

26 March 2012
[7-12]

Call for submissions – Proposal P1015

Primary Production & Processing Standard for Horticulture

FSANZ has assessed a Proposal to develop primary production and processing requirements for fresh horticultural produce. Pursuant to section 72 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act), FSANZ now calls for submissions to assist FSANZ's further consideration.

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

Under the Information Publication Scheme, all submissions on applications and proposals, will be published on our website. We will not publish any material provided in-confidence. Submissions will be published as soon as possible after the end of the public comment period. Where large numbers of documents are involved, FSANZ will make these available on CD, rather than on the website.

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

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

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

DEADLINE FOR SUBMISSIONS: 6pm (Canberra time) 21 May 2012

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

Questions about making submissions or the application process can be sent to standards.management@foodstandards.gov.au.

Hard copy submissions may be sent to one of the following addresses:

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Supporting documents

The following documents which informed the assessment of this Proposal are available on the FSANZ website at

<http://www.foodstandards.gov.au/foodstandards/proposals/proposalp1015primary5412.cfm>

SD1	Proposal P1015 – Primary Production & Processing Requirements for Horticulture: (Information paper)
SD2	Review of foodborne illness associated with selected fresh ready-to-eat horticultural produce
SD3	Review of food safety systems in Australian horticulture
SD4	Membership of the Horticulture Working Group

1. Executive summary

There are a number of industry-based schemes that are in operation within the horticulture sector that address food safety. However, these are not universally adopted and there are currently no nationally consistent food safety requirements on the primary production of horticultural produce. FSANZ is now considering developing primary production and processing requirements for the horticulture sector following several outbreaks of foodborne illness associated with horticultural produce over the last decade. This process has regard to the [Overarching Policy Guideline on Primary Production and Processing Standards](#).

FSANZ will examine possible food safety measures that could be applied to the primary production and processing of fresh horticultural produce covering the through chain activities involved in their production from on farm through to sale. Fresh horticultural produce includes fruit, vegetables (including microgreens), mushrooms, herbs and nuts that are provided for sale in the raw state.

A Review of foodborne illness associated with selected fresh ready-to-eat horticultural produce was undertaken by FSANZ to help identify the commodities and production factors most likely to result in produce contamination and outbreaks of foodborne illness. From the available data, the use of poor quality water for pre- and post-harvest activities emerged as the most common cause of produce contamination. Direct faecal contamination of produce growing in a field also emerged as a source of contamination. Multiple breaches of good hygienic practice along the supply chain were also noted in a number of outbreaks where a specific failure point was not identified.

A review of food safety systems in Australian horticulture was also undertaken to try and determine the uptake and nature of common food safety schemes used in the horticulture sector. While difficult to measure, available information provides an estimate that 70-80% of horticultural produce in Australia is grown under a scheme that includes appropriate food safety control measures.

While the available evidence provides a high degree of confidence that Australians have access to safe fresh produce, adverse events have a high impact on both the industry and consumers. This proposal will assess possible regulatory and non-regulatory options to reduce the likelihood and consequences of an adverse event associated with consuming fresh produce.

Three options are being considered at this stage:

- Option 1 (food regulatory measures)

Option 1 involves developing food safety regulatory measures in the *Australia New Zealand Food Standards Code* (the Code).

- Option 2 (other measures)

Other measures that can be considered include developing educational materials or guidelines for industry as well as self-regulatory approaches.

- Option 3 (status quo)

There would be no nationally consistent set of food safety requirements for horticultural production. Existing measures are essentially non-regulatory with industry schemes being implemented in the sector.

2. Introduction

2.1 The Proposal

Primary production and processing standards are incorporated into Chapter 4 of the *Australia New Zealand Food Standards Code* (the Code) and apply in Australia only¹. Along with other standards in the Code, they provide an approach to managing food safety in Australia that extends from production on the farm through to sale to the consumer. The process for developing such standards takes into account existing food safety requirements implemented by the sector, including any existing regulations (e.g. State legislation), industry codes of practice or guidelines and accredited food safety systems.

