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 1 of Part 3 of the FSANZ Act specifies that the Authority may accept applications for the development or variation of food regulatory measures, including standards. This Division also stipulates the procedure for considering an application for the development or variation of food regulatory measures.

FSANZ accepted Application A1074 which seeks to reduce the minimum requirement for L-histidine in infant formula products from 12 mg/100 kJ to 10 mg/100 kJ. The Authority considered the Application in accordance with Division 1 of Part 3 and has approved a draft variation to Standard 2.9.1 – Infant Formula Products.

Following consideration by the COAG 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 a draft variation to Standard 2.9.1 to require the presence of L-histidine in infant formula products, specifically infant formula, follow-on formula and infant formula products for special dietary use, at a reduced minimum level of 10 mg/100 kJ.

A minimum requirement for L-histidine of 10 mg/100 kJ is safe and supports adequate growth in formula-fed infants. The reduced level also promotes consistency between domestic and international regulations and supports global trade of infant formula products with an overall net benefit to the community.

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 1 of Part 3 of the FSANZ Act, the Authority's consideration of Application A1074 included one round of public consultation following an assessment and the preparation of a draft variation to Standard 2.9.1 and an associated report. Submissions were called for on 8 November 2012 for a six-week consultation period.

A Regulation Impact Statement was not required because the proposed variation to Standard 2.9.1 is likely to have a minor impact on business and individuals.

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

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 [1.1]

Item [1.1] replaces the existing minimum requirement for L-histidine in infant formula products of 12 mg/100 kJ, as it appears in the Table to clause 22, with a reduced level of 10 mg/100 kJ in the same Table. The minimum requirement will continue to apply to infant formula products currently regulated under Division 2 of Standard 2.9.1, specifically infant formula and follow-on formula.

6.2 Item [1.2]

Item [1.2] replaces the existing minimum requirement for L-histidine in infant formula products for special dietary use of 12 mg/100 kJ, as it appears in the Table to clause 32, with a reduced level of 10 mg/100 kJ in the same Table. The amended requirement will continue to apply to infant formula products for special dietary use, as currently regulated under Division 3 of Standard 2.9.1.