

7 July 2017
[17–17]

Call for submissions – Application A1130

Triacylglycerol Lipase as a Processing Aid (Enzyme)

FSANZ has assessed an Application made by Amano Enzyme Inc. to permit the use of triacylglycerol lipase from *Candida cylindracea* as a processing aid in the manufacture of bakery products and dairy products and in the processing of fats and oils, and has prepared a draft food regulatory measure. Pursuant to section 31 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act), FSANZ now calls for submissions to assist consideration of the draft food regulatory measure.

For information about making a submission, visit the FSANZ website at [information for submitters](#).

All submissions on applications and proposals will be published on our website. We will not publish material that that we accept as confidential, but will record that such information is held. In-confidence submissions may be subject to release under the provisions of the *Freedom of Information Act 1991*. Submissions will be published as soon as possible after the end of the public comment period. Where large numbers of documents are involved, FSANZ will make these available on CD, rather than on the website.

Under section 114 of the FSANZ Act, some information provided to FSANZ cannot be disclosed. More information about the disclosure of confidential commercial information is available on the FSANZ website at [information for submitters](#).

Submissions should be made in writing; be marked clearly with the word 'Submission' and quote the correct project number and name. While FSANZ accepts submissions in hard copy to our offices, it is more convenient to receive submissions electronically through the FSANZ website via the link on [documents for public comment](#). You can also email your submission directly to submissions@foodstandards.gov.au.

There is no need to send a hard copy of your submission if you have submitted it by email or via the FSANZ website. FSANZ endeavours to formally acknowledge receipt of submissions within 3 business days.

DEADLINE FOR SUBMISSIONS: 6pm (Canberra time) 18 August 2017

Submissions received after this date will not be considered unless an extension had been given before the closing date. Extensions will only be granted due to extraordinary circumstances during the submission period. Any agreed extension will be notified on the FSANZ website and will apply to all submitters.

Questions about making submissions or the application process can be sent to standards.management@foodstandards.gov.au.

Hard copy submissions may be sent to one of the following addresses:

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Supporting document

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

SD1 Risk and technical assessment report

¹ <http://www.foodstandards.gov.au/code/applications/Pages/A1130-Triacylglycerol-Lipase-as-a-PA.aspx>

Executive summary

Amano Enzyme Inc. submitted an Application seeking permission for a new microbial source of the already permitted enzyme, triacylglycerol lipase (EC number 3.1.1.3), sourced from *Candida cylindracea* as a processing aid used in the production of food. Triacylglycerol lipase catalyses the hydrolysis of various triglycerides (fats and oils) to produce free fatty acids and the subsequent various mono- and diglycerides. The enzyme selectively hydrolyses short and medium chain fatty acids in preference to long chain fatty acids and removes them from the 1 and 3 positions of the original triacylglycerol. The Applicant claims these reactions can produce flavour improvements of the final treated food. The enzyme is expected to be used primarily in the manufacture of bakery products and dairy products and in the processing of fats and oils.

Enzymes used in the production and manufacture of food are considered processing aids and are regulated by Standard 1.3.3 – Processing aids in the *Australia New Zealand Food Standards Code* (the Code). Enzymes permitted to be used as processing aids are listed in Schedule 18.

The evidence presented to support the proposed uses provided adequate assurance that the enzyme, in the form and prescribed amounts, is technologically justified. It has also been demonstrated to be effective in achieving its stated purpose and performing its technological function as a processing aid in the manufacture of bakery products, dairy products and the processing of fats and oil. The safety assessment has concluded that there are no safety concerns with the enzyme as a food processing aid. FSANZ also concluded that, in the absence of any identifiable hazard, an Acceptable Daily Intake (ADI) 'not specified' is appropriate. A dietary exposure assessment was therefore not required. The enzyme preparation meets international purity specifications.

FSANZ notes that the International Union of Biochemistry and Molecular Biology (IUBMB), the internationally recognised authority for enzyme nomenclature, uses the name "triacylglycerol lipase" for enzymes with an EC number of 3.1.1.3. This is the name used in the Application and this report. However, the name listed in Schedule 18 is, and will remain, as Lipase, triacylglycerol.

