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 A1184 which seeks permission to use the enzyme glucoamylase (EC 3.2.1.3) from a genetically modified (GM) strain of *Aspergillus niger* (*A. niger*) as a processing aid in starch processing and the production of potable alcohol. The Authority considered the application in accordance with Division 1 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 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 *Legislation Act 2003*.

2. Purpose

The Authority has approved a draft variation amending the table to subsection S18—9(3) of the Code to permit the use of the enzyme glucoamylase (EC 3.2.1.3), sourced from *A. niger* containing the glucoamylase gene from *Trametes cingulata* (*T. cingulata*) as a processing aid in starch processing and the production of potable alcohol.

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 A1184 included one round of public consultation following an assessment and the preparation of a draft variation and associated assessment summary. Submissions were called for on 11 February 2020 for a six-week consultation period.

The Office of Best Practice Regulation (OBPR) granted the Authority a standing exemption from needing to develop a Regulatory Impact Statement for proposed variations of the Code to permit additional processing aids (OBPR correspondence dated 24 November 2010 - reference 12065). This standing exemption was provided as permitting additional processing aids is likely to have only a minor impact on business and individuals. It is a minor, deregulatory change that allows for the introduction of a food product to the food supply that has been determined to be safe. The use of the approved processing aid is also voluntary.

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, in alphabetical order, into the table to subsection S18—9(3) of the Code.

The new entry consists of the enzyme 'Glucoamylase (EC 3.2.1.3), sourced from *Aspergillus niger* containing the glucoamylase gene from *Trametes cingulata',* for use as a processing aid in food for specific technological purposes.

The technological purposes for this enzyme are 'For use in starch processing and the production of potable alcohol'.

The permission is subject to the condition that the maximum permitted level or amount of this enzyme that may be present in the food must be consistent with good manufacturing practice.

The variation refers to 'glucoamylase', although the International Union of Biochemistry and Molecular Biology (IUBMB) uses the accepted name of 'glucan 1,4-α-glucosidase', with 'glucoamylase' being listed as an alternative name for the enzyme with EC number 3.2.1.3 (IUBMB 2017).