21 September 2012
[21-12]

Call for submissions – Proposal P1017

Criteria for *Listeria monocytogenes* – Microbiological Limits for Foods

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FSANZ has assessed a Proposal to revise Standard 1.6.1 with regards to criteria for *Listeria monocytogenes* limits in ready-to-eat foods. Pursuant to section 72 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act), FSANZ now calls for submissions to assist further consideration of the Proposal.

For information about making a submission, visit the FSANZ website at information for submitters.

All submissions on applications and proposals will be published on our website. We will not publish material that is provided in-confidence, but will record that such information is held. In-confidence submissions may be subject to release under the provisions of the *Freedom of Information Act 1991*. Submissions will be published as soon as possible after the end of the public comment period. Where large numbers of documents are involved, FSANZ will make these available on CD, rather than on the website.

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

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

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

DEADLINE FOR SUBMISSIONS: 6pm (Canberra time) 16 November 2012

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

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

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

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Table of Contents

1. Executive summary

Standard 1.6.1 – Microbiological Limits for Food was included in the *Australia New Zealand Food Standards Code* (the Code) in December 2000. Since this Standard was developed, food safety requirements have been included in the Code supporting a preventative approach to ensuring food safety. Work has also progressed internationally to establish microbiological criteria for *Listeria monocytogenes* more broadly in ready-to-eat foods. The limits for *L. monocytogenes* in Standard 1.6.1 are being reviewed to provide a nationally consistent and internationally harmonised approach.

Internationally, through the Codex Alimentarius Commission (Codex), microbiological criteria have recently been developed for two categories of food:

- ready-to-eat foods in which growth of *L. monocytogenes* will not occur (<100 cfu/g)
- ready-to-eat foods in which growth of *L. monocytogenes* can occur (not detected in 25 g)

Proposal P1017 will assess how this approach can be applied, both through amendments to Standard 1.6.1 and the development of guidance or other tools to assist industry and enforcement agencies. Particular matters to be clarified in this process include:

- definition of “ready-to-eat”
- establishing whether a food can or cannot support growth
- analytical methods.

Three options are being considered:

- Option 1 – to include limits in Standard 1.6.1 for *L. monocytogenes* on the basis of whether the food is ready-to-eat and can or cannot support its growth

- Option 2 – to delete the limits for L. *monocytogenes* in Standard 1.6.1 and establish reference criteria for *L. monocytogenes* in ready-to-eat food on the basis of whether it can or cannot support its growth

- Option 3 – make no amendments to the limits in Standard 1.6.1 (status quo)

2. Introduction

2.1 The Proposal

Microbiological standards for foods are specified in Standard 1.6.1 — Microbiological Limits for Foods in the *Australia New Zealand Food Standards Code* (the Code). This Proposal has been prepared in order to review existing limits for *Listeria monocytogenes* in Standard 1.6.1, taking into account agreed international criteria developed for *L. monocytogenes* in ready-to-eat (RTE) foods.

2.2 The current Standard

Standard 1.6.1 lists the maximum permissible microbiological limits for nominated foods, or classes of foods (available via the FSNZ website at http://www.foodstandards.gov.au/foodstandards/foodstandardscode.cfm). The Standard covers a range of food products for which end product criteria have been established, and typically adopts a vertical approach where limits are provided for specific types of food.

Regulatory limits for *L. monocytogenes* specified in Standard 1.6.1 currently apply to a limited number of foods. The limit generally specified is "not detected in 25 g" (sampling plan n=5, c=0, m=0). For RTE processed finfish, a limit of 100 cfu per 25 g is allowed in 1 out of 5 samples (sampling plan n=5, c=1, m=0, M=1). An amendment to Standard 1.6.1 is required to change the regulatory limits for *L. monocytogenes* in RTE foods.

2.2.1 Guidance documents

In addition to the limits in Standard 1.6.1, guideline criteria for *L. monocytogenes* in foods is provided in the FSANZ *Recall guidelines for packaged ready-to-eat foods found to contain Listeria monocytogenes at point of sale* (Recall Guidelines) and *Guidelines for the microbiological examination of ready-to-eat foods* (RTE Guidelines)(FSANZ 2001a; FSANZ 2001b). These guidance documents establish two sets of limits for *L. monocytogenes* in ready-to-eat foods, based on whether a food is able to support the growth of *Listeria*.

