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 Legislative and Governance Forum on Food Regulation[1], 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 sunsetting 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.

[1] 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 monocytogene*s 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.