



21 January 2010
[2-10]

PROPOSAL P1012 SEMI-DRIED TOMATOES & INGREDIENTS – TRACEABILITY & PROCESSING INITIAL CONSIDERATION REPORT

Executive Summary

The purpose of this Proposal is to consider varying the *Australia New Zealand Food Standards Code* (the Code) to include traceability and processing requirements for semi-dried tomatoes, and tomatoes and other food likely to be used in semi-dried tomatoes (Attachment 1). These national measures are proposed to ensure that sufficient records are available to respond effectively in any future outbreak, and that any hepatitis A virus is destroyed in semi-dried tomatoes or tomatoes used in semi-dried tomatoes. An explanatory statement about the proposed measures is provided (Attachment 2). As food safety requirements are outside the scope of the arrangements between Australia and New Zealand for a joint Code,¹ it is proposed that the variations not apply in New Zealand.

This issue has arisen because the measures that were put in place in Victoria in response to outbreaks of locally-acquired hepatitis A are about to expire.² The Department of Health in Victoria has advised FSANZ that regulatory measures are necessary to manage the risks associated with semi-dried tomatoes and have requested that such measures be developed as an urgent consideration. The proposed measures are generally consistent with measures in place in Victoria. Food Standards Australia New Zealand (FSANZ) has decided, pursuant to section 95 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act), to declare this Proposal urgent because it is appropriate to do so in order to protect public health and safety. FSANZ has determined that there are three viable options available for this Proposal:

- Option 1 do nothing; or
- Option 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

¹ New Zealand develops its own food standards for residues of agricultural and veterinary chemicals, food safety and primary production and processing.

² <http://www.health.vic.gov.au/foodsafety/tomatoes.htm>

Option 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. This would be generally consistent with the measures in place in Victoria. These measures would facilitate trace back in the event of a future outbreak and ensure processing to destroy any hepatitis A virus in semi-dried tomatoes or tomatoes used in semi-dried tomatoes.

Given the need to protect public health and safety, FSANZ is of the view that Option 1 (i.e. do nothing) is not acceptable. Option 2 provides a mechanism for responding and identifying affected product but does not ensure that any hepatitis A virus is destroyed in semi-dried tomatoes or tomatoes used in semi-dried tomatoes. On this basis and for the purposes of public consultation, FSANZ prefers Option 3 because it provides a broad range of national measures to protect public health and safety. Given the imminent expiration of measures currently in place in Victoria, no transition period for the proposed regulatory measures is proposed.

Preferred Approach

To protect public health and safety by varying Standard 1.6.2 and Standard 3.2.2 to include traceability and processing requirements for semi-dried tomatoes and ingredients.

Reasons for Preferred Approach

- to protect public health and safety, as measures currently in place in Victoria will expire on 9 February 2010
- the proposed measures are considered to be a proportionate response as they are focussed on semi-dried tomatoes and foods likely to be used in semi-dried tomatoes
- in the view of FSANZ, the proposed measures are generally consistent with measures in place in Victoria (See Attachment 2)
- the proposed measures will deliver the greatest net benefit to the community in that they will deliver benefits in preventing or mitigating serious illness, although it is recognised that these measures will have costs for the community, particularly industry
- outcome based measures are proposed to ensure that regulation remains relevant and effective over time, and to promote industry innovation in processing techniques.
- the measures are based on the best available scientific evidence and, in the case of the proposed traceability requirements, are consistent with international practice and current primary production and processing standards
- the measures apply throughout Australia to imported product and domestic product, and ensure safe and suitable food is provided to consumers
- the measures are transitional in nature, while more comprehensive traceability requirements and primary production and processing requirements for horticultural products are considered.

FSANZ is seeking public comment in order to assist in considering this Proposal, including:

- any information relevant to the Proposal
- parties that might be affected by having the proposed regulatory measures approved or rejected
- potential costs and benefits of affected parties, including costs associated with proposed traceability and processing requirements, and no transition period
- the need for prescriptive elements in the proposed traceability requirements
- the need for specific processing requirements in the Code, given existing practices that may be in place.

Consultation

Under section 95 of the FSANZ Act, FSANZ has declared this Proposal as urgent and will now conduct six business days of public consultation.³

Invitation for Submissions

FSANZ invites public comment on this Report and the draft variations to the Code based on regulation impact principles for the purpose of preparing an **urgent** amendment to the Code for approval by the FSANZ Board.

