

**21 June 2018**  
**[50-18]**

Approval report – Application A1151

## $\beta$ -Galactosidase from *Papiliotrema terrestris* as a Processing Aid (Enzyme)

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Food Standards Australia New Zealand (FSANZ) has assessed an Application made by Amano Enzyme Inc. Japan to permit the use of  $\beta$ -galactosidase sourced from *Papiliotrema terrestris* strain AE-BLC as a processing aid in the production of galacto-oligosaccharide (GOS) from lactose.

On 1 March 2018, FSANZ sought submissions on a draft variation and published an associated report. FSANZ received four submissions.

FSANZ approved the draft variation on 7 June 2018. The Australia and New Zealand Ministerial Forum on Food Regulation was notified of FSANZ's decision on 18 June 2018.

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 document](#)<sup>1</sup> which informed the assessment of this Application is available on the FSANZ website:

SD1 Risk and Technical Assessment Report

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<sup>1</sup> [http://www.foodstandards.gov.au/code/applications/Pages/A1151-Beta-Galactosidase%20from%20Papiliotrema%20terrestris%20as%20a%20Processing%20Aid%20\(Enzyme\).aspx](http://www.foodstandards.gov.au/code/applications/Pages/A1151-Beta-Galactosidase%20from%20Papiliotrema%20terrestris%20as%20a%20Processing%20Aid%20(Enzyme).aspx)

## Executive summary

Amano Enzyme Inc. submitted an application to Food Standards Australia New Zealand (FSANZ) seeking permission to use the enzyme  $\beta$ -galactosidase (EC 3.2.1.23) sourced from *Papiliotrema terrestris* strain AE-BLC as a processing aid. The enzyme will be used to produce galacto-oligosaccharide (GOS) from lactose.  $\beta$ -Galactosidase breaks down lactose to produce galactose and glucose. The enzyme also causes a further reaction in galactose to form GOS, which can be used as an ingredient in foods.

The enzyme is derived from a strain of *P. terrestris* (strain AE-BLC). The Applicant states that the  $\beta$ -galactosidase derived from production strain AE-BLC has enhanced acid and temperature resistance, which makes it more useful when compared with  $\beta$ -galactosidases derived from other sources.

FSANZ's risk assessment concluded that there were no public health and safety concerns associated with using  $\beta$ -galactosidase from *P. terrestris* strain AE-BLC as a food processing aid to produce GOS from lactose. 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 information presented to support the proposed uses of the enzyme preparation provided adequate assurance that the enzyme preparation, in its commercial form and proposed levels of use, is technologically justified and effective in achieving its stated purpose. Therefore, the assessment concluded that the enzyme should be permitted for use as a processing aid. The FSANZ Board has approved a draft variation to the table to subsection S18—9(3). This will permit the use of the enzyme as a processing aid in the manufacture of GOS from lactose, 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 Amano Enzyme Inc., Japan, a producer of specialty enzymes for pharmaceuticals, diagnostic medicines, and the food industry.

## 1.2 The Application

The Application was received on 2 August 2017.

The purpose of the Application was to seek permission to use the enzyme  $\beta$ -galactosidase (EC 3.2.1.23) sourced from *Papiliotrema terrestris* strain AE-BLC as a processing aid.  $\beta$ -Galactosidase will be used in the commercial production of galacto-oligosaccharide (GOS) from lactose.

The Applicant states that GOS can be used as an ingredient in various foods for both infants and adults.

$\beta$ -Galactosidase catalyses the hydrolysis of glycosidic bonds in beta-galactosides to release galactose and glucose. The enzyme is also responsible for the transgalactosylation of galactose. In transgalactosylation, where lactose is the primary substrate, the galactose released from lactose is transferred to another lactose to form GOS. This reaction is therefore of primary commercial importance, with respect to this Application. The GOS mixture obtained is expected to contain lactose as well as GOS and monosaccharides.

The enzyme is sourced from a chemically mutated strain of *P. terrestris* (strain AE-BLC). The parent microorganism is classified as *P. terrestris* (Wild type). Strain AE-BLC is sourced from the parent strain by a conventional mutation process using N-methyl-N'-nitro-N-nitrosoguanidine. The  $\beta$ -galactosidase derived from production strain AE-BLC has enhanced acid resistance and temperature resistance, when compared with  $\beta$ -galactosidases derived from other sources.

