

8 November 2013

[21-13]

Call for submissions – Proposal P1017

Criteria for *Listeria monocytogenes* – Microbiological Limits for Foods

Pursuant to section 61 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act), FSANZ now calls for submissions to assist FSANZ's consideration of the draft food regulatory measure it has prepared arising from a Proposal to revise Standard 1.6.1 with regards to criteria for *Listeria monocytogenes* limits in ready-to-eat foods.

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) 10 January 2014

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

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

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

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Supporting documents

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

www.foodstandards.gov.au/code/proposals/Pages/proposalp1017criteri5439.aspx

SD1 Draft Guidance on the application of microbiological criteria for *Listeria monocytogenes* in RTE food

SD2 Scientific basis for *Listeria monocytogenes* limits

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 food safety and work has also progressed internationally to establish microbiological criteria for *Listeria monocytogenes* (*L. monocytogenes*) more broadly in ready-to-eat foods (RTE).

Proposal P1017 proposes to replace existing limits for *L. monocytogenes* in nominated foods in Standard 1.6.1 with two sets of criteria for *L. monocytogenes* in RTE foods based on whether growth of *L. monocytogenes* will occur or not in the RTE 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)

This approach recognises that it is the potential for foods to support growth of *L. monocytogenes* that is a main factor in the risk of acquiring listeriosis. For foods in which the growth of *L. monocytogenes* will not occur, occasional low level detections (<100 cfu/g) do not present a public health risk.

P1017 has been prepared to:

- Move from a product-by-product approach which specifies *L. monocytogenes* limits for specific foods, regardless of individual product characteristics, to an internationally agreed risk-based approach that applies limits broadly to RTE foods based on product and processing characteristics. This approach means there are no gaps (e.g. products not having limits applied because they are not specifically named) and also removes the inconsistencies between current regulatory limits and existing guideline criteria.
- Review elements of Standard 1.6.1 that are out-dated or unclear such as reference methods of analysis, the purpose of Standard 1.6.1 and the presentation of information within the Schedule to the standard.

The 1st call for submissions was released for public consultation in September 2012. FSANZ has considered the issues raised during public consultation and targeted consultation at two technical workshops held with participants from government, industry and public health laboratories.

FSANZ has decided to prepare a draft variation for the following reasons:

- Increased knowledge of the factors that impact on the risk of acquiring listeriosis has permitted the classification of RTE foods on the basis of whether growth of *L. monocytogenes* can occur. Including limits for *L. monocytogenes* in Standard 1.6.1 on the basis of whether the food is ready-to-eat and can or cannot support its growth is risk-based and supported by the evidence.
- The inclusion of limits for *L. monocytogenes* in Standard 1.6.1 provides a measure to industry and regulators as to the maximum number of microorganisms that must not be exceeded to ensure food is safe. This is an important risk management tool for reducing exposure to *L. monocytogenes* and the incidence of listeriosis.

- Establishing limits across all RTE foods for *L. monocytogenes* will provide greater certainty to businesses as to when actions (such as recall) may be required.
- It removes the current inconsistency between guidance documents (e.g. Recall Guidelines) and limits in Standard 1.6.1.
- It harmonises with international approaches to applying limits for *L. monocytogenes*

To support this approach a draft guidance document *Guide to the application of limits for L. monocytogenes* has been developed and is provided for comment as Supporting Document 1 (SD1).

1 Introduction

Microbiological limits for foods are contained in Standard 1.6.1 — Microbiological Limits for Foods in the *Australia New Zealand Food Standards Code* (the Code). FSANZ is undertaking a review of the limits specified in Standard 1.6.1 and prepared a background paper outlining issues to be covered in the review and the principles and guidelines that will underpin this work (FSANZ, 2012)¹.

Since Standard 1.6.1 was introduced, FSANZ has developed Chapter 3 Food Safety Standards and sector specific Primary Production and Processing Standards (Chapter 4 Standards). These standards provide obligations on food businesses and food handlers to produce food that is safe to eat. Preventative approaches to food safety in Australia and New Zealand rely on food businesses implementing control measures throughout their production process and verifying that these measures are in place and working effectively.

Food safety programs have also been mandated for a number of businesses in response to Ministerial policy guidelines² that recommended certain food business sectors should develop and implement mandatory food safety programs including:

- food service in which potentially hazardous food is served to vulnerable populations
- businesses producing manufactured and fermented meat.

In addition to the developments in food safety management that have progressed since the development of Standard 1.6.1, other issues that have been identified include:

- 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.

P1017 is the first stage of the review of limits in Standard 1.6.1. In addition to assessing limits for *L. monocytogenes* in ready-to-eat (RTE) foods, P1017 proposes amendments to Standard 1.6.1 to address identified problems with the Standard and which will provide the basis for further revisions, including:

- updating reference methods of analysis
- including analytical units within the Schedule to the Standard
- rewording the “Purpose” to Standard 1.6.1 to more clearly reflect how the limits should be used and clarify that they apply to food for sale (i.e. are applicable at any point from the end of manufacture through to end of shelf life).

¹ <http://www.foodstandards.gov.au/industry/safetystandards/programs/Pages/default.aspx>

² <http://www.foodstandards.gov.au/code/fofr/fofrpolicy/pages/default.aspx>

1.1 The Proposal

P1017 seeks to establish two sets of criteria in Standard 1.6.1 for *L. monocytogenes* in RTE foods, consistent with internationally agreed criteria. The basis for the different criteria is whether growth of *L. monocytogenes* can occur in the RTE food. This means that the application of *L. monocytogenes* limits needs to consider the physical and chemical characteristics of the food and its shelf life.

To support this approach, FSANZ has developed a draft guidance document (SD1) on the particular criteria that could be taken into account in determining whether a food can support the growth of *L. monocytogenes* and when validation is required. Comments are sought on the draft guidance document.

1.2 The current Standard

Standard 1.6.1 lists the maximum permissible microbiological limits for nominated foods, or classes of foods (available via the FSANZ website)³. 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.

1.2.1 Guidance documents

In addition to the limits in Standard 1.6.1, current 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)⁴ and *Guidelines for the microbiological examination of ready-to-eat foods* (RTE Guidelines)⁵ (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 *L. monocytogenes* which does not align with the current Standard. It is proposed that the Recall Guidelines will no longer be needed following the finalisation of P1017.

