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[106-19]

Approval report – Application A1171

Endo-inulinase from *Aspergillus oryzae* as a processing aid (enzyme)

Food Standards Australia New Zealand (FSANZ) has assessed an application made by Puratos NV to permit the use of the enzyme endo-inulinase from a genetically modified strain of *Aspergillus oryzae* as a processing aid in hydrolysing inulin to produce fructo-oligosaccharides (FOS).

On 5 September 2019, FSANZ sought submissions on a draft variation and published an associated report. FSANZ received two submissions.

FSANZ approved the draft variation on 4 December 2019. The Australia and New Zealand Ministerial Forum on Food Regulation was notified of FSANZ's decision on 19 December 2019.

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

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Supporting document

The [following document](#)¹ which informed the assessment of this application is available on the FSANZ website:

SD1 Risk and Technical Assessment Report (unrevised at approval)

¹<http://www.foodstandards.gov.au/code/applications/Pages/A1171EndoinulinasefromGMAaspergillusoryzaeasaPAEnzyme--.aspx>

Executive summary

Puratos NV submitted an application to Food Standards Australia New Zealand (FSANZ) to use the enzyme endo-inulinase (EC 3.2.1.7) from a genetically modified (GM) strain of *Aspergillus oryzae* as a processing aid in hydrolysing inulin to produce fructo-oligosaccharides (FOS).

The FOS produced via this process can be used in a variety of foods including dairy products, cereal bars, meal replacement beverages, infant formula and baby foods as a sugar alternative, low caloric bulking agent and for dietary fibre supplementation.

Enzymes used to produce and manufacture food are considered processing aids and are regulated by Standards 1.1.1, 1.1.2, 1.3.3 and Schedule 18 of the Australia New Zealand Food Standards Code (the Code). If approved for use, this enzyme would be listed in the Table to subsection S18—9, which includes enzymes permitted for use for a specific technological purpose.

A. oryzae is a non-pathogenic microorganism (fungus) and has a history of safe use in fermentation in the food industry. It is the production organism for numerous enzyme processing aids, including 18 that are already permitted in the Code. The endo-inulinase in this application is derived from a GM strain of *A. oryzae* (strain MUCL 44346), expressing an endo-inulinase gene from *Aspergillus ficuum*.

After undertaking a risk assessment, FSANZ concludes that there are no public health and safety concerns associated with the use of this endo-inulinase. In the absence of any identifiable hazard, an acceptable daily intake (ADI) of 'not specified' is appropriate. A dietary exposure assessment was therefore not required.

The stated technological purpose of this enzyme is clearly articulated in the application. The evidence presented to support the proposed use of the enzyme provides adequate assurance that the enzyme, in the recommended form and amounts is technologically justified and has been demonstrated to be effective in achieving its stated purpose. The enzyme meets international purity specifications.

A total of two submissions were received on FSANZ's assessment report, both of which were supportive of the application and proposed draft variation to the Code.

The FSANZ Board has approved a draft variation to the Code, which permits the enzyme endo-inulinase derived from a GM strain of *A. oryzae*, containing the inulinase gene from *A. ficuum*, as a processing aid in hydrolysing inulin to produce FOS. The amount of enzyme used must be consistent with good manufacturing practice (GMP).

1 Introduction

1.1 The applicant

Puratos NV (Puratos), Belgium, is a company that develops, produces, distributes and markets raw materials for the bakery, confectionery, chocolate and catering industry.

1.2 The application

The application was received on 25 September 2018.

The application sought to change the Australia New Zealand Food Standards Code (the Code) to permit use of endo-inulinase (EC 3.2.1.7) from a genetically modified (GM) strain of *Aspergillus oryzae* (*A. oryzae*) as a processing aid in hydrolysing inulin to produce fructo-oligosaccharides (FOS).

Inulin is a generic term used to describe polysaccharides of various lengths composed of fructose, typically with a single terminal glucose. Foods that are naturally high in inulin include chicory root, Jerusalem artichoke, garlic and onion. Inulins are resistant to hydrolysis by intestinal digestive enzymes. As such, they are classified as 'non-digestible' carbohydrates and have reduced caloric value.

