

**5 February 2020**  
**[111–20]**

## **1<sup>st</sup> Call for submissions – Proposal P1052**

### **Primary Production and Processing Requirements for high-risk horticulture**

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FSANZ has assessed a Proposal to develop primary production and processing requirements for fresh high-risk horticulture in the Australia New Zealand Food Standards Code. Pursuant to section 72 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act), FSANZ now calls for submissions to assist further consideration of the Proposal.

For information about making a submission, visit the FSANZ website at [information for submitters](#).

All submissions on applications and proposals will be published on our website. We will not publish material that that we accept as confidential, but will record that such information is held. In-confidence submissions may be subject to release under the provisions of the *Freedom of Information Act 1991*. Submissions will be published as soon as possible after the end of the public comment period. Where large numbers of documents are involved, FSANZ will make these available on CD, rather than on the website.

Under section 114 of the FSANZ Act, some information provided to FSANZ cannot be disclosed. More information about the disclosure of confidential commercial information is available on the FSANZ website at [information for submitters](#).

Submissions should be made in writing; be marked clearly with the word ‘Submission’ and quote the correct project number and name. While FSANZ accepts submissions in hard copy to our offices, it is more convenient to receive submissions electronically through the FSANZ website via the link on [documents for public comment](#). You can also email your submission directly to [submissions@foodstandards.gov.au](mailto:submissions@foodstandards.gov.au).

There is no need to send a hard copy of your submission if you have submitted it by email or via the FSANZ website. FSANZ endeavours to formally acknowledge receipt of submissions within 3 business days.

**REVISED DEADLINE FOR SUBMISSIONS: 6pm (Canberra time) 25 March 2020**

**Please note the deadline has been extended from the previous date of 18 March 2020.**

Submissions received after this date will not be considered unless an extension had been given before the closing date. Extensions will only be granted due to extraordinary circumstances during the submission period. Any agreed extension will be notified on the FSANZ website and will apply to all submitters.

Questions about making submissions or the application process can be sent to [standards.management@foodstandards.gov.au](mailto:standards.management@foodstandards.gov.au).

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# Table of contents

<b>EXECUTIVE SUMMARY .....</b>	<b>2</b>
<b>1 INTRODUCTION .....</b>	<b>4</b>
1.1 THE PROPOSAL.....	4
1.2 REASONS FOR PREPARING THE PROPOSAL .....	4
1.3 PROCEDURE FOR ASSESSMENT.....	5
1.4 SCOPE.....	6
1.4.1 <i>Included in scope</i> .....	6
1.4.2 <i>'High risk' terminology</i> .....	6
1.4.3 <i>Excluded from scope</i> .....	6
<b>2 BACKGROUND .....</b>	<b>7</b>
2.1 PREVIOUS FSANZ CONSIDERATION .....	7
2.2 ACTIVITIES SINCE 2014.....	8
2.2.1 <i>Stakeholder consultations</i> .....	8
2.2.2 <i>FRSC considerations</i> .....	9
2.3 RECALLS AND INCIDENTS.....	9
2.4 TRACEABILITY.....	9
<b>3 ASSESSMENT .....</b>	<b>10</b>
3.1 MICROBIOLOGICAL ASSESSMENT .....	10
3.1.1 <i>Previous FSANZ findings</i> .....	10
3.1.2 <i>Current foodborne illness</i> .....	11
3.1.2 <i>Conclusion</i> .....	11
3.2 CHEMICAL ASSESSMENT.....	12
3.3 INDUSTRY OVERVIEW.....	12
<b>4 RISK MANAGEMENT.....</b>	<b>12</b>
4.1 REGULATORY REQUIREMENTS.....	13
4.1.1 <i>Australia New Zealand Food Standards Code</i> .....	13
4.1.2 <i>State and territory legislation</i> .....	14
4.1.3 <i>Import and export requirements</i> .....	14
4.1.4 <i>International legislation</i> .....	14
4.2 NON-REGULATORY MEASURES .....	14
4.2.1 <i>Food safety schemes</i> .....	14
4.2.2 <i>Guidance documents and other information</i> .....	15
4.3 OPTIONS.....	16
<b>5 OBLIGATIONS UNDER THE FSANZ ACT.....</b>	<b>18</b>
5.1 FSANZ OBJECTIVES .....	18
5.1.1 <i>Protection of public health and safety</i> .....	18
5.1.2 <i>Provision of adequate information relating to food to enable consumers to make informed choices</i> ..	18
5.1.3 <i>Prevention of misleading or deceptive conduct</i> .....	18
5.1.4 <i>Section 18 (2) considerations</i> .....	18
5.2 SECTION 59.....	19
<b>6 RISK COMMUNICATION .....</b>	<b>21</b>
6.1 CONSULTATION .....	21
6.1.1 <i>Summary of submissions on 2019 information paper</i> .....	22
6.2 WORLD TRADE ORGANIZATION (WTO) .....	22
<b>REFERENCES .....</b>	<b>23</b>

## Supporting documents (SD)

The following documents which informed the assessment of this Proposal are available on the FSANZ website: <http://www.foodstandards.gov.au/code/proposals/Pages/P1052.aspx>

SD1	The microbiological assessment approach and foodborne illness summary
SD2	Food safety measures for horticultural produce
SD3	Overview of the melon, berry and leafy vegetable industries in Australia

# Executive summary

The vast majority of horticultural produce in Australia is safe and healthy. However outbreaks linked to particular produce sectors continue to occur.

At the request of ministers responsible for food regulation, FSANZ is reassessing the need to amend the Australia New Zealand Food Standards Code (the Code) to enact a primary production and processing standard to manage food safety for high-risk horticulture. In May 2019, FSANZ released an information paper foreshadowing reviews of Chapters 3 and 4 of the Code, including requirements for horticulture. Feedback on the information paper showed general support for FSANZ to consider high-risk horticulture, and majority support to develop a standard and traceability provisions.

The purpose of this report is to provide a summary of FSANZ's assessment and of FSANZ's preliminary position based on that assessment. Input is invited to inform our decision on whether to prepare a variation to the Code.

The ongoing foodborne illness issues and lack of consistent and uniform regulatory measures for horticultural products suggest the current environment, which relies on non-regulatory measures, is not adequate to protect public health and safety and that regulatory measures are required.

The scope of this proposal includes primary production and primary processing activities in three sectors:

- leafy vegetables
- melons, and
- berries.

For the reasons outlined in this report, seed sprouts and ready-to-eat (RTE) and minimally processed fruits and vegetables (besides berries, melons and leafy vegetables), are excluded from the scope of this proposal. FSANZ will assess if these commodities need further consideration in future work on the review of Chapters 3 and 4 of the Code.

Microbiological hazards are the main food safety focus considered in this proposal. Outbreaks of foodborne illness continue to be associated with fresh horticultural produce in Australia and internationally. This Proposal has been informed by the following:

- The assessment undertaken for P1015; and
- An analysis of relevant Australia and international foodborne illness outbreak data between 2011-2019 (e.g. since P1015 assessment) and Australian recall data (refer SD1).

