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Supporting document 1

Microbiological assessment approach and foodborne illness summary

P1052 - Primary Production and Processing Requirements for High-Risk Horticulture

Executive summary

Outbreaks of foodborne illness have been associated with fresh horticultural produce in Australia and internationally. Food Standards Australia New Zealand (FSANZ) will undertake an assessment of the microbiological food safety risks of fresh horticultural produce in Australia to guide decisions on appropriate regulatory and non-regulatory risk management measures. We will focus particularly on commodity sectors that have been identified nationally and internationally as posing a higher risk and that have specific annexes within the Codex *Code of hygienic practice for fresh fruits and vegetables* (Codex 2017) that provide additional guidance for their hygienic production.

The primary objective of FSANZ when developing or reviewing food standards is “*the protection of public health and safety*”. FSANZ is also required to have regard to “*the need for standards to be based on risk analysis using the best available scientific evidence*”. The development and application of a Primary Production and Processing Standard for fresh horticultural produce will be dependent on an analysis of the public health and safety risks, economic and social factors and current regulatory measures and industry practices.

FSANZ uses a number of methodologies to assess public health and safety risks, including risk profiling, quantitative and qualitative assessments and scientific evaluations. The methodology utilised depends on the purpose of the assessment and on the availability, quality and quantity of relevant data. The microbiological assessment for this Proposal will involve a qualitative through-chain analysis of selected horticultural commodity sectors identified as posing a higher risk. FSANZ will be utilising a proxy approach, with specific products selected within each commodity sector to represent the variety in product types. The proxies will be chosen to facilitate assessment of a range of risk factors and a spectrum of risk across each sector. The assessment will identify if the selected sectors have additional risk factors, compared to other fresh horticultural produce, that may require additional risk management measures.

Previous work by FSANZ—in the assessment of [Proposal P1015](#)—involved reviewing reports of foodborne illness associated with fresh horticultural produce from 1990–2011 to test assumptions about which commodities and risk factors are most likely to result in produce contamination and outbreaks of foodborne illness. That review identified that the main risk factors for the primary production and processing of fresh horticultural produce are

the use of poor quality water (pre- and post-harvest), faecal contamination by wildlife, and poor hygienic practices through the supply chain. The review found that the commodity sectors most commonly involved in outbreaks included leafy vegetables, melons, berries and minimally processed produce.

A preliminary assessment of Australian and international outbreaks of foodborne illness linked to fresh horticultural produce reported in the period 2011–2019 indicates that the conclusions of FSANZ’s 2011 review are still largely applicable. Commodity sectors most often associated with outbreaks in the period 2011–2019 were leafy vegetables (lettuces, bagged salads), melons and berries. Contamination of produce typically occurred through the use of poor quality water on-farm, and failings in hygiene, sanitation and process controls throughout the production and supply chain.

FSANZ will undertake a thorough assessment of commodity specific and production related risk factors associated with the primary production and processing of fresh ready-to-eat horticulture products—with a particular focus on berries, leafy vegetables and melons—to assist in the identification of appropriate risk management measures to ensure public health and safety.

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1 Introduction

Outbreaks of foodborne illness have been associated with fresh horticultural produce in Australia and internationally. The Australia and New Zealand Ministerial Forum on Food Regulation have requested that FSANZ reassess the food safety risk management of horticultural commodity sectors that they identified as representing a higher risk to public health and safety. These sectors are those with specific annexes in the Codex *Code of hygienic practice for fresh fruits and vegetables* (Codex 2017) that provide additional guidance for their hygienic production.

The primary objective of FSANZ¹ when developing or reviewing food standards is “*the protection of public health and safety*”. FSANZ is also required to have regard to “*the need for standards to be based on risk analysis using the best available scientific evidence*”. The development and application of a Primary Production and Processing Standard for fresh horticultural produce will be dependent on an analysis of the public health and safety risks, economic and social factors and current regulatory and industry practices.

FSANZ uses a number of methodologies to assess the public health and safety risks, including risk profiling, quantitative and qualitative assessments and scientific evaluations. The methodology utilised depends on the purpose of the assessment and on the availability, quality and quantity of the data. The assessment for this Proposal will involve a qualitative through chain analysis of selected horticulture commodity sectors to identify risk factors and inform decisions on appropriate risk mitigation measures. Data on the prevalence of microbial contamination and outbreaks of foodborne illness associated with fresh horticultural produce will be analysed to assist in the identification of the particular commodities and the main contributing risk factors most likely to result in produce contamination and foodborne illness.

2 Previous FSANZ findings (1990-2011)

As part of [Proposal P1015](#) (*Primary Production & Processing Standard for Horticulture*), FSANZ undertook a review of foodborne illness associated with fresh horticultural produce (FSANZ 2011). The review was designed to test assumptions about which commodities and risk factors are most likely to result in produce contamination and outbreaks of foodborne illness. In developing the scope of the review, the horticultural commodity sectors previously identified internationally as higher risk include leafy vegetables, sprouts, berries, melons and minimally processed produce. The production factors previously identified include water (pre- and post-harvest), fertilisers, faecal contamination and food handler hygiene.