Written submissions are invited from interested individuals and organisations to assist FSANZ in further considering this Proposal. Submissions should, where possible, address the objectives of FSANZ as set out in section 18 of the FSANZ Act. Information providing details of potential costs and benefits of the proposed change to the Code from stakeholders is highly desirable. Claims made in submissions should be supported wherever possible by referencing or including relevant studies, research findings, trials, surveys etc. Technical information should be in sufficient detail to allow independent scientific assessment.

The processes of FSANZ are open to public scrutiny, and any submissions received will ordinarily be placed on the public register of FSANZ and made available for inspection. If you wish any information contained in a submission to remain confidential to FSANZ, you should clearly identify the sensitive information, separate it from your submission and provide justification for treating it as confidential commercial material. Section 114 of the FSANZ Act requires FSANZ to treat in-confidence, trade secrets relating to food and any other information relating to food, the commercial value of which would be, or could reasonably be expected to be, destroyed or diminished by disclosure.

Submissions must be made in writing and should clearly be marked with the word 'Submission' and quote the correct project number and name. While FSANZ accepts submissions in hard copy to our offices, it is more convenient and quicker to receive submissions electronically through the FSANZ website using the Changing the Code tab and then through Documents for Public Comment. Alternatively, you may email your submission directly to the Standards Management Officer at submissions@foodstandards.gov.au. There is no need to send a hard copy of your submission if you have submitted it by email or the FSANZ website. FSANZ endeavours to formally acknowledge receipt of submissions within 3 business days.

DEADLINE FOR PUBLIC SUBMISSIONS: 6pm (Canberra time) 1 February 2010

SUBMISSIONS RECEIVED AFTER THIS DEADLINE WILL NOT BE CONSIDERED

³ As January 25 and January 26 are public holidays, they are not considered business days in Australia and Wellington (NZ).

Submissions received after this date will only be considered if agreement for an extension has been given prior to this closing date. Agreement to an extension of time will only be given if extraordinary circumstances warrant an extension to the submission period. Any agreed extension will be notified on the FSANZ website and will apply to all submitters.

Questions relating to making submissions or the application process can be directed to the Standards Management Officer at standards.management@foodstandards.gov.au.

If you are unable to submit your submission electronically, hard copy submissions may be sent to one of the following addresses:

Food Standards Australia New Zealand
PO Box 7186
Canberra BC ACT 2610
AUSTRALIA
Tel (02) 6271 2222

Food Standards Australia New Zealand
PO Box 10559
The Terrace WELLINGTON 6036
NEW ZEALAND
Tel (04) 978 5636

CONTENTS

INTRODUCTION	2
1. THE ISSUE	2
2. CURRENT STANDARD	2
3. OBJECTIVES	2
4. RISK ASSESSMENT SUMMARY	3
5. OPTIONS	3
6. IMPACT ANALYSIS	4
6.1 <i>Affected Parties</i>	4
6.2 <i>Benefit/Cost Analysis</i>	5
6.3 <i>Comparison of Options</i>	6
COMMUNICATION AND CONSULTATION STRATEGY	6
7. COMMUNICATION	6
8. CONSULTATION.....	7
8.1 <i>World Trade Organization (WTO)</i>	7
CONCLUSION.....	8
9. CONCLUSION AND PREFERRED OPTION	8
9.1 <i>Reasons for Preferred Approach</i>	8
9.2 <i>Transitional Arrangements</i>	8
10. IMPLEMENTATION AND REVIEW	9
ATTACHMENT 1 - DRAFT VARIATIONS TO THE <i>AUSTRALIA NEW ZEALAND FOOD STANDARDS</i> <i>CODE</i>	10
ATTACHMENT 2 - EXPLANATORY STATEMENT OF VARIATIONS TO STANDARD 1.6.2 AND STANDARD 3.2.2 IN PROPOSAL P1012	13

SUPPORTING DOCUMENTS

The following supporting document is available on the FSANZ website at
<http://www.foodstandards.gov.au/foodstandards/proposals/> (then go to P1012)

SD1 *Semi dried tomatoes and hepatitis A virus*

Introduction

There were two outbreaks of locally-acquired hepatitis A in Australia in 2009, for which the most likely explanation was the consumption of semi-dried tomatoes. Most cases occurred in Victoria and short term measures were put in place in Victoria to prevent or reduce the possibility of a serious danger to public health and to mitigate the adverse consequences of a serious danger to public health. These measures were included in an Order under Part VII of the Food Act 1984 – Semi-dried Tomatoes made by the Chief Health Officer for the State of Victoria (the Order).⁴ In general terms, the Order applies traceability and processing requirements in relation to semi-dried tomatoes and other foods likely to be used in semi-dried tomatoes. The Order ceases to have effect after 9 February 2010.