1.4 Reasons for preparing the Proposal

The 1st call for submissions outlined a number of problems that had been identified with the current limits for *L. monocytogenes* in Standard 1.6.1 that this Proposal would address.

In particular, P1017 has been prepared to:

- move from a product-by-product approach which specified *L. monocytogenes* limits for specific foods, regardless of individual product characteristics, to an internationally agreed risk-based approach that applies limits broadly to RTE foods based on product and processing characteristics. This approach also removes inconsistencies between current regulatory limits and existing guideline criteria.

³ Standard 1.6.1 is available via: www.foodstandards.gov.au/code

⁴ <http://www.foodstandards.gov.au/publications/Pages/listeriarecallguidel5618.aspx>

⁵ <http://www.foodstandards.gov.au/publications/pages/guidelinesformicrobi1306.aspx>

- review elements of Standard 1.6.1 that are out-dated or unclear such as reference methods of analysis, the purpose of Standard 1.6.1 and the presentation of information within the Schedule to the Standard.

1.5 Procedure for assessment

The Proposal is being assessed under the Major Procedure set out in Division 2 of Part 3 of the FSANZ Act.

2 Summary of the assessment

2.1 Summary of issues raised in submissions

The assessment summary associated with the 1st call for submissions proposed three options:

- Option 1 – to include microbiological criteria 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 microbiological criteria 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 microbiological criteria in Standard 1.6.1 (status quo)

The 1st call for submissions occurred between 21 September and 16 November 2012.

FSANZ received 19 submissions from various sectors including horticulture, seafood, flight caterers, state and territory food enforcement agencies and the New Zealand Ministry for Primary Industries. Those submissions are available on the FSANZ website⁶.

Section 73 of the FSANZ Act requires FSANZ to have regard to all submissions made during the submission period when making a decision whether to prepare a Standard or a variation to a Standard; or to abandon the Proposal. FSANZ has had regard to all 19 submissions received, and where relevant, the submissions and responses have been discussed in the body of this report.

The majority of submissions supported the option to include microbiological criteria in Standard 1.6.1 for *L. monocytogenes* on the basis of whether the food is RTE and can support growth (i.e. consistent with the Codex approach). However, certain key issues were raised in submissions, which include:

- Implications for the cold smoked salmon industry and processors of similar products where the elimination of *L. monocytogenes* may be impractical (implications for meeting an “absent” in 25 g)
- Guidance as to how RTE foods are captured and validation requirements
- Clear definitions for terms such as for “ready-to-eat” and “growth”
- Consistent application of limits for *L. monocytogenes* and resulting corrective actions across jurisdictions
- Whether foods for vulnerable populations should be considered as a separate category and limits set.

A summary of the main issues emerging from those submissions is presented in Table 1.

⁶ <http://www.foodstandards.gov.au/code/proposals/Pages/proposalp1017criteri5439.aspx>

Table 1: Summary of issues

Issue	Raised by	FSANZ Response
<p>Vulnerable populations Foods intended for consumption by vulnerable sectors of the population be targeted perhaps through establishment of separate reference criteria.</p> <p>Unnecessary restriction of menus in aged care facilities altering the prevalence of malnutrition in these facilities.</p>	<p>Dietetic Industry Association</p> <p>New Zealand Industry associations</p>	<p>FSANZ considers that specific criteria for foods for vulnerable populations are not required, however FSANZ continues to work with the government food communicators group to develop key messages that jurisdictions can use for vulnerable groups in relation to limits for all RTE foods.. The draft amendments to Standard 1.6.1 apply to RTE foods on the basis of whether growth of <i>L. monocytogenes</i> can occur or not. It is the potential for <i>L. monocytogenes</i> to grow to high numbers in a RTE food that presents the risk to vulnerable persons who may consume that food.</p> <p>To specifically address risks to vulnerable populations, targeted information about foods or practices that increase the risk of them acquiring listeriosis is a preferred risk management approach. Existing materials and their adequacy will be reviewed in consultation with the jurisdictions. For example further information resources could be developed for immunocompromised people (as a result of particular diseases, treatments ageing factors) and health care settings that provide food for them. FSANZ will consult further on this matter.</p>
<p>Decision on growth/no growth Industry submitters raised concerns with determining growth or no growth of <i>L. monocytogenes</i> within a ready-to-eat product.</p> <p>Who will make the decision as to whether the food supports the growth of <i>L. monocytogenes</i> and suggested validation is required to reduce additional charges for the manufacturer</p> <p>Submissions proposed option 1 be reviewed to allow validation for ready to eat foods with a short shelf life and no kill step capability to prove that the product</p>	<p>New Zealand independent scientific organisation</p> <p>Australian and New Zealand seafood and fresh cut</p>	<p>The draft amendment includes a number of criteria for foods where the growth of <i>L. monocytogenes</i> will not occur. This includes</p> <ul style="list-style-type: none"> • the food has a refrigerated shelf life ≤ 5 days; or • the food has not had a listericidal treatment and it can be validated that the level of <i>Listeria monocytogenes</i> will not exceed 100 cfu/g throughout the food's stated shelf life. <p>This approach recognises that some foods (such as cold smoked fish) do not receive a listericidal treatment and there may be some limited growth of <i>L. monocytogenes</i>.</p> <p>Under the draft Standard 1.6.1, businesses producing such products are able to validate that the level of <i>L. monocytogenes</i> will not exceed 100 cfu /g during the product's shelf life. The product is then considered a RTE food in which the growth of <i>L. monocytogenes</i> will not occur (criteria of 100 cfu/g applies).</p>

