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

3 July 2025

347-25

Approval report – 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 amend the Australia New Zealand Food Standards Code to permit a combination of chitosan and (1,3)-β-glucans extracted from white button mushrooms (*Agaricus bisporus*) as a preservative in food and beverage products.

On 25 March 2025, FSANZ sought submissions on a draft variation and published an associated report. FSANZ received 5 submissions.

FSANZ approved the draft variation on 26 June 2025. The Food Ministers' Meeting[1] was notified of FSANZ's decision on 3 July 2025.

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

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

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Supporting document

The following document which informed the assessment of this application is available from the A1315 page of the FSANZ website:

SD Risk and technical assessment report (at approval)

The published submissions from the call for submissions can be found on the A1315 Consultation Hub page.

Executive summary

Chinova Bioworks Inc. has applied to Food Standards Australia New Zealand (FSANZ) to amend the Australia New Zealand Food Standards Code (the Code) to permit mushroom chitosan (chitosan and (1,3)-β-glucans[2]) sourced from white button mushrooms (*Agaricus bisporus*) as a preservative in a range of food and beverage products.

Agaricus bisporus is one of the most common and widely cultivated species of edible mushrooms. It includes several varieties, including white button mushrooms (champignon, immature form), brown button mushrooms (more mature form) and portobello mushrooms (fully mature). Different varieties are not meaningfully different in terms of being a source of mushroom chitosan.

Mushroom chitosan is the chitin-glucan complex found in the cell walls of most fungi and yeasts, and the composition of mushroom chitosan is similar across fungal sources—not limited to just white button mushrooms (*Agaricus bisporus*). The Code does not currently permit the use of mushroom chitosan from *A. bisporus* 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 from *A. bisporus* 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 no public health and safety concerns are associated with using mushroom chitosan from *A. bisporus* at Good Manufacturing Practice (GMP) levels.

Following assessment and preparation of a draft variation, FSANZ called for submissions from 25 March 2025 to 6 May 2025. FSANZ received a total of 5 submissions from jurisdictions, the food industry and individuals, which supported the draft variation. Several issues were raised in these submission, which FSANZ has addressed, including whether the presence of β-glucan in mushroom chitosan could exacerbate food allergies.

Based on the information above, and for the reasons set out in this report, FSANZ has approved the draft variation proposed at the call for submissions, with amendments.

The approved draft variation:

- inserts a new specification for mushroom chitosan into Schedule 3 of the Code, with which mushroom chitosan extracted from any mushrooms from the *A. bisporus* species would have to comply when used as a food additive in accordance with the Code (or sold for such use)
- amends 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
- amends Schedule 16 of the Code by listing mushroom chitosan from *A. bisporus* as an 'additive permitted at GMP' for the purposes of (among other things) Schedule 15. Schedule 15 of the Code lists permissions for certain substances to be used as food additives (including 'additives permitted at GMP') in a range of food.

[2] (1,3)-β-glucans are also referred to as β-1,3-Glucan, β-D-Glucan, (1→3), (1→3)-β-D-Glucan. Please refer to the Supporting Document for details

1 Introduction

1.1 The applicant

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

1.2 The application

This application sought to amend the Australia New Zealand Food Standards Code (the Code) to permit the use of a combination of chitosan and (1,3)-β-glucans extracted from white button mushrooms[3] (*A. bisporus*) as a preservative in a range of food and beverage products. In the application, this combination 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 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 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)(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
- 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 and an 'additive permitted at GMP' (i.e., a substance that is listed in section S16—2).

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 in 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.

Schedule 16 lists 'additives permitted at GMP' i.e. substances that may be used as food additives in foods if their use is in accordance with GMP. Mushroom chitosan from *A.*

[3] *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).

bisporus is not listed in Schedule 16.

'Additives permitted at GMP', which are listed in Schedule 16, are permitted to be used as food additives in a range of food in Schedule 15.

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 in accordance with 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 requirements that apply in each case.

Standard 1.2.1 generally requires packaged food to be labelled with a statement of ingredients in accordance with Standard 1.2.4. Subsection 1.2.4—7(1) requires food additives to be declared in the statement of ingredients in 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 Schedule 7 lists optional and prescribed class names for food additives for the purposes of section 1.2.4—7 and, in particular, lists 'preservative' as a prescribed class name for food additives.

Schedule 8 lists food additive names and any associated code numbers for the purposes of section 1.2.4—7 but does not include a name for mushroom chitosan as this substance is not currently permitted to be added to food for use as a food additive.

