



**21 March 2019**  
**[75-19]**

## Approval report – **Application A1167**

### Lactase from *Bacillus subtilis* as a PA (Enzyme)

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FSANZ has assessed an application made by DuPont Australia Pty Ltd to permit the use of Lactase ( $\beta$ -galactosidase) enzyme from *Bacillus subtilis* as a processing aid for use in dairy processing.

On 22 November 2018 FSANZ sought submissions on a draft variation and published an associated report. FSANZ received three submissions.

FSANZ approved the draft variation on 6 March 2019. The Australia and New Zealand Ministerial Forum on Food Regulation was notified of FSANZ's decision on 21 March 2019.

This Report is provided pursuant to paragraph 33(1)(b) of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act).

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### Supporting document

The [following documents](#) which informed the assessment of this application are available on the FSANZ website:

SD1 Risk and technical assessment report

## Executive summary

DuPont Australia Pty Ltd submitted an application to Food Standards Australia New Zealand (FSANZ) seeking to permit the use of the enzyme  $\beta$ -galactosidase (EC 3.2.1.23) as a processing aid. The enzyme is derived from a genetically modified strain of *Bacillus subtilis* containing the  $\beta$ -galactosidase gene from *Bifidobacterium bifidum*. Its proposed use is the production of low lactose and lactose free dairy products, and galacto-oligosaccharides (GOS).

Enzymes used to produce and manufacture food are considered processing aids and are regulated by Schedule 18 of the Australia New Zealand Food Standards Code (the Code). If approved for use, this enzyme would be listed in the table to subsection S18—9(3), which includes enzymes permitted for use for a specific technological purpose.

The FSANZ risk assessment concluded that there were no public health and safety concerns associated with using this  $\beta$ -galactosidase. In the absence of any identifiable hazard, an Acceptable Daily Intake (ADI) of 'not specified' is appropriate, which negated the need for a dietary exposure assessment.

The evidence presented to support the proposed use of the enzyme provided adequate assurance that the enzyme, in the form and prescribed amounts, is technologically justified and was demonstrated to be effective in achieving its stated purpose. The enzyme met international purity specifications.

The enzyme has been determined as Generally Recognised as Safe (GRAS) in the US and is approved in Denmark and France.

FSANZ has approved a draft variation to the Code to permit the enzyme  $\beta$ -galactosidase derived from a genetically modified strain of *B. subtilis* as a processing aid for use in the production of low lactose and lactose free dairy products and the production of GOS. This permission is subject to the condition that the amount of enzyme used must be consistent with good manufacturing practice (GMP).

# 1 Introduction

## 1.1 The applicant

The applicant is DuPont Australia Pty Ltd – A subsidiary of E. I. du Pont de Nemours and Company, a manufacturer and marketer of specialty food ingredients, food additives and food processing aids.

## 1.2 The application

FSANZ received an application from DuPont Australia Pty Ltd seeking permission for a new microbial source for the already permitted enzyme,  $\beta$ -galactosidase (EC 3.2.1.23), as a processing aid. The enzyme preparation is referred to as  $\beta$ -galactosidase in this approval report and by its proprietary name “CB108 Lactase” in the accompanying Risk and Technical Assessment Report (SD1).

The enzyme is produced by submerged fermentation of a genetically modified (GM) strain of *Bacillus subtilis* carrying the  $\beta$ -galactosidase gene from *Bifidobacterium bifidum* encoding the wild-type truncated  $\beta$ -galactosidase enzyme.

This particular  $\beta$ -galactosidase will be used in lactose-reducing enzyme preparations for certain dairy foods (e.g. milk, yogurt, cheese) at a level consistent with Good Manufacturing Practice (GMP), which limits the amount of substance that is added to food to the lowest possible level necessary to accomplish its desired effect. It is also intended for use in dairy processing, enabling the production of low lactose and lactose free dairy products. It also produces galacto-oligosaccharides (GOS), a dietary fibre, *in situ* within those foods. This  $\beta$ -galactosidase will also be used to produce GOS, which is primarily used in infant formula products.

