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

25 March 2024

333-25

Call for submissions–Application A1315 Chitosan and (1,3)-β-glucans from white button mushrooms (*Agaricus bisporus*) as a food additive

Food Standards Australia New Zealand (FSANZ) has assessed an application made by Chinova Bioworks Inc to permit a mixture of chitosan and (1,3)-β-glucans extracted from white button mushrooms (*Agaricus bisporus*) as a preservative in food and beverage 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: 11:59 pm (Canberra time) 6 May 2025

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:

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Supporting document

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

SD Risk and Technical Assessment Report

Executive summary

Food Standards Australia New Zealand (FSANZ) has assessed an application made by Chinova Bioworks Inc to amend the Australia New Zealand Food Standards Code (the Code) to permit mushroom chitosan (chitosan and (1,3)-β-glucans extracted from *Agaricus bisporus*) as a preservative in a range of food and beverage products.

Mushroom chitosan is the chitin-glucan complex found in the cell walls of most fungi and yeasts. The Code does not currently permit the use of mushroom chitosan as a preservative, and there is no specification for it in the Code or relevant international standards.

FSANZ's food technology assessment concluded that mushroom chitosan functions as a food additive (preservative) for the purposes of the Code. FSANZ's microbiological assessment concluded that the information related to the safety and efficacy of mushroom chitosan supports its use as an antimicrobial agent.

FSANZ's safety assessment concluded that no public health and safety concerns are associated with using mushroom chitosan at Good Manufacturing Practice (GMP) levels.

For reasons set out in this report, FSANZ has prepared a draft variation to the Code to permit the use of mushroom chitosan as a food additive (for use as a preservative) in food following the Code.

If approved, the draft variation would:

- insert a new specification for mushroom chitosan into Schedule 3 of the Code, with which the applicant's chitosan and (1,3)-β-glucans would have to comply when used as a food additive (or sold for such use)
- amend Schedule 8 to include 'mushroom chitosan' as the name that must be provided when declaring the proposed food additive in a statement of ingredients in accordance with section 1.2.4—7
- amend Schedule 16 of the Code to permit mushroom chitosan as a food additive in food at GMP levels

FSANZ now seeks submissions on the draft variation of the Code (Attachment A).

1 Introduction

1.1 The applicant

Chinova Bioworks Inc. is a Canadian manufacturer of chitosan from *Agaricus bisporus*.

1.2 The application

This application seeks to amend the Australia New Zealand Food Standards Code (the Code) to permit the use of a mixture of chitosan and (1,3)-β-glucans extracted from white button mushrooms[1] (*Agaricus bisporus*) as a preservative in a range of food and beverage products. This mixture is referred to as mushroom chitosan.

Chitosan is derived from chitin, a carbohydrate polymer synthesised by various arthropods, molluscs, and fungi. β-Glucans are polysaccharides of glucose molecules commonly found in oats, barley, edible fungi, seaweeds and brewer's yeast.

Mushroom chitosan would be used in a wide range of foods if approved. The applicant has requested that the usage level be the minimum level required to achieve the desired effect, following the principles of Good Manufacturing Practice (GMP),

1.3 The current standard

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

1.3.1 Permitted use

Paragraph 1.1.1—10(6)(a) of the Code provides that, unless expressly permitted by the Code, a food for sale cannot contain, as an ingredient or component, a substance that is used as a food additive.

Section 1.1.2—11 defines the expression 'used as a food additive'. Subsection 1.1.2—11(1) provides that a substance is 'used as a food additive' in relation to a food if both of the following conditions are met:

- the substance is added to the food to perform one or more technological functions listed in Schedule 14; and
- the substance is identified in subsection 1.1.2—11(2) – this includes (among other things) a substance identified in the table to section S15—5 as a permitted food additive.

Schedule 14 lists the permitted technological purposes of food additives. The table in section S14—2 provides that use as a preservative is a permitted purpose.

Section 1.3.1—3 details when substances are permitted to be used as food additives in food. The table to section S15—5 of Schedule 15 lists the specific food additive permissions for different classes of foods. Mushroom chitosan is not listed in Schedule 15.