The  $\beta$ -galactosidase enzyme preparation is sourced from *P. terrestris* strain AE-BLC through a process of fermentation. After filtration, micro-filtration and spray drying, the  $\beta$ -galactosidase enzyme powder is blended with lactose to obtain a final enzyme preparation. However, it is the  $\beta$ -galactosidase enzyme powder itself that was assessed under this Application.

The enzyme powder is inactivated by either temperature or pH changes and has no function in the final food product. The Applicant provided information about the pH and temperature for optimal enzyme activity, and advice on the temperature required to achieve enzyme inactivation.

## 1.3 The current Standard

Enzymes used to process and manufacture food are considered processing aids. Processing aids perform their technological purpose during processing and manufacture of food and do not perform a technological purpose in the final food. Only processing aids listed in Schedule 18 in the *Australia New Zealand Food Standards Code* (the Code) are permitted to be used to produce food sold in Australia and New Zealand. Permitted enzymes of microbial origin (including enzymes produced by GM microorganisms) may be listed in the table to subsection S18—4(5) or the table to subsection S18—9(3), depending on whether the

permission is for use for any technological purpose and/or any food, or for specific technological purposes and specific foods, respectively.

There is already approval for  $\beta$ -galactosidase (EC 3.2.1.23) from a range of production organisms in the Code. However, there is no permission for this enzyme derived from *P. terrestris* (strain AE-BLC) to produce  $\beta$ -galactosidase.

## **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 merited 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 as proposed following assessment was approved and is at Attachment A. The approved variation takes effect on 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 public comment on a draft variation to the Code between 1 March 2018 and 12 April 2018 after assessing the Application. Four submissions were received; one from government (Australia), one from the food industry (New Zealand), one from an organisation dealing with organic food, and one from a consumer.

The government and food industry submissions supported the Application. These submitters were satisfied that the enzyme preparation is technologically justified and presents no risk to public health and safety. However, the food industry submission included a comment about the application process more generally, expressing strong support for any actions and measures to group processing aid and food additive applications into a regular, streamlined application, assessment and approval process. This issue is broader and not specific to only this application. FSANZ considers that Part 3, Division 1 of the *Food Standards Australia New Zealand Act 1991* details the requirements for accepting, assessing and approving applications, including statutory timeframes. FSANZ must manage applications submitted to FSANZ in accordance with its statutory requirements.

The other two submissions expressed concerns about whether the process used to generate the production strain involved gene technology. One submission stated that all forms of genetic manipulation except traditional breeding methods should be clearly labelled as genetically modified organisms (GMOs). The other submission referred to the definition of gene technology in the *Gene Technology Act 2000*, and stated that all gene technology must be regulated and labelled to enable consumer choice.

The Application seeks permission to use the enzyme  $\beta$ -galactosidase sourced from a chemically mutated strain of *P. terrestris* (strain AE-BLC). Chemical mutagenesis is a conventional process that has been in use for many decades, especially as a traditional breeding technique for food crops, and has a long history of safe use. FSANZ considers that the process used to generate the *P. terrestris* production strain does not meet the definition of gene technology in the Code. On this basis the  $\beta$ -galactosidase sourced from this strain does not require regulation or labelling as a food component derived from a GMO.

Reference to the *Gene Technology Act 2000* is also made by one of the submitters. This Act is administered by the Office of the Gene Technology Regulator (OGTR) and does not apply to FSANZ. Notwithstanding this, the Act specifically excludes induced-mutagenesis techniques like chemical mutagenesis, from the definition of gene technology.

## 2.2 Risk assessment

FSANZ's risk assessment concluded that there are no public health and safety concerns associated with using  $\beta$ -galactosidase from *P. terrestris* strain AE-BLC as a food processing aid to produce GOS from lactose.