$\beta$ -Galactosidase will be used as a processing aid at low levels and has no technical function in the final food. It has been determined as GRAS in the US and is approved in Denmark and France.

## 1.3 The current standards

Australian and New Zealand food laws require food for sale to comply with the following requirements of the Code.

### 1.3.1 Permitted use

Enzymes used to process and manufacture food are considered processing aids as although they may be present in the final food, they no longer provide a technological purpose in the final food.

Paragraph 1.1.1—10(6)(c) of the Code provides that food for sale cannot contain, as an ingredient or component, a substance ‘used as a processing aid’ or a ‘food produced using gene technology’ unless that substance’s use is expressly permitted by the Code.

Section 1.1.2—13 provides that a substance is ‘used as a processing aid’ if it is added to a food to perform a technological purpose during the course of processing of food; does not perform a technological purpose in the food for sale; and is a substance listed in Schedule 18 or a substance identified in section S16—2 as an additive permitted at GMP.

Standard 1.3.3 and Schedule 18 of the Code list the permitted processing aids. Enzymes of microbial origin permitted to be used as processing aids are listed in the table to subsection S18—4(5) or in the table to subsection S18—9(3) of Schedule 18. Enzymes of microbial origin listed in the table to subsection S18—4(5) are permitted for use as processing aid for all food. The table to subsection S18—9(3) lists those substances, including enzymes, that are permitted to be used as processing aids for specific technological purposes.

There are currently permissions for  $\beta$ -galactosidase from different microbial sources within the table to subsection S18—4(5), to be used in the manufacture of all foods. However,  $\beta$ -galactosidase from this particular microbial source, the subject of this application, is not currently permitted.

### **1.3.2 Identity and purity requirements**

Paragraph 1.1.1—15(1)(b) of the Code requires substances used as processing aids to comply with any relevant identity and purity specifications listed in Schedule 3 of the Code.

Section S3—2 of Schedule 3 incorporates by reference the specifications listed in the Joint FAO/WHO Expert Committee on Food Additives (JECFA) Compendium of Food Additive Specifications (FAO/WHO 2016) and the United States Pharmacopeial Convention (USPC) Food Chemicals Codex 11<sup>th</sup> edition (USPC 2018). These include specifications for enzyme preparations used in food processing.

### **1.3.3 International standards**

Dupont's  $\beta$ -galactosidase has been determined as GRAS in the United States and is approved in Denmark and France. It is in the process of being assessed in Canada.

The Codex Alimentarius does not establish standards for processing aids or for enzymes. Individual countries regulate the use of enzymes differently to the Code. However, there are internationally recognised specifications for enzymes. These enzyme specifications are established by the JECFA and the USPC.

## **1.4 Reasons for accepting application**

The application was accepted for assessment because:

- it complied with the procedural requirements under subsection 22(2) of the FSANZ Act
- it related to a matter that (b) warranted the variation of a food regulatory measure.

## **1.5 Procedure for assessment**

The application was assessed under the General Procedure.

## **1.6 Decision**

The draft variation proposed during assessment was approved without change. The approved draft variation is at Attachment A. The variation takes effect on the date of gazettal.

The related explanatory statement is at Attachment B. An explanatory statement is required to accompany an instrument if it is lodged on the Federal Register of Legislation.

## 2 Summary of the findings

### 2.1 Summary of issues raised in submissions

FSANZ called for submissions on a proposed draft variation on 22 November 2018. Three submissions were received from

- New Zealand Ministry for Primary Industries
- Victorian Departments of Health and Human Services and Economic Development, Jobs, Transport and Resources
- Nestlé Australia Limited, Nestlé New Zealand Limited, and Cereal Partners Australia.

All three submissions supported the application. No issues were raised by submitters.

### 2.2 Risk assessment

FSANZ concluded there are no public health or safety concerns for the general population associated with the use of  $\beta$ -galactosidase from *Bacillus subtilis* as a processing aid.

No extraneous coding genetic material is carried across from the donor organism or through the large number of steps leading to the final genetic modification. The modification involving the insertion of the lactase gene has been shown to be stably inherited.

