

12 August 2021
167-21

Approval report – Application A1218

β -Galactosidase from *Bacillus subtilis* (Enzyme)

Food Standards Australia New Zealand (FSANZ) has assessed an Application made by Danisco New Zealand Ltd to seek approval for a β -galactosidase (EC 3.2.1.23) enzyme derived from a genetically modified organism to be used as a processing aid in lactose reduced dairy food production.

On 29 April 2021, FSANZ sought [submissions](#) on a draft variation and published an associated report. FSANZ received three submissions.

FSANZ approved the draft variation on 4 August 2021. The Food Minister's Meeting¹ was notified of FSANZ's decision on 12 August 2021.

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

¹ Formerly referred to as the Australia and New Zealand Ministerial Forum on Food Regulation.

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Supporting document

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

SD1 Risk assessment – Application A1218 – β -Galactosidase from *Bacillus subtilis* (Enzyme)

Executive summary

Danisco New Zealand Ltd (Danisco) submitted an application to Food Standards Australia New Zealand (FSANZ) to permit an enzyme, β -galactosidase (EC 3.2.1.23) from a particular microbial source to be used as a processing aid in the production of lactose reduced dairy products. The source is a genetically modified (GM) strain of *Bacillus subtilis* containing the gene for β -galactosidase from *Lactobacillus delbrueckii* subsp.² *bulgaricus*.

Enzymes used to produce and manufacture food are considered processing aids and are regulated by the Australia New Zealand Food Standards Code (the Code). The table to subsection S18—9(3) of Schedule 18 in the Code lists substances (including enzymes) permitted to be used as processing aids for specific technological purposes. β -Galactosidase sourced from a genetically modified (GM) strain of *Bacillus subtilis* containing the gene for β -galactosidase from *Lactobacillus delbrueckii* subsp. *bulgaricus* is not currently permitted to be used as a processing aid.

Analysis of the evidence provides adequate assurance that:

- the use of the enzyme, in the quantity and form proposed, is technologically justified, and
- the enzyme is effective in achieving its stated purpose.

β -Galactosidase performs its technological purpose during the production of dairy foods and is not performing a technological purpose in the final food, therefore functioning as a processing aid as defined in the Code. There are relevant international identity and purity specifications for the enzyme in the Code which would have to be complied with.

After undertaking a risk assessment, FSANZ concluded that the use of the enzyme under the proposed conditions of use is safe. Based on the reviewed toxicological and dietary exposure data, it was concluded that an acceptable daily intake (ADI) 'not specified' is appropriate.

Following assessment and the preparation of a draft variation, FSANZ called for submissions regarding the draft variation from 29 April to 4 June 2021. Three submissions were received in response. All submissions were supportive of the draft variation.

Based on the information above and on other relevant considerations set out in this report, FSANZ has approved a draft variation to subsection S18—9(3) of the Code to permit the enzyme β -galactosidase (EC 3.2.1.23) sourced from a GM strain of *Bacillus subtilis* containing the gene for β -galactosidase from *Lactobacillus delbrueckii* subsp. *bulgaricus*, to be used as a processing aid in the production of lactose reduced dairy foods. The permission is subject to the condition that the maximum permitted level of this enzyme that may be present in the food is consistent with Good Manufacturing Practice (GMP).

² subspecies

1 Introduction

1.1 The Applicant

The Applicant is Danisco New Zealand Ltd (Danisco). Danisco made the application on behalf of DuPont Industrial Biosciences (IB), the manufacturer/marketer of the processing aid that is the subject of the application. When the application was submitted to Food Standards Australia New Zealand (FSANZ) in November 2020, Danisco was a subsidiary of E. I. du Pont de Nemours and Company (DuPont). On 4 February 2021, FSANZ was informed that Danisco New Zealand (and Danisco Australia) had changed ownership from DuPont to International Flavours & Fragrances Inc. (IFF). Danisco New Zealand Ltd remains the applicant.

1.2 The Application

The applicant seeks to amend the Australia New Zealand Food Standards Code (the Code) to permit the enzyme, β -galactosidase (EC 3.2.1.23) from a particular microbial source to be used as a processing aid. The source is a genetically modified (GM) strain of *Bacillus subtilis* (*B. subtilis*) containing the gene for β -galactosidase from *Lactobacillus delbrueckii* (*L. delbrueckii*) subsp. *bulgaricus*.

The technological purpose of the processing aid is to reduce the lactose content in dairy foods during production. It would be used at a level consistent with GMP, which limits the amount of the enzyme that is added to food to the lowest possible level necessary to accomplish its desired effect.