[1] *Agaricus bisporus* is one of the most common and widely cultivated species of edible mushrooms. It includes several varieties, with the most familiar being white button mushrooms (champignon, immature form), brown button mushrooms (more mature form) and portobello mushrooms (fully mature).

Schedule 16 sets out the types of substances that may be used as food additives in foods at GMP levels. Mushroom chitosan is not listed in Schedule 16.

1.3.2 Identity and purity requirements

Paragraph 1.1.1—15(1)(a) requires substances used as food additives to comply with any relevant identity and purity specifications set out in Schedule 3 when added to food following the Code or sold for use in food. The Code has no relevant identity and purity specifications for mushroom chitosan.

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.

Standard 1.2.1 sets out the labelling and information requirements for food for sale, including if certain foods must bear a label or not, and the provisions that apply in each case.

Standard 1.2.4 generally requires packaged food to be labelled with a statement of ingredients. Subsection 1.2.4—7(1) requires food additives to be declared in the statement of ingredients by one of the following ways:

- if the food additive can be classified into a class of additives listed in Schedule 7 by referring to the relevant class name, followed in brackets by the name or code number of the food additive indicated in Schedule 8;
- otherwise—by referring to the name of the food additive as indicated in Schedule 8.

Note that Schedule 7 permits the use of 'preservative' as a prescribed class name.

Schedule 8 does not include a name for mushroom chitosan (i.e. chitosan and (1,3)-β-D-glucans extracted from white button mushrooms), as this substance is not currently permitted to be added to food as a food additive.

1.4 International Requirements

1.4.1 Codex Alimentarius and other 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 (Codex).

Codex STAN 192-1995 (also referred to as the General Standard for Food Additives, or GSFA) contains food additive listings by food category.

Only food additives that have been assigned an Acceptable Daily Intake (ADI) or determined, based on other criteria, to be safe by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) and have an International Numbering System (INS) designation by Codex are considered for inclusion in the GSFA.

JECFA has not evaluated chitosan or (1,3)-β-glucans extracted from white button mushrooms as a food additive, and the substances do not have an INS designation.

1.4.2 Other regulations

Mushroom chitosan:

- has GRAS status in the U.S. for use in a variety of foods and beverages as "Chitosan and 1,3-β-glucans from white button mushrooms (*Agaricus bisporus*)[2]"
- is approved for use as a preservative in Canada in a variety of foods and beverages and listed in Health Canada's List of Permitted Preservatives as an antibacterial (Class 2) and antifungal (Class 3) preservative as "Chitosan from *Agaricus bisporus* [3]
- is currently under review by the EU and the UK and is not yet approved
- is approved for use as a natural food additive for general food use in Japan and Korea[4].

1.5 Reasons for accepting the 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)
- it related to a matter that warranted the variation of a food regulatory measure.

1.6 Procedure for assessment

The application is being assessed under the General Procedure of the FSANZ Act.

2 Summary of the assessment

2.1 Risk Assessment

2.1.1 Food technology and antimicrobial activity assessment

FSANZ undertook a food technology assessment to determine if mushroom chitosan achieves its technological purpose in the quantity and form proposed (see Supporting Document 1 (SD1)).

FSANZ concludes:

- Mushroom chitosan is the chitin-glucan complex found in the cell wall of most fungi and yeasts.
- The information on the safety and efficacy of mushroom chitosan as a food preservative in various foods is consistent with its typical function of exhibiting antimicrobial properties against various microbes. Therefore, it functions as a food additive (preservative) for the purposes of the Code.
- There Code has no relevant identity and purity specifications for mushroom chitosan. Therefore, FSANZ proposes to include a specification for mushroom chitosan, i.e. chitosan and (1,3)-β-glucans extracted and purified from *A. bisporus*.
- Efficacy data demonstrate that mushroom chitosan has broad-spectrum antibacterial and antifungal preservative effects in various representative food matrices against microbes commonly associated with spoilage in these food matrices.