The earlier assessment of foodborne illness reaffirmed the assumption that fresh leafy vegetables, fresh leafy herbs, rockmelons, fresh and semi-dried tomatoes and raspberries were commonly associated with illness, while also noting the difficulties involved with source attribution and determining the exact mechanism of produce contamination. The assessment also identified key risk factors involved in produce contamination and control measures. Key contributing factors included use of pre- and post-harvest water, environmental factors and poor hygienic practices.

In addition to the earlier assessment, FSANZ undertook a preliminary assessment of Australian and international outbreaks between 2011–2019. This indicates that deaths and serious illnesses associated with high-risk horticultural produce continue to occur, and also that the conclusions of the earlier assessment still largely apply. Commodity sectors most often associated with outbreaks were leafy vegetables (lettuces, bagged salads), melons and berries. Contamination of produce most commonly resulted from using poor quality water on-farm, and failings in hygiene and sanitation throughout the production and supply chain.

There are currently no uniform and consistent national regulatory food safety requirements applying specifically to the primary production and processing of horticultural produce, except for seed sprouts. In the states and territories, food safety aspects of horticultural produce are regulated to varying degrees. Some jurisdictions set out food safety scheme requirements in regulations under their food acts.

Non-regulatory measures include industry food safety schemes which are voluntary, highly prescriptive schemes implemented by businesses wanting to comply with retailer requirements. Although there are less schemes used now than in 2012, there is still similar coverage in requirements across the supply chain. Based on limited information available, the efficacy of current schemes was unable to be determined.

Investigations into some of the more recent outbreaks indicated businesses had food safety schemes in place, but these had not been effective in avoiding an outbreak. This suggests that the level of assurance provided by such schemes may alone be insufficient to address food safety risks and to protect public health and safety.

FSANZ's preliminary view, based on the assessment to date, is that:

- The status quo (Option 1), which is based on non-regulatory measures, appears inadequate to effectively manage the risk to public health and safety.
- Development of regulatory measures (Option 2) is our preferred approach. The particular form of regulatory measure taken has yet to be decided, but may include a graduated risk-based approach, or amendments to definitions which would allow application of existing requirements to previously excluded businesses.

FSANZ's decision whether to prepare a regulatory measure and, if so, the form that that measure will take, will be informed by information received in response to this call for submissions, targeted consultation and cost benefit analysis.

The proposal is being assessed under FSANZ's major procedure, which requires two rounds of public consultation. Submitters are invited to provide comment on the issues and questions posed in this report. We will also engage with targeted industry groups, food regulators and the Horticulture Standards Development Advisory Group. Information received from submissions and targeted consultation will inform any proposed draft variation which, if made, will also be made available for public comment.

# 1 Introduction

## 1.1 The proposal

At the request of ministers responsible for food regulation, FSANZ is reassessing the need for a primary production and processing standard (PPP) to manage food safety for high-risk horticulture, including requirements for traceability.

PPP standards are incorporated into Chapter 4 of the Australia New Zealand Food Standards Code (the Code) and apply to Australia only. Together with other standards in the Code, the PPP standards provide a through-chain approach to managing food safety (i.e. from production on the farm through to sale to consumers). The development and application of standards requires analyses of:

- public health and safety risks
- economic and social factors
- existing requirements (e.g. state/territory legislation)
- industry codes of practice or guidelines, and
- accredited food safety systems.

FSANZ has developed PPP standards for the seafood, dairy, egg, meat, poultry and seed sprouts sectors.

A Horticulture Implementation Working Group (HIWG) has also been established by the Implementation Subcommittee on Food Regulation (ISFR) to ensure any amendments to the Code are consistently implemented at the national level. A Standard Development Advisory Group consisting of representatives from industry peak bodies and government regulators will be established to assist with and advise on the current work.

## 1.2 Reasons for preparing the proposal

While the vast majority of produce is safe and healthy, foodborne illness outbreaks linked to high-risk horticultural produce continue to occur.

Foodborne illness is largely preventable, but remains an ongoing and, sometimes, serious concern. In 2010, annual foodborne illness in Australia was estimated at 4.1 million cases, along with 5140 cases of non-gastrointestinal illness, 35,840 cases of sequelae (conditions that arise following illness, e.g. reactive arthritis), 31,920 hospitalisations and 86 deaths (Department of Health 2014). Of the known causes, norovirus, *Escherichia coli*, *Campylobacter* and *Salmonella* are the most common, although around 80% of foodborne illnesses have an unknown cause. Outbreaks of illness often result in damage not only to specific food businesses, but also related food businesses and whole industries. Lost productivity, impacts on lifestyle and medical expenses from foodborne illness can also result in a substantial burden for Australia. Costs associated with foodborne illness are estimated at \$1.2 billion each year (Abelson et al. 2006).

In April 2017, the Australia and New Zealand Ministerial Forum on Food Regulation (the Forum) identified reduction of foodborne illness, particularly related to *Campylobacter* and *Salmonella*, as one of its priorities. The *Australia's Foodborne Illness Reduction Strategy 2018–21*<sup>1</sup> was developed and includes food safety management in the horticulture sector as a priority focus area.

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<sup>1</sup> Available at <https://foodregulation.gov.au/internet/fr/publishing.nsf/Content/strategies>

FSANZ examined food safety management in the horticulture sector in 2011 under Proposal P1015 – PPP Standard for Horticulture<sup>2</sup> (P1015). Following consultation, FSANZ decided in 2014 that amendment of the Code was not warranted at that time, with the preferred strategy being the development by industry and state and territory governments of a strategy for maximising food safety in horticultural produce (e.g. via guides, codes of practice, education and training) (see section 2.1).

Between 2011 and 2019, there were several significant foodborne illness outbreaks in Australia associated with fresh horticultural produce involving over 408 cases of illness and 9 deaths. Two rockmelon outbreaks in 2016 and 2018 respectively, were responsible for 166 illnesses and 8 deaths. The impact of outbreaks can be significant both in terms of health (illness and/or death) and costs to the industry. For example, the 2018 outbreak of *Listeria* associated with rockmelons resulted in 22 cases of illness, 8 deaths, temporarily closed an export market and impacted the domestic market with losses to growers estimated to be around \$15 million.

Investigations into recent outbreaks indicated key contributing factors, including:

- environmental issues (rain/flooding)
- inadequate cleaning and sanitation of equipment and facilities
- lack of skills and knowledge of operators, particularly in relation to changing hazards (e.g. scaling up operations, new higher-risk products)

FSANZ's decision in 2014 to not amend the Code at that time was based in part on the fact that an estimated 70-80% of Australian horticultural produce was grown under a food safety scheme. Investigations into some of the more recent outbreaks show businesses had food safety schemes in place, but had not been effective in avoiding an outbreak. This suggests that the level of assurance provided by such schemes may alone be insufficient to address food safety risks and to protect public health and safety.

