FOOD STANDARDS
Australia New Zealand
Te Mana Kounga Kai – Ahitereiria me Aotearoa

7 May 2010
[11-10]

APPLICATION A1032
β-GALACTOSIDASE AS A PROCESSING AID (ENZYME)
APPROVAL REPORT

Executive Summary

Purpose

Food Standards Australia New Zealand (FSANZ) received an Application (A1032) from FrieslandCampina Domo on 31 August 2009. The Application seeks to amend Standard 1.3.3 – Processing Aids of the *Australia New Zealand Food Standards Code* (the Code) to include *Bacillus circulans* ATCC 31382 as a new microbial source of the enzyme β-galactosidase (EC number 3.2.1.23) in the Table to clause 17 – Permitted enzymes of microbial origin.

Background

Processing aids are required to undergo a pre-market safety assessment before approval for use in Australia and New Zealand. β-galactosidase derived from four other microbial sources (*Aspergillus niger, A. oryzae, Kluyveromyces marxianus, K. lactis*) is currently listed as a permitted processing aid in Standard 1.3.3 – Processing aids in the Table to clause 17 – Permitted enzymes of microbial origin.

The primary use of β-galactosidase is in the production of galacto-oligosaccharides (GOS), which are food ingredients. The Applicant claims that the β-galactosidase enzyme derived from *B. circulans* acts as a processing aid and is a preferred enzyme compared to the β-galactosidase enzyme produced by other microbial sources.

β-galactosidase derived from *B. circulans* ATCC 31382 for the production of GOS has recently been approved for use in France and Canada. In 1997, the European Commission (EC) Scientific Committee for Food (EFSA predecessor) concluded that a different enzyme extract, namely cycloglycosyltransferase, derived from *B. circulans* was safe. The Association of Microbial Food Enzyme Producers (AMFEP, 2009) lists *B. circulans* as a micro-organism used for enzyme production. The 41st session of Codex Committee on Food Additives (CCFA) (March, 2009) accepted a paper to update the Inventory of Substances Used as Processing Aids (IPA) to list β-galactosidase from *B. circulans*. The US Food & Drug Administration (FDA) has designated GOS produced by the enzyme β-galactosidase derived from *B. circulans* ATCC 31382 as GRAS (2007). *B. circulans* ATCC 31382 is not a genetically modified organism.

Risk and Technical Assessment

The risk assessment has considered the identity and safety of the source micro-organism (*B. circulans*), the safety of the β-galactosidase enzyme preparation and its technological suitability. The enzyme has been demonstrated to perform the specified reactions with lactose under the specified process and manufacturing conditions. Based on the available data, it was concluded that the submitted studies did not reveal any hazard-related concerns with the enzyme or source micro-organism that would preclude the listing of β-galactosidase derived from *B. circulans* as a food processing aid.

Key findings of the assessment are:

- There were no safety concerns identified for the enzyme preparation, the enzyme itself or the source micro-organism.

- As no hazards were identified for β-galactosidase derived from *B. circulans* ATCC 31382, or the micro-organism itself, no health standard was considered necessary.

- The FSANZ Acceptable Daily Intake (ADI) for β-galactosidase from *B. circulans* ATCC 31382 is 'not specified'. This means there is unlikely to be a health risk when the enzyme is used in accordance with good manufacturing practice. An estimate of dietary exposure is not required for the use of the enzyme.

- The precise taxonomic identity of the source micro-organism is uncertain. Consequently it is considered that the most informative name would be *Bacillus circulans* ATCC 31382.

- The properties of the enzyme β-galactosidase from the micro-organism *B. circulans* (ATCC 31382 were consistent with the general enzyme specifications published by the Joint FAO/WHO Expert Committee on Food Additives (JECFA).

- The enzyme β-galactosidase performs its specified technological functions under the process and manufacturing conditions for GOS production.

- There is no detectable soybean protein in the final enzyme preparation and no enzyme activity or soybean protein in the GOS product.

Labelling

The enzyme preparation contains lactose. As a Code requirement, if the final food or any of its ingredients contains milk or other products listed in the Table to clause 4 of Standard 1.2.3 – Mandatory Warning and Advisory statements and Declarations, it must be labelled accordingly.