1.3 The current standard

Australian and New Zealand food laws require food for sale to comply with relevant requirements in the Code. The requirements in the Code relevant to this application are summarised below.

1.3.1 Permitted use

Enzymes used to process and manufacture food are considered processing aids. Although they may be present in the final food, they no longer provide a technological purpose in the final food.

Paragraph 1.1.1—10(6)(c) provides that food for sale cannot contain, as an ingredient or component, a substance 'used as a processing aid' unless that substance's use as a processing aid is expressly permitted by the Code. Section 1.1.2—13 provides that a substance 'used as a processing aid' in relation to a food is a substance used during the course of processing that meets all of the following conditions: it is used to perform a technological purpose during the course of processing; it does not perform a technological purpose in the food for sale; and it is a substance listed in Schedule 18 or identified in section S16—2 as an additive permitted at GMP.

Standard 1.3.3 and Schedule 18 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), depending on whether a technological purpose has been specified. Enzymes of microbial origin listed in the table to subsection S18—4(5) are permitted for use as a processing aid to perform *any* technological purpose if the enzyme is derived from the corresponding source specified in the relevant table. The table to subsection S18—9(3) lists those substances, including enzymes derived from particular sources, that are permitted to be used as processing aids for *specific* technological purposes in relation to:

- if a food is specified—that food; or
- if no food is specified—any food.

Additionally, paragraph 1.3.3—11(c) specifies that the substance may only be used as a processing aid if it is not present in the food at greater than the maximum permitted level for that substance indicated in the table to section S18—9.

Paragraph 1.1.1—10(6)(g) requires that the presence of a food produced using gene technology as an ingredient or component in a food for sale must be expressly permitted by the Code. Paragraph 1.5.2—3(b) provides that permission in the Code for use as a processing aid also constitutes the permission required by paragraph 1.1.1—10(6)(g).

There are currently permissions for the enzyme, β -galactosidase (EC 3.2.1.23) of microbial origin within the table to subsection S18—4(5), to be used in the manufacture of all foods. There is also permission for β -galactosidase (EC 3.2.1.23) of microbial origin within the table to subsection S18—9(3). However, β -galactosidase from the particular microbial source requested in this application is not currently permitted.

1.3.2 Identity and purity requirements

Paragraph 1.1.1—15(1)(b) requires substances used as processing aids in food to comply with any relevant identity and purity specifications listed in Schedule 3.

Subsection S3—2(1) of Schedule 3 incorporates by reference the specifications listed in the Joint FAO/WHO Expert Committee on Food Additives (JECFA) Combined Compendium of Food Additive Specifications (FAO JECFA Monographs 20 (2017)) and the United States Pharmacopeial Convention Food chemicals codex (United States Pharmacopeial Convention 11th edition (2018)). Certain earlier publications from these primary sources include the relevant specifications for enzyme preparations used in food processing (JECFA (2006) and FCC (2008), respectively).

1.3.3 Labelling requirements

Paragraph 1.1.1—10(8) provides that a food for sale must comply with all relevant labelling requirements imposed by the Code for that food.

Subsection 1.2.3—4(1) requires certain foods to be declared when present in a food for sale. Paragraph 1.2.3—4(5)(c) states the food may be present as a substance used as a processing aid, or an ingredient or component of such a substance.

Paragraphs 1.2.4—3(2)(d) and (e) exempt processing aids from the requirement to be declared in the statement of ingredients, unless other requirements apply.

Section 1.5.2—4 requires processing aids that are, or have as ingredients, foods produced using gene technology to be labelled ‘genetically modified’, where novel DNA and/or novel protein from the processing aid remains present in the final food. The requirement applies to foods for sale that consist of or have as an ingredient, food that is a *genetically modified food*³ (GM) food. The requirements imposed by section 1.5.2—4 generally apply only to foods for retail sale and to foods sold to a caterer under subsections 1.2.1—8(1) and 1.2.1—9(3), and section 1.2.1—15 respectively.

1.4 Overseas approvals

Regulation (EC) No 1332/2008 (the Regulation) harmonises the rules for food enzymes in the European Union (EU). Previous to the Regulation, food enzymes used as processing aids were not regulated at the EU level. According to the Regulation, all food enzymes currently on the EU market, as well as new food enzymes, are subject to a safety evaluation by the European Food Safety Authority (EFSA) and subsequently approved by the European Commission by means of an EU list. Currently, there is no EU list of authorised food enzymes. Until the establishment of such a list (anticipated for release in 2021), EU Member States’ legislation applies. The applicant advised that the substance is currently approved for use as a processing aid in France and Denmark.

