NSW GOVERNMENT Food Authority

NSW Plant Products Food Safety Scheme

Periodic review of the risk assessment

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Contents

Executive summary

The previous risk assessment (NSW Food Authority, 2009) of the plant products food safety scheme was published in March 2009. The risk assessment was part of a comprehensive review of food safety schemes undertaken during the revision of the NSW Food Regulation, which occurs approximately every 5 years.

The Authority has produced this risk assessment as part of its program to periodically review the risk assessment of all food safety schemes conducted as part of the development of the next version of the NSW Food Regulation.

This updated risk assessment covers the plant products food safety scheme and examines developments in national food standards, new scientific literature and research on practical risk management measures, examines outbreak data and uses the collective evidence to support existing risk management approaches or suggest alternative approaches.

This risk assessment has focussed on several pathogen-commodity pairings to better comprehend the risk posed by these products. Some of the issues specifically covered within this risk assessment are:

- a review of growth data for pathogens on processed products captured under the plant products food safety scheme, specifically fresh-cut melons which have been implicated as a potential source of foodborne illness
- a review of the risk of *Listeria monocytogenes* associated with lettuce as a high risk food for service into facilities caring for vulnerable persons
- an examination of the food regulatory work being undertaken at the national level including the introduction of new national production and processing standard for seed sprouts, and the formation of a working group on fresh horticulture
- a review of foodborne illness outbreaks associated with horticultural products, including those outside the current scope of the food safety scheme
- a summary of a project undertaken by the Authority to examine the risk posed by 'gap' products that currently fall outside the scope of the food safety scheme
- the emerging issue of pine nuts and the pine mouth taste disturbance reported around the world

In general, the risk assessment supports the conclusions of the 2009 risk assessment and there appears to be no need to expand the scope of the plant products food safety scheme at this stage to address any unmanaged hazards.

1. Introduction

1.1 NSW Food Regulation 2010

The NSW Food Authority administers food law through the NSW Food Act 2003 (the Act) and the NSW Food Regulation 2010 (the Regulation). Within the Food Regulation there is a plant products food safety scheme (the Scheme) which requires facilities to be licensed for the production of:

- fresh cut fruit
- fresh cut vegetables
- seed sprouts
- vegetables in oil
- unpasteurised juice

The scheme was limited in scope to these products as a result of a risk profile commissioned by the former SafeFood Production NSW (Food Science Australia, 2000). The scheme requires businesses producing these products to implement a food safety program that complies with the requirements of Food Standards Code Standard 3.2.1 Food Safety Programs, however the scope of the scheme does not apply to the handling of food on retail premises.

1.2 The number of plant products facilities in NSW

As at November 2013, there were 53 businesses licensed to process plant products in NSW[1], with some businesses licensed to undertaken more than one activity with a secondary licence permission (Table 1). A comprehensive profile of the industry has not been done in the past decade.

Table 1. Licensed plant products processing businesses in NSW

Primary licence permission	**Secondary licence permission**				
	Process seed sprout	**Fresh cut fruit and/or vegetables**	**Extract and/or package unpasteurised juice**	**Process vegetables in oil**	**TOTAL**
Process seed sprout	**8**	1	1	-	**10**
Fresh cut fruit and/or vegetables	1	**32**	1	2	**36**
Extract and/or package unpasteurised juice	1	1	**6**	-	**8**
Process vegetables in oil	-	2	-	**7**	**9**

[1] Data extracted from NSW Food Authority Byte licensing database – November 2013

Approximately two thirds of businesses licensed under the food safety scheme process fresh cut fruit and/or fresh cut vegetables. The other plant product commodities covered under the scheme have relatively low numbers of licensees.

1.3 Updating the risk assessment

The previous risk assessment of the plant products food safety scheme was published in March 2009 (NSW Food Authority, 2009). The risk assessment was part of a comprehensive review of all the food safety schemes undertaken during the revision of the Regulation to create Food Regulation 2010.

The Authority is now updating the risk assessment information on each food safety scheme and the purpose of this document is to provide an update of the 2009 risk assessment on the plant products food safety scheme.

This updated risk assessment examines new literature and research on food safety hazards related to plant products, examines foodborne illness outbreak and recall data and uses the collective evidence to support existing risk management approaches or suggest alternatives.

1.4 Food Standards Code requirements

Since the development of the revised Regulation in 2010, Food Standards Australia New Zealand (FSANZ) raised Proposal P1004 – Primary production and processing standard for seed sprouts. This proposal found that over the past decade there have been a number of foodborne illness outbreaks both in Australia and overseas associated with eating seed sprouts. FSANZ calculated that the resulting cost to the Australian community from outbreaks in 2005 and 2006 at around $2.1 million and seed sprouts contaminated by pathogenic microorganisms were considered to present an unacceptable health risk to consumers (FSANZ 2010; 2011). As such, the development of a Production and processing standard for seed sprouts was considered necessary to address the risk (the scope of the standard does not extend back to primary production). Standard 4.2.6 in the Australia New Zealand Food Standards Code (the Code) commenced nationally on 12 July 2013. The measures in the Code now contain the requirement for a decontamination step, prior to sale of seed sprouts. This brings national requirements into line with NSW legislation that has been in place since the introduction of the plant products food safety scheme.

In addition, more recently FSANZ raised Proposal P1015 to examine the need for a Primary production and processing standard for horticulture, including a review of foodborne illness associated with ready-to-eat (RTE) produce (FSANZ, 2011d). FSANZ found that only a very small number of outbreaks (that met the strict selection criteria for inclusion in the study) in the past 20 years were associated with fresh produce in Australia. The microbiological data available from Australian surveys suggested there is a low level of microbial contamination of fruits and vegetables available in the Australian supply chain, although infrequent contamination of fresh produce with pathogenic microorganisms can occur. Where commodities could be identified as the cause of outbreaks, vegetables and fruits were contaminated in the field or during initial processing through the use of poor quality water or by direct faecal deposition on produce in the field (FSANZ, 2011d).

A Fresh Horticulture Working Group consisting of food safety regulators and the food industry was established by FSANZ to assess regulatory and non-regulatory options for the horticulture sector. The scope and effectiveness of the nine most widely implemented voluntary quality assurance programs was reviewed (Table 2).

Table 2. Horticulture production food safety systems reviewed by FSANZ

System	Version
BRC Global Standard for Food Safety	Issue 6 – July 2011
Coles Supplier Requirements - Food	CSR-FV3 May 2011
Freshcare Code of Practice	3rd Edition – July 2009
GlobalG.A.P Integrated Farm Assurance	Version 4.0_Mar2011
Salad GAP	Version 1.1 (September 2008)
SGS HACCP – Client Audit Checklist	Version 2.7 (19/06/2011)
SQF2000 Code	6th Edition August 2008 – Amended July 2010 (Level 3)
SQF1000 Code	5th Edition August 2009 – Revised January 2010 (Level 3)
Woolworths Quality Assurance – Primary Production – Produce	Version 7 January 2011

Adapted from FSANZ (2011c)

FSANZ concluded from the available evidence that the majority of fresh horticulture production occurs under voluntary quality assurance programs such as those listed in Table 2. These systems, if implemented correctly satisfactorily address the risk and provide a high degree of confidence that Australians have access to safe fresh produce. FSANZ is currently exploring whether regulatory or additional non-regulatory measures are the best way to proceed in managing these hazards in conjunction with existing schemes.

1.5 International risk assessment and research work

Since the last risk assessment prepared by the Authority for the scheme, there has been a lot of activity in international circles examining the risk posed by fresh produce. This has included the establishment of a Fresh Produce Safety Centre at the University of Sydney which aims to identify research needs and attract funding to provide appropriate solutions for the industry. The centre is also collaborating with the US Center for Produce Safety (CPS) at the University of California, Davis to share research outcomes.

A paper from Olaimet & Holley (2012) at the University of Manitoba, Canada reviewed the factors that affect the microbial safety of fresh produce and concluded that future research needs include looking at the linkage between animal feed contaminated by toxigenic *E. coli* (VTEC) and *Salmonella*, manure and contamination of produce. In areas where animal and plant production are poorly segregated this can be a particular challenge and enhances the probability that produce will be contaminated at harvest.

In the USA, Anderson, Jaykus, Beaulieu & Dennis (2011) prepared a risk ranking for fresh produce commodity and pathogen combinations. They examined a huge number of outbreaks dating back to 1996 that have occurred in the USA (Table 3) and found contamination of leafy greens to be the highest risk.

Table 3. Risk ranking of pathogen and fresh produce commodity pairs in the USA

Risk ranking (Top 15)	Commodity	Pathogen	Outbreaks	Cases
1	Leafy greens (iceberg, lettuce, mesclun, romaine, spinach)	*E. coli* O157:H7 (EHEC)	20	733
2	Tomatoes	*S. enterica*	21	2210
=3	Leafy greens (iceberg lettuce, spinach)	*Salmonella enterica*	4	145
=3	Melons (cantaloupe, honeydew, musk melon, watermelon)	*Salmonella enterica*	16	1092
=4	Crucifers (coleslaw)	*E. coli* O157:H7 (EHEC)	2	161
=4	Melons (watermelon)	*E. coli* O157:H7 (EHEC)	1	736
5	Carrots	*Salmonella enterica*	1	8
=6	Berries (strawberries)	Hepatitis A virus	4	314
=6	Green onions	Hepatitis A virus	7	1070
=6	Herbs (parsley)	*E. coli* O157:H7 (EHEC)	2	6
=6	Leafy greens (romaine lettuce)	Hepatitis A virus	1	22
=6	Leafy greens (lettuce, mesclun)	*Shigella* spp.	2	11
=6	Mixed produce	*E. coli* O157:H7 (EHEC)	12	324
=6	Tomatoes	Hepatitis A virus	1	23
Other commodity:pathogen pairs in alphabetical order				
	Berries (raspberries, blackberries, strawberries)	*Cyclospora cayetanensis*	9	1394
	Berries (strawberries, red grapes)	Norovirus	5	194
	Berries (strawberries, blueberries, red grapes)	*E. coli* O157:H7 (EHEC)	3	28
	Berries (strawberries)	*Salmonella enterica*	1	13
	Carrots	Norovirus	2	80
	Crucifers (cabbage, coleslaw, broccoli)	Norovirus	13	528
	Crucifers (cabbage, coleslaw)	*Salmonella enterica*	3	52
	Crucifers (cabbage, coleslaw)	Hepatitis A virus	2	32
	Crucifers (coleslaw)	*Bacillus cereus*	1	8
	Crucifers (coleslaw)	*Cryptosporidium parvum*	1	8
	Green onions	*C. parvum*	2	106
	Green onions	*Salmonella enterica*	1	27
	Herbs (basil)	*Cyclospora cayetanensis*	3	836
	Herbs (basil, parsley)	*Shigella* spp.	3	496
	Herbs (parsley)	*E. coli* (other pathogenic)	1	66
	Herbs (basil, cilantro)	*Salmonella enterica*	3	56
	Leafy greens (bagged lettuce, leaf, lettuce, romaine)	Norovirus	11	329
	Leafy greens (lettuce)	*Campylobacter jejuni*	3	319
	Leafy greens (mesclun)	*Cyclospora cayetanensis*	3	41
	Melons (cantaloupe, honeydew, musk melon, watermelon)	Norovirus	12	440
	Melons (honeydew)	*Shigella* spp.	1	56
	Melons (watermelon)	*Campylobacter jejuni*	1	15
	Mixed produce	Norovirus	142	6136
	Mixed produce	*Salmonella enterica*	21	696
	Mixed produce	*E. coli* (other pathogenic)	1	300
	Mixed produce	*Campylobacter jejuni*	5	210
	Mixed produce	*Cyclospora cayetanensis*	4	193
	Mixed produce	*Shigella* spp.	4	61
	Mixed produce	*Giardia lamblia*	1	50
	Mixed produce	*Salmonella* Typhi	1	16
	Mixed produce	*B. cereus*	2	6
	Mixed produce	Hepatitis A virus	2	6
	Mushrooms	*S. enterica*	1	10
	Non-citrus fruit (pineapple)	Norovirus	5	132
	Non-citrus fruit (mango)	*S. enterica*	4	131
	Peppers	*S. enterica*	2	1562
	Tomatoes	Norovirus	8	369
	Tomatoes	*Campylobacter* spp.	1	13

Adapted from Anderson et al (2011)

Another study from the University of Florida looking at pathogen-food combinations with the greatest burden on public health[2] ranked only *Salmonella* and fresh produce (8th) in the top ten (Batz, Hoffmann, & Morris Jr, 2011). Outbreaks attributed to fresh produce from all 14 pathogens was found to be responsible for 1,193,970 illnesses, 7,125 hospitalisations and 134 deaths over the period 1998-2008. Factors thought to be responsible for the high incidence of foodborne illness linked to this food category include the increased global production, distribution and consumption of fresh produce in conjunction with more intensive production methods and inconsistent application of good agricultural practices (GAP) (Olaimat & Holley, 2012).

