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

1-07
21 March 2007

.

INITIAL ASSESSMENT REPORT

APPLICATION A600

AGAROSE ION EXCHANGE RESIN AS A PROCESSING AID FOR BEER

DEADLINE FOR PUBLIC SUBMISSIONS: 6pm (Canberra time) 2 May 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

An Application has been received by FSANZ on 12 February 2006 from Food Liaison Pty Ltd acting for joint Applicants, Lion Nathan (brewer based in Auckland) and GE Health Care Bioscience AB (resin manufacturer based in Germany).

The Application (A600) seeks to obtain permission for the use of a new ion-exchange resin (called by the Applicants CSS – Combined Stabilisation System) to stabilise beer. Permission is sought for the resin as a processing aid in Standard 1.3.3 – Processing Aids of the *Australia New Zealand Food Standards Code* (the Code).

The ion exchange resin has an agarose backbone. This agarose ion exchange resin is proposed as a processing aid as an alternative to other technologies to stabilise beer by selectively removing undesirable haze forming proteins and polyphenols from the beer. Beer stabilisation improves the clarity and hence the long term shelf life of the final beer.

The agarose ion exchange resin consists of insoluble porous spherical beads with a diameter of between 100-300 μm. A stabilisation unit consists of column(s) of the resin immobilised in a liquid bed through which beer to be treated passes, so the beer has a short contact time with the resin. The resin selectively adsorbs protein and polyphenols from the beer stream. After completion of a stabilisation run the adsorbed material is removed from the beads by washing and is flushed to waste. The resin is reused after it is cleaned and regenerated (using back flushing with sodium chloride and sodium hydroxide solutions).

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 a new agarose based ion-exchange resin to be used to stabilise beer. The resin achieves this by selectively reducing the concentration of undesirable haze and particulate forming proteins and polyphenols in the treated beer by adsorbing them on the resin.

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 a new ion-exchange resin to stabilize beer. Such an approval, if accepted, would warrant a variation to Standard 1.3.3 – Processing Aids.

- There is currently no permission in the Code for this new ion-exchange resin.

- 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 Standard 1.3.3 that could achieve the same end.

- At this stage no other relevant matters are apparent.

Consultation

Public submissions are now invited on this Initial Assessment Report. Comments may be made on any aspect of the Application, though of particular interest will be information relevant to both the safety of the proposed use of the resin and potential costs and benefits of the proposed regulatory options.

Responses to the Initial Assessment Report will be used to develop the Draft Assessment Report.

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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) 2 May 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

An Application has been received by FSANZ on 12 February 2006 from Food Liaison Pty Ltd acting for joint Applicants, Lion Nathan (brewer based in Auckland) and GE Health Care Bioscience AB (resin manufacturer based in Germany). GE Health Care Bioscience is part of the General Electric company.

The Application (A600) seeks to obtain permission for the use of a new ion-exchange resin (called by the Applicants CSS – Combined Stabilisation System) to stabilise beer. Permission is sought for the resin as a processing aid in Standard 1.3.3 – Processing Aids of the Code.

CSS is an agarose based ion-exchange resin in the form of solid, insoluble, porous, spherical beads of 100-300 μm in diameter. The resin backbone is a macroporous, cross-linked polysaccharide agarose (which is a polymer of galactose and 3,6-anhydrogalactose). GE Health Care Biosciences manufacturers the CSS resin.

The agarose ion exchange resin acts as a processing aid to improve the stability of treated beer by selectively adsorbing some proportion of polyphenols and proteins from the treated beer stream using the ion exchange ability of the resin beads. These adsorbed polyphenols and proteins are deleterious to the quality of beer since they combine to form beer haze as well as aggregate to form visible particulates which are deleterious to beer quality and an indication of the end of the shelf life of the beer. Lion Nathan, being one of the Applicants, reported the technical details and some of their trial results of using the agarose resin to treat beer in a brewing conference in Hobart, Australia in March 2006[1].

1. Background

1.1 Current Standard

Standard 1.3.3 – Processing Aids contain permissions for processing aids that may be used to manufacture or process food. Processing aids not permitted in the Code may not be used for food manufacture until there has been a pre-market assessment of their use.