To date, FSANZ has developed primary production and processing standards for the seafood, dairy, poultry meat, eggs and seed sprout sectors. Proposals are currently under way examining raw milk products and major and minor meat species.

FSANZ will examine possible food safety measures that should be applied to the primary production and processing of fresh horticultural produce. A Horticultural Working Group consisting of representatives from the industry, retail, government regulators and consumers has been established by FSANZ to advise on this standard development process.

2.1.1 Scope of the Proposal

Fresh horticultural produce includes fruit, vegetables (including microgreens), mushrooms, herbs and nuts that are provided for sale in the raw state. This Proposal will cover the through chain activities involved in their production from on farm through to sale:

- growing
- harvest
- primary processing (e.g. washing, trimming, post-harvest treatments)
- packing
- storage
- transport

2.2 Current requirements

There are currently no national regulatory food safety requirements applying to the primary production of horticultural produce. Some provisions in the Chapter 3 Food Safety Standards may apply to pack house activities and transport and provide some elements of traceability (along with labelling requirements under Standard 1.2.2). These requirements are summarised in Supporting Document 1.

Figure 1 below provides a schematic representation of the food handling activities applicable to horticultural produce that are already covered by the requirements of Chapter 3. The scope of Proposal P1015 is primary production activities for which measures could be included in Chapter 4.

¹ Australia only refers to food sold for consumption in Australia. This includes imported foods, but does not include food sold in New Zealand.

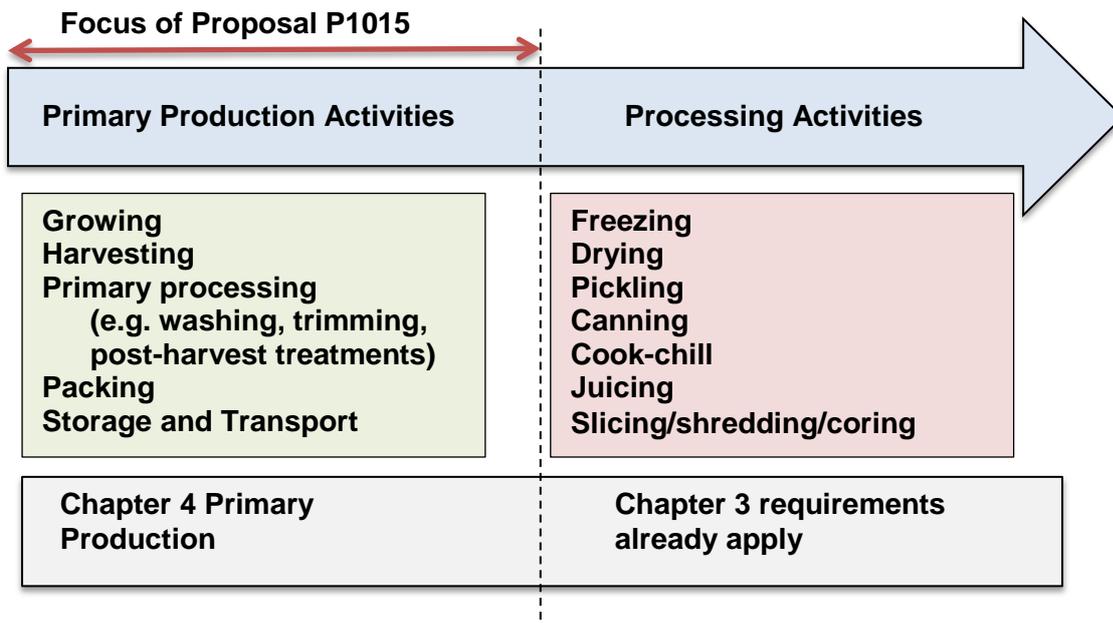


Figure 1: Schematic representation of the scope of Proposal P1015 in relation to requirements in the Code.

2.3 Reasons for preparing the Proposal

In 2002, the then Australia and New Zealand Food Regulation Ministerial Council (now known as the COAG Legislative and Governance Forum on Food Regulation) requested that FSANZ extend its evidence-based standard-setting process to examine the need for standards in the primary production sector. Since that time, FSANZ has had responsibility for developing national food safety requirements that cover all parts of the food supply chain – an integrated paddock-to plate approach.