The Department of Health, Victoria has advised FSANZ that regulatory measures are necessary to manage the risks associated with semi-dried tomatoes and have requested that such measures be developed as an urgent consideration. The Department of Health, Victoria has also 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.

1. The Issue

Poor hygienic practices have resulted in hepatitis A outbreaks and illness. Insufficient records in certain food businesses prevented timely corrective action to identify and isolate potentially affected product. When the Order in Victoria expires on 9 February 2010, there will be no specific traceability or processing requirements in place nationally to reduce the potential for a future outbreak or to respond in the event of a future outbreak associated with semi-dried tomatoes.

2. Current Standard

There are existing measures in the Code that relate to food safety practices and for food premises and equipment.⁵ While the existing measures require appropriate hygienic practices to prevent contamination with viruses they do not include specific processing requirements for hepatitis A virus. In addition, whilst there are provisions⁶ for food businesses to have a food recall system, the existing measures do not include full traceability requirements. Measures are therefore proposed, as an urgent consideration, to protect public health and safety.

3. 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.

⁴ <http://www.health.vic.gov.au/foodsafety/tomatoes.htm>

⁵ Standard 3.2.2 – Food Safety Practices and General Requirements, and Standard 3.2.3 – Food Premises and Equipment.

⁶ Standard 3.2.2 – Food Safety Practices and General Requirements.

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;
- 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.

4. Risk Assessment Summary

Hepatitis A is a contagious liver disease that results from infection with the hepatitis A virus. Symptoms of hepatitis A include abdominal pain, nausea, fever, chills and jaundice. It can range in severity from a mild illness lasting a few weeks to a severe illness with symptoms persisting for several months. Most people infected with hepatitis A recover completely without treatment. In rare cases hepatitis A infection can result in liver failure and death. Hepatitis A is spread when traces of faecal matter containing the virus contaminates hands, objects, water or food and is then taken in by mouth. Further information about the virus and how it can be transmitted is provided in the supporting documentation.

5. Options

FSANZ has determined that there are three viable regulatory options available for this Proposal. In determining viable options, food safety requirements are outside the scope of the arrangements between Australia and New Zealand for a joint Code⁷, and therefore the proposed options would not apply in New Zealand.

5.1 Option 1 – Do nothing

Under this option, no changes to the Code would occur, although this would not prevent a further Order being remade in Victoria.

5.2 Option 2 – Traceability Only

Under this option, specific regulatory measures for traceability only would be included in the Code for semi-dried tomatoes, and tomatoes and other foods likely to be used in semi-dried tomatoes. This would facilitate trace back in the event of a future outbreak.

5.3 Option 3 – Traceability and Processing Requirements

Under this option, specific regulatory measures for traceability and processing would be included in the Code for semi-dried tomatoes, and tomatoes and other foods likely to be used in semi-dried tomatoes. This Option would be generally consistent with measures in place in Victoria.

⁷ Under the Trans-Tasman Mutual Recognition Arrangement and the *Agreement between the Government of Australia and the Government of New Zealand concerning a Joint Food Standards System* (the Treaty), New Zealand develops its own food standards for residues of agricultural and veterinary chemicals, food safety and primary production and processing.

These measures would facilitate trace back in the event of a future outbreak and ensure processing to destroy any hepatitis A virus in semi-dried tomatoes or tomatoes used in semi-dried tomatoes.

5.4 Other Options Considered

In determining the options above, FSANZ also considered the following options but determined that they were not viable for the reasons provided, and they have not been assessed further:

