2 February 2017
[04–17]

Call for submissions – Application A1135

Beta-galactosidase as a Processing Aid (Enzyme)

FSANZ has assessed an Application made by Novozymes Australia Pty Ltd to permit the use of a new source of beta-galactosidase from a genetically modified strain of Bacillus licheniformis to be used as a processing aid during the production of reduced lactose or lactose free milk and dairy products 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 and proposals 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 and quicker 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) 17 March 2017

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:

Food Standards Australia New Zealand
PO Box 5423
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PO Box 10559
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Supporting document

The following document which informed the assessment of this Application is available on the FSANZ website:

SD1 Risk and technical assessment

Executive summary

Novozymes Australia Pty Ltd, a biotechnology company, submitted an Application to permit a genetically modified strain of *Bacillus licheniformis* as a new source for the enzyme β-galactosidase (lactase) as a processing aid. β-galactosidase from other microbial sources is already approved as a processing aid.

Enzymes used in processing and manufacturing food are considered processing aids. The effect of using β-galactosidase is the conversion of the milk sugar lactose into primarily glucose and galactose, which may result in improvement of organoleptic properties (taste and flavour), physiological properties (texture and freezing point) and nutritional properties (digestibility and caloric intake). Specifically, this enzyme is used to manufacture reduced-lactose and lactose-free milks and milk products.

Substances used as food processing aids need to be listed in Schedule 18 and, in the case of enzymes, both the enzyme itself and its specific source need to be listed. There is no current permission in Schedule 18 for the enzyme β-galactosidase to be sourced from *Bacillus licheniformis.*

FSANZ has determined that the evidence presented to support the proposed uses provides adequate assurance that the enzyme is technologically justified and is effective in achieving its stated purpose. The enzyme preparation meets international purity specifications for enzymes used in the production of food.

Also, FSANZ's risk assessment concludes that there are no public health and safety issues associated with the use of the enzyme preparation containing β-galactosidase produced by mutated *B. licheniformis* (strain PP3930) as a food processing aid; and that in the absence of any identifiable hazard an Acceptable Daily Intake 'not specified' is appropriate. A dietary exposure assessment is therefore not required.

In regards to labelling, FSANZ considers that the existing labelling requirements in the Code are appropriate for the labelling of foods produced using this enzyme as a processing aid.

FSANZ has considered the potential impacts of approving this Application on consumers, the food industry, and enforcement agencies. FSANZ considers that benefits that would arise from permitting the enzyme β-galactosidase to be sourced from *Bacillus licheniformis* would outweigh the costs.

Therefore, a draft variation to amend Schedule 18 to permit a genetically modified strain of *Bacillus licheniformis* as a new source for the enzyme β-galactosidase as a processing aid has been prepared.

1 Introduction

1.1 The Applicant

The Application was received from Novozymes Australia Pty Ltd, a biotechnology company, on 10 August 2016.

1.2 The Application

The Application seeks to amend Schedule 18 in the *Australia New Zealand Food Standards* Code (the Code) to permit a genetically modified strain of *Bacillus licheniformis* as a new source for the enzyme β-galactosidase (lactase) as a processing aid. The enzyme is intended for use in the preparation of reduced-lactose or lactose-free milk and dairy products. The enzyme preparation has the trade name Saphera, and it is supplied in different strengths depending on the dairy product manufacturing process.

There are no current permissions in Schedule 18 for this enzyme produced using *B. licheniformis,* although this organism is an approved the source of other enzymes in the Schedule.

The effect of using β-galactosidase is the conversion of the milk sugar lactose into primarily glucose and galactose, which may result in improvement of organoleptic properties (taste and flavour), physiological properties (texture and freezing point) and nutritional properties (digestibility and caloric intake – less added sugar needed in some products).

1.3 The current Standard

1.3.1 Standard 1.3.3 and Schedule 18

Enzymes used in processing and manufacturing food are considered processing aids, regulated under Standard 1.3.3. Only those enzymes and sources listed in Schedule 18 are permitted to be used in producing food sold in Australia and New Zealand.

Permitted enzymes of microbial origin, in conjunction with their permitted source organisms, are listed in the table to subsection S18—4(5). There is no current permission in this subsection for the enzyme β-galactosidase (EC number 3.2.1.23) sourced from *Bacillus licheniformis.*

1.3.2 International standards

Codex Alimentarius does not have specific standards for processing aids or enzymes, and many countries do not regulate processing aids or enzymes in the same manner as 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, 2006) and the Food Chemicals Codex (Food Chemicals Codex, 2015).