Horticulture sector supply chains are complex, and in many cases, not well documented. Good product traceability throughout the supply chain is central to the speed and scope of the response to food safety incidents, including:

- early withdrawal of product from marketplace
- limiting impact of an incident and/or illness, and
- limiting reputational and financial costs to industry.

Failure to prevent food safety problems and the complexity of supply chains (impacting traceability) means further regulation now needs to be considered, particularly for higher risk horticultural products.

The ongoing issues and lack of consistent and uniform regulatory measures (see below) for horticultural products prompted ministers to request FSANZ to reconsider food safety measures for high-risk horticulture. Ministers also recommended FSANZ consider food safety culture<sup>3</sup> as a means to encourage behaviour change in the sectors.

### **1.3 Procedure for assessment**

Proposal P1052 is being assessed under FSANZ's Major Procedure requirements of the FSANZ Act, which require two rounds of public consultation. Any draft variation to the Code will be provided at the next round of consultation.

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<sup>2</sup> <https://www.foodstandards.gov.au/code/proposals/Pages/proposalp1015primary5412.aspx>

<sup>3</sup> Food safety culture in a business is how everyone (owners, managers, employees) thinks and acts in their daily job to make sure that the food they make or serve is safe. More information is available at: <https://www.foodstandards.gov.au/foodsafety/culture/Pages/default.aspx>

## 1.4 Scope

The scope of this proposal is described below, including commodities being addressed and the term 'high risk'.

### 1.4.1 Included in scope

Ministers responsible for food regulation in Australia agreed on a need to reassess food safety measures in five high-risk horticultural sectors. These sectors are those with annexes to the Codex Alimentarius Code of Hygienic Practice for Fresh Fruits and Vegetables (CoHP FFV). They are: ready-to-eat and minimally processed fruits and vegetables, fresh leafy green vegetables, melons, berries and seed sprouts.

Each of these commodity sectors contain a broad range of products and an equally broad range of associated production activities. In our May 2019<sup>4</sup> information paper, FSANZ flagged a possible risk-based reduction in scope to allow our analysis to progress in a timely way. This scope reduction is supported by stakeholder submissions, preliminary risk assessment work (see section 3.1) and existing Code requirements (see section 4.1).

Therefore, the scope of this proposal includes primary production and primary processing activities of:

- leafy vegetables
- melons
- berries.

Microbiological hazards have been, and will be, the main food safety hazards considered. Chemical hazards will be discussed but are generally considered very low risk, and well managed, in Australian food production.

FSANZ has and will also consider the issues and possible risk management associated with vulnerabilities in the supply chain, including the role of traceability and use of new technologies.

### 1.4.2 'High risk' terminology

Risk is a function of how severe an adverse event is and how likely it is to occur. Whether a food is determined to be 'high risk' depends on the inherent nature of the food, whether pathogens can grow in it, and how the food is produced and consumed. Foods that are minimally processed (i.e. washed, trimmed, then packed) and are consumed fresh without a microbiocidal step to eliminate pathogens, generally present a higher risk than those that have undergone a kill step (e.g. cooking).

For the purposes of this work, the term 'high-risk horticulture' will be used to refer to those commodities captured within the scope: leafy vegetables, melons and berries.

### 1.4.3 Excluded from scope

The scope of this proposal does not include seed sprouts or ready-to-eat (RTE) and minimally processed fruits and vegetables besides berries, melons and leafy vegetables.

RTE and minimally processed fruits and vegetables is a very broad category, with no consistent definition or boundary. The archived Canadian *Code of Practice for Minimally*

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<sup>4</sup> Available at: <https://www.foodstandards.gov.au/foodsafety/standards/review/Pages/default.aspx>

*Processed Ready-to-Eat Fruit and Vegetables*<sup>5</sup> for example, refers to raw fruit and vegetables that have been minimally processed (i.e. peeled, sliced, chopped or shredded) before being packaged for sale.

In Australia, producers and/or processors who handle food for sale – such as RTE and minimally processed fruits and vegetables - are ‘food businesses’ for regulatory purposes and subject to the food safety requirements in Chapter 3 of the Code (see section 4.1). Melons and leafy vegetables are often components of RTE minimally processed fruits and vegetables (such as pre-cut fruit salad and bagged salad vegetables, respectively). Assessment work for melons and leafy vegetables may indicate whether additional products will also need consideration as part of this Proposal.

Standard 4.2.6 for seed sprouts contains requirements for traceability and processing activities that apply to sprout processors. Their activities present the most effective point for risk mitigation for food for sale. Requirements in the food safety standards (Standards 3.2.2 and 3.2.3) also apply to seed sprout processors as they are food businesses. The regulatory impact statement (RIS) for P1004 indicated that the community would receive the highest net benefit if only seed sprout processors (i.e. not producers) were regulated. Based on this and other technical information, the standard explicitly excluded requirements for seed production (i.e. primary production).

These excluded commodities are already covered by regulatory requirements in the Code. FSANZ will consider these commodities further as a part of the review of Chapter 4 of the Code.

## **2 Background**

### **2.1 Previous FSANZ consideration**

In 2011, FSANZ prepared a proposal to examine food safety management in horticulture under Proposal P1015 – PPP Standard for Horticulture.

P1015 aimed to examine the hazards associated with horticultural products, existing risk management measures, and possible measures that could be introduced into the horticulture sector. The scope of the project included fresh (raw) horticultural products: fruit, vegetables (including mushrooms and microgreens), herbs and nuts. It included through-chain production from farm to sale. A key driver for this project was the continuation of work to introduce PPP standards into commodity sectors identified by the then Ministerial Council on Food Regulation (now the Forum).

Reviews of horticulture associated foodborne illness and existing food safety systems were done and are available as supporting documents (SD2 and SD3) to P1015 respectively<sup>6</sup>.

Key findings of the P1015 assessment included:

- The review of foodborne illness confirmed the assumptions about the types of commodities and production activities most likely to result in produce contamination and outbreaks. However, the conclusions did not preclude other commodities and/or production activities being associated with future horticultural-associated outbreaks. Section 3.1.1 has further information.
- An estimated 70-80% of horticultural produce for sale in Australia was produced under a food safety scheme.

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<sup>5</sup> Available at: <https://www.inspection.gc.ca/food/archived-food-guidance/fresh-fruits-and-vegetables/food-safety/minimally-processed-ready-to-eat-fruit-and-vegetab/eng/1413673339210/1413673388676?chap=0>

<sup>6</sup> <http://www.foodstandards.gov.au/code/proposals/Pages/proposalp1015primary5412.aspx>

- Enforcement of regulatory requirements for horticulture would be challenging because the horticulture industry has a large proportion of small businesses, is diverse, changeable (in terms of commodities), and geographically spread.
- The nature and number of horticultural produce businesses was uncertain, particularly for those producing higher-risk products operating without an industry scheme.
- A 'one size fits all' regulatory approach was considered problematic to develop and deliver.
- A regulatory approach did not present the most effective approach to manage food safety risks.