2.1 Scope of the P1015 review

The scope of the P1015 review included vegetables, herbs and fruits intended to be eaten raw. Both unprocessed and minimally processed produce (e.g. pre-cut and packaged fruit, washed and bagged baby spinach, and frozen berries) were included in the scope. Sprouted seeds covered by the [Production and Processing Standard for Seed Sprouts](#) were excluded, while microgreens and snow pea shoots were included in the scope. Mixed dishes were only included if an unambiguous link could be made with a specific produce item. Juices and commodities commonly consumed cooked were excluded.

The scope of the review was limited to outbreaks that were thoroughly investigated and reported robust epidemiological and/or microbiological evidence. Only outbreaks associated with fresh horticultural produce intended to be eaten raw—with no pathogen elimination step

¹ Under the *Food Standards Australia New Zealand Act 1991*

before consumption—that occurred as a consequence of contamination during primary production or along the supply chain, including transport and distribution, were included. Processing activities undertaken on farm, such as washing and bagging, were also included.

The review examined the scientific literature published from 1990-2011.

2.2 Summary of the Australian situation (from the P1015 review)

The review identified five fresh horticultural produce related outbreaks that occurred in Australia and met the strict inclusion criteria. Three of these outbreaks were associated with domestically produced product and two with imported product (Table 1).

Table 1 Australian outbreaks identified in the P1015 review (1990-2011)

Commodity	Pathogen associated with outbreak	Year	Imported or domestic	Reference
Vegetables				
Baby corn	<i>Shigella sonnei</i>	2007	Imported	(Lewis et al. 2009)
Melons				
Rockmelon	<i>Salmonella</i> Saintpaul	2006	Domestic	(Munnoch et al. 2009)
Rockmelon and/or honeydew melon	<i>Listeria monocytogenes</i>	2010	Domestic	(OzFoodNet 2010)
Other fruit				
Papaya	<i>Salmonella</i> Litchfield	2006-2007	Domestic	(Gibbs et al. 2009)
Tomato (semi-dried)	Hepatitis A	2009	Imported	(Donnan et al. 2012)

For two of the outbreaks related to domestic product—rockmelon with *Salmonella* Saintpaul and papaya with *Salmonella* Litchfield—food safety issues were identified that may have contributed to produce contamination, including the use of untreated or inadequately treated water and incorrect use of chemical disinfectants (Gibbs et al. 2009; Munnoch et al. 2009). The source of contamination was not determined for the third outbreak related to domestic product or for either of the outbreaks related to imported product. However, poor sanitation at the packing and/or collection houses was a likely source of the *Shigella sonnei* contamination of the imported baby corn (Lewis et al. 2009).

To provide a broader picture of foodborne illness potentially linked to fresh horticultural produce in Australia, the OzFoodNet outbreak register was utilised. The OzFoodNet register contains data on all reported foodborne outbreaks² of gastrointestinal disease in Australia since 2001, including those that are not reported in the published literature and those that did not meet the strict inclusion criteria of the review. From January 2001 to June 2011, the OzFoodNet outbreak register recorded 93 produce-associated outbreaks in Australia³. Of

² OzFoodNet: Foodborne and suspected foodborne outbreaks are defined as two or more cases of illness associated with a common food.

³ OzFoodNet: To be included as a produce-associated outbreak, multi-ingredient foods or mixed dishes must have a specifically listed produce item as implicated or suspected, or as being a principal ingredient of an implicated dish, or are commonly known to contain a produce ingredient. If an ingredient other than the produce ingredient was implicated in multi-ingredient dishes, the outbreak was excluded. Where a range of possible high risk foods (other than produce) were listed, an outbreak was not included unless a produce ingredient was specifically implicated or suspected by investigators.

these, 10 were classified as confirmed⁴, 27 as suspected⁵ and 56 as possible⁶ outbreaks. Across the 93 outbreaks at least 2,822 people became ill, 321 were hospitalised and seven people died. The outbreaks were most commonly of unknown aetiology (35%), or caused by *Salmonella* Typhimurium (18%), norovirus (18%) or other *Salmonella* serovars (12%). Twenty eight percent of the outbreaks were associated with vegetables, 19% with fruit, and 48% with mixed/unspecified/other produce (OzFoodNet unpublished data 2010; 2011).

The data available from retail and through chain microbiological surveys performed in Australia from 2005-2010 indicated a low level of microbial contamination of the sampled fresh horticultural produce. However the data also showed that infrequent contamination of fresh horticultural produce with pathogenic microorganisms can occur. The FreshTest data collected for quality assurance and food safety programs within the Australian fresh produce industry had similar outcomes, indicating that pathogenic bacteria are detected infrequently. The FreshTest data showed that indicator organisms such as *Escherichia coli* and/or faecal coliforms are detected more frequently than pathogenic bacteria, especially in fresh herbs.

2.3 Summary of the international situation (from the P1015 review)

Foodborne pathogens are responsible for a number of illnesses worldwide, and fresh produce commodities are an important source of infection. The review identified 38 fresh horticultural produce related outbreaks that met the strict inclusion criteria (Table 2).

