



**21 March 2019**

**[75-19]**

Approval report – Application A1162

Triacylglycerol lipase from *Trichoderma reesei* as a processing aid (enzyme)

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Food Standards Australia New Zealand (FSANZ) has assessed an application made by AB Enzymes GmbH to permit the use of the enzyme triacylglycerol lipase from a genetically modified strain of *Trichoderma reesei* as a processing aid in baking and other cereal-based processes.

On 13 November 2018, FSANZ sought submissions on a draft variation and published an associated report. FSANZ received three submissions.

FSANZ approved the draft variation on 6 March 2019. The Australia and New Zealand Ministerial Forum on Food Regulation was notified of FSANZ's decision on 21 March 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](#)<sup>1</sup> which informed the assessment of this application is available on the FSANZ website:

SD1 Risk and Technical Assessment Report (unrevised at approval)

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<sup>1</sup><http://www.foodstandards.gov.au/code/applications/Pages/A1162.aspx>

## Executive summary

AB Enzymes GmbH submitted an application to Food Standards Australia New Zealand (FSANZ) to use the enzyme triacylglycerol lipase (EC 3.1.1.3) from a genetically modified strain of *Trichoderma reesei*, which has been genetically modified to express a triacylglycerol lipase gene from *Fusarium oxysporum*. The enzyme will be used as a processing aid in baking and other cereal-based processes.

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, this enzyme would be listed in the table to subsection S18—9(3), which includes enzymes permitted for use for a specific technological purpose.

FSANZ's risk assessment concluded that there were no public health and safety concerns associated with using this triacylglycerol lipase. In the absence of any identifiable hazard, FSANZ concluded that an acceptable daily intake (ADI) '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 as a processing aid in baking and other cereal-based processes. Specifically, the enzyme improves dough/batter processing properties and baked product quality and it has an increased capacity to withstand mechanical shock during processes. 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 effective in achieving its stated purpose. The enzyme meets international purity specifications.

A total of three submissions were received on FSANZ's assessment report, all 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 triacylglycerol lipase derived from a genetically modified strain of *T. reesei*, as a processing aid in baking and other cereal-based processes. The amount of enzyme used must be consistent with good manufacturing practice (GMP).

# 1 Introduction

## 1.1 The applicant

AB Enzymes GmbH is an industrial biotechnology company that develops, manufactures and supplies enzyme preparations for industrial applications worldwide.

## 1.2 The application

The application was received on 10 May 2018.

The application sought to change the Australia New Zealand Food Standards Code (the Code) to permit use of the enzyme triacylglycerol lipase (EC 3.1.1.3) from a genetically modified strain of *Trichoderma reesei* as a processing aid in baking and other cereal-based processes.

Wheat flour contains approximately 2.0–2.5% lipids (dry weight), and the non-polar triacylglycerols comprise a relatively small component of the total amount. During cereal-based processes, triacylglycerol lipase catalyses the hydrolysis of the ester bonds of triacylglycerols, resulting in the formation of mono- and diacylglycerols, free fatty acids, and glycerol in the wheat flour. This helps influence the interactions of the other components, including gluten and starch, during processing and, in turn, can help improve dough/batter processing properties and baked product quality.

As an enzyme processing aid, triacylglycerol lipase performs its function during food processing and has no technological function in the final food. The enzyme is denatured by heat during the baking, drying, boiling or steaming step of food production, or else through changes to the pH, depletion of the substrate, or some other alteration to the enzyme's processing conditions.

The enzyme is sourced from a genetically modified strain of *T. reesei* expressing a triacylglycerol lipase gene from *Fusarium oxysporum*. The triacylglycerol lipase from AB Enzymes has been found to have superior technical characteristics resulting in improved baked product quality. Specifically, this enzyme has been shown to have an increased tolerance to mechanical shock during processing. Although sourced from a genetically modified organism, the enzyme itself is not protein engineered.

The triacylglycerol lipase is produced by submerged fermentation. After a number of processing steps involving filtering and concentrating the liquid containing the enzyme, the resulting concentrated enzyme solution is free of the production organism and insoluble substances. The enzyme is generally sold as a powdered preparation with wheat flour as a carrier.

## 1.3 The current standard

Australian and New Zealand food laws require food for sale to comply with the Code. In relation to this application, the relevant requirements are:

### *Permitted use*

Enzymes used in processing and manufacturing 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 was 'used as a processing aid'; or a 'food

produced using gene technology', 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.

Schedule 18 currently contains permissions for triacylglycerol lipase (EC 3.1.1.3) used as a processing aid for various technological purposes. However, triacylglycerol lipase from a genetically modified strain of *T. reesei* containing a gene from triacylglycerol lipase isolated from *F. oxysporum* is not listed in Schedule 18. Therefore, its use as a processing aid is currently not permitted.