Clause 1 of Standard 1.3.3 defines a processing aid as:

> ***processing aid*** *means a substance listed in clauses 3 to 18, where –*
>
> *(a) the substance is used in the processing of raw materials, foods or ingredients, to fulfil a technological purpose relating to treatment or processing, but does not perform a technological function in the final food; and*
>
> *(b) the substance is used in the course of manufacture of a food at the lowest level necessary to achieve a function in the processing of that food, irrespective of any maximum permitted level specified.*

[1] Taylor, B., Clem, A., and David, P. (2006) Use of the Combined Stabilisation System and its impact on beer composition, *Proceedings of the Institute of Brewing & Distilling Asia Pacific Section,* Hobart, Australia

The Applicants have requested that permission for the use of the ion exchange resin be permitted as a processing aid for beer treatment only, not for all foods. They have sought permission, if approved, for the resin to be added to the Table to clause 14 – Permitted processing aids with miscellaneous functions, specifically for beer stabilisation with the function being an adsorbent to remove specific proteins and polyphenols during beer manufacture at a maximum permitted level of GMP (Good Manufacturing Practice).

Standard 1.3.3 also contains two other tables to this Application that could be relevant, namely the Table to clause 8 – Permitted ion exchange resins and the Table to clause 6 – Permitted decolourants, clarifying, filtration and adsorbent agents. However, both these Tables apply to the use of the processing aids in the course of manufacture of any food, and therefore would not limit the use of the resin to beer as requested by this Application.

1.2 Historical Background

The agarose ion exchange resin is proposed as an alternative to other currently permitted and used processing aids and technologies, which are used in the beer industry to stabilise beer to ensure maximum clarity of the final beer with little formation of visible haze and particulates. The essence of all current treatments is to reduce (but not to totally eliminate) the concentration of various polyphenol and protein fractions naturally occurring in beer which aggregate (often with other beer components such as carbohydrate and cations such as calcium) to form haze and particulates over time. Such treatments include the chill proof enzyme, usually called papain which is extracted from the papaya fruit, tannic acid, bentonite, silica gel [available in two forms, either as hydrogel (60-70% moisture) or xerogel (<7% moisture)], polyvinylpyrrolidone (PVP) as the monomer (not permitted to treat beer in the Code) or the insoluble polymer polyvinylpolypyrrolidone (PVPP).

The following indicates how the current beer stabilisation processing aids are permitted in the Code. Approved processing aids contained in Standard 1.3.3 are; the enzyme papain listed in the Table to clause 16 – Permitted enzymes of plant origin, tannic acid listed in the Table to clause 3 – Generally permitted processing aids, and PVPP listed in the Table to clause 6. Food additives listed in Schedule 2 of Standard 1.3.1 – Food Additives are also generally permitted processing aids because of subclause 3(b) of Standard 1.3.3. Therefore, the following substances are generally permitted processing aids since they are listed in schedule 2 of Standard 1.3.1; silica gel (permitted due to the entry for silicon dioxide (INS 551)) and bentonite (INS 558). As mentioned above PVP is not permitted as a processing aid to treat beer but the insoluble polymer PVPP is.

1.3 Function of the agarose ion exchange resin

Figure 1 below provides a representation of the agarose resin as contained in the Application.

The Application contains information about how the resin is manufactured including schematics of the various chemical reactions that occur. The description of the agarose ion exchange resin contained in the Application is:

> *Agarose, cross-linked and alkylated with epichlorohydrin and propylene oxide, then derivatised with tertiary amine groups whereby the amount of epichlorohydrin plus propylene oxide does not exceed 250% by weight of the starting quantity of agarose.*

This has been written to be directly comparable to the currently approved ion exchange resin listed in the Table to clause 8 of Standard 1.3.3 for a regenerated cellulose ion exchange resin. The resin of the current Application contains agarose (the sugar base of agar, which separately is an approved food additive in the Code with INS number 406) as the sugar base of the polymer while the regenerated cellulose resin is based on glucose.

