

## 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 A1218 which seeks approval for a  $\beta$ -galactosidase (EC 3.2.1.23) enzyme derived from a new genetically modified source to be used as a processing aid in lactose reduced dairy food production. The Authority considered the Application in accordance with Division 1 of Part 3 and has approved a draft variation.

Following consideration by the Food Ministers' Meeting<sup>1</sup>, 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 *Legislation Act 2003*.

## 2. Purpose

The Authority has approved a draft variation amending the table to section S18—9(3) of the Code to permit the use of the enzyme,  $\beta$ -galactosidase (EC 3.2.1.23) sourced from *Bacillus subtilis* containing the  $\beta$ -galactosidase gene from *Lactobacillus delbrueckii* subsp.<sup>2</sup> *bulgaricus*, as a processing aid in the production of lactose reduced dairy foods.

## 3. Documents incorporated by reference

This variation does not incorporate any documents by reference.

However, section 1.1.1—15 of the Code requires certain substances (such as processing aids) to comply with any relevant identity and purity specifications listed in Schedule 3. Schedule 3 incorporates documents by reference to set specifications for various substances in the circumstances specified in that Schedule. The documents incorporated include: the Joint FAO/WHO Expert Committee on Food Additives (JECFA) Compendium of Food Additive Specifications (FAO/WHO 2017); the United States Pharmacopeial Convention (2018) Food Chemicals Codex (11th edition); and the Commission Regulation (EU) No 231/2012.

## 4. Consultation

In accordance with the procedure in Division 1 of Part 3 of the FSANZ Act, the Authority's consideration of Application A1218 included one round of public consultation following an assessment and the preparation of a draft variation and associated report. Submissions were called for on 29 April 2021 for a six-week consultation period.

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<sup>1</sup> Formerly referred to as the Australia and New Zealand Ministerial Forum on Food Regulation.

<sup>2</sup> subspecies

The Office of Best Practice Regulation (OBPR) granted the Authority a standing exemption from the requirement to develop a Regulatory Impact Statement (RIS) for applications relating to processing aids and genetically modified food (OBPR correspondence dated 24 November 2010, reference 12065). This standing exemption was provided as permitting new GM foods and new processing aids is deregulatory as their use will be voluntary if the application is approved. This standing exemption relates to the introduction of a food to the food supply that has been determined to be safe.

## **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**

**Item [1]** inserts a new entry, in alphabetical order, into the table to subsection S18—9(3) of the Code.

The new entry consists of the following substance: an enzyme, 'β-Galactosidase (EC 3.2.1.23) sourced from *Bacillus subtilis* containing the β-galactosidase gene from *Lactobacillus delbrueckii* subsp. *bulgaricus*'.

The technological purpose for using this enzyme as a processing aid is 'For use in the production of lactose reduced dairy foods'.

The permission to use this enzyme as a processing aid for the stated technological purpose 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.