#### *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.

## **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 aspect of the safety assessment concluded that the enzyme meets its stated purpose, for use as a processing aid in baking and other cereal-based processes. The risk assessment concluded that, in the absence of any identifiable hazard, an ADI of 'not specified' is appropriate for the enzyme. However, the powdered preparation does contain wheat flour and, as such, may represent a concern to those who are wheat sensitive (see section 2.3.2.2 regarding risk management). 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 13 November 2018. Three submissions were received: two from government agencies and one from the food industry. All three submissions were supportive of 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 Economic Development, Jobs, Transport and Resources	Supportive.	Noted.
New Zealand Ministry for Primary Industries	Supportive.	Noted.
New Zealand Food and Grocery Council	Supportive.	Noted.

### 2.2 Risk assessment

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* is not pathogenic and is absent in the final enzyme preparation. Molecular characterisation of the production strain has confirmed the sequence of the inserted DNA is as expected and has not undergone any rearrangement, and the introduced DNA is stably inherited.

Triacylglycerol lipase from *T. reesei* was not genotoxic *in vitro* and did not cause adverse effects in a subchronic toxicity study in rats. The no observed adverse effect level (NOAEL) in the subchronic toxicity study was the highest dose tested, 1000 mg/kg bw/day on an enzyme total organic solids (TOS) basis. This is more than 11,000-fold higher than the applicant's estimate of an individual's theoretical maximal daily intake (0.09 mg TOS/kg bw/day) based on the proposed uses.

Bioinformatic analysis indicated that the enzyme has no biologically relevant homology to known protein allergens and is unlikely to pose an allergenicity concern. However, the enzyme preparation contains wheat flour as a carrier. As wheat is a major food allergen, risk management measures are indicated to protect wheat-allergic individuals (see section 2.3.2.2 below).

Based on the reviewed toxicological data it is concluded that, in the absence of any identifiable hazard, an acceptable daily intake 'not specified' is appropriate. A dietary exposure assessment is 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.

For further details, 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 triacylglycerol lipase from the genetically modified strain of *T. reesei* as a food processing aid in baking and other cereal-based processes. As processing aids require permissions in the Code, the main risk management option available to FSANZ was 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 considered for this application were 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 in Schedule 18 will also provide the permission for its potential presence in the food for sale as a food produced using gene technology. The enzyme is a food produced using gene technology for Code purposes as it is derived from 'an organism 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).

### 2.3.1 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 'triacylglycerol lipase' for the enzyme with an EC number of EC 3.1.1.3 (IUBMB 2017). This is similar to the name that is used in the proposed draft variation to the Code for this enzyme, which is lipase, triacylglycerol.

The Code does not normally identify source microorganisms at the strain level unless there are significant safety considerations associated with that strain. In this application, there are no significant concerns with the source organism, thus the proposed draft amendment will reflect that the source will be *Trichoderma reesei*, containing the gene for triacylglycerol lipase isolated from *Fusarium oxysporum*.

### 2.3.2 Labelling considerations

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 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 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.

#### 2.3.2.1 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 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 genetically modified 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' depend 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 triacylglycerol lipase 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 genetically modified strain of *T. reesei* (that is the source microorganism, not the enzyme) remains in the final food.

FSANZ however, also notes that if the food made with the enzyme is not a food for sale itself but rather is used to make an ingredient in a food for retail sale or food sold to a caterer (for example, pasta is used in a mixed food), the enzyme would not be an ingredient in the food for sale (the mixed food, such as a pasta and sauce ready meal). 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 2.2.3 of SD1 states the enzyme is denatured by heat during the boiling/steaming or baking step. Denaturation of the enzyme protein does not alter the status of the food as being genetically modified.

### **2.3.2.2 Declaration of certain substances**

A wheat-based source of nitrogen may be among the raw materials used as fermentation media in the production of the enzyme. Further, the powdered form of the enzyme preparation comprises 90.8% wheat flour as a carrier. Where wheat is present in a food for retail sale or food sold to a caterer, it must be declared in accordance with section 1.2.3—4 of Standard 1.2.3.

This enzyme is intended for use in baking processes, for foods such as bread, biscuits, tortillas, cakes, steamed bread and croissants, and in other cereal-based processes, for foods such as pastas and noodles. The presence of wheat in the final food from the enzyme preparation will trigger a mandatory allergen declaration if the ingredients of the bakery products, pasta and noodles are not wheat-based.

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).

### **2.3.3 Risk management conclusion**

The risk management conclusion is to add the permission for the new enzyme triacylglycerol lipase derived from the genetically modified strain of *T. reesei*, 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 use in baking and other cereal-based processes. 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 (retain the status quo). 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 were 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 triacylglycerol lipase from the genetically modified strain of *T. reesei* as

a processing aid in baking and other cereal-based processes.