[2] GRAS Notice [GRN] 997
[3] M-FAA-24-05; Health Canada, 2024
[4] JCCRF, 2020; MFDS, 2020

2.1.2 Safety assessment

FSANZ also undertook a safety assessment of mushroom chitosan (see SD1). The production organism has a long history of safe human consumption and is not pathogenic or toxigenic. No adverse health effects of chitosan, oligomers, or monomers were observed in humans and other animals. Foods containing β–glucans have a long history of safe human use, and there is no evidence of adverse effects. In the absence of an identified hazard, mushroom chitosan, including consideration of dietary exposure, an Acceptable Daily Intake (ADI) of 'not specified' was established.

2.2 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 set out in this report, FSANZ decided to prepare a draft variation to the Code (Attachment A) to permit the proposed use of mushroom chitosan as a food additive in certain food at GMP levels following the Code; and to include a specification for mushroom chitosan with which this mushroom chitosan would have to comply when added to food for sale under the Code (or sold for such use).

The conclusions from the safety and dietary exposure assessments were that there is no evidence of a public health and safety concern associated with using mushroom chitosan at GMP levels.

In particular:

- The production organism (*A. bisporus*) has a long history of safe human consumption.
- There is no evidence of adverse effects of chitosan, chitosan oligomers or chitosan monomers, even when used at high levels in the form of food supplements.
- Foods containing β-glucans have a long history of safe human use.

FSANZ's food technology assessment concluded that mushroom chitosan is functioning as a food additive (preservative) for the purposes of the Code.

Efficacy data demonstrate that mushroom chitosan has broad-spectrum antibacterial and antifungal preservative effects in a wide variety of foods and beverages. This supports its use as an antimicrobial agent at GMP levels.

There are no relevant specifications for mushroom chitosan in the Code.

2.2.1 Permitted use

As noted in section 2 of the preamble to the Codex Alimentarius General Standard for Food Additives (GSFA, CODEX STAN 192-1995), an ADI of 'not specified' means the food additive does not represent a hazard to health. Use of the food additive must meet the requirements of GMP (as defined in section 3.3 of the GSFA and replicated in the definition in section 1.1.2—2 of the Code). It is, therefore, appropriate for such food additives to be listed in section S16—2.

Since mushroom chitosan's ADI is 'not specified,' it is appropriate for it to be permitted as an additive at GMP, i.e., listed in section S16—2, rather than having individual permissions with numeric MPLs in Schedule 15. There is a broad range of food categories within the table to section S15—5 to which 'additives permitted at GMP' are allowed.

2.2.2 Labelling

Food additives must be listed in the statement of ingredients in accordance with requirements set out in section 1.2.4—7 of the Code. This application seeks permission for the use of mushroom chitosan (chitosan and (1,3)-β-glucans extracted from white button mushrooms) as a preservative.

'Preservative' is a prescribed class name included in Schedule 7. The presence of mushroom chitosan in a food, when used as a preservative, must therefore be listed in the statement of ingredients for the food in accordance with paragraph 1.2.4—7(1)(a), i.e. by the class name 'preservative,' followed in brackets by the name of the substance as listed in Schedule 8.

FSANZ proposes to include 'mushroom chitosan' in Schedule 8 for this purpose. This name reflects the active anti-microbial and majority component in the food additive (chitosan – see SD1) and will therefore provide a name that represents the true nature of the additive.

Codex has not assigned an INS code number to mushroom chitosan, so an INS number cannot be included in Schedule 8 for use as part of the ingredient name. A dash ('-') will therefore be included in the INS column for this additive's entry in Schedule 8 (as well as in Schedule 16 (the Schedule listing the additives permitted at GMP levels). If Codex assigns an INS code number in the future, FSANZ will consider updating the Schedule.

There are some exemptions to the above requirements for foods for sale that are not required to bear a label. These exemptions are set out in section 1.2.1—6 of the Code and include foods that are made and packaged on the premises from which it is sold and foods that are packaged in the presence of the purchaser. Information requirements that still apply to food not required to bear a label are set out in section 1.2.1—9.

