



Enquiries to: Food Safety Standards and  
Regulation  
Health Protection Branch  
Telephone: (07) 3328 9310

Queensland Health

Standards Management Officer  
Food Standards Australia New Zealand  
PO Box 5423  
KINGSTON ACT 2604

[submissions@foodstandards.gov.au](mailto:submissions@foodstandards.gov.au)

Dear Sir / Madam

**Submission: 2nd Call for submissions – Proposal P1052 *Primary Production and Processing Requirements for Horticulture (Berries, Leafy Vegetables and Melons)***

Thank you for the opportunity to provide a submission on the second call for submissions for Proposal P1052.

This submission includes comments from the Queensland Department of Agriculture and Fisheries (DAF), Safe Food Production Queensland (SFPQ) and the Department of Health (Queensland Health). As SFPQ is represented on the Horticulture Implementation Working Group, some of the comments are provided by DAF and/or Queensland Health, as the departments did not contribute to these discussions.

This submission provides technical advice and comments related to Proposal P1052. The submission does not represent a Queensland Government position, which will be a matter for the Queensland Government when notification is made by the FSANZ Board to the Food Ministers' Meeting.

In Queensland, the three agencies share through-chain responsibilities for the safety and regulation of horticulture. DAF is currently responsible for primary production of horticultural produce including industry development, research and controls for pests, diseases, and contaminants. However, any new primary production and processing standards for berries, leafy vegetable and melons would most likely be administered and regulated under the *Food Production (Safety) Act 2000* and *Food Production (Safety) Regulation 2014*, consistent with other primary production and processing requirements in Queensland. DAF is responsible for policy development of this legislation, while SFPQ is responsible for its administration and enforcement. The Minister for Health and Ambulance is the lead minister for Queensland on the Food Ministers' Meeting. Queensland Health is responsible for requirements under the *Food Act 2006* related to sale of safe and suitable food, plus monitoring and investigation of foodborne illness and outbreaks.

**Preferred Option**

It is agreed that FSANZ's conclusion that Option 3 – Introducing a combination of regulatory and non-regulatory measures – is the preferred approach to appropriately manage food safety in the fresh berries, leafy vegetables, and melon sectors.

[Redacted signature block]

[Redacted signature block]

Option 3 provides a collaborative approach to regulation that recognises tools and strategies developed by industry to promote compliance with food safety requirements and achieving best practice within food production systems and through-chain. It is our view that open and on-going collaboration can lead to sustained compliance and the identification of improvements within systems and supply chains that will impact positively on both public health and the effectiveness of production systems.

It is acknowledged from the research undertaken as part of the risk assessment and review of past foodborne illness outbreaks linked to the horticulture sector, that the most likely sources of contamination of berries, leafy vegetables and melons are animals, growing location, extreme weather events, manure and composts, water inputs, post-harvest washing and sanitisation, and poor worker and equipment hygiene.

There is no single step that can ensure product safety during production and processing, as there are multiple factors that affect the level of contamination with bacteria and viruses. These will depend on different combinations of factors during their growth, harvest and primary processing on-farm, and these factors vary between different products. However, it is noted that the chance of contaminating produce could be reduced through good agricultural practices on farm, good hygienic practices at harvest and postharvest, and controlling inputs at all stages.

As these products are most frequently consumed raw with little or no further processing, it is agreed risk management needs to begin on farm with relevant controls implemented along the supply chain and therefore supports the development of three separate Standards based on the different risk profiles and cost-benefit for the differing sectors.

### **Implementation period**

The proposed 18-month implementation period is not adequate to allow for the necessary legislative amendment required to give effect to the changes in Queensland. It is also insufficient to put in place the necessary government structures, processes and information technology systems required to implement the requirements. We also note that industry quality assurance system accreditation bodies will need to time to update their related requirements in addition to changes horticultural industry primary producers would need to implement.

A three-year implementation period after gazettal of the proposed requirements should be sufficient for the Queensland Government to make any necessary legislative amendments, introduce supporting systems and processes, and other activities to facilitate implementation of the requirements.

A longer implementation period would help to ensure a better understanding of different operating models for various sectors, as well as increasing the capacity of stakeholders to develop guidance material, as well as develop new skill sets and other supporting material. It would also provide the time necessary to explore, design and implement new institutional arrangements and operating models on the part of both government and industry.

A minimum of two years would be needed for the commencement of the first standard if it is decided to stagger the implementation of the three standards. This is because the Queensland Government would still need time to amend Queensland legislation to implement the standards and develop the supporting structures, processes, and IT systems regardless of whether commencement occurs in stages. Staggering commencement could help ensure a better understanding of different operating models for various sectors, as well as increasing the capacity of stakeholders to develop guidance material, develop new skill sets and other supporting material.

It should be noted that significant legislative changes in Queensland are likely to be required to implement the proposed standards in Queensland, unlike most changes to existing food standards. While the Queensland Government would need to confirm the legislative model in Queensland, it is likely the *Food Production (Safety) Act 2000* and/or the *Food Production (Safety) Regulation 2014*

would need to be amended, consistent with the approach for primary production and processing standards for seafood, poultry, meat, dairy, eggs and seed sprouts.