Table 2 International outbreaks identified in the P1015 review (1990-2011)

Commodity	Pathogen associated with outbreak	Year	Location of outbreak	Reference
Leafy vegetables				
Baby spinach	<i>E. coli</i> O157:H7	2006	USA	(CDC 2006; Jay et al. 2007)
Basil	<i>Cyclospora cayetanensis</i>	2001	Canada	(Hoang et al. 2005)
	<i>Salmonella</i> Senftenberg	2007	UK	(Pezzoli et al. 2008)
Coriander	<i>Salmonella</i> Thompson	1999	USA	(Campbell et al. 2001)
Lettuce	<i>E. coli</i> O157	1995	USA	(Ackers et al. 1998)
		1996	USA	(Hilborn et al. 1999)
		2005	Sweden	(Söderström et al. 2008)
	Norovirus	2010	Denmark	(Ethelberg et al. 2010)
	<i>Salmonella</i> Newport	2004	UK	(Irvine et al. 2009)
	<i>Shigella sonnei</i>	1994	Norway	(Kapperud et al. 1995)
		1994	UK	(Frost et al. 1995)
<i>Yersinia pseudotuberculosis</i> O:3	1998	Finland	(Nuorti et al. 2004)	

⁴ OzFoodNet: Confirmed outbreak: Single ingredient produce items or food where produce items were a principle ingredient and epidemiological, microbiological and trace back evidence showed that the item was contaminated in a primary produce environment.

⁵ OzFoodNet: Suspected outbreak: Single ingredient product items or a dish containing a produce item and:

- there was epidemiological and/or microbiological evidence to implicate the dish
- the produce item was a principle ingredient, or specifically listed as implicated, and
- investigators did not discount the possibility of the product being contaminated in primary produce environments.

⁶ OzFoodNet: Possible outbreak: Single ingredient produce items or dishes that contained or are commonly known to contain a produce item as an ingredient and:

- there was descriptive, epidemiological and/or microbiological evidence to implicate the dish *but*
- that a range of modes of contamination of the food were considered likely, such as ill food handler or cross-contamination *and*
- there was no particular evidence that the primary produce ingredient was the source of contamination.

Commodity	Pathogen associated with outbreak	Year	Location of outbreak	Reference
Other vegetables				
Baby corn	<i>S. sonnei</i>	2007	Denmark	(Lewis et al. 2009)
Carrots	<i>Y. pseudotuberculosis</i> O:1	2003	Finland	(Jalava et al. 2006)
		2004	Finland	(Kangas et al. 2008)
		2006	Finland	(Rimhanen-Finne et al. 2008)
Chilli peppers (possibly tomato)	<i>Salmonella</i> Saintpaul	2008	USA	(CDC 2008)
Green onions	Hepatitis A	1998	USA	(Dentinger et al. 2001)
		2003	USA	(Wheeler et al. 2005)
Peas	<i>Campylobacter jejuni</i>	2008	USA	(Gardner et al. 2011)
	<i>S. sonnei</i>	2009	Norway	(Heier et al. 2009)
Melons				
Rockmelon	<i>Listeria monocytogenes</i>	2011	USA	(CDC 2011)
		2000	USA	(CDC 2002)
	<i>Salmonella</i> Poona	2001	USA	(CDC 2002)
		2002	USA	(CDC 2002)
		1997	USA	(Mohle-Boetani et al. 1999)
<i>Salmonella</i> Saphra	2000	USA	(CDC 2002)	
Berries				
Raspberries	<i>C. cayetanensis</i>	1996	USA	(Caceres et al. 1998)
		2000	USA	(Ho et al. 2002)
	Norovirus	2009	Finland	(Maunula et al. 2009)
		2009	Finland	(Sarvikivi et al. 2012)
Strawberries	Hepatitis A	1997	USA	(Hutin et al. 1999)
	<i>E. coli</i> O157:H7	2011	USA	(Anonymous 2011a)
Other fruit				
Mamey	<i>Salmonella</i> Typhi	1999	USA	(Katz et al. 2002)
Mango	<i>Salmonella</i> Newport	1999	USA	(Sivapalasingam et al. 2003)
Tomato (fresh)	<i>Salmonella</i> Newport	2002	USA	(Greene et al. 2008)
	<i>Shigella flexneri</i> 2a	2001	USA	(Reller et al. 2006)
Tomato (semi-dried)	Hepatitis A	2010	France	(Gallot et al. 2011)
		2009-2010	Netherlands	(Petrignani et al. 2010)

Eight of the international outbreaks identified in the review documented a microbiological trace back investigation with sufficient detail to assess a probable failure point in the supply chain. The use of faecally contaminated water during the growing phase for irrigation or pesticide application was implicated in two outbreaks: lettuce with *E. coli* O157 in Sweden (Söderström et al. 2008) and fresh tomatoes with *Salmonella* Newport in the USA (Greene et al. 2008). Direct faecal contamination of horticultural produce in the field by cattle/wild pigs, wild birds or deer was implicated for three outbreaks: baby spinach with *E. coli* O157:H7 in the USA (CDC 2006; Jay et al. 2007), peas with *Campylobacter jejuni* in the USA (Gardner et al. 2011), and strawberries with *E. coli* O157:H7 in the USA (Anonymous 2011b), respectively. There were three outbreaks attributed to poor post-harvest storage and handling practices: all involved carrots contaminated with *Yersinia pseudotuberculosis* and occurred in Finland (Jalava et al. 2006; Kangas et al. 2008; Rimhanen-Finne et al. 2008).

