

1 March 2018

[40–18]

Call for submissions – Application A1151

β -Galactosidase from *Papiliotrema terrestris* as a Processing Aid (Enzyme)

FSANZ has assessed an Application made by Amano Enzyme Inc. Japan to permit the use of β -galactosidase sourced from *Papiliotrema terrestris* strain AE-BLC as a processing aid in the production of galacto-oligosaccharide (GOS) from lactose, and has prepared a draft food regulatory measure. Pursuant to section 31 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act), FSANZ now calls for submissions to assist consideration of the draft food regulatory measure.

For information about making a submission, visit the FSANZ website at [information for submitters](#).

All submissions on applications will be published on our website. We will not publish material that that we accept as confidential, but will record that such information is held. In-confidence submissions may be subject to release under the provisions of the *Freedom of Information Act 1991*. Submissions will be published as soon as possible after the end of the public comment period. Where large numbers of documents are involved, FSANZ will make these available on CD, rather than on the website.

Under section 114 of the FSANZ Act, some information provided to FSANZ cannot be disclosed. More information about the disclosure of confidential commercial information is available on the FSANZ website at [information for submitters](#).

Submissions should be made in writing; be marked clearly with the word 'Submission' and quote the correct project number and name. While FSANZ accepts submissions in hard copy to our offices, it is more convenient to receive submissions electronically through the FSANZ website via the link on [documents for public comment](#). You can also email your submission directly to submissions@foodstandards.gov.au.

There is no need to send a hard copy of your submission if you have submitted it by email or via the FSANZ website. FSANZ endeavours to formally acknowledge receipt of submissions within 3 business days.

DEADLINE FOR SUBMISSIONS: 6pm (Canberra time) 12 April 2018

Submissions received after this date will not be considered unless an extension had been given before the closing date. Extensions will only be granted due to extraordinary circumstances during the submission period. Any agreed extension will be notified on the FSANZ website and will apply to all submitters.

Questions about making submissions or the application process can be sent to standards.management@foodstandards.gov.au.

Hard copy submissions may be sent to one of the following addresses:

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Supporting document

The [following document](#)¹ which informed the assessment of this Application is available on the FSANZ website:

SD1 Risk and technical assessment report

¹ [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. has submitted an Application seeking permission to use the enzyme β -galactosidase (EC 3.2.1.23) sourced from *Papiliotrema terrestris* strain AE-BLC as a processing aid. The Applicant states that this enzyme will be used to produce galacto-oligosaccharide (GOS) from lactose. GOS can be used as an ingredient in various foods.

β -Galactosidase is used to produce galactose and glucose from lactose. When lactose is the primary substrate, galactose released from lactose reacts to form GOS. It is this reaction that is of primary commercial importance, in relation to this Application.

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, which includes enzymes permitted for use for a specific technological purpose.

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

After undertaking a risk assessment, FSANZ concludes that there are no public health and safety concerns associated with using β -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 enzyme does not have the characteristics of a potential food allergen and ingestion of any residual β -galactosidase in food products is unlikely to pose an allergenicity concern. 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 meets international purity specifications and its nomenclature is consistent with an internationally recognised naming system.

FSANZ therefore proposes a draft variation to the Code to permit the enzyme β -galactosidase derived from *P. terrestris* strain AE-BLC as a processing aid to produce 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 purpose of the Application is to seek permission to use the enzyme β -galactosidase (EC 3.2.1.23) sourced from *Papiliotrema terrestris* strain AE-BLC as a processing aid. β -Galactosidase will be used in the commercial production of galacto-oligosaccharide (GOS) from lactose.

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

β -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 process mutation using N-methyl-N'-nitro-N-nitrosoguanidine. The strain is not genetically modified. The β -galactosidase derived from production strain AE-BLC has enhanced acid resistance and temperature resistance, when compared with β -galactosidases derived from other sources.

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

The Applicant reported that the enzyme powder is inactivated by either temperature or pH changes and has no function in the final food product. The Applicant provided information regarding the pH and temperature for optimal enzyme activity, and advice regarding the temperature required to achieve enzyme inactivation was also included in the Application.

1.3 The current standard

Enzymes used in processing and manufacturing food are considered processing aids.

Paragraph 1.1.1—10(6)(c) of the *Australia New Zealand Food Standards Code* (the Code) provides that a food for sale must not have, as an ingredient or a component, a substance that is used as a processing aid, unless expressly permitted.

Section 1.1.2—13 of the Code defines the expression 'used as a processing aid'. That definition imposes certain conditions on substances permitted by Standard 1.3.3 and Schedule 18 to be used as a processing aid, such that it does not perform a technological function in the final food for sale.