The Application states that agarose beads are insoluble, porous spherical beads with a diameter of between 100-300 μm. The information about how the resin is used to stabilise beer is explained in the Application. Beer is passed through a bed of the resin where it has short contact time to selectively adsorb polyphenols and proteins from the beer stream.

A treatment chamber is filled with a floating bed of these agarose beads (commonly referred to an immobilised bed), where the solid agarose beads are packed loosely in a liquid, initially de-aerated water. (The agarose beads are initially sold, stored and transported in 20% ethanol). Before use the resin is subjected to a pre-use wash cycle of 5 column volumes of de-aerated water, 5 column volumes of sodium chloride and finally 5 column volumes of de-aerated water. There may be a number of adsorption chambers depending on the brewery needs.

Beer to be treated is first split into two separate streams where some pre-determined proportion of the beer is passed through the chamber so this beer has a short contact time with the resin and is stabilised. During this short contact time specific haze forming protein and polyphenol compounds are selectively adsorbed from the beer onto the resin. The treated beer is then blended back to the rest of the untreated beer. Over the treatment run the proportion of treated to non-treated is increased due to the increasing saturation of the agarose beads with adsorbed compounds.

When full saturation of the resin beads occurs regeneration is required using back flushing of the resin bed with first sodium chloride (12% solution) and then sodium hydroxide (4% solution). The final rinse is again de-aerated water.

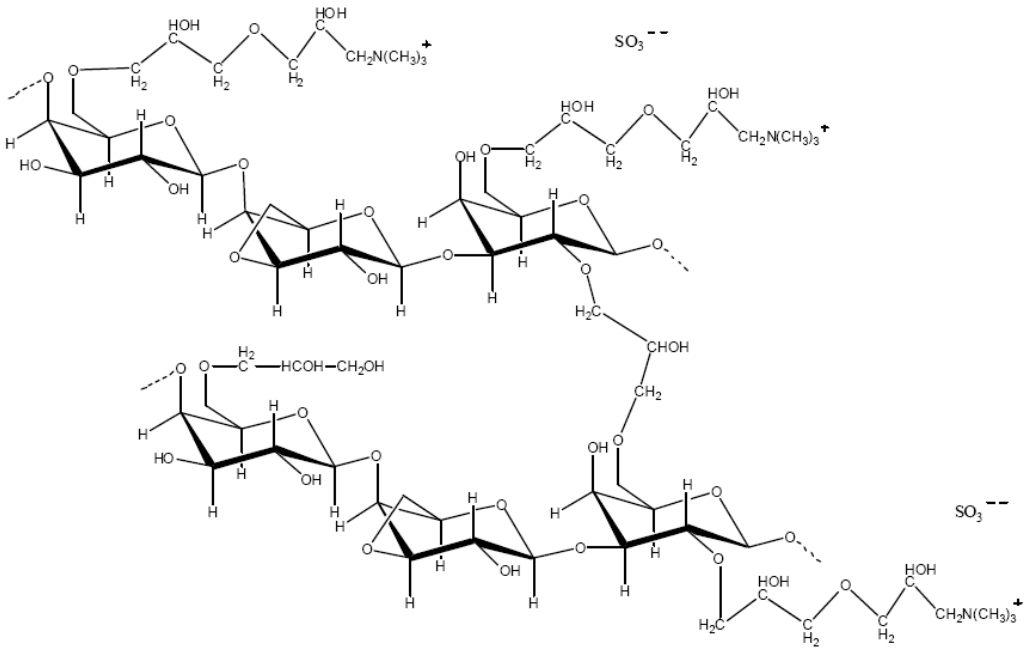

Figure 1 – Structural representation of the agarose resin which has been copied from the Application.

The intended production process limits for beer treatment is the range of -1.5 to 0.5°C for the beer temperature and beer pH range of 3 to 5. Regeneration is carried out at 20°C and the caustic washing solution has a pH of approximately 14.

