FOOD STANDARDS Australia New Zealand
Te Mana Kounga Kai – Ahitereiria me Aotearoa

22 June 2022
206-22

Decision Regulation Impact Statement

P1052 – Primary Production and Processing Requirements for Horticulture (Berries, Leafy Vegetables and Melons)

Executive summary

Fresh fruit and vegetables are an important part of a healthy diet, and horticultural produce in Australia is generally considered safe. However, in Australia and internationally, foodborne illness, deaths, product recalls and other food safety incidents continue to be associated with fresh horticultural produce. Foodborne illnesses can be reduced through appropriate food safety measures.

This Decision Regulation Impact Statement (DRIS) relates to Proposal P1052 and examines regulatory and non-regulatory measures as options to address public health and safety risks from microbiological hazards that can be present in fresh berries, leafy vegetables (e.g. lettuce, baby spinach, herbs) and melons. It incorporates evidence gathered in two rounds of general consultation and other targeted engagement. Protecting public health is a key priority in FSANZ's consideration of options.

The scope of this proposal only covers Australian domestic growers and primary processers (e.g. production and initial handling) of the three commodity groups. This DRIS does not cover New Zealand or other countries, imports or stages of supply after growing and primary processing. For instance, wholesale, retail or substantive processing that changes the nature of commodities (e.g. cutting whole fruit, juicing or slicing) are out-of-scope.

It is estimated that foodborne illnesses from in-scope commodities cost Australian consumers and the Australian health-care system $20.8 million a year. Additionally, there are substantial costs to industry and state and territory governments in managing major food safety incidents, including the recalls of contaminated produce. Such costs include direct recall costs, the loss of produce and the cost of its disposal.

Food safety incidents can also result in substantive losses of future sales for the implicated business and sometimes the wider industry, as consumers may continue to avoid the product. For instance, Melons Australia reported a $100 million plus loss of melons market sales value in years following a widespread *Listeria* illness outbreak in melons in 2018. Total costs from outbreaks are both unpredictable and variable.

The options explored in the DRIS target parts of the growing and primary processing supply chain where risks are created. The options include:

- Option 1: Status quo
- Option 2: Regulation only: regulatory oversight of fresh berries, leafy vegetables and

melons through national standard/s
- Option 3, Preferred: Regulation (as for option 2) plus supporting non-regulatory guidance
- Option 4: Non-regulation only.

Option 3 is FSANZ's preferred option for best targeting key food safety risks and reducing foodborne illness attributed to berries, leafy vegetables and melons. Option 3 includes regulatory requirements for managing inputs for growing to ensure they are safe (water, fertiliser and other inputs), mandating worker training, cleaning of premises and equipment, traceability, and not selling unsafe food. This option also includes guidance and education as non-regulatory tools to support the standards.

Berries and melons
All options moving from the status quo show net benefits for berries and melons. The preferred option gives strong net benefits for berries and melons with central estimates of:
- $0.5 costs for every $1 benefit for berries
- $0.1 costs for every $1 benefit for melons.

Leafy vegetables
Net benefits of the proposed options are also positive for leafy vegetables, although the preferred option 3 is not as positive as for the other commodities, as a percentage of costs of the regulations. Option 3 gives a central estimate of $0.7 costs for every $1 benefit.

The above figures do not include further substantial benefits of avoided major incidents with associated management, recalls and sales impacts.

Implementation
The states and territories are responsible for implementing and enforcing the standards. In estimating costs, a series of assumptions have been made about what implementation could practically look like, noting some degree of uncertainty and several compliance options may be possible. The implementation approach by jurisdictions cannot be determined until a standard is set. It is possible that further increases in net benefits could occur by reducing the potential burden on industry. Such implementation approaches could include:
- low-cost recognition of existing market-led food safety schemes in demonstrating regulatory compliance—at least 60% of affected businesses are already on these schemes
- accommodating small businesses (many of which face challenges in the post-COVID environment), such as through an emphasis on education about food safety, assessing and minimising compliance burdens to small businesses where appropriate, and/or providing greater support with compliance.

There have been two rounds of consultation on this Proposal P1052. The second round included consultation on a Consultation RIS (CRIS) that was approved by the Office of Best Practice Regulation (OBPR), Ref ID 44097.

During consultation, stakeholders provided FSANZ with new information on business numbers, numbers of businesses on market-led schemes, number of harvest days a year, costs of food recalls and other useful information. FSANZ's Cost of Illness model has also been substantially revised during this period as part of a separate research project.

The best and most up-to-date information has been used to calculate the costs and benefits of options for this DRIS. The OBPR has assessed this DRIS as adequate to inform a final decision, in accordance with the requirements of the *Regulatory Impact Analysis Guide for Ministers' Meetings and National Standard Setting Bodies*. (OBPR Letter dated 18 March 2022 and Reference: OBPR22-01822)

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1. Introduction

In 2011, at the request of food ministers (then the Australia and New Zealand Food Regulation Ministerial Council), Food Standards Australia New Zealand (FSANZ) started a review of the primary production and processing (PPP) of all horticulture under proposal P1015 *Primary Production & Processing Standard for Horticulture*. In 2014, FSANZ decided that regulation of the entire horticulture sector was not warranted, including because:

- an estimated 70–80% of horticulture produce was grown under a food safety scheme (FSS), and
- a 'one size fits all' regulatory model for the whole horticulture sector was problematic.

The current proposal, P1052 *Primary Production and Processing Requirements for Horticulture (Berries, Leafy Vegetables and Melons)*, has been raised in response to food ministers requesting FSANZ to reassess food safety in specific horticulture sectors. Unlike P1015, this proposal considers only berries, leafy vegetables and melons.

The ministers' request was based on several reasons, including the priority of reducing foodborne illnesses. *Australia's Foodborne Illness Reduction Strategy 2018–21+*[1] was developed to address that priority. In 2018, increases of foodborne illness outbreaks in Australia were noted. Ministers agreed that food safety risk management of five horticulture sectors needed to be reassessed, in:

- leafy vegetables
- berries
- melons
- ready-to-eat minimally processed fruits and vegetables
- sprouts.

Food ministers were also guided by the fact that these five commodities are the sole subjects of commodity-specific annexes in the Codex Alimentarius Commission (Codex) Code of Hygienic Practice for Fresh Fruits and Vegetables (CoHP)(Codex 2017). These annexes were developed in collaboration with the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO). They include recommendations to better manage food safety concerns in each of these commodities.

As measures to some degree are already in place in the Australia New Zealand Food Standards Code (the Code) 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 berries, leafy vegetables and melons.

There have been two rounds of consultation on this proposal, including the recent November 2021 to February 2022 consultation that included a CRIS with questions to stakeholders on the costs and benefits of proposed options. Stakeholders provided useful feedback that has helped shape this DRIS. Such feedback included business numbers, numbers of businesses on market-led schemes, number of harvest days a year and costs of food recalls and other information.

2. Scope of the proposal

This proposal covers the commodities below that are produced in Australia. That excludes production in New Zealand or other countries.

The scope also excludes exports or stages of the supply chain after growing, harvesting and

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

primary processing. For instance, the scope excludes substantive processing of commodities, such as cutting whole fruit or juicing. The scope also excludes wholesaling and retailing parts of the supply chain. Wholesale and retail food safety requirements are already covered by Chapter 3 of the Code.

2.1 Commodities

The three horticulture commodity groups in scope for this proposal are:

- fresh berries
- fresh leafy vegetables
- fresh melons.

The examples of each commodity group provided below are not exhaustive. The range of commodities covered is guided by FSANZ's microbiological assessment of berries, leafy vegetables and melons, provided as a supporting document with the 2nd call for submissions (CFS).

Berries

The four major berries grown in Australia are:

- strawberries,
- blueberries, and
- *Rubus* berries (mainly raspberries and blackberries).

There are also small quantities grown of the *Rubus* hybrid cultivars of boysenberry, loganberry, silvanberry and youngberry.

Leafy vegetables

Fresh leafy vegetables and herbs include all vegetables and herbs of a leafy nature in which the leaf is intended to be consumed fresh and raw. Examples are microgreens, baby leaves, lettuce, spinach, cabbages, chicory, leafy herbs (e.g. coriander, basil, parsley) and watercress.

The main leafy vegetable commodities grown in Australia include:

- lettuce
- leafy salad vegetables
- fresh herbs
- cabbage
- English spinach
- silverbeet
- kale
- leafy Asian vegetables.

Melons

The main melon commodities grown in Australia include:

- watermelon
- rockmelon
- honeydew.

Other melons grown in much smaller quantities include galia melon, charentais melon, Korean melon, hami melon and piel de sapo.

2.2 Activities

This proposal and the scope of activities sit within Chapter 4 – Primary Production and Processing Standards of the Code. The activities in scope for this proposal can be summarised as primary production and primary processing, as detailed below.

Primary production

For the purposes of P1052, primary production means a business, enterprise or activity that is involved in one or more of the following activities in relation to a specified commodity:

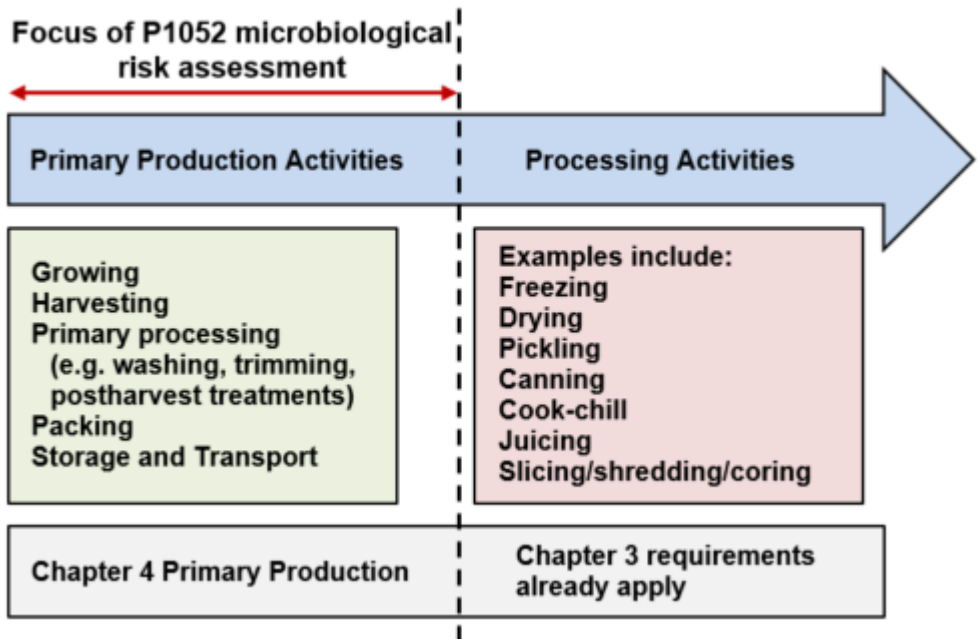
- growing and cultivating
- picking, collecting and harvesting
- treating (e.g. washing, sanitising), trimming, sorting, combining the same produce type on the primary production premises
- storing including cold/modified atmosphere storage on the primary production premises
- packing or packaging (excluding final packaging for retail sale) on the primary production premises
- transportation to, on, between or from primary production premises.

Primary processing

For the purposes of P1052, primary processing means a business, enterprise or activity that is involved in one or more of the following activities in relation to a specified commodity:

- treating (e.g. washing, sanitising), trimming, sorting, combining the same produce type on the primary processing premises
- storing including cold/modified atmosphere storage on the primary processing premises
- packing or packaging (excluding final packaging for retail sale) on the primary processing premises
- transportation to and between primary processing premises.

A schematic representation of the activities in scope of proposal P1052 is provided below.



3. Purpose of this document

This document outlines FSANZ's process in determining the most appropriate options for reducing food safety risk in the berries, leafy vegetables and melons sectors in Australia. The protection of public health and safety was the top priority that drove this process.

This DRIS has been prepared in line with the Office of Best Practice Regulation (OBPR) guideline *Regulation Impact Analysis Guide for Ministers' Meetings and National Standards Setting Bodies and assessed by OBPR as adequate* to inform a final decision. OBPR Letter dated 18 March 2022 and Reference: OBPR22-01822.

There are seven key questions to be considered by policy makers when considering regulation. These are:

- What is the policy problem?
- Why is government action needed?
- What policy options are to be considered?
- What is the likely net benefit of each option?
- Who was consulted and how was their feedback incorporated?
- What is the best option from those considered?
- How will the chosen option be implemented and evaluated?

This DRIS summarises FSANZ's consideration and responses to these questions, the FSANZ process, and the technical work.

4. What is the policy problem?

4.1 Overview

Fresh fruit and vegetables are an important part of a healthy diet, and horticultural produce in Australia is generally considered safe. However, in Australia and internationally, foodborne illness, deaths, product recalls and other food safety incidents continue to be associated with fresh horticultural produce. Foodborne illnesses can be reduced through appropriate food safety measures.

The impacts of foodborne illnesses are felt by:

- consumers (illness and potential death, particularly in the elderly)
- businesses (both affected and implicated businesses)
- 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 are estimated to cost the Australian economy $20.8 million a year in consumer illness and healthcare costs plus substantial recall costs and associated losses in market values. Melons Australia reported that the melons sector experienced a $100 million plus loss of market sales value in years following a widespread listeria illness outbreak for the melons sector in 2018. Such events are largely preventable through appropriate food safety measures.

