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

3-07
23 May 2007

INITIAL ASSESSMENT REPORT

APPLICATION A605

YEAST MANNOPROTEINS AS A FOOD ADDITIVE FOR WINE

DEADLINE FOR PUBLIC SUBMISSIONS: 6pm (Canberra time) 4 July 2007
SUBMISSIONS RECEIVED AFTER THIS DEADLINE WILL NOT BE CONSIDERED
(See 'Invitation for Public Submissions' for details)

For Information on matters relating to this Assessment Report or the assessment process generally, please refer to http://www.foodstandards.gov.au/standardsdevelopment/

Executive Summary

FSANZ received an Application from Laffort Services on 11 April 2007 seeking permission to use mannoproteins extracted from yeast cell walls as a food additive in wine to inhibit the crystallisation of potassium bitartrate. Permission is sought in Standard 1.3.1 – Food Additives and Standard 4.5.1 – Wine Production Requirements (Australia only) of the *Australia New Zealand Food Standards Code* (the Code).

Food additives are required to undergo a pre-market approval before they are approved for use.

Mannoproteins are yeast cell wall components that are proteins with large numbers of mannose groups attached. Mannoproteins are extracted from the cell walls of the common yeast *Saccharomyces cerevisiae* using an enzyme treatment. The yeast mannoprotein preparation has a molecular mass range of around 40 kDa. The yeast mannoproteins are proposed to be added to wine in a concentration range of 100-300 mg/l, which is consistent with internationally used levels.

Yeast mannoproteins are added to wine as a food additive to inhibit the formation of potassium bitartrate crystals which are commonly formed in bottled wine. The presence of potassium bitartrate crystals in wine is not a safety or wine tasting issue but rather one of aesthetics. There are two current stabilisation treatments used to prevent their formation in wine bottles. The first is called cold stabilisation and it involves keeping wine at very low temperature for a long period of time to promote early crystallisation of the tartrate (which is removed by filtration before bottling). The second method involves the use of metatartaric acid which is an approved food additive for this purpose.

Yeast mannoproteins are approved for use to stabilise wine in a number of countries (in the European Union and Argentina) and by the international organisation, the International Organisation of Vine and Wine (OIV, Office International de la Vigne et du Vin). The Agreement between Australia and the European Community on Trade in Wine, and Protocol (1994) allows the use of preparations of yeast cell wall (up to a level of 400 mg/l) for Australian and European produced wine.

This Initial Assessment Report seeks to summarise relevant information provided in the Application, to assist in identifying relevant issues that need to be addressed as part of the assessment of the Application. It also seeks to identify relevant parties who could be affected by the Application.

This Initial Assessment Report is not an assessment of the merits of the Application, but rather an assessment of whether the Application should be accepted for further consideration according to criteria laid down in the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act).

Purpose

The purpose of the Application is to seek permission for the use of mannoproteins extracted from yeast cell walls as a food additive for wine to inhibit potassium bitartrate crystallisation which commonly occurs in wine bottles. This would be an alternative treatment to the usual time-consuming and expensive wine-making practices currently undertaken to stabilise wine.

Reasons for Assessment

After considering the requirements for Initial Assessment as prescribed in section 13 of the FSANZ Act, FSANZ has decided to accept the Application for the following reasons:

- The Application seeks approval for the use of mannoproteins extracted from yeast cell walls as a food additive to inhibit potassium bitartrate crystallization. Such an approval, if accepted, would warrant variations to Standard 1.3.1 – Food Additives and 4.5.1 – Wine Production Requirements (Australia only).

- There is currently no permission in the Code for yeast mannoproteins used as a food additive to stabilize wine.

- The Application is not so similar to any previous application that it ought not be accepted.

- There are no other measures that would be more cost-effective than a variation to Standards 1.3.1 and 4.5.1 that could achieve the same end.

- At this stage no other relevant matters are apparent.

Consultation

Public submissions are invited on this Initial Assessment Report. Comments may be made on any aspect of the Application, though of particular interest will be information related to the safety of use of mannoproteins to treat wine, and how their use are regulated in other countries and by any international wine regulatory agencies.

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INVITATION FOR PUBLIC SUBMISSIONS

FSANZ invites public comment on this Initial Assessment Report for the purpose of preparing an amendment to the Code for approval by the FSANZ Board.

Written submissions are invited from interested individuals and organisations to assist FSANZ in preparing the Draft Assessment of this Application. Submissions should, where possible, address the objectives of FSANZ as set out in section 10 of the FSANZ Act. Information providing details of potential costs and benefits of the proposed change to the Code from stakeholders is highly desirable. Claims made in submissions should be supported wherever possible by referencing or including relevant studies, research findings, trials, surveys etc. Technical information should be in sufficient detail to allow independent scientific assessment.