Also in the USA, Doyle & Erickson (2012) reviewed some of the guidance documents that have been produced to assist the fresh produce industry in the USA. To reduce the risk of pathogen contamination, the US FDA, USDA and the fresh produce industry released - *Guide to Minimize Microbiological Food Safety Hazards for Fresh Fruits and Vegetables*, which underlined the major reservoirs of pathogen contamination and methods required for their control (FDA, 1998). The material in this document constituted the basis for GAPs for the produce industry and addressed common areas of concern in the growing, production, and distribution of fresh produce, focussing on risk reduction, not elimination of risk. A similar document *Guidelines for On-Farm Food Safety for Fresh Produce* was also produced by the Commonwealth Department of Agriculture, Fisheries and Forestry Australian (DAFF, 2004). Since then, many other guidance documents and research reports have been prepared either by the US industry or with input from the industry that address specific commodities, such as:

- potatoes (National Potato Council, 2013)
- green onions (Anon, 2010)
- tomatoes (United Fresh Produce Association, 2008)
- lettuce and leafy greens (California Leafy Green Products Handler Marketing Agreement, 2013)
- fresh culinary herbs (FDA, 2013)
- cantaloupe and melons (D'lima & Suslow, 2008; Parnell, Harris, & Suslow, 2005; Produce Marketing Association, 2013; Suslow, 2003)

Some of this guidance has been developed in response to repeated outbreaks associated with these types of produce. The five major categories generally covered in these documents for on-farm operations are: 1) soil and fertilisers; 2) irrigation water; 3) field and harvest personnel; 4) equipment; and 5) management.

While these projects provide an indication of the situation in the USA, the knowledge is not necessarily directly transferable to the Australian situation. In Australia we have not witnessed the same magnitude of foodborne illness outbreaks as the USA. Data indicates that fresh produce outbreaks accounted for 13% of foodborne illness outbreaks in the US between 1990 and 2005 (Doyle & Erickson, 2012). In Australia, by contrast, only 4% of all foodborne outbreaks reported from 2001 to 2005 were attributed to fresh produce (Kirk, Fullerton, & Gregory, 2008). Also to illustrate the difference between the USA and Australia, of the commodities ranked as high risk by the Anderson et al (2011) study, only melons have caused significant numbers of illness in Australia due to *Listeria monocytogenes* – see Appendix 2: Australian foodborne illness outbreaks (2009-2013). The work of Anderson et al

[2] The study looked at 14 foodborne pathogens across 12 food categories (168 pathogen-food combinations)

(2011) did not identify *Listeria* as a high risk pathogen for fresh produce commodities. These are some of the reasons that the majority of plant products have been considered a low food safety risk with minimal regulatory intervention in Australia.

2. Fresh cut fruit

The food safety scheme defines fresh cut fruit as:

"any fruit that has been processed in some way (for example, by trimming, cutting, slicing, peeling or pulling apart), but is still raw".

2.1 Hazard identification – cut melons as a potentially hazardous food

The primary hazard associated with the processing of fresh cut fruit is *Listeria monocytogenes*, predominantly through the possibility of cross contamination associated with the additional handling from cutting and slicing and packaging under storage conditions for a time that might permit growth. The Authority licenses businesses that manufacture fresh cut fruit and require them to have a food safety program in place. These measures appear to adequately address the risk.

Although the scope of the Authority's plant products food safety scheme does not extend to food handled at retail, it has been noted that there is a significant amount of unrefrigerated display of cut melons (in particular watermelon) in some supermarkets and greengrocers. From anecdotal evidence, it appears that:

- some retail stores will cut and wrap melons, displaying watermelons at room temperature (stores may be air conditioned to 20-22°C) and limit the time on display to the day of preparation
- supermarkets will often display cut and wrapped cantaloupe/rockmelon, honeydew and papaya in refrigerated display cases
- at least some greengrocers display all cut melons (including cantaloupe/rockmelon[3]) at room temperature on the day of preparation

The issue was referred to the Authority by a Local Council environmental health officer (EHO) to consider whether:

- melons, once they are cut, should be considered as a 'potentially hazardous food[4]'
- cut melons should be displayed under refrigeration?
- if cut melon are not displayed under refrigeration what other options for food safety management are available

Foods that meet both of the following criteria are considered potentially hazardous:

- the food may contain a pathogen that needs to multiply in order to cause illness, and
- the food will support the growth of this pathogen

[3] The names rockmelon (more commonly used in Australia) and cantaloupe (more commonly used in the USA) are used interchangeably in this document

[4] The term 'potentially hazardous food' has a specific meaning under Standard 3.2.2 of the Food Standards Code. It means food that must be kept at certain temperatures to minimise the growth of any pathogenic microorganisms that may be present in the food or to prevent the formation of toxins in the food.

As such, a review was undertaken by the Authority to examine the risk posed by melons (rockmelon, honeydew and watermelon) and whether this risk is exacerbated by cutting and storing at room temperature. The Code does provide for the use of alternative methods of compliance, including the use of time as a control for potentially hazardous foods. The default time control (the 4 hour / 2 hour rule) is typically accepted as safe without further validation (NSW Food Authority, 2011a). The assessment of fresh cut melons focussed on the hazards of *Salmonella* and *L. monocytogenes* as these are the two pathogens that have been most often associated with foodborne illness outbreaks from melons.

2.1.1 Growth of microorganisms on fresh cut melons

Melons may be subject to contamination on farm, in the packing shed, during distribution and during cutting. The process of cutting is a key risk because it can spread pathogenic bacteria that can become trapped in the rough skin (particularly for rockmelon) to the flesh of the melon. Castillo et al (2004) investigated US cantaloupe found 5/950 (0.5%) positive for *Salmonella* and 37/950 (3.7%) positive for *E. coli*. A study by a Victorian group of councils (FSANZ, 2011a) found *Listeria* spp in 1.5% of cut fruit samples.

The skin of fruit provides a physical barrier that is usually the key factor in controlling pathogen growth in fruit. Once the skin is breached inhibition of pathogen growth is due to the presence of organic acids and the low pH of the flesh. Because cantaloupe, honeydew, and watermelons are low acid (high pH) fruits, they offer little or no inhibition of bacterial growth. To confirm this, the Authority took some samples of melons to test for pH, and as a comparison also tested samples of papaya and pineapple (Table 4). The results confirmed the low level acidity of melons, particularly for rockmelons which can be near neutral.

Table 4. pH values measured for melons

Fruit	Number of samples	pH (mean value)	pH range
Rockmelon	8	6.6	6.3 - 7.0
Honeydew	7	6.3	6.0 - 6.5
Watermelon	6	5.8	5.4 - 6.2
Papaya	4	5.2	5.0 - 5.5
Pineapple	5	3.4	3.4 - 3.5

Many published studies also confirm the high pH level of melons and have demonstrated that cut melons will support the growth of pathogenic bacteria (Table 5). Growth has been demonstrated at room temperature and down to 10°C. Lag times and growth rates for organisms vary, but the growth of *Salmonella*, *E. coli* and *Listeria* will be more likely to occur and more rapid at higher temperatures. Importantly, it is also clear that in some cases pathogen growth was initiated rapidly in these trials.

Table 5. Growth of pathogens on fresh cut melons and melon pulp

Melon	Acid/pH	Pathogen	Temp	Lag phase (hr)	Growth rate (log cfu/g)	Generation (doubling) time (hr)	Reference
Papaya	pH 5.7	*Salmonella* spp.	4°C	No growth			Strawn et al (2010)
Cantaloupe washed with water	—	*L. monocytogenes*	5°C	2 hours		5.26	Ukuku et al (2012)
Cantaloupe washed with 2.5% hydrogen peroxide	—	*L. monocytogenes*	5°C	No growth after 72 hours			Ukuku et al (2012)
Cantaloupe washed with water	—	*L. monocytogenes*	10°C	2 hours		5.71	Ukuku et al (2012)
Cantaloupe washed with 2.5% hydrogen peroxide	—	*L. monocytogenes*	10°C	8 hour lag phase and then 0.6 log increase after 72 hours			Ukuku et al (2012)
Cantaloupe or honeydew	pH 5.87 Acidity 1.99%	*Salmonella*	10°C	Growth = numbers increase from 10^2 to 10^4 over 9 days at 10°C but is then inhibited by maximal numbers of indigenous flora (aerobes, Pseudomonas and yeast & mould) and numbers decline			Ukuku et al (2007)
Cantaloupe or honeydew	pH 7.01	*S.* Enteritidis	10°C			7.31	Penteado & Leitão (2004)
Cantaloupe or honeydew	pH 7.01	*L. monocytogenes*	10°C			7.12	Del Rosario et al (1995).
Watermelon pulp	pH 5.50	*S.* Enteritidis	10°C			7.47	Penteado & Leitão (2004)
Watermelon pulp	pH 5.50	*L. monocytogenes*	10°C			13.03	Penteado & Leitão (2004)
Papaya pulp	pH 4.87	*S.* Enteritidis	10°C			16.61	Penteado & Leitão (2004)
Papaya pulp	pH 4.87	*L. monocytogenes*	10°C			15.05	Penteado & Leitão (2004)
Papaya	pH 5.7	*Salmonella* spp.	12°C	Growth = up to 5 log increase in 5 days			Strawn et al (2010)
Cantaloupe washed with water	—	*L. monocytogenes*	20°C	2 hours		5.70	Ukuku et al (2012)
Cantaloupe washed with 2.5% hydrogen peroxide	—	*L. monocytogenes*	20°C	6 hour lag phase and then 0.8 log increase after 72 hours			Ukuku et al (2012)
Cantaloupe or honeydew	pH 7.01	*S.* Enteritidis	20°C			1.69	Penteado & Leitão (2004)
Cantaloupe or honeydew	pH 7.01	*L. monocytogenes*	20°C			1.74	Del Rosario et al (1995).
Watermelon pulp	pH 5.50	*S.* Enteritidis	20°C			1.60	Penteado & Leitão (2004)
Watermelon pulp	pH 5.50	*L. monocytogenes*	20°C			2.17	Penteado & Leitão (2004)
Papaya pulp	pH 4.87	*S.* Enteritidis	20°C			1.74	Penteado & Leitão (2004)
Papaya pulp	pH 4.87	*L. monocytogenes*	20°C			6.42	Penteado & Leitão (2004)

