

**19 December 2022**  
**[223-22]**

Approval report – Application A1220

## Beta-amylase from GM *Bacillus licheniformis* as a processing aid

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Food Standards Australia New Zealand (FSANZ) has assessed an application made by Novozymes Australia Pty Limited seeking to amend the Australia New Zealand Food Standards Code to permit beta-amylase from a genetically modified strain of *Bacillus licheniformis* to be used as a processing aid in starch processing to manufacture maltose syrup.

On 2 August 2022, FSANZ sought submissions on a draft variation and published an associated report. FSANZ received three submissions.

FSANZ approved the draft variation on 14 December 2022. The Food Ministers' Meeting<sup>1</sup> was notified of FSANZ's decision on 19 December 2022.

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

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## Supporting document

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

SD           Risk and Technical Assessment

# Executive summary

Novozymes Australia Pty Ltd applied to Food Standards Australia New Zealand (FSANZ) to amend the Australia New Zealand Food Standards Code (the Code) to permit the use of the enzyme beta-amylase (EC 3.2.1.2) from genetically modified (GM) *Bacillus licheniformis* (*B. licheniformis*) as a processing aid in starch processing to manufacture maltose syrup.

The beta-amylase enzyme is produced by submerged fermentation of *B. licheniformis* containing the beta-amylase gene from *Priestia flexa* (basionym *Bacillus flexus*). The beta-amylase gene donor was named in the application as *Bacillus flexus*. FSANZ has assessed the taxonomy of the gene donor and determined the current legitimate name to be *Priestia flexa* based on a recent revision of the *Bacillus* genus.

FSANZ undertook an assessment to determine whether the enzyme achieves the requested technological purpose in the quantity and form proposed to be used, and to evaluate public health and safety concerns associated with its use.

FSANZ concluded that the proposed use of the beta-amylase enzyme in starch processing to manufacture maltose syrup is consistent with its typical function of catalysing the hydrolysis of starch. Analysis of the evidence provides adequate assurance that the use of the enzyme, in the form and requested amount (i.e. at a level not higher than necessary to achieve the desired enzyme reaction according to Good Manufacturing Practice (GMP)), is technologically justified and has been demonstrated to be effective in achieving the stated purpose.

Beta-amylase performs its technological purpose during the manufacture of maltose syrup and is not performing a technological purpose in the final food, therefore functioning as a processing aid for the purposes of the Code. Relevant general identity and purity specifications for enzyme preparations used in food processing are included in the Code. This enzyme will have to comply with those specifications.

No public health and safety concerns were identified in the assessment of beta-amylase from GM *B. licheniformis* under the proposed conditions of use. A microbiological assessment concluded that *B. licheniformis* has a long history of safe use in food and is neither pathogenic nor toxigenic. A biotechnology assessment confirmed the genetic modification is as described and that the inserted gene has been stably introduced. A toxicological assessment combined with a dietary exposure assessment concluded the enzyme is safe under the proposed conditions of use. In the absence of any identifiable hazard, an acceptable daily intake (ADI) 'not specified' is appropriate.

Following assessment and the preparation of a draft variation to the Code, FSANZ called for submissions regarding the draft variation from 2 August to 13 September 2022. FSANZ received three submissions. Two submissions supported the draft variation. The other submission supported the draft variation in principle but requested further data regarding the sequence homology assessment for the enzyme. FSANZ has considered the specific issues raised in that submission and does not consider that further data would be useful.

Based on the information above and on other relevant considerations set out in this report, FSANZ has approved a draft variation to the table to subsection S18—9(3) of the Code to permit the enzyme beta-amylase (EC 3.2.1.2) sourced from *B. licheniformis* containing the beta-amylase gene from *P. flexa* (basionym *B. flexus*) as a processing aid. The enzyme will be permitted for use in starch processing to manufacture maltose syrup. This permission is subject to the condition that the maximum permitted level of the enzyme that may be present in the food is an amount consistent with GMP. The effect of the approved draft variation will

be to permit the proposed use of this enzyme as a processing aid in accordance with the Code.

