

## Consultation Regulation Impact Statement

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

---

#### Executive summary

This Consultation Regulation Impact Statement (CRIS) provides the methodology, considerations and processes that Food Standards Australia New Zealand (FSANZ) used when reviewing food safety in the fresh berries, fresh leafy vegetables and fresh melons sectors. It is intended to provide stakeholders with sufficient information about the preliminary proposal to enable further feedback. This work follows on from the first Call for Submissions in early 2020.

The vast majority of horticultural produce in Australia is safely produced and are an important part of a healthy and balanced diet. However, as outbreaks linked to particular horticulture sectors continue to occur, including in Australia, food ministers (the then Australia and New Zealand Ministerial Forum on Food Regulation) requested FSANZ reassess food safety risk management in the fresh berry, fresh leafy vegetable and fresh melon sectors. FSANZ has now completed its assessment for these three sectors. By and large, these foods are safe and a core part of a nutritious diet; our consideration of these commodities aims to further mitigate any food safety risks.

FSANZ's preliminary position is to recommend introduction of a combination of regulatory and non-regulatory measures to nationally manage food safety in these sectors. We propose primary production and processing (PPP) standards for each of berries, leafy vegetables and melons be introduced into the Australia New Zealand Food Standards Code. These standards would align with existing industry-led food safety schemes, be outcomes based, and be supported by non-regulated measures such as fact sheets, webinars and face-to-face meetings.

Our preliminary position is based on: the risks identified from the microbiological assessment, the current lack of national regulation in these sectors, the incomplete uptake of industry-led food safety schemes, the current cost of foodborne illness attributed to these sectors, and a cost-benefit analysis that includes costs of regulatory oversight, where relevant. We have also considered all information from the [first round of consultation](#), from which 27 responses were received. A survey of horticulture primary producers and processors also helped inform our assessment.

FSANZ estimates the costs to businesses would be offset by the benefits of a reduction in foodborne illness. Our cost-benefit analysis estimates the preferred option would cost \$0.1–0.3 to achieve every \$1 benefit for berries, \$0.2–0.6 for every \$1 benefit for leafy vegetables, and \$0.02–\$0.05 for every \$1 benefit for melons. FSANZ estimates that implementation of the preferred option would deliver approximately \$138 million in net benefits over a ten-year period.

In developing its preliminary position, FSANZ considered all options for managing food safety:

- maintaining the status quo
- regulatory measures only
- a combination of regulatory and non-regulatory measures
- non-regulatory measures only.

Noting the unique nature of each of the three horticultural sectors, FSANZ reviewed each one individually. Three separate standards are proposed: one for berries, one for leafy vegetables and one for melons. Each standard includes only those requirements relevant to the particular sector to reduce food safety risks in that sector to an acceptable level.

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

- notification of business
- traceability of produce
- management of water as an input
- construction and cleanliness of premises and equipment
- skills and knowledge
- health and hygiene
- sale and supply of safe produce.

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

- general food safety management requirements
- traceability of produce
- management of water as an input
- management of soil and fertiliser as inputs
- management of seed and seedlings as inputs (leafy vegetables only)
- management of the growing site
- management of food safety following weather events
- construction and cleanliness of premises and equipment
- maintaining an appropriate temperature of harvested produce
- appropriate washing and sanitation of produce
- management of animals and pests
- skills and knowledge
- health and hygiene
- sale and supply of safe produce.

This proposal is being assessed under FSANZ's major procedure, which requires two rounds of public consultation.

Stakeholders are now invited to provide comment on this assessment and FSANZ's preliminary position. Although a combination of regulatory and non-regulatory measures is currently FSANZ's preferred option, we are seeking information and views on all options, and all options will be considered. Questions for stakeholders are provided in section 12. Information collected will be used to inform FSANZ's final position and to prepare a Decision Regulation Impact Statement (DRIS). The DRIS will be presented to decision-makers and will also be publicly available.

# Table of contents

<b>EXECUTIVE SUMMARY</b> .....	<b>1</b>
<b>1. INTRODUCTION</b> .....	<b>4</b>
<b>2. SCOPE OF THE PROPOSAL</b> .....	<b>5</b>
2.1 COMMODITIES.....	5
<i>Berries</i> .....	5
<i>Leafy vegetables</i> .....	5
<i>Melons</i> .....	6
2.2 ACTIVITIES.....	6
<i>Primary production</i> .....	6
<i>Primary processing</i> .....	6
2.3 COUNTRIES.....	7
<b>3. PURPOSE OF THIS DOCUMENT</b> .....	<b>7</b>
<b>4. WHAT IS THE PROBLEM?</b> .....	<b>8</b>
4.1 OVERVIEW.....	8
4.2 <b>FOODBORNE ILLNESS</b> .....	8
4.3 <b>FOOD RECALLS AND NATIONAL INCIDENTS</b> .....	9
4.4 <b>COSTS OF ILLNESS</b> .....	9
4.5 <b>COSTS TO INDUSTRY</b> .....	10
4.6 <b>MICROBIOLOGICAL HAZARDS</b> .....	10
4.7 <b>PRODUCTION RISK FACTORS</b> .....	11
4.8 <b>LACK OF NATIONAL REGULATORY REQUIREMENTS</b> .....	11
4.9 <b>FOOD SAFETY SCHEMES</b> .....	12
4.10 <b>TRACEABILITY WEAKNESS</b> .....	12
<b>5. WHY IS GOVERNMENT ACTION NEEDED?</b> .....	<b>13</b>
5.1 OVERVIEW.....	13
5.2 <b>CONSUMERS</b> .....	13
5.3 <b>BUSINESSES</b> .....	13
5.4 <b>FOOD SAFETY</b> .....	14
5.5 <b>HEALTH CARE</b> .....	14
5.6 <b>NATIONAL REGULATION</b> .....	14
5.7 <b>EXPORT</b> .....	14
5.8 <b>TRACEABILITY</b> .....	14
<b>6. WHAT POLICY OPTIONS ARE TO BE CONSIDERED?</b> .....	<b>15</b>
6.1 OVERVIEW.....	15
6.2 <b>OPTION 1: RETAIN THE STATUS QUO</b> .....	15
<i>Current non-regulatory measures</i> .....	15
<i>Current regulatory measures</i> .....	16
<i>Summary</i> .....	17
6.3 <b>OPTION 2: REGULATORY MEASURES – STANDARDS FOR BERRIES, LEAFY VEGETABLES AND MELONS</b> 17	
<i>Identification of food safety risk factors</i> .....	18
<i>Berries – determining appropriate regulatory measures</i> .....	18
<i>Leafy vegetables – determining appropriate regulatory measures</i> .....	20
<i>Melons – determining appropriate regulatory measures</i> .....	22
<i>Draft standards</i> .....	24
<i>Compliance plans</i> .....	27
<i>Summary</i> .....	27
6.4 <b>OPTION 3: REGULATORY PLUS NON-REGULATORY MEASURES</b> .....	27
<i>Summary</i> .....	28

6.5	OPTION 4: NON-REGULATORY MEASURES.....	29
	<i>Summary</i> .....	29
<b>7.</b>	<b>WHAT IS THE LIKELY NET BENEFIT OF EACH OPTION? .....</b>	<b>29</b>
7.1	OVERVIEW.....	29
7.2	THE COST–BENEFIT ANALYSIS.....	29
	<i>International trade</i> .....	30
	<i>Consumer response</i> .....	30
	<i>CBA data gaps and assumptions</i> .....	31
7.3	NET BENEFIT OF OPTION 1 – RETAIN THE STATUS QUO.....	31
	<i>Current cost of illness</i> .....	31
	<i>Summary of the costs and benefits of the status quo</i> .....	32
7.4	NET BENEFIT OF OPTION 2 – REGULATORY MEASURES.....	33
7.5	NET BENEFIT OPTION 3 – REGULATORY AND NON-REGULATORY MEASURES .....	33
	<i>Costs to industry</i> .....	33
	<i>Cost-benefit ratios</i> .....	36
	<i>Net benefit estimates over 10 years</i> .....	38
	<i>Increased exports</i> .....	38
	<i>Consumer response</i> .....	39
	<i>Non-regulatory measures</i> .....	39
	<i>Other impacts</i> .....	40
	<i>Summary of the costs and benefits the option 3</i> .....	41
7.6	NET BENEFIT OF OPTION 4 – NON-REGULATORY MEASURES .....	41
	<i>Summary of the costs and benefits of option 4</i> .....	41
7.7	COMPARING THE COSTS AND BENEFITS OF THE RISK MANAGEMENT OPTIONS.....	41
	<i>Quantitative analysis</i> .....	41
<b>8.</b>	<b>WHAT IS THE BEST OPTION FROM THOSE CONSIDERED? .....</b>	<b>43</b>
8.1	OVERVIEW.....	43
8.2	FSANZ’S OBJECTIVES.....	43
8.3	OPTION 1 – STATUS QUO .....	44
8.4	OPTION 2 – REGULATORY MEASURES (STANDALONE) .....	44
8.5	OPTION 3 – REGULATORY AND NON-REGULATORY MEASURES.....	44
8.6	OPTION 4 - NON-REGULATORY MEASURES (STANDALONE).....	47
<b>9.</b>	<b>CASE STUDIES .....</b>	<b>49</b>
<b>10.</b>	<b>HOW WILL THE CHOSEN OPTION BE IMPLEMENTED AND EVALUATED?.....</b>	<b>52</b>
10.1	OVERVIEW.....	52
10.2	COMPLIANCE PLANS AND GUIDANCE DOCUMENTS .....	52
	<i>Proposed compliance plans for the leafy vegetables and melons sectors:</i> .....	52
	<i>Audits and monitoring of the leafy vegetables and melons sectors</i> .....	53
	<i>Guidance document for the berries sector</i> .....	53
10.3	GENERAL.....	54
10.4	IMPLEMENTATION PERIOD .....	54
10.5	REVIEW .....	54
<b>11.</b>	<b>WHO WAS CONSULTED AND HOW WAS THEIR FEEDBACK INCORPORATED? .....</b>	<b>55</b>
11.1	OVERVIEW.....	55
11.2	CONSULTATION .....	55
11.3	HORTICULTURE AND FOOD SAFETY WORKSHOP .....	55
11.4	HORTICULTURE INFORMATION PAPER .....	56
11.5	INDUSTRY VISITS .....	56
11.6	HORTICULTURE IMPLEMENTATION WORKING GROUP.....	57
11.7	HORTICULTURE STANDARDS DEVELOPMENT ADVISORY GROUP.....	57
11.8	PUBLIC CONSULTATION.....	58
11.9	TARGETED CONSULTATION SURVEY .....	59

11.10.....FUTURE CONSULTATION  
59

**12. QUESTIONS FOR STAKEHOLDERS ..... 60**

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

At that time, some of the key reasons for FSANZ's decision to only recommend non-regulatory options were that:

- an estimated 70–80% of horticulture produce was grown under a food safety scheme (FSS)
- the nature and number of horticulture businesses across the entire sector was uncertain, as were their current food safety management strategies
- a 'one size fits all' regulatory model for the whole horticulture sector was problematic
- enforcement of regulatory measures would be difficult across the entire horticulture sector.

