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388-26

Call for submissions – Application A1306

Chitosan from white button mushrooms (*Agaricus bisporus*) for use as a processing aid

Food Standards Australia New Zealand (FSANZ) has assessed an application made by AB Mauri to permit the use of chitosan extracted from white button mushrooms (*Agaricus bisporus*) as a processing aid in wine, beer, cider and other alcoholic beverages.

On the basis of this assessment, FSANZ has prepared a draft food regulatory measure permitting the use of mushroom (*A. bisporus*) chitosan as a fining and antimicrobial agent in wine, sparkling wine and fortified wine produced in Australia. 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](#). 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: 11:59pm (Canberra time) 28 May 2026

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 A1306 page¹ on the FSANZ website:

SD1 Risk and technical assessment report

¹ <https://www.foodstandards.gov.au/food-standards-code/applications/a1306-chitosan-agaricus-bisporus-processing-aid>

Executive summary

Food Standards Australia New Zealand (FSANZ) has assessed an application from AB Mauri to amend the Australian New Zealand Food Standards Code (the Code) seeking to permit the use of chitosan extracted from white button mushrooms (*Agaricus bisporus*) as a processing aid in wine, beer, cider and other alcoholic beverages.

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*).

Assessing a permission for chitosan from any variety of *A. bisporus* is consistent with FSANZ's risk assessment approach, which evaluates the source organism at the species level, not the varietal or developmental form.

Mushroom (*A. bisporus*) chitosan is listed as an 'additive permitted at GMP' in Schedule 16 of the Code and as such, is permitted by the Code to be used as a food additive at levels consistent with Good Manufacturing Practice (GMP) in various foods (see section 1.3.1—3 and Schedule 15 of the Code). Also, according to section 1.3.3—4 of the Code, an 'additive permitted at GMP' may be used as a processing aid in any food, including wine, beer, cider and other alcoholic beverages. This includes their use as a processing aid in wine (including sparkling and fortified wine) produced and sold in New Zealand, as well imported into and sold in Australia (including from New Zealand).

However, wine, sparkling wine and fortified wine produced in Australia must comply with the requirements of Standard 4.5.1 – Wine production requirements, which is an Australia-only standard. For Australian wine industry purposes, Standard 4.5.1 provides a definitive list of permitted processing aids and food additives for wine, sparkling wine and fortified wine produced in Australia. The Standard underpins several international trade arrangements, including the European Union (EU) Wine Agreement and the World Wine Trade Group Mutual Acceptance Agreement, which reference Standard 4.5.1 as the basis for what is permitted in Australian wine. Clause 4 to Standard 4.5.1 lists the substances permitted for use as processing aids in the production of wine, sparkling wine and fortified wine in Australia. Chitosan from *A. bisporus* is not currently listed as a permitted substance in clause 4.

Based on the above, FSANZ has assessed the proposed use of chitosan from *A. bisporus* as a processing aid for the production of wine, sparkling wine and fortified wine in Australia, for the purposes of Standard 4.5.1 of the Code.

FSANZ's assessment concluded that chitosan from *A. bisporus* performs its technological function in fining and microbial stabilisation during the production of wine, sparkling wine and fortified wine - not in the final product, and, as such, meets the definition of a processing aid for the purposes of the Code. There is a relevant identity and purity specification for chitosan from *A. bisporus* in section S3—55 of the Code, with which this substance would have to comply whenever the substance is added to food in accordance with the Code or sold for use in food.

FSANZ's risk assessment concluded there are no safety concerns from the use of chitosan from *A. bisporus* in the quantity and form required to perform its technological function in microbial stabilisation and fining in the production of wine, sparkling wine or fortified wine, which must be consistent with GMP. Fungal chitosan is already approved as a fining and antimicrobial treatment in wine in the European Union. In addition, chitosan from *A. bisporus* is approved as an antibacterial and antifungal preservative in Canada and in the United States of America in a range of foods.