# 1 Introduction

## 1.1 The applicant

The applicant is Novozymes Australia Pty Limited (Novozymes).

## 1.2 The application

The applicant is seeking to amend the Australia New Zealand Food Standards Code (the Code) to permit the use of the enzyme beta-amylase from genetically modified (GM) *Bacillus licheniformis* (*B. licheniformis*) as a processing aid. The beta-amylase enzyme is produced by submerged fermentation of *B. licheniformis* containing the beta-amylase gene from *Priestia flexa* (basionym *Bacillus flexus*). The beta-amylase gene donor named in the application is *Bacillus flexus*. Food Standards Australia New Zealand (FSANZ) has assessed the taxonomy of the donor organism and determined the current legitimate name to be *P. flexa* based on a recent revision of the *Bacillus* genus (see Section 3.1.2 of the Supporting Document (SD)). FSANZ notified the applicant about the name change and they have accepted *P. flexa* as the name of the donor species.

The stated purpose for the enzyme is for use in starch processing to manufacture maltose syrup.

The applicant markets a liquid preparation containing this enzyme as the active constituent under the name 'Secura' in other countries where use of the enzyme is permitted (see Section 2.5.3).

The applicant has indicated the enzyme is to be used at minimum levels necessary to achieve the desired effect, in accordance with Good Manufacturing Practice (GMP).

## 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 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 processing that meets all the following conditions:

- it is used to perform a technological purpose during 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 of the Code list the permitted processing aids. Enzymes of

microbial origin permitted to be used as processing aids are listed in the table to subsection S18—4(5) or in the table to subsection S18—9(3) of Schedule 18, depending on whether a technological purpose has been specified. 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 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 as an ingredient or component in a food for sale of a food produced using gene technology 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).

Beta-amylase is already permitted to be used as a processing aid by the Code including from plant sources (subsection S18—4(4) and section S18—9) and from microbial origins (subsection S18—4(5)), but not from *B. licheniformis* carrying the beta-amylase gene from *P. flexa* (basionym *B. flexus*) as requested by the applicant.

### 1.3.2 Identity and purity requirements

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

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 23 (2019)), and the United States Pharmacopeial Convention (2020) Food Chemicals Codex (12<sup>th</sup> edition). These include general specifications for enzyme preparations used in food processing that include identity and purity parameters.

### 1.3.3 Labelling requirements

Subsection 1.1.1—10(8) provides that food for sale must comply with all relevant labelling requirements in the Code.

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 of the Code requires a food for sale that consists of a *genetically modified food*<sup>2</sup> (GM food) or has a GM food as an ingredient to be labelled as 'genetically modified', unless an exemption applies. The label statement 'genetically modified' must be made in conjunction with the name of the GM food. If the GM food is used as a processing aid, this

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<sup>2</sup> 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*).

statement may be included in the statement of ingredients. Standard 1.2.1 provides that the requirements imposed by section 1.5.2—4 apply only to foods for retail sale and to foods sold to a caterer.

## **1.4 International standards**

In developing food regulatory measures, FSANZ must have regard to 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 however, as noted above, there are internationally recognised specifications for enzyme preparations established by JECFA and Food Chemicals Codex.

In addition, there is a Codex guideline, *Guidelines on Substances used as Processing Aids* (CAC/GL 75-2010), which sets out general principles for the safe use of substances used as processing aids, including that substances used as processing aids shall be used under conditions of GMP.

## **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 amending the Code to permit the use of this enzyme as a processing aid in starch processing to manufacture maltose syrup.

The draft variation as proposed following assessment was approved without change. The approved draft variation takes effect on gazettal and 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**

FSANZ sought public comments on the draft variation included in the call for submissions report between 2 August and 13 September 2022.

FSANZ received three submissions and had regard to all three submissions. New Zealand Food Safety and the New Zealand Food and Grocery Council supported the draft variation. The Victorian Departments of Health and of Jobs, Precincts and Regions were also supportive of the draft variation but raised one issue as detailed in Table 1 below.

