

23 September 2010 [20-10]

PROPOSAL P1012 SEMI-DRIED TOMATOES & INGREDIENTS – TRACEABILITY & PROCESSING ABANDONMENT OF PROPOSAL

Executive Summary

At the request of the Victorian Department of Health, FSANZ prepared a Proposal under its urgency powers¹ suggesting an amendment to the *Australia New Zealand Food Standards Code* (the Code) to put in place requirements similar to those imposed under their Emergency Order. Specifically, this Proposal, P1012 – Semi-Dried Tomatoes & Ingredients – Traceability & Processing, proposed varying Standards 1.6.2 and 3.2.2 to include traceability and processing requirements for semi-dried tomatoes, as well as for tomatoes and other food likely to be used in semi-dried tomatoes. As food safety requirements are outside the scope of the arrangements between Australia and New Zealand for a joint Code², it was proposed that the variations not apply in New Zealand.

Under Proposal P1012, FSANZ consulted on three Options:

- 1. do nothing; or
- 2. include specific regulatory measures in the Code for traceability of semi-dried tomatoes, and tomatoes and other foods likely to be used in semi-dried tomatoes, in order to facilitate trace back in the event of a future outbreak; or
- 3. include specific regulatory measures in the Code for traceability and processing of semi-dried tomatoes, and tomatoes and other foods likely to be used in semi-dried tomatoes.

FSANZ's preferred approach for consultation was Option 3 as it provided a broader range of measures to protect public health and safety in relation to semi-dried tomatoes.

Consultation

Twenty-four submissions were received from industry and government. There was limited support for the measures proposed with nine submissions not supporting any of the Options; eight submissions supporting Option 1 (do nothing); two submissions supporting Option 2 and five submissions supporting Option 3.

¹ Section 95 of the Food Standards Australia New Zealand Act 1991

² New Zealand develops its own food standards for residues of agricultural and veterinary chemicals, food safety and primary production and processing.

Submitters that supported the measures raised concerns and issues with them, including the definition of semi-dried tomatoes and the scope of the proposed traceability requirements. A number of submitters questioned the need for specific measures at this time and suggested FSANZ consider more general and preventative food safety measures rather than pursue measures for specific foods.

Alternative Options for managing hepatitis A virus contamination of semi-dried tomatoes

Alternative approaches to P1012 to address the issue of viral contamination of food were proposed during the public consultation and through the national debrief of the hepatitis A and semi-dried tomatoes incident³. These Options involve abandoning the draft standard (and Proposal P1012) and investigating alternative, more strategic approaches for managing hepatitis A in foods. All of the Options, including progressing Proposal P1012, are outlined below.

Option 1 – Progress Proposal P1012

Option 1 involves continuation of Proposal P1012 i.e. the FSANZ Board approves the draft standard and, within twelve months from the date of effect of the variation, FSANZ must undertake an Assessment of these measures, seek public comment on the Assessment (and the measures) and then re-affirm the measures.

Under this Option, there will be specific regulatory measures in the Code for traceability and processing of semi-dried tomatoes, and tomatoes and other foods likely to be used in semi-dried tomatoes.

Option 2 - Review traceability requirements in the Code

During the hepatitis A incident, investigations were difficult due to the complexity of the supply chain. At the national hepatitis A incident debrief, jurisdictions noted that there are some existing traceability requirements in the Code, however the extent and scope of existing traceability requirements, and potential gaps, in the Code should be examined. The Implementation Sub-Committee (ISC) has tasked the Incident Response Working Group⁴ to undertake this work, in addition to considering other issues that arose in regard to this incident, and report the outcomes and recommendations to ISC in February 2011.

Option 3 – An amendment to the Code to include a provision setting a limit for hepatitis A virus material in semi-dried tomatoes

This Option would involve developing a limit for hepatitis A virus material in semi-dried tomatoes. This approach would be contingent on the analytical capability and capacity being developed and maintained.

It is not clear whether presence of virus genome, as determined by PCR, correlates with a human health risk. The presence of the hepatitis A virus in food does not necessarily mean that the virus is viable as PCR can detect genomic material from inactivated or non-infectious virus.

³ This incident was managed under the Implementation Sub-Committee National Food Incident Response Protocol. As part of the process, a national debrief of the hepatitis A and semi-dried tomatoes incident was held on 7 July 2010, involving multiple participants from across the jurisdictions.

⁴ The ISC Incident Response Working Group, chaired by FSANZ with representatives of the State and Territory agencies and NZFSA, is responsible for the continual improvement of the Protocol.

Option 4 – Address this issue through the development of the Horticulture primary production and processing standard.

This Option is consistent with the view expressed in the majority of submissions that FSANZ consider more general and preventative food safety measures rather than pursue measures for specific foods.

Option 4 is based on measures that prevent hepatitis A contamination more generally (and also considers other hazards) in horticulture, and would also consider traceability requirements for horticultural commodities. This Option does not preclude a separate standard development process to deal with general traceability requirements.

Based on comments in submissions to Proposal P1012, and further consultation with the food authorities, FSANZ is proposing to abandon the draft variation to the Code and proceed with Option 4 as it provides a longer term solution and would consider problems with poor handling and hygienic practices across all /horticulture.

Decision

To abandon the draft variations to Standards 1.6.2 and 3.2.2 to include traceability and processing requirements for semi-dried tomatoes and ingredients.