Amendments to the Code did not go ahead. P1015 was abandoned in 2014 in favour of developing other measures. Reasons included:

- There was no uniform support for developing a Standard.
- A deeper understanding of the nature (and type of commodity grown), or number of horticultural businesses that are operating without an industry quality assurance/food safety system should be determined.
- Support for a collaborative approach involving the horticulture industry and state and territory governments to develop, as appropriate, targeted guidance, codes of practice, educative materials and training.
- The broader issue of ensuring through-chain traceability for all commodities needs to be addressed.

## **2.2 Activities since 2014**

A range of activities in the horticulture industry and its governance has continued since P1015 was abandoned. Within the food regulatory system, these include consultations with the horticulture industry and considerations by the Food Regulation Standing Committee (FRSC), leading to the current ministerial request to FSANZ. The main themes and decision points are summarised below.

Outside the food regulatory system, activities have included developing guidance for farmers' markets<sup>7</sup> and codes of practice, improving/consolidating industry food safety schemes (HARPS, discussed in section 4.2.1 and SD2) and establishing the Fresh Produce Safety Centre Australia and New Zealand (FPSC A-NZ)<sup>8</sup>.

### **2.2.1 Stakeholder consultations**

In 2015, a FRSC working group examined the horticulture sector, including imports and general risk factors, and proposed policy options for food safety management. FRSC agreed further work was needed to address knowledge and evidence gaps, including targeted consultation.

Consultations held in early 2016 between jurisdictions and the horticulture sector brought out key themes related to food safety:

- Engagement and information sharing – ongoing, regular engagement and communication is needed between regulators and industry about food safety and why it matters. A major challenge is the large number of peak bodies in the fresh produce sector and the lack of a single collective industry voice.
- Awareness and education – greater attention on food safety risk is needed when developing awareness, education and skills of workers along the supply chain.
- Traceability and supply chain – it is difficult to quickly identify and quantify the supply

<sup>7</sup> Available at <https://farmersmarkets.org.au/>

<sup>8</sup> <https://fpsc-anz.com/>

chain, including tracing product, which is particularly important during incident management.

- Government monitoring – industry expects that government will monitor the fresh produce sector to verify effective management of food safety.

### **2.2.2 FRSC considerations**

FRSC noted the consultation outcomes (above) and that jurisdictions and FSANZ would continue engaging with industry on improving incident response.

Following a *Salmonella* outbreak involving mixed leaf lettuce, Victoria presented two reports in late 2016 on food safety risks in the production and processing of leafy greens.

Subsequent FRSC roundtable discussions in 2017 looked at horticulture food safety issues from different perspectives (primary producers, processors and distributors, retail and food service, food regulators). The need for education, using technology as an aid, and working collaboratively were identified as key themes.

In 2018, further foodborne illness outbreaks prompted FRSC to reassess food safety management measures for horticulture. Five high-risk sectors were identified for immediate focus (aligning with Codex): ready-to-eat minimally processed fruits and vegetables, fresh leafy green vegetables, melons, berries and sprouts. FRSC agreed to advise the Forum to request FSANZ identify regulatory and non-regulatory measures for these sectors. The Forum agreed to the request in June 2018, leading to the current proposal.

## **2.3 Recalls and incidents**

FSANZ coordinates food recalls on behalf of state and territory food enforcement agencies. As part of this process, FSANZ collects information from food businesses including the type of product, reason and root cause analysis (where undertaken).

Recall data from 1989 to 2019 show horticulture recalls account for 9% (162/1674) of all recalls, with microbiological contamination the primary reason, 43% (70/162). *Listeria monocytogenes*, *Salmonella* spp., *Escherichia coli*, viruses (Hepatitis A) and other pathogens were the most common reasons. Recalled foods in the 'fruit, vegetables and herbs' category included fruit, sprouts, rockmelon and leafy greens.

Food recalls also occur as part of a response to a food outbreak or incident (which may or may not include both). Horticulture products were the only products implicated in national food incidents during the period 2016-2018.

Horticultural produced involved in incidents and/or multi-jurisdictional outbreaks for that period included:

- 2018 – *Listeria monocytogenes* in rockmelons.
- 2018 – Hepatitis A in frozen pomegranate arils
- 2017 – Hepatitis A in frozen mixed berries
- 2016 – *Salmonella* in sprouts
- 2016 – *Salmonella* in rockmelons
- 2018 – *Listeria* in frozen mixed vegetables
- 2016 – *Salmonella* in mixed lettuce
- 2015 – Hepatitis A in frozen mixed berries

## **2.4 Traceability**

The issue of traceability in the horticulture sector was flagged in P1015. Traceability is a key focus across a number of concurrent and complementary ongoing projects in the wider food

regulation system, including:

- The National Traceability Project
- FSANZ's Review of chapter 3 and 4
- The Food Export review<sup>9</sup>

In 2017, the Department of Agriculture initiated a National Traceability Project<sup>10</sup> across all agriculture sectors. The project comprised two stages: the first to assess the current state of traceability systems across agricultural commodities and review global drivers for the future. The second stage was to develop a national traceability framework. This work was completed in 2019. Industry action plans are now being developed by various sectors in cooperation with the Traceability Working Group which consists of commonwealth and state and territory jurisdictions. FSANZ has been involved in this work.

FSANZ will continue to monitor and engage in these projects, where appropriate, as this proposal progresses.

## 3 Assessment

### 3.1 Microbiological Assessment

Outbreaks of foodborne illness continue to be associated with fresh horticultural produce in Australia and internationally. This Proposal has been informed by the following:

- The assessment undertaken for P1015; and
- An analysis of relevant Australia and international foodborne illness outbreaks between 2011-2019 (e.g. since P1015 assessment) and Australian recall data (refer SD1).

#### 3.1.1 Previous FSANZ findings

In P1015, FSANZ undertook a descriptive scoping review of selected, well documented outbreaks associated with fresh ready-to-eat horticultural produce, to determine whether certain assumptions regarding the types of commodities implicated in outbreaks, and the associated production factors held true to the Australian situation.

Noting data limitations discussed in the review, the assessment reaffirmed the assumption that fresh leafy vegetables, fresh leafy herbs, rockmelons, fresh and semi-dried tomatoes and raspberries were commonly associated with illness.

The review also noted the difficulties involved with source attribution and determining the exact mechanism of produce contamination. The review identified key risk factors, but the evidence did not contain sufficient detail to determine whether risk factors differ for different production systems (e.g. field grown versus hydroponics).

Control measures to mitigate contamination were identified as:

- Pre-harvest water managed to minimise risk of contaminating produce:
  - Water used for pre-harvest activities (e.g. irrigation, application of pesticides and herbicides) are managed to avoid contamination from human activities, livestock production activities, domestic animals and wildlife.
  - Equipment used to apply water onto produce is maintained to a suitable standard to maintain the quality of the water.

