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

4-07
8 August 2007

DRAFT ASSESSMENT REPORT

APPLICATION A600

AGAROSE ION EXCHANGE RESIN AS A PROCESSING AID FOR BEER

DEADLINE FOR PUBLIC SUBMISSIONS: 6pm (Canberra time) 19 September 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

This Application was received on 12 February 2007 from Food Liaison Pty Ltd acting for joint Applicants Lion Nathan, a brewer based in Auckland and GE Health Care Bioscience AB, a resin manufacturer based in Germany.

Application A600 seeks to obtain permission for the use of a new ion exchange resin (Combined Stabilisation System) as a processing aid to stabilise beer. Processing aids are required to undergo a pre-market safety assessment before approval for use in Australia and New Zealand. Permission is sought for use of 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 contains an agarose backbone and would be an alternative to other currently available technologies to stabilise beer. It would function to selectively remove undesirable haze forming proteins and polyphenols, leading to improvements in the clarity and shelf life of 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 is passed, in order that there is a short contact time with the resin. The ion-exchange resin selectively binds protein and polyphenols from the beer stream. After passage of the beer the bound material is removed from the beads by washing and is flushed to waste. The resin is reused after it is washed and equilibrated with water and a sodium chloride and sodium hydroxide solution.

A safety assessment was conducted to identify any potential public health and safety risks associated with the use of the agarose ion exchange resin as a processing aid in the manufacture of beer. The assessment was based on data on the chemistry, impurity profile, toxicity of potential impurities and intended use pattern of the agarose ion exchange resin provided by the Applicants and obtained from the scientific literature. FSANZ concluded that there are no safety concerns based on the considerations listed below.

- Cellulose-based ion exchange resins, which use the same chemistry (i.e. epichlorohydrin cross-linking), are already permitted in the Code.

- While a number of impurities have been hypothesised to occur in extracts from the resin, the agarose ion exchange resin does not generate any detectable impurities in beer under normal processing or under abuse conditions.

- The majority of potential impurities are permitted in the Code as food additives or processing aids.

- While some of the potential impurities have genotoxic and carcinogenic potential, none of these were actually detectable in extracts of the cross-linked agarose resin.

- Contact time between beer and the agarose ion exchange resin is less than two minutes, thereby limiting the potential for impurities to enter the product. In addition, before each production cycle, the resin is cleaned, rinsed and equilibrated further minimising the concentration of potential impurities.

- The agarose ion exchange resin has been approved for use in the USA and Europe.

There are two regulatory options under consideration, to approve or not approve the use of the agarose ion exchange resin as a processing aid for beer stability treatment. Approval would benefit the beer industry, manufacturers and suppliers of alternative beer stabilisation technologies and consumers. No additional costs to government agencies or consumers have been identified.

The Draft Assessment concludes that approval of the agarose ion exchange resin as a processing aid for beer stability treatment is appropriate as no public health and safety concerns have been identified and the use is technologically justified.

Purpose

The purpose of the Application is to vary the Code to permit 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 binding them on the resin.

Preferred Approach

FSANZ recommends the proposed draft variations to Standard 1.3.3 – Processing Aids and 1.3.4 – Identity and Purity to approve the use of the agarose ion exchange resin as a processing aid for beer stability treatment and to incorporate a specification for the agarose ion exchange resin.

Reasons for Preferred Approach

This Application has been assessed against the requirements in section 15 of the Food *Standards Australia New Zealand Act 1991* (FSANZ Act). FSANZ recommends the proposed draft variations to Standards 1.3.3 and 1.3.4 for the following reasons.

- A detailed safety assessment did not identify any public health and safety concerns.
- Use of the enzyme is technologically justified as an alternative treatment to the currently permitted and used processing aids and processes.
- No issues were raised in submissions to the Initial Assessment identifying any risks associated with the proposed approval of the agarose ion exchange resin.
- The impact analysis concluded that the benefits of permitting the use of the agarose ion exchange resin outweigh any associated costs.
- The proposed variations are consistent with the FSANZ Act section 18 objectives.

Consultation

FSANZ invited public submissions on the Initial Assessment Report. Four submissions were received; three support or tentatively support the Application pending the outcome of the safety assessment and one stated no position indicating further comment would be made after Draft Assessment.

FSANZ is seeking public comment on this Draft Assessment Report to assist in assessing the Application. Comments on, but not limited to the following would be useful:

- any impacts (costs/benefits) of the proposed variations to Standards 1.3.3 or 1.3.4;
- any public health and safety considerations associated with the proposed approval; and
- any other affected parties to this Application.

Further details on making submissions are provided in the Invitation for Public Submissions section of this report.

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INVITATION FOR PUBLIC SUBMISSIONS

FSANZ invites public comment on this Draft Assessment Report based on regulation impact principles and the draft variations to the Code 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 Final Assessment of this Application. Submissions should, where possible, address the objectives of FSANZ as set out in section 18 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 confidential commercial information. Section 114 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) 19 September 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 on 12 February 2007 from Food Liaison Pty Ltd acting for joint Applicants Lion Nathan, a brewer based in Auckland and GE Health Care Bioscience AB, a resin manufacturer based in Germany. GE Health Care Bioscience is part of the General Electric company.

Application A600 seeks to obtain permission for the use of a new ion exchange resin (CSS – Combined Stabilisation System) as a processing aid in Standard 1.3.3 – Processing Aids to stabilise beer. The ion exchange resin is referred to as agarose ion exchange resin throughout this report.

The agarose ion exchange resin consists of spherical beads of 100-300 μm in diameter. The beads are composed of cross-linked polysaccharide agarose (which is a polymer of galactose and 3,6-anhydrogalactose) which enables them to be porous. GE Health Care Biosciences manufacturers the resin.