2.2.3 Specification

Section 1.1.1—15 requires that a substance used as a food additive comply with any relevant specification set out in Schedule 3 when added to food in accordance with the Code or sold for use in food. The Code does not provide relevant specifications for mushroom chitosan. The draft variation would insert a new specification for mushroom chitosan.

2.3 Risk communication

2.3.1 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 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.

FSANZ acknowledges the time taken by individuals and organisations to make submissions on this application.

Every submission on an application or proposal is considered by the FSANZ Board. All comments are valued and contribute to the rigour of our assessment.

2.3.2 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 relevant international standards (see section 1.4 above), however amending the Code to extend current permissions in Australia and New Zealand for the use of mushroom chitosan as a preservative in food and beverage products is unlikely to have a significant effect on international trade as such use is voluntary. 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.

2.4 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:

2.4.1 Section 29

2.4.1.1 Consideration of costs and benefits

Changes have been made to the Impact Analysis requirements by the Office of Impact Analysis (OIA). 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 required for the applications relating to food additives (OIA Reference: OIA23-06225). This is because applications relating to permitting the use of food additives 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 if 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 as a whole is likely to benefit, on balance, from a move from the status quo (where status quo is rejecting the application). This analysis considers permitting the use of mushroom chitosan as a food additive in food for sale.

The consideration of the costs and benefits in this section is 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 seeks to highlight the potential positives and negatives of moving away from the status quo by permitting use of the food additive in food for sale.

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.

2.4.1.2 Cost and benefits of permitting the use of this food additive

Industry may benefit from being able to use this food additive as a preservative. Due to the voluntary nature of the permission, industry will only use the food additive where they believe a net benefit exists for them.

If industry were to experience cost savings or increases because of using the food additive,

industry may pass on some of the cost savings or increases to consumers.

No safety concerns relevant to consumers have been identified.

Permitting the use of this food additive may result in a small, inconsequential cost to government in terms of an addition to the current range of food additives that are already monitored for compliance.

2.4.1.3 Conclusions from cost benefit considerations

FSANZ's assessment is that the direct and indirect benefits that would arise from permitting the use of this food additive most likely outweigh the associated costs.

2.4.1.4 Other measures

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

2.4.1.5 Any relevant New Zealand standards

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

2.4.1.6 Any other relevant matters

Other relevant matters are considered below.

2.4.2 Subsection 18(1)

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

2.4.2.1 Protection of public health and safety

FSANZ undertook a safety assessment (see section 2.2 above and the SD) and concluded there is no evidence of a public health and safety concern associated with the use of the additive as proposed in this report.

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

The labelling requirements for the additive are discussed in sections 1.3.3 and 2.2.2 of this report.

2.4.2.2 The prevention of misleading or deceptive conduct

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

2.4.3 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**

There are relevant international specifications with which the additive would have to comply with if added to foods as proposed in this report, as referenced in sections 1.3.2 and 1.4 above.

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

If the draft variation is approved, it would bring Australia and New Zealand into line with permissions for its use in other countries as outlined in section 1.4.2 above. In this way, Australia and New Zealand would remain competitive with other international markets. This would also help foster continued innovation and improvements in food manufacturing techniques and processes.

Ultimately, the domestic food industry will make their own economic decisions, considering the costs and benefits of using mushroom chitosan, to determine if it is of benefit to their business.

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

No issues were identified for this application that were 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' includes specific order policy principles for substances added to achieve a solely technological function, such as food additives. These specific order policy principles state that permission should be granted where:

(a) the purpose for adding the substance can be articulated clearly by the manufacturer as achieving a solely technological function (i.e. the 'stated purpose')

(b) the addition of the substance to food is safe for human consumption

(c) the amounts added are consistent with achieving the technological function

(d) the substance is added in a quantity and a form which is consistent with delivering the stated purpose

(e) no nutrition, health or related claims are to be made regarding the substance.

Following assessment as outlined in this report and the SD, FSANZ has determined that permitting the use of the food additive as proposed in this report is consistent with the above principles.