To this effect, FSANZ has been developing primary production and processing (PPP) Standards for identified industry sectors for inclusion in Chapter 4 of the Code.

Currently, there are no nationally consistent food safety requirements on the primary production of horticultural produce outside of industry based schemes (non-regulatory measures). The development of primary production and processing requirements for the horticulture sector is now being considered following several outbreaks of foodborne illness associated with horticultural produce over the last decade.

2.4 Procedure for assessment

The Proposal is being assessed under the Major Procedure.

3. Summary of the assessment

3.1 Technical work

3.1.1 Review of foodborne illness associated with selected fresh ready-to-eat horticultural produce

Outbreaks of foodborne illness have been associated with consumption of horticultural products both in Australia and internationally.

It is widely accepted that certain horticultural commodities are more often associated with produce-associated outbreaks, and that a number of production activities contribute to their contamination. Specific horticultural commodities identified in the literature include fresh leafy vegetables, fresh leafy herbs, melons and minimally processed produce (i.e. bagged salad). Production factors include water (pre and post-harvest), fertilisers, faecal contamination and food handler hygiene. FSANZ undertook a descriptive scoping review of well documented horticultural produce-associated outbreaks, supported by Australian epidemiological and surveillance data (where available) to determine whether these assumptions hold true to the Australian situation. The *Review of foodborne illness associated with selected fresh ready-to-eat produce* is provided as Supporting Document 2.

The review reaffirmed the assumptions identifying the commodities and production activities most likely to result in produce contamination and outbreaks of foodborne illness. However, also noted was that the findings should not preclude the potential that other commodities and/or production activities may be implicated in future horticultural-associated foodborne illness outbreaks.

3.1.1.1 Horticultural commodities

Published outbreaks examined in the review involved fresh horticultural commodities intended to be eaten uncooked without any steps to eliminate pathogens before consumption. From the reviewed outbreaks, two general commodity categories were identified; soft fruit and vegetables. Vegetables included leafy greens (lettuce, spinach), herbs (coriander, basil and Thai basil), green onions, baby corn, sugar peas, carrots and chilli peppers. Fruits included melons (rockmelon/cantaloupe, honeydew), papaya, mango, tomatoes (including semi-dried), mamey and berries (raspberries, strawberries). Of the outbreaks examined:

- Lettuce was the commodity most often associated with an outbreak. Eight outbreaks in six countries.
- Tomatoes, either semi-dried or fresh, were associated with five foodborne outbreaks, with fresh tomatoes possibly associated with a sixth outbreak that was associated with Jalapeno and Serrano peppers.
- Rockmelon (either pre-cut or whole rockmelon) was the fruit most often associated with an outbreak.
- Raspberries were associated with four outbreaks of foodborne illness.

The microbiological data available from Australian surveys suggests there is a low level of contamination of fruits and vegetables available in the Australian supply chain, although infrequent contamination of fresh produce with pathogenic microorganisms can occur.

3.1.1.2 Factors contributing to contamination

During production in the field or during storage, minimal processing or transport, produce may be exposed to pathogenic bacteria and viruses. Sources can include contaminated soil, water, animal manure (grazing animals or applied as fertiliser), farming and processing equipment, rodents, insects, wild birds, agricultural waste and people. Generally, however, there is a lack of good quality scientific data identifying the specific production and processing practice that caused produce to become contaminated or the relative contribution of potential sources of contamination.

As much horticultural produce may be consumed raw, there are no terminal processing steps (such as heat treatment) that can then be applied to eliminate any pathogenic microorganisms that may be present. Control of potential hazards may, therefore, be best managed in the field, during harvest or in the packing facility – a through-chain approach.

The following production factors were identified in the review of outbreaks of foodborne illness:

- pre-harvest water (e.g. irrigation, use in dilution of pesticides)
- post-harvest water (e.g. for washing of produce)
- incursions of animals into growing, packing and storage areas
- poor hygienic practice along the supply chain.