2.4 Overall outcomes of the P1015 review

The review identified the following commodity sectors as being associated with outbreaks: berries; leafy vegetables; melons; other vegetables (e.g. baby corn, carrots, chilli peppers, green onions and peas); and other fruit (e.g. mamey, mango, papaya, tomato). The commodities found to be most commonly linked to outbreaks were lettuce (8 outbreaks); rockmelons (7 outbreaks); fresh and semi-dried tomatoes (5 outbreaks, plus a possible association in an additional outbreak); and raspberries (4 outbreaks). *Salmonella* spp. were responsible for the greatest number of foodborne outbreaks, causing 13 outbreaks associated with a variety of commodities including leafy and other vegetables, and fruit.

Fresh produce can potentially become contaminated at any point along the supply chain. However, contamination is most likely to occur in the field, during initial processing and during the final preparation in the kitchen (Lynch et al. 2009). Contamination during the final preparation of a dish was excluded from the review, as the focus was on primary production and processing. The review identified the following production activities as common sources of produce contamination:

- The use of poor quality water pre-harvest, e.g. for irrigation water or application of pesticides
- The use of poor quality water in post-harvest processing applications, such as washing
- Wildlife incursions into growing areas prior to harvest (e.g. direct faecal contamination of produce in the field) or post-harvest (e.g. direct contamination in storage)
- Breaches of good hygienic practice along the supply chain.

The most common cause of product contamination identified was the use of poor quality water for pre-harvest activities and post-harvest processing.

The size of outbreaks vary according to the pathogen involved; source and level of contamination; volume of produce contaminated; distribution networks; site and method of final preparation; and the amount consumed. For example, the use of faecally contaminated water during the growing phase has the potential to contaminate multiple paddocks and batches of produce, and, depending on the distribution networks, there exists the potential for widespread outbreaks affecting multiple jurisdictions.

However, source attribution is very difficult, and the exact mechanism of produce contamination is rarely definitively established. The majority of outbreak reports examined in the review did not include environmental investigations and/or sufficient detail to identify the source of contamination. Typically, a number of failures in hygienic practices throughout the supply chain were identified as possibly contributing to contamination, but often there was not sufficient detail to identify specific failure points. Also, the results of the review did not contain specific detailed information to determine whether different risk factors are associated with different production systems (e.g. field grown versus hydroponics).

Microbiological data available from Australian surveys undertaken from 2005-2010 suggested a low level of contamination of fruits and vegetables in the Australian supply chain; contamination with pathogenic microorganisms occurred infrequently.

The outcomes of the P1015 review reaffirmed the assumptions regarding the particular commodities and risk factors most likely to result in produce contamination and outbreaks of foodborne illness.

3 Current situation (2011-2019)

FSANZ undertook a review of scientific literature and technical reports published in the period 2011-2019 to identify outbreaks of foodborne illness associated with fresh horticultural produce that occurred, or were reported on, since the review undertaken for Proposal P1015 (FSANZ 2011). A search of the published scientific literature was conducted using the EBSCO search engine to capture relevant studies from selected databases. Initial search results were subjected to two filtering steps similar to those applied in the P1015 review. We also analysed outbreaks described in publicly-available reports, such as those published by OzFoodNet—Australia’s enhanced foodborne disease surveillance network—and food recall data, to provide a broader overview of the incidence of horticulture-related foodborne illness and microbial contamination of fresh horticultural produce in Australia.

A brief summary of identified outbreaks and initial conclusions from this review is presented below. FSANZ will undertake a thorough analysis of these outbreak reports to identify the commodities and production factors most likely to result in produce contamination and outbreaks of foodborne illness, to guide decisions on appropriate regulatory and non-regulatory risk management measures. Stakeholders will have an opportunity to comment on this analysis and proposed risk management measures in response to the second call for submissions report for this Proposal.

3.1 Australian outbreaks of foodborne illness associated with fresh horticultural produce

Since 2011 there have been a number of outbreaks of foodborne illness associated with consumption of horticultural produce in Australia (Table 3).

Data on Australian outbreaks of foodborne illness associated with horticultural produce indicate *Salmonella* and viruses (Hepatitis A and norovirus) are responsible for the majority of recorded outbreaks. Leafy vegetables, melons and berries are the commodity sectors most often associated with these outbreaks. There was a lack of data regarding potential supply chain failure points for the majority of these outbreaks, with inadequate sanitation being the only issue identified.

Table 3 Summary of Australian outbreaks associated with fresh and minimally processed horticultural produce (2011-2019)

No.	Commodity	Pathogen	Year	Imported or domestic	No. of cases (deaths)	Epidemiology comments ¹	Supply chain failure ²	References
Leafy vegetables								
1	Leafy vegetables, salads	<i>Salmonella</i> Anatum	2012	Domestic	15	L	Contaminated raw product; inadequate cleaning of equipment	(OzFoodNet 2015)
2	Leafy salad	Norovirus	2014	Domestic	21	E	n.d.	(OzFoodNet 2017a)
3	Lettuce leaves, bagged	<i>Salmonella</i> Anatum	2016	Domestic	>23	E, L	Contaminated raw product	(NSW OzFoodNet 2017a)
Sprouts								
4	Mung bean sprouts	<i>Salmonella</i> Saintpaul	2015-2016	Domestic	>99	E, L	Contaminated raw product	(NSW OzFoodNet 2017a)
Melons								
5	Rockmelon	<i>Salmonella</i> Hvittingfoss	2016	Domestic	144	E, L	Inadequate sanitation of product	(NSW OzFoodNet 2017b)
6	Rockmelon	<i>Listeria monocytogenes</i>	2018	Domestic	22 (8)	L	Existing sanitation processes were not adapted to account for extreme weather events	(NSW OzFoodNet 2018a)
Berries								
7	Berries, mixed, frozen	Hepatitis A	2015	Imported	35	E, L	n.d.	(OzFoodNet 2017b)
8	Berries, mixed, frozen	Hepatitis A	2017	Imported	4	L	n.d.	(DHHS Victoria 2017; SA Health 2017)
9	Pomegranate arils, frozen	Hepatitis A	2018	Imported	30 (1)	E, L	n.d.	(NSW OzFoodNet 2018b)

