Executive Summary

Chitin is the main component of the cell walls of fungi, plants, and insects. Chitosan is a natural occurring polysaccharide, obtained by the de-acetylation of chitin. Chitosan and chitin-glucan are permissible products that can be used for the decrease of undesirable micro-organisms, settling aids, antioxidants, decrease of copper and iron concentrations and removal of contaminants. Chitosan can also control the growth of undesirable yeast like *Brettanomyces*, lactic acid bacteria like *Lactobacillus*, *Oenococcus* and *Pediococcus* and acetic acid bacteria like *Acetobacter.* Chitosan's mechanism of action against microorganisms comes down to its strong cationic charge when in acidic solution, and that charge binds to anionic components of the microorganism's cell wall and physically shears open the cell wall. This ionic interaction kills the microorganisms.

The degree of acetylation (DA) of chitin is a significant parameter influencing the biological, physicochemical, and mechanical properties and an important parameter that determines its classification whether it is chitin or chitosan. Chitosan is emerging as a very important raw material for the synthesis of a wide range of products used for food, medical, pharmaceutical, health care, agriculture, industry, and environmental pollution protection. Chitosan is used as a processing aid in the manufacturing of wine, beer, cider, and spirits.

Regardless of the technological purpose, the sediments that contain the chitosan are removed from the wine, must or spirits at the end of the treatment by physical separation processes such as racking, centrifugation and/ or filtration. Since chitosan is insoluble at slightly acidic to neutral pH levels, as well as in aqueous and ethanol solutions, it is unlikely that any residual chitosan will remain in the treated products. High-performance liquid chromatography analyses have confirmed that the final product is free from chitosan. Therefore, the estimated intake of chitosan from a wine source can be considered as negligible.

Resolutions permitting the use of fungal chitosan from *Aspergillus niger* and *Agaricus bisporus* as a fining agent and contaminant treatment have been granted by the International Organisation of Vine and Wine (OIV/OENO 336A/2009; 337A/2009; 338A/2009; 339A/2009) (OIV, 2011; Appendix 3 - 6). A monograph for fungal chitosan has also been added to the International Oenological Codex by decision of the OIV general assembly dated July 2009 considering the works of the group of experts "Specifications of Oenological Products" (OIV/OENO 368/2009, Appendix 7), but currently FSANZ only permit the use of chitosan from shellfish and from the fungi *A. niger* as a processing aid. As part of the OIV approval process they do evaluate toxicity of processing aids and the safety risk for wine consumers.

A number of animal, human, and *in vitro* studies on the safety of shellfish chitosan (and other sources) have been published and summarised in this application. In FSANZ application A1077 the applicants demonstrated how similar chitosan from *Aspergillus niger* are to shellfish chitosan and in the FSANZ review of all the data they accepted the safety information, and that the data are applicable to *A. niger* chitosan due to its similarity to shellfish chitosan and approved chitosan from *A. niger* as safe to use as a processing aid in wine. Likewise, in this application Chinova Bioworks demonstrated how similar chitosan from *Agaricus bisporus* is to chitosan from shellfish and from *A. niger*. Also, that their product Pinnacle Mycrobrio received GRAS status for use as a processing-aid in the manufacturing of alcoholic beverages. Both the Australian Grape and Wine and the New Zealand Winegrowers support this application.