

**5 February 2020**

**[111-20]**

**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](https://www.foodstandards.gov.au/code/proposals/Pages/proposalp1015primary5412.aspx)—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 FSANZ[[1]](#footnote-2) 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](https://www.foodstandards.gov.au/code/proposals/Pages/proposalp1015primary5412.aspx) (*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*](https://www.legislation.gov.au/Details/F2012L00023)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 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 | *Shigella sonnei* | 2007 | Imported | (Lewis et al. 2009) |
|  | | | | |
| Melons | | | | |
| Rockmelon | *Salmonella* Saintpaul | 2006 | Domestic | (Munnoch et al. 2009) |
| Rockmelon and/or honeydew melon | *Listeria monocytogenes* | 2010 | Domestic | (OzFoodNet 2010) |
|  | | | | |
| Other fruit | | | | |
| Papaya | *Salmonella* 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 outbreaks[[2]](#footnote-3) 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 Australia[[3]](#footnote-4). Of these, 10 were classified as confirmed[[4]](#footnote-5), 27 as suspected[[5]](#footnote-6) and 56 as possible[[6]](#footnote-7) 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 | *E. coli* O157:H7 | 2006 | USA | (CDC 2006; Jay et al. 2007) |
| Basil | *Cyclospora cayetanensis* | 2001 | Canada | (Hoang et al. 2005) |
| *Salmonella*Senftenberg | 2007 | UK | (Pezzoli et al. 2008) |
| Coriander | *Salmonella* Thompson | 1999 | USA | (Campbell et al. 2001) |
| Lettuce | *E. coli* 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) |
| *Salmonella*Newport | 2004 | UK | (Irvine et al. 2009) |
| *Shigella sonnei* | 1994 | Norway | (Kapperud et al. 1995) |
| 1994 | UK | (Frost et al. 1995) |
| *Yersinia pseudotuberculosis* O:3 | 1998 | Finland | (Nuorti et al. 2004) |
|  | | | | |
| Other vegetables | | | | |
| Baby corn | *S. sonnei* | 2007 | Denmark | (Lewis et al. 2009) |
| Carrots | *Y. pseudotuberculosis* 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) | *Salmonella* Saintpaul | 2008 | USA | (CDC 2008) |
| Green onions | Hepatitis A | 1998 | USA | (Dentinger et al. 2001) |
| 2003 | USA | (Wheeler et al. 2005) |
| Peas | *Campylobacter jejuni* | 2008 | USA | (Gardner et al. 2011) |
| *S. sonnei* | 2009 | Norway | (Heier et al. 2009) |
|  | | | | |
| Melons | | | | |
| Rockmelon | *Listeria monocytogenes* | 2011 | USA | (CDC 2011) |
| *Salmonella*Poona | 2000 | USA | (CDC 2002) |
| 2001 | USA | (CDC 2002) |
| 2002 | USA | (CDC 2002) |
| *Salmonella*Saphra | 1997 | USA | (Mohle-Boetani et al. 1999) |
|  | | | | |
| Berries | | | | |
| Raspberries | *C. cayetanensis* | 1996  2000 | USA  USA | (Caceres et al. 1998)  (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) |
| *E. coli* O157:H7 | 2011 | USA | (Anonymous 2011a) |
|  | | | | |
| Other fruit | | | | |
| Mamey | *Salmonella* Typhi | 1999 | USA | (Katz et al. 2002) |