*Costs and benefits permitting the use of triacylglycerol lipase from a genetically modified strain of *T. reesei* as a processing aid in baking and other cereal-based processes*

Due to the voluntary nature of the permission, industry will only use the enzyme where they believe a net benefit exists. The applicant reports the product has superior tolerance to mechanical shock during processing compared to enzymes from other approved sources. This may make manufacturing more efficient which could lead to lower production costs for industry and potentially lower prices for consumers.

The enzyme is permitted for use in France and the USA (US FDA 2016) (and is currently being considered by EFSA), 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.

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 the genetically modified strain of *T. reesei* as a processing aid in baking and other cereal-based processes 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 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 issues associated with the use of the enzyme triacylglycerol lipase sourced from the genetically modified strain of *T. reesei* as a food processing aid for use in baking and other cereal-based processes.

### **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 – 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, the enzyme has been permitted for use in several countries overseas (see section 2.5.1.1). In addition, it meets international specifications for enzyme preparations i.e. the Joint FAO/WHO Expert Committee on Food Additives (JECFA) Compendium of Food Additive Specifications (FAO/WHO 2016) and the Food Chemicals Codex specifications for enzymes (Food Chemicals Codex 10<sup>th</sup> edition (2016)).

- **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. 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 concerns associated with the production microorganism *T. reesei* or with using triacylglycerol lipase as a food processing aid in baking and other cereal-based processes. 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 indicated that the enzyme has shown great potential in food manufacturing, and a letter of support from a leading supplier of bakery ingredients, with manufacturing facilities across Australia and New Zealand states that, from the scientific evidence provided, the application of the new enzyme in the baking industry in Australia looks exceptionally positive. However, 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](#)<sup>2</sup> includes specific order policy principles for substances added to achieve a solely technological function, such as processing aids. These specific order policy principles state that permission should be granted where:

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

FSANZ determined that permitting the use of triacylglycerol lipase, sourced from *T. reesei*, as a processing aid in baking and other cereal-based processes, is consistent with these specific order policy principles for 'Technological Function'.

### 3 References

FAO/WHO (2016) General specifications and considerations for enzyme preparations used in food processing. <http://www.fao.org/docrep/009/a0691e/A0691E03.htm>

IUBMB (2017) EC 3.1.1.3. <http://www.sbcs.qmul.ac.uk/iubmb/enzyme/EC3/0101a.html#05>

The United States Pharmacopeia (2016) Food Chemicals Codex 10th Edition, United States Pharmacopeial Convention, Rockville, MD. <http://publications.usp.org/>

US Food and Drug Administration (2016) GRAS notices – GRN000631. <https://www.accessdata.fda.gov/scripts/fdcc/index.cfm?set=GRASNotices&id=631>

### Attachments

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

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

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



### Food Standards (Application A1162 – Triacylglycerol lipase 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 this variation.

Dated [To be completed by 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.

**OFFICIAL**

**1 Name**

This instrument is the *Food Standards (Application A1162 – 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), after the entry for 'Lipase, triacylglycerol (EC 3.1.1.3) sourced from *Candida cylindracea*'

Lipase, triacylglycerol (EC 3.1.1.3) sourced from <i>Trichoderma reesei</i> containing the gene for lipase, triacylglycerol isolated from <i>Fusarium oxysporum</i>	For use in the manufacture of bakery and other cereal-based products	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 A1162 which seeks permission to use the enzyme triacylglycerol lipase (EC 3.1.1.3) from a genetically modified strain of *T. reesei* as a processing aid in baking and other cereal-based processes. The Authority considered the application in accordance with Division 1 of Part 3 and has approved a draft Standard.

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 triacylglycerol lipase from a genetically modified strain of *T. reesei* as a food processing aid in baking and other cereal-based processes.

### 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 2016) and the United States Pharmacopeial Convention (2016) Food Chemicals Codex (10<sup>th</sup> 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 A1162 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 13 November for a five-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 the following into the table to subsection S18—9(3) in Schedule 18 in alphabetical order: a new entry for “lipase, triacylglycerol (EC 3.1.1.3) sourced from *T. reesei* containing the gene for lipase, triacylglycerol isolated from *F. oxysporum*” into column 1; the words “For use in the manufacture of bakery and other cereal-based products” into column 2; and “GMP” into column 3.

The new entry will, in effect, permit the enzyme triacylglycerol lipase (E.C 3.1.1.3), derived from the genetically modified strain of *T. reesei*, to be used as a processing aid in food, for the technological purpose of baking and other cereal-based processes, with the condition that the amount used must be consistent with good manufacturing practice (GMP).