The agarose ion exchange resin functions to improve the stability of treated beer by selectively binding polyphenols and proteins in beer. Polyphenols and proteins contribute to form beer haze and may also aggregate to form visible particulates. Particle formation is deleterious to beer quality and an indication of the end of the shelf life of the beer. Lion Nathan, one of the Applicants, reported the technical details and some of their trial results of using the agarose resin to treat beer at a brewing conference in Hobart, Australia in March 2006[1]. The report suggested that the agarose resin was valuable in reducing undesirable haze and particulate forming proteins and polyphenols.

1. Background

1.1 Current Standard

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

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

Currently in Standard 1.3.3, there are two tables that regulate ion exchange resins; 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 of these Tables apply to the use of processing aids in the course of manufacture of all food, and therefore would not limit the use of the agarose resin to beer as requested by the Applicants.

In addition, Standard 1.3.4 ensures that substances added to food in accordance with the Code meet appropriate specifications for identity and purity of food additives, processing aids, vitamins and minerals and other added nutrients.

There is currently no approval in Standard 1.3.3 for agarose ion exchange resins. Therefore, a safety assessment of the resin for use in stabilising beer is required before it can be approved or used for this purpose. This Application seeks permission for the use of the agarose ion exchange resin as a processing aid for beer treatment only, not for all foods. Permission is specifically sought for the resin to be added to the Table to clause 14 – Permitted processing aids with miscellaneous functions, for beer stabilisation with the function being an adsorbent to remove specific proteins and polyphenols during beer manufacture at GMP (Good Manufacturing Practice) levels. If the proposed use is approved, a specification of the agarose ion exchange resin will also be required in Standard 1.3.4.

1.2 Historical Background

The agarose ion exchange resin is proposed as an alternative to other currently permitted and used processing aids and technologies used in the beer industry to stabilise beer to ensure maximum clarity of the final beer with little formation of visible haze and particulates.

There is a range of processing aids currently permitted in Standard 1.3.3 which are used 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. These consist of the following:

- the enzyme papain (extracted form papaya fruit) 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
- polyvinylpolypyrrolidone (PVPP) listed in the Table to clause 6 – Permitted decolourants, clarifying, filtration and adsorbent agents.

In addition, under subclause 3(b) of Standard 1.3.3 the following food additives listed in Schedule 2 of Standard 1.3.1 – Food Additives are permitted to be used as treatments for beer:

- silica gel (permitted due to the entry for silicon dioxide (INS 551); and
- bentonite (INS 558).

1.3 International Standards

The Applicants state 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.

The agarose ion exchange resin has self assessed GRAS (generally recognised as safe) in the USA as 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 under consideration in this Application manufactured by GE Healthcare. It is approved for use in extracting proteins or substances from liquid, water-based foods such as milk, whey, fruit juice, beer and wine.

In Germany approval for the use of agarose resin for beer stabilisation treatment is contained in two documents detailed in the Application. The conclusion (dated 12 December 1995 and 27 March 1996) was 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.

Similarly, in Russia, approval for use of the agarose resin is contained in a document detailed in the Application. 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.

2. The Issue / Problem

Standard 1.3.3 regulates the use of processing aids in food manufacture, prohibiting their use in food unless there is a specific permission in the Standard. There is currently no approval in the Code for use of the agarose ion exchange resin. Under Standard 1.3.3 a pre-market assessment is required before processing aids can be approved for use in food manufacture. Therefore a safety assessment of using the agarose ion exchange resin to stabilise beer is required before it can be approved or used for this purpose. It is proposed to regulate agarose ion exchange resins in the Table to clause 14 – Permitted processing aids with miscellaneous functions.

Standard 1.3.4 ensures that substances added to food in accordance with the Code meet appropriate specifications for identity and purity of food additives, processing aids, vitamins and minerals and other added nutrients. A specification of the agarose ion exchange resin will be required in Standard 1.3.4 if it is to be approved for the proposed use.

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 18 of the FSANZ Act. These are:

- the protection of public health and safety;

[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 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 primary role of FSANZ in developing or varying food regulatory measures for processing aids is to ensure that the processing aid, any potential impurities and the intended use pattern do not present public health and safety concerns.

The key questions which FSANZ considered as part of this assessment were:

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

- Is there a technological need to use agarose resins in the treatment of beer?

FSANZ evaluates food-borne risks by reviewing available scientific information to estimate, either quantitatively or qualitatively, the probability of an adverse health effect as a result of human exposure to a hazard. In assessing the public health and safety implications of processing aids, FSANZ conducts a safety assessment to identify potential public health and safety risks associated with the use of the processing aid in the manufacture of food. The assessment considers data on the chemistry, impurity profile, toxicity of potential impurities and intended use pattern of the processing aid provided by the Applicants and obtained from the scientific literature. FSANZ will not approve processing aids for inclusion in the Code where there a risk to public health and safety is identified.

RISK ASSESSMENT

5. Risk Assessment Summary

5.1 Safety Assessment

A safety assessment **(Attachment 2)** was conducted to identify potential public health and safety risks associated with the use of the agarose ion exchange resin as a processing aid in the manufacture of beer. FSANZ concluded that there are no safety concerns with regard to the use of the agarose ion exchange resin as a processing aid in the manufacture of beer based on the considerations listed below.

- Cellulose-based ion exchange resins, which use the same chemistry (i.e. epichlorohydrin cross-linking), are already permitted in the Code.

- While a number of impurities have been hypothesised to occur in extracts from the resin, the agarose ion exchange resin does not generate any detectable impurities in beer under normal processing or under abuse conditions.

- The majority of potential impurities are permitted in the Code as food additives or processing aids.

- While some of the potential impurities have genotoxic and carcinogenic potential, none of these were actually detectable in extracts of the cross-linked agarose resin.

- Contact time between beer and the agarose ion exchange resin is less than two minutes, thereby limiting the potential for impurities to enter the product. In addition, before each production cycle, the resin is cleaned, rinsed and equilibrated further minimising the concentration of potential impurities.

- The agarose ion exchange resin has been approved for use in the USA and Europe.

