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

14 May 2025
340-25

Approval report – Application A1279

Lentinula edodes (shiitake mushroom) mycelia as a processing aid

---

Food Standards Australia New Zealand (FSANZ) has assessed an application made by MycoTechnology, Inc. to amend the Australia New Zealand Food Standards Code to permit a fermented preparation of *Lentinula edodes* mycelia as a processing aid.

On 2 December 2024, FSANZ sought submissions on a draft variation and published an associated report. FSANZ received one submission.

FSANZ approved the draft variation on 30 April 2025. The Food Ministers' Meeting[1] was notified of FSANZ's decision on 14 May 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

Table of contents

Supporting document

The following document which informed the assessment of this application is available on FSANZ's website: A1279 - *Lentinula edodes* (Shiitake mushroom) mycelia as a processing aid | Food Standards Australia New Zealand

SD1 Risk and technical assessment report (at Approval)

Executive summary

MycoTechnology, Inc. submitted an application to Food Standards Australia New Zealand (FSANZ) to amend the Australia New Zealand Food Standards Code (the Code) to permit a fermented preparation of *Lentinula edodes* (shiitake mushroom; *L. edodes*) mycelia as a processing aid.

The preparation is used as a fermentation aid in the fermentation of pea and rice protein, with the objective of producing ingredients that are more organoleptically acceptable to consumers.

FSANZ concluded that the applicant's fermented preparation of *L. edodes* mycelia is technologically justified as a processing aid in the quantity and form proposed. The preparation does not have any further technological function in the final pea and rice protein preparation. It therefore functions as a processing aid for the purposes of the Code.

The glycerol stock of *L. edodes* mycelia is used as the starting culture for the multi-stage successive submerged fermentations used to produce the fermented *L. edodes* preparation used as a processing aid. Since the *L. edodes* mycelia preparation is produced and used *in situ,* it was not considered appropriate to draft a specification for the preparation *per se*. Instead FSANZ included a specification for the glycerol stock of the *L. edodes* mycelia.

The *L. edodes* fruiting body has a long history of safe consumption as a food. Based on the toxicological and microbiological risk assessments, there were no public health safety concerns associated with the use of a fermented preparation of *L. edodes* mycelia as a processing aid in the production of pea and rice protein.

Following assessment and the preparation of a draft variation to the Code, FSANZ called for submissions regarding the draft variation from 2 December 2024 to 28 January 2025. FSANZ received one submission which supported the conclusion of FSANZ's assessment in general and raised several issues, which have been addressed in the preparation of this report. See section 2.1. No changes to the draft variation were required.

Based on the information above and on other relevant considerations set out in this report, FSANZ has approved the draft variation to the Code proposed at the call for submissions. The approved draft variation will amend Standard 1.3.3 by inserting a new section 1.3.3—14 – Fermentation aid—a fermented preparation of *Lentinula edodes* (shiitake mushroom) mycelia. This new section permits the use of a fermented preparation of *L. edodes* mycelium as a processing aid for the fermentation of pea protein, rice protein, and pea and rice protein, if the proportion of the fermented preparation that is used is no more than the maximum level necessary to achieve the technological purpose under the conditions of Good Manufacturing Practice. The new section also requires the glycerol stock of the *L. edodes* mycelia that is the starting culture to produce the processing aid to comply with a number of specifications (as set out in subsection 1.3.3—14(4)).

1 Introduction

1.1 The applicant

The applicant MycoTechnology, Inc. is a manufacturer of mushroom fermentation-based food ingredients.

1.2 The application

The purpose of the application is to amend the Australia New Zealand Food Standards Code (the Code) to permit a fermented preparation of *Lentinula edodes* (shiitake mushroom) mycelia as a processing aid.

It will be used for the fermentation of pea and rice protein to produce a protein ingredient with improved organoleptic properties that can be added to different foods and beverages as a source of protein. It will not be added to infant formula products.

The Advisory Committee on Novel Foods (ACNF) has previously formed a view that the final pea and rice protein product is a non-traditional food but not a 'novel food' in Australia and New Zealand. Therefore the application requested only an assessment of *L. edodes* mycelia as a processing aid. A link to the ACNF record of views can be found here Novel food - Record of views formed in response to inquiries | Food Standards Australia New Zealand.

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) of the Code 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
- it is a substance listed in Schedule 18 or identified in section S16—2 as an additive permitted at Good Manufacturing Practice (GMP).

Standard 1.3.3 and Schedule 18 of the Code list permitted processing aids.