2.3 Reasons for preparing the Proposal

The microbiological limits set in Standard 1.6.1 were established more than ten years ago when the Code was gazetted in December 2000. Since that time, food safety requirements have been developed in Chapters 3 and 4 of the Code that support a preventative approach to ensuring food safety. Work has also progressed internationally (through Codex) on the use of microbiological criteria in food safety control systems, in particular limits for *L. monocytogenes* in ready-to-eat foods.

Proposal P1017 was prepared to address a number of problems that have been identified with the current limits for *L. monocytogenes* in the Code:

- Over time, foods other than those listed in Standard 1.6.1 have also been associated with listeriosis outbreaks (e.g. cooked chicken meat, RTE minimally processed fruits and vegetables). A product-by-product (vertical) approach to setting regulatory limits for *L. monocytogenes* has meant that other ready-to eat foods that may support the growth of *L. monocytogenes* may not be regulated equivalently.

  There is an inconsistent approach between applying regulatory limits and guideline criteria.

The limits in Standard 1.6.1 for generic product categories do not allow discretion as to whether the particular properties of a food support the growth or not of *L. monocytogenes*. Foods within a category may have different product formulations and intrinsic characteristics thereby presenting different risks, however the risk management approach (and enforcement action) is the same. In contrast, the guideline criteria and international approaches further differentiate products that support the growth of *L. monocytogenes*, even within categories.

- The methods currently specified in Standard 1.6.1 reference outdated Australian/New Zealand Standard Methods for Food Microbiology (AS/NZS 1766). These Standards have been revised over time, aligning with International Standards Organization (ISO) standards and are now published as AS 5013 standards.

- There is no clear point of application for the microbiological criteria set in Standard 1.6.1. (e.g. point of manufacture, point of retail). Microbiological criteria should state the point in the food chain at which it applies, based on where maximum benefit is provided to the consumer that the food is safe and suitable for consumption.

- Food safety requirements have been included in the Code that support a preventative through-chain approach to ensuring food safety. These requirements are in the Chapter 3 food safety standards and sector-specific primary production and processing standards in Chapter 4. The obligation on food businesses to produce safe and suitable food and to implement measures that ensure this is an integral part of those requirements. For certain foods, the testing of *L*. *monocytogenes* in the production environment as well as other stages in the production system may be required to manage *Listeria* in the food supply. The role of regulatory end point limits in this context was not considered when Standard 1.6.1 was developed.

2.4 Procedure for assessment

The Proposal is being assessed under the Major Procedure.

Therefore, during the assessment of P1017 there will be two opportunities for interested parties to contribute to our work through public consultations. This assessment summary presents the first opportunity, allowing interested parties to provide comment and additional information which can further inform our understanding of testing for *L. monocytogenes* by industry and enforcement agencies, and the risk management practices currently in place.

3. Summary of the assessment

3.1 Risk assessment

3.1.1 Listeriosis

L. monocytogenes is a bacterium that causes the serious illness, listeriosis, in some people. People at risk of listeriosis include pregnant women, their unborn and new-born babies, the elderly and other people whose immune systems have been weakened by illness or immuno-suppressant drugs.

Symptoms of the severe form of listeriosis can include septicaemia (blood infection), meningitis (infection and inflammation of membranes surrounding the brain) and death. Symptoms in pregnant women may appear mild, but listeriosis can cause miscarriage, premature birth, or stillbirth.

In healthy adults and children, infection with *L. monocytogenes* causes few or no symptoms and may be mistaken for a mild viral infection or flu. Eating foods contaminated with high levels of *Listeria* is the most common way of contracting the illness.

There were 71 notified cases of listeriosis in Australia in 2010 (NNDSS 2012). This equates to 0.3 cases per 100,000 population, which was consistent with the incidence reported over the previous ten years. Seventy-five per cent (53/71) of notifications were in people aged 60 years or more.

In New Zealand, there were 23 notifications of listeriosis in 2010 (0.5 cases per 100,000 population), with a case fatality rate of 30% (ESR 2011). Similar to the situation in Australia, a high proportion of notifications were in people aged 60 years or more (13/23; 56.5%).

Additional technical information on *L. monocytogenes,* such as growth and survival characteristics, can be found in the FSANZ publication titled *Agents of foodborne illness* (FSANZ 2011).

