005-2014)	Average number of red-meat associated illnesses/annum (from 10 yr OzFoodNet data)	RR Predicted cases per annum
3 red meat related outbreaks but with no direct aetiology linking the outbreak to red meat.	24	2	• *Campylobacter* spp. in undercooked comminuted meat products (50% reduction): **0.8** • *Campylobacter* spp. in undercooked comminuted meat products (90% reduction): **0.16** • *Campylobacter* spp. in uncooked comminuted meat products: **0.11** • Total: Approximately 0 to 1

Toxoplasma gondii

Toxoplasmosis is one of the most common parasitic zoonoses worldwide. It is estimated that around a third of the world's population have the parasite (Pereira et al. 2010, Innes 2010 in FSANZ 2014). Toxoplasmosis is not a notifiable disease so incidence and prevalence in Australia is difficult to estimate. Also, the majority of infections are asymptomatic. The most reliable estimates of incidence tend to come from high risk groups, such as newborn infants. However, because environmental, water and cat exposure can also result in transmission to humans, not all new cases can be attributed to foodborne exposure, and likewise for transmission via mothers during pregnancy. Scallan et al. (2011) estimated that clinical illness develops in 15% of persons who seroconvert. Using the predicted number of cases from the Risk Ranger v2 simulation, this equates to approximately 95 cases (of the 631 cases) developing clinical illness. However, this illness is usually minor within the general population.

Based on the 2016 national live birth rate and using pregnancy exposure data from Sfameni *et al*. (1986), which suggests the rate of new infections during pregnancy is 0.5% annually in initially seronegative women, it is estimated that 1,089 pregnant women could become infected annually in Australia (out of the estimated 217,773 seronegative pregnant women delivering live births in 2016, see section 3.3.2 for this derivation). If approximately half of the pregnant mothers pass on the parasite (Singh 2016), then there would be 545 new clinical infections per year. Incorporating the assumption that 50% of these may be foodborne (Mead *et al*. 1999 in MLA Report A.MFS.0113 Panel-in-confidence 2008), then it is estimated that there are 273 foodborne clinical cases among pregnant women annually. Considering between 30% to 60% of foodborne Toxoplasmosis has been attributed to consumption of raw or undercooked meat (EFSA 2016), we could assume that there would be between approximately 82 and 164 clinical cases of Toxoplasmosis in pregnant women due to consumption of raw or undercooked meat. A previous study identified that most meatborne Toxoplasmosis was due to red meat (85%) (Guo *et al*. 2015). As such, between 70 and 140 clinical cases of *T. gondii* infection in pregnant women would be expected from eating raw or undercooked red meat. However, it is important to note that this figure does not relate to only ovine meat sources, which is the scenario considered in this risk profiling exercise. Considering this data as a proportion of the total number of initially seronegative live births based on Sfameni et al (1986) above, then the proportion of asymptomatic toxoplasmosis infections due to the consumption of raw or undercooked red meat during pregnancy (the general pregnant population) would be between 6.4% and 12.9 percent.

The Risk Ranger v2 estimation predicted 568 cases per annum, assuming 3% (the available iteration in RR) of the Australian susceptible population were pregnant. Given susceptible pregnant women only represent 1.5% of the population, we assume the number of cases would be half of those predicted, (i.e. 284 cases). Of these only half would pass the parasite to the foetus, resulting in approximately 142 clinical cases. This suggests the current estimations generated in Risk Ranger v2 align with calculated estimations using data from the previous studies described above.

Table 39. A comparison between OzFoodNet reported outbreak data with Risk Ranger predicted cases for *Toxoplasma gondii.*

OzFoodNet Surveillance Outbreaks associated with red meat (2005-2014)	Illnesses from Red-meat associated outbreaks in 10 year period (2005-2014)	Average number of red-meat associated illnesses/annum (from 10 yr OzFoodNet data)	RR Predicted cases per annum
Nil	-	-	• Toxoplasma gondii in undercooked lamb ('outside in' rolled roast or primal cut): **631** (general population)**;** **568** (pregnant women)

4.5 Review of currently available risk assessment tools used for risk ranking of food safety issues

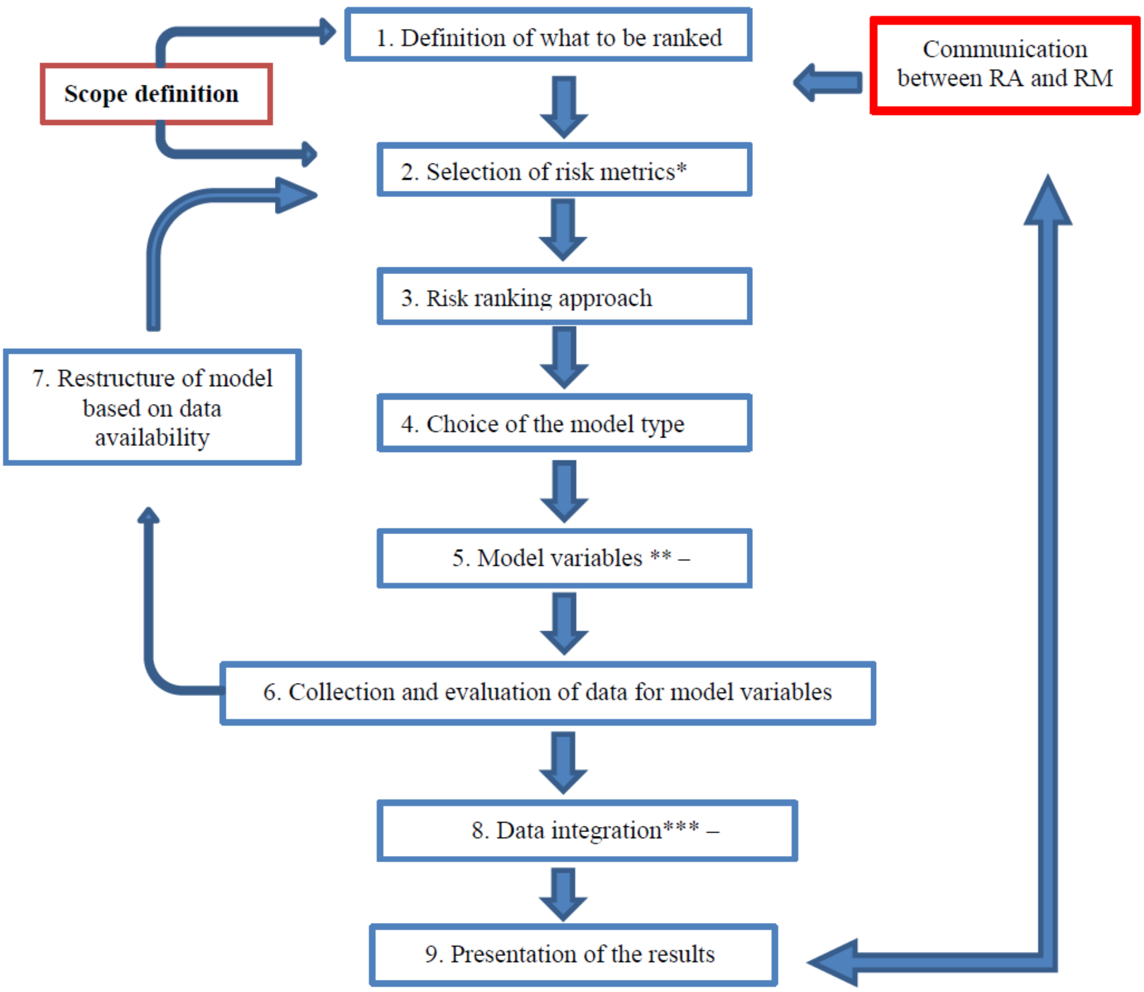
As stated in the method section, the European Food Safety Authority (EFSA 2015), via its Panel on Biological Hazards (BIOHAZ), completed a review of eight tools for risk ranking of biological hazard in food. Performance based on risk metrics, data requirements, ranking approach, model type, model variables, how uncertainty and variability were managed, and methods of data integration were assessed. The risk ranking tools selected were evaluated from a statistical/theoretical perspective and the authors noted that data, time and resources required for implementing these methods should also be considered. The EFSA review has been used in the current study to conduct a cross-comparison between quantitative and semi-quantitative techniques. The outcomes of this comparison will inform decision-making regarding the most relevant methods to employ during the second, risk ranking phase of this project (**Appendix G**). Since the review was published further iterations of some of the risk ranking tools have become available. Updated information pertaining to the tools has been integrated into the cross-comparison.

The eight tools reviewed were:

- Decision trees;
- The United States Food and Drug Administration (US-FDA) risk ranking tool: the pathogen–produce pair attribution risk ranking tool (P3ARRT);
- The EFSA food of non-animal origin risk ranking tool (EFoNAO-RRT);
- Risk Ranger;
- MicroHibro;
- Swift quantitative microbiological risk assessment (sQMRA);
- FDA-iRISK; and
- The European Centre for Disease Prevention and Control (ECDC) Burden of Communicable Disease in Europe (BCoDE) toolkit.

The EFSA review found that when the selected tools were applied to the case studies of single pathogen–multiple foods and multiple pathogens in a single food, the selection of the risk metric was reported to significantly affect the risk estimate and ranking, as risk metrics measure different things, such as the probability of illness compared to public health burden (DALYs). As such, selection of the tool will impact the outcome obtained. In relation to the performance of the risk tools evaluated, quantitative tools were identified as the most reliable for risk ranking; however, these type of tools require quality data to estimate the input parameters. Within the quantitative tools, the use of deterministic models, which do not incorporate variability and uncertainty in the input parameters and model outputs, may result in risk ranking errors. Therefore, stochastic models were identified as the models providing the most reliable risk ranking outcomes. Semi-quantitative methods incorporating ordinal scoring use scores for estimating model parameters and risks, with this method falling between a qualitative risk assessment and the numerical evaluation used in quantitative risk assessments. When using semi-quantitative models with ordinal scoring, the food–pathogen combinations are classified into broad sets of categories with little discrimination. The EFSA review and comparison of methods report a significant difference on the risk rankings obtained with ordinal scoring and quantitative deterministic models, when compared with quantitative stochastic models; with the ordinal scoring tools having the lowest performance.

The EFSA study concluded that no particular risk ranking method could be recommended in isolation as universally applicable for the purposes of the BIOHAZ Panel, therefore a ‘toolbox’ of methods was developed to cater to their conceptual 9-step risk ranking framework (Fig. 10) to help ensure consistency and transparency of process.



* "Risk metrics" is the expression of the risk (DALY – disability-adjusted life years, QALY – quality-adjusted life year incidence, etc.).
** Model variables" are the indicators used for risk ranking (prevalence, epidemiological data).
*** "Data integration" is the combination of model inputs and formulas to produce model outputs.

RA: Risk assessment; RM: Risk management.

Fig. 10. The proposed conceptual risk ranking framework for the BIOHAZ Panel (Source: EFSA 2015)

Comparisons between the different tools can be found in **Appendix G**. While each approach has advantages and disadvantages, the preferred methods to guide the risk ranking of the prioritised Product:Process:Hazard combinations (arising from the Expert Consultation) are Risk Ranger Version 2.0 and FDA-iRisk 4.0 as they were deemed the best 'fit for purpose'. The factors of data availability and quality, the characteristics of the method (including how uncertainty and variability are managed), and the practicality and ease of both access and use are seen as important. The alternative semi-quantitative tool, EFoNAO-RRT (one of two semi-quantitative methods being assessed which can, despite the food of non-animal origin connotation, be used to assess pathogen:meat product combinations), is not recommended as the tool does not take into account factors that can significantly affect the final risk, such as the initial contamination level and the serving size. In addition, the Excel spreadsheet of EFoNAO-RRT requires much manual handling in order to enter, calculate and present results making data management and scenario analysis complex. As such, Risk Ranger Version 2.0, with its greater ease of use, is considered a more appropriate tool for the ensuing risk ranking exercise. Although Risk Ranger Version 2.0 is based on deterministic calculations, the potential use of an add-on software tool, such as @Risk, would allow conducting Monte Carlo stochastic simulations and the consideration of variability and uncertainty, if appropriate data is available.

The release of the most updated version of FDA-iRisk (4.0) brings with it the ability to separate out and quantify variability versus uncertainty and express results via a suite of metrics[‡‡‡]. In addition, chemical analyses can be undertaken with the tool. Hence, if a quantitative-based analysis is possible then this method would be the primary choice as it circumvents the need to use two methods (FDA-iRisk and the BCoDE toolkit) as suggested in the EFSA review in order to achieve the most effective calculation of DALYs when comparing a number of pathogen:food combinations.

The major determinant of the actual method used will be dependent on what data (quality and quantity) is available. Foodborne disease surveillance in Australia, because of lack of investment, is poorly resourced and consequently there is poor food attribution data, which leads to inadequate information for use in quantitative risk assessments. A semi-quantitative assessment is therefore more appropriate. As with all semi-quantitative approaches the use of ordinal scores, and their integration into an analysis tool, is a limiting factor. Inherently the value of any method is determined by an understanding of its inadequacies and this knowledge should guide what decisions should (or should not) be made, based on the outputs. For the purpose of transparency, all assessment constraints should be communicated succinctly in conjunction with the results.

4.6 Evaluation of the applicability of other semi-quantitative risk profiling tools

As a result of the review conducted to identify potential risk assessment tools to conduct risk profiling of Product:Process:Hazard combinations, the cross-comparison of the various methods available and consultation with the Steering Committee, the following tools were evaluated for their suitability for the purpose of this project:

- The United States Food and Drug Administration (US-FDA) risk ranking semi-quantitative tool: the pathogen–produce pair attribution risk ranking tool (P^3ARRT) (Anderson et al. 2011);
- The EFSA food of non-animal origin risk ranking semi-quantitative tool (EFoNAO-RRT);
- The Food and Drug Administration quantitative risk assessment tool FDA-iRISK

As part of the final milestone of this project, a more detailed analysis of which combinations have sufficient and appropriate data for using iRISK to assess the risk posed by these combinations, will be conducted.

P^3ARRT

The United States FDA designed a semi-quantitative risk assessment tool for ranking pathogen-produce commodity pairs for prioritising resource allocation for more comprehensive risk modelling. The approach used by this tool is to estimate a relative risk ranking considering eight different criteria that relate to public health risk. For each criterion, data was described and categorised into four scoring bins and allocated to four ordinal scores. These criteria are listed below and described in more detail in Appendix B.

[‡‡‡] The metrics include mean risk of illness (e.g. average probability of illness from one eating occasion) and predicted total number of illnesses per year for a food-contaminant combination, for various populations as well as other public-health metrics, such as Disability-Adjusted Life Years (DALYs) and Cost of Illness (COI), and Quality-Adjusted Life Year (QALY) loss.

1. Epidemiological link
2. Disease multiplier
3. Hospitalisation and death rates
4. Susceptible population
5. Relative infectivity
6. Prevalence of contamination
7. Consumption
8. Shelf-life and growth potential

The scores for each of the criteria are then combined to produce a single score for each pathogen-commodity combination. The model to calculate the combined scores incorporates a weighting approach, where each criteria is assigned an ordinal number weight from 1 to 4. The model allows users to select the weight for each criteria, considering the individual perspectives on the importance of each criteria. The overall rank is calculated using an algorithm that considers the scores for each criterion with the corresponding weight, in which each criterion's score is multiplied by its weight and then each of the eight values are added to obtain an overall numerical score.

EFoNAO-RRT

The European Commission asked the European Food Safety Authority (EFSA) BIOHAZ Panel to identify and rank specific food/pathogen combinations from food of non-animal origin commonly linked to foodborne human cases in the European Union. The panel developed a multi-criteria analysis model, adapting the US FDA risk ranking tool (P^3ARRT) (Anderson et al. 2011) previously described. The EFoNAO Risk Ranking tool uses the following seven criteria, which describe the consequences of human health and the probability of exposure:

Consequences of human disease:

1. Strength of associations between food and pathogen based on the foodborne outbreak from EU Zoonoses Monitoring Data
2. Incidence of illness
3. Burden of disease

Probability of exposure:

4. Dose-response relationship
5. Prevalence of contamination
6. Consumption
7. Pathogen growth potential during shelf life

For each of these criterion, different scoring categories are used and assigned an ordinal score (Appendix C). The scores of the seven criteria are then summed to give a total risk score, which is used for ranking.

In contrast to Risk Ranger, PARRT and EFoNAO-RRT do not allow for the incorporation of numerical estimates, such as specific prevalence of contamination, but only a predetermined score. In addition, given these tools were developed to assess food products of non-animal origin, it does not consider an inactivation step due to meal preparation. As such, profiling meat products that undergo cooking before consumption using this tool would result in an over-estimation of the risk. Only those products that do not require cooking could be profiled using this tool.

FDA-iRISK

FDA-iRISK is a web-based system which allows for the analysis of data in relation to microbial and chemical hazards in food, providing an estimate of the health burden on a population level. The tool provides a step-wise data entry, and the user can develop risk scenarios, which consider different aspects of the hazard, the product and the processing of the product. The criteria or elements considered within the iRISK tool are:

- The food, its associated consumption data and processing/preparation methods.
- The hazard and its dose-response curve.
- The burden of disease, as the anticipated health effects of the hazard when ingested by humans.

The tool has some example risk scenarios, however, it does not provide or contain any additional scientific data, with all the data being required to be introduced by the user, including the dose-response models. Once data is introduced, the tool combines the user's input in relation to the above mentioned elements into a risk assessment model, to provide the risk of illness to the consumer. As such, the tool provides the computational infrastructure, ensuring accuracy in the mathematical modelling, using the user's technical expertise. Figures 11 and 12 below provide a schematic representation of the mathematical models (process and consumption) used.

The tool is based on a quantitative risk assessment model, which can be implemented as a deterministic or stochastic model. As such input parameters can be incorporated into the model using probability distributions to account for the potential variability in the estimates, in which case a Monte Carlo simulation is used. The tool also provides the option of specifying quantitative descriptions of uncertainty, or so-called Second Order Monte Carlo simulation.

Given this tool conducts a quantitative risk assessment, the data requirements for this tool, and the accuracy of this data, are higher than that required for semi-quantitative risk profiling tools. In addition, the purpose of this tool is not for profiling purposes but for a more accurate estimation of the risk posed by pathogen-commodity combinations, limiting its use for only those combinations for which data is available. Data available for the combinations included in the current risk profiling exercise is limited. For example, dose-response models are not available. As such, suitability of this tool for the current risk profiling exercise is questionable. A more detailed analysis of data availability and accuracy will be conducted for the final milestone of the project to identify the opportunity for using iRISK.

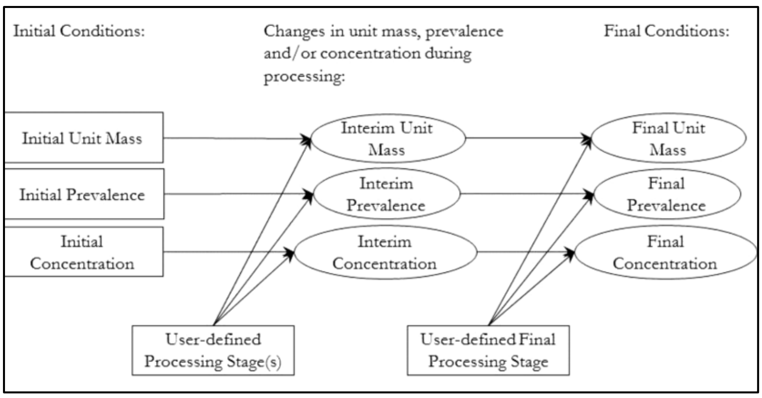


Fig 11. Mathematical structure of a process model. The user inputs initial conditions and defines sequential process stages that affect the mass, prevalence, and/or concentration of the hazard in the food. FDA-iRISK recalculates these values after every stage until the final values are obtained. (Rectangles represent user input and ovals represent FDA-iRISK results)

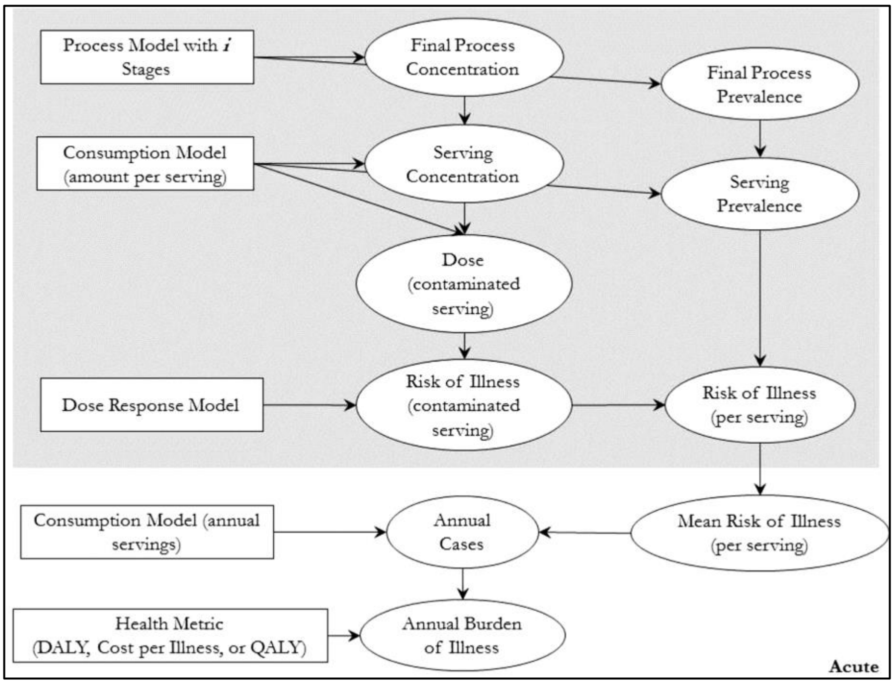


Fig 12. Mathematical structure of a risk scenario, including the outputs of the process model (Figure 11), consumption and dose response models. (Rectangles represent user input and ovals represent FDA-iRISK results)

5 Discussion and recommendations

A review of the food safety and market access risks in the red meat supply chain was conducted in this project. It has provided an updated risk profile for red meat products in Australia. The project used qualitative and semi-quantitative methods to conduct the risk profiling, with an iterative approach. As part of this approach, information was gathered through:

a. reviews of literature and available data on relevant food safety related events;
b. consultation with stakeholders involved in red meat processing;
c. an information elicitation process with Australian food safety experts; and
d. ongoing consultation with the project Steering Committee.

As part of this process, and with the aim of identifying the Hazard:Product:Process combinations to be included in this risk profiling exercise, several validation steps were conducted.

