

27 June 2019
[85-19]

Approval report – Application A1159

Triacylglycerol lipase 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 triacylglycerol lipase from a genetically modified strain of *Trichoderma reesei* as a processing aid for the production of bakery products, and cereal-based beverages and foods.

On 5 February 2019, FSANZ sought submissions on a draft variation and published an associated report. FSANZ received four 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).

Table of contents

EXECUTIVE SUMMARY	3
1 INTRODUCTION	4
1.1 THE APPLICANT	4
1.2 THE APPLICATION	4
1.3 THE CURRENT STANDARDS	4
1.4 REASONS FOR ACCEPTING APPLICATION	5
1.5 PROCEDURE FOR ASSESSMENT	5
1.6 DECISION	5
2 SUMMARY OF THE FINDINGS	6
2.1 SUMMARY OF ISSUES RAISED IN SUBMISSIONS	6
2.2 RISK ASSESSMENT	7
2.3 RISK MANAGEMENT	8
2.4 RISK COMMUNICATION	10
2.4.1 Consultation	10
2.5 FSANZ ACT ASSESSMENT REQUIREMENTS	10
2.5.1 Section 29	10
2.5.2 Subsection 18(1)	11
3 REFERENCES	13
ATTACHMENT A – APPROVED DRAFT VARIATION TO THE AUSTRALIA NEW ZEALAND FOOD STANDARDS CODE	14
ATTACHMENT B – EXPLANATORY STATEMENT	16
ATTACHMENT C – DRAFT VARIATION TO THE AUSTRALIA NEW ZEALAND FOOD STANDARDS CODE (CALL FOR SUBMISSIONS)	18

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 (amended at approval)

¹ [http://www.foodstandards.gov.au/code/applications/Pages/A1159-TriacylglycerollipasefromTrichodermareeseiasaprocessingaid\(enzyme\).aspx](http://www.foodstandards.gov.au/code/applications/Pages/A1159-TriacylglycerollipasefromTrichodermareeseiasaprocessingaid(enzyme).aspx)

Executive summary

DuPont Australia Pty Ltd submitted an application to Food Standards Australia New Zealand (FSANZ) to use the enzyme triacylglycerol lipase (EC 3.1.1.3) from a new microbial source as a processing aid. The enzyme will be used as a processing aid in the production of bakery products, and cereal-based beverages and foods.

The enzyme is derived from a genetically modified (GM) strain of *Trichoderma reesei*, expressing the gene for triacylglycerol lipase isolated from *Aspergillus tubingensis*. The *T. reesei* production strain is not toxigenic or pathogenic and is absent from the final enzyme preparation. Further, *T. reesei* has a history of safe use as the production organism for a number of enzyme processing aids already permitted in the Australia New Zealand Food Standards Code (the Code).

FSANZ's risk assessment concluded that there are no public health and safety concerns associated with using this triacylglycerol lipase. 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 the form and prescribed amounts, was technologically justified and had 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 and not a food additive. The enzyme meets international purity specifications.

A total of four submissions were received on FSANZ's assessment report. Issues raised in submissions have been addressed. A submission from the applicant requested a minor amendment to the draft variation, which was assessed and accepted. Therefore, the approved draft variation is slightly different to that provided in the Call for Submission. The difference is explained in section 2.1 of this report.

Enzymes used to produce and manufacture food are considered processing aids and are regulated by Standards 1.1.1 and 1.3.3; and Schedule 18 of the Code. The FSANZ Board has approved a draft variation to Schedule 18 of the Code. The draft variation adds the enzyme to the table to subsection S18—9(3), which includes enzymes permitted for use for specific technological purposes. The draft variation permits the use of the enzyme triacylglycerol lipase derived from a GM strain of *T. reesei*, as a processing aid in the production of bakery products, and cereal-based beverages and foods. The permission is subject to the condition that the amount of the enzyme used is 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, including enzymes.

1.2 The application

The application sought permission for a new microbial source for the currently permitted enzyme, lipase, triacylglycerol (Enzyme Commission (EC) number 3.1.1.3) as a processing aid. The enzyme was derived from a genetically modified (GM) strain of *Trichoderma reesei*, expressing the triacylglycerol lipase gene from *Aspergillus tubingensis*. The enzyme was proposed to be used as a processing aid in the production of bakery products and cereal-based beverages.

The enzyme performs its technological function in the baking industry to improve dough stability and dough/batter handling properties. In the production of cereal-based beverages and foods, the enzyme performs its technological function in the mashing step, where it contributes to the removal of fatty acids (which would otherwise affect mash separation), with particular benefits for non-malted cereals. The resulting liquid extract (wort) can then be used to produce various foods and alcoholic and non-alcoholic beverages.