Melon	Acid / pH	Pathogen	Temp	Lag phase (hr)	Growth rate (log cfu / g)	Generation (doubling) time (hr)	Reference
Cantaloupe or honeydew	pH 5.87 Acidity 1.99%	*Salmonella*	22°C	Growth = numbers increase from $10^{2.2}$ to $10^{3.5}$ over 5 hours at 22°C (but not 3 hours) numbers increase from 10^{2} to $10^{4.5}$ over 3 days			Ukuku et al (2007)
Watermelon	pH 5.6	*Salmonella*	22°C	Growth = numbers did not increase at room temperature (22°C) after storage for 3 or 5 hours prior to storage at 5°C.			Ukuku et al (2007)
Mango	pH 5.7[5]	*E. coli* O157:H7	23°C	Growth = 1.5 log increase in 24 hours then gradual decrease			Strawn et al (2010)
Papaya	pH 5.7	*E. coli* O157:H7	23°C	Growth = up to 3.5 log increase in 24 hours then gradual decrease			Strawn et al (2010)
Papaya	pH 5.7	*Salmonella* spp.	23°C	Growth = up to 4 log increase in 24 hours			Strawn et al (2010)
Cantaloupe or honeydew	Acidity is low and pH 5.94	*E. coli* O157:H7	25°C	Growth = 10^{5} – 10^{9} growth in in 24 hours grew well at 25°C including under modified atmosphere storage Rapid 10^{5} – 10^{9} growth in 24 hours			Abadias et al (2012)
Cantaloupe or honeydew	pH 7.01	*E. coli*	25°C	Growth = maximum level of $10^{6.81}$			Penteado & Leitão (2004)
Watermelon	pH 5.6	*E. coli*	25°C	Growth = maximum level of $10^{8.51}$			Del Rosario et al (1995)
Cantaloupe or honeydew	pH 7.01	*S.* Enteritidis	30°C			0.69	Penteado & Leitão (2004)
Cantaloupe or honeydew	pH 7.01	*L. monocytogenes*	30°C			0.84	Del Rosario et al (1995).
Watermelon pulp	pH 5.50	*S.* Enteritidis	30°C			0.51	Penteado & Leitão (2004)
Watermelon pulp	pH 5.50	*L. monocytogenes*	30°C			1.00	Penteado & Leitão (2004)
Papaya pulp	pH 4.87	*S.* Enteritidis	30°C			0.66	Penteado & Leitão (2004)
Papaya pulp	pH 4.87	*L. monocytogenes*	30°C			1.16	Penteado & Leitão (2004)

[5] not measured, quoting other author

There is little in the growth studies to suggest the growth of *Salmonella* in watermelon is substantially different to growth in rockmelon (cantaloupe) or honeydew. Based on the information in Table 4, papaya appears to be a little less conducive to bacterial growth than rockmelon, honeydew or watermelon due to a lower pH. However, Strawn et al (2010) found rapid growth from low numbers (10 cells/g) at 23°C (Table 5). Natural contamination rates for pathogens in melons would be expected to be low and Ukuku, Olanya, Geveke & Sommers (2012) found that the populations of *L. monocytogenes* transferred from melon rinds to fresh-cut pieces were very low (below the detection limit but were present by enrichment methodology). Increased storage temperatures reduced the lag phases and growth of *L. monocytogenes*. In the opinion of the authors, the results of this study confirmed the need to store fresh-cut cantaloupes at 5°C immediately after preparation to enhance the microbial safety of the fruit.

2.2 Exposure assessment – increasing market share

The market share of pre-packaged cut fruit continues to increase, particularly through the large supermarket chains. While the Authority does not have access to retail data detailing the growth of this product line, the convenience factor for fresh cut fruit continues to drive demand and this can be seen by the additional shelf space allocated to fresh cut fruit products.

While consumption data in Australia is limited, in the USA, the consumption of rockmelon (cantaloupe) has increased significantly, with annual per capita consumption almost doubled from 5.8 pounds (2.6 kg) in 1980 to 11.3 pounds (5.1kg) in 2002 (Bowen, Fry, Richards, & Beauchat, 2006).

2.3 Hazard characterisation – melons have a history of foodborne illness

Fresh cut fruit has been associated with cases of listeriosis through the consumption of rockmelon (cantaloupe) and honeydew, both in Australia (Munnoch et al., 2009; Sheridan et al., 2007) and overseas (Buchholz et al., 2011; EFSA, 2011a). It is clear there is a history of foodborne illness attributed to melons but the question to consider is whether cutting and display at room temperature has been implicated as a contributing factor in outbreaks.

Bowen et al (2006) identified 28 outbreaks associated with cantaloupe over a 30 year time span. Twenty five of the outbreaks were included in the Center for Disease Control (CDC) outbreak database and an additional three were reported in the scientific literature. In 14 outbreaks, foods items in addition to cantaloupe were also implicated as vehicles. Nineteen of the outbreaks (68%) were identified in the final decade of the surveillance period. Seventeen of the outbreaks (61%) were associated with cantaloupe prepared in a restaurant or by a caterer and four outbreaks (14%) were associated with cantaloupe prepared in a grocery store. The authors noted:

- although more 1,600 cases of illness associated with cantaloupe consumption were reported the true burden of illness is probably much greater. A large number of cantaloupe-related illnesses probably occurred among clusters too small to be easily detected. Outbreaks comprise a small proportion of foodborne illness each year.

Table 6. Foodborne illness outbreaks associated with melons

Year	Country	Food	Pathogen	Cases	Hospitalisations (Deaths)
2012	Europe	Watermelon	*Salmonella* Newport	50	(1)
2011	USA	Papaya	*Salmonella* Agona	97	10
2011	USA	Cantaloupe	*Listeria monocytogenes*	139	(29)
2009	USA/Canada	Melon	*Salmonella* Carrau		
2009	Australia (WA)	Papaya (paw paw)	*Salmonella* Saintpaul	11	
2008	USA	Watermelon	*Salmonella* Javiana		
2008	USA	Cantaloupe or watermelon	*Salmonella* Newport		
2007	USA	Fruit salad	*Salmonella* Litchfield	30	
2006	USA/Canada	Fruit salad	*Salmonella* Oranienburg	41	
2006	Australia	Rockmelon	*Salmonella*	100	
2006	Australia (WA)	Papaya (paw paw)	*Salmonella* Litchfield	11	3
2004	USA	Melon	*E. coli* O157:H7	6	
2003	USA	Cantaloupe, honeydew	*Salmonella* Muenchen	58	15
2003	USA	Cantaloupe, pineapple, banana	Norovirus	16	nr[6]
2002	USA/Canada	Cantaloupe	*Salmonella* Poona	58	nr
2002	USA	Cantaloupe, watermelon, grapes	*Salmonella* Berta	29	nr
2001	USA	Cantaloupe, honeydew, pineapple	Norovirus	36	0
2001	USA	Cantaloupe, pineapple	Norovirus	42	0
2001	USA	Cantaloupe	*Salmonella* Poona	50	9 (2)
2001	USA	Cantaloupe, honeydew, pineapple	*Salmonella* Poona	23	4
2001	USA	Cantaloupe, pineapple	Unknown	4	0
2001	USA	Cantaloupe	*Salmonella* Group E1	2	0
2000	USA	Cantaloupe	*Salmonella* Poona	47	11
2000	USA	Cantaloupe, turkey sandwich	Norovirus	33	0
2000	USA	Cantaloupe, turkey	Norovirus	20	nr
1999	USA	Cantaloupe, honeydew, watermelon	Norovirus	61	nr
1999	USA	Cantaloupe	Norovirus	5	0
1998	Canada	Cantaloupe	*Salmonella* Oranienburg	20	nr
1997	USA	Cantaloupe	*Salmonella* Saphra	24	6
1995	USA	Cantaloupe, ice cream	Unknown	24	0
1995	USA	Cantaloupe, watermelon	Unknown	27	0
1993	USA	Cantaloupe, honeydew	Unknown	140	0
1993	USA	Cantaloupe	*E. coli* O157:H7	24	nr
1991	USA/Canada	Cantaloupe	*Salmonella* Poona	>400	7
1991	USA	Cantaloupe	Unknown	21	0
1989	USA	Cantaloupe, honeydew and pineapple	Unknown	101	3
1989	USA	Cantaloupe	*Salmonella* Chester	245	nr
1985	USA	Cantaloupe	Unknown	77	nr
1985	USA	Cantaloupe	*Campylobacter jejuni*	16	2
1984	USA	Cantaloupe	Unknown	12	nr

Adapted from Bowen et al (2005); Buchanan (2011); Foodborne Illness Outbreak Database (MarlerClark, 2013); ProMED mail (International Society for Infectious Diseases, 2013)

[6] nr = not reported

- no single microorganism or obvious mode of contamination appeared to be the cause of the trend to increasing foodborne illness. Instead, cantaloupes are susceptible to contamination in multiple ways, including internalisation of bacteria through intact or damaged rind tissue and contact with contaminated surfaces during processing or preparation

D'lima and Suslow (2008) compiled research citations on the microbiological safety and risk reduction interventions for fresh and fresh-cut melons. The compilation includes two reports of outbreaks attributed to watermelons:

- salmonellosis where watermelon was implicated epidemiologically and microbiologically
- an epidemic of *Shigella sonnei* where watermelon was the only common source of infection and the organism was shown to be capable of multiplying to infectious doses in watermelon

Overall most outbreaks are traceable to contamination that occurred at farm. Any role played by melon cutting or unrefrigerated storage is not clear. A number of outbreaks are due to contamination of food by kitchen staff with gastric illness and in some cases display of the cut melons at 22°C will increase the risk.

2.4 Risk characterisation – control measures for cut melons

Melons clearly can be subject to contamination on farm, in the packing shed, during washing (if it occurs), during distribution and during cutting. The Authority and NSW Department of Primary Industries (DPI) have liaised with Horticulture Australia and are working to develop quality assurance education tools for melon farmers. Alvarado-Casillas et al (2010) validated a washing and sanitising step for cantaloupes handled at a packing facility in Mexico. The results supported the elimination of dump tanks. In Australia melons may be washed in dump tanks and the inconsistent use of sanitisers in the wash water has been identified as a risk factor in previous outbreaks.

The process of cutting melons can be considered a key risk factor because of the potential to spread pathogenic bacteria from the surface / skin of the melon to the flesh of the melon where it may be able to increase in numbers. Control measures that have been suggested by various authors (Buchanan, 2011; D'lima & Suslow, 2008; Parnell, et al., 2005; Suslow, 2003) include:

- use only good quality fruit, free from open wounds or defects that may have allowed bacteria to be internalised. Avoid fruit that have visible sunken areas or areas of mould or decay.
- melons should be washed with potable water before cutting or peeling.
- before cutting or other processing, a further reduction in microbial contamination may be achieved by scrubbing in the presence of sanitiser or application of an alternative surface decontamination process such as hot water, steam or other treatments.
- the exterior surface of rockmelon is more difficult to clean than the exterior of smooth, waxy melons such as honeydew and watermelon. Mechanical cleaning with brushing in combination with an approved antimicrobial agent is essential before the rind is cut and removed.

- cutting or peeling knife blades should be cleaned and disinfected on a regular basis according to written procedures to reduce the potential for cross-contaminating melons during the cutting or peeling process.
- knife blade disinfecting solutions should be monitored to ensure the disinfectant is present at sufficient levels to achieve its intended purpose and does not promote the potential for cross-contamination.
- recommending that pre-cut melons should be wrapped/packaged and refrigerated as soon as possible and distributed under refrigeration temperatures (ie 4°C or less).