No.	Commodity	Pathogen	Year	Imported or domestic	No. of cases (deaths)	Epidemiology comments ¹	Supply chain failure ²	References
Other fruit								
10	Fruit	Norovirus	2011	Domestic	15	E	n.d.	(OzFoodNet 2015)

¹ E—epidemiological study, L—laboratory confirmed link between outbreak strain and implicated commodity or farm

² n.d.—not determined

3.2 Australian recalls of fresh horticultural produce due to microbial contamination

Food recalls are performed to remove unsafe food from the marketplace to protect public health and safety. Horticulture produce has been recalled in Australia due to contamination with pathogenic microorganisms (Table 4).

Table 4: Summary of Australian recalls associated with fresh and minimally processed horticultural produce (2011-2019)

Commodity	Microbial contaminant	Year	Imported or domestic	Associated with an Australian outbreak ⁷
Leafy vegetables				
Pre-packaged salad leaves	<i>Salmonella</i>	2016	Domestic	Yes, outbreak no. 3
Loose baby spinach and mesculin lettuce	<i>Salmonella</i>	2016	Domestic	Yes, outbreak no. 3
Sprouts				
Sprouts (various)	<i>E. coli</i>	2011	Domestic	No
Alfalfa sprouts	<i>E. coli</i>	2012	Domestic	No
Mung Bean sprouts	<i>E. coli</i>	2012	Domestic	No
Sprouts salad	<i>Salmonella</i>	2014	Domestic	No
Mung Bean sprouts	<i>Salmonella</i> Saintpaul	2016	Domestic	Yes, outbreak no. 4
Mung Bean sprouts	<i>Salmonella</i>	2016	Domestic	No
Sprouts (various)	<i>Salmonella</i>	2018	Domestic	No
Alfalfa sprouts	<i>Salmonella</i>	2018	Domestic	No
Other/mixed vegetables				
Frozen carrot, sweetcorn and peas	<i>L. monocytogenes</i>	2018	Imported	No (associated with international outbreak)
Frozen mixed vegetables	<i>L. monocytogenes</i>	2018	Imported	No (associated with international outbreak)
Frozen mixed vegetables	<i>L. monocytogenes</i>	2018	Imported	No (associated with international outbreak)
Frozen peas and corn	<i>L. monocytogenes</i>	2018	Imported	No (associated with international outbreak)
Frozen mixed vegetables	<i>L. monocytogenes</i>	2018	Imported	No (associated with international outbreak)
Multiple frozen vegetable products	<i>L. monocytogenes</i>	2018	Imported	No (associated with international outbreak)
Melons				
Rockmelon	<i>L. monocytogenes</i>	2018	Domestic	Yes, outbreak no. 6
Rockmelon	<i>Salmonella</i>	2016	Domestic	Yes, outbreak no. 5
Berries				
Frozen berries	Hepatitis A	2017	Imported	Yes, outbreak no. 8
Frozen berries (mixed and raspberries)	Hepatitis A	2015	Imported	Yes, outbreak no. 7
Frozen berries (mixed)	Hepatitis A	2015	Imported	Yes, outbreak no. 7

⁷ Refers to outbreaks listed in Table 3

Commodity	Microbial contaminant	Year	Imported or domestic	Associated with an Australian outbreak ⁷
Other fruit				
Frozen pomegranates	Hepatitis A	2018	Imported	Yes, outbreak no. 9

The primary causes of fresh and minimally processed horticultural produce-related recalls were *Salmonella* and *L. monocytogenes*; other microbial pathogens associated with these recalls were *E. coli* and hepatitis A. The main commodity sectors that were recalled were sprouts and mixed vegetables. The other sectors with multiple recalls were berries, leafy vegetables and melons.

3.3 International outbreaks of foodborne illness associated with fresh horticultural produce

A search for reports of horticultural produce-associated outbreaks of foodborne illness was conducted using the EBSCO search engine to capture relevant studies from selected databases. Initial search results were subjected to two filtering steps, with articles describing 44 outbreaks meeting the search criteria (Annex 1).

Outbreaks were most commonly caused by contamination with viruses (Hepatitis A and norovirus), bacterial pathogens (particularly *Salmonella* spp., enterohaemorrhagic *E. coli* and *L. monocytogenes*) and enteric parasites (e.g. *Cyclospora cayatanensis*).

Commodity sectors most often associated with outbreaks were leafy vegetables (lettuces, bagged salads), berries, sprouts and melons.