The processes of FSANZ are open to public scrutiny, and any submissions received will ordinarily be placed on the public register of FSANZ and made available for inspection. If you wish any information contained in a submission to remain confidential to FSANZ, you should clearly identify the sensitive information and provide justification for treating it as commercial-in-confidence. Section 39 of the FSANZ Act requires FSANZ to treat in-confidence, trade secrets relating to food and any other information relating to food, the commercial value of which would be, or could reasonably be expected to be, destroyed or diminished by disclosure.

Submissions must be made in writing and should clearly be marked with the word 'Submission' and quote the correct project number and name. Submissions may be sent to one of the following addresses:

Food Standards Australia New Zealand
PO Box 7186
Canberra BC ACT 2610
AUSTRALIA
Tel (02) 6271 2222
www.foodstandards.gov.au

Food Standards Australia New Zealand
PO Box 10559
The Terrace WELLINGTON 6036
NEW ZEALAND
Tel (04) 473 9942
www.foodstandards.govt.nz

Submissions need to be received by FSANZ by 6pm (Canberra time) 4 July 2007.

Submissions received after this date will not be considered, unless agreement for an extension has been given prior to this closing date. Agreement to an extension of time will only be given if extraordinary circumstances warrant an extension to the submission period. Any agreed extension will be notified on the FSANZ website and will apply to all submitters.

While FSANZ accepts submissions in hard copy to our offices, it is more convenient and quicker to receive submissions electronically through the FSANZ website using the Standards Development tab and then through Documents for Public Comment. Questions relating to making submissions or the application process can be directed to the Standards Management Officer at the above address or by emailing slo@foodstandards.gov.au.

Assessment reports are available for viewing and downloading from the FSANZ website. Alternatively, requests for paper copies of reports or other general inquiries can be directed to FSANZ's Information Officer at either of the above addresses or by emailing info@foodstandards.gov.au.

INTRODUCTION

FSANZ received an Application from Laffort Services on 11 April 2007 seeking permission to use mannoproteins extracted from yeast cell walls as a food additive in wine to inhibit the crystallisation of potassium bitartrate. Such permission is sought in Standard 1.3.1 – Food Additives and Standard 4.5.1 – Wine Production Requirements (Australia only) of the *Australia New Zealand Food Standards Code* (the Code).

1. Background

1.1 Current Standard

Currently there is no permission for using mannoproteins extracted from yeast cell walls as a food additive for wine treatment in the Code. Mannoproteins are yeast cell wall components that are proteins with large numbers of mannose groups attached. Food additive permissions for wine are listed in both Standard 1.3.1 – Food Additives in Schedule 1 under the food category 14.2.2 (wine, sparkling wine and fortified wine) and Standard 4.5.1 – Wine Production Requirements which also contains a list of food additives permitted for wine production in Australia in the Table to clause 3. Amendments to both standards would be required if this Application is successful.

Currently an alternative food additive approved in both standards is metatartaric acid which can be used to provide short term inhibition to the crystallisation of potassium bitartrate in wine.

1.2 Historical Background

Wine, in its normal state, is supersaturated with potassium bitartrate salts which can often crystallise out in wine bottles. Potassium bitartrate crystals that form in stored wine are not considered a taste quality issue but their presence may be a consumer issue. Some consumers may believe that their presence is an indicator of poor quality so wine manufacturers try to limit the formation of potassium bitartrate crystals in bottled wine. Various wine making strategies are employed such as cold stabilisation (extended cold temperature storage for a period of time to force the crystallisation of the potassium bitartrate which is then removed before bottling) or the use of metatartaric acid which gives only relatively short term stability[1].

Historically it was believed that wine, especially red wine, naturally contained macromolecules that act as protective colloids that hinder tartrate crystallisation. It was known that the traditional practice of ageing wine on yeast lees (old dead yeast and yeast residues) gave improved tartrate stability. Recent research has established mannoproteins present in the yeast cell walls are responsible for the improved tartrate stability. This research work underpinned the development of the material which is the subject of this Application[1].

[1] Ribéreau-Gayon, P., Glories, Y., Maujean, A. and Dubourdieu, D. (2000) Handbook of Enology, Volume 2, The chemistry of wine stabilization and treatments, John Wiley & Sons, pp 15-39.

Laffort Oenologie, being the French parent company of the Applicant, holds international patents for a preparation of mannoproteins they have called Mannostab™, which they claim is unique with no equivalent product on the market.