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<sup>9</sup> Food export review: <http://www.agriculture.gov.au/ag-farm-food/food/regulation-safety/food-export-review>

<sup>10</sup> Department of Agriculture's [National Traceability Project](#) webpage

- Post-harvest water managed to minimise risk of contaminating produce:
  - Water used for post-harvest activities (e.g. washing) is of potable quality.
- Exclusion of domestic animals and wildlife from growing, packing and storage areas.
- Good hygienic practice along the supply chain.

### 3.1.2 Current foodborne illness

A subsequent preliminary assessment by FSANZ of Australian and international foodborne outbreaks linked to fresh horticultural produce between 2011–2019, indicates that the conclusions from the previous assessment of foodborne illness still largely apply.

In Australia between 2011 and 2019, outbreaks resulted in at least 408 cases of illness and nine deaths (see Table 3 in SD1). Data on Australian outbreaks indicate *Salmonella* and viruses (Hepatitis A and norovirus) are responsible for the majority of recorded horticulture associated outbreaks. Commodity sectors most often associated with outbreaks were leafy vegetables (lettuces, bagged salads), melons and berries. There is a lack of data regarding potential supply chain failure points for the majority of these outbreaks, with inadequate sanitation being the only issue identified.

Internationally, 44 outbreaks were identified, 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.

In the studies that provided a root cause analysis, 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

### 3.1.2 Conclusion

The preliminary analysis of Australian and international data on foodborne illness and microbial contamination of horticultural produce is consistent with the conclusions of FSANZ's previous assessment. The evidence assessed shows ongoing occurrences of serious illnesses (and even deaths) associated with high-risk horticultural produce.

In the next stage FSANZ will further assess the food safety risks and possible risk mitigation measures for berries, melons and leafy to assist in identification of appropriate, risk-based, risk management measures.

FSANZ seeks comments and input from stakeholders to inform its further assessment of the berries, leafy vegetables and melon sectors, particularly the following information or data:

1. Technical data on industry production and processing practices
2. Efficacy of current risk mitigation measures (including under atypical conditions e.g. extreme weather conditions)
3. Through-chain microbiological data (e.g. level, frequency and type of microbiological contamination at different production and processing stages or critical control points)

## 3.2 Chemical assessment

As discussed earlier, chemical hazards are generally considered very low risk, and well managed, in Australian food production. Agricultural and veterinary chemicals (Agvet chemicals) are regulated under national and state-based laws. In the Code, maximum residue limits and contaminants are covered under Standard 1.4.1 - Contaminants and natural toxicants and Standard 1.4.2 - Agvet chemicals.

Management of chemicals is discussed in section 2.3 of SD2 and in P1015. Based on available information, no new issues have been identified that would warrant further consideration.

## 3.3 Industry overview

An overview of the Australian production of melons, berries and leafy vegetables is provided in SD3. Information includes how and where these commodities are grown and traded, production volumes, imports and exports.

Produce in these sectors is grown in most or all states in Australia, enabling a year-round supply. Most produce is grown in open field systems, and is often picked and packed by hand. Product receives minimal processing (e.g. cooling, washing, drying, packaging) before distribution to wholesalers and retailers.

Most produce is distributed as fresh product to domestic markets. Some product is further processed (e.g. fruit cut or frozen, herbs trimmed and gas-packaged). Relatively small proportions are exported, mostly melons and strawberries. Minimal volumes are imported, mostly frozen strawberries and rubus berries.

For the 2017/18 financial year, Australia produced a total of:

- 215,519 tonnes of melons (including watermelon and muskmelons) with a production value of \$124.2 million
- 116,585 tonnes of berries (including strawberries, blueberries, blackberries and raspberries) with a production value of \$911.4 million
- 205,156 tonnes of leafy vegetables (including head lettuce, leafy salad vegetables and leafy herbs) valued at \$672.7 million.

FSANZ welcomes information in submissions that can further inform us of the number, size and location of producers in these sectors.

## 4 Risk management

Effective food safety management is based on preventing food safety problems and being able to quickly respond in the event of outbreaks or potential problems. The current food safety management framework in Australia focuses on food safety outcomes rather than prescriptive requirements. It recognises that the production of safe food can be achieved in a variety of ways, which may be different for different businesses. The framework identifies a range of management options including legislation, safety schemes, industry codes, etc.

A more detailed discussion of existing food safety management for horticultural produce is provided in SD2.

## 4.1 Regulatory requirements<sup>11</sup>

Standards in the Code are implemented and enforced at the state and territory level in Australia. An intergovernmental agreement generally requires jurisdictions to adopt model food laws to ensure consistent regulation across the country. There are currently no uniform and consistent national regulatory food safety requirements applying to the primary production and processing of horticultural produce, except for seed sprouts (see below).

### 4.1.1 Australia New Zealand Food Standards Code

The Code is a collection of food regulatory measures given effect by state, territory or other Commonwealth law. The state and territory food laws provide the basis for nationally consistent application and implementation of food regulatory measures in the Code.

With the exception of seed sprouts, there are no specific requirements in the Code applying to the primary production and processing of horticultural products.

A number of other standards exist in the Code which are generally relevant to horticultural products. These include labelling, use of food additives and processing aids, maximum levels of contaminants and natural toxicants, and maximum residue limits for agricultural and veterinary chemical residues in food. These standards were discussed in detail in P1015 SD1<sup>12</sup> and remain relevant.

Food safety is covered by several standards in the Code. These standards aim to lower the incidence of foodborne illness by strengthening food safety and traceability throughout the food supply chain. Chapter 3 contains food safety standards applicable to food businesses to ensure only safe and suitable food is available for sale. Chapter 4 contains food safety requirements applicable to primary production and processing activities. Requirements in Chapters 3 and 4 only apply in Australia.

#### ***Chapter 3 Food Safety Standards***

Chapter 3 Food Safety Standards applies to all food businesses that sell food, or handle food intended for sale. Primary food production is excluded from the definition of food business unless food is sold directly to the consumer. Primary food production means the growing, cultivation, picking, harvesting, collection or catching of food and includes:

- (a) transportation or delivery of food on, from or between the premises on which it was grown, cultivated, picked, harvested, collected or caught
- (b) packing, treating (e.g. washing) or storing of food on the premises on which it was grown, cultivated, picked, harvested, collected or caught.

#### ***Standard 4.2.6 – Production and Processing Standard for Seed sprouts***

The aim of Standard 4.2.6 is to reduce the incidence of foodborne illness associated with consumption of seed sprouts (e.g. alfalfa, onion, radish, mung bean). This standard was developed through Proposal P1004 – PPP Standard for Seed Sprouts<sup>13</sup> and commenced in 2013.

Proposal P1004 examined food safety measures that could be applied along the supply chain for seed sprouts. Seed production (on farm), seed processing and sprout production were included. The analysis included consideration of impacts of a range of proposed regulatory and non-regulatory options on each affected party, including education initiatives,

<sup>11</sup> A detailed overview of food safety management for horticultural products is summarised in SD2.