| Mango | *Salmonella* Newport | 1999 | USA | (Sivapalasingam et al. 2003) |
| Tomato  (fresh) | *Salmonella* Newport | 2002 | USA | (Greene et al. 2008) |
| *Shigella flexneri* 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 comments1** | **Supply chain failure2** | **References** |
|  | | | | | | | | |
| Leafy vegetables | | | | | | | | |
| 1 | Leafy vegetables, salads | *Salmonella* 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 | *Salmonella* Anatum | 2016 | Domestic | >23 | E, L | Contaminated raw product | (NSW OzFoodNet 2017a) |
|  | | | | | | | | |
| Sprouts | | | | | | | | |
| 4 | Mung bean sprouts | *Salmonella* Saintpaul | 2015-2016 | Domestic | >99 | E, L | Contaminated raw product | (NSW OzFoodNet 2017a) |
|  | | | | | | | | |
| Melons | | | | | | | | |
| 5 | Rockmelon | *Salmonella* Hvittingfoss | 2016 | Domestic | 144 | E, L | Inadequate sanitation of product | (NSW OzFoodNet 2017b) |
| 6 | Rockmelon | *Listeria monocytogenes* | 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 comments1** | **Supply chain failure2** | **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]](#footnote-8)** |
| --- | --- | --- | --- | --- |
|  | | | | |
| Leafy vegetables | | | | |
| Pre-packaged salad leaves | *Salmonella* | 2016 | Domestic | Yes, outbreak no. 3 |
| Loose baby spinach and mesculin lettuce | *Salmonella* | 2016 | Domestic | Yes, outbreak no. 3 |
|  | | | | |
| Sprouts | | | | |
| Sprouts (various) | *E. coli* | 2011 | Domestic | No |
| Alfalfa sprouts | *E. coli* | 2012 | Domestic | No |
| Mung Bean sprouts | *E. coli* | 2012 | Domestic | No |
| Sprouts salad | *Salmonella* | 2014 | Domestic | No |
| Mung Bean sprouts | *Salmonella* Saintpaul | 2016 | Domestic | Yes, outbreak no. 4 |
| Mung Bean sprouts | *Salmonella* | 2016 | Domestic | No |
| Sprouts (various) | *Salmonella* | 2018 | Domestic | No |
| Alfalfa sprouts | *Salmonella* | 2018 | Domestic | No |
|  | | | | |
| Other/mixed vegetables | | | | |
| Frozen carrot, sweetcorn and peas | *L. monocytogenes* | 2018 | Imported | No (associated with international outbreak) |
| Frozen mixed vegetables | *L. monocytogenes* | 2018 | Imported | No (associated with international outbreak) |
| Frozen mixed vegetables | *L. monocytogenes* | 2018 | Imported | No (associated with international outbreak) |
| Frozen peas and corn | *L. monocytogenes* | 2018 | Imported | No (associated with international outbreak) |
| Frozen mixed vegetables | *L. monocytogenes* | 2018 | Imported | No (associated with international outbreak) |
| Multiple frozen vegetable products | *L. monocytogenes* | 2018 | Imported | No (associated with international outbreak) |
|  | | | | |
| Melons | | | | |
| Rockmelon | *L. monocytogenes* | 2018 | Domestic | Yes, outbreak no. 6 |
| Rockmelon | *Salmonella* | 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 |
|  | | | | |
| 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 cayetanensis*).

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.

