17 August 2026
409-26

Approval report – Application A1338

Triacylglycerol lipase from *Komagataella phaffii* (gene donor: *Yarrowia lipolytica*) for use as a processing aid

---

Food Standards Australia New Zealand (FSANZ) has assessed an application submitted by Chr. Hansen Pty Ltd to permit the use of the enzyme triacylglycerol lipase (EC 3.1.1.3) as a processing aid to hydrolyse lipids during the manufacture of dairy-based products and plant-based dairy analogues.

On 21 April 2026, FSANZ sought submissions on a draft variation and published an associated report. FSANZ received 3 submissions.

FSANZ approved the draft variation on 5 August 2026. The Food Ministers' Meeting[1] was notified of FSANZ's decision on 17 August 2026.

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

[1] Formerly referred to as the Australia and New Zealand Ministerial Forum on Food Regulation

Table of contents

Supporting document

The following document which informed the assessment of this application is available on the Application A1338 page on the FSANZ website[2]:

SD1 Risk and technical assessment report (unchanged at approval)

The published submissions from the call for submissions can be found on the Application A1338 Consultation Hub page.

[2] https://www.foodstandards.gov.au/food-standards-code/applications/a1338-triacylglycerol-lipase-as-a-processing-aid

Executive summary

Chr. Hansen Pty Ltd applied to Food Standards Australia New Zealand (FSANZ) to amend the Australia New Zealand Food Standards Code (the Code) to permit the use of the enzyme triacylglycerol lipase (EC 3.1.1.3) as a processing aid to hydrolyse lipids during the manufacture of dairy-based products and plant-based dairy analogues. The enzyme is produced by *Komagataella phaffii* containing the triacylglycerol lipase gene from *Yarrowia lipolytica.*

FSANZ concluded that the proposed use of triacylglycerol lipase is technologically justified in the quantity and form stated by the applicant to hydrolyse lipids during the manufacture of dairy-based products and plant-based dairy analogues. The enzyme does not perform a technological function in the food for sale, therefore functioning as a processing aid for the purposes of the Code. There are relevant identity and purity specifications in the Code with which the enzyme must comply when added to food in accordance with the Code, or sold for use in food.

FSANZ assessed there are no public health and safety concerns with the use of triacylglycerol lipase produced by this *K. phaffii* under the proposed conditions of use.

Following assessment, FSANZ prepared a draft variation to the Code and called for submissions on that draft on 21 April 2026, with a 6-week consultation period. Three submissions were received – one in support of the draft variation, one from a private citizen giving conditional support, and one from another private citizen which relates to Stakeholder Engagement Registration: Development of an Australian National Campylobacter Action Plan. The latter would have no application to production and use of the enzyme concerned. FSANZ has had regard to these submissions.

After considering the submissions, and for the reasons summarised in this report, FSANZ has approved the draft variation proposed at the call for submissions.

The approved draft variation will list triacylglycerol lipase (EC 3.1.1.3), sourced from *K. phaffii* containing the triacylglycerol lipase gene from *Y. lipolytica* and its associated technological purpose in the table to subsection S18—9(3) of the Code. This table lists substances (including enzymes) permitted to be used as processing aids for specific technological purposes. The enzyme will have to be used at a level in accordance with Good Manufacturing Practice.

The effect of the approved draft variation will be to permit the use of this enzyme as a processing aid to hydrolyse lipids during the manufacture of dairy-based products and plant-based dairy analogues in accordance with the Code.

1 Introduction

1.1 The applicant

The applicant is Chr. Hansen Pty Ltd, a biotechnology company that, together with Novozymes, forms part of the Novonesis group.

1.2 The application

The purpose of the application is to amend the Australia New Zealand Food Standards Code (the Code) to permit the use of the enzyme triacylglycerol lipase (EC 3.1.1.3) as a processing aid in dairy products and plant-based dairy analogues.

The enzyme is produced by *Komagataella phaffii* containing the gene for triacylglycerol lipase from *Yarrowia lipolytica*.