1.4 Reasons for accepting Application

The Application was accepted for assessment because:

- it complied with the procedural requirements under subsection 22(2), and
- it related to a matter that might be developed as a food regulatory measure

The β-galactosidase (lactase) from a genetically modified strain of *Bacillus licheniformis* is reported to have some different characteristics to lactases from other sources. These characteristics (for example, a higher proportion of glucose and galactose) could confer more choice for reduced-lactose or lactose-free milk and dairy manufacturers and consumers. The specific lactase could only be used as a processing aid if the Code was amended.

1.5 Procedure for assessment

The Application is being assessed under the General Procedure.

2 Summary of the assessment

2.1 Risk and technical assessment

This assessment considers the use of a new source of the enzyme β-galactosidase (lactase) sourced from a genetically modified strain of *B. licheniformis* (strain PP3930), as a processing aid. β-galactosidase catalyses the hydrolysis of terminal non-reducing β-D-galactose residues in β-D-galactosides. In the case of dairy products, the reaction involves the hydrolysis of the disaccharide D-lactose, resulting in the generation of the monosaccharides, D-glucose and D-galactose. The Applicant states that the enzyme will be used during the manufacture of milk to produce low-lactose or lactose-free fresh milk and UHT milk, and subsequent production of reduced-lactose milk products.

The evidence presented to support the proposed uses provides adequate assurance that the enzyme, in the form and prescribed amounts, is technologically justified and is effective in achieving its stated purpose. The enzyme preparation meets international purity specifications for enzymes used in the production of food.

There are no public health and safety issues associated with the use of the product Saphera containing the enzyme lactase from *B. licheniformis* when used as a food processing aid on the basis of the following considerations:

- The production organism *B. licheniformis* is not toxigenic, pathogenic or sporogenic and is absent in the final enzyme preparation proposed to be used as a food processing aid. Further, *B. licheniformis* has a history of safe use as the production organism for a number of enzyme processing aids that are already permitted in the Code.

- Residual enzyme is expected to be present in the final food product but would be inactivated by heat-treatment or pasteurisation, or non-active because of lack of lactose, and susceptible to digestion like any other dietary protein.

- Bioinformatic analysis indicated that the enzyme has no biologically relevant homology to known protein allergens or toxins.

- The enzyme preparation caused no observable effects at the highest tested doses in a 90-day toxicity study in rats. The NOAEL was 0.672 g enzyme solid/kg bw/d, the highest dose tested.

- The enzyme preparation was not mutagenic *in vitro*.

Based on the reviewed toxicological data, it is concluded that, in the absence of any identifiable hazard, an Acceptable Daily Intake ‘not specified’ is appropriate. A dietary exposure assessment is therefore not required.

The Applicant states that soy and wheat products (starch hydrolysates) are used in the fermentation media. The Applicant also showed that residual soy and wheat allergens are not present in the final β-galactosidase product (not detectable).

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

2.2 Risk management

The risk assessment concludes that there are no safety risks from the use of this enzyme as intended, and that the enzyme is technologically justified and its use meets the definition of a processing aid.

Even though the Code needs to be amended to allow the use of this particular enzyme as a processing aid, there are other enzymes and technologies available to produce reduced-lactose and lactose-free milks and milk products. Accordingly this particular enzyme will only be used if manufacturers or consumers consider it will convey desirable attributes. The application lists a number of areas where the final product could be superior to existing products due to the specific characteristics of the enzyme, for example the profile of the sugars in the final product.

As processing aids require permissions in the Code, the risk management options available to FSANZ are either to prepare a draft variation or reject the Application. These options are considered in section 2.4.1.1 and take account of the safety of the enzyme preparation and its source.

Other risk management issues relate to enzyme nomenclature and labelling as discussed below.

2.2.1 Enzyme nomenclature

β-Galactosidase (EC 3.2.1.23) is already permitted as a processing aid in Schedule 18 and the risk and technical assessment confirmed that this was the appropriate name for the enzyme from *B. licheniformis*.

In addition, if approved, the source organism for the enzyme would also need to be listed in the table to subsection S18—4(5). The Code does not normally identify microorganisms down to strains, just to species. Exceptions to this are where the properties belong to a particular strain only, or if there are significant safety or other considerations associated with that strain. In this Application the properties do belong to a particular strain, and so the source organism would be identified as *Bacillus licheniformis*, containing the gene for β-galactosidase isolated from *Bifidobacterium bifidum*.

2.2.2 Labelling considerations

As the risk assessment concludes that the use of the enzyme β-galactosidase (lactase) sourced from the genetically modified strain of *B. licheniformis* poses no risk to public health and safety, FSANZ considers that the existing labelling requirements in the Code are appropriate for the labelling of foods produced using this enzyme as a processing aid.

As a general rule, processing aids are exempt from the requirement to be declared in the statement of ingredients in accordance with paragraph 1.2.4—3(2)(d) of Standard 1.2.4 – Information requirements – statement of ingredients.