1.3.2 Identity and purity requirements

Paragraph 1.1.1—15(1)(b) of the Code requires substances used as processing aids in food to comply with any relevant identity and purity specifications listed in Schedule 3 of the Code.

There is no specification for *L. edodes* mycelia within Schedule 3.

1.3.3 Labelling requirements

Subsection 1.1.1—10(8) provides that food for sale must comply with all relevant labelling

requirements imposed by the Code for that food.

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, 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.

No other national regulatory agency has considered or regulated the fermented preparation of *L. edodes* mycelia as a processing aid for the fermentation of pea and rice protein preparations. Some agencies, however, have assessed and/or regulated the final fermented pea and rice protein preparations.

In the USA the Food and Drug Administration (FDA) provided a 'no objections' letter to the applicant's self-assessment of the protein preparation as 'Generally Recognized as Safe' (GRAS) in 2020 (GRN 848) (US FDA 2020).

The applicant states that it is also permitted for use as a food ingredient in Brazil, Canada, Chile, Ecuador, the European Union, Hong Kong, India, Indonesia, Japan, Malaysia, the Philippines, South Korea, Singapore and Thailand.

In the European Union it was permitted as a novel food following an assessment by the European Food Safety Agency (EFSA) in 2022 (EFSA 2022). The European Commission Implementing Regulation is 2023/6 (EU 2023).

The Brazilian permission (Regulation No. 16/1999 and No. 17/199) is consistent with that of the European Union (Anvisa 2023).

The Food Safety and Standards Authority of India (FSSAI) permitted the use of the product as an ingredient in food with no specific limitations or conditions in May 2022 (FSSAI 2022).

Copies of the Brazilian and Indian regulations are provided in Appendix A of the application.

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 *Australia New Zealand Food Standards Act* (FSANZ Act)
- 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.

1.7 Decision

For the reasons outlined in this report, FSANZ decided to approve a draft variation amending the Code to permit the use of a fermented preparation of *Lentinula edodes* (shiitake mushroom) mycelia as a processing aid.

The draft variation as proposed following assessment was approved without change. The variation takes effect on gazettal. The approved draft variation is at Attachment A.

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

2 Summary of the findings

2.1 Summary of issues raised in submissions

On 2 December 2024, FSANZ sought submissions on a draft variation and published an associated report. Submissions closed on 28 January 2025. FSANZ received one submission from New Zealand Food Safety (NZFS) which supported the conclusion of FSANZ's assessment in general but raised a number of issues. FSANZ responses to these issues are provided in Table 1 below. No changes to the draft variation were required following consideration of the issues raised in the submission.

Table 1: Summary of issues

Issue/comment	Raised by	FSANZ response
It agreed with FSANZ's assessment that based on the available evidence that there are no safety concerns from the proposed uses of the fermented preparation of *L. edodes* mycelia at GMP levels. It further agrees that its use is technologically justified in the production of fermented pea and rice protein (FRPR).	NZFS	FSANZ notes this comment.
NZFS notes that the action of enzymes secreted by the shiitake mycelia during the main fermentation step is suggested to improve the organoleptic qualities of FPRP and could be viewed as having a processing aid function.	NZFS	FSANZ notes this comment. Section 1.1.2—13 of the Code 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 Good Manufacturing Practice (GMP). FSANZ considers that the applicant's fermented preparation of *L. edodes* mycelia is technologically justified as a processing aid in the quantity and form

Issue/comment	Raised by	FSANZ response
		proposed. The preparation does not have any further technological function in the final pea and rice protein preparation. It therefore functions as a processing aid for the purposes of the Code.
On the other hand, NZFS questions the need to regulate the fermented preparation as a processing aid noting: • microorganisms used for fermentations are usually considered as general food ingredients • the enzyme identification analysis was performed only for the main fermentation, so it is unclear whether the fermented preparation itself also contains enzyme that perform technological functions and • no other national regulatory agency has regulated the fermented preparation as a processing aid.	NZFS	FSANZ notes that processing aids are regulated differently in different parts of the world. For the reasons listed above and within this report FSANZ has assessed and proposed the regulation of the fermented *L edodes* mycelia preparation as a processing aid.
This assessment of the fermented preparation as a processing aid may set a precedent for how other fermentation organisms are considered. It notes this could include other fermentation organisms that also produce enzymes and other substances that have technological effects during a fermentation process.	NZFS	FSANZ concluded that this preparation differs to those of other microorganisms used for traditional fermentations. The technological purpose is quite different as it is aiming to modify the properties of the rice and pea proteins, not use fermentation to produce a food such as beer, wine, yoghurt etc. FSANZ will consider any future applications for other fermentation organisms on a case-by-case basis.