Issue	Raised by	FSANZ Response
<p>cannot exceed 100 cfu/g at the point of consumption.</p> <p>Submissions outlined concern regarding a nil tolerance criteria for <i>L. monocytogenes</i> resulting in significant market failure for cold smoked products and fresh cut salad products, noting this may have wide reaching economic ramifications for the whole sector.</p>	<p>industries</p> <p>New Zealand Industry associations</p>	<p>FSANZ has developed, and is seeking comment on a draft guidance document (SD1) on applying the definition of RTE foods for which the growth of <i>L. monocytogenes</i> will not occur and the validation requirements for this. Businesses are responsible for considering the characteristics of their product and determining if it supports the growth or not. This would be done, as necessary, with the appropriate enforcement agency.</p>
<p>Affordability for small manufacturers</p> <p>A submission raised the cost of testing and implications for small businesses. For example, a composite presence/absence test is more affordable than an enumeration test however detection of <i>L. monocytogenes</i> may put a manufacturer into recall mode though the level may be well below 100 cfu/g.</p>	<p>New Zealand independent scientific organisation</p>	<p>The detection of <i>L. monocytogenes</i> in a RTE food that does support growth means the food would not comply with the requirements of Standard 1.6.1. This would pose a potential risk regardless that only low numbers are present (these would grow over time).</p> <p>For RTE foods that do not support the growth, the detection of low levels does not present a risk (a limit of <100 cfu/g applies). Enforcement agencies should be able to provide advice and guidance to small businesses on sampling procedures and requirements appropriate to their product and circumstance.</p>
<p>Point of application of limits</p> <p>Several submissions raised the need for clarity in Standard 1.6.1 on the point of application of microbiological limits. Specifically, whether the limits would apply at point of manufacture, point of retail, food service or end of shelf life.</p> <p>One submitter stated, for foods in which the growth of <i>L. monocytogenes</i> can occur, a limit at end-of-shelf life should be considered, and for foods that don't support the growth of <i>L. monocytogenes</i> the same limit be applied at end of manufacture/point of sale.</p>	<p>Australian and New Zealand industry</p>	<p>Limits in Standard 1.6.1 apply to foods for sale which means they apply from the point of manufacture (at the point product is intended for sale) throughout distribution and retail until the end of shelf. The "Purpose" for Standard 1.6.1 has been revised to include that limits apply to food for sale or intended for sale.</p> <p>The limits proposed for <i>L. monocytogenes</i> do apply on the basis of whether growth will or will not occur over the stated shelf life.</p>

Issue	Raised by	FSANZ Response
<p>Definitions Several submissions raised the need for definitions, particularly for ready-to-eat, shelf life, growth and listericidal treatment in the Code. This will need to be consistent across the Code.</p> <p>One submitter suggested a definition for ready-to-eat will need to consider other definitions than the two provided for RTE foods applied in NZ. The definition should be explicit as to whether it supports or does not support the growth of <i>L. monocytogenes</i>. On this basis, the definition of RTE should provide for the exclusion of categories of food where the survival of <i>L. monocytogenes</i> is highly unlikely. This would greatly assist industry to target testing where it can most effectively contribute to Listeria management</p>	<p>Government and industry</p>	<p>The draft amendment to Standard 1.1.1 provides a definition for ready-to-eat food for application throughout the Code and is appropriate to the application of limits for <i>L. monocytogenes</i>.</p> <p>The draft amendment to Standard 1.6.1 includes a clear definition for RTE foods for which growth will not occur, specifying the parameters/criteria that need to be considered. The draft guidance document provides explanatory information, clarifying for what foods testing for <i>L. monocytogenes</i> is not appropriate, what criteria applies to other RTE foods and when validation is needed to support this.</p> <p>A definition of listericidal treatment is also included.</p>
<p>Consistency across the states and territories Two submissions raised the need for consistency across states and territories to reduce inconsistent approaches from different state health authorities. One submitter raised that some states accept that a <10 count is unlikely to pose any consumer risk and some states take the approach that any detection should warrant a recall, irrelevant of shelf life, enumeration and true risk to the public.</p>	<p>Government and industry</p>	<p>The inclusion of criteria for <i>L. monocytogenes</i> for RTE food in Standard 1.6.1 will provide greater clarity for enforcement agencies as to the limit that should be applied in different circumstances provide the basis for consistent implementation.</p>

Issue	Raised by	FSANZ Response
<p>Guidance and reference criteria</p> <p>One submitter stated further clarification and guidance from FSANZ is required as to what specific protocols should be employed to demonstrate that growth of <i>Listeria</i> will not occur in a food during the expected shelf life.</p> <p>One submitter required clarification of 'reference criteria' and another sought guidance on the use of Best Before Date or Use-by Date for products that do support the growth of <i>L. monocytogenes</i> must be provided to align with revised <i>L. monocytogenes</i> limits.</p> <p>Another submitter sought guidelines for testing <i>L. monocytogenes</i> in the environment are required and for samples that are 'borderline' (10-100 cfu/g).</p>	<p>Industry and industry associations,</p>	<p>FSANZ has developed a draft guidance document (SD1) to assist with applying the definition of RTE foods for which the growth of <i>L. monocytogenes</i> will not occur and validation requirements for this. If businesses are unable to demonstrate no growth then the default criteria of "not detected" would apply (as is currently the case).</p> <p>Microbiological limits specified in Standard 1.6.1 are food safety limits that determine the acceptance of a lot or batch of food, particularly when other information about that food (e.g. GMP and GHP controls in place) may not be known.</p> <p>The 1st Call for submissions report sought comment on the need for regulatory microbiological criteria (option 2) and whether "reference limits" were adequate e.g. benchmark levels against which unacceptable microbial contamination of food can be identified and remedial action initiated when limits are exceeded. Such limits would not be developed and applied as regulatory limits in Standard 1.6.1, but as reference limits against which a business could determine the performance of their system and implement corrective actions (including recall) as appropriate.</p> <p>This approach was not supported in submissions and the development of regulatory criteria for pathogens such as <i>L. monocytogenes</i> is regarded appropriate and provides an important risk management tool.</p> <p>The safety of a food through the legally required controls in place throughout primary production and processing (as reflected in the approach taken in specifying requirements in Chapters 3 and 4 of the Code). To verify/check that such controls are working, businesses may undertake periodic microbiological testing and sampling at points along the chain, including environmental sampling which can provide useful information to the business about process control. Codex has termed this through chain approach to food safety as process hygiene criteria. FSANZ will look further at the development of process hygiene criteria as the review of microbiological limits continues and the role of limits for indicator and index microorganisms is further assessed.</p> <p>The limits for <i>L. monocytogenes</i> proposed in the draft amendment to</p>