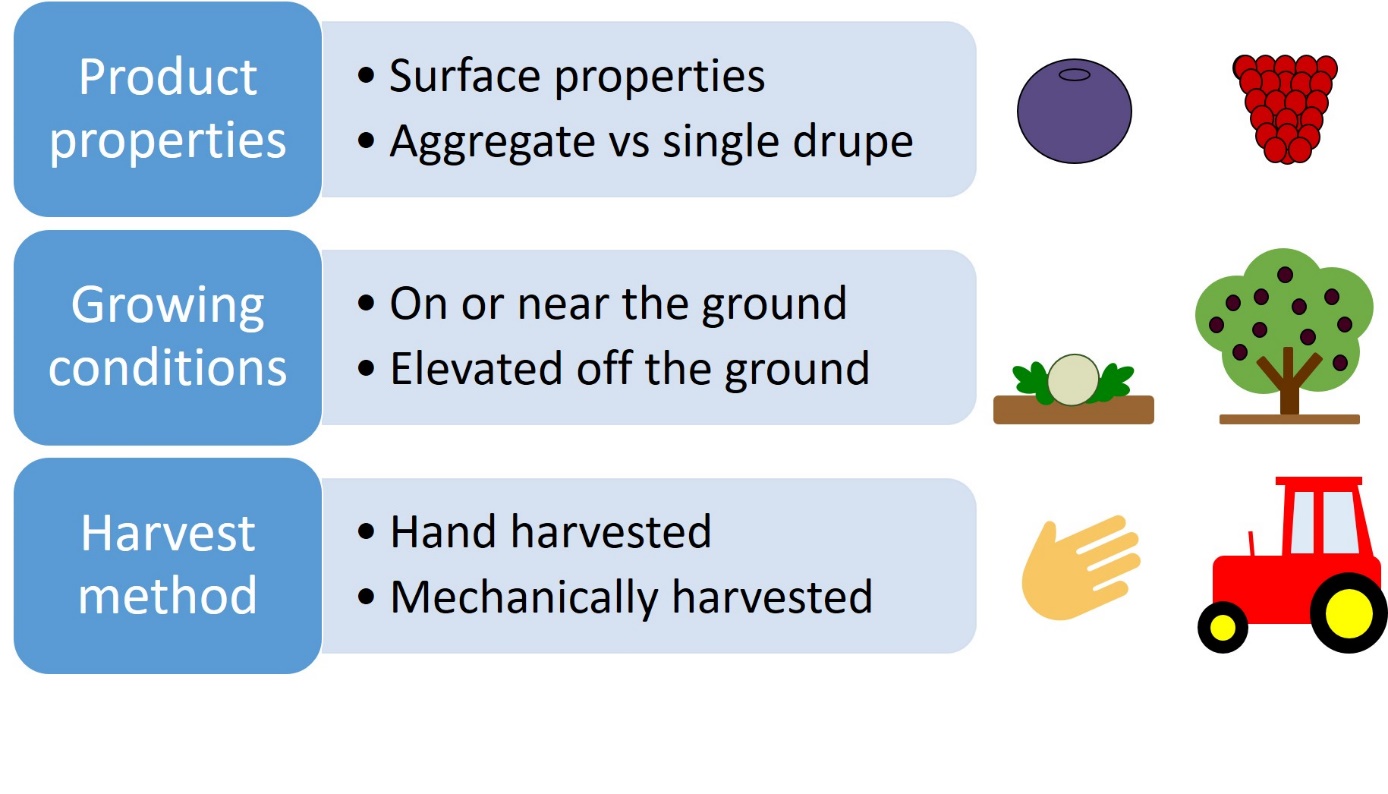
The assessment for this Proposal will identify if the selected commodity sectors—or specific commodities within them—have commodity specific characteristics or production practices that make them more vulnerable to contamination, compared to other fresh horticultural produce, and subsequently require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

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# 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 comments1** | **Supply chain failure2** | **References** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | | | | | | | | |
| Leafy vegetables | | | | | | | | |
| Lettuce, romaine | *Escherichia coli* O145 | 2010 | USA | USA | 31 | E, L | n.d. | (Taylor et al. 2013) |
| Lettuce, romaine | *E. coli* O157:H7 | 2011 | USA | USA | 58 | E | n.d. | (Slayton et al. 2013) |
| Basil | *Shigella sonnei* | 2011 | Norway | Israel | 46 | E | n.d. | (Guzman-Herrador et al. 2011; Guzman-Herrador et al. 2013) |
| Lettuce | *E. coli* O157:H7 | 2012 | USA | USA | 17 (2) | E | n.d. | (Marder et al. 2014) |
| Spinach & leafy vegetables, bagged | *E. coli* O157:H7 | 2012 | USA | USA | 33 | L | n.d. | (CDC 2012b) |
| Coriander | *Cyclospora cayetanensis* | 2013 | USA | Mexico | 270 | E | n.d. | (Abanyie et al. 2015) |
| Leafy vegetables/ bagged salads | *C. cayetanensis* | 2013 | USA | Mexico | 227 | E | n.d. | (Buss et al. 2016) |
| Watercress | *E. coli* O157:H7 | 2013 | UK | UK | 28 | E, L | Suspected contamination from nearby cattle via irrigation water. | (Jenkins et al. 2015; Launders et al. 2013) |
| Leafy vegetables/ bagged salads | *Salmonella* Coeln | 2013 - 2014 | Norway | Imported | 26 | E | n.d. | (Vestrheim et al. 2016) |
| Leafy vegetables/ bagged salads | *Listeria monocytogenes* | 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) |
| Lettuce, green coral | Norovirus | 2016 | Denmark | France | 412 | E, L | n.d. | (Müller et al. 2016) |
| Rocket | *E. coli* (EPEC & non-O157 STEC) | 2016 | Finland | Denmark | 237 | E, L | n.d. | (Kinnula et al. 2018) |
| Lettuce, romaine | *E. coli* 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 | *E. coli* O157:H7 | 2018 | USA, Canada | USA | 62 in USA 29 in Canada | L | E. coli 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) | *C. cayetanensis* | 2018 | USA | USA | 511 | L | n.d. | (CDC 2018a; FDA 2018b) |
| Spinach | *Yersinia enterocolitica* | 2019 | Denmark, Sweden | Italy | 57 | E | n.d. | (Espenhain et al. 2019) |
|  | | | | | | | | |
| Sprouts | | | | | | | | |
| Fenugreek sprouts | *E. coli* 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) |