To determine the extent of the problem, this section details findings from a review of scientific literature, outbreak reports, recall data, Australian population consumption patterns, expert elicitation and a cost-benefit analysis (CBA).

4.2 Foodborne illness

There is an estimated 4.1 million cases of foodborne gastroenteritis in Australia each year, plus 5,140 cases of non-gastrointestinal illness, 35,840 cases of sequelae (conditions that arise following illness, such as reactive arthritis), 31,920 hospitalisations and 86 deaths (Department of Health 2014). Costs associated with foodborne illness in Australia are estimated at $2.14 billion each year (reference: Australian National University (ANU) Cost of Foodborne Illness Report 2022[2]). Of the known microbiological causes, norovirus (NoV), other pathogenic *Escherichia coli*, *Campylobacter* and *Salmonella* have the highest annual costs. However, the cause of illness is not determined in around 80% of cases. Section 4.4 contains more details.

Multiple outbreaks in Australia have been associated with fresh horticultural produce. Previous FSANZ work (proposal P1015) found five outbreaks associated with fresh horticultural produce occurred 1990–2011. Three of the outbreaks were associated with domestically produced rockmelon, honeydew melon and papaya.

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:

- two outbreaks were linked to Hepatitis A virus in imported berries—no outbreaks were linked to domestic 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 domestic melons.

Internationally, berries, leafy vegetables and melons are in the top four fresh horticultural produce sectors most commonly associated with outbreaks. In 2011–2019, nine international outbreaks were linked to berries, 16 outbreaks were linked to leafy vegetables and three outbreaks were linked to melons.

In addition to the outbreaks listed above, sporadic cases of foodborne illness (i.e. those not connected with an outbreak) also add to the total burden of illness. Refer to microbiological assessment supporting document 2 (page 14). Outbreak data has limitations as causes are difficult to determine; a specific source is not identified in half of foodborne outbreaks.[3] Therefore, it is important to recognise that outbreak data are likely to only represent a small proportion of actual cases of foodborne illness, due to the reasons outlined in the supporting document.

4.3 Food recalls and national incidents

As food produced in one state can be sold in other states and territories, food recalls and incidents are often a national issue.

Horticultural produce accounts for 9% of food recalls in Australia (FSANZ data 1989–2019). Between 2011 and 2020 there were:

- three recalls for domestically produced leafy vegetables
    - two recalls in 2016 (*Salmonella* Anatum), both associated with an outbreak

[2] This Cost of Illness report looks at the range of costs associated with numerous different types of foodborne illnesses, including but not limited to treatment and medical costs, lost work hours, and willingness to pay to avoid discomfort caused by illness. See: <public web link to come>

[3] Astridge K, McPherson M, Knope K, Gregory J, Kardamanidis K, Bell E, Kirk M (2011) Foodborne disease outbreaks in Australia 2001-2009. Food Australia 63:44–50

    - one recall in 2020 (*Salmonella* spp.)
- two recalls for domestically produced melons
    - one in 2016 (*Salmonella* spp.), associated with an outbreak
    - one in 2018 (*L. monocytogenes*), also associated with an outbreak.

During 2016–2018, there were five national food incidents involving multi-jurisdictional outbreaks of foodborne illness. Horticultural products were the only products implicated in these incidents.

4.4 Costs of illness

The impact of illness associated with horticultural produce is significant in terms of people's health (illness and/or death). FSANZ has estimated the annual cost of illness in Australia attributable to the berries, leafy vegetables and melon sectors.

This cost was determined by:

- deducing the total illness burden on consumers and healthcare systems
- asking an expert panel to determine the percentage burden attributed to each commodity (based on their expert knowledge)
- using these percentages to estimate the annual cost of illness attributed to each commodity sector.

Current cost estimates of illness are provided in Table 1.

Table 1. Current estimates of annual cost of illness

Commodity	Total annual illness cost $
Berries	4.4 million
Leafy vegetables	9.3 million
Melons	7.1 million

FSANZ's Cost of Illness model has been substantially revised since the CRIS stage as part of a separate research project conducted by the ANU to review the model for estimating cost of illness. A decision was made to use the new model to estimate the likely illness cost savings due to the substantially increased sophistication of the methodology. Therefore, the best and most up-to-date information has been used to calculate the costs and benefits of options for this DRIS.

The main reason new cost of illness estimates in this DRIS are substantially lower is that a more conservative approach to estimating the longer-term health impacts of salmonella illness has been taken.

Therefore, the use of the new draft model has resulted in downwards revisions of the likely cost saving associated with the proposed interventions since the CRIS stage. In particular, cost savings estimates have reduced for longer-term salmonella illness from outbreaks caused by leafy vegetables and melons.

The above annual cost estimates do not include recall costs or market value losses to industry due to loss of reputation or altered consumer purchasing decisions. Those costs are hard to predict and can be significant.

Further details are in our updated CBA including the CBA's main body and its Appendix 2.

4.5 Costs to industry

Product recalls and food safety outbreaks cost industry in terms of both dollars and loss of reputation. Estimating the business costs associated with a food safety incident or outbreak is difficult. The magnitude of the cost to the business directly involved and to the wider industry is driven by a wide range of factors including:

- whether the food is a luxury or a staple food
- how identifiable the product is within the market
- whether any deaths occur
- the level of media attention that is received.

As part of our CBA of cost to industry, we examined the 2018 outbreak associated with *L. monocytogenes* in rockmelons, as a case study. This outbreak resulted in 22 cases of illness and eight deaths, temporarily closed an export market and impacted the broader domestic market.

Losses to growers (not just the single implicated grower) were previously estimated by FSANZ at around $15 million, but Melons Australia in its February 2022 submission put the total estimated loss at $100 million. For 2018, the outbreak year, there was a 9.8% price decline, 68.9% decline in production volume (tonnes) and a 71.9% decline in value compared to 2017. The market recovered over time, after further costs were incurred. That also led to the melons industry implementing significant extra safety measures since 2018, including best practice guidance and a food safety toolbox. Further details are provided in Appendix 5 of the CBA.

4.6 Microbiological hazards

FSANZ has investigated the microbiological hazards that may occur during primary production and processing for berries, leafy vegetables and melons. Table 2 lists the main microbiological hazards identified as contributing to illness in Australia. We considered what microorganisms are in the Australian environment, their prevalence, and their ability to survive and grow in each type of produce. We also considered Australian consumption patterns and the likelihood of the identified microorganisms causing foodborne illness. For further details on methodology and conclusions, see our microbiological assessment.

Table 2. Microbiological hazards identified in the Australian context

Commodity	Hazard
Berries	• norovirus (NoV) • shiga toxin-producing *Escherichia coli* (STEC) • Hepatitis A virus – imported berries only
Leafy vegetables	• non-typhoidal *Salmonella* spp. (*Salmonella*) • *Listeria monocytogenes* • STEC
Melons	• *L. monocytogenes* • non-typhoidal *Salmonella* spp.

4.7 Production risk factors

To understand how products can become contaminated by the identified microorganisms, we looked at key steps in growing, harvesting and on-farm processing of berries, leafy vegetables and melons. This included consideration of what the products may be exposed to in growing and pack house environments, and during handling. We concluded that contamination is most likely 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 areas exposed to urban or industrial waste
- flooding or other extreme weather events
- application of untreated or insufficiently treated manure or composts
- 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.

Production risk factors, and the level of risk they pose, varied between commodities (berries, leafy vegetables and melons), which we discuss later. Further details of our microbiological assessment are in another supporting document.

4.8 National regulatory requirements

There are currently no national or consistent food safety regulatory requirements applying to the primary production and processing of horticultural products, except for seed sprouts. Food safety of horticultural produce in Australia is managed through a combination of some state and territory level regulatory measures and industry-driven, non-regulatory measures. The current regulatory arrangements are further detailed in supporting document (SD)1 of our 2nd CFS.

Primary production and processing of horticultural products is currently regulated to varying degrees by the states and territories (jurisdictions) and not all jurisdictions have measures in place. Some jurisdictions such as New South Wales, Queensland and South Australia have amended their food acts or relevant regulations to apply food safety requirements to some horticulture primary production/ processing businesses; however requirements are not consistent across the jurisdictions.

In some jurisdictions, powers of entry have been limited to emergency orders issued under their food acts, where substantial evidence of a food safety incident has already occurred. Also, under current jurisdictional food acts primary producers are exempt from needing to register or notify their regulator about the existence of their food business. As a result, jurisdictions are constrained in their ability to proactively work with growers and primary processers to enhance food safety.

Chapter 3 of the Code sets out general food safety requirements for ‘food businesses’, which excludes primary producers (such as growers, harvesters and packers) unless they sell food directly to the consumer. This presents a national regulatory gap.

During both calls for submissions for P1052, all industry stakeholders and some others noted a need for national consistency should regulation be introduced.

We are aware that national consistency is a particular issue for larger businesses, as they are more likely to be operating across multiple jurisdictions. The number of large businesses employing 200 or more people is estimated to be 53 berry businesses, 32 leafy vegetable businesses and 6 melon businesses. National or semi-national operations may increase due to general trends towards business consolidation in the agricultural sector to achieve larger economies of size, demand for these types of food increasing and ongoing all-year-round demand requiring production in different climate zones. Farming across multiple states and territories to ensure continuous supply and the need for nationally consistent requirements was also raised by farm managers during FSANZ on-site visits.

Lack of consistency between jurisdictions creates an uneven playing field between businesses operating in different regions, and has led to industry frustration. Inconsistency creates additional administration, particularly for businesses with multi-jurisdiction presence, who must develop and maintain jurisdiction-specific approaches to food safety.

Facilitating national consistency is a priority of food regulation. It is key to maintaining a strong, robust and agile food regulation system. The Integrated Model for Standards Development and Consistent Implementation of Primary Production and Processing Standards[4] aims to support national consistency with minimal-cost effective regulation (see section 8.2).

4.9 Food safety schemes

The berry, leafy vegetable and melon sectors operate to varying degrees under industry and market-led food safety schemes (FSS), which are non-regulatory and are largely to meet requirements of retailers. Businesses can also voluntarily join FSS. For simplicity, FSS have sometimes been stated as 'voluntary schemes' in this DRIS and accompanying CBA.

FSS provide guidance on how produce should be grown, packed, prepared and distributed and food safety aspects include managing inputs; premises, equipment and personnel hygiene; and animals and pests. While FSS are not mandatory, most large retailers require them. This has led to 'non-voluntary' FSS participation by many primary production and processing businesses. 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, meaning incomplete and inconsistent coverage across the sectors
- it creates an uneven playing field (with some businesses using a 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 a 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 a FSS in place, outbreaks have continued to occur. This suggests 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.

Illnesses, recalls and outbreaks continue to occur in the current environment, which relies mainly on self-regulation through FSS. Illness has also been linked to businesses with a FSS in place. This indicates there may remain inconsistencies in the implementation of some FSS requirements and their third-party audit.

4.10 Traceability weakness

The ability to track products quickly if a food safety issue occurs can be critical to preventing illness, including the need to identify the source of produce causing illness. There are prescriptive requirements for traceability in FSS, but these only apply to businesses

[4] https://foodregulation.gov.au/internet/fr/publishing.nsf/Content/ISFR

operating under those schemes. Chapter 3 of the Code contains traceability requirements under receipt and recall clauses, but these clauses do not apply to primary producers/processors (unless selling direct to consumers).

5. Why is government action needed?

5.1 Overview

FSANZ considers that government action is required to further reduce instances of foodborne illness, and to protect consumers, industry, the health care system and our export markets. Protection of public health and safety is the top priority.

With the current measures, there remain risks of illness associated with fresh berries, leafy vegetables and melons in Australia, as outlined in the problem section. Current measures rely heavily on industry FSS that have incomplete and inconsistent uptake across the sector, creating food safety gaps.

Currently, government food regulators are limited in their ability to proactively manage horticulture production and primary processing, as they have limited knowledge and oversight of businesses and limited access to properties. This situation impacts consumers who are unable to identify produce from primary producers/ processors with adequately safe production practices. Industry is impacted by different jurisdictional requirements and/or costs to those implementing a FSS. National requirements can support consistency in implementation and effectiveness and better ensure regulatory certainty for businesses.

5.2 Consumers

Consumers lack any visibility of the primary production and processing of horticulture produce.

This lack of visibility reduces the effectiveness of market forces. Consumers can react to outbreaks, limiting or ceasing their purchase of produce associated with an outbreak. However, in many cases, illness is not associated with a known cause, so minimal information is available to guide their decisions. Even in outbreak situations, the cause of the foodborne illness may not be identified. There is also a delay in identifying a source of illness. Given the relatively quick time from harvest to point of sale, and the short interval between purchase and consumption of fresh berries, leafy vegetable and melons, there are often difficulties informing consumers of risks prior to consumption.

Consumers expect all produce to be safe. The protection of consumers and public health is a rationale for government action. Costs to consumers and health-care alone from food illnesses from berries, leafy vegetables and melons are around $20.8 million a year.

5.3 Businesses

It is in the interest of primary producers and processors to provide safe produce to customers. Providing safe produce avoids illness, avoids loss of sales and long-term reputational damage, both for affected businesses and the entire industry. However, there is a wide range of understanding and commitment to food safety across the industry. This can be due to an absence of knowledge about food safety, an unwillingness to invest in food safety, competing priorities for the business, and the fact that consumers cannot easily distinguish between those businesses that do and do not have a strong food safety culture. Robust food safety management across the entire sector is key in protecting public health. Achieving this level of management is a rationale for government action.

