27 June 2019
[85-19]

Approval report – Application A1160

Aspergillopepsin I from *Trichoderma reesei* as a processing aid (enzyme)

Food Standards Australia New Zealand (FSANZ) has assessed an application made by DuPont Australia Pty Ltd to permit the use of the enzyme Aspergillopepsin I from a genetically modified strain of *Trichoderma reesei* as a processing aid in the manufacture of potable alcohol and animal and vegetable protein products.

On 27 February 2019, FSANZ sought submissions on a draft variation and published an associated report. FSANZ received three submissions.

FSANZ approved the draft variation on 12 June 2019. The Australia and New Zealand Ministerial Forum on Food Regulation was notified of FSANZ's decision on 20 June 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 which informed the assessment of this Application are available on the FSANZ website:

SD1 Risk and technical assessment report

Executive summary

DuPont Australia Pty Ltd submitted an application to Food Standards Australia New Zealand (FSANZ) seeking to permit the use of the enzyme Aspergillopepsin I (EC 3.4.23.18) as a processing aid. The enzyme is derived from a genetically modified (GM) strain of *Trichoderma reesei* overexpressing the gene encoding a native *T. reesei*, Aspergillopepsin I. Its proposed use is in the manufacture of potable alcohol and animal and vegetable protein products.

The FSANZ risk assessment concluded that there were no public health and safety concerns associated with using this Aspergillopepsin I. 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 provides adequate assurance that the enzyme, in the form and prescribed amounts is technologically justified and has been demonstrated to be effective in achieving its stated purpose. The enzyme meets international purity specifications.

The enzyme has been determined as Generally Recognised as Safe (GRAS) in the United States and is approved in Denmark and France.

Enzymes used to produce and manufacture food are considered processing aids and are regulated by Schedule 18 of the Code. FSANZ approved the draft variation to the table to subsection S18—9(3) of the Code. The table list the enzymes that are permitted for use for a specific technological purpose. The draft variation will, in effect, permit the enzyme Aspergillopepsin I derived from the GM strain of *T. reesei*, as a processing aid for use in the manufacture of potable alcohol and animal and vegetable protein products. This permission is subject to the condition that the amount of enzyme used must be consistent with good manufacturing practice (GMP).

1 Introduction

1.1 The applicant

DuPont Australia Pty Ltd is a manufacturer and marketer of food ingredients, food additives and processing aids.

1.2 The application

The application sought permission for a new microbial source for the already permitted enzyme, Aspergillopepsin I (EC 3.4.23.18) as a processing aid. The enzyme preparation is referred to as Aspergillopepsin I in this approval report, however by its proprietary name *Acid Fungal Protease* (AFP) in the accompanying Risk and Technical Assessment Report (SD1).

The enzyme is derived from a genetically modified (GM) strain of *Trichoderma reesei* overexpressing the Aspergillopepsin I gene, a native *T. reesei* protease enzyme.

This enzyme will be used to manufacture potable alcohol and animal and vegetable protein products.

Aspergillopepsin I will be used as a processing aid at low levels, with no techniogical function in the final food.

1.3 The current standard

Australian and New Zealand food laws require food for sale to comply with the following requirements of the Code.

1.3.1 Permitted use

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

Paragraphs 1.1.1—10(6)(c) and (g) of the Code provides that food for sale cannot contain, as an ingredient or component, a substance ‘used as a processing aid’ or a ‘food produced using gene technology’ unless that use is expressly permitted by the Code.

Section 1.1.2—13 provides that a substance is ‘used as a processing aid’ if it is added to a food to perform a technological purpose during the course of processing of food; does not perform a technological purpose in the food for sale; and is a substance listed in Schedule 18 or a substance 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. Enzymes of microbial origin listed in the table to subsection S18—4(5) are permitted for use as processing aid for all food. The table to subsection S18—9(3) lists those substances, including enzymes, that are permitted to be used as processing aids for specific technological purposes.

There are currently permissions for Aspergillopepsin I from different microbial sources within the table to subsection S18—4(5), to be used in the manufacture of all foods. However, Aspergillopepsin I from this particular microbial source, the subject of this application, is not currently permitted.

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.

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 (JECFA 2016) and the United States Pharmacopeial Convention (USPC) Food Chemicals Codex 11th edition (USPC 2018). These include specifications for enzyme preparations used in food processing.

1.3.3 International standards

DuPont's Aspergillopepsin I has been determined as GRAS by a panel of scientific experts in the US and is approved in France and Denmark.