The hazard characterisation step of the project identified the Hazard:Product:Process combinations posing a food safety concern, and the qualitative assessment prioritised those combinations with a moderate to high risk ranking to be subsequently assessed in the semi-quantitative risk ranking step of the project. The evaluation of risk profiling tools available identified Risk Ranger v.2 as the most suitable tool for the purpose of this project. The outcomes of the risk ranking exercise suggest that the following combinations pose the highest risk, with this risk being moderate:

a. STEC *E. coli* O157 and *Salmonella* spp. in undercooked hamburgers; and
b. *Listeria monocytogenes* in packaged and unpackaged ready-to-eat products.

Results from this risk profiling exercise indicate that using the available data, none of the combinations resulted in a high risk for the general population. When compared to the 2002 risk profiling results, there has not been an increase in food safety risks posed by the red meat industry, with some combinations posing a lower risk due to improved food safety measures and hygiene practices. The reality check conducted suggests the predictions obtained are similar to the actual cases reported. However, it is important to consider that the predicted cases for each of the hazards do not include all potential variations of products that could be contaminated with these hazards, but only the specific combinations included in the assessment. Nevertheless these combinations were those identified by the experts as posing the highest risk and, as such, other products are likely to have a minor contribution to the overall food safety risk posed by beef, sheep or goat meat.

The outputs generated from the semi-quantitative risk profiling should be interpreted considering the amount of uncertainty in the input parameters used for each of the combinations and the assumptions used. There are a significant number of variables across the supply chain continuum that impact upon the chosen input parameters, and therefore on the resultant risk ranking outputs. These sets of variables, relevant to each stage of the chain, determine the prevalence of a hazard at each processing point and subsequently, in the final product.

This project identified data gaps that have an impact on the ability to accurately assess the food safety risk posed by red meat product combinations. A set of prioritized recommendations were developed and are described below.

1. There is a lack of information on consumption patterns and consumer exposure to particular red meat products.

Many assumptions were required to complete the risk profiling (and consequent ranking) process. Therefore the results are conveyed with a low to moderate degree of uncertainty. Having more accurate data inputs increases the confidence in the outcomes from any semi-quantitative risk assessment tool, because the accuracy is improved. Across all the product classes reviewed there is no product-specific data on consumption patterns (i.e. frequency and volume of consumption of particular red meat products by specific demographic groups). It is also difficult to account for all demographic groups, which might have different susceptibilities and be of a different proportion of the population to what Risk Ranger v2 offers as an input. Furthermore it is a challenge to account for variable preparation and storage practices. Attributing risk solely to red meat when cross-contamination, ubiquitous environmental pathogens and other meal ingredients are present might also be contributing factors to the overall pathogen load. Packaging and storage type and the inherent nature of the meat (e.g. pH, fat content, water activity) in conjunction with the use of additives (e.g. preservatives) is an important consideration in determining pathogen behaviour in terms of cell growth, inhibition, injury and recovery. These factors all contribute to uncertainty, in conjunction with debate over the infective dose of each specific pathogen.

The products below each have varying amounts of uncertainty associated with their risk ranking:

- Deli meats (packaged or unpackaged): For deli meats in general there is difficulty in attributing the proportion of contamination that may arise from red meat compared to pork or chicken mechanically deboned meat (MDM) in products that may comprise ingredients from various meat species. e.g. Strasburg. Even for products consisting of red meat only (such as roast beef or pastrami) there is no pathogen concentration data available specific for these products at the retail level.
- Packaged, cooked, ready-to-heat red meat products: Again it is difficult to attribute risk to the red meat ingredient of mixed dishes which are either designed as a full meal (e.g. curry and rice) or as a portion (e.g. lasagne). In addition, there are multiple forms of ready-to-heat products, which may include lamb or beef.
- Undercooked hamburgers: While 90 and 50% reduction in the pathogen was nominated for these products in the current risk profiling exercise, as an example of undercooked comminuted meat (for which there are a variety of meal options – such as lasagne, hamburgers, sausages, bolognaise, meatloaf) it is difficult to predict inactivation levels for a temperature/time of cooking. Such a prediction is also confounded by the protection of pathogens by the meat itself (e.g. fat content) or additional ingredients used in meal preparation.
- Uncooked primals: Because there is a range of preparation practices (e.g. even for carpaccio) it is difficult to account within a given scenario the range of handling practices. Examples of the variation include being defrosted from frozen, partially frozen from fresh to allow slicing, sourced from cryovac packaging, or being served with condiments such as lemon juice which may affect the bacterial load of the meal.
- Uncooked comminuted meat: Again methods of preparation, for products such as steak tartare, have a substantial impact on the final bacterial load. While the artisan approach to steak tartare is to mince a primal cut, there are instances where commercially prepared mince would be used as the main ingredient. In addition, it is commonly served with raw egg which poses another source of contamination.
- Kebabs: As mentioned above for other products, it is difficult to account for the range of handling practices, as is the prediction of inactivation levels associated with undercooking.
- Rolled or needle-tenderised roasts and primal roasts: It is a challenge to account for the range of products and handling practices (storage and preparation) in food service (institutional or other) and in the home, and predicting inactivation levels for degrees of undercooking.
- Vacuum-packed primals and sous vide products: Data describing concentration of contamination, production volume, channels of distribution and end use options (i.e. proportion of product being used in food service), storage type and time until consumption is very limited.

- Non-GMP salami: It is difficult to estimate the frequency and volume of consumption. It is also unknown to what degree there is compliance to artisan 'tested' methods regarding process inputs and the process of preparation itself compared to other, more risky, methods.

With some Hazard:Product:Process scenarios there was such a lack of data that it was not feasible to assess them. Therefore a more complete picture of the overall risk was unable to be developed and this may result in the risk posed by these products being underestimated and therefore not receiving appropriate attention. Specific examples include botulism in vacuum-packed meat products and the risk associated with the presence of *Rhizopus* spp.or *Mucor* spp. mycotoxins in dry-aged meat.

Recommendations:

- Conduct additional market research into the types of cuts used for dishes (e.g. types of cuts used for homemade UCFM, and proportion of red meat) and the frequency of consumption of the meals using these cuts.
    - Prioritise the above for Hazard:Product:Process combinations with the highest risk ranking and those with insufficient data to conduct the semi-quantitative risk profiling including undercooked comminuted meat products, retail deli meats and undercooked primal products (cryovaced, sous-vide, rolled, tenderised). If regulatory bodies deem dry-aged meat and vacuum-packed or modified atmosphere packaged product to be of risk then data needs to be collected to allow for a risk appraisal.

2. There is lack of accurate information on the prevalence and concentration of pathogen contamination in red meat products.

As with Point 1 above, absence of suitable information leads to uncertainty, a reduction in accuracy and confidence in the results. With each particular meal scenario, there may be variations in the type of cut being used. Having access to prevalence of contamination and concentration data that is specific to the typical cuts being used in meal preparation would substantially increase confidence in the results. This is relevant for both domestic and international markets. The data also needs to be timely and reflect current standards in hygiene as well as changes in technological adoption in processing that may impact on pathogen loading.

Recommendations:

- Conduct review of prevalence of contamination and concentration data on a regular basis (e.g. every 5 years)
- Obtain data that reflects Australia's current hygiene practices at different levels of the supply chain:
    - At the abattoir
    - Prior to distribution from the processing plant
    - Retail
        - Prioritise the above for Hazard:Product:Process combinations with the highest risk ranking and with the highest uncertainty and sample cuts / products in these combinations. These combinations include *Listeria monocytogenes* in both unpackaged and packaged, cooked, ready-to-eat meat products, and *Toxoplasma gondii* in undercooked lamb (chilled, rolled or primal cut).

3. There is a delay in OzFoodNet reporting, with available outbreak data for research purposes being delayed at least two years.

A key factor required in the monitoring of pathogen behaviour is having access to timely data to facilitate the interpretation of trends and ground-truth results from risk profiling or ranking exercises. Outbreak data, in terms of the number of illnesses per year, is also a reflection of current supply chain practices (hygiene), including meal preparation and storage and overarching risk management practices. They are an indicator of the true risk of particular Hazard:Product:Product combinations in particular preparation and consumption settings, despite the lack of food attribution data in many instances or unknown pathogen aetiology.

Recommendation:

- Provide support, in conjunction with other industry bodies and regulatory jurisdictions, for increased funding for the OzFoodNet group to allow for more timely food outbreak surveillance reporting.

4. There is a need to conduct ongoing reviews of the risk profiling given the changes in consumption patterns, cuisine trends, advances in methods of pathogen monitoring and trade agreements.

Recommendation:

- Repeat the risk ranking exercise regularly (e.g. at least every 8 years or a time frame that reflects change in practice)

In addition to the recommendations in relation to increasing the understanding of the risk posed by microbiological hazards, it is also important that physical and chemical contaminant violations continue to be monitored to ensure compliance and rectify any recurring issues. To support this compliance, monitoring the potential changes in the management practices of red meat species (including rangeland goats) in relation to chemical exposure through feed and anaphylaxis measures is recommended, with violations of maximum residue limits occurring intermittently in this sector. Furthermore, given some of the combinations posing the highest food safety risk are those involving uncooked and undercooked products, it is recommended to continue the use of consumer education campaigns on the use of appropriate food safety practices in food preparation. Finally, given the red meat industry’s importance in a global context, its performance against international benchmarks in social responsibility (e.g. its contribution to the prevention of antimicrobial resistance, environmental sustainability, animal welfare standards) should be evaluated periodically to support ongoing confidence in Australian product.

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7 Appendices

7.1 Appendix A. Qualitative risk estimation process

***Step 1*: The literature was reviewed and relevant stakeholders consulted to identify hazards that pose, or are interpreted to pose, a food safety or market access risk in the current beef, sheep or goat supply chain environment, or within the next 5 years (as an arbitrary timeline to guide consideration). The aim of this step was to identify hazards so that they could be presented for comment in the expert-elicitation process (Step 2).**

A variety of literature sources were used, including:

- Historical National Public Health Surveillance Data on foodborne outbreaks from 2010-2016 (via request from OZfoodNet); publicised and non-publicised reports from the (Australian) National Residue Survey and the Australian and Overseas Maximum Residue Limit Database, as well as data from DAWR's *E.coli* and *Salmonella* Monitoring program (ESAM); annual notifications from Australian National Notifiable Diseases Surveillance System (NNDSS); FSANZ's The 24th Australian Total Diet Survey (Phase 1, April 2014 and Phase 2, January 2016); and recalls of red meat products as noted in the ACCC's Product Safety Australia website https://www.productsafety.gov.au/recall.
- Support documents/reports forwarded to the research team by the project steering committee (including research papers and in-market information from MLA International Business Managers), CSIRO, the Australian Consulate General and Trade Victoria.
- RSS feeds looking at food trends (types of cuisine, preparation trends, preserving and packaging trends) and food safety breaches. e.g. beefcentral.com, FoodNavigator.com (General, USA, Asia), GlobalMeatNews.com, FoodQualityNews.com, MarlerBlog.
- Alerts/Newsletters from Australian and international Food Safety/Standards organisations and scientific databases (e.g. MLA, EFSA, FSANZ, USDA FSIS, Australian Food Safety Information Council, Web of Science ('pathogen' and 'risk' search alert)
- Charles Sturt University Library database searches - Primo, Scopus and Web of Science, which led to the identification of appropriate peer-reviewed journal articles and books
- Google internet searches to supplement the above data collection, where information was not readily available

Consultation with industry stakeholders from Australian red meat industry bodies and food regulatory bodies (including the NSW Food Authority, local Council, Department of Agriculture and Water Resources and the Australian Meat Industry Council) was used as an alternative approach to source appropriate information. Such communication sought to gain feedback on current or future hazards as identified by personnel actively working in fields of foodborne infection, health protection, contaminant monitoring and/or market access.

Market Access-specific information sources used to identify market access risks included:

- Industry foresight and appraisal documents from representative bodies such as MLA, AMPC, as well as government-issued documents.
- Conversing with quality assurance and export management staff from processing bodies (described below), as well as government trade staff.
- Information from MLA's in-market trade development team.
- Assessment of food and supply chain trends with consideration of potential contributors to contamination and impacts on market access.

A face to face consultation via a semi-structured interview of quality assurance or export staff within key red meat processing/exporting organisations (Teys Australia, JBS Australia and Stockyard – ***Confidential information***) was used to obtain information surrounding the challenges/pressures they were facing (or had concerns about for the future) in relation to market access, market supply and food safety, and how these might be addressed. Prior informal meetings or conversations had occurred between a researcher (FC) and the attendees but a structured secondary discussion with each party was deemed necessary to qualify and validate the anecdotal information gained from these informal encounters.

An outline to be used during the face-to-face interview was developed (**Appendix B**) to identify potential issues (described above) from the processor/exporter perspective. Contact was made and the meeting was conducted on the 18th of May 2017. Data gathered during this meeting was summarised to identify key market access issues and challenges.

***Step 2*: An expert elicitation process, via a workshop consisting of 15 Australian food safety 'experts' was performed, to gather qualitative data to ground-truth the findings of the literature review (Step 1). Their expert opinion contributed towards identifying current hazard:product:pairings and the likelihood of contamination of a food serving at point of consumption (whereby the dose of the hazard is sufficient to cause disease).**

Identification of experts

The process by which the experts were identified was iterative. Initial nominees for the expert panel were designated by the Project Steering Committee at the first project steering group meeting in November, 2016. This list was further refined and augmented, in association with Dr. Ian Jenson (Manager, Market Access Science and Technology - the project's contact point within MLA), with changes in company positions, unavailability of personnel or people's recognised suitability. Upon acceptance or decline of the invitation, some invitees suggested additional attendees or attendees to attend on their behalf. These suggestions were reviewed by the project team and consequent guest lists were amended to facilitate these changes. Members of MLA's Food Safety Risk Panel were invited to participate in the workshop. Whilst also providing their expertise, the members in attendance were able to receive an update on the progress of the project.

Table A1. List of experts participating in the expert elicitation process to gather information on hazards posing a food safety and market access risk to the red meat industry *(Confidential information)*

Name	Institution, Role
Dr. Katrina Roper	National Centre for Epidemiology and Population Health, ANU (in lieu of AProf. Martyn Kirk)
Dr. Trish Desmarchelier	Food Safety Consultant, MLA Food Safety Scientific Risk Management Panel, Project Steering Committee
Dr. Andy Pointon	Food Safety Consultant, MLA Food Safety Scientific Risk Management Panel, Project Steering Committee
Assoc. Prof. Tom Ross	Associate Professor Food Microbiology (UTas), MLA Food Safety Scientific Risk Management Panel
Dr. John Sumner	Food Safety Consultant, MLA Food Safety Scientific Risk Management Panel
Dr. Dugald MacLachlan	Director, Residues & Microbiology Policy Food Division, DAWR

Dr. Duncan Craig	Acting Senior Director, Compliance Risk, Targeting & Intelligence, Compliance Division, DAWR
Dr. Mary Wu	Technical Manager, AMIC
Dr. Scott Crerar	Section Manager, Food Standards Australia New Zealand
Dr. Craig Shadbolt	Manager, Food Incident Response and Complaints, NSW Food Authority
Dr. Malik Hussain	Senior Technical Officer, NSW Food Authority
David Lean	Program Manager, Processing Hygiene, Quality and Meat Science, AMPC
Keira Glasgow	Acting Manager, Enteric and Zoonotic Diseases, Health Protection NSW
Dr. Paul Vanderlinde	Food Safety Consultant, MLA Food Safety Scientific Risk Management Panel
Dr. Ian Jenson	Manager, Market Access Science and Technology; Food Safety Scientific Risk Management Panel, Project Steering Committee

Apologies: Associate Professor Martyn Kirk, National Centre for Epidemiology and Population Health, ANU; Dr Ben Polkinghorne, OzFoodNet; Duncan Rowland, Animal Health Australia; Dr Andreas Kiermeier, Food Safety Consultant; Dr David Jordan, NSW DPI, MLA Food Safety Risk Panel.

Data collection

Prior to the workshop participants were issued, via email, the most up-to-date epidemiological, food recall, ESAM and residue surveillance data obtained in **Step 1**. The participants gathered in a central location and, after presentations outlining the purpose of the project and a review of the previous red meat risk ranking project, they were asked to identify the Product:Process:Hazard combinations that they considered to pose a non-negligible food safety risk. In addition, the group were presented (on the day of the meeting) with food/cuisine trends (based on literature review, and depicted in 5.3.1 *Review of market access issues and estimation of risk)*, that might create a potential hazard to help ensure all threats were accounted for. Once this list was collated they were asked to estimate as a group, using pre-established qualitative descriptors, the likelihood of an infectious dose of the hazard being present in a portion of product being consumed. The qualitative likelihood descriptors used comprised a 5 point scale (Table A2). No weighting of opinion based on experience, or other variable, was used in this elicitation process.

Table A2. Qualitative likelihood descriptors and corresponding probabilities of the likelihood of contamination of a serve of the product at point of consumption, with a sufficient dose to cause disease.

Descriptor of probability/Likelihood of Contamination of a Serve <u>at Point of Consumption</u> (whereby the dose is sufficient to cause disease)	**Probability / Percentage**
1. Common (1 in 1000)	≥0.1%
2. Sometimes (1 in 10,000)	0.01-0.1%
3. Infrequent (1 in 100,000)	0.001 – 0.01%
4. Rare (1 in a 1 000 000)	0.0001 – 0.001%
5. Negligible – sufficiently low to be ignored	0% - 0.0001%

These likelihood descriptors were derived based on the following information:

- The most recent estimate of the number of foodborne illnesses per year in Australia: 4.1 million in 2010 (Glass *et al*.2014)
- Australian population at the end of 2010: 22,172,469 (http://www.abs.gov.au/AUSSTATS/abs@.nsf/DetailsPage/3101.0Sep%202016?OpenDocument)
- Based on this data the average probability of an Australian citizen of contracting a foodborne illness was estimated as: 4.1/22.2 = 18.5%; or once every 5.4 years, from all sources of food.
- Underlying assumptions: People eat 5 to 6 servings of food per day (3 main meals and several snacks = 5.5 meals per day), for 365 days of the year.
- Therefore 365 days x 5.5 meals per day x 5.4 years between cases of foodborne illness = 10,841 servings. This total was rounded to 10,000 for ease of use in this project and corresponds with the 'Sometimes' likelihood above.

During the workshop, open discussions on the likelihoods were encouraged and a consensus likelihood was obtained. Time constraints only allowed for the beef combinations to be rated during the workshop, with estimates for sheep and goat being gathered by subsequent email communication.

***Step 3*:** **The experts' likelihood estimates were reviewed and the list of Product:Process:Hazard combinations to be considered in the qualitative estimation of risk (Step 5) finalised during this step.**

Review of likelihood estimates

Data on the Product:Process:Hazard combinations and corresponding estimated likelihoods were collated on a Microsoft Excel spreadsheet. The consensus likelihoods obtained for beef were used for Sheep and Goat products on the spreadsheet with minor adjustments made (for example, where a pathogen or product lost relevance between the species). This information was sent to participant experts by email. Experts were asked to review (and return) the consensus likelihood estimates, make any necessary changes and provide commentary on the reason for those changes. In addition, experts were also asked to provide comment on any factor that might influence the estimated likelihoods (e.g. age of the animal – lamb vs. mutton). This process allowed for an individual contribution of each expert and the identification of differences in expert opinions that were not identified during the workshop.

Deriving the final likelihood estimate for each Product:Process:Hazard combination

All experts returned the spreadsheet with the reviewed estimates and all data were collected in a single database to allow for comparisons between experts. From this data:

- Those combinations considered to have a *Negligible* likelihood of contamination of a serve of the product at point of consumption (with a sufficient dose to cause illness), by all experts were not further considered in the next steps of estimating overall risk.
- For those combinations with a likelihood higher than negligible:
    - If there were no differences between expert estimates, the consensus likelihood was used.
    - If there were differences between expert estimates, the highest likelihood estimate provided by at least two experts was used, considering this would be the worst case scenario.

***Step 4*:** **Severity ratings (human health) were derived for the hazards identified in Step 1 and 2. A subsequent allocation of health severity ratings for each Product:Process:Hazard combination (identified in Step 3) was performed. A qualitative trade risk appraisal was undertaken by DAWR and AMIC representatives.**

Severity of illness:
A severity rating table, shown in Table A3, was derived for estimating the severity of illness caused by the identified Product:Process:Hazard combinations. The International Commission on Microbiological Specifications for Foods (ICMSF 2002) was used as the basis of this table, with additional references used when required. Four severity levels were used, including mild, moderate, serious and severe. Two populations were considered for the severe category, the general and immunocompromised populations.

Table A3. Severity of illness rating descriptors for contaminants relating to exposure to the general population or restricted (immunocompromised) sub-populations.

Rating	Description	Contaminant
Severe (General Population)	Severe hazard for general population: life threatening or substantial chronic sequelae or long duration.	Aflatoxins[1]; Anthrax (*Bacillus anthraxis*)[2]; Botulinum neurotoxin (*Clostridium botulinum*)[1]; Enterohaemorrhagic *E.coli*: STEC (haemorrhagic colitis and haemolytic uraemic syndrome)[1]; *Salmonella typhi*[1]; *Shigella dysenteriae* I[1];Transmissible spongiform encephalopathies (TSE)[1]. Intentional adulteration.
Severe (Immunocompromised Population)	Severe for restricted populations: life threatening or substantial chronic sequelae or long duration.	As above + *B. cereus* [3]; *Campylobacter* spp. associated with Guillain-Barré Syndrome (*C. jejuni*, *C. coli*)[1]; Clostridium (*C. botulinum* - types A and B[1], *C. perfringens -type C*[1], *C. difficile*[4]); *Cryptosporidium parvum*[1]; *Listeria monocytogenes*[1]; *Enteropathogenic and Enterotoxigenic E. coli (EPEC/EHEC)*[1]; *Mycobacterium avium subsp. Paratuberculosis*[6]; *Salmonella* spp*[8]; *Toxoplasma gondii* [7]; *Staphylococcous aureus*[1]. Addition of allergens.
Serious	Serious, incapacitating but not life threatening; sequelae infrequent; moderate duration.	*Campylobacter* spp. (*C. jejuni, C. coli*); *Cryptosporidium parvum*[1]; *Listeria monocytogenes*[1a]; *Mycobacterium avium subsp. Paratuberculosis*[5]; non-dysentery shigellosis (for young and elderly persons- *Shigella flexnari, S. boydii, S. sonei*)[1]; *Salmonella* spp*[1,8]; Staphylococcous aureus (for immunocompromised individuals)[5]. Persistent Chemical Contaminants [e.g. Organocholorinated compounds (such as Dioxins and PCB's), Arsenic, Cadmium, Lead][10]
Moderate	Moderate, not usually life threatening; no sequelae; normally short duration; symptoms are self-limiting; can be severe discomfort.	*Bacillus cereus*[1]; *Clostridium* spp. (*C. perfringens type A*[1]; *C. difficile*[4]); Enteropathogenic and Enterotoxigenic *E. coli* (EPEC/EHEC)[1]; *Listeria monocytogenes*; *Staphylococcous aureus*[1]; *Toxoplasma gondii*[6]. Mycotoxins (Other - Fumonisins, Ochrotoxin A, Trichothecane toxins, Zearlenone)[1]. Physical Contaminants[11]
Mild	Mild, transient inconvenience, full recovery.	*Cysticercus bovis*[8] Hormone Growth Promotants (HGPs)[12]

General notes informing Table A3:

- Severity categorisation considers red meat only derived contamination, not accumulation from all sources.