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. It examines the number and nature of businesses in these sectors (including the uptake of a FSS) and recommends tailored regulatory and non-regulatory options for each sector.

The ministers' request was based on several reasons. In 2017, ministers identified that reducing foodborne illness was a priority, particularly illness linked to *Campylobacter* and *Salmonella*. *Australia's Foodborne Illness Reduction Strategy 2018–21+<sup>1</sup>* was developed to address that priority, and it includes food safety management in the horticulture sector as a key focus. In 2018, increases of foodborne illness outbreaks in Australia 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 additional recommendations to better manage food safety concerns in each of these commodities.

As measures 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.

---

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

## 2. Scope of the proposal

The scope of this proposal refers to commodities, activities and countries as described below.

### 2.1 Commodities

The three horticulture products in scope for this proposal are:

- fresh berries
- fresh leafy vegetables
- fresh melons.

The examples of produce provided below are not exhaustive. The range of produce covered is guided by FSANZ's Microbiological Assessment of Berries, Leafy Vegetables and Melons (the microbiological assessment) provided as Supporting Document 2 (SD2). Food management measures may be required for any produce in these sectors where the inherent characteristics of the produce, or the growing and production activities associated with the produce, have been identified by the microbiological assessment as contributing to a risk that requires management.

#### Berries

The four major berries grown in Australia are strawberries, raspberries, blueberries and blackberries. In addition, boysenberry, loganberry, silvanberry and youngberry are *Rubus* hybrid cultivars that are grown in relatively small quantities.

FSANZ identified the following proxies in the microbiological review, to enable consideration of risks associated with berries of different surface types (e.g. smooth, aggregate) and growing conditions (bush/cane, ground), and taking into consideration the volume of product grown in Australia:

- blueberries
- raspberries
- strawberries.

#### 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 raw. Examples are microgreens, baby leaves, lettuce, spinach, cabbages, chicory, leafy herbs (e.g. coriander, basil, parsley) and watercress.

The main leafy vegetable crops grown in Australia include:

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

FSANZ identified the following as proxies in the microbiological review for fresh leafy vegetables and herbs, to enable consideration of a range of cultivation methods (e.g. hydroponic, field grown etc.), harvest methods, and variety of product types, and taking into

consideration the volume of product grown in Australia:

- lettuce (including iceberg, cos/romaine, butterhead, oak)
- spinach
- parsley (including continental and curly-leaf).

## **Melons**

Melons include watermelon, rockmelon, honeydew melon, galia melon, charentais melon, Korean melon, hami melon and piel de sapo.

The main melon crops grown in Australia include:

- watermelon
- rockmelon
- honeydew.

To consider melons of different surfaces types (e.g. netlike versus smooth) and taking into consideration the volume of product grown in Australia, FSANZ identified the following as proxies in the microbiological review for melons:

- rockmelon (netted varieties)
- watermelon.

## **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, chopping, sorting, combining the same produce type on the primary production premises
- storing 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, chopping, sorting, combining the same produce type on the primary processing premises
- storing 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.

Primary processing includes all activities not already regulated by FSANZ under [Chapter 3 – Food Safety Standards](#) of the Code. Chapter 3 applies to ‘food businesses’ (as defined in



[Standard 3.1.1](#)), and includes the sale or handling of food intended for sale and the substantial transformation (processing) of food. Primary producers and processors who substantially transform produce or who are involved in the retail sale of food would be considered a 'food business', and Chapter 3 would apply—rather than the risk management measures of this proposal.

Chapter 3 requirements do not apply to any primary production activities. Instead, the risk management measures of this proposal will apply to primary production in the berries, leafy vegetables and melons sectors.

A schematic representation of the activities in scope of proposal P1052 is provided in Figure 1 below.

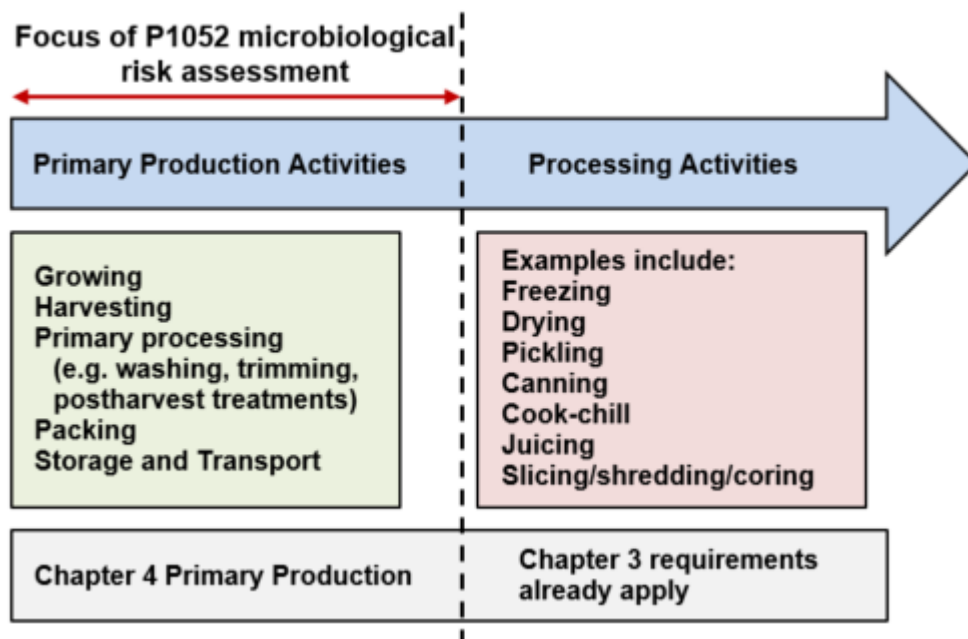


Figure 1. Schematic representation of the scope of P1052 and delineation of Chapters 3 and 4 of the Australia New Zealand Food Standards Code.

## 2.3 Countries

Any regulatory measures introduced into Chapter 4 of the Code apply in Australia only.

## 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.

This Consultation Regulation Impact Statement (CRIS) 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](#), which came into effect on 10 May 2021. 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 CRIS summarises FSANZ’s consideration and responses to these questions, the FSANZ process, and the technical work. FSANZ seeks information and feedback from stakeholders on the regulatory and non-regulatory options set out in this CRIS. Specific questions for stakeholder consideration are provided in this document (see section 12).

## 4. What is the problem?

### 4.1 Overview

Fresh fruit and vegetables are important components 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. The impacts of these events 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 present a significant cost to the Australian economy, yet 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. Details of all methodology and conclusions are in supporting documents.

### 4.2 Foodborne illness

Total foodborne illness in Australia has been estimated at 4.1 million cases per year, including 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 \$1.2 billion each year ([Abelson et al 2006](#)). Of the known microbiological causes, norovirus (NoV), *Escherichia coli*, *Campylobacter* and *Salmonella* are the most common. However, the cause of illness is not determined in around 80% of cases.

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 (HAV) 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. More information about outbreaks, the methodology used to investigate them and conclusions are provided in the microbiological assessment in SD2.

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.

### 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
  - one recall in 2020 (*Salmonella* spp.)
- two recalls for domestically produced melons
  - one in 2016 (*Salmonella* spp.), associated with an outbreak
  - one in 2018 (*Listeria 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 both in terms of people's health (illness and/or death) and costs to the industry. FSANZ 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 foodborne illness burden
- asking an expert panel to determine the percentage burden attributed to each commodity
- using these percentages to estimate the annual cost of illness attributed to each commodity sector.

Preliminary costings of illness are provided in Table 1.

**Table 1. Preliminary estimates of annual cost of illness**

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

These calculations only included costs related to illness resulting from the hazards identified by our microbiological assessment. The annual costs of illness includes the total burden of illness caused by the identified microbiological hazards in each sector. These costs are not limited to illnesses linked to an outbreak or incident, but also include single cases of illness. Further details are in Appendix 1 and 2 of our cost-benefit analysis (CBA).

## 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 *Listeria 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 estimated at around \$15 million. For that 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. 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 (SD2).

**Table 2. Microbiological hazards identified in the Australian context**

Commodity	Hazard
Berries	<ul style="list-style-type: none"> <li>• shiga toxin-producing <i>Escherichia coli</i> (STEC)</li> <li>• norovirus (NoV)</li> <li>• hepatitis A virus (HAV)</li> </ul>
Leafy vegetables	<ul style="list-style-type: none"> <li>• non-typhoidal <i>Salmonella</i> spp. (<i>Salmonella</i>)</li> <li>• STEC</li> <li>• <i>Listeria monocytogenes</i></li> </ul>
Melons	<ul style="list-style-type: none"> <li>• non-typhoidal <i>Salmonella</i> spp.</li> <li>• <i>Listeria monocytogenes</i></li> </ul>

## 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 SD2.

## 4.8 Lack of 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 SD1.

Primary production and processing of horticultural products is currently regulated to varying degrees by the states and territories. NSW, Queensland and SA all have food safety requirements for some general aspects of horticulture in regulations under their Food Acts.

Chapter 3 of the Code sets out general food safety requirements for 'food businesses', which excludes primary producers unless they sell food directly to the consumer. This presents a national regulatory gap.

During the 1<sup>st</sup> call for submissions for P1052, Melons Australia, The Fresh Produce Safety Centre, Freshcare, JAS-ANZ and One Harvest mentioned national consistency. Some of these stakeholders noted a current need for national consistency. All of these stakeholders 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, 75 leafy vegetable businesses and 6 melon businesses. National or semi-national operations are expected to increase as businesses are consolidated, demand for food increases and ongoing supply (from different climate zones) is required. 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.

The lack of national or consistent regulation makes it difficult for government food regulators to proactively support Australia's primary producers and processors. Current regulation generally only empowers regulators to manage food safety in these sectors (e.g. to legally enter premises) as a reactive measure.

Facilitating national consistency is a priority of [food regulation](#). It is key to maintaining a strong, robust and agile food regulation system. Increased national consistency in the food regulation system will result in cost savings for industry and governments.

## 4.9 Food safety schemes

The berry, leafy vegetable and melon sectors operate to varying degrees under industry Food Safety Schemes (FSS). These schemes are comprehensive but non-regulatory measures. 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
- 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 FSS, while others do not, and are therefore unable to take this into consideration when making safe food choices
- investigations into recent outbreaks have revealed that, even where businesses have FSS in place, outbreaks have continued to occur – this suggests the level of assurance provided by 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.

Detailed information on current regulatory and non-regulatory food safety measures (domestic and international) and a gap analysis of GFSI benchmarking requirements are included in this CRIS at SD1.

## 4.10 Traceability weakness

The ability to track products quickly if a food safety issue occurs can be critical to preventing illness. There are prescriptive requirements for traceability in industry schemes, but these only apply to businesses 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.