Typically, these reports did not include robust analyses of the root causes of the outbreaks—the specific production and processing practices that caused the contamination, or the relative contribution of potential sources of contamination. In the studies that did provide such evidence, the use of poor quality water for irrigation or application of crop protection chemicals; direct faecal contamination of produce growing in the field; and defects in facilities, hygiene, sanitation and process controls on farm, in processing facilities and along the supply chain were identified. These factors point to failures to implement, monitor and correct defects in Good Agricultural Practices on farm and Good Hygienic Practices post-harvest.

4 Assessment approach

The microbiological assessment for this Proposal will involve a qualitative through chain analysis of specific horticulture sectors. The assessment will identify where in the horticulture supply chain hazards may be introduced and where in the supply chain hazards may be controlled.

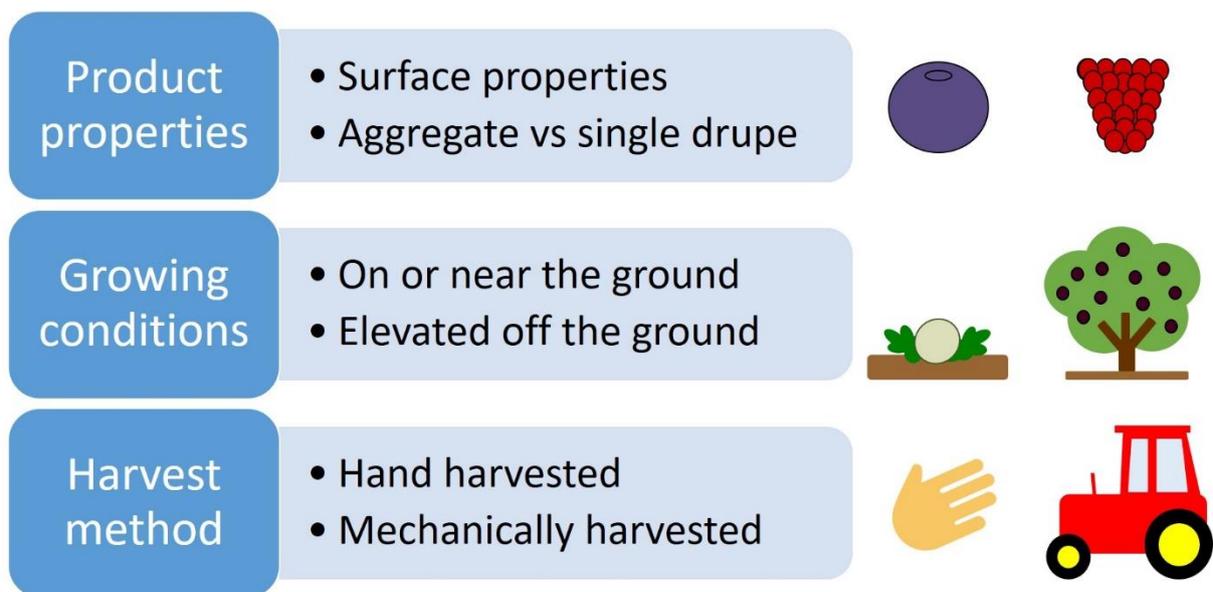
The assessment for this Proposal will identify if the selected commodity sectors—or specific commodities within them—have commodity specific characteristics or production practices that make them more vulnerable to contamination, compared to other fresh horticultural produce, and subsequently require additional risk management measures.

4.1 Proxy approach

The Australian horticulture industry is very complex. This is due to the huge diversity in the types of horticultural produce; differences in production methods; variation in size and experience of producers and processors; geographic and climatic variability between production zones; and seasonality of produce. In order to assess this diverse industry in an efficient manner, FSANZ will utilise a proxy approach. We will focus on a representative set of products and associated microbiological pathogens within each commodity sector, and assess the relevance of the findings to other products in the same sector and also more broadly across all fresh horticulture produce.

The three horticulture sectors included in the scope of the assessment are berries, leafy vegetables and melons. Specific products will be selected to represent the variety of products within each sector. Factors such as differences in the properties of the produce, growing conditions, and harvest and primary processing methods will be taken into consideration when choosing the proxies (Figure 1). The proxies will be selected such that a range of risk factors and a spectrum of risk are covered for each assessed commodity sector.

Figure 1: Factors to be considered when selecting the proxies for each commodity sector



5 Questions to be considered during the scientific assessment

The risk assessment questions outlined below will be addressed during the analysis of the risk posed by microbial hazards in fresh produce:

- What are the key risk factors associated with the primary production and processing of fresh ready-to-eat horticulture products that apply broadly to the sector?
 - What are the main risk factors and/or production activities contributing to contamination with microbiological hazards?
 - What measure/controls may have minimised contamination of produce?
 - What are the commodities most often implicated in fresh ready-to-eat horticulture product related foodborne outbreaks?

- Which commodities, or commodity groups reflected in the Codex Code of Hygienic Practice for Fresh Fruits and Vegetables pose a higher microbiological food safety risk due to their intrinsic properties and/or production method?
 - What additional measures/controls may reduce the food safety risk?

6 Conclusion

FSANZ's *Review of foodborne illness associated with selected ready-to-eat fresh produce* (FSANZ 2011), undertaken for Proposal P1015, identified particular horticultural commodity sectors and risk factors most likely to result in foodborne illness. Our preliminary analysis of Australian and international data on foodborne illness and microbial contamination of horticultural produce is consistent with the conclusions of that review, and indicates that a thorough assessment of food safety risks and possible risk mitigation measures for berries, melons and leafy vegetable should be undertaken to assist in the identification of appropriate risk management measures to ensure public health and safety.

