2 November 2017
[31-17]

Approval report – Application A1130

Triacylglycerol Lipase as a Processing Aid (Enzyme)

Food Standards Australia New Zealand (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.

On 7 July 2017, FSANZ sought submissions on a draft variation and published an associated report. FSANZ received six submissions.

FSANZ approved the draft variation on 25 October 2017. The Australia and New Zealand Ministerial Forum on Food Regulation was notified of FSANZ's decision on 31 October 2017.

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

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Supporting document

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

SD1 Risk and technical assessment report

[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 to produce 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 claimed these reactions can improve the flavours of the final treated food. The enzyme is expected to be used primarily to manufacture bakery products and dairy products, and in the processing of fats and oils.

Enzymes used to produce and manufacture 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, was technologically justified. It was also demonstrated to be effective in achieving its stated purpose and performing its technological function as a processing aid in the manufacture of bakery products and dairy products, and the processing of fats and oil. The safety assessment 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' was appropriate. A dietary exposure assessment was therefore not required.The enzyme preparation meets international purity specifications.

FSANZ noted 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.

Issues raised in response to a Call for Submissions on the Application are addressed in the report.

The Board has approved a draft variation 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). This was considered appropriate because the assessment has been conducted on the proposed use of the enzyme for specific technological purposes rather than use for any technological purpose or for any food (table to subsection S18—4(5)). The permitted 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 good manufacturing practice (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 was to seek permission for the Applicant's enzyme preparation, triacylglycerol lipase (Enzyme Commission (EC) number 3.1.1.3) sourced from *Candida cylindracea*, as a processing aid 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 and 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 claimed these reactions can produce improved flavours of the final treated food.

1.3 The current Standard

Enzymes used to process and manufacture food are considered processing aids.

Paragraph 1.1.1—10(6)(c) in the Code provides that a food for sale must not have, as an ingredient or a component, a substance that is used as a processing aid, unless expressly permitted.

Section 1.1.2—13 defines the expression 'used as a processing aid'. That definition imposes certain requirements on substances permitted by Standard 1.3.3 and Schedule 18 to be used as a processing aid. For example, that the substance not perform a technological function in the final food for sale.

Standard 1.3.3 provides permissions for certain substances to be used as processing aids in food sold in Australia or New Zealand. The provisions of that Standard generally provide that substances listed in Schedule 18 of the Code are permitted for use as processing aids.

Permitted enzymes of microbial origin (including enzymes produced by genetically modified microorganisms) may be listed in the table to subsection S18—4(5) or the table to subsection S18—9(3), depending on whether the permission is for use for any technological purpose and/or any food, or for specific technological purposes and specific foods, respectively.

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 has previously 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)	*Aspergillus oryzae*, containing the gene for lipase, triacylglycerol isolated from *Humicola lanuginosa*	1996
A402	Novo Nordisk Bioindustrial Pty Ltd (now Novozymes Pty Ltd)	*Aspergillus oryzae*, containing the gene for lipase, triacylglycerol isolated from *Rhizomucor miehei*	2001
A435	Novo Nordisk Bioindustrial Pty Ltd (now Novozymes Pty Ltd)	*Aspergillus oryzae*, containing the gene for lipase, triacylglycerol isolated from *Fusarium oxysporum*	2002
A516	Biocatalysts Ltd	*Candida rugosa*	2005
A517	Biocatalysts Ltd	*Mucor javanicus*	2006
A519	Biocatalysts Ltd	*Penicillium roquefortii*	2006
A569	Danisco Australia Pty Ltd (now DuPont Danisco)	Hansenula polymorpha, containing the gene for lipase, triacylglycerol isolated from *Fusarium heterosporum*	2006
A1036	DSM Food Specialties	Protein engineered variant *Aspergillus niger*, containing the gene for lipase, triacylglycerol isolated from *Fusarium culmorum*	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 was assessed under the General Procedure.

2 Summary of the findings

2.1 Summary of issues raised in submissions

FSANZ sought public comments on the draft variation and associated report (the Call for Submissions) between 7 July 2017 and 18 August 2017. Six submissions were received—three from government agencies, one submission from a New Zealand industry association and two (the second one providing additional comments to its first submission) from a consumer association.

Details of submissions including issues raised and FSANZ's responses are in Table 2 below.