Triacylglycerol lipase is used as a processing aid to hydrolyse lipids (triglycerides, diglycerides and monoglycerides) to yield free fatty acids and monoglycerides, diglycerides and glycerol. The enzyme is intended to be used in cheese production, the production of flavouring preparations from dairy products (enzyme-modified dairy ingredients), and the production of plant-based dairy analogues. Benefits of its action include the development of characteristic dairy-like flavours and a desirable texture in plant-based analogues.

The applicant has indicated the enzyme would be used in accordance with Good Manufacturing Practice (GMP).[3]

1.3 The current Standard

Australian and New Zealand food laws require food for sale to comply with relevant requirements in the Code. The requirements relevant to this application are summarised below.

1.3.1 Permitted use

Paragraph 1.1.1—10(6)(c) provides that food for sale cannot contain, as an ingredient or component, a substance 'used as a processing aid' unless the use of that substance as a processing aid is expressly permitted by the Code. Section 1.1.2—13 provides that a substance 'used as a processing aid' in relation to a food is a substance used during the course of processing that meets all of the following conditions:

- it is used to perform a technological purpose during the course of processing
- it does not perform a technological purpose in the food for sale, and

[3] GMP is defined in section 1.1.2—2 of the Code as follows: ***GMP*** *or* ***Good Manufacturing Practice****, with respect to the addition of substances used as food additives and substances used as processing aids to food, means the practice of:*
(a) limiting the amount of substance that is added to food to the lowest possible level necessary to accomplish its desired effect; and
(b) to the extent reasonably possible, reducing the amount of the substance or its derivatives that:
*(i) remains as a *component of the food as a result of its use in the manufacture, processing or packaging; and*
(ii) is not intended to accomplish any physical or other technical effect in the food itself;
(c) preparing and handling the substance in the same way as a food ingredient.

- it is a substance listed in Schedule 18 or identified in section S16—2 as an additive permitted at GMP.

Standard 1.3.3 and Schedule 18 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 the table to subsection S18—9(3) of Schedule 18, depending on whether a technological purpose has been specified. An enzyme of microbial origin listed in the table to subsection S18—4(5) is permitted for use as a processing aid to perform any technological purpose if the enzyme is derived from the corresponding source specified in the table. The table to subsection S18—9(3) lists those substances, including enzymes derived from particular sources, that are permitted to be used as processing aids for specific technological purposes in relation to:

- if a food is specified—that food, or
- if no food is specified—any food.

Additionally, paragraph 1.3.3—11(c) specifies that the substance may only be used as a processing aid if it is not present in the food at greater than the maximum permitted level for that substance indicated in the table to section S18—9.

There are a number of permissions in Schedule 18 for use of 'Lipase, triacylglycerol (EC 3.1.1.3)' produced by microorganisms. This includes a triacylglycerol lipase sourced from *K. phaffii* containing the triacylglycerol lipase gene from *Fusarium oxysporum*, for use in the manufacture of bread and bakery products.

K. phaffii was formerly known as *Pichia pastoris.*

Triacylglycerol lipase from *K. phaffii* containing the triacylglycerol lipase gene from *Y. lipolytica* is not listed in the table to subsection S18—4(5) nor the table to subsection S18—9(3) and so is not currently a permitted processing aid for the purposes of the Code.

1.3.2 Identity and purity requirements

Paragraph 1.1.1—15(1)(b) requires substances used as processing aids in food to comply with any relevant identity and purity specifications listed in Schedule 3 when added to food in accordance with the Code or sold for use in food.

Subsection S3—2(1) incorporates by reference the specifications listed in the Joint FAO/WHO Expert Committee on Food Additives (JECFA) Combined Compendium of Food Additive Specifications and the United States Pharmacopeial Convention Food Chemicals Codex. These include general specifications for enzyme preparations used in food processing for identity and purity parameters.

1.3.3 Labelling requirements

Subsection 1.1.1—10(8) provides that food for sale must comply with all relevant labelling requirements in the Code.

Paragraphs 1.2.4—3(2)(d) and (e) exempt processing aids from the requirement to be declared in the statement of ingredients, unless other requirements apply.

1.4 International standards

In developing food regulatory measures, Food Standards Australia New Zealand (FSANZ) must have regard to the promotion of consistency between domestic and international food

standards. In terms of food safety, the relevant international standard setting body is the Codex Alimentarius Commission (Codex).

