

**19 June 2023**

**247-23**

Approval report – Application A1229

## Carboxypeptidase from GM *Aspergillus oryzae* as a processing aid

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Food Standards Australia New Zealand (FSANZ) has assessed an application made by Novozymes Australia Pty Ltd to amend the Australia New Zealand Food Standards Code to permit the use of the carboxypeptidase enzyme, sourced from a genetically modified *Aspergillus oryzae*, as a processing aid in the manufacture and/or processing of proteins, yeast and flavourings; the manufacture of bakery products; and brewing.

On 8 February 2023, FSANZ sought submissions on a draft variation and published an associated report. FSANZ received two submissions.

FSANZ approved the draft variation on 7 June 2023. The Food Ministers' Meeting<sup>1</sup> was notified of FSANZ's decision on 19 June 2023.

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 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 submitted an application to Food Standards Australia New Zealand (FSANZ) to amend the Australia New Zealand Food Standards Code (the Code) to permit the use of the carboxypeptidase enzyme (EC 3.4.16.6), sourced from genetically modified (GM) *Aspergillus oryzae*, containing the carboxypeptidase gene from *A. oryzae*, as a new processing aid in the manufacture and/or processing of proteins, yeast and flavourings; the manufacture of bakery products; and brewing.

Carboxypeptidase is a serine carboxypeptidase which hydrolyses proteins into shorter proteins/peptides, and free amino acids by preferential release of a C-terminal arginine or lysine residue (BRENDA:EC3.4.16.6, 2022).

FSANZ identified no public health and safety concerns in the assessment of the carboxypeptidase (EC 3.4.16.4) from a genetically modified (GM) strain of *A. oryzae* under the proposed use conditions. The *A. oryzae* host is neither pathogenic nor toxigenic. Analysis of the modified production strain confirmed the presence and stability of the inserted DNA.

Carboxypeptidase does not show any sequence homology with known toxins. The enzyme was not genotoxic *in vitro*, and no treatment-related adverse effects were observed in a 90-day rat study. No biologically meaningful homology to known food allergens was identified. Based on the available evidence the enzyme is unlikely to pose a food allergenicity concern.

Following assessment and the preparation of a draft variation to the Code, FSANZ called for submissions regarding the draft variation from 8 February 2023 to 22 March 2023. FSANZ received two submissions, both supportive of the draft variation.

Based on the information above and for the reasons 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 use of the carboxypeptidase enzyme (EC 3.4.16.6) sourced from GM *A. oryzae* containing the carboxypeptidase gene from *A. oryzae* as a processing aid. The enzyme will be permitted for use in the manufacture and/or processing of proteins, yeast and flavourings; the manufacture of bakery products; and brewing.

This permission will be subject to the condition that the maximum permitted level of the enzyme that may be present in the food is an amount consistent with Good Manufacturing Process. 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

Novozymes Australia Pty Ltd is a manufacturer of enzymes, microorganisms and precision proteins based in Sydney, Australia.

## 1.2 The application

The purpose of the application was to amend the Australia New Zealand Food Standards Code (the Code) to permit the use of carboxypeptidase (EC 3.4.16.6), sourced from genetically modified (GM) *Aspergillus oryzae*, as a processing aid for use in the manufacture and/or processing of proteins, yeast and flavourings; the manufacture of bakery products; and brewing. This organism contains the carboxypeptidase gene from *A. oryzae*. Novozymes requested the approval of this carboxypeptidase to perform the technological function of hydrolysis of proteins into shorter proteins/peptides, and free amino acids by preferential release of a C-terminal arginine or lysine residue (BRENDA:EC3.4.16.6, 2022).

## 1.3 The current Standard

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

### 1.3.1 Permitted use

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 Good Manufacturing Process (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).

No sources of carboxypeptidase are approved for use in the Code.

### **1.3.2 Identity and purity requirements**

Paragraph 1.1.1—15(1)(b) of the Code requires substances used as processing aids in food 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 (USPC 2020) Food Chemicals Codex (12th edition). These include specifications for enzyme preparations used in food processing.

### **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 statement may be included in the statement of ingredients. In these circumstances, the requirements imposed by section 1.5.2—4 apply only to foods for retail sale and to foods sold to a caterer in accordance with Standard 1.2.1.

## **1.4 International standards**

In developing food regulatory measures, Food Standards Australia New Zealand (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). 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 might be developed as a food regulatory measure.

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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*).

## 1.6 Procedure for assessment

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

## 1.7 Decision

For reasons outlined 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 the manufacture and/or processing of proteins, yeast and flavourings; the manufacture of bakery products; and brewing.