Since there is no mandatory requirement for participation in a FSS, this creates an uneven playing field for businesses within the sector. This could be mitigated by government regulation, which would apply to all businesses. Government intervention could also protect safe-food businesses from reputational and financial damage resulting from outbreaks caused by businesses that do not prioritise food safety.

5.4 National regulation

There is currently a lack of national regulation for the primary production and primary processing of berries, leafy vegetables and melons. This makes it difficult for government food regulators to work pro-actively with industry, to create a strong food safety culture and deliver safe produce. The current lack of national legislation also results in national inconsistency, regulatory uncertainty and an uneven playing field between businesses. This can create unnecessary difficulties, for example, for large businesses farming and distributing produce across state and territory borders.

Government regulation in the form of a national standard would enhance the ability of regulators to work with primary producers and processors and create a nationally consistent, best-practice approach to food safety. It would also increase regulatory certainty and even-up requirements between businesses.

5.5 Exports

Australia exports limited quantities of fresh berries, leafy vegetables and melons. Export data is provided in Appendix 6 of the CBA. Exports of horticultural produce are facilitated by the Department of Agriculture, Water and Environment (DAWE) which issues phytosanitary certificates under export legislation. Food safety certification may be issued where it is an importing country requirement, but additional measures must be put in place. In the event of a food safety incident linked to exported horticultural produce, DAWE participates in the national incident response, including tracing implicated export consignments.

Australia's reputation for safe, high-quality produce has value for the whole agricultural sector. Protection of this reputation is important for trade, and the maintenance of price premiums for some Australian goods. An issue with one type of fresh produce can affect consumers' confidence in the entire horticulture sector, and potentially unrelated sectors by reducing the overall confidence in Australian goods.

Strengthening national food safety regulation supports the protection of Australia's trading reputation and is a rationale for government action.

5.6 Traceability

As with all foods, traceability of fresh produce is essential to effectively manage a food safety concern, such as an illness outbreak. Traceability is required to identify produce that may be affected, and to identify and release unaffected produce. Lack of robust, timely traceability is a key issue facing government food regulators when investigating occurrences of foodborne illness. This is particularly true for co-mingled produce sourced from multiple farms distributed through complex supply chains. Currently, there is no regulated requirement for traceability for fresh produce from the farm. Chapter 3 of the Code contains traceability requirements under receipt and recall clauses, but these clauses do not apply to primary producers/processors (unless selling direct to consumers).

Government regulation, such as including a traceability clause in the proposed PPP standards, would create an enforceable traceability requirement across the three commodity sectors. This would aid in identifying the source of the illness, identifying affected produce, reducing resources required of regulators, enabling corrective actions to be targeted, and better protect industry and consumers. The protection of businesses and consumers is a rationale for government action.

6. What policy options are to be considered?

6.1 Overview

The options identified to address foodborne illness linked to berries, leafy vegetables and melons are:

1. maintaining the status quo
2. introducing regulatory measures: separate standards for berries, leafy vegetables and melons
3. introducing a combination of regulatory and non-regulatory measures
4. introducing non-regulatory measures only.

The above are all of the options available to manage food safety in Australia and include measures currently in place. Given the different risk profiles, industry structures, cost and benefits, and other factors relevant to each commodity, food safety measures can be tailored to a commodity to best mitigate risks and meet policy objectives. Each of the available options is outlined below. Where regulatory measures are considered (options 2 and 3), draft standards and associated compliance plans are outlined, to identify the nature of changes that primary producers and processors would be required to implement.

6.2 Option 1: Retain the status quo

When considering any intervention (particularly regulation), FSANZ must first consider whether the status quo represents the best option for Australia. If so, the status quo would be recommended and retained, and P1052 would be abandoned.

The current food safety management environment for primary production and processing of horticultural products in Australia is outlined in detail in SD1 of the 2nd CFS. It includes both non-regulatory and regulatory measures applicable to primary production and processing. A summary is provided below.

Current non-regulatory measures

Non-regulatory measures include FSS and guidelines, which aim to ensure the food safety of horticultural products. Comprehensive but voluntary on-farm FSS provide guidance on how produce should be grown, packed, prepared and distributed. Compliance with the requirements of these schemes is assessed through a third-party audit. While these schemes are not mandatory, most large retailers require them. Many of these schemes are benchmarked to international Global Food Safety Initiative (GFSI) requirements.

FSANZ's analysis (see SD1 of the 2nd CFS), indicates that prescribed GFSI control measures align well with our identified risk factors, including traceability, with no significant gaps in GFSI requirements. Note, we did not assess the effectiveness of GFSI requirements. Jurisdictions are currently examining the effectiveness of GFSI requirements in more detail.

FSS uptake by sectors is varied. FSANZ estimates that approximately 75% of berry businesses, 50% of leafy vegetable businesses and 95% of melon businesses are on a FSS

(details are provided in the CBA). FSANZ believes that medium and large businesses are more likely to be on a FSS than smaller businesses. Since the CRIS, FSANZ has made upward revisions to the percentage of leafy vegetable businesses estimated be on a FSS after considering stakeholder feedback, Freshcare certifications and Australian Bureau of Statistics data.

In addition to FSS, other non-regulatory measures have been developed by jurisdictions, industry and academics to assist primary producers. These include guidelines, codes of practice and other documented advice. Some of these resources place more emphasis on food safety practices than others. Some additional initiatives targeting food safety and traceability 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.

ACCC

The Australian Competition and Consumer Commission's (ACCC) non-mandatory Horticulture Code of Practice stipulates that horticulture growers and traders have a Produce Agreement, which includes that produce be grown and packed under a food safety program and subject to an annual third-party audit. This arrangement is not enforced by the ACCC.

Current regulatory measures

National

In Australia, there are currently no national regulatory food safety requirements applying to the primary production and processing of horticultural products, except for seed sprouts. Chapter 3 of the Code applies to 'food businesses', which excludes primary production unless food is sold directly to the public.

Jurisdictional

The primary production and processing of horticultural products is regulated to varying degrees by each state and territory. Some jurisdictions have amended the definitions of 'food business' and 'primary food production' in their Food Acts to apply food safety requirements to horticulture primary production and processing. For example, New South Wales, Queensland and South Australia all have food safety requirements for some aspects of horticulture in regulations under their Food Acts. However, these requirements are not specific for berries, leafy vegetables or melons. Further information is provided in SD1 of the 2nd CFS.

Import and export

DAWE administers legislation to regulate the import and export of agricultural products, including food and plant products. The main focus of the *Biosecurity Act 2015* is to prevent the introduction and spread of pests and diseases. Imported food that meets biosecurity requirements is then monitored for compliance with the Code and the requirements of public health and safety under the *Imported Food Control Act 1992*. For many exported foods, under the *Export Control Act 2020* they must be fit for human consumption and meet importing country requirements, including for food safety. Requirements for exported plant products mainly relate to biosecurity.

Summary

Under the status quo option, no changes would be made to the regulatory and non-regulatory measures described above.

6.3 Option 2: Regulatory measures – standards for berries, leafy vegetables and melons

In this option, the proposed regulatory measures would take the form of three PPP standards in the Code (one standard each for berries, leafy vegetables and melons). Each proposed draft standard was provided in full in the main body of our 2nd Call for Submissions report and costed in the CBA. A comparative summary of the requirements of each standard is provided in Table 3.

Each proposed standard was designed:

- based on the findings of our microbiological assessment for that commodity
- to optimise costs and benefit, as guided by our CBA
- to contribute to food safety management
- to be outcomes based, rather than prescriptive
- to align with requirements in existing FSANZ standards and industry FSS
- so that they represent the minimum requirements to address key food safety risks (i.e. represent the lightest touch)
- with regard to international measures including Codex.

The proposed standards are different for each commodity, due to differences in the:

- inherent characteristics of each commodity
- primary production and processing of each commodity
- hazards identified by the microbiological assessment
- attributed illness for each commodity, discussed in the CBA
- cost and benefit ratios for each sector, discussed in the CBA.

Implementation of the standards is the responsibility of jurisdictions. The regulatory measures may require primary producers and processors of leafy vegetables and melons to be registered or licenced with jurisdictions, regardless of whether or not they are on a FSS. Jurisdictions will decide how any registration, licensing and audits/monitoring are implemented. Officials in jurisdictions are currently working together, with industry and FSS scheme providers on an implementation framework, including exploring a recognition model for businesses already under a GFSI-benchmarked FSS scheme.

Impacts of regulation are likely to be lower for primary producers and processors who currently operate under an accredited FSS compared to those not on a FSS. That is because FSS schemes already include requirements similar to FSANZ's proposed food safety requirements. Further, if jurisdictions develop a recognition system for businesses on FSS, compliance costs could be less. FSANZ understands from industry and jurisdiction feedback that medium and large businesses are more likely to be on a FSS than smaller businesses.

FSANZ also considered international standards when designing regulatory measures.

FSANZ identified primary production and processing activities strongly linked to food safety risk in each of the berries, leafy vegetables and melons sectors. After considering the findings of the CBA and the current regulatory and non-regulatory position, FSANZ identified the key risk factors where regulatory mitigation measures would likely reduce foodborne illness attributed to these commodities.

FSANZ has included minimal traceability (one step forward and one step back, and for

berries, to the growing site) for all three commodity groups as part of the proposed regulation. Traceability is an essential management tool in the event of an outbreak or product recall.

A safe sale and supply clause has also been included. This general clause is similar to that already in Standard 4.2.6 for seed sprouts. It sets out an obligation to not sell or supply commodities for human consumption where the seller/supplier ought reasonably know that the product is unacceptable and may constitute a food safety risk.

Berries – determining appropriate regulatory measures

Identified risk factors

Microbial hazards (pathogens) identified by FSANZ for the primary production and processing of berries were Hepatitis A virus (imports only), NoV and STEC. These were based on Australian and international outbreak data and international research. Characteristics of each hazard and food safety risk are summarised in section 4.7 (Production risk factors) and in the microbiological assessment.

Most foodborne NoV in a primary production context are likely to originate from infected food handlers contaminating produce during harvesting, packing and on-farm transportation.

Our proposed measures include clauses similar to those in the berries annex of the Codex CoHP. For berries, FSANZ has reduced scope of its proposed regulatory measures, compared to the Codex approach, largely in response to the lack of outbreaks directly connected with Australian produce – noting that lack of known outbreaks to-date does not equate to zero risk and the challenges in identifying outbreaks in Section 4.2.

Some activities deemed more relevant for leafy vegetables and melons were not strongly linked to food safety risk in the berries sector. Specific food safety risk factors that we attributed to berries and selected for further consideration/ regulation were:

- the application of untreated or insufficiently treated manure or compost amendments, particularly for berries growing close to the ground
- the use of contaminated water for irrigation and application of agricultural chemicals
- contamination and cross-contamination due to poor worker and equipment hygiene, both at harvest and postharvest.

Cost-benefit analysis

FSANZ completed an economic analysis of costs and benefits to inform the DRIS. A large part of estimating benefits of options was estimating reductions in annual illness cases and hence illness costs. Total illness costs for berries were the lowest of the three commodities considered. The majority of the costs were associated with NoV illnesses. Hepatitis A cases were not included in the costing for domestic berries. There are likely some illnesses attributed to domestic berries that are unreported.

Appendix 2 of the CBA provides more details of the expert elicitation process for berries and the other two commodities.

Other considerations

Under the proposals, leafy vegetables and melons will require a Food Safety Management Statement (FSMS). Berries have different risk factors. Therefore, the notification requirement for berries is proposed instead of a FSMS. FSANZ estimates there are 750 (+/- 250) berry producers nationally, and that up to 75% of these businesses are operating in accordance

with a FSS.

Regulatory risk management measures for berries

For berries, FSANZ proposes management of the following key risks through regulation:

- inputs (water, soil and fertiliser) – after requests during the 2nd consultation round to include soil and fertiliser as regulated inputs
- harvest and field packing (particularly the health and hygiene of workers and the cleanliness of tools and equipment)
- pack house and post-harvest (particularly the health and hygiene of workers and the cleanliness of equipment and premises).

FSANZ also proposes regulatory measures to support the management of the three key risks identified above:

- notification of the business
- minimal traceability
- safe sale and supply.

The proposed notification requirement would require berry primary producers and processors to provide basic details (name, address, etc.) to their relevant state or territory food authority. This information enables authorities to identify businesses to which the proposed regulation applies, and to provide non-regulatory support (e.g. fact sheets, face-to-face meetings) to help manage food safety. FSANZ does not propose to require the berries industry to comply with the General Food Safety Management Requirements (GFSMR) described in Standard 4.1.1 of the Code.[5]

A significant impact could be expected for the estimated 25% of berries businesses nationally (approximately 188 businesses) that may not be working under a FSS. These businesses may be key contributors to food safety risk and therefore reputational risk across the berries sector.

Leafy vegetables – determining appropriate regulatory measures

Identified risk factors

In 2011–2019 there were three reported outbreaks linked to the production of leafy vegetables in Australia:

- 2012 – *Salmonella* Anatum
- 2014 – NoV
- 2016 – *Salmonella* Anatum.

Between 2011 and 2020, there were three Australian recalls issued for domestically produced leafy vegetables. These were:

- 2012 – *Salmonella* Anatum, associated with an outbreak
- 2016 – *Salmonella* Anatum, associated with an outbreak
- 2020 – *Salmonella* spp.