The Codex Alimentarius 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 JECFA and the USPC.

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

FSANZ called for submissions on a proposed draft variation on 27 February 2019. Three submissions were received from;

- New Zealand Ministry for Primary Industries
- Victorian Department of Health and Human Services
- New Zealand Food and Grocery Council.

All three submissions supported the application. No issues were raised by submitters.

The New Zealand Food and Grocery Council stated in their submission that Aspergillopepsin I from *T. reesei* as a processing aid (enzyme) need not be included in ingredient listing or labelled in any other way as this is only required if the substance is present in the final food.

FSANZ does not assess whether the enzyme will be present in the final food. The food manufacturer is responsible for determining if the processing aid is present and if allergen labelling or GM labelling applies to the food or ingredient for sale.

2.2 Risk assessment

FSANZ did not identify any public health and safety concerns associated with using Aspergillopepsin I from genetically modified *T. reesei*.

T. reesei has a long history of safe use to produce enzyme processing aids, including several that are already permitted in the Code. This fungus is not toxigenic or pathogenic. No extraneous coding genetic material is carried across from the donor organism or through the large number of steps leading to the final genetic modification. The modification involving the insertion of the Aspergillopepsin I gene has been shown to be stably inherited.

There is no evidence of adverse health effects associated with the use of DuPont's Aspergillopepsin I in countries where it is already approved, including in Europe and North America. Bioinformatic searches did not indicate homology with known toxins or food allergens. *In vitro* incubation of the enzyme in simulated gastric fluid indicates that it is completely digested, and degraded to small protein fragments, within 30 minutes of incubation at body temperature. Therefore it is anticipated that this enzyme will be digested like other dietary proteins.

No major allergens are used directly in the preparation of the enzyme, although glucose used in the fermentation medium is derived from wheat. The possibility that traces of wheat protein may be present in the final preparation cannot be excluded.

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

The food technology assessment concluded that DuPont's Aspergillopepsin I, in the form and prescribed amounts, is technologically justified and has been demonstrated to be effective in achieving its stated purpose. The enzyme performs its technological purpose during production and manufacture of foods and is therefore appropriately categorised as a processing aid. The enzyme preparation 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 assessment concluded that there are no safety concerns from the use of Aspergillopepsin I from a GM strain of *T. reesei* as a food processing aid in the manufacture of potable alcohol and animal and vegetable protein products. 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 issues for this application are related to enzyme nomenclature and labelling, which are discussed below. The regulatory options analysed in section 2.3.1 take account of the safety of the enzyme.

This enzyme preparation will provide the food industry with an alternative source of Aspergillopepsin I, which is claimed to provide improved efficiencies and yields.

2.3.1 Regulatory approval for enzymes

FSANZ has concluded that the enzyme meets its stated purpose, for use as a processing aid in the manufacture of potable alcohol and animal and vegetable protein products. The risk assessment has further concluded that, in the absence of any identifiable hazard, an ADI of 'not specified' is appropriate for the enzyme and the enzyme preparation components, with ingestion of any residual Aspergillopepsin I in food products unlikely to pose an allergenicity concern.

Therefore, FSANZ approved a draft variation to permit the use of the enzyme as a processing aid for its stated purpose.

The express permission for the enzymes' use as a processing aid will also provide the permission for the enzyme's potential presence in the food for sale as a food produced using gene technology. The enzyme is a food produced using gene technology for Code purposes as it is derived from 'an organism that has been modified using gene technology'. 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 for use as a processing aid also constitutes the permission required by paragraph 1.1.1—10(6)(g).

2.3.2 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 'Aspergillopepsin I' for the enzyme with an EC number of EC 3.4.23.18 (IUBMB 2018). This name is already listed in the table to subsection S18—4(5) and will remain as such if approved and subsequently listed in the table to subsection in S18—9(3).

The nomenclature of the production and gene donor microorganisms was checked and confirmed as being appropriate as listed in the application (see section 3.2 of SD1). The source organism is *T. reesei*, which is permitted as a production microorganism numerous times within Schedule 18.

2.3.3 Labelling requirements

Paragraph 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.

Standard 1.2.4 of the Code generally requires food products to be labelled with a statement of ingredients. Sections 1.2.4—3(2)(d) and (e) of that Standard exempts substances used as processing aids from the requirement to be declared in the statement of ingredients.

The risk assessment concluded that the use of the enzyme poses no public health and safety concerns 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.

