RISK ASSESSMENT OF THE VULNERABLE PERSONS FOOD SAFETY SCHEME

Department of Primary Industries
Food Authority

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Contents

Abbreviations

AAD	Antibiotic associated diarrhoea
ABS	Australian Bureau of Statistics
ADA	American Dietetic Association
AIDS	Acquired immunodeficiency syndrome
ASCIA	Australasian Society of Clinical Immunology and Allergy Incorporated
ASQAP	Australian Shellfish Quality Assurance Program
CAR	Corrective action request
CCP	Critical control point
CFR	Case-fatality rate
CPU	Central processing units
EC	European Commission
ESL	Extended shelf life (cook chill)
FAO	Food and Agricultural Organization of the United Nations
FDA	Food and Drug Administration (US)
FSANZ	Food Standards Australia New Zealand (formerly ANZFA)
FSOM	Field staff operations manual
FSP	Food safety program
GI	Gastrointestinal
GT	Generation time
HACCP	Hazard analysis critical control point
HCT	Haematopoietic cell transplant
HUS	Haemolytic uremic syndrome
HIV	Human immunodeficiency virus
ICMSF	International Commission on Microbiological Specifications for Foods
ILSI	International Life Sciences Institute
LMD	Low microbial diet
LPD	Lag phase duration
MAP	Modified atmosphere packaging
MLA	Meat & Livestock Australia
NSW	New South Wales

NRVP	National risk validation project
PHLS	Public Health Laboratory Service (UK)
RA	Risk assessment
RTE	Ready-to-eat
SSL	Short shelf life (cook chill)
STEC	Shiga toxigenic *E. coli*
TPA	Third party auditor
UKFSA	United Kingdom Food Standards Agency
USDA	US Department of Agriculture
WHO	World Health Organization
YOPI	Young, old, pregnant and immune compromised

Names of microorganisms

Bacillus cereus	*B. cereus*
Cronobacter sakazakii	*Cr. sakazakii*
Clostridium botulinum	*Cl. botulinum*
Clostridium difficile	*Cl. difficile*
Clostridium perfringens	*Cl. perfringens*
Campylobacter jejuni	*C. jejuni*
Escherichia coli	*E. coli*
Listeria monocytogenes	*L. monocytogenes*
Salmonella Typhimurium	*S.* Typhimurium
Salmonella Enteritidis	*S.* Enteritidis
Salmonella Gaminara	*S*. Gaminara
Salmonella Hartford	*S*. Hartford
Salmonella Rubislaw	*S*. Rubislaw
Salmonella Typhimurium	*S*. Typhimurium
Staphylococcus aureus	*Staph. aureus*
Toxoplasma gondii	*T. gondii*
Vibrio vulnificus	*V. vulnificus*

Executive summary

The NSW Food Authority (the Food Authority) provides an updated risk assessment for food service to vulnerable persons. This risk assessment examines new scientific literature and information, considers feedback from industry on practical risk management measures, examines outbreak data and uses the collective evidence to support existing risk management approaches or suggest alternative approaches. The information in this risk assessment document is based on emerging knowledge on vulnerable persons food safety, the Food Authority's *Vulnerable persons food safety scheme manual* 2008, the technical review of the manual undertaken during 2010 and the scientific justification for the subsequent changes in control measures outlined in the new *Guidelines for Food service to vulnerable persons* issued in 2012 and updated in 2015. The strategies for risk management in food service settings were discussed in the technical review are included as Appendix 1.

There are 1471 facilities licensed with the Food Authority to serve food to vulnerable persons (as at May 2016). Preparation methods within these facilities vary considerably, including:

- preparation and serving of raw or ready-to-eat (RTE) foods
- preparation and serving of freshly cooked foods (cook fresh or cook serve)
- preparation and serving of previously cooked foods without further heating (leftovers)
- serving of foods previously cooked using cook chill (with or without reheating).

The Food Authority also regulates 11 facilities licensed as Central Processing Units (CPU). These are facilities where potentially hazardous food (cook fresh, short shelf life cook chill (SSL), extended shelf life cook chill (ESL)) are prepared, cooked, chilled and transported to another facility for service or further processing such as heating and plating. The Food Authority's recent project on 'Risk and control in licensed CPU' completed in 2016 identified several issues around food safety management and compliance in the facilities. Several recommendations were made to better regulate the sector including improvements in the licensing of the CPU and reviewing the protocols for food safety audits of these facilities.

This risk assessment examines the food safety hazards associated with different preparation methods and the control measures specified by the Food Authority and implemented by businesses. The assessment recognises the need to find the right balance between protecting the patients/residents from foodborne hazards and maintaining a sufficiently nutritious and interesting diet to ensure their quality of life.

An unacceptable or unpalatable diet for an elderly person can lead to a spiral of negative health effects, with malnutrition or poor nutrition increasing the likelihood of infections. Therefore, the risk management of foodborne illness in vulnerable persons facilities must be considered in a holistic way, with the knowledge that it is not possible to fully eliminate all risk from foodborne sources without having a possible adverse effect on nutrition intake. This balance between implementing food safety control measures and managing nutritional intake is especially critical for those people in long term care because of the focus on maintaining quality of life and general wellbeing.

1. Introduction

1.1 Purpose – updating the risk assessment

In 2008-2009 the NSW Food Authority (Food Authority) completed a comprehensive risk assessment (RA) for each food safety scheme (NSW Food Authority, 2009a). This included the first RA of the Vulnerable persons food safety scheme (the scheme). To inform the development of Food Regulation 2015, the Food Authority updated the RA in 2012 and revised the *Vulnerable persons food safety scheme manual* (NSW Food Authority, 2012). The Food Authority is again updating the RA information on each scheme to ensure it remains contemporary and the purpose of this document is to produce a comprehensive RA of the scheme for food service to vulnerable persons.

This updated RA examines new literature, considers feedback from industry on practical risk management measures, examines outbreak data and uses the collective evidence to support existing risk management approaches or suggest alternative approaches. The information in this RA document is based on a technical review of the *Vulnerable persons food safety scheme manual* (NSW Food Authority, 2008a; NSW Food Authority, 2012) which was undertaken during 2010, and the scientific justification for the subsequent changes in control measures outlined in the *Guidelines for food service to vulnerable persons* (NSW Food Authority, 2015).

1.2 Food Standards Code requirements

In 2008, the Australia New Zealand Food Standards Code (the Code) was amended to include Standard 3.3.1 – *Food safety programs for food service to vulnerable persons* (FSANZ, 2008). The Code defines the vulnerable population by considering the types of businesses likely to serve potentially hazardous food to persons who are located in the following (FSANZ, 2006):

- acute care hospitals
- psychiatric hospitals
- nursing home for the aged
- hospices
- same day establishments for chemotherapy and renal dialysis services
- respite care establishments for the aged
- same day aged care establishments
- low care aged care establishments
- delivered meal organisations
- childcare centres (not currently implemented in NSW)

These businesses are required to implement a documented and audited food safety program if serving food to six or more people.

These requirements were introduced as a result of the findings of the National Risk Validation Project (NRVP) report, where Food Science Australia & Minter Ellison Consulting (2002) estimated the total cost of foodborne illness in the food service to sensitive populations to be $75 million per year. This cost of foodborne illnesses has risen well above $100 million per year over the last decade.

The scope of this RA is limited to assessing the risk from foods served in the facilities covered by the Code and NSW legislation. This RA does not expressly examine the risk posed to specific groups of vulnerable persons such

as pregnant women, who are often considered at increased risk to foodborne illness, particularly from *Listeria monocytogenes*. For more information and specifically targeted guidance for pregnant women, the Food Authority has a pregnancy portal on its website at: http://www.foodauthority.nsw.gov.au/foodsafetyandyou/life-events-and-food/pregnancy/pregnancy-and-food-safety.

1.3 Evaluation of the Vulnerable persons food safety scheme

During March 2009, the Food Authority undertook an evaluation of facilities covered under the scheme. This was done as part of the development of Food Regulation 2010. This evaluation occurred while the first mandatory audits of food safety programs were being conducted on these businesses. The evaluation process also included a microbiological survey of 347 samples from 60 facilities (NSW Food Authority, 2010a). In addition to this, food safety practices were examined in over 100 facilities through a questionnaire (NSW Food Authority, 2010b). The number of facilities evaluated was considered a representative sample of the vulnerable persons businesses licensed with the Food Authority at the time of the evaluation (n = 1228).

1.4 Review of the *Vulnerable persons food safety scheme manual* 2011

Under the Food Regulation 2004, the Food Authority implemented the requirements of the *Vulnerable persons food safety scheme manual* (NSW Food Authority, 2008a). It was enforced as a condition of licence that each facility must comply with the requirements contained in the manual. With the implementation of Food Regulation 2010, the manual was kept as guidance material but compliance with it was no longer listed as a condition of licence. However, the audit checklist used by Food Authority staff to audit vulnerable persons businesses still contained references to certain elements of the 2008 manual, essentially implementing these as requirements.

During 2010, the Food Authority conducted a technical review of the manual and the audit checklist. The review focussed on the technical information provided in section 5 of the Food Authority's 2008 manual and examined the scientific basis for the requirements. The review provided a list of recommendations which were used in the development of *Guidelines for food service to vulnerable persons* (NSW Food Authority, 2011a) and amendments to the audit checklist. This guideline includes simplified information for the vulnerable persons food service sector. The review also discussed the strategies for risk management in food service settings, which are included in the scheme with minor changes as Appendix 1.

1.5 Food Regulation 2015

In NSW, the Food Authority administers food law through the NSW Food Regulation and *Food Act 2003*. Food Regulation 2004, under which the Food Authority licenses certain food businesses, was previously replaced by Food Regulation 2010 and recently by Food Regulation 2015. As per the previous regulation, the new regulation contains a Vulnerable persons food safety scheme (the scheme) as well as other schemes (meat, dairy, seafood, plant products, eggs and egg products).

The scheme covering food service to vulnerable persons requires facilities to be licensed and enforces the Code's requirement to implement a food safety program for those facilities serving six or more persons.

1.6 Updated RA of the Vulnerable persons food safety scheme 2016

This document, an updated and revised version of the RA, provides the latest scientific developments in understanding the vulnerable population food safety risks and the strategies to manage them effectively.

2. Vulnerable persons

From time to time certain population subsets within the community are more at risk to foodborne illness or can develop more serious complications from foodborne illness than the general population (Acheson and Lubin, 2008). Exactly defining who is vulnerable can be problematic. This is predominately due to the differing degree of vulnerability from one person to the next and the varying degrees of virulence of some pathogenic microorganisms to different vulnerable sub-populations (Acheson and Lubin, 2008). Acheson and Lubin (2008) provides an overview of the different factors that influence vulnerability and in general terms vulnerability is due to a suppressed immune system, either due to age, pregnancy, disease or pharmacologic therapy (i.e. chemotherapy or immunosuppressive drug use after an organ transplant). Several factors and conditions are responsible to increase the susceptibility (Table 1) to foodborne pathogens in at-risk persons.

Table 1. Factors that can increase one's susceptibility to foodborne pathogens

Factor	Condition
Primary Immunodeficiency	Genetic defects/disturbances
Secondary immune deficiencies	Age (infants and toddlers < 5 years) Age (elderly > 65 years) Pregnancy Malignancy Metabolic disorder Medications (over-the-counter or prescription) Leukaemia HIV/AIDS Immunosuppressive drugs in organ transplant Chemotherapy for cancer Radiotherapy for cancer Treatment with corticosteroids Treatment with inhibitor of tumour necrosis factor Diabetes (primary and secondary) Immune incompetence Surgical history
Other factors	Nutritional status (malnutrition protein, calories, vitamins etc.) Life style problems (alcoholism, cirrhosis) Gastric acidity variation (antacid, achlorhydria, natural variation etc.) Occupation General health

Modified from Lund (2015)

Young, old, pregnant and immune compromised (YOPI) individuals, generally referred as vulnerable persons, are particularly susceptible to foodborne disease. According to some reports they make approximately 15-20% of the population in the United States and the United Kingdom (Lund and O'Brien, 2011). According to the Australian Bureau of Statistics, the number of people aged 65 years or over reached 3.5 million in June 2014 and this accounted for 15% of the total Australian population (23.5 million) (ABS, 2014).

2.1 Vulnerable populations and susceptibility to foodborne illness

Vulnerable people show increased susceptibility to foodborne illness compared with healthy adults. They are a substantial proportion of the population and their susceptibility depends on nature of illness (chronic or acute), age, medication and life style. Different health conditions determine the extent of the increased susceptibility to foodborne illness in these individuals. For examples, a study conducted in France provided an estimate of the relative susceptibility of different groups of vulnerable persons (based on health condition) to listeriosis (FAO/WHO, 2004) (Table 2). Goulet et al (2012) estimated the susceptibility of patients with chronic lymphocytic leukaemia to listeriosis and found that occurrence is more than 1000 times greater compared to the population with no risk factors. They also listed 14 underlying conditions associated with greater than 100-fold increase in susceptibility.

Table 2. Relative susceptibilities of different subpopulations to listeriosis, calculated using relative susceptibility information from France

Condition	Relative Susceptibility
Transplant	2584
Cancer—blood	1364
Acquired immunodeficiency syndrome (AIDS)	865
Dialysis	476
Cancer—pulmonary	229
Cancer—gastrointestinal/liver	211
Noncancer liver disease	143
Cancer—bladder and prostate	112
Cancer—gynaecological	66
Diabetes—insulin-dependent	30
Diabetes—noninsulin-dependent	25
Alcoholism	18
Perinatals *	14
Aged > 65 years	7.5
Less than 65 years, no other condition (reference population)	1

* Information from the USA.

Adapted from FAO/WHO (2004) and Lund (2015)

2.2 Specific features of vulnerable sub-populations

As mentioned-above that the extent of vulnerability differs greatly between the vulnerable groups. This section will look at specific features of different vulnerable groups and their relationship with increased susceptibility toward foodborne illnesses.

2.2.1 Elderly persons

In general, people aged 65 or over are considered more susceptible to foodborne illness than less than 65 years with no health problem. This is due to the fact that the natural immunity (defences) or ability to fight diseases lessens in old age. However, people less than 65 years may have a higher level of vulnerability to foodborne illness if they suffer from chronic disease or a medical condition.

An old age is associated with several physiological and physical factors that cause an increased susceptibility to foodborne illness.

- Immune system weakens with age, which makes it harder to fight off bacteria and serious illness.
- Older people have less secretion of stomach acid to control bacteria.
- Food poisoning can be difficult to treat in older people (if infected) and can reoccur.
- Poor eyesight and sense of smell are common conditions in older adults; they may face difficulty in noticing food spills and signs of spoilage.

It is also important to note that the prevalence of chronic diseases and ailments such as malnutrition and immobility is high in old age and can increase the vulnerability to infections.

2.2.2 Pregnant women

Pregnancy is a condition when women are considered at increased risk and more susceptible to some foodborne illnesses. Therefore, when considering foodborne illness during the pregnancy they are broadly grouped as vulnerable persons. The conditions and factors that increase the vulnerability of pregnant women to foodborne illness are:

- Hormonal changes associated with pregnancy can affect an expectant mother's immune system resulting in increased susceptibility to some foodborne infections. For example, *L. monocytogenes* is of concern as it can cause premature delivery, abortion and still birth.
- Physical weakness commonly occurs in pregnant women, which make them vulnerable.
- Some pregnant women may suffer temporary health problems (such gestational diabetes) and become more susceptible to foodborne illness.
- Diet choices (or availability) during pregnancy also play a vital role in avoiding a foodborne infection.

2.2.3 Infants and young children

Young children (<5 years old), one of the most susceptible groups of the population, are considered at high risk of contracting a foodborne illness. There are several factors that contribute to their vulnerability (Gerba et al, 1996):

- Young children have less-developed immune systems and limited ability to fight infections.
- They face higher risks when exposed to foodborne pathogens and prevalence of some infections.
- They require less amount of a pathogen to cause illness due to lower body weight.

2.2.4 Persons with chronic illness

Chronic illnesses such as HIV/AIDS, cancer, diabetes make individuals more prone to contracting foodborne illness.

- HIV/AIDS persons have the weakened immune systems that put them at high risk to foodborne illness. Bacterial infections like salmonellosis can cause serious complications in HIV/AIDS patients.
- Cancer patients are also more vulnerable to foodborne illness and its serious complications due to:
    1. Cancer itself and cancer treatments (radiation, chemotherapy and other) can weaken the immune system of the patient.
    2. If contracted a foodborne infection, it may prolong the illness and potentially leading to complications and hospitalisation.
- A diabetic patient has increased risk for foodborne infection due the decreased ability of the immune system to immediately recognize harmful foodborne pathogens. Many factors contribute to their vulnerability:
    1. High glucose levels suppress the function of white blood cells that fight off infection.
    2. Less production of digestive acid that plays an antimicrobial role.
    3. Slower movement of food through the GI tract compared to non-diabetic persons may allow the pathogenic bacteria to multiply, which can lead to foodborne illness.
    4. Diabetes also affects the immune system that makes them more prone to foodborne illness.
    5. Many diabetes patients face kidney problems. Malfunctioning of kidneys gives the unhealthy bacteria an opportunity to grow out of control and cause an infection.

2.2.5 Persons naturally immune-deficient

Individuals with a genetic condition that is responsible for low immune system could put them at high risk to acquire a foodborne illness. A person with leukaemia is a typical example of naturally immuno-deficient. Goulet et al (2012) reported that people with chronic lymphocytic leukaemia were more than 1,000 times higher risk of developing listeriosis than the general French population.

2.2.6 Persons on specific medical treatment

Specific medical treatments like transplant, dialysis also put the individuals at high risk to get infected by foodborne pathogens.

- Transplant patients are at particular risk due to (Obayashi, 2012):
    1. Immunosuppressive medications make them more susceptible to illness.
    2. Solid organ transplant increased susceptibility to infections as body is in transition phase to normalise physiological systems.
    3. Transplant recipients are physically weak if contracted a foodborne illness is more likely to have a lengthier illness, undergo hospitalization, or even die.
- People who need regular dialysis are at higher risk for foodborne illnesses due to kidney disease.

2.2.7 Persons with lifestyle and diet problems

Some lifestyle and diet issues are more likely to leave individuals vulnerable to foodborne illness. Few examples are:

- Alcoholism: It may increase the risk of foodborne illness due to negative effects on metabolic activities of the body. Alcoholics are reported 18 times more likely to be sickened by a foodborne infection.
- Malnutrition: Inadequate nutrition or imbalance diet intake is known to result in higher chances for a physical and mental illnesses.
- Travellers: International or frequent travellers contract diarrhoea often through consumption of contaminated food. The factors such as low level of immunity, a change in diet, and climate increase the risk for a traveller to acquire a foodborne infection.

2.2.8 Persons on medication

Specific medication is also known to increase the susceptibility of a person to foodborne illness. One of the most frequently used examples is acid-suppressing medicine.

Susceptibility to foodborne illness may be increased by using common acid-lowering drugs because stomach acid is necessary to kill the pathogenic organisms unavoidably present in the food and drink. Using acid-suppressing drug can weaken the defence against acquiring a foodborne intestinal infection. In a systematic review published on the use of proton pump inhibitors and increased susceptibility to enteric infection, authors had discussed the association between the bacterial infections of *Salmonella*, *Listeria* and *Cl. difficile* and the use of acid-suppressing drugs (Bavishi and DuPont, 2011).

3. Risk assessment

This section will focus on microbiological hazards only as the risks posed by chemical and physical hazards are not known to be influenced by a decreased immunity. It should be noted that most of the risk assessments conducted do not specifically address establishments serving to vulnerable populations. Where they do examine specific hazards that affect the vulnerable population (e.g. *L. monocytogenes*) the context is usually within that of the general population and includes both those situated in care-type establishments and those living outside these establishments. Wherever possible, this RA will attempt to focus on the risks associated with those people within care-type establishments, although due to the lack of information specific to these establishments this may not always be possible.

3.1 Hazard identification

Each of the food service operation systems used in vulnerable persons businesses has its own hazards and risks associated with them. This updated RA considered the hazards based on food service type, and built on the hazard identification undertaken in the Food Authority's previous RA documents and evaluation programs (NSW Food Authority, 2009a; NSW Food Authority, 2012). This revised version includes more comprehensive information on several pathogens where new information has been required to implement more effective control measures, or where the pathogen was not considered in the Food Authority's 2009 risk assessment.

When considering the food safety hazards presented to vulnerable populations, the hazards can be separated into two groups:

- Specific hazards – those hazards that present a unique risk to vulnerable populations and
- General hazards – those hazards that, due to a decrease in immunity of an individual, can result in a greater prevalence in illness when compared to the general population or result in more serious illnesses.

3.1.1 Specific hazards

Vulnerable people are particularly susceptible to specific food safety hazards. Table 3 presents a summary of identified specific hazards for different sub-groups within vulnerable population. For microbiological hazards, susceptibility of a vulnerable sub-group depends on many factors where low immunity level is a major factor. Examples of the specific biological hazards include: *L. monocytogenes*, *Salmonella* and *Campylobacter* for elderly; *L. monocytogenes* and *T. gondii* for pregnant women; *Cl. botulinum*, *Cronobacter sakazakii* and *Salmonella* for infants and young children; *L. monocytogenes* for naturally or clinically reduced immune system function; *V. vulnificus* for liver disease patients; *Salmonella* for people on acid-supressing medicine; and *C. perfringens* for persons using anti-diarrhoeal medicine.

Vulnerability to chemical hazards is less dependent on immune level but different stages of life or physical condition of the individual. The foetus is vulnerable to spontaneous abortion, low birth weight, structural congenital abnormalities and carcinogensis when exposed to poisonous chemicals (IUFoST, 2015). For example, lead exposures of the foetus and the young children can retard mental and physical development and lead to reduced intelligence.

Table 3. Summary of specific hazards for vulnerable persons

Sub-group	Specific hazard	Reference
Elderly	*L. monocytogenes* *Salmonella* *Campylobacter*	McLauchlin et al. 2004 Skirrow et al. 1993 Nielsen et al. 2010
Pregnant women	*L. monocytogenes* *T. gondii*	Smith, 1999 Smith, 1999
Infants and young children	*Cl. botulinum* *Cr. sakazakii* *Salmonella* Mercury	Arnon, 2004 Bowen and Braden, 2008 Corbett and Poon, 2008
Persons with chronic illness	AIDS: *L. monocytogenes* Cancer: *L. monocytogenes* Liver diseases: *V. vulnificus*	 Decker et al. 1991; Maddocks et al. 2011 Hequet et al. 1997; Levidiotou et al. 2004 Jones and Oliver, 2009
Persons naturally immune-deficient	Leukaemia: *L. monocytogenes*	Tolomelli et al. 2014
Persons on specific medical treatment	Organ transplant: *L. monocytogenes* *T. gondii*	Fernandez-Sabe et al. 2009 Fernandez-Sabe et al. 2012
Persons with lifestyle and diet problems	Malnutrition: *L. monocytogenes*	Itoga et al. 2015
Persons on medication	Acid-suppressing medicine: *Salmonella* Anti-diarrhoeal medicine: *Cl. perfringens*	Kirchheimer et al. 2009 Bos et al. 2005

Listeria monocytogenes

L. monocytogenes stands out as one of the most common specific hazard to vulnerable populations. This is primarily due to its ability to become invasive when immune system weakens. *L. monocytogenes* is identified as an important foodborne pathogen for the elderly (McLauchlin et al. 2004; Scallan et al. 2011), pregnant women (Smith, 1999), people with AIDS and cancer (Hequet et al. 1997; Levidiotou et al. 2004; Decker et al. 1991; Maddocks et al. 2011), organ transplant patients (Fernandez-Sabe et al. 2009) and those with leukaemia (Tolomelli et al. 2014). This pathogen causes a rare but serious foodborne disease, listeriosis, which has high morbidity and mortality rate in vulnerable populations (e.g. pregnant women, the elderly, and the immunocompromised). For example, an Australian study reported the highest case-fatality rate (CFR) in elderly people (≥65 years of age) residing in long-term care facilities and the community due to listeriosis (17.8%) compared to other pathogenic infections (1.2-8.3%) (Kirk et al. 2012).