While the proposed berry standard appears less onerous for industry, additional time (two years or more) would also be required for legislative changes to implement the proposed berry standard. This is because the draft berry standard does not require businesses to have an approved food safety program or management statement, so in Queensland amendments to the *Food Production (Safety) Act 2000* may be required to either create a new form of licence (which does not require an approved plan or statement) or exempt berry producers and processors from requiring an approved plan for accreditation purposes. This would require Queensland Government approval.

### **Non-Regulatory Measures**

It is strongly recommended that non-regulatory measures extend beyond fact sheets, webinars, and other tools, which are outlined in the Consultation Regulation Impact Statement, to include measures that will ensure on-going collaboration and information sharing between all stakeholders to ensure sustained compliance and an effective, proactive system.

This could be achieved through actions such as the development of agreed regulatory principles by system participants. These principles would promote consistency, guide the development and implementation of operating models and tools to support compliance, and inform the development of a performance and outcome measurement framework to monitor the effectiveness of the national approach.

Piloting a version of the Primary Authority Model could be considered help facilitate the recognition of suitable industry certification schemes to provide as a means of reducing the burden on applicable businesses and reducing resourcing impacts on regulators.

Support is given for a through-chain education strategy irrespective of whether regulation is implemented. While it is not possible to eliminate risks to consumers from fresh produce, it is evident that multiple controls must be consistently applied and managed throughout the production, processing, and supply chain, and all those involved need to be aware of food safety risks and how to minimise them. To be effective, the strategy should target all stakeholders including processors, producers, distributors, wholesalers, retailers, and consumers. A nationally consistent approach is necessary to ensure consistent messaging and expectations by industry, who operate across jurisdictions. This will also allow jurisdictions to pool resources reducing the impact.

Consideration should also be given to the development of video learning modules, which are linked to self-assessment tools, particularly for small business who may operate outside of industry recognised certification arrangements.

SFPQ is currently working with industry in Queensland to develop an approach for achieving best practice food safety management practices, through the Horticulture Food Safety Management Project. This work, which will consider existing commercial arrangements, supply chains and data currently collected by businesses, will also assist with the implementation of the proposed standards if approved. It will also ensure that Queensland has a whole-of-industry approach that supports all horticulture sectors, not just those captured under the proposed standards.

### **Minimal Effective Regulation**

When considering legislative changes in Queensland to implement the proposed standards, the Queensland Government can consider whether fees and charges for producers may be reduced, such as those operating within an integrated supply chain under a preferred supplier arrangement with an accredited processor. Regarding the Cost Benefit Analysis and estimated fees, accreditation (licence) and application fees are set by the Queensland Government under the Food Production (Safety) Regulation 2014 (FPS Regulation).

### **Draft standard 4.2.7 - Berries**

Concern is raised regarding statements such as “government will not be routinely monitoring the berries sector, unless a food safety issue is raised” (Section 5.1). SFPQ is legally obligated under the *Food Production (Safety) Act 2000*, to monitor regulated activities, which could be achieved through information sharing, check audits and surveillance programs. The concept of only monitoring sectors if a food safety issue is raised is in direct contrast to SFPQ’s approach of proactively monitoring supply chains, rather than waiting for an issue to arise. However, SFPQ is open to exploring with stakeholders the concept of recognising certification schemes as a means of acknowledging existing industry efforts in meeting the proposed food safety outcomes of the FSANZ standards.

### **Definition of Berries and scope of draft standard 4.2.7**

The definitions of berries in draft standard 4.2.7 is inadequate to provide regulatory certainty for industry and enforcement agencies. While they may be suitable ‘working definitions’ for the proposal, there are uncertainties about what they include or exclude, which need to be rectified.

Proposed Code 4.2.7-2 *Definitions* defines berries as “berries means fresh berries; and includes strawberries, blueberries, and raspberries.” This is a circular definition, i.e. a definition using the term(s) being defined as a part of the definition. Additionally, definitions of berries vary between botanical and common. The former includes simple fleshy fruit usually with many seeds, such as the banana, grape, and tomato. With a berry derived from a single ovary of an individual flower. This would also include leathery-rinded hesperidium berries of genus *Citrus* fruits, as well as tough-skinned family Cucurbitaceae fruits (“pepos”) including watermelons, cucumbers, and gourds. Queensland recognises the proposed standard may not be intended to apply to all botanically defined berries produced in Australia, but rather those with presenting the greatest potential risk to public health via production volume and/or primary production-associated microbiological contaminant risks. However, the existing scope is not clearly defined, either via clarified definition (which cannot be circular) or individual berry product classification and included or excluded from the respective berry-associated horticultural production Code compliance requirements. Hence, we recommend amendment of the 4.2.7-2 definition to (a) remove circular definition, and (b) clarify berry definition as botanical, common or as individually Code-classified for individual produce. One possible drafting solution would be to specifically reference Schedule 22 in the meaning of berries in Standard 4.2.7.