5.2 Food Technology Considerations

Commercial beers are usually stabilised during production to ensure clarity of the beer with ageing. Current treatments are to reduce (but not to totally eliminate) the concentration of various polyphenol and protein fractions naturally occurring in beer which aggregate with other beer components to form haze and particulates with ageing.

The agarose ion exchange resin is proposed as an alternative to other currently permitted and used processing aids and technologies, to ensure maximum clarity of beer with little formation of visible haze and particulates.

The agarose ion exchange resin selectively binds the following listed polyphenols in order of increasing adsorption; catechin, Procyanidin B_3 and Prodelphinidin B_3. Haze sensitive proteins are also binded from the treated beer. Proteins that are important for foam stability are largely unaffected and so beer foam stability of the treated beers can be maintained.

The use of agarose ion exchange resin as a processing aid to stabilise beer is technologically justified as an alternative treatment to the currently permitted and used processing aids and processes. Further information is provided in the Food Technology Report at **Attachment 3**.

5.3 Dietary Exposure or Nutritional Considerations

There are no dietary exposure or nutritional issues as only low levels of extractants are expected to be leeched into the treated beer. Therefore, a detailed dietary exposure assessment and nutritional analysis was not considered necessary during the assessment process. FSANZ does not envisage any allergenicity concerns for consumers of beer treated with agarose resins as the selected binded proteins would be removed from the treated beer stream.

RISK MANAGEMENT

6. 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 ion exchange resin is considered to function as a processing aid when it is used to stabilise beer, and requires a pre-market approval under Standard 1.3.3. 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.

The Application seeks approval for the agarose ion exchange resin to be included in the Table to clause 14 – Permitted processing aids with miscellaneous functions of Standard 1.3.3. If use of the agarose ion exchange resin is approved, an amendment to Standard 1.3.4 – Identity and Purity would be required to incorporate a specification as none of the primary or secondary sources listed in clauses 2 and 3 of the Standard apply.

7. Impact Analysis

The impact analysis represents likely impacts based on available information. The impact analysis is designed to assist in the process of identifying the affected parties, any alternative options consistent with the objective of the proposed permission for the agarose ion exchange resin, and the potential impacts of any regulatory provisions. Information from public submissions is sought to make a final assessment of the proposed changes.

7.1 Affected Parties

The parties likely to be affected by the proposed amendments to the Code include:

- the beer industry;
- manufacturers and suppliers of alternative beer stabilisation technologies;
- consumers; and
- Government agencies in Australia and New Zealand involved in enforcing the Code.

7.2 Benefit Cost Analysis

In developing food regulatory measures for adoption in Australia and New Zealand, FSANZ is required to consider the impact of each option on all sectors of the community, including consumers, the food industry and governments. The regulatory impact assessment identifies and evaluates, though is not limited to, the costs and benefits of the regulation, and its health, economic and social impacts. At Final Assessment FSANZ will use the Office of Best Practice Regulation Business Cost Calculator to calculate the compliance costs of regulatory options where medium to significant competitive impacts or compliance costs are likely.

7.2.1 Option 1 – Not permit the use of the agarose ion exchange resin as a processing aid for beer stability treatment

There are no perceived benefits to industry, consumers or government regulators if this option is progressed.

This option may result in costs to the beer industry in that use of the agarose ion exchange resin as a processing aid that may improve process efficiencies will not be permitted. This may result in a competitive disadvantage for the Australian and New Zealand beer industry internationally as use of the agarose ion exchange resin is currently permitted in the United States, Germany and Russia.

This option may result in costs to manufacturers and suppliers of alternative beer stabilisation technologies as there will not be an opportunity to market the agarose ion exchange resin to the beer industry in Australia or New Zealand.

7.2.2 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

For the beer industry, adopting this option would permit the use of an alternative processing aid and technology to stabilise beer, which may have technical benefits including production of higher quality clear beer with good shelf life and possibly result in a more economic production process. The Applicants note that although there is a cost involved in setting up the equipment to use the agarose ion exchange resin, the benefit is that beer manufacturing processes that currently require two steps could be completed in one. The annual cost advantage would depend on the equipment used and the size of the brewery.

Manufacturers and suppliers of alternative beer stabilisation technologies may benefit via availability of another treatment. The Application notes that trials conducted by Lion Nathan concluded that the agarose ion exchange resin is a viable addition to the stabilisation options currently available to brewers.

Consumers may benefit through the improved quality and stability of beer products. The purpose of the agarose ion exchange resin is to reduce haze formation in beer. This will delay the onset of haze and increase shelf life of packaged beer. The Application notes that while cost savings are anticipated for the brewer if use of the agarose ion exchange resin is approved, it is not anticipated that any savings would be sufficient to have a significant effect on the price paid by consumers for beer.

No additional costs to consumers have been identified. The Application notes that safety analysis conducted by GE Healthcare found that use of the agarose ion exchange resin does not impart detectable contaminants to beer under normal processing conditions nor under abuse conditions. This analysis also found that any contaminants potentially present under the level of detection constitute an extremely low risk to beer consumers. The FSANZ Safety Assessment Report **(Attachment 2)** found that use of the agarose ion exchange resin as a processing aid in the manufacture of beer poses negligible risks to the health and safety of consumers. FSANZ does not consider there to be any dietary exposure or nutritional implications associated with the approval of the agarose ion exchange resin. Removal of certain undesirable haze forming proteins and polyphenols from beer does not raise nutritional concerns. As use of the agarose ion exchange resin has no flavour or other sensory implications it is not expected to influence the amount of beer consumed.

No additional costs to Government agencies have been identified.

7.3 Comparison of Options

In assessing applications, FSANZ considers the impact of various regulatory (and non-regulatory) options on all sectors of the community, including consumers, food industries and governments in Australia and New Zealand. For Application A600, there are no options other than variations to Standards 1.3.3 and 1.3.4.