<sup>12</sup> Available at: <https://www.foodstandards.gov.au/code/proposals/Pages/proposalp1015primary5412.aspx>

<sup>13</sup> Available at: <https://www.foodstandards.gov.au/code/proposals/pages/proposalp1004primary4361.aspx>

self-regulation and regulatory measures for both seed and sprout processors. The economic analysis indicated regulation of sprout processors only was likely to have the highest net benefit to the community. Based on the RIS and supporting technical information, only food regulatory measures for sprout processors were included in the Code.

#### **4.1.2 State and territory legislation<sup>14</sup>**

In the states and territories, food safety aspects of horticultural produce is currently regulated to varying degrees. Where requirements exist, these are limited to seed sprouts and a few other plant product industries. Some jurisdictions set out food safety scheme requirements in regulations under their Food Acts. Legislative requirements, including a comparison of each jurisdiction's definition of 'food business' and 'primary food production' is provided in SD2.

The Food Acts in the states and territories require compliance with the Code and contain provisions to improve safety and manage non-compliance, including offences for producing unsafe and unsuitable food. Primary production businesses are not exempt from general provisions to produce safe food. However, there is no requirement for businesses engaged in production and minimal processing to be identified by registration or licensing. This lack of identification/information results in difficulties accessing and sharing information to prevent or manage incidents. Powers of jurisdictional officers are limited to reactive situations; for example where an offence is likely to have occurred or when emergency orders are enforced. There are also no mandated traceability requirements outside of industry scheme requirements.

#### **4.1.3 Import and export requirements**

The import and export of food, including plant products, is regulated through legislation administered by the Department of Agriculture. Export requirements mainly focus on facilitating trade and preventing the introduction and spread of pests and diseases. Import requirements mainly cover quarantine concerns. However, the Import Food Inspection Scheme identifies certain horticultural produce that require microbial testing including but not limited to: ready-to-eat berries that will not be further processed, dried herbs and frozen spinach.

#### **4.1.4 International legislation**

Internationally, there is considerable variation in the legislation applicable to the production of horticultural produce. For example, in New Zealand the *Food Act 2014* focusses on the food production process rather than the premises on which the food is made. Food safety risk in New Zealand is managed through food control plans and, for lower risk food businesses, through national programs.

## **4.2 Non-regulatory measures**

### **4.2.1 Food safety schemes**

Food safety schemes are voluntary, highly prescriptive industry schemes that aim to ensure the safety of food during certain stages of production, packing, processing, transport, manufacture, wholesale and retail sale or food service. Horticultural businesses that sign up to a food safety scheme agree to comply with requirements on how produce is grown, packed, prepared and distributed. Compliance with a food safety scheme is usually certified through a third-party auditor.

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<sup>14</sup> The provisions in the individual states and territories acts and regulations differ and this is a general overview from the Model Food Provisions on which the state legislation is based. There are also differences in the states as to which ministers and their departments have jurisdiction over the sector.

FSANZ previously reviewed industry food safety schemes in P1015. The review aimed to determine the level of participation in, and the food safety elements of, each of the nine schemes assessed. The level of participation was unable to be determined as there were difficulties in determining the number of horticultural producers in Australia, and obtaining information from all system owners and certification bodies. Another issue was that many producers maintained certifications to multiple systems. At the time, available information suggested 70-80% of horticultural produce was grown under a scheme that included food safety control measures.

An overview of current industry schemes, including the Harmonised Australian Retailer Produce Scheme (HARPS), Freshcare Food Safety and Quality Standards, *GLOBALG.A.P.*, *SQF Food Safety Program* and *BRC Global Standard for Food*, and coverage of their requirements across the supply chain is discussed in SD2.

Key findings from this assessment are:

- Primary producers can elect to sign up to voluntary food safety schemes whereby they are audited by a third party against specified requirements.
- HARPS provides a harmonised standard used by the five major retailers in Australia. In conjunction with a base benchmarked scheme, HARPS enables growers and packers to complete a single audit rather than comply with different requirements for the major retailers.
- Base schemes associated with HARPS are GFSI benchmarked, meaning they represent global best practice in food safety management.
- The GFSI-benchmarked food safety schemes provide varying degrees of coverage across the supply chain.

Although there are less schemes used now than in 2012, there is still similar coverage in requirements across the supply chain. Not all food safety schemes reviewed address the same requirements, but this may be explained by the extent of their supply chain coverage.

Data on the number, and type, of producers who operates under an industry scheme remains difficult to obtain. Social research conducted by Agriculture Victoria in 2019 of 556 growers, showed of the 138 growers of produce considered high-risk in the scope of that research, just over half (53%) reported using a third party food safety scheme. Most of those (73%) reported using Freshcare.

Based on limited available information, the efficacy of current schemes is unable to be determined. That said, as stated above, information available to FSANZ is that foodborne illness outbreaks involving horticultural produce businesses with food safety schemes in place continue to occur. This suggests that such schemes alone may not be the most effective measure to address the food safety risk.

FSANZ welcomes information in submissions that can further inform us of the uptake and of the efficacy of industry schemes across the high-risk horticulture sectors.

#### **4.2.2 Guidance documents and other information**

Various guidance documents have recently been developed for high-risk horticultural produce in Australia (see section 3.2 of SD2 for further details). The *Guidelines for Fresh Produce Food Safety 2019* and *Melon Food Safety Best Practice Guide* focus on food safety, including identifying and mitigating microbiological hazards through primary production and processing activities.

The Codex Alimentarius Commission (Codex) Code of Hygienic Practice for Fresh Fruit and Vegetables (CoHP FFV) provides a general framework of recommendations across primary

production and primary processing activities for the horticulture sector with annexes containing additional requirements for RTE, fresh, pre-cut fruits and vegetables, sprout production fresh leafy vegetables, melons and berries (see section 3.2.5 of SD2).

Although not directly comparable, differences in key terms used in the CoHP FFV and the Code mean different food safety requirements could apply at different stages of the supply chain. According to Codex, primary production ends once product is field-packed and transported to the packing facility – regardless if this facility is also located on the property where the product was grown. Post-harvest activities are those involving minimal transformation including washing, sorting, culling, grading, cutting and trimming.

As discussed earlier (see section 4.1), the Code applies to food for sale and excludes 'primary food production' from the definition of a 'food business' unless they sell food directly to the public.

### **4.3 Options**

To decide the most effective and efficient risk management approach, FSANZ must consider various options. These options are considered below.

Based on our assessment to date and the current lack of nationally consistent regulatory requirements, our preferred approach at present is development of regulatory measures (Option 2).

#### ***Option 1 – Status quo***

The status quo must be considered by FSANZ in any proposal to change regulation. Under the status quo, there is no nationally consistent set of food safety requirements for horticultural produce. Existing measures are non-regulatory comprising of a range of industry schemes.

Based on our assessment to date, this appears not to be an option that effectively manages the risk.