### ***Table grapes***

Table grapes would appear to be captured by the definition of berries and hence within the scope of proposal and draft standard. However, they have not been identified in the 2<sup>nd</sup> Call for Submissions report or the Consultation Regulation Impact Statement (RIS). It appears that blueberries may be a suitable proxy for grapes, so the risk assessment work for blueberries may be relevant to them. However, the data will be inaccurate in the RIS for the number of growers, production volume, number of berry producers with a FSS, etc. Australia has a significant table grape industry and omission of them from the reports should be rectified. The Australian Table Grape Association Inc. should be able to provide information on their industry.

### **Strawberries**

Concern is raised about the risk assessment and proposed regulatory measures for strawberries because some risks associated with strawberries growing on the ground are not adequately captured including the management of the growing site, and animals and pests.

As the cost-benefit analysis for berries demonstrated a lower benefit to the community than other commodities, the draft Standard subsequently takes a more limited regulatory approach. However, it is unclear why the risks for strawberries were assessed as similar to the other berries. The risk assessment notes the key differences between strawberries and other berries, in that strawberries are mostly grown on the ground (noting they may be grown in limited cases hydroponically) whereas other berries are grown above the ground, e.g., on bushes or trellised vines. As such, some risks for

strawberries share more in common with leafy vegetables and melons than other types of berries, for example, risks from animal incursions and pests such as rodents, flooding, storm water runoff (noting strawberry production areas in Queensland may be seasonally subject to high rainfall events), irrigation, watering to prevent frost damage, direct contact with contaminated soil, splash from contaminated soil, contaminate dust, etc. Furthermore, it is noted that strawberries cannot be washed and sanitised during processing.

It is noted the number of foodborne illness outbreak attributed to strawberries is likely to have been under reported, probably because many are not published. For example, Appendix 2 of SD2 notes two outbreaks in the USA, while the following website indicates the USA between 1998 and 2018 had at least 34 strawberry-associated outbreaks reported to the CDC's National Outbreak Reporting System (NORS), causing 941 illnesses, 81 hospitalizations, and 2 deaths: <https://fsi.colostate.edu/strawberries/>.

It appears appropriate for businesses to ensure the site used to grow strawberries is safe (i.e., will not contaminate the produce) including that all reasonable measures to ensure that a growing site is located, designed, constructed, maintained and operated such that strawberries are not made unacceptable. This should include that the location of growing areas is not near, or on land used for livestock production or a wildlife habitat, or areas exposed to urban or industrial waste. Furthermore, consideration needs to be given to requirements to manage growing sites to reduce risks, such as reducing stormwater runoff and flooding risks, use of contaminated water, minimising ground contact, etc.

The risk assessment for strawberries should include *Salmonella spp.* or provide a rationale for its exclusion. FSANZ has noted that most berry outbreaks have been associated with STEC, Norovirus and Hepatitis A. However, theoretically, *Salmonella spp.* should also be considered as a foodborne illness risk on strawberries in Australia. Reasons include its ability to survive in the environment, its association in Australia with other horticultural produce related outbreaks of produce grown on the ground (e.g., leafy vegetables and melons), its presence in wildlife (e.g., birds and lizards) and vermin (e.g., rodents) that may be present, and potential presence in farmed animals such as poultry and cattle. Furthermore, surface water used for irrigation and surface water (e.g., flood and stormwater) may be contaminated by *Salmonella spp.* and contaminate strawberries.

#### **Draft standard 4.2.8 Leafy vegetables**

##### **Definition of Leafy vegetables and scope of draft standard 4.2.8**

The definitions of leafy vegetables in draft Standard 4.2.8 are inadequate to provide regulatory certainty for industry and enforcement agencies. While they may be suitable 'working definitions' for the proposal, there are uncertainties about what they include or exclude. To be enforceable, clarity should be provided within the drafting of the Food Standards Code rather than in guidance material.

While it is understood that FSANZ initially undertook Proposal P1052 having reviewed past outbreaks, and focussing assessment of the microbiological risks within leafy vegetables to lettuce, parsley and spinach, the exact definition of leafy vegetables is not specific enough to determine whether horticultural produce such as spring onions/shallots, leeks, potatoes, radishes, etc. would also be included, or whether these are considered "root crops" despite portions of the plants (e.g., leafy portion of a shallot) commonly being consumed.

It is important that the scope of the definition of leafy green vegetables is clarified, and clear justifications provided as to why other types of leafy vegetables (such as cabbage and spring onions) that present similar or greater potential microbiological risks, are excluded from the proposed Code amendments. Therefore, a more precise definition of leafy vegetable is required and/or a comprehensive list of vegetable produce such that inclusion or exclusion within the proposed revised standard can be readily determined, and applicability of requisite compliance plans and standards – including requirements for post-harvest sanitising procedures.