- Restricted (sub) populations include the immunocompromised (HIV, Transplant, and to a lesser degree various forms of congenital disease), foetuses, below 5 years of age, the elderly > 70 years of age, those suffering anaphylaxis.
- The choice of age of > 70 differs from the WHO definition which uses a chronological age (time elapsed since birth) of 65 years or above (World Health Organisation 2010). The evidence on which this definition is based is unknown. The original derivation of 65 was by the average life expectancy minus 10 years, however a suggested subtraction of 10-15 years currently prevails. Life expectancy has been increasing, as has healthy life expectancy (the number of years of good health that a person can expect to live at any given age - considering age-associated mortality, morbidity, and functional health status). If we modernise this calculation for an Australian situation, where the average (consolidating males and females) life expectancy is 82.5years (2014) then an elderly person would be nominated at 72.5 years old. While the allocation of a biological age would be more apt, as the ageing process is not homogenous across populations due to differences in genetics, lifestyle, and overall health, it is not a functional input for the purpose of this research.

Specific information sources used in Table A3:

[1.] Based on the ICMSF (2002) categorisation of severity.

[1a.] *L. monocytogenes* considered 'Serious' where multiplication has occurred during distribution/storage and is therefore at an infectious dose.

[2.] *Bacillus anthracis*: http://www.oie.int/fileadmin/Home/eng/Media_Center/docs/pdf/Disease_cards/ANTHRAX-EN.pdf

[3.] *B.cereus* categorisation based on: Bottone E (2010) *Bacillus cereus*, a Volatile Human Pathogen. Clin. Microbiol. Rev. April 2010; 23(2): 382-398 http://cmr.asm.org/content/23/2/382.full. Aygun FD; Aygun F and Cam H (2016) Successful Treatment of *Bacillus* cereus Bacteremia in a Patient with Propionic Acidemia. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4853947/

[4.] *C. difficile* considered a 'Moderate' severity based on Pointon A (2013) Risk-Based Profile and Risk Rating of Foodborne Hazards of Pork in Australia (Australian Pork Limited) but 'Severe' for immunocompromised individuals based on MLA (2013) *Clostridium difficile* in meat and meat products: a position paper.

[5.] *S. aureus* considered 'Serious' for immuno-compromised individuals (pers.comm Prof D.Winlaw, Cardiac Surgeon).

[6.] *Mycobacterium avium subsp. Paratuberculosis* considered Serious because of associations with Crohn's Disease and Ulcerative colitis, and therefore Severe for the immunocompromised: https://www.foodstandards.gov.au/publications/documents/edit_Report_JD%20and%20CD -%20Final%20Dec%202004.pdf; http://www.ava.com.au/policy/108-johne%E2%80%99s-disease; http://www.ava.com.au/policy/108-johne%E2%80%99s-disease; https://www.ncbi.nlm.nih.gov/pubmed/24966610

[7.] *T. gondii* considered 'Moderate' for the general population but' Severe' for a foetus or the immunocompromised [based on Scallan E *et al*. (2014) An assessment of the human health impact of seven leading foodborne pathogens in the United States using disability adjusted life years; Pointon A (2013) Risk-Based Profile and Risk Rating of Foodborne Hazards of Pork in Australia (Australian Pork Limited)].

[8.] Based on the MLA report PRMS.038c (2003) "*Through Chain Risk Profile for the Australian Red Meat Industry*" severity categorisation.

*Includes *Salmonella* enterica 1, 4, [5], 12:I Phage Type 193 (monophasic strains)

[9.] Based on Pointon A (2013) Risk-Based Profile and Risk Rating of Foodborne Hazards of Pork in Australia (Australian Pork Limited).

[10.] Chemical contaminants range in their severity. The chemicals listed are considered severe because of their environmental persistence and cumulative effects. https://www.mla.com.au/globalassets/mla-corporate/meat-safety-and-traceability/documents/on-farm-practices/property-risk-assessments/lpa-factsheet-propertyriskassessment.pdf

[11.] Physical contaminants range in their impact on human health (sharps and glass versus plastics), and may become chemical contaminants if affected thermally or a choking hazard. A moderate rating has been assigned as an 'average' of the extremes of health impact.

[12.] HGPs considered mild based on Australian literature, however does not account for compounding effects of endocrine disruptors from other food or non-food sources and administration under Good Veterinary Practice. http://www.dpi.nsw.gov.au/animals-and-livestock/beef-cattle/husbandry/hormonal-growth-promotants/q-and-a; http://feedlots.com.au/wp-content/uploads/2014/08/Fact-sheet-HGPs-OCT15.pdf

Trade impact:

The methodology employed to identify trade-related food safety issues (including non-tariff barriers) to consider for a trade severity matrix included (1) reviewing the available literature as outlined above in **Step 1**; (2) consultation with quality assurance and export management staff from processing bodies; (3) reviewing the trade issues and rating methods identified in the MLA report PRMS.038c (2003) "Through Chain Risk Profile for the Australian Red Meat Industry"; and (3) consultation with industry representatives at the expert elicitation workshop.

From these data gathering exercises, two sets of preliminary severity ratings (one from the previous exercise MLA report PRMS.038c:2003 and an alternative one based on current information) were forwarded to representatives from the Australian Meat Industry Council (AMIC) and the Department of Agriculture and Water Resources (DAWR) with trade barrier experience in Federal Government positions for consideration. After consultation, they agreed to create an updated trade severity metric. However, despite the research team seeking severity estimates only, the aforementioned personnel formulated an alternative risk ranking approach which was based on expert opinion in entirety rather than a more formal scoring of likelihood and severity (as proposed by the research team). While they were cognisant that there are many ways to achieve a ranking of trade risk, they felt the research team approach was too complex and settled on their own alternative methodology for 'the purposes of simplicity'. The reason given was that they felt that trade risk is quite nuanced and often divorced from relative food safety risk and outcomes can differ market by market. The particular example given in terms of such nuance was that some markets take a strong, more reactive, approach on encountering an issue such as China suspending a plant following a single lead detection. Alternately, in some (country) cases the response might be the recall of product and intensified testing of a specified number of future consignments with additional detections escalating the issue. Examples given included STEC and chemical residues in product destined for Japan or the USA.

A more robust approach, which reflects the thinking of the research team' was described by the 'trade' personnel involved in developing the metrics. These participants suggested that they could have looked at the markets that account for 90% of exports for each of beef, sheep meat and goat meat and then estimate (guess) the likelihood of non-compliant product (against the particular market standard) and also the likely reaction to non-compliance and consequently the estimated cost of an incident [e.g. investigation costs, suspension to China (and China represents 50% of production[§§§]), cost of alternative supply for existing contracts, issues with maintaining operations in the absence of market access etc.]. The rankings could then be weighted to take into account market size and regulatory risks and might even be expressed in dollar terms. However they felt this would generate a large matrix, would take more time than available and would likely generate similar estimates to the

[§§§] It is assumed this percentage is a reflection of total agricultural exports to China, and there may be spillover violation effects between commodities.

crude results in the table below. They intimated that a more detailed approach, such as that outlined, might be useful in highlighting industry exposure to certain markets. However it was also suggested that "we would probably already know the outcome" based on simpler approaches such as the one used. The research team agrees with the sentiment of the time constraint on delivering such a matrix and suggests that the complexity would also be exacerbated by consideration of variables such as the iterative magnitude of the severity of ongoing non-compliance/detections, as well as the appraisal of the costs relating to the damage to business relationships in terms of trust and any impacts on the volume of trade (as described in the Results section of this document).

It was decided that media coverage (broadcast, print or social) not be used as a metric as the link between likelihood and actual degree of media reporting is a tiered process, whereby the severity of the outcome (human health or trade) is the determinant for the degree of media coverage (a secondary consequence or after-effect).

Step 5: **In this step a qualitative estimation (and prioritisation) of the relative level of risk was performed, using a risk matrix paradigm to combine the likelihood (Step 3) and the severity (Step 4) of illness estimates, for each of the Product:Process:Hazard (Step 3) combinations.**
A risk matrix, shown in Table A4, was created based on the Australian/New Zealand Risk Management Standard 'AS/NZS ISO 31000:2009: Risk management – Principles and Guidelines' to qualitatively estimate the level of risk posed by the Product:Process:Hazard combinations, combining the likelihood and the severity of illness estimates. The aim of using this matrix was to be able to estimate the ***relative risk*** posed by these combinations and to prioritize them.

Table A5. Risk matrix combining the likelihood of product contamination at point of consumption and the severity of illness caused by the contamination (adapted from AS/NZS ISO 31000:2009)

	Consequences				
Likelihood	**Mild**	**Moderate**	**Serious**	**Severe (General)**	**Severe (Compromised)**
Common (1 in 1,000)	Moderate	Moderate	High	High	High
Sometimes (1 in 10,000)	Low	Moderate	High	High	High
Infrequent (1 in 100,000)	Very Low	Low	Moderate	High	High
Rare (1 in a 1 000 000)	Very Low	Very Low	Moderate	Moderate	Moderate

7.2 Appendix B. Semi-structured interview outline

KEY PROCESSOR/EXPORTER MEETING- 2 to 3 processors to allow uninhibited dialogue.
To allow uninhibited dialogue the researcher will meet with 2 to 3 Processor Quality Assurance/Export Managers on a separate occasion to source information to allow the objectives of the project to be met.

Note: Artificial barriers to trade may not be valid hazards but are technical requirements for trade.

***Question*. Have you identified a trend of higher or lower pathogen counts in the past 10 years? (or indicator organisms)**
***Question*. Are you seeing more animal health issues leading to condemnation of carcasses or higher pathogen counts, than over the past 10 years?**
What are the key food safety-related issues impacting on the number of condemned carcases?
***Question*. Are MRL violations an actionable concern for industry? If yes, what do you see as a reason for this?**

- Improved detection limits
- Knowledge, more chemicals being assessed
- Improved regulatory systems/processes overseas – instating/ decreasing MRLs
- Other

What are the circumstances leading to such violations? e.g. education, record keeping, communication on-farm or disregard of withholding periods?
Type? Antibiotic residue. Chemical residue (OCs, OPs, heavy metals), Source?
What do you see as a solution for these situations?
<u>Animal handling and welfare (food safety and market access)</u>
***Question*. Does your company have an education program with respect to feed and water intake prior to transportation?**
***Question*. Are feeding and watering curfews always being adhered to prior to lairage?** While processors have already said no, we are seeking further clarification. Producers might feed and water cattle to add extra weight at the abattoir. Also if stock end up being in transit for longer than expected they might then get access to feed/water.
***Question*. Do you have any concerns with transporters in terms of stock handling, comfort and management during loading, transit and unloading?**
-effluent dispersal e.g. between decks?
***Question*. What processes are in place for late arrivals of stock when premises are closed?**
***Question*. What are the <u>3 greatest pressures</u> on either your beef, sheep or goat supply chains that may have an effect on the final food safety outcome of these meat classes?** Understanding the pressures where control might be lost. e.g. limited supply of stock, no regular trucking company services available, what control they implement over feed…can become a cost issue as opposed to quality/risk consideration in supply.
Adverse seasonal conditions leading to-

- issues with supply
- longer transit of stock
- poorer animal health
- Lower farm returns and cheaper or decreased farm inputs
- Food or regulatory trends
- Testing procedures
- Other

***Question*. Are there any processes/activities/developments you would wish to see or change to improve any adverse/risky situations? e.g. education, training, farm record keeping, new practices**

***Question*. Does your company experience trade restrictions or customer pressure or decreased trust in your product (fresh or frozen, justified or not) with respect to shelf-life?**
***Question*. Are there barriers to your ability to access markets, or client food safety misperceptions, that you consider do or will require more attention by industry within the next 10 years?**

- requirement for longer shelf-life by retailers, importers
- lower TVC counts e.g. in product destined for cryovacing
- counts based a possible end use but not the intended use
- increasing sensitivity of chemical and other analyses
- changes in sampling or testing regimens
- Equivalence in testing
- Other trade barriers e.g. certification, accountability

Example severity ranking for discussion

Severe hazard for general population: life threatening or substantial chronic sequelae or long duration.
International trade ceased for a period of greater than 3 years.
Global media coverage for greater than 2 weeks.

IB **Severe for restricted populations**: life threatening
International trade ceased for a period of greater than 1 year.
Global media coverage for up to two weeks.

II. **Serious**, incapacitating but not life threatening; sequelae infrequent; moderate duration.
International trade suspended, until regulators allow recurrence of trade.
Media coverage (in the Asia-Pacific region)

III. **Moderate**, not usually life threatening; no sequelae; normally short duration; symptoms are self-limiting; can be severe discomfort.
Immediate reduction in domestic sales, and businesses to cease trading pending investigation of outbreak.
Media coverage within Australia lasting up to one week.

IV. **Mild, transient inconvenience, full recovery.**
Business to cease trading until local food authority authorises re-opening.
Media activity within the local municipality only.

7.3 Appendix C. Product:Process:Hazard combinations arising from the expert elicitation

Table A6. Product:Process:Hazard combinations arising from the expert elicitation

Product	Process	Beef Hazard	Sheep Meat Hazard	Goat Meat Hazard
Comminuted meat *e.g steak tartare*	**Uncooked**	*Campylobacter*	*Campylobacter*	*Campylobacter*
		Cys. bovis	-	-
		C. difficile	*C. difficile*	*C. difficile*
		Chemical Contamination-residues above international MRL	Chemical Contamination-residues above international MRL	Chemical Contamination-residues above international MRL
		Cryptosporidium	*Cryptosporidium*	*Cryptosporidium*
		Mycobacterium paratuberculosis	*Mycobacterium paratuberculosis*	*Mycobacterium paratuberculosis*
		Mycotoxins	Mycotoxins	Mycotoxins
		Physical Contamination	Physical Contamination	Physical Contamination
		Salmonella spp.	*Salmonella* spp.	*Salmonella* spp.
		Shigella	*Shigella*	*Shigella*
		STEC	STEC	STEC
		Toxoplasma gondii	*Toxoplasma gondii*	*Toxoplasma gondii*
		TSE	TSE	TSE
	Undercooked	*Campylobacter*	*Campylobacter*	*Campylobacter*
		Cys. bovis	-	-
		C. difficile	*C. difficile*	*C. difficile*
		Chemical Contamination-residues above international MRL	Chemical Contamination-residues above international MRL	Chemical Contamination-residues above international MRL
		Cryptosporidium	*Cryptosporidium*	*Cryptosporidium*
		Mycobacterium paratuberculosis	*Mycobacterium paratuberculosis*	*Mycobacterium paratuberculosis*
		Mycotoxins	Mycotoxins	Mycotoxins
		Physical Contamination	Physical Contamination	Physical Contamination
		Salmonella spp.	*Salmonella* spp.	*Salmonella* spp.
		Shigella	*Shigella*	*Shigella*
		STEC	STEC	STEC
		Toxoplasma gondii	*Toxoplasma gondii*	*Toxoplasma gondii*
		TSE	TSE	TSE
	Cooked	*Campylobacter*	*Campylobacter*	*Campylobacter*
		Cys. bovis	-	-
		C. difficile	*C. difficile*	*C. difficile*
		Chemical Contamination-residues above international MRL	Chemical Contamination-residues above international MRL	Chemical Contamination-residues above international MRL
		Cryptosporidium	*Cryptosporidium*	*Cryptosporidium*
		Mycobacterium paratuberculosis	*Mycobacterium paratuberculosis*	*Mycobacterium paratuberculosis*

		Mycotoxins	Mycotoxins	Mycotoxins
		Physical Contamination	Physical Contamination	Physical Contamination
		Salmonella spp.	*Salmonella* spp.	*Salmonella* spp.
		STEC	STEC	STEC
		Toxoplasma gondii	*Toxoplasma gondii*	*Toxoplasma gondii*
		TSE	TSE	TSE
Primal *inc. red meat consumed raw, e.g. carpaccio*	**Uncooked**	*Campylobacter*	*Campylobacter*	*Campylobacter*
		Cys. bovis	-	-
		C. difficile	*C. difficile*	*C. difficile*
		Chemical Contamination-residues above international MRL	Chemical Contamination-residues above international MRL	Chemical Contamination-residues above international MRL
		Cryptosporidium	*Cryptosporidium*	*Cryptosporidium*
		Mycobacterium paratuberculosis	*Mycobacterium paratuberculosis*	*Mycobacterium paratuberculosis*
		Mycotoxins	Mycotoxins	Mycotoxins
		Physical Contamination	Physical Contamination	Physical Contamination
		Salmonella spp.	*Salmonella* spp.	*Salmonella* spp.
		STEC	STEC	STEC
		Toxoplasma gondii	*Toxoplasma gondii*	*Toxoplasma gondii*
		TSE	TSE	TSE
	Undercooked	*Campylobacter*	*Campylobacter*	*Campylobacter*
		Cys. bovis	-	-
		C. difficile	*C. difficile*	*C. difficile*
		Chemical Contamination-residues above international MRL	Chemical Contamination-residues above international MRL	Chemical Contamination-residues above international MRL
		Cryptosporidium	*Cryptosporidium*	*Cryptosporidium*
		Mycobacterium paratuberculosis	*Mycobacterium paratuberculosis*	*Mycobacterium paratuberculosis*
		Mycotoxins	Mycotoxins	Mycotoxins
		Physical Contamination	Physical Contamination	Physical Contamination
		Salmonella spp.	*Salmonella* spp.	*Salmonella* spp.
		STEC	STEC	STEC
		Toxoplasma gondii	*Toxoplasma gondii*	*Toxoplasma gondii*
		TSE	TSE	TSE
	Cooked	*Campylobacter*	*Campylobacter*	*Campylobacter*
		Cys. bovis	-	-
		C. difficile	*C. difficile*	*C. difficile*
		Chemical Contamination-residues above international MRL	Chemical Contamination-residues above international MRL	Chemical Contamination-residues above international MRL
		Cryptosporidium	*Cryptosporidium*	*Cryptosporidium*
		Mycobacterium paratuberculosis	*Mycobacterium paratuberculosis*	*Mycobacterium paratuberculosis*
		Mycotoxins	Mycotoxins	Mycotoxins

		Physical Contamination	Physical Contamination	Physical Contamination
		Salmonella spp.	*Salmonella* spp.	*Salmonella* spp.
		STEC	STEC	STEC
		Toxoplasma gondii	*Toxoplasma gondii*	*Toxoplasma gondii*
		TSE	TSE	TSE
	Vacuum packed and appropriate cooking	*C. botulinum*	*C. botulinum*	*C. botulinum*
		Cys. bovis	-	-
		C. difficile	*C. difficile*	*C. difficile*
		Chemical Contamination-residues above international MRL	Chemical Contamination-residues above international MRL	Chemical Contamination-residues above international MRL
		Cryptosporidium	*Cryptosporidium*	*Cryptosporidium*
		L. monocytogenes	*L. monocytogenes*	*L. monocytogenes*
		Mycobacterium paratuberculosis	*Mycobacterium paratuberculosis*	*Mycobacterium paratuberculosis*
		Mycotoxins	Mycotoxins	Mycotoxins
		Physical Contamination	Physical Contamination	Physical Contamination
		Salmonella spp.	*Salmonella* spp.	*Salmonella* spp.
		STEC	STEC	STEC
		Toxoplasma gondii	*Toxoplasma gondii*	*Toxoplasma gondii*
		TSE	TSE	TSE
	Vacuum packed and *undercooked*	*C. botulinum*	*C. botulinum*	*C. botulinum*
		Cys. bovis	-	-
		C. difficile	*C. difficile*	*C. difficile*
		Chemical Contamination-residues above international MRL	Chemical Contamination-residues above international MRL	Chemical Contamination-residues above international MRL
		Cryptosporidium	*Cryptosporidium*	*Cryptosporidium*
		L. monocytogenes	*L. monocytogenes*	*L. monocytogenes*
		Mycobacterium paratuberculosis	*Mycobacterium paratuberculosis*	*Mycobacterium paratuberculosis*
		Mycotoxins	Mycotoxins	Mycotoxins
		Physical Contamination	Physical Contamination	Physical Contamination
		Salmonella spp.	*Salmonella* spp.	*Salmonella* spp.
		STEC	STEC	STEC
		Toxoplasma gondii	*Toxoplasma gondii*	*Toxoplasma gondii*
		TSE	TSE	TSE
	Fusion - cooked to common standard (commonly served undercooked)	-	-	*Campylobacter*
		Cys. bovis	-	-