Assessing the Application

In assessing the Application and the subsequent development of a food regulatory measure, FSANZ has had regard to the following matters as provided for in section 29 of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act):

- whether costs that would arise from a food regulatory measure developed or varied as a result of the application outweigh the direct and indirect benefits to the community, Government or industry that would arise from the development or variation of the food regulatory measure

- whether other measures (available to the Authority or not) would be more cost-effective than a food regulatory measure developed or varied as a result of the application

- any relevant New Zealand standards

- any other relevant matters.

Decision

To approve the draft variation to the Table to clause 17 of Standard 1.3.3 – Processing Aids, to permit the use of the enzyme β-galactosidase derived from *Bacillus circulans* ATCC 31382.

Reasons for Decision

An amendment to the Code to permit the use of β-galactosidase derived from *B. circulans* as a processing aid in Australia and New Zealand is proposed on the basis of the available evidence for the following reasons:

- A detailed safety assessment has concluded that there is no toxicology or human safety related concerns with the enzyme β-galactosidase produced by *B. circulans* ATCC 31382

- Use of the enzyme from this source is technologically justified and effective

- The source organism, *B. circulans* ATCC 31382*,* is considered as non-pathogenic and non-toxigenic

- The regulatory impact assessment indicated that there are no business compliance costs involved and/or minimal impacts on affected parties

- There are no other measures that would be more cost-effective than a variation to Standard 1.3.3 that could achieve the same end

- The proposed draft variation to the Code is consistent with the section 18 objectives of the FSANZ Act

- There are no relevant New Zealand standards.

Consultation

This Application was assessed under the General Procedure and the Assessment Report was released for public comment from 16 December 2009 to 10 February 2010. Eight submissions were received; three were from government agencies, one from a member of the Western Australian Legislative Council, two industry associations and two private individuals. The government agencies supported FSANZ's preferred option of permitting the use of the enzyme β-galactosidase derived from *B. circulans* ATCC 31382. The other submissions opposed the use of genetically modified organisms (GMO) and genetically modified food and therefore proposed an embargo on the approval of this Application. However, it should be noted that *B. circulans* is **not** a GMO. Issues raised by submitters are summarised and addressed in Section 10.1 of this Report.

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SUPPORTING DOCUMENTATION

The following material, which was used in the preparation of the Approval Report, is available on the FSANZ website at http://www.foodstandards.gov.au/foodstandards/applications/applicationa1032gala4587.cfm:

SD1: Risk and Technical Assessment Report

1. Introduction

Food Standards Australia New Zealand (FSANZ) received an Application (A1032) from Friesland Foods BV (future legal entity 'FrieslandCampina Domo') on 31 August 2009. The Application seeks to amend Standard 1.3.3 – Processing Aids of the *Australia New Zealand Food Standards Code* (the Code) to include *Bacillus circulans* ATCC 31382 as a new microbial source of the enzyme β-galactosidase (EC number 3.2.1.23), to be included in the Table to clause 17 – Permitted enzymes of microbial origin.

The primary use of β-galactosidase is to catalase the production of galacto-oligosaccharides (GOS)[1], which is a food ingredient. The Applicant claims that the β-galactosidase enzyme derived from *B. circulans* ATCC 31382 is a preferred enzyme compared to those produced by other microbial sources.

1.1. The Issue / Problem

The Applicant proposes the use of the enzyme β-galactosidase derived from *B. circulans* as a processing aid in the production of GOS. Processing aids are prohibited from use in food in Australia and New Zealand unless there is a specific permission for them in Standard 1.3.3. Processing aids (which includes enzymes) are required to undergo a pre-market assessment before they are approved for use in food manufacture in Australia and New Zealand.

β-galactosidase derived from four permitted microbial sources is already listed in Standard 1.3.3. An assessment (which includes a safety assessment) of the use of β-galactosidase derived from this alternative source, *B. circulans* ATCC 31382, is required before an approval for its use can be given (i.e. listed in Standard 1.3.3).