Authors working on melon food safety recommend refrigerated storage of cut melons. Codex Alimentarius has prepared a draft Annex IV *Annex for melons* to the *Code of hygienic practice for fresh fruits and vegetables*. Included in this annex is that while intact rockmelon may be stored at room temperature, cut products should be refrigerated within 2 hours of cutting (CAC/CCFH, 2012).

Growth data from numerous publications provides clear evidence that cut melons can be considered potentially hazardous foods, in that they are able to support the growth of pathogenic bacteria, should they be present. Despite this, there does not appear to be significant evidence in Australia showing that the current practices of displaying cut melons at room temperature on the day of preparation to be a significant health risk. The measured pH values and history of foodborne illness outbreaks tend to demonstrate that rockmelon and honeydew are the higher risk melons, and temperature control (through refrigerated storage or implementation of the 4 hour / 2 hour rule) of these should be prioritised. Given the large size of watermelons a requirement to refrigerate cut watermelon may not be practical, and to encourage a practice of cutting on demand may not necessarily see the same level of hygiene practiced as when a set time is allocated for the cutting of melons at the beginning of the day. Extended storage of cut melons for longer than one day may increase the risk further and should be discouraged.

3. Fresh cut vegetables

The food safety scheme defines fresh cut vegetable as:

"any of the following vegetables that has been processed in some way (for example, by trimming, cutting, slicing, peeling or pulling apart), but is still raw: (a) capsicum, (b) carrot, (c) celery, (d) leek, (e) mushroom, (f) spinach, (g) chinese cabbage, (h) cabbage, (i) witlof, (j) lettuce, (k) any other leafy green vegetable."

3.1 Hazard identification – *Listeria monocytogenes* and lettuce

The food safety scheme targets those vegetables where there is a likelihood they will be consumed raw. One of the main foods of interest in this category has been lettuce, and the potential risk from *L. monocytogenes*, especially for food service to vulnerable persons.

Following the issue of a circular by NSW Health in 1999 (NSW Health, 1999) - *Circular 99/95 Control of foodborne listeriosis in health care institutions* - lettuce was taken off the menu for many hospitals in NSW. The circular included lettuce among other foods, including salad vegetable, fruits and garnishes as foods that should not be served to high-risk patients unless they were subjected to a listericidal process such as cooking. The logic behind this recommendation was that the physical structure of these foods prevents scrubbing or removal of soil, where *Listeria* may often be found.

While this circular has since been superseded some facilities have still not introduced lettuce back onto the menu due to a perceived risk from *Listeria monocytogenes.*

3.2 Exposure assessment – pre-packaged fresh cuts

Globally, fruit and vegetable consumption increased on average 4.5% yearly between 1990 and 2004 (Olaimat & Holley, 2012). RTE minimally processed vegetables have gained more importance in the last 20 years due to consumer demand for fresh, convenient, preservative-free foods that may promote health.

Fresh cut products is an emerging and fast growing sector and the market share of pre-packaged cut vegetables continues to increase. Over the last 30 years there has been at least a 25% increase in the average amount of leafy green vegetables consumed in the USA (Pollack, 2001). This has been attributed to a number of factors, including improved seasonal access. Concurrent with the increase in their production and consumption, RTE vegetables have been associated with progressively more foodborne disease outbreaks, predominantly overseas.

3.3 Hazard characterisation – *Listeria* can grow on lettuce

3.3.1 How often is *Listeria* found on lettuce?

Listeria monocytogenes can be isolated from almost any foods, including RTE deli meats, milk, dairy products, soft cheeses and vegetables (Gombas, Chen, Clavero, & Scott, 2003; Lianou & Sofos, 2007). The ubiquitous nature of this pathogen and its ability to adapt to multiple environments can hinder the implementation of effective control measures.

There have been many surveys around the world looking at the prevalence of *Listeria* on lettuce, with some results showing that *Listeria* can be readily isolated from lettuce (Francis & O'Beirne, 2006; Gombas, et al., 2003; Lianou & Sofos, 2007). This is most likely due to the close contact of the lettuce with the soil it is grown in (Hanning, Johnson, & Ricke, 2008). One of the most extensive surveys undertaken for *L. monocytogenes* in bagged pre-cut leafy salads was that of Gombas et al (2003), who tested 2966 samples and found *L. monocytogenes* in 22 samples (0.74%), with all but one at a concentration of less than 100 cfu/g. Of the eight product categories examined, this was the second lowest prevalence found.

Odumeru, Mitchell, Alves, Lynch, Yee, Wang, Styliadis, & Farber (1997) detected *L. monocytogenes* in 2/24 (8.3%) and 3/15 (20%) of chopped lettuce samples stored at 4°C and 10°C for 11 days respectively. When enumerated, only one which had been stored at 10°C sample was above 100 cfu/g. Porto & Eiroa (2001) examined 100 samples of lettuce in Brazil and found *L. monocytogenes* in four samples. Two samples were enumerated by a Most Probable Number (MPN) method and found to contain very low levels of 0.9 and 1.5 per gram.

Overseas, in Japan, Koseki et al (2011) surveyed 419 samples of whole heads of iceberg lettuce and failed to detect *L. monocytogenes*. In Canada, a study of locally grown produce collected from farm markets in Alberta during 2007, no pathogenic bacteria were isolated from 128 lettuce samples (Bohaychuk et al., 2009). In Norway, 179 samples of organically grown lettuce were collected from 12 producers, with *L. monocytogenes* found in two samples (Loncarevic, Johannessen, & Rorvik, 2005). So while surveys show that

L. monocytogenes can be detected on lettuce, it does not appear to be found at a significantly higher prevalence, or at higher levels than on other RTE foods.

In Australia, Szabo, Scurrah & Burrows (2000) undertook a survey of 120 minimally processed, cut and packaged lettuce samples were purchased from retail supermarkets or provided by a salad production facility over an 8-month period. They found *L. monocytogenes* in 1/60 retail samples and 2/60 factory samples for an overall prevalence of 2.5%. Over the past several years, the NSW Food Authority testing data has only detected *Listeria innocua* in 3/113 samples of all foods containing lettuce (all 3 were egg, lettuce and mayonnaise sandwiches taken during a survey of roadside retail outlets). *L. monocytogenes* has not been detected in any food samples containing lettuce. In addition, all producers of fresh cut vegetables in NSW are required to test their product every 10 batches for *L. monocytogenes* and notify the Authority of any positive results. To date there have not been any notifications of *L. monocytogenes* in lettuce.

The outer leaves of a lettuce are more likely to be contaminated than the lettuce head, as these are more likely to be exposed to sources such as soil. The removal of these leaves may lessen the likelihood of *L. monocytogenes* being found in lettuce. In addition, washing lettuce has been shown to deliver a 1-log reduction in *L. monocytogenes* (Delaquis, Stewart, Cazaux, & Toivonen, 2002). The addition of a chlorine-based sanitiser may provide some additional reduction as residual chlorine may serve to inactivate any *L. monocytogenes* that may contaminate shortly after the washing step (Beuchat & Brackett, 1990). Currently, no sanitiser has been found to consistently produce more than a 2 log reduction of *L. monocytogenes* on cut lettuce (Hanning, et al., 2008). While this does not guarantee to eliminate the organism, it may be effective enough against naturally occurring levels of *L. monocytogenes* in lettuce in order to minimise the risk to consumers.

3.3.2 How well does Listeria grow on lettuce?

Studies show that *L. monocytogenes* is able to grow on lettuce (Beuchat & Brackett, 1990; E. Carrasco, Pérez-Rodríguez, Valero, García-Gimeno, & Zurera, 2008; Delaquis, et al., 2002; Sant'Ana, Franco, & Schaffner, 2012; Steinbruegge, Maxcy, & Liewen, 1988). The results of several growth studies are summarised in

Table 7. Results appear to be variable with Hoelzer, Pouillot & Dennis (2012) summarising growth studies of 103 experiments with *L. monocytogenes* on lettuce, 14 showed no growth, 21 showed limited growth[7] and 68 showed growth.

Steinbruegge et al. (1988) demonstrated that *L. monocytogenes* can grow on lettuce. Increases of 10- to nearly 1000-fold were detected on bite sized pieces sealed in plastic bags and stored at 5°C and 12°C, respectively, for up to 14 days. Naturally occurring *L. monocytogenes* in prepacked refrigerated RTE salads has been reported to undergo a roughly two-fold increase in population when held at 4°C for 4 days (Sizmure & Walker, 1988) cited from Beuchat & Brackett, 1990).

In most studies, storage of lettuce at 10°C or below resulted in a lag phase that lasted around two days during which time the organism does not grow. After this time the generation time (time taken to double in numbers) ranges between 11 hours and 23 hours. Storage at elevated temperatures has the effect of reducing both the lag phase and the

[7] Limited growth was defined as ≤ 0.5 log cfu growth in 10 days at 5°C

generation time and allows the organism to reach a high maximum population density. Using inoculum levels of 10^4 to 10^5 cfu/g, Beuchat & Brackett (1990) found the organism able to reach populations of 10^8 to 10^9 cfu/g after 10 days storage at 10°C, with only slight growth observed in identical samples held at 5°C.

The use of modified atmosphere packaging (MAP) with pre-packaged salads appears to neither enhance or represses the growth of *L. monocytogenes*. Beuchat & Brackett (1990) observed that *L. monocytogenes* behaved similarly in either air or modified atmosphere of 3% O_2:/ 97% N_2 when inoculated samples of iceberg lettuce were stored at 5°C or 10°C. The extended shelf life afforded by MAP packaging (in suppressing spoilage organisms) extends the time for *L. monocytogenes* to grow in the product, therefore potentially increasing the risk of foodborne illness. As shown by Szabo, Simons, Coventry and Cole (2003), after 14 days stored in a gas permeable film at 4°C and 8°C, packaged fresh pre-cut lettuce was considered organoleptically unacceptable showing obvious signs of browning, wilting, and wetness. Odumeru et al (1997) found that lettuce stored at 4°C for 11 days was slightly discoloured but acceptable, while lettuce stored at 10°C started to show discolouration as early as 4 days and appeared unacceptable with off odours after 11 days.

Beuchat & Brackett (1990) also observed that when lettuce was washed in water containing a chlorine-based sanitiser the reduction in populations of naturally occurring microflora did not appear to give a competitive advantage to growth of *L. monocytogenes* over the course of a 15-day study. Carrasco et al (2008) also showed that at 5°C the native bacterial flora of the lettuce did not affect the growth rate of *L. monocytogenes* regardless of incubation temperature, however it may have an effect on the duration of the lag phase (extending it) and lowering the maximum population density that *L. monocytogenes* can reach in the product .

Sant'Ana et al (2012) also examined the growth of *Salmonella enterica* (Typhimurium and Enteritidis) on minimally processed lettuce, iceberg and crisp varieties. The authors found that *Salmonella* survived but did not grow on minimally processed lettuce stored at 5°C, under a modified atmosphere of 5% O_2, 15% CO_2 and 80% N_2.

