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Supporting document 1

Risk and technical assessment – Application A1306

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

Executive summary

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 from mushrooms (*Agaricus bisporus*) as a processing aid in wine, beer, cider and other alcoholic beverages.

Chitosan from *A. bisporus* performs its technological function in fining and microbial stabilisation during the production of wine 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 the Code.

A risk and technical assessment for chitosan from *A. bisporus* was conducted by FSANZ as part of application A1315 – Chitosan and (1,3)-beta-glucans from white button mushrooms (*Agaricus bisporus*) as a food additive. The assessment found no public health or safety concerns regarding the production organism, 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 use of chitosan from *A. bisporus* in the quantity and form required to perform its technological function in fining and microbial stabilisation in the production of wine, which must be consistent with Good Manufacturing Practice (GMP).

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1 Introduction

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 from mushrooms (*Agaricus bisporus*) as a processing aid in wine, beer, cider and other alcoholic beverages.

Chitosan is derived from chitin, a carbohydrate polymer synthesised by various arthropods, molluscs and fungi. *A. 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 (in an immature form), brown button mushrooms (in a more mature form) and portobello mushrooms (in a fully mature form).

The mushroom chitosan preparation (Pinnacle Mycobrio™) is produced by a Canadian manufacturer, Chinova Bioworks (Chinova). In a previous application to FSANZ, Chinova applied to amend the Code 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 (FSANZ 2025a). Thus, a risk and technical assessment for chitosan from *A. bisporus* as a food additive has previously been conducted by FSANZ as part of application A1315 and is available on the FSANZ website: A1315 – Chitosan and (1,3)-beta-glucans from white button mushrooms (Agaricus bisporus) as a food additive | Food Standards Australia New Zealand (FSANZ 2025b).

For the current risk and technical assessment, FSANZ had regard to the existing permissions for mushroom chitosan in the Code. Standard 1.3.1 and Schedule 16 of the Code permit the use of chitosan from *A. bisporus* as a food additive at levels consistent with GMP in all foods. Under Standard 1.3.3 of the Code, a food additive permitted at GMP can be used as a processing aid in any food, including beer, cider and other alcoholic beverages. This includes their use in wine produced and sold in New Zealand, as well as wine imported into and sold in Australia (including from New Zealand).

1.1 Objectives of the assessment

The objectives of this risk and technical assessment were to:

- Determine whether chitosan from *A. bisporus* achieves its technical purpose as a processing aid in wine[1] in the quantity and form proposed to be used.
- Evaluate potential public health and safety concerns that may arise from the use of chitosan from *A. bisporus* as a processing aid in wine.

2 Food technology assessment

2.1 Identity, manufacturing process and methods of analysis

Mushroom chitosan is a natural co-polymer and comprises a chitin moiety (N-acetyl-d-

[1] For the purposes of the food technology assessment, all references to 'wine' capture sparkling wine and fortified wine in accordance with the definitions in sections 4.5.1—1 and 1.1.2—3 of the Code.

glucosamine units) covalently linked to a β-glucans moiety (glucose units).The identity, manufacturing process and methods of analysis for chitosan from *A. bisporus* was assessed in A1315 (shown in Supporting document; hereafter SD) (FSANZ 2025b). Therefore, further assessment of the identity, manufacturing process and methods of analysis is not required.

2.2 Specifications for identity and purity

Section 1.1.1—15 of the Code requires that a substance used as a processing aid must meet any relevant identity and purity specification in Schedule 3.

The applicant provided a proposed specification for chitosan from *A. bisporus* that aligns with the specification proposed by the applicant for A1315. FSANZ considers that the specification in S3—55 developed under A1315 for mushroom (*A. bisporus*) chitosan is appropriate for the purposes of this application (FSANZ 2025b).

Further details on purity and the development of the specification are shown in A1315 SD section 2.3 (FSANZ 2025b).

2.3 Technological purpose

Chitosan from mushroom (*A. bisporus*) is intended for use as a processing aid in the production of wine. The use of chitosan from *A. niger* in fining and for microbial stabilisation in wine and other alcoholic beverages was previously assessed in A1077[2] (shown in A1077 SD section 2.4) (FSANZ 2013b). The use of chitosan from *A. bisporus* as a food additive in all foods was previously assessed in A1315 (shown in A1315 SD section 2.4 and 2.6) (FSANZ 2025b). This assessment focuses on the use of chitosan from *A. bisporus* as a processing aid in wine, in powder form in an amount consistent with GMP.