1.3 Function of yeast mannoproteins

Mannoproteins are extracted from purified yeast (*Saccharomyces cerevisiae*) cell walls, via enzymatic extraction using β-glucanase. The mannoprotein preparation of this Application has an apparent molecular weight of around 40 kDa. The function of this mannoprotein preparation is claimed by the Applicant to inhibit tartrate crystallisation in the wine bottle. The Application states that it is proposed to treat wine with yeast mannoproteins in the range of 100-300 mg/l (the maximum proposed treatment level being 300 mg/l).

Mannoproteins of a lower molecular weight (around 32 kDa) have also been found to stabilise wine, however, in this case it is in with respect of protein instability (rather than bitartrate inhibition). The protein stabilisation function can potentially reduce or eliminate the requirement to treat wine with a filtration agent, bentonite, which is commonly used to remove excess protein from the wine, which can cause haze instability in the final wine.

Yeast mannoproteins can be called 'protective colloids' (another example is gum arabic, also called acacia gum which is currently approved in the Code as a food additive to treat wine). The Application states that the mechanism for how yeast mannoproteins perform the inhibition of bitartrate crystallisation has been postulated but has not been fully elucidated. It is believed that the mannoproteins (and other protective colloids) adsorb onto the surface of the developing crystal or crystal nucleation site being protected to maintain a separation zone around the site and hindering access to approaching molecules or particles, so limiting the growth of the crystal.

1.4 Preparation of yeast mannoproteins

The Application states that the mannoprotein preparation is produced by the β-glucanase enzymatic extraction of *Saccharomyces cerevisiae* yeast cell walls. The β-glucanase enzyme preparation is stated to be approved for use as a food processing aid, being listed in the Table to clause 17 of Standard 1.3.3 – Processing Aids of the Code. The enzyme hydrolyses the yeast cell wall which then allows the mannoproteins to be solubilised. Subsequently the enzyme digestion is ultrafiltered to remove insoluble cell wall material and the mannoprotein preparation concentrated.

1.5 International Standards

Yeast mannoproteins are approved for treatment of wine in a number of countries and by the OIV.

The European Union Council Regulation (EC) No. 2165/2005, which amends Regulation (EC) No. 1493/1999 permits 'the addition of yeast mannoproteins to ensure the tartaric and protein stabilisation of wines'[2]. The Commission Regulation (EC) No. 1410/2003 permits the use of preparations of yeast cell walls to the level of 40 g/hl (400 mg/l) for wine[3].

The Applicant indicates that Argentina also approves the use of yeast mannoproteins for wine stabilisation.

The OIV International Oenological Codex contains a specification for yeast mannoproteins (being Oeno 26/2004)[4]. This specification indicates that yeast mannoproteins can be used for tartaric and/or protein stabilisation of wine.

The Agreement between Australia and the European Community on Trade in Wine, and Protocol (1994) (Annex I) allows for the use of preparations of yeast cell wall, up to 40 g/hl for wines originating in Australia and separately for wines originating in the Community[5].

2. The Issue / Problem

Food additives are required to undergo a pre-market assessment before they are approved for use in food manufacture. There is currently no approval in the Code for the use of mannoproteins extracted from yeast cell walls to be used to inhibit potassium bitartrate crystallisation in wine. Therefore, a safety assessment is required to assess whether there are any public health and safety issues with approving the use of mannoproteins to stabilise wine. In addition, FSANZ will assess whether the proposed use is technologically justified and supported.

3. Objectives

The objective of the assessment is to determine whether it is appropriate to amend the Code to permit the use of mannoproteins extracted from yeast cell walls as a food additive for wine to inhibit potassium bitartrate crystallisation in bottled wine.

In developing or varying a food standard, FSANZ is required by its legislation to meet three primary objectives which are set out in section 10 of the FSANZ Act. These are:

- the protection of public health and safety;
- the provision of adequate information relating to food to enable consumers to make informed choices; and

[2] Official Journal of the European Union, Council Regulation (EC) No. 2165/2005 (20 December 2005) http://eur-lex.europa.eu/LexUriServ/site/en/oj/2005/l_345/l_34520051228en00010004.pdf Accessed on 17 April 2007

[3] Official Journal of the European Union, Commission Regulation (EC) No. 1410/2003 (7 August 2003) http://eur-lex.europa.eu/LexUriServ/site/en/oj/2003/l_201/l_20120030808en00090011.pdf Accessed on 17 April 2007

[4] OIV Resolution Oeno 26/2004, Paris (30 July 2004) Yeast mannoproteins, http://news.reseau-concept.net/images/oiv_uk/Client/Resolution_OENO_EN_2004_26.pdf. Accessed on 17 April 2007

[5] Agreement between Australia and the European Community on Trade in Wine, and Protocol (1994), http://www.austlii.edu.au/au/other/dfat/treaties/1994/6.html. Accessed on 17 April 2007

- the prevention of misleading or deceptive conduct.