Issue	Raised by	FSANZ Response
		<p>Standard 1.6.1 should be met through a preventative approach to food safety where food businesses implement through-chain control measures and verifying that these measures are in place and working effectively. Environmental sampling, particularly for RTE foods that support the growth of <i>L. monocytogenes</i>, should be part of this preventative approach. Sector specific guidance and requirements has been developed by state and territory enforcement agencies.</p>
<p>Phase-in period One submitter stated that if limits were included in Standard 1.6.1 for <i>L. monocytogenes</i> on the basis of whether the food is ready-to-eat and can or cannot support growth, a significant phase in period of up to 18 months would be required to enable industry to meet the new standard.</p>	<p>Australian seafood industry association</p>	<p>It is proposed that amendments to Standard 1.6.1 would come into effect on gazettal. Industry is already required to produce safe and suitable food (including with respect to <i>L. monocytogenes</i>) and limits for <i>L. monocytogenes</i> already apply to a number of foods.</p>
<p>Method of analysis Two submissions supported the need to ensure that appropriate, valid methods are used for regulatory purpose analysis.</p> <p>One submitter stated specific methodology should be nominated by specific laboratories.</p> <p>Another submitter suggested whilst the Standard 1.6.1 in the Code should not prescribe method of analysis, appropriate approval criteria for method selection be included in the Standard</p>	<p>New Zealand industry associations and New Zealand independent scientific organisation</p>	<p>The draft amendment to Standard 1.6.1 includes reference to the most recent standard methods of analysis. This reference can be routinely updated when changes occur.</p> <p>The methods referenced (including validated equivalent methods) must be used when testing a lot of food for the purposes of Standard 1.6.1 (e.g. compliance). It would be expected that other methods (including rapid methods) could also be used by industry as part of their sampling and testing program (including for environmental monitoring).</p>

2.2 Risk assessment

Listeria monocytogenes is a pathogenic bacterium which can cause invasive listeriosis, a relatively rare but often severe disease with fatality rates around 20-30%. Most often affecting individuals experiencing immunosuppression including those with chronic disease, listeriosis infection in otherwise healthy individuals generally exhibits few or no symptoms.

Foods associated with causing listeriosis have been overwhelmingly ready-to-eat (RTE) products that are typically held for extended periods at refrigerated temperatures, in which *L. monocytogenes* can grow to levels that can present a risk to consumers.

Several extensive international risk assessments have demonstrated that the risk of illness is strongly influenced by the ability of the food to support the growth of *L. monocytogenes* to high levels. Foods containing low levels (<100 cfu/g) pose very little risk, even when consumed by vulnerable individuals.

Internationally, risk-based microbiological criteria for *L. monocytogenes* in RTE foods based on whether growth can occur in a food have been established by Codex and adopted by many countries, including Canada and the European Commission.

A summary of the science/risk assessment work underpinning the criteria proposed for *L. monocytogenes* in RTE foods is provided in Supporting Document 2 (SD2).

2.3 Risk management

2.3.1 Principles for developing microbiological criteria

The Codex *Principles for the Establishment and Application of Microbiological Criteria for Foods* (CAC/GL 21 – 1997)⁷, revised in 2013, provide overarching principles for the establishment and application of microbiological criteria for foods at any point in the food chain. Australia and New Zealand participated in this revision process.

These principles informed FSANZ's approach to reviewing limits in Standard 1.6.1 of the Code. In particular:

- limits should only be included in Standard 1.6.1 where there are no other more effective tools available and where they are expected to improve the degree of protection offered to consumers (risk-based approach).
- where limits are appropriate they should be product-type specific and only applied at the point of the food chain as specified in the standard.

2.3.2 Proposed limits for *L. monocytogenes*

Increased knowledge of the factors that impact on the risk of acquiring listeriosis has permitted the classification of RTE foods on the basis of whether they can support the growth of *L. monocytogenes*. Where the growth of *L. monocytogenes* in a RTE food can occur, a not detected limit should apply:

⁷ http://www.codexalimentarius.org/?id_sta=394

Food	Microorganism/test/toxin	n	c	m
Ready-to-eat food in which the growth of <i>Listeria monocytogenes</i> can occur	<i>Listeria monocytogenes</i>	5	0	Not detected in 25g

For RTE foods in which growth will not occur, a sampling plan allowing up to 100 cfu/g can apply:

Food	Microorganism/test/toxin	n	c	m
Ready-to-eat food in which the growth of <i>Listeria monocytogenes</i> will not occur	<i>Listeria monocytogenes</i>	5	0	100 cfu/g

In classifying whether a food can support the growth of *L. monocytogenes* or not, a number of product characteristics and processing factors need to be considered. For example growth⁸ is considered not to occur in a RTE food if:

- it has a pH < 4.4 regardless of water activity; or
- it has a water activity < 0.92 regardless of pH; or
- it has a pH < 5.0 in combination with a water activity of < 0.94; or
- it has a refrigerated shelf life ≤ 5 days; or
- it is frozen (including foods consumed frozen and those intended to be thawed before consumption); or
- it can be validated that the level of *L. monocytogenes* will not increase by ≥ 0.5 log over the food's stated shelf life; or
- the food has not had a listericidal treatment and it can be validated that the level of *Listeria monocytogenes* will not exceed 100 cfu/g throughout the food's stated shelf life.

Under this approach, businesses would also be able to validate that the growth of *L. monocytogenes* will not occur in their product because, for example, they have reformulated it or applied a treatment that prevents growth.

For foods that do not receive a listericidal treatment during processing, occasional low level contamination of *L. monocytogenes* may be unavoidable. This is currently recognised in Standard 1.6.1 for ready-to-eat processed finfish for which a sampling plan for *L. monocytogenes* is specified that allows 1 in 5 samples to have 100 cfu/g (n=5, C=1, m=0, M=100). Such products could be considered a "ready-to-eat food in which the growth of *Listeria monocytogenes* will not occur" if evidence can be provided that growth is limited and would not exceed 100 cfu/g throughout the shelf life.

⁸ Growth – greater than an average of 0.5 log cfu/g increase in *L. monocytogenes* levels for at least the stated shelf life of the product.

2.3.3 Preferred option

Three options were posed for consultation in the 1st call for submissions report:

- Option 1 to include microbiological criteria 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-preferred option
- Option 2 – to delete the microbiological criteria 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 microbiological criteria in Standard 1.6.1 (status quo)

FSANZ has assessed each option and acknowledged all submissions received in the 1st call for submissions to propose an amendment to the Code based on option 1.