Following assessment, for the reasons set out in this report, FSANZ has prepared a draft variation that, if approved, would amend Standard 4.5.1 by:

- listing 'mushroom (*Agaricus bisporus*) chitosan' in the table to clause 4 as a permitted processing aid in the production of wine, sparkling wine and fortified wine, and
- specifying that 'mushroom (*Agaricus bisporus*) chitosan' may only be used in the production of wine, sparkling wine and fortified wine as a fining and antimicrobial agent, consistent with the scope of the FSANZ assessment.

If approved, that permission would be subject to the condition that the maximum permitted level or amount of that substance that may be present in the food must be consistent with GMP.

In accordance with paragraph 1.1.1—15(1)(b) of the Code, mushroom (*A. bisporus*) chitosan used for this purpose under Standard 4.5.1 would be required to meet relevant specifications listed in Schedule 3 of the Code when added to wine, sparkling wine or fortified wine, in accordance with the Code, or sold for use in that food.

If approved, the effect of the draft variation would be to allow the proposed use of mushroom (*A. bisporus*) chitosan as a processing aid in wine, sparkling wine and fortified wine produced in Australia in accordance with the Code. This is consistent with existing permissions for its use as a processing aid in wine (including sparkling and fortified wine) produced and sold in New Zealand, as well imported into and sold in Australia (including from New Zealand).

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

1 Introduction

1.1 The applicant

The applicant is AB Mauri, a manufacturer of yeast and bakery ingredients. AB Biotek, a business division of AB Mauri, specialises in fermentation products for the alcoholic beverage industry.

1.2 The application

AB Mauri has applied to Food Standards Australia New Zealand (FSANZ) to amend the Australia New Zealand Food Standards Code (the Code) to permit the use of chitosan extracted from white button mushrooms (*Agaricus bisporus*) as a fining and microbial stabilisation agent in wine, beer, cider and other alcoholic beverages.

Chitosan is derived from chitin, a carbohydrate polymer synthesised by various arthropods, molluscs and fungi. Chitosan has antimicrobial effects that decrease the growth of yeast and bacterial species. Chitosan also acts to remove impurities, such as contaminants. *A. bisporus* is one of the most common and widely cultivated species of edible mushrooms and includes several varieties, with the most familiar being white button mushrooms (in an immature form), brown button mushrooms (in a more mature form) and portobello mushrooms (in a fully mature form).

FSANZ has previously assessed an application² to permit the use of a mixture of chitosan and (1,3)- β -D-glucans extracted from *A. bisporus* as a food additive in food and beverage products. Mushroom (*A. bisporus*) chitosan is listed as an 'additive permitted at GMP' in Schedule 16 of the Code (as defined in section 1.1.2—11 of the Code). As such, mushroom (*A. bisporus*) chitosan is permitted as to be used as a food additive in various foods in accordance with the Code (see section 1.3.1—3 and Schedule 15 of the Code), including at levels consistent with Good Manufacturing Practice (GMP) in certain foods. This includes their use as a processing aid in wine (including sparkling and fortified wine) produced and sold in New Zealand, as well imported into and sold in Australia (including from New Zealand). However, wine, sparkling wine and fortified wine produced in Australia must comply with the requirements of Standard 4.5.1 – Wine production requirements, which is an Australia-only standard. Clause 4 to Standard 4.5.1 lists the substances permitted for use as processing aids in the production of wine, sparkling wine and fortified wine in Australia. Chitosan from *A. bisporus* is not currently listed as a permitted substance in clause 4.

FSANZ has assessed the proposed use of chitosan from *A. bisporus* as a processing aid for the production of wine, sparkling wine and fortified wine in Australia, for the purposes of Standard 4.5.1 of the Code.

The applicant has indicated that the processing aid would be used in accordance with GMP³.