The importance of controlling *L. monocytogenes* in foods consumed by the vulnerable population is well-documented. While the exact dose needed to cause illness in the vulnerable populations is ill-defined and open for much debate, it is generally agreed that lower infective doses are needed for illness to occur within the vulnerable population. However, the type and severity of illness may be dependent on virulence of the pathogen, host susceptibility and the food matrix (FDA/USDA, 2003). Sutherland et al (2003) notes that while the infective dose is not clearly defined, some studies suggest infective doses as low as 10^2 to 10^3 cfu/g may cause illness.

L. monocytogenes is of concern in any RTE food or foods not likely to receive a heat treatment prior to consumption. This is predominately due to the organism being ubiquitous in nature, the potential for cross-contamination after cooking and the ability of the organism to grow at refrigeration temperatures. In their risk assessment, the FDA/USDA (2003) ranks the potential risk posed by some RTE foods. Those of very high to high risk include:

- Deli meats and uncooked frankfurters
- Pâté and meat spread
- Unpasteurised milk
- Smoked seafood
- High fat and other dairy milk and
- Soft unripened cheese

Others which present a low risk include cooked crustacean, salads, fermented smallgoods, other soft cheese and fruits and vegetables.

In general terms, any foods that can support the growth of *L. monocytogenes* and does not include a cook step prior to consumption can potentially present some level of risk to vulnerable populations.

Salmonella

Salmonella is one of the major of foodborne pathogens worldwide and causes zoonotic infections (transmitted from animals to humans). The common foodborne illness is caused by non-typhoid salmonellae (*S*. Enteritidis and *S*. Typhimurium), which invade the cells lining the small intestine. Vulnerable individuals, specifically the young and the elderly (Oslen et al. 2001; Jones et al. 2008), sometimes face more serious disease such as septicaemia from non-typhoid *Salmonella* infections. The CFR for non-typhoid salmonellosis is less than 1% for general population; however, it is higher amongst some vulnerable sub-groups, particularly the elderly. The reported CFR for *S*. Enteritidis and *S*. Typhimurium in elderly (≥65 years of age) in Victoria, Australia was 1.2% and 1.6%, respectively (Kirk et al. 2012).

Clostridium botulinum

Infants are specifically susceptible to infection by spores of *Cl. botulinum* (Lund and O'Brien, 2011). These spores can germinate and colonize in the infant colon and produce botulinum neurotoxin causing infant botulism. Infant botulism, though rare, has been reported in many countries including Australia. It usually occurs in infants aged one year or less (Arnon, 2004). Symptoms include constipation followed by weak sucking and crying ability. The illness affects the nervous system and while death can occur, mortality rates are generally low due to good intensive care facilities. In cases of infant botulism, the cause is often unknown; however, the presence of *Cl. botulinum* in honey is thought to be one food source associated with infant botulism (Szabo and Gibson, 2003).

Cronobacter sakazakii

Cr. sakazakii, previously classified *Enterobacter sakazakii*, is a pathogenic microorganism that has been linked to foodborne illness outbreaks predominately affecting infants (Lenhner and Stephan, 2004; Bowen and Braden, 2008). Limited surveillance data is available; at least 120 cases worldwide with 27 deaths were reported by FAO (2008). *Cr. sakazakii* can be present in different types of food; however, powdered infant and follow-on formula have been identified as the main food vehicle, with practices such as reconstitution with warm water and holding bottles at room temperature increasing the risk of foodborne illness (FAO, 2007; FAO, 2008). According to Kalyantada et al. (2015) more than 90% of *Cronobacter* infections have been linked epidemiologically to powdered infant formula. Other factors thought to increase the risk of illness include; age of the infant, nutritional status, HIV status, other clinical conditions, pharmaceutical treatment, low birth weight and premature birth (FAO, 2008). This pathogen may cause several serious infections, including meningitis, bacteraemia, urinary tract infections, and wound infections. It is also known to infect immunocompromised adults (Healy et al. 2010). As with other *Cronobacter* species, *Cr. sakazakii* isolates are thought to have a high rate of antibiotic resistance (Lehner and Stephan, 2004).

Vibrio vulnificus

A specific sub-group within the vulnerable population are at risk from infection by *V. vulnificus*. This bacterium is found in the marine environment and can contaminate seafood. *V. vulnificus* infections normally affect people with liver dysfunctions (e.g. cirrhosis, hepatitis) and patients with malignancies or those who have undergone gastrectomy (ICMSF, 1996; Jones and Oliver, 2009). Symptoms of infection from *V. vulnificus* include fever, chills and nausea (Desmarchelier, 2003). While infections are rare, mortality rates are high. Most illnesses have been linked to consumption of raw seafood, predominately raw oysters (Desmarchelier, 2003).

Campylobacter

Campylobacter infection (campylobacteriosis) causes the largest number of cases of bacterial acute gastroenteritis worldwide. *C. jejuni* and *C. coli* are the most common microorganisms associated with campylobacteriosis. In developed countries, campylobacteriosis is more commonly reported than salmonellosis and the disease mainly infect children <5 years and young adults. For instance, there are 10 times more cases of campylobacteriosis reported than salmonellosis in Ireland (Food Safety Authority of Ireland, 2015). In Australia, the numbers of cases of campylobacteriosis have been rising since the early 1990s (http://news.nationalgeographic.com/news/2006/08/060807-poultry_2.html). Most of the bacteraemia cases (though less than 1%) were diagnosed among the very young or very old or immunocompromised patients (Skirrow et al., 1993). It is an important cause of childhood morbidity. *Campylobacter* is naturally present in the intestinal tract of animals and can be transmitted through a variety of animal origin foods i.e., the most common source is poultry.

Toxoplasma gondii

T. gondii is a parasite and causes a serious disease, toxoplasmosis, in pregnant women. At initial stage the disease is often unrecognised due to mild symptoms. Congenital infection can occur when a pregnant woman is newly infected or can be due to the reactivation of an infection contracted before pregnancy (Jones and Dubey, 2008). The source of infection is usually contaminated meat from pork, lamb and venison. However, half of the cases are due to exposure to cat (the requisite host for the parasite) faeces directly or indirectly. Outbreaks of toxoplasmosis are rarely reported and several of them have been associated with drinking water (Jones and Dubey, 2010). This is because general population if infected often have mild or no symptoms.

Mercury

Mercury is one of the common pollutants in the environment that originates from natural sources. Industrial pollution also releases mercury into the air that ends up in streams and oceans where it is converted into a harmful form of mercury (i.e. methylmercury) that can cause health implications to unborn baby and young child. Fish present in the contaminated water absorb the methylmercury through feeding and it builds up in them and could cause food poisoning in the consumer.

3.1.2 General hazards

When vulnerable populations are exposed to other pathogenic microorganisms the resulting illnesses are like to be more prevalent and more severe than in the general population. Buzby (2002) attributed this in elderly people to age related factors (e.g. decreased immune function and stomach acid production, digestive orders, medication and altered sense of smell and taste) and a decrease in stomach and intestinal contractions resulting in a longer time required to eliminate pathogens and allowing a greater time for toxin formation and damage. Buzby (2002) also reports that in the US, rates of foodborne illness can be 10 to 100 times greater for elderly people within nursing homes when compared to the general population and that the elderly are more vulnerable to gastroenteritis-induced deaths.

Other sub-groups within the vulnerable population exhibit increased sensitivity to foodborne illnesses due to decreased immunity. Acheson and Lubin (2008) contribute this increased risk due to many factors including the use of antibiotics that, while they aim to treat illnesses caused by certain pathogens, they can also eliminate from the intestinal tract certain microorganisms that inhibit or suppress the growth of pathogenic microorganisms. Cancer and transplant patients also have greater susceptibility to foodborne illness due to their treatments lowering the immune system, with mortality rates from foodborne illness higher than the general population (Acheson and Lubin, 2008).

Clostridium perfringens

The fatal cases of *Cl. perfringens* food poisoning are generally associated with the elderly in institutionalised settings (Bates and Bodnaruk, 2003) whereas in the general population fatalities are rare. A comprehensive review has been undertaken by the Food Authority on *Cl. perfringens*-associated gastroenteritis outbreaks in aged care facilities (NSW Food Authority, 2011). Determining the source of a *Cl. perfringens* gastroenteritis outbreak can be challenging, especially for outbreaks that do not follow the typical epidemiological curve where the duration of illness extends longer than 48 hours or where there are multiple peaks in the number of outbreak cases.

An investigation of a *Cl. perfringens* gastroenteritis outbreak in an aged care facility should not only examine food handling practices for a potential foodborne source, but also consider the potential for person-to-person spread and reintroduction of the organism from environmental sources. Personal hygiene of staff and patients should be regarded as critical to minimise the potential for reinfection and avoid prolonged gastroenteritis outbreaks with multiple peaks.

There is increasing evidence to suggest that isolation of *Cl. perfringens* from clinical specimens taken from gastroenteritis cases is not necessarily an indicative of a failure in food handling practices resulting in foodborne illness. The Food Authority has proposed a number of criteria which can be used to assist in establishing the source of a *Cl. perfringens* gastroenteritis outbreak. Where possible, investigations should attempt to isolate the organism from both clinical and food specimens and/or test samples to determine the presence of the *Cl. perfringens* enterotoxin (cpe) gene and its location, either on the chromosome or the plasmid. The Food

Authority will continue to work with NSW Health in refining a decision tree for responding to suspected *Cl. perfringens* gastroenteritis outbreaks in aged care facilities.

Clostridium difficile

It is a hazard that was not considered in the Food Authority's 2009 risk assessment, as there was uncertainty surrounding whether this pathogen is foodborne in nature. This updated risk assessment provides an opportunity to assess the latest information available.

Cl. difficile is a Gram positive, anaerobic spore forming and toxin producing bacterium which can be isolated from 3 to 5% of asymptomatic persons in the community. The spores are resistant to heating, drying and alcohol-based disinfectants. *Cl. difficile* has historically been regarded as a typical nosocomial (hospital-acquired) pathogen, with hospitalisation one of the main risk factors for developments of infection (Rupnik, 2010). The organism is widely recognised as the cause of around 15-25% of antibiotic associated diarrhoea (AAD) and is normally associated with treatment of patients with broad spectrum antibiotics. Within this environment, hand contamination with spores is regarded as the most important transmission mode. This is similar in mechanism for AAD described for *Cl. perfringens* (NSW Food Authority, 2011).

Symptoms of *Cl. difficile*–associated diarrhoea range from mild non-bloody profuse diarrhoea, abdominal cramps and low-grade fever, to pseudomembranous colitis. Since 2003 there have been more severe outbreaks of *Cl. difficile*–associated diarrhoea with increased mortality rates, in addition to the typical cases seen in health care settings. These have been caused by a hypervirulent *Cl. difficile* strain in North America and Europe (Hansen and Olsen, 2009). There has also been an increase in the number of cases outside of the hospital and aged care sector occurring in the general community.

In a review article by Gould and Limbago (2010), the authors stated that while foodborne transmission of *Cl. difficile* has been hypothesised as a possible source for community-associated infections, the evidence to confirm or refute this hypothesis is incomplete. Data from food surveys conducted in countries around the world showed the organism could be isolated from a significant proportion of foods, but at relatively low numbers of spores (30-100 spores/g). Typing of these isolates shows there is significant overlap between strains of human and animal origin. However, Hansen and Olsen (2009) state that while it seems likely than an animal reservoir of *Cl. difficile* exists, there is no evidence that human *Cl. difficile* infections stem from such a reservoir.

In Australia, *Cl. difficile*–associated gastroenteritis is not a notifiable disease, so it is not easy to quantify the impact it is having within the healthcare or community settings. The health departments in Australia have used the emergence of the hypervirulent strain of *Cl. difficile* overseas to reinforce normal requirements for diligent infection control measures employed in hospitals and aged care facilities. If a patient is diagnosed with *Cl. difficile*–associated diarrhoea it is important to prevent further spread to other residents/patients by:

- isolating the affected patient(s),
- cleaning the environment with a suitable disinfectant capable of killing spores (such as hypochlorite),
- discontinuing antibiotic treatment, and
- ensuring healthcare staff practice good personal hygiene through hand washing with soap and water (since the spores are not killed by alcohol-based hand gels).

The Food Authority will continue to monitor overseas data on this emerging pathogen to determine the potential impact on food service in vulnerable persons businesses.

Other pathogens where increased prevalence or severity has been observed in the vulnerable population include:

- Enteropathogenic *E. coli* – strains of shiga toxigenic *E. coli* (STEC) are known to cause severe illness in infants and the elderly and can result in death (Desmarchelier and Fegan, 2003).
- *Staph. aureus* – while for the healthy populations staphylococcal food poisoning is rarely fatal, fatalities have been reported in infants and the elderly (Stewart, 2003).
- *Bacillus cereus* – fatal cases are very rare, when reported they have been linked to children with liver failure (Dierick et al, 2005).
- Viruses (norovirus, rotavirus) – rotavirus causes the majority of gastroenteritis in children and norovirus is well-known for outbreaks in hospitals, nursing homes and day-care centres worldwide (IUFoST, 2015).
- Parasites (*Cryptosporidium*, *Giardia*) – the highest incidence of intestinal parasitic infections is observed for children aged 1-9 years (IUFoST, 2015).

3.1.3 Allergens

In addition to the microbiological hazards considered in the Food Authority's 2009 risk assessment, this risk assessment also considers allergens. Hospital admissions for severe anaphylaxis have doubled over the decade to 2009 in Australia, USA and the UK. According to recent report by ASCIA (2016), food allergy occurs at much higher rates in children (around 1 in 20) than in adults (about 2 in 100). In Australia, admissions for anaphylaxis due to food allergy in children aged up to 4 years are even higher, having increased five-fold over the same period (ASCIA, 2016). Most children allergic to cow's milk, soy, wheat or eggs will be able to tolerate these foods before they reach school age, and often before. By contrast, allergic reactions to peanuts, tree nuts, seeds and seafood persist in the majority (~75%) of children affected (ASCIA, 2010). This risk assessment examines the control measures and management strategies necessary to minimise exposure to allergens.

3.1.4 Balancing risk management with quality of life

In examining the food safety hazards associated with food service to vulnerable persons and the control measures implemented by the Food Authority, it is vitally important to find the correct balance between the need to protect the patients/residents from foodborne hazards with maintaining a sufficiently nutritious and interesting diet. One aspect the technical review of the Food Authority's 2008 manual was to achieve a satisfactory balance between assuring food safety and ensuring that the quality of life was maintained. This was considered particularly important for elderly or long-term residents of aged care facilities. Within the Food Authority's 2008 manual, a 'foods at higher risk' list was documented. This list, combined with the circular *Control of foodborne listeriosis in health care institutions* issued in 2003 by the NSW Health Department (NSW Health, 2003), had anecdotally led to some facilities stopping serving several specific foods altogether, or extending cooking times to the extent that the food was less attractive and less palatable.

For aged care facilities, the American Dietetic Association (ADA, 2005) has the position that the quality of life and nutritional status of older residents may be enhanced by liberalisation of the available diet, rather than implementing restrictions. The Association advocates the use of qualified dietetics professionals to assess and evaluate the need for medical nutrition therapy according to each person's individual medical condition, needs, desires, and rights.

For hospitals, the nutrition standards published by NSW Health state that the overall goal is 'hospitals in NSW will provide safe, nutritious and appetising high quality meals of sufficient variety that meet the needs and expectations of patients and which are a model of nutritional best practice in institutional food service' (NSW Health, 2010a).

The approach to managing food safety in vulnerable persons facilities must consider there are significant differences between long-term care (e.g. aged care facilities) and acute care facilities (e.g. short stay visits in hospitals). Traditionally at-risk groups such as pregnant women have been targeted with risk communication messages detailing which foods they should avoid to minimise the risk of listeriosis from *L. monocytogenes* (FSANZ, 2005). However, this strategy is only required for a limited time, the nine-month duration of the pregnancy. Similarly, the average stay in hospital for a patient may be only 3-4 days and therefore a restricted diet may be tolerable in these situations.

However, some long-term care patients in hospitals (e.g. spinal patients), and residents living in an aged care facility are not in a short-term situation. The average length of stay for permanent residents in residential aged care (including low care) increased from 131.3 weeks to 147.8 weeks between 1998 and 2008 (Fitzpatrick, 2011). As such, the aged care facility becomes the person's home where he or she may live out their life, and any decisions taken to limit the diet will impact on the eating pleasure available to the resident for a significant portion of their remaining life. This can limit choice and may reduce the quality of life, having an adverse effect on health unrelated to food safety issues. The ADA emphasises the assessment of risks against the benefits of therapeutic diets, especially for frail older adults, with the acknowledgement that food is an essential component of quality of life (ADA, 2005).

An unacceptable or unpalatable diet for an elderly person can lead to poor food and fluid intake, resulting in weight loss and under nutrition, and a spiral of negative health effects. Malnutrition and poor nutrition increase the likelihood of infections, pressure ulcers, anaemia, hypotension, decreased wound healing and hip fractures, and contribute to confusion and impaired cognition (ADA, 2005).

The Food Authority must consider the risk management of foodborne illness in vulnerable persons facilities in a holistic way, and accept that it is not possible to fully eliminate all risk from foodborne sources without having a possible adverse effect on nutrition intake. This balance between implementing food safety control measures and managing nutritional intake is especially critical for those people in long-term care because of the focus on maintaining quality of life and general wellbeing.

This risk assessment has attempted to view the Food Authority's recommended control measures in the scheme with this outcome in mind, and provides the justification for the changes to the risk management of food served in these facilities. The aim is to achieve a liberalised diet while still achieving an appropriate level of protection for vulnerable persons in aged care and health care facilities.

3.1.5 Types of food service operations

Preparation methods within food service facilities for vulnerable persons vary considerably, with preparation of food undertaken in a variety of methods including:

- preparation and serving of raw or ready-to-eat (RTE) foods
- preparation and serving of freshly cooked foods (cook fresh or cook serve)
- preparation and serving of previously cooked foods without further heating (leftovers)
- serving of foods previously cooked using cook chill (with or without reheating).

The NRVP examined statistics from 1999 which counted 1190 hospitals in Australia serving 140 million meals annually (Food Science Australia & Minter Ellison Consulting, 2002). At the time, fewer than 20% of these institutions used contract caterers but it was observed that there was a significant trend to merge kitchens and move to cook chill operations from a central kitchen where chilled meals are plated, taken to wards and reheating

carts are plugged in at the ward level. The report also stated there were 3037 nursing homes/aged care facilities serving over 200 million meals across Australia annually. About 27% of these were catered for by small catering companies. Again, the trend at the time was identified as moving away from freshly cooked meals to cook chill provided by large catering companies. Similarly, the report found there was a wide range of operations and service types used to produce meals for delivery to housebound people (Table 4).

Assaf (2008) found that cook chill is a significant food service operation only in large hospitals while cooking for immediate service (cook fresh) is predominant in smaller hospitals. This tends to be the situation in the aged care industry also. Currently, there are only thirteen businesses licensed as central processing facilities in NSW (Table 5), some of which are doing extended shelf life cook chill using specialised systems such as CapKold®. However, these central facilities may supply a large number (>20) of smaller facilities with cook chill foods.

Since the NRVP report the trend to outsourcing food service operations to commercial caterers continues. A 2011 report states that hospitals, nursing homes and aged care centres continue to outsource their food service needs to operators in the catering and food service contractor industry. This is regarded as a growing market for the sector, with strict food safety and handling regulations stated as one reason prompting many health care institutions to outsource their catering requirements (Allday, 2011).

Table 4. Food service operations types for delivered meal organisations

Source	% of meals
Hospital supplied as hot	35.8
Cooked fresh in their own kitchen	24.9
Commercial caterer supplied in frozen form	22.3
Hospital supplied as cook chill	17.5
Cooked and frozen in their own kitchen	9.6
Commercial caterer supplied as cook chill	8.7
Cook chill in their own kitchen	6.6

Adapted from Food Science Australia & Minter Ellison Consulting (2002)

3.2 Exposure assessment

3.2.1 The number of facilities in NSW

As at May 2016, the Food Authority had 1471 facilities licensed under the Vulnerable persons food safety scheme in various categories (see Table 5). Note that this does not include childcare facilities, which are not covered under NSW Food Regulation 2015. There is an existing regulatory framework and local councils conduct food safety inspections of certain childcare facilities at least annually.

As mentioned previously, the current structure of the vulnerable persons food service industry is moving towards commercial caterers, with almost one third of facilities licensed by the Food Authority (517 out of 1471) contracting out all or some operations. There is an increase of 20% in the number of licensed commercial caterers since 2012. In some cases, a contractor is doing all or most of the handling of RTE potentially hazardous foods in a facility owned by a hospital or aged care facility.

Table 5. Licensed vulnerable persons facilities in NSW

Licence category	No. of licensed facilities
Facility operator processes and/or serves	863
Facility operator contracts out all processing and serving	232
Facility operator contracts out some activities	28
Contractor to a facility	257
CPU facility	13
Delivered meal organisations	65
Food for a delivered meal organisation	13
TOTAL	1471

Data from NSW Food Authority Byte licensing database – May 25, 2016

3.2.2 The consumption of high risk foods and number of meals served

Estimating the exact portion of the vulnerable population who are in care-type establishment that provide food and the number of meals served by these facilities is difficult, although there is some information that may be used to estimate potential numbers of both.

The more recent ABS data showed an 18% increase in the number of people aged 65 or older during five years (June 2009 to June 2014) in NSW and there were 1.2 million aged people at June 2014 (ABS, 2014).