2. Background

2.1 Current Standard

Standard 1.3.3 regulates the use of processing aids in food manufacturing. Clause 1 of Standard 1.3.3 states:

Processing aid *means a substance listed in clauses 3 to 18, where –*

(a) the substance is used in the processing of raw materials, foods or ingredients, to fulfil a technological purpose relating to treatment or processing, but does not perform a technological function in the final food; and

(b) the substance is used in the course of manufacture of a food at the lowest level necessary to achieve a function in the processing of that food, irrespective of any maximum permitted level specified.

The Table to clause 17 – Permitted enzymes of microbial origin contains a list of permitted enzymes of microbial origin for use as processing aids.

[1] **Galacto-oligosaccharides (GOS)** generally comprised of a chain between 2 and 8 saccharide units with one of these being a terminal glucose and the remaining saccharide units being galactose and disaccharides comprised of two molecules of galactose. GOS occur naturally in human milk, and can be manufactured from lactose through enzymatic conversion.

The enzyme β-galactosidase currently listed in Table to clause 17 is derived from four permitted microbial sources: the moulds *Aspergillus niger* and *A. oryzae* and the yeasts *Kluyveromyces lactis* and *K. marxianus*. *B. circulans* is not currently listed in the Code.

2.2 International Considerations

Health Canada has no objection to the use of β-galactosidase from *B. circulans* in the production of GOS from lactose (Letter dated 15 October, 2009) and the Republic of France has acknowledged *B. circulans* ATCC 31382 as an industrial source for the production of β-galactosidase (Journal Officiel de la République Française, Dec 2001).

The Ministry of Health and Welfare, Japan (Apr 1996) lists β-galactosidase as a food additive from a natural origin. The information provided by the Applicant does not, however, indicate whether approval has been given by the Japanese authorities for the use of β-galactosidase from any specific micro-organism e.g. *B. circulans*.

The EC Scientific Committee for Food has reported on the safety of *B. circulans* as an enzyme source of cycloglycosyltransferase, which is used to produce β-cyclodextrins for stabilising flavourings (1997).

The Association of Microbial Food Enzyme Producers (AMFEP, 2009) noted that *B. circulans* belongs to a group of micro-organisms used for enzyme production 'that are accepted as harmless contaminants present in food'.

The Applicant noted that the 41st session of Codex Committee on Food Additives (CCFA) (Shanghai, PRC, March 2009) accepted a paper to update the Inventory of Substances Used as Processing Aids (IPA) to list 'Lactase or β-galactosidase from *B. circulans'.* Neither β-galactosidase from *B. circulans* nor any other enzyme preparation from *B. circulans* has been referred to JECFA.

GOS produced by the enzyme derived from *B. circulans* ATCC 31382 has been designated as GRAS by the US Food and Drug Administration (FDA) in GRAS Notice No. GRN 000236 (2007).

2.3 Nature of the Enzyme and Source of Organism

β-galactosidase is a hydrolase enzyme that catalyses the hydrolysis of β-galactosides (e.g. lactose) into monosaccharides (e.g. galactose and glucose). Under specific reaction conditions, the β-galactosidase may exhibit high galactosyl transferring activity resulting in the formation of galacto-oligosaccharides (GOS). Therefore the enzyme may perform both hydrolysis and polymerisation with the equilibrium dependent on the reaction conditions (Supporting Document 1 – Section 1.3).

The commercial enzyme preparation consists of two β-galactosidase isoforms that have high hydrolysis specificity to β-1,4 linkages (Supporting Document 1 – Section 1.3). The enzyme preparation has been observed to have no other enzymatic activities.

The source micro-organism for the production of β-galactosidase indicated by the Applicant is *B. circulans*. The micro-organism, which is a non-genetically modified micro-organism, has been deposited with the American Type Culture Collection (ATCC) as ATCC 31382 by the enzyme producer. This specified source has been used in the various safety studies submitted in this Application. There is sufficient information to identify the micro-organism with a reasonable level of confidence (Supporting Document 1 – Section 3).

2.4 Technological purpose of the enzyme

The enzyme, β-galactosidase, is used as a food processing aid in the production of galacto-oligosaccharides (GOS). It was reported to be the most employed enzyme for the industrial production of GOS (Neri et al., 2009). Under specific process conditions and a high lactose concentration, the lactose becomes the acceptor group and β-galactosidase catalyses the transgalactosylation reaction. This results in polymerisation instead of hydrolysis, in which the lactose molecule is attached to the galactose residue and forms a GOS.