An amendment to Standard 1.3.3 to approve the use of the agarose ion exchange resin as a processing aid for beer stability treatment is required. In addition, an amendment to Standard 1.3.4 – Identity and Purity to incorporate a specification for the agarose ion exchange resin is also required, as none of the primary or secondary sources listed in clauses 2 and 3 of that Standard apply.

Therefore, **option 2** is preferred due to the following reasons:

- There are no public health and safety concerns associated with the proposed amendments (this benefit also applies to option 1).

- Use of the enzyme is technologically justified as an alternative treatment to the currently permitted and used processing aids and processes.

- No issues were raised in submissions to the Initial Assessment identifying any risks associated with the proposed approval of the agarose ion exchange resin.

The conclusion of the impact analysis is that the benefits of permitting the use of the agarose ion exchange resin outweigh any associated costs.

COMMUNICATION AND CONSULTATION STRATEGY

8. Communication

As this Application is considered routine and applications to permit a processing aid do not normally generate public interest, FSANZ has adopted a basic communication strategy, with a focus on informing the community that a change to the Code is being contemplated.

FSANZ publishes the details of the Application and subsequent assessment reports on its website, notifies the community to the period of public consultation through newspaper advertisements, and issues media releases drawing attention to proposed Code amendments. Once the Code has been amended, FSANZ incorporates the changes in the website version of the Code and, through its email and telephone advice service, responds to industry enquiries.

Should the media show an interest in this Application, FSANZ can provide background information and other advice, as required.

9. Consultation

FSANZ invited public submissions on the Initial Assessment Report. The public comment period commenced on 21 March 2007 and closed six weeks later on 2 May 2007. Four submissions were received; three support or tentatively support the Application pending the outcome of the safety assessment and one stated no position indicating further comment would be made after Draft Assessment. Submissions received during the first round of public comment are summarised in **Attachment 4**.

FSANZ is seeking public comment on this Draft Assessment Report to assist in assessing the Application. Comments on, but not limited, to the following would be useful:

- any impacts (costs/benefits) of the proposed variations to Standards 1.3.3 or 1.3.4;
- any public health and safety considerations associated with the proposed approval; and
- any other affected parties to this Application.

9.2 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.

Application A600 requests a permission in the Code for the use of the agarose ion exchange resin as a processing aid to stabilise beer. Codex Alimentarius Commission (Codex) standards are used as the relevant international standard or basis as to whether a new or changed standard requires a WTO notification. Codex does not regulate processing aids and there are no other relevant international standards. The use of processing aids in food product manufacturing is unlikely to have an effect on trade between member nations. As the agarose ion exchange resin is a processing aid, there is no requirement to include it on product labels.

Amending the Code to allow the use of the agarose ion exchange resin as a processing aid to stabilise beer is considered unlikely to have a significant effect on international trade. For these reasons it was determined that there is no need to notify this Application as a Sanitary and Phytosanitary (SPS) measure in accordance with the WTO Agreement on the Application of SPS Measures.

CONCLUSION

10. Conclusion and Preferred Approach

This Application has been assessed against the requirements for Draft Assessments in section 15 of the Food *Standards Australia New Zealand Act 1991* (FSANZ Act). FSANZ recommends the proposed draft variations to Standards 1.3.3 – Processing Aids and 1.3.4 – Identity and Purity.

Preferred Approach

FSANZ recommends the proposed draft variations to Standard 1.3.3 – Processing Aids and 1.3.4 – Identity and Purity to approve the use of the agarose ion exchange resin as a processing aid for beer stability treatment and to incorporate a specification for the agarose ion exchange resin.

10.1 Reasons for Preferred Approach

FSANZ recommends the proposed draft variations to Standards 1.3.3 and 1.3.4 for the following reasons.

- A detailed safety assessment did not identify any public health and safety concerns.
- Use of the enzyme is technologically justified as an alternative treatment to the currently permitted and used processing aids and processes.
- No issues were raised in submissions to the Initial Assessment identifying any risks associated with the proposed approval of the agarose ion exchange resin.
- The impact analysis concluded that the benefits of permitting the use of the agarose ion exchange resin outweigh any associated costs.
- The proposed variations are consistent with the FSANZ Act section 18 objectives.

11. Implementation and Review

If the variations to the Code proposed through this Application are progressed, the amendments take effect on gazettal and would be subject to existing compliance arrangements.

ATTACHMENTS

1. Draft variations to the *Australia New Zealand Food Standards Code*
2. Safety Assessment Report
3. Food Technology Report
4. Summary of Submissions

Attachment 1

Draft variations to the *Australia New Zealand Food Standards Code*

To commence: on Gazettal

[1] ***Standard 1.3.3*** *of the Australia New Zealand Food Standards Code is varied by inserting in the* Table to clause 14 –

Agarose ion exchange resin being 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	Removal of specific proteins and polyphenols from beer	GMP

[2] ***Standard 1.3.4*** *of the Australia New Zealand Food Standards Code is varied by inserting in the* Schedule –

Specification for agarose ion exchange resin

(a) This specification relates to 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.

(b) The resins are limited to use in aqueous process streams for the removal of proteins and polyphenols from beer. The pH range for the resins shall be no less than 2 and no more than 4, and the temperatures of water and food passing through the resin bed shall not exceed 2˚C.

(c) When subjected to the extraction regime listed in the CFR Title 21 part 173.25(c)(4), but using dilute hydrochloric acid at pH 2 in place of 5% acetic acid, the ion exchange resins shall result in no more than 25 ppm of organic extractives.

Attachment 2

Safety Assessment Report

Introduction

This safety assessment was conducted to identify potential public health and safety risks associated with the use of Combined Stabilisation System (CSS) Adsorber as a processing aid in the manufacture of beer to selectively remove undesirable compounds (turbidity-forming protein and polyphenols) in order to improve its stability. The agarose ion exchange resin is referred to as CSS Adsorber in this Report. The assessment was based on data on the chemistry, impurity profile, toxicity of potential impurities and intended use pattern of CSS Adsorber provided by the Applicants and obtained from the scientific literature.