The NSW Food Authority (2008b) surveyed other businesses included in the definition of Standard 3.3.1 – *Food safety program for food service to vulnerable populations* of the Code and found that:

- there were 1867 facilities in NSW as defined by Standard 3.3.1 (excluding childcare facilities),
- these facilities serve approximately 106,824,172 meals each year, and
- The 2009 RA conducted by the Food Authority estimated that vulnerable persons facilities covered under the food safety scheme served more than one hundred million meals each year (NSW Food Authority, 2009a). The number of facilities currently licensed with the Food Authority is slightly less than in 2009, most likely due to centralisation and outsourcing of meal preparation to professional catering companies. However, Fitzpatrick (2011) found that the number of facilities in the Australian nursing home sector has continued to increase by 1% per year. As such, the overall number of meals served by licensed facilities and their contractors is not likely to have changed significantly since the 2009 estimates.

Therefore, in total “food service to vulnerable populations” facilities would serve approximately 133 million meals per year in NSW. Approximately, 25% of these meals are provided by the 11 CPUs operating in the state at that time. It would be expected that some of the components of these meals may present a risk to sub-groups within the vulnerable population.

3.2.3 Prevalence of pathogens in food

Limited information is available on the prevalence of pathogens or other microorganisms in foods served to vulnerable populations. Other sections within this document provide some general information on the prevalence of microorganisms in certain commodities some of which would be served to vulnerable populations.

A study conducted by Gillespie et al (2001) looked at the microbiological quality of sliced cold RTE meats from catering establishments. They found that 26% of samples were categorised as unsatisfactory when compared to UK Public Health Laboratory Services microbiological guidelines, with 0.4% of samples categorised as unacceptable or potentially hazardous. Gillespie et al (2001) also compared the results of various food handling practices and found:

- A higher level of unsatisfactory or unacceptable results with product made external to the kitchen when compared to product made in-house
- A higher level of unsatisfactory or unacceptable results with product purchased pre-sliced when compared to product sliced in-house.

A review of ready-to-use vegetables from healthcare facilities found *L. monocytogenes* in 5/135 samples (3.7%) and found total bacterial levels similar to samples that had been subjected to temperature abuse scenarios (Odumeru et al, 1997).

During 2005 and 2006, Little et al (2008) undertook a study on the microbiological safety of sandwiches served in hospitals and other healthcare establishments in the UK. In this study, they found *L. monocytogenes* in 2.7% of 88 samples which included samples collected from wards. They also found a higher frequency of *L. monocytogenes* in sandwiches prepared outside the establishment, where the filling included poultry meat or contained salad ingredients, soft cheese and/or mayonnaise.

A recent report commissioned by the UK Food Standards Agency found pre-packed sandwiches were responsible for almost all *Listeria* outbreaks in hospitals since 2003. These findings prompted the Agency to revise its guidance to hospitals and care homes on minimising the risk of *Listeria* (UKFSA, 2016).

During the previous evaluation of the vulnerable persons food service sector, the Food Authority tested 342 samples of food in 2003 (Table 6). During the development of Food Regulation 2010, a follow up evaluation was conducted which included a survey of 347 samples of food served to vulnerable persons in 60 facilities (Table 7)

Of the samples taken in the 2009 evaluation survey, 342 out of 347 (98.5%) were categorised as good or acceptable when assessed against the Food Authority's microbiological guidelines (NSW Food Authority, 2009b). Of the products considered unsatisfactory, one was a puréed vegetable meal with levels of *Bacillus cereus* greater than 1000 cfu/g, indicating potential issues with equipment sanitation and/or product temperature abuse. The other three samples categorised as unsatisfactory were all sliced RTE meats, with a total plate count greater than 10^7 cfu/g. The one sample categorised as potentially hazardous was a commercially produced custard which contained *L. monocytogenes*. A product recall of the custard was undertaken in NSW and Queensland due to this result. *Cl. perfringens* was not detected in any of the 229 samples tested for this organism (cooked and puréed vegetables and meat, and cooked desserts).

In comparing the results with the 2003 survey, there was considerable improvement in the microbiological standards for sandwiches. All sandwiches tested in 2009 were categorised as good or acceptable. This is encouraging, as sandwiches served in hospitals have been the subject of several surveys in the UK after four of seven listeriosis clusters were epidemiologically associated with sandwiches. Meldrum and Smith (2007) found the

overall positive rate for *L. monocytogenes* in UK hospital sandwiches was 27 out of 950 (2.84%) for enriched culture and 2 out of 950 (0.21%) for direct counts (the lower limit for detection being 20 cfu/g). One sandwich was above the unsatisfactory level of >100 cfu/g, with a count of 1200 cfu/g. The overall positive findings of the UK survey lead the authors to conclude that hospital sandwiches generally presented a low hazard to consumers. An interesting observation was that sandwiches made off site were more likely to be contaminated than sandwiches made at the facility. In early 2011 another cluster of three cases of listeriosis occurred in the Midlands region of England where consumption of pre-packed sandwiches from an external supplier was implicated as the cause (Coetzee et al, 2011).

Table 6. Microbiological results from NSW Food Authority 2003 evaluation

Food group	No. of samples	Microbiological quality			
		Good	Acceptable	Unsatisfactory	Potentially hazardous
Sandwiches	39	22	6	11	-
Salad	23	13	6	4	-
Fruit salad	10	10			-
Cooked dessert	62	57	2	3	-
Vegetables	36	36	-	-	-
Puréed vegetables	53	51	2	-	-
Meat	84	84	-	-	-
Puréed meat	35	33	1	1	-
TOTAL	342	306 (89.5%)	17 (5.0%)	19 (5.5%)	-

Adapted from NSW Food Authority (2004)

Table 7. Microbiological results from NSW Food Authority 2009 evaluation

Food group	No. of samples	Microbiological quality			
		Good	Acceptable	Unsatisfactory	Potentially hazardous
Sandwiches	47	45	2	-	-
Fresh-cut fruit	16	16	-	-	-
Salad	15	15	-	-	-
Cooked meat	47	46	1	-	-
Puréed meat	36	33	3	-	-
Cooked vegetables	33	32	1	-	-
Puréed vegetables	63	60	2	1	-
Cooked dessert	36	33	2	-	1
Sliced RTE meat	14	10	1	3	-
Other	40	39	1	-	-
TOTAL	347	329 (94.8%)	13 (3.7%)	4 (1.2%)	1 (0.3%)

Adapted from NSW Food Authority (2010a)

3.3 Hazard characterisation

3.3.1 Not all vulnerable persons are the same

Similar to the Code definition, the US FDA Food Code (FDA, 2009) defines highly susceptible population as persons who are more likely than other people in the general population to experience foodborne disease because they are:

- immunocompromised, preschool age children, or older adults, and
- obtaining food at a facility that provides services such as custodial care, health care, or assisted living, such as a child or adult day care centre, kidney dialysis centre, hospital or nursing home, or nutritional or socialisation services such as a senior centre.

Therefore, both the *Code* and the FDA Food Code similarly define vulnerable/highly susceptible persons as all persons who are in the care of these types of facilities. However, it is increasingly acknowledged that the susceptibility to foodborne illness will vary considerably across patients/residents located within a vulnerable persons facility, and the food safety control measures required to protect these people can also vary considerably.

The original guidance material for hospitals and aged care prepared by the Food Authority and the Food Authority's 2008 manual tended to recommend the most stringent requirements for application to all vulnerable persons. In reality, three distinct groups of vulnerable persons can be defined that have different food safety requirements based on their medical conditions and relative susceptibility to foodborne illness. As such, different diet restrictions may be successfully applied based on the degree of susceptibility (Table 8).

The degree of susceptibility to foodborne illness (particularly listeriosis from *L. monocytogenes*) ranges from partially vulnerable to what the Institute of Life Sciences Institute (ILSI, 2005) refer to as 'exquisitely sensitive consumers' (Group 3 in Table 8).

For the exquisitely sensitive consumers there is potential for them to become ill when exposed to low numbers of *L. monocytogenes* or other opportunistic pathogens and for more severe outcomes to occur. As such, the primary control measure for reducing the risk to this population may be a restricted low microbial diet (LMD) during those periods when they are most severely immunocompromised (ILSI, 2005). This will minimise the risk of exposure to opportunistic pathogens which have the potential to cause illness in people who are highly immunocompromised. This is discussed further in Section 4 and Appendix 1.

Table 8. Susceptibility groupings for determination of diet

Grouping	Susceptibility
Group 1 Low risk	Located within a vulnerable persons facility but condition does not belong to an 'at-risk' group (e.g. mental health or 'osteo' patients). This group may be fed an unrestricted diet prepared in accordance with the Code requirements with no additional precautions.
Group 2 Increased risk	At increased risk of contracting foodborne disease, such as pregnant women, elderly, mildly immunocompromised patients and those with heart disease. This would form the majority of the hospital and aged care population. Some control measures need to be implemented to satisfactorily address the hazards present in some foods. A food safety program implementing control measures is required for the preparation of this 'ward diet'.
Group 3 Highest risk Neutropenic patients	At high risk of contracting a foodborne disease (e.g. patients undergoing transplantation or experiencing transplant complications, severely immunosuppressed). These patients have historically been fed a low microbial diet when the immune system is severely suppressed to prevent infection. The evidence for the effectiveness of a low microbial diet in limiting infections in neutropenic patients (e.g. neutrophil counts <1,000 cells/µL) has been discussed in many publications, but a low microbial diet has been included in the Therapeutic diet specifications for adult inpatients (NSW Health, 2010b).

Adapted from: Dykewicz (2001); NSW Health (2010b); Mank and Davies (2008); Mank et al (2008); Pentland (unpublished); Restau and Clark (2008); van Tiel et al (2007); Tomblyn et al (2009)

Table 9. Factors that increase the susceptibility of the elderly to foodborne illness

Age-induced decrease in stomach acid production allows ingested pathogens to enter the intestinal tract
Age-induced decrease in cellular and humoral immunity due to decreased T-cell activity decreases resistance to pathogens
Age-induced decrease in peristalsis (as well as use of anti-motility drugs) does not allow the speedy elimination of enteric pathogens. The resulting proliferation of pathogens in the gut allows toxin formation and/or attachment and damage to the intestinal wall
Decreased food consumption and poor nutrition may lead to nutritionally acquired immunodeficiency syndrome (NAIDS) which, combined with the normal age related decrease in immune function places an additional strain on the immune system's ability to fight pathogens
The nursing home environment, the morbid conditions of nursing home clientele, intense use of antibiotics in nursing homes, and the poor personal hygiene practised by some nursing home residents facilitates spread of infection
The high percentage of elderly who are too poor to have adequate nutrition and medical care

Adapted from Smith (1998)

Group 2 from Table 8 have a higher risk of listeriosis than the healthy population, but are less sensitive to *L. monocytogenes* than the exquisitely sensitive consumers. This group includes pregnant women, diabetics, those on kidney dialysis and elderly with no underlying immunosuppressive conditions. For the elderly, the susceptibility to other foodborne pathogens may also increase due to age-induced factors (Table 9). Healthy individuals under 65 years of age have a minimal risk of listeriosis and are in general less susceptible to foodborne pathogens (Group 1).

While there is the need to strictly control foodborne hazards for those vulnerable persons listed as Group 3 in Table 8, exactly defining the control measures to satisfactorily manage the range of susceptibilities across Group 2 provides a challenge in terms of managing risk. Defining who is vulnerable and most susceptible to foodborne pathogens can be problematic due to the differing degree of vulnerability from one person to the next and the varying degrees of virulence of some pathogenic microorganisms to different vulnerable sub-populations.

Therefore, while the term 'vulnerable persons' is used within the Code to describe all people served food within health care and aged care facilities, the reality is that there is a significant range of susceptibilities across this group of people within those facilities. The Food Authority has previously never made any distinction between the susceptibility of vulnerable persons, instead taking a 'one size fits all approach' to food safety in health care and aged care facilities. The Food Authority's approach now has been adapted so that resources are focused on reducing the risk associated with high risk foods served to the highest risk consumers, rather than treating all foods and all consumers as equally risky.

3.3.2 Foodborne outbreaks 1995-2010

The Food Authority's 2009 risk assessment reviewed the foodborne disease outbreak data from 1995 to 2008 and found the most common organisms implicated in hospital and aged care facility outbreaks were *Salmonella*, *Cl. perfringens*, *L. monocytogenes* and *Campylobacter* (NSW Food Authority, 2009a). Between 1995 and 2008, there have been 67 foodborne illness outbreaks across Australia involving establishments that serve food to vulnerable populations, with 1138 illnesses, 64 hospitalisations and 12 fatalities (Table 10). From the available data

it appeared that inappropriate food handling practices may have been a contributing cause to many of these outbreaks. The gastroenteritis outbreaks in vulnerable persons facilities during 2009-2010 are shown in Table 11.

The overall proportion of illness in hospitals and aged care facilities due to foodborne sources may actually be quite a small proportion of the overall infection load. A review article by Utsumi et al (2010) examined infectious outbreaks in elderly care facilities from a variety of sources, including respiratory and gastrointestinal infections. The authors found that infections of the respiratory tract accounted for 45% of the 206 outbreaks reported, gastrointestinal infections 36%, skin infections 7% and eye infections 2%. Of the gastrointestinal infections, the main causes were found to be norovirus, *Cl. perfringens*, rotavirus, *E. coli*, *Shigella* and *Salmonella* (no information was included whether these were considered to be foodborne). Listeriosis was not mentioned in the review. The mean attack rates for *Cl. perfringens* was 48% for residents, while for norovirus the attack rate was 45% for residents and 42% for staff. For *E. coli* the mean attack rate was 31% for both staff and residents, demonstrating significant person-to-person spread of the infection. Outbreaks of gastroenteritis in elderly care facilities were found to last from one day up to 90 days.

Table 10. Summary of foodborne illness outbreaks attributed to food served to vulnerable persons

Hazard	Australian outbreaks (1995-2008)	Cases	Hospitalisations	Deaths
Salmonella spp.	23	395	43	4
Cl. perfringens	10	267	1	1
Campylobacter spp.	7	101	6	0
L. monocytogenes	5	24	5	7
Norovirus	4	111	0	0
Toxin	3	44	1	0
Viral	3	38	0	0
B. cereus	1	19	0	0
Staph. aureus	1	7	0	0
Cryptosporidium	1	4	0	0
Pathogenic *E. coli*	1	2	0	0
Unknown	8	126	8	0
TOTAL	67	1138	64	12

Table 11. Gastroenteritis outbreaks attributed to vulnerable persons facilities 2009-2010

Hazard	Australian outbreaks (2009-2010[1])	Cases
Salmonella spp.	10	118
Cl. perfringens	8	159
Campylobacter spp.	1	5
Norovirus	1	17
Unknown	7	53
TOTAL	27	352

An outbreak in 1998-99 in aged care facilities and hospitals in the Hunter Valley, NSW highlighted the risks of listeriosis from foods served in these establishments. The implicated food was fruit salad and the outbreak affected 9 patients, with 6 deaths resulting. All patients were elderly, and some had underlying conditions making them more susceptible to infection with *L. monocytogenes*. All the establishments served food prepared in a central catering facility (Food Science Australia & Minter Ellison Consulting, 2002). One sample of fruit salad subsequently tested positive for low levels (<50 cfu/g) of *L. monocytogenes*, a level considered unlikely to cause illness, even in immunosuppressed individuals.

A survey was undertaken by OzFoodNet during 2007-08 of gastroenteritis in 16 aged care facilities (a total of 567,894 bed days) in NSW. This found 411 episodes of infectious gastroenteritis (not limited to foodborne) in 366 persons during the study period, including 20 outbreaks of gastroenteritis resulting in 384 episodes of gastroenteritis. The cause was known for eight of the outbreaks, with norovirus affecting 233 people in six outbreaks and *Cl. perfringens* affecting 77 people in two outbreaks. Few of the outbreaks examined in this study were shown to be food related. The study showed that the incidence of gastroenteritis in residents of aged care facilities in NSW was 0.21 episodes per year. This incidence is lower than for elderly people living in the community, where people aged 65 years and older experience approximately 0.4 episodes per person per year (Kirk, 2009).

In contrast, Smith (1998) examined statistics on foodborne illness from the US and found that *Staph. aureus* and *Cl. perfringens* were more common in nursing home populations than in the general population. In the US, rates of foodborne illness can be 10 to 100 times greater for elderly people within nursing homes when compared to the general population, and the elderly are more vulnerable to gastroenteritis-induced deaths (Table 12).

[1] 2010 data up till March 2010 as published by OzFoodNet. 2009 data include 18 cases from a childcare centre which are not currently covered under Food Regulation 2010

Table 12. Comparable death rates from foodborne disease in the US

Pathogen	Deaths per thousand cases	
	General population	Nursing home population
Campylobacter	2.1	11.1
Cl. perfringens	0.46	4.0
Escherichia coli O157:H7	21.8-26.8	117.6
Salmonella spp.	1.5	37.8
Staph. aureus	0.0	3.9

Adapted from Smith (1998)

Viruses are a significant and emerging cause of gastroenteritis in hospitals and aged care facilities. Koopmans and Duizer (2004) noted that the majority of outbreaks of gastroenteritis in institutions, such as nursing homes and hospitals, are likely to be caused by viruses potentially resulting from person to person spread.

Previous sections of this document provide some insight into the factors why some groups within the population are more vulnerable to foodborne illness than others. This can be further illustrated by reviewing foodborne illness surveillance data. Table 13 provides a breakdown on the percentage of outbreaks reported to have occurred in facilities serving food to the vulnerable populations. Based on NSW Food research (2008a) and ABS data (ABS, 2005; ABS, 2008), the percentage of the NSW population within facilities catering to vulnerable populations is approximately 2.5%. When this is compared to the figures in Table 13, foodborne illness affecting individuals in facilities catering to vulnerable populations are over-represented compared to the entire population which may be an indication of their increased vulnerability.

Table 13. Institutional foodborne illness outbreaks as a percentage of all outbreaks

Year	Outbreaks (% of total)	Cases (% of total)	Hospitalisation (% of total)	Deaths (% of total)
2001	5.8%	2.9%	1.4%	NR[2]
2002	8.7%	5.6%	4.8%	50%
2003	15.1%	16.2%	32.4%	66.7%
2004	9.3%	8.1%	24.1%	NR
2005	12.7%	10.3%	6.0%	NR
2006	6.1%	6.4%	24.6%	NR

Adapted from outbreak data from OzFoodNet 2002-2006 (OzFoodNet Working Group, 2003; 2004; 2005; 2006; 2007)

[2] NR – not reported

3.3.3 Recent foodborne illness outbreaks involving food service establishments for vulnerable populations

An overview of recent foodborne outbreaks that affected aged people in NSW is presented in Table 14.

Table 14. Foodborne illness outbreaks associated with aged care facilities in NSW (2010-2016)

Year	Outbreaks	Cases	Hospitalisation	Deaths
2010	4	33	1	0
2011	0	0	0	0
2012	1	3	2	0
2013	1	3	3	1
2014	3	22	2	0
2015	1	30	12	2
2016[3]	2	12	3	0

Adapted from outbreak data published in NSW OzFoodNet reports 2010-2016.

One of the recent aged care outbreaks in NSW was significant. During a *Salmonella* poisoning outbreak in 2015, thirty people fell ill at 10 aged care centres in the Illawarra, southern Sydney and the ACT. Most of the cases were reported in the residents of centres run by an aged care provider. This outbreak had two fatalities. The Food Authority and ACT Health conducted rigorous scientific testing at the affected aged care centres and found *Salmonella* in food distributed by the catering arm of the aged care provider to its nursing homes. This outbreak indicated the loophole in overall implementation of the scheme and recent changes in the food supply to hospitals and aged care facilities. Food safety guidelines for the contract suppliers to vulnerable persons facilities are needed.

In New Zealand, four cases of listeriosis were recorded during an outbreak of *Listeria* in Hawke's Bay in 2012. Among the infected people, two were elderly and died while other two recovered. Hawke's Bay District Health Board (DHB) worked closely with the Ministry for Primary Industry (MPI) to establish the source of the outbreak. *L. monocytogenes* was detected in RTE meats supplied to the hospital. The outbreak sent fresh warning to be very aware of food safety risks, particularly to those who fall within the immune compromised group, elderly or pregnant. It is important to note that Hawke's Bay hospital was registered under the Food Hygiene Regulations 1974 and operates a food safety program.

In a global context, Lund (2015) listed outbreaks in EU and US that affected vulnerable persons and outlined the implicated foods (Table 15). Facts based analysis revealed that the most of the foodborne outbreaks are caused by well-known factors and loop-holes in the implementation of the food safety plans. Factors such as food from unsafe sources, inadequate cooking, improper holding temperatures, contaminated equipment and cross-contamination, and poor personal hygiene are frequently identified in post-outbreaks investigations. Majority of the outbreaks were associated with consumption of raw or rare meat or raw goat's milk or fresh produce.

[3]Based on data for quarters 1 and 2. Data for quarters 3 and 4 is not available yet.