1.4 International standards

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 Commission (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 are determined to be safe, based on other criteria, 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 *A. bisporus* as a food additive, and the substances do not have an INS designation.

1.4.2 Other regulations

Mushroom chitosan:

- has Generally Recognised As Safe (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*)[4]"
- is approved for use as a preservative in Canada in a variety of foods and beverages and is listed in Health Canada's List of Permitted Preservatives as an antibacterial (Class 2) and antifungal (Class 3) preservative as "Chitosan from *Agaricus bisporus* [5]
- 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[6].

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 of the FSANZ Act.

1.7 Decision

For the reasons outlined in this report, FSANZ decided to approve a draft variation amending the Code to permit mushroom chitosan (chitosan and (1,3)-β-glucans) extracted from *A. bisporus* as a preservative in a range of foods.

The draft variation proposed at the call for submissions was approved with the following amendments after FSANZ had regard to all submissions:

- The name of the variation has been changed to: *Food Standards (Application A1315 – Chitosan and (1,3)-β-glucans from* Agaricus bisporus *as a food additive) Variation*.
- The specifications have been amended to specify *Agaricus bisporus* as the source of mushroom chitosan.
- The name of the substance in the table to subsection S3—2(2) was changed to 'mushroom (*Agaricus bisporus*) chitosan' for consistency with the heading of the new specification for this substance in Schedule 3.
- The references to the name of the additive permitted at GMP in Schedule 16 has been amended to 'Mushroom (*Agaricus bisporus*) chitosan'

The approved draft variation takes effect on gazettal and is at Attachment A.

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

The draft variation to the Code (at the consultation stage) is at Attachment C.

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

2 Summary of the findings

2.1 Summary of issues raised in submissions

FSANZ received a total of 5 submissions to the call for submissions between 25 March 2025 and 6 May 2025 (See Table 1 below). The submissions are publicly available on the FSANZ website A1315 Consultation hub page.

Four submissions supported approval of the draft variation. The New Zealand Food & Grocery Council (NZFGC) supported the draft variation proposed in the call for submissions, assuming that no allergenicity concerns remain after FSANZ has assessed whether the presence of β-glucan in mushroom chitosan could exacerbate food allergies. FSANZ has addressed this matter, with the response to this and other issues raised in submissions provided in Table 1 below.

Table 1. Summary of issues raised in submissions and FSANZ's response

Issues raised	FSANZ response
Private individual	
Supports the proposed variation to the Food Standards Code	Noted
New Zealand Food & Grocery Council (NZFGC)	
NZFGC supports the proposed variation to the Code. NZFGC is aware of some studies that appear to indicate that the presence of β-glucan may worsen food allergies in experimental models. Given its presence in the additive, further examination is recommended. Assuming no allergenicity concerns remain after the above assessment is conducted, NZFGC supports the variation as drafted.	FSANZ has considered the potential of β-glucan in mushroom chitosan to exacerbate food allergies. • β-glucan has an extensive history of safe consumption in food – there are no reports in humans of β-glucan (as opposed to chitosan) acting as a food allergen or an adjuvant to a food allergen • FSANZ reviewed the publication by He *et al* (2023)[7] which reports such an adjuvant effect in a murine model. FSANZ notes that the dietary level of β-glucan in the study was higher than expected human exposure. It is noted that spontaneous sensitisation murine models poorly replicate human food allergy (Kanagaratham et al 2018)[8]. • FSANZ concludes there is no allergenicity concern that the presence of the β-glucan component in mushroom chitosan could exacerbate food allergies. FSANZ has amended the appropriate section of the Supporting Document (SD) to provide additional information on β-glucan.
New Zealand Food Safety (NZFS)	
Agree with FSANZ's assessment that mushroom chitosan at GMP levels poses no public health concerns and is technologically justified. FSANZ has set an ADI of 'not specified' for mushroom chitosan due to the absence of identified hazards.	Noted.
Private individual	
The proposal lacks details on microbial hurdles or HACCP to prevent	FSANZ assessed the applicant's HACCP plan and manufacturing process. Because of the confidential nature of this information, full

[7] He et al (2023) β-1,3-glucan, but not β-1,3/1,6-glucan, exacerbates experimental food allergy, while both increase IgA induction. Allergy https://doi.org/10.1111/all.15841

[8] Kanagaratham et al (2018). Experimental models for studying food allergy. Cellular and Molecular Gastroenterology and Hepatology 6(3): 356-369