3.3.3 History of outbreaks from lettuce

In a risk assessment on RTE foods conducted in the USA, there were no reported, epidemiologically confirmed cases of listeriosis infection involving the consumption of lettuce reported over more than 25 years (FDA & USDA, 2003). Because of this, prepacked pre-cut lettuce and other vegetables were ranked as a low-risk category for acquiring foodborne listeriosis, responsible for less than one case per year. A review conducted by Hanning, Johnson & Ricke (2008) focused on exploring possible reasons why no recent outbreaks of listeriosis due to contaminated pre-cut packaged lettuce have been reported. There were several factors thought to be responsible, such as:

- lettuce typically has a short shelf life (<15 days from harvest), meaning the opportunity for *L. monocytogenes* to grow to high levels is limited
- potential inhibition of *L. monocytogenes* due to competition by indigenous microflora of lettuce (this has been studied by numerous authors and differing results found)
- some properties of lettuce possibly cause *L. monocytogenes* to become avirulent (there does not appear much evidence to support this theory)

Table 7. Growth of *Listeria monocytogenes* on lettuce

Product	Treatment	Temp	Lag phase (hr)	Growth rate (log cfu/hr)	Generation (doubling) time (hr)	Reference
Lettuce, iceberg	Unwashed	1°C	No growth after 14 days			Delaquis et al (2002)
Lettuce, iceberg	Washed in chlorinated water at 4°C	1°C	Numbers declined over 14 days			Delaquis et al (2002)
Lettuce, iceberg	Washed in chlorinated water at 47°C	1°C	Growth = 1 log in 14 days			Delaquis et al (2002)
Lettuce, iceberg	Pre-cut, packaged in gas permeable film	4°C	Growth = 1 log in 7 days, 1.1 log in 14 days			Szabo et al (2003)
Lettuce, iceberg	MAP packaged	5°C	134	0.013	23.2	Carrasco et al (2008)
Lettuce, iceberg	Untreated	5°C	60.1	0.021	14.3	Koseki et al (2005)
Lettuce, iceberg	Treated with acidic electrolysed water for 5 mins	5°C	52.4	0.026	11.6	Koseki et al (2005)
Lettuce, whole	Washed, torn into bite sized pieces and sealed in air	5°C	No growth in 2 out of 4 trials Growth (2 trials) = 0.3 log in 7 days Growth (2 trials) = 1.13 log in 14 days			Steinbruegge et al. (1988)
Lettuce, iceberg	Whole leaves, not treated with chlorine, packaged in 3%O_2/97%N_2 or air	5°C	Growth = 0.5 log in 15 days			Beuchat & Brackett (1990)
Lettuce, iceberg	Whole leaves, chlorine treated, packaged in 3%O_2/97%N_2 or air	5°C	Growth = 0.0 log in 8 days / 1.1 in 15 days			Beuchat & Brackett (1990)
Lettuce, iceberg	Shredded, not treated with chlorine, packaged in 3%O_2/97%N_2 or air	5°C	No growth in 15 days			Beuchat & Brackett (1990)
Lettuce, iceberg	Shredded, chlorine treated, packaged in 3%O_2/97%N_2 or air	5°C	Growth = 0.0 log in 8 days / 1 log in 15 days			Beuchat & Brackett (1990)
Lettuce, iceberg	Shredded, stored in air	7°C	Growth = < 1 log in 7 days			Jacxsens et al (1999)
Lettuce, iceberg	Shredded, (2-3% O_2/2-3%CO_2/94-96% N_2)	7°C	Growth = < 1 log in 7 days			Jacxsens et al (1999)
Lettuce	Packed, minimally processed (5%O_2/15% CO_2 /80%N_2)	7°C	45.5	0.0165	18.2	Sant'Ana (2012)
Lettuce	Packed, minimally processed (5%O_2/15% CO_2 /80%N_2)	7°C	56.6	0.0191	15.8	Sant'Ana (2012)
Lettuce	Packed, minimally processed (5%O_2/15% CO_2 /80%N_2)	7°C	76.4	0.0141	21.3	Sant'Ana (2012)
Lettuce, iceberg	Pre-cut, packaged in gas permeable film	8°C	Growth = 1.9 log in 7 days / 2.7 log in 14 days			Szabo et al (2003)
Lettuce	Cut, modified atmosphere environment	8°C	Growth = 1.5 log in 12 days			Francis & O'Beirne (2001)
Lettuce	Cut, modified atmosphere environment	8°C	Growth = 1.4 log in 12 days			Francis & O'Beirne (2001)
Lettuce	Packed, minimally processed (5%O_2/15% CO_2 /80%N_2)	10°C	39.1	0.0225	13.4	Sant'Ana (2012)
Lettuce	Packed, minimally processed (5%O_2/15% CO_2 /80%N_2)	10°C	44.6	0.0272	11.1	Sant'Ana (2012)
Lettuce	Packed, minimally processed (5%O_2/15% CO_2 /80%N_2)	10°C	48.7	0.0233	12.9	Sant'Ana (2012)
Lettuce, iceberg	Unwashed	10°C	Growth = 1 log in 14 days			Delaquis et al (2002)
Lettuce, iceberg	Washed in chlorinated water at 4°C	10°C	Growth = 2 log in 7 days /2 log reduction next 7 days			Delaquis et al (2002)
Lettuce, iceberg	Washed in chlorinated water at 47°C	10°C	Growth = 3 log in 14 days			Delaquis et al (2002)
Lettuce, iceberg	Untreated	10°C	45.6	0.047	6.4	Koseki et al (2005)
Lettuce, iceberg	Treated with acidic electrolysed water for 5 mins	10°C	39.7	0.049	6.1	Koseki et al (2005)
Lettuce, iceberg	Whole leaves, not treated with chlorine, packaged in 3%O_2/97%N_2 or air	10°C	Growth = 2 log in 3 days / 3 log in 10 days			Beuchat & Brackett (1990)
Lettuce, iceberg	Whole leaves, chlorine treated, packaged in 3%O_2/97%N_2 or air	10°C	Growth = 2 log in 3 days / 3 log in 10 days			Beuchat & Brackett (1990)
Lettuce, iceberg	Shredded, not treated with chlorine, packaged in 3%O_2/97%N_2 or air	10°C	Growth = 2 to 3 log in 10 days			Beuchat & Brackett (1990)
Lettuce, iceberg	Shredded, chlorine treated, packaged in 3%O_2/97%N_2 or air	10°C	Growth = 2.5 to 3.5 log in 10 days			Beuchat & Brackett (1990)
Lettuce, butterhead	Washed, sealed in air	10°C	Growth = 1.5 logs in 7 days			Carlin & Nguyen-The (1994)

Product	Treatment	Temp	Lag phase (hr)	Growth rate (log cfu/hr)	Generation (doubling) time (hr)	Reference
Lettuce, lamb's	Washed, sealed in air	10°C	1.0 decrease in 7 days			Carlin & Nguyen-The (1994)
Lettuce, whole	Washed, torn into bite sized pieces and sealed in air	12°C	No growth in 2 out of 5 trials Growth (3 trials) = 2.04 log in 7 days Growth (3 trials) = 3.05 log in 14 days			Steinbruegge et al. (1988)
Lettuce, iceberg	MAP packaged	13°C	—	0.019	15.8	Carrasco et al (2008)
Lettuce, iceberg	Untreated	15°C	10.2	0.090	3.3	Koseki et al (2005)
Lettuce, iceberg	Treated with acidic electrolysed water for 5 mins	15°C	8.5	0.092	3.3	Koseki et al (2005)
Lettuce	Packed, minimally processed (5%O_2/15% CO_2 /80%N_2)	15°C	8.4	0.0656	4.6	Sant'Ana (2012)
Lettuce	Packed, minimally processed (5%O_2/15% CO_2 /80%N_2)	15°C	14.4	0.0605	5.0	Sant'Ana (2012)
Lettuce	Packed, minimally processed (5%O_2/15% CO_2 /80%N_2)	15°C	8.4	0.0495	6.1	Sant'Ana (2012)
Lettuce	Packed, minimally processed (5%O_2/15% CO_2 /80%N_2)	20°C	6.9	0.172	1.8	Sant'Ana (2012)
Lettuce	Packed, minimally processed (5%O_2/15% CO_2 /80%N_2)	20°C	5.4	0.069	4.4	Sant'Ana (2012)
Lettuce	Packed, minimally processed (5%O_2/15% CO_2 /80%N_2)	20°C	5.7	0.094	3.2	Sant'Ana (2012)
Lettuce, iceberg	Untreated	20°C	4.8	0.156	1.9	Koseki et al (2005)
Lettuce, iceberg	Treated with acidic electrolysed water for 5 mins	20°C	3.9	0.147	2.0	Koseki et al (2005)
Lettuce	Packed, minimally processed (5%O_2/15% CO_2 /80%N_2)	25°C	4.3	0.152	2.0	Sant'Ana (2012)
Lettuce	Packed, minimally processed (5%O_2/15% CO_2 /80%N_2)	25°C	3.6	0.122	2.5	Sant'Ana (2012)
Lettuce	Packed, minimally processed (5%O_2/15% CO_2 /80%N_2)	25°C	3.2	0.110	2.7	Sant'Ana (2012)
Lettuce, iceberg	Untreated	25°C	3.8	0.200	1.5	Koseki et al (2005)
Lettuce, iceberg	Treated with acidic electrolysed water for 5 mins	25°C	3.7	0.194	1.6	Koseki et al (2005)
Lettuce, whole	Washed, torn into bite sized pieces and sealed in air	25°C	No growth in 1 out of 5 trials Growth (4 trials) = 0.31 log in 7 days Growth (4 trials) = 1.27 log in 14 days			Steinbruegge et al. (1988)
Lettuce, whole	Washed, torn into bite sized pieces (open)	25°C	No growth in 1 out of 4 trials Growth (3 trials) = 0.33 log in 7 days Growth (3 trials) = 1 log in 14 days			Steinbruegge et al. (1988)
Lettuce	Packed, minimally processed (5%O_2/15% CO_2 /80%N_2)	30°C	1.4	0.24	1.3	Sant'Ana (2012)
Lettuce	Packed, minimally processed (5%O_2/15% CO_2 /80%N_2)	30°C	2.5	0.20	1.5	Sant'Ana (2012)
Lettuce	Packed, minimally processed (5%O_2/15% CO_2 /80%N_2)	30°C	3.4	0.19	1.6	Sant'Ana (2012)

While there have been no confirmed cases, it is worthwhile mentioning that there have been several incidents where circumstantial evidence possibly implicates lettuce (among other foods) as a vehicle of listeriosis infection. These episodes do involve variable levels of confidence, as detailed below:

- Bendig and Strangeways (1989) proposed that a 74 year old post operative patient in a London hospital may have acquired listeria septicaemia and meningitis from consuming contaminated lettuce. *L. monocytogenes* serotype 1/2c was isolated from 1 of 11 (9.1%) samples of washed English round lettuce prepared in the hospital's kitchen, but a different serotype (1/2a) was isolated from the patient
- Celery, tomatoes or lettuce were also implicated (although not conclusively) on epidemiological grounds in 23 listeriosis cases (5 deaths) from eight Boston-area hospitals during 1979 (Ho, Shands, Friedland, Eckind, & Fraser, 1986). No exact cause was established as no attempt was made to isolate the organism (Ryser, 1999)
- There was some circumstantial evidence for the possible involvement of lettuce in one cluster of 8 cases in Melbourne (Tan, Li, Heaton, & Forsyth, 1995), with the same PFGE type isolated from a case and a lettuce from the garden of one patient

3.4 Risk characterisation – lettuce as a source of food poisoning

The risk of acquiring foodborne illness from lettuce may be due to processing and handling factors such as:

- vegetables are grown atop soil that may be a reservoir of foodborne pathogens
- the washing process reduces, but does not eliminate, bacteria
- pathogens could be introduced during processing by contaminated equipment
- damage to leaves introduced by cutting may allow bacterial attachment
- storage conditions might provide the conditions and time for bacterial growth, and
- consumers typically do not cook or wash these foods before consuming

Given that *L. monocytogenes* is found on lettuce and is able to grow under mild temperature abuse, it is not a surprise that NSW Health authorities took a deliberately conservative decision to minimise the risk of hospital patients contracting listeriosis by removing lettuce from the diet. However, there has been no conclusive links to show that lettuce has been a cause of listeriosis cases, even with the increased popularity and consumption of pre-packaged lettuce that extends the shelf life potentially increasing the opportunities for *L. monocytogenes* to grow.