One possible drafting solution would be to specifically list the horticultural commodities to be captured by Standard 4.2.8. Another would be to reference relevant classes of foods (including commodity lists) in Schedule 22, such as the listing for “Leafy vegetables (including brassica leafy vegetables)”. However, it appears referencing Schedule 22, as currently drafted, would not provide an ideal solution, unless suitably amended. For example, the ‘Leafy vegetables’ list includes commodities that appear to be not intended for captured by Standard 4.2.8, such as grape leaves. Furthermore, Schedule 22 does not include a commodity list for ‘brassica leafy vegetables’, so does not provide clarity for cabbages, broccoli, etc.

### ***Spring onions and cabbage***

Queensland Health and DAF strongly argue spring onions (shallots) should be included within the scope of Proposal P1052 because the production and characteristics of spring onions share many similarities to leafy vegetables. A national *Salmonella Saintpaul* outbreak in 2020/21 (Incident NFIRP 2021-01) was likely to be associated with contaminated spring onions. The outbreak demonstrated the food safety hazards and risks for spring onions were very similar to leafy vegetables as discussed in Proposal P1052. However, we understand the scope of P1052 did not include spring onions. If it is not possible for spring onions to be included within the scope of P1052, it is strongly recommended a proposal is raised immediately following the conclusion of P1052 to examine developing a regulatory measure to control primary production and processing risks for spring onions.

Queensland Health and DAF question whether cabbages should be considered a leafy vegetable for the purposes of potential microbiological risks similar to lettuces (e.g., similar to iceberg lettuce).

### **Compliance Plans**

The example compliance plans developed by the Horticulture Implementation Working Group are noted and help clarify how the proposed standards, which lack detail being outcome based, may be implemented. Since the draft compliance plans are the responsibility of the Horticulture Implementation Working Group, comments prepared by Queensland Health on the compliance plans are provided in **Attachment 1** for the consideration of the Working Group and FSANZ. It is argued that because the draft standards lack criteria that are auditable and enforceable, it is critical that appropriate criteria are developed, particularly for water quality and sanitising treatments.

### **Responses to Section 12 Questions for stakeholders of Consultation Regulation Impact Statement**

As government agencies, we are unable to comment on most of the questions.

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

We are unable to provide specific industry data. However, it is likely the data is an underestimate regarding berries and leafy vegetables because some horticultural commodities have not been included. We also argue that some additional horticultural commodities should be included.

#### ***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?***

No comment.

#### ***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?***

No comment.

- 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?**

No comment.

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

No comment.

- 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%.

No comment.

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

No comment. This question is more appropriate for industry.

- 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).

No comment.

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

No comment. This question is more appropriate for industry.

- 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.

The costings are for businesses and do not include costs to government agencies administering and enforcing the requirements.

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

No comment.

- 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

The proposed requirements may potentially provide additional industry benefits such as fewer food safety related incidents (leading to withdrawal and recalls), improved product quality and extended shelf-life of product due to greater control.

The traceability requirements should assist in managing food safety incidents, only if commodity distribution information is substantially improved and standardised. For example, a business presenting to a food enforcement agency a box of unsorted printed invoice receipts may comply with the traceability requirement but hinder timely and effective investigation and management. The draft traceability requirement would also benefit from requirement about the timeliness of provision of the information and standardisation of terminology and documentation.

The government's capacity to effectively and efficiently manage food safety incidents may possibly be improved if specific standard criteria are introduced allowing enforcement, and jurisdiction's authorised agencies to act at a presumed source, have staff with the specific on-the-ground applied skills and experience.

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

No comment.

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

No comment.

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

No comments.

**16. Do you think certain locations might be affected 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?**

Audit costs may be higher in remote areas due to increased travel costs and travel time.

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

No comment.

**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.

Soil and fertilisers, especially those derived from animal waste, present food safety risks for strawberries, which are grown on the ground. We believe risk from soil and fertilisers need to be controlled for strawberries, and any other berries grown on the ground. This should include mulches, which may come into contact with berries.

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



As discussed in this submission, it appears that grapes, particularly table grapes, would be captured by the berry standard. If grapes are included, the costs and benefits for grapes will also need to be included.

In this submission, we argue that additional requirements should be required for strawberries due to the additional risks for strawberries given they are grown on the ground. The cost benefit analysis will need be updated if the draft standard is amended to include additional requirements for strawberries.

Food Safety Standards and Regulation Unit  
Health Protection Branch  
Department of Health  
Queensland Government

16 February 2022

## ADDITIONAL COMMENTS ON COMPLIANCE PLANS

The following comments, prepared by Queensland Health, are provided for consideration by FSANZ and the Horticulture Implementation Working Group, based on the example compliance plans released by FSANZ in the 2<sup>nd</sup> Call for submissions for Proposal P1052.

### **General comments**

It is argued that because the draft standards outcomes based and lack details on how the standards may be achieved for certain horticultural commodities, it is critical that appropriate criteria are developed, particularly for water quality and sanitising treatments.

