

17 November 2021
179-21

2nd Call for submissions – Proposal P1052

Primary Production and Processing Requirements for Horticulture (Berries, Leafy Vegetables and Melons)

FSANZ is reviewing food safety in the fresh berries, leafy vegetables and melons sectors and whether additional measures, such as standards, should be introduced to manage food safety.

Pursuant to section 61 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act), FSANZ now calls for submissions to assist FSANZ's consideration of the draft food regulatory measures (three draft standards) and proposed non-regulatory measures we have prepared arising from proposal P1052.

For information about making a submission, visit the FSANZ website at [current calls for public comment and how to make a submission](#).

All submissions on applications and proposals will be published on our website. We will not publish material that we accept as confidential. In-confidence submissions may be subject to release under the provisions of the *Freedom of Information Act 1982*. Submissions will be published as soon as possible after the end of the submission period.

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](#).

For information on how FSANZ manages personal information when you make a submission, see FSANZ's [Privacy Policy](#).

Submissions should be made in writing; be marked clearly with the words 'Submission P1052 Primary Production and Processing Requirements for Horticulture (Berries, Leafy Vegetables and Melons)'. Electronic submissions can be made through the FSANZ website via the link [how to make a submission](#). You can also email your submission to submissions@foodstandards.gov.au. FSANZ also accepts submissions in hard copy to our Australia and/or New Zealand offices.

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.

DEADLINE FOR SUBMISSIONS: 6pm (Canberra time) 9th February 2022

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 a submission or application and proposal processes can be sent to standards.management@foodstandards.gov.au.

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Supporting documents

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

CRIS	The Consultation Regulation Impact Statement
SD1	Current food safety measures for horticultural produce (domestic and international)
SD2	Microbiological assessment of berries, leafy vegetables and melons
SD3	Cost benefit analysis
SD4	Compliance plans
SD5	Horticulture Standards development Advisory Group (SDAG)
SD6	Sanitary and Phyto-sanitary notification.

Executive summary

The vast majority of horticultural produce in Australia is safely produced and is an important part of a healthy and balanced diet. However, outbreaks linked to particular sectors continue to occur, including in Australia. In June 2018, the then Australia and New Zealand Ministerial Forum on Food Regulation (the Forum - now the Food Ministers' Meeting) noted the increase of foodborne illness outbreaks in Australia and requested that Food Standards Australia New Zealand (FSANZ) reassess food safety risk management across several horticultural sectors.

FSANZ has now assessed the proposal in accordance with the *Food Standards Australia New Zealand Act 1991* (Cth). We reviewed food safety risk and risk management associated with the primary production and primary processing of fresh berries, leafy vegetables and melons. Our assessment included an analysis of the current regulatory and non-regulatory environment in Australia and overseas, a microbiological assessment, cost-benefit analysis (CBA) and a survey of primary producers and processors. We also met with stakeholders.

Our analysis of the current regulatory and non-regulatory position identified there are currently no national or consistent regulatory requirements for food safety that apply to the primary production and processing of horticultural products, except for seed sprouts. There is a reliance on non-regulatory measures, such as food safety schemes (FSS). FSS are an important food safety measure. However, they are not taken up by all businesses and there is a lack of incentive for them to do so unless supplying major retailers.

The microbiological assessment identified the following microbial hazards of greatest concern:

- for berries: shiga toxin-producing *Escherichia coli* (STEC), norovirus (NoV) and hepatitis A virus (HAV)
- for leafy vegetables: STEC, non-typhoidal *Salmonella* spp. (*Salmonella*) and *Listeria monocytogenes* (*Listeria*)
- for melons: *Salmonella* and *Listeria*.

The most likely sources of contamination includes animals, growing location, extreme weather events, manure and composts, water inputs, postharvest washing and sanitisation, and poor worker and equipment hygiene.

The CBA attributed the current cost of illness of these hazards as: \$6.5 million for berries, \$52.9 million for leafy vegetables and \$30.7 million for melons.

We also considered outbreaks of foodborne illness in these sectors, cost to industry and government of introducing food safety measures and appropriate protection of consumers.

We assessed four options:

- Option 1 – Retaining the status quo
- Option 2 – Introducing regulatory measures
- Option 3 – Introducing a combination of regulatory and non-regulatory measures
- Option 4 – Introducing non-regulatory measures alone.

FSANZ assessed each option in accordance with the relevant legislation, and, on the basis of that assessment, has concluded that option 3 is our preferred approach. The combination of regulatory and non-regulatory measures proposed by this option represent the most cost-effective way to reduce foodborne illness in each of the relevant sectors. Given this conclusion, FSANZ prepared three standards - one each for berries, leafy vegetables and melons to introduce regulatory measures. We have also drafted the supporting non-regulatory measures.

These standards were designed, through our CBA, to be the minimal regulation needed to achieve appropriate food safety outcomes for each sector. The standards align with existing FSS to reduce any impact on industry. The impacts are expected to be minimal for businesses already operating under a FSS.

Non-regulatory measures would include fact sheets and webinars to support food safety. These would be produced in collaboration with industry.

Average ongoing per annum cost estimates are dependent on existing levels of food safety management in each business. Businesses already operating under a FSS would be expected to incur significantly lower costs, as they are already operating in accordance with the proposed measures:

- For businesses with FSS (or equivalent measures) in place: \$0 for berries; \$1,540 for leafy vegetables; \$1,540 for melons
- For businesses with some food safety management in place (50% of the proposed measures): \$1,056 for berries; \$7,036 for leafy vegetables; \$4,056 for melons
- For businesses without any food safety management, costs will be similar to what businesses implementing industry-driven schemes have already invested: \$2,113 for berries; \$12,533 for leafy vegetables; \$6,573 for melons.

Costs are average estimates only, actual costs would vary by individual business. Some initial one-off costs would also apply and these are discussed in the main body of this document.

FSANZ estimates the costs to businesses would be offset by the benefits of reducing foodborne illness. Our CBA estimates that option 3 would cost:

- 10-30 cents to achieve every \$1 benefit for berries
- 20-60 cents for every \$1 benefit for leafy vegetables
- 2-5 cents for every \$1 benefit for melons.

FSANZ estimates that implementation of the preferred option would deliver approximately \$138 million in net benefits over a ten-year period.

The proposed standards are attached to this second call for submission. Standards are implemented by state and territory governments through compliance plans that support consistent national application. The Horticulture Implementation Working Group (HIWG) has prepared draft compliance plans that provide detail on how each standard would be implemented and monitored if approved.

This proposal is being assessed under FSANZ's major procedure, which requires two rounds of public consultation. FSANZ completed a [first round of public consultation](#) in March 2020. Each submission received in response to the consultation was considered as part of our assessment. FSANZ now seeks submissions to inform its decision whether this proposed regulatory (and non-regulatory) approach and the related proposed Standards should be approved, amended or rejected.

Proposal P1052 at a glance

FSANZ prepared proposal P1052 to assess whether amendments to the Australia New Zealand Food Standards Code (the Code) are required to manage the food safety risks associated with the primary production and primary processing of berries, leafy vegetables, and melons.

FSANZ assessed that proposal in accordance with the *Food Standards Australia New Zealand Act 1991* (Cth). Our assessment concluded that amendment of the Code is required. We propose that:

- the Code be amended to include a Primary Production and Processing (PPP) standard for each of the three sectors, supported by:
 - non-regulatory measures, such as fact sheets and webinars produced in collaboration with industry.

Our assessment is that these proposed measures represent the most cost-effective way to reduce foodborne illness in the three sectors. FSANZ therefore prepared a draft PPP standard for each sector. Table 1 below summarises the requirements that each proposed PPP standard will set if approved.

Table 1. Proposed requirements for inclusion in PPP standards

Requirement	Berries	Leafy vegetables	Melons
Notification of business	✓	x	x
General food safety management requirements	x	✓	✓
Traceability: one step forward, one step back	✓	✓	✓
Management of water as an input	✓	✓	✓
Management of soil and fertiliser as inputs	x	✓	✓
Management of seed and seedling as inputs	x	✓	x
Management of the growing site	x	✓	✓
Management of food safety following weather events	x	✓	✓
Construction and cleanliness of premises and equipment	✓	✓	✓
Maintaining an appropriate temperature of harvested produce	x	✓	✓
Appropriate washing and sanitisation of produce	x	✓	✓
Management of animals and pests	x	✓	✓
Skills and knowledge	✓	✓	✓
Health and hygiene of personnel and visitors	✓	✓	✓
No sale or supply of unacceptable commodity	✓	✓	✓

Abbreviations

CBA	cost-benefit analysis
CFS	call for submissions
CoHP FFV	Code of Hygienic Practice for Fresh Fruit and Vegetables
CRIS	consultation regulation impact statement
DAWE	Australian Department of Agriculture, Water and the Environment
FSANZ	Food Standards Australia New Zealand
FSS	food safety scheme
GFSI	Global Food Safety Initiative
HAV	Hepatitis A virus
HIWG	Horticulture Implementation Working Group
ISFR	Implementation Sub-Committee for Food Regulation
NoV	Norovirus
PPP	primary production and processing
SD	supporting document
SDAG	Standards Development Advisory Group
STEC	shiga-toxin producing <i>Escherichia coli</i>

1 Introduction

1.1 The Proposal

This proposal was prepared to review food safety risks in specific horticulture sectors (fresh berries, leafy vegetables and melons) and to determine whether amendments to the Australia New Zealand Food Standards Code (the Code) are required to manage these risks.

This review was requested by food ministers following several significant foodborne illness outbreaks involving fresh produce. These incidents indicated a potential failure to prevent food safety problems during production and primary processing and complex supply chains that impacted their traceability. Ministers requested FSANZ consider all available options, including the need for standards development for certain horticultural products, to determine if there could be potential net benefits from well-targeted interventions.

Primary production and processing (PPP) standards are incorporated into Chapter 4 of 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). During the development and application of standards, FSANZ has prepared analyses of:

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

The Implementation Subcommittee on Food Regulation (ISFR) established the Horticulture Implementation Working Group (HIWG) to ensure any proposed amendments to the Code, if approved and adopted, could be consistently implemented at the national level.

A Standard Development Advisory Group (SDAG) consisting of representatives from industry peak bodies and government regulators was also established to provide advice on the work.

1.2 Reasons for preparing the proposal

While the vast majority of produce is safe and healthy, foodborne illness outbreaks linked to particular horticultural produce continue to occur. In Australia and internationally, foodborne illness, deaths, product recalls and other food safety incidents continue to be associated with fresh horticultural produce. The impacts of these events are felt by:

- consumers (illness and potential death, particularly in the elderly)
- businesses (both affected and implicated businesses in the same sector)
- horticultural sectors (an entire sector may feel the effects of a localised outbreak)
- governments (costs of responding and investigating causes)
- domestic markets
- export markets.

Such events present a significant cost to the Australian economy, yet are largely preventable through appropriate food safety measures.

During 2011–2019 there were ten outbreaks of foodborne illness associated with the consumption of horticultural produce in Australia. Berries, leafy vegetables and melons were associated with seven of the ten outbreaks, as follows:

- two outbreaks were linked to HAV in imported berries—no outbreaks were linked to domestically-produced product

- three outbreaks were linked to Salmonella Anatum and NoV in domestic leafy vegetables
- two outbreaks, resulting in 275 reported cases and 10 deaths, were linked to Salmonella Hvittingfoss and Listeria monocytogenes in domestically-produced melons.

Reducing foodborne illness is a high priority for the Food Ministers Meeting (FMM). Addressing food safety management in the horticulture sector is a priority focus area under the *Australia's Foodborne Illness Reduction Strategy 2018–21*¹.

There are currently no national or consistent regulatory requirements for food safety that apply to the primary production and processing of horticultural products, except for seed sprouts. The lack of national regulation makes it difficult for government food regulators to monitor and proactively support Australia's primary producers and processors.

The berry, leafy vegetable and melon sectors operate to varying degrees under industry food safety schemes (FSS). These schemes are comprehensive but not mandatory, though large retailers require them. Businesses not supplying major retailers are unlikely to participate in a FSS, due in part to the additional costs and administration involved.

FSANZ considers this situation problematic because:

- not all businesses operate under a FSS
- it creates an uneven playing field (with some businesses using FSS and others not), both in terms of costs and food safety outcomes
- it is difficult for food regulators to support Australia's primary producers and processors, and to proactively manage food safety in these sectors on behalf of consumers
- consumers may be unaware that some primary producers and processors participate in FSS, while others do not, and are therefore unable to take this into consideration when making safe food choices
- investigations into recent outbreaks have revealed that, even where businesses have FSS in place, outbreaks have continued to occur, suggesting the level of assurance provided by a FSS alone may be insufficient to address food safety risks to protect public health and safety, and some regulatory oversight may improve their effectiveness
- requirements for traceability in industry schemes are generally only applied by businesses operating under those schemes.

1.3 Procedure for assessment

This proposal is being assessed as a major procedure, involving two rounds of public consultation. In March 2020, FSANZ released for public consultation a first call for submissions (CFS). A total of 27 submissions were received.

To guide this proposal and its preferred option, this document considers matters raised in these submissions and additional analyses, including:

- current domestic and international food safety measures for horticultural produce (in supporting document SD1)
- a microbiological risk assessment (SD2)
- a cost-benefit analysis (SD3)
- a survey of primary producers and processors.

This second call for submissions also provides:

- compliance plans for drafted standards, should standards be set (SD4)
- information on the SDAG (SD5)
- a consultation regulation impact statement, including questions for stakeholders.

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

This document also includes:

- the proposed amendments to the Code – that is, proposed Standard 4.2.7, proposed Standard 4.2.8 and proposed Standard 4.2.9 – Production and Processing Standards for Berries, Leafy Vegetables and Melons (respectively), at Attachment A
- a draft Explanatory Statement (combined for the three proposed standards), at Attachment B
- a summary of submissions from the first CFS, at Attachment C.