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

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 (Application A1315 – Chitosan and (1,3)-β-glucans from white button mushrooms (*Agaricus bisporus*) as a food additive) 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 the Delegate]

[Insert name 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 A1315 – Chitosan and (1,3)-β-glucans from white button mushrooms (*Agaricus bisporus*) as a food additive) Variation*.

2 Variation to standards in the *Australia New Zealand Food Standards Code*

The Schedule varies Standards in the *Australia New Zealand Food Standards Code*.

3 Commencement

The variation commences on the date of gazettal.

Schedule

Schedule 3—Identity and Purity

[1] Subsection S3—2(2) (table)

Insert:

mushroom chitosan	section S3—55

[2] After section S3—54

Insert:

S3—55 Specification for mushroom (*Agaricus bisporus*) chitosan

For mushroom (*Agaricus bisporus*) chitosan, the specifications are the following:

(a) chemical structure—a natural co-polymer and comprises a chitin moiety (N-acetyl-d-glucosamine units) covalently linked to a beta-glucans moiety (glucose units);

(b) description—white to beige, odourless and flavourless powder, almost completely insoluble in aqueous or organic medium;

(c) average molecular weight—10 to 400 kDa;

(d) degree of deacetylation—70.0 to 95.0 mol%;

(e) water—less than 5.0%;

(f) total chitosan content on a dry weight basis—not less than 95.0%;

(g) total beta-glucan content on a dry weight basis—not more than 5.0%.

Schedule 8—Food additive names and code numbers (for statement of ingredients)

[3] Subsection S8—2 (table titled "Food additive names—alphabetical listing")

Insert:

Mushroom chitosan	–

[4] Subsection S8—2 (table titled "Food additive names—numerical listing", after the table item dealing with "Monk fruit extract or luo han guo extract")

Insert:

–	Mushroom chitosan

Schedule 16—Substances that may be used as food additives

[5] Subsection S16—2 (table titled "Additives permitted at GMP—alphabetical listing")

Insert:

Mushroom chitosan	–

[6] Subsection S16—2 (table titled "Additives permitted at GMP—numerical listing", after the table item dealing with "Monk fruit extract (luo han guo extract)")

Insert:

– Mushroom chitosan

Attachment B – Draft Explanatory Statement

DRAFT EXPLANATORY STATEMENT

Food Standards Australia New Zealand Act 1991

Food Standards (Application A1315 – Chitosan and (1,3)-β-glucans from white button mushrooms (*Agaricus bisporus*) as a food additive) 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 developing 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 A1315, which seeks to permit a mixture of chitosan and (1,3)-β-glucans extracted from white button mushrooms (*Agaricus bisporus*) as a food additive for use as a preservative in food and beverage products. The Authority considered the Application in accordance with Division 1 of Part 3 and has prepared a draft variation - the *Food Standards (Application A1315 – Chitosan and (1,3)-β-glucans from white button mushrooms (*Agaricus bisporus*) as a food additive) 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 to:

- Amend Schedule 16 of the Code to permit mushroom chitosan as a food additive at GMP levels.
- Insert a new specification for mushroom chitosan in Schedule 3.
- Amend Schedule 8 to prescribe the name that must be listed on the statement of ingredients on a label of food containing mushroom chitosan in accordance with section 1.2.4—7.

4. Documents incorporated by reference

The draft variation does not incorporate any documents by reference.

However, if approved, the draft variation would vary Schedule 3 of the Code which does incorporate documents by reference. Section 1.1.1—15 of the Code requires certain substances (such as substances used as food additives) to comply with any relevant identity and purity specifications listed in Schedule 3.

Schedule 3 incorporates documents by reference to set specifications for various substances in the circumstances specified in that Schedule. The documents incorporated include: the Joint FAO/WHO Expert Committee on Food Additives (JECFA) Combined Compendium of Food Additive Specifications (FAO JECFA Monographs 26 (2021)); the United States Pharmacopeial Convention (2022) Food Chemicals Codex (13th edition); and the Commission Regulation (EU) No 231/2012.