Maintaining the status quo (option 3) does not address the identified problems with Standard 1.6.1 and is not generally supported by submitters. No case was established for option 3 (i.e. retaining the current limits or the status quo) as shown in an analysis of this option:

- The status quo reflects a product-by-product (vertical) approach to setting limits which has meant that other ready-to-eat foods that may support the growth of *L. monocytogenes* have not been regulated equivalently.
- The current limits in Standard 1.6.1 for generic product categories (e.g. “packaged cooked cured/salted meat”) 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. This poses a disincentive for industry to reformulate products or include treatments that prevent or retard the growth of *L. monocytogenes*.
- The status quo represents an inconsistent approach between applying regulatory limits and guideline criteria such as the *Recall guidelines for packaged ready-to-eat foods found to contain Listeria monocytogenes at point of sale* (Recall Guidelines). This gives industry and regulators a lack of clarity and certainty as to corrective actions required when *L. monocytogenes* is detected at low levels (e.g. if recall is required)
- The status quo is not supported by the current risk based approach incorporated in the Codex Guidelines on the Application of General Principles of Food Hygiene to the Control of *Listeria monocytogenes* in Foods (CAC/GL 61 – 2007) and informed by the risk assessment work undertaken by the FAO/WHO Joint Expert Meeting on Risk Assessment (JEMRA) on *L. monocytogenes* in ready-to-eat foods.

The only case for retaining current limits was in relation to limits for ready-to-eat processed finfish however an approach for this sector can be accommodated through the preferred option (option 1).

Option 2 proposed that limits not be included in the Code but established as reference limits. However, this has been assessed as not being an appropriate approach and was not supported in submissions.

The role of having regulatory limits for *L. monocytogenes* in foods is recognised as an important risk management measure which works towards reducing exposure to *L. monocytogenes* and the incidence of listeriosis.

FSANZ prefers option 1 (to include microbiological criteria 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) for the following reasons:

- It is supported by the available science and is risk-based.
- It harmonises with international approaches to applying limits for *L. monocytogenes*.
- It moves from a product-by-product vertical approach to an holistic approach for the management of *L. monocytogenes*. Establishing limits across all RTE foods for *L. monocytogenes* will provide greater certainty to businesses as to when actions (such as a recall) may be required.
- It removes the current inconsistency between guidance documents (e.g. Recall Guidelines) and limits in Standard 1.6.1.

Consequently, FSANZ has decided to prepare a draft variation to Standard 1.6.1 to include microbiological criteria 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 1).

Draft amendments to Standard 1.6.1 have been prepared and are provided at Attachment A. To support this approach a guidance document *Guide to the application of limits for L. monocytogenes* has been developed and is provided as SD1.

2.4 Risk communication

2.4.1 Consultation

Consultation is a key part of FSANZ's standards development process.

The process by which FSANZ considers standards matters is open, accountable, consultative and transparent. Public submissions are called to obtain the views of interested parties on the draft variation to the Code. FSANZ places all Proposal documents and submissions on the FSANZ website. All public comments received are reviewed and considered before approval of the variation to the Code by the FSANZ Board.

FSANZ acknowledges the time taken by individuals and organisations to make submissions on this Proposal.

Every submission on an application or proposal is reviewed by FSANZ staff, who examine the issues identified and prepare a response to those issues. While not all comments may be taken on board during the process, they are valued and all contribute to the rigour of our assessment. Submissions received on the 1st call for submissions report allowed FSANZ to target industry consultations and follow up with industry visits with processed finfish manufacturers and fresh cut producers.

FSANZ also acknowledges the expertise of members of a technical advisory group comprised of experts from government, industry (including meat, dairy, smoked finfish and horticulture) and public health laboratories. This group was convened in September 2012 and in September 2013 to provide technical input into the assessment process, particularly in relation to the supporting guidance.

2.4.2 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, FSANZ's social media tools and Food Standards News.

The key message for vulnerable populations to avoid certain foods—such as cold meats, pâté, pre-packaged salads and soft cheeses—because they have a higher risk of *Listeria* contamination, remains unchanged.

In addition, specific key messages about the Proposal have been prepared to ensure stakeholders clearly understand the proposed changes. FSANZ is working with jurisdictions on these key messages to ensure consistency.

2.4.2 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.

There are relevant international standards and amending the Code to specify microbiological limits for *L. monocytogenes* in RTE foods on the basis of whether growth can occur or not is unlikely to have a significant effect on international trade as it is consistent with internationally agreed approaches. Therefore, a notification to the WTO under Australia's and New Zealand's obligations under the WTO Sanitary and Phytosanitary Measures Agreement was not considered necessary.

2.5 FSANZ Act assessment requirements

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

2.5.1 Section 59

2.5.1.1 Cost benefit analysis

In assessing Proposals such as P1017, FSANZ is required to have regard to whether the costs that would arise from a proposed measure outweigh the direct or indirect benefits of the proposed measure.

Advice from the Office of Best Practice Regulation (OBPR) (reference 13573) is that a Regulatory Impact Statement (RIS) is not needed for the proposed amendments to Standard 1.6.1 as they are unlikely to result in changes for business. This is based on the following considerations:

- All food businesses manufacturing ready-to-eat foods already have obligations to produce and sell safe food.
- Limits for *L. monocytogenes* in RTE foods provides clarity primarily to enforcement agencies as to acceptable levels of *L. monocytogenes* in RTE foods for sale, taking into consideration the nature of the product and processing factors.

Notwithstanding the above OBPR advice, a basic cost benefit analysis has been undertaken for the purposes of section 59 (see below). This is not intended to be an exhaustive, quantitative dollar analysis of the options.

Consumers: Option 1 will ensure that limits for *L. monocytogenes* are applied consistently across all RTE foods. This benefits consumers as limits for *L. monocytogenes* in Standard 1.6.1 can provide an important risk management tool for reducing exposure to *L. monocytogenes* and the incidence of listeriosis.

Government: Enforcement agencies are currently able to refer to the Recall Guidelines when *L. monocytogenes* is detected in foods for which there are no limits currently specified in Standard 1.6.1. This has led to an inconsistent approach and lack of certainty in enforcement and corrective actions to be applied (e.g. recall). Option 1 provides regulators and industry with a clear approach that can be consistently applied, particularly as to corrective actions required when *L. monocytogenes* is detected at low levels (e.g. if recall is required).

Industry: As above, Option 1 provides industry with certainty as to the level of *L. monocytogenes* that must not be exceeded to ensure food is safe and the corrective actions required. It allows the particular properties of a food and processing factors to be taken into account, providing industry with flexibility and greater incentive to, for example, reformulate products so they don't support the growth of *L. monocytogenes*.

The above suggests that the potential benefits of approving a variation outweigh the potential costs.