- *Ongoing advice to consumer to thoroughly cook semi-dried tomatoes.* While advice to consumers is regarded as a useful short-term measure for mitigating impacts during an incident, it is not viable as a preventative measure to protect public health and safety. Furthermore, this option may be viewed as imposing an unreasonable expectation on consumers (to cook product) which is a ready-to-eat product and should not contain any hepatitis A virus if appropriate practices are being observed. Such general advice may also reduce consumer confidence with those producers that are producing product with appropriate hygienic practices.
- *Labelling measures to thoroughly cook semi-dried tomatoes.* This type of measure could mitigate risks for consumers where this information is practical. However, it is not suitable in a situation where good hygienic practices should be preventing the problem from occurring. Similarly, producers should not have to label products with specific directions for use where these would be unnecessary if appropriate hygienic practices are used.
- *Limits or prohibitions on hepatitis A virus.* Based on information provided to FSANZ, current testing capability is insufficient to support the introduction of specific limits or prohibitions.
- *Codes of Practice.* The success of such an approach needs strong industry wide commitment and evidence that voluntary participation can be effective in preventing food-borne illness. However, given the public health and safety concern, this option is not considered viable at this time.

6. Impact Analysis

FSANZ is required to consider the impact of various regulatory (and non-regulatory) options on all sectors of the community, which includes consumers, food industry and governments in Australia and New Zealand. The benefits and costs associated with proposed variations to the Code will be analysed using regulatory impact principles.

6.1 Affected Parties

1. those sectors of the food industry producing semi-dried tomatoes or ingredients likely to be used in semi-dried tomatoes, including importers and producers in regional and rural areas
2. consumers of semi-dried tomatoes
3. Government agencies, including those agencies responsible for responding to food recalls, food incidents and the investigation of food-borne illness.

6.2 Benefit/Cost Analysis

6.2.1 Option 1 – Do Nothing

6.2.1.1 Costs

Assuming that industry has not put measures in place since the outbreaks, if a further outbreak occurred, there may be a reduced capacity to respond and mitigate the adverse public health consequences and reputation damage to the industry. If traceability were not in place, specific costs would include the need to withdraw all product during an outbreak (rather than specific batches) and an inability to identify the source which would mean that future outbreaks could not be prevented. If there were no specific processing requirements for semi-dried tomatoes or tomatoes used in semi-dried tomatoes, the potential for hepatitis A contamination may be higher.

6.2.1.2 Benefits

In theory and assuming the Order in Victoria is not remade, industry could provide product without the need to specifically process it or ensure that sufficient written records are available, with commensurate cost savings.

6.2.2 Option 2 – Traceability Only

6.2.2.1 Costs

Maintaining sufficient records will require the development or maintenance of administrative processes to ensure these records are available. These costs have already been incurred in Victoria but would continue to apply after the Order expires, if the proposed regulatory measures were included in the Code. In some cases, these additional costs would be incurred by suppliers of foods for use in semi-dried tomatoes, even though this may only represent a small proportion of their total sales. In other jurisdictions, these arrangements may need to be developed with commensurate costs. Horticultural producers may incur average annual ongoing costs of \$AUD3000⁸ per business for record keeping in current prices. These costs may be passed on to consumers.

6.2.2.2 Benefits

While not preventing a future incident, this Option would ensure that an effective response could be implemented in the event of a future incident and facilitate containment of potentially affected product to mitigate adverse consequences for public health. This option would allow food regulatory agencies to identify and instigate corrective action in relation to those businesses that may be supplying contaminated product. It would also minimise impacts on those businesses that are currently preventing contamination by following good hygienic practices and would be consistent with international standards/practices in relation to traceability. The annual costs of food-borne hepatitis A in Australia are estimated at \$AUD 3.5 million⁹ in current prices.

⁸Based on \$AUD2640 in 2004 as per NSWFA Plant Products Food Safety Scheme Regulation, 2004

⁹Based on annual costs of food-borne illness in Australia (2006).

<http://www.health.gov.au/internet/ozfoodnet/publishing.nsf/Content/annual-cost-foodborne-illness.htm~annual-cost-foodborne-illness-06.htm~annual-cost-foodborne-illness-06.6.htm>

FSANZ invites comment on the need for traceability requirements, including the need for prescriptive elements for traceability (see the draft variations at Attachment 1). FSANZ seeks specific comment on the costs and benefits of the proposed traceability requirements, including that no transition period is proposed for these measures.

6.2.3 Option 3 – Traceability and Processing Requirements

6.2.3.1 Costs

This option would impose additional processing costs on those businesses that are currently preventing contamination by following good hygienic practices and in some cases may render product unviable. These costs have already been incurred in Victoria but would continue to apply after the Order expires, if the proposed measures were included in the Code. In other jurisdictions, these arrangements may need to be developed with commensurate costs, including developing and verifying parameters for destroying hepatitis A virus throughout the supply chain. As outlined in Option 2, average annual ongoing costs per business for record keeping is estimated at \$AUD3000. These costs may be passed on to consumers.