2 Background

In 2011, at the request of food ministers, FSANZ commenced a review of the primary production and processing of horticulture under proposal [P1015 Primary Production & Processing Standard for Horticulture](#). In 2014, FSANZ decided that regulation of the entire horticulture sector was not warranted. The preferred strategy to improve food safety was for industry and government to develop non-regulatory measures.

At that time, the key reasons FSANZ only recommended non-regulatory options were:

- an estimated 70–80% of horticulture produce was grown under a FSS
- the nature and number of horticulture businesses across the entire sector was uncertain, as were their current food safety management strategies
- a ‘one size fits all’ regulatory model for the whole horticulture sector was problematic
- there was difficulty enforcing regulatory measures across the entire horticulture sector.

In 2017, ministers identified that reducing foodborne illness was a priority, particularly illness linked to *Campylobacter* and *Salmonella*. *Australia’s Foodborne Illness Reduction Strategy 2018–21*² was developed to address that priority, and it includes food safety management in the horticulture sector as a key focus.

In 2018, increases of foodborne illness outbreaks in Australia associated with fresh horticultural produce were noted. Ministers agreed that food safety risk management of five horticulture sectors needed to be reassessed: berries, leafy vegetables, melons, ready-to-eat minimally processed fruits and vegetables and sprouts.

Food ministers noted there are commodity-specific annexes in international guidance for these five commodities i.e. the [Code of Hygienic Practice for Fresh Fruits and Vegetables \(Codex 2017\)](#). The annexes include measures to better manage food safety concerns in each of these horticultural commodities. They were developed by the Codex Alimentarius Commission (Codex) under the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO). These annexes were included to provide additional guidance for commodities commonly associated with foodborne illness.

As measures in the Code were already in place for seed sprouts ([Standard 4.2.6](#)) and ready-to-eat minimally processed fruits and vegetables ([Chapter 3—Food Safety Standards](#)), the scope of P1052 was limited to these three commodities.

Noting findings in P1015 about complexity of the entire horticultural sector, this proposal examines the number and nature of businesses in the berry, leafy vegetable, melon sectors, including the uptake of FSS and more tailored regulatory and non-regulatory options for each sector.

² Available at <https://foodregulation.gov.au/internet/fr/publishing.nsf/Content/strategies>

3 Stakeholder views

3.1 Who did we consult?

FSANZ sought public comment on a first CFS released in March 2020. Subscribers and interested parties were notified about the consultation via the FSANZ Notification Circular, media release and through FSANZ's website, social media and Food Standards News. Attachment C contains a summary of comments received in these submissions and our response. FSANZ has regarded all submissions in the preparation of this report. An overview of the main issues raised in submissions is provided below.

During 2019–early 2020, FSANZ held targeted consultations with industry and visited farms to understand industry practices and constraints. Our officers travelled to several farms, including one strawberry farm and three leafy vegetable farms in Victoria, and one melon farm in NSW. While onsite, FSANZ spoke to stakeholders and observed the growing sites (e.g. open field, protected cultivation systems and hydroponics), harvesting and the activities of the packing shed. These visits further informed the development of draft regulatory measures. FSANZ was unable to attend further planned visits due to COVID-19 restrictions. Further information on consultation activities is in section 11 of the CRIS.

FSANZ established a Standards Development Advisory Group (SDAG) to provide expert advice during the progress of the proposal. The SDAG includes representatives of key peak industry bodies and government food regulators from each state and territory. Information on the SDAG is provided in SD5.

FSANZ also worked closely with the Horticulture Implementation Working Group (HIWG) to ensure any reform, if required, would have a nationally consistent approach to food safety management in these sectors. This HIWG includes regulators from each state and territory and the Australian Government Department of Agriculture, Water and the Environment (DAWE).

To inform work on this proposal, FSANZ invited berry, leafy vegetable and melon producers and processors to participate in a survey. The purpose of the survey was to learn more about the business operations of these stakeholders, their food safety culture and the cost associated with managing food safety. The survey was open from 17 December 2020 to 31 January 2021. FSANZ has analysed the results of this survey and the findings have guided the risk management options and measures presented in this second CFS.

3.2 What were we told?

The main points raised in submissions and by stakeholders include:

- concern about use of the term 'high-risk' (food) in the original proposal name, which may mislead consumers that fresh horticultural products are inherently unsafe
- regulation could bring potential audit, administrative, financial and other burdens
- regulation could push small-scale operators out of business
- additional costs and activities associated with regulation may create barriers for new producers entering the market
- berries, leafy vegetables and melons have been singled out and all horticulture produce should be included in the review
- regulators support greater regulation in these sectors to mitigate existing food safety issues, including outbreaks, and to protect the industry, consumers and Australia's export reputation.

3.3 How did feedback influence our assessment?

To avoid misinterpretation, FSANZ removed reference to 'high-risk' from the proposal, including in the title. FSANZ agreed it was important to reinforce that fruit and vegetables are an important part of a healthy diet.

To develop the lightest regulatory touch that achieves satisfactory food safety outcomes, we selected only critical food safety hazards to manage in each sector. We then considered the cost-benefit ratios in each sector, and fine-tuned the regulation until positive net benefits were achieved.

We estimated costs to businesses to identify likely up-front and ongoing costs of complying with the proposed regulation (refer to the CBA in SD3). These estimates were based on businesses' current food safety management practices, including whether they are on a FSS or not.

Impacts on small businesses in-particular were considered. Advice to FSANZ is that, if new regulations were found to be warranted and approved, food regulators would support businesses, particularly small ones, to become compliant with that new regulation, easing uptake through guidance documents and templates. In relation to fees, regulators already have the ability to alter the fee structure for small businesses, which can include reduced fees or a fee-free threshold. Fees are charged per hour (rather than at a flat rate), and therefore can scale up or down depending on business size.

Barriers for market entry were considered. Regulators confirmed they currently assist new businesses to establish, and this would continue under any new arrangements, if regulatory standards are adopted.

The scope of P1052 remains berries, leafy vegetables and melons - it was not expanded to other sectors. This is because of known foodborne illness outbreaks linked to these three sectors in Australia and overseas. Development of standards for these commodities also aligns with international measures, particularly Codex annexes for berries, leafy vegetables and melons. Food ministers requested that FSANZ consider specific horticultural sectors only.

3.4 Summary

In general, industry supported the status quo and expressed concerns that regulation doesn't recognise industry efforts to address food safety, may cause additional burden and focuses on only three commodities. FSANZ has provided the details of industry feedback and concerns raised in the first call for submissions in Attachment C of this report.

Government stakeholders generally considered the current situation does not adequately address known food safety risks in these sectors, and supported the development of regulation. Government stakeholders considered regulation would potentially benefit:

- consumers (by reducing foodborne illness attributed to these sectors)
- industry (by reducing costs to businesses resulting from outbreaks, making recalls easier, creating an even playing field, and reducing reputational loss to non-implicated businesses arising from illnesses caused by other businesses within their sector)
- Australia's market access, through its reputation as a producer of safe food.

Both industry and government identified the need for traceability requirements and supported a nationally consistent approach to horticulture food safety.

4 Risk assessment

FSANZ assessed the proposal in accordance with the *Food Standards Australia New Zealand Act 1991* (Cth). To identify risk and risk management options for the primary production and primary processing of fresh berries, leafy vegetables and melons in Australia, FSANZ has completed a:

- gap analysis of existing food safety measures to identify current regulatory and non-regulatory measures, and has modelled the proposed measures off existing measures.
- microbiological risk assessment to identified risk factors and mitigation measures
- a cost-benefit analysis to inform the most appropriate risk management measures.

4.1 Current domestic and international food safety measures for horticulture

FSANZ reviewed all relevant legislation to determine current regulatory requirements. The scope of this review included growing, harvesting, primary processing (e.g. washing, trimming and postharvest treatments), packing, storage, transport, export and import of horticultural products. We worked with peak industry bodies and government food regulators to identify existing non-regulatory measures. We compared the main food safety risk factors and control measures we identified with high-level Global Food Safety Initiative (GFSI) benchmarking requirements for food safety schemes. Details are provided in SD1.

Why did we do this work?

This review helped to:

- document existing measures
- create a baseline for this review
- examine differences between Australian states and territories
- compare existing measures to international standards, and to other countries
- determine whether the existing measures adequately support food safety in Australia
- create a gap analysis between existing measures and the P1052 proposal
- align the proposed measures to existing practices, reducing impact on industry and government food regulators.

What did we find?

Australia

In Australia there is no nationally consistent regulation (e.g. standard) applying to the primary production and processing of horticultural products, except for seed sprouts. Some state and territory jurisdictions have established general FSS requirements for horticulture in regulations under their food acts, but they are not specific to the three sectors.

Non-regulatory measures are in place in Australia for each of the three sectors. Comprehensive but voluntary on-farm FSS provide guidance on how produce should be grown, packed, prepared and distributed. Many of these schemes are benchmarked to international (GFSI) requirements and include control measures that cover the microbiological risk factors FSANZ identifies in this proposal. Compliance with FSS is assessed through a third-party audit. While FSS are voluntary, most large retailers require them and this captures many, but not all, producers. FSS provide varying degrees of coverage across the supply chain and are not picked up by all businesses in the berries, leafy vegetables or melons sectors. FSANZ estimates that approximately 75% of berry businesses, 25% of leafy vegetable businesses and 95% of melon businesses are on a FSS (details are provided in the CBA).

In addition to FSS, non-regulatory measures have been developed by jurisdictions to assist primary producers. These include guidelines, codes of practice and other documented advice. Some of these documents place more emphasis on food safety practices than others. Some initiatives targeting food safety and traceability have been completed or are being trialled, particularly for melons. Food safety culture initiatives are also expanding, with the growing recognition of the importance of behaviour and commitment to ensuring safe food during production stages.

International

Internationally, Codex has developed guidance documents to address specific horticulture sectors. There are commodity-specific annexes for five commodities in the [Code of Hygienic Practice for Fresh Fruits and Vegetables \(Codex 2017\)](#): seed sprouts, ready-to-eat minimally processed fruits and vegetables, berries, leafy vegetables and melons.

In other countries, there is considerable variation in the legislation applied to the safe production of horticultural produce.

Conclusion

There are some existing regulatory measures in place for horticulture in some jurisdictions. There is no nationally consistent standard or other regulated measures specifically for berries, leafy vegetables or melons. Without a national standard or other regulated measures specifically for berries, leafy vegetables or melons, there are gaps in food safety management. Australia has gaps in its regulatory position for berries, leafy vegetables and melons compared to international guidance developed by Codex.

There are a raft of industry-led non-regulatory measures that are beneficial in managing food safety in the horticulture sector. Information and guidance is also provided by jurisdictions.

4.2 Microbiological assessment

FSANZ assessed the microbiological risks associated with fresh berries, leafy vegetables and melons in Australia. Full details are provided in SD2.

Why did we do this work?

Fresh fruit and vegetables occasionally cause foodborne illness. Berries, leafy vegetables and melons are among the more common that cause such illness. To reduce illness, we first need to understand how these horticultural products become contaminated with hazardous bacteria and viruses. We can then determine which control measures will be most effective in reducing the likelihood of contamination, and which measures can reduce the amount of bacteria and viruses on products if contamination occurs. This information then informs the development of regulations and other food safety measures that aim to minimise future foodborne illness outbreaks.

How did we do it?

We reviewed relevant scientific literature and assessed the available data. Since there are many types of berry, leafy vegetable and melon products, we limited our assessment to a few examples in each category. The products were selected to cover a range of cultivation and growing conditions, product characteristics and harvest methods.

The products we assessed were:

- berries: blueberries, raspberries and strawberries
- leafy vegetables: lettuce, parsley and spinach
- melons: rockmelon and watermelon.

The assessment considered HAV, *Listeria monocytogenes*, NoV, *Salmonella* and STEC as key microbial hazards.

We identified the key steps in growing, harvesting and on-farm processing. For each step, we looked at factors that might affect contamination in the final product. The following factors were considered:

During the growing phase	Harvest and field packing operations	On-farm processing postharvest
<ul style="list-style-type: none">• animal intrusion• characteristics of the production environment• extreme weather events• seeds and seedlings• soil, manures and fertilisers• water for irrigation and applying fertilisers or chemicals	<ul style="list-style-type: none">• method of harvesting (e.g hand-picked or mechanical)• worker health and hygiene• cleaning and sanitisation of equipment	<ul style="list-style-type: none">• handling and hygiene control• water use (e.g. for washing and sanitising products)• worker health and hygiene• the cold chain• cleaning and sanitisation of equipment and facilities

What did we find?

Contamination of the horticultural products assessed is most likely to be caused by:

- wildlife or domestic animals in or near fields where the crops are growing
- location of growing areas near or on land used for livestock production or as a wildlife habitat, or exposed to urban or industrial waste
- the occurrence of flooding or other extreme weather events
- the application of untreated or insufficiently treated manure or composts
- the use of contaminated water for irrigation, application of agricultural chemicals and/or postharvest washing and sanitising of products
- poor postharvest washing and sanitisation practices (for leafy vegetables and melons)
- poor worker and equipment hygiene, both at harvest and postharvest.

We also found there are some risk factors that apply only to one or a few of the products assessed. For example, some products have rougher surfaces, which can hold onto soil and contaminants more easily. As another example, some products are more at risk of contamination from poor worker hygiene and sanitation during picking or packing.

The limited availability of data—especially Australian data—and the large number of potential pathways by which products could become contaminated meant that we could not directly compare the level of risk between or within the three commodity sectors.

A range of possible control measures that could reduce the chance of contamination of berries, leafy vegetables and melons during primary production and processing were identified. These include:

- applying good agricultural practices on-farm
- good hygienic practices at harvest and postharvest
- controlling inputs at all stages along the primary production and processing chain (including the effective use of sanitisers when applied).

Producers should also respond to changes in the growing environment—such as extreme weather events—that can spread contamination.

Conclusion

There is currently no single step during primary production and processing that can ensure the safety of these horticultural products, which are generally consumed raw, with little or no further processing.