Over this same period, 16 international outbreaks were linked to leafy vegetables. Hazards identified included (in order of descending frequency) *E.coli*, *Cyclospora*, NoV, *Listeria*, *Salmonella*, *Shigella* and *Yersinia*. The leafy vegetable sector is one of the four fresh minimally processed horticulture sectors most commonly associated with international

[5] The GFSMR requires a food safety management statement to be approved by the relevant state or territory government food regulator and engages potential ongoing verification activities, accrues licencing fees etc.

outbreaks. Further detail about outbreaks and prevalence is in section 4 of our microbiological assessment in another supporting document.

Microbial hazards of concern were based on consideration of Australian and international outbreak data and other international research. Each hazard's characteristics are summarised in the microbiological assessment, with detail in its Appendices 7, 9 and 10.

Microbial hazards of leafy vegetables that FSANZ considered relevant in the Australian context, and further examined, were:

- *Salmonella* spp.
- STEC
- *L. monocytogenes*.

Food safety risk factors that FSANZ attributed to leafy vegetables and regulatory risk management measures considered and proposed

Food safety risk factors	Considered	Proposed
incursion by wildlife and domestic animals	✓	✓
characteristics of the production site including surrounding and prior land use, particularly for open-field production	✓	✓
occurrence of weather events, such as flooding or heavy rain, which could transfer pathogens to produce, fields, or irrigation water sources	✓	✓
contamination of seeds and seedlings	✓	✓
application of untreated or insufficiently treated manure or compost amendments, particularly for plants growing close to the ground	✓	✓
use of contaminated water for irrigation and for the application of agricultural chemicals	✓	✓
contamination and cross-contamination due to poor worker and equipment hygiene, both at harvest and postharvest	✓	✓
inadequate washing and sanitiser application	✓	✓
inadequate cold chain maintenance	✓	✓

FSANZ has also included the following proposed regulatory measures to support the management of the key risks factors identified above:

- GFSMR
- minimal traceability
- safe sale and supply.

The GFSMR, defined in Standard 4.1.1, include requirements for the business to write a food safety management statement and for this statement to be approved (or recognised) by a food regulatory authority and subject to ongoing monitoring.

Cost-benefit analysis

FSANZ completed an economic analysis of costs and benefits to inform the DRIS. The relatively high estimated illness cost for leafy vegetables is largely a result of the higher occurrence of *Salmonella* and the severity of listeriosis. That said, the estimated costs per case of *Salmonella* have been revised downwards since the CRIS with FSANZ's more sophisticated Cost of Illness model.

Other considerations

FSANZ's review also considered the extent of the current regulatory and non-regulatory framework, including existing FSS and the level of sign-up to these schemes. After receiving advice in submissions from the leafy vegetables industry and re-examining estimated business numbers from the Australian Bureau of Statistics[6], FSANZ now estimates there are 640 (+/- 120) leafy vegetable producers nationally, and that about 50% of these businesses operate on an accredited FSS. The lack of existing national regulation and the lower uptake of a FSS compared to other commodities influenced FSANZ's final position.

Melons – determining appropriate regulatory measures

Identified risk factors

In the period between 2010 and 2019 there were three reported outbreaks linked to the production of melons in Australia. These were:

- 2010 – *L. monocytogenes*
- 2016 - *Salmonella* Hvittingfoss
- 2018 – *L. monocytogenes*.

In 2011–2020 there were two Australian recalls issued for domestically produced melons:

- 2016 - *Salmonella* spp., associated with an outbreak
- 2018 – *L. monocytogenes,* associated with an outbreak.

Over this same period, three international outbreaks were linked to melons. Hazards identified included *Salmonella* Typhimurium and *Salmonella* Newport*.* The melons sector is one of the four fresh minimally processed horticulture sectors most commonly associated with international outbreaks. Further detail about outbreaks and prevalence is presented in the microbiological assessment.

The melons industry has been proactive with increasing food safety measures since 2018, including through development and implementation of a comprehensive best-practice toolbox. In 2022, 95% or more of melons businesses operate under a FSS.

Microbial hazards of melons that FSANZ considered to be relevant in the Australian context, and examined further, were:

- *L. monocytogenes*.
- *Salmonella* spp.

FSANZ's selection of microbial hazards of concern was based on consideration of Australian and international outbreak data and other international research. The characteristics of each hazard are summarised in the microbiological assessment with further detail in its Appendices 6, 8 and 10.

Food safety risk factors that FSANZ attributed to melons and regulatory risk management measures considered and proposed

Food safety risk factors	Considered	Proposed
incursion by wildlife and domestic animals	✓	✓
characteristics of the production site including surrounding and prior land use, particularly for open-field production	✓	✓

[6] ABS Stats: 71210DO004_201920 Agricultural Commodities, Australia–2019-20

Food safety risk factors	Considered	Proposed
occurrence of weather events, such as flooding or heavy rain, which could transfer pathogens to produce, fields, or irrigation water sources	✓	✓
application of untreated or insufficiently treated manure or compost amendments, particularly for plants growing close to the ground	✓	✓
use of contaminated water for irrigation and for the application of agricultural chemicals	✓	✓
contamination and cross-contamination due to poor worker and equipment hygiene, both at harvest and postharvest	✓	✓
inadequate washing and sanitiser application	✓	✓
inadequate cold chain maintenance	✓	✓

FSANZ has also included the following proposed regulatory measures to support management of the key risks factors identified above:

- GFSMR
- minimal traceability
- safe sale and supply.

The GFSMR defined in Standard 4.1.1 include requirements for the business to write a food safety management statement and for this statement to be approved (or recognised) by an authority and subject to ongoing monitoring.

Cost-benefit analysis

FSANZ completed an economic analysis of costs and benefits to inform the DRIS. As for the other two commodities, a large part of estimating benefits of options was estimating reductions in annual illness cases and hence illness costs. For melons, listeriosis with an estimated six acute cases per year, was the highest cost illness followed by salmonellosis illness (with costs revised downwards since the CRIS). FSANZ notes that since 2018, the melons industry has been very proactive with implementing additional safety measures.

All other options, including the preferred option, were found to have net benefits over the status quo from reducing listeriosis and salmonellosis, plus other illnesses for the other two commodities. More details are in Section 7 and in the CBA supporting document.

Other considerations

FSANZ estimates that there are 225 (+/- 75) melon producers nationally and that approximately 95% of these businesses are already signatory to a FSS, reflecting the drive for additional safety in this sector. Although these FSS schemes are voluntary, they are a requirement when supplying to major retailers.

Draft standards

Each of FSANZ's proposed draft regulatory measures are provided in Attachment A:

- 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.

Table 3 provides a comparative summary of the three proposed standards.

Table 3. Summary of the proposed standards, for comparison across sectors

Requirement	Berries	Leafy Vegetables	Melons
Notification (1) A primary horticulture producer and processor must provide specified information to the relevant authority before engaging in a relevant activity. (2) In this section, specified information means the following: (a) the contact details of the primary horticulture producer of 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 of 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. * Note: notification is part of general food safety management requirements so did not require separate listing	✓	✗*	✗*
General food safety management requirements A primary horticulture producer and a primary horticulture processor must comply with the general food safety management requirements *Note: This requirement includes notification.	✗	✓	✓
Traceability A primary horticulture producer and a primary horticulture processor must have in place a system that can identify: (a) from whom [*the commodity*] were received; and (b) to whom [*the commodity*] were supplied. #Note: and for berries, identification of the growing site	✓#	✓	✓
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 commodity*] unacceptable: a) soil; b) soil amendments (including manure, human biosolids, compost, and plant bio-waste); and c) fertiliser	✓	✓	✓

Requirement	Berries	Leafy Vegetables	Melons
d) water.			
Inputs – seed and seedling 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 leafy vegetables unacceptable: (a) seeds; (b) seedlings.	✗	✓	✗
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 [*the commodity*] are not made unacceptable.	✗	✓	✓
Weather events A primary horticulture producer and a primary horticulture processor must take appropriate remedial action to ensure that [*the commodity*] adversely affected by weather conditions are not unacceptable.	✗	✓	✓
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 [*the commodity*] 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 [*the commodity*] are not made unacceptable.	✓	✓	✓
Temperature of harvested [the commodity] A primary horticulture producer and a primary horticulture processor must keep harvested [*the commodity*] at a temperature that does not make [*the commodity*] unacceptable.	✗	✓	✓
Washing and sanitisation of harvested [the commodity] A primary horticulture processor must take all reasonable measures to ensure that: (a) visible extraneous material on harvested [*the commodity*] does not make [*the commodity*] unacceptable; and	✗	✓	✓

Requirement	Berries	Leafy Vegetables	Melons
(b) any washing or sanitising of harvested [*the commodity*] does not make [*the commodity*] unacceptable.			
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 [*the commodity*] are not made unacceptable.	✗	✓	✓
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.	✓	✓	✓
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 [*the commodity*] unacceptable.	✓	✓	✓
Sale or supply of unacceptable [the commodity] A primary horticulture producer and a primary horticulture processor must not sell or supply [*the commodity*] for human consumption if they ought reasonably know or ought reasonably suspect that [*the commodity*] are unacceptable.	✓	✓	✓

Compliance plans

Standards in the Code are implemented by the jurisdictions. Compliance plans supporting the standards' implementation by businesses at a practical level are developed by a jurisdictional working group. While the standards are outcomes based, the compliance plans outline how primary producers and processors will be expected to demonstrate the outcomes have been met. These plans also allow for greater understanding of the effects of the proposed regulation. Jurisdictions are working with industry and existing FSS scheme providers to determine details of implementation models. A transition period of 2.5 years will be allowed for implementation after gazettal of the proposed standards.

Summary

Under option 2, regulation would be introduced for the primary production and processing of berries, leafy vegetables and melons. Regulatory requirements for each sector are summarised in Table 3 above. Compliance plans (for the leafy vegetables and melons

sectors) and a guidance document (for the berries sector) were provided during consultation to demonstrate how the proposed regulation would likely be implemented.

6.4 Option 3: Regulatory plus non-regulatory measures

This option is an extension of option 2 (regulation only), and would also include development of non-regulatory measures through collaboration between government and industry during the 2.5 year transition period. Option 3 represents the most robust option of those reviewed.

Regulatory measures (standards) would be as discussed in option 2, outlined above.

Non-regulatory measures are not mandatory; however, they are considered to further support the protection of consumers from foodborne illness, and of industry and government from risk. Proposed non-regulatory measures include guidelines, fact sheets, animations, webinars and face-to-face meetings created by FSANZ in consultation with jurisdictions and peak industry bodies. More details and costings of non-regulatory measures are in section 7.5. Industry are keen to be involved in developing different media in multiple languages.

FSANZ acknowledges the horticulture industries' continued investment in non-regulatory activities and the ongoing role they play in improving food safety. Activities include the development of guidance for farmers' markets[7], codes of practice, updating FSS and establishing the Fresh Produce Safety Centre Australia and New Zealand[8]. Various guidance has also been developed through industry and government collaboration; for example, the *Guidelines for Fresh Produce Food Safety 2019* and the Melon Food Safety Toolbox[9].

6.5 Option 4: Non-regulatory measures

This option would recommend non-regulatory measures only, the same as those outlined in option 3 above. Further information is provided in the CBA.

7. What is the likely net benefit of each option?

7.1 Overview

FSANZ prepared a CBA to look at the net benefits of each option, and which measures (if any) should be introduced. Information and costings were examined for each option and for each sector.

FSANZ had regard to implementation costs in its assessment. See, for example, sections 2.1 and 2.5.1.1 of the Approval Report and SD2 (CBA). How the approved draft standards are implemented by the jurisdictions remains a matter for the jurisdictions to determine. FSANZ's understanding is that jurisdictions have yet to agree on a model for implementation and have committed to work with industry in developing a model.

When developing its cost and benefit estimates, FSANZ considered implementation costs such as those associated with rights of entry, licensing, registration and audit to account for the possibility that they may form part of the implementation model adopted by jurisdictions. The draft standards approved by FSANZ do not contain or impose such requirements (for example, Standard 4.2.7 imposes a notification requirement only).

[7] Available at https://farmersmarkets.org.au/
[8] https://fpsc-anz.com/
[9] Melon food safety toolbox: practical resources for implementing best practice (nsw.gov.au)

FSANZ has revised certain costs and benefits since the CRIS after receiving useful information from stakeholders and using a more sophisticated Cost of Illness model as part of continuous improvement.

Retaining the status quo was not associated with any additional costs or health benefits and the current cost of illness would still apply. Regulation was estimated to have a positive net benefit for berries and melons. Regulation was estimated to have a positive but lower net benefit for leafy vegetables, depending on how jurisdictions implement the regulation. Regulation combined with non-regulatory measures was found to have the highest net benefit in all three commodity groups. Non-regulatory measures, as a standalone, was found to have some benefit.

7.2 The cost–benefit analysis

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

- the net benefits of each option, qualitative and quantitative
- whether it is appropriate to introduce regulation and/or non-regulatory measures
- the most appropriate form of regulation and/or non-regulatory measures.

The CBA is provided with this DRIS. It includes additional detailed analyses on:

- business costs (CBA Appendix 1) – details on the CBA figures and assumptions
- expert elicitation (CBA Appendix 2) – estimates of the percentage of total burden of illness in Australia (caused by the hazards identified in the microbiological assessment) which may be attributed to berries, leafy vegetables and melons
- possible government costs of the regulatory options (CBA Appendix 3) – how implementation and ongoing costs to government regulators were calculated
- possible government costs of the non-regulatory option (CBA Appendix 4) – how design and delivery of costs to government and industry bodies were calculated
- business costs of a food safety incident: a case study (CBA Appendix 5) – examines the costs of the 2018 *Listeria* outbreak associated with rockmelons, to help visualise the impact of outbreaks and their significance both in terms of health (illness and/or death) and costs to the industry
- international trade (CBA Appendix 6) – see below
- consumer response (CBA Appendix 7) – see below.

