

14 February 2025
329-25

Approval report – Application A1301

Triacylglycerol lipase from GM *Komagataella phaffii* as a processing aid

Food Standards Australia New Zealand (FSANZ) has assessed an application made by Danstar Ferment AG, an affiliate of Lallemand Inc, to amend the Australia New Zealand Food Standards Code to permit triacylglycerol lipase (EC 3.1.1.3) from genetically modified *Komagataella phaffii* to be used as a processing aid in the manufacture of bread and bakery products, and has prepared a draft food regulatory measure.

On 6 September 2024 FSANZ sought submissions on a draft variation and published an associated report. FSANZ received two submissions.

FSANZ approved the draft variation on 5 February 2025. The Food Ministers' Meeting¹ was notified of FSANZ's decision on 14 February 2025.

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

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

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Supporting documents

The [following document](#) which informed the assessment of this application is available on the A1301 page on the FSANZ website:

SD Risk and technical assessment

Executive summary

Danstar Ferment AG, an affiliate of Lallemand Inc, has 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.

The enzyme is proposed for use as a processing aid in the manufacture of bread and bakery products. The triacylglycerol lipase is sourced from genetically modified (GM) *Komagataella phaffii* (previously named *Pichia pastoris*) containing the triacylglycerol lipase gene from *Fusarium oxysporum*.

The proposed use of triacylglycerol lipase is technologically justified in the quantity and form proposed during the manufacture of bread and bakery products. 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 for the enzyme in the Code with which the enzyme would have to comply.

No public health and safety concerns were identified in the assessment of triacylglycerol lipase produced by this GM *K. phaffii* under the proposed use conditions. *K. phaffii* has a long history of safe use as a production microorganism of enzyme processing aids, including several that are already permitted in the Code. The production organism is neither pathogenic nor toxigenic. Analysis of the GM production strain confirmed the presence and stability of the inserted DNA. Bioinformatics analysis indicated that the triacylglycerol lipase does not have substantial homology with known toxins or food allergens.

Following assessment and the preparation of the draft variation, FSANZ called for submissions regarding the draft variation. Two submissions were received, one from a jurisdiction and one from an individual. The jurisdiction supported approval of the draft variation. The individual did not support approval of the draft variation, without providing reasons.

Based on the information above and on other relevant considerations set out in this report, FSANZ has approved a draft variation amending the table to subsection S18—9(3) of the Code. The effect of the approved draft variation will be to permit the use of the enzyme triacylglycerol lipase (EC 3.1.1.3) sourced from GM *K. phaffii* containing the triacylglycerol lipase gene from *Fusarium oxysporum* as a processing aid in the manufacture of bread and bakery products, in accordance with the Code. The permission will be subject to the condition that the maximum permitted level or amount of the enzyme that may be present in the food must be an amount consistent with Good Manufacturing Practice.

1 Introduction

1.1 The applicant

The applicant is Danstar Ferment AG, an affiliate of Lallemand Inc.

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. It is proposed for use during the manufacture of bread and bakery products.

The enzyme is produced from genetically modified (GM) *Komagataella phaffii* containing the triacylglycerol lipase gene from *Fusarium oxysporum*. Thus *K. phaffii* is the host (source) species and *F. oxysporum* is the donor for the gene.

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

The applicant has indicated that the enzyme is to be used at minimum levels necessary to achieve the desired effect, in accordance with Good Manufacturing Practice (GMP).

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 that substance’s use 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
- 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 in the table to subsection S18—9(3) of Schedule 18, depending on whether a technological purpose has been specified. Enzymes of microbial origin listed in the table to subsection S18—4(5) are 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.

Paragraph 1.1.1—10(6)(g) requires that the presence as an ingredient or component in a food for sale of a food produced using gene technology must be expressly permitted by the Code. Paragraph 1.5.2—3(b) provides that permission in the Code for use as a processing aid also constitutes the permission required by paragraph 1.1.1—10(6)(g).