3.1.2 International risk assessments

Several extensive quantitative risk assessments have been undertaken internationally to evaluate the relative risks of *L. monocytogenes* contamination in different ready-to-eat foods, as well as the factors that contribute to those risks (FDA/FSIS 2003; WHO/FAO 2005).

The FAO/WHO Joint Expert Meeting on Risk Assessment (JEMRA) completed a risk assessment of *L. monocytogenes* in ready-to-eat foods in 2005 at the request of the Codex Committee on Food Hygiene (CCFH) during development of microbiological criteria to accompany the *Guidelines on the Application of General Principles of Food Hygiene to the Control of* Listeria monocytogenes *in Foods* (CAC/GL 61 – 2007). Australian and New Zealand governments actively participated in the development of these criteria, consulting with government and industry stakeholders throughout the process.

The JEMRA risk assessment focussed on four RTE foods in order to provide examples of how different factors interact to affect the risk of acquiring listeriosis. These were:

1. foods that are commonly consumed, have very low frequencies and levels of contamination with *L. monocytogenes* and allow for growth of the organism during storage (e.g. pasteurised milk)

2. foods that are commonly consumed, have very low frequencies and levels of contamination with *L. monocytogenes* but do not allow for growth of the organism during storage (e.g. frozen ice-cream)

3. foods that are often contaminated with *L. monocytogenes*, are produced without any lethal processing step, but their final composition prevents growth of the organism during storage (e.g. fermented meat products)

4. foods that are often contaminated with *L. monocytogenes*, are produced without any lethal processing step, and their final composition allow for growth of the organism during storage (e.g. cold-smoked fish).

An overall conclusion of the JEMRA risk assessment was that nearly all cases of listeriosis result from the consumption of high numbers of the pathogen. The greatest risk associated with RTE foods is therefore the small portion of products with high contamination levels of *L. monocytogenes.*

It was also demonstrated that the potential for growth of *L. monocytogenes* strongly influences the subsequent risk of listeriosis. The extent to which growth occurs was dependent on the characteristics of the food and the conditions and duration of refrigerated storage.

For the RTE foods selected in the model, their ability to support the growth of *L. monocytogenes* led to an increase in the risk of listeriosis of 100- to 1000-fold on a per-serving basis.

Control measures that reduce the frequencies of contamination were shown to have a proportional reduction in the rates of illness, provided the proportions of high contaminations are reduced similarly. Control measures that prevent the occurrences of high levels of contamination at consumption were expected to have the greatest impact on reducing rates of listeriosis.

3.1.2.1 Comparison of different microbiological criteria

JEMRA considered the impact of different criteria on the predicted number of cases of listeriosis. Assuming 100% compliance, JEMRA predicted that increasing the limit (criterion) of listeria from 0.04 CFU/g (equivalent to 'not detected' in five 25 g samples) to a limit of 100 CFU/g resulted in a 10-fold increase in the incidence of listeriosis cases. However, the JEMRA model demonstrated that the predicted risk of illness was more strongly driven by the defect rate (i.e. the percentage of servings that exceed the specified limit), rather than the numeric value of the criterion. For example, when defect rates were >0.0001% (i.e. greater than 1 defective unit per 1,000,000) the difference in the predicted number of cases between the two limits was minimal (see Table 1).

This emphasises the importance of having control measures that reduce the frequency of contamination and prevent occurrence of high levels at consumption.

Table 1: Hypothetical "what if" scenario demonstrating the effect of defect rate on the number of 'predicted cases' of foodborne listeriosis (taken from Table 5.4 of WHO/FAO 2005).

Assumed percentage of "defective '" servings[(1)]	Predicted number of listeriosis cases [(2)]	
	Initial standard of 0.04 CFU/g	Initial standard of 100 CFU/g
0	0.5	5.7
0.00001	1.7	6.9
0.00011	12.3	17.4
0.001	119	124
0.01	1185	1191
0.018	2133	2133
0.1	11837	11848
1	117300	117363

NOTES: (1) For the purpose of the scenario, all defective servings were assumed to contain 10^8 CFU/g.
(2) for the purposes of this scenario, an r- value of 5.85 X10-^{12} was employed and a standard serving size of 31.8 g was assumed. In the case of 100 CFU/g calculations, the defective servings were assumed to be proportionately distributed according to the number of servings within each cell concentration bin.