The terms 'triacylglycerol lipase' and 'lipase, triacylglycerol' are used interchangeably throughout the report, depending on the context. Permissions in the Code for the enzyme are listed as lipase, triacylglycerol so that is how the draft variation is written and when the draft variation is discussed. For most other occasions the more generic name of triacylglycerol lipase is used.

1.3 The current standards

Australian and New Zealand food laws require food for sale to comply with the Code. In relation to this application, the relevant requirements are described in the sections that follow.

1.3.1 Permitted use

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

Paragraph 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' respectively, unless expressly permitted by the Code.

Section 1.1.2—13 provides that a substance is 'used as a processing aid' if it is used 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 (Good Manufacturing Practice).

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.

Lipase, triacylglycerol from different microorganisms is permitted for use, with listings in both of the above-mentioned tables. However, lipase, triacylglycerol derived from *T. reesei*, containing the gene for lipase, triacylglycerol isolated from *A. tubingensis* is not currently permitted to be used as a processing aid.

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) 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.

1.3.3 International standards

The applicant's lipase, triacylglycerol has been determined as Generally Recognized as Safe (GRAS) in the United States.

The Codex Alimentarius does not establish standards for processing aids or enzymes. Individual countries regulate the use of enzymes differently to the Code. However, as outlined in section 1.3.2 above, there are internationally recognised specifications for enzymes established by JECFA and the Food Chemicals Codex.

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 warranted the variation of a food regulatory measure.

1.5 Procedure for assessment

The application was assessed under the General Procedure.

1.6 Decision

The draft variation as proposed following assessment was approved with amendments. Amendments were made in response to a submission received from the applicant during the call for submissions stage, requesting that the stated technological purpose be revised to more accurately reflect the cereal-based goods produced. The variation takes effect on the date of gazettal. The approved draft variation is at Attachment A.

The related explanatory statement is at Attachment B. An explanatory statement is required to accompany an instrument if it is lodged on the Federal Register of Legislation.

The draft variation on which submissions were sought (which was subsequently amended) is at Attachment C.

2 Summary of the findings

2.1 Summary of issues raised in submissions

FSANZ sought public comments on the proposed draft variation included in the call for submissions report between 5 February and 19 March 2019. Four submissions were received: one from the applicant, one from the food industry, and two from government agencies who both supported the assessment and raised no issues. Issues raised in submissions have been addressed in Table 1 below; this also involved amendments to the draft variation as noted.

Table 1: Summary of issues raised in submissions

Issue	Raised by	FSANZ response (including any amendments to drafting)
<p>The submitter (applicant) requested that the draft variation be amended so that the stated technological purpose for the enzyme more accurately reflects the cereal-based goods produced.</p> <p>At the call for submissions stage, the technological purpose described in the draft variation was 'for use in the production of bakery products and brewing of cereal-based beverages'. However, in their submission, the applicant requested that the range of cereal-based products be expanded to include 'cereal-based foods and beverages'.</p> <p>The enzyme is to be used to produce liquid worts from cereal mash, where it imparts process efficiencies, especially in the production of mash from non-malted cereals. The wort can be used not only in the brewing of cereal-based beverages, but can also be concentrated to produce malt syrups, which in turn can be spray-dried to produce malt flours. The malt extract can then be used in producing cereal-based foods and beverages. Irrespective of the final products, the function and substrate of the triacylglycerol lipase in this manufacturing process remains the same.</p>	<p>DuPont Australia Pty Ltd (the applicant)</p>	<p>The additional explanation and justification provided by the applicant in their submission to amend the draft variation has been assessed by FSANZ and deemed acceptable. FSANZ notes that the use of the enzyme in producing the liquid wort from the cereal mash remains the same, irrespective of the final product. Sections 2.1.2 and 2.1.3 of SD1 have been revised accordingly.</p> <p>FSANZ agreed that the draft variation be amended to better reflect the range of goods produced as a result of using the enzyme in wort production and also to limit potential confusion which became apparent when the terms were further considered. A specific additional concern noted was the possibility that all beverages would be considered by having the term 'and beverages' at the end of the phrase. To address this potential for possible confusion it was decided to swap the terms around; to now read 'cereal-based beverages and foods'.</p> <p>Therefore, the specific technological purpose in the draft variation was amended as follows: 'For use in the production of bakery products, and brewing of cereal-based beverages and foods'.</p> <p>FSANZ also made a slight change to the name of the permitted substance, for clarity and consistency with other entries in the table to subsections S18—4(5) and S18—9(3) of Schedule 18.</p>