Table 15. Examples of foodborne outbreaks and contributing factors in vulnerable populations in EU/USA

Place, Date	Pathogen	Setting	Cases {Hospitalized} (Deaths)	Food Implicated	Factors Leading to Outbreaks
Austria, 2006	*C. jejuni, C. coli*	Tertiary care hospital	7 (0) patients, 14 staff (0)	Poultry dishes	Prepared in hospital kitchen with no HACCP system in place
UK, 2011	*C. jejuni, C. coli*	Wedding party	49 {0} (0)	Chicken liver-pâté	Undercooked (cooked to 60 °C)
USA, 2012	*C. jejuni*	Community	148 {10} (0)	Unpasteurized milk	No inactivation
USA, 2012	*C. jejuni*	Community	6 {2} (0)	Chicken liver	Undercooked
USA 2001	*Clostridium perfringens*	Residential care facility for mentally ill	7 {2} (2) Deaths associated with constipation resulting from medication	Thanksgiving meal with turkey	Large amount of food prepared well in advance of serving
UK, 2005	*Clostridium perfringens*	Buffet lunch at event	54 {nr} (nr)	Chicken curry	Prepared in a domestic kitchen, not registered with local authority, bulk of cooked curry left to cool at ambient temperature for ~10 h.
USA, 2010	*Clostridium perfringens*	Psychiatric hospital	42 (3) patients, 12 (0) staff. Deaths associated with impaired intestinal motility	Cooked chicken	Cooked ~24 h before serving, not cooled adequately
USA, 2012–2013	*E. coli* O157	Community	17 {0} (0)	Raw ground beef	Traditional practice, previous outbreaks.
Germany, 2011	*E. coli* O104:H4	Community	3816 {~800} (54)	Raw, sprouted seeds (fenugreek)	Difficult to disinfect before sprouting.
USA, 2012	*E. coli* O157	Schools, daycare, long-term care facilities	17 {6} (2)	Packaged salad lettuce	Possible contamination during growth in field
Denmark, 2009	*Listeria*	Meals-on-wheels	7 {7} (2)	Sliced beef with sauces and vegetables, intended for microwave cooking by consumer	Beef had been cooked by the supplier at a lower temperature than usual. Four patient had cancer, one had systemic lupus erythematosus, three were aged >80
Austria, Germany, Czech Republic 2009–2010	*Listeria*	Community	34 {nr} (8)	'Quargel' cheese (Red smear cheese)	Cheese made with pasteurized milk, but contamination probably occurred when cheeses were coated with a culture of *Brevibacterium linens*: subsequent holding at 12 °C–16 °C probably allowed multiplication of listeria
USA, 2010	*Listeria*	Five hospitals	10 {5} (5)	Diced celery, often in sandwiches.	Probably contaminated in the field
USA 2010–2015	*Listeria*	Hospital	10 {10} (3)	Milkshakes made with ice-cream product	Unsatisfactory hygiene in factory producing ice-cream
Denmark, 2005	Norovirus	Hospital, nursing homes, meals-on-wheels service, restaurant, company canteen	>1000 {~400} (0)	Imported frozen raspberry pieces,	Contamination during growth/harvesting on small farms
Germany, 2012	Norovirus	Mainly schools and canteens	~11,000 {38} (0)	Imported frozen strawberries	Possible contamination during growth/harvesting
Denmark, Finland, Norway, Sweden, 2013	Hepatitis A virus	Community	>106 {nr} (nr)	Imported frozen strawberries	Possible contamination during growth/harvesting
Austria, 2009	Norovirus	Hospital, rehabilitation centre and convalescent home	114 (0) Patients and staff affected	Sliced cold sausage; meat dish with salad; spinach pancake	Contamination by one of five asymptomatic excreters among kitchen staff who prepared food. No HACCP in place
UK, Norway, France, Sweden, Denmark, 2010	Norovirus	Mainly restaurants	334 cases, 65 clusters {nr} (nr)	Oysters	Probably contaminated in oyster-growing areas and inadequately cooked
Denmark, 2005	*S.* Typhimurium DT104*	Restaurant	40 {11} (0)	Carpaccio (thinly sliced, raw fillet of beef)	Imported, contaminated beef uncooked
Netherlands, 2005	*S.* Typhimurium DT104*	Community, food from mobile caterers a risk factor	169 {0} (0)	Steak tartare (raw, minced beef)	Imported, contaminated beef uncooked
Germany, The Netherlands 2011	*S.* Newport	Rehabilitation clinic and Asian restaurants in Germany, hospital in the Netherlands	126 {30} (0)	Mung bean sprouts	Sprouts served raw or undercooked
Netherlands, 2012	*S.* Thompson	Community	>1149 {>46} (>4)	Smoked salmon	Transport of salmon on reusable, porous dishes on processing lines.
UK, 2014 (part of multinational outbreak)	*S.* Enteritidis	Hospital canteen, (patients, staff and visitors affected),three restaurants	287 {78} (1)	Eggs from a German producer	Not reported, probably undercooked

* MDR = multi antibiotic-resistant; nr = not reported.

Adapted from Lund (2015)

3.3.4 Food service operations

Food service operations by establishments preparing foods for vulnerable populations can undertake a variety of methods to prepare these foods. The types of operations can include:

- Preparation and plating of raw or RTE foods
- Preparation and plating of previously cooked foods without further heating
- Preparation and plating of freshly cooked foods
- Reheating and plating of foods previously cooked using:
  - Cook chill for short shelf life (SSL), or
  - Cook chill for extended shelf life (ESL).

There are also some other specific operations for certain sub-groups that present specific hazards and will influence the risk to the vulnerable populations. Examples of these include:

- Visitors to some establishments (e.g. hospitals, aged care facilities) bringing food to patients or residents, some of which can present a risk to the sub-population (Wall, 2008)
- Texture-modified or puréed foods provide the opportunity for recontamination of cooked foods due to improperly cleaned and sanitised equipment (Tallis et al, 1999)
- Extended storage and handling of reconstituted infant formula can increase the risk of foodborne illness in infants due to *Cr. sakazakii* (Lehner and Stephan, 2004).

In addition to these operations, food establishments may also purchase some foods or meals ready cooked, which then require little or minimal handling by the establishment.

The hazard and subsequent risks associated with the foods served to the vulnerable populations will be influenced by the type of operations they undertake. For example:

- Inadequate control of the cook chill process (e.g. poor cooling rates, improper storage temperatures and inadequate reheating) can result in the growth and survival of pathogenic microorganisms (Cox and Bauler, 2008).
- Improper storage time and temperature of RTE foods that require no further heat treatment can result in the growth of *L. monocytogenes* (ILSI, 2005).
- Inadequate cooking and poor post-cooking temperature growth can result in the survival and subsequent growth of pathogenic microorganisms (Cox and Bauler, 2008).
- For foods served raw, inadequate control steps to minimise the presence of pathogenic microorganisms and inhibit their growth during storage (Desmarchelier and Fegan, 2003; Sutherland et al, 2003).

In a project conducted by the Food Authority on risk and control in licensed CPU facilities (FA2.1-7) in 2016, all CPU facilities licensed under the Vulnerable persons food safety scheme were inspected for compliance with the Standard 3.3.1. The project examined the controls recommended by the Food Authority's *Guidelines for food service to vulnerable persons*, the Food Authority's policies for food service sector, food safety policies or procedures developed by the facilities, and routine auditing of these facilities (NSW Food Authority, 2016a). There were 11 licensed facilities producing over 90,000 meals per day in NSW.

The project report identified several issues with the audit and compliance of the food safety programs (FSPs) of the CPU facilities and overall operation and regulation of the food service sector for vulnerable persons. Some examples of the major CARs raised at the inspections in relation to FSP are as follows:

- 45% of facilities had not adequately examined their food handling operations to identify potential hazards
- 45% of facilities had not systematically identified all hazards (physical, chemical, microbial, allergens etc.) for all production steps occurring at the facility
- 91% of facilities had not implemented adequate control measures for all identified hazards
- 91% of facilities did not have appropriate validation references for their critical limits

It must be noted that the CPU project used specially developed auditing protocol. The CPU facilities (11) represent a small fraction of total licenced businesses (2121) in the sector. Compliance rate of the sector with food safety program was 98% in 2015-2016 (NSW Food Authority, 2016b).

Key recommendations made in the project report:

1. Number of facilities identified
   - Development of a technical document is needed to more clearly define the types of facilities that are classified as CPUs.
   - List of processes and activities need to be added to each category of VP license.
2. Audit time vs inspection time
   - Determination of minimum audit hours for CPU facilities to ensure thorough audit reports.
   - Updates are required in the Food Authority's Field Staff Operations Manual (FSOM) and Third Party Auditors (TPA) manuals for audit hours for all TPA auditable license permissions.
3. Examination of FSPs
   - Ensuring the TPA manuals contain sufficient information regarding review of FSP for accuracy.
   - Each year inspections need to be conducted 6-8 weeks after audit by TPA or NSWFA auditor.
   - Inspections should be used to verify both the activities of the facility and the TPA auditors' performance at the audit

The report also included several recommendations to improve the understanding and control of allergens, traceability and recall, approved suppliers, RTE Meat & RTE foods for the CPU staff members and TPA auditors through the development of technical documents and workshops on these specific issues.

3.4 Risk characterisation

As stated earlier, impact and severity of the health risk on vulnerable people due to different hazards is highly dependent on the nature of hazard and sub-group. A summary of general health risks to vulnerable people is given in the Table 16. Risks of some specific illnesses are described in following sections.

3.4.1 Risk of listeriosis

The main hazard affecting the vulnerable population that has been studied is *L monocytogenes*. FAO (2004) published a risk assessment on *L. monocytogenes* in RTE foods that assessed the relative susceptibility of different groups within the population to listeriosis (Table 17). From this table, the sub-groups within the vulnerable population are more susceptible to listeriosis and in turn the food served to them presents a greater risk of foodborne illness than the food consumed by the general population.

The high risk associated with listeriosis in establishments serving foods to the vulnerable population has also been noted in the NRVP (Food Science Australia & Minter Ellison Consulting, 2002). In this report the authors ranked *L. monocytogenes* and foodservice operations for sensitive populations as the highest risk rating due to the ability of the pathogen to grow at refrigeration temperatures and the high mortality and hospitalisation rates associated with the listeriosis infection.

In their risk assessment on *L. monocytogenes* in RTE foods, the FDA/USDA (2003) estimated the number of cases of listeriosis per serving and per annum for different food categories for certain sub-groups of the vulnerable population. Assuming similar consumption rates in Australia and using Australian population figures, the potential number of listeriosis cases per year within Australia for each food category can be estimated.

It can be seen from this data that the risk of contracting listeriosis from any single serving of food is extremely rare, even for the highest risk foods (e.g. deli meats, estimated cases are 3.0×10^{-7} per serve for the elderly, therefore 30 million serves of deli meats would result in 1 case of listeriosis). However, when combined with the number of meals consumed by the elderly each year (not only those residing in facilities), there is the potential for 70 cases of listeriosis each year. Due to the control measures initiated by establishments serving vulnerable populations, the number of people exposed to *L. monocytogenes* is likely to be much lower.

Goulet et al (2012) calculated the impact of specific underlying conditions on the occurrence of listeriosis using several measures: mean incidence rates per 100 000 persons with the underlying condition, risk ratios that compared these incidence rates to the incidence rate of a reference population of persons <65 years of age with no underlying conditions, number of deaths by underlying condition reported among cases of listeriosis, and case-fatality ratios of listeriosis by group of persons with underlying condition. Ranking of population at risk for listeriosis is given in the Figure 1. Liver cancer, chronic lymphocytic leukaemia, lung cancer and pancreatic cancer patients were identified at high risk of listeriosis with fatal outcome.

Table 16. Health risks of different hazards to vulnerable persons

Health risk	Consequences
Listeriosis	Elderly: High case-fatality rates Pregnant women: Foetal loss, stillbirth, birth of severely infected infant Chronic patients: High rate of mortality Low immune: High rate of mortality
Toxoplasmosis	Pregnant women: Miscarriage, stillbirth, preterm birth Infants: Neurologic disorder (mental retardation and visual impairment) HIV/AIDS patients: Encephalitis, early death
Salmonellosis	HIV/AIDS: Prolonged diarrhoea, multiple recurrences, septicaemic and metastatic infection, high case-fatality rates Organ transplant patients: Bacteraemia
Botulism	Infants: Neurotoxicity
Cr. sakazakii infection	Infants: Meningitis, bacteraemia, urinary tract infections, wound infections Immunocompromised adults: Infection
V. vulnificus infection	Liver disease patients: Septicaemia
Hepatitis E Virus	Liver disease patients: High rate of mortality
Mercury poisoning	Pregnant women: Harm to an unborn baby Infants: Harm to young child's developing nervous system

Table 17. Estimated cases of listeriosis for vulnerable population sub-groups for each food category

Product	Intermediate age[3]		Elderly		Perinatal	
	Per serve[4]	Per annum[5]	Per serve	Per annum	Per serve	Per annum
Dairy						
Pasteurised fluid milk	4.4×10^{-10}	2.6	3.4×10^{-9}	4.2	1.5×10^{-7}	0.7
High fat and other dairy products	1.0×10^{-9}	1.4	8.3×10^{-9}	2.9	3.2×10^{-7}	0.3
Soft unripened cheese	5.8×10^{-10}	0.2	4.9×10^{-9}	0.4	2.0×10^{-7}	0.04
Unpasteurised fluid milk	2.9×10^{-9}	0.09	2.2×10^{-8}	0.1	9.9×10^{-7}	0.03
Fresh soft cheese	1.2×10^{-10}	<0.01	1.0×10^{-9}	<0.01	4.2×10^{-8}	<0.01

3 Intermediate age includes susceptible populations not captured in other groups (e.g. cancer, AIDS and transplant patients).

4 The risk per serving is inherent to the particular food category, and is therefore assumed to be the same in Australia as that calculated for the USA (FDA/USDA, 2003). This is based on the assumption that consumption patterns for these foods are identical in Australia and the USA.

5 The risk per annum has been adapted from USA population data contained in the FDA/USDA (2003) risk assessment of 260 million and extrapolated to Australian population data of approximately 21.6 million (ABS, 2009) by dividing by a factor of 12.

Product	Intermediate age[3]		Elderly		Perinatal	
	Per serve[4]	Per annum[5]	Per serve	Per annum	Per serve	Per annum
Ice-cream/frozen dairy products	1.3×10^{-14}	<0.01	9.2×10^{-14}	<0.01	6.5×10^{-12}	<0.01
Processed cheese	1.4×10^{-14}	<0.01	9.3×10^{-14}	<0.01	6.7×10^{-12}	<0.01
Hard cheese	3.4×10^{-15}	<0.01	9.2×10^{-15}	<0.01	8.1×10^{-13}	<0.01
Cultured milk products	9.5×10^{-15}	<0.01	5.6×10^{-14}	<0.01	4.7×10^{-12}	<0.01
Soft ripened cheese	2.1×10^{-12}	<0.01	2.2×10^{-11}	<0.01	1.3×10^{-9}	<0.01
Semi-soft cheese	$2.9x\ 10^{-12}$	<0.01	3.0×10^{-11}	<0.01	1.6×10^{-9}	<0.01
Meat						
Deli meats	3.3×10^{-8}	49.1	3.0×10^{-7}	70.8	1.2×10^{-5}	13.4
Pâté and meat spreads	1.2×10^{-8}	0.1	1.1×10^{-7}	0.2	4.5×10^{-6}	0.03
Frankfurters (reheated)	2.7×10^{-11}	<0.01	2.7×10^{-10}	0.02	1.6×10^{-8}	<0.01

Product	Intermediate age[3]		Elderly		Perinatal	
	Per serve[4]	Per annum[5]	Per serve	Per annum	Per serve	Per annum
Dry/Semi-dry fermented sausages	6.0×10^{-12}	<0.01	6.2×10^{-11}	<0.01	3.7×10^{-9}	<0.01
Plant Products						
Fruit	5.0×10^{-12}	0.02	5.1×10^{-11}	0.05	2.8×10^{-9}	<0.01
Vegetables	8.4×10^{-13}	<0.01	8.2×10^{-12}	<0.01	4.8×10^{-10}	<0.01
Deli type salads	1.7×10^{-13}	<0.01	1.4×10^{-12}	<0.01	8.8×10^{-11}	<0.01
Seafood						
Cooked RTE crustacean	2.2×10^{-9}	0.08	1.9×10^{-8}	0.1	7.4×10^{-7}	0.03
Smoked seafood	2.1×10^{-9}	0.03	1.9×10^{-8}	0.07	8.4×10^{-7}	<0.01
Raw seafood	1.3×10^{-11}	<0.01	1.3×10^{-10}	<0.01	6.7×10^{-9}	<0.01
Preserved seafood	6.4×10^{-12}	<0.01	6.7×10^{-11}	<0.01	4.1×10^{-9}	<0.01

Adapted from FDA/USDA (2003)

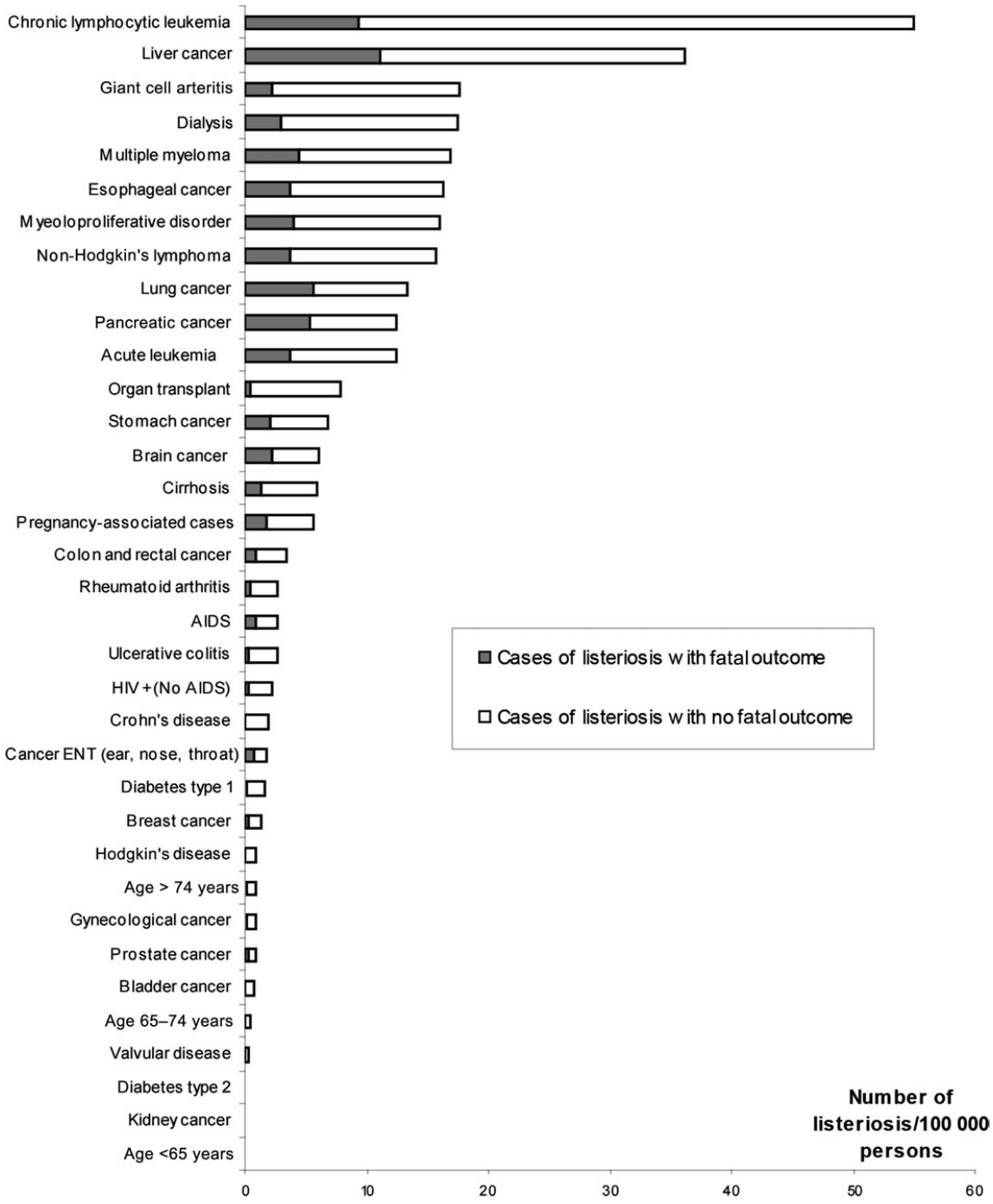

Figure 1. Ranking of population at risk for listeriosis by incidence of listeriosis (adapted from Goulet et al, 2012)

3.4.2 Risk of foodborne illness associated with *Cl. perfringens*

A risk profile published by Meat and Livestock Australia (2003) examined the risk posed by *Cl. perfringens* in institutional meals for the aged care where food safety programs have been implemented. In determining the risk, factors such as severity, probability, and the effect of processing and handling were considered. From this information, it was concluded that the risk rating of *Cl. perfringens* in institutional meals for the aged was high with an estimated of 250 cases of *Cl. perfringens* foodborne illness in Australia per year. The ABS (2008) estimates that 33.8% of the population aged over 65 reside in NSW. Assuming the proportion of elderly within aged care facilities is similar, it can be estimated that the number of cases of foodborne illness due to *Cl. perfringens* in facilities in NSW would be 84.5 per annum.

3.4.3 Risk of foodborne illness associated with *V. vulnificus*

Nazir et al (2016) used a case of a 40-year-old man to demonstrate the unique susceptibility of *V. vulnificus* to the people with cirrhosis. This study showed a relationship between elevated iron saturation and Vibrio septicaemia as well as the rapidity and severity of the disease progression. Extreme atraumatic cellulitis and severe sepsis were observed in decompensated alcoholic liver cirrhosis condition. The symptoms progressed rapidly to compartment syndrome despite broad-spectrum antibiotics management. *V. vulnificus* was detected in local cultures following debridement and patient history revealed consumption of raw oysters 48 h before the presentation of illness symptoms.

3.4.4 Risk based on meals served and prevalence rates

The potential risk can also be calculated using the information collected on the number of meals served within establishments catering to the vulnerable population and studies undertaken on the prevalence of pathogens in foods from these establishments. As reported by Gillespie et al (2001), 15/3494 (0.4%) of cold sliced RTE meats where found to be of unacceptable / potentially hazardous, due to the presence of high levels of *E. coli*, *Staph. aureus*, *Listeria* and *Cl. perfringens*. Using the information collected by the NSW Food Authority on meals served and assuming one meal per day consists of sliced cold meat then it could be expected that:

- 142,432 meals per annum served in establishments catering to the vulnerable population could be potentially hazardous.

As mentioned previously, the contamination rate *of L. monocytogenes* in RTE vegetables and sandwiches from health care facilities were found to be 3.7% and 2.5% respectively (Odumeru et al, 1997; Little et al, 2008). Again, assuming these foods were served at one meal per day, the number of meals potentially contaminated with *L. monocytogenes* would be:

- 1,137,498 meals per annum containing RTE vegetables at other facilities serving to vulnerable populations
- 961,417 sandwiches served per annum at other facilities catering to vulnerable populations.

These figures are likely to be an over estimation as exact information on meal types is not known and it is likely that establishments will have risk managements strategies in place to minimise the risks associated with food service to vulnerable populations.

Characterising the risk associated with other hazards within food service for vulnerable populations is problematic due to the lack of information on the types of meals served within these establishments.

4. Control measures

It is clear from the information in previous sections that vulnerability of the at-risk populations is due to decreased immunity and higher contractibility of foodborne illness. Several control measures and protection strategies are required for the production and supply of meals (and food products) for vulnerable people in hospitals, aged care homes or in the community. The potential control measures for establishments serving vulnerable populations including:

- Implementation of food safety system
- Substitution of high risk foods with lower risk alternatives
- Effective cleaning and sanitation of fruits and vegetables to be consumed raw
- Proper cooking of foods
- Limited storage of pre-prepared infant formula
- Minimise storage times of foods to be consumed without further heat treatment
- Prevent cross-contamination of foods
- Effective cleaning and sanitation of equipment, particularly those used for foods that will not receive a further heat treatment
- Good personal hygiene
- Use of low microbial diets
- Testing of RTE meat and foods by CPU facilities.

4.1 Implementation of food safety system by food supply service

The risk characterisation and predicted number of listeriosis cases stated previously are generally not observed due to the risk management strategies or control measures implemented by establishments serving food to vulnerable populations. The main strategy to assist in reducing the risk of foodborne illness at these establishments is the effective development and implementation of a food safety program. Woody and Benjamin (2008) provide an overview of the practicalities of implementing a food safety program in healthcare settings. In addition, in implementing the requirements of Standard 3.3.1 – *Food safety program for food service to vulnerable populations* of the Code, the NSW Food Authority developed guidance material to assist industry meet the requirements (NSW Food Authority, 2015).

International examples of food regulations relevant to vulnerable populations include the EU regulation on the hygiene of foodstuffs (EC 2004) and Food Hygiene (England) Regulations 2006. It is required under these regulations that food business operators, including those supply meals in hospitals and institutions, should put in place, implement and maintain a HACCP (hazard analysis and critical control point principles) based food safety system (ILSI, 2004). HACCP is a universally accepted food safety management system and several prerequisite programs such as Good Manufacturing Practice, raw material control, production control, pest control, sanitation and maintenance, use of approved suppliers and supplier auditing schemes are required for effective and efficient functions of this system.

