

**7 July 2017**  
**[17–17]**

Approval report – Application A1135

## Beta-galactosidase as a Processing Aid (Enzyme)

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Food Standards Australia New Zealand (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.

On 2<sup>nd</sup> February 2017, FSANZ sought submissions on a draft variation and published an associated report. FSANZ received three submissions.

FSANZ approved the draft variation on 22 June 2017. The Australia and New Zealand Ministerial Forum on Food Regulation (Forum) was notified of FSANZ's decision on 6 July 2017.

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

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### Supporting document

The [following document](#) 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  $\beta$ -galactosidase (lactase) as a processing aid.  $\beta$ -galactosidase from other microbial sources is already approved as a processing aid.

Enzymes used in processing and manufacturing food are considered processing aids.  $\beta$ -galactosidase converts 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 of the *Australia New Zealand Food Standards Code* (the Code) 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  $\beta$ -galactosidase to be sourced from *B. 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 to produce food.

FSANZ's risk assessment concluded that there are no public health and safety issues associated with using the enzyme preparation containing  $\beta$ -galactosidase produced by modified *B. licheniformis* (strain PP3930) as a food processing aid.

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

FSANZ considered the potential impacts of approving this Application on consumers, the food industry, and enforcement agencies. FSANZ concluded that benefits that would arise from permitting the enzyme  $\beta$ -galactosidase to be sourced from *B. licheniformis* would outweigh the costs.

Therefore, a draft variation was prepared to amend Schedule 18 to permit a genetically modified strain of *B. licheniformis* as a new source for the enzyme  $\beta$ -galactosidase as a processing aid.

Three submissions were received on the draft variation and related assessment summary, one from an industry peak body and two from governments. All three submitters supported the draft variation, and did not raise any other issues.

Accordingly, the draft variation as proposed following assessment was approved without change.

# 1 Introduction

## 1.1 The Applicant

The Application was received from Novozymes Australia Pty Ltd, a biotechnology company.

## 1.2 The Application

The Application sought 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  $\beta$ -galactosidase (lactase) as a processing aid. The enzyme is intended for use in preparing 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 source of other enzymes in the Schedule.

The effect of using  $\beta$ -galactosidase is converting the milk sugar lactose into primarily glucose and galactose, which may result in improved 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  $\beta$ -galactosidase (EC number 3.2.1.23) sourced from *B. 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 warranted the variation of a food regulatory measure].

## 1.5 Procedure for assessment

The Application was assessed under the General Procedure.

## 1.6 Decision

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

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

# 2 Summary of the findings

## 2.1 Summary of issues raised in submissions

Three submissions were received, two from government and one from an industry peak body.

All three supported the proposed variation and two also provided an analysis of their reasoning. No issues were raised.

## 2.2 Risk assessment

The assessment considered the use of a new source of the enzyme  $\beta$ -galactosidase (lactase) sourced from a genetically modified strain of *B. licheniformis* (strain PP3930), as a processing aid.  $\beta$ -galactosidase catalyses the hydrolysis of terminal non-reducing  $\beta$ -D-galactose residues in  $\beta$ -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 stated 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 provided 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 using the product Saphera containing the enzyme lactase from *B. licheniformis* when used as a food processing aid based on 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 no-observed-adverse-effect-level (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 was concluded that, in the absence of any identifiable hazard, an Acceptable Daily Intake 'not specified' is appropriate. A dietary exposure assessment was therefore not required.

The information provided by the Applicant stated that soy and wheat products (starch hydrolysates) are used in their fermentation media. However, information was provided showing that residual soy and wheat allergens are not present in the final  $\beta$ -galactosidase product (not detectable).

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

## **2.3 Risk management**

The risk assessment concluded that there were no safety risks from using this enzyme as intended, and that the enzyme was technologically justified and its use met the definition of a processing aid.

Even though the Code needed 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 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.

Risk management issues relating to enzyme nomenclature and labelling are discussed below.

### **2.3.1 Enzyme nomenclature**

$\beta$ -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*.

The source organism for the enzyme also needs 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 is identified as *B. licheniformis*, containing the gene for  $\beta$ -galactosidase isolated from *Bifidobacterium bifidum*.

### **2.3.2 Labelling considerations**

As the risk assessment concluded that the use of the enzyme  $\beta$ -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 labelling 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) in 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) in 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 Applicant provided evidence that while soy and wheat products (starch hydrolysates) are used in their fermentation media, residual soy and wheat allergens were not present in the final  $\beta$ -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 in 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 stated 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)).