² A1315 – Chitosan and (1,3)-beta-glucans from white button mushrooms (*Agaricus bisporus*) as a food additive, available on the FSANZ website: <https://www.foodstandards.gov.au/food-standards-code/applications/A1315-chitosan-and-beta-glucans-from-white-button-mushrooms-as-food-additive>

³ GMP is defined in section 1.1.2—2 of the Code as follows: **GMP or Good Manufacturing Practice**, with respect to the addition of substances used as food additives and substances used as processing aids to food, means the practice of:

(a) limiting the amount of substance that is added to food to the lowest possible level necessary to accomplish its desired effect; and

(b) to the extent reasonably possible, reducing the amount of the substance or its derivatives that:

(i) remains as a *component of the food as a result of its use in the manufacture, processing or packaging;

and

(ii) is not intended to accomplish any physical or other technical effect in the food itself;

FSANZ has revised the name of the application following its acceptance for assessment to *A1306 – Chitosan from white button mushrooms (Agaricus bisporus) for use as a processing aid*, aligning the application name with the amendment to the Code requested by the applicant and specifying the source as mushroom.

1.3 The current standard

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

1.3.1 Permitted use

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

Section 1.1.2—13 provides that a substance ‘used as a processing aid’ in relation to a food is a substance used during the course of processing that meets all of the following conditions:

- it is used to perform a technological purpose during the course of processing
- it does not perform a technological purpose in the food for sale
- it is a substance listed in Schedule 18 or identified in section S16—2 as an additive permitted at GMP.

Two standards in the Code provide permissions for the use of processing aids in wine manufacture.

Standard 1.3.3 provides permissions for certain substances to be used as processing aids in food (including wine) sold in Australia or New Zealand.

Section 1.3.3—3 provides a substance may be used as a processing aid in relation to food if:

- the substance is permitted to be used as a processing aid for that food by Standard 1.3.3, and
- the proportion of the substance that is used is no more than the maximum level necessary to achieve the technological purpose under conditions of GMP.

Section 1.3.3—4 permits an ‘additive permitted at GMP’ to be used as a processing aid in any food if it is used at a level necessary to achieve a technological purpose in the processing of that food.

Subsection 1.1.2—11(3) defines an ‘additive permitted at GMP’ as meaning a substance that is listed in section S16—2. Mushroom (*A. bisporus*) chitosan is already listed in the table to section S16—2 as an additive permitted at GMP.

As mushroom (*A. bisporus*) chitosan is listed in Schedule 16 as an additive permitted at GMP, mushroom (*A. bisporus*) chitosan is already permitted by the Code to be used as a food additive at levels consistent with GMP in various foods in accordance with the Code (see section 1.3.1—3 and Schedule 15).

The above, in effect, permits the use of mushroom (*A. bisporus*) chitosan as a processing aid

(c) preparing and handling the substance in the same way as a food ingredient.

in wine, including sparkling wine and fortified wine, produced and sold in New Zealand and in wine, including sparkling wine and fortified wine, imported into and sold in Australia (including from New Zealand).

The above does not apply to wine, sparkling wine and fortified wine produced in Australia.

Despite any contrary provision elsewhere in the Code, wine, sparkling wine and fortified wine produced in Australia must comply with the requirements of Standard 4.5.1, which is an Australia-only standard (see clause 2 of Standard 4.5.1).

For Australian wine industry purposes, Standard 4.5.1 provides a definitive list of permitted processing aids and food additives for wine, sparkling wine and fortified wine produced in Australia. The Standard underpins several international trade arrangements, including the European Union (EU) Wine Agreement and the World Wine Trade Group Mutual Acceptance Agreement, which reference Standard 4.5.1 as the basis for what is permitted in Australia.

Clause 4 to Standard 4.5.1 lists the substances permitted for use as processing aids in the production of wine, sparkling wine and fortified wine in Australia. Chitosan from *A. bisporus* is not listed as a permitted substance for that purpose.

1.3.2 Identity and purity requirements

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

The specification in section S3—55 sets out relevant specifications for mushroom (*A. bisporus*) 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.

Paragraphs 1.2.4—3(2)(d) and (e) exempt processing aids from the requirement to be declared in the statement of ingredients, unless other requirements apply.

1.4 International standards

1.4.1 International

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). There is no Codex 'general standard' for processing aids, nor is there a Codex standard for wine. However, there is a Codex guideline, *Guidelines on Substances used as Processing Aids* (CAC/GL 75-2010), which sets out general principles for the safe use of substances used as processing aids, including that substances used as processing aids shall be used under conditions of GMP.