There is no Codex 'general standard' for processing aids. However, as noted in section 1.3.2 of this report, there are internationally recognised specifications for enzyme preparations established by JECFA and Food Chemicals Codex.

Additionally, there is a Codex guideline, *Guidelines on Substances used as Processing Aids* (CAC/GL 75-2010), which sets out general principles for the safe use of substances used as processing aids, including that substances used as processing aids shall be used under conditions of GMP.

1.4.1 Overseas regulations

The enzyme has been authorised for use in Denmark. The United States Food and Drug Administration (US FDA) provided a 'no questions' response to Chr. Hansen's Generally Recognized as Safe (GRAS) notification (GRN No. 1201).

1.5 Reasons for accepting application

The application was accepted for assessment because:

- it complied with the procedural requirements under subsection 22(2) of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act) and
- it related to a matter that warranted the variation of a food regulatory measure.

1.6 Procedure for assessment

The application was assessed under the General Procedure in accordance with the FSANZ Act.

1.7 Decision

Following assessment, FSANZ prepared a draft variation amending the Code to permit the use of the enzyme triacylglycerol lipase (EC 3.1.1.3) as a processing aid to hydrolyse lipids during the manufacture of dairy-based products and plant-based dairy analogues.

For the reasons outlined in this report and after consideration of submissions received during the consultation period, FSANZ approved the draft variation without change. The approved draft variation takes effect on gazettal and 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.

2 Summary of the findings

2.1 Summary of issues raised in submissions

FSANZ called for submissions on a draft variation to the Code from 21 April to 2 June 2026. Three submissions were received (see Table 1 below). The submissions are publicly available on the FSANZ website Application A1338 Consultation Hub page.

Table 1: Summary of issues

Issue	Raised by	FSANZ response
Conditional support, contingent on continued avoidance of animal (vivisection) testing.	Private individual – WSL	FSANZ would like to thank this submitter for their comments concerning the use of animals for toxicological testing. Toxicological data requirements for assessing the safety of substances added to, or present in, food are informed by internationally recognised risk assessment principles, including those established by the Food and Agriculture Organization of the United Nations and the World Health Organization. Consistent with these principles, FSANZ considers relevant laboratory animal data as part of the scientific weight-of-evidence used to characterise potential food-related health risks. FSANZ scientists are experienced in evaluating the relevance and limitations of such data for human health risk assessment, including the appropriateness of extrapolating findings from laboratory animal studies to humans. While no experimental model is a perfect substitute for humans, laboratory animal studies remain an internationally accepted and scientifically useful method for identifying and characterising the potential toxicity of substances in food. Such studies can provide information on possible effects across mammalian organs, tissues, physiological systems and metabolic processes, and are considered alongside other relevant evidence. Importantly, Australia and New Zealand recognise the 3Rs (Replacement, Reduction and Refinement) as critical components of the ethical, humane and responsible care and use of animals for scientific purposes. For this application, FSANZ considered the available toxicological and other relevant evidence and concluded there are no safety concerns associated with the proposed use of this triacylglycerol lipase under the stated conditions of use.
The submitter sought justification for the need for the processing aid.	Private individual – WSL	FSANZ concluded the proposed use of this triacylglycerol lipase to be technologically justified. There are already several permissions in Schedule 18 for use of 'Lipase, triacylglycerol (EC 3.1.1.3)' produced by various microorganisms. Use of this enzyme is voluntary and would provide industry with an additional option for use where technologically appropriate based on a consideration of costs and benefits.

Issue	Raised by	FSANZ response
Regarding its use in non-dairy applications, some consumers, especially those who prefer minimally processed foods, may be concerned that the processing aid used in the production of such foods is not labelled.	Private individual – WSL	As noted in Section 1.3.3 above, paragraphs 1.2.4—3(2)(d) and (e) of the Code exempt processing aids from the requirement to be declared in the statement of ingredients. Processing aids are typically not required to be declared in the statement of ingredients because they do not perform a technological purpose in the final food for sale and are usually present at negligible levels.
The submission relates to Stakeholder Engagement Registration: Development of an Australian National Campylobacter Action Plan.	Private individual – CK	The National Campylobacter Action Plan, when developed, would not apply to production and use of the enzyme concerned.
Supported.	NZ MPI	Noted.