Triacylglycerol lipase sourced from animal origin is permitted in subsection S18—4(3), and from a number of microbial sources under subsections S18—4(5) and S18—9, however there is no permission in the Code for triacylglycerol lipase from GM *K. phaffii* containing the triacylglycerol lipase gene from *F. oxysporum*.

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 of the Code.

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 (FAO JECFA Monographs 26 (2021)), and the United States Pharmacopeial Convention (2022) Food chemicals codex (13th edition). 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.

Section 1.5.2—4 of the Code requires a food for sale that consists of a *genetically modified food*² (GM food) or has a GM food as an ingredient to be labelled as 'genetically modified', unless an exemption applies. The statement 'genetically modified' must be made in conjunction with the name of the GM food. If the GM food is used as a processing aid, this statement may be included in the statement of ingredients. The requirements imposed by section 1.5.2—4 apply to foods for retail sale and to foods sold to a caterer in accordance with Standard 1.2.1.

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). In contrast to food additives, there is no Codex 'general standard' for enzymes, however as noted in Section 1.3.2 above, there are internationally recognised specifications for enzyme preparations established by JECFA and

² Section 1.5.2—4(5) defines *genetically modified food* to mean a "food produced using gene technology that

- a) contains novel DNA or novel protein; or
- b) is listed in Section S26—3 as subject to the condition that its labelling must comply with this section' (*that being section 1.5.2—4*).

Food Chemicals Codex.

In addition, 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.

1.5 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 the FSANZ Act.

1.7 Decision

For the reasons outlined in this report FSANZ decided to approve a draft variation amending the Code to permit triacylglycerol lipase (EC 3.1.1.3) from GM *K. phaffii* to be used as a processing aid during the manufacture of bread and bakery products.

The draft variation as proposed following assessment was approved without change after FSANZ had regard to both submissions. 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 the draft variation included in the call for submissions report between 6 September 2024 and 18 October 2024. Two submissions were received, one from New Zealand Food Safety (NZFS) and one from an individual. NZFS supported approval of the draft variation, being to amend the Code to permit triacylglycerol lipase (EC 3.1.1.3) from genetically modified *K. phaffii* to be used as a processing aid. The individual did not support approval of the draft variation, however no further statements or comments were provided to explain that view.

2.2 Risk assessment

FSANZ undertook an assessment to determine whether the enzyme achieves its technological purpose in the quantity and form proposed, and to evaluate public health and safety risks that may arise from the use of this enzyme (see the Supporting Document (SD)). Summaries of both assessments are provided below.

2.2.1 Food technology assessment

The proposed use of the triacylglycerol lipase as a processing aid in the manufacture of

bread and bakery products is consistent with its typical function of catalysing the hydrolysis of triglyceride ester bonds and also acting on phospholipids and galactolipids, converting them to more efficient emulsifying structures. The use of triacylglycerol lipase improves crumb structure, bread volume and shape in bread and bakery products. It is functioning as a processing aid for the purposes of the Code where it does not perform a technological purpose in the food for sale. FSANZ also concluded that the evidence presented to support its proposed use provides adequate assurance that the use of the enzyme, in the quantity and form proposed to be used (which must be consistent with GMP), is technologically justified and has been demonstrated to be effective in achieving its stated purpose.

2.2.2 Risk assessment

K. phaffii has a long history of safe use as a production microorganism of enzyme processing aids. The production organism is neither pathogenic nor toxigenic. Analysis of the GM production strain confirmed the presence and stability of the inserted DNA.

Sufficient information has been provided to assess the safety of the triacylglycerol lipase that is the subject of this application. While a history of safe use for this specific enzyme has not been established, the production organism has a long history of safe use and raises no issues regarding the presence of secondary metabolites of toxicological concern in the enzyme preparation. The enzyme is rapidly destroyed under conditions replicating those in the human stomach and duodenum, and no significant homology between the enzyme and any known toxins or allergens was identified.