With the current measures, incidents and illness associated with fresh horticulture produce, particularly the berry, leafy vegetable and melon sectors, continue to occur in Australia. Current measures rely heavily on FSS that are not taken up across the entire sector, creating food safety gaps. This impacts consumers who are unable to identify produce from producers with adequately safe production practices. Industry is impacted by different jurisdictional requirements and/or costs to those implementing a voluntary FSS. National requirements can support consistency in implementation and effectiveness.

### **5.2 Consumers**

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

This lack of visibility and expertise in the consumer base 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.

For the most part, it is not possible for consumers to know whether producers have incorporated safe food handling measures through production and primary processing. Consumers expect all produce to be safe. The protection of consumers and public health is a rationale for government action.

### **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 unequitable playing field for businesses within the sector. This would be mitigated by government regulation, which would apply to all businesses. Government intervention would also protect safe-food businesses from reputational and financial damage resulting from outbreaks caused by businesses that do not prioritise food safety. The protection of businesses is a rationale for government action.

## **5.4 Food safety**

FSS and a range of other resources and incentives have been introduced by industry to reduce the occurrence of foodborne illness. Major retailers require participation in a FSS.

However, not all businesses currently participate in FSS, and there is little incentive for these businesses to do so. FSS are not government mandated or underpinned by legislation. This creates a food safety gap. Government regulation would ensure that food-safe practices, similar to those currently supported by FSS, would be applied across the entire sector and underpinned by legislation. The protection of food safety is a rationale for government action.

## **5.5 Health care**

The cost of illness has been discussed as part of 'The problem' (section 4). Protection of the Australian health care system from the cost of illness and death is a rationale for government action.

## **5.6 National regulation**

As previously described, 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 food safety culture and deliver safe produce. The current lack of national legislation also results in national inconsistency. 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 set of guidelines.

## **5.7 Export**

Australia exports limited quantities of fresh berries, leafy vegetables and melons. Export data is provided in Appendix 6 of our CBA. Exports of horticultural produce are facilitated by the Department of Agriculture, Water and Environment (DAWE) and issue 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 will participate in the national incident response, including tracing implicated export consignments.

Australia's reputation for safe, high-quality produce has value for the agricultural sector. Protection of this reputation is important for trade, and the maintenance of price premiums for 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.

## **5.8 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 entire sector. This would aid in identifying the source of the illness, identifying affected produce, reducing resources required of regulators, 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. 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 reviewed the GFSI requirements against every step of primary production and processing including growing, harvesting, processing, packing and distribution. We investigated control measures set out by GFSI against the main risk factors identified in our

microbiological assessment. Our analysis (see SD1), indicates that prescribed GFSI control measures align well with our identified risk factors, including traceability. There appears to be no significant gaps in the GFSI requirements for horticultural production and processing in the Australian context. Note, we did not assess the effectiveness of GFSI requirements.

The degree of FSS uptake by sectors provides varying degrees of coverage. FSANZ estimates that approximately 75% of berry businesses, 25% of leafy vegetable businesses and 95% of melon businesses are on a FSS (details are provided in the CBA). FSANZ believes that medium and large businesses are more likely to be on a FSS than smaller businesses.

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 documents place more emphasis on food safety practices than others. Some initiatives targeting food safety and traceability have been completed or are being trialled, particularly for melons. Food safety culture initiatives are also expanding, with the growing recognition of the importance of behaviour and commitment to ensuring safe food.

## **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 generally excludes primary producers unless they sell food directly to the consumer. The Australian Competition and Consumer Commission's (ACCC) Horticulture Code of Practice prescribed under the *Competition and Consumer Act 2010* requires horticulture growers and traders to have a Produce Agreement. The default specifications of this agreement include that produce is to be grown and packed under a Hazard Analysis Critical Control Point (HACCP)-based food safety program that is subject to an annual third-party audit. However, this requirement is not mandated, and can be removed if agreed between the grower and trader. This arrangement is not directly enforced by the ACCC. It is only overseen by the third-party auditor.

### ***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 are not specific for berries, leafy vegetables or melons. Further information is provided in SD1.

### ***Import and export***

DAWE administers legislation to regulate the import and export of agricultural products, including food and plant products. The main focus of import legislation 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 and the regulatory and non-regulatory measures described above. Current measures would continue to apply to the primary production and processing of berries, leafy vegetables and melons.

### 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 standard has been provided in full in the main body of our 2<sup>nd</sup> call for submissions report. 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 set out overarching regulatory measures that 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 achieve the appropriate food safety outcomes (i.e. represent the lightest touch).

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.

To ensure reasonable, low impact/cost regulation, FSANZ has aligned proposed regulatory measures to those of existing FSS. We anticipate (based on our gap analysis provided in SD1) that primary producers and processors who currently operate in accordance with an accredited FSS will already meet proposed regulatory measures, and any impact will be minimal. FSANZ understands from industry and jurisdiction feedback that medium and large businesses are more likely to be on a FSS than smaller businesses.

FSANZ considered international standards when designing regulatory measures. Our proposed measures include clauses similar to those in the berries annex of the [Codex CoHP](#). It is worth noting that, for berries, FSANZ has minimised its proposed regulatory measures, in comparison to the Codex approach, largely in response to the lack of outbreaks connected with Australian produce – noting that analysis of outbreaks to date does not equate to zero future risk.

For berries, leafy vegetables and melons, FSANZ has also included minimal traceability (one step forward and one step back) 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 in the proposed regulation for berries, leafy vegetables and melons. 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 berries, leafy vegetables or melons for human consumption where the seller/supplier ought reasonably know that the product is unacceptable and may constitute a food safety risk.

## **Identification of food safety risk factors**

To identify and evaluate any food safety risks associated with primary production and processing of berries, leafy vegetables and melons, FSANZ considered:

- outbreaks and the prevalence of microbial hazards
- the characteristics of microbial hazards
- the inherent characteristics of berries
- risk factors of the primary production environment
- risk factors of harvest and field packing
- risk factors of the pack house and post-harvesting
- consumption patterns.

## **Berries – determining appropriate regulatory measures**

### ***Identified risk factors***

Microbial hazards (pathogens) we identified for berries were HAV, NoV, STEC and *Salmonella* spp. These were based on consideration of Australian and international outbreak data and international research. Characteristics of each hazard are summarised in section 7 of the microbiological assessment (SD2), with further detail in its Appendices 6, 8 and 10.

FSANZ considered the inherent characteristics of berries and the influence these characteristics have on contamination with, and growth and persistence of the identified hazards. Characteristics evaluated included pH (acidity), water and sugar content, surface attributes and berries' susceptibility to damage. The interplay of these characteristics and the microbial hazards identified for berries are described in section 8.2 of the microbiological assessment. For example, the pH of berries generally doesn't support the growth of bacteria; however, there is evidence that viruses, such as HAV, can persist on the surface of berries.

FSANZ examined activities in primary production and processing of berries that may contribute to food safety risk. These are discussed in sections 9–11 of the microbiological assessment. FSANZ then selected only those primary production and processing activities strongly linked to food safety risk in the berries sector. Some activities deemed more relevant for leafy vegetables and melons were not strongly linked to food safety risk in the berries sector. These risk activities have not been included in the list below.

Specific risk factors that we attributed to berries and selected for further consideration/regulation were:

- incursion by wildlife and domestic animals
- the occurrence of weather events, such as flooding or heavy rain, that could transfer pathogens to produce, fields, or irrigation water sources
- 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 CRIS. In the case of berries, there are no reported outbreaks from domestically produced berries and there is a low estimated illness cost i.e. it is a low cost problem.

### ***Other considerations***

FSANZ estimates there are 750 (+/- 250) berry producers nationally, and that up to 75% of these businesses are operating in accordance with a FSS. Because of this high level of existing FSS uptake, our CBA shows less net benefit of regulation in the berry sector.

### ***Regulatory risk management measures for berries***

After considering the findings of the CBA and the current regulatory and non-regulatory position, FSANZ identified only those key risk factors where mitigation measures would have the most impact in reducing food safety risks in the berries sector. A significant impact could be expected for the estimated 25% of businesses (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 sector.

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

- inputs (water)
- 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 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 these businesses to help manage food safety in a collaborative manner. FSANZ does not propose to require the berry industry to comply with the General Food Safety Management Requirements (GFSMR) described in Standard 4.1.1 of the Code.<sup>2</sup>

FSANZ also considered managing the risk of application of untreated or insufficiently treated manure or compost amendments, particularly for berry plants growing close to the ground. The proposed berries standard does not currently include a clause to manage this risk, as:

- The risk is not the same across the sector: berries growing closer to the ground are more likely to be contaminated.
- The cost-benefit estimates for the berries sector indicated that reduced regulation is required, comparative to the leafy vegetables and melons sector.
- We determined the key identified risks (e.g. water inputs) were the most important to manage; the next most important being soil, soil amendments and fertilisers.

Section 9.5 of the microbiological assessment presents these findings.

FSANZ has considered modifying the 'Inputs -water' clause in the proposed berries standard to also manage the food safety risk associated with soil, soil amendments and fertiliser. This clause would read:

---

<sup>2</sup> 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.

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 berries unacceptable:*

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

In addition to the feedback on the proposed regulatory measures for berries, FSANZ is also seeking feedback on the regulatory management of soil, soil amendments and fertilisers as part of this 2<sup>nd</sup> call for submissions. A question for stakeholders regarding this issue is included at the end of this document (see section 12).

## **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 outbreaks. Further detail about outbreaks and prevalence is in section 4 of our microbiological assessment (SD2).

Microbial hazards of concern were based on consideration of Australian and international outbreak data and other international research. The characteristics of each hazard are summarised in section 7 of the microbiological assessment, with further detail in 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
- *Listeria monocytogenes*.

FSANZ also considered the inherent characteristics of leafy vegetables and the influence these characteristics have on contamination with, growth of, and persistence of the microbial hazards identified above. Characteristics evaluated included pH, water activity, the characteristics of the leaf, and the size and structure of the plant. The interplay of these

characteristics and the microbial hazards identified for leafy vegetables are described in section 8.1 of the microbiological assessment. When assessing the potential for microbial contamination, we also investigated the influence of cut or damaged surfaces and storage temperatures on identified hazards, and the ability of these hazards to internalise in the tissue of leafy vegetables.

Activities associated with the primary production and processing of leafy vegetables that may contribute to food safety risk were also analysed (see sections 9-11 of the microbiological assessment). FSANZ then selected only those primary production and processing activities strongly linked to food safety risk in the leafy vegetable sector.

Risk factors that FSANZ attributed to leafy vegetables and selected for further consideration/regulation were:

- incursion by wildlife and domestic animals
- characteristics of the production site including surrounding and prior land use (particular for open-field production)
- occurrence of weather events, such as flooding or heavy rain, that 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 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.

Risk factors specific to leafy vegetables are further discussed in section 13.3.1 of the microbiological assessment.