The designation of primary production into Activity Groups with respectively applicable compliance plans is to be commended. A recommendation as part of non-regulatory measures is production of easier to interpret format communications materials allowing primary producers to identify their individual respective required compliance and activity plans and requirements quickly and accurately. However, we recognise this may additionally be communicated via modifications to existing food safety arrangements standards (e.g., HACCP based food safety programs, industry approved quality assurance programs) to comply with amended Code compliance requirements, including primary produce classification and monitoring standards.

### ***Use of existing food safety arrangements to meet the outcomes of a food safety management statement.***

Clarification is sought on whether the indication in both leafy vegetables and melons compliance plans “*Note that businesses with existing food safety arrangements (e.g. HACCP based food safety programs, industry approved quality assurance programs (e.g. Freshcare, BRC, SQF, HARPS) could be considered to meet the outcomes of a food safety management statement*” applies specifically to the food safety management *statement*, or holistically to the respective compliance plan? A food safety management *statement* is only one overarching component of a Good Agricultural Practices (GAP) quality assurance system, with GAP delineating the recommended conditions, growing practices, and harvesting practices for minimizing risk of microbial contamination to produce safe and wholesome produce. Typically, a signed/otherwise acknowledged management *statement of intent to comply with the practices*, rather than the practices themselves.

As the horticulture-associated foodborne illness (FBI) outbreaks specifically cited in Proposal P1052 occurred under current industry approved quality assurance schemes (generally, if not specifically associated with the respective FBI outbreaks), and the proposed Code-amendment compliance requirements are intended to improve practices to reduce public health risk, it should be clarified whether they intend that accreditation with *existing* food safety arrangements (e.g. Freshcare Standard 4.2) *as-is* would satisfy requirements of the respective Code-amended compliance plan. Or whether it is expected that the accreditation *standards* of the various industry approved quality assurance programs (which define audit scope and criteria) must then comply with the respective Code-amended compliance plan(s). Clarification is sought as the former circumstance, creating potential for “grandfathering” of existing food safety arrangements, would likely create a variable-compliance-criteria across the sectors, as opposed to “normalisation” of horticultural production minimum management and monitoring compliance requirements. Whereas we seek the latter option.

### **Berries**

The example compliance plans developed by the Horticulture Implementation Working Group are noted and concern is expressed that the berries guidance document is a template to be used by businesses as part of the notification process, not a document outlining minimum requirements considered applicable to meet the requirements set out in the draft Standard.

Acknowledging that many horticultural producers and processors have previously not been captured by any regulatory food safety requirements, it is reasonable to assume some businesses would not be aware of what is expected of them. For example, the template asks businesses to describe how

their business ensures water, used at all stages of processing, is of suitable quality and does not make berries unacceptable. However, as the document is a template rather than a guidance document, it does not provide any advice or criteria as to what is considered suitable. For example, using potable water, what 'potable water' means, reference to the Australian Drinking Water Guidelines, or any information or advice in relation to onsite water sources, such as bores or creeks and the frequency at which they must be tested to ensure quality.

The proposed Primary Production (PP) Standards for berries (P1052 2<sup>nd</sup> CFS, Table 1) does not include compliance plan requirements relating to (a) General food safety management requirements, (b) management of the growing site, (c) management of food safety following weather events or (d) management of animals and pests, while these are requirements for leafy vegetables and melons. Each of these are more general requirements of Good Agricultural Practices (GAP) (e.g. FAO, BSI) and must be included in the associated PP standards. For example:

- (a) general food safety management requirements – FSANZ describes this as “businesses will need to have an approved statement that sets out all their food safety risks and how they will manage these risks, and operate according to this statement”
  - This should be expected as a basic compliance aspect of any primary production activity potentially presenting a substantial public health risk via microbiological contamination (or other).
- (b) “management of water as an input – “businesses will need to make sure the water used with (*leafy vegetables and melons*) is safe (i.e. it will not contaminate the produce).”
  - Regardless of the nature of the berries produced, at a minimum the need for monitoring the microbiological quality of pre-harvest water should be risk assessed as part of (a). If found to present a low risk via *clearly* defined criteria in the standard. For example, maximum levels of indicator bacteria such as *E. coli* in preharvest irrigation water for respective growth conditions, e.g. edible portion does not contact soil and/or irrigation water, spray – versus drip or furrow or hydroponic system irrigation. If assessed as low risk (a risk assessment matrix is recommended) monitoring requirements may range from nil to some clearly defined frequency and microbiological limit(s).
- (c) management of soil and fertiliser as inputs – businesses will need to make sure the soil and fertilisers (including compost and manure) used with (*leafy vegetables and melons*) is safe (i.e. will not contaminate the produce).
  - Similarly to (b) above, this should initially be assessed as per (a) and based on resultant assessed risk, respective standards for compliance and monitoring required to control them. For example, berries where the edible portion is grown on the ground (e.g. strawberries), or may be expected to be impacted by soil via splash or significant soil-dust generation must ensure compost and soil amendments are compliant with AS4454-2012, and where produced on site, they are compliant with AS4454-2012 microbiological criteria (*E. coli* < 100 cfu/g, *Salmonella* Not Detected/25 g) – inclusive of criteria for sampling (frequency, mass to be collected, composited/non-composited, per production lot/batch or via process validation with periodic [defined] less frequent verification.) Noting specific *additional* ex-4454-2012 restrictions and microbiological requirements for application of biosolids to horticulture for human consumption. For berries assessed as per (a) as low risk, such assessment may not be required.
- (d) management of seed and seedlings as inputs (*leafy vegetables only*) – businesses will need to make sure the leafy vegetable seed and seedlings used are safe (i.e. are not contaminated).
  - It is generally agreed that seed berry seed stock microbiological contamination does not generally present a significant public health risk via contamination of resultant edible portion of plants. It is also recognised control procedures generally taken to reduce risks associated with introduction plant pathogenic microorganisms via seeds and seed crops will additionally reduce risk of seeds introducing