**Table 1: Summary of issues**

Summary of issue	Raised by	FSANZ response
<p><b>Note the sequence homology assessment identified a 44.7% identity with a known food allergen (Tri a 17, derived from wheat) over an 80 amino acid window, which is above the 35% threshold suggested to indicate potential allergenicity. However, FSANZ concluded the enzyme was unlikely to pose any allergenic concerns in food.</b></p> <p><b>Codex guidelines recognise no single criterion can predict allergenicity and on this basis, recommend a stepwise approach that draws on evidence and data from multiple sources to assess allergen potential in newly expressed proteins. The departments support this approach and suggest further data for the enzyme, such as protein digestibility or immunological assays should be considered given the sequence homology assessment indicated potential for allergenicity.</b></p> <p><b>Note the purification processes in the manufacture of the enzyme do not reduce potential safety hazards as the presence of allergens even at minute levels can elicit an allergenic response in some individuals.</b></p>	<p>Victorian Departments of Health and of Jobs, Precincts and Regions</p>	<p>The FSANZ approach to the assessment of potential allergenicity, as outlined in the FSANZ Application Handbook, is based on the Codex guidelines and follows a stepwise, case by case approach. Part of that stepwise approach is to consider exposure to the protein, including the contribution of processing, in reaching a conclusion about the potential human health risk.</p> <p>FSANZ has carefully considered the issues raised by the Departments, including the suggestion that additional data be requested, however FSANZ does not consider that the further data would add to the weight of evidence, which already points to a low human health risk.</p> <p>In relation to the sequence homology with Tri a 17, we note this protein is also a beta-amylase and that some homology or percentage identity between beta-amylases would be expected based on a common function. By itself, this does not constitute evidence for an allergenic hazard.</p> <p>Based on the information available from the WHO/IUIS Allergen Nomenclature Sub-Committee (allergen.org), FSANZ does not consider the evidence sufficient to conclude that exposure to Tri a 17 induces clinical allergic response, although it does elicit responses such as IgE binding and basophil activation in vitro.</p> <p>The threshold of 35% identity over 80 or more amino acids is used for screening purposes in a weight of evidence approach that is based on scientific advice issued by the FAO/WHO in 2001 which informed the development of the Codex guidelines. Since that time further evidence indicates that the 35% threshold is overly conservative and is prone to false positive findings in relation to the potential for cross-reactivity. A conventional FASTA alignment over the entire length of the protein produces fewer false positive findings and equivalent false negative rates compared to the 80 amino acid search (Ladics et al 2007). FSANZ therefore considers the results of a full-length search to be more reliable and meaningful than the 80 amino acid search when comparing identities of proteins to allergens. When the bioinformatic comparison for the beta-amylase was measured over the full length of the protein, the % identity was found to be 25.7%, which is not considered to be biologically meaningful. FSANZ notes the Codex guideline allows for the use of other scientifically justified criteria to determine if homology results are biologically meaningful.</p> <p>In general, &lt;50% amino acid identity among proteins rarely results in antigenic cross-reactivity. Greater than &gt;70% identity is necessary before there is a high risk of cross-reactivity (Ladics et</p>



al 2014). Given FSANZ's assessment indicated the identified homology with Tri a 17 was not biologically meaningful, there is no justification for undertaking specific serum screening. The Codex guideline only recommends these additional studies be undertaken when a protein originates from a source known to be allergenic, or if it has biologically meaningful sequence homology with a known allergen.

In relation to the digestibility study proposed by the Departments, recent information and evidence indicates the pepsin digestion assay (for protein digestibility) is unlikely to be a good predictor of allergenic potential (EFSA 2021). FSANZ therefore does not consider such a study is likely to provide any additional useful information for the allergenicity assessment. EHC 240 Principles and Methods for the Risk Assessment of Chemicals in Food (IPCS 2009) states '...data on resistance to pepsinolysis from in vitro tests are currently not considered to be strong evidence for the absence of the intrinsic allergenicity of a protein, although they still may have some utility as part of a weight-of-evidence approach.'