2.5.1.2 Other measures

There are no other measures (whether available to FSANZ or not) that would be more cost-effective than a food regulatory measure developed or varied as a result of the Proposal.

2.5.1.3 Any relevant New Zealand standards

Standard 1.6.1 establishes microbiological limits for food for sale in Australia and New Zealand.

2.5.1.4 Any other relevant matters

See below.

2.5.2. Subsection 18(1)

FSANZ has considered the three objectives in subsection 18(1) of the FSANZ Act during the assessment and in deciding to prepare a draft variation.

2.5.2.1 Protection of public health and safety

FSANZ considers that preparation of the draft variation is consistent with this objective. 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, newborn babies and the elderly.

Establishing appropriate microbiological limits for foods is an important element within a risk management framework for managing *L. monocytogenes* in the food supply.

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

The provision of adequate information relating to food is not directly relevant to the draft variation to Standard 1.6.1.

However, 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 such as 'Listeria and food advice for people at risk'. The amendment of limits for *L. monocytogenes* in Standard 1.6.1 does not impact consumer messages in relation to Listeria. However, this assessment process has identified an opportunity to review and update existing advice. FSANZ will progress this in collaboration with state and territory jurisdictions.

2.5.2.3 The prevention of misleading or deceptive conduct

No issues were identified.

2.5.3 Subsection 18(2) considerations

FSANZ has also had regard to:

- **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 P1017 and is satisfied that it reflects the best available scientific evidence.

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

The preparation of a draft variation to Standard 1.6.1 that established limits for *L. monocytogenes* in RTE foods on the basis of whether growth can occur is in line with the approach agreed internationally (through Codex).

- **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**

No issues were identified.

- **any written policy guidelines formulated by the Ministerial Council⁹.**

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

3. Draft variation

The draft variation is at Attachment A. The variation is intended to take effect on gazettal and stock in trade provisions under subclause 1(2) of Standard 1.1.1 will not apply.

A draft explanatory statement is at Attachment B. An explanatory statement is required to accompany an instrument if it is lodged on the Federal Register of Legislative Instruments.

4. References

FSANZ (2012) Our proposals to change the Code- Proposal P1017 - Criteria for *Listeria monocytogenes* – Microbiological Limits for Foods. Food Standards Australia New Zealand, Barton, ACT, Australia.
www.foodstandards.gov.au/code/proposals/Pages/proposalp1017criteri5439.aspx . Accessed 6 November 2013

FSANZ (2012) Review of microbiological limits specified in Standard 1.6.1 background paper. Food Standards Australia New Zealand, Barton, ACT, Australia.
www.foodstandards.gov.au/code/microbiolimits/ . Accessed 6 November 2013

[Food Regulation Sub Committee \(2003\) Ministerial Policy Guidelines on Food Safety Management in Australia.](http://www.foodstandards.gov.au/industry/safetystandards/programs/documents/Food_Safety_Management_in_Aust_Policy_Guidelines.pdf)
http://www.foodstandards.gov.au/industry/safetystandards/programs/documents/Food_Safety_Management_in_Aust_Policy_Guidelines.pdf . Accessed 6 November 2013

FSANZ (2001a) Recall guidelines for packaged ready-to-eat foods found to contain *Listeria monocytogenes* at point of sale. Food Standards Australia New Zealand, Barton, ACT, Australia.
<http://www.foodstandards.gov.au/publications/Pages/listeriarecallguidel5618.aspx> . Accessed 16 September 2013a

FSANZ (2001b) Guidelines for the microbiological examination of ready-to- eat foods. Food Standards Australia New Zealand, Barton, ACT.
<http://www.foodstandards.gov.au/publications/pages/guidelinesformicrobi1306.aspx> . Accessed 16 September 2013b

FSANZ (2012) P1017 1st call for submissions report. Food Standards Australia New Zealand, Barton, ACT. http://www.foodstandards.gov.au/code/proposals/documents/P1017_CFS.pdf . Accessed 14 October 2013

FSANZ (2012) P1017 submissions. Food Standards Australia New Zealand, Barton, ACT.
www.foodstandards.gov.au/code/proposals/Documents/P1017%20Submissions.zip . Accessed 6 November 2013

Codex (1997) *Principles for the Establishment and Application of Microbiological Criteria for Foods*:
www.codexalimentarius.org/download/standards/394/CXG_021e.pdf . Accessed 6 November 2013

⁹ Now known as the COAG Legislative and Governance Forum on Food Regulation

Attachments

- A. Draft variations to the *Australia New Zealand Food Standards Code*
- B. Draft Explanatory Statement

Attachment A – Draft variations to the *Australia New Zealand Food Standards Code*



Food Standards (Proposal P1017 – Criteria for *Listeria monocytogenes* – Microbiological Limits for Foods) Variation

The Board of Food Standards Australia New Zealand gives notice of the making of this variation under section 92 of the *Food Standards Australia New Zealand Act 1991*. The Standard commences on the date specified in clause 3 of this variation.

Dated [To be completed by Standards Management Officer]

Standards Management Officer
Delegate of the Board of Food Standards Australia New Zealand

Note:

This variation will be published in the Commonwealth of Australia Gazette No. FSC **XX on XX Month 20XX**. This means that this date is the gazettal date for the purposes of clause 3 of the variation.

“2 Application to stock in trade

Subclause 1(2) of Standard 1.1.1 does not apply in relation to any variation made by Food Standards (Proposal P1017 – Criteria for *Listeria monocytogenes* – Microbiological Limits for Foods) Variation.

3 Sampling of food for microbiological analysis

- (1) At the point of sampling, the number of sample units to be taken from a lot of food must be equal to the number specified in Column 3 of the Schedule in relation to the food.
- (2) An authorised officer who takes or otherwise obtains a sample of food for the purpose of submitting it for microbiological analysis –
 - (a) shall not divide that sample into separate parts; and
 - (b) where the sample consists of one or more than one sealed package of a kind ordinarily sold by retail, must submit for such analysis that sample in that package or those packages in an unopened and intact condition.
- (3) Where an authorised officer takes or otherwise obtains a sample of food which is the subject of a suspected food poisoning incident or consumer complaint, the results of an analysis conducted on such food are not invalid by reason that fewer sample units than prescribed have been analysed or that a sample unit analysed is smaller than prescribed.