In developing and varying standards, FSANZ must also have regard to:

- the need for standards to be based on risk analysis using the best available scientific evidence;
- the promotion of consistency between domestic and international food standards;
- the desirability of an efficient and internationally competitive food industry;
- the promotion of fair trading in food; and
- any written policy guidelines formulated by the Ministerial Council.

4. Key Assessment Question

The key question which FSANZ needs to consider as part of this assessment, at Draft Assessment is:

- Is the presence of mannoproteins extracted from yeast cell walls safe as a food additive to inhibit potassium bitartrate crystallisation in packaged (essentially bottled) wine?

RISK ASSESSMENT

5. Safety Assessment

Preparations of living yeast cells or yeast cell walls are currently commercialised as food supplements or medicines. Humans have consumed yeasts and yeast cell wall preparations from the common yeast *S. cerevisiae* since they have been brewing beer and baking bread, so there is a history of consumption of yeast.

FSANZ will be specifically assessing the safety of the enzyme β-glucanase which is used to produce the mannoprotein preparation. In particular, an assessment of the safety of the source of the enzyme, whether the enzyme is present in the mannoprotein preparation (and hence the final wine) or inactivated will be assessed as part of the Safety Assessment Report prepared for the Draft Assessment Report.

The Application contains information on the toxicity of the yeast mannoproteins. As well, the Application contains studies and summaries of literature searches on the toxinogenic or pathogenic potential of the yeast strain *S. cerevisiae*, and any possible mutagenic toxicity effects of the yeast cell wall mannoproteins.

Some dietary modelling assessment work related to the consumption of the additive, being consumption of yeast mannoproteins, is contained in the Application. The modelling provided indicates that the contribution of mannoproteins from its use as a food additive in wine compared to the overall consumption in the human diet is quite minor, being around 2%. These calculations will be checked as part of the Draft Assessment.

6. Food Technology Considerations

The Application contains data from trials where the efficacy of the yeast mannoproteins have been assessed compared to more traditional stability treatments to prevent potassium bitartrate crystallisation, such as metatartaric acid addition and cold stabilisation. These results will be assessed to consider the efficacy of the proposed purpose of the food additive, in a Food Technology Report at Draft Assessment. Also in the Draft Assessment will be an assessment and understanding of how the yeast mannoproteins are extracted and the specification of the yeast mannoproteins.

RISK MANAGEMENT

7. Options

FSANZ is required to consider the impact of various regulatory (and non-regulatory) options on all sections of the community, especially relevant stakeholders who may be affected by this Application.

Food additives used for food sold in Australia and New Zealand are required to be listed in Standard 1.3.1. Food additives used for wine manufacture in Australia are also required to be listed in Standard 4.5.1. Yeast mannoproteins used as a food additive to stabilise wine to inhibit potassium bitartrate crystallisation requires a pre-market approval under both standards, Standard 1.3.1 and 4.5.1. It is not appropriate to consider non-regulatory options.

Two regulatory options have been identified for this Application:

Option 1 Not permit the use of yeast mannoproteins as a food additive for wine to inhibit potassium bitartrate crystallisation.

Option 2 Amend Standards 1.3.1 and 4.5.1 to approve the use of yeast mannoproteins as a food additive for wine to inhibit potassium bitartrate crystallisation.

If the Application is successful the approval for yeast mannoproteins will be added into Schedule 1 of Standard 1.3.1 under the food category 14.2.2 – Wine, sparkling wine and fortified wine. Permission would also be added into the Table to clause 3 of Standard 4.5.1.

The specification for the yeast mannoprotein preparation of this Application is contained in the OIV specifications which currently are not one of the primary or secondary sources of specifications contained in Standard 1.3.4 – Identity and Purity. Therefore, a decision will need to be made whether the OIV specifications are added as a secondary source in clause 3 of Standard 1.3.4 or whether a specification needs to be written and incorporated into the Schedule of this standard.

8. Impact Analysis

8.1 Affected Parties

The parties likely to be affected by this Application include:

1. the wine industry in both Australia and New Zealand who wish to have an alternative treatment to stabilise wine to inhibit potassium bitartrate crystallisation;

2. consumers who may benefit as a result of improved appearance of wine, with less formation of bitartrate crystals forming in their stored wine;

3. Government agencies in Australia and New Zealand who enforce the Code; and

4. manufacturers and suppliers of alternative stability treatments to the wine industry.