		C. difficile	*C. difficile*	*C. difficile*
		Chemical Contamination-residues above international MRL	Chemical Contamination-residues above international MRL	Chemical Contamination-residues above international MRL
		Cryptosporidium	*Cryptosporidium*	*Cryptosporidium*
		Mycobacterium paratuberculosis	*Mycobacterium paratuberculosis*	*Mycobacterium paratuberculosis*
		Mycotoxins	Mycotoxins	Mycotoxins
		Physical Contamination	Physical Contamination	Physical Contamination
		Salmonella spp.	*Salmonella* spp.	*Salmonella* spp.
		STEC	STEC	STEC
		TSE	TSE	TSE
	Roast - served warm	*Cys. bovis*	-	-
		C. difficile	*C. difficile*	*C. difficile*
		C. perfringens	*C. perfringens*	*C. perfringens*
		Chemical Contamination-residues above international MRL	Chemical Contamination-residues above international MRL	Chemical Contamination-residues above international MRL
		Cryptosporidium	*Cryptosporidium*	*Cryptosporidium*
		Mycobacterium paratuberculosis	*Mycobacterium paratuberculosis*	*Mycobacterium paratuberculosis*
		Mycotoxins	Mycotoxins	Mycotoxins
		Physical Contamination	Physical Contamination	Physical Contamination
		S. aureus	*S. aureus*	*S. aureus*
		Salmonella spp.	*Salmonella* spp.	*Salmonella* spp.
		STEC	STEC	STEC
		Toxoplasma gondii	*Toxoplasma gondii*	*Toxoplasma gondii*
		TSE	TSE	TSE
	Aged	*Cys. bovis*	-	-
		C. difficile	*C. difficile*	*C. difficile*
		Chemical Contamination-residues above international MRL	Chemical Contamination-residues above international MRL	Chemical Contamination-residues above international MRL
		Cryptosporidium	*Cryptosporidium*	*Cryptosporidium*
		L. monocytogenes	*L. monocytogenes*	*L. monocytogenes*
		Mycobacterium paratuberculosis	*Mycobacterium paratuberculosis*	*Mycobacterium paratuberculosis*
		Mycotoxins	Mycotoxins	Mycotoxins
		Physical Contamination	Physical Contamination	Physical Contamination
		S.aureus	*S.aureus*	*S.aureus*
		Salmonella spp.	*Salmonella* spp.	*Salmonella* spp.
		STEC	STEC	STEC
		Toxoplasma gondii	*Toxoplasma gondii*	*Toxoplasma gondii*
		TSE	TSE	TSE
	Sous vide (appropriate cooking method)	*C. difficile*	*C. difficile*	*C. difficile*

		C. perfringens	*C. perfringens*	*C. perfringens*
		Chemical Contamination-residues above international MRL	Chemical Contamination-residues above international MRL	Chemical Contamination-residues above international MRL
		Cryptosporidium	*Cryptosporidium*	*Cryptosporidium*
		L. monocytogenes	*L. monocytogenes*	*L. monocytogenes*
		Mycobacterium paratuberculosis	*Mycobacterium paratuberculosis*	*Mycobacterium paratuberculosis*
		Mycotoxins	Mycotoxins	Mycotoxins
		Other parasites	Other parasites	Other parasites
		Physical Contamination	Physical Contamination	Physical Contamination
		Salmonella spp.	*Salmonella* spp.	*Salmonella* spp.
		STEC	STEC	STEC
		Toxoplasma gondii	*Toxoplasma gondii*	*Toxoplasma gondii*
		TSE	TSE	TSE
UCFM	**Prepared, under Good Manufacturing Practice**	Mycotoxins	Mycotoxins	Mycotoxins
(Uncooked Comminuted Fermented Meat)		*Salmonella* spp.	*Salmonella* spp.	*Salmonella* spp.
		S. aureus	*S. aureus*	*S. aureus*
		STEC	STEC	STEC
	Preparation, not under GMP	*L. monocytogenes* (added in by a Participant)	*L. monocytogenes* (added in by a Participant)	*L. monocytogenes* (added in by a Participant)
		Mycotoxins	Mycotoxins	Mycotoxins
		Salmonella spp.	*Salmonella* spp.	*Salmonella* spp.
		S. aureus	*S. aureus*	*S. aureus*
		STEC	STEC	STEC
Kebabs		*L. monocytogenes*	*L. monocytogenes*	*L. monocytogenes*
		Salmonella spp.	*Salmonella* spp.	*Salmonella* spp.
		STEC	STEC	STEC
Shelf-stable meat		*S. aureus*	*S. aureus*	*S. aureus*
		Salmonella spp.	*Salmonella* spp.	*Salmonella* spp.
		STEC	STEC	STEC
Cooked, ready to eat	**Unpackaged**	*C. perfringens*	*C. perfringens*	*C. perfringens*
		L. monocytogenes	*L. monocytogenes*	*L. monocytogenes*
		S.aureus	*S.aureus*	*S.aureus*
		Shigella (added in by a Participant)	*Shigella* (added in by a Participant)	*Shigella* (added in by a Participant)
	Packaged (vacuum, MAP etc)	*L. monocytogenes*	*L. monocytogenes*	*L. monocytogenes*
Cured meat		*C. botulinum*	*C. botulinum*	*C. botulinum*
		Chemical Contamination-	Chemical Contamination-	Chemical Contamination-

		residues above international MRL	residues above international MRL	residues above international MRL
		L. monocytogenes	*L. monocytogenes*	*L. monocytogenes*
Paté		*Campylobacter*	*Campylobacter*	*Campylobacter*
		L. monocytogenes	*L. monocytogenes*	*L. monocytogenes*
		Salmonella spp.	*Salmonella* spp.	*Salmonella* spp.
		Shigella	*Shigella*	*Shigella*
		STEC	STEC	STEC
Offal (commonly undercooked)		*Campylobacter* (added in by a Participant)	*Campylobacter* (added in by a Participant)	*Campylobacter* (added in by a Participant)
		Cys. bovis	-	-
		C. difficile	*C. difficile*	*C. difficile*
		Chemical Contamination- residues above international MRL	Chemical Contamination- residues above international MRL	Chemical Contamination- residues above international MRL
		Cryptosporidium	*Cryptosporidium*	*Cryptosporidium*
		Mycobacterium paratuberculosis	*Mycobacterium paratuberculosis*	*Mycobacterium paratuberculosis*
		Mycotoxins	Mycotoxins	Mycotoxins
		Physical Contamination	Physical Contamination	Physical Contamination
		Salmonella spp.	*Non-Typhi Salmonella* spp.	*Salmonella* spp.
		-	*Typhi Salmonella* spp.	-
		STEC	STEC	STEC
		Toxoplasma gondii	*Toxoplasma gondii*	*Toxoplasma gondii*
		TSE	TSE	TSE
Beef (general)		AMR	AMR	AMR
		Anthrax	-	-
		Chemical Contamination- residues above international MRL	Chemical Contamination- residues above international MRL	Chemical Contamination- residues above international MRL
		Endocrine disruptors	-	-
		HGPs	-	-
		Illegal slaughter / poor handling at abattoir	Illegal slaughter / poor handling at abattoir	Illegal slaughter / poor handling at abattoir
		Intentional adulteration	Intentional adulteration	Intentional adulteration
		Mycotoxins	Mycotoxins	Mycotoxins
		Phytotoxins	Phytotoxins	Phytotoxins
		Retail products - addition of allergens for presentation or preserving (eg sulphites)	Retail products - addition of allergens for presentation or preserving (eg sulphites)	Retail products - addition of allergens for presentation or preserving (eg sulphites)
Canned meat		*B. cereus*	*B. cereus*	*B. cereus*
		C. botulinum	*C. botulinum*	*C. botulinum*
Gelatin		*Salmonella* spp.	*Salmonella* spp.	*Salmonella* spp.
		STEC	STEC	STEC
		TSE	TSE	TSE

7.4 Appendix D. Qualitative risk estimates for: 1) Beef Hazard:Product:Process combinations for immunocompromised populations; 2) Sheep and Goat Meat Hazard:Product:Process combinations for general and immunocompromised populations; and, 3) Cross-comparison of hazard:product:process combinations between species for immunocompromised populations

Table A7. Qualitative risk estimates for Beef Hazard:Product:Process combinations for an immunocompromised population

Likelihood x Severity (Qualitative Estimates)	Hazard	Product	Process	Minimum Likelihood Estimate	Severity
High	*C. difficile*	Offal (commonly undercooked)		3	1
	C. perfringens	Primal	Roast - served warm	2	1
	L. monocytogenes	Cooked, ready to eat	Packaged (vacuum, MAP etc)	2	1
	L. monocytogenes	Cooked, ready to eat	Unpackaged	3	1
	L. monocytogenes	Cured meat		3	1
	L. monocytogenes	Paté		3	1
	Mycobacterium paratuberculosis	Offal (commonly undercooked)		3	1
	Salmonella spp.	Comminuted meat	Uncooked	3	1
	Salmonella spp.	Offal (commonly undercooked)		3	1
	Salmonella spp.	Paté		3	1
	Salmonella spp.	Shelf-stable meat		3	1
	Salmonella spp.	UCFM	Preparation, not under GMP	3	1
	Salmonella spp.	UCFM	Prepared, under Good Manufacturing Practice	3	1
	STEC	Paté		3	1
	STEC	Shelf-stable meat		3	1
	STEC	UCFM	Preparation, not under GMP	2	1
	STEC	UCFM	Prepared, under Good Manufacturing Practice	3	1

	STEC	Comminuted meat	Uncooked	2	1
	STEC	Comminuted meat	Undercooked	3	1
	STEC	Primal	Fusion - cooked to common standard (commonly served undercooked)	3	1
	STEC	Offal (commonly undercooked)		2	1
Moderate	*Campylobacter*	Comminuted meat	Uncooked	4	2
	Campylobacter	Paté		4	1
	C. botulinum	Primal	Vacuum packed and appropriate cooking	4	1
	C. botulinum	Primal	Vacuum packed and undercooked	4	1
	C. difficile	Comminuted meat	Cooked	4	1
	C. difficile	Comminuted meat	Undercooked	4	1
	C. difficile	Primal	Undercooked	4	1
	C. difficile	Primal	Aged	4	1
	C. difficile	Primal	Cooked	4	1
	C. difficile	Primal	Fusion - cooked to common standard (commonly served undercooked)	4	1
	C. difficile	Primal	Roast - served warm	4	1
	C. difficile	Primal	Uncooked	4	1
	C. difficile	Primal	Vacuum packed and appropriate cooking	4	1
	C. difficile	Primal	Vacuum packed and *undercooked*	4	1
	C. perfringens	Cooked, ready to eat	Unpackaged	4	1
	Chemical Contamination- residues above international MRL	Comminuted meat	Uncooked	4	2
	Chemical Contamination- residues above international MRL	Cured meat		4	2

	Chemical Contamination- residues above international MRL	Primal	Aged	4	2
	Cryptosporidium	Comminuted meat	Uncooked	4	1
	Cryptosporidium	Comminuted meat	Undercooked	4	1
	Cryptosporidium	Offal (commonly undercooked)		4	1
	L. monocytogenes	Primal	Vacuum packed and *undercooked*	4	1
	Mycotoxins (Aflatoxin)	Primal	Sous vide (appropriate cooking method)	4	1
	Mycotoxins (Aflatoxin)	Offal (commonly undercooked)		4	1
	S. aureus	UCFM	Preparation, not under GMP	3	2
	S. aureus	Shelf-stable meat		4	2
	Salmonella spp.	Comminuted meat	Undercooked	4	1
	Salmonella spp.	Primal	Fusion - cooked to common standard (commonly served undercooked)	4.5	1
	Salmonella spp.	Primal	Uncooked	4	1
	STEC	Primal	Uncooked	4	1
	Toxoplasma gondii	Primal	Undercooked	4	1
	Toxoplasma gondii	Primal	Cooked	4	1
	Toxoplasma gondii	Primal	Uncooked	4	1
	Toxoplasma gondii	Primal	Vacuum packed and *undercooked*	4	1
Very Low	*Cys. bovis*	Comminuted meat	Uncooked	4	3
	Cys. bovis	Comminuted meat	Undercooked	4	4
	Cys. bovis	Offal (commonly undercooked)		4	4
	Mycotoxins (Mycotoxins (Other - Fumonisins, Ochrotoxin A, Trichothecane toxins, Zearlenone)	Primal	Sous vide (appropriate cooking method)	4	3

	Mycotoxins (Mycotoxins (Other - Fumonisins, Ochrotoxin A, Trichothecane toxins, Zearlenone)			4	3
	Physical Contamination	Comminuted meat	Uncooked	4	3
	Physical Contamination	Comminuted meat	Undercooked	4	3

Table A8.1. Qualitative risk estimates for Sheep meat Hazard:Product:Process combinations for the general population

Likelihood x Severity (Qualitative Estimates)	Hazard	Product	Process	Minimum Likelihood Estimate	Severity
High	*L. monocytogenes*	Cooked, ready to eat	Packaged (vacuum, MAP etc.)	2	2
	STEC	Paté		3	1
	STEC	UCFM	Prepared, under Good Manufacturing Practice	3	1
	STEC	UCFM	Preparation, not under GMP	3	1
	STEC	Comminuted meat	Uncooked	2	1
	STEC	Comminuted meat	Undercooked	3	1
	STEC	Offal (commonly undercooked)		2	1
Moderate	*Campylobacter*	Paté		4	2
	Chemical Contamination-residues above international MRL	Comminuted meat	Uncooked	4	2
	Chemical Contamination-residues above international MRL	Cured meat		4	2
	C. botulinum	Primal	Vacuum packed and appropriate cooking	4	1
	C. botulinum	Primal	Vacuum packed and *undercooked*	4	1
	C. perfringens	Primal	Roast - served warm	2	3
	Cryptosporidium	Comminuted meat	Uncooked	4	2

Cryptosporidium	Comminuted meat	Undercooked	4	2
Cryptosporidium	Offal (commonly undercooked)		4	2
L. monocytogenes	Cooked, ready to eat	Unpackaged	3	2
L. monocytogenes	Cured meat		3	2
L. monocytogenes	Primal	Vacuum packed and *undercooked*	4	2
L. monocytogenes	Paté		3	2
Mycobacterium paratuberculosis	Offal (commonly undercooked)		3	2
Mycotoxins (Aflatoxin)	Primal	Sous vide (appropriate cooking method)	4	1
Mycotoxins (Aflatoxin)	Offal (commonly undercooked)		4	1
Salmonella spp.	Comminuted meat	Uncooked	3	2
Salmonella spp.	Comminuted meat	Undercooked	4	2
Salmonella spp.	Primal	Uncooked	4	2
Salmonella spp.	Primal	Fusion - cooked to common standard (commonly served undercooked)	4	2
Salmonella spp.	Offal (commonly undercooked)		3	2
Salmonella spp.	Paté		3	2
Salmonella spp.	Shelf-stable meat		4	2
Salmonella spp.	UCFM	Prepared, under Good Manufacturing Practice	3	2
Salmonella spp.	UCFM	Preparation, not under GMP	3	2
STEC	Shelf-stable meat		4	1
STEC	Primal	Uncooked	4	1
STEC	Primal	Fusion - cooked to common standard (commonly	4	1

			served undercooked)		
Low	*C. difficile*	Offal (commonly undercooked)		3	3
	S. aureus	UCFM	Preparation, not under GMP	3	3
Very Low	*C. difficile*	Comminuted meat	Undercooked	4	3
	C. difficile	Comminuted meat	Cooked	4	3
	C. difficile	Primal	Uncooked	4	3
	C. difficile	Primal	Undercooked	4	3
	C. difficile	Primal	Vacuum packed and appropriate cooking	4	3
	C. difficile	Primal	Vacuum packed and ***undercooked***	4	3
	C. difficile	Primal	Fusion - cooked to common standard (commonly served undercooked)	4	3
	C. difficile	Primal	Roast - served warm	4	3
	C. difficile	Primal	Aged	4	3
	C. perfringens	Cooked, ready to eat	Unpackaged	4	3
	Mycotoxins (Mycotoxins (Other - Fumonisins, Ochrotoxin A, Trichothecane toxins, Zearlenone)	Primal	Sous vide (appropriate cooking method)	4	3
	Mycotoxins (Mycotoxins (Other - Fumonisins, Ochrotoxin A, Trichothecane toxins, Zearlenone)	Offal (commonly undercooked)		4	3
	Physical Contamination	Comminuted meat	Uncooked	4	3
	Physical Contamination	Comminuted meat	Undercooked	4	3
	S. aureus	Shelf-stable meat		4	3
	Toxoplasma gondii	Comminuted meat	Uncooked	4	3
	Toxoplasma gondii	Comminuted meat	Undercooked	4	3

	Toxoplasma gondii	Primal	Uncooked	4	3
	Toxoplasma gondii	Primal	Undercooked	4	3

Table A8.2. Qualitative risk estimates for Goat Meat Hazard:Product:Process combinations for a general population

Likelihood x Severity (Qualitative Estimates)	Hazard	Product	Process	Minimum Likelihood Estimate	Severity
High	L. monocytogenes	Cooked, ready to eat	Packaged (vacuum, MAP etc.)	2	2
	Salmonella spp.	Comminuted meat	Uncooked	2	2
	STEC	UCFM	Prepared, under Good Manufacturing Practice	3	1
	STEC	UCFM	Preparation, not under GMP	3	1
	STEC	Comminuted meat	Uncooked	2	1
	STEC	Comminuted meat	Undercooked	3	1
	STEC	Primal	Uncooked	3	1
	STEC	Offal (commonly undercooked)		2	1
Moderate	Chemical Contamination- residues above international MRL	Comminuted meat	Uncooked	4	2
	Chemical Contamination- residues above international MRL	Cured meat		4	2
	C. botulinum	Primal	Vacuum packed and appropriate cooking	4	1
	C. botulinum	Primal	Vacuum packed and undercooked	4	1
	C. perfringens	Primal	Roast - served warm	2	3
	Cryptosporidium	Comminuted meat	Uncooked	4	2
	Cryptosporidium	Comminuted meat	Undercooked	4	2
	Cryptosporidium	Offal (commonly undercooked)		4	2
	L. monocytogenes	Cooked, ready to eat	Unpackaged	3	2
	L. monocytogenes	Cured meat		3	2
	L. monocytogenes	Paté		3	2
	Mycobacterium paratuberculosis	Offal (commonly undercooked)		3	2
	Mycotoxins (Aflatoxin)	Primal	Sous vide (appropriate cooking method)	4	1

	Mycotoxins (Aflatoxin)	Offal (commonly undercooked)		4	1
	Salmonella spp.	Comminuted meat	Undercooked	4	2
	Salmonella spp.	Primal	Uncooked	3	2
	Salmonella spp.	Primal	Fusion - cooked to common standard (commonly served undercooked)	4	2
	Salmonella spp.	Offal (commonly undercooked)		3	2
	Salmonella spp.	Paté		3	2
	Salmonella spp.	Shelf-stable meat		4	2
	Salmonella spp.	UCFM	Prepared, under Good Manufacturing Practice	3	2
	Salmonella spp.	UCFM	Preparation, not under GMP	3	2
	STEC	Shelf-stable meat		4	1
	STEC	Primal	Fusion - cooked to common standard (commonly served undercooked)	4	1
Low	*C. difficile*	Offal (commonly undercooked)		3	3
	S. aureus	UCFM	Preparation, not under GMP	3	3
Very Low	*C. difficile*	Comminuted meat	Undercooked	4	3
	C. difficile	Comminuted meat	Cooked	4	3
	C. difficile	Primal	Uncooked	4	3
	C. difficile	Primal	Undercooked	4	3
	C. difficile	Primal	Vacuum packed and appropriate cooking	4	3
	C. difficile	Primal	Vacuum packed and undercooked	4	3
	C. difficile	Primal	Fusion - cooked to common standard (commonly served undercooked)	4	3
	C. difficile	Primal	Roast - served warm	4	3
	C. difficile	Primal	Aged	4	3
	C. perfringens	Cooked, ready to eat	Unpackaged	4	3
	Mycotoxins (Mycotoxins (Other - Fumonisins, Ochrotoxin A, Trichothecane toxins, Zearlenone)	Primal	Sous vide (appropriate cooking method)	4	3

	Mycotoxins (Mycotoxins (Other - Fumonisins, Ochrotoxin A, Trichothecane toxins, Zearlenone)	Offal (commonly undercooked)		4	3
	Physical Contamination	Comminuted meat	Uncooked	4	3
	S. aureus	Shelf-stable meat		4	3
	Toxoplasma gondii	Comminuted meat	Uncooked	4	3
	Toxoplasma gondii	Primal	Uncooked	4	3
	Toxoplasma gondii	Primal	Undercooked	4	3

Table A8.3. Qualitative risk estimates for Sheep Meat Hazard:Product:Process combinations for an immunocompromised population

Likelihood x Severity (Qualitative Estimates)	Hazard	Product	Process	Minimum Likelihood Estimate	Severity
High	*C. difficile*	Offal (commonly undercooked)		3	1
	C. perfringens	Primal	Roast - served warm	2	1
	L. monocytogenes	Cooked, ready to eat	Packaged (vacuum, MAP etc.)	2	1
	L. monocytogenes	Cooked, ready to eat	Unpackaged	3	1
	L. monocytogenes	Cured meat		3	1
	L. monocytogenes	Paté		3	1
	Mycobacterium paratuberculosis	Offal (commonly undercooked)		3	1
	Salmonella spp.	Comminuted meat	Uncooked	3	1
	Salmonella spp.	Offal (commonly undercooked)		3	1
	Salmonella spp.	Paté		3	1
	Salmonella spp.	UCFM	Prepared, under Good Manufacturing Practice	3	1
	Salmonella spp.	UCFM	Preparation, not under GMP	3	1
	STEC	Paté		3	1
	STEC	UCFM	Prepared, under Good Manufacturing Practice	3	1
	STEC	UCFM	Preparation, not under GMP	3	1
	STEC	Comminuted meat	Uncooked	2	1
	STEC	Comminuted meat	Undercooked	3	1
	STEC	Offal (commonly undercooked)		2	1
Moderate	Chemical Contamination-residues above international MRL	Comminuted meat	Uncooked	4	2
	Chemical Contamination-residues above international MRL	Cured meat		4	2

C. botulinum	Primal	Vacuum packed and appropriate cooking	4	1
C. botulinum	Primal	Vacuum packed and <u>*undercooked*</u>	4	1
C. difficile	Comminuted meat	Undercooked	4	1
C. difficile	Comminuted meat	Cooked	4	1
C. difficile	Primal	Uncooked	4	1
C. difficile	Primal	Undercooked	4	1
C. difficile	Primal	Vacuum packed and appropriate cooking	4	1
C. difficile	Primal	Vacuum packed and undercooked	4	1
C. difficile	Primal	Fusion - cooked to common standard (commonly served undercooked)	4	1
C. difficile	Primal	Roast - served warm	4	1
C. difficile	Primal	Aged	4	1
C. perfringens	Cooked, ready to eat	Unpackaged	4	1
Campylobacter	Paté		4	2
Cryptosporidium	Comminuted meat	Uncooked	4	1
Cryptosporidium	Comminuted meat	Undercooked	4	1
Cryptosporidium	Offal (commonly undercooked)		4	1
L. monocytogenes	Primal	Vacuum packed and undercooked	4	1
Mycotoxins (Aflatoxin)	Primal	Sous vide (appropriate cooking method)	4	1
Mycotoxins (Aflatoxin)	Offal (commonly undercooked)		4	1
S. aureus	Shelf-stable meat		4	2
S. aureus	UCFM	Preparation, not under GMP	3	2
Salmonella spp.	Comminuted meat	Undercooked	4	1
Salmonella spp.	Primal	Uncooked	4	1
Salmonella spp.	Primal	Fusion - cooked to common standard (commonly served undercooked)	4	1
Salmonella spp.	Shelf-stable meat		4	1
STEC	Shelf-stable meat		4	1