Labelling requirements apply where novel DNA and/or novel protein from the processing aid remains present in the food (paragraph 1.5.2—4(1)(b) of Standard 1.5.2 – Food produced using gene technology). In such cases, the statement 'genetically modified' must be declared on the label of the food in conjunction with the name of the processing aid. As the source organism that is genetically modified is not present in the final enzyme preparation (the source organism is removed through purification processes), no novel DNA remains in the enzyme preparation or in the final food. Although residual protein from the enzyme preparation is expected to be present in the final food, the enzyme protein is identical to enzymes found in nature. Consequently, the residual protein from the enzyme preparation is not considered to be novel protein for the purposes of genetically modified labelling. Therefore, as no novel DNA or novel protein is present in the final food, there are no genetically modified labelling requirements for use of this enzyme as a processing aid in the production of food.

The Application states that while soy and wheat products (starch hydrolysates) are used in the fermentation media, residual soy and wheat allergens were not present in the final β-galactosidase preparation (not detectable). However, if soybeans and cereals containing gluten are present in a food for sale, including when present as a processing aid or an ingredient or component of a processing aid, they are required to be declared (section 1.2.3—4 of Standard 1.2.3 – Information requirements – warning statements, advisory statements and declarations).

Nutrition content claims and health claims made about a food prepared using the lactase enzyme as a processing aid must meet Standard 1.2.7 – Nutrition, health and related claims. The applicant states that the lactase enzyme is intended to be used as a processing aid in the dairy industry for making lactose reduced/free products. Under this Standard, the claims 'lactose free' and 'low lactose' are permitted (subject to composition conditions in Schedule 4 – Nutrition, health and related claims), however other nutrition content claims about lactose, such as 'reduced lactose' are not (subsection 1.2.7—12(5)).

2.3 Risk communication

2.3.1 Consultation

Consultation is a key part of FSANZ's standards development process. The process is open, accountable, consultative and transparent. Public submissions are called for to obtain the views of interested parties on issues raised by the Application and the impacts of regulatory options.

FSANZ has applied a basic communication strategy to this Application. The call for submissions will be notified via the Food Standards Notification Circular, media release, FSANZ's social media tools and Food Standards News.

FSANZ acknowledges the time taken by individuals and organisations to make submissions, and every submission on an application is considered by the FSANZ Board. All comments are valued and contribute to the rigour of our assessment.

Following this round of public consultation, the draft variation will be considered for approval by the FSANZ Board, taking into account comments received in 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 food standards and amending Schedule 18 to permit a genetically modified strain of *Bacillus licheniformis* as a new source for the enzyme β-galactosidase (lactase) is unlikely to have a significant effect on international trade. The enzyme preparation complies with international specifications for food enzymes provided by JECFA (JECFA, 2006) and the Food Chemicals Codex (9th Edition) (Food Chemicals Codex, 2015). It is also one of a range of sources of β-galactosidase available to the food industry. Therefore, a notification to the WTO under Australia's and New Zealand's obligations under the WTO Technical Barriers to Trade 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 has 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

FSANZ is required 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 benefits and costs associated with the proposed amendments to the Code are analysed using regulatory impact principles. The level of analysis is commensurate with the nature of the Application and significance of the impacts.

The Office of Best Practice Regulation, in a letter dated 24 November 2010 (reference 12065), provided a standing exemption from the need to assess if a Regulation Impact Statement is required for applications relating to processing aids, as they are machinery in nature and their use is voluntary. However, FSANZ has undertaken a limited impact analysis.

This consideration of the costs and benefits of the draft variation is not intended to be an exhaustive, quantitative economic analysis and, in fact, most of the effects considered cannot be assigned a dollar value. Rather, the assessment aims to highlight the qualitative effects that are relevant to the draft variation. These considerations are deliberately limited to broad areas such as trade, consumer information and compliance.

For consumers, there are no costs associated with the draft variation. The Applicant notes that using β-galactosidase from *Bacillus licheniformis*, compared to β-galactosidase from other sources, may result in a reduced need for added sugars plus the sweetness level not changing during the shelf-life of the dairy product.

For the food industry, the Applicant claims that the use of this enzyme in food processing is superior to the traditional yeast-based lactase because the desired lactose level can be more precisely measured and easily reached, particularly because a much lower level of oligosaccharides are formed during the enzyme reaction. The potential consumer benefits noted above would also benefit the manufacturer and marketer. As the proposed draft variation is a voluntary permission, any costs to food manufacturers would be assessed by them in terms of their specific benefits.

For government agencies, no changes in costs or benefits are likely as a result of this option.

Overall, the direct and indirect benefits that would be gained if this Application was approved would outweigh any costs to the community, Government or industry.