Table 2: Summary of issues

Issue	Raised by	FSANZ response
Concern expressed that enzymes have been classified (or are being re-classified) as processing aids and not food additives. By doing this they are exempt from food labelling and consumers are being denied this information and consumer choice.	Food Intolerance Network	The same issue was raised by this submitter for Applications A1125, A1126 and also A1131. FSANZ's response is unchanged to that provided in the Approval Report for A1125, but is summarised here. A processing aid is defined in section 1.1.2—13 of the Code as a substance used 'to perform a technological purpose in the course of processing [food]; and does not perform a technological purpose in a food for sale'. In general, enzymes used in the manufacture of food are captured by this definition and are regulated as processing aids. This has not changed; there has not been any re-classification of enzymes. FSANZ's assessment of the Application concluded that it was appropriate to permit the triacylglycerol lipase enzyme for use in the manufacture of food as a processing aid. The issue of labelling processing aids in the statement of ingredients was considered in 1997 as part of Proposal P143 – Assessment of provisions for the statement of ingredients[2]. The exemption for processing aids was developed as a pragmatic approach taking into account the costs to the food industry of additional labelling and possible benefits to consumers. In addition, the exemption is consistent with labelling requirements internationally including within Codex Alimentarius.
There is some evidence of harm from enzymes that was presented to the Codex Committee on Food Additives (CCFA) in 2017 (CX/FA 17/49/12)[3].	Food Intolerance Network	The report of the 49th Session of the CCFA (REP17/FA)[4] (paragraph 112) that considered the document, CX/FA 17/49/12, makes no reference to information regarding amylases (INS 1100 i, ii, iii, iv, v, vi), proteases (INS 1101 i, ii, iii, iv, v, vi), and lipases (INS 1104), other than to note that the proposed deletion of these substances from *Class Names and the International Numbering System (INS) for Food Additives (CAC/GL 36-1989)* is outside the mandate of the working group established to consider such matters.
There is recent scientific	Food	FSANZ notes that the Budnik et al. paper investigates the sensitising effects of occupational

[2] Copy available upon request to standards.management@foodstandards.gov.au.
[3] Paper prepared by an electronic working group led by Iran for the Joint FAO/WHO Food Standards Programme Codex Committee on Food Additives (CCFA) 49th Session (March 2017) *Proposed draft revision to the International Numbering System (INS) for food additives* (CAC/GL 36-1989).
[4] Report of the 49th session of the Codex Committee on Food Additives, Macao SAR, China, 20-24 March 2017, available at this link http://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FMeetings%252FCX-711-49%252FReport%252FREP17_FAe.pdf

Issue	Raised by	FSANZ response
evidence of harm from genetically modified enzymes (Budnik et al. (2016))[5].	Intolerance Network	exposure to enzymes used in flavour, detergent and pharmaceutical production. Occupational exposure is very different to exposure via the diet, both in terms of the route of exposure (which would generally be via inhalation and dermal exposure), and the level to which individuals may be exposed. Exposure to enzymes could be potentially high in the case of occupational handling, where the physical form of the enzyme that the individuals may be exposed to may be a purified and concentrated dust or powder, at very high levels, and on a regular basis. This is very different to what consumers would be exposed to via the diet, which is likely to be very low concentrations of the enzyme through ingestion of a blended food ingredient. In addition, residual enzyme in the final food is likely to be inactive and susceptible to digestion, like other dietary proteins. Therefore, any findings of this study are not directly relevant to consumers who might be exposed to trace levels through food. The hazard assessment conducted for this particular enzyme considered the potential allergenicity of the triacylglycerol lipase (in terms of ingestion) and concluded that there were no concerns (see section 2.2). The enzyme is digested (i.e. broken down to constituent amino acids) in the gastro-intestinal tract and it has no homology to known allergens. The source microorganism for the enzyme of this Application is not genetically modified.
The submitter would resist any attempt to remove the following enzymes from the Code (in Schedule 8 – Food additive names and code numbers (for statement of ingredients)) and hide them as processing aids: • **1100 α-Amylase** • **1101 Proteases (papain, bromelain, ficin)** • **1102 Glucose oxidase** • **1104 Lipases**	Food Intolerance Network	There is no intention to remove the enzymes in Schedule 8 as part of the assessment of this Application, noting they are listed there for labelling purposes and are not permissions to use. That is well outside the scope of the assessment. With the exception of lysozyme (which, in terms of its technological purpose, is classified as a preservative (food additive)), the enzymes mentioned are permitted for use as processing aids under Schedule 18. Food additive permissions are provided in Schedules 15 and 16. Lysozyme is the only enzyme listed which is permitted as a GMP food additive in section S16—2 which, because of subsection 1.1.2—13(3), is also a processing aid. How the substance (enzyme) performs its technological purpose determines whether it is considered a food additive or processing aid. In summary, if it performs its purpose during the manufacture or processing but not in the final food, then it is considered a

[5] Budnik LT, Scheer E, Burge PS, Baur X (2017) Sensitising effects of genetically modified enzymes used in flavour, fragrance, detergence and pharmaceutical production; cross-sectional study. Occupational and Environmental Medicine 74(1):39-45.