2.2 Risk assessment

FSANZ conducted a risk assessment to determine whether the fermented preparation of *L. edodes* mycelia achieves its technological purpose in the quantity and form proposed, and to evaluate public health and safety concerns that may arise from the use of this preparation (see SD1). A summary of the risk assessment is provided below.

The *L. edodes* fruiting body has the history of safe consumption as a food. Using a budget method approach, the dietary exposure assessment calculated the theoretical maximum daily intake (TMDI) of the processing aid to be 7.5 mg/kg bw/day. For the Australian and New Zealand population groups assessed, the mean and 90th percentile consumption of all mushrooms were estimated to be 200 – 600 mg/kg bw/day and 400 – 1400 mg/kg bw/day respectively. These results demonstrate that the exposure to the processing aid is well below the estimated consumption of mushrooms for the population groups assessed.

The microbiological risk assessment undertaken by FSANZ has not identified any public health and safety concerns associated with the use of a fermented preparation of *L. edodes* as a processing aid. *L. edodes* mycelium has been determined to be neither pathogenic nor

toxigenic. Considering the history of safe consumption of the *L. edodes* fruiting body as a food, FSANZ considered that no toxicological or genotoxicity studies were required for the use of *L. edodes* mycelium as a processing aid. On this basis, the FSANZ risk and technical assessment did not establish an ADI for *L. edodes* mycelium as a processing aid.

Overall, FSANZ concludes that there are no safety concerns from the use of a fermented preparation of *L. edodes* mycelia as a processing aid.

2.3 Risk management

Following assessment, FSANZ prepared a draft variation and called for submissions on that draft variation between 2 December 2024 and 28 January 2025.

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

Having regard to the submission received, and for the reasons set out in this report, FSANZ approved the draft variation proposed at the call for submissions (see Attachment A).

The conclusions from the risk and technical assessment were that the proposed use of a fermented preparation of *L. edodes* mycelia as a processing aid is technologically justified. No safety concerns were associated with its proposed use.

The permission to use this fermented preparation is subject to the condition that the maximum permitted level or amount of the processing aid that may be present in the food must be consistent with GMP.

Other risk management considerations for this application were related to regulatory approval, specifications and labelling. These are discussed below.

2.3.1 Regulatory approval

A specification is not appropriate for the final processing aid preparation since it is produced and used *in-situ* during the fermentation of rice and pea protein.

Therefore, FSANZ determined that the most appropriate approach was to provide a permission and relevant specification for the starting material within a new separate section in Standard 1.3.3.

As stated above, FSANZ approved the draft variation to permit the use of a fermented preparation of *Lentinula edodes* (shiitake mushroom) mycelia as a processing aid.

2.3.2 Specifications

Section 1.1.1—15 requires a substance that is *used as a processing aid* must comply with any relevant specification set out in Schedule 3 of the Code.

Specifications are established for identity and purity purposes and to ensure that the substance that is marketed is representative of the substance that has undergone the safety assessment.

As above, the fermented preparation of *L. edodes* mycelia is produced and used *in-situ.* Therefore, it was not considered appropriate to draft a specification for the preparation *per se*. Instead FSANZ included a specification for the glycerol stock[2] of the *L. edodes* mycelia that is the starting culture to produce the processing aid. The starting culture is used for the multi-stage successive submerged fermentations used to produce the fermented preparation of *L. edodes* mycelia used as a processing aid.

The specification for inclusion in Standard 1.3.3 for the glycerol stock of *L. edodes* mycelia, linked to the permission for its use as a processing aid, is shown in Table 1.

Table 1 Specification for the glycerol stock of *Lentinula edodes* (shiitake mushroom) mycelia

The glycerol stock needs to comply with these requirements:

Name of the species	*Lentinula edodes*
Arsenic	Not more than 10 µg/kg
Cadmium	Not more than 5 µg/kg
Lead	Not more than 5 µg/kg
Mercury	Not more than 5 µg/kg
Aerobic plate count	Not more than 10 CFU/g

2.3.3 Labelling

The generic exemption from listing processing aids in the statement of ingredients would apply to foods produced using this processing aid (see section 1.3.3 above).

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. The call for submissions was notified via the Food Standards Notification Circular, media release, FSANZ's digital 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 comments received from the call for submissions.