	STEC	Primal	Uncooked	4	1
	STEC	Primal	Fusion - cooked to common standard (commonly served undercooked)	4	1
	Toxoplasma gondii	Comminuted meat	Uncooked	4	1
	Toxoplasma gondii	Comminuted meat	Undercooked	4	1
	Toxoplasma gondii	Primal	Uncooked	4	1
	Toxoplasma gondii	Primal	Undercooked	4	1
Very Low	Mycotoxins (Mycotoxins (Other - Fumonisins, Ochrotoxin A, Trichothecane toxins, Zearlenone)	Primal	Sous vide (appropriate cooking method)	4	3
	Mycotoxins (Mycotoxins (Other - Fumonisins, Ochrotoxin A, Trichothecane toxins, Zearlenone)	Offal (commonly undercooked)		4	3
	Physical Contamination	Comminuted meat	Uncooked	4	3
	Physical Contamination	Comminuted meat	Undercooked	4	3

Table A8.4. Qualitative risk estimates for Goat Meat Hazard:Product:Process combinations for an immunocompromised population

Likelihood x Severity (Qualitative Estimates)	Hazard	Product	Process	Minimum Likelihood Estimate	Severity
High	*C. difficile*	Offal (commonly undercooked)		3	1
	C. perfringens	Primal	Roast - served warm	2	1
	L. monocytogenes	Cooked, ready to eat	Packaged (vacuum, MAP etc.)	2	1
	L. monocytogenes	Cooked, ready to eat		3	1
	L. monocytogenes	Cured meat		3	1
	L. monocytogenes	Paté		3	1
	Mycobacterium paratuberculosis	Offal (commonly undercooked)		3	1
	Salmonella spp.	Comminuted meat	Uncooked	2	1
	Salmonella spp.	Primal	Uncooked	3	1
	Salmonella spp.	Offal (commonly undercooked)		3	1
	Salmonella spp.	Paté		3	1
	Salmonella spp.	UCFM	Prepared, under Good Manufacturing Practice	3	1
	Salmonella spp.	UCFM	Preparation, not under GMP	3	1
	STEC	UCFM	Prepared, under Good Manufacturing Practice	3	1
	STEC	UCFM	Preparation, not under GMP	3	1
	STEC	Comminuted meat	Uncooked	2	1
	STEC	Comminuted meat	Undercooked	3	1
	STEC	Primal	Uncooked	3	1
	STEC	Offal (commonly undercooked)		2	1

Moderate	Chemical Contamination-residues above international MRL	Comminuted meat	Uncooked	4	2
	Chemical Contamination-residues above international MRL	Cured meat		4	2
	C. botulinum	Primal	Vacuum packed and appropriate cooking	4	1
	C. botulinum	Primal	Vacuum packed and undercooked	4	1
	C. difficile	Comminuted meat	Undercooked	4	1
	C. difficile	Comminuted meat	Cooked	4	1
	C. difficile	Primal	Uncooked	4	1
	C. difficile	Primal	Undercooked	4	1
	C. difficile	Primal	Vacuum packed and appropriate cooking	4	1
	C. difficile	Primal	Vacuum packed and undercooked	4	1
	C. difficile	Primal	Fusion - cooked to common standard (commonly served undercooked)	4	1
	C. difficile	Primal	Roast - served warm	4	1
	C. difficile	Primal	Aged	4	1
	C. perfringens	Cooked, ready to eat	Unpackaged	4	1
	Cryptosporidium	Comminuted meat	Uncooked	4	1
	Cryptosporidium	Comminuted meat	Undercooked	4	1
	Cryptosporidium	Offal (commonly undercooked)		4	1
	Mycotoxins (Aflatoxin)	Primal	Sous vide (appropriate cooking method)	4	1
	Mycotoxins (Aflatoxin)	Offal (commonly undercooked)		4	1

	S. aureus	Shelf-stable meat		4	2
	S. aureus	UCFM	Preparation, not under GMP	3	2
	Salmonella spp.	Comminuted meat	Undercooked	4	1
	Salmonella spp.	Primal	Fusion - cooked to common standard (commonly served undercooked)	4	1
	Salmonella spp.	Shelf-stable meat		4	1
	STEC	Shelf-stable meat		4	1
	STEC	Primal	Fusion - cooked to common standard (commonly served undercooked)	4	1
	Toxoplasma gondii	Comminuted meat	Uncooked	4	1
	Toxoplasma gondii	Primal	Uncooked	4	1
	Toxoplasma gondii	Primal	Undercooked	4	1
	Mycotoxins (Aflatoxin)	Primal	Sous vide (appropriate cooking method)	4	1
	Mycotoxins (Aflatoxin)	Offal (commonly undercooked)		4	1
Very Low	Physical Contamination	Comminuted meat	Uncooked	4	3
	Mycotoxins (Mycotoxins (Other - Fumonisins, Ochrotoxin A, Trichothecane toxins, Zearlenone)	Primal	Sous vide (appropriate cooking method)	4	3
	Mycotoxins (Mycotoxins (Other - Fumonisins, Ochrotoxin A, Trichothecane toxins, Zearlenone)	Offal (commonly undercooked)		4	3

Table A9.1. Additional 'high' rated risk hazard:product:process combinations for restricted populations with a cross-comparison between species

Hazard		Beef	Sheep	Goat
C. difficile	Offal (commonly undercooked)	✓	✓	✓
C. perfringens	Roast - served warm	✓	✓	✓
L. monocytogenes	Cured meat	✓	✓	✓
L. monocytogenes	Pate	✓	✓	✓
Salmonella spp.	Uncooked comminuted meat	✓	✓	× (Already high for a general population)
Salmonella spp.	Uncooked primal cut	×	×	✓
Salmonella spp.	Pate	✓	✓	× (not rated*)
Salmonella spp.	GMP UCFM	✓	✓	✓

* Not rated as considered of negligible occurrence in global cuisine.

Table A9.2. Additional 'moderate' rated risk hazard:product:process combinations for restricted populations with a cross-comparison between species

Hazard		Beef	Sheep	Goat
C. difficile	Undercooked comminuted meat	✓	✓	✓
C. difficile	Cooked comminuted meat	✓	✓	✓
C. difficile	Uncooked primal	✓	✓	✓
C. difficile	Undercooked primal	✓	✓	✓
C. difficile	Cooked primal	✓	×	×
C. difficile	Aged primal cuts	✓	✓	✓
C. difficile	Vacuum packed primal and appropriate cooking	✓	✓	✓
C. difficile	Vacuum packed primal and undercooked	✓	✓	✓
C. difficile	Fusion-style primal cuts- cooked to common standard (commonly served undercooked)	✓	✓	✓
C. difficile	Roast - served warm	✓	✓	✓
C. perfringens	Unpackaged, cooked, ready to eat	✓	✓	✓
S. aureus	Shelf-stable meat	✓	✓	✓
S. aureus	Non-GMP UCFM	✓	✓	✓
Toxoplasma gondii	Uncooked comminuted meat	×	✓	✓
Toxoplasma gondii	Undercooked comminuted meat	×	✓	×
Toxoplasma gondii	Uncooked primal	✓	✓	✓
Toxoplasma gondii	Undercooked primal	✓	✓	✓
Toxoplasma gondii	Cooked primal	✓	×	×
Toxoplasma gondii	Vacuum packed primal and undercooked	✓	×	×

7.5 Appendix E. Market Access Review: Outcomes of the literature review and consultations in relation to market access issues

The Australian red meat industry was worth over $11 billion in 2015-16 in export alone. Its strength is relied upon by a number of communities both regionally and in metropolitan centres. It is therefore imperative that industry resilience is a priority and that it is maintained through the contribution of government and industry in partnership. When considering the impact of a food safety concern the trade repercussions, or impact upon returns to the Australian economy, should be contemplated both by value and volume, not each in isolation. A processing plant's viability relies on all parts of the carcass receiving some form of return and also on volume throughput. In understanding what volumes of products are going to which destination, in what form it is transported, the value of that product and its end use, allow for a better interpretation of the inherent risk carried.

Market access is a broad term which encompasses a range of themes and is affected at either a government, customer (business to business) or consumer level. Access to a market is generally determined on a regulatory basis or on collective marketing principles (the 8 P's included in a marketing mix) such as product, price, promotion, place, people, process and physical evidence (including packaging and branding), productivity and quality, to which perception (around the value offering) should be added. On a government tier, market access may be driven through government intervention in terms of trade agreements, reform, regulation such as Appropriate Level of Protection (ALOP), or restrictions and closure based around food safety, biosecurity, or the less tangible protection of domestic suppliers. From a marketing perspective, purchase drivers such as trust and loyalty (relationships) and product attributes such as safety, quality, integrity and cost affect business customer interactions. On either level, relationships or product attributes, market access can be restricted or closed with any infringement on regulatory agreements or customer perception (with respect to the aforementioned product attributes). Trending consumer expectations or desires and the power of that influence on collective demand/the market, in turn influences buyers and government with respect to the volume and the types of red meat products imported by various markets. All three layers impact on the propensity of Australian red meat industry to access and supply markets. As a major exporter, any changes to access to our overseas markets can have a significant and far-ranging impact on the red meat industry. Such events can affect both immediate and longer term market share and therefore profitability. They affect the whole supply chain and therefore can be far-reaching by influencing the social framework, services and infrastructure of rural communities where processing establishments and red meat producers reside.

In terms of overarching market access risks, the AMPC document entitled "Strategic Risks facing the Australian Red Meat Industry" (2016) gives a quite thorough analysis of the challenges befalling the red meat industry. As such, this report will not re-address the information contained in this pre-existing document but rather it will provide a precis of relevant content, as well as additional commentary on subjects of particular pertinence to this project.

Trade agreements

Entry into a market may be altered, in the longer term, through government to government access negotiations and trade reform or abruptly through food safety concerns. Trade agreements (multilateral, regional or bilateral) at the government level facilitate trade access, however restrictions underpinning such entry can impinge on the financial benefits of the trade deal (from the exporter's perspective). Quotas (volume and number of export-registered slaughter establishments) aside, economic pressure on suppliers due to product labelling, audit and/or verification of product 'cleanliness' may be present . Some of these factors operate at a government level (the declaration of all STECS, and current discourse regarding anti-microbial resistant strains of *Salmonella* also being considered adulterants in the US) or at a customer level, and are due to risk management or aversion or misunderstanding of the true implication of the data presented on a food safety basis. Precedents (for compliance) set by global economies, such as the US or the EU, can force positive change in food safety systems, therefore improving risk management within all supplying nations however such regulatory burden does come at a cost and can impact on their export competitiveness. Australia's increasing reliance on exports due to declining domestic demand (AMPC 2016), and other nations improved access through trade agreements heightens the requirement for ongoing effort to defend Australia's existing rights and to secure improvements to export conditions (MLA 2017) has the potential itself to be a barrier. Efforts by government and industry trade advocacy groups need to be well-coordinated, sustained and negotiated to keep markets open or access improved.

Tariff and non-tariff trade barriers

Impediments to trade are imposed in many forms and many of Australia's overseas markets are subject to some form of entry barrier. Tariffs and quotas are the most common border protection measures. Year 2015 tariffs and quotas for Australia's key sheepmeat and beef markets are presented on the MLA website (2017). However, as reported by MLA (*Market Access* 2017) "non-tariff barriers including unfair competition in the form of subsidies, technical imposts, and exports from countries that subsidise their domestic industries, are also major issues". Technical imposts may include product registration and food safety rules, whilst other barriers may take the form of port delays or 'approved establishment' restrictions. Major markets such as China and the US typify such barriers with, for example, China's limitation on the number of Australian plants approved for export (particularly for chilled beef) and restrictions on edible offal exports. Technical market access parameters prevail with the US such as the *E.coli* sampling program and testing at point of entry; the *Salmonella* sampling program; label approvals and port mark compliance (MLA *Market Snapshot*: *Beef*, 2017). It is only through government negotiations and the provision of evidence-based technical submissions, in conjunction with industry and customer 'push' tactics, that these barriers may be removed.

Free trade agreements (FTA)

The reduction or elimination of tariffs as well as improvements to other trade restrictive measures through FTA's has been of great benefit to the red meat industry. While it has been estimated that the three most recent FTAs Australia has concluded: Korea (KAFTA), Japan (JAEPA) and China (ChAFTA) will result in a combined $20 billion in extra value for the Australian industry over the next 20 years (MLA 2017) there are still lag periods and no restrictions on what other barriers may be presented to either leverage other trade deals or protect domestic industries.

"Nevertheless, the temptation to ward off the challenge of competitive imports is always present. And richer governments are more likely to yield to the siren call of protectionism, for short term political gain — through subsidies, complicated red tape, and hiding behind legitimate policy objectives such as environmental preservation or consumer protection as an excuse to protect producers" (World Trade Organisation, 2017).

Appropriate Level of Protection (ALOP)

Under WTO law, each member state's sovereign right to choose its own level of regulation is called the 'appropriate level of protection' (ALOP) or 'acceptable risk' which may or may not be based on an international standard (e.g. Sanitary and Phytosanitary Measures Agreement). ALOP defines the realm of issues that are outside the scope of scrutiny for WTO adjudicative bodies (Rigod 2015). Policy around acceptable risk implies rationally based judgements determined by weighing up costs and benefits (societal and economic) so as to reflect community and industry views on risk taking and the benefits of trade. However the ALOP can play a protectionist role despite obligations of minimising trade effects and measures being no more trade restrictive than required to meet its own animal/plant health or food safety objectives. “For instance, governments can use the ALOP to shield their industry from foreign competition by choosing an ALOP that corresponds to the specifications of domestic products but which, at the same time, removes imports from the market that do not meet these requirements. This is probable, if the production technologies of the domestic and the foreign industry differ and the ALOP is used to favour the home industry” (Rigod 2015). The resultant protectionism and non-technical trade barriers, being disguised as technical trade barriers, can limit market access despite the caveat of minimisation of trade effects on the exporting country.

For a particular import proposal, there are often a number of alternative measures which, singly or in combination, may be used to achieve the importing Member’s ALOP (for example, treatment, inspection, testing). In choosing among such alternatives, the importing Member needs to adopt those measures which are no more trade restrictive than required to meet its animal/plant health or food safety objectives, if the measures proposed are technically and economically feasible. Meeting an importing country’s ALOP, such as the USA’s zero tolerance policy on STECs, can be difficult especially when requirements are technically feasible but seemingly excessive and can therefore present significant technical barriers to trade. The ability to achieve these stipulations can present further problems and come at a cost so therefore impact on competitiveness, such as the required sampling methods and regimens or those import regulations associated with product age and expiry dates (leaving little shelf-life once through port). Recommendations around food safety/traceback can be challenged to achieve greater efficiencies, without creating a change in the overall risk outcome. Recent extensions to shelf-life of product travelling to the Middle East exemplifies such negotiation. In addition breakthroughs in efficiency from a processor point of view (e.g. pallet labelling to the US as opposed to individual box labelling) is also an example of improving efficiency of production without compromising safety or changing risk status.

Biosecurity

Incidences of humans acquiring an animal-borne infectious disease can affect consumption of red meat as a fear factor enters the consumer’s decision-making process. Strong biosecurity and surveillance measures by the Australian Government (with support from industry) help limit Australia’s exposure to unwanted disease, and therefore enhance our market access capabilities. Regaining market access after it is lost is a very costly exercise, both from a time and economic perspective.

‘The International Trade Commission said trade restrictions put in place because of mad cow disease cost the U.S. beef industry between $1.5 billion and $2.7 billion in annual revenue between 2004 and 2007. Japan and Korea were responsible for $9.4 billion of the $11 billion estimated in total lost revenue… U.S. officials had hoped a decision last year by the World Organization for Animal Health, which gave the United States a "controlled risk" status for beef safety, would boost beef exports significantly, but it has been slow going (Doering C 2008)”.

Business to business

The cost of red meat production and processing in Australia is relatively high against a global standard, creating a significant barrier to trade. Processors/exporters are looking more and more towards a heightened value proposition and more niche opportunities to counteract the higher cost of production (Australian Meat Processing sector 2017) but these markets need to researched in terms of desired attributes (credence[****], quality or integrity) accessed, developed and maintained in an already competitive environment. While our traceability systems have been a key to competitive advantage in the past, it is becoming less and less due to systems improvements in other countries, so alternative value propositions need to be fostered. For example, the presence of bacterial counts on any scale are deemed, by customers of some exporting establishments, to be a risky business proposition despite them being at a safe Port of Entry level. The consequent feeling of unease may directly align with customer confidence in the product and the supplier of it, and hence the strength/resilience of the relationship. Inherently this can affect the diversity of the customer's supplier base (to allay risk of issues with supply) and longer term market access for companies should an unforeseen problem occur that has the potential to significantly damage business associations. A resilient relationship is more likely to overcome any infringements to customer confidence in a product or brand.

Supply Limitations and Climatic Pressures – effects on the value chain

Over recent years, a major barrier to market access has been the limitation to supply due to drought and the consequent cost of production. In addition the industry remains constrained by several fundamental aspects stemming from inconsistent supply and quality. There is a need to develop supply chains, which better satisfy the needs of an identified market (consistently), and thus add value to the industry.

The rangeland goat supply is considered highly volatile when compared to the cyclical nature typical of sheep and cattle production (MLA 2015). It is largely influenced by water availability (or lack of) and harvesting logistics, both of which are heavily dependent upon weather. Dry conditions see an increase in goat slaughter, while more favourable conditions can cause a subsequent reduction in the number of goats processed. To ensure the continued development of a viable rangeland goat industry, producers have moved from opportunistic harvesting operations to increasingly managed production systems. Preference is shown for tall, wide framed, short haired goats and sire introduction and breeding and culling measures (Goat Industry Council of Australia 2017), for attributes and performance, have been employed to bolster the meeting of market specifications and business efficiency. .Improvements in the management of rangeland goats have led to increased returns for producers through increased supply and improvements in quality, carcase weights and product consistency. It has been suggested that the increase in management is creating more risk with respect to non-compliances of maximum residue limits.

For the beef and sheep meat sectors, there has been the need for stock to travel larger distances to slaughter which may affect animal stress levels and consequent shedding (and thus food safety) as well as general stock (meat quality) condition. It is envisaged that more extreme climatic events will occur with climate change (AMPC 2016) and this may contribute to longer transit times as a) alternative routes are needed to avoid floodwaters/ seek more stable road surfaces or b) as in the drought scenario, stock need to be sourced from further away to keep processing facilities operating and markets supplied. Changing climatic conditions, such as increased temperatures, can affect animal production in terms of health status and condition and consequent susceptibility to disease. The productive capacity of agricultural resource base already suffers ongoing challenges due to land degradation (e.g. salinity, acidity, erosion) or water availability and/or quality but overall industry

[****] Food attributes that cannot be readily observed by consumers but that may add value to the product.

efficiencies will be further exacerbated with movement of herds to more temperate locations and away from existing supply chain infrastructure.

Drought and flood conditions can also mean higher feed costs, and these elements combined with lower stock scoring at the processing facility contribute to decreased farm-gate returns. Rebuilding herds takes time, and with market forces driving costs of 'restockers' up, it can also be a costly exercise for buyers at whatever the level of genetic proficiency being sought. Thus the exercise can be self-limiting or can drive up the costs of production leaving less collateral for farm improvements, or lead to cost-cutting which could ultimately affect the health status of stock entering the supply chain if feed, biosecurity or vaccine status or transport quality measures are compromised.

In conjunction, there is competition from the live animal export trade in all three species. Not being able to fulfil a market request by volume or specification due to decreased stock levels opens up access for the competition to secure the contract. Regaining that market is generally a lot harder than losing it in the first place, requiring liaison and negotiation and potential price cuts.

Economic pressures, higher costs of production and decreased animal health status can all be on the continuum toward consequent food safety implications. The ability of the supply chain to innovate and mitigate potential challenges to efficiency of supply will enhance market access and help to address 'social licence to operate' concerns with infirm stock.

Animal health and food safety

While animal welfare features as a consumer trend or expectation, the link between animal welfare and food safety is recognised and continues to be investigated to increase knowledge around the determinants of the elements and strength of that connection, and the consequent impacts of varying levels of physiological stress. Research shows, as has communication with processing industry personnel, that ensuring suppliers meet appropriate company standards is an ongoing concern for the industry with consideration of measures to ensure compliance still being considered.

Issues affecting animal stress level and therefore bacterial load:

- Heat
- Transporter handling
- Feed and water curfews
- Long haul transport and consequent discomfort
- Separation from their 'friends' in the herd
- Lairage practices, such wash downs, especially in cool temperatures

To help decrease pathogen loads herd health needs to be a primary consideration for producers. Immunological robustness results from a balanced feed regimen (with nutritional and feed type requirements being met to maintain animal health); low-stress stock handling; appropriate management practices when introducing new stock; and exercising grazing management practices to minimise cross-infection. The final step, within the jurisdiction of the farming community, is selecting quality transporters and understanding and adhering to, feed and water curfews prior to transit.

Non-compliances and Maximum Residue Limit violations

Non-compliances can have a severe impact on market access, ranging from trade suspensions to impingements on customer trust. Irrespective of the low numbers of Australian non-compliances (with respect to MRLs) or the possible source of contamination (e.g. not adhering to withholding periods, age of stock, soil or feed) levels of detection above that considered safe for human consumption could therefore lead to serious repercussions for trade and the reputation of red meat. Land and stock management, functional record keeping, an appreciation of food safety and communication with processors are imperative to keep specific (violating) stock out of the food chain. For examples see Table 4 'Risk Ranking of prioritised trade severity issues' in the Methodology section of the Milestone Report.