International trade

When evaluating various options, FSANZ considered current export volumes in the berries, leafy vegetables and melons sectors and the impact that any regulation would have on current and future exports. A detailed study is provided in Appendix 6 of the CBA.

Australian food is well recognised internationally for its quality and safety, enabling market access in several export countries at premium pricing. Potential trade impacts have been raised as an issue requiring examination as part of the CBA.

Currently only around 2–3% of domestic production revenues for berries and leafy vegetable are from exports. This figure is higher for melons, at around 20%. There seems to be a strong domestic production focus for fresh berries and fresh leafy vegetables and comparatively fewer export opportunities. As a result, introducing regulation is expected to have a minimal export impact in these sectors. There is greater export trade in melons and there may be an export impact in the melons sector only.

Evidence of any sort of price premium for 'clean green' Australian produce only exists for lettuces, with lower prices being received for melons and berries than are received by most other export countries.

Given the above, it is unclear if the proposed regulation will impact exports. Exports are driven by many factors other than domestic food regulation, including market access, compliance with importing country standards, international price competitiveness and marketing. However, further domestic food safety incidents could negatively affect export markets, of particular concern to the melon industry.

Food that meets the requirements of the *Biosecurity Act 2015*[10] and enters Australia is subject to the *Imported Food Control Act 1992*[11]. The *Imported Food Regulations 2019*[12] establishes the Imported Food Inspection Scheme[13] (IFIS) and together with the *Imported Food Control Order 2019*[14]*,* sets compliance requirements for imported food.

Information about import requirements is available on the DAWE[15] website.

Consumer response

When evaluating various options, FSANZ considered the impact that any regulation would have on consumers, and therefore industry. We examined published national and international journals to understand these impacts on consumers. A detailed report of this study is provided in Appendix 7 of the CBA.

We estimate the proposed regulatory and non-regulatory food safety strategies may translate into an increased consumer purchase cost, and an increased demand from some consumers, due to increased confidence in food safety.

Available studies suggest that the net impact in terms of consumer demand should be relatively benign. That said, any purchase cost increases would have greatest impact on consumers with low incomes, whether because they reduce consumption of fruit or vegetables, or face greater financial challenges from paying higher prices.

CBA data gaps and assumptions

This CBA relied on the best available information at this point in time, but data gaps remain and a number of assumptions needed to be made. It has not been possible to readily quantify all relevant costs and benefits. However, during consultation, stakeholders were asked to provide more information. Useful information from stakeholders included numbers of leafy vegetable businesses, numbers of leafy vegetable businesses on a FSS, numbers of annual working days for harvesting berries, and other information.

Estimating the business costs associated with a food safety incident or outbreak is difficult. The magnitude of the costs to the businesses directly involved and to the wider industry is driven by a wide range of factors, including:

- whether the food is a luxury or a staple

[10] Available at: https://www.legislation.gov.au/Series/C2015A00061
[11] Available at: https://www.legislation.gov.au/Series/C2004A04512
[12] Available at: https://www.legislation.gov.au/Details/F2019L01006
[12] Available at https://www.awe.gov.au/biosecurity-trade/import/goods/food/inspection-compliance/inspection-scheme

[14] Available at: https://www.legislation.gov.au/Details/F2019L01233
[15] See: http://www.agriculture.gov.au/import

- how identifiable the product is within the market
- whether any deaths occur
- the level of media attention that is received.

Regardless of the challenges of estimating these costs, they are likely to be substantial in many instances. A case study looking at potential costs to industry of an outbreak or other food safety incident is provided in Appendix 5 of the CBA.

Implementation costs such as notification, licensing, audits and monitoring as well as education and awareness raising will vary by jurisdiction and circumstances of a business. Implementation approach and associated costs will be determined by jurisdictions with the transition period allowing time for its development. Jurisdictions are working with industry and scheme operators as well as FSANZ to consider options that reduce duplication and potentially costs.

Summary data from the CBA has been included in the following sections of this document on estimated net benefits of each option, based on currently available information.

7.3 Net benefit of option 1 – Retain the status quo

Under the status quo option, proposal P1052 would be abandoned and the current food safety framework would continue.

Current cost of illness

To examine the status quo, FSANZ estimated the annual cost of illness currently attributable to each sector.

Identified microbiological hazards in Australia for each commodity are listed in Table 2 earlier in this document (section 4.6).

To determine the total cost of illness specifically linked to berries, leafy vegetables and melons, the total illness burden was deduced and then an expert elicitation process was used to determine the percentage burden attributed to each commodity. An expert elicitation process uses a panel of experts to estimate the value of insufficient, uncertain or missing data. The expert elicitation model, methodology and results are further described in Appendix 2 of the CBA.

The expert estimates of the percentage of the total burden of illness in Australia which can be attributed to berries, leafy vegetables and melons is provided in Table 4.

Table 4. Median attribution percentage by pathogen and commodity

Commodity	Pathogen	Median % attribution
Berries	NoV	0.6
	STEC	1.0
Leafy vegetables	*L. monocytogenes*	7.5
	Salmonella	1.7
	STEC	5.0
Melons	*L. monocytogenes*	8.7
	Salmonella	0.9

L. = *Listeria,* NoV = norovirus, STEC = shiga toxin-producing *E. coli*.

FSANZ used these percentages to then estimate the annual cost of illness that can be

attributed to each of these sectors. Our costings are in Table 5 and reflect the revised and more sophisticated Cost of Illness model that has substantially revised *Salmonella* illness costs downwards.

Table 5. Estimates of annual cost of illness

Commodity	Total illness cost pa ($)
Berries	**4.4 million** NoV contributes the highest cost, followed by STEC
Leafy vegetables	**9.3 million** *Salmonella* contributes the highest cost, followed by *L. monocytogenes* and *STEC*
Melons	**7.1 million** *L. monocytogenes* contributes the highest cost, followed by *Salmonella*

L. = Listeria, NoV = norovirus, STEC = shiga toxin-producing *E. coli*.

Estimated costs of illness and estimated benefits of reducing illnesses are based on a cost model that accounts for costs of visits to general practitioners from a foodborne illness, hospitalisations for some people with a foodborne illness, lost working days, willingness to pay money to avoid illnesses and the value of a human life for those that die from a foodborne illness.

Summary of the costs and benefits of the status quo

Under the status quo the following can be expected:

- continued outbreaks, illness, deaths, recalls and incidents, noting potential reductions in future melon incidents due to improved safety practices implemented by melon growers since 2018
- annual costs of illness described above would remain (i.e. berries $4.4 million, leafy vegetables $9.3 million, melons $7.1 million)
- no additional benefits in terms of food safety
- no nationally consistent set of regulatory requirements for berries, leafy vegetables or melons
- no nationally consistent set of non-regulatory measures (FSANZ acknowledges industry uptake of FSS)
- continued uneven playing field for industry and a potential lack of appropriate food safety management across the sectors—industry FSS only apply to businesses that uptake and apply them. Primary producers and processors supplying major retailers are required by the retailer to participate in a FSS. Other growers and processors may not participate and may have less robust food safety management.
- no change required of industry or government
- no additional costs incurred by industry, government or consumers.

7.4 Net benefit of option 2 – Regulatory measures

FSANZ's CBA concluded that there will only be a minor cost difference between options 2 (regulation) and option 3 (regulation combined with non-regulation) and that option 3 would provide a greater net benefit. A very marginal reduction of foodborne illness costs, at less than 0.1% of costs over ten years would justify the small costs of moving from option 2 to option 3.

As a result, the CBA for option 2 mirrors the majority of the analysis for option 3, and is outlined in the next section.

7.5 Net benefit option 3 – Regulatory and non-regulatory measures – Preferred option

This is FSANZ's preferred option and expected to give higher overall net benefits than other options. FSANZ estimated a range of costs and cost-benefit ratios for each commodity that could be expected from implementing option 3.

Costs to industry

FSANZ estimated the costs to industry of implementing option 3 for each commodity. Figures are provided both per business and for the entire sector. A summary of these costings is provided in Table 6, with detail provided in the CBA.

Table 6. Summary of estimated medium cost to businesses and total costs to industry 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 $
MEDIUM estimate - per **business** not already on a FSS but 50% compliant	530	1,656	700	7,035	700	4,055
MEDIUM estimate - total **industry** costs	119,330	310,592	227,080	2,460,637	10,955	185,417

The table above excludes the relatively minor costs of option 3's non-regulatory component incurred by jurisdictions.

In general, businesses currently operating under a FSS (or equivalent) will incur lower costs in meeting the proposed regulation. These businesses are expected to be already operating in a manner that would likely meet the requirements of regulation. Businesses not operating under a FSS may still be complying with, for example, 50% of the proposed regulatory requirements and would only be expected to incur 50% of the costs. This 50% figure was questioned during consultation by some stakeholders, although there is still insufficient evidence to model using another percentage figure.

Businesses with very little food safety management in place would be expected to incur the greatest costs; this is demonstrated in Table 7. It is important to take a business's current level of food safety management into consideration when reviewing potential costs.

Table 7. Summary of estimated costs to businesses 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: Assumed annual	30 (notifications only)	0	0	654 (licences only	0	654 (licences only)

licencing costs						
Businesses not already on a FSS but with some food safety management in place (50% of the proposed measures) Includes notifications ($30 for berries), assumed licencing and audits ($654 and $885 respectively for leafy veg. and melons) and 50% of the costs of implementing all measures in the proposed standard	530	1,656	700	7,035	700	4,055
Businesses without any food safety management in place. Costs will be similar to what businesses implementing industry-driven schemes have already invested Includes notifications, assumed licencing, audits and 100% of the costs of implementing all measures in the proposed standard	1,030	3,313	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.

FSANZ has estimated the cost to a berry business of notifying food regulators of its existence is $30. Inspections by government regulators would occur if a food safety concern was raised. The inspection may involve a walk-through and review of how the business implements the proposed standard. FSANZ has estimated $250-500 per inspection for an average-sized berry producer. These costs are approximates only and based on current fees for inspecting food business (rather than inspections in the horticulture sector). In some jurisdictions there are currently no set charges for inspecting horticultural businesses, so the fee provided is indicative only.

FSANZ has estimated the cost of assumed licencing and auditing or monitoring leafy vegetables and melon businesses against the proposed PPP standards, based on an average of licence fee figures provided by state and territory governments in April 2021. Assumed licencing/re-licencing fees are estimated at $624 each year. Fees per audit are estimated to be $485 each year. Actual audit fees (if imposed) may vary greatly from this average, depending on size and other aspects of a business as well as the implementation model developed by jurisdictions. Additionally, there are costs of business time taken for the licensing and audit processes, e.g. applying for a licence and co-operating with auditors when they visit the businesses.

The cost of industry time to familiarise with the new regulation, preparing for and attending audits etc. are based on data in the TQA report, Quantifying the costs of compliance with quality assurance 2011, and has been calculated as:

a. $60 per hour for manager
b. $40 per hour for another worker
c. $70 per hour for an industry representative.

Further detail of all of these calculations is provided in Appendix 1 of the CBA.

Small businesses

FSANZ has sought to reduce burdens of regulation where possible, and achieve the desired food safety outcomes for consumers and reduce foodborne illness attributed to these commodities. The protection of public health and safety is FSANZ's top priority.

The costs of establishing compliance against the proposed standards (changing business operations, updating equipment, training, etc.) can be influenced by the size of a business. Economies of scale also come into play with audit and other monitoring fees charged by government food regulators. Smaller businesses may be audited/monitored relatively quickly and accrue smaller fees.

However, after also considering stakeholder feedback, FSANZ acknowledges that costs for small businesses may be a larger percentage of turnover than for larger businesses. Some already marginally profitable small enterprises may exit the market because of the proposed requirements, particularly given challenges of the post-COVID environment. That may have some (but unknown) impacts on affordability of fresh local produce. Appendix 7 of the CBA provides more details on consumer research. Some small businesses may also substitute towards growing other crops not covered by standards.

FSANZ discussed with state and territory government jurisdictional representatives about accommodating small businesses under the proposed standards. Jurisdictions might consider assessing burdens faced by small businesses and minimising burdens where appropriate, without compromising food safety. International examples of accommodating small businesses such as the USA's Food Safety Management Act[16] might be useful references.

It is also noted that very small businesses produce relatively small volumes of commodities compared to the entire market. Jurisdictions will make the final decisions about appropriate implementation and compliance pathways for small businesses. FSANZ notes efforts underway among jurisdictions and industry to develop education materials and tools to promote awareness of food safety specifically in these sectors.

Guidance materials developed by government to support implementation by industry of new PPP standards are also intended to help small businesses. These include compliance plans, templates for food safety requirements, record keeping, etc.

To help small businesses understand the implications of the costs associated with the proposed standards, FSANZ has provided:

- estimates of government fees in the CBA.
- estimates of business costs in the CBA
- case studies in section 9 of this document.

FSANZ is mindful, however, that the biggest indicator of the likely costs for any business (regardless of size) is the extent to which they are currently following a FSS or equivalent. This is why we have focussed on providing costing estimates reflecting different levels of

[16] See: FSMA Final Rule on Produce Safety | FDA

current FSS compliance.