5. Consultation

In accordance with the procedure in Division 1 of Part 3 of the FSANZ Act, the Authority's consideration of Application A1315 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 be open for a 6-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 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 Regulatory Impact Statement (RIS). FSANZ's assessment is that a RIS is not required for this application. Prior to these changes, the OIA advised FSANZ that a RIS was not required for applications relating to food additives. This is because applications relating to permitting the use of food additives 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 RIS for application A1315 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*.

[5] Formerly known as the Office of Best Practice Regulation (OBPR)

7. Variation

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 A1315 – Chitosan and (1,3)-β-glucans from white button mushrooms (*Agaricus bisporus*) as a food additive) 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.

Item [1] and **[2]** of the Schedule to the variation would amend Schedule 3 of the Code.

Schedule 3 contains specifications for the purposes of section 1.1.1—15 of the Code. Section 1.1.1—15 requires certain substances, e.g. substances used as food additives, to comply with any relevant identity and purity specifications listed in Schedule 3 when added to food in accordance with the Code or sold for use in food. Specifications include those set out in provisions which are listed in the table to subsection S3—2(2) (see paragraph S3—2(1)(a)).

Item [1] would insert into columns 1 and 2 of the table to subsection S3—2(2), in

alphabetical order, new references to 'mushroom chitosan' and 'section S3—55' respectively. These new references relate to the new provision that would be inserted by **item [2]** below.

Item [2] would insert a new section S3—55 into Schedule 3 which sets out the specifications relating specifically to mushroom chitosan, the new substance sought to be permitted by the applicant.

Consequently, the proposed permission for mushroom chitosan to be used as a food additive would be subject to the requirement in section 1.1.1—15 that the substance must comply with these specifications when added to food in accordance with the Code or sold for use in food.

Items [3]- and **[4]** of the Schedule to the draft variation would amend Schedule 8 of the Code.

Schedule 8 contains the food additive names and code numbers that are required to be used on the statement of ingredients in accordance with subsection 1.2.4—7(1); and for the definition of code number in section 1.1.2—2.

Items [3] and **[4]** would amend Schedule 8 by inserting 'mushroom chitosan' into each of the following tables to section S8—2:

- the table titled 'Food additive names—alphabetical listing'—to be inserted in alphabetical order
- the table titled 'Food additive names—numerical listing'—to be inserted after the table item dealing with 'Monk fruit extract or luo han guo extract'.

No INS number (or code number as it is referred to in Schedule 8) is included in those entries as there is no current INS number for mushroom chitosan. So, a dash (-) would be included in place of an INS or code number in both tables.

Items [5] and **[6]** of the Schedule to the draft variation would amend Schedule 16 of the Code.

Schedule 16 of the Code sets out additives permitted at GMP (in alphabetical and numerical listings).

Items [5] and **[6]** would amend Schedule 16 by inserting 'mushroom chitosan' into each of the following tables under S16—2:

- the table titled ‘Additives permitted at GMP—alphabetical listing’—to be inserted in alphabetical order
- the table titled ‘Additives permitted at GMP—numerical listing’—to be inserted after the table item dealing with ‘Monk fruit extract (luo han guo extract)’.

No INS number is included in those entries as there is no current INS number for mushroom chitosan. So, a dash (-) would be included in place of an INS or code number in both tables.

The effect of these proposed amendments would be to permit the use of mushroom chitosan as an ‘additive permitted at GMP’ in accordance with the Code. Paragraph 1.1.1—10(6)(a) and section 1.3.1—3 of the Code permit the use as a food additive of ‘additives permitted at GMP’ in accordance with Schedule 15 of the Code. Schedule 15 lists certain foods in which ‘additives permitted at GMP’ may be used as a food additive. Subsection 1.3.1—4(1) of the Code provides that an additive permitted at GMP that is permitted to be used as a food additive by Schedule 15 may be present in a food for sale as a result of use in accordance with GMP. ‘GMP’ or Good Manufacturing Practice is defined in section 1.1.2—2 of the Code.