Our microbiological assessment also considered Australian consumption patterns of leafy vegetables—see section 6 of that assessment.

### ***Cost-benefit analysis***

FSANZ completed an economic analysis of costs and benefits to inform the CRIS. The high estimated illness cost for leafy vegetables is largely a result of the higher occurrence of *Salmonella* and the severity and the long term impacts of Listeriosis.

### ***Other considerations***

FSANZ's review of food safety in the leafy vegetable sector also considered the extent of the current regulatory and non-regulatory framework, including existing FSS and the level of sign-up to these schemes. FSANZ estimates there are 1500 (+/- 500) leafy vegetable producers nationally, and that only about 25% of these businesses are operating in accordance with an accredited FSS. The lack of existing national regulation and the low level of uptake of a FSS influenced FSANZ's final position.

### ***Regulatory risk management measures for leafy vegetables***

After considering the CBA and the current regulatory and non-regulatory position, FSANZ identified key risk factors in the leafy vegetable sector, where mitigation measures would have the most impact in reducing food safety risks.

FSANZ proposes management of the following key risks through regulation:

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

- general food safety management requirements
- minimal traceability
- safe sale and supply.

The GFSMR are defined in the Code in [Standard 4.1.1](#). The GFSMR 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 verification activities.

## **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 - *Listeria monocytogenes*
- 2016 - *Salmonella* Hvittingfoss
- 2018 - *Listeria monocytogenes*.

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

- 2016 - *Salmonella* spp., associated with an outbreak
- 2018 - *Listeria 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 section 4 of the microbiological assessment (SD2).

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

- *Salmonella* spp.
- *Listeria monocytogenes*.

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 section 7 of the microbiological assessment, with further detail provided in Appendices 6, 8 and 10.



We also considered the inherent characteristics of melons and the influence these characteristics have on contamination with, growth of, and persistence of the microbial hazards identified above. Characteristics evaluated included pH, water activity, sugar content and the surface characteristics of melons. The interplay of these characteristics and the microbial hazards identified for melons are described in section 8.3 of the microbiological assessment. FSANZ also investigated the influence of smooth or rough surfaces of melons and storage temperatures on the identified hazards.

Activities associated with the primary production and processing of melons that may contribute to food safety risk were also examined. These are discussed in sections 9–11 of the microbiological assessment. FSANZ then selected only those primary production and processing activities strongly linked to food safety risk in the melons sector.

Risk factors that FSANZ attributed to melons and selected for further consideration/ regulation were:

- 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
- 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.

Risk factors specific to melons are further discussed in section 13.3.3 of the microbiological assessment.

### ***Cost-benefit analysis***

FSANZ completes an economic analysis of costs and benefits to inform the CRIS. The CBA estimated (through the expert elicitation process) that the current cost of illness associated with melons is \$30.7 million per annum, with salmonellosis contributing to the highest cost, followed by listeriosis (listeriosis costs approximately \$5.6 million across the estimated six acute cases per year).

### ***Other considerations***

FSANZ's review of the melons sector also considered the extent of the current regulatory and non-regulatory framework, including existing FSS and the level of sign-up to these schemes. FSANZ estimates that there are 225 (+/- 75) melon producers nationally and that approximately 95% of these businesses are already signatory to a FSS. FSANZ appreciates that the majority of melon growers already participate in a FSS and that, although these schemes are voluntary, they are a requirement when supplying to major retailers.

### ***Regulatory risk management measures for melons***

After considering the CBA and the current regulatory and non-regulatory position, FSANZ identified key risk factors where mitigation measures would have the most impact in reducing food safety risks in the melon sector.

FSANZ proposes management of the following key risks through regulation:

- 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, that 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 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 included the following proposed regulatory measures to support management of the key risks factors identified above:

- general food safety management requirements
- minimal traceability
- safe sale and supply.

The GFSMR are defined in the Code [Standard 4.1.1](#). The GFSMR includes 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 verification activities.

### Draft standards

Each of FSANZ's proposed regulatory measures are provided for comment in Attachment A of the 2<sup>nd</sup> call for submissions report as:

- 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

An explanatory statement accompanies the draft standards and provides further context and information. Table 3 below 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
<p><b>Notification</b></p> <p>(1) A primary horticulture producer and processor must provide specified information to the relevant authority before engaging in a relevant activity.</p> <p>(2) In this section, specified information means the following information:</p> <p>(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;</p> <p>(b) a description of the activities the primary horticulture producer of the primary horticulture</p>	✓	✗	✗

Requirement	Berries	Leafy Vegetables	Melons
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.			
<b>General food safety management requirements</b> A primary horticulture producer and a primary horticulture processor must comply with the general food safety management requirements Note: This requirement includes notification.	x	✓	✓
<b>Traceability</b> A primary horticulture producer and a primary horticulture processor must have in place a system that can identify: (a) from whom [ <i>the commodity</i> ] were received; and (b) to whom [ <i>the commodity</i> ] were supplied.	✓	✓	✓
<b>Inputs – water</b> A primary horticulture producer and a primary horticulture processor must take all reasonable measures to ensure that water inputs do not make [ <i>the commodity</i> ] unacceptable.	✓	✓	✓
<b>Inputs – soil and fertiliser</b> 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 [ <i>the commodity</i> ] unacceptable: a) soil; b) soil amendments (including manure, human biosolids, compost, and plant bio-waste); and c) fertiliser.	x	✓	✓
<b>Inputs – seed and seedling</b> 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.	x	✓	x
<b>Growing sites</b> A primary horticulture producer must take all reasonable measures to ensure that a growing site is located,	x	✓	✓

Requirement	Berries	Leafy Vegetables	Melons
designed, constructed, maintained and operated such that [ <i>the commodity</i> ] are not made unacceptable.			
<p><b>Weather events</b></p> <p>A primary horticulture producer and a primary horticulture processor must take appropriate remedial action to ensure that [<i>the commodity</i>] adversely affected by weather conditions are not unacceptable.</p>	X	✓	✓
<p><b>Premises and equipment</b></p> <p>(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:</p> <p>(a) allows for effective cleaning and sanitisation of the premises and equipment; and</p> <p>(b) does not make [<i>the commodity</i>] unacceptable.</p> <p>(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 [<i>the commodity</i>] are not made unacceptable.</p>	✓	✓	✓
<p><b>Temperature of harvested [<i>the commodity</i>]</b></p> <p>A primary horticulture producer and a primary horticulture processor must keep harvested [<i>the commodity</i>] at a temperature that does not make [<i>the commodity</i>] unacceptable.</p>	X	✓	✓
<p><b>Washing and sanitisation of harvested [<i>the commodity</i>]</b></p> <p>A primary horticulture processor must take all reasonable measures to ensure that:</p> <p>(a) visible extraneous material on harvested [<i>the commodity</i>] does not make [<i>the commodity</i>] unacceptable; and</p> <p>(b) any washing or sanitising of harvested [<i>the commodity</i>] does not make [<i>the commodity</i>] unacceptable.</p>	X	✓	✓
<p><b>Animals and pests</b></p> <p>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 [<i>the commodity</i>] are not made unacceptable.</p>	X	✓	✓

Requirement	Berries	Leafy Vegetables	Melons
<p><b>Skills and knowledge</b></p> <p>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:</p> <ul style="list-style-type: none"> <li>(a) knowledge of food safety and food hygiene matters; and</li> <li>(b) skills in food safety and food hygiene matters commensurate with their work.</li> </ul>	✓	✓	✓
<p><b>Health and hygiene of personnel and visitors</b></p> <p>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 [<i>the commodity</i>] unacceptable.</p>	✓	✓	✓
<p><b>Sale or supply of unacceptable [<i>the commodity</i>]</b></p> <p>A primary horticulture producer and a primary horticulture processor must not sell or supply [<i>the commodity</i>] for human consumption if they ought reasonably know or ought reasonably suspect that [<i>the commodity</i>] are unacceptable.</p>	✓	✓	✓

## Compliance plans

FSANZ standards are implemented by the jurisdictions. When a draft standard is provided for consultation, a draft compliance plan that supports its implementation by businesses at a practical level is also developed. Draft compliance plans for each of the proposed standards have been prepared by the Horticulture Implementation Working Group (HIWG), whose members include government officers in each state and territory responsible for food safety in the horticulture sector. While FSANZ's standards are outcomes based, the compliance plans outline how primary producers and processors will be expected to demonstrate that the outcomes have been met. These compliance plans allow for greater understanding of the effects of the proposed regulation.

Further information about the compliance plans and implementation of the proposed regulations is provided in section 10 of this CRIS.

## 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) have been provided to demonstrate how the proposed regulation would 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 the development of non-regulatory measures developed through collaboration between

government and industry. 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 industry and government from risk. Proposed non-regulatory measures are listed in Table 4.

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<sup>3</sup>, codes of practice, updating FSS and establishing the Fresh Produce Safety Centre Australia and New Zealand (FPSC A-NZ)<sup>4</sup>. Various guidance documents have also been developed through industry and government collaboration; for example, the *Guidelines for Fresh Produce Food Safety 2019* and the *Melon Food Safety Best Practice Guide*.

## Summary

Under option 3, regulation (as described in section 6.2 above) would be supported by voluntary non-regulatory components, such as facts sheets, animations, webinars and face-to-face meetings.

**Table 4. Proposed non-regulatory measures and responsibilities**

Activity	Description	Who
Fact sheets	Two facts sheets for each sector.  One set of fact sheets describes microbial hazards attributed to each sector.  The second set of fact sheets would describe the new requirements.  Delivered to industry via e-mail.	Created by FSANZ in consultation with jurisdictions and peak industry bodies.  Printed and displayed by industry.
Animations	One web-based animation for each sector.  Animations would highlight the microbial hazards associated with each sector and introduce the new requirements.  Animations would also direct to further information.	Created by FSANZ in consultation with jurisdiction and peak industry bodies.  Used as training material by industry.
Links to useful resources	Providing links to useful information to industry.  Linking to existing resources describing food safety in the horticultural sector and the promotion of food safety culture.	Provided by FSANZ.  Links to information used by industry.
Webinars	Webinars provided over the 18-month	Prepared by FSANZ and

<sup>3</sup> Available at <https://farmersmarkets.org.au/>

<sup>4</sup> <https://fpsc-anz.com/>

Activity	Description	Who
	<p>implementation period.</p> <p>The content of these webinars to be discussed with peak industry bodies, based on the needs of industry.</p> <p>Webinars would likely include PowerPoint presentations, speakers and a question and answer session.</p>	<p>jurisdictions and peak industry bodies.</p> <p>Delivered by FSANZ and jurisdictions and peak industry bodies.</p> <p>Used as training material by industry.</p>
Face-to-face meetings with industry.	One to two face-to-face meeting per sector, over the 18-month implementation period.	<p>Prepared by FSANZ and jurisdictions and peak industry bodies.</p> <p>Delivered by FSANZ and/or jurisdictions and peak industry bodies.</p> <p>Used as training material by industry.</p>

## 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 in SD3.

### Summary

Under option 4, voluntary non-regulatory measures (such as fact sheets, animations, webinars and face-to-face meetings) would be recommended.