The following information is taken from the Application. A single stabilisation chamber has dimensions of 2 metre in diameter, a resin height of 30 cm, giving a column volume of 1000 litre of resin. The volume of beer treated through this column would 100,000 litres, at a flow rate of 1,500 litres per hour, meaning a typical run would be 67 hours. For such a stabilisation run 18 kg of adsorbed proteins and polyphenols would be removed from the beer stream and sent to waste. A commercial unit may contain a number of individual chambers depending on the volume and rate of beer to be treated. Commercial trials are reported in the Application that use three chambers of 900 litre volume to treat 940,000 litres of beer at a flow rate of 60,000 litres/hr.

The Application states that the stability of the resin has a lifetime of 750-1500 cycle, where a complete cleaning cycle is performed every five cycles. This could lead to the useable lifetime of the resin being at least 2 years before the resin would need to be replaced.

1.4 International Standards

The Application states that the agarose ion exchange resin is approved in the USA, Germany and Russia. The Application contains copies of the approvals, including translations of the German and Russian approval certificates.

It is stated that the approval for the resin in the USA is as a self assessed GRAS (generally recognised as safe), confirmed by the Food and Drug Administration (FDA) in Food Contact Substance Notification FCN 000531, effective October 26 2005[2]. This notification is specific to the resin of this Application manufactured by GE Healthcare. It is approved for repeated use in extracting proteins or substances from liquid, water-based foods such as milk, whey, fruit juice, beer and wine.

The German approval for the use of agarose resin for beer stabilisation treatment is contained in two documents (copies in German and their English translations) contained in the Application. This approval is specifically for beer treatment. This approval occurred after various extraction experiments were performed to ensure the safety and integrity of the treated beer. The experimental methods and results are included in these two documents. The first document assessed the extraction of seven substances, toluene, epichlorohydrine, allyl glycidyl ether, acetone, ethanol, glucose and hydroxyl methyl furfurane, while the second assessed the extraction of chloride when twice the concentration of the resin is used compared with normal practice. The conclusion of these documents (dated 12 December 1995 and 27 March 1996) is that the resin complies with the Beer Decree (from 2nd July 1990, BGBI, Y 1990, part 1, p. 1332-1333; last modified 23rd November 1993, BGBI, Y 1993, part 1, p. 1912) and is permitted as beer fining.

The Russian approval for use of the agarose resin is contained in two documents (copies in Russian and their English translation) contained in the Application.

[2] Inventory of Effective Food Contact Substance Notifications, US FDA, Center for Food Safety and Applied Nutrition/ Office of Food Additive Safety, at http://vm.cfsan.fda.gov/~dms/opa-fcn.html (assessed on 23 February 2007)

The document is a Sanitary-Epidemiological Certificate, provided by the Ministry of Healthcare of the Russian Federation, North-West Region on Transport, of 21 October 2003, for use of the resin as an adsorbent for use in brewing. The certificate reported results where they analysed for the extractants; formaldehyde, benzene, ethyl acetate, ethanol, lead, mercury and cadmium from the resin using distilled water and 2% citric acid as the model solutions. The results for all were less than the prescribed maximum allowed levels.

2. The Issue / Problem

Processing aids 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 (specially Standard 1.3.3 which regulates the approval of processing aids) for the resin. Therefore a safety assessment of stabilising beer using the resin is required before it can be approved or used for this purpose.

3. Objectives

The objective of the assessment is to determine whether it is appropriate to amend the Code to permit the use of the agarose ion exchange resin as a processing aid to stabilise beer.

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
- 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 Questions

The key questions which FSANZ needs to consider as part of this assessment, specially at Draft Assessment are:

- Are there any public health and safety issues with approving the agarose ion exchange resin as a processing aid for the stabilisation of beer?

- Are there any issues with how the agarose ion exchange resin will be used to treat beer?

RISK ASSESSMENT

5. Safety Assessment

The Application contains information about the manufacture of the resin and how it will be used as a processing aid to stabilise beer. Included in this information are details of the stability of the resin, both in normal usage during beer treatment and under abuse situations (that is higher temperature regeneration and use) as well as analysis of various extraction chemicals from the resin again during normal use conditions, and under extreme worse case situations. An analysis of both the materials used to manufacture the resin and the various chemicals that may be extracted from the resin and their safety if they are leeched into the food supply will form part of the Safety Assessment Report.