The Organisation Internationale de la Vigne et du Vin, or International Organisation of Vine and Wine (OIV), is an intergovernmental organisation that sets non-mandatory international standards and provides scientific and technical guidance on viticulture, winemaking, wine, wine-based beverages and other vine-based products. Its International Code of Oenological Practices comprises approved oenological treatments and practices and guidelines for good

practice to ensure safety and quality in wine production. The International Code of Oenological Practices includes resolutions for fungal chitosan as a fining and antimicrobial agent in wine (refer to section 2.3 of Supporting Document 1 (SD1)).

1.4.2 Overseas regulations

The chitosan preparation that is the subject of this application is approved for use in Canada. The preparation is included in the Health Canada List of Permitted Preservatives as an antibacterial (Class 2) and antifungal (Class 3) preservative.

The United States of America (US) Food and Drug Administration (FDA) has responded that it has 'no questions' to the GRAS notification (GRN 997) for the chitosan preparation from *A. bisporus* for use as an antimicrobial in a range of foods. GRAS notifications, and 'no questions' responses from the US FDA to GRAS notifications, do not constitute safety assessments by a national agency.

Fungal chitosan is approved as a fining and antimicrobial treatment in wine in the EU, according to the European Commission Regulation (EU) No 53/2011⁴. The permissions and functions are similar to those provided in the OIV resolutions, as shown in Appendix 13 of the regulation and section 2.3 of the SD1.

As noted above, mushroom (*A. bisporus*) chitosan is permitted for use as a processing aid in relation to any food, e.g. wine production in New Zealand under Standard 1.3.3 of the Code.

Further details on approvals by other regulatory agencies are provided in section 3.4 of the SD1.

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)
- 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 in accordance with the FSANZ Act.

2 Summary of the assessment

FSANZ has undertaken an assessment to determine whether mushroom (*A. bisporus*) chitosan achieves its technological purpose in the quantity and form proposed, and to evaluate public health and safety risks that may arise from the proposed use of this substance (as shown in SD1). Summaries of both assessments are provided below.

2.1 Food technology assessment

Chitosan from mushroom (*A. bisporus*) performs its technological function in fining and microbial stabilisation during the production of wine, sparkling wine and fortified wine and not in the final product, and as such, meets the definition of a processing aid for the purposes of

⁴ <https://eur-lex.europa.eu/eli/reg/2011/53/oj/eng>

the Code. In the food technology assessment, all references to 'wine' includes sparkling wine and fortified wine in accordance with the definitions for wine, sparkling wine and fortified wine in Standard 4.5.1—1 and Standard 1.1.2—2 of the Code.

There is a relevant identity and purity specification for chitosan from *A. bisporus* in the Code.

2.2 Risk assessment

As stated previously, a safety assessment for chitosan from *A. bisporus* as a food additive has been conducted by FSANZ as part of application A1315. FSANZ has used the safety assessment as the basis of its evaluation.

The risk and technical assessment of A1315 found no public health or safety concerns regarding *A. bisporus*, which is neither pathogenic nor toxigenic.

No adverse effects of chitosan, chitosan oligomers, or chitosan monomers were observed in toxicological studies. Genotoxicity studies show no evidence of genotoxicity. Chitosan from *A. bisporus* is not expected to pose a food allergenicity concern under the proposed conditions of use. FSANZ conducted a literature review of toxicological and epidemiological evidence published since the A1315 assessment and did not identify any new studies that were relevant to the safety assessment.

A dietary exposure assessment was not conducted for this application as the dietary exposure scenario was within the worst-case exposure scenario assessed for A1315.

Based on the reviewed data, it is affirmed that in the absence of any identifiable hazard, an ADI 'not specified' remains appropriate.

FSANZ concludes there are no safety concerns from the proposed use of chitosan from *A. bisporus* in the quantity and form required to perform its technological function in for the microbial stabilisation and fining in the production of wine, sparkling wine and fortified wine in Australia, which must be consistent with GMP.