## **2.4 Risk communication**

### **2.4.1 Consultation**

Consultation is a key part of FSANZ’s standards development process. The process is open, accountable, consultative and transparent. FSANZ applied a basic communication strategy to this Application. The call for submissions was notified via the Food Standards Notification Circular, media release, FSANZ’s social media tools and Food Standards News. Public submissions were called for on 2 February 2017 to obtain the views of interested parties on issues raised by the Application and the impacts of regulatory options, and closed on 16 March 2017.

Three submissions were received, all supporting the proposed variation. FSANZ acknowledges the time taken by individuals and organisations to make submissions on this Application.

Every submission was considered by the FSANZ Board. All comments are valued and contribute to the rigour of our assessment.

## **2.5 FSANZ Act assessment requirements**

### **2.5.1 Section 29**

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

The direct and indirect benefits that would arise from the food regulatory measure varied as a result of the Application outweigh the costs to the community, Government or industry that would arise from the variation of the food regulatory measure.

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.

For consumers, there are no costs associated with the draft variation. The Applicant noted that using  $\beta$ -galactosidase from *B. licheniformis*, compared to  $\beta$ -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 claimed that using 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 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 variation.

#### **2.5.1.2 Other measures**

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

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

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

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

Other relevant matters are considered below.

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

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

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

FSANZ undertook a safety assessment (SD1), summarised in Section 2.2 above, which concluded that there are no public health and safety issues associated with using the enzyme preparation containing  $\beta$ -galactosidase produced by mutated *B. licheniformis* (strain PP3930) as a food processing aid.

### **2.5.2.2 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 2.3.2. The existing labelling requirements in the Code are considered to be appropriate for the permitted use of the enzyme in foods.

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

The evidence presented in the Application to support the proposed uses provided 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.

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

FSANZ has also had regard to:

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

FSANZ used the best available scientific evidence to conduct the risk analysis. 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 Applicant expects that introducing 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 use of  $\beta$ -galactosidase (lactase) from *B. licheniformis* is currently undergoing various international registrations. The enzyme preparation is approved in Denmark, has a 'no questions' response from the USFDA regarding Novozymes' determination that the beta-galactosidase enzyme preparation is GRAS for its intended use, and approval has been obtained in Mexico.

It is therefore appropriate that the local Australian and New Zealand food industries could also benefit by gaining permission to use this enzyme preparation.

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

The enzyme preparation has been assessed as safe by FSANZ, and would be an additional version of currently approved enzyme preparations used for the same purpose. Its use and labelling requirements, including foods made using the enzyme, are currently regulated and so there is no impact on fair trading in food.

- **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](#) 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  $\beta$ -galactosidase (lactase) from *Bacillus licheniformis* as a processing aid is consistent with the specific order policy principles for 'Technological Function'.

## **Attachments**

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

## **Attachment A – Approved 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.



## Attachment B – Explanatory Statement

### 1. Authority

Section 13 of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act) provides that the functions of Food Standards Australia New Zealand (the Authority) include the development of standards and variations of standards for inclusion in the *Australia New Zealand Food Standards Code* (the Code).

Division 1 of Part 3 of the FSANZ Act specifies that the Authority may accept applications for the development or variation of food regulatory measures, including standards. This Division also stipulates the procedure for considering an application for the development or variation of food regulatory measures.

FSANZ accepted Application A1135 which seeks to permit the use of a genetically modified strain of *Bacillus licheniformis* as a new source for the enzyme  $\beta$ -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.

Following consideration by the Australia and New Zealand Ministerial Forum on Food Regulation, section 92 of the FSANZ Act stipulates that the Authority must publish a notice about the standard or draft variation of a standard.

Section 94 of the FSANZ Act specifies that a standard, or a variation of a standard, in relation to which a notice is published under section 92 is a legislative instrument, but is not subject to parliamentary disallowance or sunseting under the *Legislation Act 2003*.

### 2. Purpose

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

The effect of the proposed variation is to permit the use of the enzyme  $\beta$ -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– Processing aids.

### 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 included one round of public consultation following an assessment and the preparation of a draft Standard and associated assessment summary. Submissions were called for on 2<sup>nd</sup> February 2017 for a six-week consultation period.

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 of the variation amends Schedule 18 of the Code 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*.