## 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. 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. Regulation combined with non-regulation was found to have the highest net benefit. Non-regulation, as a standalone measure, was found to have some benefit.

### 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 real-world costs and benefits. As part of any proposal, FSANZ prepares a CBA. The CBA is used by FSANZ to consider:

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

The CBA for this proposal is provided as SD3. It includes additional detailed analyses on:

- Business costs (Appendix 1) – additional details for the CBA figures and assumptions
- Expert elicitation (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
- Government costs of the regulatory options (Appendix 3) – how implementation and ongoing costs to government regulators were calculated, and some simplified costings (preliminary assessment against draft compliance plans, quantified costs and benefits to be more fully considered for DRIS)
- Government costs of the non-regulatory option (Appendix 4) – how design and delivery of costs to government and industry bodies were calculated (to be more fully considered for the DRIS)
- Business costs of a food safety incident: a case study (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 (Appendix 6) – see below
- Consumer response (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, creating 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 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 as a result there may be a likely 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.

### **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 to 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. Further research is needed before being able to offer a definitive view in the context of the specific commodities covered by this proposal. Additional information provided by stakeholders will be used to refine these costs and assumptions, and an updated analysis will be provided in the DRIS.

### **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, preliminary analysis has been provided to assist stakeholders and decision makers.

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
- 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.

The cost to governments to implement and enforce the legislative options has only been preliminarily assessed at this point, using the draft compliance plans. The DRIS will include a more fullsome consideration of quantified costs and benefits.

These gaps and assumptions are clearly identified in the CBA. Further information is being sought from stakeholders to help us analyse the relative costs and benefits of the options.

The CBA (SD3) is provided for comment, and includes questions for stakeholders to help us further refine costings for the preparation of the DRIS.

Summary data from the CBA has been included in the following sections of this document to help communicate the likely net benefit of each option to stakeholders.

## **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 above (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 5.

**Table 5. Median attribution percentage by pathogen and commodity**

Commodity	Pathogen	Median % attribution
Berries	HAV	2.1
	NoV	0.6
	STEC	1.0
Leafy vegetables	<i>Listeria monocytogenes</i>	7.5
	<i>Salmonella</i>	1.7
	STEC	5.0
Melons	<i>Listeria monocytogenes</i>	8.7
	<i>Salmonella</i>	0.9

HAV = Hepatitis A virus, 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 preliminary costings are in Table 6. Further details are provided in Appendix 1 of the CBA.

**Table 6. Preliminary estimates of annual cost of illness**

Commodity	Total illness cost pa (\$)
Berries	6.5 million
Leafy vegetables	52.9 million
Melons	30.7 million

For berries, the estimated current annual cost of illness is \$6.5 million. NoV contributes the highest cost, followed by STEC and HAV.

For leafy vegetables, the estimated current annual cost of illness is \$53 million. *Salmonella* contributes the highest cost, followed by *Listeria* and STEC.

For melons, the estimated current cost of illness is \$30.7 million, with *Salmonella* contributing to the highest cost, followed by *Listeria*. *Listeria* contributes to costs of approximately \$5.6 million across the estimated six acute cases per year.

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

### Summary of the costs and benefits of the status quo

Under the status quo the following can be expected:

- Outbreaks, illness, deaths, recalls and incidents can be expected to continue at currently reported levels, noting possible reductions in melon incidents due to improved safety practices implemented by some melons growers since 2018.
- The annual cost of illness can be expected to continue as described above (i.e. berries \$6.5 million, leafy vegetables \$52.9 million, melons \$30.7 million).

- There would be no additional benefits in terms of food safety.
- There would be no nationally consistent set of non-regulatory requirements. FSANZ acknowledges industry uptake on a limited range of FSSs.
- Although industry FSS currently exist, these only apply to those businesses that uptake and effectively apply them. Primary producers and processors supplying to major retailers are required by the retailer to participate in an FSS, but other primary producers and processors may not be following good food safety measures. This would continue to result in the uneven playing field for industry and the potential lack of appropriate food safety management by businesses not participating in a FSS.
- There would be no nationally consistent set of regulatory requirements for berries, leafy vegetables or melons.
- 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. Current regulation generally only empowers regulators to manage food safety in these sectors (e.g. to legally enter premises) as a reactive measure.
- There would be no change required of industry or government.
- There would be no additional costs incurred by industry, government or consumers. Costs associated with outbreaks/illnesses remain; however, the current number and cost of outbreaks would continue to apply.

## 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.

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

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

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 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 7, with detail provided in the CBA.

**Table 7. 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 <b>business</b>	470	1,056	700	7,036	700	4,056
MEDIUM estimate - total <b>industry</b> costs	108,080	198,092	789,040	8,160,996	10,955	185,529

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 already be operating in a manner that would 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. Businesses with very little food safety management in place would be expected to incur the greatest costs; this is demonstrated in Table 8. It is important to take a business's current level of food safety management into consideration when reviewing potential costs.

**Table 8. 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 \$
<b>Businesses with FSS (or equivalent measures) in place</b>  Berries: Initial notification  Leafy vegetables and melons: Annual licencing and auditing costs	30	0	0	1,540	0	1,540
<b>Businesses with some food safety management in place (50% of the proposed measures)</b>  Includes notifications, licencing, audits and 50% of the costs of implementing all measures in the proposed standard	470	1,056	700	7,036	700	4,056
<b>Businesses without any food safety management in place. Costs will be similar to what businesses implementing industry-driven schemes have</b>	910	2,113	1,400	12,533	1,400	6,573

already invested						
Includes notifications, licencing, audits and 100% of the costs of implementing all measures in the proposed standard						
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. Although the proposed regulations would apply to all berry primary producers and processors, audits or monitoring by regulators would not be required. This removes the cost of licensing, assessment of a food safety management statement and routine audits/monitoring for this sector completely. However, inspections by government regulators would occur if a food safety concern was raised (e.g. through a genuine complaint). The inspection would take the form of a walk-through of the business and review of how the business had implement the proposed standard. A rough estimate of the inspection cost has been provided by Victoria, as many berry producers are located in this state. Agriculture Victoria has estimated \$250–500 per inspection for an average-sized producer. These costs are based on current fees for inspecting food business. There are currently no set charges for inspecting horticultural businesses in Victoria and as such the inspection fee provided is indicative only.

FSANZ has estimated that the cost of 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. Licencing/re-licencing fees are estimated at \$624 each year. Fees per audit are estimated to be \$485 each year. Actual audit fees may vary greatly from this average, depending on size and other aspects of a business.

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.

We encourage industry to consider their individual business when reviewing the costs estimates provided in the CBA, to form a clearer picture of likely costs. Further detail of all of these calculations is provided in Appendix 1 of the CBA.

### **Small businesses**

FSANZ has proposed what we believe to be the least burdensome/costly regulation to achieve the desired food safety outcomes for consumers. This has been done partly to alleviate impacts on small businesses.

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. It is often cheaper to update operations and equipment on a smaller scale.

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.

FSANZ has spoken with the HIWG members (states and territory government representatives) about their fee-free thresholds for small businesses for certain activity associated with enforcing implementation of food standards (such as registration and audit/monitoring). A fee-free threshold is likely to be considered for small businesses (as currently occurs in some situations/sectors) to ensure the viability of commerce in each jurisdiction.

Regulators have the discretion to exempt administrative requirements and fees for small businesses for example:

- licencing and/or
- the licencing fees and/or
- the requirement for a food safety management statement (FSMS).

These exemptions do not provide exemptions from the requirements of the standards, but rather the costs to smaller business and the resources required of businesses.

For example, small businesses may not require a license (and therefore would not be required to pay a licencing fee), or the requirement to prepare and maintain a FSMS. All other requirements of the standards would apply. Small-medium businesses may be given an administrative exemption from paying license fees, but would need to have a license to operate and to prepare and maintain a FSMS. Large businesses would be required to be licensed, to pay the license fees and would have to prepare and maintain a FSMS.

To minimise regulatory burden (particularly for small businesses), guidance materials are developed by government to support implementation by industry of new PPP standards. 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 FSANZ has focussed on providing costing estimates that reflect different levels of current FSS compliance.

FSANZ does not believe that these standards will affect the viability of small businesses. We welcome feedback from stakeholders on this analysis as part of the 2<sup>nd</sup> call for submissions and have included questions for stakeholders at the end of this document (section 12).

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.

### **Cost-benefit ratios**

For each commodity, there is an expected positive net benefit. 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.

## Berries

The CBA determined it would cost \$0.1–0.3 to achieve every \$1 benefit if option 3 was implemented for berries (Table 9). At an assumed 15% efficacy in reducing berry-related foodborne illness, the base estimate of illness cost savings is \$1 million each year.

**Table 9. Cost-benefit ratio for berries**

Commodity	Cost-benefit ratios for commodity group Central efficacy range
Berries	\$0.1–0.3 costs for every \$1 benefit.
Harvest and packing season assumed as 60 days per year.	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 \$4.6 million to \$6.1 million (15% efficacy at a 7% per annum discount rate). The net benefit estimate is \$5,333,026 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 CBA determined that it would cost \$0.2–0.6 to achieve every \$1 benefit if option 3 was implemented (Table 10).

The estimated net benefit over a ten-year period of implementing option 3 ranges from \$61m to \$120m. This arises from the likely avoided illness cost for the leafy vegetable industry sector. This results in an average of \$90.4m positive net benefit over 10 years (at a 40% efficacy, at a 7% per annum discount rate). The central net benefit estimate is \$90,440,567.

**Table 10. Cost-benefit ratio for leafy vegetables**

Commodity	Cost-benefit ratios for commodity group Central efficacy range
Leafy vegetables	\$0.2–0.6 costs for every \$1 benefit.
Harvest and packing season assumed as 310 days per year.	Net benefit predicted.  [Assumed efficacy of 40%. This higher efficacy value is a result of the lower number of leafy vegetable businesses currently on a FSS. As a result, regulation in a largely unregulated 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 75% of businesses (approximately 1125 businesses), which may not be working under a FSS and may be key contributors to risk across the sector.

## Melons

The CBA determined it would cost \$0.02 to \$0.05 to achieve every \$1 benefit if option 3 was implemented (Table 11). At a 20% efficacy, the base estimate of illness cost savings is \$6.1 million.

**Table 11. Cost-benefit ratio for melons**

Commodity	Cost-benefit ratios for commodity group Central efficacy range
Melons	\$0.02–\$0.05 costs for every \$1 benefit.
Harvest and packing season assumed as 60 days per year.	Net benefit very likely [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 \$41.1 million to \$42.4 million (20% efficacy at a 7% per annum discount rate). The central net benefit estimate is \$41.8 million.