Based on the safety assessment and considering the theoretical maximum daily intake (0.127 mg Total Organic Solids/kg body weight/day), no public health and safety concerns were identified in the assessment of the triacylglycerol lipase produced by this GM *K. phaffii* under the proposed use conditions.

2.3 Risk management

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

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

- approve the draft variation proposed following assessment, or
- approve that draft variation subject to such amendments as FSANZ considers necessary, or
- reject that draft variation.

Following the call for submissions and having regard to both submissions received, for the reasons set out in this report, FSANZ considers it appropriate to approve the draft variation proposed following assessment without change (Attachment A).

The conclusions from the risk and technical assessment were that the proposed use of the enzyme is technologically justified and there were no safety concerns associated with its proposed use.

The permission to use this triacylglycerol lipase is subject to the condition that the maximum permitted level or amount of enzyme that may be present in food must be consistent with GMP.

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

2.3.1 Regulatory approval

As stated above, FSANZ has approved a draft variation to permit the use of the enzyme triacylglycerol lipase (EC 3.1.1.3) from GM *K. phaffii* as a processing aid in the manufacture of bread and bakery products.

The express permission for the enzyme to be used as a processing aid will also provide the permission for its potential presence in food for sale as a food produced using gene technology (see section 1.3.1 above). The enzyme is a food produced using gene technology for Code purposes as it is derived from an organism that has been modified using gene technology (see subsection 1.1.2—2(3) of the Code)³.

2.3.2 Enzyme nomenclature, source microorganism nomenclature and specifications

FSANZ notes that 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 the SD). Under the Code, the enzyme is listed as Lipase, triacylglycerol (EC 3.1.1.3). The approved draft variation follows this format 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.

Nomenclature for the host and gene donor organisms – *Komagataella phaffii* and *Fusarium oxysporum* respectively – is in accordance with accepted international norms for fungal taxonomy. As stated above (section 1.2), *Komagataella phaffii* was formerly known as *Pichia pastoris*.

There are relevant identity and purity specifications in primary sources of specifications listed in Schedule 3 for enzyme preparations used in food processing (refer to section 1.3.2 above).

2.3.3 Labelling

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

As explained in section 1.3.3, the Code requires certain foods for sale to be labelled as 'genetically modified', unless an exemption listed in subsection 1.5.2—4(1) applies. It is likely that these exemptions will apply to food for sale manufactured using this triacylglycerol lipase enzyme. This is because novel DNA or novel protein from the production strain *K. phaffii* is unlikely to be present in such foods. However, if the labelling exemptions in subsection 1.5.2—4(1) do not apply, the requirement to label as 'genetically modified' will apply.

2.3.4 Risk management conclusion

The risk management conclusion was to permit the enzyme triacylglycerol lipase (EC 3.1.1.3) produced from GM *K. phaffii* containing the triacylglycerol lipase gene from *F. oxysporum* as a processing aid in the manufacture of bread and bakery products (see section 1.2 above). The enzyme and its associated technological purposes would be listed in the table to subsection S18—9(3) of the Code, which includes enzymes permitted for a

³ Food produced using gene technology' is defined in subsection 1.1.2—2(3) as meaning 'a food which has been derived or developed from an organism which has been modified by gene technology'.

specific technological purpose.

The maximum permitted level or amount of the enzyme that may be present in the food will have to 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 as a food produced using gene technology.

2.4 Risk communication

2.4.1 Consultation

Consultation is a key part of FSANZ's standards development process. FSANZ developed and applied a standard communication strategy to this application. Call for submissions was notified via the FSANZ Notification Circular, media release, FSANZ's social media 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 to make submissions on this application.

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

2.5 FSANZ Act assessment requirements

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

2.5.1 Section 29

2.5.1.1 Consideration of costs and benefits

Changes have been made to the impact analysis requirements by the Office of Impact Analysis (OIA)⁴. Impact analysis is no longer required to be finalised with the OIA. Prior to these changes, the OIA advised FSANZ that a Regulatory Impact Statement (RIS) was not needed for applications relating to processing aids and GM foods. This is because applications relating to permitting the use of processing aids and GM foods that have been determined to be safe are minor and deregulatory in nature, as their use will be voluntary if the draft variation concerned is approved. Under the new approach, FSANZ's assessment is that a RIS is not required for this application.