From the available data, the use of poor quality water for pre- and post-harvest activities emerged as the most common cause of produce contamination. Direct faecal contamination of produce growing in a field also emerged as a source of contamination. Multiple breaches of good hygienic practice along the supply chain were also noted in a number of outbreaks where a specific failure point was not identified.

3.1.2 Review of food safety systems in Australian horticulture

Food safety schemes have been developed for the fresh produce sector in Australia and implemented widely. FSANZ contracted Tasmanian Quality Assured Australia (TQA Australia) to report on the uptake and nature of common food safety schemes used in horticulture. The report *Review of Food Safety Systems in Australian Horticulture* is provided as Supporting Document 3. Nine food safety systems were selected, believed to be the most widely accepted 3rd party audited systems in Australian horticulture:

- BRC Global Standard for Food Safety – Issue 6 – July 2011
- Coles Supplier Requirements – Food (CSR-FV3 May 2011)
- Freshcare Code of Practice (3rd Edition – July 2009)
- Global G.A.P Integrated Farm Assurance – Version 4.0_Mar2011
- Salad GAP – Version 1.1 (September 2008)
- SGS HACCP – Client Audit Checklist Version 2.7 (19/06/2011)
- SQF2000 Code – 6th Edition August 2008 – Amended July 2010 (Level 3)
- SQF1000 Code – 5th Edition August 2009 – Revised January 2010 (Level 3)
- Woolworths Quality Assurance – Primary Production – Produce – Version 7 January 2011.

3.1.2.1 Industry coverage

The first part of the TQA project was to determine the level of participation in these food safety systems in Australian horticulture. This was difficult because there are a number of organisations collecting and collating information on the number of producers (with numbers often differing) and a number of systems owners and certification bodies collating information on food safety system certifications. Many producers maintain certifications to multiple systems but this number does not relate to the number of producers. On available information it is estimated that 70-80% of horticultural produce in Australia is grown under such a scheme.

FSANZ welcomes information in submissions which can further inform us of the uptake of industry schemes in the horticulture sector; the nature of these schemes; the types of horticultural produce being covered by such schemes, and the industry/commercial requirements that drive their uptake.

3.1.2.2 Food safety schemes

The second part of the project reviewed the food safety elements of selected systems, examining a number of broad topics including:

- regulatory requirements
- control of inputs
- good manufacturing practices (GMP)
- good agricultural practices (GAP)
- control of storage
- control of processing / preparation / handling
- transport
- calibration
- control of plant and equipment
- cleaning schedule / sanitation
- pest control
- product identification and traceability
- control of use of chemicals
- training
- personal hygiene
- control of microbiological hazards on-farm
- system auditing frequency, training, qualifications for auditors, corrective actions.

The findings are detailed in the report (Supporting Document 3), including the applicability of each system across the food supply chain and the requirements of each system in respect to the food safety element identified.

3.2 Regulatory options and impacts

When assessing this Proposal and the subsequent development of any food regulatory measure, FSANZ has to have regard to the following matters in section 59 of the FSANZ Act:

- whether costs that would arise from a food regulatory measure developed or varied as a result of the proposal outweigh the direct and indirect benefits to the community, Government or industry that would arise from the development or variation of the food regulatory measure
- there are no other measures that would be more cost-effective than development of or a variation to a Standard that could achieve the same end
- any relevant New Zealand standards
- any other relevant matters.

In order to decide the most effective and efficient risk management approach, FSANZ must consider various risk management options. These options include the *status quo* (the situation if no action is taken) as a comparative measure against appropriate regulatory or other interventions.

New Zealand has its own food safety legislation for food business and primary producers, which is developed and implemented by the Ministry of Agriculture and Forestry (MAF)².

² Formally the New Zealand Food Safety Authority (NZFSA)

3.2.1 Risk management options

3.2.1.1 Option 1 – food regulatory measures

Option 1 involves developing food safety regulatory measures in the Code (which may be supported by non-regulatory measures such as industry guidance or consumer education). These measures would apply along the production chain where cost benefit analysis can demonstrate such measures are commensurate with risk and are cost effective. Such requirements would be subject to the impact analysis which will evaluate the costs and benefits accruing to all stakeholders.