Consumer trends: attitudes and behaviour

There is a growing awareness that consumer requirements must be at the forefront of efforts to ensure the sustainability of agrifood chains (Boyle and O'Driscoll 2011). Consumer demands must be considered to ensure continued access, both in market entry and trade growth. An AMPC report stated that one of the 8 key trends impacting the industry was 'increasing global standards of environmental protection, food safety and animal welfare' (AMPC 2016). Often government mandates are the result of increased constituent pressure. Consumer focus on food safety has manifested as a non-negotiable expectation and is supported by a regulatory network to help safeguard both domestic and international markets, along with focussed research instigated by industry bodies to increase knowledge of, assess, and manage if required any known potential risks. Other, less tangible, credence drivers relating to ethics and social responsibility (ESR) or perceived health attributes can impinge on consumer purchasing behaviour. Such consumer aspirations centre around the 'naturalness' of agrifood chains based around system inputs, animal welfare and human health (e.g. antibiotic-free, controlled use of antibiotics, preservative-free, organic, green, natural, fair treatment of animals, including bobby calves and vealers). While 'willingness to pay' motivations may not be always apparent in the purchase of branded product (purchase behaviour disparity is evident), these values are often reported in the literature as important to purchase decisions, as is the perceived quality of the product. Eating quality might not just be a culmination of physical taste attributes such as flavour and tenderness, but also how associated credence attributes resonate with the consumer's life values while partaking in the consumption event.

Social licence to operate

Along with animal welfare, reduced use of antibiotics, effects of intensive farming practices on stock and the environment, carbon neutrality and sustainable practices (in terms of resource use and emissions) through chain are all factors considered within an industry's social licence to operate. Keeping a watching brief on which elements are having the greatest impact on purchasing behaviour, and responding to them via research into innovation, targets, frameworks and marketing, is key to market access. In 2004, it was concluded that 'the multiple objectives of industry–farmer EMS partnerships, while involving consumer concerns about food production, will be limited by the fact that consumer purchasing behaviour does not reflect concern about sustainable food production. In contrast, food consumers appear much more concerned about food and health, food safety and animal welfare' (Cary et al. 2004). This sentiment has been mirrored in recent times with reporting from MLA that "in recent years, a range of factors have contributed to fluctuating consumer demand for lamb in Australia. Social factors have continued to grow in importance to the consumer – with environmental awareness, animal welfare concerns and food integrity among the most prevalent (MLA Market Information Report 2017 p17)". However, review of the prioritisation of these factors, and the consideration of new entries to the list, should be undertaken on a timely basis. Industry needs to be careful that the pressures of fulfilling societal needs for environmental footprint reductions does not compromise food safety (e.g. decreasing water use, using recycling water, or using less power for chilling or freezing processes).

Animal welfare/well-being and the consumer

The animal-welfare friendly driver resonates globally amongst various consumer segments. European business performance and consumer insights on purchase behaviour associated with animal welfare issues have been reported on by interest groups as well as the European Commission Parliament's

'Intergroup on the Welfare and Conservation of Animals' through a special Eurobarometer survey (European Commission Directorate-General for Health and Food Safety 2016). *"Increasingly, companies describe farm animal welfare in terms of the financial and reputational opportunities that can be delivered….and that these opportunities can be accessed at scale and can make a material difference to earnings across the value chain as well as future profitability". The Eurobarometer survey last year showed that four in five European consumers wanted to see improvements made in relation to farm animal welfare. More than half looked for animal welfare logos when shopping* (Food Navigator 2017). The same Eurobarometer report stated that around 90% of respondents said they were in favour of ensuring that countries importing meat to the EU adhered to the same welfare standards as those in Europe, again substantiating the degree of consumer interest in this area but also indicating it as the responsibility of the global marketplace.

Australian research indicates that animal welfare is also important to Australian consumers. *"The growth in ethical consumption is illustrated by an upward trend in the ethical food market. This market is defined as consisting of organic products, those trading under the Fairtrade mark, free-range eggs, farmers' market produce and Freedom Foods*[††††]*"*. The market for such produce has grown rapidly in both the USA (Williams et al. 2008). These trends are being followed in Australia *(*Bhaskaran *et al*. *2006).* The main implication of these findings for larger grocery retailers is that their store brands *"may be seen as more ethical in themselves if they offer products with an ESR pedigree, particularly those that are ethically farmed and related to animal welfare; thus encouraging ESR consumers to use them for their main shop"* (Williams et al. 2010).

The notion of using animal welfare as a point of marketing differentiation is already evident in the branding of various meat products, including red meat, as evidenced through reports of Australian companies specifically targeting this credence value. "*The OBE Organic supply chain is driving the development of a slaughter data facility called Feedback Loop, which aims to improve producer productivity and animal health and welfare performance…it sees animal wellbeing as one of the 'new frontiers' in commercial beef brand development"* (Condon J 2017). The new Rangelands beef brand (March 2017, a partnership between Western Australian processor Harvey Beef and the Kimberley and Pilbara Cattlemen's Association) also has a focus on animal welfare in response to consumer concerns around how their food is produced (Condon J 2017). Brand messaging on the new beef range of mince, sausages and burgers will reflect the commitment of cattle producers to strict animal welfare standards, as well as hormone and chemical-free status. In recognition of the importance of welfare, MLA is introducing a welfare module to its Livestock Product Assurance (LPA) scheme. This is further discussed in the 'Industry and Government suggested initiatives to enhance food safety and market access' section in the main body of the Progress Report.

Health drivers

The place of red meat in a healthy diet is subject to conjecture – from one perspective red meat benefits from the push for higher protein-based diets and the burgeoning protein snack market due to its nutritional density and taste, yet the association with colonic cancers and gastrointestinal inflammation pathways has a negative impact (is red meat actually safe to eat?). Marketers of red meat need to be aware of all perceptions to position the product (reaching the most advantageous compromise) to maintain or grow consumption within more sophisticated markets. Consumer perception on the safety of red meat is the key to market access.

Preservative and salt use

Consumers are also seeking less preservative use, predominantly from synthetic/artificial sources, but also from salt-derived sources (e.g. smallgoods) to reduce their overall salt intake, which again has

[††††] The United Kingdom's RSPCA's farm animal welfare assurance scheme.

been linked to health impacts. While manufacturers have been trialling high pressure processing, as an alternative preservation technique, other factors such as meat colour alteration, affect its overall effectiveness as a viable substitute.

The cooking 'from scratch' phenomenon as part of a healthier lifestyle e.g. home-made sausages or preservative-free sausages, can increase risk as the preservative 'safety net' is not present. In addition the home environment is subject to many interruptions which can place much pressure on the time/temperature continuum underpinning food safety. Consumer education in appropriate food handling is paramount in these situations.

Antibiotic-free and hormone-free production systems

Antibiotic-free and hormone-free are two other product attributes that are becoming more prominent in the market. Irrespective of their health impact (e.g. as endocrine disruptors), consumer perception determines their importance through shopping spend. Antibiotic-free is two-fold in its impact i.e. as an unwanted additive, but also its association with the global push against antimicrobial resistance (AMR). Sixty percent of surveyed Australian consumers claimed they want to avoid antibiotics/hormones as the number one ranked concern as cited in MLA's Beef Market Snapshot (2017) publication. Thermal degradation (during cooking) of antibiotics has been described by Tien, Khalil and Bayen (2016). The authors found that various studies confirmed that the thermal degradation of various classes of antibiotics followed a general ordered trend in terms of their heat stability. The thermal degradation of particular groups are temperature-dependent, and under certain temperatures, prolonged heating time helps to induce more degradation. Furthermore, they found that the food matrix composition and physico-chemistry, (e.g. pH, fat content), the cooking methods, and the presence of food additives were shown to be parameters possibly influencing antibiotic degradation. It was noted that thermal processing usually results in a decrease in the concentration of parent antibiotic residues in food, but degradation by-products have not yet been properly characterized. As some of these products are hazardous, the report suggests that further investigation is needed to determine their impact on food safety and human health. It was therefore difficult to definitively conclude whether or not antibiotic degradation during food processing is necessarily beneficial in terms of food safety.

Potential risks associated with red meat consumption

One of the most consistent epidemiological associations between diet and human disease risk is the impact of red meat consumption (beef, pork, and lamb, particularly in processed forms[‡‡‡‡]). While risk estimates vary, associations are reported with all-cause mortality, colorectal and other carcinomas, atherosclerotic cardiovascular disease, type II diabetes, and possibly other inflammatory processes. The carcinogenicity of consumption of red meat (beef, veal, pork, lamb, mutton, horse, and goat) and processed red meat has been emphasized in a recent World health Organisation- International Agency of Research for Cancer (WHO-IARC) summary (Bouvard *et al*. 2015). Mechanisms for disease promotion have included DNA damage due to N-nitroso compounds (NOCs); mutagens generation by high temperature grilling; high dietary intake of saturated fat and elevated salt intake (with processed meats in particular); pro-oxidant effects of heme and iron (the strongest carcinoma association being with colorectal cancer); production of Trimethylamine-N-oxide (TMAO) generation by gut microbiota and environmental pollutants (e.g. heavy metals) contaminating red meat have all been associated with red-meat consumption but none are specific to red meat.

New hypotheses have been postulated specific to red meat, including (1) infectious agents (viruses) in beef (*Bos taurus* in particular) and (2) metabolic incorporation on a non-human sialic acid *N*-

[‡‡‡‡] Refers to meat that has been transformed through salting, curing, fermentation, smoking or other processes to enhance flavour or improve preservation.

glycolylnueruaminic acid (Neu5Gc) into the tissues of red meat consumers and the subsequent interaction with inflammation-provoking antibodies against this xenoautoantigen (thereby causing xenosialitis). While experimental evidence is not yet available with respect to the viral agents, epidemiological observations have led researchers (zur Hausen and de Villiers in 2015) to hypothesize whether 'species-specific infectious agents could be potentially carcinogenic when transmitted to humans and act synergistically with compounds originated during processing or cooking of beef". With respect to the second hypothesis the authors demonstrated that "Neu5Gc incorporation and interaction with anti-Neu5GC antibodies contribute toward one of the hallmarks of cancer, tumour-promoting inflammation" (Alisson-Silva *et al*. 2016). A watching brief on any further investigation of both scenarios is warranted to prepare an industry response should it be required.

Chemicals, such as Persistent Chemical Contaminants, heavy metals, or toxins (such as mycotoxins) have been recorded within red meat tissue (offal and/or muscle). Levels have exceeded maximum residue limits (where limits exist) in various circumstances so these contaminants, having the potential to enter the red meat supply chain and impact health, warrant due consideration as per Table 3 in the Milestone Report.

The generation of chemicals as a result of the method of cooking has been noted by various authors. Alisson-Silva *et al*. (2016) specifically comment on red meat by citing that heterocyclic amines (HCAs) and polycyclic aromatic hydrocarbons (PAHs) known mutagens found in red meat which are generated by cooking meat at high temperatures and for long durations. PAHs can also be generated at various concentrations by a variety of cooking methods, including baking and grilling as well as during smoking of processed foods. FSANZ's The 24th Australian Total Diet Survey (Phase 1, April 2014 and Phase 2, January 2016) reported two anomalies, based around acrylamide (fried lean beef mince) and printing ink found on beef sausages and lamb chops (discussed in the processing section). Acrylamide was found at higher than expected levels seemingly a result of the cooking process ('lean dry fry until thoroughly browned, do not scrape pan) at that particular time as there had been no reports of concerns emanating from other diet surveys internationally. Fried lean beef mince had the two highest acrylamide concentrations at 950 and 840 µg/kg (these levels are considered high) respectively from individual analyses with a mean concentration of 239 µg/kg. (FSANZ 2016). For 9-month-old infants the food group 'meats, poultry, offal and eggs' was the second highest contributor (22%) to estimated acrylamide dietary exposure, where mince was the main food contributing (16%) to exposure. As the infant diet had a higher consumption amount for mince compared to these other foods, it made a higher contribution to acrylamide dietary exposure for this age group. ~~T~~he food group "meats, poultry, offal and eggs" was a consistently high contributor to estimated dietary exposure across all age groups. According to FSANZ (in the report), this is the first time that such a level of acrylamide had been reported in meat. "*The JECFA (2011a) safety assessment reported a mean acrylamide concentration of 42 µg/kg in meats and offal. The USFDA (2009b) survey did not detect any acrylamide in fried beef mince. Therefore it was considered that the result warranted further investigation to check if it is reproducible, and to determine the exact conditions under which beef and other meats could form such high levels of acrylamide in the absence of an obvious carbonyl source. Therefore, the level of acrylamide obtained under such conditions could be an analytical artefact and not a true reflection of exposure via food"*. FSANZ noted that the formation of acrylamide is unpredictable. The same food type may show high levels of acrylamide in one analysis and no detectable levels in the next.

Direct red meat replacement with more 'credence-fulfilling' alternatives (such as lab-grown meat or texture-identical vegetable-based products) or the removal of red meat from the diet (or a stance on the continuum in between) is a real challenge to red meat access. Campaigns such as "Meat-free Monday" have arisen as a result of groups advocating less consumption of red meat for human health, animal welfare, and environmental reasons. An increase in vegetarian diets has led to a rise in demand for meat alternatives. Fortunately, economically for industry, replicating the texture of meat, which is vital to consumer enjoyment, is not easily achieved. Current MLA Market Reports note that social trends, such as vegetarianism, will provide an increasingly difficult environment for red meat in Australia. Innovations, such as lab-grown meat, also presents future challenge as it satisfies various elements of the modern consumer's credence priorities. While the cost of production is currently prohibitive, economies of scale may circumvent this in the future.

Increased pathogen virulence and antimicrobial resistance

There is an ever growing push for less antibiotic use in production systems to maintain the efficacy of the existing suite of prophylactic measures. An estimated 25000 human deaths per annum occur in the EU as a direct result of infections caused by AMR (EFSA, 2016) or 700,000 deaths per year globally (European Commission Heath and Food Safety 2017). This pressure, while achieving an ultimate benefit for the human species, means the red meat industry needs to find viable alternatives to maintaining animal health. As mentioned previously declarations of resistant forms of *Salmonella* being legally classified as an adulterant have entered discussion in US parliament. Action groups, such as the Centre for Public Health and in the US have requested that certain strains of antibiotic-resistant *Salmonella* to be adulterants. Currently the FSIS (2017) does not consider *Salmonella* an adulterant in raw meat products. Therefore, a positive test result for *Salmonella* in imported raw beef product, sampled by FSIS IPP, does not require a regulatory control action to be taken.

Resistant pathogens entering the food chain are an ongoing global concern and various developed countries are taking an active stance in combatting this issue through education and (banning). EFSA's campaign for reducing antibiotic use is founded on these principles:

- "Set targets for reducing the use of critically important antimicrobials that are vital for the treatment of serious human diseases.
- Veterinarians should be accountable for their prescribing decisions. Antimicrobials should not be used to prevent diseases in healthy animals. The preventive use of antimicrobials should be phased out
- Consider alternatives to antimicrobials that have been shown to improve animal health and that could reduce the need for antimicrobials. These include probiotics, prebiotics, bacteriophages and organic acids.
- A clear EU legal framework is needed to boost the development and possible authorisation of products that can be used as alternatives to antimicrobials. This includes better farming practices to prevent the introduction of diseases to farms, improving the health and welfare of animals, and protecting them from diseases through vaccines or genetic selection.
- Farming systems where antimicrobials are often used should be evaluated. Alternative systems leading to a reduced use of antimicrobials should be explored.
- Education and awareness of AMR should be addressed to all levels of society but in particular to veterinarians and farmers."

In addition companies, including red meat manufacturers, are taking a stance on antibiotic use and using it as a marketing advantage (such as Smithfield Meats and Tyson Foods in the US, with Australian meat suppliers emulating this trend). The push to move away from non-therapeutic use of antimicrobials will have a significant impact on the feedlot sector and suppliers of such products. This may result in a change to claims associated with merchandise e.g. they are not being used to increase growth/feed conversion but to treat acidosis.

Convenience

Convenience for the consumer (ways to: cook product, attain product, and to package or bundle product) is a driver of many product innovations. However the time-poor consumer may display riskier 'short-cut' behaviours and be more willing to chance food safety for the sake of less effort. Responding to the time-poor consumer has resulted in availability pre-packaged processed goods ready or close to ready for consumption (ready to eat, or heat and serve), as well as items that have been pre-tenderised (mechanically) or pre-marinated. With the increased number of inputs (and critical control points) associated with tertiary processing the risk to food safety inherently increases.

Cost

According to results from the MLA Global Consumer Tracker 2016, in the US, lamb is associated with good animal welfare, becoming a more popular protein and a superior meat that consumers are willing to pay more for. However, lamb scored negatively for versatility, ease and convenience of preparation and cost (MLA Sheepmeat Market Information Report 2017). MLA's Beef *Market Snapshot* (2017) reported that in June 2016, the main reason for eating less red meat in the Australian market was the cost, followed by health concerns, then concern about the treatment of animals, not liking the taste anymore, environmental concerns, then other (not disclosed). Cost factors (in comparison to other protein sources) are an ongoing market access challenge domestically and internationally. While perceptions around the relative cost (to nutritional value) of meat might be misguided the issue also creates a challenge to increasing market share/access. Value of the Australian dollar is the primary determinant for our trading terms.

Cool chain and chain of custody failures

New methods of food delivery being trialled may pose a food safety risk whereby the reliance on technology, or persons not fully appreciative of the risk cool chain breakdowns carry, may prove detrimental. In association with product delivery to premises or homes, the chain of custody (or who bears ownership or responsibility for the product) can become nebulous. This is particularly evident with home-delivery (e.g. products being left in warm conditions, favourable to bacterial growth). MLA trend analysis documents note that "the growth of E-Commerce shopping elsewhere, especially in China, a trend to keep a close eye on in the Australian foodservice sector in 2017 is the tech-driven food delivery avenues, such as Deliveroo and UberEats" (p17). In Australia, and other parts of the world, robotic delivery, is also being tested. Regulation may sometimes be lagging behind the advent of innovation, thus exposing the food industry to risk. In other situations, simple education in correct product handling procedures, might be of foremost importance to allay risk. This sentiment is also important to other transport and retail environments. The (farmer) market environment may pose a risk whereby vendor storage conditions and monitoring may be sub-optimal. Inappropriate placement of temperature monitoring probes in eskies, display cabinets and transport vehicles (thereby generating misleading information) tends to be an ongoing issue e.g. time temperature recorders only in one place in the vehicle rather than having probes distributed within load or probes being placed next to ice packs not central to the product being kept cool.

Innovations in processing

Manufacturing Processes

While automation and machination can be used to increase efficiency (DEXA), convenience (mobile abattoirs) and enhance food quality (e.g. the use of blade or needle tenderisers) pathogen colonisation may also increase if good hygiene practices are not followed and biofilms, that form a protective matrix, are allowed to form. It is hoped that future technologies will aid in managing foodborne illness. Such technologies include biotracing, 'omic technologies and other methods of monitoring pathogen behaviour (including gene expression) *in situ* on food surfaces and on implements and preparation surfaces (with respect to contact area and topography).

Packaging techniques

To be truly viable the development of multi-functional packaging (e.g. packaging with biodegradable, active and intelligent functions) or other innovations such as edible coatings/films or nanomaterial packaging, need to maintain or extend key product characteristics yet still meet retailer and consumer's packaging expectations in terms of sustainability and as a communiqué (AMPC 2015). . These characteristics may include quality (comprising various attributes such as colour, texture, etc.), food safety and shelf-life (through management of micro-environmental conditions/atmosphere and provision of an effective barriers to physical, chemical or biological contamination and be leak-proof) Chemical migration from packaging is still under review for various technologies. During the research conducted for FSANZ's 24th Australian Total Diet Survey (Phase 1, April 2014 and Phase 2, January 2016) two types of printing inks, arising from migration from packaging, were detected in red meat products (beef sausages and lamb chops). These were ethyl 4-(dimethylamino)benzoate (EDAB) in beef sausages and lamb loin chops; and 2-hydroxy-2-methylpropiophenone (HMPP) in beef sausages. While it was concluded, in an Australian context, that the 'public health and safety risk associated with EDAB is likely to be low' and for HMPP it was indicated that there was 'a negligible public health and safety risk'. As an export-oriented economy who are looking more toward value-adding in the current competitive environment, processors need to be mindful of the import regulations within the destination country for chemical loading and ensure the packaging chosen keeps consumers safe while trying to satisfy all the desired pre-requisites.

Maintenance of quality associations with brand Australia

The risk to Australian product integrity with respect to re-branding of non-Australian product as Australian, the potential for contamination during the cutting / packing process of primals overseas or the slaughter of live animals in overseas destinations is a market concern, especially for reputation. One of the comments that came back from the MLA Middle East North Africa market is 'frozen primals partially defrosted and cut into portions then re-freezing for re-export' which indicates this practice exists. Extending traceability measures beyond Australian borders is an important consideration for the red meat industry.

Recurring issues that pose a risk

There are several issues that have historically posed a risk to red meat food safety and quality and therefore market access. These are:

- human resource management, whereby staff strikes impact on throughput and food safety in chain elements leading to the processing plant (such as time in lairage) and beyond (e.g. distribution of product) and shelf-life can therefore be affected.
- General business pressure causing human error, such as the requirement for increased throughput leading to increased chances of a food-safety incident occurring.
- Stock entering the chain within withholding periods or presenting with elevated chemical levels from recent exposure or a result of compounding effects from recurrent exposure.
- Pre-slaughter cattle cleanliness affected by season, stress, transport and distance to market.
- Consumer behaviour in terms of care in food preparation and storage. Research suggests that 30% of foodborne illness is caused by cross-contamination in the home (Jakobsen and Verran 2011). Other factors include not cooling cooked foods appropriately or not defrosting appropriately. Consumer expectations can be that presented product has no potential for contamination (sterile).

Food safety risk associated with emerging food industry trends

Review of literature, and discussion with industry personnel, led to the compilation of the following products being noted as of potential future concern, as a result of changing food habits and cuisine as well as processing technologies. Not all products are supported by foodborne outbreak data or noted as violations in the National Residue Survey. However, it is felt a level of risk inherently resides with most products from the perspective of the expert consultation participants (as indicated by the resulting risk categories in Table 7 and in **Appendices D)**, feedback from the international market team within MLA, and confirmed by the existence of research reports examining such topics.

MLA's market research documents summarise particular traditional food preparation or culinary trends specific to the markets of greatest focus. To compliment this information MLA's international trade development team supplied information in the following table after being asked to identify more risky products in their areas of jurisdiction.