Therefore, it is proposed to permit the enzyme, lipase, triacylglycerol (EC 3.1.1.3) sourced from *Candida cylindracea* in the table to subsection S18—9(3) (Permitted processing aids—various technological purposes). The technological purpose is for use in the manufacture of bakery products and dairy products and in the processing of fats and oils. The maximum permitted level is GMP.

1 Introduction

1.1 The Applicant

The Applicant is Amano Enzyme Inc., Japan, a producer of specialty enzymes for pharmaceuticals, diagnostic medicines, and the food industry.

1.2 The Application

The purpose of the Application is to seek permission for the Applicant's enzyme preparation, being triacylglycerol lipase (Enzyme Commission (EC) number 3.1.1.3) sourced from *Candida cylindracea* as a processing aid intended for use in the manufacture of bakery products and dairy products and in the processing of fats and oils. The source microorganism is not genetically modified but has been obtained from a chemically mutated production strain.

Triacylglycerol lipase catalyses the hydrolysis of various triglycerides (fats and oils) to produce free fatty acids, with subsequent formation of various mono- and diglycerides. The enzyme preparation selectively hydrolyses short and medium chain fatty acids in preference to long chain fatty acids and removes them from the 1 and 3 positions of the original triacylglycerol. The Applicant claims these reactions can produce flavour improvements of the final treated food.

1.3 The current Standard

Enzymes used in the production and manufacture of food sold in Australia and New Zealand are considered processing aids (Standard 1.3.3 of the *Australia New Zealand Food Standards Code* (the Code)). Only those enzymes listed in Schedule 18 – Processing Aids in the Code are permitted to be used in producing food sold in Australia and New Zealand. Permitted enzymes of microbial origin are listed in the table to subsection S18—4(5) in Schedule 18 while some may be also permitted in the table to subsection S18—9(3) with the technological purpose being for the production of certain foods.

The permissions to use enzymes as processing aids are derived from the definition of 'used as a processing aid' in section 1.1.2—13 and repeated in section 1.3.3—2 (extract provided below).

In this Code, a reference to a substance that is **used as a processing aid** in relation to a food is a reference to a substance that is used during the course of processing:

- (a) to perform a technological purpose in the course of processing; and
- (b) does not perform a technological purpose in the food for sale; and

The Code lists the enzyme with EC number 3.1.1.3 as lipase, triacylglycerol, rather than the name used in the Application and this report of triacylglycerol lipase. There are currently thirteen sources of the enzyme, along with a protein engineered variant of the enzyme, in the table to subsection S18—4(5). However, *C. cylindracea* is currently not one of the approved sources of the enzyme.

C. cylindracea is not a source microorganism or a donor or host microorganism for other permitted enzymes in Schedule 18.

FSANZ assessed and approved a number of applications for lipase, triacylglycerol (EC 3.1.1.3) as noted in Table 1 below.

Table 1: FSANZ earlier applications that permitted other forms of the enzyme triacylglycerol lipase (EC 3.1.1.3)

Application #	Applicant	Microbial source	Gazettal
A264	Novo Nordisk Bioindustrial Pty Ltd (now Novozymes Pty Ltd)	<i>Aspergillus oryzae</i> , containing the gene for lipase, triacylglycerol isolated from <i>Humicola lanuginosa</i>	1996
A402	Novo Nordisk Bioindustrial Pty Ltd (now Novozymes Pty Ltd)	<i>Aspergillus oryzae</i> , containing the gene for lipase, triacylglycerol isolated from <i>Rhizomucor miehei</i>	2001
A435	Novo Nordisk Bioindustrial Pty Ltd (now Novozymes Pty Ltd)	<i>Aspergillus oryzae</i> , containing the gene for lipase, triacylglycerol isolated from <i>Fusarium oxysporum</i>	2002
A516	Biocatalysts Ltd	<i>Candida rugosa</i>	2005
A517	Biocatalysts Ltd	<i>Mucor javanicus</i>	2006
A519	Biocatalysts Ltd	<i>Penicillium roquefortii</i>	2006
A569	Danisco Australia Pty Ltd (now DuPont Danisco)	Hansenula polymorpha, containing the gene for lipase, triacylglycerol isolated from <i>Fusarium heterosporum</i>	2006
A1036	DSM Food Specialties	Protein engineered variant <i>Aspergillus niger</i> , containing the gene for lipase, triacylglycerol isolated from <i>Fusarium culmorum</i>	2010

1.3.1 International Standards

The enzyme preparation has been approved for use in food production in Japan and China.