Reasons for Decision

FSANZ is recommending addressing this issue through the development of the primary production and processing standard for horticulture as:

- this approach will enable a systematic examination of commodities linked to foodborne illness; understanding intrinsic commodity characteristics and their association with risk; and the impact of market channels and operation size on hazard exposure
- issues raised during the consultation on Proposal P1012 can be considered under this approach i.e. potential hepatitis A contamination in food should be managed with measures that prevent contamination from occurring, rather than measures that attempt to 'cure' the problem after it has occurred
- this approach facilitates the application of 'through-chain' preventative measures and traceability to all relevant foods rather than being applied to specific foods on an outbreak by outbreak basis

This standard development process will commence in early 2011 and will consider the issues raised during the consultation on Proposal P1012.

In the short-term, the ISC Incident Response Working Group will consider the range of issues identified during this incident, including existing measures in food legislation to manage future outbreaks and the extent and scope of existing traceability requirements, and potential gaps, in the Code. The working group will report back to ISC at the February 2011 meeting on the outcomes and recommendations.

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SUPPORTING DOCUMENT

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The following supporting document, previously referenced in the Initial Consultation Report, is available on the FSANZ website at http://www.foodstandards.gov.au/foodstandards/proposals/proposalp1012semidri4698.cfm

SD1 Semi dried tomatoes and hepatitis A virus

Introduction

At the request of the Victorian Department of Health, FSANZ prepared an urgent Proposal, P1012 in January 2010. The purpose of Proposal P1012 was to consider varying Standards 1.6.2 and 3.2.2 in the *Australia New Zealand Food Standards Code* (the Code) to include traceability and processing requirements for semi-dried tomatoes, as well as for tomatoes and other food likely to be used in semi-dried tomatoes.

The Victorian Department of Health provided FSANZ with a CSIRO report *Semi dried tomatoes and hepatitis A virus* (provided in supporting documentation). FSANZ is grateful to the Victorian Department of Health, the Victorian Department of Primary Industries and the CSIRO for providing this report to FSANZ.

As food safety requirements are outside the scope of the arrangements between Australia and New Zealand for a joint Code⁵, it was proposed that the variations not apply in New Zealand.

1. The Issue

There were two hepatitis A outbreaks during 2009 that were associated with the consumption of semi-dried tomatoes. Most cases occurred in Victoria and short term measures were put in place in Victoria to protect public health and safety. These measures were included in an Order made under the *Food Act 1984* (Victoria). The Order applied traceability and processing requirements on the proprietors of certain food businesses in relation to semi-dried tomatoes and ingredients.

The Order ceased to have effect after 9 February 2010. Victorian authorities advised FSANZ that regulatory measures are necessary to manage the risks associated with semi-dried tomatoes and requested that measures to protect public health and safety be developed as an urgent consideration.

Given the imminent expiration of the measures in place in Victoria, Proposal P1012 was declared urgent in accordance with section 95 of the *Food Standards Australia New Zealand Act 1991* on 18 January 2010.

2. Objectives

In developing or varying a food standard, FSANZ is required by its legislation to meet three primary objectives which are set out in section 18 of the FSANZ Act. These are:

- the protection of public health and safety; and
- the provision of adequate information relating to food to enable consumers to make informed choices; and
- the prevention of misleading or deceptive conduct.

In developing and varying standards, FSANZ must also have regard to:

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

⁵ New Zealand develops its own food standards for residues of agricultural and veterinary chemicals, food safety and primary production and processing.

- 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; and
- any written policy guidelines formulated by the Ministerial Council.

3. Relevant Issues

3.1 Consultation on Proposal P1012

FSANZ, having declared this Proposal as urgent under section 95 of the FSANZ Act, conducted six business days of public consultation (21 January – 1 February 2010) and consulted on three Options:

- 1. do nothing; or
- 2. include specific regulatory measures in the Code for traceability of semi-dried tomatoes, and tomatoes and other foods likely to be used in semi-dried tomatoes, in order to facilitate trace back in the event of a future outbreak; or
- 3. include specific regulatory measures in the Code for traceability and processing of semi-dried tomatoes, and tomatoes and other foods likely to be used in semi-dried tomatoes.

FSANZ's preferred approach for consultation was Option 3 as it provided a broader range of measures to protect public health and safety in relation to semi-dried tomatoes.

Twenty-four submissions were received from industry and government. There was limited support for the measures proposed with nine submissions not supporting any of the Options; eight submissions supporting Option 1 (do nothing); two submissions supporting Option 2 and five submissions supporting Option 3. Submitters that supported the measures raised concerns and issues with them, including the definition of semi-dried tomatoes and the scope of the proposed traceability requirements. A number of submitters questioned the need for specific measures at this time and suggested FSANZ consider more general and preventative food safety measures.

The enforceability and practicality of processing requirements were questioned given the lack of adequate validation. A number of submitters expressed the view that contamination with hepatitis A should be prevented with good hygienic practices, rather than inactivated in contaminated food.

A number of submitters considered that traceability requirements should be considered for foods generally rather than on a specific food by food basis. This, it was suggested, would ensure through chain food safety management and avoids market distorting aspects or collateral costs to industry or specific food producers.

There were problems with the definition of semi-dried tomatoes and submitters commented on the lack of an objective differentiation between 'semi-dried tomatoes' and 'sun-dried tomatoes'. This is important because the proposed measures were to apply to the former but not the latter.

A summary of submissions is at Attachment 1.

3.2 National debrief of the hepatitis A and semi-dried tomatoes incident

South Australia Health triggered the National Food Incident Response Protocol (the Protocol)⁶ on 22 May 2009 in responding to the outbreak. The incident was stood down in April 2010.

A formal review is implemented following each incident managed under the Protocol to assess efficiency of process and procedures with the Implementation Sub-Committee (ISC) amending the Protocol, as appropriate. As part of this process, a national debrief of the hepatitis A and semi-dried tomatoes incident was held on 7 July 2010, involving multiple participants from across the jurisdictions.