microorganism presenting potential human health risks to berry primary production environments.

- (e) management of the growing site – businesses will need to make sure the site used to grow (*leafy vegetables or melons*) is safe (i.e. will not contaminate the produce)
  - This is a general GAP requirement which should be addressed at a minimum via requirement for (a). For example, assessment of a growing site for susceptibility to flooding, dust storms, animal intrusion and/or proximal potential sources of contaminants via pre-harvest water (flocks of birds regularly congregate at/in irrigation water sources?; and/or roost and/or defecate on berries?) or dust (e.g. feedlot, intensive animal production/processing/housing-stabling). As above, the assessed risk (optimally via well-defined risk matrix) should then indicate compliance requirements – if any.
- (f) management of food safety following weather events – businesses will need to make sure (*leafy vegetables or melons*) exposed to storms, floods, dust etc. are managed (by disposing of them; redirecting them; or trimming, cleaning, sanitising etc.) so that no unsafe produce is sold or supplied for consumption.
  - This is also a general GAP requirement which must be assessed as per (a) at a minimum, with associated actions defined in response to flooding or storms where the berries are impacted. For example, procedures for harvesting of berries from the ground, or impacted by splashback from soil after storms (noting possible actions could include discard produce, quarantine, assess as suitable for washing, sanitising, sale for non-RTE purposes where further antimicrobial treatment will occur such as thermal processing to make jam).

#### **Compliance plan A: Horticulture production (grows and harvests horticulture produce)**

##### *Traceability*

Variability in traceable record formats presents a *substantial* collation and analysis challenge to timely and effective food traceback during foodborne illness outbreaks. It is noted that “Producer must maintain records of all horticulture produce sold or supplied”. FSANZ should promote some normalisation of record keeping in this regard as part of non-regulatory measures. Either through creation of standard reporting formats, tools, etc., or promotion of same.

##### *Inputs: Soil, soil amendments and fertilisers*

It is indicated under *Monitoring requirements – Industry* – that fertiliser/compost produced on-site applied to produce be of suitable microbiological quality and verified by the business *may* be subject to microbiological tests to verify practices and confirm the absence of known foodborne pathogens (e.g. *Salmonella*.) FSANZ should clarify the specific requirements, e.g. AS4454-2012; *E. coli* < 100 cfu/g, *Salmonella* Not Detected/25g as well as frequency of testing (per composted lot?, annually?, commissioning, then at defined intervals unless production practices/inputs significantly changed with or without decreased monitoring frequency to some minimum as process is assessed as compliant)?

##### *Compliance Plan A - Inputs: Water (pre-harvest)*

Compliance plan A requirements regarding pre-harvest water quality lack microbiological quality criteria defining “suitable”. These must be *clearly*, accurately, and unambiguously defined in terms of maximum contaminant levels (MCL), specific measurand (e.g. CFU *E. coli*/100 ml) and test frequency. Noting MCL’s typically vary depending on factors such as: whether pre-harvest water comes into direct or indirect contact with edible portion of the crop and minimum period between last application and harvesting.

Test frequency is a particular issue and must be clearly defined. We note that some existing industry approved quality assurance program requirements related to assessment of pre-harvest water quality are so generic as to allow a single annual test from a single production area source (e.g.

dam) where water from multiple sources (e.g. multiple dams) may be used. The representativeness of a single, 100 ml sample in terms of assessment of microbiological quality varies significantly. From good for a protected groundwater source, moderate-to-poor for lacustrine (lake, dam) to practically nil for riverine sources (creeks, rivers – particularly those significantly seasonally, or event-associated flow-regime impacted. Given a clearly defined MCL, the accuracy of compliance assessment associated with frequently currently accepted single-sample/year monitoring, similarly varies from good, to practically nil.