Under option 1, a range of regulatory approaches can be assessed from specifying particular control measures or tools that should be in place (such as management of inputs or traceability) to requiring a business to demonstrate, through a food safety management system, that it has analysed its hazards and has effective control measures in place.

In relation to option 1, the impact analysis will consider:

- the nature of the risk inherent for particular commodities or production activities
- where in the production chain (or for what products) will any interventions have the greatest impact
- whether existing regulatory requirements (e.g. Chapter 3 requirements) should/could apply the feasibility/practicality of implementing and enforcing particular measures.

If the impact analysis determines that food regulatory measures are not a cost effective option, the proposal will be abandoned and the status quo (option 3) will remain or other measures (option 2) may be implemented.

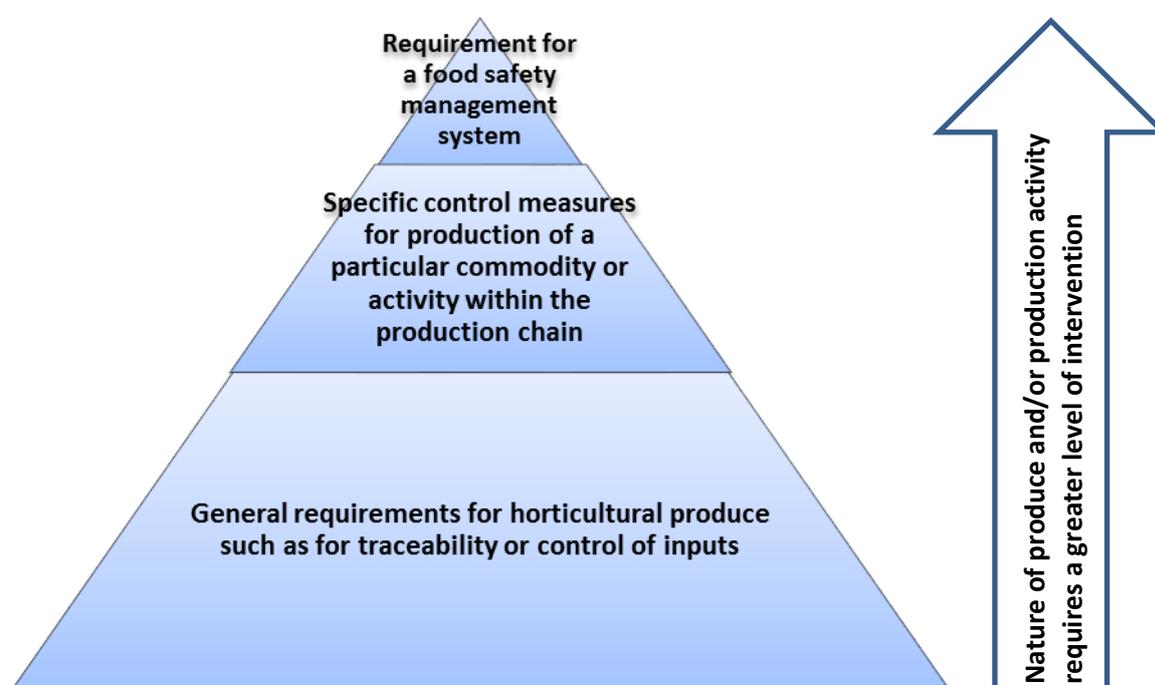


Figure 2: Schematic representation of regulatory interventions that can be considered under Option 1

General requirements

Requirements that are repeated across primary production and processing standards and referred to as general requirements primarily include traceability and control of inputs.

Traceability is an important tool for enabling the source and distribution of produce to be identified at each stage throughout the chain. When something does go wrong, an effective traceability system allows corrective actions to be implemented quickly and can minimise any negative impact.

Control of inputs, in relation to horticulture, means the management of water (irrigation or wash water), chemicals and fertilisers in order to prevent or minimise contamination of produce by hazards (microbiological, chemical and physical). Such measures would be expected as part of adherence to good agricultural practices.