A  $\beta$ -galactosidase with an identical amino acid sequence showed no evidence of genotoxicity in a bacterial reverse mutation assay or a chromosomal aberration assay. In a 90-day oral gavage study in rats, the NOAEL was the highest dose tested, 1000 mg/kg bw/day total protein, which is equivalent to 1416.4 mg/kg bw/day TOS. The tolerable maximum daily intake (TMDI) is calculated to be 2.25 mg/kg bw/day TOS. From these values, the Margin of Exposure (MoE) is approximately 630.

Bioinformatic data indicated a lack of homology with known toxins or allergens. Batch analyses showed that levels of wheat and soy residues from the fermentation medium were below the limit of detection in the enzyme preparation. On this basis, the risk of allergic reaction to wheat or soy in the enzyme preparation is considered low.

Based on the reviewed data it is concluded that in the absence of any identifiable hazard, an Acceptable Daily Intake (ADI) 'not specified' is appropriate. A dietary exposure assessment was therefore not required.

The food technological assessment concluded that  $\beta$ -galactosidase, in the form and prescribed amounts, is technologically justified and has been demonstrated to be effective in achieving its stated purpose.  $\beta$ -Galactosidase performs its technological purpose during production and manufacture of foods and is therefore appropriately categorised as a processing aid. The  $\beta$ -galactosidase enzyme preparation meets international purity specifications.

For further details on the risk assessment, refer to the Risk and Technical Assessment Report (SD1).

### 2.3 Risk management

The risk assessment concluded that there are no safety concerns relating to the use of  $\beta$ -galactosidase from this genetically modified strain of *B. subtilis* as a food processing aid to produce low lactose and lactose free dairy products and GOS. As processing aids require

permissions in the Code, the main risk management options available to FSANZ were to approve or reject the application to amend the Code and, if approved, to impose any conditions that may be appropriate. Other risk management issues for this application related to enzyme nomenclature and labelling, are discussed below. The regulatory options analysed in section 2.3.1 below take account of the safety of the enzyme.

$\beta$ -galactosidase will provide the food industry with an alternative source of  $\beta$ -galactosidase which the applicant states will be able to generate GOS *in situ* in raw milk and whey, even in situations where the lactose content is as low as 5%. The benefits provided are the ability to produce low lactose and lactose free dairy foods with reduced total sugars and caloric content and enable those foods to contain GOS.

### 2.3.1 Regulatory approval for enzymes

Following a safety assessment FSANZ has concluded that this  $\beta$ -galactosidase meets its stated purpose. The risk assessment has further concluded that, in the absence of any identifiable hazard, an ADI of 'not specified' is appropriate for the enzyme and ingestion of any residual  $\beta$ -galactosidase in food products is unlikely to pose an allergenicity concern.

Therefore, FSANZ approved the draft variation to permit the use of the enzyme as a processing aid for its stated purpose.

The express permission for the enzyme to be used as a processing aid in Schedule 18 will also provide permission for the enzyme's potential presence in food for sale as a food produced using gene technology. The enzyme is a food produced using gene technology for Code purposes as it is derived from 'an organism that has been modified using gene technology'. Paragraph 1.1.1—10(6)(g) requires that the presence as an ingredient or component in a food for sale of a food produced using gene technology must be expressly permitted by the Code. Section 1.5.2—3 of Standard 1.5.2 provides that permission for use as a processing aid also constitutes the permission required by paragraph 1.1.1—10(6)(g).

### 2.3.2 Enzyme and source microorganism nomenclature

The International Union of Biochemistry and Molecular Biology (IUBMB), the internationally recognised authority for enzyme nomenclature, uses the accepted name " $\beta$ -galactosidase" for the enzyme with an EC number of EC 3.2.1.23 (IUBMB 2018). This name is already listed in the table to subsection S18—4(5) and will remain as such if approved and subsequently listed in the table to subsection in S18—9(3).