Contamination of berries, leafy vegetables and melons with bacteria and viruses depends on different combinations of factors during their growth, harvest and primary processing on-farm. How much these factors are controlled affects the overall safety of these products. Therefore, multiple controls need to be consistently applied and managed throughout the production, processing and supply chain.

It is not possible to completely eliminate risk to consumers from fresh produce. All those involved—farmer, processor, retailer and consumer—need to be aware of food safety risks and seek to minimise them. However, this assessment concludes that the risk management required to ensure end product safety of these commodities needs to begin on farm.

4.3 Summary of risk assessment

Our assessment concluded that amendment of the Code is required based on the:

- lack of national or consistent food safety regulations
- reliance on FSS
- incomplete uptake of FSS
- microbial hazards identified
- current levels of illness
- protection of public health and safety.

5 Risk management

5.1 Principles

FSANZ has established a risk management framework based on five principles, outlined below, to guide our risk management approach. These principles reflect FSANZ’s priority objective of addressing the risk to public health and safety in Australia. They also reflect stakeholder comments on the need for a national approach to safe food production of berries, leafy vegetables and melons, with minimal burden on industry. The principles are:

- protection of public health and safety
- cost-effective, minimal measures to strengthen food safety management
- national consistency of food safety management
- standards to be based on best available scientific evidence
- promotion of fair trading in food.

Principle	Proposed outcome
Protection of public health and safety	Reduction in foodborne illnesses attributed to berries, leafy vegetables and melons. Traceability requirements improve identifying and removing affected food, reducing cases of foodborne illness.
Cost-effective,	Regulatory measures align with industry best practices, reducing

Principle	Proposed outcome
minimal measures	<p>costs to businesses that already have best practice in place.</p> <p>Berries: Proposed risk management measures are minimal in the berries sector, largely because domestically produced berries have not been connected to outbreaks. Further, as a food safety management statement is not required for the berries sector, government regulators will not be routinely monitoring the berries sector, unless a food safety issue is raised.</p> <p>Leafy vegetables and melons: Each proposed clause was designed so that the cost and benefit (in reducing illness) represents the lightest touch possible with an overall positive cost benefit ratio.</p>
National consistency	<p>All businesses meet a minimum base level of food safety.</p> <p>There is a level playing field for all industry operations and requirements for managing food safety. Provides common accountability framework for all industry players, based on scientific risk.</p> <p>Allows for consistent implementation of national requirements.</p> <p>All food handlers, on farm and at initial processing stages, gain and apply the same level of food safety skills and knowledge.</p> <p>Australia maintains its reputation as a producer and exporter of safe food.</p>
Best available scientific evidence	<p>FSANZ's microbiological risk assessment considered the best scientific information currently available. We examined our previous assessments and updated data on Australian and international foodborne illness outbreaks associated with fresh horticultural produce (see section 4.2), as well as related recall data.</p> <p>Information in the Codex CoHP FFV has also been drawn upon to develop appropriate risk management measures.</p>
Promotion of fair trading in food	<p>Introduction of nationally consistent food safety requirements can encourage a more level playing field for all producers in the market place.</p>

5.2 Risk management options

FSANZ assessed four risk management options.

- Option 1 – Retaining the status quo
- Option 2 – Introducing regulatory measures
- Option 3 – Introducing a combination of regulatory and non-regulatory measures
- Option 4 – Introducing non-regulatory measures alone.

Each option was assessed against the criteria set out in section 59 of the Act (refer to section 7).

5.3 Cost-benefit analysis (CBA)

Summary

Our Cost-benefit Analysis considered the net benefits of each option and which measures (if any) should be introduced. Information and costings were examined for each option and

each sector. Retaining the status quo did not incur any additional costs or health benefits, and the current cost of illness would still apply. Regulation was estimated to have a positive net benefit. Regulation combined with non-regulation was found to have the highest net benefit. Non-regulation, as a standalone measure, was found to have some benefit.

Why did we do this work?

FSANZ is committed to ensuring that any proposed food safety measures are based on the best available scientific advice, taking into account real-world costs and benefits. As part of any proposal FSANZ prepares a CBA. The CBA is used by FSANZ to consider:

- the relative costs and benefits of each option
- whether it is appropriate to introduce regulation and/or non-regulation
- the most appropriate form of this regulation and/or non-regulation.

How did we do it?

This CBA calculated the regulatory and non-regulatory options in detail, comparing them to the status quo. We did this to identify the option with the highest net benefit in terms of reducing illness in each sector against the costs of implementing each option.

The CBA considered:

- the current cost of illness caused by the microbiological hazards identified in each sector
- the cost to industry and government of implementing each option
- the estimated efficacy of each option in reducing illness in each sector
- the cost-benefit ratios of each option
- a case study in the melons sector
- effects on international trade
- consumer behaviour.

What was the outcome?

The CBA determined the total annual cost of illness in Australia resulting from the hazards identified by our microbiological assessment. Details of this process are provided in Appendix 2 of the CBA. A summary is provided in Table 2 below.

Table 2. Estimated annual cost of illness per sector for the microbial hazards identified in P1052

Commodity	Total annual illness cost \$
Berries	6.5 million
Leafy vegetables	52.9 million
Melons	30.7 million

The CBA next determined the costs to business, across each of the three sectors, of implementing each clause of the proposed standards. Separate costs were calculated for businesses currently on a FSS and for businesses not on a FSS. Costs for businesses on a FSS (or equivalent) are significantly lower, as they have already implemented most of the measures in the proposed standards. For example, the only cost to a berry business operating under a FSS would be a one-off notification fee of \$30. Table 3 contains the summary of the estimated costs and more detail on the CBA can be found at SD3.

Table 3. Summary of estimated total costs to businesses, by sector, of implementing option 3

Estimate	Berries		Leafy vegetables		Melons	
	Initial costs \$	Ongoing costs per year \$	Initial costs \$	Ongoing costs per year \$	Initial costs \$	Ongoing costs per year \$
Businesses with FSS (or equivalent measures) in place Berries: Initial notification Leafy vegetables and melons: Annual licencing and auditing costs	30	0	0	1,540	0	1,540
Businesses with some food safety management in place (50% of the proposed measures) Includes notifications, licencing, audits and 50% of the costs of implementing all measures in the proposed standard	470	1,056	700	7,036	700	4,056
Businesses without any food safety management in place. Costs will be similar to what businesses implementing industry-driven schemes have already invested Includes notifications, licencing, audits and 100% of the costs of implementing all measures in the proposed standard	910	2,113	1,400	12,533	1,400	6,573
Note: This table includes the costs of formal audits by government food regulators. Alternative, lower cost, monitoring arrangements may be considered at a state and territory level for businesses already certified against a FSS.						

We estimated the numbers of businesses in each sector, the percentage of those businesses already on a FSS and the estimated cost to the industry. A summary is provided in Table 4 and further details are provided in the CBA at SD3.

Table 4. Summary of estimated total costs to industry of implementing option 3

	Berries	Leafy vegetables	Melons
Estimated number of businesses (central estimate)	750	1,500	225
Percentage of businesses on a FSS (or equivalent)	75%	25%	95%
Total costs to industry of implementing option 3 (Medium estimate)	\$108,080 (initial) \$198,092 (p.a.)	\$789,040 (initial) \$8,160,996 (p.a.)	\$10,995 (initial) \$185,529 (p.a.)

The CBA then compared the costs of implementing each option against the cost savings, in terms of reduction of illness as a result of implementing each option. A summary of this CBA is provided in Table 5 below. The second column of this table provides a comparison of the estimated costs of implementing the proposed regulatory measures for each sector against the estimated benefit in reducing illness in each sector. For example, in the berries sector, the CBA estimates that for every 10-30 cents spent implementing the berries standard, we should see a \$1 reduction in the cost of illness associated with this sector. The final column of this table summarises the level of reduction of illness that would be required for the non-regulatory measures to be beneficial. For example, in the melons sector, if the additional non-regulatory measures reduced illness by just 0.04%, there would be a cost benefit in introducing them.

Non-regulatory measures on their own are not likely to have a significant impact without regulatory status of requirements. Non-regulatory measures may have a further impact on reducing foodborne illness when added to regulatory measures.

Table 5. Comparison of the costings and net benefit for each risk management option (benchmarked against the status quo – central efficacy ranges)

Commodity group	Regulatory measures	Non-regulatory measures
Berries	Estimated cost of 10-30 cents to achieve every \$1 of benefit. Net benefit likely.	A reduction of illness of less than 0.2% would justify implementing additional non-regulatory measures.
Leafy vegetables	Estimated cost of 20-60 cents to achieve every \$1 of benefit. Net benefit likely.	Reduction of illness of 0.02% would justify implementing additional non-regulatory measures.
Melons	Estimate cost of 2-5 cents to achieve every \$1 of benefit. Net benefit very likely.	A reduction of illness of 0.04% would justify implementing additional non-regulatory measures.

Conclusion

Our initial estimates indicate that option 3 (a combination of regulatory and non-regulatory measures) will result in the greatest net benefit, at least \$138 million over a 10 year period. Further details are provided in the CBA (SD3).

5.4 Proposed risk management measure (preferred option)

The most likely sources of contamination of berries, leafy vegetables and melons were identified. These include animals, growing location, extreme weather events, manure and composts, water inputs, postharvest washing and sanitisation, and poor worker and equipment hygiene. Multiple factors affect the level of contamination, and these factors vary between different products.

There is no single step that can ensure product safety during production and processing. The chance of contaminating produce could be reduced through good agricultural practices on farm, good hygienic practices at harvest and postharvest, and controlling inputs at all stages.

These fresh products are generally consumed raw, with little or no further processing. It is not possible to completely eliminate risk to consumers. Multiple controls are needed throughout the supply chain, but risk management needs to begin on farm.

Our preliminary position

Our assessment indicates a combination of regulatory and non-regulatory measures provides the most cost-effective way to manage food safety in these sectors. Our preliminary preferred position is to recommend both regulatory and non-regulatory measures to manage food safety in these sectors.

This position is based on:

- risks identified by the microbiological assessment
- the cost of foodborne illness attributed to these sectors
- the current lack of nationally consistent regulation in these sectors, both in terms of content and coverage
- the incomplete uptake of industry-led food safety schemes
- a positive cost-benefit analysis.

Sector-specific regulatory measures

Based on the findings of our assessment, we prepared three draft proposed Standards – one for each sector.

Each commodity and sector presented different risk profiles and costs associated with managing risks. As a result, the measures in each Standard that we have proposed to manage food safety are fine-tuned and specific to each sector. Our considerations in determining these specific risk management measures for each sector are set out in the Consultation Regulation Impact Statement (CRIS). They are summarised below.

Berries

For the berries sector, the proposed standard includes requirements for:

- notification of business – provide authorities with contact details and describe berry activities
- traceability of produce – must be able to identify where berries have been received from, and where they have supplied berries to

- management of water as an input – make sure the water used with berries is safe (i.e. it will not contaminate the produce)
- construction and cleanliness of premises and equipment – premises and equipment will need to be properly constructed and kept clean so that berries will not become unsafe
- skills and knowledge – everyone working with berries will need to know what to do and have the skills to keep berries safe to eat
- health and hygiene – everyone working with berries will need to be well and personally clean to keep the berries they handle safe
- sale and supply of safe produce – businesses will not be permitted to sell or supply berries for people to eat if the produce is unsafe.

Leafy vegetables and melons

For the leafy vegetables and melon sectors, the proposed standards include:

- general food safety management requirements – businesses will need to have an approved statement that sets out all their food safety risks and how they will manage these risks, and operate according to this statement
- traceability of produce – businesses will need to be able to identify where leafy vegetables or melons have been received from, and where they have supplied their produce to
- management of water as an input – businesses will need to make sure the water used with leafy vegetables and melons is safe (i.e. it will not contaminate the produce)
- management of soil and fertiliser as inputs – businesses will need to make sure the soil and fertilisers (including compost and manure) used with leafy vegetables and melons is safe (i.e. will not contaminate the produce)
- management of seed and seedlings as inputs (leafy vegetables only) – businesses will need to make sure the leafy vegetable seed and seedlings used are safe (i.e. are not contaminated)
- management of the growing site – businesses will need to make sure the site used to grow leafy vegetables or melons is safe (i.e. will not contaminate the produce)
- management of food safety following weather events – businesses will need to make sure leafy vegetables or melons exposed to storms, floods, dust etc. are managed (by disposing of them; redirecting them; or trimming, cleaning, sanitising etc.) so that no unsafe produce is sold or supplied for consumption
- construction and cleanliness of premises and equipment – premises and equipment will need to be properly constructed and kept clean so that leafy vegetables and melons will not become unsafe
- maintaining an appropriate temperature of harvested produce – businesses will need to make sure harvested leafy vegetables and melons are kept at a temperature (cooled if needed) that keeps the produce safe, preventing growth of harmful microorganisms
- appropriate washing and sanitation of produce – businesses will need to make sure harvested leafy vegetables and melons are clean and that any washing and sanitisation steps are done correctly
- management of animals and pests – businesses will need to take all reasonable steps to prevent animals and pests from contaminating leafy vegetables and melons
- skills and knowledge – everyone working with leafy vegetables and melons will need to know what to do and have the skills to keep the produce safe to eat
- health and hygiene – everyone working with leafy vegetables or melons will need to be well and personally clean to keep the produce they handle safe
- sale and supply of safe produce – businesses will not be permitted to sell or supply leafy vegetables or melons for people to eat if that produce is unsafe.

6 Risk communication

6.1 Communicating how the proposed standards will work

FSANZ has been working with states and territories to ensure the proposed standards, if approved, could be implemented in each jurisdiction. As part of this work, the HIWG has developed compliance plans and guidance for industry to provide examples of what each standard - if approved - would look like at a practical level.

For the leafy vegetable and melon sectors, compliance plans (provided in SD4) detail how primary producers and processors could meet the clauses of each proposed standard. These sectors would be regularly monitored by government food safety officers to ensure the requirements are met.