2.3.1 Microbial stabilisation

Chitosan is effective against a range of microorganisms, yeasts and moulds that can result in wine spoilage (Marin et al. 2021). Studies on the antimicrobial effects of chitosan found most microorganism species in grapes and wine can be reduced and/or removed, however effectiveness varies depending on the species, the composition of the wine such as pH and the stage in the winemaking process at which chitosan is added (Miot-Sertier et al. 2022).

The degree of deacetylation (DDA) and molecular weight (MW) are important factors in its antimicrobial function. The values in the S3-55 specification in the Code are 70 to 95 mol% and 10 to 400 kDa respectively.

Chitosan is effective in microbial stabilisation by eliminating and/or reducing bacteria and yeast including *Brettanomyces, Acetobacter and Lactobacillus* species. (AB Biotek 2025). *Brettanomyces bruxellensis* yeast results in the production of undesirable volatile phenols in red wine stored and aged in barrels (Miot-Sertier et al. 2022). *Brettanomyces* yeast is responsible for a horse sweat or mousy taint in wine (Marin et al. 2021). The addition of chitosan can result in *Brettanomyces* cells falling to the base of the barrel where the wine can be removed from the cells and any other sediment followed by filtration of the wine (AB Biotek 2025).

Lactic acid bacteria (LAB) found in wine can increase the risk of microbial spoilage by

[2] https://www.foodstandards.gov.au/food-standards-code/applications/applicationa1077fung5726

increasing volatile acidity and result in what is referred to as wine mousiness and ropiness (Miot-Sertier et al. 2022). The use of chitosan has been shown to significantly reduce LAB levels in contaminated wine (Miot-Sertier et al. 2022).

The International Organisation of Vine and Wine (OIV) resolution, OENO 338A/2009 specifies chitosan's role in microbial stabilisation to reduce undesirable micro-organisms, notably *Brettanomyces* at levels not exceeding 10 g/hectolitre (hL) with sediment removed following treatment (OIV 2009).

AB Biotek's product information for this chitosan from *A. Bisporus* includes a range of use levels for different stages in winemaking. For grape juice and wine, it can be used as a preventative measure at use levels of 5–10 mL/hL, while to remove wine faults due to microorganisms use levels of 10–15 mL/hL are required. When added to wine post-fermentation use levels can range from 10–100 mL/hL, with higher levels needed for reduced or no alcohol wine (AB Biotek 2025).

2.3.2 Fining

Fining in winemaking is a process used to remove suspended solids in wine. Suspended solids, including proteins can result in cloudiness or haziness in wine (Marin et al. 2021). Details of the role of chitosan in fining are provided in the SD for A1077 (FSANZ 2013b). In summary, most of the suspended solids in wine have an electrical charge. Chitosan has a positive charge, so it functions by attracting negatively charged particles causing flocculation followed by sedimentation in the barrel or tank. The sediment can then be removed from the wine usually by racking and/or filtration. Chitosan is often used together with enzymes to remove haziness in white wine, the result of heat-unstable proteins unfolding and aggregating (Marin et al. 2021).

The OIV has 3 winemaking resolutions, OENO 336A/2009[3], 337A/2009[4] and 338A/2009[5] that specify chitosan's role in fining (OIV 2009):

- in wine musts, to facilitate settling and clarification and for prevention of protein haze
- to reduce turbidity by forming a precipitate of suspended solids
- to reduce heavy metal content and haze and possible contaminants.

The presence of some metals during winemaking and storage including iron and copper can also contribute to wine haze where they can act as catalysts for oxidation of compounds in wine such as organic acids and phenolic compounds resulting in browning of the wine (Marin et al. 2021). Chitosan has been shown to be effective in sorption of metals and preventing wine haze and browning (Marin et al. 2021). Product information from AB Biotek notes its function as an antioxidant (AB Biotek 2025).

2.3.3 Function as a processing aid

Following the use of chitosan in fining or as an antimicrobial agent, the resulting sediment containing chitosan is removed from the wine by physical separation processes such as racking (removing sediment from the wine) and/or filtration. Since chitosan is insoluble at

[3] https://www.oiv.int/node/3478/download/pdf

[4] https://www.oiv.int/node/3480/download/pdf

[5] https://www.oiv.int/node/3482/download/pdf

slightly acidic to neutral pH levels found in wine, as well as in aqueous and ethanol solutions, it is unlikely that any residual chitosan will remain in the treated wine. Information provided by the applicant using high-performance liquid chromatography showed the final product is free from chitosan. This confirms that chitosan does not provide a technological function in the final food, hence is correctly categorised as a processing aid.

2.4 Food technology conclusion

FSANZ concludes that chitosan from *A. bisporus* performs its technological function of fining and microbial stabilisation during the production of wine and does not perform a technological function in the final food. It therefore functions as a processing aid for the purposes of the Code.