Positive impacts on small business include that the standards address the key (evidenced) food safety risks and help industry mitigate those risks to avoid future problems, using a preventative outcomes-based approach.

If standards are gazetted, such implementation decisions would be made by jurisdictions likely during the 2.5 year transition period to regulations taking full effect.

Cost-benefit ratios

For berries, leafy vegetables and melons, there is an expected positive net benefit. The net benefit for leafy vegetables is expected to be lower as a proportion of the costs of regulations. Full details of the analysis for this option is provided in the CBA. The figures outlined below account for costs to industry and costs of the non-regulatory option to jurisdictions. Assumed efficacy figures are expert-based estimated percentage reductions of illness costs after implementing option 3. Central assumed efficacy (reduced illness costs) from option 3 is 15% for berries, 40% for leafy vegetables and 20% for melons.

Berries

The CBA determined a central estimate of $0.5 costs to every $1 benefit for berries if option 3 was implemented, with a range of $0.2 to $0.7 to achieve every $1 benefit (Table 8). At an estimated 15% base efficacy in reducing berry-related foodborne illness, the base estimate of illness cost savings is $0.7 million a year.

Table 8. Cost-benefit ratio for berries

Commodity	Cost-benefit ratios for commodity group Central efficacy range
Berries Harvest and packing season assumed as 210 days per year, based on updated estimates during the 2nd consultation round.	$0.5 costs for every $1 benefit ($0.2 to $0.7 range). Net benefit predicted. [Assumed efficacy of 15%].

Note: Based on FSANZ's central prediction of efficacy of option 3 to reduce current Australian annual foodborne illnesses originating from primary production and processing.

The estimated net benefit over a ten-year period of implementing option 3 ranges from $1.2 million to $3.5 million (15% efficacy at a 7% per annum discount rate). The central net benefit estimate is $2,363,158 over 10 years.

A significant impact could be expected for the estimated 25% of businesses (approximately 188 businesses) which may not be working under a FSS and may be key contributors to risk across the sector.

Leafy vegetables

The expected net benefits of option 3 are positive but lower for leafy vegetables as a percentage of costs, compared to berries and melons. On balance, the CBA estimates a positive net benefit with a central estimate of $0.7 cost to every $1 benefit (Table 9) with a range of between $0.3 and $1.0 cost for every $1 of benefit.

The central estimate is a $8.6m positive net benefit over 10 years (at a 40% efficacy, at a 7%

per annum discount rate) or precisely $8,590,339.

There are some risks of a negative net benefit if costs of compliance are higher than anticipated or efficacy of the standard is lower than 40%. That said, recognising existing FSS and accommodating the needs of small businesses would reduce such risks. Benefits are also likely to be more positive than the $0.7 costs to $1 benefit figure suggests through standards improving businesses' ability to avoid expensive food recalls.

At an estimated 40% efficacy, the base estimate of illness cost savings is $3.7 million a year.

Table 9. Cost-benefit ratio for leafy vegetables

Commodity	Cost-benefit ratios for commodity group Central efficacy range
Leafy vegetables Harvest and packing season assumed as 310 days per year.	$0.7 costs for every $1 benefit ($0.3 to $1.0 range). Net benefit predicted. [Assumed efficacy of 40%. This higher efficacy value is because of the higher number of leafy vegetable businesses not yet on a FSS. As a result, regulation in a less regulated sector is likely to have a larger effect in reducing foodborne illness.]

Note: Based on FSANZ's central prediction of efficacy of option 3 to reduce current Australian annual foodborne illnesses originating from primary production and processing.

A significant impact could be expected for the estimated 50% of businesses (approximately 320 businesses), which may not be working under a FSS and may be key contributors to risk across the sector. Smaller leafy vegetables businesses not yet on a FSS may also experience highest costs of complying.

Melons

The CBA determined a central estimate of $0.1 costs to every $1 benefit if option 3 was implemented, with a range of $0.1 to $0.2 to achieve every $1 benefit (Table 10). This takes account of the lower costs of illness under FSANZ's improved cost model. At a 20% efficacy, the base estimate of illness cost savings is $1.4 million a year.

Table 10. Cost-benefit ratio for melons

Commodity	Cost-benefit ratios for commodity group Central efficacy range
Melons Harvest and packing season assumed as 60 days per year.	$0.1 costs for every $1 benefit (<$0.1 to $0.2 range). Net benefit predicted.[Assumed efficacy of 20%].

Note: Based on FSANZ's central prediction of efficacy of option 3 to reduce current Australian annual foodborne illnesses originating from primary production and processing.

The estimated net benefit over a ten-year period ranges from $7.9 million to $9.3 million (20% efficacy at a 7% per annum discount rate). The central net benefit estimate is $8.6 million.

FSANZ acknowledges the melons industry has made significant efforts to improve food

safety since 2018 and the majority of melon growers already participate in a FSS. We also recognise that, although FSS are not government-mandated, they are a requirement when supplying to major retailers.

Net benefits may be over-estimated here if recent measures by the melons industry in themselves reduce future illness outbreaks and illness costs from melons.

Net benefit estimates over 10 years

The expected net benefits over a ten-year period of implementing option 3 are provided in Table 11. Details of these calculations and the underlying assumptions are provided in SD3.

FSANZ estimates that the implementation of option 3 would deliver approximately $19.5 million in net benefits over a ten-year period over all three commodity groups of berries, leafy vegetables and melons.

This estimated net benefits figure has reduced substantially since the CRIS, because of a new and more sophisticated Cost of Illness Model and estimates produced by the ANU for FSANZ, as part of continually improving our knowledge base. Estimated costs of *Salmonella* illness are especially lower under the new model.

That said, the $19.5 million figure may be an underestimate, as FSANZ was unable to quantify all benefits at this time, including direct and indirect costs of recalls.

Table 11. Net benefit estimates over 10 years

Commodity	Central business cost estimates
Berries	$ 2,363,158
Leafy vegetables	$ 8,590,339
Melons	$ 8,586,834

Note: $AU late 2020 - Central efficacies at 7% discount rate

Ability for jurisdictions to work more proactively with growers

The proposed standards provide jurisdictions with a mechanism to use their legislation to check businesses are implementing measures in the standards. Combined with the requirement for businesses to be known to jurisdictions, the standards would enable jurisdictions to work proactively with growers through monitoring and non-regulatory measures to better prevent an issue and to respond quickly when there is one.

Increased exports

Potential trade impacts have been raised as an issue to examine in the CBA of regulation. Australian food is well recognised internationally for its quality and safety, creating market access in several export countries at premium pricing. The vegetable export value is projected to increase from $457 million (m) to $565m between 2018–19 and 2025–26[17]. Similarly, fruit exports are projected to increase from $1,493 m to $1,783 m over the same period.

However, closer analysis of specific commodities reveals that different markets can work quite differently. It is not clear that increased regulation leads directly to increased exports. The cost competitiveness of Australian producers also needs to be considered.

[17] Australian Bureau of Agricultural and Resource Economics and Sciences (2019) Agricultural commodities and trade data. 2019: Rural Commodities - Horticulture.

Exports only account for a small (but potentially growing) percentage of berries sales value of around 3%. Leafy vegetables (Australian lettuce exports) also only generate export revenue of around 2-3% of sales value at $10-15m a year, with other leafy greens and fresh salads adding around $5m (ABARES[18]). A greater proportion of melons are being exported: 20.4% of sales value. Evidence of any sort of price premium only exists for lettuces, with lower prices being received for melons and berries than many other export countries.

It is unlikely that trade impacts will be significant to consideration of the costs and benefits for berries and leafy vegetables. There is a strong domestic production focus for these industries and price premiums over competing export countries appear limited.

There could be positive trade implications for the melon industry, which exports over 20% of domestic production values. A more extensive analysis of possible trade implications of increased food safety regulation is provided in Appendix 6 of the CBA.

Consumer response

The proposed regulatory and non-regulatory food safety strategies have been estimated to translate into an increased consumer purchase cost and an increased demand from some consumers due to increased confidence in food safety. That said, purchase cost increases would negatively impact lower-income consumers the most.

While available studies suggest that the net impact in terms of consumer demand should be relatively benign, further research is needed to offer a more definitive view. Details of the consumer research to date is provided in Appendix 7 of the CBA.

Non-regulatory measures

The additional non-regulatory measures included in option 3 are described and costed below (Table 12). The cost to individual businesses for reading the material, participating in webinars and so on has been included as the 'initial costs of familiarising with new rules'.

FSANZ has also estimated costs to peak industry bodies for engagement in the non-regulatory measures and included these figures in all cost calculations. However, non-regulatory activities are not legislated and there is no mandated requirement for industry to participate in these activities. Industry has also indicated their interest in working with government to produce other helpful materials, including different types of media in multiple languages.

Table 12. Proposed non-regulatory measures and costs

Activity	Who	Cost to jurisdictions $	Cost to industry $
Fact sheets	Created by FSANZ in consultation with jurisdictions and peak industry bodies. Printed and displayed by industry.	Subtotal = 9,631	Subtotal = 9,240 The costs of industry peak body

18 Australian Bureau of Agricultural and Resource Economics and Sciences (2019) Agricultural commodities and trade data. 2019: Rural Commodities - Horticulture. https://www.agriculture.gov.au/sites/default/files/documents/ACS2019_HorticultureTables_v1.0.0.xlsx. Accessed 9 November 2020

Animations	Created by FSANZ in consultation with jurisdiction and peak industry bodies. Used as training material by industry.	Subtotal = 5,586	representatives collaborating in the design of fact sheets, animations and webinars and attending face-to-face meetings.
Links to useful resources	Provided by FSANZ. Links to information used by industry.	Subtotal = 353	
Webinars	Prepared by FSANZ and jurisdictions and peak industry bodies. Delivered by FSANZ and jurisdictions and peak industry bodies. Used as training material by industry.	Subtotal = 9,703	
Face-to face meetings with industry	Prepared and delivered by FSANZ, jurisdictions and peak industry bodies.	Subtotal = 16,735	
		Total = **42,007**	Total = **9,240**

The CBA concluded that the additional non-regulatory measures could be justified if they resulted in a reduction of illness of less than 0.1% over ten years. Given this, option 3 (rather than option 2) is FSANZ's preferred option.

Other impacts

FSANZ has identified the impacts of regulation by social group, provided in Table 13.

Table 13. Major impacts of regulation, by social group

Social group	Notes on impacts
Primary producers	Costs: - potentially increased production costs Benefits: - reduction in the risk of a food safety incident, saving costs - improved capacity to effectively and efficiently manage a food safety incident, reducing costs - inventory management and other business management benefits from better record keeping - potential additional sales in export markets - reduced risks of market damage caused by others
Food processors	Costs: - potentially increased input costs - increased production costs Benefits: - reduction in the risk of a food safety incident, saving costs - improved capacity to effectively and efficiently manage a food safety incident, reducing costs - inventory management and other business management benefits

	- potential additional sales in export markets - reduced risks of market damage caused by others
Food retailers	Costs: - potentially increased input costs Benefits: - improved capacity to effectively and efficiently manage a food safety incident, reducing costs - inventory management and other business management benefits - reduced risks of market damage caused by others
Consumers	Costs: - potential increased costs of purchase Benefits: - improved safety of products meaning a reduced likelihood of illness
Government	Costs: - increased implementation and enforcement cost of new regulation Benefits: - improved capacity to effectively and efficiently manage a food safety incident, reducing costs - savings in health care expenditure

Summary of the costs and benefits of option 3

If option 3 were implemented, the following can be expected:

- net benefits for each sector, although less of a net benefit for leafy vegetables
- reduced outbreaks, illness, deaths, recalls and incidents
- reduced annual cost of illness
- a nationally consistent set of regulatory requirements for berries, leafy vegetables and melons
- empowerment of government food regulators to support Australia's primary producers and processors and proactively manage food safety in these sectors on behalf of consumers
- better protection of consumers
- required changes in industry to implement the regulation, particularly those businesses not currently invested in food safety management
- potential requirements of government food regulators to licence, audit/ monitor compliance
- potential additional costs for industry, government or consumers—however, these may be offset by reductions in costs associated with illness.

7.6 Net benefit of option 4 – Non-regulatory measures

This option relies on self-regulation. Self-regulation can produce benefits for food safety, particularly when coupled with third-party audit regimes. However self-regulation is unlikely to change the behaviour of those businesses that most need to change; that is, businesses that do not currently participate in a FSS. Cost and benefits of non-regulatory measures are described in option 3.

Summary of the costs and benefits of option 4

If option 4 were implemented, the following can be expected:

- slightly reduced outbreaks, illness, deaths, recalls and incidents
- slightly reduced annual cost of illness
- minimal additional benefits to food safety.
- no nationally consistent set of regulatory requirements for berries, leafy vegetables or melons
- minimal requirements of industry or government
- minimal additional costs incurred by industry, government or consumers.

7.7 Comparing the costs and benefits of the risk management options

Quantitative analysis

To support a comparison of the four potential options, FSANZ has undertaken some quantitative analysis. This compares the direct benefits that may be achieved from a reduction in foodborne illness, against the costs of the different options to industry and government.

Our analysis included:

- a comparison of the costs and benefits that are readily quantifiable (provided in this document, below)
- a simplified estimation of cost of regulation to business (see Appendix 1 of the CBA)
- an expert elicitation process to estimate the contribution of berries, leafy vegetables and melons to the total number of illnesses in Australia (see Appendix 2 of the CBA).

How these costs can be calculated, and some simplified costings are discussed in the CBA. Costings for non-regulatory measures are explained in Appendix 4 of the CBA.