The issues identified during this incident ranged from a lack of clarity in some procedural aspects of the Protocol to specific problems with traceability and testing methodology. During the incident, investigations were difficult due to the complexity of the supply chain; analytical testing was a challenge and it took some time to confirm a satisfactory testing methodology; and interpretation of the test results was problematic as the accepted test does not confirm viability of the virus.

In discussion with the jurisdictions on the status of Proposal P1012 at the national debrief, alternative Options were proposed and FSANZ developed a paper on the advantages and disadvantages of these Options for jurisdictions' consideration (further information is provided in section 4).

At the August 2010 meeting, ISC considered the recommendations arising from the debrief and agreed to convene the Incident Response Working Group⁷ to consider the range of issues identified and report back at the February 2011 meeting. These considerations will include an evaluation of existing measures in food legislation⁸ to manage future outbreaks and the extent and scope of existing traceability requirements, and potential gaps, in the Code.

4. Alternative Options

Alternative approaches to address the issue of viral contamination of food have been proposed during the public consultation and through the national debrief of the hepatitis A and semi-dried tomatoes incident. These approaches include the introduction of a limit for hepatitis A virus material in the Code; reviewing traceability requirements in the Code and developing a primary production and processing standard for horticulture. An analysis of each Option, including progressing Proposal P1012, is provided below.

⁶ In May 2007, the Australia and New Zealand Food Regulation Ministerial Council (ANZFRMC) endorsed the Protocol developed by FSANZ on behalf of the Implementation Sub-Committee (ISC) to ensure an effective system for the consistent management of national food incidents. The Protocol is available at http://www.health.gov.au/internet/main/publishing.nsf/Content/foodsecretariat-isc.htm

⁷ The ISC Incident Response Working Group, chaired by FSANZ with representatives of the State and Territory agencies and NZFSA, is responsible for the continual improvement of the Protocol.
⁸ These measures have been highlighted in submissions and include the need for businesses to only accept food

⁸ These measures have been highlighted in submissions and include the need for businesses to only accept food that is protected from contamination and to require processing to reduce pathogens to safe levels. In addition, the Code includes generic lot identification requirements and includes requirements for certain food businesses to have a system in place to ensure the recall of unsafe food.

4.1 Option 1 – continue with Proposal P1012

Option 1 involves continuation of Proposal P1012 i.e. the FSANZ Board would approve the draft standard and, within twelve months from the date of effect of the variation, FSANZ must undertake an Assessment of these measures, seek public comment on the Assessment (and the measures) and then re-affirm the measures.

Under this Option, there would be specific regulatory measures in the Code for traceability and processing of semi-dried tomatoes, and tomatoes and other foods likely to be used in semi-dried tomatoes.

4.1.1 Advantages

- A broad range of national measures provided to protect public health and safety.
- The proposed measures are generally consistent with measures implemented through the Order made under the *Food Act 1984* (Victoria).
- The measures are transitional in nature, while more comprehensive traceability requirements and primary production and processing requirements for horticultural products are considered.

4.1.2 Disadvantages

- There is very limited support for the measures from both government and industry with issues raised in regard to the definition of semi-dried tomatoes, scope of the proposed traceability requirements and questioning the need for specific measures at this time. These concerns were reiterated by jurisdictions at the national debrief of the hepatitis A incident held in July 2010.
- The jurisdictions and industry have raised concerns about the enforceability and practicality of the processing requirements given the lack of adequate validation. The CSIRO report *'Semi-dried Tomatoes and Hepatitis A Virus'* stated there are no validated protocols for inactivation of hepatitis A virus in semi-dried tomatoes.
- This Proposal focuses on including specific processing requirements in the Code for semi-dried tomatoes to ensure the destruction of any hepatitis A virus. The majority of submissions advised that preventative measures are considered a more appropriate means of ensuring that hepatitis A virus does not contaminate food. This view was also expressed in the CSIRO report.
- This Proposal includes regulatory requirements for traceability in the Code specifically for semi-dried tomatoes.

A number of submitters considered that traceability requirements should be considered for foods generally rather than on a specific food by food basis. This would ensure through chain food safety management and avoids market distorting aspects or collateral costs to industry or specific food producers.

The following approaches would involve abandoning the draft variation to the Code (and Proposal P1012) and investigating alternative, more strategic approaches for managing hepatitis A in foods.

4.2 Option 2 – review traceability requirements in the Code

At the national hepatitis A incident debrief, jurisdictions noted that there were some existing traceability requirements in the Code and the extent and scope of existing regulatory requirements, and potential gaps, should be examined.

4.2.1 Advantages

- This approach would allow traceability requirements to be considered generally rather than on a specific food by food basis. Based on comments made in submissions, the development of more general traceability requirements is considered appropriate and more practical than developing traceability requirements on a food by food basis.
- Developing general traceability requirements would allow such measures to be considered, developed and implemented consistently with a through chain approach. It would also avoid the need to define specific foods and would also reduce the potential for market distorting aspects.
- Issues regarding implementation of any existing or proposed traceability requirements could be examined by FSANZ and ISC.

4.2.2 Disadvantages

- There is no consensus on the need for, or detail of, traceability requirements. There will need to be significant consultation with government and all industry sectors on the scope of the requirements, including any exemptions and the degree of traceability required.
- Traceability is not a control measure on its own but a tool to improve food safety control. This approach does not consider whether there are appropriate food safety measures that could be applied to particular horticultural commodities or whether current requirements in Chapter 3 of the Code and State and Territory Food Acts are appropriate for managing this risk.