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 the Joint FAO/WHO Expert Committee on Food Additives (JECFA 2006) and the Food Chemicals Codex (Food Chemicals Codex 2014).

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 is being assessed under the General Procedure.

2 Summary of the assessment

2.1 Risk assessment

FSANZ conducted a risk assessment on permitting a new enzyme, triacylglycerol lipase sourced from *C. cylindracea* as a processing aid. This assessment is provided as SD1 and its conclusions are summarised below.

The stated purpose of this enzyme preparation, namely, for use as a processing aid intended for use in baking, milk and dairy processing, and fats and oil processing, is clearly articulated in the Application. The evidence presented to support the proposed uses 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. That is, it performs its technological purpose during processing and manufacture of food and does not perform a technological purpose in the final food since it is inactivated. It is therefore appropriately categorised as a processing aid and not a food additive. The enzyme preparation meets international purity specifications.

There are no public health and safety concerns associated with the use of triacylglycerol lipase from *C. cylindracea* as a food processing aid, on the basis of the following considerations:

- The production organism is not toxigenic or pathogenic. *C. cylindracea* has a long history of safe use overseas in the production of lipases for a range of industrial purposes, including use as a food processing aid.
- Triacylglycerol lipase was not genotoxic *in vitro*.
- The enzyme preparation caused no observable adverse effects. The no observed adverse effect level (NOAEL) in a 13-week repeated dose oral toxicity study in rats was the highest dose tested and corresponds to 10,200 mg/kg bw/day or 581 mg total organic solids (TOS)/kg bw/day. This is more than 5000-fold higher than the Applicant's estimate of an individual's theoretical maximal daily intake (0.102 mg TOS/kg bw/day) based on the proposed uses in the manufacture of bakery products and dairy products and in the processing of fats and oils.
- Triacylglycerol lipase from *C. cylindracea* does not share amino acid sequence homology with any known allergens. No reports of allergenic responses resulting from use overseas have been identified.

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

2.2 Risk management

The risk assessment conclusions provide evidence that there are no safety risks from the use of this enzyme as a food processing aid. 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 impose any conditions that may be appropriate. Other risk management options available for this Application are related to labelling and enzyme nomenclature which are discussed in sections 2.2.3 and 2.2.2, respectively. The regulatory options analysed in section 2.4.1.1 take account of the safety of the enzyme preparation.

2.2.1 Regulatory approval for enzymes

The food technology aspect of the risk assessment has concluded that the enzyme meets its stated purpose, as a processing aid for use in baking, milk and dairy processing, and fats and oil processing. The safety assessment has further concluded that in the absence of any identifiable hazard that an ADI of 'not specified' is appropriate for the enzyme.

Therefore, it is proposed to permit the use of the enzyme as a processing aid for its stated

use in baking, milk and dairy processing, and fats and oil processing, which are the uses for which it has been requested to be permitted.

2.2.2 Enzyme nomenclature

FSANZ notes that the International Union of Biochemistry and Molecular Biology (IUBMB), the internationally recognised authority for enzyme nomenclature, uses the name “triacylglycerol lipase” for enzymes with an EC number of 3.1.1.3 (IUBMB 2017). This is the name used in the Application and in this report but the name listed in Schedule 18 is, and will remain, as Lipase, triacylglycerol as it is similar to the IUBMB name, is understood by relevant stakeholders as the name in the Code and is used for a number of other source organisms.

The source microorganism is stated in the Application as *C. cylindracea*.