2.2 Food technology assessment

FSANZ undertook a food technology assessment to determine whether the processing aid achieves its technological purpose as described in the application (see SD1).

FSANZ concluded:

- The proposed use of the enzyme was consistent with its function, specifically, to hydrolyse lipids during the manufacture of dairy-based products and plant-based dairy analogues
- The enzyme functions as a processing aid for the purposes of the Code and does not perform a technological purpose in the food for sale
- The evidence presented to support its proposed use provides adequate assurance that its use, in the quantity and form proposed to be used (which must be consistent with GMP), is technologically justified.

There are relevant identity and purity specifications in the Code with which the enzyme will have to comply when it is added to food in accordance with the Code or sold for use in food.

2.3 Risk assessment

FSANZ assessed the public health and safety risks associated with the enzyme and its use as a processing aid (see SD1). A summary of this risk assessment is provided below.

The microbiological assessment undertaken by FSANZ did not identify any public health and safety concerns associated with the use of the production organism *K. phaffii,* as a source of triacylglycerol lipase. It is neither pathogenic nor toxigenic. Analysis of the production strain confirmed the presence and stability of the inserted DNA.

Sufficient information was provided by the applicant to assess the safety of the enzyme. Bioinformatics analysis identified no significant homology between it and any known toxins or allergens. The enzyme preparation is not expected to pose a food allergenicity concern under the proposed conditions of use.

Studies with a lipase enzyme produced by a related production strain identified no evidence of genotoxicity *in vitro* or *in vivo* and no adverse effects were observed in a 90-day oral toxicity study in rats. The no observed adverse effect level (NOAEL) was 1680 mg/kg bw/day total organic solids (TOS), the highest dose tested.

The theoretical maximum daily intake (TMDI) of this triacylglycerol lipase was calculated to be 0.45 mg TOS/kg bw/day. A comparison of the NOAEL and the TMDI gave a large Margin of Exposure (MOE) of approximately 3,700.

Based on the reviewed data, FSANZ concluded that, in the absence of any identifiable hazard, an Acceptable Daily Intake (ADI) 'not specified' was appropriate.

2.4 Risk management

Following assessment, FSANZ prepared a draft variation and called for submissions on that draft variation during a period of 6 weeks.

The risk management options available to FSANZ following the call for submissions were to:

- approve the draft variation proposed at the call for submissions, or
- approve that draft variation subject to such amendments as FSANZ considered necessary, or
- reject that draft variation.

The conclusions from the technical and risk assessment were that the proposed use of triacylglycerol lipase as a processing aid is technologically justified and there are no safety concerns associated with its proposed use.

Having regard to the submissions received, and for the reasons set out in this report, FSANZ considered it appropriate to approve the draft variation proposed following assessment (Attachment A).

Risk management considerations for this application relating to the regulatory approval, nomenclature, specifications and labelling are discussed below.

2.4.1 Regulatory approval for processing aids

As stated above, FSANZ has approved a draft variation to permit the use of the enzyme as a processing aid to hydrolyse lipids during the manufacture of dairy-based products and plant-based dairy analogues. The express permission also provides the permission for the enzyme's potential presence in the food for sale (Attachment A).

2.4.2 Enzyme nomenclature, source microorganism nomenclature and specifications

The International Union of Biochemistry and Molecular Biology (IUBMB) lists the accepted name 'triacylglycerol lipase' for the enzyme EC 3.1.1.3 (see section 2.1 of SD1). The name in the proposed draft variation is 'Lipase, triacylglycerol', to maintain a consistent approach with existing permissions for this enzyme derived from other sources.

Nomenclature for the host and gene donor organisms – *Komagataella phaffii* and *Yarrowia lipolytica*, respectively – is in accordance with accepted international norms for bacterial taxonomy.

There are relevant identity and purity specifications in primary sources of specifications listed

in Schedule 3 of the Code for enzyme preparations used in food processing (refer to section 1.3.2 of this report). As stated above, this enzyme will have to comply with those specifications whenever it is added to food in accordance with the Code or sold for such use.

2.4.3 Labelling

Relevant labelling provisions in the Code will apply to foods for sale that are manufactured using this processing aid (see section 1.3.3 of this report).