8.2 Benefit Cost Analysis

In developing food regulatory measures suitable for adopting in Australia and New Zealand, FSANZ is required to consider the impact of all options on affected parties in both countries. The benefit cost analysis identifies and evaluates, though is not limited to, the costs and benefits of the regulation, and its health, economic and social impacts.

FSANZ seeks comments on the following questions to assist completing this section at Draft Assessment. The Application also contains some information on this aspect.

- **What are the potential benefits or costs of this Application to you as a stakeholder (wine industry representative, consumer, Government agency, or other interested party)? Do the benefits outweigh the costs?**

COMMUNICATION AND CONSULTATION STRATEGY

9. Communication

It is considered that this Application will be a routine matter. Therefore, FSANZ has applied a basic communication strategy. This will involve advertising the availability of assessment reports for public comment in the national press and making the reports available on the FSANZ website. FSANZ will also issue media releases drawing journalists' attention to the reports.

The Applicant, and individuals and organisations who make submissions on this Application will be notified at each stage of the assessment of the Application. If approval is recommended, once the FSANZ Board has approved the Final Assessment Report, we will notify the Australia New Zealand Food Regulation Ministerial Council. The Applicant and stakeholders, including the public, will be notified of the gazettal of changes to the Code in the bi-national press and on the FSANZ website.

FSANZ provides an advisory service to the jurisdictions on changes to the Code.

10. Consultation

10.1 Public Consultation

Public comment on this Initial Assessment is sought.

The purpose of the Initial Assessment Report is to seek early input on a range of specific issues known to be of interest to various stakeholders, to seek input on the likely regulatory impact at an early stage and to seek input from stakeholders on any relevant matter in relation to this Application.

All stakeholders that make a submission in relation to the Application will be included on a mailing list to receive further FSANZ documents in relation to the Application. If readers of this Initial Assessment Report are aware of other interested parties, they should bring this to their attention. Other interested parties, as they come to the attention of FSANZ, will also be added to the mailing list for public consultation.

At this stage FSANZ is seeking public comment to assist it in assessing this Application. All stakeholders must observe the relevant due date for submissions.

FSANZ seeks comment on this Application which include, but is not exclusive to, the following issues:

- **Would treating wine with yeast mannoproteins, to a maximum level of 300 mg/l, cause any deleterious effects to the final bottled wine?**
- **Any food technology issues related to the production of the mannoproteins and their use to treat wine.**
- **Is it appropriate to include the OIV International Oenological Codex as a secondary source for specifications in the Code?**
- **Any information relating to the international approval and use of yeast mannoproteins as a food additive to inhibit potassium bitartrate crystallisation and their use for protein stabilisation of wine.**

10.2 World Trade Organization

As members of the World Trade Organization (WTO), Australia and New Zealand are obligated to notify WTO member nations where proposed mandatory regulatory measures are inconsistent with any existing or imminent international standards and the proposed measure may have a significant effect on trade.

There are relevant international standards being the OIV International Oenological Codex which approves the use of yeast mannoproteins to treat wine. Amending the Code to allow the use of yeast mannoproteins to treat wine to inhibit tartrate crystallisation is unlikely to have a significant effect on international trade as it already has approval in the OIV, the EU and Argentina and is approved in the Agreement between Australia and the European Community on trade in wine. This issue will be fully considered at Draft Assessment and, if necessary, notification will be recommended to the agencies responsible in accordance with Australia's and New Zealand's obligations under the WTO Technical Barriers to Trade (TBT) or Sanitary and Phytosanitary Measures (SPS) Agreements. This will enable other WTO member countries to comment on proposed changes to standards where they may have a significant impact on them.

CONCLUSION

11. Conclusion

After considering the requirements for Initial Assessment as prescribed in section 13 of the FSANZ Act, FSANZ has decided to accept the Application for the following reasons:

- The Application seeks approval for the use of mannoproteins extracted from yeast cell walls as a food additive to inhibit potassium bitartrate crystallization. Such an approval, if accepted, would warrant variations to Standard 1.3.1 – Food Additives and 4.5.1 – Wine Production Requirements (Australia only).

- There is currently no permission in the Code for mannoproteins used as a food additive to stabilize wine.

- The Application is not so similar to any previous application that it ought not be accepted.

- There are no other measures that would be more cost-effective than a variation to Standards 1.3.1 and 4.5.1 that could achieve the same end.

- At this stage no other relevant matters are apparent.