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

12 December 2007
[8-07]

FINAL ASSESSMENT REPORT

APPLICATION A600

AGAROSE ION EXCHANGE RESIN AS A PROCESSING AID FOR BEER

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 paid Application for a new processing aid 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. The purpose of the processing aid is to selectively adsorb undesirable haze and particulate forming proteins and polyphenols in the manufacturing of beer.

Processing aids are required to undergo a pre-market safety assessment before approval for use in Australia and New Zealand. Application A600 seeks to amend Standard 1.3.3 – Processing Aids of the *Australia New Zealand Food Standards Code* (the Code) to include agarose ion exchange resin, also referred to as Combined Stabilisation System (CSS), as a processing aid for beer stability treatment. It also seeks to include a specification for the agarose ion exchange resin in the Schedule to Standard 1.3.4 – Identity and Purity.

The ion exchange resin is an alternative to other currently available technologies to stabilise beer. It functions as an adsorber to selectively remove undesirable haze forming proteins and polyphenols, leading to improvements in the clarity and shelf life of beer.

The safety assessment indicates that the agarose ion exchange resin poses no public health and safety concern to consumers. 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:

- 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.

The only regulatory options identified were to approve or not approve the use of the agarose ion exchange resin as a processing aid for beer stability treatment. There is likely to be an overall benefit to consumers, the beer industry and manufacturers and suppliers of alternative beer stabilisation technologies from the approval of an agarose ion exchange resin.

There is unlikely to be a significant impact on government compliance agencies as a result of the use of the agarose ion exchange resin. No additional costs to consumers have been identified.

Purpose

The Applicants sought amendment in Standard 1.3.3 Processing Aids to add an agarose-based ion exchange resin as a processing aid to be used to stabilise beer.

Decision

Approval is given to amend Standard 1.3.3 – Processing Aids to include the agarose ion exchange resin in the Table to clause 14 – Permitted processing aids with miscellaneous functions, as a processing aid for beer stability treatment. The specification for the agarose ion exchange resin will be added to the Schedule to Standard 1.3.4 – Identity and Purity.

Reasons for decision

The proposed draft variations to the Code are consistent with the section 18 objectives of the FSANZ Act. FSANZ recommends the draft variations to the Code for the following reasons:

- The 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 Draft Assessment identifying any risks associated with the proposed approval of the agarose ion exchange resin.
- Agarose ion exchange resin has desirable qualities that are of interest to the beer manufacturing industry.
- The regulation impact analysis concluded that the benefits of permitting the use of the agarose ion exchange resin outweigh any associated costs.
- To achieve what the Application seeks, there are no alternatives that are more cost-effective than a variation to Standards 1.3.3 and 1.3.4.

Consultation

The Initial Assessment Report was circulated for a round of public comment from 21 March 2007 until 2 May 2007. Four submissions were received and none of these submissions objected to the further assessment of the agarose ion exchange resin.

The Draft Assessment Report was advertised for public comment between 8 August 2007 and 19 September 2007. Six submissions were received during this period. All six submitters supported the incorporation of the agarose ion exchange resin into Standard 1.3.3.

One submitter's support was for the approval to reflect that the agarose was only to be used as a processing aid for beer stability treatment. One submission suggested that there may be a small cost to laboratories in developing methods to analyse beer for the potential low level concentrations of contaminants for enforcement activities. At **Attachment 4** is a summary of the submissions received during the first and second rounds of public comment. FSANZ has taken the submitters' comments into account in preparing the Final Assessment of this Application.

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INTRODUCTION

1. Introduction

1.1 Nature of Application

FSANZ received a paid Application (A600) 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 was seeking to amend Standard 1.3.3 – Processing Aids of the *Australia New Zealand Food Standards Code* (the Code) to include an agarose ion exchange resin as a processing aid for beer stability treatment in the Table to clause 14 – Permitted processing aids with miscellaneous functions. The Application also sought to add a specification for the agarose ion exchange resin to the Schedule to Standard 1.3.4 – Identity and Purity.

In their Application, the Applicants refer to the agarose based ion exchange resin as a Combined Stabilisation System (CSS) to stabilise beer. CSS is 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).

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. Polyphenols and proteins 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.