The intended use of the beta-amylase that is the subject of A1220 is to hydrolyse starch in order to produce maltose syrups. As described in the application, during subsequent steps of syrup production, over 99% of the enzyme is removed by processes that include filtration, ion exchange chromatography, carbon treatment and crystallisation. As a result, FSANZ considers there to be a very low likelihood that any enzyme is present in the final food. This further adds to the weight of evidence indicating the potential human health risk is low.

## 2.2 Risk assessment

FSANZ has assessed the public health and safety risks associated with beta-amylase produced by GM *B. licheniformis* and its proposed use as a processing aid. A summary of this risk assessment is provided below.

The proposed use of this beta-amylase as a processing aid in starch processing for maltose syrup production is technologically justified.

No public health and safety concerns were identified in the assessment of beta-amylase from GM *B. licheniformis* under the proposed conditions of use. A microbiological assessment concluded that *B. licheniformis* has a long history of safe use in food and is neither pathogenic nor toxigenic. A biotechnology assessment confirmed the genetic modification is as described and that the inserted gene has been stably introduced. A toxicological assessment combined with a dietary exposure assessment concluded the enzyme is safe under the proposed conditions of use.

In the absence of any identifiable hazard, an acceptable daily intake (ADI) of 'not specified' is appropriate.

For further details on the risk assessment, refer to the SD – Risk and Technical Assessment.

## 2.3 Risk management

The risk management options available to FSANZ after assessment were to either:

- reject the application, or
- prepare a draft variation of the Code.

The conclusions from the risk and technical assessment were that the proposed use of the enzyme is technically justified and there were no safety concerns associated with its proposed use at levels consistent with GMP.

FSANZ therefore considered it appropriate to prepare a draft variation amending the Code to permit the proposed use of this enzyme in starch processing to manufacture maltose syrup and called for submissions on the draft variation.

Following the call for submissions and having regard to all submissions received, for the reasons set out in this report, FSANZ considers it appropriate to approve the draft variation proposed following assessment without change (see Attachment A).

Risk management considerations for this application relating to the enzyme and source microorganism nomenclature, specifications and labelling are discussed below.

### 2.3.1 Regulatory approval for enzymes

Beta-amylase performs its technological purpose during the processing of starch to produce maltose syrup and does not perform a technological purpose in the final food. On that basis, the enzyme would function as a processing aid for the purposes of the Code. Based on the food technology assessment, FSANZ concluded that the proposed use of this enzyme is consistent with its typical function of catalysing the hydrolysis of starch to maltose. As stated above (Section 1.7), FSANZ has approved a draft variation to permit the use of the enzyme as a processing aid in the production of maltose syrup.

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 according to the Code as it is derived from 'an organism that has been modified using gene technology' (see subsection 1.1.2—2(3) of the Code).

### **2.3.2 Enzyme nomenclature, source microorganism nomenclature and specifications**

FSANZ notes that the International Union of Biochemistry and Molecular Biology (IUBMB) uses the accepted name 'β-amylase'. This is the name used in the approved draft variation and the name used in existing permissions for beta-amylase in Schedule 18. The word 'beta' has been used in this report and was used by the applicant in the application, instead of its symbol.

Nomenclature for the host and gene donor organisms (*Bacillus licheniformis* and *Priestia flexa* (basionym *Bacillus flexus*), respectively) is in accordance with accepted international norms (see Section 1.2 of this report).

There are relevant identity and purity general specifications for enzyme preparations in two of the primary sources of specifications listed in Schedule 3 of the Code, namely the JECFA Combined Compendium of Food Additive Specifications and the United States Pharmacopeial Convention Food Chemicals Codex (refer to Section 1.3.2 above). As noted in Section 2.2.3 of the SD, the enzyme will have to comply with those identity and purity specifications.

### **2.3.3 Labelling**

The generic labelling provisions in the Code will apply to foods for sale that are manufactured using this processing aid. See Section 1.3.3 above.