FSANZ appreciates that the majority of melon growers already participate in a FSS. We also recognise that, although these schemes are voluntary, they are a requirement when supplying to major retailers.

### Net benefit estimates over 10 years

The expected net benefits over a ten-year period of implementing option 3 are provided in Table 12. Details of these calculations and the underlying assumptions are provided in SD3.

FSANZ estimates that the implementation of option 3 would deliver approximately \$138 million in net benefits over a ten-year period. This figure may be an underestimate, as FSANZ was unable to quantify all benefits at this point in time.

**Table 12. Net benefit estimates over 10 years**

Commodity	Central business cost estimates
Berries	\$5,333,026
Leafy vegetables	\$90,440,567
Melons	\$41,776,414

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

### Increased exports

Potential trade impacts have been raised as an issue to examine in the analysis of costs and benefits 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 (DAWE ABARES 2021). Similarly, fruit exports are projected to increase from \$1493m to \$1783m 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.

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<sup>5</sup>). 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.

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 13). The cost to individual businesses for reading the material, participating in webinars etc. 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.

**Table 13. 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 representatives collaborating in the design of fact sheets, animations and webinars and attending face-to-face meetings.
Animations	Created by FSANZ in consultation with jurisdiction and peak industry bodies. Used as training material by industry.	Subtotal = 5,586	
Links to useful resources	Provided by FSANZ Links to information used by industry.	Subtotal = 353	

<sup>5</sup> 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](https://www.agriculture.gov.au/sites/default/files/documents/ACS2019_HorticultureTables_v1.0.0.xlsx). Accessed 9 November 2020

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 = 9703	
Face-to face meetings with industry	Prepared and delivered by FSANZ, jurisdictions and peak industry bodies.	Subtotal = 16,735	
		Total = <b>42,007</b>	Total = <b>9,240</b>

The CBA concluded that the additional non-regulatory measures could be justified if they resulted in a reduction of illness of less than 0.25% 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 14.

**Table 14. Major impacts of regulation, by social group**

Social group	Notes on impacts
Primary producers	<ul style="list-style-type: none"> <li>- Potentially increased production costs</li> <li>- Reduction in the risk of a food safety incident, saving costs</li> <li>- Improved capacity to effectively and efficiently manage a food safety incident, reducing costs</li> <li>- Inventory management and other business management benefits from better record keeping</li> <li>- Potential additional sales in export markets</li> <li>- Reduced risks of market damage caused by others</li> </ul>
Food processors	<ul style="list-style-type: none"> <li>- Potentially increased input costs</li> <li>- Increased production costs</li> <li>- Reduction in the risk of a food safety incident, saving costs</li> <li>- Improved capacity to effectively and efficiently manage a food safety incident, reducing costs</li> <li>- Inventory management and other business management benefits</li> <li>- Potential additional sales in export markets</li> <li>- Reduced risks of market damage caused by others</li> </ul>
Food retailers	<ul style="list-style-type: none"> <li>- Potentially increased input costs</li> <li>- Improved capacity to effectively and efficiently manage a food safety incident, reducing costs</li> <li>- Inventory management and other business management benefits</li> <li>- Reduced risks of market damage caused by others</li> </ul>
Consumers	<ul style="list-style-type: none"> <li>- Improved safety of products meaning a reduced likelihood of illness</li> <li>- Potential increased costs of purchase</li> </ul>
Government	<ul style="list-style-type: none"> <li>- Increased implementation and enforcement cost of new regulation</li> <li>- Improved capacity to effectively and efficiently manage a food safety incident, reducing costs</li> </ul>

### **Summary of the costs and benefits the option 3**

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

- Net benefits for each sector.
- Outbreaks, illness, deaths, recalls and incidents can be expected to be reduced.
- The annual cost of illness can be expected to be reduced.
- There would be a nationally consistent set of regulatory requirements for berries, leafy vegetables and melons.
- Government food regulators would be empowered to support Australia's primary producers and processors and proactively manage food safety in these sectors on behalf of consumers. Current regulation generally only empowers regulators to manage food safety in these sectors (e.g. to legally enter premises) as a reactive measure.
- Consumers would be better protected.
- There would be changes required of industry to implement the regulation, particularly for those businesses not currently invested in food safety management.
- Government food regulators would be required to audit or monitor compliance.
- Additional costs may be incurred by 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 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:

- Outbreaks, illness, deaths, recalls and incidents can be expected to be slightly reduced.
- The annual cost of illness can be expected to be slightly reduced.
- There would be minimal additional benefits in terms of food safety.
- There would be no nationally consistent set of regulatory requirements for berries, leafy vegetables or melons.
- 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. Current regulation generally only empowers regulators to manage food safety in these sectors (e.g. to legally enter premises) as a reactive measure.
- There would be minimal requirements of industry or government.
- There would be 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).

Costs to governments to implement the regulatory options have only been preliminarily assessed. How these costs can be calculated, and some simplified costings are discussed in Appendix 3 of the CBA. Costings for non-regulatory measures are explained in Appendix 4 of the CBA. These costings will be able to be more robustly assessed following the second CFS. The DRIS will include this fuller consideration of quantified costs and benefits.

A comparison of the costings for options 2, 3 and 4 is shown in Table 15. Option 3 (a combination of regulation and non-regulation) provides a positive net benefit of \$138 million 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.

**Table 15. Comparison of the costings for each risk management option (benchmarked against the status quo – central efficacy ranges)**

Commodity	Non-regulatory option 4 <sup>a</sup>	Regulatory only option 2 <sup>b</sup>	Regulatory-plus option 3 <sup>c</sup>
<p>Berries</p> <p>Harvest and packing season assumed as 60 days a year.</p>	<p>Costs estimated at \$113,832 for berries. Largely one-off costs.</p>	<p>\$0.1 to \$0.3 = costs to \$1 benefit.</p> <p>Net benefits likely.</p> <p><i>Assumed efficacy = 15%.</i></p>	<p>Reduction of less than 0.2% of cases would justify benefits over ten years. Marginal efficacy compared to option 2 likely to be very small.</p>
<p>Leafy vegetables</p> <p>Almost all-year round harvest and packing season assumed of 310 days a year.</p>	<p>Costs estimated at \$210,582 for leafy vegetables. Largely one-off costs.</p>	<p>\$0.2 to \$0.6 = costs to \$1 benefit</p> <p>Net benefits likely.</p> <p><i>Assumed efficacy = 40% because low percentages of large numbers of leafy vegetable businesses are not on a voluntary food safety scheme.</i></p>	<p>Reduction of 0.02% of cases would justify benefits over ten years. Marginal efficacy compared to option 2 likely to be very small.</p>
<p>Melons</p> <p>Harvest and packing season assumed as 60 days a year.</p>	<p>Costs estimated at \$46,107 for melons. Largely one-off costs.</p>	<p>\$0.02 to \$0.05 = costs to \$1 benefit.</p> <p>Net benefits very likely.</p>	<p>Reduction of 0.04% of cases would justify benefits over ten years. Marginal efficacy compared to</p>

		Assumed efficacy = 20%.	option 2 likely to be very small.
--	--	-------------------------	-----------------------------------

- a. Efficacy has not been analysed. Without regulatory back-up of notifications, licensing and audits/monitoring, non-regulatory guidance is likely to have zero or very marginal impacts.
- b. Based on central prediction of effectiveness (efficacy) of options reducing current Australian annual foodborne illnesses originating in the growing, harvesting or initial processing of each commodity. Central business costs +/-50%.
- c. Option 3 costs include both regulatory option 2 and non-regulatory option 4. Costs of option 4 estimated as costs to jurisdictions of designing and distributing fact sheets, online animations, webinars, training, and face-to-face meetings, plus costs to industry of involvement and collaboration.

## 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 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.

### 8.2 FSANZ's objectives

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

FSANZ must also have regard to 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* (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.

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. The CBA has heavily influenced our choice of risk management options and the risk management measures for berries, leafy vegetables and melons.

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.

### **8.3 Option 1 – Status quo**

FSANZ's preliminary 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 preliminary conclusion is that introduction of standalone standards is not our preferred option. Regulatory measures are best supported by non-regulatory measures such as 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.

### **8.5 Option 3 – Regulatory and non-regulatory measures**

After examining all available risk management options, FSANZ's preliminary conclusion is that option 3 is our preferred option.

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 current levels of illness, outbreaks and incidents, the current system needs strengthening—particularly in the leafy vegetables and melons sectors.

Existing FSS in Australia for fresh produce cover the requirements of the proposed PPP standards. FSANZ anticipates that there would be minimal impact for those businesses currently signatory to a FSS. However, PPP standards will ensure a consistent and appropriate level of food safety management across all berry, leafy vegetable and melon businesses. Reductions in illnesses and outbreaks also lead to an increase in consumer confidence and business sustainability.

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

Table 16 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 16. Benefits of reducing illnesses and their associated annual costs across Australia after implementation of option 3**

Commodity	Pathogens contributing to foodborne illness					Total illness cost/year	Plausible range in estimated illness cost savings per year benefits	Base estimate of illness cost savings per year benefits
	<i>Listeria</i> cost/year	STEC cost/year	<i>Salmonella</i> cost/year	Norovirus cost/year	Hep A cost/year			
Berries	NA	\$128,155 Est. 41 cases per year 8 times as many as reported	NA	\$6,370,355 Est. 10,763 cases per year Much more than reported.	\$0 Around 5 reported per year. Almost all from import sources.	\$6,498,510	\$0.3m to \$3.2m Based on 5% to 50% efficacy.	\$1.0m Based on 15% efficacy.
Leafy vegetables	\$4,803,655 Est. 5 acute cases per year. As many as reported.	\$640,778 Est. 206 cases per year. 8 times as many as reported.	\$47,436,198 Est. 1881cases per year. 7 times as many as reported.	NA	NA	\$52,880,631	\$5.3m to \$37m Based on 10 - 70% efficacy.	\$21.2m Based on 40% efficacy.
Melons	\$5,572,240 Est. 6 acute cases per year. As many as reported.	NA	\$25,113,280 Est. 996 cases per year. 7 times as many as reported.	NA	NA	\$30,685,520	\$3.1m to \$15.3m Based on 10 - 50% efficacy.	\$6.1m Based on 20% efficacy.

NA = not applicable, Est. = established



Table 17 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 17. 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%	6,089,724	5,333,026	4,576,328
Leafy vegetables At central efficacy = 40%	119,502,569	90,440,567	61,378,565
Melons At central efficacy = 20%	42,440,432	41,776,414	41,112,395

Table 18 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 18. Cost-benefit ratios for implementing option 3**

Commodity group	Central efficacy range <sup>a</sup>
Berries Harvest and packing season assumed as 60 days a year.	\$0.1 to \$0.3 = Costs to \$1 benefit. Net benefits likely. Assumed efficacy = 15%.
Leafy vegetables Almost all-year round harvest and packing season assumed of 310 days a year.	\$0.2 to \$0.6 = Costs to \$1 benefit. Net benefits likely. Assumed efficacy = 40% since low percentages of large numbers of businesses are not on a food safety scheme.
Melons Harvest and packing season assumed as 60 days a year.	\$0.02 to \$0.05 = Costs to \$1 benefit. Net benefits very likely. 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 preliminary 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 food borne 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. Activities include the development of guidance for farmers, codes of practice, FSSs and establishing the Fresh Produce Safety Centre Australia and New Zealand (FPSC A-NZ)<sup>6</sup>. Various guidance documents have also been developed through industry and government collaboration: for example, the Guidelines for Fresh Produce Food Safety 2019 and the Melon Food Safety Best Practice Guide.