For the berries sector, a proposed guideline document (in SD4) has been prepared in lieu of a compliance plan. This is due to the lower risk profile of the berries sector and cost-benefits ratio of risk mitigation. If this approach were adopted, food regulators would not routinely monitor berry businesses but would inspect them if a food safety issue is raised. Berry businesses would still need to meet the proposed standard, and the self-assessment tool provided in the proposed guidance document should assist this.

Fact sheets and webinars developed in collaboration with industry would provide businesses with additional information and guidance to meet the standards.

An 18-month implementation period (post gazettal of the proposed standards) has been recommended for all three standards. Compliance against the proposed standards would not be mandated until after this implementation period. Led by jurisdictions, information on the changes and how to comply with them would be made available to businesses during the implementation period to support them to prepare.

6.2 World Trade Organization (WTO)

As members of the World Trade Organization (WTO), Australia is 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.

FSANZ is providing initial SPS notification that Australia is reviewing food safety of primary production and processing in the berries, leafy vegetables and melons sectors, that will apply in Australia. Regulation of imported foods is the responsibility of the DAWE. Any changes to the regulation of imported food products will be communicated by DAWE through a future SPS notification process. [FSANZ provides import risk advice](#) to DAWE on whether imported foods pose a potential medium or high risk to public health and safety. DAWE use this advice to manage food safety risks at the border. This proposal is unlikely to result in any changes to the current import conditions for food.

This proposal will not affect Australian biosecurity import conditions. Biosecurity is concerned with exotic diseases of animals and plants, not endemic diseases of humans.

7 FSANZ Act assessment requirements

7.1 Section 59

When assessing this proposal and the subsequent development of a food regulatory

measure, FSANZ gave regard to the following matters in section 59 of the FSANZ Act.

Consideration of costs and benefits

Paragraph 59(2)(a) requires FSANZ to have regard to whether the costs that would arise from a proposed measure outweigh the direct or indirect benefits of the proposed measure. A CRIS has been completed and approved by the Office of Best Practice Regulation. The CRIS is provided with this CFS.

Other measures

Paragraph 59(2)(b) requires FSANZ to have regard to whether other measures (available to FSANZ or not) would be more cost-effective. We reviewed existing measures as part of option 1 (status quo) and consider the incomplete uptake of existing industry FSS and jurisdictional regulatory approaches do not adequately address the food safety issues. FSANZ's assessment is that the most cost-effective measures would be adoption of the proposed draft standards combined with non-regulatory measures.

Any relevant New Zealand standards

Paragraph 59(2)(c) requires FSANZ to have regard to any relevant New Zealand standards. FSANZ notes the primary production and processing standards (chapter 4 of the Code) do not apply in New Zealand.

Any other relevant matters

Other relevant matters include the objectives of standard-setting, which are set out in subsection 18 of the FSANZ Act and discussed below.

7.2 Subsection 18(1)

FSANZ has considered the three objectives in subsection 18(1) of the FSANZ Act during this assessment.

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 some horticulture products. 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 FSS 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 illnesses 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.

The provision of adequate information for consumers to make informed choices

Consumers may be unaware that some primary producers and processors participate in FSS, while others do not, and are therefore unable to take this into consideration when making safe food choices

The prevention of misleading or deceptive conduct

FSANZ has not identified any issues relevant to this objective.

7.3 Subsection 18(2)

FSANZ has also considered the following in subsection 18(2) of the *FSANZ Act*.

18 (2) In developing or reviewing food regulatory measures and variations of food regulatory measures, the Authority must also have regard to the following:

- (a) the need for standards to be based on risk analysis using the best available scientific evidence;*
- (b) the promotion of consistency between domestic and international food standards;*
- (c) the desirability of an efficient and internationally competitive food industry;*
- (d) the promotion of fair trading in food;*
- (e) any written policy guidelines formulated by the Forum on Food Regulation for the purposes of this paragraph and notified to the Authority.*

The microbiological assessment provided the best available scientific evidence on hazards occurring at different stages of production and primary processing. The CBA provided additional analysis and guided each risk management measure selected for inclusion in the draft proposed Standards. These documents formed the primary basis for risk identification and management throughout this proposal.

FSANZ considered international guidelines (i.e. Codex) and in particular, the specific annexes for berries, leafy vegetables and melons. We considered Codex's rationale for including these annexes and risk management measures best applied in the Australian context.

The CBA analysed the effects of the introduction of Standards on exports and on consumer demand. These were identified as minimal (however were difficult to determine with a high level of confidence). FSANZ risk managers took these findings into consideration when designing all risk management measures, focusing on light touch and cost minimal regulatory requirements.

Risk managers considered the need for promotion of fair trading, this influenced our decision to introduce national regulation that would be applicable to all businesses in these sectors.

This review was requested of FSANZ by food ministers.

Further analysis is found in supporting documents.

Standards to be based on risk analysis using best available scientific evidence

FSANZ's microbiological risk assessment considered the best scientific information currently available. We examined our assessments and updated data on Australian and international foodborne illness outbreaks associated with fresh horticultural produce (see section 4.2), as well as related recall data. Information in the Codex CoHP FFV has also been drawn upon to develop appropriate risk management measures. Refer to SD2.

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. Refer to SD1.

Desirability of an efficient and internationally competitive food industry

FSANZ has had regard to the public health and safety risks associated with 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.

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.

Written policy guidelines formulated by the Forum on Food Regulation

The Ministerial Council Overarching Policy Guideline on Primary Production and Processing Standards³ 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.

8 Proposed standards

FSANZ has prepared three draft standards for the Code - one each for berries, leafy vegetables and melons. These draft standards are provided as Attachment A.

A draft explanatory statement (combined for the three standards) is provided as Attachment B. An explanatory statement is required to accompany an instrument if it is lodged on the Federal Register of Legislation.

Stakeholders are now invited to provide comment on this assessment and the three proposed standards. Although a combination of regulatory and non-regulatory measures is FSANZ's preferred option, we are seeking information and views on all options, and all options will be considered. The information and views provided will inform a decision by FSANZ whether to accept, amend or reject its proposed approach and the proposed requirements contained in the draft standards.

8.1 Transitional arrangements

An 18-month implementation period (post gazettal of the proposed standards) has been recommended for all three standards. Compliance against the proposed standards would not be mandated until after this implementation period.

Implementation

Implementation of the proposed standards is the responsibility of the states and territories. ISFR facilitates the consistent national implementation of standards by developing agreed approaches and compliance materials.

The HIWG was established by ISFR for this purpose. They are using the [Integrated Model](#)

³ Available at <https://foodregulation.gov.au/internet/fr/publishing.nsf/Content/food-policies>

[for Standards Development and Consistent Implementation of Primary Production and Processing Standards](#)⁴. Working together with FSANZ, the HIWG has developed a range of tools to help businesses and regulators understand how a primary production and processing standard, if and when approved, would be implemented by jurisdictions. These tools include proposed compliance plans for the leafy vegetables and melons sectors, and a proposed guideline document for the berry industry. These documents are provided for information and comment in SD4.

9 Attachments

- Attachment A. Draft variations to the *Australia New Zealand Food Standards Code*
- Attachment B. Draft Explanatory Statement
- Attachment C. FSANZ response to submissions from first call for submissions

⁴ <https://foodregulation.gov.au/internet/fr/publishing.nsf/Content/ISFR>

Attachment A – Draft variations to the *Australia New Zealand Food Standards Code*

Three draft standards are provided:

- **Berries:** Draft Standard 4.2.7 Primary production and processing standard for Berries
- **Leafy Vegetables:** Draft Standard 4.2.8 Primary production and processing standard for Leafy Vegetables
- **Melons:** Draft Standard 4.2.9 Primary production and processing standard for Melons

A consequential variation to the Code to support the proposed standards is also attached.

Draft variation to the *Australia New Zealand Food Standards Code – Berries*



Standard 4.2.7 – Primary production and processing standard for Berries

The Board of Food Standards Australia New Zealand gives notice of the making of this Standard under section 92 of the *Food Standards Australia New Zealand Act 1991*. The Standard commences on a date 18 months after the date of gazettal.

Dated [To be completed by the Delegate]

[Name of Delegate]

Delegate of the Board of Food Standards Australia New Zealand

Note:

This Standard will be published in the Commonwealth of Australia Gazette No. FSC XX on XX Month 20XX. This means that this date is the gazettal date for the purposes of the above notice.

Standard 4.2.7 Primary production and processing standard for Berries

Note 1 This instrument is a standard under the *Food Standards Australia New Zealand Act 1991* (Cth). The standards together make up the *Australia New Zealand Food Standards Code*. See also section 1.1.1—3.

Note 2 This Standard applies in Australia only.

Division 1 Preliminary

4.2.7—1 Name

This Standard is *Australia New Zealand Food Standards Code – Standard 4.2.7 – Primary production and processing standard for Berries*.

Note Commencement:
This Standard commences on a date 18 months after the date of gazettal, being the date specified as the commencement date in notices in the *Gazette* and the *New Zealand Gazette* under section 92 of the *Food Standards Australia New Zealand Act 1991* (Cth). See also section 93 of that Act.

4.2.7—2 Definitions

In this Standard:

berries means fresh berries; and includes strawberries, blueberries, and raspberries.

growing site means any site used to grow berries; and includes an open, partially enclosed or enclosed planting area.

harvest means all activities related to the collection and removal of berries from a growing site; and includes picking, cutting, field packing (including packaging for retail sale), and transport from the growing site to the next step in the supply chain.

premises and equipment means equipment, infrastructure, structures and vehicles that:

- (a) are used by a primary horticulture producer or by a primary horticulture processor; and
- (b) have direct or indirect contact with berries.

primary horticulture producer means a business, enterprise or activity that involves the growing and/or harvesting of berries.

primary horticulture processor means a business, enterprise or activity that involves one or more of the following activities in relation to berries that have been harvested:

- (a) washing;
- (b) trimming;
- (c) chopping;
- (d) sorting;
- (e) sanitising;
- (f) combining products;
- (g) packing; and
- (h) transport between primary processing premises.

relevant activity means:

- (a) in relation to a primary horticulture producer, the growing and/or harvesting of berries; and
- (b) in relation to a primary horticulture processor, any the following:

- (i) washing harvested berries;
- (ii) trimming harvested berries;
- (iii) chopping harvested berries;
- (iv) sorting harvested berries;
- (v) sanitising harvested berries;
- (vi) combining harvested berries;
- (vii) packing harvested berries; and
- (viii) transporting harvested berries between primary processing premises.

Note 1 In this Code (see section 1.1.2—2(3) of Standard 1.1.2)

relevant authority means an authority responsible for the enforcement of the relevant application Act

Note 2 In this Chapter (see clause 1 of Standard 4.1.1):

inputs includes any feed, litter, water (including recycled water), chemicals or other substances used in, or in connection with, the primary production or processing activity.

Note 3 Clause 3 of Standard 4.1.1 sets out when a food will be unacceptable for the purposes of this Standard.

4.2.7—3 Application

- (1) This Standard applies to primary horticulture producers and to primary horticulture processors in Australia.
- (2) This Standard does not apply to the retail sale of berries.

4.2.7—4 Notification

- (1) A primary horticulture producer and a primary horticulture processor must provide the specified information to the relevant authority before engaging in a relevant activity.
- (2) In this section, **specified information** means the following information:
 - (a) the contact details of the primary horticulture producer or the primary horticulture processor, including the name of their business and the name and business address of the proprietor of their business;
 - (b) a description of the activities the primary horticulture producer or the primary horticulture processor will undertake in relation to berries; and
 - (c) the location or locations of each activity referred to in paragraph (b) that is within the jurisdiction of the relevant authority.
- (3) A primary horticulture producer and a primary horticulture processor must notify the relevant authority of any proposed change to specified information provided to a relevant authority in accordance with this section before that change occurs.

4.2.7—5 Traceability

A primary horticulture producer and a primary horticulture processor must have in place a system that can identify:

- (a) from whom berries were received; and
- (b) to whom berries were supplied.

4.2.7—6 Inputs - water

A primary horticulture producer and a primary horticulture processor must take all reasonable measures to ensure that water inputs do not make the berries unacceptable.

4.2.7—7 Premises and equipment

- (1) A primary horticulture producer and a primary horticulture processor must take all

reasonable measures to ensure that premises and equipment are designed, constructed, maintained and operated in a way that:

- (a) allows for effective cleaning and sanitisation of the premises and equipment; and
 - (b) does not make berries unacceptable.
- (2) A primary horticulture producer and a primary horticulture processor must ensure that premises and equipment are kept clean, sanitised and in good repair to the extent required to ensure that berries are not made unacceptable.

4.2.7—8 Skills and knowledge

A primary horticulture producer and a primary horticulture processor must ensure that persons who engage in a relevant activity, or who supervise a person who engages in a relevant activity, have:

- (a) knowledge of food safety and food hygiene matters; and
- (b) skills in food safety and food hygiene matters

commensurate with their work.

4.2.7—9 Health and hygiene of personnel and visitors

A primary horticulture producer and a primary horticulture processor must take all reasonable measures to ensure that personnel and visitors exercise personal hygiene and health practices that do not make berries unacceptable.

4.2.7—10 Sale or supply of unacceptable berries

A primary horticulture producer and a primary horticulture processor must not sell or supply berries for human consumption if they ought reasonably know, or ought reasonably suspect, that the berries are unacceptable.

Draft variation to the *Australia New Zealand Food Standards Code – Leafy Vegetables*



Standard 4.2.8 – Primary production and processing standard for Leafy Vegetables

The Board of Food Standards Australia New Zealand gives notice of the making of this Standard under section 92 of the *Food Standards Australia New Zealand Act 1991*. The Standard commences on a date 18 months after the date of gazettal.

Dated [To be completed by the Delegate]

[Name of Delegate]

Delegate of the Board of Food Standards Australia New Zealand

Note:

This Standard will be published in the Commonwealth of Australia Gazette No. FSC XX on XX Month 20XX. This means that this date is the gazettal date for the purposes of the above notice.