2.3 Risk management

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

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

For the reasons listed in this report, FSANZ decided to prepare a draft variation to the Code to permit the use of mushroom (*A. bisporus*) chitosan as a processing aid in the production of wine, sparkling wine and fortified wine in Australia, for the technological purpose of a fining and antimicrobial agent.

The application sought permission for chitosan extracted from white button mushrooms (*A. bisporus*) as a processing aid in the production of wine, beer, cider and other alcoholic beverages in Australia. Following assessment, FSANZ is proposing to permit the use of chitosan from any variety of mushroom extracted from *A. bisporus* as a processing aid in accordance with the Code, including (but not limited to) having to comply with the specifications in section S3—55 of the Code when added to food in accordance with the Code or sold for use in food.

A permission for chitosan from any variety of *A. bisporus* would be consistent with FSANZ's

risk assessment approach, which evaluated the source organism at the species level, not the varietal or developmental form. There is no evidence indicating any change in toxigenicity, pathogenicity, or risk profile across the morphological forms of *A. bisporus*.

If approved, the draft variation would insert 'mushroom (*Agaricus bisporus*) chitosan' into the table to clause 4 of Standard 4.5.1 which lists substances permitted to be used as processing aids in the production of wine, sparkling wine and fortified wine in Australia. The technological purpose of mushroom (*A. bisporus*) chitosan would be restricted to that of being a fining and antimicrobial agent. If approved, this proposed permission would be subject to the condition that the maximum permitted level or amount of the processing aid present in a food must be consistent with GMP (see subclause 5(8) of Standard 4.5.1).

This would provide regulatory certainty for the industry that mushroom (*A. bisporus*) chitosan may be used for the same technological purpose in Australian wine, sparkling wine and fortified wine as for which they are currently permitted in wine produced and sold in New Zealand and in wine imported from New Zealand and sold in Australia (including from New Zealand).

Other risk management considerations for this application are related to specifications and labelling, as discussed below.

2.3.1 Regulatory approval

FSANZ has prepared a draft variation to permit the use of mushroom (*A. bisporus*) chitosan as a processing aid in the production of wine, sparkling wine and fortified wine in Australia for the technological purpose of a fining and antimicrobial agent, in accordance with the Code.

2.3.2 Specifications

As stated in section 1.3.2, paragraph 1.1.1—15(1)(b) of the Code requires substances used as processing aids in food to comply with any relevant identity and purity specifications listed in Schedule 3 when added to food in accordance with the Code or sold for use in food.

There is a relevant identity and purity specification in section S3—55 for mushroom (*A. bisporus*) chitosan.

2.3.3 Labelling

Relevant labelling provisions in the Code would apply to foods for sale that are manufactured using this substance. See section 1.3.3 of this report.

2.3.4 Risk management conclusion

FSANZ is proposing to permit the use of mushroom (*A. bisporus*) chitosan as a processing aid in the production of wine, sparkling wine and fortified wine in Australia. If approved, the processing aid would be listed in the table to clause 4 of Standard 4.5.1, which lists substances permitted to be used as processing aids in the production of wine, sparkling wine or fortified wine in Australia. Its use would be restricted to that of a fining and antimicrobial agent. The maximum permitted level of mushroom (*A. bisporus*) chitosan that may be present in the food would need to be in an amount 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. All calls for submissions are notified via the FSANZ Notification Circular, FSANZ's digital channels and Food Standards News.

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

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

2.4.2 World Trade Organization (WTO)

As a member of the World Trade Organization (WTO), Australia is 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.

As stated in section 1.4.1, there are no Codex standards for processing aids for wine. Amending Standard 4.5.1 of the Code to permit mushroom (*A. bisporus*) chitosan as a processing aid is unlikely to have a significant effect on international trade as permissions already exist for mushroom (*A. bisporus*) chitosan in wine produced in New Zealand and other countries where it is imported and sold in Australia.

Therefore, a notification to the WTO under Australia's obligations under the WTO Technical Barriers to Trade or Application of Sanitary and Phytosanitary Measures Agreement was not considered necessary.