Stakeholders are invited to provide technical data on industry production and processing practices; the efficacy of current risk mitigation measures (including under atypical conditions e.g. extreme weather conditions); and through-chain microbiological data (e.g. level, frequency and type of microbiological contamination at different production and processing stages or critical control points) relevant to the horticulture sectors being assessed.

FSANZ welcomes comments on the proxy approach and the choice of proxies within the berry, leafy vegetables and melon sectors.

Annex 1

Summary of international outbreaks associated with fresh and minimally processed horticultural produce

Commodity	Pathogen	Year	Location/s	Commodity origin	No. of cases (deaths)	Epidemiology comments ¹	Supply chain failure ²	References
Leafy vegetables								
Lettuce, romaine	<i>Escherichia coli</i> O145	2010	USA	USA	31	E, L	n.d.	(Taylor et al. 2013)
Lettuce, romaine	<i>E. coli</i> O157:H7	2011	USA	USA	58	E	n.d.	(Slayton et al. 2013)
Basil	<i>Shigella sonnei</i>	2011	Norway	Israel	46	E	n.d.	(Guzman-Herrador et al. 2011; Guzman-Herrador et al. 2013)
Lettuce	<i>E. coli</i> O157:H7	2012	USA	USA	17 (2)	E	n.d.	(Marder et al. 2014)
Spinach & leafy vegetables, bagged	<i>E. coli</i> O157:H7	2012	USA	USA	33	L	n.d.	(CDC 2012b)
Coriander	<i>Cyclospora cayetanensis</i>	2013	USA	Mexico	270	E	n.d.	(Abanyie et al. 2015)
Leafy vegetables/ bagged salads	<i>C. cayetanensis</i>	2013	USA	Mexico	227	E	n.d.	(Buss et al. 2016)
Watercress	<i>E. coli</i> O157:H7	2013	UK	UK	28	E, L	Suspected contamination from nearby cattle via irrigation water.	(Jenkins et al. 2015; Launderers et al. 2013)
Leafy vegetables/ bagged salads	<i>Salmonella</i> Coeln	2013 - 2014	Norway	Imported	26	E	n.d.	(Vestheim et al. 2016)
Leafy vegetables/ bagged salads	<i>Listeria monocytogenes</i>	2015 - 2016	USA, Canada	USA	19 (1) in USA 14 (3) in Canada	E, L	Multiple defects in facilities, hygiene, sanitation and process controls in the produce processing facility.	(Public Health Agency of Canada 2016; Self et al. 2016; Self et al. 2019)

Commodity	Pathogen	Year	Location/s	Commodity origin	No. of cases (deaths)	Epidemiology comments ¹	Supply chain failure ²	References
Lettuce, green coral	Norovirus	2016	Denmark	France	412	E, L	n.d.	(Müller et al. 2016)
Rocket	<i>E. coli</i> (EPEC & non-O157 STEC)	2016	Finland	Denmark	237	E, L	n.d.	(Kinnula et al. 2018)
Lettuce, romaine	<i>E. coli</i> O157:H7	2018	USA, Canada	USA	210 (5) in USA 8 in Canada	L	Outbreak strain identified (by WGS) in canal water used to irrigate and dilute crop protection chemicals applied by aerial and land-based sprays on farms identified in trace back.	(CDC 2018b; FDA 2018a; Public Health Agency of Canada 2018)
Lettuce, romaine	<i>E. coli</i> O157:H7	2018	USA, Canada	USA	62 in USA 29 in Canada	L	<i>E. coli</i> O157:H7 closely related (by WGS) to outbreak strain found in sediment in a water reservoir on a farm identified in trace back.	(CDC 2019b; FDA 2019; Public Health Agency of Canada 2019)
Packaged salad (romaine lettuce and carrots)	<i>C. cayetanensis</i>	2018	USA	USA	511	L	n.d.	(CDC 2018a; FDA 2018b)
Spinach	<i>Yersinia enterocolitica</i>	2019	Denmark, Sweden	Italy	57	E	n.d.	(Espenhain et al. 2019)
Sprouts								
Fenugreek sprouts	<i>E. coli</i> O104:H4	2011	Germany & 15 other countries	Egypt (seeds)	4075 (>50)	E, L	n.d.	(Buchholz et al. 2011; EFSA 2011; Foley et al. 2013; Frank et al. 2011a; Frank et al. 2011b; King et al. 2012; WHO 2011)