Standard 4.2.8 Primary production and processing standard for Leafy Vegetables

Note 1 This instrument is a standard under the *Food Standards Australia New Zealand Act 1991* (Cth). The standards together make up the *Australia New Zealand Food Standards Code*. See also section 1.1.1—3.

Note 2 This Standard applies in Australia only.

Division 1 Preliminary

4.2.8—1 Name

This Standard is *Australia New Zealand Food Standards Code – Standard 4.2.8 – Primary production and processing standard for Leafy Vegetables*.

Note Commencement:
This Standard commences on a date 18 months after the date of gazettal, being the date specified as the commencement date in notices in the *Gazette* and the *New Zealand Gazette* under section 92 of the *Food Standards Australia New Zealand Act 1991* (Cth). See also section 93 of that Act.

4.2.8—2 Definitions

In this Standard:

leafy vegetables means fresh leafy vegetables; and includes baby leaves, lettuce, and leafy herbs.

growing site means any site used to grow leafy vegetables; and includes an open, partially enclosed or enclosed planting area.

harvest means all activities related to the collection and removal of leafy vegetables from a growing site; and includes picking, cutting, field packing (including packaging for retail sale), and transport from the growing site to the next step in the supply chain.

premises and equipment means equipment, infrastructure, structures and vehicles that:

- (a) are used by a primary horticulture producer or by a primary horticulture processor; and
- (b) have direct or indirect contact with leafy vegetables.

primary horticulture producer means a business, enterprise or activity that involves the growing and/or harvesting of leafy vegetables.

primary horticulture processor means a business, enterprise or activity that includes one or more of the following activities in relation to leafy vegetables that have been harvested:

- (a) washing;
- (b) trimming;
- (c) chopping;
- (d) sorting;
- (e) sanitising;
- (f) combining products;
- (g) packing; and
- (h) transport between primary processing premises.

relevant activity means:

- (a) in relation to a primary horticulture producer, the growing and/or harvesting of leafy vegetables; and
- (b) in relation to a primary horticulture processor, any the following:

- (i) washing harvested leafy vegetables;
- (ii) trimming harvested leafy vegetables;
- (iii) chopping harvested leafy vegetables;
- (iv) sorting harvested leafy vegetables;
- (v) sanitising harvested leafy vegetables;
- (vi) combining harvested leafy vegetables;
- (vii) packing harvested leafy vegetables; and
- (viii) transporting harvested leafy vegetables between primary processing premises.

Note 1 In this Chapter (see clause 1 of Standard 4.1.1):

general food safety management requirements means the requirements in Division 2 of Standard 4.1.1.

inputs includes any feed, litter, water (including recycled water), chemicals or other substances used in, or in connection with, the primary production or processing activity.

Note 2 Clause 3 of Standard 4.1.1 sets out when a food will be unacceptable for the purposes of this Standard.

4.2.8—3 Application

- (1) This Standard applies to primary horticulture producers and to primary horticulture processors in Australia.
- (2) This Standard does not apply to the retail sale of leafy vegetables.

4.2.8—4 General food safety management requirements

A primary horticulture producer and a primary horticulture processor must comply with the general food safety management requirements.

4.2.8—5 Traceability

A primary horticulture producer and a primary horticulture processor must have in place a system that can identify:

- (a) from whom leafy vegetables were received; and
- (b) to whom leafy vegetables were supplied.

4.2.8—6 Inputs – seed, seedling, soil, fertiliser and water

A primary horticulture producer and a primary horticulture processor must take all reasonable measures to ensure that any of the following inputs do not make leafy vegetables unacceptable:

- (a) seeds;
- (b) seedlings;
- (c) soil;
- (d) soil amendments (including manure, human biosolids, compost, and plant bio-waste);
- (e) fertiliser; and
- (f) water.

4.2.8—7 Growing sites

A primary horticulture producer must take all reasonable measures to ensure that a growing site is located, designed, constructed, maintained and operated such that leafy vegetables are not made unacceptable.

4.2.9—8 Weather events

A primary horticulture producer and a primary horticulture processor must take appropriate remedial action to ensure that leafy vegetables adversely affected by

weather conditions are not unacceptable.

4.2.8—9 Premises and equipment

- (1) A primary horticulture producer and a primary horticulture processor must take all reasonable measures to ensure that premises and equipment are designed, constructed, maintained and operated in a way that:
 - (a) allows for effective cleaning and sanitisation of the premises and equipment; and
 - (b) does not make leafy vegetables unacceptable.
- (2) A primary horticulture producer and a primary horticulture processor must ensure that premises and equipment are kept clean, sanitised and in good repair to the extent required to ensure that leafy vegetables are not made unacceptable.

4.2.8—10 Temperature of harvested leafy vegetables

A primary horticulture producer and a primary horticulture processor must keep harvested leafy vegetables at a temperature that does not make the leafy vegetables unacceptable.

4.2.8—11 Washing and sanitisation of harvested leafy vegetables

A primary horticulture processor must take all reasonable measures to ensure that:

- (a) visible extraneous material on harvested leafy vegetables is removed; and
- (b) any washing or sanitising of harvested leafy vegetables does not make the leafy vegetables unacceptable.

4.2.8—12 Animals and pests

A primary horticulture producer and a primary horticulture processor must take all reasonable measures to minimise the presence of animals, vermin and pests in growing sites, and in premises and equipment, to ensure that leafy vegetables are not made unacceptable.

4.2.8—13 Skills and knowledge

A primary horticulture producer and a primary horticulture processor must ensure that persons who engage in a relevant activity, or who supervise a person who engages in a relevant activity, have:

- (a) knowledge of food safety and food hygiene matters; and
- (b) skills in food safety and food hygiene matters

commensurate with their work.

4.2.8—14 Health and hygiene of personnel and visitors

A primary horticulture producer and a primary horticulture processor must take all reasonable measures to ensure that personnel and visitors exercise personal hygiene and health practices that do not make leafy vegetables unacceptable.

4.2.8—15 Sale or supply of unacceptable leafy vegetables

A primary horticulture producer and a primary horticulture processor must not sell or supply leafy vegetables for human consumption if they ought reasonably know, or ought reasonably suspect, that the leafy vegetables are unacceptable.

Draft variation to the *Australia New Zealand Food Standards Code* – Melons



Standard 4.2.9 – Primary production and processing standard for Melons

The Board of Food Standards Australia New Zealand gives notice of the making of this Standard under section 92 of the *Food Standards Australia New Zealand Act 1991*. The Standard commences on a date 18 months after the date of gazettal.

Dated [To be completed by the Delegate]

[Name of Delegate]

Delegate of the Board of Food Standards Australia New Zealand

Note:

This Standard will be published in the Commonwealth of Australia Gazette No. FSC XX on XX Month 20XX. This means that this date is the gazettal date for the purposes of the above notice.

Standard 4.2.9 Primary production and processing standard for Melons

Note 1 This instrument is a standard under the *Food Standards Australia New Zealand Act 1991* (Cth). The standards together make up the *Australia New Zealand Food Standards Code*. See also section 1.1.1—3.

Note 2 This Standard applies in Australia only.

Division 1 Preliminary

4.2.9—1 Name

This Standard is *Australia New Zealand Food Standards Code* – Standard 4.2.9 – Primary production and processing standard for Melons.

Note Commencement:
This Standard commences on a date 18 months after the date of gazettal, being the date specified as the commencement date in notices in the *Gazette* and the *New Zealand Gazette* under section 92 of the *Food Standards Australia New Zealand Act 1991* (Cth). See also section 93 of that Act.

4.2.9—2 Definitions

In this Standard:

melons means fresh melons; and includes watermelon, rock melon, honeydew melon, and piel de sapo.

growing site means any site used to grow melons; and includes an open, partially enclosed or enclosed planting area.

harvest means all activities related to the collection and removal of melons from a growing site; and includes picking, cutting, field packing (including packaging for retail sale), and transport from the growing site to the next step in the supply chain.

premises and equipment means equipment, infrastructure, structures and vehicles that:

- (a) are used by a primary horticulture producer and a primary horticulture processor; and
- (b) have direct or indirect contact with melons.

primary horticulture producer means a business, enterprise or activity that involves the growing and/or harvesting of melons.

primary horticulture processor means a business, enterprise or activity that involves one or more of the following activities in relation to melons that have been harvested:

- (a) washing;
- (b) trimming;
- (c) chopping;
- (d) sorting;
- (e) sanitising;
- (f) combining products;
- (g) packing; and
- (h) transport between primary processing premises.

relevant activity means:

- (a) in relation to a primary horticulture producer, the growing and/or harvesting of melons; and
- (b) in relation to a primary horticulture processor, any the following:

- (i) washing harvested melons;
- (ii) trimming harvested melons;
- (iii) chopping harvested melons;
- (iv) sorting harvested melons;
- (v) sanitising harvested melons;
- (vi) combining harvested melons;
- (vii) packing harvested melons; and
- (viii) transporting harvested melons between primary processing premises.

Note 1 In this Chapter (see clause 1 of Standard 4.1.1):

general food safety management requirements means the requirements in Division 2 of Standard 4.1.1.

inputs includes any feed, litter, water (including recycled water), chemicals or other substances used in, or in connection with, the primary production or processing activity.

Note 2 Clause 3 of Standard 4.1.1 sets out when a food will be unacceptable for the purposes of this Standard.

4.2.9—3 Application

- (1) This Standard applies to primary horticulture producers and to primary horticulture processors in Australia.
- (2) This Standard does not apply to the retail sale of melons.

4.2.9—4 General food safety management requirements

A primary horticulture producer and a primary horticulture processor must comply with the general food safety management requirements.

4.2.9—5 Traceability

A primary horticulture producer and a primary horticulture processor must have in place a system that can identify:

- (a) from whom melons were received; and
- (b) to whom melons were supplied.

4.2.9—6 Inputs – soil, fertiliser and water

A primary horticulture producer and a primary horticulture processor must take all reasonable measures to ensure that any of the following inputs do not make the melons unacceptable:

- (a) soil;
- (b) soil amendments (including manure, human biosolids, compost, and plant bio-waste);
- (c) fertiliser; and
- (d) water.

4.2.9—7 Growing sites

A primary horticulture producer must take all reasonable measures to ensure that a growing site is located, designed, constructed, maintained and operated such that melons are not made unacceptable.

4.2.9—8 Weather events

A primary horticulture producer and a primary horticulture processor must take appropriate remedial action to ensure that melons adversely affected by weather conditions are not unacceptable.

4.2.9—9 Premises and equipment

- (1) A primary horticulture producer and a primary horticulture processor must take all reasonable measures to ensure that premises and equipment are designed, constructed, maintained and operated in a way that:
 - (a) allows for effective cleaning and sanitisation of the premises and equipment; and
 - (b) does not make melons unacceptable.
- (2) A primary horticulture producer and a primary horticulture processor must ensure that premises and equipment are kept clean, sanitised and in good repair to the extent required to ensure that melons are not made unacceptable.

4.2.9—10 Temperature of harvested melons

A primary horticulture producer and a primary horticulture processor must keep harvested melons at a temperature that does not make the melons unacceptable.

4.2.9—11 Washing and sanitisation of harvested melons

A primary horticulture processor must take all reasonable measures to ensure that:

- (a) visible extraneous material on harvested melons is removed; and
- (b) any washing or sanitising of harvested melons does not make the melons unacceptable.

4.2.9—12 Animals and pests

A primary horticulture producer and a primary horticulture processor must take all reasonable measures to minimise the presence of animals, vermin and pests in growing sites, and in premises and equipment, to ensure that melons are not made unacceptable.

4.2.9—13 Skills and knowledge

A primary horticulture producer and a primary horticulture processor must ensure that persons who engage in a relevant activity, or who supervise a person who engages in a relevant activity, have:

- (c) knowledge of food safety and food hygiene matters; and
- (d) skills in food safety and food hygiene matters

commensurate with their work.

4.2.9—14 Health and hygiene of personnel and visitors

A primary horticulture producer and a primary horticulture processor must take all reasonable measures to ensure that personnel and visitors exercise personal hygiene and health practices that do not make melons unacceptable.

4.2.9—15 Sale or supply of unacceptable melons

A primary horticulture producer and a primary horticulture processor must not sell or supply melons for human consumption if they ought reasonably know, or ought reasonably suspect, that the melons are unacceptable.

Draft variation to the Code consequential to the proposed standards



Food Standards (Proposal P1052 – Primary Production and Processing Requirements for Horticulture (Berries, Leafy Vegetables and Melons) – Consequential Amendments) Variation

The Board of Food Standards Australia New Zealand gives notice of the making of this Variation under section 92 of the *Food Standards Australia New Zealand Act 1991*. The Variation commences on the date specified in clause 3 of this Variation.

Dated [To be completed by the Delegate]

[Name of Delegate]

Delegate of the Board of Food Standards Australia New Zealand

Note:

This Variation will be published in the Commonwealth of Australia Gazette No. FSC XX on XX Month 20XX. This means that this date is the gazettal date for the purposes of the above notice.

1 Name

This instrument is the *Food Standards (Proposal P1052 – Primary Production and Processing Requirements for Horticulture (Berries, Leafy Vegetables and Melons) – Consequential Amendments) Variation*.

2 Variation to Standards in the *Australia New Zealand Food Standards Code*

The Schedule varies a Standard in the *Australia New Zealand Food Standards Code*.

3 Commencement

The Variation commences immediately after all of the following Standards have commenced:

- (a) Standard 4.2.7;
- (b) Standard 4.2.8;
- (c) Standard 4.2.9.

SCHEDULE

Standard 1.1.1—Structure of the Code and general provisions

[1] Subsection 1.1.1—2(2)

Omit:

Standard 4.2.6 Production and Processing Standard for Seed Sprouts

Substitute:

Standard 4.2.6 Production and Processing Standard for Seed Sprouts

Standard 4.2.7 Primary Production and Processing Standard for Berries

Standard 4.2.8 Primary Production and Processing Standard for Leafy Vegetables

Standard 4.2.9 Primary Production and Processing Standard for Melons

Attachment B – Draft Explanatory Statement

1. Authority

Section 13 of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act) provides that the functions of Food Standards Australia New Zealand (the Authority) include the development of standards and variations of standards for inclusion in the *Australia New Zealand Food Standards Code* (the Code).

