

# 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.

The Authority prepared Proposal P1039 to include food safety microbiological criteria for infant formula in Schedule 27- Microbiological limits in food. These criteria align with international (Codex) standards. The Authority considered the Proposal in accordance with Division 2 of Part 3 and has approved a draft variation.

Following consideration by the Australia and New Zealand Ministerial Forum on Food Regulation, section 92 of the FSANZ Act stipulates that the Authority must publish a notice about the 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 *Legislation Act 2003*.

## 2. Purpose

The Authority has approved the variation to Standard 1.1.2 and Schedule 27 to align the Code's food safety microbiological criteria for powdered infant formula products with international (Codex) standards.

## 3. Documents incorporated by reference

The variations to food regulatory measures do not incorporate any documents by reference.

## 4. Consultation

In accordance with the procedure in Division 2 of Part 3 of the FSANZ Act, the Authority's consideration of Proposal P1039 included one round of public consultation following an assessment and the preparation of a draft variation to the Code and an associated report. Submissions were called for on 9 October 2015 for a six-week consultation period.

A Regulation Impact Statement was not required because the proposed variations to Standard 1.1.2 and Schedule 27 are likely to have 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

Item [1] varies subsection 1.1.2—2(3) of Standard 1.1.2 by replacing the definition for **SPC**. The new definition reflects the variation made by item [2.2] below, which removes the limit for SPC in powdered infant formula from the Code.

Item [2] varies Schedule 27.

Item [2.1] replaces the Note to section 27—2 to reflect the variation made by item [1] above. The new Note refers to the amended definition of **SPC** in subsection 1.1.2—2(3) of Standard 1.1.2.

Item [2.2] omits section S27—3. Section S27—3 provides that the limit for SPC in section S27—4 does not apply to powdered infant formula products that contain lactic acid producing microorganisms. This exemption is no longer required as item [2.3] removes the limits for SPC in powdered infant formula products from the Code.

Item [2.3] replaces the table to section S27—4. The new table:

- separates the microbiological limits for powdered infant formula products into two new food categories: powdered infant formula products and powdered follow-on formula
- removes the current limits specified in the table for Coliforms, Coagulase-positive staphylococci, *Bacillus cereus* and SPC in respect of these foods
- amends the sampling plan for *Salmonella* in these foods by replacing 10 with 60 in Column 2(n) in the table
- inserts new limits for *Cronobacter* in powdered infant formula products, where the number of sample units (n) is 30, the acceptable microbiological limit (m) is 'not detected in 10g', and the number of sample units allowed to exceed that acceptable microbiological limit (c) is 0. These limits do not apply to powdered follow-on formula.

The stock-in-trade exemption provided by section 1.1.1—9 of Standard 1.1.1 does not apply to any of the above variations. See clause 3 of the instrument.