The applicant provided an externally produced GRAS (Generally Recognised As Safe) opinion on the safety of *L. delbrueckii bulgaricus* β -galactosidase produced in *B. subtilis*. This opinion has not been submitted to the US Food and Drug Administration (FDA) as a GRAS notification.

1.5 Reasons for accepting Application

The Application was accepted for assessment because:

- it complied with the procedural requirements under subsection 22(2) of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act)
- it related to a matter that warranted the variation of a food regulatory measure.

1.6 Procedure for assessment

The Application was assessed under the General Procedure in the FSANZ Act.

1.7 Decision

For reasons set out in this report, FSANZ decided to approve a draft variation permitting the use of this enzyme as a processing aid in lactose reduced dairy food production, as requested by the applicant.

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.

³ Section 1.5.2—4(5) defines *genetically modified food* to mean a *food produced using gene technology that

- a) contains novel DNA or novel protein; or
- b) is listed in Section S26—3 as subject to the condition that its labelling must comply with this section (*that being section 1.5.2—4*).

2 Summary of the findings

2.1 Summary of issues raised in submissions

FSANZ called for submissions on a draft variation to the Code from 29 April to 4 June 2021. Three submissions were received, two from government agencies and one from an industry body. All submitters supported the application and draft variation (see Table 1).

Table 1: Summary of submitters comments

Submitter	Comments
New Zealand Food Safety	Supports the draft variation
Victorian Department of Health and the Victorian Department of Jobs, Precincts and Regions	Supports progression of the application
New Zealand Food and Grocery Council	Supports the draft variation

2.2 Risk assessment

FSANZ has assessed the risks associated with the use of β -galactosidase enzyme (EC 3.2.1.23) from a GM strain of *B. subtilis*, containing the β -galactosidase gene from *L. delbrueckii* subsp. *bulgaricus* as a processing aid in the production of lactose reduced dairy foods (see SD1). A summary of this risk assessment is provided below.

There are no safety concerns associated with the use of β -galactosidase derived from this particular source, as a food processing aid at GMP levels in the production of lactose reduced dairy foods.

The safety assessment did not identify any concerns associated with the host organism, *B. subtilis*, or the gene donor organism, *L. delbrueckii* subsp. *bulgaricus*. The host is neither pathogenic nor toxigenic and has a long history of safe use in food. Characterisation of the GM production strain confirmed both the presence and stable inheritance of the inserted β -galactosidase gene. Bioinformatic analyses found no similarity of the enzyme protein to known toxins or allergens.

The no observed adverse effect level (NOAEL) in a 13-week repeated dose oral toxicity study in rats was the highest dose tested and corresponds to 1000 mg/kg body weight/day total organic solids (TOS). This is more than 100-fold higher than the theoretical maximum daily intake (TMDI) estimated by FSANZ when using conservative assumptions (9.7 mg TOS/kg body weight/day), and more than 200-fold higher than FSANZ's estimate of exposure over a long period of time or a lifetime (4.8 mg TOS/kg body weight/day), based on the proposed use, as stated in the Application.

Based on the reviewed toxicological and dietary exposure data, it was concluded that an acceptable daily intake (ADI) 'not specified' is appropriate.

2.3 Risk management

2.3.1 Regulatory approval for processing aids

As outlined above, FSANZ has concluded from the risk assessment undertaken that there are no safety concerns relating to the proposed use of this β -galactosidase enzyme (EC 3.2.1.23) as a processing aid.

From the food technology assessment, FSANZ concluded that the proposed use of this β -

galactosidase enzyme in the production of lactose reduced dairy foods is consistent with its typical function of catalysing the hydrolysis of lactose. Analysis of the evidence provides adequate assurance that the use of this enzyme, in the quantity and form proposed to be used, which must be consistent with GMP controls and processes, is technologically justified.

β -Galactosidase performs its technological purpose during the production of dairy foods and is not performing a technological purpose in the final food, therefore functioning as a processing aid as defined in the Code.

FSANZ therefore considers it is appropriate to permit the use of the enzyme β -galactosidase (EC 3.2.1.23) from a GM strain of *B. subtilis* containing the β -galactosidase gene from *L. delbrueckii* subsp. *bulgaricus*, as a processing aid to reduce the lactose content of dairy foods during production. The permission is subject to the condition that the maximum permitted level of this enzyme that may be present in the food is consistent with GMP. A draft variation to the Code has been prepared to permit the proposed use of this enzyme (Attachment A). There are relevant identity and purity specifications for the enzyme in Schedule 3 of the Code which would have to be complied with.