Commodity	Pathogen	Year	Location/s	Commodity origin	No. of cases (deaths)	Epidemiology comments ¹	Supply chain failure ²	References
Alfalfa sprouts	<i>Salmonella</i> Cubana	2012	USA	USA	19	L	Multiple defects in facilities, hygiene, sanitation and process controls in the sprout growing facility.	(FDA 2012)
Mung bean sprouts	<i>L. monocytogenes</i>	2014	USA	USA	5 (2)	L	Multiple defects in facilities, hygiene, sanitation and process controls in the sprout processing and packaging facility.	(FDA 2015)
Alfalfa sprouts	<i>Salmonella</i> Muenchen, <i>Salmonella</i> Kentucky	2015–2016	USA	USA	26	L	Contaminated seed the likely source.	(CDC 2016d; FDA 2016)
Other vegetables								
Celery	<i>L. monocytogenes</i>	2010	USA	USA	10 (5)	E,L	Multiple defects in facilities, hygiene, sanitation and process controls in the produce processing facility.	(Gaul et al. 2013)
Tomatoes	<i>Salmonella</i> Strathcona	2011	Denmark	Italy	43 (1)	E	n.d.	(Muller et al. 2016)
Vegetables, various, frozen	<i>L. monocytogenes</i>	2013–2016	USA	USA	9 (1)	L	n.d.	(CDC 2016b)
Cucumber	<i>Salmonella</i> Newport	2014	USA	USA	275 (1)	E	n.d.	(Angelo et al. 2015)
Cucumber	<i>Salmonella</i> Poona	2015	USA	Mexico	907 (6)	E, L	n.d.	(CDC 2016c; Laughlin et al. 2019)
Peas, sugar snap	<i>C. cayetanensis</i>	2015	Canada	Guatemala	45	E	n.d.	(Whitfield et al. 2017)

Commodity	Pathogen	Year	Location/s	Commodity origin	No. of cases (deaths)	Epidemiology comments ¹	Supply chain failure ²	References
Frozen corn (possibly other frozen vegetables)	<i>L. monocytogenes</i>	2015-2018	Austria, Denmark, Finland, Sweden, UK	Hungary	47 (9)	L	Persistent contamination at the processing plant, despite cleaning and disinfection.	(EFSA 2018a, 2018b)
Melons								
Watermelon	<i>Salmonella</i> Typhimurium	2009	New Zealand	New Zealand	18	E	Multiple defects in facilities, hygiene, sanitation and process controls by the watermelon grower/seller.	(McCallum et al. 2010)
Watermelon	<i>Salmonella</i> Newport	2011-2012	England, Wales, Northern Ireland, Scotland, Ireland, Germany	Brazil	63 (3)	E, L	n.d.	(Byrne et al. 2014)
Rockmelon	<i>Salmonella</i> Typhimurium, <i>Salmonella</i> Newport	2012	USA	USA	261 (3)	L	Multiple defects in GAP, facilities, hygiene, sanitation and process controls on farm and in product distribution.	(CDC 2012a; FDA 2013)
Berries								
Blueberries	<i>Salmonella</i> Newport	2010	USA	USA	6	E	n.d.	(Miller et al. 2013)
Raspberries, frozen	Norovirus	2010 - 2011	Denmark	Serbia	242	E, L	n.d.	(Muller et al. 2015)
Strawberries, fresh	<i>E. coli</i> O157:H7	2011	USA	USA	15 (2)	E	Contamination by deer faeces; failures in GAP on farm.	(Laidler et al. 2013)

Commodity	Pathogen	Year	Location/s	Commodity origin	No. of cases (deaths)	Epidemiology comments ¹	Supply chain failure ²	References
Strawberries, frozen	Norovirus	2012	Germany	China	~11,000	E, L	n.d.	(Bernard et al. 2014; Made et al. 2013)
Strawberries, frozen	Hepatitis A	2012 - 2013	Denmark, Finland, Norway, Sweden	Egypt, Morocco	106	E	n.d.	(Gillesberg Lassen et al. 2013; Gossner and Severi 2014; Nordic Outbreak Investigation Team 2013)
Berries, mixed, frozen	Hepatitis A	2013 - 2014	Italy & 9 other countries	Suspected: Poland, Bulgaria	>1400	E, L	n.d.	(EFSA 2014; Guzman-Herrador et al. 2014; Guzman-Herrador et al. 2015; Scavia et al. 2017; Severi et al. 2015; Wenzel et al. 2014)
Strawberries, frozen	Hepatitis A	2016	USA	Egypt	143	L	n.d.	(CDC 2016a)
Raspberries/blueberries, mixed, frozen	Hepatitis A	2017	Netherlands	Bulgaria	14	E	n.d.	(Mollers et al. 2018)
Strawberries, frozen	Hepatitis A	2018	Sweden, Austria	Poland	34	E, L	n.d.	(Enkirch et al. 2018)
Other fruit								
Mamey	<i>Salmonella</i> Typhi	2010	USA	Guatemala	12	E	Multiple defects in facilities, hygiene, sanitation and process controls in the produce processing facility.	(Loharikar et al. 2012)
Papaya	<i>Salmonella</i> Agona	2011	USA	Mexico	106	E, L	n.d.	(Mba-Jonas et al. 2018)
Pomegranate arils	Hepatitis A	2012	Canada	Egypt	8	E, L	n.d.	(Swinkels et al. 2014)

Commodity	Pathogen	Year	Location/s	Commodity origin	No. of cases (deaths)	Epidemiology comments ¹	Supply chain failure ²	References
Apples, caramel apples	<i>L. monocytogenes</i>	2014–2015	USA	USA	35 (7)	E, L	n.d.	(CDC 2015, 2019a)
Papaya	<i>Salmonella</i> (multiple serotypes)	2016–2017	USA	Mexico	244	E, L	Produce prepared, packed or held under insanitary conditions.	(Hassan et al. 2019)

¹ E—epidemiological study, L—laboratory confirmed link between outbreak strain and implicated commodity or farm

² n.d.—not determined

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