In the USA, CSS Adsorber is 'generally recognized as safe' (GRAS) for use as an ion exchange resin for the extraction of proteins or other substances from liquid and water-based food materials (e.g. milk, whey, fruit juice, beer and wine). In Germany and Russia, CSS Adsorber is approved for use as a processing aid for beer similar to the current Australian application.

Physico-chemical properties

The CSS Adsorber is a cation exchange resin consisting of a matrix of highly cross-linked, insoluble, agarose beads. The CAS Registry Name is Agarose, polymer with (chloromethyl)oxirane, 2-hydroxy-3-(2-hydroxy-3-(trimethylammonio)propoxy)propyl ethers, sulfates salts (CAS Registry Number 846053-13-2); Trade names include Q Sepharose® Big Beads Food Grade or Q Sepharose® BB.

The CSS Adsorber has a working temperature range of -2-40ºC and a working pH range of 2-12. The lifetime of CSS Adsorber is reportedly two years as the resin loses its capacity to bind the target compounds due to the absorption of extraneous compounds.

Manufacture

In brief, the manufacturing process involves firstly dispersing an aqueous solution of agarose in toluene to give droplets of 100-300 µm in diameter. The gel is cross-linked with epichlorohydrin and sodium hydroxide in the presence of sodium sulfate. The product is washed, wet-sieved then reacted with allyl glycidyl ether in alkali to form the intermediate, allyl sepharose. The last step involves reacting allyl sepharose with bromine to form a bromohydrin, followed by reaction with trimethylamine in alkali. After each manufacturing step, the product is washed repeatedly with an appropriate solution.

Impurities

On theoretical grounds, the Applicants listed a number of potential manufacturing impurities, which are summarised in Table 1.

The maximum concentrations of these impurities in aqueous extracts[3] from the CSS Adsorber were either: (1) estimated from elemental analysis of carbon, nitrogen, sulfur and bromine or (2) measured directly for five specific substances (allyl glycerol ether, 2,3-epoxy-1-propanol, allyl glycidyl ether, epichlorohydrin, 3-chloro-1,2-propandiol). It should be noted that none of the latter five substances were actually detected and therefore maximal residual concentrations were reported as the limit of detection (LOD).

Table 1: Potential impurities in CSS Adsorber

Impurity	**CAS Registry Number**	**Maximum residual concentration (mg/kg wet weight)**
Soluble agarose fragments (agar)	9012-36-6	7.1[1]
Ethyl cellulose	9004-57-3	5.5[1]
Polyoxyethylene nonylphenyl phosphate ester sodium salt	68954-84-7	10.9[1]
Glycerol	56-81-5	7.7[1]
Sodium acetate	6131-90-4	10.2[1]
Sodium formate	141-53-7	17.0[1]
Sodium sulphate	7757-82-6	14.7[1]
Sodium chloride	7647-14-5	Trace amounts[1]
Sodium bicarbonate	144-55-8	21.0[1]
Ethanol	64-17-5	5.8[1]
Toluene	108-88-3	3.3[1]
Sodium bromide	7647-15-6	0.76[1]
Trimethylamine	75-50-3	8.7[1]
Sodium glycollate	2836-32-0	12.2[1]
Betaine	07-43-7	5.8[1]
Bromine	7726-95-6	0.40[1]
Sodium bromate	7789-38-0	0.64[1]
Sodium borate	1303-96-4	25.2[1]
Allyl glycerol ether	123-34-2	0.07[2]
Bromoacetic acid	79-08-3	0.70[1]
2,3-epoxy-1-propanol	556-52-5	0.5[2]
Allyl glycidyl ether	106-92-3	0.05[2]
Epichlorohydrin	106-89-8	0.05[2]
3-chloro-1,2-propandiol	96-24-2	0.07[2]

1 = estimated from elemental analysis of carbon, nitrogen, sulfur and bromine; 2 = direct measurement (LOD)

Toxicological Assessment

Toxicity profile of potential impurities

The majority of impurities described in Table 1 are listed in the Code as approved food additives or processing aids. Details of these substances and their permitted levels are summarised in Table 2.

[3] The extraction procedure for impurity analysis involved either pressurised fluid extraction at 10 MPa and 4ºC for 5 minutes or extraction at atmospheric pressure and 20-40ºC for 160 hours.

Table 2: Potential impurities in CSS Adsorber approved in the Code as additives or processing aids

Impurity	Permission	Maximum permitted concentration
Soluble agarose fragments (agar)	Food additive 406 [Standard 1.3.1 (Substances added to food – food additives), Schedule 2 of the Code]	In accordance with Good Manufacturing Practice (GMP)
Glycerol	Food additive 422 (Standard 1.3.1, Schedule 2 of the Code)	In accordance with GMP
Sodium acetate	Food additive 262 (Standard 1.3.1, Schedule 2 of the Code)	In accordance with GMP
Sodium formate	Processing aid [Standard 1.3.3 (Substances added to food – processing aids), Clause 18 (Permitted microbial nutrients and microbial nutrient adjuncts) of the Code]	In accordance with its use as a microbial nutrient in the course of the manufacture of any food
Sodium sulphate	Food additive 514 (Standard 1.3.1, Schedule 2 of the Code)	In accordance with GMP
Sodium bicarbonate	Food additive 500 (Standard 1.3.1, Schedule 2 of the Code)	In accordance with GMP
Ethanol	Processing aid [Standard 1.3.3, Clause 3 (Generally permitted processing aids) of the Code]	At a level necessary to achieve function during manufacture
Toluene	Processing aid [Standard 1.3.3, Clause 13 (permitted extraction solvents) of the Code]	1 mg/kg
Trimethylamine	Constituent in other ion exchange resins [Standard 1.3.3, Clause 8 (permitted ion exchange resins) of the Code]; permitted in accordance with GMP	In accordance with GMP
Sodium bromate	Processing aid to control germination in malting [Standard 1.3.3, Clause 14 (Permitted processing aids with miscellaneous functions) of the Code]	LOD
Sodium borate (borate)	Constituent in packaged water [Standard 2.6.2 (Non alcoholic beverages – non alcoholic beverages and brewed soft drinks), Clause 2 (composition of packaged water) of the Code]	30 mg/L
Epichlorohydrin	Constituent in other ion exchange resins (Standard 1.3.3, Clause 8 of the Code)	In accordance with GMP