2.2.3 Labelling considerations

As a general rule, processing aids (which include a number of permitted enzymes of microbial origin as listed in the table to subsection S18—4(5)) are exempt from the requirement to be declared in the statement of ingredients in accordance with paragraphs 1.2.4—3(2)(d) and (e) in Standard 1.2.4 – Information requirements – statement of ingredients.

The risk assessment concluded that the use of the enzyme preparation poses no risk to public health and safety and 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 produced using this enzyme as a processing aid and no additional labelling requirements are proposed.

2.2.4 Risk management conclusion

The risk management conclusion is to add the permission for lipase, triacylglycerol (EC 3.1.1.3) sourced from *C. cylindracea* into the table to S18—9(3). The technological purpose is for use in the manufacture of bakery products and dairy products, and in the processing of fats and oils. The maximum permitted level is GMP.

2.3 Risk communication

2.3.1 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.

The draft variation will be considered for approval by the FSANZ Board taking into account public comments received from this call for submissions.

2.3.2 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 for enzymes and amending the Code to permit the use of the enzyme triacylglycerol lipase from a new source microorganism for use as a processing aid is unlikely to have a significant effect on international trade as the enzyme preparation complies with international specifications for food enzymes. 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.

2.4 FSANZ Act assessment requirements

When assessing this Application and the subsequent development of a food regulatory measure, FSANZ has had regard to the following matters in section 29 of the FSANZ Act:

2.4.1 Section 29

2.4.1.1 Consideration of costs and benefits

FSANZ is required to consider the impact of various regulatory and non-regulatory options on all sectors of the community, especially relevant stakeholders who may be affected by this Application. The benefits and costs associated with the proposed amendments to the Code were analysed using regulatory impact principles. The level of analysis was commensurate with the nature of the Application and significance of the impacts.

Two regulatory options were considered:

- (1) prepare a draft variation to Schedule 18 to permit the use of the enzyme, triacylglycerol lipase (EC number 3.1.1.3) sourced from *C. cylindracea*, as a processing aid for use in the manufacture of bakery products and dairy products and in the processing of fats and oils
- (2) reject the Application.

The Office of Best Practice Regulation, in a letter dated 24 November 2010 (reference 12065), provided a standing exemption from the need to assess if a Regulation Impact Statement is required for Applications relating to processing aids, as they are machinery in nature and their use is voluntary. However, FSANZ undertook a limited impact analysis.

A consideration of the costs and benefits of the regulatory options was not intended to be an exhaustive, quantitative economic analysis of the options and, in fact, most of the effects that were considered cannot be assigned a dollar value.

Rather, the assessment sought to highlight the qualitative effects of criteria that were relevant to each option. These criteria are deliberately limited to those involving broad areas such as trade, consumer information and compliance.

Option 1 – Prepare a draft variation to Schedule 18

Sector	Costs or benefits to sector
Consumers	There are no costs or benefits to consumers associated with this option.

Sector	Costs or benefits to sector
Industry	There are already a number of permitted triacylglycerol lipase enzyme preparations obtained from different source microorganisms in the Code. This will be an alternative source of the enzyme, obtained from a non-genetically modified organism. Which enzyme preparation food manufacturer's use will be dependent on a range of factors, including economic and performance for the proposed use.
Governments	There are no costs or benefits to governments associated with this option.

Option 2 – Reject the Application

Sector	Costs or benefits to sector
Consumers	There are no benefits or costs to consumers of this option.
Industry	There are no benefits to industry from this option, as an alternative source of the enzyme will not be available.
Governments	There are no benefits or costs to governments for this option.

The direct and indirect benefits that would arise from a food regulatory measure developed or varied as a result of the Application outweigh the costs to the community, Government or industry that would arise from the development or variation of the food regulatory measure.

2.4.1.2 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.

2.4.1.3 Any relevant New Zealand standards

Schedule 18 applies in both Australia and New Zealand.

2.4.1.4 Any other relevant matters

Other relevant matters are considered below.

2.4.2 Subsection 18(1)

FSANZ has also considered the three objectives in subsection 18(1) of the FSANZ Act during the assessment.