2.4.1.2 Other measures

FSANZ considers that 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

Standard 1.3.3 and Schedule 18 apply to both Australia and New Zealand

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), summarised in Section 2.1 above, which concluded that there are no public health and safety issues associated with the use of the enzyme preparation containing β-galactosidase produced by mutated *B. licheniformis* (strain PP3930) as a food processing aid.

2.4.2.2 The provision of adequate information relating to food to enable consumers to make informed choices

The labelling requirements for the enzyme processing aid are discussed in Section 2.2.2. The existing labelling requirements in the Code are considered to be appropriate for the permitted use of the enzyme in foods.

2.4.2.3 The prevention of misleading or deceptive conduct

The evidence presented in the Application to support the proposed uses provides adequate assurance that the enzyme is technologically justified and is effective in achieving its stated purpose as a processing aid.

The generic labelling requirements for making voluntary nutrition content and health claims (section 2.2.2 above), including claims such as, 'lactose free', and 'low lactose' will apply to prevent consumers being misled or deceived.

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. The Applicant submitted a dossier of scientific studies as part of their Application. Additional 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, and many countries do not regulate processing aids or enzymes in the same manner as the Code.

However, there are internationally recognised specifications for enzymes provided by the Joint FAO/WHO Expert Committee on Food Additives (JECFA, 2006) and the Food Chemicals Codex (Food Chemicals Codex, 2015), and this enzyme complies with those specifications..

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

The use of β-galactosidase (lactase) from *Bacillus licheniformis* is currently undergoing various international registrations. The enzyme preparation is approved in Denmark, has a 'no questions' response from the USFDA[1] regarding Novozymes' determination that the beta-galactosidase enzyme preparation is GRAS for its intended use, and approval has been obtained in Mexico.

The Applicant expects that the introduction of this enzyme to the Australia/New Zealand market will provide benefits to food manufacturers and may result in preferred reduced-lactose and lactose-free dairy products and ingredients.

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

The enzyme preparation has been assessed as safe by FSANZ. It meets international specifications and is undergoing approval in other countries. It is therefore appropriate that the local Australian and New Zealand food industries can also benefit by gaining permission to use this enzyme preparation.

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

The Ministerial *Policy Guideline on the 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 with regard to the substance.

FSANZ considers that permitting the use of the enzyme β-galactosidase (lactase) from *Bacillus licheniformis* as a processing aid is consistent with the specific order policy principles for 'Technological Function'.

[1] http://www.fda.gov/Food/IngredientsPackagingLabeling/GRAS/NoticeInventory/ucm462492.htm
[2] http://www.foodstandards.gov.au/code/fofr/fofrpolicy/pages/default.aspx

3 Draft variation

The draft variation to the 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 Legislation.

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 A1135 – Beta-galactosidase 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 A1135 – Beta-galactosidase 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 omitting from the table to subsection S18—4(5)

β-Galactosidase (EC 3.2.1.23)	*Aspergillus niger* *Aspergillus oryzae* *Bacillus circulans* ATCC 31382 *Kluyveromyces marxianus* *Kluyveromyces lactis*

and substituting

β-Galactosidase (EC 3.2.1.23)	*Aspergillus niger* *Aspergillus oryzae* *Bacillus circulans* ATCC 31382 *Bacillus licheniformis*, containing the gene for β-Galactosidase isolated from *Bifidobacterium bifidum* *Kluyveromyces marxianus* *Kluyveromyces lactis*

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 A1135 which seeks to permit the use of a genetically modified strain of *Bacillus licheniformis* as a new source for the enzyme β-galactosidase (lactase) as a processing aid. The Authority considered the Application in accordance with Division 1 of Part 3 and has prepared a draft variation.

2. Purpose

The Authority has prepared an amendment to the Code to permit a new microbial source for the enzyme 'β-Galactosidase (EC number 3.2.1.23)', namely *Bacillus licheniformis* containing the gene for β-Galactosidase isolated from *Bifidobacterium bifidum*.

The effect of the proposed variation is to permit the use of the enzyme 'β-Galactosidase (EC number 3.2.1.23)' derived from this new source as a processing aid in food in accordance with Standard 1.3.3 of the Code.

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 A1135 will include one round of public consultation following an assessment and the preparation of a draft Standard and associated assessment summary.

A Regulation Impact Statement was not required because the proposed variation to Schedule 18 is 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 amends Schedule 18 by omitting the entry for the enzyme 'β-Galactosidase (EC 3.2.1.23)' in the table to subsection S18—4(5) and substituting it with a new entry for that enzyme. The new entry includes an additional microbial source for the enzyme 'β-Galactosidase (EC 3.2.1.23)': *Bacillus licheniformis*, containing the gene for β-Galactosidase isolated from *Bifidobacterium bifidum*.