Table 3 summarises information provided by the Applicants and obtained from the scientific literature on the toxicity of the various impurities potentially present in CSS Adsorber, which are not covered by permissions in the Code. While a number of these compounds have genotoxic and/or carcinogenic potential, none were detectable in aqueous extracts of the resin. In addition, the Applicants indicated that no impurities were detectable in beer under real use, or abuse, conditions.

Table 3: Toxicity profiles of potential impurities

Impurity	Toxicity profile
Ethyl cellulose	Joint FAO/WHO Expert Committee on Food Additives (JECFA) have evaluated a number of modified celluloses, including ethyl cellulose, which are used as thickening agents in the food industry. No safety concerns were identified and therefore no group[1] acceptable daily intake (ADI) was specified for modified celluloses (WHO 1990). The use of several modified celluloses from this group are permitted in the Code: hydroxypropyl cellulose (463), hydroxypropyl methylcellulose (464), methyl cellulose (461), methyl ethylcellulose (465) and sodium carboxymethyl cellulose (466)
Polyoxyethylene nonylphenyl phosphate ester sodium salt	Inert constituent of pesticide products (US EPA)
Sodium bromide	Used as a human medicine, and agricultural chemical (antimicrobial/algicide). Evaluated by the Joint FAO/WHO Meeting on Pesticide Residues (JMPR) in 1988; ADI of 0-1 mg/kg bw/day.
Sodium glycolate	Approved as an indirect food additive in the USA
Betaine	Significant natural component of many foods (reviewed by Craig 2004)
Bromine	Evaluated by the International Program on Chemical safety (IPCS) (PIM 080) who identified that industrial (occupational) use posed the greatest hazard to human health. Due to its high reactivity with other elements, inorganic bromides found in the environment pose no danger of poisoning.
Allyl glycerol ether	Non genotoxic
Bromoacetic acid	Equivocal evidence of genotoxicity. Evidence of developmental toxicity in rats.
2,3-epoxy-1-propanol (glycidol)	No evidence of teratogenicity. Evidence of genotoxicity. Evidence of carcinogenic activity in rats and mice in 2-year gavage studies. (Irwin 1990) The International Agency for Research on Cancer (IARC) (2000) classified this compound as a probable human carcinogen (Group 2A)
Allyl glycidyl ether	Evidence of genotoxicity. Equivocal evidence of carcinogenicity in rats following 2-years of inhalational exposure. Some evidence of carcinogenic activity in the respiratory tract of male mice following 2-years of inhalational exposure. (Boorman 1990)
3-chloro-1,2-propandiol	Assessed by JECFA in 2001. Evidence of genotoxicity and carcinogenicity. The Committee noted that the dose that caused tumours in rats (19 mg/kg bw per day) was approximately 20 000 times the highest estimated intake of 1,3-dichloro-2-propanol by consumers of soya sauce (1 µg/kg bw per day). A provisional maximum tolerable daily intake was set at 2 µg/kg bw.

1 = ethyl cellulose, ethyl hydroxyethyl cellulose, hydroxypropyl cellulose, hydroxypropyl methyl cellulose, methyl cellulose, methyl ethyl cellulose, and sodium carboxymethyl cellulose.

Discussion

Data and information submitted in support of this application were adequate to assess the risks to human health and safety from the use of CSS Adsorber as a processing aid in the manufacture of beer.

The use of CSS Adsorber as a processing aid in the manufacture of beer poses negligible risks to the health and safety of consumers based on the following considerations:

- Cellulose-based ion exchange resins, which use the same chemistry (i.e. epichlorohydrin cross-linking), are already permitted in the Code.

- While a number of impurities have been hypothesised to occur in extracts from the resin, CSS Adsorber does not generate any detectable impurities in beer under normal processing or abuse conditions.
- The majority of potential impurities are permitted in the Code as food additives or processing aids.
- While some of the potential impurities have genotoxic and carcinogenic potential, none of these were actually detectable in extracts of the cross-linked agarose resin.
- The actual contact time between beer and the CSS Adsorber is less than two minutes, thereby limiting the potential for impurities to enter the product. In addition, before each production cycle, the resin is cleaned, rinsed and equilibrated further minimising the concentration of potential impurities.
- CSS Adsorber has been approved for use in the USA and Europe.

Conclusion

There are no safety concerns with regard to the use of CSS Adsorber as a processing aid in the manufacture of beer.

References

Boorman G (1990) NAP technical report on the toxicology and carcinogenesis studies of allyl glycidyl ether (CAS No. 106-92-3) in Osborne-Mendel rats and B6C3F1 mice (inhalation studies). NTP TR 376. NIH Publication No. 90-2831. US Department of Health and Human Services, Public Health Service, National Institutes of Health.

Craig SAS (2004) Betaine in human nutrition. American Journal of Clinical Nutrition **80**: 539-49

IARC (2000) Volume 77: Some industrial chemicals. IARC monographs on the evaluation of carcinogenic risks to humans. http://www.inchem.org/documents/iarc/vol77/77-14.html

Irwin (1990) NTP technical report on the toxicology and carcinogenesis studies of glycidol (CAS No. 556-52-5) in F344/N rats and B6C3F$_1$ mice (gavage studies). NTP TR 374. NIH Publication No. 90-2829. US Department of Health and Human Services, Public Health Service, National Institutes of Health.