Division 2 of Part 3 of the FSANZ Act specifies that the Authority may prepare a proposal for the development or variation of food regulatory measures, including standards. This Division also stipulates the procedure for considering a proposal for the development or variation of food regulatory measures. FSANZ considered Proposal P1052 in accordance with Division 2 of Part 3 and has prepared three draft standards; and one draft variation.

2. Purpose

The Authority prepared draft standards 4.2.7, 4.2.8 and 4.2.9 to minimise food safety risks associated with the primary production and processing of fresh berries, leafy vegetables and melons.

The Authority prepared a draft variation of subsection 1.1.1—2(2) as a consequence of the new draft Standards.

3. Documents incorporated by reference

The draft standards and draft variation do not incorporate any documents by reference.

4. Consultation

In accordance with the procedure in Division 2 of Part 3 of the FSANZ Act, the Authority's consideration of Proposal P1052 will include two rounds of public comment following an assessment; targeted communication with key stakeholders; and the preparation of three draft standards and associated assessment summaries.

The first call for submissions was issued on 5 February 2020 and ended on 25 March 2020.

Targeted consultation was undertaken in December 2020 - January 2021.

Following this second public consultation, FSANZ will consider whether to approve, amend or reject the draft standards, having regard to all submissions received.

FSANZ will continue to consult with the Standard Development Advisory Group and Horticulture Implementation Working Group.

The Office of Best Practice Regulation has approved the Regulation Impact Statement (RIS) for Proposal P1052 prepared by the Authority.

5. Statement of compatibility with human rights

This instrument is exempt from the requirements for a statement of compatibility with human rights as it is a non-disallowable instrument under section 94 of the FSANZ Act.

6. The draft Standards

General: Each draft Standard would be introduced by two notes providing information about the place of the standard within the Code and the application or otherwise of the relevant draft Standard in New Zealand. The first note in each draft Standard explains that the instrument would be a standard under the FSANZ Act, and that the relevant draft Standard and the other standards together make up the Code. The second note in each draft Standard explains that the relevant draft Standard applies only in Australia.

Section 1 [draft Standards 4.2.7, 4.2.8 and 4.2.9]: This provision would establish the name of the relevant draft Standard i.e.:

- the *Australia New Zealand Food Standards Code – Standard 4.2.7 – Primary production and processing standard for berries*;
- the *Australia New Zealand Food Standards Code – Standard 4.2.8 - Primary production and processing standard for leafy vegetables*;
- the *Australia New Zealand Food Standards Code – Standard 4.2.9 - Primary production and processing standard for melons*.

The note to section 1 in each draft Standard explains that, if approved, the draft standard would commence on the date that is 18 months following the date of gazettal, being the date specified in accordance with section 92 of the FSANZ Act.

Section 2 [draft Standards 4.2.7, 4.2.8 and 4.2.9]: This provision would set out the definitions for key words and phrases used in the standards, or signposts to where those definitions are provided in other standards in the Code.

[draft Standard 4.2.7] Berries means fresh berries and includes strawberries, blueberries, raspberries. The definition is inclusive in that the specific products listed in it are intended as examples of berries, rather than constituting an exhaustive list.

[draft Standard 4.2.8] Leafy vegetables means fresh leafy vegetables and includes baby leaves, lettuce and leafy herbs. The definition is inclusive in that the specific products listed in it are intended as examples of leafy vegetables, rather than constituting an exhaustive list. 'Leafy vegetables' does not include seed sprouts. Seed sprouts are covered by Standard 4.2.6.

[draft Standard 4.2.9] Melons means fresh melons and includes watermelon, rock melon, honeydew melon, and piel de sapo. The definition is inclusive in that the specific products listed in it are intended as examples of melons, rather than constituting an exhaustive list.

[All draft Standards]

Growing site means any site used to grow berries / leafy vegetables / melons; and includes an open, partially enclosed or enclosed planting area. The definition clarifies that the standard applies to open fields as well as other cropping arrangements in fully or partially enclosed structures, such as hydroponic set ups.

Harvest means all activities related to the collection and removal of berries / leafy vegetables / melons from a growing site; and includes picking, cutting, field packing (including packaging for retail sale), and transport from the growing site to the next step in the supply chain.

Premises and equipment means equipment, infrastructure, structures and vehicles that a) are used by a primary horticulture producer or by a primary horticulture processor; and b) have direct or indirect contact with berries / leafy vegetables / melons. Examples of 'indirect contact' include pipes used to carry irrigation water, and equipment that may be placed on a food contact surface.

Primary horticulture producer means a business, enterprise or activity that is involved in the growing and / or harvesting of berries / leafy vegetables / melons.

Primary horticulture processor means a business, enterprise or activity that is involved in one or more of the following activities in relation to berries / leafy vegetables / melons, that have been harvested: washing, trimming, chopping, sorting, sanitising, combining products, packing, and transport between primary processing premises. Primary processing is intended to include minimal post-harvest processing activities and does not include further processing such as freezing, drying, cooking, canning or blending with other ingredients. Transport other than transport from primary processing facilities is not included. Chapter 3 would already apply to these further processing and transport activities.

Relevant activity means, in relation to a primary horticulture producer, the growing and/or harvesting of berries / leafy vegetables / melons. In relation to a primary horticulture processor, relevant activities mean the following activities with harvested berries / leafy vegetables / melons: washing, trimming, chopping, sorting, sanitising, combining products, packing, and transport between primary processing premises. The definition is provided to clarify which activities pertain to certain requirements in the standard. Primary processing relevant activities are intended to include minimal post-harvest processing activities and not to include further processing activities such as freezing, drying, cooking, canning or blending berries or leafy vegetables or melons with other ingredients. Chapter 3 would already apply to these further processing activities. Transport other than transport from primary processing facilities is not included in the definition. Chapter 3 would already apply to these transport activities.

Notes [draft Standard 4.2.7 (berries)]: Notes 1, 2 and 3 to section 2 signpost relevant definitions contained in other parts of the Code. Note 1 refers readers to the definition of *relevant authority* in section 1.1.2—2(3). Note 2 refers readers to the definition of *inputs* in clause 1 of Standard 4.1.1. Note 3 refers readers to clause 3 of Standard 4.1.1, which sets out when a food will be unacceptable for the purposes of Chapter 4 Standards, which would include this draft Standard.

Notes [draft Standards 4.2.8 (leafy vegetables) and 4.2.9 (melons)]: Notes 1 and 2 in section 2 signpost relevant definitions contained in other parts of the Code. Note 1 refers readers to the definitions of *general food safety management requirements* and *inputs* in clause 1 of standard 4.1.1. Note 2 refers readers to clause 3 of Standard 4.1.1, which sets out when a food will be unacceptable for the purposes of Chapter 4 Standards, which would include these draft Standards.

Section 3 [draft Standards 4.2.7, 4.2.8 and 4.2.9]: This provision deals with the application of each relevant draft Standard. Subsection (1) of this provision provides that the relevant draft standard would apply only to primary production and primary processing in Australia. Subsection (2) of this provision provides that the standard would not apply to retail sale activities of berries / leafy vegetables / melons. Chapter 3 of the Code already applies to retail activities.

Section 4 [draft Standard 4.2.7 (berries)]: This provision sets out notification requirements for primary producers and primary processors of berries. Subsection 4.2.7—4(1) would require a primary producer of berries and a primary processor of berries to provide **specified information** to the relevant authority of business activities related to berries, before engaging in relevant activities. Subsection 4.2.7—4(2) defines 'specified information', as meaning:

- a) contact details including the name of the business and the name and business address of the proprietor of the business
- b) a description of activities undertaken with berries; and
- c) the location/s of each activity that is within the jurisdiction of the relevant authority.

Subsection 4.2.7—3 would require notification of the relevant authority of any proposed change to the specified contact details, activities or location, before that change occurs.

Section 4 [4.2.8 and 4.2.9 (leafy vegetables and melons)]: The provision in each of these draft Standards would require a primary horticulture producer and a primary horticulture processor of leafy vegetables / melons to comply with the general food safety management requirements in Standard 4.1.1. Clauses 4 and 5 of Standard 4.1.1 set out the general food safety management requirements; and requirements specifically related to a food safety management statement (FSMS). The primary horticulture producer and primary horticulture processor would (among other things) need to prepare a FSMS setting out how the requirements in Chapter 4 of the Code are being complied with. In accordance with clause 5 of standard 4.1.1, this statement would have to be approved or endorsed or recognised by the relevant authority.

Section 5 [draft Standards 4.2.7, 4.2.8 and 4.2.9]: This provision would require a primary horticulture producer and a primary horticulture processor to have a system in place that could identify from whom berries / leafy vegetables / melons were received and to whom they were supplied. The intent is that the system would enable the business to trace the produce one step back and one step forward, as a minimum, if a food safety issue occurs and a product recall is required.

Section 6 [draft Standard 4.2.7 (berries only)]: This provision would require a primary producer and a primary processor of berries to take all reasonable measures to ensure that water does not make berries unacceptable. 'Water' is intended to include recycled water, but is not intended to include falling rain.

Section 6 [draft Standard 4.2.8 (leafy vegetables only)]: This provision would require a producer and a primary processor of leafy vegetables to take all reasonable measures to ensure that specified inputs do not make leafy vegetables unacceptable. The specified inputs are seeds, seedlings, soil, soil amendments (including manure, human biosolids, compost, and plant bio-waste), fertiliser, and water. 'Water' is intended to include recycled water, but is not intended to include falling rain.

Section 6 [draft Standard 4.2.9 (melons only)]: This provision would require a primary producer and a primary processor of melons to take all reasonable measures to ensure that specified inputs do not make melons unacceptable. The specified inputs are seeds; seedlings; soil; soil amendments (including manure, human biosolids, compost, and plant bio-waste); fertiliser; and water. 'Water' is intended to include recycled water, but is not intended to include falling rain.

Section 7 [draft Standard 4.2.7 (berries)] and section 9 [draft Standards 4.2.8 (leafy vegetables) and 4.2.9 (melons)]: These provisions deal with premises and equipment. Subsection (1) of each provision would require a primary horticulture producer and a primary horticulture processor to take all reasonable measures to ensure that premises and equipment are designed, constructed, maintained and operated in a way that allows for effective cleaning and sanitisation of the premises and equipment; and does not make berries / leafy vegetables / melons unacceptable. Subsection (2) of each provision would require a primary horticulture producer and a primary horticulture processor to ensure that premises and equipment are kept clean, sanitised and in good repair to the extent required to ensure that berries / leafy vegetables / melons are not made unacceptable. The intent of these provisions is that premises and equipment, including transport vehicles, do not present

a source of product contamination, damage or other adverse outcome.

Section 7 [draft Standards 4.2.8 (leafy vegetables) and 4.2.9 (melons)]: These provisions would require a primary horticulture producer of leafy vegetables / melons to ensure that a growing site is located, designed, constructed, maintained and operated such that leafy vegetables / melons are not made unacceptable. These provisions would also require ongoing management of growing sites by primary producers to ensure leafy vegetables or melons do not become unacceptable during growing and harvest activities.

Section 8 [draft Standard 4.2.7 (berries)], and section 13 [draft Standards 4.2.8 (leafy vegetables) and 4.2.9 (melons)]: These provisions would require a primary horticulture producer and a primary horticulture processor to ensure that persons engaged in; or supervising a person engaged in, relevant activities listed for berries / leafy vegetables / melons have skills and knowledge in both food safety and food hygiene commensurate with their work. The purpose of this provision is to ensure those people do not make the product unacceptable through contamination or other adverse outcomes.

Section 8 [draft Standards 4.2.8 (leafy vegetables) and 4.2.9 (melons)]: These provisions would require a primary horticulture producer and a primary horticulture processor to take appropriate remedial action to ensure that leafy vegetables / melons adversely affected by weather conditions (e.g. a flood, hail storm or dust storm) are not unacceptable. The intent is that any unacceptable leafy vegetables or melons do not enter the fresh produce supply chain. Examples of appropriate remedial action are product disposal, treatment of product to thoroughly remove adversely affected areas (e.g. through trimming, cleaning, sanitisation), or diversion of product to another supply chain where adequate treatment (e.g. retorting) will ensure the safety of the product.

Section 9 [draft Standard 4.2.7 (berries)] and section 14 [draft Standards 4.2.8 (leafy vegetables) and 4.2.9 (melons)]: These provisions would require a primary horticulture producer and a primary horticulture processor to take all reasonable measures to ensure that personnel and visitors exercise personal hygiene and health practices that do not make berries / leafy vegetables / melons unacceptable. The intent is that personnel and visitors do not present a source of product contamination or other adverse product outcome from illness or poor hygiene practices.

Section 10 [draft Standard 4.2.7 (berries)] and section 15 [draft Standards 4.2.8 (leafy vegetables) and 4.2.9 (melons)]: These provisions would prohibit a primary horticulture producer or a primary horticulture processor from selling or supplying berries / leafy vegetables / melons for human consumption if they ought reasonably know, or ought reasonably suspect, that the relevant food is unacceptable. This requirement is intended to prevent the introduction or transfer of unacceptable berries / leafy vegetables / melons through the fresh food supply chain.

Section 10 [draft Standards 4.2.8 (leafy vegetables) and 4.2.9 (melons)]: These provisions would require a primary horticulture producer and a primary horticulture processor to keep harvested leafy vegetables / melons at a temperature that would not make the produce unacceptable. The intent of these provisions is that harvested product is cooled, if necessary, and kept cool during post-harvest handling, transport and storage to prevent or minimise growth of any pathogenic microorganisms that may be present on harvested leafy vegetables or melons. Primary producers and primary processors must consider the location and timing of relevant activities (for example, the time taken to harvest product and transport it to a primary processing facility), to ensure the harvested product does not remain at temperatures for a time that would enable microbial growth to levels that would make the product unacceptable.