Specific or additional control measures

Specific or additional control measures could be applied to particular commodities or activities based on the inherent risk posed. For example, health and hygiene requirements may be appropriate for those commodities picked by hand and unlikely to undergo any hazard reduction step before consumption. Preventing or minimising contamination during transport or pack house operations may also be appropriate. Other measures could include requirements on premises and equipment or skills and knowledge requirements in relation to particular activities.

Food safety management system

Depending on the nature of the produce and/or production activities involved, a business could be required to demonstrate, through a documented food safety management system, that it has analysed its hazards and has effective control measures in place. Such requirements have been included in Chapter 4 standards for commodities such as bivalve molluscs and seed sprouts.

3.2.1.2 Option 2 – other measures

FSANZ must also have regard to other measures that would be more cost-effective than regulatory requirements in the Code. This may include a consideration of:

- what/whether there are additional measures that industry can implement to ensure all producers of fresh produce operate under a scheme
- whether developing educational materials or guidance (by industry or government) would provide an adequate level of assurance that fresh horticultural produce is produced and supplied with appropriate food safety controls in place.

3.2.1.3 Option 3 – status quo

Under the status quo, there is no nationally consistent set of food safety requirements for horticultural production. Existing measures are essentially non-regulatory with industry schemes being implemented in the sector.

There are a number of comprehensive on-farm food safety schemes available for horticultural production.

These schemes are voluntary, highly prescriptive and independently audited. Despite the voluntary nature of the schemes, market forces, particularly retailer demand, mean that an estimated 70-80% of horticultural produce is grown under such a scheme.

Large retailers have also developed their own on-farm food safety schemes. They require their own food safety scheme to be implemented (with accreditation and auditing) before they will source from a grower. Such schemes include Woolworths Quality Assured (WQA) and Coles Requirements.

In relation to option 3 the impact analysis will assess whether the status quo provides adequate assurance to consumers and industry that adequate food safety controls are in place for fresh produce production and supply.

FSANZ welcomes any information or comment in submissions that can further inform this assessment of the options proposed.

3.2.2 Impact Analysis and affected parties

The preferred option decided through the assessment of Proposal P1015 will be based on an analysis that considers:

- who is affected by the problem and the proposed solution
- evaluation of the risk mitigation measures required
- costs and benefits to affected parties of the interventions associated with each option.

A regulation impact assessment will be undertaken by FSANZ in consultation with the Office of Best Practice Regulation (OBPR). A detailed cost-benefit analysis (Regulation Impact Statement) will be provided for consultation in the call for submissions at the next stage of the assessment.

Consultation is an important part of this process. Parties that have been identified as being affected by this Proposal include:

- industry, including growers, packers, transporters, wholesalers and retailers
- state and territory government, particularly those agencies or bodies with responsibility for implementing and enforcing food regulatory measures for primary production
- consumers.

3.2.3 Addressing FSANZ's objectives for standards setting

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

3.2.3.1 Protection of public health and safety

Fresh horticultural produce contaminated with pathogenic micro-organisms such as *Salmonella* spp. and pathogenic *Escherichia coli*, presents an unacceptable health risk to consumers. In recent years, contaminated fresh produce has been responsible for outbreaks of foodborne illness both internationally and in Australia.

Control measures can be implemented throughout the production chain to minimise the likelihood of an adverse event.

Currently, there are no regulatory requirements on primary producers of fresh produce in Australia that enforce implementation of these control measures. Industry ensures these controls are in place by requiring growers to comply with certified industry schemes. However:

- approximately 20 % of produce grown in Australia is not produced under an industry scheme;
- outbreaks of foodborne illness have occurred even when schemes have been in place.

While the available evidence provides a high degree of confidence that Australians have access to safe fresh produce, adverse events can happen and have a significant effect on both the industry and consumers. This proposal will assess possible regulatory and non-regulatory options to reduce the likelihood and consequences of an adverse event associated with consuming fresh produce.

3.2.3.2 *The provision of adequate information relating to food to enable consumers to make informed choices*

The provision of adequate information relating to food to enable consumers to make informed choices is not relevant to the assessment of Proposal P1015. Labelling provisions that relate to lot identification and name and address of supplier will be taken into consideration when considering measures such as traceability.