3.1.3 Conclusion

Exposure to high levels of *L. monocytogenes* in food can cause serious illness in certain high-risk populations. International risk assessments demonstrate that the risk of illness is strongly influenced by the ability of the food to support the growth of *L. monocytogenes* to these high levels.

Control measures that prevent the occurrences of high levels of contamination at consumption are expected to have the greatest impact on reducing rates of listeriosis.

3.2 Regulatory options and impacts

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

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

In order to decide the most effective risk management approach, different risk management options are considered. These options include the *status quo* (the situation if no action is taken) as a comparative measure against other approaches.

At this stage in the assessment of P1017, the Office of Best Practice Regulation (OBPR) has advised that changes to Standard 1.6.1 in relation to limits for *L. monocytogenes* are unlikely to require a RIS.

3.2.1 Risk management options

Three options are being considered under Proposal P1017:

- Option 1 – to include limits in Standard 1.6.1 for *L. monocytogenes* on the basis of whether the food is ready-to-eat and can or cannot support its growth

- Option 2 – to delete the limits for *L*. *monocytogenes* in Standard 1.6.1 and establish reference criteria for *L. monocytogenes* in ready-to-eat food on the basis of whether it can or cannot support its growth

- Option 3 – make no amendments to the limits in Standard 1.6.1 (status quo)

3.2.1.1 Option 1 – Amend the limits for Listeria monocytogenes in Standard 1.6.1

Option 1 proposes changing the limits set for *L. monocytogenes* in standard 1.6.1 to include two sets of criteria:

- criteria for foods in which growth of *L. monocytogenes* will not occur (<100 cfu/g)
- criteria for foods in which growth of *L. monocytogenes* can occur (not detected in 25 g)

This reflects the approach adopted by the Codex Committee on Food Hygiene (Codex 2007).

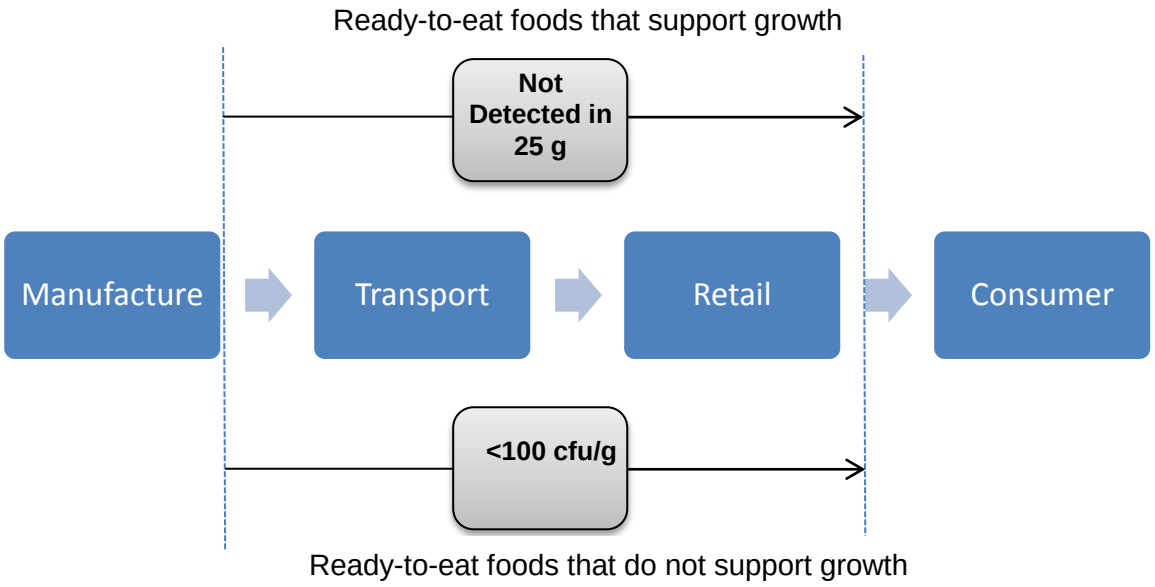

Figure 1: Schematic representation of the application of limits for L. monocytogenes in ready-to-eat foods proposed under option 1

The sampling plans proposed are outlined below:

Microbiological criteria for ready-to-eat foods in which growth of *L. monocytogenes* will not occur

Point of application	Microorganism	n	c	m	Class Plan
Ready-to-eat food from the end of manufacture to the point of sale.	*Listeria monocytogenes*	5	0	100 cfu/g	2

Microbiological criteria for ready-to-eat foods in which growth of *L. monocytogenes* can occur

Point of application	Microorganism	n	c	m	Class Plan
Ready-to-eat food from the end of manufacture to the point of sale.	*Listeria monocytogenes*	5	0	Absence in 25 g (<0.04 cfu/g)	2

Changes to the Code under Option 1 would be consistent with the approach in establishing limits for *L. monocytogenes* in the FSANZ guidance documents (Recall Guidelines and RTE Guidelines).