2.5 FSANZ Act assessment requirements

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

2.5.1 Section 29

2.5.1.1 Consideration of costs and benefits

FSANZ has assessed that a Regulation Impact Statement is not required for this application. This is because permitting the proposed use of mushroom (*A. bisporus*) chitosan as a processing aid is determined to be safe and considered deregulatory in nature, as its use will be voluntary if the draft variation concerned is approved.

However, FSANZ had 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 (as per paragraph 29(2)(a) of the FSANZ Act).

The consideration of the costs and benefits in this section is not intended to be an exhaustive, quantitative economic analysis of the proposed measures. In fact, most of the effects that were considered cannot easily be assigned a dollar value. Rather, the

assessment seeks to highlight the potential positives and negatives of moving away from the status quo by permitting the proposed use of mushroom (*A. bisporus*) chitosan as a processing aid for wine, sparkling wine and fortified wine produced in Australia.

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.

2.5.1.2. Costs and benefits of the proposed measure

The proposed use of mushroom (*A. bisporus*) chitosan is already permitted for:

- all beer and cider produced or sold in Australia and New Zealand
- wine, including sparkling wine and fortified wine, produced in New Zealand
- wine, including sparkling wine and fortified wine, imported into Australia (including from New Zealand).

Any benefits from approving the draft variation would accrue to Australian wine producers, given the use of mushroom (*A. bisporus*) chitosan is not currently permitted to be used as a processing aid for wine, sparkling wine nor fortified wine produced in Australia.

If the draft variation is approved, industry might benefit from several improvements and efficiencies from the proposed use of mushroom (*A. bisporus*) chitosan as a processing aid for wine, sparkling wine and fortified wine produced in Australia. Due to the voluntary nature of the permission, industry would only use the chitosan as proposed where they believe a net benefit exists for them, either in terms of increasing the quality of their product or reducing production costs.

If industry experiences cost savings by using mushroom (*A. bisporus*) chitosan, cost savings may be passed on to consumers. Consumers might also experience improvements to the quality and taste of Australian-produced wine, sparkling wine and fortified wine, depending on how the substance might impact final products.

Permitting the proposed use of this chitosan might result in a small, inconsequential cost to government in terms of an addition to the current range of processing aids that are already monitored for compliance.

2.5.1.3. Conclusions of costs and benefits

FSANZ's assessment is that the direct and indirect benefits that would arise from permitting the proposed use of mushroom (*A. bisporus*) chitosan as a processing aid for wine produced in Australia, as proposed, would likely outweigh the associated costs.

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

There are no 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 risk and technical assessment and concluded there were no public health and safety concerns associated with the proposed use of chitosan from *A. bisporus*, as shown in section 2.2 and the SD1. Mushroom (*A. bisporus*) chitosan is already permitted for use as a food additive in various foods in accordance with the Code.

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

If approved, existing labelling requirements would apply to mushroom (*A. bisporus*) chitosan when used as a processing aid to enable consumers to make informed choices (see sections 1.3.3 and 2.3.3 of this report).

2.5.2.3 The prevention of misleading or deceptive conduct

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

2.5.3 Subsection 18(2) considerations

FSANZ has also had regard to:

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

FSANZ used the best available scientific evidence to conduct the risk analysis. The applicant submitted a dossier of information and scientific literature as part of their application. This dossier, together with other technical and scientific information, was considered by FSANZ in assessing the application. The risk assessment is provided in SD1.

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

In terms of food safety, the relevant international standard setting body is Codex. There is no Codex 'general standard' for processing aids, nor is there a Codex standard for wine. However, there is a Codex guideline, Guidelines on Substances used as Processing Aids (CAC/GL 75-2010), which sets out general principles for the safe use of substances used as processing aids, including that substances used as processing aids shall be used under conditions of GMP, as discussed in section 1.4.1.

As stated in sections above, mushroom (*A. bisporus*) chitosan is already permitted for use as a processing aid, in accordance with the Code, for wine, sparkling wine and fortified wine produced in New Zealand and in other countries where permitted. This is the same substance as the chitosan that is the subject of this application. The proposed amendment to Standard 4.5.1 would provide regulatory certainty for the industry that mushroom (*A. bisporus*) chitosan could be used as a processing aid in wine, sparkling wine and fortified wine produced in Australia, if approved.