6.2.3.2 Benefits

In addition to the benefits in Option 2, this option would ensure more comprehensive protection of public health and safety and would be generally consistent with those measures that currently apply to businesses providing product in or to Victoria. As outlined in Option 2, the annual costs of food-borne hepatitis A in Australia are estimated at \$AUD 3.5 million¹⁰ in current prices.

FSANZ invites comment on the need for specific processing requirements, given other measures that apply. FSANZ also seeks specific details on the costs associated with the proposed processing requirements, including that no transition period for these measures is proposed.

6.3 Comparison of Options

Given the need to protect public health and safety, FSANZ is of the view that Option 1 (i.e. do nothing) is not acceptable. FSANZ considers that Option 2 provides a mechanism for responding and identifying affected product, and assists in preventing recurrence; although it does not ensure that hepatitis A virus is destroyed in semi-dried tomatoes or tomatoes used in semi-dried tomatoes. FSANZ prefers Option 3 because it provides a broader range of measures to protect public health and safety in relation to semi-dried tomatoes.

FSANZ invites comment on the comparison of options.

Communication and Consultation Strategy

7. Communication

Hepatitis A is a serious illness and FSANZ considers that public health and safety should be protected. Any interested party can comment on the proposed measures during the submission period.

¹⁰ Based on annual costs of food-borne illness in Australia (2006).
<http://www.health.gov.au/internet/ozfoodnet/publishing.nsf/Content/annual-cost-foodborne-illness.htm~annual-cost-foodborne-illness-06.htm~annual-cost-foodborne-illness-06.6.htm>

Given the short submission period, key stakeholders will be contacted to ensure they are aware of the opportunity to comment on the Proposal.

8. Consultation

FSANZ is seeking public comment in order to assist in considering this Proposal, including:

- any information relevant to the Proposal
- parties that might be affected having this Proposal approved or rejected
- potential costs and benefits to the identified affected parties.

Under section 95 of the FSANZ Act, FSANZ has declared this Proposal as urgent and will now conduct six business days of consultation with stakeholders. January 25¹¹ and January 26¹² are public holidays and therefore not business days under Section 4 of the FSANZ Act.

Under the urgency provisions of the FSANZ Act, the key basis for exercising these powers is to protect public health and safety. If approved, FSANZ must within 12 months of gazettal, undertake further consultation and assessment of this decision and any variation to the Code.

FSANZ acknowledges that this Proposal will be of interest to a broad range of stakeholders and has applied a general communication strategy to this Proposal. This will involve notifying the availability of the Assessment Report for public comment to an extensive database of interested parties and making the reports available on the FSANZ website for public access. FSANZ will also consult key stakeholders through targeted consultation mechanisms.

In addition, individuals and organisations that make submissions on this Proposal will be notified at each stage of the assessment of the Proposal. If the FSANZ Board approves the draft variation to the Code, FSANZ will notify the Ministerial Council of its decision. Stakeholders, including the public, will be notified of the gazettal of changes to the Code in the national press and on the FSANZ website.

8.1 World Trade Organization (WTO)

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

There are relevant international standards or requirements in relation to traceability of foods. However, FSANZ has not identified any specific processing requirements in international standards to ensure that hepatitis A in foods is destroyed, although international standards do include hygienic practice measures to ensure that foods are not contaminated with hepatitis A.

This issue will be fully considered prior to approval. FSANZ has made an emergency notification to the agencies responsible in accordance with Australia's obligations¹³ under the WTO Sanitary and Phytosanitary Measures (SPS) Agreement. This will enable other WTO member countries to comment on proposed changes where they may have a significant impact on them.

¹¹ Wellington Anniversary Day

¹² Australia Day

¹³ This does not refer to New Zealand because the proposed measures are to apply in Australia only.

Conclusion

9. Conclusion and Preferred Option

There were two outbreaks of locally-acquired hepatitis A in Australia in 2009. Based on the information currently available, the most likely explanation was the consumption of semi-dried tomatoes.

Preferred Approach

To protect public health and safety by varying Standard 1.6.2 and Standard 3.2.2 to include traceability and processing requirements for semi-dried tomatoes and ingredients.

