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[09–14]

Approval Report – Proposal P1017

Criteria for *Listeria monocytogenes* – Microbiological Limits for Foods

Food Standards Australia New Zealand (FSANZ) has assessed a proposal prepared by FSANZ to revise Standard 1.6.1 with regards to criteria for *Listeria monocytogenes* limits in ready-to-eat foods.

On 8 November 2013, FSANZ sought submissions on a draft variation to Standards 1.1.1, 1.6.1, 3.2.2 and 4.2.5 and published associated reports. FSANZ received 20 submissions.

FSANZ approved the draft variation on 14 May 2014. The COAG Legislative and Governance Forum on Food Regulation¹ (Forum) was notified of FSANZ's decision on 26 May 2014.

This Report is provided pursuant to paragraph 63(1)(b) of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act).

¹ Previously known as the Australia and New Zealand Food Regulation Ministerial Council

Table of Contents

| | |
|--|-----------|
| EXECUTIVE SUMMARY | 2 |
| 1 INTRODUCTION | 3 |
| 1.1 THE PROPOSAL | 3 |
| 1.2 THE CURRENT STANDARD | 3 |
| 1.3 REASONS FOR PREPARING PROPOSAL | 3 |
| 1.4 PROCEDURE FOR ASSESSMENT | 4 |
| 1.5 DECISION | 4 |
| 2 SUMMARY OF THE FINDINGS | 4 |
| 2.1 SUMMARY OF ISSUES RAISED IN SUBMISSIONS | 4 |
| 2.2 RISK ASSESSMENT | 11 |
| 2.3 RISK MANAGEMENT | 11 |
| 2.3.1 <i>Guidance document</i> | 12 |
| 2.4 RISK COMMUNICATION..... | 12 |
| 2.4.1 <i>Consultation</i> | 12 |
| 2.4.3 <i>World Trade Organization (WTO)</i> | 13 |
| 2.5 FSANZ ACT ASSESSMENT REQUIREMENTS | 13 |
| 2.5.1 <i>Section 59</i> | 13 |
| 2.5.2 <i>Subsection 18(1)</i> | 14 |
| 6 REFERENCES | 15 |
| ATTACHMENT A – APPROVED DRAFT VARIATIONS TO THE <i>AUSTRALIA NEW ZEALAND FOOD STANDARDS CODE</i> | 17 |
| ATTACHMENT B – EXPLANATORY STATEMENT | 22 |
| ATTACHMENT C – DRAFT VARIATIONS TO THE <i>AUSTRALIA NEW ZEALAND FOOD STANDARDS CODE (CALL FOR SUBMISSIONS VERSION)</i> | 25 |
| ATTACHMENT D – DRAFT VARIATION TO THE <i>AUSTRALIA NEW ZEALAND FOOD STANDARDS CODE IN MARCH 2015 FOLLOWING P1025</i> | 30 |

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 Guidance on the application of microbiological criteria for *Listeria monocytogenes* in RTE food– Proposal P1017 (at Approval)

- SD2 Scientific basis for *Listeria monocytogenes* limits – Proposal P1017 (at Approval)

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, additional food safety requirements have been included in the Code supporting a preventative approach to food safety. Work has also progressed internationally to establish microbiological criteria for *Listeria monocytogenes* (*L. monocytogenes*) more broadly in ready-to-eat (RTE) foods.

Proposal P1017 was prepared to establish appropriate microbiological limits, for *L. monocytogenes* in RTE foods, as consistent with internationally agreed criteria. The proposal assessed two criteria for *L. monocytogenes* in RTE food, based on whether bacterial growth can occur in the food. The application of these criteria takes into account the physical and chemical characteristics of the RTE food, along with its shelf life.

FSANZ has decided to amend the Code 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* can or will not occur in the RTE food:

- RTE foods in which growth of *L. monocytogenes* will not occur (less than 100 cfu/g).
- RTE foods in which growth of *L. monocytogenes* can occur (not detected in 25 g).

This approach recognised that the potential for foods to support growth of *L. monocytogenes* 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 (less than 100 cfu/g) do not present a public health risk.

The proposal was assessed under the Major Procedure.

The approach is risk-based and flexible, supported by the evidence and is consistent with international approaches. It also addresses current inconsistencies between guidance documents (e.g. Recall Guidelines) and limits in Standard 1.6.1.

Including limits for *L. monocytogenes* in Standard 1.6.1 across a broad range of RTE foods provides a measure of certainty 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.

Amendments were also made to Standard 1.6.1 to provide contemporary reference methods of analysis and to Standard 4.2.5 to clarify an editorial note in relation to the amended Standard 1.6.1.

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

P1017 is the first stage of a broader review of limits in Standard 1.6.1.

1 Introduction

1.1 The Proposal

Proposal P1017 is the first stage of a broader review of microbiological limits in Standard 1.6.1. A background paper outlining the issues to be addressed in the review and the principles and guidelines that will underpin this work is available on the FSANZ website². The main drivers for the review have been the development of through-chain food safety requirements that support a preventative approach to food safety and work that has progressed internationally through Codex on the use of microbiological criteria and in the management of *L. monocytogenes* in foods.

Proposal P1017 was prepared to establish appropriate microbiological limits, for *L. monocytogenes* in ready-to-eat (RTE) foods, as consistent with internationally agreed criteria³. The proposal assessed two criteria for *L. monocytogenes* in RTE food, based on whether bacterial growth can occur in the food. The application of these criteria takes into account the physical and chemical characteristics of the RTE food, along with its shelf life.

Establishing appropriate microbiological limits in Standard 1.6.1 for RTE foods is an important element within a risk management framework for managing *L. monocytogenes* in the food supply. To support this approach, a draft guidance document 'Guide to the application of limits for *L. monocytogenes*' has been developed and is provided as SD1. Consequential amendments were also made to Standard 4.2.5 to improve clarity of an associated editorial note in relation to Standard 1.6.1 as amended.