The express permission for the enzyme to be used as a processing aid would also provide the permission for its potential presence in the food for sale as a food produced using gene technology. The enzyme is a food produced using gene technology for Code purposes as it is derived from 'an organism that has been modified using gene technology' (see subsection 1.1.2—2(3) of the Code).⁴

FSANZ notes 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 the number EC 3.2.1.23 (IUBMB 2020). This is the name that is used in the approved draft variation to the Code.

2.3.2 Labelling requirements

The generic exemption from listing processing aids in the statement of ingredients would apply to foods manufactured using this processing aid (see Section 1.3 above).

2.3.2.1 Labelling requirements for food produced using gene technology

Standard 1.5.2 in effect provides that a substance used as a processing aid that contains novel DNA or novel protein is a GM food. In contrast to the generic exemption for listing processing aids, subsection 1.5.2—4(2) states that the information relating to foods produced using gene technology must include the statement 'genetically modified' in conjunction with the name of the GM food. Subsection 1.5.2—4(3) states that if the GM food is used as a processing aid, the information may be included in the statement of ingredients.

The requirement for labelling as 'genetically modified' differs depending on whether the GM food is an ingredient of the food for sale or not. A food for retail sale or sold to a caterer that contains β -galactosidase sourced from the GM strain *B. subtilis* as an ingredient (e.g. the enzyme is used in the manufacture of cheese), would be required to be labelled 'genetically modified' in conjunction with the name of the enzyme.

⁴ 'Food produced using gene technology' is defined in subsection 1.1.2—2(3) as meaning 'a food which has been derived or developed from an organism which has been modified by gene technology'.

FSANZ notes however, if the food made using the enzyme (e.g. cheese) is not a food for sale itself (e.g. an ingredient in a mixed food such as topping on a pizza), the enzyme would not be an ingredient in the food for sale. Therefore, the requirement to label β -galactosidase as 'genetically modified' would not apply because the labelling requirements only apply to food for sale that consists of, or has as an ingredient, a GM food (subsection 1.5.2—4(1)).

2.3.2.2 Declaration of certain substances

Section 3.4 of SD1 states that while soy and wheat products are used as ingredients in the fermentation process to manufacture this enzyme, residual soy and wheat allergens cannot be detected in the final β -galactosidase preparation. However, if soy or wheat is present, including when present as a processing aid or an ingredient or component of a processing aid, they must be declared in accordance with Division 3 of Standard 1.2.3. If the food is not required to bear a label, the allergen information must be displayed in connection with the display of the food or provided to the purchaser on request (subsections 1.2.1—9(6) and (7) of Standard 1.2.1).

2.3.2.3 Nutrition content claims and health claims

Nutrition content claims and health claims made about a food prepared using the β -galactosidase enzyme as a processing aid must comply with requirements in Standard 1.2.7. The applicant states that the enzyme is intended to be used as a processing aid in dairy processing to reduce the lactose content of dairy 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 'lactose reduced', are not permitted (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. FSANZ developed and applied a standard 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 standards' development matters is open, accountable, consultative and transparent. Public submissions were called to obtain the views of interested parties on issues raised by the application and the impacts of regulatory options.

FSANZ acknowledges the time taken by individuals and organisations to make submissions on this application. All comments are valued and contribute to the rigour of our assessment.

The draft variation was considered for approval by FSANZ having regard to all submissions made during the call for submissions period.

2.5 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.

2.5.1 Section 29

2.5.1.1 Consideration of costs and benefits

The Office of Best Practice Regulation (OBPR) granted FSANZ a standing exemption from the requirement to develop a Regulatory Impact Statement for applications relating to processing aids and GM food (OBPR correspondence dated 24 November 2010, reference 12065). This standing exemption was provided as permitting new GM foods and new processing aids is deregulatory as their use will be voluntary if the application is approved. This standing exemption relates to the introduction of a food to the food supply that has been determined to be safe.

FSANZ, however, gave consideration to the costs and benefits that may arise from the proposed measure for the purposes of meeting FSANZ Act considerations. The FSANZ Act requires FSANZ to have regard to whether costs that would arise from the proposed measure outweigh the direct and indirect benefits to the community, government or industry that would arise from the proposed measure (paragraph 29(2)(a)).

