

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 A1096 which seeks to approve a genetically modified strain of *Bacillus licheniformis* as a source for a protein engineered variant of the enzyme endo-1,4- β -xylanase for use in the bread-making industry. The Authority considered the Application in accordance with Division 1 of Part 3 and has prepared variations to the Code.

Following consideration by the Australia and New Zealand Ministerial Forum on Food Regulation¹, 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 sunseting under the *Legislative Instruments Act 2003*.

2. Purpose

The Authority has approved a protein engineered variant of endo-1,4- β -xylanase produced by a genetically modified *B. licheniformis* as a processing aid. This requires an addition to the Table to clause 17 (Permitted enzymes of microbial origin) in Standard 1.3.3 – Processing Aids.

A further amendment to this Table is proposed to ensure the current scientific nomenclature is also applied to the enzyme when derived from other permitted sources. That is, the current entry for hemicellulase endo-1,4- β -xylanase is replaced by the name endo-1,4-beta-xylanase.

3. Documents incorporated by reference

The variations 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 A1096 included one round of public consultation following an assessment and the preparation of a draft Standard and associated report. Submissions were called for on 25 July 2014 for a six-week consultation period.

¹ convening as the Australia and New Zealand Food Regulation Ministerial Council

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.

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

Permissions for the new enzyme, being the protein engineered variant of endo-1,4-beta-xylanase, sourced from a genetically modified form of the microorganism *Bacillus licheniformis*, has been added into the Table to clause 17 of Standard 1.3.3.

The current accepted scientific common name of the enzyme is as noted above (i.e. endo-1,4- β -xylanase), which has been updated from the name currently listed in the Table for the same enzyme. Therefore changes were also made to replace the enzyme name 'hemicellulose endo-1,4- β -xylanase' with 'endo-1,4-beta-xylanase'; both with the same EC number of 3.2.1.8.

FSANZ decided to replace the ' β ' symbol with the written term 'beta' in the nomenclature for the new enzyme entries since Greek symbols in the Code are not always correctly displayed when the Code is viewed using certain types of electronic platforms.