Definition of ready-to-eat food

The codex definition of ready-to eat is “any food which is normally eaten in its raw state or any food handled, processed, mixed, cooked, or otherwise prepared into a form which is normally eaten without further listericidal steps. Ready-to-eat food is defined in Standard 3.2.2 as:

> ***Ready-to-eat*** *means food that is ordinarily consumed in the same state as that in which it is sold and does not include nuts in the shell and whole, raw fruits and vegetables that are intended for hulling, peeling or washing by the consumer.*

The definition of ready-to-eat applied to any microbiological criteria in Standard 1.6.1 will take into account existing definitions.

FSANZ welcomes information or comment on existing definitions for "ready-to-eat" and specific considerations that may need to be taken into account when applying criteria for *L. monocytogenes* to this category of foods.

Growth or no growth

Ready-to-eat foods in which growth of *L. monocytogenes* will not occur would be based on scientific justification. Examples of factors that can control growth include (Codex 2007):

- a pH below 4.4
- a water activity (a_w) of <0.92
- a combination of factors, e.g. combination of pH<5.0 with a_w<0.94
- freezing.

In the absence of this information a ready-to-eat food could be presumed to support the growth of *L. monocytogenes* and a not detected criterion applied.

There are a number of tools and guidance materials that have been developed internationally to assist industry and government in relation to requirements for *L. monocytogenes*, including:

- New Zealand

Draft Guidance for the Control of *Listeria monocytogenes* in Ready-To-Eat Foods (MAF 2011)
Defining "Short Shelf Life" foods with respect to risk from *Listeria monocytogenes* (Ross 2010)

- Canada

Policy on Listeria monocytogenes in Ready-to-Eat Foods (Health Canada 2011)
Listeria monocytogenes Challenge Testing of Ready-to-Eat refrigerated Foods (Health Canada 2010)

- United Kingdom

Shelf life of ready to eat food in relation to *L. monocytogenes* – Guidance for food business operators (CFA 2010)

- European Union

Guidance document on *Listeria monocytogenes* shelf-life studies for ready-to-eat foods, under Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs (EC 2008)

- United States

Guidance for industry: Control of *Listeria monocytogenes* in refrigerated or frozen ready-to-eat foods (FDA 2008)

FSANZ welcomes information or comment on whether adequate guidance or tools are available for industry or enforcement agencies to validate whether a food can support the growth of *L. monocytogenes* or not.

Methods of Analysis

Standard 1.6.1 prescribes methods of analysis to determine the levels of microorganisms in foods for regulatory purposes. Currently, Standard 1.6.1 references Australian/New Zealand Standard Methods for Food Microbiology (AS/NZS 1766), or those that have been determined equivalent according to AS/ANZ 4659.

These have been superseded by the AS 5013 Standards which have largely aligned with latest ISO methods.

FSANZ welcomes comment on the need to specify methods of analysis in the Code or whether other mechanisms can be used in order to ensure consistent application of microbiological criteria.

3.2.1.2 Option 2 – No limits in Standard 1.6.1

Option 2 proposes to delete limits for *L. monocytogenes* from Standard 1.6.1 and establish criteria for *L. monocytogenes* in RTE foods as reference criteria. Integral to this approach is the implementation and verification of appropriate hygiene and manufacturing controls during food processing as required under Chapters 3 and 4 of the Code.

Currently only a defined number of foods have limits for *L. monocytogenes* in Standard 1.6.1. Additional criteria for *L. monocytogenes* (mainly in dairy products) were established in the User Guide to Standard 1.6.1 (FSANZ 2001c) as "advisory criteria that provide benchmark levels against which unacceptable microbial contamination of food can be identified and remedial action initiated when limits are exceeded".

Building on this approach, a comprehensive set of advisory or reference criteria could be developed to support a through chain, preventative approach to food safety and the production of safe and suitable food without a need for regulatory limits. Reference criteria for *L. monocytogenes* would be established on the basis of whether the food can or cannot support growth, as outlined under option1.