*P. terrestris* strain AE-BLC was not pathogenic *in vivo* and not toxigenic *in vitro*.  $\beta$ -Galactosidase from *P. terrestris* was not genotoxic and did not cause adverse effects in a subchronic toxicity study in rats. The enzyme does not have the characteristics of a potential food allergen and ingestion of any residual  $\beta$ -galactosidase in food products is unlikely to pose an allergenicity concern.

In the absence of any identifiable hazard an Acceptable Daily Intake 'not specified' is appropriate. A dietary exposure assessment was therefore not required.

The evidence presented to support the proposed uses provides adequate assurance that the enzyme, in the form and prescribed amounts, is technologically justified and has been demonstrated to be effective in achieving its stated purpose. The 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 public health and safety concerns from the use of  $\beta$ -galactosidase, sourced from a chemically mutated strain of *P. terrestris* (strain AE-BLC), as a processing aid to produce GOS from lactose. As processing aids require permissions in the Code, the main risk management option available to FSANZ is to approve or reject the request to amend the Code and, if approved, to impose any conditions that may be appropriate. Other risk management issues for this Application are related to international standards, enzyme nomenclature and labelling, which are discussed below. The regulatory options analysed in section 2.5.1.1 take account of the safety of the enzyme.

The Application requested an amendment to Schedule 18 of the Code to 'permit the use of  $\beta$ -galactosidase from *P. terrestris* (EC 3.2.1.23) as a processing aid', without specifying the strain name (AE-BLC), or unequivocally seeking permission for use in the production of GOS from lactose. FSANZ's risk assessment looked specifically at the enzyme produced by strain AE-BLC and its role in GOS production, in accordance with the data provided with the Application. Therefore, the variation to the Code permits the use of this enzyme specifying: (i) its microbial source down to the strain level; and (ii) its specific technological purpose. The Applicant has confirmed they had no objection to this approach.

### **2.3.1 International standards**

The Codex Alimentarius does not have standards for processing aids or enzymes. Individual countries regulate the use of enzymes differently to how they are regulated by the Code. However, there are internationally recognised specifications for enzymes. These enzyme specifications are provided through the Joint FAO/WHO Expert Committee on Food Additives (JECFA) Compendium of Food Additive Specifications (FAO/WHO 2016) and the Food Chemicals Codex specifications for enzymes (Food Chemicals Codex 2017). These are primary sources of specifications and are listed in Schedule S3—2 of the Code. Enzyme preparations need to meet these specifications, as well as specifications for heavy metals that are also listed in Schedule 3 (section S3—4), if they are not contained within specifications in sections S3—2 or S3—3.

As a newly developed product, the enzyme sourced from *P. terrestris* strain AE-BLC is not currently permitted for use in any country. However, the Applicant has advised that an application to permit its use has been lodged in Denmark and will be lodged in France. A generally recognised as safe (GRAS) notification will also be prepared for use in the USA.

### **2.3.2 Enzyme nomenclature**

FSANZ noted that 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 3.2.1.23 (IUBMB 2018). This is the name that is used in the proposed draft variation to the Code for this enzyme.

*P. terrestris* strain AE-BLC is the source microorganism used to produce  $\beta$ -galactosidase.

### **2.3.3 Labelling considerations**

As a general rule, processing aids (which include a number of permitted enzymes as listed in Schedule 18) are exempt from the requirement to be declared in the statement of ingredients in accordance with paragraphs 1.2.4—3(2)(d) and (e) in Standard 1.2.4 – Information requirements – statement of ingredients.

The risk assessment concluded that using the enzyme preparation poses no public health and safety issues. Therefore, the generic labelling exemption will apply to the use of this enzyme preparation in foods.

### **2.3.4 Risk management conclusion**

The proposed use of  $\beta$ -galactosidase as a processing aid to produce GOS from lactose, in its commercial form and proposed levels of use, is technologically justified. The risk assessment conclusions indicated that there were no public health and safety concerns associated with its use. The risk management conclusion is therefore to add the permission for the new enzyme  $\beta$ -galactosidase derived from *P. terrestris* strain AE-BLC, as a processing aid into the table to S18—9(3), which includes enzymes permitted for a specific technological purpose. The technological purpose is for use in the production of GOS from lactose. The maximum permitted level is an amount consistent with GMP. Note that the permission will apply specifically to that particular strain of *P. terrestris*, that is, strain AE-BLC.