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

The proposed amendment would better align Australian wine production standards with New Zealand and overseas regulations, giving Australian wine, sparkling wine and fortified wine producers regulatory certainty of the use of mushroom (*A. bisporus*) chitosan as a fining and antimicrobial agent for the removal of suspended solids and for microbial stabilisation in wine, sparkling wine and fortified wine, with potential for improved quality in these products. This will help foster continued innovation and improvements in food manufacturing techniques and processes.

Ultimately, individual wine makers will make their own commercial decisions on whether the proposed use of this substance is of benefit to their particular business.

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

No issues were identified for this application relevant to this objective.

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

The Ministerial Policy Guideline *Addition to Food of Substances other than Vitamins and Minerals*⁵ includes specific order policy principles for substances added to achieve a solely technological function, such as processing aids. These specific order policy principles state that permission should be granted where:

- the purpose for adding the substance can be articulated clearly by the manufacturer as achieving a solely technological function (i.e. the 'stated purpose')
- the addition of the substance to food is safe for human consumption
- the amounts added are consistent with achieving the technological function
- the substance is added in a quantity and a form which is consistent with delivering the stated purpose
- no nutrition, health or related claims are to be made in regard to the substance.

FSANZ determined that permitting the proposed use of this substance would be consistent with these specific order policy principles for 'technological function'. All other relevant requirements of the policy guideline would be similarly met.

3 Draft variation

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

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

Attachments

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

⁵ <https://www.foodregulation.gov.au/resources/publications/policy-guideline-addition-substances-other-vitamins-and-minerals>

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



Food Standards (Application A1306 – Chitosan from mushrooms (*Agaricus bisporus*) for use as a processing aid) Variation

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

Dated [To be completed by Delegate]

[Insert name 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 A1306 – Chitosan from mushrooms (Agaricus bisporus) for use as a processing aid) Variation*.

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

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

3 Commencement

The variation commences on the date of gazettal.

Schedule

Standard 4.5.1— Wine Production Requirements (Australia Only)

[1] After subclause 4(4)

Insert:

(5) Mushroom (*Agaricus bisporus*) chitosan may only be used in the production of wine, sparkling wine and fortified wine as a fining and antimicrobial agent.

[2] Table to clause 4

Insert:

Mushroom (*Agaricus bisporus*) chitosan

Attachment B – Draft Explanatory Statement

DRAFT EXPLANATORY STATEMENT

Food Standards Australia New Zealand Act 1991

Food Standards (Application A1306 – Chitosan from mushrooms (*Agaricus bisporus*) for use as a processing aid) Variation

1. Authority

Section 13 of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act) provides that the functions of Food Standards Australia New Zealand (the Authority) include the development of standards and variations of standards for inclusion in the *Australia New Zealand Food Standards Code* (the Code).

Division 1 of Part 3 of the FSANZ Act specifies that the Authority may accept applications for the development or variation of food regulatory measures, including standards. This Division also stipulates the procedure for considering an application for the development or variation of food regulatory measures.

The Authority accepted Application A1306 which seeks to permit the use of chitosan extracted from white button mushrooms (*Agaricus bisporus*; hereafter *A. bisporus*) as a processing aid in wine, beer, cider, and other alcoholic beverages. The Authority considered the Application in accordance with Division 1 of Part 3 and has prepared a draft variation – the *Food Standards (Application A1306 – Chitosan from mushrooms (*Agaricus bisporus*) for use as a processing aid) Variation* (the draft 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 sunset provisions of the *Legislation Act 2003*. Subsections 44(1) and 54(1) of that Act provide that a legislative instrument is not disallowable or subject to sunset if the enabling legislation for the instrument (in this case, the FSANZ Act): (a) facilitates the establishment or operation of an intergovernmental scheme involving the Commonwealth and one or more States; and (b) authorises the instrument to be made for the purposes of the scheme.

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). 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 food laws. These standards or instruments are then administered, applied and enforced by these jurisdictions' regulators as part of those food laws.