The nomenclature of the host and gene donor microorganisms was checked and confirmed as being appropriate as listed in the application (see section 3.2 of SD1). The host is *Bacillus subtilis*, which is listed as either a host or source microorganism within Schedule 18, and *Bifidobacterium bifidum* is the gene donor microorganism.

### 2.3.3 Labelling requirements

Paragraph 1.1.1—10(8) of the Code provides that food for sale must comply with all relevant labelling requirements imposed by the Code for that food.

Standard 1.2.4 of the Code generally requires food products to be labelled with a statement of ingredients. Paragraph 1.2.4—3(2)(d) of that Standard exempts substances used as processing aids from the requirement to be declared in the statement of ingredients.

The risk assessment concluded that the use of the enzyme poses no public health and safety concerns and that it performs its technological purpose as a processing aid. Therefore, the

generic exemption from declaration of processing aids in the statement of ingredients will apply to foods containing this processing aid and no new labelling requirements are proposed.

### **2.3.3.1 Labelling requirements for food produced using gene technology**

Standard 1.5.2 outlines provisions for labelling of foods produced using gene technology. The enzyme is a food produced using gene technology for Code purposes. Section 1.5.2—4 indicates that labelling requirements apply to processing aids that are foods produced using gene technology, where novel DNA and/or novel protein from the processing aid remains present in the final food.

Section 1.5.2—4 requires certain foods for sale that consist of, or have as an ingredient, food that is genetically modified to be labelled as 'genetically modified'. FSANZ also notes that the Code's labelling requirements – including those imposed by section 1.5.2—4 – generally apply only to foods for retail sale and to foods sold to a caterer under subsection 1.2.1—8(1) and section 1.2.1—15, respectively. The requirements for labelling as 'genetically modified' differ depending on whether the genetically modified food is an ingredient of the food for sale or not, as follows.

If a food for retail sale or sold to a caterer contains the enzyme  $\beta$ -galactosidase as an ingredient, that food would be required to be labelled 'genetically modified' in conjunction with the name of the processing aid, if novel DNA or novel protein from the genetically modified strain of *B. subtilis* (that is the source microorganism, not the enzyme) remains in that food.

FSANZ notes the enzyme is also used as a processing aid to manufacture GOS, which is used as an ingredient of another food for sale. FSANZ's assessment is that in this instance the GOS itself is not a food produced using gene technology as, in contrast to the enzyme processing aid used for its manufacture, it is not derived from an organism that has been modified using gene technology. The requirement to label as 'genetically modified' (in relation to the processing aid or the GOS) would not apply to that food for sale because the labelling requirements only apply to food that consists of, or has as an ingredient, a GM food (section 1.5.2—4(1)).

### **2.3.3.2 Lactose claims**

Nutrition content claims and health claims made about a food prepared using the enzyme as a processing aid must meet Standard 1.2.7 – Nutrition, health and related claims. The applicant stated the enzyme is intended to be used as a processing aid in the dairy industry for making low lactose and lactose free dairy products with reduced total sugars and caloric content. Under this standard, the claims 'lactose free', 'low lactose', 'reduced sugar' and 'reduced energy' are permitted subject to composition conditions in Schedule 4. Other nutrition content claims about lactose, such as 'reduced lactose' are not permitted under Standard 1.2.7—12(5)).

### **2.3.4 Risk management conclusion**

The risk management conclusion is to add the permission for the  $\beta$ -galactosidase derived from a genetically modified strain of *B. subtilis*, as a processing aid into the table to subsection S18—9(3), which includes enzymes permitted for a specific technological purpose. The technological purpose is for use in the production of low lactose and lactose free dairy products and the production of GOS. The level of usage is an amount consistent with GMP.



The express permission for the enzymes' use as a processing aid in Schedule 18 will also provide the permission for the enzyme's potential presence in the food for sale as a food produced using gene technology.

## **2.4 Risk communication**

### **2.4.1 Consultation**

Consultation is a key part of FSANZ's standards development process. FSANZ developed and applied a basic communication strategy to this application. All calls for submissions are notified via the Food Standards Notification Circular, media release, FSANZ's social media tools and Food Standards News.

