FOOD STANDARDS Australia New Zealand
Te Mana Kounga Kai – Ahitereiria me Aotearoa

6 September 2024
305–24

Call for submissions – Application A1301

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

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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 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. Pursuant to section 31 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act), FSANZ now calls for submissions to assist consideration of the draft food regulatory measure.

Submissions on this application need to be made through the Consultation Hub (https://consultations.foodstandards.gov.au/).

All submissions on applications and proposals will be published on the Consultation Hub. We will not publish material that we accept as confidential. In-confidence submissions may be subject to release under the provisions of the *Freedom of Information Act 1982*. Submissions will be published following consultation and before the next stage in the statutory assessment process.

Under section 114 of the FSANZ Act, some information provided to FSANZ cannot be disclosed. More information about the disclosure of confidential commercial information is available on the FSANZ website at Making a submission.

For information on how FSANZ manages personal information when you make a submission, see FSANZ's Privacy Policy.

FSANZ also accepts submissions in hard copy to our Australia and/or New Zealand offices. There is no need to send an email or hard copy of your submission if you have submitted it through the FSANZ Consultation Hub.

DEADLINE FOR SUBMISSIONS: 6pm (Canberra time) 18 October 2024

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

For information about making a submission, visit the FSANZ website at current calls for public comment and how to make a submission.

Questions about making a submission or application and proposal processes can be sent to standards.management@foodstandards.gov.au.

Submissions in hard copy may be sent to the following addresses:

Food Standards Australia New Zealand
PO Box 5423
KINGSTON ACT 2604

Food Standards Australia New Zealand
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Tel +61 2 6271 2222

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Supporting document

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

SD Risk and technical assessment

Executive summary

Danstar Ferment AG, an affiliate of Lallemand Inc (Danstar Ferment AG), 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 genetically modified 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, for reasons set out in this report, FSANZ has prepared a draft variation to amend subsection S18—9(3) of the Code by listing this enzyme and its associated technological purpose in the table to subsection S18—9(3). This table lists substances (including enzymes) permitted as processing aids for specific technological purposes. The draft variation, if approved, would permit the use of the enzyme triacylglycerol lipase (EC 3.1.1.3) sourced from *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 would 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.

FSANZ now seeks submissions on the draft variation of the Code.

1 Introduction

1.1 The Applicant

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

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*[1] (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, 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 Alimentarius '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 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

[1] 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*).

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.

2 Summary of the assessment

FSANZ has undertaken 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.

2.1 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 is 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 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 genetically modified 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 itself 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 itself 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

The risk management options available to FSANZ after assessment, were to either:

- reject the application, or
- prepare a draft variation of the Code.

For the reasons listed in this report, FSANZ decided to prepare a draft variation to the Code permitting the proposed use of triacylglycerol lipase (EC 3.1.1.3) produced from GM *K. phaffii* containing the triacylglycerol lipase gene from *F. oxysporum* as a processing aid. The permission would be used during the manufacture of bread and bakery products. If approved, this permission would be subject to the condition that the maximum permitted level or amount of enzyme used in the food must be consistent with GMP.

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.

Other risk management considerations for this application are related to the enzyme and source microorganism nomenclature, specifications and labelling. These are discussed below.

2.3.1 Regulatory approval

As stated above, FSANZ has prepared a draft variation to permit the use of the enzyme 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 also provides 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[2].

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). For consistency, the proposed draft variation follows this format.

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

[2] 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'.

this processing aid (see Section 1.3.3 above).

2.3.4 Risk management conclusion

The risk management conclusion is 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). If approved, 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 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 also provides 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. All calls for submissions are notified via the FSANZ Notification Circular, media release, FSANZ's social media channels and Food Standards News.

The process by which FSANZ approaches standards development matters is open, accountable, consultative and transparent. Public submissions are called to obtain the views of interested parties on the draft variation.

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

2.4.2 World Trade Organization (WTO)

As members of the World Trade Organization (WTO), Australia and New Zealand are obliged to notify WTO Members where proposed mandatory regulatory measures are not substantially the same as existing international standards and the proposed measure may have a significant effect on trade.