Section 11 [draft Standards 4.2.8 (leafy vegetables) and 4.2.9 (melons)]: These provisions would require a primary horticulture processor to take all reasonable measures to ensure that visible extraneous material (for example, surface dirt) is removed from harvested leafy vegetables / melons, and that any wash or sanitisation step used does not make leafy vegetables / melons unacceptable. The intent for washing is that where a wash step is used, the washing cleans the produce and does not introduce contamination (for example through use of excessively dirty water) or make the produce otherwise unacceptable. The intent for sanitisation is that when a sanitisation process is used, the process reduces microorganisms on the surface of leafy vegetables or melons to safe levels and does not make the product unsafe or otherwise unacceptable; for example, through use of inadequate sanitiser concentration. Under Standard 4.1.1, only approved chemicals could be used to treat fresh leafy vegetables or melons.

Section 12 [draft Standards 4.2.8 (leafy vegetables) and 4.2.9 (melons)]: These provisions would require a primary horticulture producer and a primary horticulture processor to take all reasonable measures to minimise the presence of animals, vermin and pests at growing sites and in premises and equipment, to ensure that leafy vegetables / melons are not made unacceptable. The intent of this requirement is that growing areas, premises and equipment are designed, constructed and maintained in such a way to prevent and minimise entry and harbourage of domestic or wild animals, vermin and pests to an extent that would cause leafy vegetables or melons to become unacceptable.

7. The draft Variation

Clause 4 of the *Food Standards (Proposal P1052 – Primary Production and Processing Requirements for Horticulture (Berries, Leafy Vegetables and Melons) – Consequential Amendments) Variation* (the draft Variation) states that the draft Variation would commence after the new draft Standards commence.

Item [1] of the draft Variation would amend subsection 1.1.1—2(2) by omitting the reference to ‘Standard 4.2.6 Production and Processing Standard for Seed Sprouts’ in the list of standards in that subsection and replacing that reference with references to:

“Standard 4.2.6 Production and Processing Standard for Seed Sprouts
Standard 4.2.7 Primary Production and Processing Standard for Berries
Standard 4.2.8 Primary Production and Processing Standard for Leafy Vegetables
Standard 4.2.9 Primary Production and Processing Standard for Melons”

Subsection 1.1.1—2(2) lists all the standards of the Code arranged into Chapters, Parts and a set of Schedules. The list does not currently contain references to the new draft Standards.

The effect of this amendment, if both the new draft Standards and this Variation are approved, would be that the new draft Standards would be listed in subsection 1.1.1—2(2), under Chapter 4 (Primary production standards), in numerical order according to the number of the relevant draft Standard.

Attachment C – FSANZ response to first call for submissions

All responses to FSANZ’s first call for submission (CFS) have been [published on our web site](#). The table below provides a summary of these submissions (grouped by key issue) and FSANZ’s response.

Issue	Stakeholder groups	FSANZ response
Option 1 (Status quo)		
<p>Option 1 was generally supported by industry.</p> <ul style="list-style-type: none"> The status quo was generally supported as it adequately addresses food safety, especially for businesses operating under food safety schemes (FSS). The status quo may not be as appropriate for some specific products (e.g. rockmelon). Data on foodborne illness outbreaks presented by FSANZ as evidence is considered inadequate to support additional regulation in most cases, particularly for domestically produced fresh berries. 	<p>Industry (industry bodies, producers, quality assurance, non-government organisations (NGOs))</p>	<p>The status quo FSANZ has now completed a microbiological assessment of these commodities. This assessment advises that the status quo may not adequately address food safety risk, particularly in the absence of mandatory FSS; which has resulted in gaps in industry uptake. The effectiveness of these schemes in mitigating food safety risks has also been questioned, as outbreaks have been traced to businesses with FSS in place. FSANZ is however mindful of these existing FSS and has considered these in all stages of this proposal.</p> <p>Product-specific risk management FSANZ has now prepared draft risk management options and measures, presented in the Consultation Regulation Impact Statement (CRIS). These risk management measures cover all products within each commodity. However, the draft measures are outcomes focused and as such may be tailored to specific produce as appropriate, in accordance with the level of risk they pose. The key message is that food safety needs to be <i>appropriately</i> managed.</p> <p>Data utilised The FSANZ microbiological assessment considered Australian and international data to form a robust picture of the industry. The assessment looked at information including outbreaks, hazard prevalence, methods of production and the handling of produce. All data is presented in Supporting Document 2 (SD2).</p>

		<p>The microbiological assessment indicates that risk management measures will be useful in reducing outbreaks in sectors that have previously experienced outbreaks, and aid in preventing future outbreaks in sectors that have not experienced domestic outbreaks – such as berries.</p>
<p>Option 1 was not supported by food regulators, some industry representatives and a retailer.</p> <ul style="list-style-type: none"> The current situation is inadequate, as evidenced by recalls, foodborne illness outbreaks, and investigations finding inadequacies in food safety management. 	<p>Regulators (Commonwealth, state and local), industry (industry bodies, NGOs), retail</p>	<p>Lack of support for the status quo</p> <p>As a result of several outbreaks, food ministers (the Australia and New Zealand Ministerial Forum on Food Regulation; the Forum) requested FSANZ to review several horticultural sectors often associated with these outbreaks. The Forum was concerned that the current situation may not adequately protect the public from foodborne illness.</p> <p>The microbiological assessment (SD2) provides details of:</p> <ul style="list-style-type: none"> Australian outbreaks associated with horticulture Australian recalls associated with horticulture international outbreaks associated with horticulture. <p>Berries (imported), leafy vegetables and melons are the commodity sectors most often associated with these outbreaks.</p> <p>The assessment also cautions that <i>‘the outbreak data suggests that few outbreaks related to horticultural produce are reported’</i> and that <i>‘difficulties exist in identifying and attributing illness to a particular food’</i>.</p> <p>Inadequacies in the status quo are also highlighted by instances of foodborne illness occurring where FSS were in place.</p> <p>The current lack of regulation, nationally consistent requirements, and the lack of saturation of voluntary uptake of FSS also contribute to inadequacies in the status quo.</p>

		FSANZ's preferred approach is a combination of regulatory and non-regulatory measures, as described in the CRIS.
Option 2 (Food regulatory measures)		
<p>Option 2 was supported by regulators and retailers.</p> <ul style="list-style-type: none"> Regulation has the potential to improve food safety outcomes and market access. 	<p>Regulators (Commonwealth, state and local), retail</p>	<p>Potential to improve food safety FSANZ considers potential benefits of regulation may include:</p> <ul style="list-style-type: none"> improved food safety a reduction in outbreaks and incidents government and industry working together to protect public health – which in turn protects industry increased consumer confidence a nationally consistent framework the creation of a level playing field for all primary producers and primary processors in these sectors enhanced traceability export opportunities through trade facilitation.
<p>Option 2 was generally not supported by industry.</p> <ul style="list-style-type: none"> Regulation will increase administrative and financial burdens. No strong evidence regulation will improve the current situation. 	<p>Industry (industry bodies, producers, NGOs)</p>	<p>Potential burden of regulation FSANZ provides the following documents to provide greater clarity to industry on the proposed regulatory measures, and to allow for consideration of benefits and burdens.</p> <ul style="list-style-type: none"> CRIS cost-benefit analysis (CBA, in SD3) compliance plans (SD4) <p>FSANZ's position is to create good food safety outcomes without placing unnecessary administrative or financial burdens on industry. To ensure this, a CBA is prepared for any proposed regulation. Risk management measures are then reassessed according to the findings of this analysis until suitable cost-effective measures are identified.</p> <p>Regulation and improvement of food safety FSANZ has taken these comments on board. For the reasons</p>

		<p>stated in this CFS and the supporting documents, our preferred approach is the strong integration of regulatory and non-regulatory measures (such as fact sheets and educational webinars) – particularly targeted at those with little knowledge of food safety risks and risk management.</p>
<p>Food safety schemes (FSS)</p>		
<p>The majority of industry considered that FSS are being used by the majority of horticultural growers.</p> <ul style="list-style-type: none"> • These FSS provide adequate standards for addressing food safety risks. • These schemes are science- and HACCP-based, internationally benchmarked as best practice, and independently audited. 	<p>Industry (industry bodies, large producers, quality assurance)</p>	<p>FSS as adequate standards FSANZ agrees that existing FSS do provide some level of protection. However, the efficacy of current industry FSS is unable to be determined due to limited information.</p> <p>It is also worth noting that foodborne illness outbreaks (involving horticultural produce) continue to occur, even where businesses have FSS in place. This suggests that such schemes alone may not be the most effective measure to address the food safety risk.</p> <p>Robustness of FSS FSANZ is aware of and agrees that many existing schemes have been well considered and are robust. FSANZ has considered them when making decisions about measures proposed in standards. However, these schemes are not currently legislated and as such there is no obligation to follow them or ensure there is consistent understanding of each requirement.</p> <p>For the reasons stated in this CFS and its supporting documents, our preferred approach aims to have the principles of these existing schemes (relating to preventing microbial disease outbreaks) adequately supported by a legislated national standard.</p>
<p>The majority of industry considered that the existing Global Food Safety Initiative (GFSI) benchmarked FSS should be recognised as meeting requirements.</p>	<p>Industry (industry bodies, producers, quality assurance)</p>	<p>Recognition of existing FSS FSANZ understands these views and considered existing FSS throughout the development of this proposal.</p> <p>In recognition of these schemes, and to reduce any burden on</p>

		<p>industry caused by introducing the proposed standards, FSANZ has aligned requirements in each standard to those in FSS.</p> <p>Businesses already operating under a current FSS should experience minimal regulatory impact. In turn, regulation will support the existing food safety principles contained in these schemes.</p>
<p>Industry advised that FSS while considered 'voluntary' are effectively mandatory in the current market.</p> <ul style="list-style-type: none"> Wholesale markets and major retailers require proof of a GFSI-benchmarked scheme on-farm. Horticultural Produce Agreements for growers supplying to wholesalers in Australia's central market locations include requirements for growers to operate under a GFSI-benchmarked program. 	<p>Industry (industry bodies)</p>	<p>'Voluntary' GFSI certified schemes</p> <p>FSANZ agrees that for producers supplying to major markets and retailers, the existing 'voluntary' schemes have become 'mandatory'. However, none of these FSS are legislated and not all of industry operates under a FSS.</p>
<p>Regulators considered that FSS are generally inadequate, in terms of variation in coverage and implementation.</p>	<p>Regulators (state and territory governments)</p>	<p>Percentage uptake of FSS</p> <p>FSANZ was originally asked by the Forum to investigate food safety in horticultural produce under proposal P1015. One of the findings (and therefore assumptions) of this proposal was that <i>'an estimated 70-80% of horticultural produce in Australia is grown under a food safety scheme that contains measures to control identified risks'</i>. On the strength of this and several other assumptions, that proposal was abandoned in favour of non-regulatory measures.</p> <p>New research shows this may not be a true representation of the current situation – with the percentage uptake of FSS being much lower across certain sectors. This could create a potential food</p>

		<p>safety risk.</p> <p>The current proposal has estimated the present level of FSS uptake as:</p> <ul style="list-style-type: none"> • berries sector: 75% • leafy vegetables sector: 25% • melons sector: 95% (high due to recent outbreaks). <p>However, in 2016 the Victorian Department of Economic Development, Jobs, Transport and Resources and FSANZ conducted a survey of strawberry growers in Victoria's Yarra Valley. The survey found that only 56% of growers (who participated in the survey) had a quality assurance/food safety program in place. More data on the uptake of FSS is in the CBA and CRIS.</p>
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Regulatory measures

<p>Industry expressed that regulation should bring smaller producers under recognised FSS, or at least under a minimum requirement. This should not discourage continuation of current production activities or stop new producers entering the market.</p>	<p>Industry (industry bodies, producers, NGOs, business)</p>	<p>Producers not participating in a FSS FSANZ agrees that those producers not currently managing production through any FSS are critical to reach. This will be easier under the proposed regulation.</p> <p>Flexibility in implementation 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 producers and/or processors. The framework identifies a range of management options including, for example, legislation, FSS and industry codes.</p> <p>Implementation of standards developed by FSANZ is the responsibility of the state and territory governments. A Horticulture Implementation Working Group (HIWG), consisting of representatives from states and territories, FSANZ and the</p>
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		<p>Australian Government Department of Agriculture, Water and the Environment (DAWE) has been engaged throughout this proposal and developed possible compliance plans to align with the draft risk management options, if adopted. Possible compliance plans are provided with this 2nd CFS.</p> <p>FSANZ welcomes feedback, including any known or perceived disincentives that introducing a new standard would create for small players and those considering entering these sectors. The CRIS includes dedicated questions for stakeholders seeking further information on this subject (in section 12).</p> <p>Note: FSANZ has also contacted the Australian Small Business and Family Enterprise Ombudsmen, seeking contact with smaller businesses in these sectors.</p>
<p>Industry requested that import conditions should align with domestic requirements (e.g. for berries) to achieve ‘a level playing field’.</p> <p>It was noted by industry that DAWE is considering potential introduction of import requirements that will recognise particular schemes or equivalence.</p>	<p>Industry (quality assurance)</p>	<p>Imported product DAWE will continue to manage the import of food into Australia through the Imported Food Program and supporting legislation.</p> <p>Australian legislation does not apply to the primary production and primary processing of imported foods, which occurs overseas. As such, FSANZ and DAWE have to take a different approach to the management of imported foods. Currently, FSANZ provides import risk advice to DAWE to guide their regulation and recently updated the advice on berries.</p> <p>Primary processing and primary production standards (i.e. chapter 4 of the Code) does not apply to New Zealand. These activities are managed under separate New Zealand legislation.</p> <p>It is unlikely that this proposal will change the existing import conditions.</p>
<p>Scope of the proposal</p>		