2.3.3.1 Labelling requirements for food produced using gene technology

Standard 1.5.2 outlines provisions for labelling of foods produced using gene technology. The enzyme is a food produced using gene technology in accordance with the Code. Section 1.5.2—4 indicates labelling requirements apply for processing aids that are foods produced using gene technology, where novel DNA or novel protein from the processing aid remains present in the final food.

Section 1.5.2—4 requires certain foods for sale that consist of or have as an ingredient, food that is a GM food to be labelled as 'genetically modified'. FSANZ also notes that the Code's labelling requirements – including those 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. The requirements for labelling as 'genetically modified' differ depending on whether the GM 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 Aspergillopepsin I as an ingredient, that food would be required to be labelled 'genetically modified' in conjunction with the name of the processing aid, if novel DNA or novel protein from the GM strain of *T. reesei* (that is the source microorganism, not the enzyme) remains in that food.

However, if the enzyme is used to manufacture an ingredient that is itself not a food for sale, but is used as an ingredient in a food for retail sale or in food sold to a caterer, the labelling statement 'genetically modified' would not apply (for example, the enzyme is used in the manufacture of whey protein hydrolysate (an animal protein product), which is then used as an ingredient in a food). In this case, the requirement to label as 'genetically modified' would not apply to the use of the enzyme in whey protein hydrolysate because it is not an ingredient in a food for retail sale or food sold to a caterer (section 1.5.2—4(1)).

2.3.3.2 Declaration of certain substances

Section 2.1 states that the possibility that traces of wheat protein may be present in the final enzyme preparation cannot be excluded. If wheat is present in a food, including when present as a processing aid or an ingredient or component of a processing aid, it must be declared in accordance with section 1.2.3—4 of Standard 1.2.3. If the food is not required to bear a label, the allergen information must be displayed in connection with the display of the food or provided to the purchaser on request (section 1.2.1—9).

2.3.4 Risk management conclusion

The risk management conclusion is to add the permission for Aspergillopepsin I derived from a GM strain of *T. reesei*, as a processing aid into the table to subsection S18—9(3), which includes enzymes permitted for a specific technological purpose. The technological purpose is for use in the manufacture of potable alcohol and animal and vegetable protein products. 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 on the application was considered by the FSANZ Board. All comments are valued and contribute to the rigour of our assessment.

2.4.2 World Trade Organization (WTO)

As members of the World Trade Organization (WTO), Australia and New Zealand are obliged to notify WTO members where proposed mandatory regulatory measures are inconsistent with any existing or imminent international standards and the proposed measure may have a significant effect on trade.

There are no relevant international standards and amending the Code to permit a new microbial source of a currently permitted enzyme is unlikely to have a significant effect on international trade as Codex Alimentarius does not have standards for enzymes used as processing aids. Therefore, a notification to the WTO under Australia's and New Zealand's obligations under the WTO Technical Barriers to Trade or Application of Sanitary and Phytosanitary Measures Agreement was not considered necessary.

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, has given 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 (S.29 (2)(a)).

The purpose of this consideration is 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 considers the option of accepting the application to permit the use of Aspergillopepsin I from the GM strain of *T. reesei* as a processing aid to produce potable alcohol and animal and vegetable protein products. FSANZ is of the view that no other realistic food regulatory measures exist.

The consideration of the costs and benefits in this section is not intended to be an exhaustive, quantitative economic analysis of the proposed measures and, in fact, most of the effects that were considered cannot easily be assigned a dollar value. Rather, the assessment seeks to highlight the likely positives and negatives of moving away from the status quo by permitting the use of Aspergillopepsin I from the GM strain of *T. reesei* as a processing aid in the manufacture of potable alcohol and animal and vegetable protein products.

Costs and benefits of permitting the use of Aspergillopepsin I from a GM strain of T. reesei as a processing aid in the manufacture of potable alcohol and animal and vegetable protein products.

Due to the voluntary nature of the permission, industry will only use the enzyme where it believes a net benefit exists. This enzyme is an alternative to already permitted forms of the enzyme which provides options to food manufacturers. The production organism contains a number of copies of the Aspergillopepsin I gene which may make it more efficient and cost effective to use. Which enzyme preparation a food manufacturer purchases for specific uses will depend on a range of factors, including economic and performance for the proposed use.

The enzyme is permitted for use in France, Denmark and the USA, which 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.

There are unlikely to be any direct benefits or costs to consumers of this option. However, reduced productions costs, depending on how competitive the relevant markets are, could result in reduced costs for consumers.