### **2.3.4 Risk management conclusion**

The risk management conclusion is to permit the enzyme beta-amylase (EC 3.2.1.2) sourced from a GM strain of *B. licheniformis* containing the beta-amylase gene from *P. flexa* (basionym *B. flexus*) for use as a food processing aid. The enzyme will be listed in the table to subsection S18—9(3) of the Code, which includes enzymes permitted for a specific technological purpose. The technological purpose of this enzyme will be use as a processing aid in starch processing in the production of maltose syrup. The maximum level at which the enzyme may be present in the food will be an amount consistent with GMP. The express permission for the enzyme to be used as a processing aid in Schedule 18 of the Code will also provide the permission for the enzyme's potential presence in the food for sale as a food produced using gene technology.

## **2.4 Risk communication**

Consultation is a key part of FSANZ's standards development process.

FSANZ developed and applied a standard 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.

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 a submission on this application.

The draft variation was considered for approval by the FSANZ Board 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 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 foods (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 concerned 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 is likely to benefit, on balance, from a move from the status quo. This analysis considered permitting the proposed use of the enzyme beta-amylase (EC 3.2.1.2) from GM *B. licheniformis* as a processing aid in starch processing to manufacture maltose syrup.

The consideration of the costs and benefits in this section is not intended to be an exhaustive, quantitative economic analysis of the proposed measure. In fact, most of the effects that were considered cannot easily be assigned a dollar value. Rather, the assessment sought to highlight the likely positives and negatives of moving away from the status quo by permitting the use of the enzyme produced from the GM strain of *B. licheniformis*.

FSANZ's conclusions regarding costs and benefits of the proposed measure are set out below.

#### **2.5.1.1.1 Costs and benefits of permitting the use of enzyme beta-amylase (EC 3.2.1.2) sourced from a GM strain of *B. licheniformis* as a processing aid**

##### *Industry*

The enzyme beta-amylase is already available to industry from other production sources. Due to the voluntary nature of the permission, industry will use beta-amylase from this additional source, GM *B. licheniformis*, where businesses in the industry believe a net benefit exists for them. An additional source of this enzyme may help industry save on production costs of starch processing to manufacture maltose syrup.

The applicant advised that use of this enzyme from this source already has approval for various purposes in France, Denmark, Brazil and Mexico. On that basis, approval of this beta-amylase in the Code may help some of Australia's and New Zealand's sales in international markets. There may, however, be more competing imports in the domestic market from countries that use this enzyme into the future.

#### *Consumers*

Industry may pass cost savings to consumers, where it is cheaper to source beta-amylase from GM *B. licheniformis* in production processes.

#### *Government*

Permitting the proposed use of this beta-amylase may result in a small cost to government in terms of an addition to the current range of processing aids that are monitored for compliance.

#### *Conclusions from cost benefit considerations*

FSANZ's assessment at the call for submissions stage was that the direct and indirect benefits that would arise from permitting the proposed use of the enzyme beta-amylase from a GM strain of *B. licheniformis* as a processing aid in starch processing to manufacture maltose syrup most likely outweigh the associated costs. No further information was received during the consultation process that changed that assessment.

#### **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 relevant standards 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 undertook a safety assessment (see the SD) and concluded there were no public health and safety concerns associated with the proposed use of this enzyme.

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

The labelling requirements for this enzyme are discussed in Section 2.3.3 of this report.

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

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

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

There are relevant international specifications for enzyme preparations, being the JECFA Compendium of Food Additive Specifications and the Food Chemicals Codex specifications for enzymes referred to in Section 1.3 of this report, with which this enzyme must comply.

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

The applicant advised that their beta-amylase enzyme is currently used in a range of countries, where there are no restrictions on the use of enzyme processing aids or where the enzyme is covered by a country positive list or specific approval. They also advised that their beta-amylase enzyme (or their preparation containing the enzyme) has been approved for use in Denmark, France, Brazil and Mexico.