Endo-inulinase breaks down (2→1)-β-D-fructosidic linkages in inulin to form shorter chains of FOS. FOS is highly soluble and has technological properties similar to those of sugar. FOS can be used in a variety of foods such as dairy products, cereal bars, meal replacement beverages, infant formula and infant foods as a sugar alternative, low caloric bulking agent and for dietary fibre supplementation.

As a processing aid, the enzyme is not present or active in the final food or else present in negligible amounts with no technological function in FOS or the final food to which FOS is added. In producing FOS, the enzyme is subjected to an evaporation step which involves temperatures of up to 95°C, which inactivates the enzyme.

The enzyme is sourced from a GM strain of *A. oryzae* (strain MUCL 44346), expressing an endo-inulinase gene from *Aspergillus ficuum*. This proprietary strain from Puratos will provide food processors with an alternative enzyme preparation for producing FOS.

The endo-inulinase is produced by submerged fermentation, which involves the growth of the microorganism and production of the enzyme. Subsequent steps involve the separation of the enzyme from the fermentation medium, purification and formulation of the enzyme preparation.

1.3 The current standard

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

Permitted use

Enzymes used to process and manufacture food are considered processing aids. Paragraph 1.1.1—10(6) of the Code provides that a food for sale must not have, as an ingredient or a component, a substance that is used as a processing aid unless expressly permitted.

Section 1.1.2—13 of the Code defines the expression 'used as a processing aid'. That

definition imposes certain conditions on substances permitted by Standard 1.3.3 and Schedule 18 to be used as a processing aid, such that it does not perform a technological function in the final food for sale.

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.

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. Section 1.5.2—3 of Standard 1.5.2 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).

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.

Labelling requirements

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

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 prevail.

Section 1.5.2—4 requires processing aids that are 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. 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 subsection 1.2.1—8(1) and section 1.2.1—15 respectively.

1.3.1 International standards

The Codex Alimentarius Commission does not establish standards for processing aids or for enzymes. Individual countries regulate the use of enzymes differently to the Code. However, there are internationally recognised specifications for enzymes. These enzyme specifications are established by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) (FAO/WHO 2017) and the Food Chemicals Codex (Food Chemicals Codex 2018).

1.4 Reasons for accepting application

The application was accepted for assessment because:

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

1.5 Procedure for assessment

The application was assessed under the General Procedure.

1.6 Decision

The food technology component of the Risk and Technical Assessment Report concluded that the enzyme meets its stated purpose, which is to hydrolyse inulin to produce FOS. The risk assessment concluded that, in the absence of any identifiable hazard, an ADI of 'not specified' is appropriate for the enzyme. Bioinformatic analysis identified potential homology to minor allergens in tomato. Tomato is not considered a major allergen and is widely used in food (for further details, refer to the Risk and Technical Assessment Report (SD1)). Therefore, FSANZ permits the use of the enzyme as a processing aid for its stated purpose.

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

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 proposed draft variation on 5 September 2019. Two submissions were received, both from government agencies, and both supported the application and proposed draft variation to the Code (Table 1).

Table 1: Summary of issues raised by submissions

Raised by	Issue	FSANZ response
Victorian Department of Health and Human Services and the Victorian Department of Jobs, Precincts and Regions	Supportive	Noted. No response required
New Zealand Food Safety, Ministry for Primary Industries	Supportive	Noted. No response required

2.2 Risk assessment

No public health and safety concerns associated with the use of endo-inulinase from a GM *A. oryzae* were identified as a result of the hazard assessment.

The production organism is not toxigenic nor pathogenic. *A. oryzae* has a history of safe use as the production organism for a number of enzyme processing aids that are already permitted in the Code. Molecular characterisation of the production strain confirmed the sequence of the inserted DNA has not undergone any rearrangement, and the introduced DNA is stably inherited.

This endo-inulinase has been used in the EU, with no reports of adverse effects in consumers.

Results of genotoxicity assays were negative, and the enzyme shows no significant homology with known protein toxins. The No Observed Adverse Effect Level (NOAEL) in a

13-week repeat-dose oral gavage study in rats was 27500 UI/kg bw/day, equivalent in Total Organic Solids (TOS) to 189.65 mg/kg bw/day. The Theoretical Maximum Daily Intake (TMDI), expressed in TOS is 0.0069 mg/kg bw/day, and the Margin of Exposure (MoE) is therefore 27,486.