Guidance documents such as the Recall Guidelines have also been developed to provide guidance to state and territory health authorities as to when the presence (or level) of *L. monocytogenes* in a food (where no standard exists) presents a public health risk and a recall action is warranted. A number of recalls of ready-to-eat foods (including custard, milk, mousse deserts, dips) due to the presence of *L. monocytogenes* have occurred despite no regulatory standard being established (a summary of recall data is provided in Attachment 1).

FSANZ welcomes comment on the role or need for regulatory limits in Standard 1.6.1 to ensure a safe food supply. Can reference criteria provide adequate support for enforcement agencies (and guidance to industry) to ensure food businesses produce safe and suitable food?

3.2.1.3 Option 3 – Status quo

Regulatory limits for L*. monocytogenes* are currently specified in Standard 1.6.1. These limits are generally "not detected in 25 g" (sampling plan n=5, c=0, m=0) and are set for a limited number of foods:

- butter made from unpasteurised milk and/or unpasteurised milk products
- soft and semi-soft cheese (moisture content > 39%) with pH >5.0
- all raw milk cheese (cheese made from milk not pasteurised or thermised)
- unpasteurised milk for retail sale
- packaged cooked cured/salted meat
- packaged heat treated meat paste and packaged heat treated pâté

- ready-to-eat processed finfish, other than fully retorted finfish[1]
- bivalve molluscs that have undergone processing other than depuration

Recall guidelines were also developed (finalised in April 2001) to provide national guidance on when the presence or level of *L. monocytogenes* in foods (for which no regulatory limit has been specified) presents a public health risk which may warrant recall action. The guidelines provide two action levels for categories of ready-to-eat food products:

- Not detected in 25 g (for ready-to-eat foods requiring refrigerated storage and able to support the growth of *L. monocytogenes* and ready-to-eat foods that have been implicated in human listeriosis, such as soft cheeses, smoked fish etc.)

- ≥100 cfu per gram (in all other packaged ready-to-eat foods)

Since 2010, 134 Australian food recalls and 38 New Zealand food recalls have resulted due to the detection of *L. monocytogenes,* this data is summarised in Attachment 1. These recalls have involved a range of products though most have been associated with meat, dairy and seafood products (of various types).

3.3.1 Addressing FSANZ's objectives for standards setting

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

3.3.1.1 Protection of public health and safety

Infection by *L. monocytogenes* can be very serious for people whose immune systems are weakened by disease or illness as well as pregnant women and their unborn children, new-born babies and the elderly. Establishing appropriate microbiological limits (regulatory/non-regulatory) for foods is an important measure to be considered within a risk management framework for managing *L*. *monocytogenes* in the food supply.

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

Consumer education and advice is also an important component of a risk management framework for *L. monocytogenes*. FSANZ has developed consumer advice which it provides electronically via the FSANZ website as well as publishing and distributing brochures. Any information or issues raised through the assessment of Proposal P1017 will be taken into account in a future review of these materials.

3.3.1.3 The prevention of misleading or deceptive conduct

The prevention of misleading or deceptive conduct is not relevant to the assessment of Proposal P1017.

3.3.1.4 Subsection 18(2) considerations

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

[1] Sampling plan for this category of food in Standard 1.6.1 is n=5, c=1, m=0, M=100 (i.e. allows one out of five samples to contain *L. monocytogenes* up to 100 cfu/g).

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

Several quantitative risk assessments have been undertaken internationally that have assessed:

- how different factors interact to affect the risk of acquiring listeriosis
- the association between the growth of *L. monocytogenes* and subsequent risk of listeriosis
- the association between standards for *L. monocytogenes* in foods and listeriosis cases.

FSANZ has had regard to this risk assessment work in assessing Proposal P1017.

- *the promotion of consistency between domestic and international food standards*

Option 1 under this Proposal proposes to change the microbiological criteria specified for *L. monocytogenes* in Standard 1.6.1 in accordance with the approach agreed internationally (through Codex) for ready-to-eat foods.

- *the desirability of an efficient and internationally competitive food industry*

Aligning microbiological criteria with an internationally agreed approach is supportive of an efficient and internationally competitive food industry.

- *the promotion of fair trading in food*

The promotion of fair trading in food is not a consideration in the assessment of Proposal P1017.