## **2.4 Risk communication**

### **2.4.1 Consultation**

Consultation is a key part of FSANZ's standards development process. The process by which FSANZ considers standard development matters is open, accountable, consultative and transparent. FSANZ calls for submissions on draft variations to obtain the views of interested parties on issues raised by the application and the effects of regulatory options.

FSANZ released the draft variation for public comment between 1 March and 12 April 2018. The call for submissions was notified via the FSANZ Notification Circular, media release, FSANZ's social media tools and Food Standards News. Subscribers and interested parties were also notified.

FSANZ acknowledges the time taken by individuals and organisations to make submissions on this Application. The Applicant and organisations that made submissions on this Application will be notified at each stage of the assessment.

Documents relating to Application A1151, including submissions received, are available on the [FSANZ website](#)<sup>2</sup>.

## **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 the approval of additional processing aids (OBPR correspondence dated 24 November 2010, reference 12065). This standing exemption was provided as permitting additional processing aids is a minor, deregulatory change and their use is voluntary. This standing exemption relates to the introduction of a food to the food supply that has been determined to be safe.

However, notwithstanding that exemption, 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 (S.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. FSANZ is of the view that no other realistic food regulatory measures exist beyond the consideration of approving or not approving the Application.

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 accepting the Application to permit the use of  $\beta$ -galactosidase sourced from *P. terrestris* strain AE-BLC as a processing aid to produce GOS from lactose.

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<sup>2</sup> [http://www.foodstandards.gov.au/code/applications/Pages/A1151%E2%80%93Beta-Galactosidase%20from%20Papiliotrema%20terrestris%20as%20a%20Processing%20Aid%20\(Enzyme\).aspx](http://www.foodstandards.gov.au/code/applications/Pages/A1151%E2%80%93Beta-Galactosidase%20from%20Papiliotrema%20terrestris%20as%20a%20Processing%20Aid%20(Enzyme).aspx)



FSANZ has not identified significant costs to consumers, governments, or industry that might arise from approving this Application.

The use of the enzyme as a processing aid in the manner proposed will not pose a health or safety risk for consumers (see above). Consumers may benefit from the choice of additional (and improved quality) food products that become available due to permitting the use of the enzyme. It is also possible that the prices for some products may be reduced if the enzyme allows food products to be produced more cheaply.

There are other methods for producing GOS from lactose, which means it is likely that the availability of a range of foods for both infants and adults containing GOS as an ingredient will remain the same.

Its use by industry is voluntary. Therefore, it will only be used where industry believes a net benefit exists. Approving this Application will give industry an alternative means of producing GOS from lactose, which can then be used as an ingredient in various foods. If this is a superior production method, it may decrease production costs for industry.

The proposed amendment to the Code is deregulatory in nature. FSANZ's assessment is that the direct and indirect benefits that would arise from a food regulatory measure varied as a result of the Application outweigh the costs to the community, government or industry that would arise from varying that food regulatory measure.

#### **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 as a result of the application, namely a variation to the table to subsection S18—9(3).

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

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 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 undertook a safety assessment (SD1) and concluded there were no public health and safety concerns relating to the use of the enzyme  $\beta$ -galactosidase, sourced from a chemically mutated strain of *P. terrestris* (strain AE-BLC), as a food processing aid to produce GOS from lactose.

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

The labelling considerations for the enzyme processing aid are discussed in Sections 2.3.3 and 2.1.

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

There were 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 used the best available scientific evidence to conduct the risk analysis which is provided in SD1 – the Risk and Technical Assessment Report. The Applicant submitted a dossier of scientific studies as part of their Application. Other technical information sourced by FSANZ, including scientific literature, was also used in assessing the Application.

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

There are no Codex Alimentarius Standards for processing aids or enzymes. However, the enzyme meets international specifications for enzyme preparations, these being the JECFA Compendium of Food Additive Specifications and the Food Chemicals Codex specifications for enzymes. These are primary sources of specifications and are listed in Schedule S3—2 of the Code. Enzyme preparations permitted for use in the Code need to meet these specifications, among others listed in Schedule 3, as appropriate (see Section 2.3.1).