2.4.2.1 Protection of public health and safety

FSANZ has undertaken a safety assessment (SD1), summarised in section 2.1 and concluded there are no public health and safety concerns relating to permitting the enzyme triacylglycerol lipase sourced from *C. cylindracea* as an enzyme processing aid.

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

No issues have been identified. The labelling requirements for processing aids are discussed in Section 2.2.3 – Labelling considerations.

2.4.2.3 The prevention of misleading or deceptive conduct

There are no issues identified with this Application relevant to this objective.

2.4.3 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 has used the best available scientific evidence to conduct the risk analysis, which is provided in SD1. The Applicant submitted a dossier of scientific studies as part of their Application. Other technical information, 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 enzymes. However, this enzyme is permitted for use in Japan and China. It also meets international specifications for enzyme preparations, being the JECFA Compendium of Food Additive Specifications and the Food Chemicals Codex.

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

Permission for this enzyme preparation provides food manufacturers with an alternative source which should add to competition to supplying enzymes to the food manufacturing industries.

- **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](#)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 has determined that permitting the use of the enzyme triacylglycerol lipase from *C. cylindracea* as a processing aid is consistent with the specific order principles for 'Technological Function'.

² <http://www.foodstandards.gov.au/code/fofr/fofrpolicy/pages/default.aspx>

3 Draft variation

The draft variation to the Code is at Attachment A and is intended to take effect on gazettal.

A draft 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.

4 References

Food Chemicals Codex 9th Edition (2014), The United States Pharmacopeia, United States Pharmacopeial Convention, Rockville, MD.
<http://www.usp.org/food-ingredients/food-chemicals-codex>

International Union of Biochemistry and Molecular Biology (IUBMB) Enzyme Nomenclature for EC 3.1.1.3 located at <http://www.chem.qmul.ac.uk/iubmb/enzyme/EC3/1/1/3.html> Assessed 6 April 2017

JECFA (2006) General specifications and considerations for enzyme preparations used in food processing. <http://www.fao.org/docrep/009/a0691e/A0691E03.htm>

Attachments

- A. Draft variation to the *Australia New Zealand Food Standards Code*
- B. Draft Explanatory Statement

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



Food Standards (Application A1130 – Triacylglycerol Lipase as a Processing Aid (Enzyme)) Variation

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

Dated [To be completed by Standards Management Officer]

Standards Management Officer
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 A1130 – Triacylglycerol Lipase as a Processing Aid (Enzyme)) Variation*.

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

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

3 Commencement

The variation commences on the date of gazettal.

Schedule

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

Lipase, triacylglycerol (EC 3.1.1.3) sourced from <i>Candida cylindracea</i>	For use in the manufacture of bakery products and dairy products and in the processing of fats and oils.	GMP
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Attachment B – Draft 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 A1130 which seeks to permit the use of the enzyme triacylglycerol lipase from a new source microorganism, being *Candida cylindracea* as a processing aid in the manufacture of bakery products and dairy products and in the processing of fats and oils. The Authority considered the Application in accordance with Division 1 of Part 3 and has prepared a draft variation.

2. Purpose

The Authority has proposed that the enzyme triacylglycerol lipase sourced from *C. cylindracea* is permitted as a processing aid in the manufacture of bakery products and dairy products and in the processing of fats and oils, at GMP. This requires an addition to the table to subsection S18—9(3) in Schedule 18.

3. Documents incorporated by reference

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

4. Consultation

In accordance with the procedure in Division 1 of Part 3 of the FSANZ Act, the Authority's consideration of Application A1130 will include one round of public consultation following an assessment and the preparation of a draft variation and associated assessment summary. A call for submissions (including the draft variation) will occur for a six week consultation period.

A Regulation Impact Statement was not required because the proposed variation to Schedule 18 is 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 variation inserts a new entry into the table to subsection S18—9(3) in Schedule 18. The name of the enzyme in the table is lipase, triacylglycerol which has the Enzyme Commission (EC) number 3.1.1.3. The source microorganism is *Candida cylindracea*. The technological purpose is for use in the manufacture of bakery products and dairy products and in the processing of fats and oils. The maximum permitted level is GMP.