Additionally, its technological function in fining and microbial stabilisation aligns with the relevant OIV resolutions.

There is a relevant identity and purity specification for chitosan from *A. bisporus* in the Code (S3—55 – Mushroom (*Agaricus bisporus*) chitosan).

3 Safety assessment

The objective of this safety assessment was to evaluate any potential public health and safety concerns associated with the use of chitosan from *A. bisporus* as a processing aid.

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 2025b). FSANZ has used the safety assessment as the basis of its evaluation.

3.1 Production organism history of use

The production organism has a long history of safe human consumption. FSANZ's microbiological risk assessment has not identified any public health and safety concerns associated with the use of *A. bisporus*, which is neither pathogenic nor toxigenic, in the production of mushroom chitosan to be used as a processing aid.

3.2 Safety of chitosan

3.2.1 History of safe use

Chitosan has a history of safe use in food production. Chitosan from *A. bisporus* has been approved for use as a food additive by FSANZ and is included in Schedule 16 of the Code, as part of application A1315 (FSANZ 2025a). In addition, Chitosan from *A. niger* has been approved for use as a processing aid for the production of wine by FSANZ and is included in Schedule 18 and Standard 4.5.1 (Wine Production Requirements; Australia only) of the Code, as part of application A1077 (FSANZ 2013a).

3.2.2 Toxicology data

For A1315, the applicant submitted a literature review of toxicological and epidemiological studies of chitosan which was reviewed by FSANZ in the assessment.

Briefly, the systemic absorption of chitosan in the stomach and small intestine varies depending on the molecular weight, viscosity and the DDA. The chitosan from *A. bisporus* for

use as a processing aid has an equivalent average molecular weight (10–400 kDa) and DDA (>80%) as the food additive assessed in A1315. Following dietary intake, chitosan is expected to remain intact in the upper gastrointestinal tract and be subject to fermentation by microbiota in the large intestine.

No adverse effects of chitosan, chitosan oligomers, or chitosan monomers have been observed in acute, subchronic, or chronic studies in rodents. No relevant reproductive or developmental toxicity studies were identified; however, systemic absorption of chitosan is negligible and therefore effects on reproduction or development are not considered likely. No adverse effects of chitosan supplements were reported in human trials. Genotoxicity studies show no evidence of genotoxicity.

FSANZ conducted a literature review to determine whether there is any new information that would require a revision of the safety assessment conclusions from A1315. FSANZ did not identify any new studies that were relevant to the safety assessment.

3.2.3 Potential for allergenicity

In a literature review, Peng et al. (2022) found only one case of allergic reaction to chitosan via the oral route. On this basis, FSANZ concludes that allergy to chitosan is rare and unlikely to be of concern. FSANZ notes that the chitosan is likely to be removed completely during the wine production process and therefore any exposure would be negligible.

3.2.4 Assessments by other regulatory agencies

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 at an average molecular weight of 90–120 kDa and DDA not less than 80% (Health Canada 2023).

The United States (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 at levels of 0.015–0.15g per 100g at a molecular weight ranging from 10 to 400 kDa and DDA ≥80% (FDA 2022). GRAS notifications, and ‘no questions’ responses from the US FDA to GRAS notifications, do not constitute safety assessments by a national agency.

4 Dietary exposure assessment

A dietary exposure assessment was not conducted for this application because the budget method calculation conducted for A1315 considered the worst-case exposure scenario to chitosan (i.e. a higher chitosan concentration in all foods and beverages than the concentration suggested for production of wine, beer, cider and other alcoholic beverages in this application) (FSANZ 2025b).

5 Discussion

Chitosan from *A. bisporus* performs its technological function of microbial stabilisation and fining during the production of wine 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 mushroom (*A. bisporus*) chitosan in the Code.

The safety of chitosan from *A. bisporus* as a food additive has previously been reviewed by FSANZ as part of application A1315. No public health or safety concerns were identified

concerning the use of the production organism, which is neither pathogenic nor toxigenic.

No adverse effects of chitosan, chitosan oligomers, or chitosan monomers have been observed in acute, subchronic, or chronic studies in rodents. Systemic absorption of chitosan is negligible and therefore effects on reproduction or development are not considered likely. No adverse effects of chitosan supplements were reported in human trials. Genotoxicity studies show no evidence of genotoxicity. Allergic reactions to oral exposure are extremely rare, and under the proposed conditions of use, dietary intake of chitosan from *A. bisporus* is expected to be negligible.

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 use of chitosan from *A. bisporus* in the quantity and form required to perform its typical function in microbial stabilisation and fining in the production of wine, which must be consistent with GMP.

6 References

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