However there is no industry-wide requirement to participate in these food safety measures or any schemes. Businesses not covered by FSSs are often not members of any industry organisations, and are highly varied in terms of 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 of 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 measure to address the food safety risk.

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 preliminary 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 preliminary position is that non-regulatory activities should be supported by regulation.

---

<sup>6</sup> <https://fpsc-anz.com/>

## 9. Case studies

Three case studies are provided to assist stakeholders to determine:

- the implications of the proposed standards
- what changes they need to make in their business
- 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 Appendix 1 of the CBA.

### 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
- 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 NSW 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]
- adjustment production to better mitigate the effects of weather events [\$480pa]
- better maintain the premises and equipment [\$668pa]
- clean the premises and equipment [\$2267pa]
- wash and sanitise produce [\$4333pa]
- 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 fees (\$885pa).

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 18 months 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) and audit fees (\$1770pa) and Grace has factored in 8 hours of staff time to update her FSMS. In subsequent years, licencing, audit costs and maintaining the FSMS will equate to \$2,704 or 0.02% of annual turnover.

# 10. How will the chosen option be implemented and evaluated?

## 10.1 Overview

Based on its assessment, and for the reasons outlined above, FSANZ's preferred option is a combination of regulatory and non-regulatory measures. To that end, FSANZ has prepared three draft Standards, one each for leafy vegetables, berries and melons.

Implementation of the proposed standards is the responsibility of the states and territories. Proposed compliance plans have been prepared for the leafy vegetables and berries sector. These plans set out the monitoring requirements for industry and the monitoring requirements for government which would be introduced with the proposed standards, if approved. For the berries sector, a guidance document has been prepared in lieu of a compliance plan; as a food safety management statement has not been proposed. The guidance document enables those in the berries sector to meet the proposed standard, if approved.

An 18-month implementation period has been recommended for all three proposed standards.

## 10.2 Compliance plans and guidance documents

Implementation of the proposed standards is the responsibility of the states and territories. FSANZ has been working with states and territories to ensure the standards, if approved, can be implemented in each jurisdiction.

The Implementation Sub-Committee for Food Regulation (ISFR) facilitates the consistent national implementation of standards by developing agreed implementation approaches and compliance materials. A Horticulture Implementation Working Group (HIWG) was established by ISFR for this purpose. The HIWG consists of state and territory government representatives, the Australian Government Department of Agriculture, Water and the Environment and FSANZ. They are using the [Integrated Model for Standards Development and Consistent Implementation of Primary Production and Processing Standards<sup>7</sup>](#) (the Integrated Model). This process seeks to develop a range of tools to assist businesses and regulators understand how a primary production and processing standard would be implemented by jurisdictions. Other primary production and processing standards have also used the Integrated Model.

FSANZ's standards are outcomes based. Each standard had been 'translated' by the HIWG into working documents for implementation. These documents detail what primary producers and processors in each of the three sectors must do to meet the requirements of the proposed standards. The HIWG was instrumental in preparing the compliance plans for leafy vegetables and melons and the guidance document for the berries sector.

### **Proposed compliance plans for the leafy vegetables and melons sectors:**

The following compliance plans have been prepared:

- Compliance plan for leafy vegetables. Plan A Horticultural production
- Compliance plan for leafy vegetables. Plan B Horticultural primary processing
- Compliance plan for melons. Plan A Horticultural production

---

<sup>7</sup> <https://foodregulation.gov.au/internet/fr/publishing.nsf/Content/ISFR>



- Compliance plan for melons. Plan B Horticultural primary processing.

Each compliance plan sets out the requirements of the proposed standards and the activities required of industry to meet the requirements if those standards – as currently drafted - are approved. The plans also detail how each activities could be monitored by regulators to confirm compliance; an example is provided in Table 18.

**Table 18. Example of a compliance requirement. Melons: Plan B Horticulture primary processing.**

<b>Compliance requirement - Industry</b>	<b>Monitoring requirements - Industry</b>	<b>Monitoring requirements - Government</b>
<p>Inputs Water (post-harvest)</p> <p>Outcome – Chemical, physical and microbiological hazards associated with inputs are appropriately managed during primary processing so that melons are not made unacceptable.</p> <p>- Sanitisation chemicals used are appropriate as food grade sanitisers.</p> <p>- 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.</p>	<p>- 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.</p> <p>- Business may need to demonstrate compliance to the relevant jurisdictional <i>Safe Drinking Water Act</i>.</p>	<p>The business has evidence in its food safety management statement (FSMS) to inform where:</p> <p>- Control measures (if applied) have been implemented and are monitored (e.g. sanitiser concentration logs).</p>

The compliance plans clearly articulate how each of the proposed standards – if approved - should be implemented by industry and how they will be monitored for compliance. The plans set out what the proposed regulation will mean for primary producers and processors of leafy vegetables and melons.

### **Audits and monitoring of the leafy vegetables and melons sectors**

State and territory food regulators would be responsible for monitoring compliance against the proposed leafy vegetables and melons standards. In some cases audits may be used as the verification tool. However other monitoring arrangements could include, self-assessment, sharing information with government food regulators, benchmarking, etc. FSANZ has used the term ‘audits’ and has costed for audits in this proposal as audits represent the highest resource commitment and costs to industry. It is more likely that audits will be required for businesses who are not currently managing and/or documenting their food safety practices (e.g. businesses not on a FSS).

### **Guidance document for the berries sector**

In lieu of a compliance plan, a guideline document has been prepared for the berries sector. This is due to the lower risk profile of the berries sector and cost-benefits ratio of risk mitigation.

The proposed standard for berries does not include a FSMS (as defined in FSANZ standard 4.1.1). This means that government food regulators would not be routinely monitoring the

FSMS or the berry business for compliance against the proposed standards. Inspections would only occur if a food safety issues is raised. It would still be a legal requirement for berry businesses to meet the proposed standard. The guidance document has been provided to assist industry to meet the regulation of the draft standard, if approved. It would not be mandatory for berry businesses to complete this guidance document. An example of a section of this document is provided in Table 19.

**Table 19. A sample section of the berries guidance document**

<b>Compliance requirement</b>	<b>Monitoring requirements - Industry</b>	<b>Monitoring requirements - Industry</b>
Inputs - Water	Describe how your business ensures water, used at all stages of processing, is of suitable quality and does not make Berries unacceptable. Include details of the evidence the business maintains to verify this.	<p><b>[Free text ]</b></p> <p>This free text section can be used by each business to describe what they need to do to meet the requirements and how they may monitor their own compliance. Examples of activities and monitoring are provided in the compliance plan for leafy vegetables and melons.</p>

The compliance plans and guidance document are provided for comment in SD4.

**10.3 General**

The HIWG has met on multiple occasions during assessment of Proposal P1052 and will continue to do so as feedback is received. The HIWG is consulting with industry stakeholders through the Horticulture SDAG and relevant state and territory forums.

Jurisdictions have actively inputted into the CRIS by providing estimate data on the costs of licensing and audit arrangements. Given the expected range of business sizes in the sectors that will be captured, it is anticipated some form of licensing thresholds would be considered by jurisdictions, if the Standards in their current form were approved. Licensing thresholds do not necessarily result in no regulatory capture as they principally concern deployment of jurisdictional resources, rather than exclusion from compliance requirements with the Food Standards Code.

**10.4 Implementation period**

An implementation period is proposed from the date standards would be gazetted and registered as a legislative instrument. This period would enable industry and government authorities adequate time to put measures in place to meet the standard’s requirements. For these PPP standards, an 18-month implementation period is being proposed. State and territory governments have advised FSANZ are happy to work with industry to help in the transition.

**10.5 Review**

States and territories would be responsible for any subsequent review of implementation and compliance materials.



# 11. Who was consulted and how was their feedback incorporated?

## 11.1 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
- the 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 1<sup>st</sup> call for submissions
- a public survey.

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 considered all feedback to shape the proposed options to best balance these opinions. This included creating minimal measures, aligned to existing FSS, to address food safety concerns, ensuring that costs to business would be minimal and that the proposed measures, if approved, would have a positive net benefit. FSANZ has also proposed an 18-month implementation period.

## 11.2 Consultation

Consultation is a key part of FSANZ's standards development process, and is underpinned by our statutory consultation process. FSANZ consults with stakeholders to ensure an understanding of their business and to seek information and advice to inform the proposal review and standards development processes.

Stakeholders are given the opportunity to provide input into the standards development process through invited membership on the FSANZ SDAG and through public consultation rounds. Some stakeholders are also provided the opportunity to input into development of implementation materials, through discussions with the ISFR HIWG.

The communication plan developed by FSANZ to support proposal P1052 included two calls for submissions, workshops, industry visits and a survey. FSANZ consulted with industry to understand their food safety practices and constraints. FSANZ has also engaged with the Horticulture SDAG and the ISFR HIWG. These consultations have better informed the proposed regulatory and non-regulatory measures which are being considered for each commodity type. Further information about this consultation process and the feedback received is provided below.

## 11.3 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 (see below) and informed commencement of Proposal P1052.

## 11.4 Horticulture information paper

The outcomes from the Horticulture and Food Safety Workshop contributed to an [information paper](#) which was released for stakeholder comment in May 2019. This paper outlined the background to the review, the issues that FSANZ would consider and the proposed timelines. A key focus was addressing the request from the then (ministerial) Forum that FSANZ consider the potential development of a PPP standard for certain horticultural commodities to manage food safety on-farm, including requirements for traceability. It also addressed the Forum's request to review food safety risk management for the food service and related retail sectors<sup>8</sup>.

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

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

## 11.5 Industry visits

FSANZ visited producers and processors of identified horticulture products in NSW 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.

These visits provided FSANZ with an opportunity to communicate with stakeholders about their businesses and the P1052 proposal. They were also designed to encourage stakeholder engagement with the P1052 proposal and provided an opportunity for stakeholders to offer feedback. FSANZ officers were able to observe various production methods and the food safety activities of producers and/or processors of berries, leafy vegetables and melons. State government and industry representatives also accompanied FSANZ and participated in consultation.

FSANZ examined the production of berries in Australia through desktop research, consultation with jurisdictions, and an 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. FSANZ officers were unable to participate in planned visits to blueberry and raspberry growing and packing

---

<sup>8</sup> Proposal P1053 Food Safety Management Tools is addressing this request.

operations, due to COVID-19 restrictions. We have provided an overview of the primary production and processing of blueberries, raspberries and strawberries in section 5.2 of the microbiological assessment. Production and processing in the Australian context guided our evaluations.