Issues raised	FSANZ response
pathogenic bacteria transmission in case of failure. Are additional measures beyond GMP needed for microbial safety, such as heat treatment or separating the process's inlet and outlet? While cGMP may suffice, FSANZ should ensure that the proposed and future processes guarantee microbial quality.	details could not be disclosed in FSANZ's public assessment. FSANZ found no health and safety risks.
NSW Food Authority (NSWFA)	
Agree with FSANZ that the use of mushroom chitosan as a food additive (preservative) is technologically justified and poses no public health and safety concerns at the GMP level. However, NSWFA: 1. Requests clarification on whether approval as a food additive prevents using the same material to achieve beneficial physiological effects.	Noted. No. For the purposes of this application, the approved draft variation permits the use of mushroom chitosan extracted from *A. bisporus* only as a food additive (specifically as a preservative in a range of food). This does not prevent using the same material for a different purpose. However, we note that any uses other than as a preservative may require a variation to the Code.
2. Is concerned that an extension of the use as a food additive may raise questions about whether the definition of a nutritive substance is also relevant. 3. Questions if adding mushroom chitosan as a food additive and a food ingredient (dietary fibre) is possible. Unclear if a product containing mushroom chitosan beyond the GMP level as a food additive can make compliant dietary fibre claims.	There is no such concern. For the purposes of this application, the permission related to mushroom chitosan will be restricted to mushroom chitosan being used as a preservative in accordance with the Code (i.e. not as fibre or other for other purposes). That permission will not extend nor limit potential uses for other purposes, such as a nutritive substance or food ingredient. The definition of 'nutritive substance' is outside the scope of and not relevant for the purposes of this application.
5. Requests further clarification on the boundaries of the permission through A1315. This issue originates from the ambiguity in the Code's current definition of nutritive substance. Therefore, we urge FSANZ to consider this matter through P1024.	Noted.
6. Recommends amending the title of section S3—55 to 'Specification for mushroom chitosan', to ensure consistency with the specifications.	Amendments made.
7. Recommends adding the source species (*A. bisporus*) to the proposed specifications unless a discussion on permitting mushroom chitosan from any other sources is added to the report.	FSANZ has added the source species (*A. bisporus*) to the proposed specifications.
8. Is unaware of any existing approval in the Code for chitosan from any source as a food additive. The SD implies there are additive permissions for mushroom chitosan.	FSANZ agrees there are no existing approvals of chitosan as a food additive and has made amendments to the SD to clarify this.

2.2 Risk assessment

2.2.1 Food technology assessment and antimicrobial activity assessment

FSANZ undertook a food technology assessment to determine if mushroom chitosan from *A. bisporus* achieves its technological purpose in the quantity and form proposed (see SD1).

Mushroom chitosan is a copolymer of chitosan and (1,3)-β-glucans.

FSANZ concludes:

- Mushroom chitosan is the chitin-glucan complex found in the cell wall of most fungi and yeasts.
- The species *A. bisporus*, the source of mushroom chitosan in this application, includes several varieties. The different varieties are not meaningfully different from a Risk Assessment perspective.
- The composition of mushroom chitosan is similar across fungal sources.
- 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.
- The Code has no relevant identity and purity specifications for mushroom chitosan from *A. bisporus*. Therefore, FSANZ proposes to include a specification for mushroom chitosan.
- 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.

2.2.2 Safety assessment

FSANZ undertook a safety assessment of mushroom chitosan from *A. bisporus* (see SD1).

The assessment found there are no public health or safety concerns associated with using mushroom chitosan at GMP levels.

A comprehensive scientific literature search revealed only one case of an allergic reaction to chitosan administered orally. FSANZ did not find any cases of human food allergy due to β-glucan. Based on weight-of-evidence, FSANZ concludes that potential allergy to mushroom chitosan is very rare. The production organism (i.e. *A. bisporus*) has a long history of safe human consumption and is not pathogenic or toxigenic. No adverse health effects of the chitosan component of mushroom 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 and following consideration of dietary exposure, an ADI of 'not specified' was established.

2.3 Risk management

Following the assessment, FSANZ prepared a draft variation and called for submissions on that draft variation from 25 March 2025 to 6 May 2025.

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

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

Having regard to the submissions received, and for the reasons set out in this report, FSANZ considers it appropriate to approve the draft variation proposed following assessment with

amendments (Section 1.7) (Attachment A).