Bioinformatic analysis identified potential homology to minor allergens in tomato. Tomato is not considered a major allergen and is widely used in food.

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

The evidence presented to support the proposed use of the enzyme provided adequate assurance that the enzyme, in its recommended form and amounts, is technologically justified and has been demonstrated to be effective in achieving its stated purpose. The enzyme meets international purity specifications.

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

2.3 Risk management

The Risk and Technical Assessment Report concluded that there are no safety concerns from using this enzyme for its stated purpose, in the form and quantities consistent with GMP. As processing aids require permissions in the Code, the main risk management option available to FSANZ is to approve or reject the request to amend the Code and, if approved, to impose any conditions that may be appropriate. Other risk management considerations for this application are related to enzyme nomenclature and labelling, which are discussed below. The regulatory options analysed in section 2.5.1.1 take account of the safety of the enzyme.

The express permission for the enzyme's use as a processing aid will also provide the permission for the potential presence of the enzyme 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 section 1.3 for further details regarding permissions for use for foods produced using gene technology.

2.3.1 Enzyme and source microorganism nomenclature

FSANZ noted that the International Union of Biochemistry and Molecular Biology (IUBMB), the internationally recognised authority for enzyme nomenclature, uses the 'accepted' name 'inulinase' for the enzyme with an EC number of EC 3.2.1.7 (IUBMB 2017). 'Other' names for this enzyme include 'endo-inulinase', which is the name used throughout the application, this document, and Supporting Document 1. However, the accepted name 'inulinase', with the EC number EC 3.2.1.7 is the name that will be used in the proposed draft variation to the Code for this enzyme.

The nomenclature of the gene donor and production microorganisms were checked and confirmed as being appropriate as listed in the application (see section 3.1 of SD1). The source organism *A. oryzae* is already permitted as a production microorganism for numerous enzymes within Schedule 18.

2.3.2 Labelling considerations

The risk assessment concluded that the use of the enzyme preparation poses no concern to public health and safety and that it performs its technological purpose as a processing aid. Therefore, the generic exemption from declaration of processing aids in the statement of ingredients will apply to foods containing this processing aid and no new labelling requirements are proposed.

2.3.2.1 Labelling requirements for food produced using gene technology

The requirements for labelling as 'genetically modified' differ depending on whether the genetically modified food is an ingredient of the food for sale or not, as follows. If a food for retail sale or sold to a caterer contains the enzyme endo-inulinase as an ingredient, that food will be required to be labelled 'genetically modified' in conjunction with the name of the processing aid, if novel DNA or novel protein from the genetically modified strain of *A. oryzae* (that is the source microorganism, not the enzyme) remains in that food for sale.

FSANZ however, notes that the enzyme is used as a processing aid to manufacture FOS. If FOS is not a food for sale itself but is used as an ingredient in a food for retail sale or food sold to a caterer, the enzyme will not be an ingredient in the food for sale containing the FOS. The requirement to label as 'genetically modified' will not apply to that food for sale because the labelling requirements only apply to food that consists of, or has as an ingredient, a genetically modified food (section 1.5.2—4(1)).

2.3.3 Risk management conclusion

The risk management conclusion is to add the permission for endo-inulinase from a GM strain of *A. oryzae*, expressing an endo-inulinase gene from *A. ficuum*, as a processing aid into the table to S18—9(3), which includes enzymes permitted for a specific technological purpose. The technological purpose is for the hydrolysis of inulin to produce FOS. The maximum permitted level is an amount consistent with GMP.

2.4 Risk communication

2.4.1 Consultation

Consultation is a key part of FSANZ's standards development process. FSANZ developed and applied a basic 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 standard development matters is open, accountable, consultative and transparent. Public submissions are 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. Every submission was considered by the FSANZ Board. All comments are valued and contribute to the rigour of our assessment.

2.5 FSANZ Act assessment requirements

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 permitting the use of processing aids (OBPR correspondence dated 24 November 2010, reference number 12065). This standing exemption was provided as permitting processing aids is machinery in nature and the use of the processing aid is voluntary once the application has been successfully approved. This standing exemption relates to the introduction of a processing aid to the food supply that has been determined to be safe.