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

$\beta$ -Galactosidase derived from *P. terrestris* strain AE-BLC is Amano Enzyme Inc.'s newly-developed product and, as such, it is not currently permitted for use in any country. However, the Applicant has advised that an application to permit its use has been lodged in Denmark and will be lodged in France. A GRAS notification will also be prepared. The uptake of its use on the international market will depend on the outcome of these applications and the GRAS notification. In the meantime, approval of this Application in Australia and New Zealand will ensure that, if it is approved elsewhere, Australia and New Zealand industry will remain competitive with other international markets.

The outcome of the risk assessment indicated that there are no public health and safety issues associated with the use of this enzyme. It is therefore appropriate that Australian and New Zealand food industries are given the opportunity to benefit from the use of an enzyme with enhanced functionality. Approval in Australia and New Zealand will also help foster continued innovation and improvements in food manufacturing techniques and processes in the local region.

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

FSANZ identified no issues identified relevant to this objective. As mentioned above, the enzyme has been assessed as safe for use as a processing aid to produce GOS from lactose.

- **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>3</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 determined that permitting the use of  $\beta$ -galactosidase, sourced from *P. terrestris* strain AE-BLC, as a processing aid for producing GOS from lactose, is consistent with these specific order policy principles for 'Technological Function'.

### 3 References

FAO/WHO (2016) General specifications and considerations for enzyme preparations used in food processing. <http://www.fao.org/docrep/009/a0691e/a0691e00.htm>

Food Chemicals Codex 10th Edition (2017), The United States Pharmacopeia. United States Pharmacopeial Convention, Rockville, MD. <http://www.foodchemicalscodex.org/>

FSANZ (2018) *Australia New Zealand Food Standards Code*. <http://www.foodstandards.gov.au/code/Pages/default.aspx>

IUBMB (2018) EC 3.2.1.23. <http://www.sbcs.qmul.ac.uk/iubmb/enzyme/EC3/2/1/23.html>

### Attachments

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

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<sup>3</sup> <http://foodregulation.gov.au/internet/fr/publishing.nsf/Content/publication-Policy-Guideline-on-the-Addition-of-Substances-other-than-Vitamins-and-Minerals>

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



### Food Standards (Application A1151 – $\beta$ -Galactosidase from *Papiliotrema terrestris* as a Processing Aid (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 Standards Management Officer]

Standards Management Officer  
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 A1151 –  $\beta$ -Galactosidase from *Papiliotrema terrestris* as a Processing Aid (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) from<br><i>Papiliotrema terrestris</i> strain<br>AE-BLC. | For use in the production of<br>*galacto-oligosaccharides from lactose. | GMP |
|---|---|-----|

## **Attachment B – 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 A1151 which seeks to permit the use of  $\beta$ -galactosidase derived from a chemically mutated production strain of *Papiliotrema terrestris* (strain AE-BLC) as a processing aid in the production of galacto-oligosaccharide (GOS) from lactose. The Authority considered the Application in accordance with Division 1 of Part 3 and has approved a draft Standard.

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 draft variation of a standard.

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 sunseting under the *Legislation Act 2003*.

### **2. Purpose**

The purpose of the variation is to permit the use of the enzyme  $\beta$ -galactosidase, derived from a chemically mutated production strain of *Papiliotrema terrestris* (strain AE-BLC), as a processing aid to produce GOS from lactose.

### **3. Documents incorporated by reference**

The variation to food regulatory measures does 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 A1151 included one round of public consultation following an assessment and the preparation of a draft variation and associated report. Submissions were called for on 1 March 2018 for a six-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

Item [1] of the variation inserts a new entry into the table to subsection S18—9(3) in Schedule 18 of the Code.

The effect of the new entry is to permit the use of the enzyme  $\beta$ -galactosidase (EC number 3.2.1.23), derived from a chemically mutated production strain of *Papiliotrema terrestris* (strain AE-BLC), as a processing aid in food for the technological purpose of producing GOS from lactose, subject to the condition that the amount used must be consistent with good manufacturing practice (GMP).