There are no relevant international standards (i.e. Codex Alimentarius Standards) and amending the Code to permit the proposed use of this enzyme as a processing aid is unlikely to have a significant effect on international trade. Therefore, a notification to the WTO under Australia's and New Zealand's obligations under the WTO Technical Barriers to Trade or Application of Sanitary and Phytosanitary Measures Agreement was not considered necessary.

2.5 FSANZ Act assessment requirements

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

2.5.1 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)[3]. 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 rejecting the application). This analysis considers the costs and benefits of approving this application.

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

FSANZ's conclusions regarding the costs and benefits of the proposed measure are set out below. However, information received from the call for submissions may result in FSANZ arriving at a different outcome.

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 is that the direct and indirect benefits that would arise from permitting triacylglycerol lipase 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.

Information received through this call for submissions process may result in FSANZ arriving at a different outcome.

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

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**

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 Food Chemicals Codex, with which this enzyme would have to comply.

As noted in section 1.4 above, 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**

The applicant has applied for approval of the enzyme subject to this application in a number of other jurisdictions (the European Union, United States, Canada). 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 domestic food industry will make their own economic decisions, taking into account the costs and benefits of using the new enzyme, to determine if it is of benefit to their particular 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*[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 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.

3 Draft variation

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

A draft explanatory statement is at Attachment B. An explanatory statement is required to accompany an instrument if it is lodged on the Federal Register of Legislation.

Attachments

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

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

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

FOOD STANDARDS Australia New Zealand
Te Mana Kounga Kai – Ahitereiria me Aotearoa

Food Standards (Application A1301 – Triacylglycerol lipase from GM *Komagataella phaffii* as a processing aid) Variation

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

Dated [To be completed by Delegate]

[Insert 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 – Draft Explanatory Statement

DRAFT 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 Authority accepted Application A1301 which seeks to permit the use of the enzyme triacylglycerol lipase (EC 3.1.1.3) from 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 prepared a draft variation - the *Food Standards (Application A1301 – Triacylglycerol lipase from GM* Komagataella phaffii *as a processing aid) Variation.*

2. Variation will be a legislative instrument

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

If approved, this instrument would not be 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 Food Ministers Meeting (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 prepared 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 sourced from genetically modified *Komagataella phaffii* containing the lipase triacylglycerol gene from *Fusarium oxysporum* as a processing aid for use in the manufacture of bread and bakery products. If approved, this permission would be 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 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 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 will include one round of public consultation following an assessment and the preparation of a draft variation and associated assessment summary. A call for submissions (including the draft variation) will occur for a six-week consultation period.

Changes have been made to the impact analysis requirements by the Office of Impact Analysis (OIA) [5]. Impact analysis is no longer required to be finalised with the OIA. Under the new approach to impact analysis, FSANZ will assess whether an application requires a regulation impact statement. FSANZ's assessment is that a regulatory impact statement is not required for this application. Prior to these changes, the OIA advised FSANZ that a Regulatory Impact Statement was not required for applications relating to processing aids and food produced using gene technology (GM food). This is because applications relating to permitting the use of processing aids and GM food that have been determined to be safe are considered to be minor and/or deregulatory in nature, as their use will be voluntary if the draft variation concerned is approved. FSANZ's decision not to develop a regulation impact statement is consistent with the OIA's prior advice.

6. Statement of compatibility with human rights

If approved, this instrument would be exempt from the requirements for a statement of compatibility with human rights as it would be a non-disallowable instrument under section 44 of the *Legislation Act 2003*.

7. Variation

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

References to ‘variation’ in this section are references to the draft variation.

Clause 1 of the variation provides that the name of the variation is the *Food Standards (Application A1301 – Triacylglycerol 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 would insert a new entry, in alphabetical order, into the table to subsection S18—9(3) of the Code.

The new entry would consist 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 permitted technological purpose for this enzyme would be prescribed in column 2 of the table i.e. for use in the manufacture of bread and bakery products.

The permission would be 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.

If approved, the draft variation would permit the proposed use of the enzyme lipase, triacylglycerol (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.