#### ***Option 2 – Food regulatory measures***

Information received in submissions and further assessment will inform our decision whether to prepare a regulatory measure and, if so, the form that that measure will take. Options for regulatory measures may include:

##### **2.A Amendment of State and Territory Food Acts**

The Inter-Government Agreement on Food requires jurisdictions to adopt and use in their Food Acts the provisions in Annex A of that Agreement. These include the model definitions of 'food business' and 'primary food production'. The intent was to ensure a uniform scheme and consistency between the Code (definitions) and the state and territory laws (Food Acts) that rely on the Code. Some jurisdictions have amended the definitions of 'food business' and 'primary food production' in their Food Acts to apply food safety requirements to horticulture primary production and processing.

At the November 2019 Forum meeting, ministers agreed to comprehensively review the food regulation system, including its legislative foundation, which would include the FSANZ Act and Code, and Model Food Provisions.

States and territories could amend the definitions of 'food business' and 'primary food production' in their own Acts, as some have done already, to apply existing Chapter 3 food safety requirements, or await the outcome of the review of the food regulatory system.

## **2.B Variations to the Code**

This option would involve developing, or varying, food safety requirements for high-risk horticulture products in the Code which would apply nationally by and as part of State and Territory food laws. These requirements may be supported by non-regulatory measures such as industry guidance, promotion of food safety culture or consumer education.

### **2.B.1 Code definitions**

Definitions of food business and primary food production in Chapter 3 are activity based and not location based. Based on these, on-farm packing, treating or storing of food, where the food handled was grown on the same premises, and is not sold directly to the consumer, is a primary production activity and is not covered by Chapter 3 standards. Requirements could apply to activities such as washing, trimming, packing and other post-harvest treatments if these activities occur on premises other than where the produce was grown. Requirements for food transport also apply to the transport of fresh produce except for on-farm transport activities.

One option might be to amend the definition of primary food production to capture only in-field activities and transportation and delivery to the packing shed (regardless of location). This would align with the Codex definition and mean all subsequent activity would be that of a 'food business'.

Specific standards could be developed for food businesses 'handling', as currently defined, or selling (wholesale or retail) for high-risk horticulture.

### **2.B.2 Graduated risk-based approach**

Under this option, a range of regulatory approaches can be assessed. These may range from general requirements including management of inputs or traceability, to more specific additional controls for particular higher risk commodities, or requiring a food safety management system.

Graduated risk-based requirements may be considered for all, or some, products within each commodity group, across all or some commodities, and/or applied based on the outcomes of cost-benefit work (see section 5.2)

FSANZ welcomes the views of submitters on the range of regulatory approaches to be considered under Option 2, including:

- Whether existing regulatory requirements (e.g. Chapter 3 requirements) should/could apply and the feasibility/practicality of implementing and enforcing particular measures.
- The nature of the risk for particular commodities or production activities
- Where in the production chain (or for what products) any interventions have the greatest impact
- Options to apply a tiered regulatory approach across businesses and/or commodities proportional to risk.

## 5 Obligations under the FSANZ Act

The *Food Standards Australia New Zealand Act 1991* (FSANZ Act) contains requirements applying to the development or variation of standards. Under section 18 (Objectives of the Authority) of the FSANZ Act, when developing or reviewing a standard we must meet the objectives outlined below.

### 5.1 FSANZ objectives

#### 5.1.1 Protection of public health and safety

FSANZ has assessed the available evidence and information on the food safety risks, and risk management measures currently applying to high-risk horticulture. Several significant foodborne illness outbreaks associated with fresh horticultural produce have occurred between 2011 and 2019 which resulted in over 408 cases of illness and 9 deaths. Investigations into some of the more recent outbreaks indicated businesses had food safety schemes in place, but these had not been effective in avoiding an outbreak. This suggests that the level of assurance provided by such schemes alone may not provide the necessary assurance to address food safety risks and protect public health and safety.

The ongoing issues and lack of regulatory measures for horticultural products suggest the current environment, which relies on non-regulatory measures, is not adequate to protect public health and safety and that regulatory measures are required.

#### 5.1.2 Provision of adequate information relating to food to enable consumers to make informed choices

FSANZ has considered this and conclude this is not relevant to this matter.

#### 5.1.3 Prevention of misleading or deceptive conduct.

FSANZ has not identified any issues relevant to this matter.

#### 5.1.4 Section 18 (2) considerations

- **the need for standards to be based on risk analysis using the best available scientific evidence**

FSANZ's risk analysis considered the best scientific information currently available to FSANZ. FSANZ had regard to assessments undertaken for the purposes of P1015 and updated data on Australian and international foodborne illness outbreaks associated with fresh horticultural produce (see section 3.1), as well as related recall data. Further information and data is sought from stakeholders through this CFS to further inform that assessment and our decision making.

We will build upon these findings to inform our decisions on appropriate and effective risk mitigation in the next stage of this work. Information in the Codex CoHP FFV will also be drawn upon to develop appropriate risk management measures.

- **the promotion of consistency between domestic and international food standards**

Internationally, there is considerable variation in the legislation applicable to the production of horticultural produce. We have considered international and domestic standards, including requirements for import and export of food in our assessment.

- **the desirability of an efficient and internationally competitive food industry**

FSANZ has had regard to the public health and safety risks associated with high-risk horticulture and the impacts these can have on the domestic and international food industry.

FSANZ does not anticipate any significant impact on efficiency and international competition from introduction of any proposed regulatory measure. This issue will be fully considered at the next stage of the assessment and, if necessary, notification will be made in accordance with Australia's and New Zealand's obligations under either the WTO Technical Barriers to Trade or Application of Sanitary and Phytosanitary Measures Agreements.

- **the promotion of fair trading in food**

Introduction of nationally consistent food safety requirements can encourage a more level playing field for all producers in the market place.

- **any ministerial policy guidelines.**

The Ministerial Council Overarching Policy Guideline on Primary Production and Processing Standards<sup>15</sup> contains high-order principles that must be considered when a standard is developed. These principles state that standards will be outcomes-based and address food safety across the entire food chain where appropriate. Standards will also ensure the cost of the overall system is proportionate with the assessed level of risk. They will provide a regulatory framework that only applies to the extent justified by market failure. We have considered these guidelines in our assessment.

## 5.2 Section 59

Under section 59 (Assessing a proposal) of the FSANZ Act, we must have regard to:

- **whether costs that would arise from a food regulatory measure developed or varied as a result of the proposal outweigh the direct and indirect benefits to the community, government or industry that would arise from the development or variation of the food regulatory measure**

FSANZ has had regard to the possible costs and benefits identified with developing a regulatory measure for high-risk horticulture. FSANZ had regard to the cost benefit analysis for P1015 and preliminary information summarised in this CFS.

For the purposes of P1015, FSANZ considered the costs and benefits of developing a horticulture standard to producers, consumers and governments (discussed in section 2.3.1.1 and Table 3 of the P1015 Abandonment Report). This included the potentially disproportional impact of costs associated with implementing regulatory measures to smaller producers, and/or the impact of those producers operating without an industry food safety scheme. At the time, it was estimated 70-80% of produce was grown under an industry scheme that contained requirements to manage food safety risks. For the purposes of P1015, FSANZ determined that other measures were available that would be more cost-effective than developing a food regulatory measure.