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 called for submissions on a draft variation to the Code from 8 February 2023 to 22 March 2023. Two submissions were received. Both submitters supported permitting the use of the new GM microbial source for the enzyme carboxypeptidase as a processing aid in the manufacture and/or processing of proteins, yeast and flavourings; the manufacture of bakery products; and brewing.

The submissions were received from:

- New Zealand Food Safety
- New Zealand Food and Grocery Council.

## 2.2 Risk assessment

FSANZ has assessed the public health and safety risks associated with carboxypeptidase from *A. oryzae* that is produced by GM *A. oryzae* and its proposed use as a processing aid. A summary of this risk assessment is provided below.

No public health and safety concerns were identified in the assessment of carboxypeptidase from GM *A. oryzae* under the proposed conditions of use. A microbiological assessment concluded that *A. oryzae* 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. Carboxypeptidase does not show any sequence homology with known toxins. The enzyme was not genotoxic *in vitro*, and no treatment-related adverse effects were observed in a 90-day rat study. No biologically meaningful homology to known food allergens was identified. Based on the available evidence the enzyme is unlikely to pose a food allergenicity concern.

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

For further details on the risk assessment, refer to SD1 – 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 technologically 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 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

FSANZ's assessment confirmed that carboxypeptidase performs its technological purpose in the course of processing and it does not perform a technological purpose in the food for sale. On that basis, the enzyme would function as a processing aid for the purposes of the Code. From the food technology assessment, FSANZ concluded that the proposed use of this enzyme is consistent with its typical function of catalysing the breakdown of proteins, releasing shorter proteins/peptides and amino acids. As stated above, FSANZ has approved a draft variation to permit the use of the enzyme as a processing aid in the manufacture and/or processing of proteins, yeast and flavourings; the manufacture of bakery products; and brewing.

The express permission for the enzyme to be used as a processing aid will 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 which has been modified using gene technology' (see subsection 1.1.2—2(3) of the Code)<sup>3</sup>.

### 2.3.2 Enzyme nomenclature

FSANZ noted that the International Union of Biochemistry and Molecular Biology (IUBMB), the internationally recognised authority for enzyme nomenclature, uses the 'accepted' name 'carboxypeptidase' for the enzyme with an EC number of EC 3.4.16.6 (IUBMB 2018).

There are relevant identity and purity specifications for the enzyme in two of the primary sources of specifications listed in Schedule 3, namely the JECFA Combined Compendium of Food Additive Specifications and the United States Pharmacopeial Convention Food chemicals codex (refer to Section 1.3.2 of this report above).

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<sup>3</sup> 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'.

### **2.3.3 Labelling**

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

### **2.3.4 Risk management conclusion**

The risk management conclusion is to permit the enzyme carboxypeptidase (EC 3.4.16.6) sourced from *A. oryzae*, containing a carboxypeptidase gene from *A. oryzae*, for use as a food processing aid. The permission 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 the manufacture and/or processing of proteins, yeast and flavourings; the manufacture of bakery products; and brewing. The maximum permitted level or amount of the enzyme that may be present in the food will have to be 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**

### **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 were notified via the Food Standards Notification Circular, media release, FSANZ's social media channels and Food Standards News.

The process by which FSANZ considers standards' development matters is open, accountable, consultative and transparent. Public submissions were called for to assist consideration of the draft variation to the Code. FSANZ acknowledges the time taken by individuals and organisations to make submissions 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 Impact Analysis (OIA)<sup>4</sup> granted FSANZ a standing exemption from the requirement to develop a Regulatory Impact Statement for applications relating to processing aids and genetically modified foods (OIA correspondence dated 24 November 2010, reference 12065). This standing exemption was provided as permitting new processing aids and GM foods 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.

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<sup>4</sup> Formerly known as the Office of Best Practice Regulation (OBPR).



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 (i.e. rejecting the application). This analysis considered permitting the proposed use of the enzyme carboxypeptidase from GM *A. oryzae* to be used as a processing aid in the manufacture and/or processing of proteins, yeast and flavourings; the manufacture of bakery products; and brewing.

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 proposed use of the enzyme carboxypeptidase produced from GM *A. oryzae*.

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

*Costs and benefits of permitting the use of the enzyme carboxypeptidase (EC 3.4.16.6) sourced from the GM strain of A. oryzae as a processing aid*

#### *Industry*

Due to the voluntary nature of the permission, industry will only use the enzyme where they believe a net benefit exists for them. Industry may benefit from having additional choice available to them in the manufacture and/or processing of proteins, yeast and flavourings; for use in the manufacturing of bakery products; and in brewing.