Issue	Raised by	FSANZ response (including any amendments to drafting)
<p>The submitter supported the proposed variation to the Code. However, they requested FSANZ consider including other formats of final food that could benefit from the application of the enzyme, specifically, cereal-based food and beverages. This request mirrored that of the applicant above. The submitter reported that amending the proposed variation to the Code as described would increase flexibility in the choice of raw materials, and lower manufacturing costs for food manufacturers.</p>	<p>Nestle Australia and New Zealand</p>	<p>See FSANZ's response to DuPont's submission above.</p>

2.2 Risk assessment

The evidence presented to support the proposed use of the enzyme provided adequate assurance that the enzyme, in the form and prescribed amounts, was technologically justified and had been demonstrated to be effective in achieving its stated purpose. The applicant stated that the enzyme has superior tolerance to withstand mechanical shock during processing compared to the enzyme from different sources. The enzyme meets international purity specifications.

The submitted data and information from other sources, were considered adequate to define the hazard of triacylglycerol lipase from *T. reesei*. The production organism, *T. reesei*, was not pathogenic and was not detected in the final enzyme preparation. Molecular characterisation of the production strain confirmed the sequence of the inserted DNA had not undergone any rearrangement, and the introduced DNA was stably inherited.

The enzyme showed no evidence of genotoxicity in a bacterial reverse mutation assay or a chromosomal aberration assay in human lymphocytes. In a 90-day oral gavage study in rats, the no observed adverse effect level (NOAEL) was the highest dose tested, 160.6 mg/kg bodyweight (bw)/day total protein, which was equivalent to 123.15 mg/kg bw/day enzyme total organic solids (TOS). The applicant's estimated theoretical maximum daily intake (TMDI) based on the proposed uses was 0.410 mg/kg bw/day TOS. From these values, the Margin of Exposure was approximately 300.

Bioinformatic data indicated a lack of homology with known toxins or allergens, and the enzyme was unlikely to pose an allergenicity concern. The applicant indicated that enzyme preparations used for bakery production may contain wheat as a carrier. The enzyme product may also contain traces of soy and gluten-containing cereals due to such materials being used in the fermentation media.

Based on the reviewed data it was concluded that in the absence of any identifiable hazard an acceptable daily intake (ADI) 'not specified' was appropriate. A dietary exposure assessment was therefore not required.

For further details on the risk assessment, refer to the Risk and technical assessment report (SD1). This report has been amended subsequent to the call for submissions, providing further details around the cereal-based beverages and foods that can be produced as a result of using the enzyme during the mashing process.

2.3 Risk management

The risk assessment concluded that there are no safety concerns from the use of triacylglycerol lipase from a GM strain of *T. reesei* as a food processing aid in the production of bakery goods, and cereal-based beverages and foods. No information was provided following the Call for Submissions to suggest that that assessment was incorrect. As processing aids require permissions in the Code, the main risk management options available to FSANZ following the Call for Submissions were to approve, reject or amend the draft variation to amend the Code. Risk management issues for this application relating to enzyme nomenclature and labelling are discussed below. The regulatory options analysed in section 2.5.1.1 take account of the safety of the enzyme.

2.3.1 Regulatory approval for enzymes

The food technology assessment concluded that the enzyme meets its stated purpose, for use as a processing aid in the production of baked products, and cereal-based beverages and foods. The risk assessment concluded that, in the absence of any identifiable hazard, an ADI of 'not specified' was appropriate for the enzyme and ingestion of any residual triacylglycerol lipase in food products was 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 enzyme's use as a processing aid also provides 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' (i.e., genetically modified *T. reesei*). 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 (Food produced using gene technology) provides that permission for use as a processing aid (i.e. within Schedule 18) 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 'triacylglycerol lipase' for the enzyme with an EC number of EC 3.1.1.3 (IUBMB 2018). This is similar to the name that is used in the draft variation to the Code for this enzyme, which is lipase, triacylglycerol.

The nomenclature of the production and gene donor microorganisms was confirmed as being appropriate as listed in the application (see section 3.2 of SD1). The host and production microorganism is *T. reesei*, which is listed as a production microorganism for a number of other enzymes in Schedule 18, and *A. tubingensis* is the gene donor microorganism.