Table A10. Regional use of red meat in MLA's countries of focus

Product name / category	Species / parts	Description of production and product	Country – regions or specific community	How often consumed?	Are there any known / suspected problems?
Mettwurst – other fermented products	*Beef /lamb*	*Fermented pork; sometimes with beef lamb and not heat treated. Spread on bread.*	*Australia – particularly South Australia*	*Common*	*E. coli outbreak in 1995*
Doner kebab	*Lamb / Beef*	*Layers of meat with seasoning formed into a cylinder on skewer, may be undercooked and handled before consumption.*	*Australia*	*Popular snack Found in many fast food service areas.*	*Salmonella and E. coli illness*
Intestinal casings	*Lamb – green runners*	*Intestines are stuffed with various vegetables and spices and cooked*	*Australia – Greek community*	*Infrequently (Easter)*	*Regulator concerned about risks.*
Steak tartare	*Beef*	*Meat dish made from finely chopped or minced raw beef.*	*EU/Russia*	*Common dish in the restaurant's menu but not frequently consumed*	*Possible contamination by bacteria and parasites such as Toxoplasma gondii and Taenia saginata.*
Carpaccio	*Beef*	*Dish made with thinly sliced raw meat.*	*EU/Russia*	*Common*	
Bleu/rare steaks	*Beef*	*Cooked very quickly; the outside is seared, but the inside is usually cool and barely cooked.*	*EU/Russia*	*Infrequently*	
Deli meats	*Beef /lamb*	*Highly processed meat*	*EU/Russia*	*Popular*	*Products are higher in fat, nitrates, and sodium. As a result, processed meats significantly contribute to incidence of heart disease and diabetes.*
Burgers, sausages, bratwurst, doner kebabs (alternative word shawarma used in Russia), pelmeni (dumplings),	*Beef /lamb*		*EU/Russia*	*Popular*	*Minced/chopped meat can be health-risky if treated in a way that bacteria on the surface may*

different kind of meat pies					*be moved towards the centre.*
Raw sausages (salami)	*Beef*	*Dried, smoked, cured*	*EU/Russia*	*Popular*	
Blood sausages or black pudding	*Beef*	*In EU it is generally made from pork fat or beef suet, pork blood and a relatively high proportion of oatmeal, in some recipes mixed with oat groats and sometimes even barley groats.* *In Russia the main ingredient is beef/veal/pork blood and pork fat/skin/other offal.*	*EU/Russia*	*Infrequently*	
Liver Sausages	*Beef*	*It is produced from beef/veal/pork/chicken liver and some other offal like heart, kidney, lungs etc.*	*EU/Russia*	*Popular mainly because it's cheap*	
Basturma	*Beef*	*Cured beef tenderloin*	*Russia*	*Infrequently*	
Pastroma	*Beef*	*Smoked pickled meat*	*Russia*	*Infrequently*	
Raw offal	*Pork*		*Japan*	*Infrequently*	
Raw liver	*Beef*	*It was not heated beef at some foodservice area especially Korean BBQ restaurant as 'Liver Sashimi'.*	*Japan*	*Foodservice area*	*E.coli and Salmonella*
Raw meat	*Pork and beef*	*It was not heated beef at some foodservice area especially Korean BBQ restaurant as 'Ukke'.*	*Japan*	*Pork infrequently Beef at some foodservice area*	*Beef (Ukke) had E.coli outbreak in Apr 2011, banned to eat from Jul 2011 under the law.*
Kofta and kebab	*Lamb*		*MENA*	*Often*	
Portion cuts	*Beef*	*Frozen primals partially defrosted and cut into portions then refreezing for re-export*	*MENA*	*Becoming more popular with trade importers*	
Dry Ageing	*Beef*		*UAE*	*Becoming popular with a few high end restaurants*	
Raw Kibbeh	*Beef or Lamb*	*Minced meat mixed with herbs and oil and eaten raw*	*MENA*	*Often – popular local dish*	
Carpaccio	*Beef*	*Thin sliced raw beef.*	*UAE*	*High end restaurants*	
Shawarma	*Beef and Lamb*	*Similar to doner kebab but not made from reformed meat, but from thin sliced layering of pieces, usually lamb or veal mixed with lamb tail fat.*	*MENA*	*Everyday*	
Processed cooked product	*Beef*	*Injected, tumbled and cooked roast beef for the QSR and retail market.*	*MENA*	*Everyday*	
Sous vide	*Beef*	*Increasing practice in the restaurant and food*	*UAE*	*Everyday*	

		service/function catering market.			
Smallgoods	*Beef*	*Raw and cured bresaola and salamis now being manufactured in the market.*	*MENA*	*Everyday*	
Beef Jerky/Biltong	*Beef*	*Raw product dry cured.*	*MENA*	*Everyday*	
Hot bars	*Beef/lamb*	*Cooked meat kept in bain-marie.*	*USA All over*	*Frequently*	*Temperature too low*
Burgers	*Mainly beef, but some lamb*	*Waiters frequently ask how well done the guest would like it,*	*USA All over*	*Frequently*	*E coli in particular the STECs*
Sous vide	*Beef/lamb*	*Low temperature cooking in water.*	*USA Food Service*	*Frequently*	*Temperature too low and/or no further cooking.*
Needling/tenderising	*Beef*	*Common practice to tenderise steaks.*	*USA All over*	*Frequently*	*Has to be approved but possibly could lead to issues.*
Heat and eat	*Beef*	*RTE or left overs where product is "re-cooked".*	*USA All over*	*Frequently*	*No major issues but handling instructions must be on RTE.*
Aged	*Beef*	*Dry or less commonly wet aging of beef at 1 to 4 degrees C.*	*USA Restaurants especially*	*Becoming more common*	*No as product is often further prepared or cooked.*
Various beef products	*Beef*	*Various from Adams Farm Slaughterhouse.*	*USA Retail and Restaurants*		*June to Sep 2016 outbreak of E coli O157 H7*
Satay	*Lamb / Beef*	*Small marinated Meat cubes on stick skewers – (Sticks often washed / sticks reused with contaminated water in outdoor markets) Meat is often undercooked in periods of high turnover.*	*Malaysia /* Singapore	*Frequent street food / also popular on Malaysian airlines.*	*E.coli and Salmonella illness (Gastroenteritis) Groups like AVA* Singapore *continue to monitor strict CCP (less so in Malaysia).*
Gourmet Beef Hamburgers	*Beef / Pork*	*Undercooked hamburgers for in hotel in house dining (Hotel room service / Gourmet Food service chains). Meat is rare or underdone. (Gourmet Patties (including Wagyu) are delivered fresh but often stored and used beyond expiry dates.*	*Indonesia Philippines Malaysia*	*Frequent in house cuisine for travellers.*	*E.coli and Salmonella illness often associated with local water (wash) contaminate and meat used beyond recommended expiry dates. (Reluctance to throw away due to value of meat).*
Fresh Carcass / cut	*Beef / Lamb / Pork / Chicken / Fish*	*Heavy reliance on the traditional markets – fresh kill and daily delivery / meat temperature / shelf life / hand to hand handling of product / surface wash down with locally contaminated water.*	*ASEAN*	*Daily shoppers*	*All levels of contaminates however cooking methods of 4-5 hours into soups / curries eliminate the microbial growth. Often at point of*

		This includes the utensil / plate / deliver wash down at point of consumption.			*consumption (post purchase and cook) that creates the dangers of microbial spread.*
Curries	*Beef / Lamb / Goat*	*Duration of cooking eliminates a look of foodborne pathogens.*	*ASEAN / Subcontinent*	*Daily*	*More the service facilities or outlet utensils (not meat).*

Source: Dr I. Jenson (MLA 2017)

Products/processes of concern, as a result of changing food preparation or cuisine habits, and processing technologies:

- Offals:
  - green runners (the intestinal runners left after stripping of ingesta – used for casings)
  - Kidney
  - Heart
  - Liver
- Needle/blade tenderised products – biofilms
- Jerky (also known as non-fermented dried meat protein snacks)
- Ready-to-heat meat products (e.g. sous vide, meal kits)

Restaurant or Consumer cuisine / preparation trends:

- dry-aging (restaurant or home)
- Fermentation of meat products (in the restaurant or at home)
- Consumption of home-made sausages
- Consumption of raw Australian product (overseas) e.g. carpaccio/steak tartare/filet américain/kibbeh
- Consumption of raw product (domestic) e.g. carpaccio/steak tartare
- Reduced cooking times to achieve rare product
- Preparation of bone broth (time and temperature control for safety)
- Cross-contamination in food preparation (e.g. consumers not exercising care)
- The presence of antimicrobial-resistant organisms
- Antibiotic-free production systems
- Reduced use of preservatives (synthetic or other) e.g. lowering salt content of processed goods
- Residue violations in red meat products (chemical)
- Residue violations in red meat products (antibiotic)
- Preparation and cooking practices in mobile food service/retail situations e.g. farmers markets (including slaughter methods and delivery methods to buyers), festivals, fairs, food trucks/pop-up restaurants and similar (time/temperature storage, display, cooking)
- Home delivery practices of meat or meat containing products – retail or food service (time and temperature control for safety)
- Exported meat being used beyond recommended expiry dates / washed in local (contaminated) water.

Industry and Government suggested initiatives to enhance food safety and market access

The following points have been compiled from discussions with industry and government:

Improving transparency, traceability and integration along the supply chain

- Enhancing the value to the NLIS by using its capability to help keep Australia's red meat industry ahead of the competition:
    - by including HGP status (to reduce risk of an adverse event)
    - As a supply chain integration tool along the supply chain by producers updating their stock status or to flag an exposure (to reduce risk of an adverse event) as needed and processors providing feedback on carcass attributes.
    - Consideration of scanning stock as they exit the farm for traceability and transparency (of stock movements) purposes and to reduce the risk of an adverse event.
    - Improved integration of NLIS into livestock management, including for disease and residues (linking of state databases on livestock disease status of PICs to NLIS with access for state and federal regulators).
- Getting farmers/producers to better identify themselves as a food (safety) business, and the repercussions to them and the businesses they supply if something goes wrong. Ultimately their market is the consumer also, both in terms of human health and the eating experience.

Regulation and systems auditing

- Systems implemented are made as user friendly/easy to use as possible to avoid disincentives for compliance (especially NLIS).
- Nationally consistent rules and regulations on off-label use and veterinary prescribing rights.
- Nationally consistent livestock feed standards and legislation.
- A strengthened LPA program would be beneficial, especially with respect to record keeping of chemical use {i.e. the ability to verify that withholding periods (WHPs) and export slaughter intervals (ESIs) have been observed if selling for slaughter, or information on chemical or prophylactic use is transferred with animals so buyers can ensure that WHPs and ESIs have been complied with}.
- LPA audits could be made more random (less forewarning) or increased in frequency, as a means to reduce risk.
- Regulatory bodies to persist with follow up of 'repeat offenders' who are still to sell into the market but carry high inherent risk.

Meeting consumer expectations

Enhancing the LPA system by adding in a welfare module was a change desired by the processing sector. However, the value of such a system is ultimately decided by customers/clients in terms of whether it meets their consumer's expectations and from a producer/transporter/processor/auditing point of view, whether meeting those expectations is economically sound and achievable. It is hoped that the design of the system has incorporated all sectors of the supply/value chain in collaboration to create a baseline set of standards, so all parties have the opportunity to 'own' the measures, and that the requirements are truly representative of more general consumer sentiment (as opposed to activists). Specific areas of focus are:

- Chain member's ability to assess suitability, and preparation, of stock for transport to a saleyard or abattoir.
- Chain member skill in transporter selection (ability to discern positive transporter attributes).
- Truck condition etc. which has a big impact on the welfare process.
- Ensuring the land transport guidelines are seamless from prior to when stock board the truck to when they are offloading. It is imperative that MLA's fit to load information should be integrated into the LPA requirements.

- Information held by government parties on the types of issues abattoirs are identifying in delivered livestock be considered and worked into any module supporting documentation.
- Integrating the Sustainability framework in a similar way.
- Fast-tracking of research into alternative measures (and the economics of them) considered more humane, to meet consumer expectations (e.g. alternative practices to castration, hot branding and de-horning).

Trade agreements

- To decrease the risk of third party Halal certifiers (of Australian premises) not meeting importing country regulations, due consideration be given to the Federal government employing a Muslim certifier as a tool to instil confidence in importing nations as well as ascribe more accountability in trade suspension events.
- Stronger negotiation skills needed at a Federal level to ensure action is on behalf of the exporters rather than the importing nation, to help with efficiencies of supply.
- Where breakthroughs are made in shelf-life negotiations, the ability of smaller exporters supplying to those new specifications should be analysed, as a risk-management tool.

Ahead of the game

- Understanding what qualifying document might be required to take advantage of new trading terms and having systems (and collaborations) already in place e.g. establishment of shelf-life trials or residue trials.

Maintaining or gaining access to markets

- Skin-on goats to the EU – revisiting/renegotiating trading (including quota) terms to allow skin-on access.
- More accredited plant access to China to allow goat meat export.

Ensuring education program of US inspectors, with respect to skin pigmentation issues (vs being a microbiological issue) in the US, is continuing in a positive direction.

7.6 Appendix F. 6D listeriocidal process

Table A11. Holding times at product core temperatures required to deliver 6 log reductions in *Listeria monocytogenes* counts.

Temperature (°C)	Time (min)
55	200
56	146
57	108
58	79
59	58
60	44
61	33
62	24
63	18
64	13
65	10
66	7
67	6
68	4
69	3
70-72	2
73-76	1
76 or warmer	<1

Source: MLA (2015) Guidelines for the safe Manufacture of smallgoods- 2nd edition
Notes: A 6D process is a process which reduces the bacterial count from 1000,000 to <1.

7.7 Appendix G. Comparison between quantitative and semi-quantitative methods for risk ranking food safety hazards

Table A12. Comparison between quantitative and semi-quantitative methods for risk ranking food safety hazards

Method	Institutional Use	User Interface System / Outputs	Data Inputs	Advantages	Disadvantages/Omissions
FDA-iRISK® 4.0 *(Quantitative)*	- Risk ranking is based on factors that affect the food safety risk to a specific population, arising from a specific food product and specific hazard, during the steps from primary production to consumption. - Probabilistic uncertainty and variability. - (BCoDE + FDA-iRISK®): FDA-iRISK® was identified as a priority tool in a risk-ranking toolbag developed by EFSA's BIOHAZ Panel. Originally launched in 2012, the next iterative update (4.0) is now live (as of July 2017). Resulting from the review it was suggested the outputs of iRisk® be used in conjunction with the European Centre for Disease Prevention and Control's 'Burden of Communicable Diseases in Europe' (BCoDE) - a refined DALY calculator based on epidemiological data. The BCoDE program uses a different approach to estimate DALYs compared to FDA-iRisk®. The updated version of FDA-iRISK®, with the inclusion of QALYs, may remove the need for the	- Web-based free software. - Sensitivity Analysis is available directly from the 'Edit Risk Scenario' page, to answer "what-if" questions; and can be performed on acute and chronic risk scenarios. - The program has the ability to combine scenarios from different repositories in a single risk ranking. It can assess risks and interventions for a) one hazard in different foods b) multiple hazards in a single food, c) multiple food-hazard combinations and d) acute exposure to a hazard (microbial and chemical) and chronic exposure to a chemical hazard. - Results can be expressed in a variety of ways • Mean risk of illness (e.g. average probability of illness from one eating occasion) and predicted	7 input elements: **<u>Element 1: Foods</u>**. The definition of food and its description will affect the process model. **<u>Element 2: Hazards</u>**. The type of hazard will affect process model options and dose–response options provided within FDA-iRISK for the hazard. **<u>Element 3: Population Groups</u>**. The choice of the population group is associated with the choice of dose–response model (e.g. two dose–response models for L. monocytogenes, one for high-risk population and another for low-risk population), specific patterns of health effects (e.g. pregnant women re abortion) and the consumption patterns (e.g. specific diet per age group). **<u>Element 4: Process Models.</u>** The process model describes the impact of the different process stages (primary production, food processing, food handling, etc.) on the concentration and prevalence of the hazard in the considered food. -The modelling tool has options for the process pathway (e.g. sampling process type, parallel process model definition) -Maximum Population Density (MPD) is included for microbial models. -Variability distributions include: Beta, Beta General, Normal (Truncated), and Triangular (Truncated) The process model is designed as a series of process stages, events or steps along the farm-to-fork continuum. At each process stage, the user provides the expected impact of the considered	- takes into account the main factors affecting the risk and follows the risk assessment paradigm respecting the laws of probability and calculus. - Can be used by persons who might not have extensive mathematical modelling experience. - Probabilistic uncertainty and variability (by implementing a 2D Monte Carlo calculation structure) can be included by the user. - Can separate and quantify variability versus uncertainty. - FDA-iRISK can work with parametric distributions (beta-PERT, normal, triangular and uniform) and non-parametric distribution: cumulative empirical distribution. - FDA-iRISK accepts direct input of log-reduction fixed values or distributions. - Predictive models (for microbial growth and inactivation) can be accessed.	- Reliance on Quantitative Data (limits to food type inputs – only those where dose-response relationship data distributions exist) - Uses only fixed values of prevalence. - Gamma distribution is not implemented in FDA-iRISK so manipulation of data may be required prior to entry into the simulation. - Eating occasions per year are fixed values.

Method	Institutional Use	User Interface System / Outputs	Data Inputs	Advantages	Disadvantages/Omissions
	BCoDE tool to be used in combination with the tool. - BCoDE has been described in the BIOHAZ report as a "detailed and user-friendly DALY calculator, but used in combination with FDA-iRISK gave a more effective calculation of DALYs". i.e. The number of illnesses for a specific food or food category estimated with FDA-iRisk was the input. "When many pathogen/food combinations are to be ranked, the application of a combined bottom-up and top-down risk ranking approach using the risk ranking tools FDA-iRISK and BCoDE, respectively, is more appropriate. The combined approach includes an initial priority ranking using the BCoDE tool, which limits the number of pathogens based on available epidemiological data. In a next step, the number of food–pathogen combinations is further decreased based on data and information of their risk profiles. In the last step, a quantitative bottom-up approach is applied for the remaining food–pathogen combinations using the FDA-iRISK tool".	total number of illnesses per year for a food-contaminant combination, for various populations. • as other public-health metrics, such as Disability-Adjusted Life Years (DALYs) and Cost of Illness (COI), and with Quality-Adjusted Life Year (QALY) loss (new to v4.0). • 'exposure only' modelling that takes into account contamination in food and consumption patterns. Allows users to calculate the amount of consumers' exposure to a particular contaminant without needing to estimate the number of illnesses or when there is a lack of data for the dose-response model. - Reports include weighted scenarios when generating risk estimates; and scenario ranking reports and	stage on the prevalence and concentration of the hazards and on the unit size of the food. The effect, such as increase/decrease of the prevalence, increase/ decrease of the hazard concentration in food, can be expressed as a *fixed value* or as a *probability distribution*. Data required for the output of the process model as a probability distribution of the concentration of the hazard in a food serving and the prevalence of contaminated servings are: • the initial prevalence • distribution of the hazard concentration • the unit mass • data related to process stages from farm to table of the food supply chain up to the point of consumption (the number of stages depends on the food definition, hazard characteristics and the scope of the risk assessment). e.g. the initial prevalence and concentration could be at retail level or at the primary production level. The template proposes nine process types: (1) increase by growth; (2) increase by addition (as cross-contamination from the processing environment) including rare event additions; (3) decrease; (4) pooling; (5) partitioning; (6) evaporation or dilution; (7) partial redistribution that models partial cross-contamination among food units. The total hazard(s) load remains constant; (8) total redistribution: the total hazard(s) load is redistributed to all food units; (9) no change. **Element 5: Consumption Models**. The consumption models are defined in relation to the specific population groups. For microbial hazards, the required inputs are the serving size (fixed value or distribution) per each food eating occasion and the number of eating occasions per year. For chemicals, the distribution of the average amount of the food eaten daily over a period of time or a	-Chemical analysis can be performed, as can analysis for naturally-occurring toxins. - The user can create a multi-food scenario to capture chronic exposure of the consumer to a hazard found in multiple foods. - Users can compare risks from hazards among consumers with different dietary patterns. - Scenarios from different repositories can be combined in a single risk ranking. Users can import data (empirical distribution) from an external file, e.g. import dose-response and consumption models from a shared library. - A variety of outputs as per the User Interface / Outputs column (Column 2 of this table). - Variations can be simulated in a given step or steps in the food-production ("processing") model already built, without having to rebuild the entire model. - Prior to final reporting a filtering system using the description of the different scenarios can be used to enable the different possibilities of ranking (comparisons).	