Carrasco, Pérez-Rodríguez, Valero, García-Gimeno, & Zurera (2010) under took a quantitative risk assessment of *L. monocytogenes* in RTE lettuce salads in Spain and found that significant factors in minimising the potential number of listeriosis cases are the use of specific mixture of gases (CO_2 5.5% / O_2 3% / N_2 92.5%) in packaged product and a reduction in shelf life to lessen the opportunity for the organism to grow. They also considered preventing high risk consumers from consuming these products as an effective risk management measure, however this does not consider the holistic benefits associated with eating fresh produce (NSW Food Authority, 2012b). Keeping RTE food products at refrigerated temperatures for the shortest possible time is considered an effective strategy to minimise the potential growth of *L. monocytogenes* and ensure that exposure is minimised (Garrido, García-Jalón, Vitas, & Sanaa, 2010).

The risk assessment conducted by the Authority on food service to vulnerable persons did not highlight lettuce as a high risk food, but nominated a control measure of limiting shelf life to

seven days for packaged pre-cut vegetables, fruit and salads (NSW Food Authority, 2012). This follows on from Odumeru et al (1997) proposing that limiting the shelf life of all RTE vegetable types for use in hospitals to 7 days as an effective control measure to minimise the levels of *L. monocytogenes* to ≤ 100 cfu/g. At this level, the number of listeriosis cases is likely to be reduced by 99% and even immunocompromised patients are unlikely to be affected (Chen, Ross, Scott, & Gombas, 2003).

For lettuce that is not packaged with a modified atmosphere, the growth of the native microflora on lettuce may result in a product that is no longer organoleptically acceptable after 14 days, meaning that lettuce may be obviously spoiled before *L. monocytogenes* can multiple to a large dose to infect a patient.

The key to minimising health risks associated with the possible presence of the *L. monocytogenes* in lettuce are:

- strict adherence to good manufacturing practices and sanitation
- effective temperature control during storage and distribution
- appropriate packaging and storage conditions
- limiting the shelf-life with a `use-by-date', or else using the product quickly so that there is not sufficient time for *L. monocytogenes* to grow to elevated levels

Using current manufacturing practices, it is difficult to eliminate all pathogens from minimally processed lettuce, as it is with many other raw RTE foods. The scientific literature demonstrates that low levels of *L. monocytogenes* may infrequently contaminate lettuce (and other RTE vegetables), but there is little to suggest that lettuce is a food with any higher risk than other raw RTE foods. As such there is little basis for excluding it from 'normal' hospital menus. However, exclusion from the low microbial diet used for severely immunocompromised patients may still be warranted (NSW Agency for Clinical Innovation, 2011).

4. Seed sprouts

The food safety scheme defines seed sprouts as:

"sprouted seeds (other than wheat grass) or sprouted beans".

As of 12 July 2013, Standard 4.2.6 – Production and processing standard for seed sprouts of the Australia New Zealand food Standards Code came into effect which defines seed sprouts as "sprouted seeds or sprouted beans for human consumption that include all or part of the seed". As part of the scientific justification for this proposal developing this standard, FSANZ undertook an evaluation of both the microbiological and chemical hazards associated with seed sprouts. The results of this work are summarised here.

4.1 Hazard identification – *E. coli* and *Salmonella*

The hazards initially identified for seed sprouts in the Food Science Australia risk profile (Food Science Australia, 2000) were pathogenic *E. coli* and *Salmonella* (high risk) and *L. monocytogenes* and *Bacillus cereus* (medium risk). The evaluation of microbiological hazards by FSANZ (2009) confirmed this by detailing *Salmonella* and enterohaemorrhagic *E. coli* (EHEC) as the aetiological agents most commonly reported in outbreaks.

A report by Kiermeier, May & Holds (2013) reaffirms *Salmonella* and *E. coli* as the target organisms, and undertook research into seed decontamination step targeting the reduction of these organisms. The FSANZ risk assessment report also concluded that, despite the limited data available, there was nothing to indicate that chemical hazards are a major concern for seed sprouts (FSANZ, 2009).

4.2 Exposure assessment – sprouts are not a widely consumed product

The Authority has no data to indicate whether consumption rates of seed sprouts have differed significantly since the last risk assessment. The number of licensed processors in NSW remains small, with eight facilities licensed to process seed sprouts in the state.

There is very limited Australian or international information on the extent of sprout consumption. In their risk assessment, FSANZ used the data from the 1995 National Nutrition Survey (McLennan & Podger, 1995) which indicated that approximately 4% of respondents consumed seed sprouts. The average quantities consumed were also quite small, as shown in Table 8. According to FSANZ (2009), people generally consume seed sprouts because of health and culinary factors (eg the use of bean sprouts in Asian dishes). There is also 'indirect' consumption of seed sprouts where they are incorporated in dishes as a garnish.

Table 8. Mean daily consumption of alfalfa sprouts

Food	Adult males (25-34 yrs)	Adult females (25-34 yrs)	Boys (12 yrs)	Girls (12 yrs)	Toddler (2 yrs)	Infant (9 months)
	g/day	g/day	g/day	g/day	g/day	g/day
Alfalfa sprouts	6	8	4	3	1	<1

Adapted from ANZFA (2001a) with data from McLennan & Podger (1995)

The seed sprout variety consumed most frequently was alfalfa sprouts whereas bean sprouts were consumed in the largest quantities. The range of seed sprout products has steadily increased in recent years as has their availability at retail outlets and their use by the food service sector.

4.3 Hazard characterisation – sprouts have caused many outbreaks

Between 1988 and 2008 there have been over 40 reported outbreaks worldwide attributed to consumption of contaminated seed sprouts (FSANZ, 2009). The most commonly reported aetiological agents in these outbreaks have been various serovars of *Salmonella* spp. and enterohaemorrhagic *E. coli* (EHEC). *B. cereus* and *Yersinia enterocolitica* have also been responsible for outbreaks of foodborne illness associated with seed sprouts in the past, but not recently (Cover & Aber, 1989; Portnoy, Goepfert, & Harmon, 1976). Alfalfa and mung bean sprouts have been the most commonly reported seed sprouts implicated in outbreaks of foodborne illness. The majority of sprout-associated outbreaks have been reported in the United States, however, outbreaks have also occurred in Canada, Sweden, Finland, Denmark, United Kingdom, Japan and Australia.

The largest reported outbreak occurred in Japan in 1996, with over 10,000 notified cases and was attributed to consumption of radish sprouts contaminated with *E. coli* O157:H7 (Michino et al., 1999; Watanabe et al., 1999). An outbreak due to *S.* Oranienburg occurred in Western Australia during November 2005-January 2006 that was epidemiologically linked to

consumption of alfalfa sprouts. This was later confirmed microbiologically, with *S.* Oranienburg being isolated from the implicated alfalfa sprouts. A total of 125 cases of salmonellosis were reported, resulting in 11 hospitalisations (FSANZ, 2009).

In May 2006, another outbreak of *S.* Oranienburg was reported in Victoria, with a total of 15 cases attributed to consumption of alfalfa sprouts. In the outbreak, *S.* Oranienburg was isolated from the implicated alfalfa sprouts as well as from seed obtained from the sprouting facility. Molecular typing of the *S.* Oranienburg isolates from both the Victorian and Western Australian outbreaks showed indistinguishable patterns by pulsed field gel electrophoresis. Trace back of seeds associated with these outbreaks found that the seed originated from the same Australian state but from different seed suppliers (FSANZ, 2009).

In Western Australia and Victoria 141 cases of food-borne salmonellosis were associated with the consumption of raw sprouts in 2005 and 2006. Thirteen out of the 141 cases were hospitalised. Most cases of salmonellosis manifests as mild self-limiting gastroenteritis, with about 73% of the affected people seeking medical attention (FSANZ, 2009).

Factors contributing to these adverse health events include:

- the inherent nature of the product (eg a RTE product in which the production process supports the growth of microbial pathogens if present)
- scientific uncertainty around the most effective pathogen mitigation steps
- a lack of through-chain risk mitigation measures (either regulatory or non-regulatory).

4.3.1 *Escherichia coli* from seed sprouts in Europe

In addition to the Australian outbreaks, in 2011 the safety of seed sprouts was drastically highlighted with a large, severe outbreak due to enterohaemorrhagic *Escherichia coli* (EHEC) O104:H4. In Germany, between the 1st of May and the 28th of June 2011 the outbreak caused 838 cases of Haemolytic Uraemic Syndrome (HUS), 3091 reported cases of diarrhoea and 47 people died (EFSA, 2011b).

European and German officials eventually identified fenugreek seeds from Egypt which were used to produce seed sprouts. However, problems with traceability led to the wrong commodity being initially implicated in the outbreak, with huge resulting financial implications for Spanish farmers. The large and intricate supply chain involved in the supply of seed and the resulting sprouts created difficulties in identifying the cause of the outbreak (Buchholz, et al., 2011; Werber et al., 2012).

The implicated seed, consisted of a batch of 15,000 kilograms of fenugreek seeds imported from Egypt to Germany in November 2009, which was distributed to at least 70 companies in 12 countries across Europe. Several other smaller outbreaks also occurred across Europe which assisted in identifying the cause.

In response, the European Union ordered member states to recall all fenugreek seeds imported from Egypt between 2009 and 2011 and placed a ban on the importation of all Egyptian seeds and beans for sprouting until at least the end of October.

While the actual source of the bacteria was not determined, it is likely that the contamination occurred on the farm where the seeds were grown. The contamination typically reflects a production or distribution process which allowed contamination with faecal material of human and/or animal origin.

The scope of the plant products food safety scheme does not extend back to on-farm practices and the new Production and processing standard in the Code does not extend back to on-farm practices as this was not deemed appropriate under a cost benefit analysis.

4.4 Risk characterisation – no validated CCP to control the risk

Seed sprouts remain a high risk food because there is still no validated Critical Control Point that can eliminate the potential hazards that arise because the seeds are germinated under conditions that are conducive to growth of pathogens (Kiermeier, et al., 2013).

4.4.1 Seed decontamination

Previously, to reduce the risk from seed sprouts the Authority introduced a requirement in the *NSW Plant Products Manual* (now superseded) as a condition of licence to include a decontamination step for seeds prior to sprouting that involved the use of 20,000ppm or stronger solution of Calcium hypochlorite (or another sanitiser solution of equivalent effectiveness) for pre-soaking seeds before germination. However the use of this sanitiser at such strengths can pose potential occupational health and safety risks and alternatives have been investigated by the industry. Seed decontamination methods have also been a continual focus of international research (Bari, Enomoto, Nei, & Kawamoto, 2009; Bari, Enomoto, Nei, & Kawamoto, 2010; Ding, Fu, & Smith, 2013).

While this manual is no longer in effect, the requirement to include a decontamination step is detailed in Standard 4.2.6 of the Code and the template food safety program supplied to seed spouters by the Authority includes the use of a seed decontamination step. Kiermeier et al (2013) concluded that seed decontamination treatments should be able to achieve at least a 5-log reduction in pathogen load, in particular *E. coli* O157:H7 and *Salmonella.* The practicality of any decontamination step is determined by a number of factors, such as the:

- lethal effect on pathogens
- rate of loss of germination
- safety for staff using the chemicals for decontamination

There are many factors which can affect the lethal effect on the seeds:

- whether the seeds are scarified (seed coatings are scratched to increase the uptake of water and increase germination rates) or not, and
- if seeds are pre-soaked prior to germination

The only potential decontamination treatments that were practical for the Australian industry were calcium hypochlorite, peracetic acid and dry heat. Kiermeier et al (2013) found that information on how to manage decontamination steps is one area which would be of benefit to many manufacturers. While it was a common response to regard soaking seed in free chlorine as an important control point, even a critical control point, it was almost never monitored as a CCP.