The purpose of this consideration was to determine if the community, government and industry as a whole is likely to benefit, on balance, from a move from the status quo, where the status quo is rejecting the application. This analysis considered permitting the use of β -galactosidase derived from a new source, i.e. from a GM strain of *B. subtilis* containing the gene for β -galactosidase from *L. delbrueckii* subsp. *bulgaricus*, for use as a processing aid in the production of dairy foods to reduce lactose content.

The consideration of the costs and benefits in this section is not intended to be an exhaustive, quantitative economic analysis of the proposed measures and, in fact, most of the effects that were considered cannot easily be assigned a dollar value. Rather, the assessment seeks to highlight the likely positives and negatives of moving away from the status quo by permitting the proposed use of β -galactosidase derived from this new source as a processing aid.

2.5.1.1.1 Industry

The proposed use of β -galactosidase derived from this new source as a processing aid may reduce costs (of reducing lactose content) and/or increase access to this processing aid for industry. The applicant has provided evidence of a dosage advantage using the β -galactosidase that is the subject of this application in lactose reduction of 20-50% compared to other commercially available lactase, subject to the hydrolysis conditions used and the lactose concentration in the product. Due to the voluntary nature of the permission, industry would use this particular β -galactosidase as a processing aid where they believe a net benefit exists.

Use of β -galactosidase from this GM strain of *B. subtilis* as a processing aid is already permitted in France and Denmark. The international permissions for use of this enzyme as a processing aid may be a business opportunity for Australian and New Zealand industries, although there may also be competing imports from these countries into the domestic market.

2.5.1.1.2 Consumers – mainly lactose intolerant consumers

Industry may pass some of the cost savings to consumers where it is cheaper to acquire this β -galactosidase and to reduce lactose content. Lactose-intolerant consumers may also benefit from a greater number of processed dairy foods that contain lower lactose content if permission to use β -galactosidase from this source as a processing aid results in increased opportunities to produce more dairy foods with reduced lactose content.

2.5.1.1.3 Government

Permitting β -galactosidase derived from this particular source to be used as a processing aid may result in a small cost to government in terms of adding this new substance to the current range of processing aids that are monitored for compliance.

2.5.1.1.4 Conclusions from cost benefit considerations

FSANZ's assessment at the call for submissions was that the direct and indirect benefits that would arise from permitting the use of β -galactosidase from a GM strain of *B. subtilis* containing the β -galactosidase gene from *L. delbrueckii* subsp. *bulgaricus* as a processing aid in the production of lactose reduced dairy foods most likely outweigh the associated costs. No further information was received during the consultation process that changed the findings from the analysis of costs and benefits in the call for submissions.

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

The Standards in the Code which are relevant to the permitted use of the enzyme processing aid in question apply in both Australia and New Zealand. There are no relevant New Zealand only Standards.

2.5.1.4 Any other relevant matters

Other relevant matters are considered below.

2.5.2 Subsection 18(1)

FSANZ 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 has undertaken a safety assessment (SD1) and concluded that there are no public health and safety concerns relating to the use of the β -galactosidase enzyme (EC 3.2.1.23) from a GM strain of *B. subtilis*, containing the β -galactosidase gene from *L. delbrueckii* subsp. *bulgaricus*, as a processing aid in the production of lactose reduced dairy foods.

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

Existing labelling requirements in the Code related to β -Galactosidase are discussed in Section 2.2.2 of the report above.

2.5.2.3 The prevention of misleading or deceptive conduct

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

2.5.3 Subsection 18(2) considerations

FSANZ has also had regard to:

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

FSANZ has used the best available scientific evidence to conduct the risk analysis. The risk assessment is provided in SD1. The applicant submitted a dossier of scientific studies as part of the application. This dossier, together with other technical information including scientific literature, was considered by FSANZ in assessing the application.

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

In terms of food safety, the relevant international standard setting body is the Codex Alimentarius Commission (Codex). In contrast to food additives, there is no Codex Alimentarius 'general standard' for enzymes. There are however, internationally recognised specifications for enzymes. These enzyme specifications are provided through the Joint FAO/WHO Expert Committee on Food Additives (JECFA) Compendium of Food Additive Specifications (JECFA 2006) and the Food Chemicals Codex specifications for enzymes (FCC 2008) (refer to Section 1.3 of this report).

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

The conclusion of the risk assessment was that there are no public health and safety issues associated with using this β -galactosidase as a processing aid during production to reduce the lactose content of dairy foods. It is therefore appropriate that Australian and New Zealand food industries are given the opportunity to benefit from the proposed use of this enzyme as an alternative to those currently permitted. Which enzyme preparation a food manufacturing company uses will depend on a number of economic and other factors.