Issue	Raised by	FSANZ response
• **1105 Lysozyme.**		processing aid (see definition within section 1.1.2—13 as noted above in the first issue) and so does not need to be labelled. If it performs its technological purpose in the final food (as does lysozyme, in its role as a preservative) then it is considered a food additive (see section 1.1.2—11) and so needs to be labelled as per the requirements in section 1.2.4—7. As a final point, food manufacturers can add extra labelling information to that mandated by the Code; i.e. they can label for enzymes used as processing aids.
Concern that some of the food category terms used in the draft variation referring to the use of the enzyme are not defined by the Code. These terms are "bakery products", "dairy products" and "fats and oils". **The proliferation of food terms that are not defined in the Code (Standard 1.1.2) makes interpretation and enforcement difficult.**	South Australia Health	This Application is not the vehicle to consider a change to the Code's structure and use of definitions. In terms of the draft variation in issue, FSANZ does not see a need to provide a prescriptive, all-inclusive definition detailing what is and what is not an 'oil', 'fat', 'a dairy product' and a 'bakery product' for the purposes of this one processing aid permission. These terms are already present and undefined in the Code (see, for example, Standard 2.2.1 and Schedules 10, 15, 17, and 22). Where definitions are provided (e.g., definition of 'dairy products'), these definitions are only illustrative (ie, 'dairy products' includes …) and are not prescriptive. In the absence of a definition, these terms generally have their accepted and ordinary meaning. FSANZ is unaware of any evidence of a problem with this approach to date. Nor has any other jurisdiction raised this as an issue. We will discuss this further with the submitter.

2.2 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 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.

After undertaking a risk assessment, FSANZ concluded that there are no public health and safety issues associated with the use of the enzyme triacylglycerol lipase, sourced from *Candida cylindracea*, as a processing aid intended for use in baking, milk and dairy processing, and fats and oil processing.

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.

2.3 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 enzyme nomenclature and labelling, which are discussed in sections 2.3.2 and 2.3.3 respectively. The regulatory options analysed in section 5.1.1 take account of the safety of the enzyme preparation.

2.3.1 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, and not as a food additive. 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.

2.3.2 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*.

2.3.3 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.

2.3.4 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.

3 Decision

The draft variation as proposed following assessment was approved without change. The variation takes effect on 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.

4 Risk communication

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.

5 FSANZ Act assessment requirements

5.1 Section 29

5.1.1 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 did undertake a limited consideration of the costs and benefits that would arise from permitting this Application.

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.
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 manufacturers 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 outweighed the costs to the community, government or industry that would arise from the development or variation of the food regulatory measure.

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.

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.

5.1.4 Any other relevant matters

Other relevant matters are considered below.

5.2. Subsection 18(1)

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

5.2.1 Protection of public health and safety

FSANZ had undertaken a safety assessment (SD1), summarised in section 2.2 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.

5.2.2 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 2.3.3 – Labelling considerations.

5.2.3 The prevention of misleading or deceptive conduct

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

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 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 to assess 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 in supplying enzymes to the food manufacturing industries.

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

FSANZ did not identify any relevant issues relating to this consideration.

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

The Policy Guideline for the Addition to Food of Substances other than Vitamins and Minerals[6] includes specific order policy principles for substances added to achieve a solely technological function, such as food additives. 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 sourced from *C. cylindracea* as a processing aid is consistent with the specific order principles for 'Technological Function'.

6 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

[6] http://www.foodstandards.gov.au/code/fofr/fofrpolicy/pages/default.aspx

International Union of Biochemistry and Molecular Biology (IUBMB) Enzyme Nomeclature 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. Approved draft variation to the *Australia New Zealand Food Standards Code*
B. Explanatory Statement

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

Food Standards (Application A1130 – Triacylglycerol Lipase 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 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 *Candida cylindracea*	For use in the manufacture of bakery products and dairy products and in the processing of fats and oils.	GMP

Attachment B – Explanatory Statement

1. Authority

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

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

The Authority accepted Application 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.

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

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

2. Purpose

The Code does not currently permit the use of the enzyme triacylglycerol lipase sourced from *C. cylindracea* to be used as a processing aid. The purpose of this variation is to permit the use of this enzyme as a processing aid only in the manufacture of bakery products and dairy products and in the processing of fats and oils, at GMP.

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 included one round of public consultation following an assessment and the preparation of a draft variation and associated report. Submissions were called for on 7 July 2017 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.

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 of the Code. 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 prescribed 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.