2.4.4 Risk management conclusion

The risk management conclusion is to permit the enzyme triacylglycerol lipase (EC 3.1.1.3) produced by *K. phaffii* containing the triacylglycerol lipase gene from *Y. lipolytica* as a processing aid to hydrolyse lipids during the manufacture of dairy-based products and plant-based dairy analogues.

The enzyme and its associated technological purpose will be listed in the table to subsection S18—9(3) of the Code, which includes enzymes permitted for a specific technological purpose. The maximum permitted level or amount of the enzyme that may be present in the food must be an amount consistent with GMP. The express permission for the enzyme to be used as a processing aid in Schedule 18 of the Code will also provide the permission for the enzyme's potential presence in the food for sale.

2.5 Risk communication

2.5.1 Consultation

Consultation is a key part of FSANZ's standards development process. FSANZ developed and applied a standard communication strategy to this application. All calls for submissions are notified via the FSANZ Notification Circular, digital channels and Food Standards News.

The process by which FSANZ considers standards development matters is open, accountable, consultative and transparent. Public submissions were called to assist consideration of the draft variation to the Code. FSANZ acknowledges the time taken by individuals and organisations who made submissions on this application.

The draft variation was considered for approval by the FSANZ Board having regard to all submissions made during the call for submissions period.

2.6 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:

2.6.1 Section 29

2.6.1.1 Consideration of costs and benefits

FSANZ assessed that a Regulation Impact Statement was not required for this application. This was because applications relating to permitting the use of processing aids are determined to be safe and considered to be minor in impact or deregulatory in nature, as their use will be voluntary if the draft variation concerned is approved.

However, FSANZ had 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 (as per paragraph 29(2)(a) of the FSANZ Act).

The consideration of the costs and benefits in this section were not intended to be an exhaustive, quantitative economic analysis of the proposed measures and, in fact, most of the effects that were considered could not easily be assigned a dollar value. Rather, the assessment sought to highlight the potential positives and negatives of moving away from the status quo by permitting the proposed use of the enzyme triacylglycerol lipase (EC 3.1.1.3) from this source as a processing aid in dairy and plant-based dairy analogues.

FSANZ's conclusions regarding the costs and benefits of the proposed measure are set out below.

Costs and benefits of permitting the proposed use of this processing aid

Industry might benefit from improvements to the quality and hence demand for certain dairy products and plant-based dairy analogues. Industry might also benefit from production efficiencies from using this processing aid. Due to the voluntary nature of the permission, industry would only use the processing aid as proposed where they believe a net benefit exists for them.

If industry were to experience cost savings because of using this processing aid, industry might pass on some of the cost savings to consumers. Consumers might also experience improvements to the quality and taste of certain dairy products and plant-based dairy analogues for which the processing aid is used.

Permitting the proposed use of this enzyme as a processing aid might result in a small, inconsequential cost to government in terms of an addition to the current range of processing aids that are already monitored for compliance.

FSANZ's assessment at the call for submissions was that the direct and indirect benefits that would arise from permitting the proposed use of this enzyme as a processing aid would likely outweigh any costs. No further information was received during the consultation process that changed that assessment.

2.6.1.2 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.

2.6.1.3 Any relevant New Zealand standards

The standards in the Code that are relevant to the permitted use of processing aids apply in both Australia and New Zealand. There are no relevant New Zealand only standards.

2.6.1.4 Any other relevant matters

Other relevant matters are considered below.

2.6.2 Subsection 18(1)

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

2.6.2.1 Protection of public health and safety

FSANZ undertook a risk and technical assessment and concluded there were no public health and safety concerns associated with the proposed use of this enzyme (see section 2.3 of this report and SD1).

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

Existing labelling requirements will apply to this enzyme processing aid in accordance with the Code (see sections 1.3.3 and 2.4.3 of this report).

2.6.2.3 The prevention of misleading or deceptive conduct

There were no issues identified with this application relevant to this objective.

2.6.3 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. The applicant submitted a dossier of information and scientific literature as part of their application. This dossier, together with other technical and scientific information, was considered by FSANZ in assessing the application.