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 requires most packaged food to be labelled with a statement of ingredients. Sections 1.2.4—3(2)(d) and (e) of that Standard exempt processing aids from the requirement to be declared in the statement of ingredients.

The risk assessment concluded that the use of the enzyme preparation posed 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 applies 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. Section 1.5.2—4 indicates that labelling requirements apply for processing aids that are foods produced using gene technology, where novel DNA or novel protein from the processing aid remain 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'. The Code's labelling requirements – including those imposed by section 1.5.2—4 – generally apply only to foods for retail sale (subsection 1.2.1—8(1)) and to foods sold to a caterer (section 1.2.1—15). 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.

The enzyme itself will be a food produced using gene technology for Code purposes. That is, as a food that was produced or derived from an organism (ie, the *T. reesei*) which has been modified by gene technology.

If the enzyme remained in a food for retail sale or sold to a caterer as an ingredient of that food, and if novel DNA or novel protein from the genetically modified strain of *T. reesei* (that is the source microorganism, not the enzyme) remained present in that food, the food would be required to be labelled 'genetically modified' in conjunction with the name of the processing aid.

However, if the enzyme itself was not an ingredient in the food for sale, that food would not be required to be labelled as 'genetically modified'. The requirement to label as 'genetically modified' would 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)).

Section 2.1.3 of SD1 states the enzyme is denatured in subsequent steps after it has performed its technological purpose, usually by a heating step (e.g. boiling step in brewing and heating during baking). Denaturation of the enzyme protein does not alter the status of the food as being genetically modified.

2.3.3.2 Declaration of certain substances

Soy-bean grits and glucose sources from cereals containing gluten (not wheat) are among the raw materials used as fermentation media to produce the enzyme. Further, the powdered form of the enzyme preparation used for bakery purposes may include wheat starch as the carrier. Where cereals containing gluten (including wheat) are present in a food for retail sale or food sold to a caterer, including when present as a processing aid or an ingredient or component of a processing aid, they must be declared in accordance with section 1.2.3—4 of Standard 1.2.3 (Information requirements – warning statements, advisory statements and declarations).

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 of Standard 1.2.1).

2.3.4 Risk management conclusion

The risk management conclusion was to permit the new enzyme lipase, triacylglycerol derived from a GM strain of *T. reesei*, as a processing aid into the table to S18—9(3). This table includes enzymes permitted for a specific technological purpose. The technological purpose is for the production of bakery products, and cereal-based beverages and foods. 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 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.

FSANZ developed and applied a basic communication strategy to this application. The call for submissions was notified via the Food Standards Notification Circular, media release, FSANZ's social media tools and Food Standards News.

The process by which FSANZ considers standard development matters is open, accountable, consultative and transparent.

The applicant, individuals and organisations that made submissions on this application will be notified at each stage of the assessment.

2.5 FSANZ Act assessment requirements

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, had 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 required 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 was likely to benefit, on balance, from a move from the status quo (i.e. rejecting the application). This analysis considered permitting the use of triacylglycerol lipase from a GM strain of *T. reesei* as a processing aid in the production of bakery goods, and cereal-based beverages and foods. FSANZ was of the view that no other realistic food regulatory measures exist, and no information received in submissions resulted in FSANZ arriving at a different outcome.

The consideration of the costs and benefits in this section was not intended to be an exhaustive, quantitative economic analysis of the proposed measures and, in fact, most of the effects that were considered could not 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 this enzyme.

*Costs and benefits permitting the use of triacylglycerol lipase from a genetically modified strain of *T. reesei* as a processing aid*

Due to the voluntary nature of the permission, industry will only use the enzyme where they believe a net benefit exists. Industry will benefit from having additional choice available to them. The applicant reported the enzyme preparation to have superior tolerance to mechanical shock during processing compared to enzymes from sources which are currently approved in the Code. The enzyme also improves dough stability and handling properties in baking, as well as improving the volume and structure of bread and other baked goods. This may make manufacturing more efficient, which could lead to lower production costs for industry and, in turn, potentially lower prices for consumers. The enzyme is also claimed by the applicant to impart process efficiencies in the production of liquid wort from mash separations, especially of non-malted cereals, compared to other enzymes.

The enzyme is permitted for use in the United States, and this may present a business opportunity for Australian and New Zealand industries, although there may also be competing imports from these countries into the domestic market.

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 was that the direct and indirect benefits that would arise from permitting the use of triacylglycerol lipase from a GM strain of *T. reesei* as a processing aid would 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

Schedule 18 applies 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 (SD1) and concluded there were no public health and safety concerns with the use of the enzyme triacylglycerol lipase sourced from a GM

strain of *T. reesei* as a food processing aid for the proposed purposes.