Therefore, all food supply services for vulnerable groups must comply with legal and food safety requirements i.e., implementation of an appropriate food safety management system and use safe food-handling techniques.

4.2 Substitution of high risk foods with lower risk alternatives

Raw or unpasteurized milk, soft or mould-ripened cheese made with unpasteurized milk, unpasteurized fruit and vegetable juices, raw salad vegetables and fruit cuts, shellfish harvested from unclassified areas, raw vegetable sprouts are known as higher risk foods for the vulnerable people. Therefore, recommendations are to avoid high risk foods and foods from unsafe and unhygienic sources. This is particularly important in the case where foods will be consumed without further processing, such as cooking. Foods such as pasteurised and long life milk and juices, canned meat, properly cooked meat, poultry and fish, and shelf stable food products are generally considered low risk for the vulnerable people.

4.3 Proper cooking of foods

Some foods are naturally high in microbial load and cooking to an adequate temperature is necessary for inactivation of vegetative bacterial cells of the foodborne pathogens, including *Campylobacter* spp., STEC, *Salmonella* spp. and *L. monocytogenes*. The recommended cooking temperatures to cook foods for vulnerable people are given in Table 18 (further details see Appendix 1).

Table 18. Recommended cooking temperatures for cook serve foods by the Food Authority

Products	Internal temperature (°C)
Eggs	Cook until white is firm and yolk begins to thicken
Dishes containing eggs (e.g. sauces, custards)	71
Poultry (chicken and turkey, whole or parts)	74
Fish	63
Meat (beef, veal, lamb) (Steaks and roasts) – Medium rare	63
Meat (beef, veal, lamb) – Medium	71
Meat (beef, veal, lamb) – Well done	77
Minced meat (beef, veal, lamb, pork hamburgers, sausages)	71
Minced poultry (chicken and turkey hamburgers, sausages)	74
Pork (Medium)	71
Pork (Well done)	77
Sauces using raw meat, poultry or fish	Bring to the boil
Leftovers < 48 hours old (reheat)	60

Products	Internal temperature (°C)
Cook chill foods (reheat) > 48 hours old	70 for two minutes
Foods cooked using these temperatures should be stored under temperature control and served within 48 hours.	
Alternatively, a facility may choose to cook all products to an internal temperature of 75°C.	

Adapted from NSW Food Authority (2015)

4.4 Safe storage of the food products

Foods are subject to microbial growth during storage, this is very important when storage temperature is not properly controlled. A temperature range of 5°C to 60°C is considered as danger zone from microbial growth point of view in food safety management. Therefore, storage temperature and duration are key parameters to ensure the safety of foods. Some examples of safe storage of the food products are given below:

- Infant formula should be prepared enough for a single use. However, limited period storage is recommended for pre-prepared infant formula under controlled temperature, it should be kept at a temperature of 5°C or less for no longer than 24 hours (NSW Food Authority, 2015).
- It is required to minimise storage times of foods to be consumed without further heat treatment i.e., once preparation is finished, all sandwiches and salads are either to be served immediately, or placed into the cool room and served within 48 hours (NSW Food Authority, 2015).
- Cooling and storage requirement for meals (particularly meat dishes) prepared in advance to be served later (NSW Food Authority, 2015).
  - Cooling process should reduce temperature from 60°C to 21°C within 2 hours and from 21°C to 5°C within 4 hours.
  - Storage temperatures between 12°C and 50°C encourage microbial growth. Some bacteria like *Cl. perfringens* forms spores that are heat-resistant and are not inactivated by cooking. Storage of meals at the temperatures can allow the spores to germinate and the vegetative bacteria to multiply to numbers that can cause food-poisoning after consumption.
- Storage of chilled foods should be at <5°C for the duration of the shelf life to reduce growth of food-poisoning bacteria and maintain the safety and quality of the food. *L. monocytogenes* can grow slowly at temperatures as low as 3°C - 5°C.

4.5 Prevent cross-contamination of foods and cleaning of equipment

A number of major foodborne outbreaks were caused by the cross-contamination of the food products after processing. General sources of cross-contamination include food handler, processing equipment, packaging material, raw ingredients, air, insects and rodents. One of the most common reasons of cross-contamination is mixing of raw foods and RTE foods; therefore, it is required to keep raw foods and RTE foods separated, thorough cleaning and sanitation of food-contact surfaces and equipment after contact with raw foods (particularly meat slicers), and use of separate equipment and utensils for each item of raw food and for cooked food.

4.6 Maintenance of good personal hygiene

Good personal hygienic practices such as effective hand washing is important to prevent risk of infection. Personal hygiene practices described in the guidelines for food service to vulnerable persons (NSW Food Authority, 2015) include:

- Staff must practise good personal hygiene at all times.
- There should be a procedure for food handlers suffering from a foodborne disease.
- There should be an adequate number of suitable hand wash basins in accessible and appropriate areas with an adequate supply of warm water, liquid soap, paper towels and waste bins for their food handlers.
- Food handlers should avoid direct contact with RTE food and use utensils whenever possible. If it is not feasible to use a utensil, then gloves should be worn. Hygiene programs should therefore include observations of food handling and handwashing practices of the kitchen staff.
- Food handlers should wear hair covering while working in food production areas or if there is a risk of contamination. Staff members who are serving food do not have to wear hair nets but should take all precautions to prevent hair from contaminating the food.

4.7 Low microbial diets

Provision of low-microbial diets or neutropenic diets to recognised vulnerable groups of people has been proposed by many authors (Lund, 2014; Carr and Halliday, 2015). It is logical to develop, promote and implement policies to prepare foods with low microbial load for people with impaired immune systems as it is well-documented that vulnerable people need lower infectious dose of foodborne pathogens compared to healthy population.

4.8 Testing of RTE meat and foods

An important recommendation of the Food Authority's project on risk and control in licensed CPU facilities (FA2.1-7) is that CPU facilities should implement testing for RTE foods in line with the other food handling activities in the NSW Food Safety Schemes Manual and the RTE food guidelines (NSW Food Authority, 2016b). New testing requirements are being considered and, if implemented, the information will be provided to all CPU facilities.

4.9 Specific guidelines

NSW Food Authority has published several guidelines and fact sheets to improve food safety of vulnerable populations. Following are available online:

- Guidelines for food service to vulnerable persons
  http://www.foodauthority.nsw.gov.au/_Documents/industry/guidelines_vulnerable_persons.pdf
- Food safety during pregnancy
  http://www.foodauthority.nsw.gov.au/_Documents/foodsafetyandyou/pregnancy_brochure.pdf
- Food safety tips for childcare centres
  http://www.foodauthority.nsw.gov.au/_Documents/retailfactsheets/food_safety_tips_for_childcare_centres.pdf
- Cooking with kids
  http://www.foodauthority.nsw.gov.au/_Documents/retailfactsheets/cooking_with_kids.pdf

- Food brought from home
  http://www.foodauthority.nsw.gov.au/_Documents/retailfactsheets/food_brought_from_home.pdf
- Health & hygiene requirements of food handlers
  http://www.foodauthority.nsw.gov.au/_Documents/retailfactsheets/health_hygiene_of_food_handlers.pdf
- Personal hygiene checklist
  http://www.foodauthority.nsw.gov.au/_Documents/retailfactsheets/personal_hygiene_checklist.pdf
- Central Processing Unit Inspection Project
  http://www.foodauthority.nsw.gov.au/_Documents/projectoutcomes/cpu_project_outcomes.pdf

Conclusion

A small sub-group within the population are known to be more susceptible to foodborne illness. This group is generally referred to as the vulnerable population and includes children less than five years of age, the elderly over 65 and those with underlying immune suppressant conditions. The hazards affecting the vulnerable population can be unique to certain groups such as *L. monocytogenes* and *Cr. sakazakii* or may involve well known foodborne pathogens such as *Salmonella* resulting in more severe illness in the vulnerable persons.

According to current estimates, there are more than 1.2 million vulnerable persons in NSW and the number is expected to increase due to aging population in the future. A vast majority of the vulnerable people will be in hospitals, nursing or care homes while rest will be living in the community. Therefore, it is crucial to ensure the supply of safe food to vulnerable people in all these places. This tends to be reflected in epidemiological data, where institutional outbreaks are over-represented in the number of foodborne illness outbreaks, cases of illness and deaths from food sources. Based on prevalence data for bacterial pathogens, it is estimated that less than 1% meals (over one million of the 133 million) served at institutions catering to vulnerable populations in NSW each year might be potentially contaminated with a food pathogen.

The Food Authority must consider the risk management of foodborne illness in vulnerable persons facilities in a holistic way, and accept that it is not possible to fully eliminate all risk from foodborne illness without having a possible adverse effect on nutrition intake. As such, the review of the Food Authority's requirements has considered the importance of balancing the need to protect the patients/residents from foodborne hazards with maintaining a sufficiently nutritious and interesting diet. Elderly people may become quite fussy with their diet and if, due to Food Authority requirements, the diet becomes unattractive, then staff may have difficulty in enticing them to eat. This can lead to a whole range of health-related issues unrelated to food safety. This is particularly important for long term residents of aged care facilities and long term hospital patients (see Appendix 1 for risk management in food service settings).

It is not considered feasible that processed food delivered to hospitals and aged care facilities could be produced completely *Listeria*-free. It is acknowledged that food served in hospitals and aged care facilities might be contaminated with low levels of *L. monocytogenes*. The ILSI Expert Panel concluded that reducing the number of servings of food contaminated with high numbers of L. *monocytogenes* cells would have the most significant impact on reducing foodborne listeriosis (ILSI, 2005). The methods for achieving this include time and temperature controls (including freezing) or reformulation of foods so that they retard or do not support the growth of the organism. The Food Authority should continue to work with manufacturers of higher risk foods to implement control measures at this stage, rather than rely on control measures implemented at the food service stage alone.

The best risk management options for vulnerable persons facilities are to emphasise the basics, the good hygienic practices that all food service operations should implement. Investigations of foodborne illness outbreaks consistently show that the majority can be attributed to:

- poor hygiene,
- inadequate cooking, handling and storage of food, including cross contamination, and
- failure to ensure that the food supplied to the hospital in the first place was safe and of appropriate quality.

The Food Authority's new guideline seeks to emphasise the implementation of good personal hygiene and good hygienic practice for staff working in this sector, as well as the establishment of an approved supplier program to

ensure the quality and safety of the food being served. Advice on the avoidance of high risk foods and the use of low microbial diets should be given to documented vulnerable people, pregnant women, elderly, the infant and young.

It must also be recognised that a significant number of gastroenteritis outbreaks, particularly in aged care facilities, are due to person to person spread of viral gastroenteritis (Kirk, 2009), although food handlers can be a potential cause of outbreaks. The latter can occur mainly through staff working while infected with a foodborne disease, inadequate levels of staffing in the hospital kitchen, poor training, low wages and lack of support from managers (Lund and O'Brien, 2009). The avoidance of gastroenteritis outbreaks in vulnerable persons facilities can be improved by adhering to good personal and food hygiene and HACCP principles. This emphasises the importance in implementing control measures such as FSP at establishments catering to the vulnerable populations, to ensure the safety of their consumers. The recommendations from the Food Authority's project (2016) on the risk and control in licenced CPU facilities also suggested to improve the overall operation and regulation of the food service sector for vulnerable persons.

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Appendix 1 – Risk management in food service settings

(The technical review of the risk assessment of the vulnerable persons food safety scheme (NSW/FA/CP056/1204) was completed in 2010 that included recommended control measures in section 5. With minor modification the section 5 is also included in the revised Risk Assessment of the Vulnerable Persons Food Safety Scheme 2016 as appendix 1)

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Tables

1. Risk management in food service settings

The main strategy to assist in reducing the risk of foodborne illness at facilities providing food to vulnerable persons has been the effective development and implementation of a food safety program in accordance with Food Standards Code requirements. Woody and Benjamin (2008) provide an overview of the practicalities of implementing a food safety program in healthcare settings. In addition, many facilities now buy in pre-prepared foods to limit the amount of handling that occurs within the food service facility. This has increased the importance of implementing an approved supplier program to ensure there are control measures in place for instances where potentially hazardous RTE foods are bought in. A recent project completed in 2016, examined the controls recommended by the Food Authority's Guidelines for Food Service to Vulnerable Persons and any policies or procedures that the facilities had put in place to control food safety (NSW Food Authority, unpublished) and also made similar recommendation to improve the regulation of this sector. Table 1 highlights different risks identified in this Scheme and management requirement by the NSW Food Authority.

Table 1. Management of food safety risks for vulnerable persons by the Food Authority

Risk	Likelihood	Status	Management strategies
Listeriosis	High	Managed	Temperature control during storage and service Cook chill with SSL Risk management of high risk foods
Salmonellosis	High	Managed	Temperature control during storage and service Risk management of high risk foods
Botulism	High	Managed	Cook chill with ESL
Cr. sakazakii infection	High	Managed	Risk management of specific foods (infant formula)
Hepatitis E Virus	High	Managed	Guidelines to avoid viral infections
Mercury poisoning	Medium	Managed	Guidelines for pregnant women and children on consumption of foods with high mercury contents
Toxoplasmosis	Medium	Managed	Guidelines on consumption of undercooked meats or unwashed fruit and vegetables
V. vulnificus infection	Medium	Managed	Guidelines for people suffering from a liver disease

The following sections of the Scheme were specifically covered by the technical review of the Food Authority's 2008 manual and in the development of the new guideline for food service to vulnerable persons (NSW Food Authority, 2012; NSW Food Authority 2015). It examines the science behind the original requirements and, where necessary, provides the justification for any changes in recommended control measures and management strategies.

2. Risk management by temperature control during food storage and service

2.1 Cooking temperatures for cook serve

Cook serve foods are those foods that are cooked with the intention of immediate service or service within 48 hours as leftovers. The cooking temperatures required for cook serve are not as stringent as required for cook chill, as there is less time between cooking and serving, and therefore less opportunity for pathogenic bacteria to grow.

The Food Authority's 2008 manual previously contained the cooking temperature of 70°C for two minutes as an example critical control point (CCP) for cooking foods. This was also included on the audit checklist and was thus enforced as a CCP during audits. While this time and temperature combination is appropriate to deliver a 6 log reduction in *L. monocytogenes*, this is not the target organism in all foods. In addition, there is a risk that this cooking regime can potentially lead to overcooking and make the food unattractive or unpalatable to patients/residents leading to the kind of nutrient deficiency that could lead to other adverse health outcomes.

The controls implemented for cook serve foods should ensure that all potentially hazardous foods are cooked to an appropriate temperature to ensure the elimination of the target non-sporing pathogen for the particular food. The food safety control measures should also ensure that, as far as possible, the nutritional value of the food is maintained.

In the new guideline produced by the Food Authority (NSW Food Authority, 2015), the recommended cooking temperatures for cook serve foods have been amended in accordance with the Food Authority's advice to general consumers available on the website (see Table 2).

All foods not served immediately should be stored under temperature control, in accordance with Food Standards Code requirements, and used within 48 hours (an example of this would be leftover meat used in sandwiches the next day).

It is acknowledged that not all facilities may want different cooking temperatures for different foods, and as an alternative may choose to implement simplified cooking requirements and use a single time/temperature combination for all foods. However, this can be the choice of the catering operator and the Food Authority's position is not to enforce 70°C for two minutes as a minimum requirement for cooking of all foods, as there is no food safety basis for it.

Table 2. Recommended cooking temperatures for cook serve foods by the Food Authority

Products	Internal temperature (°C)
Eggs	Cook until white is firm and yolk begins to thicken
Dishes containing eggs (e.g. sauces, custards)	71
Poultry (chicken and turkey, whole or parts)	74
Fish	63
Meat (beef, veal, lamb) (Steaks and roasts) – Medium rare	63
Meat (beef, veal, lamb) – Medium	71

Products	Internal temperature (°C)
Meat (beef, veal, lamb) – Well done	77
Minced meat (beef, veal, lamb, pork hamburgers, sausages)	71
Minced poultry (chicken and turkey hamburgers, sausages)	74
Pork (Medium)	71
Pork (Well done)	77
Sauces using raw meat, poultry or fish	Bring to the boil
Leftovers < 48 hours old (reheat)	60
Cook chill foods (reheat) > 48 hours old	70 for two minutes
Foods cooked using these temperatures should be stored under temperature control and served within 48 hours.	
Alternatively, a facility may choose to cook all products to an internal temperature of 75°C.	

Adapted from NSW Food Authority (2015)

2.2 Cook chill preservation system

Cook chill is the term used to describe food preservation systems where there is a significant time interval between the food being cooked and served, during which time the food is kept in chilled storage. In most cook chill foods, temperature is the only significant control measure for preventing growth of pathogenic bacteria during the shelf life of the food (Cox and Bauler, 2008). The term cook chill is not meant to include foods refrigerated for normal cook serve catering purposes. There are several different types of cook chill operations, which may involve short shelf life SSL or ESL products and the products may or may not be reheated just prior to serving. Temperature control is required for all of these operations where potentially hazardous food is being handled.

There are no specific legal requirements relating to cook chill in the Food Standards Code, apart from the requirements in Standards 3.2.2 relating to:

- cooling of cooked foods from 60°C to 21°C in two hours, and from 21°C to 5°C in four hours, and
- temperature control of potentially hazardous food in that the food must be stored at a temperature of 5°C or below.

There has been a progressive shift in the food service to vulnerable persons sector towards the use of cook chill processing technology with the consolidation of catering operations and the production of bulk pumpable products for distribution from central processing facilities out to multiple locations. The move to cook chill operations and the longer shelf life of these foods means that temperature control is even more critical (Cox and Bauler, 2008).

The primary control measures associated with cook chill foods consist of adequate cooking, rapid cooling and storage temperature to minimise growth of pathogens during the interval prior to serving. The cooking process used in cook chill normally aims to achieve a 6 log reduction (6D or 99.99%) in the target organism of concern at the slowest heating point (AQIS, 1992). The pathogens of concern for cook chill foods are spore forming bacterial

pathogens (*Clostridium botulinum*, *C. perfringens* and *Bacillus cereus*) and pathogens that can grow at refrigeration temperatures (*L. monocytogenes*, non-proteolytic C. botulinum and Bacillus weihenstephanensis, the new species designation for B. cereus strains that can grow between 4 and 10°C). C. botulinum is the organism of most concern as it is both a spore former and thus able to survive normal cooking temperatures and is able to grow and produce toxin at temperatures as low as 4°C. *L. monocytogenes* is able to grow at temperatures down to 0°C, but is inactivated by normal cooking. For SSL cook chill the target organism is *L. monocytogenes* while for ESL cook chill the target organism is non-proteolytic *C. botulinum* (Cox and Bauler, 2008).

The temperature to be used for storage of cook chill foods will be dependent on a number of factors such as:

- the pasteurisation/cook treatment used,
- the shelf life of the product (SSL vs. ESL),
- factors limiting the growth of pathogens in the product (such as pH and water activity of the food), and
- whether the food is reheated prior to serving.

The Food Authority's 2008 manual (NSW Food Authority, 2008a) previously required all cook chill foods to be held at 3°C, referencing the AQIS Code of Practice (AQIS, 1992) for this requirement. However, the AQIS Code of Practice states the following storage conditions, depending on the level of heat treatment used:

- for heat-treated refrigerated foods packaged for extended shelf life which have not been given a 6D process for non-proteolytic *C. botulinum* and/or which have only been cooked before packing and the filling operation was not aseptic, keep refrigerated at not more than 3°C (where storage and distribution of not more than 3°C cannot be guaranteed, this process option must not be used)
- for heat-treated refrigerated foods packaged for extended shelf life which have been given a 6D process for non-proteolytic *C. botulinum* and, if cooked before packing, the filling operation was aseptic, keep refrigerated at not more than 5°C
- if the storage and distribution system cannot guarantee the above temperatures (3°C or 5°C), the shelf life of the product must be limited to a maximum of 5 days

The AQIS Code also states that 'where the recommended storage temperature is exceeded, if the temperature of a product designed to be stored at less than 3°C is between 3°C and 5°C, the product should be consumed within 10 days of manufacture'.

The ability of some facilities to achieve a maximum storage temperature of 3°C for the storage of cook chill foods was questionable, and in excess of that required by the Food Standards Code. According to Cox and Bauler (2008) the shelf life of cook chill foods may commonly be up to 10 days at 5°C.

An examination of the potential growth rates of the target organisms was undertaken using the predictive models in ComBase (Baranyi and Tamplin, 2004). The generation time (GT = the time taken for bacteria to double in numbers) was estimated in addition to the lag phase duration (LPD = the time taken for bacteria to adapt to their environment before they begin to grow). LPD was initially calculated using the lag time to generation time ratio from Ross (1999) which estimates that most lag times are 4–6 times the length of the generation time, however a final conservative value of 2.5 x GT was used in these calculations (as applied by Dalgaard pers comm).

A log increase (the time taken for bacterial numbers to increase 10-fold) is equivalent to 3.32 generations of bacterial growth (McMeekin et al, 1993), therefore the time for a two log increase was calculated as 2 x 3.32 x GT

and adding in the predicted LPD. A two log increase of *L. monocytogenes* and *Cl. botulinum* is extremely conservative given the cooking process should deliver a 6 log decrease in the relevant target organism. Storage at both 3°C and 5°C was examined (where the model limits permitted).

From the predictions in Table 3 the storage of cook chill foods at 5°C for five days should result in food that is safe and suitable, especially when used in conjunction with a 6D cook. In practice, the shelf life of these products may be longer, up to ten days without making the food unsafe or unsuitable, however this should be validated by the facility. Aseptic packaging of cook chill foods and the use of vacuum packaging or modified atmosphere packaging (MAP) may result in much longer shelf lives. For ESL products, it may be necessary to store these foods at 3°C to achieve the extended shelf life. However, the Food Authority considers that it is not necessary for products that are to be consumed within five to ten days to be stored at 3°C.

Table 3. Predicted time for a two log increase in *L. monocytogenes* and *Cl. botulinum*

Organism	Predicted generation time (GT)[1]	Estimated lag phase (LPD) 2.5xGT	Time to a two log increase (LPD+2x3.32xGT)
Clostridium botulinum	4°C[2] – 23.1	57.75 hr	211.1 (8.8 days)
Clostridium botulinum	5°C – 16.0 hrs	40.0 hr	146.2 (6.1 days)
Listeria monocytogenes	3°C – 22.5 hrs	56.25 hr	205.7 (8.6 days)
Listeria monocytogenes	5°C – 14.6 hrs	36.5 hr	133.4 (5.6 days)

GT = generation time LPD = Lag phase duration (calculated as 2.5 x GT) Log increase = 3.32 x GT

While it is acknowledged that inadequate control of the cook chill process (e.g. inadequate cooking, poor cooling rates, improper storage temperatures and inadequate reheating) might provide opportunity and condition for the growth and survival of pathogenic microorganisms (Cox and Bauler, 2008), the implementation of food safety programs by cook chill manufacturers and appropriate training can minimise the risk of this occurring. Despite the potential risks associated with extended storage period between cooking and serving potentially allowing growth of contaminating microorganisms, food service using cook chill has an excellent safety record in Australia and overseas.