4 Reference methods of analysis

The following Australian Standard (AS) and Australian New Zealand (AS/NZS) reference methods, as in force at the commencement of this provision, must be used to determine whether a food has exceeded the maximum permissible levels of foodborne microorganisms specified in the Schedule in relation to that food –

- (a) the methods prescribed by AS 5013; or
- (b) any equivalent method as determined by AS/NZS 4659; or
- (c) for packaged water, packaged ice or mineral water—AS/NZS 4276.

5 Microbiological limits in foods

- (1) A food that is listed in Column 1 of the Schedule in this Standard must comply with this Standard, including the microbiological limits set in relation to that food in the Schedule.
- (2) A food does not comply with this Standard if –
 - (a) the number of defective sample units taken from a lot of that food is greater than the number specified in Column 4 of the Schedule; or
 - (b) the level of microorganism in any sample unit taken from a lot of that food is greater than the level specified in Column 6 of the Schedule.

6 Food not supporting the growth of *Listeria monocytogenes*

For the purposes of the Schedule, the growth of *Listeria monocytogenes* will not occur in a ready-to-eat food if –

- (a) the food has a pH < 4.4 regardless of water activity; or
- (b) the food has a water activity < 0.92 regardless of pH; or
- (c) the food has a pH < 5.0 in combination with a water activity of < 0.94; or
- (d) the food has a refrigerated shelf life ≤ 5 days; or
- (e) the food is frozen (including foods consumed frozen and those intended to be thawed before consumption); or
- (f) it can be validated that the level of *Listeria monocytogenes* will not increase by > 0.5 log over the food's stated shelf life; or

- (g) the food has not had a listericidal treatment and it can be validated that the level of *Listeria monocytogenes* will not exceed 100 cfu/g throughout the food's stated shelf life.

7 Powdered infant formula products

The limit for SPC in the Schedule does not apply to powdered infant formula products that contain lactic acid producing microorganisms.”

[2.6] omitting the Schedule and substituting

“SCHEDULE

Microbiological limits in food

Column 1	Column 2	Column 3	Column 4	Column 5	Column 6
Food	Microorganism/test/toxin	n	c	m	M
Butter made from unpasteurised milk and/or unpasteurised milk products	<i>Campylobacter</i>	5	0	not detected in 25 g	10 ² cfu/g
	Coagulase-positive staphylococci	5	1	10 cfu/g	
	Coliforms	5	1	10 cfu/g	
	<i>Escherichia coli</i>	5	1	3 cfu/g	
	<i>Salmonella</i>	5	0	not detected in 25 g	
SPC	5	0	5x10 ⁵ cfu/g		
All cheese	<i>Escherichia coli</i>	5	1	10 cfu/g	10 ² cfu/g
Soft and semi-soft cheese (moisture content > 39%) with pH >5.0	<i>Salmonella</i>	5	0	not detected in 25 g	
All raw milk cheese (cheese made from milk not pasteurised or thermised)	<i>Salmonella</i>	5	0	not detected in 25 g	
Raw milk unripened cheeses (moisture content > 50% with pH > 5.0)	<i>Campylobacter</i>	5	0	not detected in 25 g	
Dried milk	<i>Salmonella</i>	5	0	not detected in 25 g	
Unpasteurised milk for retail sale	<i>Campylobacter</i>	5	0	not detected in 25 mL	10 ³ cfu/mL 9 MPN/mL
	Coliforms	5	1	10 ² cfu/mL	
	<i>Escherichia coli</i>	5	1	3 MPN/mL	
	<i>Salmonella</i>	5	0	not detected in 25 mL	
SPC	5	1	2.5x10 ⁴ cfu/mL	2.5x10 ⁵ cfu/mL	
Packaged cooked cured/salted meat	Coagulase-positive staphylococci	5	1	10 ² cfu/g	10 ³ cfu/g
Packaged heat treated meat paste and packaged heat treated pâté	<i>Salmonella</i>	5	0	not detected in 25 g	
All comminuted fermented meat which has not been cooked during the production process	Coagulase-positive staphylococci	5	1	10 ³ cfu/g	10 ⁴ cfu/g
	<i>Escherichia coli</i>	5	1	3.6 MPN/g	9.2 MPN/g
	<i>Salmonella</i>	5	0	not detected in 25 g	
Cooked crustacea	Coagulase-positive staphylococci	5	2	10 ² cfu/g	10 ³ cfu/g
	<i>Salmonella</i>	5	0	not detected in 25 g	
	SPC	5	2	10 ⁵ cfu/g	10 ⁶ cfu/g

Column 1	Column 2	Column 3	Column 4	Column 5	Column 6
Food	Microorganism/test/toxin	n	c	m	M
Raw crustacea	Coagulase-positive staphylococci	5	2	10 ² cfu/g	10 ³ cfu/g
	<i>Salmonella</i>	5	0	not detected in 25 g	
	SPC	5	2	5x10 ⁵ cfu/g	5x10 ⁶ cfu/g
Bivalve molluscs, other than scallops	<i>Escherichia coli</i>	5	1	2.3 MPN/g	7 MPN/g
Ready-to-eat food in which the growth of <i>Listeria monocytogenes</i> will not occur	<i>Listeria monocytogenes</i>	5	0	100 cfu/g	
Ready-to-eat food in which the growth of <i>Listeria monocytogenes</i> can occur	<i>Listeria monocytogenes</i>	5	0	not detected in 25 g	
Cereal based foods for infants	Coliforms	5	2	<3 MPN/g	20 MPN/g
	<i>Salmonella</i>	10	0	not detected in 25 g	
Powdered infant formula products	<i>Bacillus cereus</i> /g	5	0	100 cfu/g	
	Coagulase-positive staphylococci	5	1	Not detected in 1 g	10 cfu/g
	Coliforms	5	2	<3 MPN/g	10 MPN/g
	<i>Salmonella</i> SPC	10 5	0 2	not detected in 25 g 10 ³ cfu/g	10 ⁴ cfu/g
Pepper, paprika and cinnamon	<i>Salmonella</i>	5	0	not detected in 25 g	
Dried, chipped, desiccated coconut	<i>Salmonella</i>	10	0	not detected in 25 g	
Cocoa powder	<i>Salmonella</i>	5	0	not detected in 25 g	
Cultured seeds and grains (bean sprouts, alfalfa etc)	<i>Salmonella</i>	5	0	not detected in 25 g	
Pasteurised egg products	<i>Salmonella</i>	5	0	not detected in 25 g	
Processed egg product	<i>Salmonella</i>	5	0	not detected in 25 g	
Mineral water	<i>Escherichia coli</i>	5	0	not detected in 100 mL	
Packaged water	<i>Escherichia coli</i>	5	0	not detected in 100 mL	
Packaged ice	<i>Escherichia coli</i>	5	0	not detected in 100 mL	

[2.7] updating the Table of Provisions to reflect these variations

[3] **Standard 3.2.2** is varied by omitting the definition of **ready-to-eat food** from clause 1

[4] **Standard 4.2.5** is varied by omitting the Editorial note at the end of clause 21 and substituting

“

Editorial note:

For subclause 21(1), Standard 1.6.1 specifies microbiological limits for processed egg products for sale.