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, depending on whether a technological purpose has been specified (FSANZ 2017).

There is already approval for β -galactosidase (EC 3.2.1.23) from a range of production organisms in the Code. However, there is currently no permission for this enzyme derived from *P. terrestris*. Therefore, the Code must be amended to permit the use of the chemically mutated production strain of *P. terrestris* (strain AE-BLC) to produce β -galactosidase.

1.3.1 International Standards

Codex Alimentarius does not have Standards for enzyme processing aids or other processing aids. Individual countries regulate the use of enzymes differently to how they are regulated in the Code.

However, there are internationally recognised specifications for enzymes. These enzyme specifications are provided by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) (FAO/WHO 2016) and the Food Chemicals Codex (Food Chemicals Codex 10 2016).

β -Galactosidase is listed in the Inventory of Processing Aids Database compiled by the Codex Committee on Food Additives. However, as the β -galactosidase enzyme powder, sourced from *P. terrestris* strain AE-BLC, is Amano Enzyme Inc.'s newly developed product, the enzyme sourced specifically from *P. terrestris* is not currently listed in the inventory.

In addition, 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.

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; and
- it related to a matter that might be developed as a food regulatory measure.

1.5 Procedure for assessment

The Application is being assessed under the General Procedure.

2 Summary of the assessment

2.1 Risk assessment

There are no public health and safety issues associated with the use of β -galactosidase from *P. terrestris* strain AE-BLC as a food processing aid in the production of GOS from lactose.

P. terrestris strain AE-BLC was not pathogenic *in vivo* and not toxigenic *in vitro*. β -Galactosidase from *P. terrestris* was not genotoxic and did not cause adverse effects in a subchronic toxicity study in rats.

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

The enzyme does not have the characteristics of a potential food allergen and ingestion of any residual β -galactosidase in food products is unlikely to pose an allergenicity concern.

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).

2.2 Risk management

The risk assessment concluded that there are no safety risks from the use of β -galactosidase, sourced from a chemically mutated strain of *P. terrestris* (strain AE-BLC), as a processing aid in the production of 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 enzyme nomenclature and labelling, which are discussed below. The regulatory options analysed in section 2.4.1.1 take account of the safety of the enzyme.

It is noted that the Application requested an amendment to Schedule 18 of the Code to 'permit the use of β -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. However, FSANZ's risk assessment looked specifically at the enzyme that is produced from strain AE-BLC, and its role in GOS production, in accordance with the data provided with the Application. Therefore, it is proposed that the permission in the Code for this enzyme: (i) specifies its microbial source down to the strain level; and (ii) clearly stipulates its technological purpose.

If permitted, this enzyme will provide commercial manufacturers of GOS with an alternative method of production, which has enhanced acid resistance and temperature resistance, when compared with β -galactosidases derived from other sources.

2.2.1 Regulatory approval for enzymes

The food technology aspect of the risk assessment has concluded that the enzyme meets its stated purpose, for use as a processing aid in the production of GOS from lactose. 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 β -galactosidase in food products is unlikely to pose an allergenicity concern.

Therefore, FSANZ proposes permitting the use of the enzyme as a processing aid for its stated purpose.

2.2.2 Enzyme and source microorganism nomenclature

FSANZ noted that the International Union of Biochemistry and Molecular Biology (IUBMB), the internationally recognised authority for enzyme nomenclature, uses the 'accepted' name ' β -galactosidase' for the enzyme with an EC number of 3.2.1.23 (IUBMB 2017). 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 β -galactosidase.

2.2.3 Labelling considerations

As a general rule, processing aids, including those in subsection in S18—9(3), 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. This includes when the processing aid is used to produce an ingredient such as GOS, which is then added as an ingredient to the food for sale.

The risk assessment concluded that the use of the enzyme preparation poses no risk to public health and safety 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 additional labelling requirements are proposed.

2.2.4 Risk management conclusion

The risk management conclusion is to add the permission for the new enzyme β -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.

2.3 Risk communication

2.3.1 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.

2.3.2 World Trade Organization (WTO)

As members of the World Trade Organization (WTO), Australia and New Zealand are obliged to notify WTO 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 no relevant international standards (i.e. Codex) and amending the Code to approve the enzyme as a processing aid is unlikely to have a significant effect on international trade as the enzyme meets the international specifications for enzymes (i.e. the JECFA Compendium of Food Additive Specifications (FAO/WHO 2016) and the Food Chemicals Codex specifications for enzymes (Food Chemicals Codex 10 2016)). 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.