Approval for use of the applicant's beta-amylase will bring Australia and New Zealand into line with other jurisdictions where it is already permitted for use. In this way, Australia and New Zealand would remain competitive with other international markets. This will also help foster continued innovation and improvements in food manufacturing techniques and processes.

The conclusion of the risk assessment is there are no public health and safety concerns associated with the proposed use of the enzyme as a food processing aid. It is therefore appropriate that Australian and New Zealand food industries are given the opportunity to benefit from this alternative enzyme for the application proposed by the applicant.

Ultimately, the domestic food industry will make their own economic decisions, taking into account the costs and benefits of using the new enzyme, to determine if it is of benefit to their particular business.

- **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 Food Ministers' Meeting**

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

*Minerals*<sup>3</sup> includes specific order policy principles for substances added to achieve a solely technological function, such as processing aids. These specific order policy principles state that permission should be granted where:

- the purpose for adding the substance can be articulated clearly by the manufacturer as achieving a solely technological function (i.e. the 'stated purpose')
- the addition of the substance to food is safe for human consumption
- the amounts added are consistent with achieving the technological function
- the substance is added in a quantity and a form which is consistent with delivering the stated purpose
- no nutrition, health or related claims are to be made in regard to the substance.

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

### 3 References

EFSA (2021) Statement on in vitro protein digestibility tests in allergenicity and protein safety assessment of genetically modified plants. EFSA Journal 2021;19(1):6350

IPCS (2009) Environmental Health Criteria 240: Principles and Methods for the Risk Assessment of Chemicals in Food <https://www.who.int/publications/i/item/9789241572408>

Ladics GS, 1, Bannon GA, Silvanovich A and Cressman RF (2007). Comparison of conventional FASTA identity searches with the 80 amino acid sliding window FASTA search for the elucidation of potential identities to known allergens. Molecular Nutrition & Food Research 51, 985 - 998

Ladics GS, Fry J, Goodman R, Herouet-Guicheney C, Hoffmann-Sommergruber K, Madsen CB, Penninks A, Pomés A, Roggen EL, Smit J and Wal J-M (2014) Allergic sensitization: screening methods. Clinical and Translational Allergy 4:13

Parte, A.C., Sardà Carbasse, J., Meier-Kolthoff, J.P., Reimer, L.C. and Göker, M. (2020). List of Prokaryotic names with Standing in Nomenclature (LPSN) moves to the DSMZ. International Journal of Systematic and Evolutionary Microbiology, 70, 5607-5612; DOI: 10.1099/ijsem.0.004332

### Attachments

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

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<sup>3</sup> [Food regulation website](#)

## Attachment A – Approved draft variation to the Australia New Zealand Food Standards Code



### Food Standards (Application A1220 – Beta-amylase from GM *Bacillus licheniformis* as a processing aid) 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 the Delegate]

[Insert Delegate's name and position title]

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 A1220 – Beta-amylase from GM Bacillus licheniformis as a processing aid) 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**

**Schedule 18—Processing aids**

**[1] Subsection S18—9(3) (table)**

Insert:

$\beta$ -Amylase (EC 3.2.1.2) sourced from <i>Bacillus licheniformis</i> containing the $\beta$ -amylase gene from <i>Priestia flexa</i> (basionym <i>Bacillus flexus</i> )	For use in starch processing to manufacture maltose syrup	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 A1220 which sought to amend the Code to permit the enzyme beta-amylase ( $\beta$ -amylase) from a genetically modified strain of *Bacillus licheniformis* to be used as a processing aid in starch processing to manufacture maltose syrup. 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' Meeting (FMM), section 92 of the FSANZ Act stipulates that the Authority must publish a notice about the standard or draft variation of a standard.

### 2. Variation is a legislative instrument

The approved draft variation is a legislative instrument for the purposes of the *Legislation Act 2003* (see section 94 of the FSANZ Act) and is publicly available on the Federal Register of Legislation ([www.legislation.gov.au](http://www.legislation.gov.au)).