FSANZ, however, gave consideration to the costs and benefits that would arise from this 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 (S.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 either approving or rejecting the application. A consideration of costs and benefits was included in the call for submissions (CFS) report based on the information and data held at that time. No further information has been received during the consultation process to date that influenced the findings from the analysis of costs and benefits in the CFS.

The consideration of the costs and benefits outlined in this section is not intended to be an exhaustive, quantitative economic analysis of the measure and, 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 endo-inulinase from the GM strain of *A. oryzae* as a processing aid in hydrolysing inulin to produce FOS.

Costs and benefits of permitting the use of the enzyme endo-inulinase (EC 3.2.1.7) from a GM strain of A. oryzae as a processing aid

A. oryzae is the production organism for numerous enzyme processing aids, including 18 that are already permitted in the Code. The endo-inulinase in this application is derived from a GM strain of *A. oryzae* (strain MUCL 44346), expressing an endo-inulinase gene from *A. ficuum*. Different inulinase preparations have different optimal pH and temperature ranges, to suit a range of food processing environments. Therefore, this particular endo-inulinase will provide manufacturers of FOS with an alternative enzyme preparation, thus giving them a wider choice of products to suit their specific food processing application.

Due to the voluntary nature of the permission, industry will only use the enzyme where they believe a net benefit exists. There are other inulinase preparations available to industry and it is of benefit to industry to have additional choice available to them, especially where the enzyme is more effective or cheaper.

The enzyme is currently used in the US (as self-affirmed GRAS) and EU. This 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.

Endo-inulinase breaks down (2→1)-β-D-fructosidic linkages in inulin to form shorter chains of FOS. FOS can be used in a variety of foods including dairy products, cereal bars, meal

replacement beverages, infant formula and baby foods as a sugar alternative, low caloric bulking agent and for dietary fibre supplementation. This may expand the range of these products available to consumers.

Where using this endo-inulinase enzyme is more effective or cheaper for manufacturers, there may be benefits to the consumer where cost savings are passed on.

Permitting the enzyme may result in a small cost to government in terms of adding the enzyme to the current range of processing aids that are monitored for compliance.

Conclusions from cost benefit considerations

FSANZ's assessment is that the direct and indirect benefits that would arise from permitting the use of this endo-inulinase as a processing aid is likely to outweigh the associated costs.

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 as a result of the application.

2.5.1.3 Any relevant New Zealand standards

Standards 1.1.1, 1.1.2 and 1.3.3 and Schedule 18 apply in both Australia and New Zealand and there are no other 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 also considered the three objectives in subsection 18(1) of the FSANZ Act during the assessment.

2.5.2.1 Protection of public health and safety

FSANZ undertook a safety assessment (SD1) and concluded there were no public health and safety concerns associated with the 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 considerations for the enzyme processing aid are discussed in section 2.3.2.

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 used the best available scientific evidence to conduct the risk analysis which is provided in SD1 – the Risk and Technical Assessment Report. The applicant submitted a dossier of scientific studies as part of their application. Other technical information sourced by FSANZ, including scientific literature, was also used in assessing the application.

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

There are no Codex Alimentarius Standards for processing aids or enzymes. However, it meets general specifications for enzymes set out in the JECFA Compendium of Food Additive Specifications and the Food Chemicals Codex specifications for enzymes.

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

The enzyme is already used in several countries, and it is currently being evaluated by JECFA and EFSA. Therefore, the approval for use of this enzyme would bring Australia and New Zealand into line with jurisdictions overseas. In this way, Australia and New Zealand will remain competitive with international market.

The conclusion of the risk assessment was that 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 this alternative enzyme preparation for the production of FOS.

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 businesses.

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

FSANZ identified no issues 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 Minerals](#)² includes specific order policy principles for substances added to achieve a solely technological function, such as processing aids. These specific order policy principles state that permission should be granted where:

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

FSANZ determined that permitting this enzyme is consistent with these specific order policy principles for 'Technological Function'.