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http://www.inchem.org/documents/jmpr/jmpmono/v88pr03.htm

WHO (2000) Evaluation of certain food additives and contaminants (Thirty-fifth report of the Joint FAO/WHO Expert Committee on Food Additives). WHO Technical Report Series No 789.

WHO (2001) Safety evaluation of certain food additives and contaminants 1,3-dichloro-2-propanol. WHO Food Additive Series 48 http://www.inchem.org/documents/jecfa/jecmono/v48je19.htm

Attachment 3

Food Technology Report

A600 – Agarose ion exchange resin as a processing aid for beer

Summary

Commercial beers are usually stabilised during production to ensure clarity of the beer with ageing. Current treatments are to reduce (but not to totally eliminate) the concentration of various polyphenol and protein fractions naturally occurring in beer which aggregate with other beer components to form haze and particulates with ageing.

The agarose ion exchange resin is proposed as an alternative to other currently permitted and used processing aids and technologies, to ensure maximum clarity of beer with little formation of visible haze and particulates.

The agarose ion exchange resin selectively binds the following listed polyphenols in order of increasing adsorption; catechin, Procyanidin B_3 and Prodelphinidin B_3. Haze sensitive proteins are also binded from the treated beer. Proteins that are important for foam stability are largely unaffected and so beer foam stability of the treated beers can be maintained.

The use of agarose ion exchange resin as a processing aid to stabilise beer is technologically justified as an alternative treatment to the currently permitted and used processing aids and processes.

Introduction

An Application has been received by FSANZ for joint Applicants, Lion Nathan (brewer based in Auckland) and GE Health Care Bioscience AB (resin manufacturer based in Germany).

The Application seeks permission for the use of a new ion exchange resin 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 is based on the macroporous, cross-linked polysaccharide agarose (which is a polymer of galactose and 3,6-anhydrogalactose units).

Background

Nearly all commercial beer is stabilised to ensure clarity of both the initial beer and beer after it has aged. 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 agarose ion exchange resin is proposed as an alternative to other currently permitted 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.

Function of the agarose ion exchange resin

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

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 description is 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 Application contains agarose (the sugar base of agar, being more specifically subunits of galactose) as the sugar base of the polymer while the regenerated cellulose resin is based on glucose.

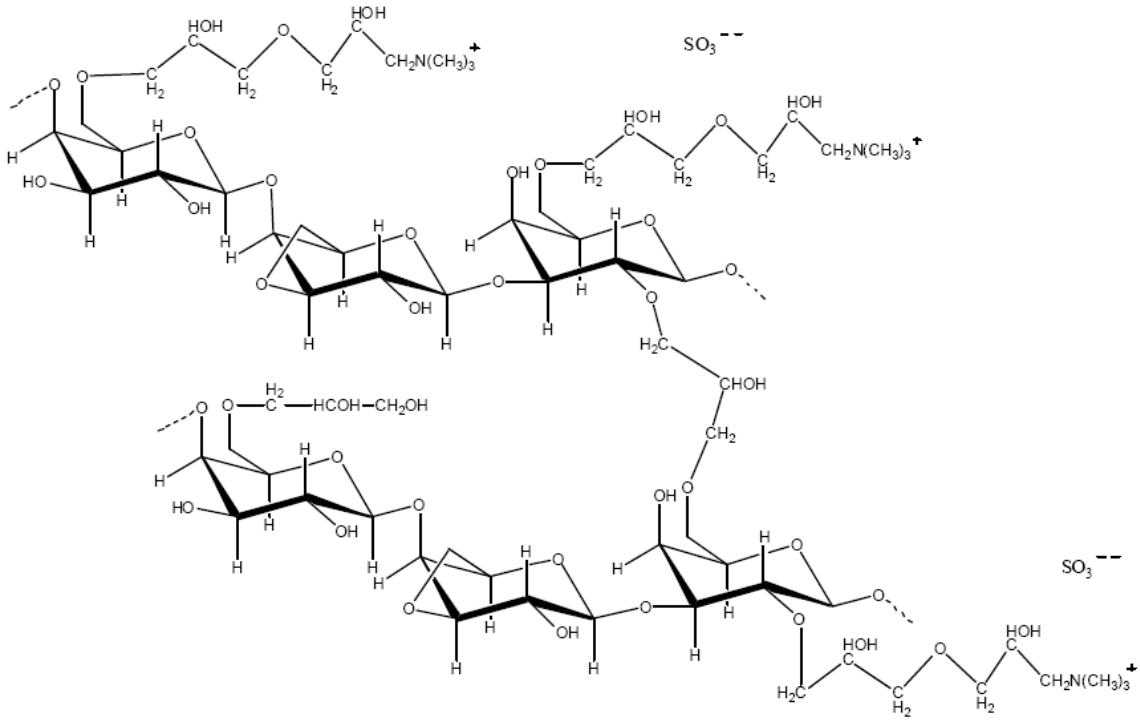

Figure 1: Structural representation of the agarose resin (copied from the Application)

The agarose resin beads are insoluble, porous spherical beads with a diameter of between 100-300 µm. Beer is passed through a bed of the resin where it has short contact time to selectively bind 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 (1 M) and finally 5 column volumes of de-aerated water. There may be a number of adsorption chambers set up as a treatment unit depending on the brewery needs in terms of rate and volume of beer they are required to stabilise.

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 binded 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). Finally the resin is flushed with hot water (80°C), followed by cold de-aerated water. Plant results (over 6 months) conducted by Lion Nathan indicate this cleaning regime ensures no microbiological contamination of the resin bed and hence treated beer.

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

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 be 100,000 litres, and at a flow rate of 1,500 litres per hour, 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.

Specification of the agarose ion exchange resin

The comparable cellulose ion exchange resin which is permitted as an ion exchange resin in Standard 1.3.3 in the Code has an individual specification referenced for it in Standard 1.3.4 – Identity and Purity.

The Applicants have proposed the following specification for the agarose ion exchange resin to be written into Standard 1.3.4 of the Code.