The safety and dietary exposure assessments concluded 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. Different varieties of *A. bisporus* are equally safe and suitable for human consumption.
- There is no evidence of adverse effects of chitosan (one component of mushroom chitosan) chitosan oligomers or monomers, even when used at high levels in the form of food supplements.
- Foods containing β-glucans have a long history of safe human consumption.

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

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

While the composition and characteristics of chitosan extracted from *A. bisporus* can vary due to several factors, the composition of mushroom chitosan is similar across fungal sources. Setting out specifications ensures that mushroom chitosan from *A. bisporus* will function and be permitted as a preservative for the purposes of the Code.

There are no relevant specifications for mushroom chitosan from *A. bisporus* in the Code.

2.3.1 Permitted use

As noted in section 2 of the preamble to the Codex Alimentarius GSFA (CODEX STAN 192-1995), an ADI of 'not specified' means the food additive does not represent a hazard to health. The 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 the ADI of mushroom chitosan from *A. bisporus* is 'not specified,' it is appropriate for this mushroom chitosan to be permitted as an additive at GMP i.e. listed in the table to section S16—2, rather than having individual permissions with numeric maximum permitted levels 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.

2.3.2 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 sought permission to use mushroom chitosan (chitosan and (1,3)-β-glucans) extracted from *A. bisporus* as a preservative.

'Preservative' is a prescribed class name for food additives 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.

Schedule 8 will be amended to include 'mushroom chitosan' 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 from *A. bisporus*, so an INS number cannot be included in Schedule 8 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 additives permitted at GMP levels). If Codex assigns an INS code number in the future, FSANZ will consider updating those schedules.

There are some exemptions to the above requirements for foods for retail 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 made and packaged on the premises where 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.

Where food is sold to a caterer, the statement of ingredients containing declarations of food additives must be set out in the label of that food (if any); or provided in documentation provided to the caterer (see subsection 1.2.1—16)."

2.3.3 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 approved draft variation will insert a new specification for mushroom chitosan extracted from *A. bisporus*.

2.3.4 Risk management conclusion

The risk management conclusion is to permit using mushroom chitosan from *A. bisporus* as a preservative in a range of foods.

The specification for mushroom chitosan from *A. bisporus* will be inserted into Schedule 3 of the Code, with which chitosan and (1,3)-β-glucans extracted from any mushroom in the *A. bisporus* species (including white button mushrooms) would have to comply when used as a food additive (or sold for such use). The specifications ensure that mushroom chitosan from *A. bisporus* will function as a preservative for the purposes of the Code.

Schedule 8 will be amended to include 'mushroom chitosan' as the food additive name that must be provided when declaring the proposed food additive in a statement of ingredients in accordance with section 1.2.4—7.

Schedule 16 of the Code will be amended to list 'mushroom (*Agaricus bisporus*) chitosan' as an additive permitted at GMP. Therefore, under Schedule 15, mushroom chitosan from *A. bisporus* will then be permitted to be used as an additive permitted at GMP in various classes of food, including beverage products. However, its use, including the maximum permitted level or amount of the additive present in the food, will have to be consistent with GMP.

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 FSANZ Notification Circular, media release, FSANZ's digital channels and Food Standards News.

The process by which FSANZ considers standards development matters is open, accountable, consultative and transparent. Public submissions were called to assist consideration of the draft variation to the Code.

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

The FSANZ Board had regard to all submissions received during the call for submissions period when considering approval of the draft variation.

2.5 FSANZ Act assessment requirements

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

2.5.1 Section 29

2.5.1.1 Consideration of costs and benefits

Changes have been made to the impact analysis requirements set 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 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 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 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.

2.5.1.2 Costs and benefits of permitting the proposed use of this additive

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

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

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

2.5.1.3 Conclusions from cost benefit assessment

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. No further information was received during the consultation process that changed that assessment.

2.5.1.4 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.

2.5.1.5 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.

2.5.1.6 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 additive.

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 mushroom chitosan in accordance with the Code to enable consumers to make informed choices (see sections 1.3.3 and 2.3.2 of this report).

2.5.2.3 The prevention of misleading or deceptive conduct

No issues were identified with this application that were 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**

There will be relevant specifications in the Code, with which the additive would have to comply when added to foods as proposed in this report (or sold for such use), as referenced in section 1.3.2 above. However, there are no international specifications which will be relevant for this substance (see section 1.4 above).

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

Details on international permissions for use of the additive that is the subject of this application were provided as confidential commercial information and considered as part of this assessment.