3.2.3.3 *The prevention of misleading or deceptive conduct*

The prevention of misleading or deceptive conduct is not relevant to the assessment of Proposal P1015.

3.2.3.4 *Subsection 18(2) considerations*

FSANZ has also had regard to the matters listed in subsection 18(2):

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

FSANZ has already undertaken technical work, including a review of foodborne illness data associated with horticultural produce (discussed under Section 3.1), in order to inform the assessment of P1007. We will continue to base risk management decisions on the available science.

- the promotion of consistency between domestic and international food standards

FSANZ will have regard to international approaches to managing hazards in horticulture, in particular the *Codex Code of Practice for Fresh Fruits and Vegetables*³ which identifies through chain control measures for minimising contamination of produce with microbial, chemical and physical hazards.

- the desirability of an efficient and internationally competitive food industry

Any measures that FSANZ may develop should be commensurate with risk and not impose any unnecessary additional economic burden on the horticulture industry.

³ Codex Alimentarius Commission CAC/RCP 53-2003.

To this effect, FSANZ will provide a regulatory impact assessment in line with the requirements of the Office of Best Practice Regulation.

- the promotion of fair trading in food

The promotion of fair trading in food is not a consideration in the assessment of Proposal P1015.

- any written policy guidelines formulated by the Ministerial Council.

The Ministerial Council developed an *Overarching Policy Guideline on Primary Production and Processing Standards*. This policy guideline specifies a number of high order principles for primary production and processing standards outlining that they will:

- be outcomes-based
- have a consistent regulatory approach across the Standards
- be consistent with the approach outlined in Chapter 3 of the Code
- be consistent with Codex standards
- address food safety across the entire food chain where appropriate
- facilitate trade and comply with Australia's obligations under World Trade Organization (WTO) Agreements
- promote consumer confidence
- ensure the cost of the overall system should be commensurate with the assessed level of risk
- provide a regulatory framework that only applies to the extent justified by market failure.

3.3. Risk communication

3.3.1 Consultation

Consultation is a key part of FSANZ's standards development process. FSANZ acknowledges the time taken by individuals and organisations to make submissions on this proposal. Every submission on an application or proposal is reviewed by FSANZ staff, who examine the issues identified and prepare a response to those issues. While not all submissions can be taken on board during the process, they are valued and all contribute to the rigour of our assessment.

Consultation with affected parties will include the FSANZ statutory consultation processes, as well as engagement through the Horticulture Working Group⁴. Targeted consultations with growers and pack house operations will also be undertaken in order for FSANZ to understand industry practices and constraints to better inform any measures that may be considered.

Additionally, FSANZ released a consultation paper on [Improving food safety for fresh horticultural produce](#) in mid-2011, calling for comments on our approach to examining the safety of horticultural produce in Australia. A report summarising the responses received was published on the FSANZ website in December 2011.

⁴ Membership of the Horticulture Working Group is provided in Supporting Document 4.

3.3.2 Summary of submissions received on consultation paper

FSANZ received 25 submissions from peak bodies, retailers, private companies, state food authorities and departments of health, agriculture and primary industries on the consultation paper released in May 2011. Many submitters argued that most farmers do a good job of managing on-farm food safety hazards through implementing food safety schemes (e.g. Freshcare, WQA, Coles Requirements etc). However, there are considerable concerns from growers, retailers and government about the risk to Australia's reputation posed by the minority of farmers without a food safety scheme. Views differed regarding the best approach to managing the potential problem.

The most common themes from submissions were:

- the reputational and financial dangers to the industry from farmers without adequate food safety schemes in place
- that FSANZ should acknowledge the good work done already, especially in terms of implementation of on-farm food safety schemes, and avoid duplication
- that the costs to farmers of any intervention should be minimised
- that FSANZ should be looking at risk-based rather than commodity-based interventions.

Apart from these four major points, other concerns were common to several submissions. These included the importance of national consistency and traceability, as well as concerns that imported food be treated in the same way as domestically-produced food.

3.3.3 World Trade Organization (WTO)

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

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