FSANZ, however, has considered the costs and benefits that may arise from the proposed measure for the purposes of meeting FSANZ Act considerations. The FSANZ Act requires FSANZ to have regard to whether costs that would arise from the proposed measure outweigh the direct and indirect benefits to the community, government or industry that would arise from the proposed measure (paragraph 29(2)(a)).

The purpose of this consideration is to determine if the community, government and industry is likely to benefit, on balance, from a move from the status quo (where the status quo is

⁴ [Regulatory Impact Analysis Guide for Ministers' Meetings and National Standard Setting Bodies | The Office of Impact Analysis \(pmc.gov.au\)](#)

rejecting the application). This analysis considers the costs and benefits of approving this application.

The consideration of the costs and benefits in this section was not intended to be an exhaustive, quantitative economic analysis of the proposed measure. In fact, most of the effects that were considered cannot easily be assigned a dollar value. Rather, the assessment sought to highlight the positives and negatives of moving away from the status quo by approving the draft variation to the Code proposed by the application.

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 enzyme

Industry may benefit from several improvements and efficiencies from the use of this enzyme in the manufacture of bread and bakery products. Due to the voluntary nature of the permission, industry will only use the enzyme as proposed where they believe a net benefit exists for them.

If industry were to experience cost savings because of using this enzyme, industry may pass on some of the cost savings to consumers.

Permitting the proposed use of this enzyme may 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.

Conclusions from cost benefit assessment

FSANZ's assessment was that the direct and indirect benefits that would arise from permitting triacylglycerol lipase (EC 3.1.1.3) from *GM K. phaffii* to be used as a processing aid in the manufacture of bread and bakery products is likely to outweigh the associated costs. No further information was received during the consultation process that changed that assessment.

2.5.1.2 Other measures

There are no other measures (whether available to FSANZ or not) that would be more cost-effective than a food regulatory measure developed or varied as a result of the application.

2.5.1.3 Any relevant New Zealand standards

The relevant standards in the Code apply in both Australia and New Zealand. There are no other relevant New Zealand only standards.

2.5.1.4 Any other relevant matters

Other relevant matters are considered below.

2.5.2. Subsection 18(1)

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

2.5.2.1 Protection of public health and safety

FSANZ undertook a safety assessment (see section 2.2 above and the SD) and concluded

there were no public health and safety concerns associated with the proposed use of this enzyme.

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

Existing labelling requirements will apply to this enzyme and its proposed use in accordance with the Code to enable consumers to make informed choices (see sections 1.3.3 and 2.3.3).

2.5.2.3 The prevention of misleading or deceptive conduct

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

2.5.3 Subsection 18(2) considerations

FSANZ has also had regard to:

- **the need for standards to be based on risk analysis using the best available scientific evidence**

FSANZ used the best available scientific evidence to conduct the risk analysis. The applicant submitted a dossier of information and scientific literature as part of its application. This dossier, together with other technical and scientific information, was considered by FSANZ in assessing the application. The risk assessment is provided in the SD.

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

As noted in sections 1.3.2 and 1.4 above, the relevant international standard setting body is Codex. In contrast to food additives, there is no Codex 'general standard' for enzymes, however there are internationally recognised specifications for enzyme preparations established by JECFA and Food Chemicals Codex, with which this enzyme would have to comply.

In addition, 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.

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

At the time the application was lodged, the applicant stated they had applied for approval of the enzyme subject to this application in a number of other jurisdictions (the European Union, United States, Canada). Since that time, the applicant has advised the following:

- The EU dossier is still under evaluation
- The United States Food and Drug Administration provided the applicant with a 'No Question Letter' in August 2024. This will be recorded in the [GRAS Notice Inventory | FDA](#) under GRN 1154.
- Health Canada provided the applicant with a 'Notice of Favourable Decision' in October 2024. This approval will be published in the [List of Permitted Food Enzymes](#)

The applicant also advised that the enzyme subject to this application has been approved in Denmark and France.