The Applicant claims the β-galactosidase derived from *B. circulans* ATCC 31382 is their preferred enzyme for the production of their GOS because it is more effective and produces GOS with the required properties. The Applicant has an exclusive agreement with Daiwa Kasei K. K., Japan for the supply of Biolacta®N5, the commercial form of β-galactosidase derived from *B. circulans*.

3. Objectives

The objective of this Assessment is to determine whether it is appropriate to amend the Code to permit the use of the enzyme β-galactosidase derived from *B. circulans* ATCC 31382 as a processing aid. The safety of any possible contaminants arising from the host organism and the enzyme production process was also assessed.

In developing or varying a food standard, FSANZ is required by its legislation to meet three primary objectives which are set out in section 18 of the FSANZ Act. These are:

- the protection of public health and safety; and
- the provision of adequate information relating to food to enable consumers to make informed choices; and
- the prevention of misleading or deceptive conduct.

In developing and varying standards, FSANZ must also have regard to:

- the need for standards to be based on risk analysis using the best available scientific evidence;
- the promotion of consistency between domestic and international food standards;
- the desirability of an efficient and internationally competitive food industry;
- the promotion of fair trading in food; and
- any written policy guidelines formulated by the Ministerial Council[2].

[2] In May 2008, the Australia and New Zealand Food Regulation Ministerial Council endorsed the Policy Guideline on Addition to Food of Substances other than Vitamins and Minerals (http://www.foodstandards.gov.au/foodstandards/changingthecode/ministerialcouncilpolicyguidelines/policyguidelineonthe4132.cfm). This includes policy principles in regard to substances added for technological purposes such as food additives and processing aids.

4. Questions to be answered

The key questions which FSANZ considered as part of the assessment were:

1. Is the new microbial source *B. circulans* ATCC 31382 safe for producing β-galactosidase?

2. What is the risk to public health and safety from the use of β-galactosidase derived from *B. circulans* ATCC 31382 as a processing aid?

3. Does the enzyme achieve its claimed technical functions?

4. Does the final enzyme preparation contain any allergenic materials?

5. Risk Assessment

The risk assessment has considered the identity and safety of the source micro-organism (*B. circulans* ATCC 31382*),* the safety of the β-galactosidase enzyme preparation and its technological suitability.

For this assessment, in addition to information supplied by the Applicant, other available resource material including published scientific literature and general technical information was used. A detailed report of the combined safety and technical assessment is provided in the Risk and Technical Assessment Report (Supporting Document 1). The key findings from the report are summarised and presented under the questions posed in Section 4 of this report.

5.1 Is the new microbial source, *B. circulans* ATCC 31382 safe for producing β-galactosidase?

The risk assessment concluded that this micro-organism is not a toxigenic species (Section 3.1). The single, oral administration of live *B. circulans* ATCC 31382 to mice was not associated with any toxicity when assessed up to 14 days after inoculation (Section 4.3). The Applicant has noted that this micro-organism has a history of safe use in the preparation of commercial enzymes for the food industry. The latter is supported by a number of international organisations, foreign governments (Section 7.1) and a report published by the European Commission's Scientific Committee for Food (SCF, 2007). Overall, there were no concerns with the safety of *B. circulans* ATCC 31382*,* when used as a source of β-galactosidase.

5.2 What is the risk to the public from the use of β-galactosidase derived from *B. circulans* as a processing aid?

The risk assessment did not raise any safety concerns from the proposed use of this enzyme as a processing aid. The same enzyme, from other microbial sources, is already listed in the Code as a processing aid (Table to clause 17 of Standard 1.3.3). The Applicant has indicated that the enzyme is removed via acid/heat treatment and filtration from the final GOS product (Section 5.4.4). Any residual enzymic protein would be in the form of inactivated enzyme, which would be metabolised like any other protein in the gastrointestinal tract.

The enzyme preparation did not contain any detectable mycotoxins (aflatoxin B1, ochratoxin A, sterigmatocystin, zearalenone and T-2 toxin) or antibiotic activity to *Staphylococcus aureus, Escherichia coli*, *B. cereus, B. circulans* (ATCC 4516), *Streptococcus pyogenes,* or *Serratia marcescens* (Section 4.6). Overall, there were no concerns with the safety of the enzyme preparation or the enzyme itself when used as a processing aid.