1.2 The current Standard

Standard 1.6.1 lists the maximum permissible microbiological limits for nominated foods, or classes of foods. This Standard has typically adopted a vertical approach, establishing limits for specific types and limited number of foods. Regulatory limits for *L. monocytogenes* specified in Standard 1.6.1 applied to a limited number of foods and the limit generally specified was "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 was allowed in 1 out of 5 samples (sampling plan n=5, c=1, m=0, M=1).

Guideline criteria for *L. monocytogenes* in foods is also 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*.

1.3 Reasons for preparing Proposal

A number of problems were identified with the previous limits for *L. monocytogenes* in Standard 1.6.1. P1017 was prepared to:

² <http://www.foodstandards.gov.au/code/microbiollimits/Documents/20120210-reviewing-micro-limits-background-paper-word.doc>

³ Codex (2007) Guidelines on the Application of General Principles of Food Hygiene on the Control of *Listeria monocytogenes* in Foods (CAC/GL 61 - 2007). Codex Alimentarius Commission, Geneva, Switzerland.

⁴ http://www.codexalimentarius.org/download/standards/10740/CXG_061e.pdf

⁵ <http://www.foodstandards.gov.au/publications/Pages/listeriarecallguidel5618.aspx>

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

- 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 proposal also addresses inconsistencies between current regulatory limits and existing guideline criteria.
- review elements of Standard 1.6.1 that were 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.

1.4 Procedure for assessment

The proposal was assessed under the Major Procedure.

1.5 Decision

The draft variation as proposed following assessment was approved with amendments.

The variation takes effect on gazettal.

The approved draft variation, as varied after consideration of submissions, is at Attachment A. The 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.

The draft variation on which submissions were sought is at Attachment C.

2 Summary of the findings

2.1 Summary of issues raised in submissions

The 2nd Call for Submissions on proposed draft variations to the Code was from 8 November 2013 to 10 January 2014 and 20 submissions were received. One late comment was also received following the closing date from an Australian jurisdiction. The majority of the submissions were generally supportive of FSANZ's proposed option to establish microbiological criteria for *L. monocytogenes* in RTE foods based on whether the food supports growth.

Specific issues raised in relation to the proposed draft variations included:

- definitional issues
- the requirement for an improved cost benefit analysis
- issues with the proposed changes to formatting of the Schedule to Standard 1.6.1 (i.e. including analytical units in the standard where previously no units were prescribed)
- reference methods of analysis not including linkages to International Standards methods and the applicability of Australian Standards methods in New Zealand
- sampling requirements
- various implementation issues
- suggested improvements to the guidance document (SD1) and scientific basis (SD2)

Where relevant, the submissions and responses have been discussed in the body of this report and a summary of all the submissions and the response to these submissions is provided in Table 1.

Table 1: Summary of issues

| Issue | Raised by | FSANZ response (including any amendments to drafting) |
|---|--|---|
| <p>Requirement for a RIS</p> <p>FSANZ should consider undertaking a more detailed cost-benefit analysis</p> | <p>Government (enforcement agency) and an Industry Association</p> | <p>The OBPR had advised FSANZ at the beginning of the project that a RIS was unlikely to be required; this was due to the fact that food businesses manufacturing RTE foods were already under obligations to produce and sell safe food. However, FSANZ was to consult further following public consultation.</p> <p>In further consultation with OBPR following the 2nd Call for Submissions (CFS), the OBPR confirmed that the proposed changes were likely to have only a minor regulatory impact on businesses and individuals and a RIS was not required. Notwithstanding this advice, a basic cost benefit analysis was undertaken for the purposes of section 59 of the FSANZ Act.</p> |
| <p>Lack of a stock in trade provision</p> | <p>Industry Association</p> | <p>The requirement to produce safe food and effectively control pathogens such as <i>L. monocytogenes</i> has not changed. Stock-in-trade provisions (Subclause 1(2) of Standard 1.6.1) were introduced by FSANZ to allow for long shelf life foods (greater than 12 months), produced prior to an amendment to the Code, to continue to be traded under previous requirements. The definition for RTE foods, included for the purposes of Standard 1.6.1, now specifically excludes shelf-stable foods. This provision is therefore not applicable to <i>L. monocytogenes</i> limits in RTE foods.</p> <p>The stock in trade variation as proposed will now no longer be needed.</p> |
| <p>Sampling requirement</p> <p>1. The requirement to test large numbers (n=5) of separate packaged high value products (e.g. whole legs of ham) is an excessive cost to manufacturers.</p> <p>2. There may be situations where there is not enough product available for testing</p> | <p>Industry and Government</p> | <p>Proposed variations will not be progressed. There will be no change from the current standard.</p> <p>1 .Microbiological criteria contained in Standard 1.6.1 use internationally agreed sampling plans (International Commission on Microbiological Specifications for Foods) in which a minimum number of sample units are taken (generally n=5) to represent the lot. This provides an appropriate degree of confidence that a pathogen is not present or is at a safe level (based the probability of accepting or rejecting a lot of food at a given level of contamination). Testing in accordance with the sampling plan in Standard 1.6.1 is required when testing is undertaken for regulatory/compliance purposes. It would be expected that routine monitoring and verification testing is undertaken as appropriate by industry to provide the level of confidence that their food safety system is working.</p> <p>2. Alternative sampling instructions for authorised officers during a food poisoning incident or consumer complaint, enabling fewer sample units or less volume to be taken are currently specified in the standard.</p> |