Option 3 (a combination of regulation and non-regulation) provides the most positive net benefit of the four options considered. The net benefit of Option 3 is $19.5 million (over ten years) when the industry costs are balanced against likely avoided illness-related costs.

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. As previously stated, a reduction of less than 0.1% of cases over ten years would justify the additional small costs of non-regulatory measures.

8. What is the best option from those considered?

8.1 Overview

FSANZ considered all four options and evaluated them against each other and criteria including such as the protection of public health, the need for regulation or other options, and the lightest touch approach possible. FSANZ considers that option 3 provides the most cost-effective approach to reduce foodborne illness across all three horticulture sectors and is expected to result in the largest net benefit to the community. Option three is also supported by stakeholders, if existing FSS are recognised and the needs of small businesses are accommodated.

8.2 FSANZ's objectives

When considering developing or varying a food standard, FSANZ is required to have regard to the statutory assessment criteria set by the *Food Standards Australia New Zealand Act 1991* (FSANZ Act). These include the three primary objectives for food standards development that are set out in section 18 of that Act. These are:

(a) the protection of public health and safety
(b) the provision of adequate information relating to food to enable consumers to make informed choices
(c) the prevention of misleading or deceptive conduct.

The objectives or criteria that FSANZ must have regard to also include the following:

- the need for standards to be based on risk analysis using the best available scientific evidence
- the promotion of consistency between domestic and international food standards
- the desirability of an efficient and internationally competitive food industry
- the promotion of fair trading in food
- any written policy guidelines formulated by the Ministerial Council (now the Food Ministers' Meeting); and
- any other relevant matter.

FSANZ has regard for the *Overarching Policy Guideline on Primary Production and Processing Standards*[19] (policy guideline) approved in 2006 by food ministers. The policy guideline contains high-order principles that must be considered when a standard is developed. The guideline ensures that standards protect public health and safety and result in the development of minimal effective regulation.

Throughout this proposal FSANZ has worked with jurisdictions through the Integrated Model for Standards Development and Consistent Implementation of Primary Production and Processing Standards[20]. This model was developed by the Food Regulation Implementation Sub-Committee to facilitate national consistency in implementation, provide FSANZ with advice during standard development, and provide tools to assist businesses to achieve compliance.

FSANZ's risk assessment and risk management approach is consistent with the Codex risk analysis framework. Further information about FSANZ's risk management approach is described on the FSANZ website and can be found in the Risk Analysis in Food Regulation publication.

FSANZ's risk management objectives also consider the cost of implementing any proposed risk management measures against the relative benefits achieved in terms of improved food safety outcomes. FSANZ also considers feedback provided through our stakeholder consultations.

FSANZ has considered each of these objectives to determine the:

- best available options for managing food safety for berries, leafy vegetables and melons
- most effective risk management measures in terms of costs and benefits to the Australian public.

[19] Forum-Policy Guideline-Primary Production and Processing Standards.pdf (foodregulation.gov.au)
[20] https://foodregulation.gov.au/internet/fr/publishing.nsf/Content/ISFR

8.3 Option 1 – Status quo

FSANZ's conclusion is that maintaining the status quo is not our preferred option. The status quo does not adequately support public health and safety objectives. Illness, deaths, recalls, outbreaks and incidents can be expected to continue at current levels, with associated costs. There would be no nationally consistent set of regulatory requirements for berries, leafy vegetables or melons. This is not helpful for multi-jurisdictional businesses, exporters and export regulators. Although industry FSS currently exist, these only apply to those businesses who sign up. Lack of uptake of FSS would continue to result in the uneven playing field for industry and the potential lack of appropriate food safety management by those not participating. Government food regulators would not be empowered to support Australia's primary producers and processors or proactively manage food safety in these sectors on behalf of consumers.

8.4 Option 2 – Regulatory measures (standalone)

FSANZ's conclusion is that introduction of standalone standards is not our preferred option. As stakeholders have signalled, regulatory measures are best supported by non-regulatory measures including fact sheets, animations, webinars and face-to-face meetings, developed and delivered cooperatively between industry and government. The additional non-regulatory measures (proposed by option 3) add low extra costs to industry. Only a minimal reduction in illness would need to be attributed to these additional non-regulatory measures to justify the costs.

This option would allow regulators on growing and processing sites in non-emergencies.

8.5 Option 3 – Regulatory and non-regulatory measures

After examining all available risk management options and considering feedback from consultations (refer to section 10), FSANZ's conclusion is that option 3 is our preferred option to reduce foodborne illness attributed to the three sectors. This option is also supported by industry and government stakeholders for a nationally consistent approach to strengthening food safety management in these sectors.

FSANZ considers that, in general, the Australian horticulture industry operates at a high level of food safety. This is supported by horticultural produce agreements and industry initiatives such as FSS. However, based on levels of illness, outbreaks and incidents, the current system needs strengthening—particularly in the leafy vegetables and melons sectors.

Requirements in existing FSS in Australia for fresh produce align with the requirements of the proposed PPP standards. FSANZ anticipates that there would be minimal impact for those businesses currently complying with a FSS. However, PPP standards will ensure a consistent and appropriate level of food safety management across all berry, leafy vegetable and melon businesses. Standards would also enable regulators to enter growing and processing sites outside of emergency situations, for a proactive approach. Reductions in illnesses and outbreaks also lead to an increase in consumer confidence and business sustainability.

Net benefits would be further increased if duplication is reduced between GFSI-benchmarked FSS and proposed requirements, with jurisdictions working for consistent implementation and adequate guidance for businesses, and assessing and accommodating the needs of smaller businesses.

PPP standards would result in consistency and transparency for industry and government and demonstrate regulatory requirements to our trading partners.

Table 14 lists the benefits of reducing illness caused by the hazards identified by the microbiological assessment in each sector. Further detail is provided in the CBA.
Table 15 provides the net benefit estimates of implementing option 3 in each sector over a ten-year period. The data provided below is sourced from the CBA for the 7% discount rate (the CBA also costs out the 3% and 10% discount rates). The data provided below is for the central efficacy range of implementing option 3 (the CBA also costs out the low and high efficacy rate). Further detail is provided in the CBA.

Table 14. Benefits of reducing illnesses and their associated annual costs across Australia after implementation of option 3

Commodity	Pathogens contributing to foodborne illness							
	***Listeria* cost/year**	**STEC cost/year**	***Salmonella* cost/year**	**Norovirus cost/year**	**Hepatitis A cost/year**	**Total illness cost/year**	**Plausible range** in estimated illness cost savings per year **benefits**	**Base** estimate of illness cost savings per year **benefits**
Berries	Not applicable	$178,050 *41 est. cases p.a. ***Eight** times as many as reported	Not applicable	$4,262,190 *10,763 est. cases p.a. * **Much more** than reported	$0 *Around five reported p.a., but almost all originate from imports	$4,440,240	$0.2m to $2.2m based on 5% to 50% efficacy	$0.7m based on 15% efficacy
Leafy vegetables	$4,135,969 *Five est. acute cases p.a. ***As many** as reported	$890,248 *206 est. cases p.a. ***Eight** times as many as reported	$4,268,864 *1,881 est. cases p.a. ***Seven** times as many as reported	Not applicable	Not applicable	$9,295,081	$0.9m to $6.5m based on 10% to 70% efficacy	$3.7m based on 40% efficacy
Melons	$4,797,724 *Six est. acute cases p.a. * As many as reported	Not applicable	$2,259,987 *996 est. cases p.a. *Seven times as many as reported	Not applicable	Not applicable	$7,057,711	$0.7m to $3.5m based on 10% to 50% Efficacy	$1.4m based on 20% Efficacy

NA = not applicable, Est. = established, STEC = shiga toxin-producing *E. coli*.

Table 15. Net benefit estimates over 10 years: 7% per annum discount rate

Costs to benefit ratios over 10 years (net present value)	Central business costs $ minus 50%	Central business costs $	Central business costs $ plus 50%
Berries At central efficacy =15%	3,520,558	2,363,158	1,205,758
Leafy vegetables At central efficacy = 40%	17,352,122	8,590,339	-171,444
Melons At central efficacy = 20%	9,250,458	8,586,834	7,923,211

Table 16 provides the estimated cost-benefit ratios of implementing option 3 at the central efficacy range. The CBA also provides the cost-benefit ratios at the worst case efficacy range.

Option 3 provides a cost-effective approach to reduce foodborne illness across all three horticulture sectors and is expected to result in the largest net benefit to the community.

Table 16. Cost-benefit ratios for implementing option 3

Commodity group	Central efficacy range[a]
Berries Harvest and packing season assumed as 210 days a year.	Central estimate = $0.5 Costs to $1 benefit. Range = $0.2 to $0.7 Costs to $1 benefit. Assumed efficacy = 15%.
Leafy vegetables Almost all-year round harvest and packing season assumed of 310 days a year.	Central estimate = $0.7 Costs to $1 benefit. Range = $0.3 to $1.0 Costs to $1 benefit. Assumed efficacy = 40% since larger numbers of businesses are not on a food safety scheme.
Melons Harvest and packing season assumed as 60 days a year.	Central estimate = $0.1 Costs to $1 benefit. Range = $0.1 to $0.2 Costs to $1 benefit. Assumed efficacy = 20%.

a. Based on the central prediction of effectiveness (efficacy) of option 3 to reduce Australian annual foodborne illnesses originating in the growing, harvesting or initial processing of each commodity. Central business costs +/-50%.

8.6 Option 4 - Non-regulatory measures (standalone)

The Office of Best Practice Regulation (OBPR) reference document '*Regulatory Impact Analysis Guide for Ministers' Meetings and National Standard Setting Bodies*, includes the following guidance on self-regulation.

Self-regulation

Self-regulation may consist of industry-written rules and codes of conduct enforced by the industry itself. Where industry participants understand and appreciate the need for self-regulation, this can be a good option.

Any red tape resulting from self-regulation is usually minimal and often administered sympathetically by the industry. Self-regulation is a good option where the consequences of market failure are low and the market is likely to move towards an optimal outcome by itself.

Self-regulation is not a viable option if an industry has no incentive to comply with its own rules. In some cases, self-regulation may create public concern, where, for example, perceived conflicts of interest could threaten safety, such as in food-handling, healthcare or aviation. Self-regulation should be approached carefully where previous attempts to achieve compliance or penalise non-compliance have failed.

FSANZ assessed option 4 against the above criteria and came to the conclusion that self-regulation alone does not align with government guidelines and would not provide appropriate food safety management.

Self-regulation is recommended where the consequences of market failure are low risk. Outbreaks of foodborne disease have resulted in illness and deaths, which cannot be considered as low-risk consequences.

FSANZ acknowledges that many industry bodies are working hard to optimise food safety outcomes through self-regulation, including the requirements of major retailers. FSANZ acknowledges the horticulture industries' continued investment in self-regulatory activities and the ongoing role they play in improving food safety (see section 6.4).

However, there is no industry-wide requirement to participate in these food safety measures or any schemes. Businesses not covered by a FSS are often not members of any industry organisations, and have highly varied language, background, literacy, education, knowledge and motivation in terms of food safety. There is no indication that self-regulation can work for businesses that currently sit outside the self-regulation framework. There are insufficient incentives for these businesses to become involved in formal schemes and no sanctions for not becoming involved.

FSANZ also notes that foodborne illness outbreaks involving horticultural produce have occurred in businesses with a FSS in place. This suggests that non-regulatory measures alone may not be the most effective way to address food safety risks.

The OBPR has specifically provided the example of 'food handling' as an activity where self-regulation may create public concern due to the perception that conflicts of interest could threaten safety. Self-regulation should be considered cautiously in the food safety space.

FSANZ's conclusion is that non-regulatory measures (in the absence of any regulatory measures) are not our preferred option. Participation in non-regulated food safety activities are 'voluntary' and unlikely to result in appropriate food safety management across the entire sector. It is assumed that, in the absence of supporting regulation (as outlined in option 3), the effects of these non-regulatory tools to reduce food safety will be significantly reduced. FSANZ's position is that non-regulatory activities should be supported by regulation.

9. Case studies

Three case studies are provided to illustrate:

- the implications of the proposed standards
- what changes are needed for businesses
- the likely costs for a range of different business types and sizes.

Individual cost estimates for a wider range of scenarios are provided and explained in further detail in the CBA. Jurisdictions will work with industry to support uptake of the standards and reduce unnecessary duplication and administration where appropriate. Implementation is the responsibility of state and territory regulators and may or may not include licencing, registration and auditing / monitoring requirements included in the case studies below:

Case study 1 – Micro berry business

Nick owns a small farm growing highbush blueberries in Tasmania. Nick sells his produce to wholesalers at the local markets. His annual aggregated turnover is $60,000 per annum.

Nick has not signed up to a food safety scheme, but he is committed to food safety. He has already adopted a range of food safety measures on the berry farm, including:

- high quality water
- high quality soil and fertilisers
- clean premises and equipment
- food safety skills and knowledge
- personal hygiene
- removal from sale of unacceptable berries.

Nick has looked at the proposed standard and the guidance document for berries. He has decided all he needs to do to meet the new requirements is to:

- contact the Tasmanian Department of Primary Industries, Parks, Water and Environment (DPIPWE) and provide his business details and contact number [$30 upfront]
- improve traceability by keeping better records of the wholesalers he sells his berries to [$100pa].

In the first year Nick will need to spend $130 in order to become compliant with the proposed standard. This equates to 0.22% of his annual $60,000 turnover. In subsequent years Nick will need to spend $100 to retain appropriate traceability records, 0.17% of turnover.