2.5 FSANZ Act assessment requirements

2.5.1 Section 29

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] Typically, glycerol is used as an anti-freezing (cryoprotectant) carrier solution to store the stock of starting culture of *L. edodes* mycelia at very low temperatures (-80°C) to maintain viability.

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 analyses are 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 required for the applications relating to GM food and processing aids. This is because applications relating to permitting the use of GM food and processing aids that have been determined to be safe are considered to be 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 was not required for this application.

Analysis of costs and benefits under the FSANZ Act

FSANZ, however, gave consideration to 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 was 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 considered permitting the proposed use of the fermented preparation of *L. edodes* mycelia as a processing aid.

The consideration of the costs and benefits in this section was not intended to be an exhaustive, quantitative economic analysis of the proposed measures and, in fact, most of the effects that were considered cannot 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 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.

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

Industry may benefit from a number of improvements and efficiencies from the use of the processing aid. Due to the voluntary nature of the permission, industry will only use the processing aid as proposed where they believe a net benefit exists for them in terms of cost savings or improving the quality of their product.

If industry were to experience cost savings as a result of using the processing aid, industry may pass on some of the cost savings to consumers. Consumers may also have access to a wider range or better quality of products as a result of the change.

Government may incur some minimal additional enforcement costs as a result of the change.

Conclusions from cost benefit considerations

FSANZ's assessment at the call for submissions stage was that the direct and indirect benefits that would arise from permitting the proposed use of the fermented preparation of *L. edodes* mycelia as a processing aid most likely outweigh the associated costs. No further information was received during the consultation process that changed that assessment.

[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 apply in both Australia and New Zealand. There are no 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 SD1) and concluded there were no public health and safety concerns associated with the proposed use of this processing aid.

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

The labelling requirements for this processing aid are discussed in section 2.2.3 of this report.

2.5.2.3 The prevention of misleading or deceptive conduct

There are 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, which is provided in SD1. 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 promotion of consistency between domestic and international food standards**

As noted in section 1.4 there are international permissions for the food ingredient produced using the processing aid in this application. However, there are not explicit permissions for the processing aid itself, just the food ingredient produced using the processing aid. This is explained by the different approaches taken to regulating processing aids in the Code in Australia and New Zealand compared to other international food agencies.

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

As noted in section 1.4 there are international permissions for the food ingredient produced using the processing aid in this application. If the draft variation is approved, it would make Australia and New Zealand consistent with the other countries which have permitted the food ingredient produced using the processing aid.

- **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 a fermented preparation of *L. edodes* mycelia as a processing aid would be consistent with these specific order policy principles for 'Technological Function'. All other relevant requirements of the policy guideline are similarly met.

4 References

Anvisa 2023, Brazilian Health Regulatory Agency 2023, National Health Surveillance Agency, Second Directorate, Food General Management, Risk and Efficacy Assessment Management, Opinion Nº 0164041/23-7.

EFSA 2022, Scientific Opinion on the safety of pea and rice protein fermented by Shiitake (*Lentinula edodes*) mycelia as a Novel food pursuant to Regulation (EU) 2015/2283 (EFSA Panel on Nutrition, Novel Foods and Food Allergens/NDA). EFSA J 20(4):7205 [24pp]. https://doi.org/10.2903/j.efsa.2022.7205 Available at: https://www.efsa.europa.eu/en/efsajournal/pub/7205

EU 2023, COMMISSION IMPLEMENTING REGULATION (EU) 2023/6 of 3 January 2023 authorising the placing on the market of pea and rice protein fermented by *Lentinula edodes* (Shiitake mushroom) mycelia as a novel food and amending Implementing Regulation (EU) 2017/2470, http://data.europa.eu/eli/reg_impl/2023/6/oj

FSSAI 2022, Application No 80/Std/PA/FSSAI/202, approval for "FermentIQ Protein Powder PTP", 4 May 2022.

US FDA 2020, GRN 848 [Pea and rice protein fermented by Shiitake mycelia) Myco Technology, Inc. Aurora (CO)] US Food and Drug Administration, Center for Food Safety and Applied Nutrition

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

(CFSAN) Office of Food Additive Safety, Silver Spring (MD)
https://www.fda.gov/media/135942/download, and FDA no questions notice:
https://www.fda.gov/media/135941/download

Attachments

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

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

Food Standards (Application A1279 – *Lentinula edodes* (Shiitake mushroom) mycelia 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 Standards Management Officer]

[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 A1279* – Lentinula edodes *(Shiitake mushroom) mycelia 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

Standard 1.3.3—Processing aids

[1] After section 1.3.3—13

Insert:

1.3.3—14 Fermentation aid—a fermented preparation of *Lentinula edodes* (shiitake mushroom) mycelia

(1) In this section, a **fermented preparation** means a fermented preparation of *Lentinula edodes* (shiitake mushroom) mycelia.