| Issue | Raised by | FSANZ response (including any amendments to drafting) |
|--|--|--|
| <p>Purpose statement - Further clarity required around why microbiological limits are in the code</p> | <p>Government (enforcement agencies)</p> | <p>The intent of the purpose statement is to cover three main elements:</p> <ul style="list-style-type: none"> • Standard 1.6.1 establishes microbiological limits against which a lot of food should comply when tested for regulatory/compliance purposes. • Sampling plans are set out in the Schedule to the Standard. • Foods failing to comply with these limits should be considered to pose a risk to human health and should not be offered for sale. <p>FSANZ considered suggested wording changes in finalising this proposal.</p> |
| <p>Inclusion of amendments to other areas of Standard 1.6.1 that are NOT related to <i>L. monocytogenes</i> and RTE foods</p> <p>Concern about lack of consultation with all affected industry stakeholders</p> | <p>Industry/Industry Associations</p> | <p>Amendments to the standard that were out-dated or unclear such as the reference methods of analysis, the purpose statement for Standard 1.6.1 and the presentation of information within the Schedule to the standard were included under P1017.</p> <p>The 1st CFS report outlined that P1017 would address outdated methods, together with a number of problems that were identified with the previous limits for <i>L. monocytogenes</i> in the Code.</p> <p>The draft variation to Standard 1.6.1 at 2nd CFS did not change existing limits (other than for <i>L. monocytogenes</i>) but only sought to clarify them (e.g. including appropriate analytical units) and update methodology. However, FSANZ has noted the concerns raised by the inclusion of “MPN” in the Schedule (discussed further below) and will now not proceed with this amendment in P1017.</p> <p>FSANZ acknowledges that the title of the proposal could have better reflected a broader scope for additional changes proposed to Standard 1.6.1. Those not progressed under P1017 will be assessed in further stages of the review of Standard 1.6.1.</p> |
| <p>Inclusion of specific units describing the results of testing for indicator organisms - coliform and <i>E. coli</i> tests.</p> <p>“MPN/g” or “MPN/mL” as included in schedule</p> | <p>Industry/Industry Associations</p> | <p>The inclusion of analytical units did not change the limits or application of the standard; it only sought to clarify the basis for the previous limits set. Advice from public health laboratory experts confirms that under the existing Australian Standards (AS) methods, it would not be technically possible to obtain the limits specified for coliforms and/or <i>E. coli</i> testing (e.g. 2.3, 3.6 or 9.2) without using an MPN method.</p> <p>Concerns were noted in proposal P1025 (Code Revision), identifying issues with the inclusion of microbiological limits without having clear units specified.</p> <p>FSANZ considered at the 2nd CFS that the inclusion of “MPN” in the Schedule was important as it clarifies the basis on which these limits were set. However, concerns raised regarding consultation on this matter were noted and this amendment has been deferred for consideration in further stages of the review of Standard 1.6.1.</p> |

| Issue | Raised by | FSANZ response (including any amendments to drafting) |
|---|--|---|
| <p>Method of analysis</p> <p>1. Routine updating when reference method changes</p> <p>2. International equivalents (ISO standards)</p> | <p>Government (enforcement agencies)</p> <p>Industry Association</p> | <p>1. The draft variation to Standard 1.6.1 included reference to the standard methods of analysis as in force at the commencement of the provision. This reference can be routinely updated by FSANZ when the Code is amended through a Code Maintenance Proposal. FSANZ has now established internal procedures to ensure that this update will occur in a timely manner using the code maintenance proposals.</p> <p>2. In relation to ISO methods, the draft variation to Standard 1.6.1 was amended to also include reference to the applicable ISO methods. It is noted that AS5013 methods are based on, and are almost identical, to the corresponding ISO methodology.</p> <p>The methods referenced (which also provide for alternative equivalent methods following validation) provide the basis on which the limits in the Schedule are set and must be used when testing a lot of food for the purposes of Standard 1.6.1 (i.e. regulatory/compliance testing). It would be expected that other methods (including rapid methods) would be used by industry as part of their routine sampling and testing program (including for environmental monitoring).</p> |
| <p>Definition of RTE food</p> <p>Consideration should be given to using the Codex definition.</p> <p>Including the definition for RTE in Standard 1.1.1 could be problematic - definitions should be provided as appropriate where they apply.</p> <p>The scope of foods captured is too broad for <i>Lm</i> limits.</p> | <p>Industry/Industry Associations and Government</p> | <p>It was noted there are a number of other definitions within the Code (e.g. Standard 4.2.3, Standard 3.3.1) which define RTE foods specifically for the purpose of those particular standards. Therefore, the definition for RTE food was removed from being a draft variation to Standard 1.1.1.</p> <p>The draft variation to Standard 1.6.1 was amended instead to include a definition of RTE foods for the purposes of that standard and the application of limits for <i>L. monocytogenes</i>. This definition specifies that <i>L. monocytogenes</i> limits were not intended to apply to shelf stable foods or commodities such as raw whole fruits and vegetables, nuts in the shell and live bivalve molluscs.</p> |

