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.

The Authority accepted Application A1098 which seeks to approve a new enzyme, serine protease (chymotrypsin), sourced from a genetically modified strain of *Bacillus licheniformis* containing the genes for chymotrypsin from *Nocardiopsis prasina* as a processing aid. The Authority considered the Application in accordance with Division 1 of Part 3 and has approved a draft Standard.

Following consideration by the Australia and New Zealand Ministerial 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 chymotrypsin produced by a genetically modified microorganism, *B. licheniformis* containing the gene for serine protease (chymotrypsin) from *N. prasina*. This requires an addition to the Table to clause 17 (Permitted enzymes of microbial origin) in Standard 1.3.3 – Processing Aids. The nomenclature for the enzyme for inclusion in Standard 1.3.3 was determined as “chymotrypsin” as this is consistent with the IUBMB naming system.

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 A1098 included one round of public consultation following an assessment and the preparation of a draft Standard and associated report. Submissions were called for on 16 January 2015 for approximately a six-week consultation period.

A Regulation Impact Statement was not required because the proposed variations to Standard 1.3.3 are likely to have a minor but beneficial impact on business and individuals.

[1] convening 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. Variation

The variation inserts a new entry into the Table to clause 17 of Standard 1.3.3. The new entry will permit the use of chymotrypsin (EC 3.4.21.1) from a genetically modified form of the microorganism *B. licheniformis*, containing the genes for chymotrypsin from *N. prasina*, as a processing aid in the production of food.