Cook chill with SSL

The information contained in the Food Authority's new guideline now aligns with Food Standards Code requirements so that, provided a cook chill food is cooked to deliver a minimum 6 log reduction of *L. monocytogenes* (70°C for two minutes, or equivalent), the cook chill food can be stored at 5°C. The Food Authority has defined short shelf life cook chill as having a shelf life of up to ten days, with a shelf life of up to five days not requiring a validation. Any shelf life greater than five days should be validated by the food service provider.

[1] Based on optimum conditions for growth of pH = 7 and water activity = 0.997

[2] Lower temperature limit of the ComBase predictor model for *Clostridium botulinum* growth

Cook chill with ESL

To extend the shelf life beyond ten days normally requires the use of specialised equipment and a thermal treatment that delivers a 6 log reduction in C. botulinum as a minimum, along with aseptic filling. Systems such as CapKold® can produce cook chill food with a shelf life of up to 45 days. The process normally involves heating to 95°C and cooling to below 5°C in 90 minutes in hermetically sealed containers. Because different cook chill systems have different shelf lives for different foods, it is difficult for the Food Authority to justify specifying a particular shelf life or storage conditions. The requirement now included in the Food Authority's new guideline is that manufacturer's documented instructions must be followed in establishing the shelf life and the storage temperature. The shelf life of the product may be dependent on other controlling factors in the food such as pH and water activity.

For extended shelf life cook chill, cooling must be undertaken in accordance with system's specifications and according to the lethality of the heat treatment used, method of packaging and intended shelf life of the product. While rapid cooling within 90 minutes may be appropriate for the production of ESL cook chill meals, to routinely achieve this rapid cooling requires specialised equipment. For ESL cook chill, cooling should be undertaken in accordance with the manufacturer's documented specification for the equipment used.

Storage of extended shelf life cook chill should be undertaken in accordance with system's documented specifications and according to the lethality of the heat treatment and method of packaging, but a maximum temperature of 5°C or less should be specified in accordance with Food Standards Code requirements. The shelf life of ESL cook chill foods must be set in accordance with the food service system's specifications.

2.3 Cooling times for cooked foods

In the Food Authority's new guidelines document the general requirement for cooling of cooked foods has been aligned with the Food Standards Code requirement for foods to be cooled from 60°C to 21°C in two hours, then from 21°C to 5°C in a further four hours unless the business can demonstrate that an alternative cooling process will not adversely affect the safety of the food. There is no food safety justification for requiring food service facilities serving vulnerable persons to have cooling requirements in excess of that specified in the Food Standards Code. To facilitate proper cooling, it is important that facilities place food into appropriately sized containers. Shallow containers are considered most suitable to allow bulk foods to cool quickly, and facilities should use containers no deeper than 10cm, unless they have in place special blast chillers capable of effectively bringing the temperature down in larger containers.

2.4 Reheating foods and hot holding

In the Food Authority's 2008 manual, vulnerable persons facilities were advised that the minimum core temperature for reheating foods was 60°C. However, the manual also stated that it was advisable to reheat to 70°C for two minutes (or equivalent such as 75°C instant) and this temperature was to be achieved within two hours of commencing reheating. In addition, the checklist against which vulnerable persons facilities were audited required that during cooking/reheating the product temperature reached >75°C.

The target time specified in the Food Authority's 2008 manual for hot holding was 30 minutes (with a maximum of two hours). The corrective action if the temperature during hot holding dropped below 60°C was specified as 'stop serving, resume serving when product temperature is 60°C. If food falls below 60°C for 30 minutes discard'.

In the Food Authority's new guideline (NSW Food Authority, 2011a), the requirements for reheating foods have been reformatted to align with *Food Standards Code recommendations in Safe Food Australia* (ANZFA, 2001b),

the guide to compliance with Standards 3.2.2 and 3.2.3 of the Food Standards Code, it states that potentially hazardous foods that have been previously cooked and cooled are not required to be reheated to temperatures higher than 60°C. However, it goes on to say that food businesses may be advised to heat food to at least 70°C for at least two minutes.

Although heating to 70°C for at least two minutes will destroy foodborne bacteria that may have grown in the food during post-cook storage, it is not specified as a requirement, rather as a recommendation, in the Food Authority's new guideline because:

- it should not be necessary if the food has been cooked and cooled correctly and protected from contamination, which are all requirements of Standard 3.2.2 of the Food Standards Code
- if potentially hazardous cooked food has not been handled safely, heating the food to at least 70°C for at least two minutes cannot be relied upon to make the food safe, as it will not destroy the toxin produced by Staphylococcus aureus. This pathogen may be present in the food from contamination after cooking
- it may not be possible to heat foods to 70°C for two minutes, for example, foods that are high in protein may denature.

Food should be reheated in the minimum time possible (time to reach 60°C should be limited to no more than 1.5 hours). Where foods are hot held after cooking, they should be kept under temperature control during plating, that is, foods to be served hot should be kept at 60°C or above, or if the temperature of the food falls below 60°C it must be discarded after two hours. Total time between plating and consumption should not exceed two hours, through application of the '4-hour/2-hour rule' (ANZFA, 2001b).

In situations where food has been stored under refrigeration for longer than 48 hours, or where food has been texture modified or puréed after cooking, the Food Authority considers there is a slightly higher risk due to an increased potential for the food to become contaminated and/or for pathogen growth to occur. As such, the new guideline has retained the recommendation to reheat these foods to a higher temperature of 70°C for two minutes.

Food should only be reheated once, with any leftovers of the reheated food discarded. With food that has been reheated more than once, there is a significantly higher risk of temperature abuse and potential microbial growth. Leftover food that has not been reheated or served may be placed back under temperature control and used within 48 hours, provided the '4-hour/2-hour rule' has been observed.

2.5 Time and temperature between plating and serving food

The audit checklist for the Food Authority's 2008 manual stated 'food is to be consumed within 30 minutes of the food being out of temperature control'. The review of this requirement considered that the 30-minute timeframe was excessively cautious and could potentially amount to a lot of unnecessary food wastage, especially since elderly patients/residents may be quite deliberate in slowly consuming their food. It was considered unfortunate that the Food Authority's requirements might mean that food is removed from patients/residents and thrown out before they had finished it.

Food that has been served should be subject to temperature control in accordance with the Food Standards Code, which allows for the use of the '4-hour/2-hour rule'. If the food has been out of temperature control during preparation and transport for prolonged periods (i.e. more than two hours) this still allows up to two hours after serving which will result in safe and suitable food. Therefore, food can safely remain with patients/residents for up

to two hours, after which time any food not consumed should be discarded and neither reheated nor returned to chilled or frozen storage.

Foods that are warmed prior to serving (e.g. milk for cereal and babies' bottles) should be served immediately.

2.6 Cold storage shelf life for foods

During the review of the Food Authority's 2008 manual it was noted that there was some inconsistency in the manual regarding storage time and temperatures for food. A storage temperature of 3°C was listed as best practice for cook chill, while 5°C was listed for other foods. In order to simplify requirements and maintain consistency with the Food Standards Code, 5°C has now been recommended in the Food Authority's new guideline as the storage temperature for all foods. As noted previously, for extended shelf life cook chill, storage at 3°C may be required to achieve the shelf life, depending on the degree of thermal treatment and food formulation. Storage of these foods should be done in conjunction with the ESL food service system's instructions.

The recommended storage time is a difficult concept to specify, as there are many different foods and ingredients which will all have varying shelf lives. The Food Authority's new guideline recommends that all foods and ingredients must be used within their 'use-by' date and/or following any instructions included on the label by the manufacturer (e.g. use within two days of opening). In the absence of instructions, all opened and leftover potentially hazardous foods should be stored under temperature control and used within 48 hours.

Some foods are often stored refrigerated after opening to minimise the risk from spoilage, such as jams, hard cheeses, and condiments. These foods are not considered potentially hazardous foods as they are more likely to spoil than support the growth of pathogenic microorganisms. They are likely to be labelled with a 'best before' date and, as such, may have a much longer shelf life than 48 hours. It may be unclear to a business if a food is potentially hazardous or not, as not all businesses will have the skills and knowledge to easily determine this. As a general guide, if these products are protected from contamination then a recommended maximum shelf life of 10 days at 5°C or less should be adopted. In addition, the Food Authority's guideline *Potentially hazardous foods – foods that require temperature control for safety* (NSW Food Authority, 2008b) may assist.

2.7 Thawing frozen food

The use of the '4-hour/2-hour rule' is appropriate as temperature control for thawing food, particularly for food that is subsequently going to be cooked. The Food Authority's 2008 manual contained several elements in the appendix on thawing of frozen food. For food thawed in water, the corrective action was specified as discarding the food if the water temperature was greater than 21°C. For food thawed in the microwave, the corrective action was to discard the thawed food if 30 minutes had elapsed.

A review of these requirements considered that it is the temperature of the thawed food itself which should be the critical factor, not water temperature or a 30-minute timeframe. Most thawed food will be cooked or reheated prior to consumption. So minimising the time the food spends at temperatures that support the growth of foodborne pathogens (i.e. between 5°C and 60°C) while thawing is important; 30 minutes is highly conservative. The use of the '4-hour/2-hour rule' allows for the temperature of thawing food to exceed 5°C for up to two hours, at which time it would need to be either used immediately, placed into the refrigerator, or cooked.

2.8 Menu design

The menu should be designed to ensure that the food served to all residents/patients is safe. Each vulnerable persons facility should consider food safety risks in the development of its menu, and implement appropriate

control measures to address the risks. The Food Authority's new guideline recommends that all higher risk foods and ingredients should be received through approved suppliers and recommends against sourcing unpackaged foods from delicatessens or retail stores as there is a higher chance of cross contamination, especially for sliced meats (Endrikat et al, 2010).

Highly immunocompromised patients such as organ and bone marrow transplant patients, cancer patients undergoing chemotherapy or radiotherapy and individuals with AIDS may become ill when exposed to low numbers of opportunistic pathogens (Acheson and Lubin, 2008). For this group a low microbial diet (LMD) is recommended.

2.9 Serving food to highly immunocompromised individuals

A recent review of diets served in NSW health care facilities recommended a low microbial diet be maintained for neutropenic patients (NSW Health, 2010) and the menu planning guidelines for a LMD have been prescribed in the Therapeutic Diet Specifications for adult inpatients (see Table 4).

A LMD is not a sterile diet, but a diet where certain foods are excluded and safer foods are substituted in order to reduce the risk of foodborne disease and infection (ILSI, 2005; Lund and O'Brien, 2009; Tomblyn et al, 2009). LMDs are commonly introduced for neutropenic patients where the neutrophil count falls to less than 1000 cells/µL. At this level the risk of infection increases somewhat, however when it falls to below 500 cells/µL the risk of infection increases greatly.

The practice of diet modification has been in place for many years in health care facilities to ensure the safety of highly immunocompromised patients. The effectiveness of this diet has recently been questioned by some (Mank et al, 2008; Restau and Clark, 2008), with research into the balance between managing food safety and nutritional intake. Where modified diets may be required, clinicians should be consulted on any dietary recommendations. However, this type of diet is not considered appropriate or required for the broader vulnerable persons groups where susceptibilities to foodborne illness are not at this extremely high level.

Table 4. Low microbial diet specification for neutropenic patients

Diet: Microbial – low

Aim: To provide a diet which limits foods which are at high risk of carrying foodborne disease.

Characteristics: Avoids food with a high bacterial or fungal load. Sterile diets are no longer used because of lack of cost-effectiveness.

Indications:

- Patients with neutropenia (neutrophil count ≤ 1000 cell/µL).
- Patients who are severely immunosuppressed (e.g. post-transplant; undergoing some cancer treatments).

However, as food safety has improved, the standard hospital diet may be considered safe for most immunocompromised patients.

Nutritional adequacy: Nutritionally adequate

Precautions: As these patients are often malnourished, nutritional supplements may be required and these patients should be supervised by a dietician. All salads and sandwiches must be prepared on the day of service and not purchased pre-prepared.

Specific menu planning guidelines

Food group	Allowed	Not allowed
Sandwiches	All breads Pasteurised meats (cooked in bag) and sliced with correct food hygiene practices Boiled eggs, canned fish Commercially packaged mild cheese (e.g. cheddar) Cottage cheese may be used if served on the day the package is opened.	Sliced processed meats (e.g. ham, chicken roll) Cold chicken or turkey Smoked meat and fish Pâtés and meat spreads
Salads, dressings	Sanitised vegetables only[3] Boiled eggs, canned fish Pasteurised meats (cooked in bag) and sliced using correct food hygiene practices Commercially packaged mild cheese (e.g. cheddar) Cottage cheese may be used if served on the day the package is opened Portion packs of commercial mayonnaise and dressings	Leafy green vegetables Salad dressings made with blue cheese or raw eggs Sliced processed meats (e.g. ham, chicken roll) Cold chicken or turkey Smoked meat and fish Peeled prawns Raw sprouts
Breads, cereals	All breads, processed ready-to-eat Cooked breakfast cereals All cooked pasta and rices	Raw oats Muesli
Spreads	Jams, peanut butter, Vegemite™	Pâtés and meat spreads, honey
Hot breakfast choices	All cooked	
Fruit, yoghurt	Sanitised fresh fruit Portion control packs of fruit	Fresh fruit with a rough texture (e.g. raspberries, rockmelons) All yoghurt
Sauces, gravies	All cooked	
Desserts	Hot desserts Heat-treated, portion-controlled cold desserts Refrigerated commercial and homemade cakes, pastries and puddings Normal frozen ice-cream	Unrefrigerated cream-filled pastries Soft serve ice-cream
Milk and cheese	All pasteurised milk and milk products Commercially packaged mild cheese (e.g. cheddar)	Soft, semi-soft and surface ripened cheese (e.g. brie, camembert, feta, blue)

[3] The NSW Health guideline refers to the Food Authority's requirement in the Food Authority's 2008 to sanitise all raw fruit and vegetables (this is no longer a requirement in the new guideline, but may still be appropriate for a low microbial diet)

Food group	Allowed	Not allowed
	Cottage and ricotta cheese may be used if served on the day the package is opened	
Beverages	Pasteurised fruit juices in sealed portions Tea, coffee, soft drink	Fresh and unpasteurised juices Herbal teas
Biscuits	All portion packs	
Miscellaneous	Nutritional supplements	Raw nuts and nuts in shells Raw oysters
Hot main dishes	All well cooked meat, poultry, fish and eggs.	Undercooked meat, poultry or fish Raw tofu, smoked fish, tempeh
Starchy vegetables/ pasta/rice	All cooked	
Vegetables	All cooked	Unwashed raw vegetables and sprouts, including lettuce, mushroom and shredded carrots
Soups	All hot soups	Cold soups Miso soup

3 Risk management of higher risk foods

The Food Authority's 2008 manual included a list of 'foods at higher risk', which was developed in response primarily to the risks of *L. monocytogenes*, *Salmonella* and pathogenic *E. coli* being present in the food served to vulnerable persons. The list of foods at risk for Listeria was copied from the FSANZ brochure Listeria and food – advice for people at risk (FSANZ, 2005) and was not made specific to food service facilities catering to vulnerable persons. Foods containing raw eggs, lightly cooked egg products and seed sprouts were also added to the list in the 2008 manual as being high risk for *Salmonella* or *E. coli* contamination (NSW Food Authority, 2008a).

A review of the 'foods at higher risk' list was undertaken to reflect the most up-to-date knowledge of the hazards and the susceptibility of at-risk groups, and because this list may have unduly limited the choice of foods available to serve patients where facilities had chosen to remove these items from the menu, rather than risk receiving a critical Corrective Action Request (CAR) during a regulatory audit.

The results of the Food Authority's 2009 evaluation also prompted a review of the 'foods at higher risk' list was. Almost half of the facilities that responded to the survey served some foods listed in the 'foods at higher risk' list, mainly pre-sliced deli meats, fresh cut rockmelon and lightly cooked eggs (see Table 5). In addition, one third of respondents had not undertaken a risk assessment of the high risk foods being served. This was stated in the Food Authority's 2008 manual as being a critical CAR which would mean a failure at audit.

Table 5. Number of vulnerable persons facilities serving high risk foods

High risk foods	Percentage of vulnerable persons businesses serving
Pre-sliced ready-to-eat meat	50%
Fresh cut rockmelon	48%
Lightly-cooked eggs	40%
Pre-packaged salads	11%
Cold cooked ready-to-eat chicken	7%
Soft cheese (brie or camembert)	4%
Raw eggs	2%
Seed sprouts (alfalfa)	2%
Pâté	0%
Chilled raw seafood	0%

Adapted from NSW Food Authority (2010)

It was recognised that if facilities wanted to continue to serve these high risk foods, then a better risk management approach would be for the Food Authority to recommend various control options. It would then be up to individual facilities to choose which control measure to implement or demonstrate that any alternative control measure delivered an equivalent food safety outcome.

The Food Authority examined similar control measures employed elsewhere for higher risk foods, such as the US Food Code (FDA, 2009), which includes a section entitled 'Special requirements for highly susceptible populations'.

This requires that highly susceptible people are not served:

- raw animal foods, such as raw fish, raw-marinated fish, raw shellfish and steak tartar
- a partially cooked animal food such as lightly cooked fish, rare meat, soft-cooked eggs that are made from raw shell eggs, and meringue
- raw seed sprouts
- unpasteurised juice.

In addition, the US Food Code requires that pasteurised shell eggs, pasteurised liquid, frozen or dry eggs or egg products are used instead of raw shell eggs in the preparation of foods such as Caesar salad, hollandaise or béarnaise sauce, mayonnaise, eggnog, ice-cream and egg-fortified beverages.

These control measures are not specifically targeted at controlling any one particular pathogen, but identify several of the foods more commonly implicated with foodborne illness through pathogens such as *Salmonella*, pathogenic *E. coli* and *L. monocytogenes*.

However, most advice regarding vulnerable persons tends to target foods regarded as being high risk from *L. monocytogenes*, and most control measures are aimed at minimising the risk from this organism. Therefore, the Food Authority attempted to better define which characteristics of a food contributed to its ranking as higher risk, and where additional control measures were warranted.

ILSI (2005) described high risk foods (in terms of risk due to listeriosis) as having the following properties:

- Potential for contamination with *L. monocytogenes*
- Able to support the growth of *L. monocytogenes* to high numbers
- Are ready-to-eat
- Require refrigeration
- Are stored for an extended period of time.

The ability of a food to support the growth of *L. monocytogenes* is important, as most foods that become contaminated with *L. monocytogenes* typically have very low levels of the organism present – in most cases between 0.04 cfu/g (equivalent to one cell in 25 g, the limit of detection of testing) and 10 cfu/g. This was demonstrated through a large data set of 31,705 food samples published by the NACMCF (2005), including data of Gombas et al (2003), which showed that the detection rate for *L. monocytogenes* was 1.82%, but that levels less than 10 cfu/g constituted 92% of positive detections (Table 6). Another study by Little et al (2009) in the UK found *L. monocytogenes* in 166 out of 6984 (2.4%) RTE food samples, with levels above 100 cfu/g in 0.3% of samples. Ross (2010) calculated the median concentration from the data of Gombas et al (2003) to be less than 1 cfu/10g and the median concentration from the data of Little et al (2009) to be less than 2 cfu/g.

Risk assessment data has consistently shown that the risk of listeriosis is increased in RTE foods which support the growth of *L. monocytogenes* and have extended shelf lives, and that the majority of listeriosis cases result from levels of *L. monocytogenes* greater than 100 cfu/g in the food (FDA/USDA, 2003; WHO/FAO, 2004). The FDA/USDA (2003) risk assessment of *L. monocytogenes* in RTE foods estimated that more than 96% of listeriosis cases are due to doses greater than 100,000 cfu *L. monocytogenes*/serve (Table 7). While Ross (2010) states that relatively large doses of *L. monocytogenes* (i.e. of the order of tens of thousands of cells or more) are now believed necessary to cause listeriosis.

This combination of low contamination rates and high doses required to cause illness means that in most cases, growth of the organism is required to occur in the product. From the median values of *L. monocytogenes* found in the surveys by Gombas et al (2003) and Little et al (2009), up to two logs of growth (100-fold increase) would be tolerable and still achieve an appropriate level of protection for the majority of vulnerable persons.

In accordance with this observation, under European Union regulations (EC 2073/2005), a RTE food or ingredient with a refrigerated shelf life of less than five days is unable to support the growth of *L. monocytogenes* (growth being defined as an increase of 0.5 log cfu/g or more during the shelf life of the food).

Other intrinsic characteristics of a food that does not support the growth of *L. monocytogenes* include:

- Food with a pH value less than 4.4 (regardless of water activity)
- Food with a water activity value less than 0.92 (regardless of pH)
- Food with a combination of factors (e.g. pH < 5.0 and water activity < 0.94)
- Frozen foods.

Table 6. Number of *L. monocytogenes* detected in US food samples

		Level of *L. monocytogenes* detected in food (cfu/g)							
Food	Detected/Samples (%)	0.04-0.1	0.11-1	1.1-10	11-100	101-1000	1001-10,000	to 100,000	to 1,000,000
Smoked seafood	114 / 2644 (2.53%)	67	11	19	8	6	1	0	2
Seafood salads	115 / 2446 (3.35%)	82	19	10	2	2	0	0	0
Bagged pre-cut leafy salad	22 / 2966 (0.57%)	17	1	1	2	1	0	0	0
Deli salads	202 / 8549 (1.89%)	162	28	9	2	0	1	0	0
Deli meat	82 / 9199 (0.46%)	42	20	10	2	7	1	0	0
Fresh soft cheese	5 / 2931 (0.07%)	2	0	0	3	0	0	0	0
Blue vein cheese	23 / 1623 (1.11%)	18	3	1	1	0	0	0	0
Soft mould ripened cheese	14 / 1347 (0.89%)	12	0	2	0	0	0	0	0
Pasteurised milk	1 / 5804 (0.02%)	1	0	0	0	0	0	0	0
	577 / 31,705 (1.82%)	402 (1.27%)	82 (0.26%)	52 (0.16%)	20 (0.06%)	16 (0.05%)	3 (0.009%)	0 (0.000%)	2 (0.006%)

Table 7. Estimated dose per serving and incidence of foodborne listeriosis

L. monocytogenes in food at time of consumption (cfu/serving)	% servings annually	% listeriosis cases attributable
0.04	96.37	0.02
0.1	1.90	<0.01
1	0.91	0.01
10	0.43	0.03
100	0.21	0.13
1000	0.10	0.60
10,000	0.05	2.85
100,000	0.02	13.47
>1,000,000	0.01	82.89

Adapted from FDA/USDA (2003)

Similarly, Health Canada has a revised policy on *L. monocytogenes* in RTE foods which include 'Category 2A RTE foods'. This category includes RTE refrigerated foods with a shelf life of less than five days. The policy states that this time would not allow sufficient time, under reasonably foreseeable conditions of distribution, storage and use, for *L. monocytogenes* to grow to levels above 100 cfu/g by the end of the stated shelf life (Health Canada, 2010). The level of 100 cfu/g is widely recognised as achieving an appropriate level of protection for the consumer without being overly onerous on food manufacturers by requiring zero tolerance for the organism. The Canadian Category 2A RTE foods includes foods that can support the growth of *L. monocytogenes* but the amount of growth is generally limited because of a number of factors such as short refrigerated shelf-life, a large background microflora containing anti-Listeria lactic acid and/or other bacteria, etc. The Health Canada policy states that these Category 2A foods should receive a medium-low priority, with regards to the level of inspection and compliance activity but that it would need to be verified that levels of *L. monocytogenes* in product are consistently equal to or less than 100 cfu/g during the whole shelf-life of these products (Health Canada, 2010).