<p>Supportive of the current scope of primary production of berries, leafy vegetables and melons.</p>	<p>Commonwealth and state regulators, retailer</p>	<p>Scope of proposal P1052 Noted.</p>
<p>States, territories and industry each requested that, if regulatory measures are introduced, the scope should include all horticultural produce.</p> <ul style="list-style-type: none"> • Suggestions by regulators to include additional commodities (such as nuts, edible flowers, tomatoes, dates and semi-dried fruit, all fresh herbs and fresh coconut). • Suggestions by regulators that sprouts and minimally processed, ready-to-eat fruits and vegetables should remain in scope. 	<p>Regulators (Commonwealth and state) industry (industry bodies, producers, quality assurance)</p>	<p>Inclusion of additional products The Forum requested that FSANZ reconsider the need for a primary production and processing (PPP) standard to manage food safety for specified horticulture – namely, for berries, leafy vegetables, melons, seed sprouts and ready-to-eat and minimally processed fruits and vegetables.</p> <p>The scope of this proposal was limited to berries, leafy vegetables and melons, since standards were already in place for seed sprouts and ready-to-eat-fruits and vegetables.</p> <p>Ready-to-eat fruits and vegetables In Australia, businesses who handle ready-to-eat and processed fruits and vegetables for sale (e.g. pre-cut salads) are classed as ‘food businesses’. Food businesses are subject to the existing food safety requirements of chapter 3 of the Code. As a result, they were not included in the scope of this proposal.</p> <p>Sprouts FSANZ has already developed a PPP standard for seed sprouts (Standard 4.2.6). As a result, sprouts were not included in the scope of this proposal.</p> <p>FSANZ notes suggestions of products for future reviews.</p>
<p>Consider physical and chemical risks in additional to microbiological risks.</p>	<p>Regulators (state)</p>	<p>Physical and chemical hazards Chemical and physical hazards are generally considered low risk, and well managed in Australian food production through good agricultural, manufacturing and hygiene practice. Agriculture and veterinary chemicals (Agvet chemicals) are regulated under national and state-based laws. In the Code, maximum residue limits and contaminants are covered under Standards 1.4.1 and</p>

		<p>1.4.2. Standards 3.2.2 and 3.2.3 also require food businesses to protect food from the likelihood of all types of contamination.</p> <p>Further to this, chemical and physical risks were not included in the scope, as the Forum's primary objective was to review and reduce foodborne illness resulting from microbial contamination.</p>
Scope should focus on high-risk processes and not high-risk commodities.	Industry (industry bodies)	<p>Commodity v processes</p> <p>The Forum's decision to request FSANZ to review commodities (rather than processes) was based on the observation that outbreaks of foodborne illness continued to be associated with certain commodities. Commodities, rather than processes, are more strongly linked to recent and reoccurring outbreaks.</p> <p>Although FSANZ's review is based on commodities, the draft risk management options are aligned to processes within these commodity groups.</p>
Introduction of unannounced audits should be considered.	Industry (industry associations)	<p>Unannounced audits</p> <p>State and territory food regulators are responsible for monitoring compliance against the proposed leafy vegetables and melons standards. In some cases audits will be used as the verification tool. However, other monitoring arrangements could include self-assessment, sharing information with government food regulators, benchmarking, etc.</p> <p>Possible compliance plans prepared by the HIWG have been provided with this 2nd CFS for information and comment (in SD4).</p>
Evidence is lacking to support fresh berries be included in the proposal. Incidents with berries were linked to imported frozen products only, not the Australian fresh berry industry.	Regulators (state), industry (industry bodies, producers, quality assurance, NGOs)	<p>The inclusion of berries</p> <p>FSANZ acknowledges that outbreaks associated with fresh berries have been, so far, limited to imported product.</p> <p>Berries were brought into scope by the Forum, who was concerned that outbreaks could also occur in Australia and requested that</p>

		<p>FSANZ review this risk. Such reviews are important to determine what risk, if any, consumers (and in turn industry) may be exposed to; and if risk is identified, appropriate measures to reduce this risk. In assessing risk, FSANZ considers a broad range of factors such as hazard prevalence, methods of production and handling, and hazard control measures, in addition to Australian data on outbreaks of foodborne illness.</p> <p>As a result of our assessment, FSANZ is proposing minimal regulation in the berries sector. We have removed the requirement for preparation and approval of a food safety management statement (FSMS) in the berries sector. The removal of the FSMS also removes any routine audit of this sector by government food regulators against the proposed standards.</p> <p>Further information can be found in the:</p> <ul style="list-style-type: none"> • CRIS • microbiological assessment (SD2) • CBA (SD3) • Possible compliance plans (SD4) <p>All of these supporting documents are provided for review and comment with this 2nd CFS.</p>
<p>Consider cool chain maintenance and document through chain. There is poor control at the retail end with unrefrigerated product.</p>	<p>Regulators (state), industry (industry bodies, producers, quality assurance, NGOs)</p>	<p>Cool chain – Primary Production and Processing These comments are appreciated. FSANZ has considered temperature management of produce following harvest in the proposal.</p> <p>Cool chain – Retail Proposal P1052 does not extend to retail operations, which are already covered under chapter 3 of the Code.</p>
<p>Terminology</p>		

<p>Industry were concerned that calling commodities 'high-risk' creates a perception that products are dangerous to consume and that consumption may decrease.</p>	<p>Industry (industry bodies, industry schemes)</p>	<p>'High risk' terminology removed Following consultation, FSANZ has now amended the name of proposal P1052 from:</p> <ul style="list-style-type: none"> • Primary Production and Processing Requirements for High-risk Horticulture, to: • Primary Production and Processing Requirements for Horticulture (Berries, Leafy Vegetables and Melons). <p>The updated title removes misinterpretation of the term 'high-risk' in association with these horticulture products. Fruits and vegetables are an important part of a healthy diet. The proposal's scope is to review the risk of foodborne illness associated with horticultural commodities, rather than the nutritional and other health benefits of the commodities. The revised title also highlights the specific commodities being reviewed by FSANZ.</p> <p>No changes have been made to the proposal scope or body of work.</p>
<p>Further define and clarify the three commodity sectors included in scope.</p>	<p>Regulators (state), industry (industry bodies, quality assurance)</p>	<p>In-scope commodities FSANZ agrees that definitions should include the specific produce included in this proposal in each of the commodity sectors.</p> <p>FSANZ has considered commodity definitions already utilised in Codex and other sources. Definitions have been aligned with findings of our microbiological assessment.</p> <p>The current working definitions for these terms have been provided in the draft standards and explanatory statement (Attachments A and B).</p> <p>FSANZ encourages stakeholders to review these documents and provide feedback regarding the specific produce to be included in scope. FSANZ will continue collaborating with jurisdictions to refine these working definitions, as part of compliance planning.</p>

Traceability		
<p>One step forward and back approach supported but it is not the preferred approach.</p>	<p>Regulators (state)</p>	<p>One step forward and back traceability Through-chain traceability, beyond the one step forward one step back approach, would place a greater requirement on these three commodities than any other food product in Australia. In addition, the ability to trace beyond one step forward and back could be a significant resource burden where produce from different growers is combined.</p> <p>FSANZ considers one step forward and back traceability to be the most suitable option, particularly as the proposal focusses on primary production. Through-chain traceability could be considered in the future.</p>
<p>Through chain traceability is the preferred approach as the current minimum standard is from production to customer, and one step forward one step back traceability doesn't provide enough information in illness outbreaks.</p>	<p>Regulators (state), industry (industry bodies)</p>	<p>Through-chain traceability FSANZ encourages robust traceability programs. However, 'production to consumer' traceability is not within the scope of this primary production proposal.</p>
<p>Traceability is being adopted in the horticulture industry, driven partly by commercial imperatives, negating the need for regulation.</p>	<p>Industry (industry bodies)</p>	<p>Regulation of traceability FSANZ agrees with the importance of traceability. The fact that traceability is already being adopted in industry will help alleviate any burden felt by regulating this activity.</p> <p>FSANZ's position is that regulation of this activity remains important because:</p> <ul style="list-style-type: none"> • traceability is a critical step in risk management • regulation establishes traceability across industry • regulation provides a mechanism for states and territories to achieve better outcomes • not all businesses are currently adopting these measures.

<p>Explore technology to improve traceability. Development and trial of traceability options, especially digital options, should be encouraged.</p>	<p>Regulators (state) industry (industry bodies, producers, business)</p>	<p>Emerging technology FSANZ encourages the approval and use of emerging and novel technology to improve traceability. However, this is outside FSANZ's current purview.</p> <p>Traceability options The general requirement for traceability is set out in the proposed standards. As with all chapter 4 PPP standards, these requirements are outcomes based, rather than setting out prescriptive requirements.</p> <p>Implementation of any standard is the responsibility of the jurisdictions. A possible compliance plan developed by the jurisdictions is provided with this 2nd CFS and outlines the expectations for what is required to meet the proposed standard, if approved.</p>
<p>Traceability requirements should be practical, cost effective, align with retailer requirements and have the support of industry.</p>	<p>Industry (industry bodies, producers)</p>	<p>Cost effectiveness of traceability As part of these considerations FSANZ has also looked at traceability requirements in existing FSS.</p> <p>FSANZ has considered the practicalities and cost effectiveness of traceability (as a general principle). This is outlined in the CBA (SD3).</p> <p>Since the standards are outcomes based, FSANZ has not broken this down any further (i.e. compared particular methodologies). This will be managed by each jurisdiction.</p>
<p>Enforcement consistency</p>		
<p>Measures should take a national approach, as there are current challenges faced by variations in requirements between different jurisdictions.</p>	<p>Industry (industry bodies, producers, quality assurance)</p>	<p>Nationally consistent implementation FSANZ acknowledges the need for nationally consistent implementation.</p> <p>Implementation of standards developed by FSANZ is ultimately</p>

		<p>the responsibility of jurisdictions. The Implementation Subcommittee for Food Regulation (ISFR) established the HIWG to work towards consistent implementation. The HIWG used the Integrated Model for Standards Development and Consistent Implementation of PPP Standards to develop possible compliance plans.</p> <p>This approach also seeks to develop a range of tools to help businesses and regulators understand how a PPP standard, if approved, would be implemented by jurisdictions; further aiding nationally consistent implementation.</p>
Target businesses without schemes	Industry (industry bodies, producers, quality assurance)	<p>Targeted enforcement FSANZ agrees that businesses that do not currently operate under a FSS, or equivalent, should be identified:</p> <ul style="list-style-type: none"> a) to achieve parity across the industry in managing food safety risks and associated costs b) as these businesses may be less likely to understand food safety risks or the appropriate management of these risks, and therefore may be more likely to be connected with an illness or an outbreak. <p>This suggestion was also raised by the SDAG, which is also attended by state and territory regulators who will take the lead with implementation. The proposed standards would enable regulators to pro-actively monitor businesses not on a FSS.</p>
Non-regulatory measures		
There was strong support to consider education and training programs and guidelines for industry, education for consumers, and resources and training to improve food safety culture in industry.	All stakeholder groups	<p>Education and training Forum's request to FSANZ was to consider both regulatory and non-regulatory (e.g. education and training) measures. FSANZ has considered both in its assessment of this proposal. FSANZ's preferred position is for regulatory and non-regulatory measures to achieve the required food safety outcomes.</p>

<p>Food safety culture has been added to the GFSI benchmarking requirements and should be in GFSI-benchmarked schemes in their next revision.</p>	<p>Industry (industry bodies, producers)</p>	<p>Noted. FSANZ supports strengthening food safety culture to achieve better food safety outcomes.</p>
<p>There is a need for training of auditors to enable them to better focus on food safety issues and help businesses resolve problems.</p>	<p>Regulators (state), industry (experienced professional)</p>	<p>Auditor training FSANZ agrees that competent auditors and appropriate auditing is essential to the success of any regulation.</p> <p>If the proposed standards were introduced, monitoring would be the responsibility of the jurisdictions. Government food regulators have a wealth of knowledge about food safety in the primary industry sectors and the monitoring of food safety.</p> <p>In some instances, monitoring by these regulators would take the form of formal auditing. Auditing would be most likely when jurisdictions lacked confidence in the food safety of a business or the availability of evidence of food safety. Monitoring could take the form of self-assessment, sharing information with regulators, benchmarking, etc.</p> <p>Compliance plans have been provided with this 2nd CFS (SD4).</p>
<p>Training to support any new legislation would be beneficial.</p>	<p>Regulators (local)</p>	<p>General training FSANZ has proposed the following non-regulatory activities to support the proposed standards:</p> <ul style="list-style-type: none"> • fact sheets • animations • links to useful documents etc. • webinars • face to face meetings. <p>Further detail is provided in the CRIS.</p>

Adopt participatory or industry-led approach.	Industry (industry bodies, NGOs)	<p>Industry-led approach</p> <p>It is anticipated that non-regulatory measures would be created and delivered collaboratively between FSANZ, jurisdictions and peak industry bodies. All non-regulatory material would be made freely available to industry.</p>
Regulation alone will not address issues in the current situation.	Industry (industry bodies)	<p>Regulation in isolation</p> <p>FSANZ agrees that regulation in isolation will not address food safety issues in the berries, leafy vegetables or melons sectors.</p> <p>The draft standards have been prepared to support existing, as well as future, non-regulatory measures. Non-regulatory measures are also proposed (see list above).</p>
Other		
Fresh produce should have a labelling system that specifies food additives.	Business	<p>Food additives</p> <p>Consideration of food additives labelling is not within the scope of this proposal. Labelling requirements for food additives are covered under existing Standards 1.2.4 and 1.3.1.</p>
Office of Best Practice Regulation should be engaged.	Industry (NGO)	<p>A CRIS has been prepared in consultation with the Office of Best Practice Regulation (OBPR). The CRIS has been approved by the OBPR and has been included in this 2nd CFS.</p> <p>FSANZ will prepare a Decision Regulation Impact Statement after we consider the information provided in response to the 2nd CFS.</p>