Pre-harvest water microbiological MCL's generally vary based on the factors cited above. However, FSANZ should note MCLs may be based on single-sample threshold, and/or multiple-sample "statistical-average" criteria. FSANZ is directed to the recent US FDA Establish Requirements established for [water quality and testing of irrigation water under the Food Safety Modernization Act \(FSMA\) Final Rule for Produce Safety](#). This includes: clearly defined, risk assessment-based, pre-harvest microbiological water quality limits based on (*E. coli*/100 ml) multiple-samples over time as both a geometric mean (GM) and statistical threshold value (STV); clearly defined sampling frequency for different water source types; effective [non-regulatory guidance materials](#) and free [Excel](#), [app](#) and [online calculators](#). For example:

- "Surface water testing will require a minimum of 20 initial samples collected over two to four years. After that, farms must test a minimum of five samples a year. The microbial water quality profile will thus be updated annually on a rolling basis using a minimum of 20 samples. The calculation of the GM and STV will typically be based on the five new samples and 15 of the most recent earlier samples. Ground water testing will require a minimum of four initial samples over one year, followed by a minimum of one new sample each year. The profile will be updated annually using at a minimum the most recent four samples. These are the minimum numbers of samples we consider statistically necessary to provide a picture of the surface and ground water quality.
- The GM/STV criteria, and the associated testing requirements, do not apply to water that does not come in direct contact with the harvestable portion of the produce. For example, these requirements will not apply to water used for drip irrigation of tree crops that grow high above the ground and are not likely to touch the ground.
- Farms that use a public water system or supply will not have to test their water, provided that there are documents establishing that the public water meets specific criteria."

This approach takes into account the differing nature of water sources in terms of temporal variability in microbiological quality, is metrologically sound, based on quantitative human health risk assessment, and allows decreased monitoring based on source type and performance history with respect to water quality. It is recommended this approach be carefully reviewed and it, or a similar approach, be considered for the assessment criteria of pre-harvest microbiological water.

As noted in comments related to performance evaluation and verification of sanitisation efficacy Compliance Plan B - *Processing operations: washing and sanitising*, it is strongly recommended FSANZ review The US FDA FSMA Produce Safety Rule for potential applicability regarding the [0.5 log/day \(between last water application to harvest; maximum 4 days credit\) log<sub>10</sub>-reduction credit](#) where pre-harvest water source microbiological quality does not meet the maximum contaminant criteria (GM or STV in this case).

### **Compliance Plan B - Inputs: Water (post-harvest)**

#### *Compliance Plan B - Processing operations: washing and sanitising*

While compliance plan B requirements regarding post-harvest water quality cite "potable quality" as defined by jurisdictional Safe Drinking Water Act microbiological quality criteria – all of which reference the Australian Drinking Water Guidelines criteria of < 1 CFU *E. coli*/100 ml – again, monitoring *frequency* is not defined. Similar to pre-harvest water quality monitoring, it was noted that some existing industry approved quality assurance program requirements related to assessment of post-harvest water quality allow a *single* annual test from a single production area source (e.g. bore) where water from multiple sources (e.g. multiple bores) may be used. As above, the representativeness of a single, 100 ml annual sample in terms of assessment of microbiological

quality varies significantly. From good for a frequently pumped, protected groundwater source, to quite variable for variable sources, or those requiring treatment to achieve the quality criterion (surface or rainwater). Given a clearly defined MCL, the accuracy of compliance assessment associated with frequently currently accepted single-sample/year monitoring, similarly varies from good to poor. It is recommended FSANZ clearly define sampling frequency criteria. Noting that this may be allowed to be reduced to some *carefully considered minimum* level (as set by FSANZ) based on acceptable compliance history, but with additional, clearly specified verification sampling criteria for changes in source water and/or treatment systems.

Additionally, initial sampling frequency should be based on source risk, i.e. lower for protected groundwater sources, greater for treated systems. These comments are also applicable to *Compliance Plan B - Processing operations: washing and sanitising* pre-wash rinse water, for which a quality criterion of < 100 CFU *E. coli*/100 ml is indicated. This generally implies - and in practice is often the case - untreated, or minimally treated surface water. As such, test frequency to assess compliance with the microbiology quality criterion should reflect its classification in terms of potential temporal variability and test result(s) representativeness.

Throughout both compliance plans, minimum test frequency must be defined. It is emphasised that industry approved quality assurance program auditors are generally restricted to auditing against the *specific respective accrediting body standard only*. cursory review of audit reports from industry approved quality assurance programs have indicated testing of incorrect water sample volumes, single annual test results from a single surface water source accepted when different surface water sources than that tested drawn for post-harvest use, and approved but non-compliant water system “commissioning” testing requirements. We therefore feel it is critical the Code-defined standards contained within the Compliance Plans contain clear microbiological water quality testing frequencies and criteria, and that all associated qualifiers listed as *should* (discretionary) must be revised to *must* (mandatory), e.g.

- Water used for washing and sanitising produce prior to packing for further sale and supply ~~should~~ must meet <1 cfu *E. coli* /100 mL product (refer correct measurand convention below).
- Water for use in handwashing ~~should~~ must be < 1 cfu *E. coli*/100 mL or else an alcohol-based hand sanitiser should be used.