The Authority will continue to work with the industry to find suitable seed decontamination steps that are practical and effective. However it is unclear what the minimum benchmark should be for a seed decontamination step. The Canadian Food Inspection Agency stipulates the use of decontamination treatments that can achieve a least a 3 log, or 99.9%, reduction of micro-organisms (Canadian Food Inspection Agency, 2007). Although FSANZ (2010) refers to treatments that can achieve substantial (> 5 log) reductions, the Code itself is not

prescriptive, simply stating "a sprout processor must implement effective decontamination processes prior to sale or supply of seed sprouts".

4.4.2 Testing requirements - spent irrigation water and finished product

Kiermeier et al (2013) noted that the work of Stewart, Reineke, Ulaszek & Tortorella (2001), Liu and Schaffner (2007)and Fu, Reineke, Chirtel & Vanpelt (2008) led to the monitoring of spent irrigation water as a reliable means of indicating pathogens in product, with levels in spent water being >90% of those in alfalfa sprouts. Montville and Schaffner (2005) modelled the sprout production process and determined that sampling sprouts and spent water at the end of production was more effective in detecting pathogens than sampling dry seed.

Both the Canadian code of practice (Canadian Food Inspection Agency, 2007) and NSW Food Safety Schemes Manual (NSW Food Authority, 2010) require seed sprout processors to test spent water and final product testing (as shown in Table 9).

Table 9. Sampling and analysis requirements for seed sprout processors

Product to be tested	Test to be conducted	Limit	Frequency
Seed used for sprouting (pre-screening test)	*Salmonella* **Method:** 1L sample of spent irrigation water from a test bath of seeds made up of 3kg taken evenly across the batch	Not detected in 100 mL	Every delivery batch of seeds
Spent irrigation water used for seed sprouting	*Salmonella* **Method:** 1L composite sample taken evenly across each sprouting container from each production batch. Irrigation water should be sampled just before harvest or at least 48 hrs after lay	Not detected in 100 mL	Every 10 batches
Seed sprouts (finished product)	*E. coli* **Method:** 1 x 100g sample of any finished single sprout type from each process line	Not exceeding 100/g	Every 10 batches

From NSW Food Authority (2010)

While there are no CCPs that can completely guarantee a safe seed sprouts product, the measures introduced for NSW producers of seed sprouts have certainly helped improve the microbiological quality of sprouts produced in NSW. Appendix 1 shows the recalls that have occurred over the past 4 years, and while there have been 3 recalls of sprouts none of them were produced in NSW. The testing required by the Authority may allow sprout producers to

detect any microbiological issues before the sprouts make it to market. The report of Kiermeier et al (2013) notes that sprout producers in states other than NSW were less likely to undertake testing, and in some cases did almost no testing of either seed or final product. Given the outcome-based nature of the Food Standards Code's requirements, NSW will still need to include specific testing requirements, as currently included in the NSW Food Safety Schemes Manual and shown in Table 9.

5. Vegetables in oil

The food safety scheme defines vegetables in oil as:

"(a) fruits, vegetables or herbs, or (b) parts of fruits, vegetables or herbs, or (c) a combination of anything in paragraph (a) or (b), immersed wholly or partly in oil."

Standard 2.3.1 of the Code requires fruit and vegetables in brine, oil, vinegar or water, other than commercially canned fruit and vegetables, must not have a pH greater than 4.6.

5.1 Hazard identification – botulism is a real risk

The initial risk assessment identified *Clostridium botulinum* as a potential hazard in these products, particularly for poorly acidified products. While these products are safe if refrigerated, they represent a potential food poisoning hazard unless certain basic precautions are taken in their preservation (NSW Food Authority, 2011b). This is an inherent risk in the processing of these products if they are not prepared appropriately and there is nothing to suggest that this situation has changed. Foods acidified to a pH below 4.6 do not in general support the growth of food poisoning bacteria including *C. botulinum*.

According to CSIRO (2011), attempts to preserve these products without acidification seem to be based on two false assumptions. The first of these is that the addition of oil has a preservative effect, which is incorrect. The only function of the oil is to prevent oxidation from the air in the container which can lead to discolouration of some foods. By excluding air from the surface of the food this is establishing anaerobic conditions which actually favour the growth of *C. botulinum*.

The other incorrect assumption which is often made is that some herbs and spices, and especially garlic, have significant antimicrobial properties. The preservative effect of these materials including garlic is slight and inconsistent. This has been highlighted through foodborne botulism incidents in Canada and the United States during the 1980's. It is therefore essential that sufficient acid is added to the vegetable before oil is poured on so that any *C. botulinum* or other potentially dangerous bacteria cannot grow. This will not guarantee that the products will not spoil if not kept properly refrigerated, but it will ensure they do not become potentially hazardous.

If the vegetables are dried prior to being stored in oil, a different set of circumstances applies. Correctly dried vegetables and herbs will not support the growth of food poisoning bacteria but they may still support the growth of spoilage organisms such as yeasts and moulds. Moulds will usually only be a problem on exposed surfaces but yeasts bring about fermentation in the absence of air (CSIRO, 2011).

5.2 Exposure assessment – vegetables in oil remain a niche product

The number of commercial manufacturers of these niche products remains small, with only seven businesses licensed in the state. The increasing popularity of farmers markets may encourage other people to attempt to manufacture these products without the necessary skills and knowledge.

5.3 Hazard characterisation – severe outcomes rare but possible

While rare, the illness caused by *C. botulinum* toxin is severe, with a fatality rate from foodborne botulism between 5-15% (E.A. Szabo & Gibson, 2003). There have been no cases of foodborne illness attributed to these products in Australia, but the instances of botulism overseas during the 1980's led to the introduction of the requirement in the Code to acidify these products to a pH value of 4.6 or less.

5.4 Risk characterisation – regulations still applicable to manage risk

The application of food safety skills and knowledge is very important for these products to be made safely, and problems have occurred when home made products are then attempted to be made in commercial quantitates. The requirements of the food safety scheme provide a baseline entry level to manufacture these products commercially and may be a deterrent to those without the appropriate skills from attempting to make these products.

6. Unpasteurised juices

The food safety scheme defines unpasteurised juice as:

"fruit or vegetable juice, or a mixture of such juice, that has not been subject to pasteurisation". Pasteurisation is further defined as heating to a minimum temperature of 72°C for 15 seconds, or any other technology or method that provides an equivalent lethal effect.

6.1 Hazard identification – pathogens not able to grow

A survey conducted in Spain by Sospredo et al (2012) found that freshly squeezed orange juice was quite acidic, with an average pH value of 3.5. Therefore it is highly unlikely that any pathogenic organisms that may contaminate the juice could grow. Of the 190 samples analysed for the survey, two samples were found to contain *Staphylococcus aureus* and one sample was found to contain *Salmonella*.

Juicing machines may have contact services that are difficult or time consuming to clean, potentially allowing the formation of biofilms.

6.2 Exposure assessment – low levels of production

There are six licensed facilities making unpasteurised juice in NSW, with another two businesses having the approval to manufacture juice as a secondary permission.

The scope of the scheme does not extend to unpasteurised juice produced at retail establishments. These retail juice bars come under the jurisdiction of local councils. The popularity of these outlets has increased in the past decade but it is not clear what the

proportion of unpasteurised juice consumed by the population originates from retail outlets. As an indication, Sospredo et al (2012) estimated that in Spain around 40% of orange juice consumption in that country could be attributed to freshly squeezed juice in foodservice establishments.

6.3 Hazard characterisation – no recent outbreaks

In Australia, the number of outbreaks involving unpasteurised juice is minimal, but it was a large outbreak in South Australia in 1999 affecting over 500 people attributed to Nippy's orange juice contaminated with *Salmonella* Typhimurium 135a that really highlighted the risk. This outbreak was traced back to oranges from a fresh fruit packing house. *S.* Typhimurium 135a was traced to the wash tank where fungicide was added to the oranges, but it was not clear where the initial contamination originated. This outbreak led to the introduction of a requirement for citrus packers in South Australia to have a food safety program.

6.4 Risk characterisation – new technology as an alternative

The risk from unpasteurised juice is relatively low, provided good quality fruit is used to manufacture the juice and this fruit is washed and/or sanitised prior to juicing. It is considered that the implementation of a food safety program and verification testing of finished product is sufficient to manage the risk. An application A411 to ANZFA in 2001 to require unpasteurised juice to be labelled - indicating that the juice was not pasteurised - did not proceed (ANZFA, 2001b).

A Victorian business is using high pressure processing for juices offered nationally in supermarkets. Should a NSW business seek to use the same technology and can demonstrate that the time and pressure being applied to the product meets the equivalent of a pasteurisation step, then these products would not be considered unpasteurised juice and would not required to be licensed with the Authority.

7. Other horticultural products

The scope of the plant products food safety scheme has not significantly changed since it was first introduced in April 2005, with the same five categories of products being covered. The only modification to the scheme has been some minor changes to definitions being made in subsequent revisions to provide clarification.

The risk assessment provides an opportunity to validate whether the scope of the scheme remains valid, and as such a review of foodborne illness outbreaks and the findings of the Authority's "gap" project are summarised here.

7.1 Foodborne illness outbreaks from horticultural products

Since the Authority's 2009 risk assessment there has been two major outbreak of foodborne illness in Australia attributed to horticultural products outside of the current scope of the plant products food safety scheme. The factors behind these outbreaks were examined to determine whether there should be a review of the scheme's scope to include such products.

Several other small outbreaks were also noted where plant products were incriminated (sometimes among other food types) in most cases in food service settings where handling may be a major contributing cause.

7.1.1 Hepatitis A from semi-dried tomatoes

Donnan et al (2012) reported on a large outbreak of Hepatitis A which affected individuals in several Australian states during 2009, resulting in a two-fold increase in cases reported to state health departments compared with the previous year. Two peaks of infection occurred (April–May and September–November), with surveillance data suggesting locally acquired infections from a widely distributed food product.

Testing conducted on semidried tomatoes collected in June 2009 found Hepatitis A virus RNA in 21 of 67 samples of. Of these 13/21 samples (62%) contained only imported semidried tomatoes, 3/21 (14%) were likely to have contained both imported and local semidried tomatoes, and 5/21 (24%) were reported to be made exclusively from Australian tomatoes.

Trade-level recalls were conducted by a South Australian wholesaler in May 2009 and by a Victorian manufacturer in October 2009. In November 2009, Victoria's chief health officer exercised an emergency power under the Victorian Food Act 1984 and required semidried tomato manufacturers to either pasteurise finished semidried tomato products or ensure the sanitisation of all tomatoes prior to drying.

Vegetables and herbs to be packed in oil without treatment with vinegar should be dried almost to crispness. Tomatoes, including sun-dried tomatoes, are a special case. The pH of fresh tomatoes is normally just below 4.6. When the tomatoes are dried, the natural acid components are concentrated and the pH is reduced. It will often be close to 4.0 in the dry product and therefore the risk of food poisoning should be greatly reduced (CSIRO, 2011).