As outlined in section 3.2, this work will progress as the ISC Incident Response Working group will be considering a broad range of issues arising from the hepatitis A debrief, including traceability.

FSANZ would need to prepare a new Proposal if there is to be a variation to the Code.

4.3 Option 3 – include a limit for Hepatitis A virus material in semi-dried tomatoes

This Option would involve an amendment to the Code to include a provision setting a limit for hepatitis A virus material in semi-dried tomatoes. This approach would be contingent on the analytical capability and capacity being developed.

FSANZ has recently been informed that laboratory capability for detecting and measuring hepatitis A virus genomic material in semi-dried tomatoes is available. The University of Melbourne Microbiological Diagnostic Unit has refined the methodology and is working with the aim of establishing the capability to perform this testing in Australia.

Work on hepatitis A virus testing in Australia requires the use of laboratories that not only have the technical capacity, but approval from several government agencies and international accreditation bodies.

Virus detection methods are based on detection of virus genome using molecular techniques such as polymerase chain reaction (PCR).

4.3.1 Advantages

- A specific measure that could be implemented quickly (once the issues above are addressed).
- This measure is likely to have less problems from an implementation perspective than applying specific traceability and processing requirements.

4.3.2 Disadvantages

- It is not clear whether presence of virus genome, as determined by PCR, correlates with a human health risk. The presence of the hepatitis A virus in food does not necessarily mean that the virus is viable as PCR can detect genomic material from inactivated or non-infectious virus.
- If there is a kill step in the production, PCR tests may still detect the RNA.
- As virus detection in food has not been done before, and routine surveillance of food has not been performed, regular testing may reveal that there is low level background presence of hepatitis A virus RNA in the Australian environment and/or food.
- Currently, there are no internationally recognised standard methods for determining hepatitis A in food, and quality assurance measures are generally not well developed.
- Limits are not currently incorporated internationally as an element of regulatory controls because of the limitations mentioned above. However, testing may be a useful tool for producer programs where there is suspicion of virus contamination.

FSANZ would need to prepare a new Proposal if there is to be a variation to the Code.

4.4 Option 4 – address this issue through the development of a primary production and processing standard

This Option is consistent with the view expressed in the majority of submissions that FSANZ consider more general and preventative food safety measures rather than pursue measures for specific foods.

Option 4 is based on measures that prevent hepatitis A contamination more generally (and also considers other hazards) in horticulture, and would also consider traceability requirements for horticultural commodities. This Option does not preclude a separate standard development process to deal with general traceability requirements.

4.4.1 Advantages

- This approach will enable a systematic examination of commodities linked to foodborne illness; understanding intrinsic commodity characteristics and their association with risk; and the impact of market channels and operation size on hazard exposure.
- This work can be done in stages following consultation on a scoping exercise.
- Issues raised during the consultation on Proposal P1012 can be considered under this approach i.e. potential hepatitis A contamination in food should be managed with measures that prevent contamination from occurring, rather than measures that attempt to 'cure' the problem after it has occurred.
- This approach facilitates the application of 'through-chain' preventative measures and traceability to all relevant foods rather than being applied to specific foods.
- Traceability issues can be included within this work.

4.4.2 Disadvantages

• Extended timeframe for standard development process; however there has been preliminary work on the scope and commodities potentially captured within the scope of horticulture. As described above, work can be staged reflecting the relative risk of different commodities.

FSANZ would need to prepare a new Proposal if there is to be a variation to the Code.

At the national debrief of the hepatitis A incident, FSANZ was requested to circulate a paper on these alternative Options through ISC for jurisdictions' consideration. The consensus amongst jurisdictions was to progress Option 4 i.e. address this issue through the development of the Horticulture / Fresh Produce primary production and processing standard. Jurisdictions also supported examining traceability requirements. As discussed in section 3.2, this work will be progressed in the last quarter of 2010 by the ISC Incident Response Working Group.

5. Conclusion and Decision

In regard to Option 1 (continue to progress P1012), based on comment in submissions to Proposal P1012, there is no general consensus on the detail of requirements or the means of addressing the problems. There are divergent views on the businesses to which the measures should apply; the foods to which the measures should apply and the degree of traceability required. There are also implementation and compliance issues associated with the proposed measures and doubt from some submitters as to whether additional measures are needed. In addition, there is a consensus that preventative and general food safety requirements for traceability and horticulture processing need to be considered to protect public health and safety. For these reasons, an urgent Proposal is not considered to be the most suitable mechanism for addressing these complex issues and divergent views.

Option 2 proposes reviewing traceability requirements. The ISC Incident Response Working group will be considering a broad range of issues arising from the hepatitis A debrief, including traceability.

In regard to incorporating a limit for hepatitis A virus material in the Code (Option 3), there are still a number of technical issues with the methodology that limit its application as a regulatory measure.

Option 4 is consistent with the view expressed in the majority of submissions that FSANZ consider more general and preventative food safety measures rather than pursue measures for specific foods. This approach is based on measures that prevent hepatitis A contamination more generally (and also considers other hazards) in horticulture, and would also consider traceability requirements for horticultural commodities. This Option does not preclude a separate standard development process to deal with general traceability requirements. This Option has more advantages than the other approaches.

Based on submissions to P1012, and further consultation with the food authorities, FSANZ is proposing to abandon the draft variation to the Code and proceed with Option 4 as it provides a longer term solution and would consider problems with poor handling and hygienic practices across all fresh produce/horticulture.

Decision

To abandon the draft variations to Standards 1.6.2 and 3.2.2 to include traceability and processing requirements for semi-dried tomatoes and ingredients.