| Issue | Raised by | FSANZ response (including any amendments to drafting) |
|--|-----------------------------------|--|
| Definitions including: <ul style="list-style-type: none"> • Microorganism, 'test' • Listericidal treatment • Authorised officer • 'toxin' in relation to microorganism | Government/Industry Association | <p>The proposed definitional change of “microorganism” was provided for the purposes of paragraph 5(b), to capture the elements (e.g. SPC) of column 2 of the Schedule that were not technically considered a microorganism but instead were considered a test for microorganisms. However, the inclusion of the word ‘test’ was noted as an inappropriate inclusion in a definition for microorganism. The proposed variation will not proceed at this time.</p> <p>The draft variation to Standard 1.6.1 was amended to include a definition for “listericidal process”.</p> <p>This definition of Authorised officer sits within State and Territory legislation. This matter is being considered via proposal P1025. No changes will be made to clause 3 and ‘sampling of foods for microbiological analysis’ under P1017.</p> <p>The inclusion of ‘toxin’ was to reflect that limits for toxins (e.g. <i>Staphylococcus aureus</i> enterotoxin) could be included in the Schedule in the future. However, as there are currently no toxin tests listed, this term was deleted from the draft variation to Standard 1.6.1.</p> |
| Suggestion of including definitions of ‘growth’ and ‘lot’ | Government | <p>Growth is inherent in the wording of paragraph 6(1)(f) of the draft variation to Standard 1.6.1: “the level of <i>Listeria monocytogenes</i> will not increase by greater than 0.5 log cfu/g for at least the expected shelf life.”</p> <p>‘Lot’ - is defined in the Code in Standard 1.1.1.</p> |
| Inconsistencies between P1025 and P1017 - confusion | Industry Association/Government | <p>P1017 and P1025 are separate proposals. It is proposed that the revised Code that is anticipated as the outcome of P1025 will be amended in March 2015 to include variations made in this Proposal P1017. A draft instrument outlining the variation that is likely to be required is at Attachment D.</p> |
| Criteria for growth Questions raised in relation to criteria included (or not) in the standard: <ul style="list-style-type: none"> • defined shelf life (5 days) • frozen foods • growth • should shelf stable foods be excluded | Government (enforcement agencies) | <p>The parameters against which the growth of <i>L. monocytogenes</i> does not occur have been established by Codex and supported by the scientific literature.</p> <p>Further information supporting the criteria was provided in the guidance document.</p> <p>A definition for RTE food was included in the draft variation to Standard 1.6.1 that excludes shelf stable products.</p> |
| Removal of the entry for infant formula with added lactic acid bacteria | NZ Government | <p>FSANZ assessed that there was a duplication of limits for infant formula products containing added lactic acid bacteria (this product already covered by the limits for infant formula) and the reason the limits were removed was specified in the draft explanatory statement. As Standard 1.6.1 limits apply to food for sale, or intended for sale, a limit for SPC in a final product containing added lactic acid bacteria would be inappropriate.</p> |

| Issue | Raised by | FSANZ response (including any amendments to drafting) |
|---|--|--|
| Inclusion of limits for foods intended for vulnerable populations | NZ Government Industry | <p>FSANZ has assessed that this is an implementation issue and that foods for vulnerable populations is best addressed in Australia through the food safety program requirements under Standard 3.3.1 and associated specific guidance to businesses. Specific measures for the management of <i>L. monocytogenes</i> can be implemented and verified through those requirements. In New Zealand, the Ministry for Primary Industry's 'Listeria risk management strategy' including the document "Guidance for the Control of <i>Listeria monocytogenes</i> in ready-to-eat foods" provides guidance in relation to microbiological levels for <i>L. monocytogenes</i> in foods intended for consumption by vulnerable groups.</p> <p>To specifically address risks to vulnerable populations, targeted communications/ the provision of information about foods or practices that increase the risk of them acquiring listeriosis is the preferred risk management approach (see below).</p> |
| FSANZ to continue to work with the government food communicators group to develop key messages | Government/Dietitians Association of Australia (DAA) | <p>A review of existing materials and the development of new resources in this area have been proposed to ensure nationally-consistent messages around reducing the risks of listeriosis in the community are up to date and relevant.</p> |
| Role of indicator organisms and limits for organisms that do not necessary reflect food safety concerns | NZ Government | <p>There are a number of limits for indicator organisms and tests (e.g. coliforms, <i>E. coli</i>, SPC) in Standard 1.6.1 which would be better used as process hygiene criteria (guidance criteria). FSANZ will address the issue of the role of indicator tests in a further stage of the review of Standard 1.6.1.</p> |
| Food regulators should not be required to act as an advisory body to businesses Additional support and guidance requested for regulatory authorities Additional inclusions suggested for SD1 | Government (enforcement agencies) | <p>FSANZ has produced a guidance document on the application of microbiological criteria for <i>L. monocytogenes</i> in RTE foods.</p> <p>Various other activities are currently ongoing (via the Implementation Subcommittee for Food Regulation) to revise and/or develop additional guidance material on <i>L. monocytogenes</i> control and management guidelines, including:</p> <ul style="list-style-type: none"> • 'National Guidelines – Pathogen Management' • 'Regulatory guidelines for the control of <i>Listeria</i>' • development of more generic guidance materials for the control of <i>L. monocytogenes</i> applicable to other sectors producing ready-to-eat food not covered by the industry specific documents stated above (e.g. seafood and horticulture) <p>Industry groups/associations also support food manufacturers. For example, Meat and Livestock Australia (MLA) Limited has produced guidance for industry on <i>Listeria</i> control, testing and validation.</p> |

| Issue | Raised by | FSANZ response (including any amendments to drafting) |
|---|---|--|
| <p>SD1 – Guidance document</p> <p>Lack of clarity around the types of products intended to be captured</p> | <p>Government, Industry and Industry Associations</p> | <p>The draft variation to Standard 1.6.1 was amended to include a definition of RTE foods for the purposes of that standard and the application of limits for <i>L. monocytogenes</i>. This definition specifies that <i>L. monocytogenes</i> limits are not intended to apply to shelf stable foods or commodities such as raw whole fruits and vegetables, nuts in the shell and live bivalve molluscs.</p> <p>Typographical and language improvements have been made to the document.</p> |
| <p>SD2 – Scientific basis document</p> | <p>Industry Associations</p> | <p>FSANZ has considered and referenced suggested additional international risk assessments and risk management models.</p> <p>Small typographical errors were also rectified.</p> |

2.2 Risk assessment

L. 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 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.

A summary of the science/risk assessment work underpinning the criteria proposed for *L. monocytogenes* in RTE foods is provided in Supporting Document 2 to the 2nd Call for Submissions document.

2.3 Risk management

Following consideration of the assessment findings, a basic cost-benefit analysis and the issues raised during consultation, FSANZ has approved the draft variation to Standard 1.6.1. The variation includes microbiological criteria for *L. monocytogenes* on the basis of whether the food is ready-to-eat and can or cannot support its growth.