Australia and New Zealand will remain competitive with other international markets, where

approval for the use of the enzyme in other markets is granted in the future. This will also help foster continued innovation and improvements in food manufacturing techniques and processes.

The conclusion of the risk assessment is 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 objective.

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

The Ministerial Policy Guideline *Addition to Food of Substances other than Vitamins and Minerals*⁵ 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 proposed 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

⁵ <https://foodregulation.gov.au/internet/fr/publishing.nsf/Content/publication-Policy-Guideline-on-the-Addition-of-Substances-other-than-Vitamins-and-Minerals>

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



Food Standards (Application A1301 – Triacylglycerol lipase from GM *Komagataella phaffii* 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 Delegate]

[Insert name and position of 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 A1301 – Triacylglycerol lipase from GM Komagataella phaffii 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 *Fusarium oxysporum*

For use in the manufacture of bread and bakery products.

GMP

Attachment B – Explanatory Statement

EXPLANATORY STATEMENT

Food Standards Australia New Zealand Act 1991

Food Standards (Application A1301 – Triacylglycerol lipase from GM Komagataella phaffii 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 purpose of the application was to permit the use of the enzyme triacylglycerol lipase (EC 3.1.1.3) from a genetically modified *Komagataella phaffii* containing the triacylglycerol, lipase gene from *Fusarium oxysporum* as a processing aid. The enzyme is proposed for use during the manufacture of bread and bakery products. The Authority considered the application in accordance with Division 1 of Part 3 and has approved a draft variation - the *Food Standards (Application A1301 – Triacylglycerol lipase from GM Komagataella phaffii as a processing aid) 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 approved 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.

This instrument is not subject to the disallowance or sunset 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 sunset 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 sunset 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 triacylglycerol lipase enzyme (EC 3.1.1.3) sourced from genetically modified *Komagataella phaffii* containing the triacylglycerol lipase gene from *Fusarium oxysporum* as a processing aid for use in the manufacture of bread and bakery products.

The 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. 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 2021) and the United States Pharmacopeial Convention (2022) Food Chemicals Codex (13th 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 A1301 included one round of public consultation following an assessment and the preparation of a draft variation and associated report. Submissions were called for on 6 September 2024 for a 6-week consultation period. 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.

Changes have been made to the impact analysis requirements by the Office of Impact Analysis (OIA)⁶. Impact analysis is no longer required to be finalised with the OIA. Prior to these changes, the OIA advised FSANZ that a Regulatory Impact Statement (RIS) was not needed for applications relating to processing aids and genetically modified food. This is because applications relating to permitting the use of processing aids and genetically modified food that have been determined to be safe are minor and deregulatory in nature, as their use will be voluntary if the draft variation concerned is approved.

⁶ Regulatory Impact Analysis Guide for Ministers' Meetings and National Standard Setting Bodies | The Office of Impact Analysis (pmc.gov.au)

Under this approach, FSANZ's assessment is that a RIS is not needed for this application.

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 A1301 – Triacylglycerol lipase from GM Komagataella phaffii 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 *Fusarium oxysporum*'

The International Union of Biochemistry and Molecular Biology (IUBMB) lists the accepted name 'triacylglycerol lipase' for the enzyme with the EC number of EC 3.1.1.3. However, in the Code, the enzyme is listed as Lipase, triacylglycerol (EC 3.1.1.3). The variation follows this format 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 permitted technological purpose for this enzyme is prescribed in column 2 of the table i.e. for use in the manufacture of bread and bakery products.

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 item [1] of the Schedule to the variation is to permit the use of the enzyme triacylglycerol lipase (EC 3.1.1.3) sourced from *Komagataella phaffii* containing the lipase, triacylglycerol gene from *Fusarium oxysporum* as a processing aid in accordance with the Code.