Permitting the enzyme preparation may result in a small cost to government in terms of adding it 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 Aspergillopepsin I from the GM strain of *T. reesei* as a processing aid to manufacture potable alcohol and animal and vegetable protein products most likely 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 or varied 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 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 risk and technical assessment (SD1) and concluded there were no public health and safety concerns associated with using the enzyme Aspergillopepsin I sourced from the GM strain of *T. reesei* as a food processing aid to manufacture potable alcohol and animal and vegetable protein products.

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

The labelling approach for the processing aid discussed in Section 2.3.3 above. This approach is consistent with the existing provisions in the Code for the labelling of permitted processing aids.

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 when undertaking the risk analysis, which is provided in SD1 – the risk and technical assessment report. The applicant submitted a dossier of scientific studies and other technical information including scientific literature. This dossier, together with other technical information including scientific literature identified by FSANZ was 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, this enzyme is determined as GRAS in the US and is approved in Denmark and France. In addition, it meets international specifications for enzyme preparations; being the JECFA and USPC specifications for enzymes.

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

As mentioned above, this enzyme is already permitted in several countries. Therefore, the approval for use of this enzyme would bring Australia and New Zealand into line with other jurisdictions where it is already authorised for use. In this way, Australia and New Zealand will remain competitive with other international markets.

The outcome of the risk assessment indicated that there are no public health and safety issues associated with the production microorganism *T. reesei* or with using Aspergillopepsin I as a food processing aid to manufacture potable alcohol and animal and vegetable protein products. It is therefore appropriate that Australian and New Zealand food industries are given the opportunity to benefit from the use of this enzyme.

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

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

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

The Ministerial Policy Guideline Addition to Food of Substances other than Vitamins and Minerals[1] 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 use of Aspergillopepsin I, sourced from *T. reesei,* as a processing aid is consistent with the specific order principles for 'Technological Function'.

3 References

IUBMB (International Union of Biochemistry and Molecular Biology) Enzyme Nomenclature for EC 3.4.23.18. Accessed 12 November 2018

JECFA (2016) Combined compendium of food additive specifications Accessed 15 November 2018

USPC (2018) Food Chemicals Codex 11th Edition, United States Pharmacopeial Convention, Rockville, MD. Accessed 23 January 2019

Attachments

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

[1] Food regulation website

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

Food Standards (Application A1160 – Aspergillopepsin I from *Trichoderma reesei* as a processing aid (enzyme)) Variation

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The Board of Food Standards Australia New Zealand gives notice of the making of this variation under section 92 of the *Food Standards Australia New Zealand Act 1991*. The variation commences on the date specified in clause 3 of the variation.

Dated [To be completed by the Delegate]

Insert Delegate 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 the above notice.

1 Name

This instrument is the *Food Standards (Application A1160 – Aspergillopepsin I from* Trichoderma reesei *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 section S18—9(3), in alphabetical order

Aspergillopepsin I (EC 3.4.23.18) sourced from *Trichoderma reesei* containing the gene for aspergillopepsin I isolated from *Trichoderma reesei*	For use in the manufacture of potable alcohol and of animal and vegetable protein products.	GMP

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 A1160 which seeks to permit the use of Aspergillopepsin I (EC 3.4.23.18) from a GM strain of *Trichoderma reesei* as a processing aid in the manufacture of potable alcohol production and animal and vegetable protein products. The Authority considered the Application in accordance with Division 1 of Part 3 and has approved a draft variation to the Code.

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 sunsetting under the *Legislation Act 2003*

2. Purpose

The Authority has approved a draft variation to amend the table to subsection S18—9(3) in Schedule 18 of the Code to permit the use of the enzyme Aspergillopepsin I from a GM strain of *T. reesei* as a food processing aid in potable alcohol production and protein processing.

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 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) Compendium of Food Additive Specifications (FAO/WHO 2016) and the United States Pharmacopeial Convention (2016) Food Chemicals Codex (10th 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 A1160 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 27 February 2019 for a seven-week consultation period.

A Regulation Impact Statement was not required because the proposed variations to Schedule 18 are likely to have a minor impact on business and individuals.

5. Statement of compatibility with human rights

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

6. Variation

The approved draft variation inserts a new entry into the table to subsection S18—9(3) in Schedule 18.

The new entry will permit the use of the enzyme, Aspergillopepsin I (EC 3.4.23.18) sourced from a GM strain of *Trichoderma reesei,* as a processing aid in food for a specific technological purpose, with the condition that the amount used must be consistent with good manufacturing practice. The technological purpose is for use in the potable alcohol production and protein processing.