This draft variation to Standard 1.6.1:

- is supported by the available science and is risk-based
- harmonises with international approaches to applying limits for *L. monocytogenes*
- moves from a product-by-product vertical approach to a holistic, risk-based approach for the management of *L. monocytogenes*. Taking into account individual product and processing characteristics. 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.
- removes the current inconsistency between guidance documents (e.g. Recall Guidelines) and microbiological limits in Standard 1.6.1.

A definition for “ready-to-eat food’ has now been included within Standard 1.6.1 which excludes foods that have clearly received a processing step to reduce potential *L. monocytogenes* contamination to safe levels (e.g. canned/retorted products), or are not intended to be captured due to their inherent characteristics (e.g. dry products such as biscuits, nuts). This inclusion is intended to provide clarity that the intent of the Standard is to capture higher-risk RTE foods.

FSANZ has also included reference to ISO standards as prescribed by the International Organization for Standardization (on which the Australian Standards are based), in addition to the specification of the Australia Standards AS5013 series.

FSANZ has also replaced the proposed definition of listericidal treatment with a definition of “listericidal process”, being defined as “a process that reduces *Listeria monocytogenes* microorganisms to a safe level”.

FSANZ has revised the subclause (in clause 6) to more clearly capture products such as fresh cut horticultural produce and RTE refrigerated processed finfish, thereby providing examples of products that are not expected to support the growth of *L. monocytogenes* to levels over 100 cfu/g.

The draft variations to Standard 1.6.1 also included consequential amendments due to other elements that were out-dated, inconsistent or unclear such as definitions, reference methods of analysis and the purpose of Standard 1.6.1. A clarification of an editorial note in Standard 4.2.5 is also included.

2.3.1 Guidance document

To support the limits for *L. monocytogenes* in RTE foods, a guidance document was provided for authorities and producers of RTE food. Following consultation, it was amended to further clarify the purpose and application of these limits. This document is provided as SD1.

2.4 Risk communication

2.4.1 Consultation

FSANZ developed a communication strategy for this proposal. As part of this strategy web material was prepared and updated as needed to communicate proposed changes to stakeholders.

Calls for submissions were promoted using media releases, social media and publications, such as Food Standards News.

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 was considered by the FSANZ Board. All comments are valued and contribute to the rigour of our assessment. Where relevant, the submissions and responses have been discussed in the body of this report and a summary of all the submissions and the response to these submissions is provided in Table 1.

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 again in September 2013, to provide technical input to the assessment process, particularly in relation to the supporting guidance documents.

2.4.2 Communication

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. A review of existing materials, such as 'Listeria in food – advice for people at risk' is proposed.

In addition, specific key messages about the Proposal were prepared to ensure stakeholders clearly understand the proposed changes. FSANZ has worked with jurisdictions on these key messages to ensure consistency.

2.4.3 World Trade Organization (WTO)

As members of the World Trade Organization (WTO), Australia and New Zealand are obligated to notify WTO member nations where proposed mandatory regulatory measures are inconsistent with any existing or imminent international standards and the proposed measure may have a significant effect on trade. The draft variation to Standard 1.6.1 is consistent with the risk management approach agreed internationally (through Codex) and therefore it was considered not necessary to consult WTO.

2.5 FSANZ Act assessment requirements

2.5.1 Section 59

2.5.1.1 Cost benefit analysis

FSANZ is required to have regard to whether the direct and indirect benefits that would arise from a food regulatory measure developed or varied as a result of this proposal outweigh the costs to the community, Government or industry of the proposed measure.

The Office of Best Practice Regulation (OBPR) (reference 13573) advised that a Regulation Impact Statement was not needed for the proposed amendments to Standard 1.6.1 as they were unlikely to result in changes for business and likely to have a minor regulatory impact on business and individuals. This was based on the following considerations:

- All food businesses manufacturing RTE 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 OPBR advice, a basic qualitative cost benefit analysis was undertaken for the purposes of section 59. This analysis is not intended to be exhaustive and quantification of alternatives has not been undertaken. The following benefits and costs appear to exist for the following groups when the proposed approach is compared against the status quo.

Consumers: Benefits – The amended Standard 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.
Costs – Additional costs are unlikely to be experienced by consumers.

Government: Benefits – 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. food recall). The draft variation 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).

Costs – Regulators are unlikely to experience additional costs associated with enforcing the amended limits.

Industry: Benefits – The amended Standard 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 providing a risk-based approach 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*. This approach is also consistent with internationally agreed criteria.
Costs – Industry is unlikely to incur additional costs.

On the basis of the simple analysis above, benefits will almost certainly exceed 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

There are no other relevant matters.

2.5.2 Subsection 18(1)

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

2.5.2.1 Protection of public health and safety

FSANZ considered the preparation of the draft variation to be 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, new-born babies and the elderly. Establishing appropriate microbiological limits for foods is an important element within a wider 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'⁶. 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.

⁶ <http://www.foodstandards.gov.au/consumer/safety/listeria/documents/listeria-1.pdf>

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**

FSANZ has had regard to international risk assessment work when assessing P1017 and is satisfied that it reflects 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
- **the promotion of consistency between domestic and international food standards**

The draft variation to Standard 1.6.1 is consistent with the risk management 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 Council⁷.**

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

6 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.
<http://www.foodstandards.gov.au/code/proposals/Pages/proposalp1017criteri5439.aspx>. Accessed 6 November 2013

⁷ Now known as the COAG Legislative and Governance Forum on Food Regulation

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. 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/listeriarecallguide15618.aspx>. Accessed 16 September 2013

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 2013

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

Attachments

- A. Approved draft variations to the *Australia New Zealand Food Standards Code* (final version)
- B. Explanatory Statement
- C. Draft variations to the *Australia New Zealand Food Standards Code* (call for submissions version)
- D. Draft variation to the *Australia New Zealand Food Standards Code* in March 2015 following P1025

Attachment A – Approved 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.