The process by which FSANZ considers standard development matters is open, accountable, consultative and transparent. Public submissions are called to obtain the views of interested parties on issues raised by the application and the impacts of regulatory options.

The draft variation will be considered for approval by the FSANZ Board taking into account public comments received from this call for submissions.

FSANZ acknowledges the time taken by individuals and organisations to make submissions on this application. Every submission on the application was considered by the FSANZ Board. All comments are valued and contribute to the rigour of our assessment.

### **2.4.2 World Trade Organization**

As members of the World Trade Organization (WTO), Australia and New Zealand are obliged to notify its members where proposed mandatory regulatory measures are inconsistent with any existing or imminent international standards and the proposed measure may have a significant effect on trade.

There are not any relevant international standards and amending the Code to permit a new microbial source of a currently permitted enzyme is unlikely to have a significant effect on international trade as Codex Alimentarius does not have regulations for enzymes used as processing aids. Therefore, a notification to the WTO under Australia's and New Zealand's obligations under the WTO Technical Barriers to Trade or Application of Sanitary and Phytosanitary Measures Agreement was not considered necessary.

## **2.5 FSANZ Act assessment requirements**

### **2.5.1 Section 29**

#### ***2.5.1.1 Consideration of costs and benefits***

The Office of Best Practice Regulation (OBPR) granted FSANZ a standing exemption from the requirement to develop a Regulatory Impact Statement for permitting new processing aids (OBPR correspondence dated 24 November 2010, reference 12065). This standing exemption was provided as permitting processing aids is machinery in nature as they are part of implementing a regulatory framework where the use of the new aids is voluntary once the application has been successfully approved. This standing exemption relates to the introduction of a food to the food supply that has been determined to be safe.

FSANZ, however, has given consideration to the costs and benefits that may arise from the

proposed measure for the purposes of meeting FSANZ Act considerations. The FSANZ Act requires FSANZ to have regard to whether costs that would arise from the proposed measure outweigh the direct and indirect benefits to the community, government or industry that would arise from the proposed measure (paragraph 29 (2)(a)).

The purpose of this consideration is to determine if the community, government and industry as a whole is likely to benefit, on balance, from a move from the status quo (i.e. rejecting the application). This analysis considers permitting the use of  $\beta$ -galactosidase derived from a genetically modified strain of *B. subtilis*, as a processing aid into the table to subsection S18—9(3) which includes enzymes permitted for a specific technological purpose. FSANZ is of the view that no other realistic food regulatory measures exist, however information received may result in FSANZ arriving at a different outcome.

The consideration of the costs and benefits in this section is not intended to be an exhaustive, quantitative economic analysis of the proposed measures and, in fact, most of the effects that were considered cannot easily be assigned a dollar value. Rather, the assessment seeks to highlight the likely positives and negatives of moving away from the status quo by permitting the use of the enzyme.

*Costs and benefits of permitting the use of enzyme  $\beta$ -galactosidase derived from a genetically modified strain of *B. subtilis* as a processing aid*

$\beta$ -Galactosidase facilitates the production of low lactose and lactose free dairy foods and is also used to produce GOS. The benefits provided are the ability to produce low lactose and lactose free dairy foods with reduced caloric content. This particular source of  $\beta$ -galactosidase is claimed by the applicant to be able to generate GOS in situ in raw milk and whey, even in situations where the lactose content is as low as 5%. Due to the voluntary nature of the permission, industry will only use the  $\beta$ -galactosidase enzyme where it believes a net benefit exists. There are other enzymes available to industry that perform similar functions and it is of benefit to industry to have additional choice available to them, especially where the enzyme is more effective or cheaper.

$\beta$ -Galactosidase has been determined as GRAS in the US and is approved in Denmark and France. The international permissions of this enzyme may be a business opportunity for Australia New Zealand industries, although there may also be competing imports from these countries into the domestic market.

There may be benefits to the consumer where cost savings from using the enzyme is passed on to customers.

Permitting the enzyme may result in a small cost to government in terms of adding the enzyme to the current range of processing aids that are monitored for compliance.