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

No issues were identified for this application relevant to this objective.

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

The Ministerial Policy Guideline Addition to Food of Substances other than Vitamins and Minerals⁵ 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

⁵ Available on the [Food regulation website](#) (accessed 13 October 2020).

- no nutrition, health or related claims are to be made in regard to the substance.

FSANZ has determined that permitting the proposed use of this enzyme as a processing aid is consistent with the specific order policy principles for 'Technological Function'. All other relevant requirements of the policy guideline are similarly met.

3 References

FCC (2008). Enzyme preparations. In: Food Chemicals Codex, 6th edition. Rockville (MD): United States Pharmacopeial Convention, pp. 413-417.

JECFA (2006) General Specifications and Considerations for Enzyme Preparations. In: *Combined Compendium of Food Additive Specifications [Online Edition]*. World Health Organization, Geneva, Switz. Available at: <http://www.fao.org/food/food-safety-quality/scientific-advice/jecfa/jecfa-additives/en/>. Accessed 11 June 2021

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 A1218 – β -Galactosidase from *Bacillus subtilis* (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 the Delegate]

[Insert name and title of the 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 A1218 – β -Galactosidase from Bacillus subtilis (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 into the table to subsection S18—9(3), in alphabetical order

β -Galactosidase (EC 3.2.1.23) sourced from <i>Bacillus subtilis</i> containing the β -galactosidase gene from <i>Lactobacillus delbrueckii</i> subsp. <i>bulgaricus</i>	For use in the production of lactose reduced dairy foods.	GMP
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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.

The Authority accepted Application A1218 which seeks approval for a β -galactosidase (EC 3.2.1.23) enzyme derived from a new genetically modified source to be used as a processing aid in lactose reduced dairy food production. The Authority considered the Application in accordance with Division 1 of Part 3 and has approved a draft variation.

Following consideration by the Food Ministers' Meeting¹, 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 approved a draft variation amending the table to section S18—9(3) of the Code to permit the use of the enzyme, β -galactosidase (EC 3.2.1.23) sourced from *Bacillus subtilis* containing the β -galactosidase gene from *Lactobacillus delbrueckii* subsp.² *bulgaricus*, as a processing aid in the production of lactose reduced dairy foods.

3. Documents incorporated by reference

This variation does not incorporate any documents by reference.

However, section 1.1.1—15 of the Code requires certain substances (such as processing aids) to comply with any relevant identity and purity specifications listed in Schedule 3. Schedule 3 incorporates documents by reference to set specifications for various substances in the circumstances specified in that Schedule. The documents incorporated include: the Joint FAO/WHO Expert Committee on Food Additives (JECFA) Compendium of Food Additive Specifications (FAO/WHO 2017); the United States Pharmacopeial Convention (2018) Food Chemicals Codex (11th edition); and the Commission Regulation (EU) No 231/2012.

4. Consultation

In accordance with the procedure in Division 1 of Part 3 of the FSANZ Act, the Authority's consideration of Application A1218 included one round of public consultation following an assessment and the preparation of a draft variation and associated report. Submissions were

¹ Formerly referred to as the Australia and New Zealand Ministerial Forum on Food Regulation.

² subspecies

called for on 29 April 2021 for a six-week consultation period.

The Office of Best Practice Regulation (OBPR) granted the Authority a standing exemption from the requirement to develop a Regulatory Impact Statement (RIS) for applications relating to processing aids and genetically modified food (OBPR correspondence dated 24 November 2010, reference 12065). This standing exemption was provided as permitting new GM foods and new processing aids is deregulatory as their use will be voluntary if the application is approved. This standing exemption relates to the introduction of a food to the food supply that has been determined to be safe.

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] inserts a new entry, in alphabetical order, into the table to subsection S18—9(3) of the Code.

The new entry consists of the following substance: an enzyme, 'β-Galactosidase (EC 3.2.1.23) sourced from *Bacillus subtilis* containing the β-galactosidase gene from *Lactobacillus delbrueckii* subsp. *bulgaricus*'.

The technological purpose for using this enzyme as a processing aid is 'For use in the production of lactose reduced dairy foods'.

The permission to use this enzyme as a processing aid for the stated technological purpose is subject to the condition that the maximum permitted level or amount of this enzyme that may be present in the food must be consistent with Good Manufacturing Practice.