1 Name

This instrument is the Food Standards (*Proposal P1017 – Criteria for Listeria monocytogenes – Microbiological Limits for Foods*) Variation.

2 Variations to Standards in the *Australia New Zealand Food Standards Code*

The Schedule varies Standards in the *Australia New Zealand Food Standards Code*.

3 Commencement

The variations commence on gazettal.

SCHEDULE

[1] Standard 1.6.1 is varied by

[1.1] omitting the heading of the Standard “MICROBIOLOGICAL LIMITS FOR FOOD” and substituting “MICROBIOLOGICAL LIMITS IN FOOD”

[1.2] omitting the Purpose and substituting

“Purpose

This Standard specifies the microbiological food safety criteria which determine the acceptability of a lot or consignment of food for sale or intended for sale. The Schedule to the Standard sets out sampling plans and the limits that a lot or consignment of food must comply with. Foods that fail to meet these limits may pose a risk to human health and must not be offered for sale.”

[1.3] inserting in clause 1, in alphabetical order

“**listericidal process** means a process that reduces *Listeria monocytogenes* microorganisms in the food to a safe level.”

“**ready-to-eat food** means a food that –

- (a) is ordinarily consumed in the same state as that in which it is sold; and
- (b) will not be subject to a listericidal process before consumption; and
- (c) is not one of the following –
 - (i) shelf stable foods;
 - (ii) whole raw fruits;
 - (iii) whole raw vegetables
 - (iv) nuts in the shell;
 - (v) live bivalve molluscs.”

[1.4] omitting subclause 2(2) and substituting

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

[1.5] omitting clause 4 and substituting

“4 Reference methods of analysis

(1) The following reference methods must be used to determine whether a food has exceeded the maximum permissible levels of microorganisms specified in the Schedule in relation to that food –

- (a) for a food other than packaged water, packaged ice or mineral water –

- (i) the relevant method prescribed by Australian Standard AS5013; or
- (ii) the relevant method referenced by Australian Standard AS5013 and prescribed by the International Organization for Standardization; or
- (iii) any equivalent method as determined by –

- (A) Australian New Zealand Standard AS/NZS 4659; or
- (B) ISO 16140:2003; and

- (b) for packaged water, packaged ice or mineral water—the relevant method prescribed by Australian New Zealand Standard AS/NZS 4276.

(2) A reference to a Standard in subclause (1) is a reference to that Standard as in force at the commencement of this provision.”

[1.6] inserting after clause 5

“6 Food in which growth of *Listeria monocytogenes* will not occur

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

- (a) the food has a pH less than 4.4 regardless of water activity; or
- (b) the food has a water activity less than 0.92 regardless of pH; or
- (c) the food has a pH less than 5.0 in combination with a water activity of less than 0.94; or
- (d) the food has a refrigerated shelf life no greater than 5 days; or
- (e) the food is frozen (including foods consumed frozen and those intended to be thawed immediately before consumption); or
- (f) it can be validated that the level of *Listeria monocytogenes* will not increase by greater than 0.5 log cfu/g over the food’s stated shelf life.

(2) For the purposes of the Schedule, a ready-to-eat food that does not receive a listericidal process during manufacture is taken to be a food in which growth of *Listeria monocytogenes* will not occur if the level of *Listeria monocytogenes* will not exceed 100 cfu/g within the food’s expected shelf life.

(3) For the purposes of subclause (2), a ready-to-eat food that does not receive a listericidal process during manufacture is taken to include –

- (a) ready-to-eat processed finfish; and
- (b) fresh cut and packaged horticultural produce.”

[1.7] omitting the Schedule and substituting

“SCHEDULE

Microbiological limits in food

| Column 1 | Column 2 | Column 3 | Column 4 | Column 5 | Column 6 |
|--|----------------------------------|----------|----------|----------------------|--------------------|
| Food | Microorganism | n | c | m | M |
| Butter made from unpasteurised milk and/or unpasteurised milk products | <i>Campylobacter</i> | 5 | 0 | not detected in 25 g | |
| | Coagulase-positive staphylococci | 5 | 1 | 10 /g | 10 ² /g |
| | Coliforms | 5 | 1 | 10 /g | 10 ² /g |
| | <i>Escherichia coli</i> | 5 | 1 | 3 /g | 9 /g |
| | <i>Salmonella</i> | 5 | 0 | not detected in 25 g | |

| Column 1 | Column 2 | Column 3 | Column 4 | Column 5 | Column 6 |
|---|----------------------------------|----------|----------|-----------------------|-----------------------|
| Food | Microorganism | n | c | m | M |
| | SPC | 5 | 0 | 5×10^5 /g | |
| All cheese | <i>Escherichia coli</i> | 5 | 1 | 10 /g | 10^2 /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 /mL 9 /mL |
| | Coliforms | 5 | 1 | 10^2 /mL | |
| | <i>Escherichia coli</i> | 5 | 1 | 3 /mL | |
| | <i>Salmonella</i> | 5 | 0 | not detected in 25 mL | |
| | SPC | 5 | 1 | 2.5×10^4 /mL | 2.5×10^5 /mL |
| Packaged cooked cured/salted meat | Coagulase-positive staphylococci | 5 | 1 | 10^2 /g | 10^3 /g |
| | <i>Salmonella</i> | 5 | 0 | not detected in 25 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 /g | 10^4 /g |
| | <i>Escherichia coli</i> | 5 | 1 | 3.6 /g | 9.2 /g |
| | <i>Salmonella</i> | 5 | 0 | not detected in 25 g | |
| Cooked crustacea | Coagulase-positive staphylococci | 5 | 2 | 10^2 /g | 10^3 /g |
| | <i>Salmonella</i> | 5 | 0 | not detected in 25 g | |
| | SPC | 5 | 2 | 10^5 /g | 10^6 /g |
| Raw crustacea | Coagulase-positive staphylococci | 5 | 2 | 10^2 /g | 10^3 /g |
| | <i>Salmonella</i> | 5 | 0 | not detected in 25 g | |
| | SPC | 5 | 2 | 5×10^5 /g | 5×10^6 /g |
| Bivalve molluscs, other than scallops | <i>Escherichia coli</i> | 5 | 1 | 2.3 /g | 7 /g |
| Ready-to-eat food in which growth of <i>Listeria monocytogenes</i> will not occur | <i>Listeria monocytogenes</i> | 5 | 0 | 10^2 cfu/g | |