Such testing frequency requirements may be water source(s) and/or treatment system (as applicable) based (see above). If such criteria (sampling frequency) are proposed for specification ex-Code, e.g. via non-regulatory industry guidance material, FSANZ must note, as described above, that jurisdictional authorities may be unable to take enforcement action unless the Code amendments specifically state that the guidance materials *must* be used as the basis for regulatory compliance with Code Compliance Plans. Noting again that industry approved quality assurance program *standards* define the *minimum* food safety system requirements against which compliance is assessed for accreditation. FSANZ and jurisdictional food safety authorities cannot rely on an expectation approved quality assurance programs to require compliance criteria within their standards not specified as mandatory in the Code.

FSANZ should also note that the international convention for reporting such results is now recommended as “*E. coli* Not Detected/100 ml” with testing laboratories now advised to move to this reporting format. Additionally, the order and spacing convention for the specified measurand is as follows: (existing – “< 1 CFU *E. coli*/100 ml; to be replaced over time with “*E. coli* Not Detected/100 ml”. Lower case cfu may also be used.

#### *Sanitisation efficacy verification and performance evaluation*

The introduction of compliance requirements regarding washing and sanitising of leafy greens and melons should be considered. However, the proposed requirements are vague and lack defined criteria regarding efficacy. Specifically, validation (and ongoing verification) of same. This is particularly important as the efficacy validation requirement is mandatory. Efficacy is most commonly assessed as log<sub>10</sub>-reduction value (LRV) in indicator bacteria. This is defined as the reduction in culturable indicator bacteria in sample(s) of the commodity post-wash/sanitising treatment from pre-

treatment value, expressed as the base-10 logarithm value. The indicator bacteria generally being *E. coli* as faecal, total coliforms as a general Gram-negative Enterobacteriaceae-, and Standard Plate Count (SPC) as a general heterotrophic bacterial-indicators. With the cost of testing for these indicators generally varying substantially between *E. coli* and total coliforms (higher cost) and SPC (lower cost), noting that it is unlikely a pre-wash/sanitised commodity routinely contains levels of *E. coli* sufficient to assess log<sub>10</sub>-reduction, which requires a minimum pre-treatment level of ca. 2 log<sub>10</sub> (e.g. 100 cfu/unit mass) to measure a minimum 2 log<sub>10</sub> efficacy.

Unless validation and verification use spiked samples, which is often logistically difficult and costly. Efficacy validation of sanitisation processes is typically carried out by the sanitiser manufacturer either through controlled spiked-commodity validation trials, or values are used which are generally reported via well-supported efficacy history in the literature and/or industry reference materials. Therefore, the end-user/primary producer typically *verifies* sanitiser efficacy performance, unless *clearly defined* validation assessment procedures and criteria are available which are not overly onerous on the end-user in terms of costs and labour. Additionally, verification of sanitisation performance efficacy is not a one-off, but a factor assessed periodically to demonstrate ongoing satisfactory performance. With *consistency* in satisfactory sanitisation/washing (noting washing alone in the absence of sanitiser may, in some cases, achieve acceptable LRV and/or resultant washed-sanitised commodity level of microbiological quality, e.g. < 10 cfu *E. coli*/10 g).

Regardless, in order to ensure consistency of sanitisation efficacy and end-product microbiological quality across the commodity primary production industry falling under the proposed P1052 compliance plan requirements, the following processes and criteria must be described:

- Maximum post-wash/sanitisation contaminant levels
- Minimum LRV(s)
- Acceptable procedures for sanitisation efficacy validation (e.g. validation documentation from manufacturer, general literature-supported/industry-verified history-of-use)
- Acceptable processes for sanitisation verification, including indicator(s), minimum number of sample units tested, sampling (composited, discrete), minimum sample unit size, minimum frequency of ongoing performance verification)
- Post-wash/sanitisation maximum contaminant/indicator level – noting this *value* may vary by commodity but must be defined as a minimum requirement.

The same general aspects as indicated above related to microbiological water quality test frequency should apply. Including defined test procedures and efficacy criteria on process commissioning and/or substantial wash/sanitisation process changes, and to verify ongoing performance. And that such frequencies may be reduced to some clearly described minimum commensurate with a history of satisfactory performance. These requirements do not have to be overly onerous (e.g. use of SPC for LRV performance verification), but must be clearly defined to promote consistency, set minimum Code-mandated criteria for industry approved quality assurance program standards, and jurisdictional enforcement. Note that leaving these criteria non-mandated or vague, and relying on “industry-approved” standards not specified in the Code would create substantial enforcement difficulties for jurisdictions.

Additionally, as for microbiological water quality criteria, if such wash/sanitisation performance evaluation criteria are proposed for specification *ex-Code*, e.g., via non-regulatory industry guidance material, FSANZ must note, as described above, that jurisdictional authorities may be unable to take enforcement action unless Code amendments specifically state that the guidance materials *must* be used as the basis for regulatory compliance with Code Compliance Plans.