FSANZ examined the production of leafy vegetables in Australia through desktop research, consultation with jurisdictions and 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. FSANZ officers were unable to participate in planned visits to additional growing and packing operations in Tasmania and NSW, due to COVID-19 restrictions. We have provided an overview of primary production and processing of leafy vegetables, in section 5.1 of the microbiological assessment. Production and processing in the Australian context guided our evaluations.

FSANZ examined the production of melons in Australia through desktop research, consultation with jurisdictions and an onsite visit to a melon farm in NSW. While onsite, FSANZ observed the growing sites, harvesting, and the activities of the packing shed. FSANZ officers were unable to participate in planned visits to additional growing and packing operations in Queensland, due to COVID-19 restrictions. FSANZ has provided an overview of the primary production and processing of melons in section 5.3 of the microbiological assessment (see SD2). Production and processing in the Australian context guided our evaluations.

Note: FSANZ was unable to visit as many producers and processors as planned due to COVID-19 restrictions. Stakeholders in other regions were consulted through phone and teleconference.

## **11.6 Horticulture Implementation Working Group**

Implementation of any standard is the responsibility of the state and territory government jurisdictions. The HIWG has been established by ISFR to ensure any amendments to the Code are consistently implemented at the national level. Further information about the HIWG is provided in section 10 of this CRIS.

The HIWG met multiple times during the P1052 project, and will continue to do so after the 2<sup>nd</sup> call for submissions is published and stakeholder feedback is received. The HIWG was instrumental in preparing the draft Compliance Plans, presented at SD4.

## **11.7 Horticulture Standards Development Advisory Group**

FSANZ has also 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.

The SDAG met twice (14 May and 9 December 2020). The first meeting focused on benefits and challenges in managing horticulture food safety risks. The second meeting focussed on the risk assessment, CBA and potential risk management options.

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 upon request, 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.

Further details about the SDAG are included at SD5.

## 11.8 Public consultation

FSANZ is assessing Proposal P1052 as a major proposal, meaning that two statutory consultation processes are required.

First round – The [1<sup>st</sup> call for submissions report](#) was released from 5 February 2020 to 25 March 2020. Comment was sought from stakeholders about developing regulatory measures for berries, leafy vegetables and melons, as opposed to continuing to rely on non-regulatory measures. There were a total of 27 submissions received from horticulture producers/processors, industry representatives and jurisdictions. Submissions received from the 1<sup>st</sup> call for submissions have informed the P1052 assessment.

In general, industry supported the status quo and expressed concerns that regulation may cause additional burden on the industry. Government generally considered the current situation to be inadequate and supported the development of regulation. Regulation was considered to potentially benefit Australia's reputation and improve export market access. A need for traceability and a nationally consistent approach to horticulture food safety were supported.

Concerns raised by stakeholders during the 1<sup>st</sup> call for submissions included:

- the additional burden on the industry
- concerns about potential audit, administrative, financial and regulatory burdens of regulation
- that regulation could push out small-scale businesses
- that the additional costs and activities associated with regulation create barriers to entry
- that berries, leafy vegetables and melons had been singled out and that all horticulture produce should be included.

FSANZ has considered these concerns and acted as follows:

- During its review of food safety hazards in the microbiological assessment, FSANZ selected only those hazards that were critical to address in each sector. We considered the cost-benefit ratios in each sector and adjusted the regulation until positive net benefits were achieved in each sector. This has resulted in the lightest touch possible (in terms of costs and activities) to achieve satisfactory food safety outcomes, while reducing risk of illness for the largest group of stakeholders, Australian consumers.
- Audit, administrative and other costs have been noted and estimated in the CBA for consideration by stakeholders. Much of the upfront cost will be determined by each business's current level of commitment to and compliance with food safety. This has been examined in the CBA, which provides different cost estimates depending on current compliance levels with FSS. These figures have been provided to help each business identify where they are currently sitting in terms of food safety managements and the likely up-front and ongoing costs of compliance with the proposed regulation.
- Small businesses were considered. Government food regulators already have the ability to alter the fee structure for small businesses. This can include reduced fees or a fee-

free threshold. Further, fees are charged per hour (rather than at a flat rate), naturally scaling up or down depending on business size. Government food regulators will also support businesses (particularly small businesses) to become compliant with new regulation, easing uptake through guidance documents and templates.

- Barriers for entry were considered. Government food regulators confirmed that they currently assist and facilitate the establishment of new businesses.
- FSANZ has not altered the scope of P1052; which remains focussed on berries, leafy vegetables and melons. This reflects current Codex annexes, as described earlier.

Second (current) round – Submitters are invited to provide comment on the issues and questions posed in the 2<sup>nd</sup> call for submissions report. The purpose of the 2<sup>nd</sup> call for submissions is to provide an update on FSANZ's preliminary position of the proposal based on the risk assessment, risk management options, costs and benefits and current food safety measures for horticulture produce. The 2<sup>nd</sup> call for submissions will seek feedback on the proposed draft regulatory measures.

Information received from submissions and targeted consultation will inform a decision by FSANZ whether to accept, amend or reject its proposed approach and regulatory measures. In accordance with the requirements of the FSANZ Act, FSANZ has regard to all submissions.

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

## **11.9 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.

FSANZ has analysed the results of this survey and the findings have guided the risk management options and measures presented in this second call for submissions.

## **11.10 Future consultation**

The 2<sup>nd</sup> call for submissions will include a six (or more) week consultation period. FSANZ will seek comment on the microbiological assessment, CBA and the risk management options, including the proposed standards and compliance plans. FSANZ has included questions for stakeholders in the 2<sup>nd</sup> call for submissions. These questions relate to assumptions made and further information required to inform our modelling. FSANZ appreciates all information received.

Details for making a submission are included in the front page of the 2<sup>nd</sup> call for submissions report. Further details on making a submission are also available on the FSANZ website. FSANZ welcomes and will consider all submissions as part of the assessment process for

this proposal. All feedback will be reviewed and will be used to guide final recommendations.

FSANZ's P1052 team will be available throughout this consultation period to provide advice and answer questions. If you would like our team to contact you, please contact [standards.management@foodstandards.gov.au](mailto:standards.management@foodstandards.gov.au)

## 12. Questions for stakeholders

### Questions for stakeholders

We have relied on the best available information to inform the consideration of costs and benefits, however there are gaps in the available information. We are seeking additional information from stakeholders to test our assumptions and improve the analysis for the decision impact regulation statement (DRIS).

Answers to the following questions should be included with submissions. Our analysis of the answers provided is improved by knowing:

- The nature of your business (e.g. grower, primary processor, transporter, wholesaler)
- The sector/s you participate in (i.e. berries, leafy vegetables, melons)
- The size of your business, either in terms of full time employees or aggregated annual turnover.

**1. We estimate the following number of businesses in each sector. Is there alternative information you would like us to consider?**

The estimated number of primary production and primary processing businesses in Australia are:

- 750 for berries,
- 1,500 for leafy vegetables
- 225 for melons.

**2. We estimate that the following percentages of businesses are currently participating in a FSS. Is there alternative information you would like us to consider?**

The estimated proportions are:

- 75% for berries
- 25% for leafy vegetables
- 95% for melons.

**3. We have assumed that, on average, businesses not on a FSS are already 50% compliant with the measures proposed by option 3 (regulation and non-regulation). Is there alternative information you would like us to consider?**

## Questions for stakeholders - continued

**4. We have estimated that if business are already 50% compliant, costs of regulation can be reduced by 50%. Is there alternative information you would like us to consider?**

Note: Notification, licencing and audit costs have not been deflated by 50% in our existing calculations, because they would likely need to be paid by all businesses not yet on an FSS, regardless of current compliance levels.

**5. We have estimated the average length of the harvest and packing seasons. Is there alternative information you would like us to consider?**

The estimated seasons:

- 60 working days for berries
- 60 working days for melons
- 310 working days for leafy vegetables.

**6. We have estimated the following efficacy (and ranges) of reducing illness by implementing option 3. Is there alternative information you would like us to consider?**

Efficacy describes the level of reduction of illness. The estimated efficacy:

- 15% for berries – with a range of 5-50%
- 20% for melons – with a range of 10-50%
- 40% for leafy vegetables – with a range of 10-70%.

**7. Do you agree with the proposed washing and sanitisation cost estimates?**

In practice, this requirement may only involve the removal of extraneous material from the produce. Washing is not mandatory; however, any washing should not make crops unacceptable. FSANZ estimates that the requirement will have a relatively large cost for leafy vegetables and melons. It is estimated to take 20 minutes a day (beyond business as usual) to ensure visible extraneous material is removed from harvested horticultural products. This is only required on harvest days (i.e. 60 days p.a. for berries and melons and 310 days p.a. for leafy vegetables). There are minimal costs of materials involved beyond the one-off cost of modifying general farm and processing equipment.

**8. We estimate that washing and sanitisation of equipment would take 10 minutes a day. Is there alternative information you would like us to consider?**

This is only required on harvest days (i.e. 60 days p.a. for berries and melons and 310 days p.a. for leafy vegetables).

**9. Do you agree with the proposed traceability cost estimates?**

FSANZ has estimated that there will be a low additional costs as a result of the requirement for minimal traceability. Record keeping is already required for tax purposes (i.e. documenting sales and purchases). We have assumed an additional \$100 per business for minimal traceability resulting from the implementation of option 3.

**10. Are there any categories of costs or benefits that we have not accounted for?**

See appendix 1 of the consideration of costs and benefits for details of cost categories.

**11. Do the detailed assumptions for each crop group in appendix 1 of the consideration of costs and benefits sound reasonable?**



**12. Do you agree with the following benefits of implementing option 3 (or can provide additional information about these benefits)?**

- Health related benefits
- Improved capacity to effectively and efficiently manage a food safety incident, reducing costs
- Improved inventory and business management
- Potential additional export sales
- Government's improved capacity to effectively and efficiently manage a food safety incident
- A reduction in illness costs

**13. How might implementing option 3 affect business viability?**

**14. How might implementing option 3 specifically affect small businesses?**

**15. Do you think that implementing option 3 will have any flow-on impacts for business in the supply chain e.g. transport**

**16. Do you think certain locations might be effected more than others from implementing option 3?**

For instance, might businesses in remote areas experience notably different effects than businesses nearer cities; might businesses based in certain climatic regions experience more difficulties?

**17. How might implementing option 3 affect the price of each commodity or quantities bought or sold?**

**18. Berries: Do you think that the berries standard should also include the regulation of soils and fertilisers?**

If soil and fertiliser were included, the input clause in the proposed standard would be updated as follows:

**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 berries unacceptable:

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

**19. Is there any other information you would like to provide?**

When providing information, please provide evidence to support your views. Thank you