| Column 1 | Column 2 | Column 3 | Column 4 | Column 5 | Column 6 |
|--|----------------------------------|----------|----------|--|--------------------|
| Food | Microorganism | n | c | m | M |
| Ready-to-eat food in which 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 <i>Salmonella</i> | 5 10 | 2 0 | less than 3 /g not detected in 25 g | 20 /g |
| Powdered infant formula products | <i>Bacillus cereus</i> | 5 | 0 | 10 ² /g | |
| | Coagulase-positive staphylococci | 5 | 1 | not detected in 1 g | 10 /g |
| | Coliforms | 5 | 2 | less than 3 /g | 10 /g |
| | <i>Salmonella</i> | 10 | 0 | not detected in 25 g | |
| | SPC | 5 | 2 | 10 ³ /g | 10 ⁴ /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 | |

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

[2] **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 – 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.

Following consideration by the COAG Legislative and Governance Forum on Food Regulation⁸, section 92 of the FSANZ Act stipulates that the Authority must publish a notice about the standard or draft variation of a standard.

Section 94 of the FSANZ Act specifies that a standard, or a variation of a standard, in relation to which a notice is published under section 92 is a legislative instrument, but is not subject to parliamentary disallowance or sunseting under the *Legislative Instruments Act 2003*.

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. An editorial note in Standard 4.2.5 has also been included to improve clarity.

The draft amendments to Standard 1.6.1 will also address other issues identified with the Standard, including new definitions, updating the “Purpose” of the Standard, updating reference methods of analysis, and the movement of analytical units from Column 2 to Column 5 in the Schedule to the Standard.

3. Documents incorporated by reference

The variation to Standard 1.6.1 incorporates by reference the following:

- microbiological methods prescribed by Australian Standard 5013 series;
- microbiological methods (as referenced by AS5013 methods) and prescribed by the International Organization for Standardization;
- equivalent methods as prescribed by Australian New Zealand (AS/NZS) method 4659 and/or ISO16140:2003; and
- AS/NZS 4276 method for packaged water, packaged ice or mineral water.

⁸ Previously known as the Australia and New Zealand Food Regulation Ministerial Council

4. Consultation

In accordance with the procedure in Division 2 of Part 3 of the FSANZ Act, the Authority's consideration of Proposal P1017 included two rounds of public comment following an assessment and the preparation of a draft Standard and associated reports. Submissions were called for on 8 November 2013 for a ten-week consultation period.

A Regulation Impact Statement was not required as the proposed variations to Standard 1.6.1 were 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. Variation

6.1 Item [1]

Item 1 amends Standard 1.6.1.

Item 1.1 omits the heading of Standard 1.6.1 "MICROBIOLOGICAL LIMITS FOR FOOD" substituting with "MICROBIOLOGICAL LIMITS IN FOOD".

Item 1.2 replaces the Purpose statement of Standard 1.6.1 with a new Purpose statement. The new Purpose statement states that Standard 1.6.1 specifies the microbiological food safety criteria which determine the acceptability of a lot or consignment of food for sale or intended for sale. The Schedule to the Standard also sets out sampling plans and the limits that a lot or consignment of food must comply with. Foods that fail to meet these limits may pose a risk to human health and must not be offered for sale.

Item 1.3 inserts new definitions for "listericidal process" and "ready-to-eat food" into clause 1 of Standard 1.6.1.

Item 1.4 omits subclauses 2(2) of Standard 1.6.1 and replaces this with a new clause 2(2).

This variation has been included as a consequence of removing the 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 1.5 replaces clause 4.

New clause 4 specifies the reference methods that must be used to determine whether a food has exceeded the maximum permissible levels of foodborne microorganisms specified in the Schedule to Standard 1.6.1. This incorporates reference to both Australian Standards and international standards prescribed by the International Organization for Standardization.

Item 1.6 adds a new clause 6.

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.

Item 1.7 omits the existing Schedule to Standard 1.6.1 and replaces it with a new Schedule. The new Schedule was amended as follows:

- the title “Microbiological Criteria (clause 2)” is replaced with “Microbiological limits in food”
- the units currently included in Column 2 are deleted and included under Columns 5 and 6
- 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”
- the limits for “powdered infant formula products with added lactic acid producing culture” are deleted as mentioned above
- numerical numbering is replaced by scientific notation (e.g. 100 became 10^2) for consistency across the Schedule.

Item 1.8 updates the Table of Provisions to reflect these variations.

6.2 Item [2]

Item 2 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.

Attachment C – Draft variations to the *Australia New Zealand Food Standards Code* (call for submissions version)



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> | 10 | 0 | not detected in 25 g | |
| Pepper, paprika and cinnamon | <i>Salmonella</i> | 5 | 0 | 10 ³ cfu/g | 10 ⁴ cfu/g |
| | | 5 | 2 | 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 D – Draft variation to the *Australia New Zealand Food Standards Code* in March 2015 following P1025

Background

FSANZ is reviewing the Australian New Zealand Food Standards Code in order to improve its clarity and legal efficacy. This review is being undertaken through Proposal P1025. FSANZ released a draft revision of the Code for public comment in May 2013. The draft revision has changed the Code's structure and format. The draft instrument below reflects those changes. A further draft revision of the Code and call for submissions will be released in the near future.