5.1 Reasons for Decision

FSANZ is recommending abandoning the draft variation to the Code (and Proposal P1012) to include traceability and processing requirements for semi-dried tomatoes and ingredients and address this issue through the development of the primary production and processing standard for horticulture as:

- this approach will enable a systematic examination of commodities linked to foodborne illness; understanding intrinsic commodity characteristics and their association with risk; and the impact of market channels and operation size on hazard exposure
- issues raised during the consultation on Proposal P1012 can be considered under this approach i.e. potential hepatitis A contamination in food should be managed with measures that prevent contamination from occurring, rather than measures that attempt to 'cure' the problem after it has occurred
- this approach facilitates the application of 'through-chain' preventative measures and traceability to all relevant foods rather than being applied to specific foods on an outbreak by outbreak basis

5.2 Proposed action

FSANZ will address hepatitis A contamination of semi-dried tomatoes through the development of the Horticulture / Fresh Produce primary production and processing standard. This standard development process will commence in early 2011 and consider the issues raised during the consultation on Proposal P1012. This process will consider problems with poor handling and hygienic practices across all horticulture products. The extended timeframe of the standard development process can be reduced by initially addressing higher risk products.

In the short-term, the ISC Incident Response Working Group will examine the issues identified during the hepatitis A outbreak, particularly existing measures in food legislation to manage future outbreaks and the extent and scope of existing traceability requirements, and potential gaps, in the Code. The working group will report back to ISC at the February 2011 meeting on the outcomes and recommendations.

ATTACHMENT

1. Summary of issues raised in public submissions

Attachment 1

Summary of issues raised in the public submissions

Submitter	Comments
DLA Phillips Fox – representing Ausfresh Pty Ltd, Pronto e Fresco Pty Ltd, Bowen Tomato Co Pty Ltd and Sundown Food Australia Pty Ltd	 Supports Option 1. States that the initial problem was the importation of cheap semi-dried tomatoes from countries which have endemic hepatitis A virus (HAV). Notes that other measures would be more effective than those stated in the Proposal. The proposed standards are ambiguous, unworkable, and should be abandoned. Notes that any proposed traceability provisions should be clarified and amended to accommodate the business practices of the major retail suppliers of semi-dried tomatoes in Australia. That the guidelines in the Codex Alimentarius (general principles of food hygiene to the control of viruses in foods) should be adopted in respect of all foods, and not specifically tomatoes.
Riviana Foods Pty Ltd	 Supports Option 1. Notes that as a producer of shelf stable semi-dried tomatoes they have concerns that the regulations may preclude Australian semi-dried tomato manufacturers from selling IQF semi-dried tomatoes to them as a raw ingredient. Notes HAV is a disease that is usually transmitted via the faecal-oral route. Questions how does this standard seek to address the issue of food service food handlers who have purchased a compliant product but have then contaminated it through poor hygiene practices? Queries if HAV virus ever been detected in raw Australian tomatoes and why they are implicated as the cause? Questions if time/temperatures and/or equivalent processes will be explained in other documentation?
Good Aussie Food Company	 Does not support any of the Options presented. A clear definition is required as to what constitutes a semi dried tomato – confusion is this regard may have clouded the health investigation. Notes semi sun dried tomatoes are field dried and represent a higher risk than semi oven dried tomatoes. Notes it is possible to successful dry tomatoes at the high temperatures of 90/100 degrees C or above, however there is reluctance in the industry due to old generation drying equipment. Notes that mixing of Australian and importer product may have 'muddied the waters' for traceability in the recent outbreak.
Fruitmark	 Does not support any of the Options presented. Notes that semi-dried tomatoes grown in the sun may be a higher contamination/ health risk. Strongly recommends any regulations made disallow semi dried tomatoes being dried by the sun.
Scalzo Food Industries	 Does not support any of the Options presented. Notes that the microbial contamination risk of semi sun dried tomatoes and oven semi dried tomatoes are widely different. With oven dried tomatoes being a lower risk being processed in a closed factory environment under closely regulated hygienic conditions.
Blue Bird Products	 Support Option 1. Notes no clear evidence has linked the HAV outbreak and consumption of semi-dried tomatoes, only speculation and hypothesis – infection may have also been from other fresh produce or food handlers. Notes that the Standard should consider all fresh and dried vegetables and fruits and not specifically semi-dried tomatoes. Notes alternative processing requirements should be included. Notes that a 'paper trail' traceability system would not be possible for larger retailers and may lead to a complete deletion of the food category with massive financial impact on producers, farmers and the local economy.