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 triacylglycerol lipase are discussed in section 2.3.3 – Labelling requirements.

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 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, 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, the enzyme has been permitted for use in the US. In addition, it meets international specifications for enzyme preparations, these being 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**

As mentioned above, the use of this enzyme is already permitted in the United States.

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. This will also help foster continued innovation and improvements in food manufacturing techniques and processes.

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 triacylglycerol lipase as a food processing aid for its proposed purposes. It is therefore appropriate that Australian and New Zealand food industries are given the opportunity to benefit from the use of this enzyme with enhanced functionality.

The applicant reports the product to have superior tolerance to mechanical shock during processing compared to enzymes from sources which are currently approved in the Code. This may make manufacturing more efficient, which could lead to lower production costs for industry and, in turn, potentially lower prices for consumers.

- **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 the use of triacylglycerol lipase, sourced from *T. reesei*, as a processing aid was consistent with these specific order policy principles for 'Technological Function'.

3 References

FAO/WHO (2017) [General specifications and considerations for enzyme preparations used in food processing](#).

IUBMB (2017) [EC 3.1.1.3](#).

The United States Pharmacopeia (2018) [Food Chemicals Codex 11th Edition](#), United States Pharmacopeial Convention, Rockville, MD.

Attachments

- A. Approved draft variation to the Australia New Zealand Food Standards Code
- B. Explanatory statement
- C. Draft variation to the Australia New Zealand Food Standards Code (call for submissions)

² <http://foodregulation.gov.au/internet/fr/publishing.nsf/Content/food-policies>

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



Food Standards (Application A1159 – Triacylglycerol lipase from *Trichoderma reesei* 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 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 clause 3 of the variation.

1 Name

This instrument is the *Food Standards (Application A1159 – Triacylglycerol lipase 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

Lipase, triacylglycerol (EC 3.1.1.3) sourced from <i>Trichoderma reesei</i> containing the gene for lipase, triacylglycerol isolated from <i>Aspergillus tubingensis</i>	For use in the production of bakery products, and cereal-based beverages and foods.	GMP
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Attachment B – Explanatory Statement

1. Authority

Section 13 of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act) provides that the functions of Food Standards Australia New Zealand (the Authority) include the development of standards and variations of standards for inclusion in the *Australia New Zealand Food Standards Code* (the Code).

Division 1 of Part 3 of the FSANZ Act specifies that the Authority may accept applications for the development or variation of food regulatory measures, including standards. This Division also stipulates the procedure for considering an application for the development or variation of a food regulatory measure.

The Authority accepted application A1159 which sought to permit the use of the enzyme triacylglycerol lipase (EC 3.1.1.3) sourced from a genetically-modified (GM) strain of *Trichoderma reesei* (*T. reesei*) as a processing aid for the production of bakery products, and cereal-based beverages and foods. The Authority considered the application in accordance with Division 1 of Part 3 and has approved a draft variation.

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 the draft variation to amend the table to subsection S18—9(3) in Schedule 18 of the Code to permit the use of lipase, triacylglycerol (EC 3.1.1.3) sourced from a GM strain of *T. reesei* as a food processing aid in the production of bakery products, and cereal-based beverages and foods.

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 A1159 included one round of public consultation following an assessment and the preparation of a draft variation and associated report. Submissions were called for on 5 February 2019 for a six-week consultation period.

A Regulation Impact Statement was not required because the proposed variation to Schedule 18 was likely to have a minor impact on business and individuals (OBPR reference number 12065).

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

The new entry would permit the use of the enzyme, lipase, triacylglycerol (EC 3.1.1.3) sourced from *T. reesei* containing the gene for lipase, triacylglycerol isolated from *A. tubingensis* as a processing aid. The specific technological purpose of this enzyme processing aid would be for the production of bakery products, and for the production of cereal-based beverages and foods. A condition of the permission is that the maximum permitted level or amount that may be used must be consistent with good manufacturing practice.

Attachment C – Draft variation to the *Australia New Zealand Food Standards Code* (call for submissions)



Food Standards (Application A1159 – Triacylglycerol lipase from *Trichoderma reesei* 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 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 A1159 – Triacylglycerol lipase 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

Lipase, triacylglycerol (EC 3.1.1.3) sourced from *Trichoderma reesei* containing the lipase 3 gene from *Aspergillus tubingensis*

For use in the production of bakery products and brewing of cereal-based beverages.

GMP