Limiting the shelf life of RTE foods as a control measure was investigated in the FDA/USDA risk assessment in 2003, which examined several 'what-if' scenarios including estimating the effect of shelf life on the predicted number of listeriosis cases. The scenarios tested included maximum storage times for deli meats of 4, 7, 10, 14, 17, 21, and 28 days. Shortening the shelf life to ten days was found to reduce the estimated number of cases in the elderly sub-population by 32.5%. Further reducing the shelf life to seven days resulted in approximately a 60% reduction in the number of listeriosis cases from deli meats (FDA/USDA, 2003).

Another study by Carrasco et al (2010) examined the effect of shortening the shelf life of RTE lettuce salads on the high risk population of Spain. Reducing the shelf life of the product to seven days resulted in a 24% reduction in predicted number of listeriosis cases. A further reduction to a five-day shelf life resulted in a 62% reduction. Along

with storage temperature (potential for growth) and serving size (exposure to the organism), shelf life was the third most important factor in determining the number of listeriosis cases.

Taking these findings into account, with a view to minimising the risk from listeriosis the Food Authority has created a revised list of control measures for certain higher risk foods. These are included as recommendations in the new guideline (NSW Food Authority, 2011a) and shown in Table 8. The revised list and recommended control measures attempt to better balance the risk management between making a fully nutritious and enjoyable diet available, and providing an appropriate level of protection against foodborne illness.

While risk assessment data may be used to justify limiting the shelf life of a food to minimise the risk from *L. monocytogenes*, the practicality of implementing a limited shelf life recommendation is difficult to gauge. As most products are labelled with a 'use-by' or 'best before' date rather than a 'packed on' date, it may be difficult for aged care facilities and hospitals to determine the actual age of the product unless manufacturers are willing to cooperate and provide this information. In addition, many products may go through an extended supply chain, particularly for remotely located facilities and product may be older than seven days by the time it reaches the facility. In essence, the risk communication message should be that these higher risk products need to be used and consumed within the shortest timeframe possible to minimise the risk of potential *Listeria* growth. In practice, this may be out of the control of many facilities.

The recommended control measures in Table 8 make the distinction between patients/residents with increased susceptibility (Groups 1 and 2 in Table 8) and those considered highly/exquisitely susceptible (where the implementation of a low microbial diet may be required) (see Table 4). The recommendations in Table 8 for higher risk foods that may support the growth of *L. monocytogenes*, such as RTE meats, pâté and dips, cold-smoked salmon and pre-cut vegetables, fruits and salads, includes an option of limiting the shelf life of these foods to a maximum of seven days from packaging. This is recommended as an additional method for minimising the risk of *L. monocytogenes* growing to levels considered to be an infectious dose. The intent of this recommendation is to reduce the risk compared to product that is distributed for retail sale, for example deli meats may have a six to seven-week shelf life which may allow the organism to grow up to much higher levels, with a greater risk of causing infection in susceptible individuals.

3.1 Ready-to-eat meat and poultry

There is evidence to show the pre-sliced deli meats and RTE poultry are more likely to be contaminated with *L. monocytogenes* than other foods. The FDA/USDA risk assessment ranked deli meats as the highest risk food of the 23 RTE foods examined (FDA/USDA, 2003). It was estimated that deli meats caused approximately 90% of listeriosis cases in the elderly sub-population group (~850 cases per year). Australian risk assessment data estimated that ready-to-eat processed luncheon meats may be contaminated with *L. monocytogenes* at a rate of 4.7% and be responsible for up to 40% of human cases of listeriosis in Australia each year (Ross et al, 2009).

Slicing, dicing and shredding of RTE meat products are high risk operations for contamination of these products with *L. monocytogenes* (Endrikat et al, 2010). The recommendation previously put forward in the Food Authority's 2008 manual was for facilities to purchase whole chubs of meat and slice them on site, freezing any leftover portions. Site visits to three major food service facilities during the review of the manual requirements showed that slicing often takes place on deli-style slicers. However, unless these slicers are thoroughly cleaned and sanitised this may also contribute to contamination of the product with *L. monocytogenes*.

Table 8. Recommended control measures for higher risk foods

Food type	Control measures – options for controlling hazards
Cooked meat and poultry	All meat and poultry are cooked in accordance with minimum recommended cooking temperatures Purchase packaged, whole portions of unsliced ready-to-eat meats and poultry and slice in central processing unit, kitchen or service departments and limit shelf life to seven days after slicing and re-packaging Purchase meats pre-sliced from a licensed manufacturer with a *Listeria* management program. Apply a limited shelf life of no more than seven days from date of packaging[4]. It is not recommended to purchase sliced meats from delicatessens or retail shops etc. Use canned or shelf stable meats Purchase frozen cooked meats
Dairy	Serve dairy products made from pasteurised milk Serve soft cheeses with a shelf life limited to no more than seven days from date of packaging2
Seafood	All seafood is cooked May serve cold-smoked seafood, with limited shelf life of seven days from date of packaging2 Use canned seafood or shelf stable seafood Purchase frozen seafood

[4] Applies to product that will support the growth of *Listeria monocytogenes* (defined as an increase of 0.5 log cfu/g or more during the shelf life of the food). Foods that **do not** support the growth of *L. monocytogenes* include:

- food with a pH value less than 4.4 (regardless of water activity),
- food with a water activity value less than 0.92 (regardless of pH),
- food with a combination of factors (e.g. pH < 5.0 and water activity < 0.94),
- frozen foods,
- food with a refrigerated shelf life of less than 5 days.

Eggs	Do not use any cracked or dirty eggs Serve eggs that are cooked until the white is firm and yolk begins to thicken Use pasteurised egg in dishes which will not be cooked
Fruits, vegetables and salads	Inspect all fresh produce prior to use and remove dirty, cut, mouldy and bruised stock. Wash all fruit and vegetables under running potable water[5] Serve packaged pre-cut vegetables, fruit and salads with a shelf life limited to no more than 7 days from date of packaging[2] Wash and sanitise melons (e.g. rockmelons/cantaloupe, honeydew) in sanitisers appropriate for fresh produce Serve seed sprouts only if they are cooked Use canned or shelf stable pre-packaged fruit and vegetables
Juices	Serve pasteurised juices Inspect all fresh produce prior to use and remove dirty, cut, mouldy and bruised stock. Wash all fruit and vegetables under running, potable water prior to juicing. Serve freshly squeezed juice immediately after preparation
Pâté and dips	Serve shelf stable pâté, pastes and dips (e.g. canned) Serve pâté, pastes and dips that have been fully cooked with a shelf life limited to no more than 7 days from date of packaging[2]

Alternative control measures can be used where it can be demonstrated during audit that the measures adequately control the hazard, such as:

- certificate of analysis from the manufacturer
- product cooked in bag and not re-packaged

Adapted from NSW Food Authority (2015)

[5] Fruit and vegetables that will not be cooked may be sanitised in a sanitiser appropriate for fresh produce as an additional control measure

Since the initial recommendation by the Food Authority for vulnerable persons facilities to slice deli meats on-site, new requirements have been implemented for the meat industry including the implementation of a *Listeria* management program for processors of RTE meat. This is required as a condition of licence in NSW (NSW Food Authority, 2008c). While this does not guarantee that the product will be free of *Listeria*, it should ensure that the rate and level of any contamination is minimised. Since additional control measures were implemented in the US, there has been a decrease in the prevalence of *L. monocytogenes* in product manufactured in federally inspected meat processing facilities (Endrikat et al, 2010). The use of growth inhibitors (antimicrobials) against *L. monocytogenes*, such as sodium lactate (additive code 325), potassium lactate (326), potassium diacetate (261) and sodium diacetate (262) in deli meats, is an option that Australian manufacturers are beginning to explore and use, and this has been shown to decrease the risk even further by stopping or slowing the growth of *L. monocytogenes* (MLA, 2011)

In the Food Authority's new guideline, the recommended control measures specifically recommended against facilities sourcing unpackaged RTE meats from retail or delicatessen outlets. Several recent studies examined the risk of listeriosis from pre-packaged deli meats against meats sliced at retail in the US (Endrikat et al, 2010; Pradhan et al, 2010) and found meats sliced at a deli to be a higher risk. It was estimated that the number of deaths in the elderly population attributed to retail sliced deli meats (without a growth inhibitor) was 108.2 compared to 18.1 from pre-packaged meats, a relative risk ratio of 5.97 (Endrikat et al, 2010). Pradhan et al (2010) found that ham contaminated at retail was estimated to be responsible for 3.2 times more listeriosis deaths in the US elderly population, and turkey 1.7 times. These estimates were made on the prevalence of *L. monocytogenes* in pre-packaged deli meats of 0.4% against 2.7% in meat sliced in store, from the data of Gombas et al (2003). The additional handling involved in slicing the product at retail level was proposed as one of the reasons for this finding. With the use of deli-style slicers by vulnerable persons facilities, there may be similar risk factors in these facilities slicing meats on-site, unless these meats are consumed shortly after slicing.

The Food Authority has recommended several different control measures for RTE meats, as these are considered the highest risk product. In order to minimise the growth of *L. monocytogenes* in the product, any product sold to vulnerable persons facility should have a short shelf life or contain growth inhibitors to minimise the risk from *L. monocytogenes*, compared to product that is distributed for retail sale (which may have in excess of a six to seven-week shelf life). The extended shelf life, in the absence of growth inhibitors, is one of the major risk factors which may allow the organism to grow to infective dose levels.

3.2 Pâté and dips

In the FDA/USDA (2003) risk assessment on listeriosis in RTE foods, pâté and meat spreads were ranked third in terms of risk per serve. In terms of risk per annum, pâté and meat spreads were estimated to cause 3.8 cases of listeriosis per annum in the US. The Australian risk assessment conducted by Ross et al (2009) also examined the risk of listeriosis from pâté products and estimated the contamination rate with *L. monocytogenes* at 1.2%, with these products predicted to cause a case of listeriosis once every three years.

Shelf stable pâté, meat or fish pastes, such as those in cans or pouches that do not require refrigeration, would have been subjected to a cooking step that would ensure that *Listeria* is not present in the final product. For other types of pâté production where the product is also fully cooked but requires refrigeration, there may potentially be opportunities for *L. monocytogenes* to contaminate the product post-cook. Despite the information from Ross et al (2009) suggesting these products are relatively low risk, in the Food Authority's new guideline the Food Authority recommends that only shelf stable pâté and dips be served, or the shelf life limited to seven days from packaging.

3.3 Dairy

Unpasteurised milk

In Australia, unpasteurised (raw) cows milk is not permitted to be sold under the Food Standards Code and is not commercially available. However, in NSW the Food Authority has exempted producers of goats milk from the requirement to pasteurise. Under the Food Standards Code any unpasteurised milk or unpasteurised liquid milk products must be labelled with a warning statement to the effect that 'the product has not been pasteurised'.

During the past five Food Standards Australia New Zealand (FSANZ) approved two proposals; Proposal 1007 (2 May 2012) and Proposal 1022 (16 December 2014), Primary Production & Processing Requirements for Raw Milk Products. To assess whether raw milk products should be made available in Australia, FSANZ undertook risk assessments on raw cows milk (FSANZ, 2009a), raw goats milk (FSANZ 2009b) and raw milk cheeses (FSANZ, 2009c). For both raw cows and goats milk, the risk assessment concluded that a range of pathogenic microorganisms may contaminate raw milk and the consumption of raw milk was an unacceptable risk to public health. Proposal 1007 approved the manufacture of certain cooked curd cheeses and Proposal 1022 extended the approval to raw milk cheeses with physio-chemical characteristics that support food safety.

Although, the Food Authority currently allows the sale of raw goat milk, serving unpasteurised milk to vulnerable persons is an unacceptably high risk; pasteurised milk provides an acceptable alternative and should be used in all cases.

Cheese

All cheeses may be subject to post-process contamination, however many soft cheeses contain the right biochemical and physical properties for *L. monocytogenes* to potentially grow to high levels (FSANZ, 2009c). Some cheeses, particularly soft and semi-soft cheeses, have been associated with outbreaks of listeriosis overseas. While often this has involved cheeses made from raw milk, some outbreaks have also included cheese made from heat-treated milk where post pasteurisation contamination has occurred. While the adoption of good manufacturing practices by the dairy industry has minimised the risk of contamination in recent years, there has still been a number of recalls in the past years of cheese products for microbial contamination, including *L. monocytogenes* (Table 9).

Table 9. Recalls of cheese in Australia 2009-2011

Year	Cheese	Reason for recall
2011	Fetta	*E. coli*
2010	Cheddar, Gouda, Norwegino, Tilsit	*L. monocytogenes*
2010	Various cheeses	*L. monocytogenes*
2010	Mozzarella	*Salmonella*
2009	Brie and Camembert	*E. coli*
2009	Smoked cheese	*E. coli*
2009	Soft cheeses	*L. monocytogenes*
2009	Brie and Camembert	*E. coli*

Data from www.recalls.gov.au

There is little epidemiological evidence linking soft cheeses with cases of listeriosis in Australia and due to the implementation of food safety programs in dairy processing facilities, the effectiveness of pasteurisation should ensure that all cheeses made from pasteurised milk are safe to consume if packaged, stored and handled correctly. However, given the intrinsic nature of soft cheeses and the potential for *L. monocytogenes* to grow in these products, a control measure for these products is warranted. The Food Authority's new guideline lists soft cheeses as a food requiring measures to control the risk for *L. monocytogenes* (limiting the shelf life).

Some specific types of imported unpasteurised milk cheeses are currently permitted under the Food Standards Code, including Gruyere, Sbrinz, Emmental and Roquefort cheese. However, since there are pasteurised cheese varieties available as a suitable alternative, the Food Authority has persisted with the recommendation to avoid all dairy products made from unpasteurised milk. FSANZ approved (Proposal 1022, 16 December 2014) the production and sale of selected cheeses made from unpasteurised milk. The approval under the Standard 4.2.4 requires strict through-chain control over the production, transport and processing of raw milk to ensure final product is safe for consumers.

Ice-cream

Soft serve ice-cream has previously been listed as a high risk food with respect to *L. monocytogenes* (FSANZ, 2005), primarily due to the potential for contamination from poorly maintained and poorly cleaned equipment. Since soft serve ice-cream mix is not stored frozen, but at temperatures less than 5°C, and only aged and frozen at the retail point of sale, there is potential for slow growth of the organism in the food. Although there are no human illness data indicating problems, Lake et al (2009) concluded there was potential for *L. monocytogenes* growth in soft serve ice-cream between preparation and consumption.

A 1992 survey by the Western Australia Health Department found *L. monocytogenes* in one sample from 114 tested (cited in Lake et al, 2009) and there seems to be no Australian microbiological survey data since that time. Given the lack of data on the microbiological quality of soft serve and frozen yoghurt, the Food Authority undertook a survey study (November 2012–February 2014) and found these products possess low risk as *E. coli*, *Salmonella* or *L. monocytogenes* were not detected in the 153 samples tested (NSW Food Authority, 2014). It has not been listed in the Food Authority's guideline, as the risk is considered low and it is not considered to be a regular part of food service to vulnerable persons.

3.4 Seafood

The US Food Code (FDA, 2009) requires a food establishment that serves a highly susceptible population to not serve raw animal foods such as raw fish, raw-marinated fish and raw molluscan shellfish. The Food Authority has aligned with this advice in its new guideline by recommending that all seafood is cooked.

Raw seafood such as oysters, sashimi and sushi is considered high risk for a number of organisms, in particular viral contamination for raw shellfish and Vibrio spp. for raw seafood. NSW and other Australian states have environmental controls in place to ensure that shellfish are harvested under safe conditions. Compliance with the requirements of the Australian Shellfish Quality Assurance Program (ASQAP), now mandated through the Food Standards Code, appears to have improved the safety of shellfish over the past decade. However there still appears to be sporadic episodes of foodborne illness where oysters have been implicated.

Cold smoked salmon has long been considered a higher risk food for listeriosis (Rørvik, 2000; ANZFA, 2002; Pouillot et al, 2009). The ANZFA risk assessment concluded that there was potential for smoked salmon to be contaminated with *L. monocytogenes* and that growth of the organism in the product is moderate. With a shelf life

of 4-6 weeks, *L. monocytogenes* could potentially grow to levels that may pose a risk to public health and safety. While Rørvik (2000) concluded that consumers may be sporadically exposed to *L. monocytogenes* from smoked salmon, exposure to hazardous levels does not occur often, as contamination levels are low. However, to prevent growth to hazardous levels the author did state that the declared shelf life under refrigeration should be shorter than that customarily stipulated by many producers. In the Food Authority's new guideline, a control measure to limit the shelf life to seven days has been recommended as a suitable control measure.

Some facilities, particularly aged care facilities, may wish to serve raw oysters for special occasions such as Christmas or Easter. While the Food Authority does not recommend serving these foods as part of the normal menu, the risk of foodborne illness is also dependent on the frequency of consumption and the dose of the organism. Provided these foods are obtained from a licensed supplier, serving raw shellfish at special functions once or twice a year may be considered acceptable, although there is an increased risk of foodborne illness, the holistic health benefits may outweigh those risks.

3.5 Eggs and food containing eggs

The Food Authority's 2008 manual listed lightly cooked eggs (including poached eggs), mousse, hollandaise sauce, meringue on the high risk food list. The inclusion of poached eggs on this list has been subject to some discussion in recent times and the risk posed by 'lightly cooked' egg products was reviewed.

Requirements for cooking eggs contained in the FDA Food Code (FDA, 2009) requires eggs 'broken and prepared in response to a consumer's order and for immediate service' to be cooked to 63°C for 15 seconds or for eggs that are not cooked for immediate consumption, 68°C for 15 seconds (70°C instant). Advice from the American Egg Board (2010) states that whole eggs should be cooked until the white is set (completely coagulated and firm) and the yolk is beginning to thicken (no longer runny but not hard). These visual cues are considered adequate to have met the necessary time and temperature requirements for safety as egg white coagulates between 62°C and 65°C and yolk between 65°C and 70°C. The guidelines for cooking scrambled eggs are that they should be cooked until firm throughout with no visible liquid egg remaining. Therefore, the American Egg Board advised that it is not necessary to cook eggs until hard or rubbery to kill any bacteria that may be present.

Davis et al (2008) examined seven different cooking methods for eggs and evaluated the inactivation of *Salmonella* and found 'sunny side up' fried eggs the cooking method that gave the least reduction in numbers of *Salmonella*, not poached eggs as mentioned in the Food Authority's 2008 manual. The inoculum level used in the experiments by Davis et al (2008) was 4.3 log cfu/mL, much higher than natural contamination levels.

Based on these requirements and recommendations, the control measures proposed in the Food Authority's new guideline for food service facilities are:

- Serve eggs that are cooked until the white is firm and yolk begins to thicken.

These guidelines allow facilities some flexibility to serve poached and other 'lightly cooked' eggs to vulnerable persons provided the eggs are cooked until the white is firm and the yolk begins to thicken, which should equate to a temperature of at least 63°C being reached and an adequate reduction of *Salmonella* being achieved. For those people considered highly vulnerable (e.g. on low microbial diets), consideration may need to be given as to whether eggs should be served, and if so, then as an added precaution, these eggs may need to be cooked until both white and yolk are firm.

The Food Authority's 2008 manual listed 'foods containing raw eggs intended to be consumed uncooked' as foods at higher risk of *Salmonella*. The manual listed raw egg mayonnaise and eggnog as two foods where raw eggs are often consumed uncooked. This is similar in concept to the US Food Code (FDA, 2009), however the FDA goes

further by requiring a food establishment that serves a highly susceptible population to use pasteurised eggs or pasteurised egg products (instead of raw eggs) in the preparation of:

- foods such as Caesar salad, hollandaise or béarnaise sauce, mayonnaise, meringue, eggnog, ice-cream and egg-fortified beverages, and
- recipes in which more than one egg is broken and the eggs are combined (with exceptions for when eggs are combined and then cooked immediately for consumption, eggs are included in foods that are baked or the food is prepared under a HACCP plan).

These measures and the prohibition on soft cooked eggs applied by the FDA are aimed at controlling the risk from trans-ovarian *Salmonella* Enteritidis (SE), a serovar of *Salmonella* which is not endemic in Australian egg layer hens (NSW Food Authority, 2009). In the US, *Salmonella* Enteritidis is thought to be present in 0.01% of eggs in the retail market. When present in an egg, the number of SE cells present is generally thought to be less than 20 per egg (Chantarapanont et al, 2000). Because SE may be laid inside the egg, it is a far greater food safety hazard than other strains of *Salmonella* which are external to the egg. Most other *Salmonella* strains contaminate the shell of the egg through environmental sources (e.g. faecal material, litter), and may only enter the egg under certain circumstances. Any *Salmonella* cells that do pass through the pores in the egg shell and into the albumen are not able to grow due to the high pH. The number of cells that do pass into the egg is very low and growth will not occur until the vitelline membrane surrounding the yolk has broken down allowing the *Salmonella* to gain access to the protein rich yolk.

In Australia, OzFoodNet has attributed a large increase in notifications of *Salmonella* Typhimurium phage type 170/108 from 2009 to early 2011 in part to uncooked eggs and foods containing eggs (OzFoodNet Working Group, 2010). In 2008, Roberts-Witteveen et al (2009) reported an outbreak of *Salmonella* Typhimurium phage type 44 in an aged care facility affecting 8 out of 45 residents. The implicated food was a dessert containing raw eggs supplied from a local farm. The same *Salmonella* phage type was detected on an egg in an unopened box from this supplier.

While the broader association with illness may also be due to corresponding factors such as temperature abuse and use of cracked or dirty eggs, the risk assessment undertaken by the Food Authority on the egg food safety scheme in 2009 recommended that vulnerable persons facilities not use raw eggs in foods that will not be cooked (NSW Food Authority, 2009). The Food Authority's new guideline maintains this position by recommending that cracked and dirty eggs are not used (in line with the Food Standards Code requirements) and pasteurised eggs are used in dishes which will not be cooked.