Submitter	Comments
Palomba Antipasti Pty Ltd	 Supports Option 3 – that manufacturing process and traceability should be automatically part of the FSC and HACCP. Do not agree with pasteurisation but instead tomatoes should be sanitised with 200 ppm chlorine.
Coles Supermarkets Ltd	 Supports Option 1. Notes there are already adequate measures in the Code that require good food safety practices. Questions if the proposal presented is an effective response to the recent outbreaks and the need for regulatory intervention? Notes that end to end traceability would impose unnecessary costs on retailers - which would ultimately be passed on to the consumer. Would only support scientifically validated processing requirements. Would support alternative non- legislative options such as provision of advice to the consumer.
Woolworths Limited	 Supports none of the Options / Option 1. Has no comments regarding the proposed processing requirements. They have significant concerns with regards to the traceability requirements noting that they will impose extensive record keeping requirements on retailers. They believe retailers should be exempted from the traceability requirements. If traceability requirements remain, expects that they would be forced to withdraw the majority of semi-dried tomato products that it currently stocks across its full supermarket network. Due to cost, time and operational difficulty. This would cause significant commercial detriment to semi-dried tomato producers in Australia and a loss of choice and range for consumers. Notes that they are broadly supportive of there being appropriate product traceability arrangements in general and that current procedures are in place to protect public health and safety. Under the WQA Std, suppliers of semi-dried tomatoes are already required to have in place appropriate procedures to ensure that all material used in, or produced by, their production processes is clearly identified and traceable. Notes that all suppliers to Woolworths are to be certified to the Woolworths Quality Assurance (WQA) Standard (including 3rd party auditing on a 6 monthly basis).
National Assoc of Retail Grocers of Australia	 Supports Option 1. Notes the source of contamination was not confirmed and that HAV infection can occur across a wide range of produce types – being most often associated with poor hygiene. Notes that regulation of local product is unnecessary. Recommends a more comprehensive approach with an emphasis on good agricultural and manufacturing practice and checks on imported sources of semi-dried tomatoes and ingredients.
Silliker Australia Pty Ltd	 Supports Option 3. Considers the most likely causal event that resulted in HAV infections may be post processing handling. Notes that risk associated with post processing contamination with HAV is not covered in the processing requirements proposed. Notes that guidance is needed for the definition of 'destroy'. Notes that the current drying practices utilised by Australian manufactures would likely 'destroy' HAV if present (based on interpretation of data obtained from other studies reported in the CSIRO report). Notes that food manufactures that produce product for immediate consumption should not be exempt from traceability requirements. Not appropriate that proposed traceability measures do not require a business to identify the specific batch of food that was used in each batch of semi-dried tomatoes.

Submitter	Comments
Food Technology Association of Australia	 Supports Option 2 – 'reluctantly' - noted several issues that must be considered. Queries why other fresh, dried and otherwise processed fruits and vegetables were not included in the proposal - which may potentially have the same risk. Notes semi-dried tomatoes are not the only possible potential substrate for the HAV virus. Other non-heat treated products that are collected and processed by hand would also be susceptible to potential contamination and hence should be included in a similar Proposal and not ignored until a problem arises. The cause of the outbreak is as yet inconclusive; however human contamination of semi-dried tomatoes is a likely cause. Queries why semi-sun dried tomatoes seem to be excluded – exclusion of 'tomatoes which have only been dried by the sun' may lead to confusion. CSIRO report does not specifically recommend heat treatment as a preventative method for HAV contamination. The suggested requirements do not include specific parameters, such as time, temperature and a subsequent cooling regime. Post processing contamination has not been considered. The option 3 would impose an unacceptable burden on industry. The option of regulating full traceability of all ingredients in all food manufacturing should be contemplated - as in the case of a recall, with traceability being an invaluable tool. Suggests FSANZ should re-examine the current Food Safety Standards which address Good Manufacturing Practices and traceability as a whole.
University of Melbourne, MDU	 Does not clearly support any of the Options presented. Definition of 'destroy' and 'lethal effect' needs to be tightened. Showing equivalence of processing would require testing and detection of HAV virus this could be problematic as there is limited routinely available testing which distinguishes viable virus from non-viable virus. Other food vehicles which may have been involved in the recent outbreak have not been addressed in the proposal (e.g. berries) The definition of semi-dried tomatoes and sun-dried tomato is likely to be problematic. An objective measure such as water activity should be specified. To distinguish between semi-dried tomatoes and dressed product, the term 'processed semi-dried tomatoes' could be used. Notes the requirements for traceability should include food businesses – notes public health risk is not reduced at the caterer. The traceability measures should require a business to identify the specific batch of food/ingredient used in each batch of semi-dried tomatoes.
Food and Beverage Importers Association (FBIA)	 Supports Option 1. Questions the reasons for developing an urgent proposal – no specific evidence to support the urgent development of a national standard. Notes that there has been no review of the Victorian measures and their effectiveness is unknown. Notes all foods must be safe for consumption and Good Agricultural and Manufacturing Practices should be followed. The CSIRO report highlighted a number of knowledge gaps and made recommendations for research. Suggests the alternative of an industry code of practice. Concerned with the definition of semi-dried tomatoes and suggests that a moisture content criterion should be included (e.g. semi dried > 25% moisture content). Does not see the relevance in exempting sun dried tomatoes purely due to the method of drying. The looseness of the definitions raises concerns about whether the standard would be enforceable. Notes that the proposed regulatory measures do not include an exemption for businesses that prepare or serve semi-dried tomatoes for sale to a member of the public for immediate consumption – questions if this is practical? Suggests the issue is best dealt with by the development of a Primary Production and Processing Standard under chapter 4. Disagrees with the need to introduce urgent traceability provisions for semi-dried tomatoes nationally.