3. Purpose

Following assessment of the application undertaken by the Authority, the Authority has

prepared a draft variation to amend Standard 4.5.1 (an Australia only standard) to permit the use of mushroom (*A. bisporus*) chitosan as processing aid in the production of wine, sparkling wine and fortified wine in Australia as a fining and antimicrobial agent.

If approved, this permission would be subject to the condition that the maximum permitted level or amount of mushroom (*A. bisporus*) chitosan that may be present in the food must be consistent with good manufacturing practice (GMP).

4. Documents incorporated by reference

The draft variation prepared by the Authority does not incorporate any documents by reference.

5. Consultation

In accordance with the procedure in Division 1 of Part 3 of the FSANZ Act, the Authority's consideration of Application A1306 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 variation) will be open for a 6-week consultation period.

The Office of Impact Analysis (OIA)⁶ has delegated to relevant decision-makers, in this case FSANZ, the assessment of whether an application requires a regulation impact statement. FSANZ's assessment is that a regulation impact statement is not required for this application. FSANZ's decision not to develop a regulation impact statement for this application is consistent with the OIA's prior advice about applications relating to permitting the use of processing aids that have been determined to be safe and if their use will be voluntary if the draft variation concerned is approved.

6. Statement of compatibility with human rights

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

7. Variation

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 A1306 – Chitosan from mushrooms (Agaricus bisporus) for use as a processing aid) Variation*.

Clause 2 of the variation provides that the Code is amended by the Schedule to the variation.

Clause 3 of the variation provides that the variation will commence on the date of gazettal of the instrument.

Schedule to the variation

Items [1] and [2] of the Schedule to the variation would amend clause 4 of Standard 4.5.1 of the Code.

⁶ [Regulatory Impact Analysis Guide for Ministers' Meetings and National Standard Setting Bodies | The Office of Impact Analysis \(pmc.gov.au\)](https://www.pmc.gov.au/regulatory-impact-analysis-guide-for-ministers-meetings-and-national-standard-setting-bodies)

Standard 4.5.1 sets out requirements for wine, sparkling wine and fortified wine produced in Australia only.

Clause 4 of this Standard sets out what substances are permitted to be used as processing aids in the production of wine, sparkling wine or fortified wine; and any specific technological purposes associated those substances.

Item [1] of the Schedule to the variation would insert new subclause 4(5) after subclause 4(4). New subclause 4(5) specifies the technological purpose of mushroom (*A. bisporus*) chitosan i.e. it provides that mushroom (*A. bisporus*) chitosan may only be used in the production of wine, sparkling wine and fortified wine as a fining and antimicrobial agent.

Item [2] of the Schedule to the variation would insert a new entry, in alphabetical order, into the table to clause 4 of Standard 4.5.1.

This table lists substances that are permitted to be used as processing aids in the production of wine, sparkling wine or fortified wine.

The new entry would list the following substance in the table: 'mushroom (*Agaricus bisporus*) chitosan'.

If approved, the effect of the proposed amendments in **items [1]** and **[2]** would be that mushroom (*A. bisporus*) chitosan would be permitted to be used as a fining and antimicrobial agent in the production of wine, sparkling wine and fortified wine produced in Australia in accordance with the Code.

As mushroom (*A. bisporus*) chitosan is an *additive permitted at GMP* for the purposes of the Code, that permission would be subject to the condition that the maximum permitted level or amount of the substance that may be present in the food must be consistent with GMP.

'Additive at GMP' is defined in section 1.1.2—11 of the Code.

'GMP or Good Manufacturing Practice' is defined in subsection 1.1.2—2(3) of the Code.

Also, according to subclause 5(8) of Standard 4.5.1, the use of mushroom (*A. bisporus*) chitosan would have to be consistent with conditions of GMP (as defined by subsection 1.1.2—2(3) of the Code).

As stated above, if approved, the effect of the variation would be to permit the proposed use of mushroom (*A. bisporus*) chitosan as a processing aid in the production of wine, sparkling wine and fortified wine in Australia in accordance with the Code.