² <http://foodregulation.gov.au/internet/fr/publishing.nsf/Content/publication-Policy-Guideline-on-the-Addition-of-Substances-other-than-Vitamins-and-Minerals>

3 References

FAO/WHO (2017) General specifications and considerations for enzyme preparations used in food processing. <http://www.fao.org/docrep/009/a0691e/A0691E03.htm>

IUBMB (2017) EC 3.2.1.7. <https://www.qmul.ac.uk/sbcs/iubmb/enzyme/EC3/2/1/7.html>

The United States Pharmacopeia (2018) Food Chemicals Codex 11th 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

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



Food Standards (Application A1171 – Endo-inulinase from *GM Aspergillus oryzae* as a Processing Aid (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 Delegate]

[Insert details 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 A1171 – Endo-inulinase from GM Aspergillus oryzae as a Processing Aid (Enzyme)) Variation*.

2 Variation to a standard in the *Australia New Zealand Food Standards Code*

The Schedule varies a Standard in the *Australia New Zealand Food Standards Code*.

3 Commencement

The variation commences on the date of gazettal.

Schedule

[1] Schedule 18 is varied by inserting in the table to subsection S18—9(3), in alphabetical order

Inulinase (EC 3.2.1.7) sourced from <i>Aspergillus oryzae</i> containing the inulinase gene from <i>Aspergillus ficuum</i>	Hydrolysing inulin to produce fructo-oligosaccharides	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 A1171 which seeks permission to use the enzyme endo-inulinase (EC 3.2.1.7) from a genetically modified (GM) strain of *Aspergillus oryzae* (*A. oryzae*) as a processing aid in the hydrolysis of inulin to produce fructo-oligosaccharides (FOS). The Authority considered the application in accordance with Division 1 of Part 3 and has approved a draft Standard.

The Authority noted that the IUBMB uses the ‘accepted’ name ‘inulinase’ for this enzyme (IUBMB 2017). ‘Other’ names for this enzyme include ‘endo-inulinase’, which is the name used throughout the application, this document, and Supporting Document 1. However, the accepted name ‘inulinase’ is the name that has been used in the variation to the Code for this enzyme

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

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

2. Purpose

The Authority has approved a variation to amend the table to subsection S18—9(3) in Schedule 18 of the Code to permit the use of the enzyme endo-inulinase (EC 3.2.1.7) from a GM strain of *A. oryzae* as a processing aid in hydrolysing inulin to produce FOS.

3. Documents incorporated by reference

The variations to food regulatory measures do not incorporate any documents by reference.

Existing provisions of the Code incorporate a document by reference that will prescribe identity and purity specifications for the processing aid to be permitted by the 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) Compendium of Food Additive Specifications (FAO/WHO 2017) and the United States Pharmacopeial Convention (2018) Food Chemicals Codex (11th edition). These include specifications for enzyme preparations used in food processing.

4. Consultation

In accordance with the procedure in Division 1 of Part 3 of the FSANZ Act, the Authority's consideration of Application A1171 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 5 September for a six-week consultation period.

The Office of Best Practice Regulation (OBPR) granted FSANZ a standing exemption from needing to develop a Regulatory Impact Statement for proposed variations of the Code to permit additional processing aids (OBPR correspondence dated 24 November 2010 - reference 12065). This standing exemption was provided as permitting additional processing aids is likely to have only a minor impact on business and individuals. It is a minor, deregulatory change that allows for the introduction of a food product to the food supply that has been determined to be safe. The use of the approved processing aid is also voluntary.

5. Statement of compatibility with human rights

This instrument is exempt from the requirements for a statement of compatibility with human rights as it is a non-disallowable instrument under section 94 of the FSANZ Act.

6. Variation

Item [1] of the variation inserts in the table to subsection S18—9(3) in Schedule 18 in alphabetical order, a new entry for "Inulinase (EC 3.2.1.7) sourced from *Aspergillus oryzae* containing the inulinase gene from *Aspergillus ficuum*" into column 1, and "Hydrolysing inulin to produce fructo-oligosaccharides" into column 2, and "GMP" into column 3.

The new entry will, in effect, permit the enzyme endo-inulinase (EC number 3.2.1.7), derived from the GM strain of *A. oryzae*, to be used as a processing aid in food, with a technological purpose of hydrolysing inulin to produce FOS, with the condition that the amount used must be consistent with good manufacturing practice (GMP).