#### *Consumers*

Consumers may benefit from a greater availability of foods. Industry may pass cost savings to consumers, where it is cheaper to source carboxypeptidase from this GM strain of *A. oryzae* in production processes.

#### *Government*

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

#### *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 proposed use of the enzyme carboxypeptidase from GM *A. oryzae* (as a processing aid in the manufacture and/or processing of proteins, yeast and flavourings; the manufacture of bakery products; and brewing) 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 SD1) 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 1.3.3 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 relevant technical and scientific information, was considered by FSANZ in assessing the application. The risk assessment is provided in SD1.

- **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 approval for use of this enzyme brings Australia and New Zealand into line with the other countries where it is already authorised for use. In this way, Australia and New Zealand will 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 production microorganism or with using 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 the proposed use of this alternative enzyme.

Ultimately, food businesses 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>5</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 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

FAO/WHO (2006) Combined compendium of food additive specifications, Food and Agriculture Organization of the United Nations, Rome. <http://www.fao.org/docrep/009/a0691e/A0691E03.htm>

IUBMB EC 3.4.16.6. <https://iubmb.qmul.ac.uk/enzyme/EC3/4/16/6.html>

The United States Pharmacopeia (2020) Food Chemicals Codex 12<sup>th</sup> Edition, United States Pharmacopeial Convention, Rockville, MD. <http://publications.usp.org/>

### Attachments

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

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<sup>5</sup> [Food regulation website](#)

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



### Food Standards (Application A1229 – Carboxypeptidase from GM *Aspergillus oryzae* 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 Delegate*]

[*Name and position of 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 A1229 – Carboxypeptidase from GM Aspergillus oryzae 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:

Carboxypeptidase (EC 3.4.16.6) sourced from *Aspergillus oryzae* containing the carboxypeptidase gene from *Aspergillus oryzae*

For use in

GMP

- (a) brewing; and
- (b) the manufacture of bakery products; and
- (c) the manufacture and/or processing of the following types of food:
  - (i) flavourings; and
  - (ii) proteins; and
  - (iii) yeast.

## Attachment B

### **EXPLANATORY STATEMENT**

*Food Standards Australia New Zealand Act 1991*

#### ***Food Standards (Application A1229 – Carboxypeptidase from GM *Aspergillus oryzae* as a processing aid) Variation***

##### **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 A1229 which sought to amend the Code to permit the use of the carboxypeptidase enzyme (EC 3.4.16.6) from a genetically modified (GM) strain of *Aspergillus oryzae* as a processing aid for use in the manufacture and/or processing of proteins, yeast and flavourings; the manufacture of bakery products; and brewing. The Authority considered the Application in accordance with Division 1 of Part 3 and has approved a draft variation – the *Food Standards (Application A1229 – Carboxypeptidase from GM *Aspergillus oryzae* as a processing aid) 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 will be 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 carboxypeptidase (EC 3.4.16.6) sourced from a GM strain of *Aspergillus oryzae* containing the carboxypeptidase gene from *Aspergillus oryzae* as a processing aid in the manufacture and/or processing of proteins, yeast and flavourings; the manufacture of bakery products; and brewing. This permission is subject to the condition that the amount of enzyme used 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 Food Chemicals Codex (12<sup>th</sup> edition, 2020). 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 A1229 included one round of public consultation following an assessment and the preparation of a draft variation and associated assessment summary. Submissions were called for on 8 February 2023 for a six-week consultation period.

The Office of Impact Analysis<sup>6</sup> granted the Authority a standing exemption from the requirement to develop a Regulatory Impact Statement for applications relating to permitting new processing aids and GM foods (OBPR correspondence dated 24 November 2010, reference 12065). This standing exemption was provided as permitting new processing aids and GM foods 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.

### **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 approved draft variation 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 enzyme in column 1 of the table:

- 'Carboxypeptidase (EC 3.4.16.6) sourced from *Aspergillus oryzae* containing the carboxypeptidase gene from *Aspergillus oryzae*'

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<sup>6</sup> Formerly known as the Office of Best Practice Regulation (OBPR).

The permitted technological purpose for this enzyme is prescribed in column 2 of the table i.e. for use as a processing aid in the manufacture and/or processing of proteins, yeast and flavourings; the manufacture of bakery products; and brewing.

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 approved draft variation is to permit the proposed use of the enzyme, carboxypeptidase (EC 3.4.16.6) sourced from *Aspergillus oryzae* containing a carboxypeptidase gene from *Aspergillus oryzae* as a processing aid in accordance with the Code.