(a) *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;*

(b) The resins are limited to use in aqueous process streams for the removal of proteins and polyphenols from beer. The pH range for the resins shall be no less than 2 and no more than 4, and the temperatures of water and food passing through the resin bed shall not exceed 2°C.

(c) When subjected to the extraction regime listed in the CFR Title 21 part 173.25(c)(4), but using dilute hydrochloric acid at pH 2 in place of 5% acetic acid, the ion exchange resins shall result in no more than 25 ppm of organic extractives.

The Application contains an analysis certificate confirming that their resin conforms with this specification. If this Application is successful a specification will need to be added into Standard 1.3.4.

Manufacture of the resin

The manufacturing process to produce the agarose ion exchange resin is reported in the Application and is given below. The Application also contains chemical structural diagrams indicating the stages of the production as well as schematics showing the steps to produce the resin.

An aqueous solution of agarose is dispersed in toluene to give droplets of 100-300 µm. After cooling and washing, the gel is cross-linked with epichlorohydrin and 50% sodium hydroxide in the presence of sodium sulphate. The product is then washed and wet-sieved, where after it is reacted with allyl glycidyl ether in alkali.

The product is washed repeatedly with 95% ethanol and with distilled water. The intermediate allyl sepharose may be stored in 20% ethanol.

Finally the allyl sepharose is reacted with bromine forming a bromohydrin followed by reaction with trimethylamine in alkali. The product is washed repeatedly with distilled water, wet-sieved and stored in 20% ethanol.

Efficacy of the resin

The co-applicant, Lion Nathan Ltd performed laboratory and then plant trials at their Toohey's Brewery in Sydney on the agarose ion exchange resin to assess how the resin system compared to their current treatments in the stability of beer (Taylor et al, 2006). The treatment they compared the agarose resin treatment to is using the combined silica hydrogel and PVPP treatment. Results and details of the trials are reported in the reference as well as the Application.

Lion Nathan reported that polyphenol adsorption was selective by the resin with adsorption of the following polyphenols listed in order of increasing adsorption; catechin, Procyanidin B_3 and Prodelphinidin B_3. Haze sensitive proteins (that is proteins that are known to promote the formation of haze in beer) were also adsorbed from the treated beer. But proteins that are important for foam stability (Z4, Z7 and LTP1) were largely unaffected and so beer foam stability of the treated beers was maintained.

Lion Nathan concluded that the agarose ion exchange resin system did stabilise the treated beer and improve the physical stability of the final beer. They additionally conclude that the agarose ion exchange resin was a viable alternative for the stabilisation of beer.

They believe the system will be of benefit to their products and if approval for use of the resin to treat beer is agreed they will invest resources to implement the process into their beer manufacturing process.

Conclusion

The use of agarose ion exchange resin as a processing aid to stabilise beer is technologically justified as an alternative treatment to the currently permitted and used processing aids and processes.

References

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

Code of Federal Regulations, CFR Title 21 section 173.25 – Ion-exchange resins, http://frwebgate5.access.gpo.gov/cgi-bin/waisgate.cgi?WAISdocID=577848375259+5+0+0&WAISaction=retrieve (accessed 31 May 2007)

Attachment 4

Summary of Submissions

Round one – Initial Assessment

At Initial Assessment early input was sought on a range of specific issues known to be of interest to various stakeholders in relation to the Application.

Public comment was sought on the following issues:

- the safety of the agarose ion exchange resin when used as a processing aid to stabilise beer;
- whether use of the agarose ion exchange resin to treat beer would cause any deleterious effects to the beer or beer consumers;
- food technology issues arising from the use of the resin to treat beer;
- international approval and use of the resin to treat beer; and
- cost benefit impacts.

Submissions were received from the Food Technology Association of Victoria Inc., New Zealand Food Safety Authority, Queensland Government and Australian Food and Grocery Council (AFGC). Other correspondence was received from the NSW Food Authority. Comments are summarised in the table below.

Submitter	Comments
Food Technology Association of Victoria Inc.	Supports option 2 to amend standard 1.3.3 to approve the use of the agarose ion exchange resin as a processing aid for beer stability treatment.
New Zealand Food Safety Authority	No comments at this stage of the process, may comment at Draft Assessment.
Queensland Government	Offered tentative support for option 2 to amend standard 1.3.3 to approve the use of the agarose ion exchange resin as a processing aid for beer stability treatment. Final position reliant upon reviewing documentation supplied by the Applicants and FSANZ particularly as it relates to the safety assessment of the use of the agarose ion exchange resin as a processing aid.

Submitter	Comments
Australian Food and Grocery Council	Supports option 2 to amend Standard 1.3.3 to approve the use of the agarose on exchange resin as a processing aid for beer stability treatment. The AFGC advocates that the use of food additives and processing aids should be permitted providing that they are safe at the intended levels of consumption and fulfil a technological function. While noting the necessity for FSANZ to conduct a safety assessment of the agarose ion exchange resin considering the potential impact of residual agarose extractants in beer that may be consumed, the AFGC considers it unlikely there will be a significant risk given the levels are extremely low and too low to be of dietary concern. The AFGC supports encouraging the development and application of the agarose ion exchange resin. The AFGC states that the technology supersedes older technologies that introduced a theoretical risk of exposure to allergens. The AFGC considers the potential improvements in quality, stability and lower risks to consumers may lead to a more competitive industry and encourage investment and research and development in the beverage industry. The AFGC notes that FSANZ has been provided with copies of international approvals. The AFGC considers that given the very strict laws enacted in Germany on purity of beer production, this Application is unlikely to result in a reduction in the quality, nature or substance of beer from the use of the agarose ion exchange resin.
Other correspondent	**Comments**
NSW Food Authority	Supports consideration of the Application for use of the agarose ion exchange resin as a processing aid in beer only in the absence of further supporting data with respect to the safety assessment. The NSW Food Authority does not envisage any significant costs to the Authority arising from this Application.