5.3 Does the enzyme perform its technical function as specified?

The enzyme, β-galactosidase ATCC 31382 (Section 1.3), is used as a food processing aid in the production of galacto-oligosaccharides (GOS) (Sections 5.2, 5.4.3). β-galactosidase was reported to be the most employed enzyme for the industrial production of GOS (Neri *et al.*, 2009). β-galactosidase from the commercial enzyme preparation (Biolacta®N5), has specific transgalactosylation activity specifically selected for the production of GOS of a quality desired by the Applicant. GOS produced by Biolacta®N5 consist mainly of 2-4 monomer units.

5.4 Does the final enzyme preparation contain any allergenic materials?

This enzyme is considered unlikely to pose an allergenic risk due to its homology to other β-galactosidases already in the Code (Section 4.2). Therefore it is not necessary to perform an analysis of homology of this enzyme to allergenic sequences. Although soybean meal is used as a fermentation medium in the production of the enzyme preparation, there was no detectable soybean protein present in the final preparation (limits of detection = 1 mg/kg) (Section 5.4.4). Overall, the preparation containing β-galactosidase from *B. circulans* was not considered to pose an allergenic risk to consumers.

Lactose is used as a standardising agent for keeping the enzymatic activity at the same level in each enzyme preparation. Therefore the final enzyme preparation will contain milk product and it must be labelled in accordance with the requirements of Standard 1.2.3 – Mandatory Warning and Advisory Statements and Declarations.

5.5 Conclusion of risk assessment

The Risk Assessment concludes that the use of β-galactosidase derived from *B. circulans* ATCC 31382 as a processing aid does not pose a public health and safety risk and its use is technologically justified by its manufacturing user.

6. Risk Management

Based on the risk assessment conclusions, there is no need to develop any specific risk management strategy for β-galactosidase derived from *B. circulans* ATCC 31382 and it has been assessed as a routine enzyme processing aid application.

If approved, because β-galactosidase derived from *B. circulans* ATCC 31382 is used as a processing aid and no enzyme is expected to be present in the final food product, no ingredient labelling will be required, apart from that identified in Section 5.4 above. The source organism is killed and removed during the manufacturing process used for producing the enzyme preparation. This is typical for enzymes sourced from micro-organisms approved in the Code.

The supplier of the Applicant's enzyme currently uses soybean meal as a fermentation medium. Evaluation tests including DNA extraction followed by a polymerase chain reaction (PCR) technique certified that soybean protein could not be found in the enzyme final preparation and the GOS products. The detection limit of the test is 1 mg/kg. No labelling of soy protein is necessary.

7. Options

Processing aids used in Australia and New Zealand are required to be listed in Standard 1.3.3. The β-galactosidase enzyme acts as a processing aid when it is used in the production of GOS, and requires a pre-market approval under Standard 1.3.3.

Two options have been identified for this Application:

Option 1: Reject the Application, thus maintaining the *status quo*.

Option 2: Permit the use of β-galactosidase derived from *B. circulans* ATCC 31382 as a food processing aid.

8. Impact Analysis **(OBPR Ref 10848)**

In developing food regulatory measures for adoption in Australia and New Zealand, FSANZ is required to consider the impact of all options on all sectors of the community, including consumers, the relevant food industries and governments. The regulatory impact assessment identifies and evaluates, though is not limited to, the costs and benefits arising from the regulation and its health, economic and social impacts.

The regulatory impact analysis is designed to assist in the process of identifying the affected parties and the likely or potential impacts the regulatory provisions will have on each affected party. Where medium to significant competitive impacts or compliance costs are likely, FSANZ will seek further advice from the Office of Best Practice Regulation (OBPR) and estimate compliance costs of regulatory options. The level of analysis is commensurate to the issue and the regulatory impacts of the application or proposal.

FSANZ conducted, with OBPR subsequently approving, a preliminary assessment of this Application which concluded that there were no business compliance costs involved and/or minimal impact on affected parties.