This instrument is not subject to the disallowance or sunset provisions of the *Legislation Act 2003*. Subsections 44(1) and 54(1) of that Act provide that a legislative instrument is not disallowable or subject to sunset if the enabling legislation for the instrument (in this case, the FSANZ Act): (a) facilitates the establishment or operation of an intergovernmental scheme involving the Commonwealth and one or more States; and (b) authorises the instrument to be made for the purposes of the scheme. Regulation 11 of the *Legislation (Exemptions and other Matters) Regulation 2015* also exempts from sunset legislative instruments a primary purpose of which is to give effect to an international obligation of Australia.

The FSANZ Act gives effect to an intergovernmental agreement (the Food Regulation Agreement) and facilitates the establishment or operation of an intergovernmental scheme (national uniform food regulation). That Act also gives effect to Australia's obligations under an international agreement between Australia and New Zealand. For these purposes, the Act establishes the Authority to develop food standards for consideration and endorsement by the FMM. The FMM is established under the Food Regulation Agreement and the international agreement between Australia and New Zealand, and consists of New Zealand, Commonwealth and State/Territory members. If endorsed by the FMM, the food standards on gazettal and registration are incorporated into and become part of Commonwealth, State and Territory and New Zealand food laws. These standards or instruments are then administered, applied and enforced by these jurisdictions' regulators as part of those food laws.

### 3. Purpose

The Authority has approved a draft variation amending the table to subsection S18—9(3) in Schedule 18 of the Code to permit the use of the enzyme  $\beta$ -amylase (EC 3.2.1.2) sourced from *Bacillus licheniformis* containing the  $\beta$ -amylase gene from *Priestia flexa* (basionym *Bacillus flexus*) as a processing aid in starch processing to manufacture maltose syrup. This permission is subject to the condition that the maximum permitted level or amount of the enzyme that may be present in the food must be consistent with Good Manufacturing Practice (GMP).

### 4. Documents incorporated by reference

The approved draft variation does not incorporate any documents by reference.

However, existing provisions of the Code incorporate documents by reference that will prescribe identity and purity specifications for the processing aid to be permitted by the approved draft variation. Section 1.1.1—15 of the Code requires substances used as processing aids to comply with any relevant identity and purity specifications listed in Schedule 3 of the Code. Section S3—2 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 23 (2019)) and the United States Pharmacopeial Convention (2020) Food Chemicals Codex (12th edition). These include general specifications for the identity and purity of enzyme preparations used in food processing.

### 5. Consultation

In accordance with the procedure in Division 1 of Part 3 of the FSANZ Act, the Authority's consideration of Application A1220 included one round of public consultation following an assessment and the preparation of a draft variation and associated report. Submissions were called for on 2 August 2022 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 for applications relating to permitting new processing aids and genetically modified foods (OBPR correspondence dated 24 November 2010 - reference 12065). This standing exemption was provided as permitting new genetically modified foods and new processing aids is deregulatory as their use will be voluntary if the application concerned is approved. This standing exemption relates to the introduction of a food to the food supply that has been determined to be safe.

### 6. 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 44 of the *Legislation Act 2003*.

### 7. Variation

Item [1] of the Schedule to the variation inserts a new entry, in alphabetical order, into the table to subsection S18—9(3) in Schedule 18. The new entry consists of the following enzyme in column 1 of the table:

- $\beta$ -Amylase (EC 3.2.1.2) sourced from *Bacillus licheniformis* containing the  $\beta$ -amylase gene from *Priestia flexa* (basionym *Bacillus flexus*).

The technological purpose for this enzyme prescribed in column 2 of the table is use as a processing aid in starch processing to manufacture maltose syrup. Specifically, the enzyme catalyses the hydrolysis of starch to maltose.

The permission is subject to the condition, as prescribed in column 3 of the table, that the maximum permitted level or amount of this enzyme that may be present in the food must be consistent with GMP.

The effect of the variation is to permit the proposed use of  $\beta$ -amylase (EC 3.2.1.2) sourced from *Bacillus licheniformis* containing the  $\beta$ -amylase gene from *Priestia flexa* (basionym *Bacillus flexus*) as a processing aid in accordance with the Code.