Between 2011 and 2019, there were several significant foodborne illness outbreaks in Australia associated with fresh horticultural produce involving over 408 cases of illness and 9 deaths. The impact of outbreaks can be significant both in terms of health (illness and/or

<sup>15</sup> Available at <https://foodregulation.gov.au/internet/fr/publishing.nsf/Content/food-policies>

death), costs to the specific food business involved, related food businesses and whole industries. For example, the 2018 outbreak of *Listeria* associated with rockmelons resulted in 22 cases of illness, 8 deaths, temporarily closed an export market and impacted the domestic market with losses to growers estimated to be around \$15 million. This suggests that an alternative conclusion (to that of P1015) may now be able to be drawn given the more targeted scope and extended history of incidents.

Lost productivity, impacts on lifestyle including pain and suffering and medical expenses from foodborne illness can also result in a substantial burden for Australia. At a population level, costs associated with foodborne illness are estimated at \$1.2 billion each year (Abelson et al. 2006).

Horticultural produce accounted for 9% of all recorded recalls (1989-2019). During 2016-2018, horticultural products were the only products implicated in national food incidents (n=5), and nine recalls were coordinated as part of multi-jurisdictional outbreaks. Food recalls can be a considerable cost to a food business. The cost of advertising in newspapers alone can be thousands of dollars. Other costs that a food business may incur include supermarket fees to remove product from sale, advertising costs, product disposal or destruction, and loss in productivity and earnings. Businesses may experience a reputational loss leading to decreased consumer confidence and sales which can ultimately lead to the failure of not only the business whose product was implicated, but in extreme circumstances, other industry members.

Data on the number, and type, of producers who operate under an industry scheme remains difficult to obtain. Investigations into some of the more recent outbreaks show businesses had food safety schemes in place, but these had not been effective in avoiding an outbreak. This suggests that the status quo (Option 1), which is based on non-regulatory measures such as industry schemes and codes of practice, may no longer be sufficient to address food safety risks and protect public health and safety.

Limited data is currently available on which to complete an informed cost benefit analysis for high-risk horticulture. Further information and data is sought to inform our decision on whether to prepare a regulatory measure and, if so, the form that that measure will take.

### *Cost–benefit information*

The analysis of the costs and benefits of horticulture regulation is likely to be complex and challenging as there are numerous information gaps. While outbreaks linked to horticultural produce have affected numerous people, the vast majority of produce is safe and healthy. This means determining the most effective interventions that will have a net benefit is potentially difficult and will require careful consideration and design.

The type of information we need for our assessment includes:

- 1. from consumers:**
  1. potential improvement in wellbeing as a result of safer food (i.e. avoided illness)
- 2. from government:**
  1. costs to implement and enforce new regulation
  2. reduction in government costs as a result of reduced outbreaks, incidents and illness
- 3. from businesses:**
  1. increased costs from regulation (some of which may end up being transferred to consumers)
  2. reduction in costs as a result of reduced incidents and outbreaks
  3. increased sales opportunities to markets that value safe food.

FSANZ would welcome in views in submissions to inform the cost-benefit work including:

- What sort of interventions should FSANZ consider in its analysis?
- Should consideration be given to regulating different sorts of businesses differently?
- Should we be aiming to achieve complete through-chain traceability from paddock to plate, or only the capacity to trace one step forward and one step back?
- Do you think information technology can reduce the cost of tracing horticultural products through the supply chain? How could it better meet the needs of industry, government and consumers?
- What are the benefits of enhanced food safety regulation in terms of protecting or accessing overseas markets?

Where possible, quantitative or qualitative evidence should be provided to support your point of view.

- **whether other measures would be more cost-effective than development of or a variation to a standard and could achieve the same end**

FSANZ's preliminary view is that regulation may be required (i.e. Option 2) as continued reliance on voluntary industry schemes and other non-regulatory measures such as codes of practice, may not adequately protect consumers and public health and safety.

Further analysis of the costs and benefits of the regulatory options, and whether other measures would be more cost-effective will be considered in a Consultation Regulatory Impact Statement (CRIS) and a Decision Regulatory Impact Statement (DRIS). These statements will be produced in accordance with Council of Australian Governments (COAG) Best Practice Regulation Guidelines. The CRIS will be released for consultation with the second call for submissions on this proposal. The DRIS will be provided to decision makers, then publically released once a decision has been made.

- **any relevant New Zealand standards**

Chapter 4 Primary Production and Processing Standards do not apply in New Zealand. No other standards have been identified.

- **any other relevant matters.**

FSANZ has assessed the proposal under the obligations listed above for developing, reviewing and varying standards. No other relevant matters have been identified.

## **6 Risk communication**

### **6.1 Consultation**

Consultation is a key part of our process. We acknowledge the time taken by individuals and organisations to make submissions on this proposal. While not all submissions can be taken on board during the process, they are valued and all contribute to the rigour of our assessment.

Consultation with affected parties will include the FSANZ statutory consultation processes (including at least one further call for submissions). We will engage with the Horticulture Standards Development Advisory Group and the Horticulture Implementation Working Group (HIWG). We will also target consultations with industry to understand industry practices and constraints. These consultations will better inform any measures that may be considered.

The release of this consultation paper will also be supported by a media release, updated website information, notification via our Food Standards News subscription service and social media channels.

### **6.1.1 Summary of submissions on 2019 information paper**

In May 2019, FSANZ released an information paper for comment about the review of Chapters 3 and 4 of the Code. It outlined the background to the review, the issues that FSANZ would consider and the proposed timelines. A key focus was addressing the request from Forum that FSANZ consider the potential development of a PPP standard for high-risk horticulture to manage food safety on-farm, including requirements for traceability.

In total, 35 submissions were received from stakeholders including local, state and federal government, non-government organisations, retail, training organisations and industry associations. Of these submissions, 28 contained comments relevant to the high-risk horticulture work.

There was general support to consider requirements for high-risk horticulture, and there was majority support to develop a PPP standard for high-risk horticulture. Views were mixed on the extent of the scope. The potential for additional burdens to be placed on farmers was a primary concern. Many comments also suggested FSANZ look at existing on-farm schemes used across the industry. There was support for the development of traceability provisions, addressing new technologies and the need to consult widely.

## **6.2 World Trade Organization (WTO)**

As members of the WTO, Australia and New Zealand are obliged to notify WTO members where proposed mandatory regulatory measures are inconsistent with any existing or imminent international standards, and the proposed measure may have a significant effect on trade.

This issue will be fully considered at the next stage of the assessment and, if necessary, notification will be made in accordance with Australia's and New Zealand's obligations under either the WTO Technical Barriers to Trade or Application of Sanitary and Phytosanitary Measures Agreements. This will enable other WTO members to comment on any proposed amendments.

## References

- Abelson, P.; Forbes, M.P; Hall, G. (2006): The annual cost of foodborne illness in Australia.
- Department of Health (2014): Foodborne Illness in Australia: Annual incidence circa 2010.