8.1 Affected Parties

The affected parties to this Application include:

- The manufacturing company (the Applicant, which has an exclusive agreement with their Japanese supplier of the enzyme) which intends to produce and market GOS in Australia and Asia, using β-galactosidase from *B. circulans* ATCC 31382 as a processing aid
- Manufacturers of products containing GOS
- Consumers of food products containing GOS
- Australian, State, Territory and New Zealand Government enforcement agencies that enforce food standards.

8.2 Benefit Cost Analysis

8.2.1 Option 1: Reject the Application

This option is the *status quo*, with no changes to the Code.

Rejecting the Application results in no new costs or benefits to any party.

8.2.2 Option 2: Permit the use of β-galactosidase derived from B. circulans ATCC 31382 *as a food processing aid*

- Industry could benefit from being able to use β-galactosidase derived from *B. circulans* ATCC 31382 as a processing aid. The Applicant has indicated their intention to produce GOS in Australia and consequently it could reduce the cost of GOS in Australia and New Zealand. The use of the enzyme is technologically justified and the GOS product produced from *B. circulans* ATCC 31382 is claimed to be commercially preferred.

- *Manufacturing companies* of food products containing GOS in Australia and the Asian region might benefit from having an alternative source of GOS.

- *Consumers* of food products containing GOS might benefit as GOS produced from the use of β-galactosidase derived from *B. circulans* ATCC 31382 is presumably a preferred GOS product. There should be no added cost to consumers. There are also no safety concerns relating to its use.

- *Jurisdictions* are not expected to incur any significant cost to determine compliance as a result of the amendment compared with current monitoring and compliance activities.

No further quantitative estimates, including additional enforcement costs from any parties are available. Any costs incurred by manufacturers (then passed on to the consumers) would be incurred voluntarily and determined by market forces rather than regulatory pressures.

8.3 Comparison of Options

In assessing applications, FSANZ considers the impact of various regulatory (and non-regulatory) options on all sectors of the community, including consumers, food industries and governments in Australia and New Zealand.

For this Application, Option 1, the *status quo*, does not provide any additional benefit or cost to the food industry, consumers or governments.

Option 2 is favoured since there are potential benefits for the manufacturer of GOS and manufacturers of food containing GOS, as well as consumers. No significant adverse costs have been identified with Option 2 for government stakeholders compared with the *status quo*. As there were no public health and safety issues identified, and use of this enzyme would be voluntary thereby increasing choice, Option 2 is the preferred option.

9. Communication

FSANZ has applied a basic communication strategy to Application A1032. This involved advertising in the national presses the availability of the Assessment Report for public comment, which gave people without access to the internet a chance to participate in the process, as well as making the reports available on the FSANZ website.

The Applicant, individuals and organisations making submissions to this Application have been notified at each stage of the Application. FSANZ will notify the Board's approval of the draft variation to the Ministerial Council.

The Applicant and stakeholders, including the public generally, will be notified of the gazetted changes to the Code in the national press and on the FSANZ website.

10. Consultation

FSANZ sought comment from the public and other interested stakeholders to assist in assessing this Application. The public comment period closed on 10 Feb 2010 and there will be no further round of public comment.

Comments were sought in relation to scientific aspects of the Application including the technological function and any safety considerations, as well as information relating to any potential costs or benefits associated with use of β-galactosidase derived from *B. circulans* ATCC 31382 as a processing aid.

10.1 Summary and responses to issues raised in the submissions

Issues raised by submitters are summarised in Table 1 and since no additional issues were raised that are relevant to this Application, the decision in this Approval Report remains the same as in the Assessment Report.

Table 1: Summary and responses to issues in A1032 Assessment submissions

Submitter	Issues/Comments	Proposed Action/ Responses
New Zealand Food Safety Authority	Supports Option 2.	None.
New South Wales Food Authority	Supports progression of the Application.	None.
Queensland Health, Queensland Government	Supports Option 2. Noting the possible presence of allergens, Queensland Health requested that the onus be on the GOS producer to always provide this advice.	None. This Application is for the approval of *B. circulans* and not the GOS product. Therefore the concern is not relevant to this Application. This issue has been discussed with Queensland Health.
Australian Food & Grocery Council	Supports the Application.	None.
Food Technology Association Australia	Supports Option 2.	None.
Hon Lynn MacLaren MLC Member for South Metropolitan Region	Opposes GMO and the current labelling requirements of food produced using GM.	None. *B. circulans* ATCC 31382 is not a GMO.
Private – Shirley Collins	Embargo approval of GM food until the publication of the Food Labelling Review and the report from Judy Carman[3].	None. *B. circulans* ATCC 31382 is not a GMO.