- *any written policy guidelines formulated by the Ministerial Council.*

There are no written policy guidelines relevant to the assessment of this Proposal.

3.3. Risk communication

FSANZ has developed and applied a basic communication strategy to this Proposal. All calls for submissions are notified via the FSANZ Notification Circular, media release and through FSANZ's social media tools and the Food Standards News.

Subscribers and interested parties are also notified about the availability of reports for public comment.

The process by which FSANZ considers standard development matters is open, accountable, consultative and transparent. Public submissions are called to obtain the views of interested parties on issues raised by the Proposal and the impacts of regulatory options.

Individuals and organisations that make submissions on this Proposal will be notified at each stage of the assessment.

If a draft variation to the Code is approved by the FSANZ Board, that decision will be notified to the Legislative and Governance Forum on Food Regulation. If the decision is not subject to a request for a review, all interested parties, including the public, will be notified of the gazettal of the variation to the Code in the national press and on the FSANZ website.

3.3.1 World Trade Organization (WTO)

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

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

5. References

CFA (2010) Shelf life of ready to eat food in relation to *L. monocytogenes* - Guidance for food business operators. Chilled Food Association. http://www.chilledfood.org/MEDIA/NEWS/2010/New+Shelf+Life+Guidance+for+Ready+to+Eat+Foods . Accessed 14 June 2012

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EC (2008) Guidance document on *Listeria monocytogenes* shelf-life studies for ready-to-eat foods, under Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs. Commission of the European Communities, Brussels, Belgium. http://ec.europa.eu/food/food/biosafety/salmonella/docs/guidoc_listeria_monocytogenes_en.pdf. Accessed 14 June 2012

ESR (2011) Foodborne disease in New Zealand, 2010. Institute of Environmental Science and Research Ltd, Christchurch, New Zealand. http://www.foodsafety.govt.nz/elibrary/industry/FBI-report-2011.pdf. Accessed 14 June 2012

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Attachment A – Summary of food recalls in Australia from 2000 – June 2012 due to the detection of *L. monocytogenes*

Food Type	Number of recalls
Dairy products	
• Cheese (ranging from fresh, to ricotta, feta, cheddar and parmesan)	18
• Milk/cream	6
• Ice cream/gelato	2
• Dairy desserts (including custard, mousse)	8
RTE meats (non-poultry)	
• Sandwich meats (cooked whole and sliced including beef, pork, silverside, lamb and ham)	37
• Other processed meats (such as pastrami, chorizo and other sausage products)	16
• Bacon (not RTE)	1
RTE poultry meats	
• Poultry meat, smoked sliced or shaved	8
• Chicken roasted or barbeque	3
• Pressed chicken meat	1
Seafood	
• Smoked salmon/trout/saithe	6
• Mousses/terrines	3
• Caviar	1
• Smoked mussels	1
• Smoked trout dip	1
Fresh produce	
• Sprouts alfalfa/various	2
• Lettuce (fresh-cut)	1
• Parsley	1
Prepared meals	
• Prepared (meat based) meals	4
• Prepared salads	3
• Sandwiches (egg)	1
• Cabanossi and cheese	1
Dips	
• Vegetable based	3
• Dairy based	1
Other	
• Tofu	1
• Chocolate sauce	1
• Lamingtons	1
• Cheesecake/cheesecake filling	2
TOTAL	**134**

Attachment B – Summary of food recalls in New Zealand from 2000 – July 2012 due to the detection of *L. monocytogenes*

Food Type	Number of recalls
Dairy products	
• Cheeses	2
• Milk/cream	3
• Yoghurt	1
RTE meats (non-poultry)	
• Sandwich meats (cooked whole and sliced including beef, pork, silverside, lamb and ham)	6
• Other processed meats (such as cooked sausages, salami and pepperoni and other unspecified smallgoods)	5
• Bacon (not RTE)	1
RTE poultry meats	
• Poultry meat; cooked or smoked, and whole birds, portions, sliced or shaved	5
Seafood	
• Other seafood (including seafood salads)	3
• Smoked mussels	3
• Salmon dip	1
Fresh produce	
• Fresh-cut leafy salads	2
Prepared meals	
• Prepared salads including meat	1
• Prepared salads	1
• Sandwiches	1
Dips	
• Vegetable based	2
• Dairy based	1
TOTAL	**38**