9.1 Reasons for Preferred Approach

- to protect public health and safety, as measures currently in place in Victoria will expire on 9 February 2010
- the proposed measures are considered to be a proportionate response as they are focussed on semi-dried tomatoes and foods likely to be used in semi-dried tomatoes
- in the view of FSANZ, the proposed measures are generally consistent with measures in place in Victoria
- the proposed measures will deliver the greatest net benefit to the community in that they will deliver benefits in preventing or mitigating serious illness, although it is recognised that these measures will have costs for the community, particularly industry
- outcome based measures are proposed to ensure that regulation remains relevant and effective over time, and to promote industry innovation in processing techniques
- the measures are based on the best available scientific evidence and, in the case of the proposed traceability requirements, are consistent with international practice and current primary production and processing standards
- the measures apply throughout Australia to imported product and domestic product, and ensure safe and suitable food is provided to consumers
- the measures are transitional in nature, while more comprehensive traceability requirements and primary production and processing requirements for horticultural products are considered.

9.2 Transitional Arrangements

Given the need to protect public health and safety and the imminent expiration of measures currently in place in Victoria, no transition period for the proposed national regulatory measures is proposed. This means that the measures would apply from gazettal to all product in the supply chain. FSANZ is inviting comment on the implications of these measures.

10. Implementation and Review

If approved, FSANZ must within 12 months of gazettal, undertake further consultation and assessment of this Proposal and any variation to the Code.

ATTACHMENTS

1. Draft variations to the *Australia New Zealand Food Standards Code*
2. Explanatory Statement of Variations to Standard 1.6.2 and Standard 3.2.2.

Draft variations to the *Australia New Zealand Food Standards Code*

Section 94 of the FSANZ Act provides that standards or variations to standards are legislative instruments, but are not subject to disallowance or sunseting

[1] **Standard 1.6.2** of the *Australia New Zealand Food Standards Code* is varied by –

[1.1] *inserting immediately before clause 1 –*

Division 1 – Processing requirements

[1.2] *inserting after clause 8 –*

Division 2 – Special processing requirements for semi-dried tomatoes

9 Meaning of semi-dried tomatoes

(1) In this Division, **semi-dried tomatoes** means –

- (a) tomatoes that have been partially dried; or
- (b) a food represented as semi-dried tomatoes.

(2) However, a food consisting of tomatoes which have only been dried by the sun is not semi-dried tomatoes.

(3) To avoid doubt, semi-dried tomatoes may include foods other than tomatoes including herbs, spices and oil.

10 Application of stock in trade provision

Subclause 1(2) of Standard 1.1.1 does not apply to the provisions in this Division.

11 Processing requirements for semi-dried tomatoes

Semi-dried tomatoes must not be sold unless –

- (a) the semi-dried tomatoes have been pasteurised by –
 - (i) heating for a time and at a temperature sufficient to destroy hepatitis A virus; or
 - (ii) using any other process that provides an equivalent or greater lethal effect on hepatitis A virus; or
- (b) all of the tomatoes in the semi-dried tomatoes have been treated or subjected to another process that is sufficient to destroy hepatitis A virus.

12 Record keeping requirements for processors

(1) A food business which processes semi-dried tomatoes in accordance with paragraph 11(a) must keep records of any processing that the semi-dried tomatoes have received.

(2) A food business which processes tomatoes likely to be used in semi-dried tomatoes in accordance with paragraph 11(b) must keep records of any processing that the tomatoes have received.

Editorial note:

Division 7 of Standard 3.2.2 provides special traceability requirements for food businesses that receive or supply semi-dried tomatoes.

[1.3] *updating the Table of Provisions to reflect the above variations*

[2] **Standard 3.2.2** of the Australia New Zealand Food Standards Code is varied by

[2.1] *inserting after clause 25 –*

Division 7 – Special traceability requirements for semi-dried tomatoes

26 Interpretation

In this Division –

relevant food means –

- (a) semi-dried tomatoes; or
- (b) tomatoes or other food likely to be used in semi-dried tomatoes.

semi-dried tomatoes has the meaning given by clause 9 of Standard 1.6.2.

27 Application of stock in trade provision

Subclause 1(2) of Standard 1.1.1 does not apply to the provisions in this Division.

28 Traceability requirements for businesses that receive semi-dried tomatoes

A food business that receives relevant food (**the recipient**) must record, in writing, and retain –

- (a) the name and address of each food business or other person that supplied the recipient with the relevant food; and
- (b) details to enable the identification of each batch of relevant food, including –
 - (i) a unique number or code assigned to each batch of relevant food and;
 - (ii) the date on which the relevant food was received by the recipient.