”

Attachment B – Draft Explanatory Statement

1. Authority

Section 13 of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act) provides that the functions of Food Standards Australia New Zealand (the Authority) include the development of standards and variations of standards for inclusion in the *Australia New Zealand Food Standards Code* (the Code).

Division 2 of Part 3 of the FSANZ Act specifies that the Authority may prepare a proposal for the development or variation of food regulatory measures, including standards. This Division also stipulates the procedure for considering a proposal for the development or variation of food regulatory measures.

FSANZ prepared Proposal P1017 to assess limits for *Listeria monocytogenes* in ready-to-eat food for inclusion in Standard 1.6.1. The Authority considered the Proposal in accordance with Division 2 of Part 3 and has approved a draft Standard.

2. Purpose

The Authority has approved draft amendments to Standard 1.6.1 to replace existing limits for *Listeria monocytogenes* in nominated foods with two sets of limits for *Listeria monocytogenes* in ready-to-eat foods based on whether the growth of *Listeria monocytogenes* will or will not occur in that food.

The draft amendments to Standard 1.6.1 will also address other issues identified with the Standard, including updating the reference methods of analysis, the “Purpose” of the Standard and inclusion of analytical units in the Schedule to the Standard.

3. Documents incorporated by reference

The variation to Standard 1.6.1 does incorporate by reference the following:

- microbiological methods prescribed by Australian Standard 5013 series;
- equivalent methods as determined by Australian New Zealand (AS/NZS) method 4659;
- AS/NZS 4276 method for packaged water, packaged ice or mineral water.

4. Consultation

In accordance with the procedure in Division 2 of Part 3 of the FSANZ Act, FSANZ’s consideration of P1017 requires a further round of public comment following an assessment of the Proposal and the preparation of a draft variation to Standard 1.6.1 and associated reports.

A Regulation Impact Statement has not been prepared as the proposed variations to Standard 1.6.1 are likely to have only a minor impact on business and individuals.

5. Statement of compatibility with human rights

This instrument is exempt from the requirements for a statement of compatibility with human rights as it is a non-disallowable instrument under section 94 of the FSANZ Act.

6. Variations

6.1 Item [1]

Item 1.1 inserts a definition for “ready to eat” into clause 2 of Standard 1.1.1. This definition will apply throughout the Code.

Item 1.2 amends the Glossary of symbols and units provided by the Table to clause 8 of Standard 1.1.1 to insert an entry for “cfu/mL”.

6.2 Item [2]

Item 2 amends Standard 1.6.1.

Item 2.1 amends the heading of Standard 1.6.1 from “Microbiological Limits For Food” to “Microbiological Limits in Food”.

Item 2.2 amends the Purpose of Standard 1.6.1. The new Purpose specifies microbiological food safety criteria that define the acceptability of a lot or consignment of food for sale or intended for sale. In addition it states that sampling plans and limits that a lot or consignment of food must comply with when sampled, against which compliance is assessed, are specified in the Schedule to the Standard.

Item 2.3 inserts new definitions for “listericidal treatment” and “MPN” into clause 1 of Standard 1.6.1.

Item 2.4 inserts a new definition of “microorganism” into clause 1 of Standard 1.6.1 to reflect amendments to column 2 of the Schedule to that Standard.

Item 2.5 omits clauses 2 to 5 of Standard 1.6.1 and replaces them with new clause 2 and clauses 4 to 7. Clause 3 remains the same.

New clause 2 provides that the amendments made by P1017 to Standard 1.6.1 are not subject to the stock in trade exemption provided by subclause 1(2) of Standard 1.1.1.

New clause 4 specifies the reference methods to be used to determine whether a food has exceeded the maximum permissible level of foodborne microorganisms specified in the Schedule to Standard 1.6.1.

New clause 5 provides that a food listed in Column 1 of the Schedule to Standard 1.6.1 must comply with that Standard, including the microbiological limits set out in relation to that food in the Schedule to that Standard.

New clause 6 specifies when the growth of *Listeria monocytogenes* will not occur in a ready-to-eat food for the purposes of the Schedule to Standard 1.6.1.

New clause 7 provides that the limit for SPC in the Schedule does not apply to powdered infant formula products that contain lactic acid producing microorganisms. This amendment has been included as a consequence of removing limits for “powdered infant formula products with added lactic acid producing cultures” from the Schedule as it was considered to be an unnecessary duplication of limits for “powdered infant formula products”.

Item 2.6 omits the existing Schedule to Standard 1.6.1 and replaces it with a new Schedule. The new Schedule contains the following changes:

- the title “Microbiological Criteria (clause 2)” is replaced with “Microbiological limits in food”;
- the heading under Column 2 of the Schedule is changed to “Microorganism/test/toxin” to more correctly reflect what may be included in this column;
- the units currently included in Column 2 are deleted and included under Columns 5 and 6;
- MPN is included in relation to limits based on this methodology;
- the limits for *Listeria monocytogenes* in nominated foods are deleted and replaced by limits for “Ready-to-eat food in which the growth of *Listeria monocytogenes* will not occur” and “Ready-to-eat food in which the growth of *Listeria monocytogenes* can occur”; and
- the limits for “powdered infant formula products with added lactic acid producing culture” are deleted as mentioned above.

6.3 Item [3]

Item 3 deletes the definition of “ready-to-eat food” from clause 1 of Standard 3.2.2 as this definition is now included in Standard 1.1.1.

6.3 Item [4]

Item 4 omits the Editorial Note at the end of clause 21 of Standard 4.2.5 and replaces it with a new Editorial Note to clarify that Standard 1.6.1 only specifies microbiological limits for processed egg products for sale - not regulates them.