(2) A fermented preparation may be *used as a processing aid to perform the technological purpose of a fermentation aid in fermentation of any of the following foods if the conditions listed in subsections (3) and (4) are complied with:

(a) pea protein;
(b) rice protein;
(c) pea and rice protein.

(3) The proportion of the fermented preparation that is used is no more than the maximum level necessary to achieve the technological purpose listed in subsection (2) under conditions of GMP.

(4) The fermented preparation must be produced from a glycerol stock of *Lentinula edodes* (shiitake mushroom) mycelia that complies with each of the following specifications:

(a) species—*Lentinula edodes*;
(b) arsenic—not more than 10 µg/kg;
(c) cadmium—not more than 5 µg/kg
(d) lead—not more than 5 µg/kg;
(e) mercury—not more than 5 µg/kg;
(f) aerobic plate count—not more than 10 cfu/g.

Attachment B – Explanatory Statement

EXPLANATORY STATEMENT

Food Standards Australia New Zealand Act 1991

Food Standards (Application A1279* – Lentinula edodes *(Shiitake mushroom) mycelia 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 A1279 which sought to amend the Code to permit a fermented preparation of *Lentinula edodes* (shiitake mushroom) mycelia for use as a processing aid in the fermentation of pea protein, rice protein and pea and rice protein. The Authority considered the application in accordance with Division 1 of Part 3 and has approved a draft Variation - the *Food Standards (Application A1279* – Lentinula edodes *(Shiitake mushroom) mycelia 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 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 the draft variation to amend Standard 1.3.3 of the Code to permit the use of a fermented preparation of *Lentinula edodes* (shiitake mushroom) mycelia as a processing aid in the fermentation of pea protein, rice protein and pea and rice protein; and to set conditions for that substance's use as a processing aid.

4. Documents incorporated by reference

The draft variation does not incorporate any documents by reference.

5. Consultation

In accordance with the procedure in Division 1 of Part 3 of the FSANZ Act, the Authority's consideration of Application A1279 included 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) was open for an eight-week 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)[5]. Impact analyses are 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 required for the applications relating to processing aids. This is because applications relating to permitting the use of processing aids that have been determined to be safe are considered to be 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 was not required 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 A1279* – Lentinula edodes *(Shiitake mushroom) mycelia 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

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

the instrument.

Item [1] of the Schedule to the draft variation amends Standard 1.3.3 of the Code.

Item [1] inserts a new section 1.3.3—14, titled ‘Fermentation aid—a fermented preparation of *Lentinula edodes* (shiitake mushroom) mycelia.

New subsection 1.3.3—14(1) provides that, for the purposes of section 1.3.3—14, a ‘fermented preparation’ means a fermented preparation of *Lentinula edodes* (shiitake mushroom) mycelia.

New subsection 1.3.3—14(2) provides that the fermented preparation may be used as a processing aid for the technological purpose of a fermentation aid in the fermentation of any of the following: pea protein, rice protein or pea and rice protein. The new subsection provides an express permission for the purposes of paragraph 1.1.1—10(6)(c) of the Code That paragraph provides that a 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.

New subsection 1.3.3—14(3) sets a condition for use of the fermented preparation as a processing aid. That is, that the proportion of the fermented preparation that is used is no more than the maximum level necessary to achieve, under conditions of ‘GMP’, its technological purpose as a fermentation aid in the fermentation of pea protein, rice protein or pea and rice protein. ‘GMP’ or ‘Good Manufacturing Practice’ is defined in subsection 1.1.2—2(3) of the Code

New subsection 1.3.3—14(4) also sets a condition for use of the fermented preparation as a processing aid. The subsection provides that the permission provided by subsection 1.3.3—14(2) is limited to a fermented preparation that is produced from a glycerol stock of *Lentinula edodes* (shiitake mushroom) mycelia that meets each of the specifications prescribed in subsection 1.3.3—14(4).

The effect of item [1] of the Schedule to the variation is to permit the proposed use of a fermented preparation of *Lentinula edodes* (shiitake mushroom) mycelia as a processing aid in accordance with the Code.