The FSANZ Board is expected to consider P1025 and the proposed changes to the Code in late 2014. If approved, it is expected that the new Code will commence in 2015 and will repeal and replace the current Code. The new Code will then need to be amended to incorporate any outstanding changes made to the current Code, such as the variations proposed by P1017. This is the rationale for the draft variation below. It is provided for background only. Its content and structure may change as P1025 progresses.

Draft instrument

Food Standards Code—Variation

Made under the *Food Standards Australia New Zealand Act 1991*

1 Name of instrument

This instrument is the *Food Standards Australia New Zealand Code — Revocation and Transitional Variation 2015 (No. 1)*.

2 Commencement

This instrument commences on the day after it is registered.

3 Variation of Standard 1.1.2

Schedule 1 varies the Australia New Zealand Food Standards Code – Standard 1.1.2 – Definitions used throughout the Code.

4 Variation of Standard 1.6.1

Schedule 2 varies the Australia New Zealand Food Standards Code – Standard 1.6.1 – Microbiological limits for food.

5 Variation of Standard 4.2.5

Schedule 3 varies the Australia New Zealand Food Standards Code – Standard 4.2.5 – Primary production and processing standard for eggs.

6 Variation of Schedule 27

Schedule 4 varies the Australia New Zealand Food Standards Code – Schedule 27 – Microbiological limits for food.

Schedule 1 Variation of Standard 1.1.2

(section 3)

[1] In subsection 1.1.2—2(3), insert the following in alphabetical order:

listericidal process means a process that reduces *Listeria monocytogenes* microorganisms in the food to a safe level.

ready-to-eat food means a food that –

- (a) is ordinarily consumed in the same state as that in which it is sold; and
- (b) will not be subject to a listericidal process before consumption; and
- (c) is not one of the following –
 - (i) shelf stable foods;
 - (ii) whole raw fruits;
 - (iii) whole raw vegetables
 - (iv) nuts in the shell;
 - (v) live bivalve molluscs.

Schedule 2 Variation of Standard 1.61

(section 4)

[1] Omit subsection 1.6.1—3(5), substitute

(5) The following reference methods must be used to determine whether a food has exceeded the maximum permissible levels of microorganisms specified in the Schedule in relation to that food –

- (b) for a food other than packaged water, packaged ice or mineral water –
 - (i) the relevant method prescribed by Australian Standard AS5013; or
 - (ii) the relevant method referenced by Australian Standard AS5013 and prescribed by the International Organization for Standardization; or
 - (iii) any equivalent method as determined by –
 - (A) Australian New Zealand Standard AS/NZS 4659; or
 - (B) ISO 16140:2003; and
- (b) for packaged water, packaged ice or mineral water—the relevant method prescribed by Australian New Zealand Standard AS/NZS 4276.

(6) A reference to a Standard in subclause (5) is a reference to that Standard as in force at the commencement of this provision.

[2] insert, after section 1.6.1—3

1.6.1--4 Food in which growth of *Listeria monocytogenes* will not occur

(1) For the purposes of section S27—3, growth of *Listeria monocytogenes* will not occur in a ready-to-eat food if –

- (a) the food has a pH less than 4.4 regardless of water activity; or
- (b) the food has a water activity less than 0.92 regardless of pH; or
- (c) the food has a pH less than 5.0 in combination with a water activity of less than 0.94; or
- (d) the food has a refrigerated shelf life no greater than 5 days; or
- (e) the food is frozen (including foods consumed frozen and those intended to be thawed immediately before consumption); or
- (f) it can be validated that the level of *Listeria monocytogenes* will not increase by greater than 0.5 log cfu/g over the food's stated shelf life.

(2) For the purposes of section S27—3, a ready-to-eat food that does not receive a listericidal process during manufacture is taken to be a food in which growth of *Listeria monocytogenes* will not occur if the level of *Listeria monocytogenes* will not exceed 100 cfu/g within the food's expected shelf life.

(3) For the purposes of subclause (2), a ready-to-eat food that does not receive a listericidal process during manufacture is taken to include –

- (c) ready-to-eat processed finfish; and
- (d) fresh cut and packaged horticultural produce.

Schedule 3 Variation of Standard 4.2.5

(section 5)

[1] Omit the editorial note at the end of clause 21, substitute:

Editorial note:

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

Schedule 4 Variation of Schedule 27

(section 6)

[1] Omit the table, substitute

Microbiological limits for foods

| Column 1 | Column 2 (n) | Column 3 (c) | Column 4 (m) | Column 5 (M) |
|---|-----------------|-----------------|-------------------------|--------------------|
| <i>Butter made from unpasteurised milk and/or unpasteurised milk products</i> | | | | |
| <i>Campylobacter</i> | 5 | 0 | not detected in 25 g | |
| Coagulase-positive staphylococci | 5 | 1 | 10 /g | 10 ² /g |
| Coliforms | 5 | 1 | 10 /g | 10 ² /g |

Microbiological limits for foods (cont)

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

Microbiological limits for foods (cont)

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

Microbiological limits for foods (cont)

| Column 1 | Column 2 (n) | Column 3 (c) | Column 4 (m) | Column 5 (M) |
|---------------------------------|-------------------------|-------------------------|---------------------------|-------------------------|
| <i>Pasteurised egg products</i> | | | | |
| <i>Salmonella</i> | 5 | 0 | not detected in 25 g | |
| <i>Processed egg product</i> | | | | |
| <i>Salmonella</i> | 5 | 0 | not detected in 25 g | |
| <i>Mineral water</i> | | | | |
| <i>Escherichia coli</i> | 5 | 0 | not detected in 100 mL | |
| <i>Packaged water</i> | | | | |
| <i>Escherichia coli</i> | 5 | 0 | not detected in 100 mL | |
| <i>Packaged ice</i> | | | | |
| <i>Escherichia coli</i> | 5 | 0 | not detected in 100 mL | |