Submitter	Comments
	 Notes that packaged pasteurised semi-dried tomatoes would also be affected by traceability requirements and this is not consistent with the VIC order. There is no evidence of risk for this product. Suggests that there would be considerable merit in assessing whether a broad standard for traceability requirements should be including under Chapter 3.
Australian Food and Grocery Council	 Rejects all the Options proposed. However accepts there is a need to do something and that the status quo is unacceptable. Notes the Options presented do not represent good regulatory practice or effective risk management, and the justification for the urgency of the action is highly questionable. Doubts there is sound evidence of the current and ongoing need to specifically manage this outbreak with urgent measures. Notes other commodities have been associated with HAV and that an infected food handler is often the source of contamination. Notes FSANZ should only pursue processing requirements consistent with chapter 4 of the FSC and that a separate proposal should be raised to introduce a general standard for the traceability of all foods and ingredients. Notes there would be unfavourable consequences of implementing a ad-hoc approach to food traceability requirements and notes it would be more effective to implement a national approach through consistent generic regulation across all risk categories, for suppliers, manufactures and retailers. Suggests a better way forward would be the development of Primary Production and Processing Standard for Semi-dried and dried tomatoes, while the requirements for traceability are considered as a general standard applicable to all ingredients and foods.
New Zealand Food Safety Authority (NZFSA)	 Does not clearly support any of the Options presented. Notes that the CSIRO report highlights the lack of available methods for HAV detection in foods. Notes that NZFSA will be undertaking work to progress a systematic methods development and validation programme for priority food-borne viruses, including HAV. Questions whether the proposed processing requirement can be implemented, given the lack of methodology for HAV detection in foods and the absence of a validated time-temperature combination for pasteurisation/heat treatment. Considers the processing requirements to be a reactionary response to a problem associated with poor handling and hygienic practices. Promotion of Good Hygienic Practices would be a better alternative. Suggests consistency of terms be considered (e.g.' pasteurised' and 'treated'; 'destroy', 'inactivated' and/or 'eliminated/removed') Notes the definition of partial and semi-dried tomatoes could be expanded, by including parameters such as water activity. If sun dried tomatoes are excluded, evidence should be provided to show that sundried tomatoes are not susceptible to HAV contamination. Notes that instead of requiring that records be kept in writing, records could also be kept electronically. Suggests that Good Hygienic Practices and traceability requirements should apply to all foods. Proposes that Good Hygienic Practices and traceability requirements and exporters who ship much of the fresh produce imported into Australia and would represent a barrier to trade.
Victorian Department of Health	 Supports Option 3. Notes it is desirable to adopt a national standard to prevent further outbreaks for the protection of public health and safety. Notes non-regulatory measure such as a code of practice would not be effective in this industry due to the breadth and complexity of the supply chain. Notes it is important that the Standard does not contain a transition period. Acknowledges that if a Standard is approved a cost benefit analysis would be completed within 12 months of gazettal.

Submitter	Comments
	 Acknowledges that product specific requirement in the FSC is the exception rather than the rule however the permanence of this would be assessed as part of the ongoing assessment process. Notes the current level of immunity for HAV in the Australian community is low. Notes it is appropriate to exclude fully sun dried tomatoes from the Standard as there was no reason to suggest they were involved in the outbreak. Notes semi-dried tomatoes may be partially dried in the sun and it is recommend the exclusion for products dried in the sun is removed. Notes processing requirement should be altered to not place the onus on prosecution/enforcement agencies of proving an alternative process was sufficient to destroy HAV. Businesses should not be given the option of adopting alternative methods over the first 12 months unless they are validated by an independent body or sound scientific research. Suggests that a chlorination processing requirement could be included. The traceability clause should require businesses that process semi-dried tomatoes to keep records that identify the batches of ingredients used in each batch of semi-dried tomatoes produced. Packaged pasteurised product should be excluded from the traceability requirements. Agrees the start date of the standard should be the date of gazettal with other states dealing with implementation issues via a protocol around the timing of commencement of enforcement in their state.
Tasmanian Department of Health & Human Services	 Supports Option 3. Agrees that national measures are necessary to ensure that the manufacture of semi- dried tomatoes better address the public health risk associated with HAV contamination. Agrees that traceability measures are an appropriate interim measure in order to facilitate any further outbreak responses. Notes that a later review of processing requirements should include alternatives such as through-chain accreditation systems that promote GAP and GMP. The processing requirement of treatments of tomatoes to destroy HAV virus will be difficult to enforce due to lack of laboratory capability in Australia, and lack of published knowledge on the survival of HAV in semi-dried tomatoes and tomatoes. As there is no validated protocol for inactivation of HAV - a more prescriptive approach may be necessary to provide industry with an indication of what is required. Support that traceability requirements are currently required however they recommend this is removed as soon as processing controls become reliable in delivering a safe product. The definition of semi-dried tomatoes may be produced by rehydrating sun-dried tomatoes and these should not be excluded even if they were dried by the sun. Suggests Clause 9(3) should be modified to state 'Semi-dried tomatoes may contain foods other than tomatoes including herbs, spices and oil'. Notes that it is not clear if there is a need for an exemption for traceability requirement for businesses that prepare or serve semi-dried tomatoes for sale to a member of the public for immediate consumption.
Department of Health WA	 Supports Option 2. Due to the brief consultation period they were unable to determine the effect of the proposal on the WA tomato industry and on WA Department of Health. Notes the definition of semi dried tomatoes as currently suggested is difficult and should ideally include semi dried, semi sun dried, sun semi dried and sun dried. Notes the reason given in the proposal for requiring traceability is to enable an effective response in future outbreaks – standards should be set as a minimum outcome based requirement for a food business to ensure the safety of food, not as a tool to facilitate an investigation by a regulator. Traceability is supported on the basis that all food manufacturing businesses should maintain appropriate traceability records of inputs through to outputs. Insufficient evidence has been demonstrated as to the source and cause of the recent outbreak – the risk assessment is considered inadequate, the probability of infection occurring has not been addressed.