*Conclusions from cost benefit considerations*

FSANZ's assessment is that the direct and indirect benefits that would arise from permitting the use of  $\beta$ -galactosidase derived from a genetically modified strain of *B. subtilis* as an enzyme processing aid most likely outweigh the associated costs.

**2.5.1.2 Other measures**

There are no other measures (whether available to FSANZ or not) that would be more cost-effective than a food regulatory measure developed or varied as a result of the application.

### **2.5.1.3 Any relevant New Zealand standards**

Standards 1.1.1, 1.1.2 and 1.3.3 and Schedule 18 apply in both Australia and New Zealand. There are no relevant New Zealand only Standards.

### **2.5.1.4 Any other relevant matters**

Other relevant matters are considered below.

## **2.5.2. Subsection 18(1)**

FSANZ has also considered the three objectives in subsection 18(1) of the FSANZ Act during the assessment.

### **2.5.2.1 Protection of public health and safety**

FSANZ has undertaken a safety assessment (SD1) and concluded there are no public health and safety concerns with permitting the use of  $\beta$ -galactosidase sourced from *B. subtilis* containing the  $\beta$ -galactosidase gene from *B. bifidum* as a processing aid in food for the proposed purpose.

### **2.5.2.2 The provision of adequate information relating to food to enable consumers to make informed choices**

The labelling approach for the processing aid is discussed in Section 2.3.3 above. This approach is consistent with the existing provisions in the Code for the labelling of permitted processing aids.

### **2.5.2.3 The prevention of misleading or deceptive conduct**

There are no issues identified with this application relevant to this objective.

## **2.5.3 Subsection 18(2) considerations**

FSANZ has also had regard to:

### **the need for standards to be based on risk analysis using the best available scientific evidence**

FSANZ has used the best available scientific evidence to conduct the risk analysis, which is provided in SD1. The applicant submitted a dossier of scientific studies as part of the application. Other technical information identified by FSANZ, including scientific literature, was also used to assess the application.

### **the promotion of consistency between domestic and international food standards**

There are no Codex Alimentarius Standards for enzymes. However, this enzyme is determined as GRAS in the US and is approved in Denmark and France. It also meets international specifications for enzyme preparations, being the JECFA Compendium of Food Additive Specifications and the Food Chemicals Codex.

### **the desirability of an efficient and internationally competitive food industry**

Permission for the  $\beta$ -galactosidase enzyme preparation provides food manufacturers with an alternative enzyme, which should add to competition in supplying enzymes to the food

manufacturing industries.

### **the promotion of fair trading in food**

No issues were identified for this application relevant to this objective.

### **any written policy guidelines formulated by the Forum on Food Regulation**

The Ministerial Policy Guideline Addition to Food of Substances other than Vitamins and Minerals<sup>1</sup> includes specific order policy principles for substances added to achieve a solely technological function, such as processing aids. These specific order policy principles state that permission should be granted where:

- the purpose for adding the substance can be articulated clearly by the manufacturer as achieving a solely technological function (i.e. the 'stated purpose')
- the addition of the substance to food is safe for human consumption
- the amounts added are consistent with achieving the technological function
- the substance is added in a quantity and a form which is consistent with delivering the stated purpose
- no nutrition, health or related claims are to be made in regard to the substance.

FSANZ has determined that permitting the use of  $\beta$ -galactosidase sourced from *B. subtilis* containing the gene for  $\beta$ -galactosidase from *B. bifidum* as a processing aid is consistent with the specific order principles for 'Technological Function'.