Two extraction protocols were undertaken by the Applicants to assess both the stability of the resin and subsequent extractants. They are: high pressure and elevated temperature for a short period of time; and an extended time period at elevated temperatures, being specifically:

1. Pressurised fluid extraction at 10 MPa (high positive pressure) and 40°C for 5 minutes; and
2. Extraction at atmospheric pressure at both 20°C and 40°C for 160 hours.

In normal operation the resin will be in contact with beer for only a short period of time (60-240 seconds) and at low temperatures (-1.5 - 0.5°C).

There are no dietary exposure or nutritional considerations for this Application since only extremely low levels of extractants may be leeched into the treated beer, which have no allergencity concerns (to be confirmed at Draft Assessment) and would be far too small to be of a dietary or nutrition interest. The product removes components from the treated beer stream, being selected adsorbed proteins and polyphenols.

6. Food Technology Considerations

The Application contains details about the manufacture and use of the resin for beer stabilisation. It also contains details on the specification of the resin. These matters, as well as whether there is a technological justification for the product will be considered as part of a Food Technology Report at Draft Assessment. Lion Nathan, being one of the Applicants, has performed research and development on this product and believe there is a benefit and hence a technological justification for them such that, if approval is gained they state they would implement use of the technology in their commercial production of beer.

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.

Processing aids used in Australia and New Zealand are required to be listed in Standard 1.3.3 – Processing Aids. The agarose resin acts as a processing aid when it is used to stabilise beer, and requires a pre-market approval under Standard 1.3.3, and 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 the agarose ion exchange resin as a processing aid for beer stability treatment.

Option 2 Amend Standard 1.3.3 to approve the use of the agarose ion exchange resin as a processing aid for beer stability treatment.

If option 2 is successful the Applicant has asked that the approval for the resin be added into Table to clause 14 (Permitted processing aids with miscellaneous functions) of Standard 1.3.3. It would also mean that a new specification for the agarose resin would need to be incorporated into Standard 1.3.4 – Identity and Purity, since the specification is not covered by any of the primary or secondary sources (clause 2 and 3 respectively) in the Standard.

8. Impact Analysis

8.1 Affected Parties

The parties likely to be affected by this Application include:

1. the beer industry who will have an alternative processing aid and technology to use to stabilise their beer, which may have technical benefits by producing higher quality clear beer with good shelf life and possibly more economically;

2. manufacturers and suppliers of alternative beer stabilisation technologies, who will have competition;

3. consumers who may benefit as a result of better quality beer products; and

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

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 question 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 (beer industry representative, consumer or Government agency, or other interested party)? Do the benefits outweigh the costs?

COMMUNICATION

9. Communication and Consultation Strategy

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 Ministerial Council. The Applicant and Stakeholders, including the public, will be notified of the gazettal of changes to the Code in the national press and on the website.

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

10. Consultation

Public comment on this Initial Assessment Report 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 matter of interest to them in relation to the 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 others who might have an interest in this Application, they should bring this to their attention. Other interested parties as they come to the attention of FANZ 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 not exclusive to, the following issues:

- The safety of the agarose ion exchange resin when used as a processing aid to stabilise beer.

- Would using the agarose ion exchange resin to treat beer cause any deleterious effects to the beer or beer consumers?
- Any food technology issues arising from the use of the resin to treat beer.
- Any information about the international approval and use of the resin to treat beer.

10.1 World Trade Organization (WTO)

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 not any relevant international standards and amending the Code to allow the use of the agarose resin as a processing aid to stabilise beer is unlikely to have a significant effect on international trade since Codex does not regulate processing aids. 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 a new ion-exchange resin to stabilize beer. Such an approval, if accepted, would warrant a variation to Standard 1.3.3 – Processing Aids.

- There is currently no permission in the Code for this new ion-exchange resin.

- 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 Standard 1.3.3 that could achieve the same end.

- At this stage no other relevant matters are apparent.