The amendments in the draft variation will bring Australia and New Zealand into line with other countries where this substance is permitted to be used as a food additive. 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 its own economic decisions, considering the costs and benefits of using mushroom chitosan, to determine if it benefits their 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*[9] 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:

- 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.

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.

Attachments

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

B. Explanatory Statement

C. Draft variation to the Australia New Zealand Food Standards Code (call for submissions)

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

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

Food Standards (Application A1315 – Chitosan and (1,3)-β-glucans from *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* 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 (*Agaricus bisporus*) 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) source–*Agaricus bisporus*.

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

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

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

(f) water—less than 5.0%;

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

(h) 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 (*Agaricus bisporus*) 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 (*Agaricus bisporus*) chitosan

Attachment B–Explanatory Statement

EXPLANATORY STATEMENT

Food Standards Australia New Zealand Act 1991

Food Standards (Application A1315 – Chitosan and (1,3)-β-glucans from* 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 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 A1315, which sought to amend the Code to permit the use of a combination of chitosan and (1,3)-β-glucans extracted from *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 approved a draft variation – the *Food Standards (Application A1315 – Chitosan and (1,3)-β-glucans from* Agaricus bisporus *as a food additive) Variation* (the approved draft variation).

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

2. Variation is a legislative instrument

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

This instrument is not subject to the disallowance or 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 permit a combination of chitosan and (1,3)-β-glucans (mushroom chitosan) extracted from *Agaricus bisporus* to be used as a food additive in a range of food, including beverages, in accordance with the Code. The amendments include:

- Amending Schedule 16 of the Code to list 'mushroom (*Agaricus bisporus*) chitosan' as an additive permitted at GMP.
- Inserting a new specification for mushroom chitosan extracted from *Agaricus bisporus* in Schedule 3 of the Code.
- Amending Schedule 8 of the Code to list 'mushroom chitosan' as the food additive name that must be listed in the statement of ingredients for food containing mushroom chitosan in accordance with section 1.2.4—7.

4. Documents incorporated by reference

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

However, the approved draft variation will 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 when added to food in accordance with the Code (or sold for such use).

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 included one round of public consultation following an assessment and the preparation of a draft variation and associated report. Submissions were called for over a consultation period from 25 March 2025 until 6 May 2025. 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) [10]. 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.

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

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 A1315 – Chitosan and (1,3)-β-glucans from* 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.

Items [1] and **[2]** of the Schedule to the variation 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] inserts a new entry into the table to subsection S3—2(2) consisting of the substance 'mushroom (*Agaricus bisporus*) chitosan' in alphabetical order in column 1 and its associated provision 'section S3—55' in column 2. These new references relate to the new provision that would be inserted by **item [2]** below.

Item [2] inserts a new section S3—55 into Schedule 3 which sets out the specifications relating specifically to mushroom chitosan from *Agaricus bisporus*, which includes the substance sought to be permitted by the applicant.

Agaricus bisporus is the species name of several varieties of mushrooms, including white button mushrooms.

Consequently, the permission for this mushroom chitosan to be used as a food additive is 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 variation 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]** 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 from *Agaricus bisporus*. So, a dash (-) is included in place of an INS or code number in both tables.

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

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

listings). ‘GMP’ or Good Manufacturing Practice is defined in section 1.1.2—2 of the Code.

Subsection 1.3.1—3 provides that a substance may be used as a food additive in relation to food if (among other things):

- the substance is permitted to be used as a food additive for that food by Schedule 15; and
- any restrictions on the use of that substance as a food additive set out in this Standard or in Schedule 15 are complied with.

Schedule 15 lists a range of foods, including beverage products, in which ‘additives permitted at GMP’ may be used as food additives.

Items [5] and **[6]** amend Schedule 16 by inserting ‘mushroom (*Agaricus bisporus*) chitosan’ into each of the following tables to section 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 from *Agaricus bisporus*. So, a dash (-) is included in place of an INS or code number in both tables.

The effects of amendments in **items [5]** and **[6]** are:

- mushroom chitosan from *Agaricus bisporus* is an ‘additive permitted at GMP’,
- as an ‘additive permitted at GMP’, mushroom chitosan from this source is permitted to be used as a food additive in a range of food, including beverage products, as set out in Schedule 15, in accordance with the Code,

This permission is subject to the condition that an ‘additive permitted at GMP’ 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 (see subsection 1.3.1—4(1) of the Code).

Attachment C–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

---

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