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).

FSANZ had completed a review of the Code undertaken under Proposal P1025[1] in order to improve the Code's clarity and legal efficacy. A revised Code has been approved and will commence on 1 March 2016. It will replace the existing Code, which will be repealed on that date.

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 A1099 which seeks to approve an enzyme, serine protease (trypsin), sourced from a genetically modified strain of Fusarium venenatum containing the gene for serine protease from Fusarium oxysporum, as a processing aid.

The Authority considered the Application in accordance with Division 1 of Part 3 and has approved a draft variation to Standard 1.3.3 of the existing Code.

The Authority has also approved a draft variation to Schedule 18 of the revised Code to ensure that, on 1 March 2016, the revised Code is consistent with the existing Code as amended by the draft variation.

Following consideration by the Australia and New Zealand Ministerial Forum on Food Regulation[2], section 92 of the FSANZ Act stipulates that the Authority must publish a notice about the draft variation.

Section 94 of the FSANZ Act specifies that 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. Commencement

The approved variation to the revised Code takes effect on 1 March 2016. This is the date on which the existing Code is repealed and the revised Code comes into effect.

3. Purpose

The Authority has approved trypsin (EC 3.4.21.4) produced by a genetically modified microorganism, *F. venenatum* containing the gene for serine protease (trypsin) from *F. oxysporum*. This requires the addition of a new entry into the table to subsection S18—4(5) in Schedule 18 of the revised Code. The nomenclature for the enzyme for inclusion in Standard 1.3.3 was determined as 'trypsin' as this is consistent with the IUBMB naming system.

[1] http://www.foodstandards.gov.au/code/proposals/Pages/proposalp1025coderev5755.aspx
[2] convening as the Australia and New Zealand Food Regulation Ministerial Council

4. Documents incorporated by reference

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

5. Consultation

In accordance with the procedure in Division 1 of Part 3 of the FSANZ Act, the Authority's consideration of Application A1099 included one round of public consultation following an assessment and the preparation of a draft variation 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 Application is likely to have a minor but beneficial impact on business and individuals.

6. 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] of the Schedule to the Variation amends Schedule 18 of the revised Code by inserting a new entry into the table to subsection S18—4(5).

The new entry permits the use of trypsin (EC 3.4.21.4) from a genetically modified form of the microorganism *F. venenatum*, containing the gene for trypsin from *F. oxysporum*, as a processing aid in the production of food.