| Alfalfa sprouts | *Salmonella* 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 | *L. monocytogenes* | 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 | *Salmonella* Muenchen, *Salmonella* Kentucky | 2015–2016 | USA | USA | 26 | L | Contaminated seed the likely source. | (CDC 2016d; FDA 2016) |
|  | | | | | | | | |
| Other vegetables | | | | | | | | |
| Celery | *L. monocytogenes* | 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 | *Salmonella* Strathcona | 2011 | Denmark | Italy | 43 (1) | E | n.d. | (Muller et al. 2016) |
| Vegetables, various, frozen | *L. monocytogenes* | 2013–2016 | USA | USA | 9 (1) | L | n.d. | (CDC 2016b) |
| Cucumber | *Salmonella* Newport | 2014 | USA | USA | 275 (1) | E | n.d. | (Angelo et al. 2015) |
| Cucumber | *Salmonella* Poona | 2015 | USA | Mexico | 907 (6) | E, L | n.d. | (CDC 2016c; Laughlin et al. 2019) |
| Peas, sugar snap | *C. cayetanensis* | 2015 | Canada | Guatemala | 45 | E | n.d. | (Whitfield et al. 2017) |
| Frozen corn (possibly other frozen vegetables) | *L. monocytogenes* | 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 | *Salmonella* 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 | *Salmonella* Newport | 2011-2012 | England, Wales, Northern Ireland, Scotland, Ireland, Germany | Brazil | 63 (3) | E, L | n.d. | (Byrne et al. 2014) |
| Rockmelon | *Salmonella* Typhimurium, *Salmonella* 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 | *Salmonella* 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 | *E. coli* O157:H7 | 2011 | USA | USA | 15 (2) | E | Contamination by deer faeces; failures in GAP on farm. | (Laidler et al. 2013) |
| 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 | *Salmonella* 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 | *Salmonella* 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) |
| Apples, caramel apples | *L. monocytogenes* | 2014–2015 | USA | USA | 35 (7) | E, L | n.d. | (CDC 2015, 2019a) |
| Papaya | *Salmonella* (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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1. Under the *Food Standards Australia New Zealand Act 1991* [↑](#footnote-ref-2)
2. OzFoodNet: Foodborne and suspected foodborne outbreaks are defined as two or more cases of illness associated with a common food. [↑](#footnote-ref-3)
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. [↑](#footnote-ref-4)
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. [↑](#footnote-ref-5)
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. [↑](#footnote-ref-6)
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. [↑](#footnote-ref-7)
7. Refers to outbreaks listed in Table 3 [↑](#footnote-ref-8)