- **the promotion of consistency between domestic and international food standards**

In terms of food safety, the relevant international standard setting body is Codex. There is no Codex 'general standard' for enzymes, however as noted in section 1.3.2 of this report, there are internationally recognised specifications for enzyme preparations established by JECFA and Food Chemicals Codex, with which this enzyme will have to comply when added to food in accordance with the Code or sold for use in food.

There is also a Codex guideline, *Guidelines on Substances used as Processing Aids* (CAC/GL 75-2010), which sets out general principles for the safe use of substances used as processing aids, including that substances used as processing aids shall be used under conditions of GMP (see section 1.4 of this report).

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

As stated in section 1.4.1 of this report, the enzyme has been authorised for use in Denmark and self-affirmed as GRAS in the USA. Australia and New Zealand will remain competitive with international markets where approval for the use of the enzyme is granted. This will also help foster continued innovation and improvements in food manufacturing techniques and processes.

The conclusion of the risk and technical assessment was that there are no public health and safety concerns associated with the proposed use of this enzyme as a processing aid. It is therefore appropriate that Australian and New Zealand food industries are given the opportunity to benefit from the use of this enzyme for the applications proposed by the applicant. Ultimately, the 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 business.

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

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

- **any written policy guidelines formulated by the Food Ministers' Meeting**

The Ministerial Policy Guideline *Addition to Food of Substances other than Vitamins and Minerals*[4] 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 this enzyme is consistent with these specific order policy principles for 'technological function'. All other relevant requirements of the policy guideline are similarly met.

Attachments

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

[4] https://www.foodregulation.gov.au/resources/publications/policy-guideline-addition-substances-other-vitamins-and-minerals

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

Food Standards (Application A1338 – Triacylglycerol lipase from *Komagataella phaffii* (gene donor: *Yarrowia lipolytica*) for use as a processing aid) 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 the Delegate]

[To be signed by the Delegate]
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 A1338 – Triacylglycerol lipase from* Komagataella phaffii *(gene donor:* Yarrowia lipolytica*) for use as a processing aid) 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

Schedule 18—Processing aids

[1] Subsection S18—9(3) (table)

Insert:

Lipase, triacylglycerol (EC 3.1.1.3) sourced from *Komagataella phaffii* containing the lipase, triacylglycerol gene from *Yarrowia lipolytica*	To hydrolyse lipids in the manufacture of dairy-based products and plant-based dairy analogues	GMP

Attachment B – Explanatory Statement

EXPLANATORY STATEMENT

Food Standards Australia New Zealand Act 1991

Food Standards (Application A1338 – Triacylglycerol lipase from Komagataella phaffii *(gene donor:* Yarrowia lipolytica*) for use as a processing aid) Variation*

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 A1338 which sought to amend the Code to permit the use of the enzyme triacylglycerol lipase (EC 3.1.1.3), from *Komagataella phaffii* containing the triacylglycerol lipase gene from *Yarrowia lipolytica* as a processing aid to hydrolyse lipids during the manufacture of dairy-based products and plant-based dairy analogues. The Authority considered the application in accordance with Division 1 of Part 3 and has approved a draft variation – the *Food Standards (Application A1338 – Triacylglycerol lipase from* Komagataella phaffii *(gene donor:* Yarrowia lipolytica*) for use as a processing aid) Variation* (the approved draft variation).

Following consideration by the Food Ministers' Meeting (FMM), section 92 of the FSANZ Act stipulates that the Authority must publish a notice about the draft variation.

2. Variation is a legislative instrument

The approved draft variation is a legislative instrument for the purposes of the *Legislation Act 2003* (see section 94 of the FSANZ Act) and is publicly available on the Federal Register of Legislation (www.legislation.gov.au).

This instrument is not subject to the disallowance or sunsetting provisions of the *Legislation Act 2003.* Subsections 44(1) and 54(1) of that Act provide that a legislative instrument is not disallowable or subject to sunsetting if the enabling legislation for the instrument (in this case, the FSANZ Act): (a) facilitates the establishment or operation of an intergovernmental scheme involving the Commonwealth and one or more States; and (b) authorises the instrument to be made for the purposes of the scheme. Regulation 11 of the *Legislation (Exemptions and other Matters) Regulation 2015* also exempts from sunsetting legislative instruments a primary purpose of which is to give effect to an international obligation of Australia.