3.6 Fruits, vegetables and salads

The Food Authority's 2008 manual and audit checklist required that all fresh fruit and vegetables served to vulnerable persons were washed in clean (potable) water then sanitised by soaking in 100 ppm (free) chlorine for five minutes or in an appropriate validated equivalent commercial chemical preparation. This requirement was implemented because a range of microbiological pathogens have been associated with fresh fruit and vegetables overseas, including *Salmonella* spp., Shigella spp., pathogenic strains of *E. coli*¸ *L. monocytogenes*, Norovirus and Hepatitis A virus and parasites such as Cyclospora (Food Science Australia, 2000).

The stringent control measures were also prompted in part by the outbreak in 1998-99 in aged care facilities and hospitals in the Hunter Valley, NSW, which highlighted the risks of listeriosis from foods served in these establishments. The implicated food was fruit salad and the outbreak affected nine patients, with six deaths resulting. All patients were elderly, and some had underlying conditions making them more susceptible to infection

with *L. monocytogenes*. All the establishments served food prepared in a central catering facility (Food Science Australia & Minter Ellison Consulting, 2002). One sample of fruit salad subsequently tested positive for low levels (<50 cfu/g) of *L. monocytogenes*, a level considered unlikely to cause illness, even in the most immunosuppressed individuals. This outbreak prompted the NSW Health Department to issue a Circular on *Listeria* in 2003 leading to several foods such as lettuce being removed from the menu in many facilities (NSW Health, 2003).

With horticulture products there is potential for contamination to occur at any point from growing (soil, fertilisation, irrigation water, animal/bird waste, infected workers) through to harvesting, processing (including washing), distribution, marketing and consumption. However, the hazards in most fresh fruit and vegetables are controlled primarily through the growing and harvesting practices and controls of inputs. The highest food safety risk is for those products consumed whole (without peeling) and raw, such as apples, pears, berries and grapes (Food Science Australia, 2000).

After harvest most fruit is washed through immersion or spraying with water, fungicide and/or pesticide at least once during handling and packing operations. Apples and pears are dumped into water for flotation onto sorting and grading equipment, and may be dipped into antioxidant and calcium solutions to improve storage quality and reduce spoilage. Wax, with or without fungicide, may also be applied to fruit such as apples and oranges before packing. The practice of collecting fallen fruit is discouraged as fruit on the ground has a markedly higher chance of having microbial contamination present (Food Science Australia, 2000).

Fruits and vegetables are an important part of a balanced healthy diet, providing essential nutritional elements. A survey of hospital patients conducted by Kennewell and Kokkinakos (2001) on food preference found that having fresh fruit on the menu may be an important factor in patient satisfaction. Nine of the 15 most popular food items were fresh fruit.

Any control measures that the Food Authority requires for food service to vulnerable persons needs to be mindful of the food safety risks compared with the health benefits that fruits and vegetables provide. It should be acknowledged that overseas trends in foodborne illness from fresh produce have not been reflected in Australia. Although there is little data on prevalence of pathogens associated with fresh fruit and vegetables in Australia, it is assumed the prevalence is extremely low given there is little epidemiological evidence to associate fresh produce with foodborne illness. The Food Authority has conducted limited testing of fresh produce and fresh cut vegetables (NSW Food Authority, 2007) with 118 out of 119 (99%) categorised as satisfactory. The single marginal result was due to low numbers of *E. coli* at 4 cfu/g.

Fresh fruit served whole is a low risk food group, as it tends to have a thick protective skin that prevents penetration of pathogens (the exception being berries). In addition, most are harvested from trees or bushes where there is less likelihood of contamination from soil. The exception to this appears to be melons. There have been several outbreaks of listeriosis attributed to these products (see next section). On the surface of most other fruit, many microbial pathogens cannot survive or grow due to the low pH environment. However, when fresh fruits are sliced, cut or additionally processed, the removal of the protective outer surface of the fruit may increase the potential for pathogens to survive and/or grow (Food Science Australia, 2000).

Tomblyn et al (2009) examined control measures for some of the most vulnerable patients in Haematopoietic cell transplant (HCT) recipients, with the adage ‘if you can’t peel or wash it, don’t eat it’. They advised that washing of fruits and vegetables in tap water was worthwhile, even for those with skin or rinds, organic foods and pre-packaged items labelled as pre-washed. Such washing may prevent many contamination-related infections, but not all. Bassett & McClure (2008) conducted a risk assessment of fresh fruit and found that washing fruit with water alone can reduce the level of microorganisms, in some instances as effectively as using disinfectants. The

magnitude of the effect was found to be dependent on the fruit type, the organism and the method of washing. Washing of fruit in potable water alone may deliver approximately a one log reduction in bacteria, and sanitising in a commercial sanitising solution may be effective in delivering an additional one to three log reduction.

Some control must be exerted during the washing of fruit and vegetables, as under certain conditions microorganisms can become internalised through damage to the natural structure such as punctures, scars, cuts and splits, and the placing of warm fruit into cooler, contaminated water. The Food Authority's new guideline recommends washing fruit and vegetables in running potable water to minimise the risk of bacterial contamination. Because certain fruits and vegetables are susceptible to infiltration of microorganisms during soaking or submersion, it is recommended that this is avoided. Washing must be used in conjunction with inspection to remove any dirty, cut, bruised fruit and vegetables beforehand. Facilities may choose to apply sanitiser as an added safety margin, but this is no longer listed as a requirement by the Food Authority.

The risk of contamination increases when fresh fruits are sliced, or there is potential for cross contamination from equipment to occur, as demonstrated by outbreaks of listeriosis where pre-prepared tuna salad was implicated as a source of several cases (Shetty et al, 2009; Cokes et al, 2011). Investigations were unable to determine if a contaminated ingredient was responsible, or whether it was due to cross contamination from equipment, such as a can opener used to open the tins of tuna. Control measures should ensure that good hygienic practices are employed, including personal hygiene of any food handlers, and hygiene in the food preparation area. Temperature control is important for cut fruits, which need to be refrigerated after peeling, cutting or cooking.

The Food Authority's new guideline focuses on two higher risk plant products, melons and seed sprouts.

Rockmelon/cantaloupe and honeydew melons

Melons are considered higher risk because they grow close to the ground and the surface of the fruit may become contaminated with soil. In addition, melons have a relatively neutral pH compared with other fruits, which increases the risk that any contaminating bacteria may be able to survive and/or grow. In addition, the skin of rockmelon tends to be uneven and difficult to clean, and porous, which may allow the penetration of pathogens and agricultural chemicals into the fruit. Melons are often dipped in a sanitising solution after harvest to minimise the risks.

Rockmelon and honeydew have caused several large outbreaks in the US (Bowen et al, 2006) and in Australia (Sheridan et al, 2007). Two large outbreaks occurred in the US in 1990 and 1991 due to *Salmonella*-contaminated rinds. There was also a multi-state *Salmonella* outbreak in Australia affecting 115 people attributed to rockmelons in 2006 (Munnoch et al, 2009) and cases of listeriosis attributed to rockmelons in early 2010 (OzFoodNet Working Group, 2010). Traceback investigations conducted in Victoria, NSW and Queensland indicated a common source for some of the melons, in south central NSW. The Victorian investigation isolated the outbreak strain of *Listeria* in samples in a facility that manufactured fruit salad. Isolates were obtained from the by-products of manufacturing (waste juice from a stainless steel tub and fruit rinse water), and from a wash taken from the surface of a honeydew melon.

Pathogens can be transferred from the contaminated rind to the interior flesh during cutting (Guzman, 1997). Fully mature cantaloupes have a pH between 6 and 7 and serve as excellent substrates for the growth of bacteria at warmer temperatures. Other outbreaks involving *Salmonella*, *Campylobacter* and *E. coli* were related to cross contamination during preparation in kitchens. It is important that utensils used to cut and slice rockmelon and honeydew are cleaned and sanitised so they do not cross contaminate these fruits.

Evaluation results from a NSW Food Authority survey show that, despite rockmelon being listed as a high risk food in the Food Authority's 2008 manual, it continues to be served by almost half of facilities. Because of these findings, it is considered that more stringent requirements should remain in place for handling rockmelons and honeydew melons and they should be sanitised in a commercial sanitiser appropriate for use with fruit and vegetables, and used in accordance with the manufacturer's recommendations. Guidelines for in-house melon preparation should include cleaning the surface thoroughly using potable water and an appropriate sanitiser. Parnell et al (2005) recommend scrubbing in addition to washing for melons to reduce bacterial load on their outer surface. The use of a sanitiser was also recommended to limit the potential spread of contamination on and among melons. Only cleaned and sanitised utensils and surfaces must come into contact with the fruit. Any cut fruit must be stored at 5°C or below in line with Food Standards Code temperature control requirements for potentially hazardous foods.

Seed sprouts

Seed sprouts are considered high risk products, which has prompted FSANZ to develop a primary production and processing standard (FSANZ, 2010). While any type of seed sprout has the potential to become contaminated, foodborne illness data from the last 30 years tends to indicate that alfalfa and mung bean sprouts, and to a lesser degree cress, clover and radish sprouts, have been implicated in causing human illness. Alfalfa sprouts have a long history of causing illness in the US and the FDA Food Code 2009 lists raw seed sprouts as a food that may not be served or offered for sale in a ready-to-eat form to highly susceptible populations (FDA, 2009).

More recently, seed sprouts have been implicated in one of the largest and most costly foodborne outbreaks in German history involving 3408 cases including 798 with haemolytic uremic syndrome (HUS) and 39 dead (as at 20 June 2011). There have been outbreaks in Australia attributed to seed sprouts. In 2005-2006 traceback investigations in Western Australia and Victoria implicated seed produced in South Australia as a cause of an outbreak of *Salmonella* Oranienburg (NSW Food Authority, 2009a).

The plants products scoping study undertaken by Food Science Australia (on behalf of the then SafeFood NSW) identified seed sprouts as a high risk product (Food Science Australia, 2000). Seed sprouts were incorporated into the scope of the plant products food safety scheme under the NSW Food Regulation, and included as part of Food Regulation 2010. As a result of this legislation, businesses producing seed sprouts in NSW must be licensed and implement a food safety program. Despite the introduction of these risk management strategies, seed sprouts remain an inherently high risk food for *Salmonella* and pathogenic *E. coli* due to:

- the potential sources of contamination of seeds used for sprouting
- the lack of a validated seed disinfection step
- favourable conditions for microbial growth used during sprouting.

Seed sprouts were previously listed in the Food Authority's 2008 manual as a high risk food. This information has been carried over into the Food Authority's new guideline with the recommended control measure being 'serve seed sprouts only if they are cooked'. Evaluation data from a NSW Food Authority survey shows that only 2% of vulnerable persons food service facilities were feeding seed sprouts to their patients, so this is unlikely to have a large impact on menu design. If seed sprouts were an integral part of a menu, the Food Authority's advice remains that serving seed sprouts cooked would be considered a safer alternative.

3.7 Juices

Unpasteurised juice was also listed as one of the high risk foods in the Food Authority's 2008 manual and an examination of the risks from these products show that it remains an unacceptable risk to serve unpasteurised juices to vulnerable persons.

Fresh, chilled, unpasteurised orange juice was the cause of a foodborne illness outbreak in South Australia in 1999. There were approximately 500 laboratory confirmed cases of *Salmonella* Typhimurium phage type 135a infection but no deaths were recorded. The same year, the then ANZFA examined an application to label any unpasteurised juice as 'unpasteurised' in Application 411 (ANZFA, 2001a). The risk assessment undertaken for A411 concluded that all juice (fruit and vegetable) has the potential to be contaminated with microbiological hazards and that juice that has not undergone any form of treatment (such as pasteurisation) is more likely to be contaminated with pathogens than treated juice. It also concluded that while there is a low probability of untreated juice being contaminated with dangerous pathogens, if it is, the consequences can be severe for at-risk groups and in extreme cases death could occur (ANZFA, 2001a).

In the US there have been several foodborne illness outbreaks attributed to consumption of unpasteurised juice (CSIRO, 1997; Leudtke and Powell, 2000; ANZFA, 2001a), including:

- in 1995, an outbreak involving 63 cases due to *S*. Hartford, *S*. Gaminara and *S*. Rubislaw was reported at a Walt Disney World theme park after people drank unpasteurised orange juice. There were 63 cases from 21 states (average age 10 years old) and 22% were hospitalised. No deaths occurred.
- in 1996, there were outbreaks of *E. coli* 0157:H7 infections and cryptosporidiosis associated with unpasteurised apple cider and apple juice.
- in 1999, an outbreak involving over 400 people with one death as a result of unpasteurised orange juice contaminated with *S*. Muenchen.
- in 2000, 74 confirmed cases of salmonellosis were reported across seven states due to *S*. Enteritidis. No deaths occurred.
- in 2005, the US FDA issued a nationwide warning to consumers against drinking unpasteurised orange juice products distributed under a variety of brand names because of contamination with *S*. Typhimurium.

In total, between 1995 and 2005 more than 1700 people in Canada and the United States fell ill after consuming juice and cider. Most of these outbreaks involved unpasteurised juices and ciders such as apple cider, orange juice and lemonades. Other fresh fruit juice outbreaks included pineapple, carrot, coconut, cane sugar, banana, acai and mixed fruit juices. The most common pathogens were *E. coli* O157 and O111, *Salmonella*, *Cryptosporidium* and norovirus.

Since November 1999, the US FDA has required that fruit juice products carry warning statements unless they have been pasteurised or treated in another way capable of achieving a five log reduction 'of the most resistant microorganism of public health significance'. The warning statement required is 'WARNING: This product has not been pasteurised and, therefore, may contain harmful bacteria that can cause serious illness in children, the elderly, and persons with weakened immune systems'. The US Food Code also states that unpasteurised juice must not be served to a highly susceptible population (FDA, 2009).

The Food Authority licenses nineteen producers of unpasteurised juices (current as at May 2016) and allows the sale of appropriately labelled product to the general population. However, considering past outbreaks associated with unpasteurised juices and the fact there is a nutritious and clearly safer alternative product in pasteurised juice

available, then the Food Authority advises that only pasteurised juices should be served to residents and patients. The option to serve freshly squeezed juice is given, provided the following control measures are implemented:

- dirty, cut, mouldy and bruised stock is removed
- all fruit and vegetables are washed under running, potable water prior to juicing
- fresh squeezed juice is served immediately after preparation.

4 Risk management of specific foods and situations

4.1 Preparation of texture modified, puréed foods and supplements

Texture modified meals are provided for residents or patients who have difficulty chewing or swallowing. This includes foods that have been vitamised, puréed or minced, as well as liquid meal supplements. These foods are at greater risk of microbial contamination because:

- there is additional handling associated with texture modification
- the temperature of hot food drops during texture modification, potentially allowing bacterial growth
- the process of texture modification will redistribute any bacteria present on the surface of the food throughout the entire volume.

The preparation of texture modified foods requires good hygienic practices to be implemented to ensure the safety of texture modified, puréed and cut up foods. In some cases, a blender, stab mixer or emulsifier might be required to achieve an adequate mix for a puréed food and these pieces of equipment can be very difficult to clean. The hygiene of milkshake mixers and food mixers is an area that is often overlooked as staff might not be aware that food residues can get into unseen areas. Attention to cleaning and sanitation procedures is required along with deeper cleaning requiring disassembly of the equipment.

There are a number of texture-modifying agents, and individual directions for use should be followed. Pre-gel starches do not need to be cooked to thicken, and can be added to hot drinks that have been allowed to cool slightly. These foods should be prepared according to the directions for use of the thickening agent or the recipe. The preparation of nutritional supplements and milkshakes also requires special attention. Supplements and shakes should be prepared according to the directions for use of the supplement or the recipe.

Contamination and inadequate cleaning of blenders and mixers has been identified during Food Authority audits of vulnerable persons facilities as a problem area and has resulted in the issuing of corrective action requests (CARs) during audits. Foodborne illnesses attributable to contaminated blenders have been reported from a NSW vulnerable persons facility (Shadbolt pers comm) and a contaminated immersion blender was the cause of a salmonellosis outbreak in 133 people in a camp in the USA (Daly et al, 2010). A suspected malfunctioning shaft seal may have allowed for internal contamination of the blender, with yellow material in the upper motor housing and brown material from the blender shaft seal yielding positive swabs for S. Enteritidis. The design of the blender did not allow easy disassembly for cleaning.

The Food Authority's new guideline includes a section on texture modified foods to highlight the risks from these types of food preparation activities. Where foods are puréed or cut up after cooking, the Food Authority has recommended that these foods are reheated to 70°C for two minutes because of the potential exposure to contaminants after cooking. It is considered reasonable to recommend a cooking process designed to inactivate *Listeria*, as the consequences regarding effect on texture are minimal for puréed foods.

4.2 Preparation of infant formula

The Food Authority's 2009 risk assessment examined in detail the risks from reconstituted powdered infant formula in detail. Powdered infant formula is not a commercially sterile product, and may be subject to contamination by opportunistic pathogens such as *Cr. sakazakii* and *Salmonella* through improper cleaning of production lines (FAO, 2007). While these pathogens do not grow in the powder, they can survive for many months and can become potential hazards when the powder is reconstituted and held at favourable temperatures where growth may occur. While in previous outbreaks it appeared to be premature infants and those with underlying medical conditions that

were at highest risk for developing a *Cr. sakazakii* infection, healthy infants may not always be immune to infections (Nazarowec-White and Farber, 1997; FAO, 2008).

The Food Authority's new guideline has a section for the preparation of infant formula. The important elements for preparation of infant formula are personal hygiene for staff and implementing good hygienic practice to ensure that prepared formula is not temperature abused giving organisms such as *Salmonella* and *Cr. sakazakii* the opportunity to grow to levels that can cause illness. Best guidance is to prepare and store infant formula according to the manufacturer's instructions. Directions for use of infant formula have been very carefully crafted. They are specific to the product in use, whether it is liquid or powdered infant formula. It is important for staff preparing infant formula to practice good hygiene during preparation, keep any prepared formula refrigerated, and discard it after 24 hours.

4.3 Foods brought in from home

The Food Authority's 2008 manual stated that facilities should have a policy around managing food brought in from homes to a client in an aged care facility. The practicality is that it would be difficult, and unnecessary, for facilities to enforce a ban on foods brought in from home. It is recommended that facilities have a policy in place to try and ensure that any food brought in from home does not include unsuitable foods as listed in Table 8. This could be done by providing information to the friends and relatives of patients/residents. However, it is acknowledged that this is largely out of the control of the facility.

4.4 Allergen control

According to the Australasian Society of Clinical Immunology and Allergy Incorporated (ASCIA), hospital admissions for severe anaphylaxis have doubled over the last decade in Australia, USA and the UK. In Australia, admissions for anaphylaxis due to food allergy in children aged 0 to 4 years are even higher, having increased five-fold over the same period. Most children allergic to cows milk, soy, wheat or eggs will be able to tolerate these foods before they reach school age, and often before. By contrast, allergic reactions to peanuts, tree nuts, seeds and seafood persist in the majority (~ 75%) of children affected (ASCIA, 2010).

Due to the broader range of allergens and the increasing incidence in the young, childrens hospital wards are very likely to have allergic patients at some time. However, with a much lower incidence of food allergies in the elderly, small aged care facilities might never have had an allergic resident. The control measures required to control exposure to allergens must be specific to the risk presented by the vulnerable persons being served by the facility.

The recommendation contained in the Food Authority's new guideline states that, where necessary, control measures should be implemented to control allergens. In practice, most providers of vulnerable persons care (possibly all providers of childrens services and many providers of general services) may require a documented allergen management plan in their food safety programs (consistent, but not limited to controlling the allergens identified in Standard 1.2.3 of the Food Standards Code). It is certainly good practice for providers that are reasonably likely to receive a patient or resident with any food-related allergies to have a system in place for identifying these individuals upon admission to the facility and designing the menu to reduce the risk of allergens and, where possible, have an allergen-free alternative meal option.

The food safety program should identify the hazard(s) associated with allergen contamination (cross contact) through the hazard analysis, and implement appropriate control measures. An allergen management plan should consider the supply of food consistent with therapeutic diet specifications (NSW Health, 2010) and the prevention of cross contact by allergenic foods through the use of separate preparation times, use of dedicated equipment or thorough cleaning between uses.

5 Risk management through cleaning and sanitation

5.1 Dishwasher temperature

This issue of dishwasher temperature was raised by the Food Authority auditors as an area where clarification of requirements was needed. The Food Authority's 2008 manual and the audit checklist both specified 82°C as the minimum rinse temperature for a dishwasher used by a facility to ensure that utensils were clean and sanitised. Appendix 4 of the Safe Food Australia user guide (ANZFA, 2001b) contains information on the use of dishwashers by food businesses. Sanitising eating and drinking utensils can be achieved through the use of hot water, chemicals or other processes.

The difficulty in implementing the 82°C requirement was that many smaller facilities were using domestic dishwashers which do not have a temperature gauge and no way to determine if the 82°C was being achieved. Since a limit of 82°C was specified in the audit checklist this was treated by auditors as a critical limit and a CCP, however this was difficult to validate or verify.

While the temperature of the water is important for sanitising, it is important that the dishwasher does not become too hot initially. The best temperature for washing utensils may be between 54°C and 60°C and higher temperatures may tend to bake food residue on (ANZFA, 2001b). In addition, during the sanitising rinse if the temperature exceeds 90°C at the manifold the water can begin to vaporise, reducing its ability to convey sufficient heat to utensil surfaces.

Commercial dishwashers are generally designed to rinse at 82°C. The lower temperature limit is 74°C for a stationary rack single temperature machine, and 82°C for other machines such as conveyor rack systems. These temperatures are based on the sanitising rinse contact time to achieve the 71°C temperature on the surface of utensils within the dishwasher, defined as a sanitising rinse in the US Food Code (FDA, 2009).

The review of the Food Authority's 2008 manual requirements conceded that where domestic dishwashers are used by facilities it is difficult to regard this as a CCP, just as sanitising food contact surfaces of bench tops is not regarded as a CCP, but part of good hygienic practice. The Food Authority's new guideline has modified the requirement to remove a minimum temperature and instead focuses on the correct use and maintenance of the dishwasher to ensure that it is used in accordance with manufacturer's specifications. Where equipment and utensils are cleaned and sanitised in a dishwasher, the following should be done to ensure the dishwasher is working correctly:

- the dishwasher should be regularly maintained and serviced according to manufacturer's instructions and a detergent and/or sanitiser appropriate for the equipment should be used in the dishwasher
- the dishwasher should be operated using the hottest rinse cycle available (economy cycle should not be used as this is not designed to provide a high enough temperature for the time needed to sanitise)
- a visual check should be done of equipment and utensils when removed from the dishwasher to ensure they are clean
- the dishwasher should be cleaned so that there is no accumulation of food residues.

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Department of Primary Industries
Food Authority

6 Avenue of the Americas, Newington NSW 2127
PO Box 6682, Silverwater NSW 1811
T 1300 552 406
contact@foodauthority.nsw.gov.au
ABN 47 080 404 416

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