Media releases were issued by Departments of Health in Victoria, South Australian, and Queensland in May 2009 and by Victorian, Western Australian, and Tasmanian departments in November 2009. Notification of the Australian outbreak under the World Health Organization (WHO) International Health Regulations, via the WHO International Food Safety Authorities Network and the European Centre for Disease Control, allowed identification of related Hepatitis A clusters in the Netherlands and France (Petrignani et al., 2010). Sequencing showed the Hepatitis A virus from the Netherlands and Australian outbreaks to be identical, however the Hepatitis A virus in France was of a similar but non-identical strain. Case-control studies identified semidried tomatoes as the source of infection in both countries (Petrignani, et al., 2010).

The scope of the scheme does not extend to imported products and it is likely that the contamination may have occurred on farm.

7.1.2 Listeriosis from rockmelons

A multi-jurisdictional outbreak of *L. monocytogenes* occurred in 2010, affecting nine people (eight were hospitalised) and the suspected source was rockmelon and/or honeydew melon eaten fresh or used in the preparation of fruit salads (OzFoodNet Working Group, 2010a, 2010b). This investigation triggered the National Food Incident Response Protocol on 16 July 2010. The confirmed cases consisted of four from Victoria, three from NSW and two from Queensland and aged between 53 and 95 years of age. All were considered immunocompromised. The outbreak strains were considered rare and had not previously been isolated from human cases in Australia.

There was a co-incidental finding of the outbreak strains in samples taken from a facility that manufactured fruit salad as part of an investigation into a separate cluster of *Listeria* cases in Victoria. The strains of *L. monocytogenes* were isolated from by-products of manufacturing (waste juice from a stainless steel tub and fruit rinse water) and from a rinse taken from the

surface of a honeydew melon. However this manufacturer did not distribute interstate and so was unable to explain the origin of interstate cases.

Separately, the outbreak strain was isolated from a sample of fruit salad taken by a local council at a delicatessen in Victoria, while a second sample of fruit salad taken from a different delicatessen yielded the second outbreak strain. These fruit salads were both prepared at the premises using whole fresh fruit. The Victorian Department of Health also tested a range of other food samples, and none yielded the outbreak strain.

Trace-back conducted in Victoria, NSW and Queensland indicated a common source for some of the melons, in south central NSW. Onset dates for cases were between February and May 2010, and the supply of melons from growing districts is known to be seasonal, suggesting that the source of infection was likely to be a supplier from southern regions of Australia that ceased production after this time. There were no further outbreak cases during the year which supported this theory.

The scheme does not extend to on-farm practices or to packing sheds where the contamination may have occurred.

7.2 Other products

Since the introduction of the plant products food safety scheme, a number of additional plant-based products have been identified by the Authority as potentially "high risk". As such, products including tofu, tempeh, kimchi, vegetable-based dips, mixed salads, fresh herbs and edible seaweeds were reviewed (NSW Food Authority, 2013).

The information in the literature review is supplemented by a survey of the microbiological quality of a number of the product categories. Chemical attributes of some of the products were also assessed.

The findings of the literature review, combined with an assessment of microbiological status and chemical attributes of the products, found that food safety issues with these products are rare and sporadic. Requirements set out in the Food Standards Code coupled with inspection of businesses are likely to provide adequate food safety control. Further regulation by broadening the scope of the plant products food safety scheme was found not to be warranted.

A recent food poisoning outbreak has drawn attention to a market in the food service industry for chopped parsley for use in kebabs. Chopped parsley must be expected to have a slightly higher risk profile than bunch parsley. Some further testing will occur as a consequence of the outbreak investigation. Based on an the very small number of foodborne illness outbreaks attributed to parsley in the USA[8] further testing is not expected to identify a substantial problem.

[8] http://wwwn.cdc.gov/foodborneoutbreaks/

7.3 Pine nuts and pine mouth

An emerging issue since the 2009 risk assessment has been the phenomenon of people experiencing a bitter or metallic taste after the consumption of pine nuts. This taste disturbance has been referred to as 'pine mouth' or 'pine nut syndrome' and can last from a few days up to two weeks.

Not all people who consume pine nuts become afflicted with the taste disturbance. The pine nuts do not taste any different at the time, but after 1 to 3 days the bitter or metallic taste becomes apparent. The symptoms are exacerbated by the consumption of food and drink, but normally disappear after several days and there are no adverse health effects.

Table 10. Plant products reviewed by the NSW Food Authority

Group	Example of products	Risk rating according to the scoping study (FSA, 2000)
Soy products	Tofu & fermented soy products (eg tempeh) Soy milk & milk products (eg soy yoghurt & soy cheese)	Medium risk for *B. cereus* Low risk for *Salmonella* spp. and *Y. enterocolitica*
Fermented vegetables	Kimchi	
Vegetable based dips & sauces	Sesame-based dips (eg tahini, hommus & baba ghanoush) Salsa-style dips Pesto-style dips (eg pesto, tapenades)	For tahini & hommus: Medium risk for *Salmonella* spp. and *B. cereus* For guacamole & olive tapenade: Medium risk for pathogenic *E. coli*, acid tolerant *Salmonella* spp., psychrotrophic *B. cereus* and *Cl. botulinum*
Salads (exclude fresh cut vegetables)	eg potato salad, rice salad, coleslaw, and other mixed salads	Salad with mayonnaise based dressing: Medium risk for pathogenic *E. coli* and *Salmonella* Low risk for *L. monocytogenes*
Fresh cut vegetables excluded in the FSS	Fresh herbs Snow pea sprouts	Medium risk for pathogenic *E. coli*, *Salmonella* spp., *Shigella* spp. Low risk for *B. cereus, L. monocytogenes*, Enteric parasites and viruses
Edible seaweeds		

Cases of pine mouth are not common, however since 2009 there appears to have been a rise in numbers internationally with several hundred complaints lodged with agencies across countries including France, the UK and USA. In contrast, the number of reported cases in

Australia has been very small. Identification of any implicated pine nut species is made difficult by the common practice of mixing different species for retail sale.

The cause of pine mouth has not been determined, but several researchers have indicated that a particular species and source of pine nut, *Pinus armandii* exported from the Shaanxi and Shanxi regions of China, may be responsible for causing the symptoms. This species of pine nut was previously only consumed locally and not widely exported for consumption as whole nuts.

In response to the increased number of pine mouth cases, Chinese authorities implemented measures to accredit exporters of pine nuts and implement strict control measures to ensure *Pinus armandii* are no longer exported. In addition, the international standards setting body Codex Alimentarius Commission moved to exclude *Pinus armandii* as well as another species of pine nut, *Pinus massoniana* from its list of edible tree nuts.

The Authority prepared an issues paper on behalf of the Implementation Sub-committee (ISC) for the Coordinated Food Survey Plan (NSW Food Authority, 2012a). The paper examined case reports and the most recent research into possible causes of the pine mouth taste disturbance. Australian food regulatory authorities continue to monitor the ongoing effectiveness of industry measures introduced in China and monitor any reports of pine mouth cases in Australian consumers. Where cases are reported, attempts are made to determine the source and species of pine nuts causing the taste disturbance to better inform future responses.

After a quiet period with no notifications for over 18 months, between August and December 2013 there had been 14 cases of pine mouth reported to the Authority, most associated with pine nuts purchased through major retailers. Follow up action was occurring with those retailers.

8. Conclusion

During the previous revision of the NSW Food Regulation, the scope of the plant products food safety scheme was left virtually untouched, and still requiring food safety controls for the five plant products categorised as high risk by the Food Science Australia scoping study (Food Science Australia, 2000). This risk assessment has revisited specific elements of products covered by the scheme and found that the current control measures equate in most cases with international best practices.

Increasingly overseas there have been a number of large scale foodborne illness outbreaks associated to fruit and vegetables, such as leafy greens, spinach and rockmelon. A similar trend has not been observed in Australia to date, and the national work undertaken by FSANZ suggests that the voluntary quality assurance programs implemented by the industry for on-farm activities manages the risk well. There does not appear to be unmanaged risks within the regulatory system for plant products that would require extending the scope of the scheme.

Appendix 1: Recalls of horticultural products between 2009 and 2013[9]

The following table lists the consumer-level recalls for microbiological hazards attributed to all horticultural-based products within Australia from 2009 to 2013.

Product	Reason for recall	Was the recall instigated due to illness?	Distribution	Year
1. Spiced coated fried peanuts	Aflatoxin	Not reported	VIC, SA only	2013
2. Dried mint	*Salmonella*	Not reported	VIC	2012
3. Sprouts (mung bean)	*E. coli*	Not reported	VIC only	2012
4. Sprouts (alfalfa, onion and mung bean mix)	*E. coli*	Not reported	VIC , NSW only	2012
5. Salad – chickpea with roast pumpkin	*Listeria monocytogenes*	Not reported	NSW and VIC only	2012
6. Spices	*Salmonella*	Not reported	NSW only	2012
7. Dried mint	*Salmonella*	Not reported	VIC only	2012
8. Almonds	*Salmonella*	Not reported	National	2012
9. Almonds	*Salmonella*	Not reported	QLD only	2012
10. Almond kernels	*Salmonella*	Not reported	National	2012
11. Bean curd	*Bacillus cereus*	Not reported	VIC only	2012
12. Bean curd	*Bacillus cereus*	Not reported	VIC only	2012
13. Spices (bottle set)	*Salmonella*	Not reported	ACT, NSW, TAS and VIC only	2012
14. Almonds	*Salmonella*	Not reported	National	2011
15. Apricot kernels	Hydrocyanic acid	Potentially 1 case	National	2011
16. Tapioca chips	Hydrocyanic acid	Not reported	NSW only	2011
17. Tapioca chips	Hydrocyanic acid	Not reported	NSW, ACT, VIC, WA and QLD	2011
18. Sprouts (various types)	*E. coli*	Not reported	SA only	2012
19. Tahini	*Salmonella*	Not reported	VIC only	2010
20. Pistachios	*Salmonella*	Not reported	National except WA	2009
21. Pistachios	*Salmonella*	Not reported	ACT, NSW, SA, VIC and WA	2009
22. Pistachios	*Salmonella*	Not reported	SA, WA, VIC, QLD, NSW	2009
23. Fermented Bean curd 24. Preserved Bean curd 25. Preserved Bean sauce	*Bacillus cereus*	Not reported	QLD, SA, TAS, VIC, WA	2009
26. Preserved Bean curd	*Bacillus cereus*	Not reported	VIC	2009

From ACCC and FSANZ recall statistics

Note – Of the recalls noted above, only sprouts fall within the scope of the Plant products food safety scheme and none of the sprouts products recalled were produced in NSW.

[9] Does not include recalls due to physical contaminants or non-declaration of allergens

Appendix 2: Australian foodborne illness outbreaks (2009-2013)

The following table lists foodborne illness outbreaks affecting two or more people from 2009 to 2012 and attributed to horticulture-based products. This table also includes foods that are outside of the scope of the Plant products food safety schemes, but are included here from completeness.

State	Year	Food vehicle	Agent	Number affected	Setting prepared
VIC	2011	Fruit platter	Norovirus	15	Restaurant
VIC	2010	Beef curry and rice	*Bacillus cereus*	24	Restaurant
WA	2010	Cantaloupe, mint, lettuce	Cyclospora	314	Cruise/airline
NSW	2010	Suspected peanut/cashew mix	*Salmonella* Typhimurium PT 170	19	Restaurant
Multi-state	2010	Melons and/or melons contained within fruit salads	*Listeria monocytogenes*	9	Community
WA	2009	Semi-dried tomatoes	Hepatitis A	9	Commercially manufactured
SA	2009	Potato salad	*E. coli* O157	31	Camp
WA	2009	Paw paw	*Salmonella* Saintpaul	17	Primary produce
Multi-state	2009	Semi-dried tomatoes	Hepatitis A	125	Primary produce

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