Nick understands that he is responsible for meeting the requirements of the proposed standard. The Tasmanian DPIPWE does not intend to routinely audit or monitor Nick's berry business for compliance against the proposed standard, although it may inspect his business if a legitimate food safety concern is raised.

Case study 2 – Small leafy vegetable business

Jasper runs a small farm in New South Wales that grows salad leafy vegetables. His harvested produce is trimmed and sorted on farm for sale to restaurants. His annual aggregated turnover is $200,000 per annum and he employs two farm hands.

Jasper has not considered any food safety risks associated with horticultural produce and has not invested in food safety.

Jasper reviews the proposed standard and compliance plan for leafy vegetables. He realises he will need to make significant changes in his business and improve the food safety knowledge and skills of himself and his two employees. He will need to:

- become familiar with food safety and the new standard [$480 upfront]
- create a food safety management statement $1520 in the first year & $1120 in subsequent years.]
- improve traceability [$100pa]
- source seeds and seedlings from suppliers who have implemented programs to assure the microbiological safety of the product [$120pa]
- cease using untreated manures and swap to products of suitable microbiological quality [$120 upfront & $200pa - $320 in the first year & $200 in subsequent years.]
- start treating dam water before spraying it onto leafy vegetables [$400 upfront & $200pa]
- adjust production to better mitigate the effects of weather events [$480pa]
- better maintain the premises and equipment [$668pa]
- clean the premises and equipment [$2,267pa]
- wash and sanitise produce [$4,333pa]
- control animal pests [$960pa]
- develop food safety skills and knowledge, including on-going training [$345pa]
- improve hygiene practices [$200pa].

Jasper will also need to factor in government licencing ($654pa) and audit costs ($885pa). Jasper's audit costs may reduce if alternative monitoring and audit arrangements are agreed by NSW DPI.

Based on FSANZ estimates, it will cost Jasper a total of $13,933 in the first year and $12,533 each subsequent year to shift from zero food safety compliance to ongoing full compliance with the proposed standard. In the first year, these costs equate to 7% of his annual $200,000 turnover and 6.3% in subsequent years.

Jasper realises it will take him 6 months to become compliant. He contacts the NSW Department of Primary Industries (DPI) seeking food safety advice and to discuss his concerns about implementation. The NSW DPI advises him that the proposed national standard will be phased in over 2.5 years and that they will work with businesses to help them become compliant. They also discuss the approval process of Jasper's food safety management statement, licencing and auditing arrangements.

Case study 3 – Large melon business

Grace owns and manages a large business in Queensland which produces watermelons. The average aggregated annual turnover of the farm is $12 million.

Grace has a contract to sell all of her produce to a major retailer and already participates in a food safety scheme. Everyone on the farm is invested in food safety and their knowledge, equipment and processes all meet or exceed the requirements.

Grace's executive team reviewed the proposed standard and compliance plan for melons. They have concluded that they are meeting the food safety requirements of the standard, however they will need to update their current food safety management statement (FSMS) to better demonstrate this.

Grace contacts Safe Food Production Queensland (Safe Food) to discuss updates she thinks may be required to their current food safety management statement (FSMS). Safe Food confirm that Grace will need to update the FSMS to better describe:

- how they currently manage of the impact of weather events
- how food safety skills are taught and maintained.

Based on FSANZ's estimates, Grace calculates that it will cost her an additional $3,104 in the first year to fully comply, which is 0.03% of her 12M annual turnover. This figure includes licencing ($654pa). Grace has factored in 8 hours of staff time to update her FSMS. In subsequent years, licencing and maintaining the FSMS will equate to $2,704 or 0.02% of annual turnover.

10. Who was consulted and how was their feedback incorporated?

10.1 Overview

FSANZ has engaged stakeholders through:

- a horticulture and food safety workshop, discussing Chapter 3 and 4 of the Code with industry representatives, states and territories
- visits to berry, leafy vegetable and melon farms, although numbers of visits were limited due to COVID-19 restrictions
- expert consultation (microbiological review)
- OBPR
- the Horticulture Implementation Working Group (HIWG), which includes food regulators from each state and territory
- a Standards Development Advisory Group (SDAG), which includes industry representatives and food regulators from each state and territory
- public consultation through the 1st and 2nd calls for submissions
- public surveys.

Feedback provided included the need for food safety regulation in these sectors and concerns about food safety regulation and the burden (including costs) it may place on industry, particularly for small and emerging businesses. FSANZ has considered all feedback to shape the proposed options to best balance the opinions and evidence provided.

10.2 Horticulture and food safety workshop

FSANZ held a face-to-face Horticulture and Food Safety Management Workshop on 31 January and 1 February 2019. This workshop covered the review of Chapters 3 and 4 of the Code. The objectives of the workshop were to clarify the scope of the review and explore effective risk management options in relation to horticulture and food service food safety management. The workshop was attended by representatives of industry and jurisdictions.

General agreement on the scope, risk management options and challenges to implementation were the key outcomes of the workshop. The discussion highlighted that there were significant differences in the regulatory systems of different jurisdictions. There were consistent views for a collaborative model using existing mechanisms. The overall outcome was to provide a well-defined food safety system that is enforceable, clearly understandable and compatible with the existing food safety system that will encourage compliance by all businesses. The discussion points of the workshop were consolidated in an information paper and informed commencement of Proposal P1052.

10.3 Industry visits

FSANZ visited producers and processors of identified horticulture products in New South Wales and Victoria between late 2019 and early 2020. The purpose of the visits was to establish relationships with stakeholders, and for FSANZ officers to gain a greater understanding of the production of berries, leafy vegetables and melons and the food safety practices in these sectors, to support our assessment work. State government and industry representatives also accompanied FSANZ and participated in consultation.

Unfortunately COVID-19 restrictions have limited the ability of FSANZ officers to visit and get as much observational experience of growing and packing operations as was hoped. The limited visits that FSANZ has made include:

- one onsite visit to a strawberry farm and distributor in Victoria. While onsite, FSANZ observed the growing sites (open field, protected cultivation systems and hydroponics), harvesting, and the activities of the packing shed.

- onsite visits to three leafy vegetable farms in Victoria. While onsite, FSANZ observed the growing sites (open field, protected cultivation systems and hydroponics), harvesting, and the activities of the packing shed.

- one onsite visit to a melon farm in New South Wales. While onsite, FSANZ observed the growing sites, harvesting, and the activities of the packing shed.

10.4 Horticulture Implementation Working Group

Implementation of any standard is the responsibility of the state and territory government jurisdictions. The HIWG was established by ISFR to ensure any amendments to the Code are consistently implemented at the national level. The HIWG met multiple times during the P1052 project.

10.5 Horticulture Standards Development Advisory Group

FSANZ held targeted consultations with industry and jurisdictions to understand industry practices and constraints through the Horticulture SDAG, established in early 2020. Group members are from both government and industry. The Horticulture SDAG assists FSANZ in developing any primary production and processing requirements for horticulture through the provision of scientific, technical, regulatory, cost and benefit analysis advice.

As a result of feedback provided through the Horticulture SDAG, FSANZ amended the name of proposal P1052 from *PPP Requirements for High-risk Horticulture*, to *PPP Requirements for Horticulture (Berries, Leafy Vegetables and Melons).* The title of the proposal was updated to remove any misinterpretation of the term 'high-risk', in association with these horticulture products.

In addition, FSANZ has held discussions with individual members of the Horticulture SDAG to receive feedback and gather information relating to specific member issues.

FSANZ held two SDAG meetings where stakeholders could raise their concerns and suggestions about the proposed options. This included one SDAG webinar towards the end of the second consultation round in February 2022. Jurisdictions are now leading meetings with industry around how proposed requirements, if gazetted, would be implemented, including to understand how industry food safety schemes operate and possible recognition options.

10.6 Targeted consultation survey

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.

There were 33 responses from a range of individuals representing industry, horticulture producers and processors. The respondents were primarily representing medium-large size business, dominated by berries, followed by leafy vegetables and melons. A range of activities including growing, packing and processing were conducted by the businesses surveyed. The survey findings guided the risk management options.

10.7 Public consultation

During the 2nd Call for Submissions from November 2021 to February 2022, FSANZ sought further public feedback on the proposed measures. We also included questions on the proposed options and evidence to inform further refinement of costs and benefits. Submissions were received from 32 stakeholders from government, industry, peak bodies or individuals. A summary of the submissions and FSANZ's responses are provided in our Approval Report.

Overall, there was majority support for introducing regulation (i.e. standards) and supporting them with guidance and materials to ensure safe production of these commodities. Government submitters strongly supported regulatory measures, while industry support was conditional on the basis that implementation should recognise their commercial food safety schemes.

Some industry and grower representatives were opposed to any regulation. Several submissions were concerned about the impact on small businesses. Costs and additional

burdens associated with implementation were raised in most industry submissions.

State and territory jurisdictions submitted that they sought to work with industry on alternative compliance approaches including a recognition model and real-time data monitoring.

There was strong agreement on the need for non-regulatory measures, particularly guidance on food safety in horticulture and supporting materials; these were particularly important for small businesses. Submissions commented on the scope of standards and some amendments to specific requirements were agreed (e.g. definitions, traceability and soil inputs). Stakeholders requested the transition period be extended.

Some submissions provided information on costs and benefits, including market values of different industries, financial impacts of food safety outbreaks to industry, updates on numbers of growers and primary producers, updated audit costings and other matters.

FSANZ acknowledges the time taken by individuals and organisations to make submissions and contribute information and advice on this proposal. All comments were valued and contributed to the rigour of our assessment.

10.8 Main changes following public consultation and stakeholder feedback

After considering stakeholder feedback, FSANZ has made the following main changes to the proposals since the 2nd consultation round:

- extended the transition period for implementation of the proposed PPP Standard to 2.5 years after new legislation is gazetted (instead of 18 months)
- improved definitions: removed chopping and added storage to definitions of primary processor & primary processing activities, and amended the berry definition to provide clarity and consistency with some other definitions (levies)
- added soil, soil amendments and fertilisers to the input clause for berries to capture (straw)berries grown close to ground.
- strengthened the traceability clause for berries to include traceability to the growing site.

We have assessed the information provided on costs and benefits, and incorporated relevant information into our final costings presented in this report. That includes remodelling certain costs, benefits and business number estimates based on evidence-backed stakeholder feedback, including:

- now estimating 640 leafy vegetable businesses in Australia
- now estimating 320 leafy vegetable businesses on a FSS
- now assuming 210 annual harvest days for berries
- incorporating costs of added soil, soil amendments and fertilisers for berries businesses
- accounting for reduced costs of foodborne illness under the more sophisticated ANU model.

11. How will the chosen option be implemented and evaluated?

11.1 Overview

Implementation of the proposed standards is the responsibility of the states and territories.

The Implementation Sub-Committee for Food Regulation (ISFR) facilitates the consistent national implementation of standards by developing agreed implementation approaches and compliance materials. An implementation working group (HIWG) was established by ISFR for this purpose.

The HIWG consists of state and territory government representatives, DAWE and FSANZ. They are using the Integrated Model (see section 8.2) to develop a range of tools to assist businesses and regulators understand how a PPP standard would be implemented. Other PPP standards have also used the Integrated Model for national consistency.

11.2 Compliance framework

The HIWG drafted compliance plans and guidance to facilitate consistent implementation of the standards across jurisdictions (see Table 17 for an example).

These documents will be refined and other guidance developed during the transition period. Jurisdictions noted in submissions their commitment to work with industry and scheme owners on a recognition model that considers FSS as a means of demonstrating compliance. This model may include approval processes, ongoing monitoring and response to food safety issues. Jurisdictions have also committed to support small businesses and those not already on a FSS to understand their food safety risks and comply with the standards.

Table 17. Example of a compliance requirement. Melons: Plan B Horticulture primary processing

Compliance requirement – Industry	Monitoring requirements – Industry	Monitoring requirements - Government
Inputs Water (post-harvest) Outcome – Chemical, physical and microbiological hazards associated with inputs are appropriately managed during primary processing so that melons are not made unacceptable. - Sanitisation chemicals used are appropriate as food grade sanitisers. - Water sources: if non-potable water is used, it is frequently tested so that it is shown to be equivalent to potable water. In all instances use of potable water is preferred for primary processing operations.	- Potable (drinking quality) water is used to process horticulture produce, or records are maintained of the treatment of non-potable water, to ensure it is not a source of contamination for processed horticulture produce. - Business may need to demonstrate compliance to the relevant jurisdictional *Safe Drinking Water Act.*	The business has evidence in its food safety management statement (FSMS) to inform where: - Control measures (if applied) have been implemented and are monitored (e.g. sanitiser concentration logs).

Government and industry stakeholders that responded to the consultation are strongly supportive of national non-regulatory measures to support the standards and improve food safety culture. Industry has indicated willingness to assist in preparation of targeted educational resources, especially in languages other than English. The melons industry has extended an offer for regulators to observe some on-farm GFSI-FSS audits.

11.3 Transition period and review

A 2.5 year implementation period is proposed from the date the approved draft PPP

standards would be gazetted and registered as a legislative instrument (if endorsed by the Food Ministers Meeting). This period would give industry and government authorities time to put measures in place to meet the standard's requirements, including development of a recognition model for food safety schemes. State and territory governments will work with industry to support them in the transition.

FSANZ periodically reviews standards. States and territories would be responsible for any review of implementation and compliance materials.