Method	Institutional Use	User Interface System / Outputs	Data Inputs	Advantages	Disadvantages/Omissions
		annualized or full lifespan results for risk scenarios for chronic exposure. There are multiple options for ranking risk estimates.	lifetime and the number of consumers are required. -Chronic consumption can be defined in "g/kg-day". -Variability distributions include: Beta, Beta General, Lognormal, Normal (Truncated), and Triangular (Truncated) **Element 6: Dose–Response Models**. The dose–response models are defined in relation to the specific population groups and allow monotonically decreasing dose-response to allow evaluation of health benefits. *Microbial hazards include*: Threshold Linear and Weibull. *Acute chemical hazards* include: Cumulative Lognormal and Weibull *Chronic chemical hazards* include: Log-Logistic with Background, Probit, Restricted Weibull, and Restricted Log Probit **Element 7: Health Outcomes.**		
microHibro *(Quantitative)*	Developed as an easy-to-use tool to end-users, risk managers, food business operators and risk assessors by companies Hibro and Optimum Quality. Original focus on RTE products, then was expanded to include other food categories.	Web-based, publicly available (at the time of writing the site was not accessible), stochastic modelling tool. Risk modelling module can incorporate deterministic or quantitative values for initial concentration, growth, inactivation, recontamination and dose–response. Information about the variables can be included as either deterministic or stochastic data. It provides an estimation of the risk and the probability of disease. Inserting	Model based on pathogen prevalence and concentration data initially then probabilistic exposure assessment based on four key variables, i.e. growth, inactivation/survival, transfer/cross-contamination and dose–response, that can be defined by using either point-estimate or probability distributions of mass, temperature, pH, time, etc. The types of distributions include continuous (normal, exponential, uniform and triangular) discrete (binomial and Poisson) distributions. For continuous distributions, the concentration unit is log10 colony-forming units (CFU). Discrete distributions, because of their discrete nature, are defined by arithmetic units, i.e. CFU. Distributions are defined by giving values to the parameters of the selected distribution. e.g. in the case of normal distribution, the parameters to be defined are the standard deviation and mean. These are the input elements that can be selected:	- Considered a flexible tool. The flexibility of the tool allows the addition of further components. - It takes into account all the factors affecting the final risk following the risk assessment paradigm and respects the laws of probability and calculus. - Various probability distributions are available for describing input data (normal, gamma, uniform, exponential, triangular, Poisson). - Growth or inactivation of the pathogens can be estimated within the tool using the appropriate growth model.	- In its current form, the tool can estimate only the probability of illness and the number of illnesses. - Uses a log scale in the calculation so it actually provides the mean of the log probability of illness, which can be significantly different from the arithmetic mean of the probability of illness. - Limited number of iterations in Monte Carlo simulation performed with this tool. In the stochastic application, the number of iterations in the Monte Carlo simulation procedure has to be set in advance, without taking into account simulation

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		variables as point-estimate values or distributions, microHibro calculates outputs as frequency distribution of microbial growth and of probability of illness. The risk metric used is the "probability of illness". The application incorporates a module for growth predictions in different vegetable matrices and microorganisms as well as a module which allows the user to design and simulate exposure models to estimate the final concentration at the moment of consumption. It allows models selected by the user to be introduced into the application. Sensitivity analysis tools can be then applied to assess how variables and factors can impact the number of cases, i.e. public health.	**Element 1**: **Initial Concentration, Mass and Prevalence**. The initial concentration and prevalence can be implemented as distributions selected from a list or as fixed values, whereas mass can be included only as a fixed value. **Element 2: Growth**. The user can choose: (1) a selection of published models available, (2) to include additional models or (3) to introduce a distribution among the ones available in the tool or to include a fixed value. The mass can also be included. **Element 3: Microbial Transfer**. Information about cross-contamination can be implemented. In order to do so, either distributions (from a list of continuous and discrete ones) or fixed values of the percentage of transfer of microorganisms and microbial concentration can be selected. The mass and probability of occurrence can also be included as fixed values. **Element 4**: **Reduction in the Concentration of Microorganisms**. Factors meaning a decrease in microbial concentration can also be considered. The user can choose: (1) a selection of published models available, (2) to include additional models or (3) to introduce a distribution among the ones available in the tool or to include a fixed value. The mass can also be included. **Element 5: Dose–Response models**. There are dose–response models available in the tool or the user can implement new models.	- Has an advanced user interface and the user can design any step in the food chain from farm to fork. Also allows for effective data management and analysis of different scenarios combining hazards, consumption patterns and processing stages. - Both risk assessment and growth/inactivation models can be saved and shared online with other users.	convergence criteria. In the current version of the tool, the Monte Carlo process is very slow and may result in differences in the outputs for different number of iterations and between different simulations. - The user can run the tool only in a stochastic way since the deterministic application cannot take into account the prevalence of the pathogens. - All probability distributions are assumed to describe variability since the current version does not include uncertainty. - The development for a risk assessment application is in progress and there is a need for further improvements in the calculations and the presentation of the results.
Swift quantitative microbiological risk assessment (sQMRA) *(Quantitative)*	Stochastic: considers variability but not uncertainty. Tool, developed by Evers and Chardon (2012, 2013) for food safety risk assessment developed by the Dutch National Institute for Public Health and the Environment. Uses the @RISK add-in to Excel.	-Microsoft Excel spreadsheet format. -covers the food chain from retail to preparation and consumption and carries on to infection and illness. -- Key outputs for risk ranking are: • contamination level (prevalence and number) at portion and population level	In summary, the tool requires the input of quantitative data concerning factors that will affect the food safety risk for consumers, arising from a specific food product and specific hazard, during the steps from retail to consumption i.e. data on prevalence and concentration of pathogens at retail, food consumption, effects of storage, cooking and cross-contamination in the kitchen, a dose–response relationship and on disease burden and cost of illness 14 categories of input variables. : **1. Portions consumed**	-Takes into account all the factors affecting the risk and follows the risk assessment paradigm respecting the laws of probability and calculus. - The tool can provide both deterministic and stochastic outputs for risk ranking using single values or distributions for the respective input parameters. - Growth of the pathogens during storage can be	Quantitative data input restricted to the retail-to-consumption part of the food chain. 7 pre-defined reference datasets for risk ranking. Only a limited number of probability distributions are available for describing these data. This limitation may lead to erroneous ranking outputs when input data are not in a form that can be described by

Method	Institutional Use	User Interface System / Outputs	Data Inputs	Advantages	Disadvantages/Omissions
		in several steps of the food chain, and compared with a chosen reference model; •infection, illness, disease burden and cost-of-illness at portion and population level, and compared with a chosen reference model.	2. **Pathogen prevalence in retail** (pre-retail processing - such as smoking, salting, drying and cooking is accounted for by including a reduction factor <1 with which raw meat concentrations are multiplied to obtain realistic retail concentrations.) 3. **Portion size** 4. **Pathogen concentration** 5. **Storage conditions** 6. **Growth and inactivation characteristics of pathogen** 7. **Cross-contamination parameters** 8. **Preparation categories (see below)** 9. **Probability of survival during preparation** 10. **Endpoint dose–response model** 11. **Dose–response parameters** 12. **Probability of illness given infection** 13. **DALY per case** 14. **Cost-of-illness per case.** Includes (over the initial version): • growth or inactivation during storage by the consumer (Storage at the consumer's home is distinguished in three categories: at room temperature, in the refrigerator and in the freezer. Growth of microorganisms, which occurs above the minimum growth temperature, is described by an exponential primary growth model combined with the temperature-dependent part of the gamma model as secondary growth model) • an extended cooking module/ effect of heating • a choice of two dose–response models, • extended results presentation and reference and user-defined comparison datasets. • provides estimates for severity of illness, using DALYs and cost-of-illness.	estimated within the tool using the appropriate parameters in a secondary cardinal model. - The Excel spreadsheet form of the tool provides an informative summary of input data and allows for adequate checks on input validity. - The output results are provided at a very detailed level, for different steps in the food chain. They are therefore very useful to evaluate the impact of using different risk metrics for ranking purposes. - For a single pathogen in multiple food products, including DALYs and cost-of-illness as risk metrics does not affect the ranking; however comparing the ranking results for different metrics provides important insights. - Several summary graphs and tables are available. The built-in graphical presentations focus on comparison of the risk in relation to different storage conditions and preparation methods for the food product.	an available probability distribution. Some pre-processing of inputs may be necessary as the tool only accepts inputs in one format. Pre-processing of data may not always be straight-forward and might require considerable skills in quantitative microbiology. - Models only variability not uncertainty. All probability distributions are assumed to describe variability. - In the stochastic application, the number of iterations in the Monte Carlo simulation procedure has to be settled in advance without taking into account simulation convergence criteria. This may result in differences in the outputs for different number of iterations and between different simulations. - Cannot work with percentiles, only with log-normal distributions. - Cannot accept direct input of log-growth but calculates growth according to an exponential growth model with a gamma model for the impact of temperature on the growth rate. - The spreadsheet form makes file management very complex with each scenario (pathogen–product pair and/or differences in input parameters) requiring a different file to be stored which complicates quality

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			• The spreadsheet then converts the inputs into risk estimates using established algorithms. Three types of food products are distinguished based on different characteristics in relation to inactivation of microorganisms during the heating process in the kitchen and which are therefore modelled differently: • S (surface), where the microbial contamination is only on the meat surface. These are whole pieces of meat, from large (steak) to small (strips), but also bacon and some ham types. • I (internal), where the microbial contamination is mainly on the inside of the product. This includes roulades, cordon blue, minced meat products (e.g. roll, steak tartare, sausages, burgers) and products that are pasted and/or squeezed (schnitzels, nuggets, luncheon meats). Surface contamination is neglected in the calculations. • D (dividable), which is minced meat. This is distinguished as a separate category as it can be heated either as a whole (meatball; microbial contamination on the inside so heating effect like category I), or divided into crumbs, i.e. very small pieces (microbial contamination (almost) at the surface so that heating effect can be estimated as for category S). - For all variables, variability distributions are optional. The user can also enter deterministic information. - For risk ranking, seven pre-defined reference datasets are available in the tool, with the CARMA model for *Campylobacter* on broiler meat (Nauta		assurance and comparison of different scenarios. Model extensions in the future are possible and desirable, related to the very large diversity of meat products and ways of consumer storage and preparation. Suggestions are listed below. Potential additions: Could include minor food categories, e.g. snacks.; the potentially important raw beef product carpaccio (limited consumption data); possible effect of food processors injecting meat with fluids or tenderizing meat; possible inactivating effect of marinating; differentiate in the effect of heating (currently a 6.5 log10 reduction) for the different pre-retail categories; investigate in more detail the issues of pre-retail heating of meat products consisting of aggregated small pieces of meat (i.e. non-intact meat); include the effect of pre-retail freezing of meat, be it during transport of imported meat, or during storage at the butcher/abattoir; Lahou *et al*. [75] showed that meat temperature will initially remain high on the serving plate. Include this additional inactivating effect; include possible reheating of food (e.g. microwave); include variability and uncertainty in pathogen concentrations and

Method	Institutional Use	User Interface System / Outputs	Data Inputs	Advantages	Disadvantages/Omissions
			et al. 2007) offered as default. The user can also enter additional scenarios. Once a user-defined reference pathogen–product combination is available in the tool, it can be selected with a drop-down list in the RESULTS sheet for 1:1 comparisons with the model scenario.		parameter values when more data become available. .
EFSA food of non-animal origin risk ranking tool (EFoNAO-RRT)—(adapted from the US-FDA risk ranking tool, P3ARRT) *(Semi-Quantitative)*	Irrespective of the title, the tool can model meat product risk.	Microsoft Excel spreadsheet format. Semi-quantitative risk metrics (scores) calculated as the sum of scores of ordinal scoring criteria. The bottom-up approach to the tool adheres (approximately) to the standard microbial risk assessment paradigm by inclusion of the following criteria related to exposure and risk: - prevalence of contamination; - pathogen growth potential during shelf life; - consumption; - dose–response relationship. The top-down approach/ criteria reflect the public health burden by inclusion of the following criteria: - - strength of epidemiological link, reflecting the extent of reported outbreaks;	The EFoNAO-RRT includes input data for 10 variables used to categorise the 7 criteria related to health consequences or risk of the pre-selected pathogen commodity pairs. A total of 32 pathogen-commodity pairs are included in the tool. The pathogen—commodity pairs were selected by identifying outbreaks associated with fresh produce from the reported food-borne outbreaks in EU Zoonoses Monitoring between 2007 and 2011. Only data from outbreaks classified as moderate to very strong (according to the number of cases) and that occurred in Europe are included. The criteria are: (1) **Strength of associations between food and pathogen** (number of reported outbreaks and cases), (2) I**ncidence of illness** (notified number of cases and disease multiplier for under-reporting from EU *Salmonella* multiplier or multipliers, anchored to EU *Salmonella* (Scallan et al. 2011)), (3) B**urden of disease** (DALY5 per 1 000 cases based on data from the Netherlands (Havelaar et al. 2012)), (4) **Dose–response relationship** (only three scoring levels), (5) **Prevalence of contamination**, (6) **Consumption** (percentage of consumers consuming, at least once, any specific food belonging to each EFoNAO category during the study period), and	- The scoring system allows for using qualitative or uncertain input data. - The multi-criterion model is easy to communicate to risk managers. - It is possible for the user to modify input data and how output is calculated in the spreadsheet model. For instance, definitions of scoring categories (bins) as well as the weights for each criterion can be modified	- As a combined bottom-up and top-down approach, the tool provides an evaluation of risk based on certain selected criteria without following the risk assessment paradigm. - Pre-selected pathogen commodity pairs (based on European data). - Does not take into account uncertainty and variability. - EFoNAO tool provides ordinal or qualitative categorical risk metrics and thus cannot be compared with other deterministic tools with regard to log probability of illness. - Does not take into account factors that can significantly affect the final risk, such as the initial contamination level and the serving size. - Along with the (above) missing factors that affect the final risk, the ordinal scoring of the criteria, the correlation between some criteria and the lack of a biological or epidemiological interpretation

Method	Institutional Use	User Interface System / Outputs	Data Inputs	Advantages	Disadvantages/Omissions
		- - incidence of illness, reported cases corrected by a hazard-specific multiplier reflecting the "true" extent of illness; and - - burden of disease, reflecting the public health burden per 1 000 cases due to risk groups and more severe consequences. The overall rank per pathogen–commodity pair incorporates all seven criteria scores and is estimated via an algorithm that balances the score for each criterion with the weight of that criterion. The result is an overall numerical score for each pathogen–commodity pair that is produced by first multiplying each variable's score by its weight and then adding each of these seven values. This is the basis of ranking from high to low risk.	(7) **Pathogen growth potential during shelf life** (combined score from growth potential and shelf life).		of the risk metric outputs may lead to erroneous risk rankings. - An evaluation of risk based on certain selected criteria without following the risk assessment paradigm. - Rankings of different pathogens based on the sum of scores, not DALYs and provides limited discriminatory capability amongst rankings. - The Excel spreadsheet requires much manual handling in order to enter, calculate and present results making data management and scenario analysis complex. Note: P3ARRT, a tool with the same structure, has a much more advanced user interface.
Risk Ranger Version 2.0 *(Semi-Quantitative)*	Used by the creators in food risk assessment in an Australian context. Designed as a rapid "broad brush" estimation of risk to allow risk managers to prioritise hazard/product pairings for more intensive risk assessment studies.	Microsoft Excel spreadsheet format	The tool requires the user to select from qualitative statements and/or to provide quantitative data concerning factors that that will affect the food safety risk to a specific population, arising from a specific food product and specific hazard, during the steps from harvest to consumption. The spreadsheet converts the qualitative inputs into numerical values and combines them with the quantitative inputs in a series of mathematical and logical steps using	-Ease of use. -the Excel form of the tool provides flexibility. -The spreadsheet converts the qualitative inputs into numerical values to allow calculations to occur.	-Potentially too simplistic to generate reliable outputs. -Deterministic and does not take into account variability and uncertainty. - Although the model structure and data integration generally follow the logic of

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	Previously used in the last risk assessment performed for the Australian Red Meat Industry and the Australian Seafood Industry.		standard spreadsheet functions. These calculations are used to generate indices of the public health risk and consequent risk ranking. A numerical assessment of risk from 0-100 is assigned to the hazard:product pairings (0= no risk, 100 means every member of the population would eat the item of food (product) containing a lethal dose of the hazard every day). (1) hazard severity, (2) susceptibility of the consumer, (3) frequency of consumption, (4) proportion of population consuming, (5) size of population of interest, (6) proportion of product contaminated, (7) effect of process, (8) potential for recontamination after processing, (9) effect of post-processing control system, (10) increase from level at processing required to reach an infectious or toxic dose for the average consumer, and (11) effect of preparation of meal.	-useful in risk profiles when the rating is used to assess different production methods or consumption patterns. -can quickly provide assessments of the consequences of different methods of handling food. - Proposed for update to include DALY calculations (in 12-18 months) and minimum and maximum ‘expected’ options, over the current simple ‘expected’ to cater for variabilities. i.e. the next iteration of Risk Ranger is likely to also include some capacity to include stochastic features to address variability and the translation into best estimates of the most probable risk, as well as confidence intervals. - Can be combined with other software such as @Risk* for taking into account variability/uncertainty using Monte Carlo simulation. [Guillier et al. (2013) extended Risk Ranger towards a probabilistic version, distinguishing uncertainty and variability. However, this version requires an expert elicitation procedure in which the expert is asked for two quantiles to assess variability as well as given quantiles to incorporate an uncertainty level].	the standard risk assessment paradigm, there are some weak points. In particular, data integration when compared to simplified quantitative models. - Lacks DALY calculations. - The maximum population density of pathogens following growth is also not considered. As a result, the sum of the initial concentration and the growth during retail and domestic storage can be unrealistically high, resulting in over-estimation of risk. - The serving size, which can be an important factor affecting the final risk, is not included as an input parameter. Serving size can be taken into account only indirectly in the estimation of the increase in the post-processing contamination level that would cause infection or intoxication to the average consumer. - Might produce lower values for the probability of illness per serving because this tool uses single (mean) values of the input parameters and does not take into account their variability. - Does not use a full dose–response relationship. Instead, a threshold value is

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				*deterministic risk analysis in spreadsheet models can be replaced easily with a Monte Carlo simulation using @RISK in Excel. @RISK adds new functions to Excel for defining probability distributions and analysing output results.	assumed for the contamination level that would cause infection or intoxication to the average consumer, without taking into account variability in the dose–response. Therefore data integration is simplistic compared with full sQMRA models. - For some input parameters, the options provided in the risk spreadsheet are limited so the option with the closest value to the (actual) input data has to be chosen. This can therefore affect the risk ranking. - Data management and scenario analysis with Risk Ranger is complex. Each scenario (pathogen–product pair and/or differences in input parameters) requires a different file to be stored which complicates quality assurance evaluation and comparison of different scenarios. Because risk metrics for each pair of food–pathogen are produced separately they then require a manual comparison. -There is no graphical representation of the results.

A description of the criterion and corresponding scoring categories of the Pathogen-Produce Pair Attribution Risk Ranking Tool (P^3ARRT)

1. Epidemiological link: The epidemiological link criterion represents the historical association between any one pathogen-commodity pair and the occurrence of foodborne disease outbreaks. As such, data from outbreaks caused by each pathogen-commodity combinations is used in this criterion, considering the number of outbreaks and the total number of cases reported for each outbreak.

2. Disease multiplier: The disease multiplier is a pathogen-specific value that is multiplied by the number of cases to account for unreported and undiagnosed cases.

3. Hospitalisation and death rates: Hospitalisation and death rates for each pathogen, independently of food vehicle.

4. Susceptible population

5. Relative infectivity: The required dose to cause disease for each pathogen, independently of food vehicle.

6. Prevalence of contamination: Probability that the product is contaminated with the pathogen.

7. Consumption: Percentage of the population consuming a product category on any given day.

8. Shelf-life and growth potential: Likelihood and extent of growth of a particular pathogen in a contaminated produce commodity.

Scores used for these criteria:

	1. Epidemiological link		**2. Disease multiplier**	**3. Hospitalization and death rate**		**5. Relative infectivity**	**7. % consuming**
Score	# outbreaks	total cases		Hospitalization (%)	Mt (%)		
1	any	< or = 100	1-5	<10%	<0.1%	> or = 100,001	<1%
2	1 -2	> 100	6-25	10-20%	0.1-0.5	1001 - 100,000	1-5%
3	3-5	> 100	26-60	20-50%	0.5-1	101-1000	5-10%
4	>5	> 100	>60	>50%	>1%	1-100	>10%

	4. Susceptible population		6. Prevalence of contamination	
Score	Category	Strength for evidence	Category	Weighted average prevalence
1	None	No one is more susceptible than others	Unknown	Unknown, poorly characterized
2	Some	Young children or the elderly have a higher prevalence of disease	Low	<1%
3	Medium	Severity of disease increases with age	Medium	>1 - < or = 5%
4	Strong	Children, pregnant women, immunocompromised	High	>5%

	8. Shelf-life and growth potential				
Score	Category	Shelf-life	Category	Evidence of growth	Growth potential score + shelf-life score
1	Very short	0-7d	None	Organism does not grow or may be inactivated	≤2
2	short	7-14d	No evidence	Lack of evidence that bacteria may grow and includes conflicting studies	3-4
3	moderate	15-48d	Some	Some evidence that bacteria may grow (e.g. higher pH or bruising/damage) and includes conflicting studies	5-6
4	long	> or = 49	Strong	Likely growth at room temperature (22-24C)	7-8

A description of the criterion and corresponding scoring categories of the EFSA – BIOHAZ Risk Ranking tool for food of non-animal origin (*EFoNAO-RRT)*

Consequences of human disease:

1. Strength of associations between food and pathogen based on the foodborne outbreak from EU Zoonoses Monitoring Data

Score	Category	Number of outbreaks	Total cases
1	Weak	i. Has been reported in the EU as part of outbreaks, sporadic cases or analytical epidemiological studies but not in 2007-2011 Zoonoses monitoring data set; or	NA
		ii. Considered by expert review as relevant to the EU from information in the worldwide literature and not included in (i) above; or	
		iii. Have been associated with a FBO RASFF notification (subset of 19 notifications) and not included in (i) or (ii) above.	
2	Moderate	Have been associated with a single outbreak reported in the EU (2007-2011 data Zoonoses monitoring /Appendix B)	Any cases
3	Strong	i. Have been associated with 2-4 outbreaks reported in the EU (2007-2011 Zoonoses monitoring data/Appendix B) or	Any cases
		ii. Have been associated with ≥ 5 FBOs reported in the EU (2007-2011 Zoonoses monitoring data/Appendix B)	<100
4	Very strong	Have been associated with ≥ 5 FBOs reported in the EU (2007-2011 Zoonoses monitoring data/Appendix B)	< or = 100

2. Incidence of illness

This criteria considers the notifications of illness for each hazard and the under-reporting, using a multiplier for each specific hazards (without consideration of attribution to source) that describes the degree of under-reporting. Using notifications and the multiplier the estimated incidence of illness is calculated and allocated in different scores.

Score	Incidence of illness	Score intervals
1	Low	< 100,000
2	Medium	100,000 - 999,999
3	High	1,000,000 - 10,000,000
4	Very high	>10,000,000

3. Burden of disease

The burden of disease criterion is measured by the disability adjusted life years (DALY) per thousand cases, considering acute illness, long-term effects as well as mortality, and is estimated for specific foodborne infections.

Score	DALY	DALY per 1,000 cases score intervals
1	Low	<10
2	Medium	10-99
3	High	100-999
4	Very High	>999

Probability of exposure:

4. Dose-response relationship

Score	Dose-response relationship
1	Pathogen growth to high numbers (>10^5 CFU/g) is needed for toxin production and induction of disease
2	Pathogen growth is needed to inducedisease in humans (e.g. C. botulinum, L. monocytogenes)
3	Low numbers can cause disease (e.g. *Salmonella* spp., *Shigella* spp., virus, protozoa)

5. Prevalence of contamination

Score	Prevalence	Explanation
1	Zero prevalence	Available prevalence studies indicate 0 prevalence
2	Unknown prevalence	Not possible to draw any conclusions on the prevalence based on the avaialble data
3	Low prevalence (<1%)	Pathogens occur in product and cause outbreaks, and are likely ot have an origin from human or animal contamination
4	> or = 1%	Would also include e.g. Bacilly spp. and L. monocytogenes, which originate from the environment and may in some instances be underestimated.

6. Consumption

Score	Percentage of consumers
1	Low <1%)
2	Moderate (1-2%)
3	High (>2 - 20%)
4	Very high (>20%)

7. Pathogen growth potential during shelf life

Score	Category	Shelf-life	Score	Evidence of growth
1	Very short	0-7d	1	No growth possible (too low pH, too low water activity, too low temp, competing microflora)
2	short	7-14d	2	Poorly documented
3	moderate	15-28d	3	Growth possible but not in all circumstances (e.g. only if temp abused)
4	long	> 28d	4	Growth possible and very likely

Combined score	Combined pathogen growth potential and shelf-life
1	2
2	3-4
3	5-6
4	7-8