## **3 References**

FAO/WHO (2016) [General specifications and considerations for enzyme preparations used in food processing](#). Accessed 29 October 2018

IUBMB (International Union of Biochemistry and Molecular Biology) [Enzyme Nomenclature for EC 3.2.1.3](#). Accessed 3 October 2018

USPC (2018) [Food Chemicals Codex 11th Edition](#), United States Pharmacopeial Convention, Rockville, MD. Accessed 31 October 2018

## **Attachments**

- A. Approved draft variation to the *Australia New Zealand Food Standards Code*
- B. Explanatory Statement

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<sup>1</sup> [Food regulation website](#)

## Attachment A – Draft variation to the *Australia New Zealand Food Standards Code*



### Food Standards (Application A1167 – Lactase from *Bacillus subtilis* as a PA (Enzyme)) Variation

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The Board of Food Standards Australia New Zealand gives notice of the making of this variation under section 92 of the *Food Standards Australia New Zealand Act 1991*. The variation commences on the date specified in clause 3 of this variation.

Dated [To be completed by Delegate]

[Insert Delegate's name and Title]

Delegate of the Board of Food Standards Australia New Zealand

**Note:**

This variation will be published in the Commonwealth of Australia Gazette No. FSC XX on XX Month 20XX. This means that this date is the gazettal date for the purposes of clause 3 of the variation.

**1 Name**

This instrument is the *Food Standards (Application A1167 – Lactase from Bacillus subtilis as a PA (Enzyme)) Variation*.

**2 Variation to a standard in the Australia New Zealand Food Standards Code**

The Schedule varies a Standard in the *Australia New Zealand Food Standards Code*.

**3 Commencement**

The variation commences on the date of gazettal.

**Schedule**

**[1] Schedule 18** is varied by inserting in the table to subsection S18—9(3), in alphabetical order

$\beta$ -Galactosidase (EC 3.2.1.23) sourced from <i>Bacillus subtilis</i> containing the gene for $\beta$ -galactosidase isolated from <i>Bifidobacterium bifidum</i> .	For use in the production of lactose reduced dairy foods and for the production of galacto-oligosaccharides.	GMP
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## Attachment B – Draft 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 A1167 which seeks to permit the use of a  $\beta$ -galactosidase enzyme from *Bacillus subtilis* as a processing aid for use in dairy processing. The Authority considered the application in accordance with Division 1 of Part 3 and has approved a draft variation to the Code.

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 sunseting under the *Legislation Act 2003*

### 2. Purpose

The Authority has approved a draft variation to permit the enzyme  $\beta$ -galactosidase sourced from *Bacillus subtilis* containing the gene for  $\beta$ -galactosidase from *Bifidobacterium bifidum*, to be used as a processing aid for use in the production of low lactose and lactose free dairy products and galacto-oligosaccharides at GMP. This permission requires an addition to the table to subsection S18—9(3) in Schedule 18.

### 3. Documents incorporated by reference

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

Existing provisions of the Code incorporate a document by reference that will prescribe identity and purity specifications for the processing aid to be permitted by the draft variation. Section 1.1.1—15 of the Code requires substances used as processing aids to comply with any relevant identity and purity specifications listed in Schedule 3 of the Code. Section S3—2 of Schedule 3 incorporates by reference the specifications listed in the Joint FAO/WHO Expert Committee on Food Additives (JECFA) Compendium of Food Additive Specifications (FAO/WHO 2016) and the United States Pharmacopeial Convention (2016) Food Chemicals Codex (10<sup>th</sup> edition). These include specifications for enzyme preparations used in food processing.

### 4. Consultation

In accordance with the procedure in Division 1 of Part 3 of the FSANZ Act, the Authority's consideration of application A1167 included one round of public consultation following assessment and the preparation of a draft variation and associated assessment summary.

Submissions were called for on 22 November 2018 for an eight-week consultation period.

A Regulation Impact Statement was not required because the proposed variations to Schedule 18 are likely to have a minor 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**

The approved draft variation inserts a new entry into the table to subsection S18—9(3) in Schedule 18.

The new entry will permit the use of the enzyme,  $\beta$ -galactosidase (EC 3.2.1.23) sourced from *Bacillus subtilis* containing the gene for  $\beta$ -galactosidase from *Bifidobacterium bifidum*, as a processing aid in food for a specific technological purpose, with the condition that the maximum permitted level or amount that may be used must be consistent with good manufacturing practice. The technological purpose is for use in the production low lactose and lactose free dairy products and galacto-oligosaccharides.