29 Traceability requirements for businesses that supply semi-dried tomatoes

A food business that supplies relevant food (**the supplier**) must record, in writing, and retain –

- (a) the name and address of each food business to which the supplier supplied relevant food; and
- (b) details to enable the identification of each batch of relevant food, including –
 - (i) a unique number or code assigned to each batch of relevant food; and
 - (ii) the date on which the relevant food was supplied by the supplier.

Editorial note:

Division 2 of Standard 1.6.2 provides special processing requirements for semi-dried tomatoes.

[2.2] *updating the Table of Provisions to reflect the above variations*

Explanatory Statement of Variations to Standard 1.6.2 and Standard 3.2.2 in Proposal P1012

EXPLANATORY STATEMENT OF PROPOSED VARIATIONS TO STANDARD 1.6.2

Item 1.1

This item inserts a division heading to allow a separate division for semi-dried tomatoes to be created in Standard 1.6.2.

Item 1.2

This item inserts a new Division 2 in Standard 1.6.2 which contains processing requirements for semi-dried tomatoes.

The new clause 9 sets out the definition of 'semi-dried tomatoes' which is used throughout the division. The definition includes products represented as semi-dried tomatoes and is intended to include 'semi sun dried tomatoes' but not 'sun-dried tomatoes'. Subclause 9(3) makes it clear that a food can still be 'semi-dried tomatoes' if it contains other foods (such as herbs, spices and oil).

Clause 10 makes it clear that the stock in trade provisions do not apply to the new Division 2. Accordingly, the variations would need to be complied with when the provisions come into effect, including product in the supply chain.

Clause 11 is intended to prohibit the sale of semi-dried tomatoes unless:

- the semi-dried tomatoes are pasteurised to destroy hepatitis A virus or have been subjected to any other process that provides an equivalent lethal effect on hepatitis A virus; or alternatively
- all the tomatoes in the semi-dried tomatoes have been processed (including treated) to destroy hepatitis A virus.

These processing requirements provide industry with alternative means of ensuring that semi-dried tomatoes do not contain hepatitis A virus. The processing requirements do not include a specific process but do specify an outcome of this process i.e. destruction of hepatitis A virus. This will facilitate development and innovation in processing techniques for destroying hepatitis A virus.

Clause 12 provides that businesses processing the semi-dried tomatoes or tomatoes to destroy hepatitis A virus must also maintain written records of any processing.

FSANZ is of the view that these requirements are generally consistent with the existing requirements in the Order that is currently in effect in Victoria. However, 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. Comment on this is sought.

Item 1.3

This is a machinery variation to consequentially amend the *Table of Provisions* in Standard 1.6.2.

Item 2.1

Item 2.1 inserts a new Division 7 in Standard 3.2.2 which contains traceability requirements for semi-dried tomatoes.

Clause 26 adopts the definition of 'semi-dried tomatoes' from Standard 1.6.2. That clause also defines the term 'relevant food' as a convenient means of describing the foods for which records would need to be kept.

Clause 27 makes it clear that the stock in trade provisions do not apply to the new Division 2. Accordingly, the variations would need to be complied with when the provisions come into effect, including product in the supply chain.

Clauses 27 and 28 require certain food businesses to maintain sufficient written records about the batches of product they receive or supply, as well as details of the relevant supplier or recipient. This would apply for those businesses that:

- receive or supply semi-dried tomatoes, or
- receive or supply tomatoes or other food likely to be used in semi-dried tomatoes.

The proposed record keeping requirements in clause 28 for supply of a relevant food only apply when the relevant food is supplied to a food business. For example, they do not apply where the immediate recipient is a member of the public (i.e. a consumer purchasing the product at retail).

Prescriptive record keeping requirements are proposed to ensure that adequate trace back can occur in the event of a future outbreak.

FSANZ is of the view that these proposed requirements are generally consistent with the existing requirements in the Order that is currently in effect in Victoria. However, the proposed regulatory measures would require maintenance of sufficient records for packaged pasteurised semi-dried tomatoes. FSANZ understands that this is not a current requirement in the Order in Victoria. In addition, the proposed measures do not require a business to identify the specific batch of food that was used in each batch of semi-dried tomatoes. FSANZ understands that this is different from the Order in Victoria. Comment on this is sought.