Submitter	Comments
	 There are current adequate requirements in place to ensure the safety of semi dried tomatoes without the need for specific processing requirements. Proposed processing requirement are not consistent with other commodities in the code. There is no information on the organoleptic or nutritional effects of heat treatment on semi-dried tomatoes. There is no validated minimum processing method that will inactivate HAV. There is no transitional period proposed – time would be needed for equipment to be obtained and processes developed. The public perception and limiting damage to the tomato industry in general needs to be considered.
New South Wales Food Authority	 Does not support any of the Options currently presented. Food is not a common route of transmission of HAV with humans being the primary host for the virus which is normally spread by the faecal-oral route. For food to become infective it must have come in contact with faeces from an infected person or via an infected food handler. HAV contamination of semi-dried tomatoes specifically does not appear to be an industry wide problem – this does not support the development of an emergency standard. The CSIRO report notes that there is no straight forward means for eliminating HAV virus on fresh produce. The initial consideration report does not sufficiently consider exposure assessment or risk characterisation, potential exposure may be minimal and the evidence does not support the development of an emergency standard. Would prefer to see some discussion on the potential for extending the scope of the Primary Production and Processing Standards for plant products to include high risk vegetables (such as semi-dried tomatoes). Feels it is impracticable to expect business to immediately comply with the new regulations without exhaustive guidance material being developed for businesses. Questions why heat treatment is preferred over chlorine wash when the data presented by the CSIRO paper indicated pasteurisation has a variable effect whereas chlorine appears to be more effective. Notes that requiring traceability requirements for the defined 'relevant foods' in addition to tomatoes (including herbs, spices and oil) would be too broad and problematic. This would lead to onerous burden to a large number of primary producers and wholesalers. Additionally these industries would not have enough time to implement systems. It was suggested that only manufacturers' processors of semi-dried tomatoes should be required to substantiate the source of their product and ingredients. Traceability require
Department of Health South Australia	 While supporting the intent of Option 3 a number of issues have been highlighted. Noted the measures are transitional in nature and in the future more comprehensive traceability and primary production and processing requirements for horticultural products should be implemented. It is recommended that the definition of semi dried tomatoes be made more specific by including parameters for water activity or percentage moisture. Have concerns regarding the ability of regulatory agencies to enforce and the industry's ability to comply with the processing requirements specified. Guidance material for enforcement agencies and industry around acceptable time and temperature parameters to destroy the hepatitis A virus should be developed to aid implementation. Record keeping requirements are supported for processors of semi-dried tomatoes but not for businesses that prepare or serve semi-dried tomatoes for sale to a member of the public for immediate consumption.

Submitter	Comments
	 Notes traceability requirements are necessary to assist investigations in the event of a future outbreak – but should be limited to semi-dried tomatoes and tomatoes intended to be used for semi-dried tomatoes (not other ingredients). The scope of businesses proposed to be subject to traceability requirements is too broad. Traceability requirements for businesses that receive semi-dried tomatoes should be limited to 'food businesses engaged in the wholesale supply, manufacture or importation' of the relevant food – being consistent with Standard 3.2.2. Exemption from traceability requirements should be given for semi-dried tomatoes that are packaged and fully labelled in a form for the final consumer, such as jars of semi-dried tomatoes.
Whitsunday Regional Council	 Supports Option 3. Notes information provided on processing is not specific making it hard for local governments to enforce and ensure compliance. Alternatives to pasteurisation have not been considered (e.g. chlorine wash). It is understood testing for HAV is difficult – how will businesses and regulatory agencies be able to monitor this?. It is suggested that testing capabilities be improved. A section in the Code should outline frequency and testing requirement of tomatoes including microbiological testing. Food Safety Programs for manufacturers was suggested.
Department of Agriculture, Fisheries and Forestry	 Supports the development of a Standard to protect public health and safety but has a number of queries and concerns. Queries why sun-dried tomatoes are excluded? Queries if there is sufficient evidence on the inactivation of HAV in semi- dried tomatoes to meet the proposed processing requirements? – more specific guidance would need to be provided by FSANZ. Queries why FSANZ has not considered validation of measures and/or verifications of processing requirements? Issues with terminology of 'destroy' as opposed to 'inactivate'. Queries whether it is reasonable to expect a tomato supplier to know definitely if their product is likely to be used in semi-dried tomatoes. Notes trace back may not be effective as there is no requirement to link input with output. Traceability requirements should ideally be consistent with Codex and what is currently prescribed in Chapter 4 standards (one step forward, one step back).
QLD Health	 Supports Option 1. Insufficient evidence has been provided on the source of contamination for this outbreak, the mechanism of contamination, whether local or importer tomatoes or other ingredients were implicated – more investigation is needed. Insufficient evidence on identification and consideration of alternative non regulatory measures – the proposal has failed to examine other options (e.g. industry code of practices, QA measures etc). Opposed to an ad hoc reactionary approach to developing Standard in response to a food borne illness outbreak – inconsistent with previous outbreaks. Notes it is unclear why sun dried and fresh tomatoes are excluded. Advised that the proposed measures have the potential to seriously adversely affect the Qld semi-dried tomato industry. Uncertain whether the proposed pasteurisation requirements could be adequately monitored for imported product – could greatly disadvantage the Australian semi-dried tomato industry. Insufficient guidance has been provided as to time-temp requirements to deactivate HAV. Testing is difficult, making it hard for industry to validate. Other measures which may be equally as effective as pasteurisation have not been considered. Regulators and auditors will not be able to effectively monitor or enforce these pasteurisation requirements. Current traceability requirements in the Code and in the 'FSANZ Recall protocol' contain guidance for keeping records and aligning with the principles of good manufacturing practices. Consideration should be given to facilitate greater awareness and enforcement of current requirements for health and hygiene of food handlers (Standard 3.2.2) and for provision of hygienic equipment (Standard 3.2.3).

Submitter	Comments
	 As per the findings in the CSIRO report, good agricultural practices and good hygienic practices throughout the food chain would be most effective and it appears that a horticultural Primary Production and processing Standard would be an effective means of preventing contamination. Consider a time limit (sunset clause) for the traceability requirements. AQIS should be engaged to ensure appropriate border surveillance for imported semi-dried tomatoes.