The FSANZ Act gives effect to an intergovernmental agreement (the Food Regulation Agreement) and facilitates the establishment or operation of an intergovernmental scheme (national uniform food regulation). That Act also gives effect to Australia's obligations under an international agreement between Australia and New Zealand. For these purposes, the Act establishes the Authority to develop food standards for consideration and endorsement by

the FMM. The FMM is established under the Food Regulation Agreement and the international agreement between Australia and New Zealand, and consists of New Zealand, Commonwealth and State/Territory members. If endorsed by the FMM, the food standards on gazettal and registration are incorporated into and become part of Commonwealth, State and Territory and New Zealand food laws. These standards or instruments are then administered, applied and enforced by these jurisdictions' regulators as part of those food laws.

3. Purpose

The Authority has approved a draft variation amending the table to subsection S18—9(3) in Schedule 18 of the Code to permit the use of the enzyme triacylglycerol lipase (EC 3.1.1.3), from this *Komagataella phaffii* as a processing aid to hydrolyse lipids during the manufacture of dairy-based products and plant-based dairy analogues. This permission is subject to the condition that the maximum permitted level or amount of the enzyme that may be present in the food must be consistent with good manufacturing practice (GMP).

4. Documents incorporated by reference

The approved draft variation does not incorporate any documents by reference.

However, existing provisions of the Code incorporate documents by reference that would prescribe identity and purity specifications for the processing aid to be permitted by the approved draft variation. Section 1.1.1—15 of the Code requires substances used as processing aids to comply with any relevant identity and purity specifications listed in Schedule 3 of the Code when added to food in accordance with the Code or sold for use in food.

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 2025) and the United States Pharmacopeial Convention (2024) Food Chemicals Codex (14th edition). These include general specifications for the identity and purity parameters of enzyme preparations used in food processing.

5. Consultation

In accordance with the procedure in Division 1 of Part 3 of the FSANZ Act, the Authority's consideration of Application A1338 included one round of public consultation following an assessment and the preparation of a draft variation and associated assessment summary. FSANZ called for submissions on the draft variation from 21 April to 2 June 2026. Further details of the consultation process, the issues raised during consultation and by whom, and the Authority's response to these issues are available in an approval report published on the Authority's website at www.foodstandards.gov.au.

A regulation impact statement (RIS) was not prepared. FSANZ's assessment was that a RIS was not required for this application. This was on the basis that the application was minor and deregulatory in nature. It sought to permit the use of a processing aid found to be safe and that use is voluntary if the draft variation concerned is approved. This position is consistent with previous advice from the Office of Impact Analysis (OIA23-06225)[5].

[5] Regulatory Impact Analysis Guide for Ministers' Meetings and National Standard Setting Bodies | The Office of Impact Analysis (pmc.gov.au).

6. 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 44 of the *Legislation Act 2003*.

7. Variation

References to 'variation' in this section are references to the approved draft variation.

Clause 1 of the variation provides that the name of the variation is the *Food Standards (Application A1338 – Triacylglycerol lipase from* Komagataella phaffii *(gene donor:* Yarrowia lipolytica*) for use as a processing aid) Variation.*

Clause 2 of the variation provides that the Code is amended by the Schedule to the variation.

Clause 3 of the variation provides that the variation will commence on the date of gazettal of the instrument.

Schedule to the variation

Item [1] of the Schedule to the variation inserts a new entry, in alphabetical order, into the table to subsection S18—9(3) of the Code.

The new entry consists of the following enzyme in column 1 of the table:

- 'Lipase, triacylglycerol (EC 3.1.1.3) sourced from *Komagataella phaffii* containing the lipase, triacylglycerol gene from *Yarrowia lipolytica'*

The permitted technological purpose for this enzyme is prescribed in column 2 of the table i.e. To hydrolyse lipids in the manufacture of dairy-based products and plant-based dairy analogues.

The permission is subject to the condition, as prescribed in column 3 of the table, that the maximum permitted level or amount of this enzyme that may be present in the food must be consistent with GMP.

The effect of the amendment in item [1] is to permit the proposed use of the enzyme triacylglycerol lipase (EC 3.1.1.3) from this *Komagataella phaffii* as a processing aid in accordance with the Code.