2.4 FSANZ Act assessment requirements

When assessing this Application and the subsequent development of a food regulatory measure, FSANZ had regard to the following matters in section 29 of the FSANZ Act:

2.4.1 Section 29

2.4.1.1 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 consider the impact of various regulatory and non-regulatory options on all sectors of the community, especially relevant stakeholders who may be affected by this Application. The level of analysis is commensurate with the nature of the Application and significance of the impacts. The costs and benefits associated with the proposed amendments to the Code are analysed using regulatory impact principles.

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 developed or varied as a result of the Application outweigh the costs to the community, government or industry that would arise from developing or varying that food regulatory measure.

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

There are other methods for producing GOS from lactose, thus 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. However, if this is a superior production method, it may decrease costs of the foods containing GOS or have other benefits.

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 for both infants and adults.

2.4.1.2 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.

2.4.1.3 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 and there are no other relevant New Zealand only standards.

2.4.1.4 Any other relevant matters

Other relevant matters are considered below.

2.4.2 Subsection 18(1)

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

2.4.2.1 Protection of public health and safety

FSANZ undertook a safety assessment (SD1) and concluded there were no public health and safety issues associated with the use of the enzyme β -galactosidase, sourced from a chemically mutated strain of *P. terrestris* (strain AE-BLC), as a food processing aid in the production of GOS from lactose.

2.4.2.2 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 Section 2.2.3.

2.4.2.3 The prevention of misleading or deceptive conduct

There were no issues identified with this Application relevant to this objective.

2.4.3 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 its Application. Other technical information 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; being the JECFA Compendium of Food Additive Specifications and the Food Chemicals Codex specifications for enzymes.

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

β -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 will remain competitive with other international markets. This also helps foster continued innovation and improvements in food manufacturing techniques and processes.

The outcome of the risk assessment indicated that there are no public health and safety issues associated with the production microorganism *P. terrestris* strain AE-BLC or with using β -galactosidase as a food processing aid in the production of GOS from lactose. It is therefore appropriate that Australian and New Zealand food industries are given the opportunity to benefit from the use of this enzyme with enhanced functionality.

The Applicant states that it is expected that the introduction of β -galactosidase derived from *P. terrestris* strain AE-BLC to the Australia/New Zealand market will be well received. However, the domestic food industry will make their own economic decisions, taking into account the costs and benefits of using the new enzyme, to determine if it is of benefit to their business.

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

FSANZ identified no issues identified relevant to this objective. As mentioned above, FSANZ's risk assessment is that there are no public health and safety issues associated with the production microorganism *P. terrestris* strain AE-BLC or with using β -galactosidase as a food processing aid in the production of 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*² 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 the β -galactosidase enzyme powder, 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 Draft variation

The draft variation to the revised Code is at Attachment A and is intended to take effect on gazettal.

A draft explanatory statement is at Attachment B. An explanatory statement is required to accompany an instrument if it is lodged on the Federal Register of Legislative Instruments (FRLI).

4 References

FAO/WHO (2016) General specifications and considerations for enzyme preparations used in food processing. http://www.fao.org/ag/agn/jecfa-additives/docs/enzymes_en.htm

² <http://www.foodstandards.gov.au/code/fofr/fofrpolicy/pages/default.aspx>

Food Chemicals Codex 10th Edition (2016), The United States Pharmacopeia. United States Pharmacopeial Convention, Rockville, MD.

<http://www.foodchemicalscodex.org/>

FSANZ (2017) *Australia New Zealand Food Standards Code*.

<http://www.foodstandards.gov.au/code/Pages/default.aspx>

IUBMB (2017) EC 3.2.1.23. <http://www.sbcs.qmul.ac.uk/iubmb/enzyme/EC3/2/1/23.html>

Attachments

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

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



Food Standards (Application A1151 – β -Galactosidase from *Papiliotrema terrestris* as a Processing Aid (Enzyme)) Variation

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 Name and Position of Delegate

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 – β -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

β -Galactosidase (EC 3.2.1.23) from <i>Papiliotrema terrestris</i> strain AE-BLC.	For use in the production of *galacto-oligosaccharides from lactose.	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.

FSANZ accepted Application A1151. It seeks an amendment to the Code to permit the use of β -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 prepared 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 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 draft variation is to amend the table to subsection S18—9(3) in Schedule 18 of the Code to permit the use of the enzyme β -galactosidase, derived from a chemically mutated production strain of *Papiliotrema terrestris* (strain AE-BLC), for use as a processing aid in the production of GOS from lactose.

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 A1151 will include one round of public consultation following an assessment and the preparation of a draft variation and associated assessment summary. A call for submissions (including the draft variation) will occur for a six-week consultation period.

The Office of Best Practice Regulation (OBPR) granted FSANZ 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

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

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