[3] This is a report being prepared for the Public Health Association of Australia (PHAA) by Judy Carman, a spokesperson on genetically modified (GM) foods, on the safety aspects of GM foods.

Submitter	Issues/Comments	Proposed Action/ Responses
Private – Michelle Denise	Defer the approval of the product until after the publication of Food Labelling Review and Judy Carman's report.	None. FSANZ has a statutory obligation to consider all applications within a statutory timeframe and cannot hold up a consideration process on the grounds that information may become available at a future point.

10.2 World Trade Organization (WTO)

As members of the World Trade Organization (WTO), Australia and New Zealand are obligated to notify WTO member nations 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.

Amending the Code to approve β-galactosidase from *B. circulans* ATCC 31382 as a processing aid is unlikely to have a significant effect on trade. The enzyme preparation complies with the international specifications for food enzymes of JECFA and Food Chemicals Codex, so there does not appear to be a need to notify the WTO. For these reasons FSANZ did not notify the WTO under either the Technical Barriers to Trade or Sanitary and Phytosanitary Measures Agreements.

11. Conclusion and Decision

This Application has been assessed against the requirements of Section 29 of the FSANZ Act.

This Approval Report concludes that the use of the enzyme β-galactosidase derived from *B. circulans* ATCC 31382 as a processing aid is technologically justified and does not pose a public health and safety risk.

An amendment to the Code to give approval to the use of the enzyme β-galactosidase derived from *B. circulans* ATCC 31382 as a processing aid in Australia and New Zealand is recommended on the basis of the available scientific information.

The proposed draft variation is provided in **Attachment 1**.

Decision

To approve the draft variation to the Table to clause 17 of Standard 1.3.3 – Processing Aids, to permit the use of the enzyme β-galactosidase derived from *Bacillus circulans* ATCC 31382.

11.1 Reasons for Decision

An amendment to the Code to permit the use of β-galactosidase derived from *B. circulans* as a processing aid in Australia and New Zealand is proposed on the basis of the available evidence for the following reasons:

- A detailed safety assessment has concluded that there was no toxicology or human safety related concerns with the enzyme β-galactosidase produced by *B. circulans* ATCC 31382

- Use of the enzyme from this source is technologically justified and effective

- The source organism, *B. circulans* ATCC 31382*,* is considered as non-pathogenic and non-toxigenic

- The regulatory impact assessment indicated that there were no business compliance costs involved and/or minimal impacts on affected parties

- There are no other measures that would be more cost-effective than a variation to Standard 1.3.3 that could achieve the same end

- The proposed draft variation to the Code is consistent with the section 18 objectives of the FSANZ Act

- There are no relevant New Zealand standards.

12. Implementation and Review

The FSANZ Board's decision on this Approval Report will be notified to the Ministerial Council Following notification, the proposed draft variation to the Code is expected to come into effect on gazettal, subject to any request from the Ministerial Council for a review of FSANZ's decision.

ATTACHMENT

1. Draft variation to the *Australia New Zealand Food Standards Code*

Attachment 1

Draft variation to the *Australia New Zealand Food Standards Code*

Section 87(8) of the FSANZ Act provides that standards or variations to standards are legislative instruments, but are not subject to disallowance or sunsetting

[1] ***Standard 1.3.3*** *of the Australia New Zealand Food Standards Code is varied by –*

[1.1] *inserting the subclause number* (1) *before the words* In this Standard *in clause 1, and inserting after that subclause –*

(2) In this Standard, the letters 'ATCC' followed by a number is a reference to the number which the American Type Culture Collection uses to identify a prokaryote.

[1.2] *inserting in the* Table to clause 17 *for the enzyme* β-Galactosidase EC 3.2.1.23 *the source –*

Bacillus circulans ATCC 31382