1.2 Summary of Proposed Amendments

The Applicants proposed that the following Standards be amended to allow the use of the agarose based ion exchange resin in the manufacture of beer:

- The Table to clause 14 Permitted processing aids with miscellaneous functions of Standard 1.3.3; and

- Standard 1.3.4.

Whilst the Table to clause 8 Permitted ion exchange resins in Standard 1.3.3 gives a general permission for ion exchange resins in all foods, the Application is seeking to allow this agarose-based ion exchange resin only in the manufacture of beer. The Table to clause 14 of Standard 1.3.3 can be amended to allow for this.

Since the Draft Assessment Report was released, the Applicants advised that they would like to make a slight change, to be more practical, to the proposed specification for inclusion in Standard 1.3.4. The request was to change paragraph (b) and increase the pH from 4 to 5 and to add an extra sentence to include that the pH and temperature restrictions do not apply to cleaning processes.

The proposed changes are highlighted below in bold:

(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* ***5****, and the temperatures of water and food passing through the resin bed shall not exceed 2˚C.* ***pH and temperature restrictions do not apply to cleaning processes.***

This request seems reasonable as the specification needs to be practical for commercial use and consequently the specification has been amended.

2. Background

2.1 Current Standard

Standard 1.3.3 regulates processing aids that may be used in the manufacture or processing of food, which includes beer manufacture. A processing aid is defined in Standard 1.3.3 as:

> *a substance 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.*

There is currently no permission for an agarose-based ion exchange resin as a processing aid in beer manufacture in the Table to clause 14 – Permitted processing aids with miscellaneous functions within Standard 1.3.3, nor within clause 8 of Standard 1.3.3, which lists permitted ion exchange resins that can be used in the course of manufacture of any food.

Standard 1.3.4 provides specifications for some processing aids. As there is currently no permission for an agarose based ion exchange resin in Standard 1.3.3, there is no specification for an agarose based ion exchange resin in Standard 1.3.4. This Application seeks to include a specification in the Standard.

2.2 Historical Background

There are numerous ion exchange resins approved in the Code as processing aids for use in the manufacture of any food. Some of which may be being used in the manufacture of beer. However, the agarose ion exchange resin proposed is an alternative to other currently permitted processing aids and technologies that are used in the beer industry. 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 essence of 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.

The agarose based ion exchange resin aims to stabilise beer by ensuring the maximum clarity of the final beer by reducing the concentration of the proteins and polyphenolic compounds in the final beer and thus reduce the visible haze and particulates.

The following beer stabilisation processing aids are currently permitted in Standard 1.3.3:

- 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 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.

2.3 Function of the agarose ion exchange resin

The Application contained 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 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 solution 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.

The intended production process limits for beer treatment is the range of -1.5°C 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 m in diameter, a resin height of 30 cm, giving a column volume of 1000 L of resin. The volume of beer treated through this column would be 100,000 L, at a flow rate of 1,500 L 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 were reported in the Application to use three chambers of 900 L volume to treat 940,000 L of beer at a flow rate of 60,000 L/hr.

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

2.4 International Standards

The Application states that the agarose ion exchange resin is approved in the USA, Germany and Russia. The Application contained 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 United States Food and Drug Administration (USFDA) in Food Contact Substance Notification FCN 000531, effective October 26 2005[1]. 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 the agarose resin for beer stabilisation treatment was contained in the Application in two documents (copies in German and their English translations). The approval is specifically for beer treatment. The approval was given after extraction experiments were performed to ensure the safety and integrity of the treated beer. The experimental methods and results were included in the two documents provided by the Applicants. 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) was that the resin complied 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 in beer fining.

[1] 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 Russian approval for the use of agarose resin for beer stabilisation treatment was contained in the Application in one document (copy in Russian and an English translation). 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.

3. The Regulatory Problem

Processing aids are required to undergo a pre-market assessment before they are approved for use in food manufacture.

The Table to clause 14 of Standard 1.3.3 contains a list of permitted processing aids with miscellaneous functions. There is currently no listing for an agarose based ion exchange resin in this Table nor is there any approval elsewhere in Standard 1.3.3 for this ion exchange resin as a processing aid. Therefore an assessment (which includes a safety assessment) of the use of the processing aid is required before an approval for its use can be given.

Additionally, there is currently no specification in Standard 1.3.4 for an agarose based ion exchange resin, so a new specification will be required.

4. Objectives

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;
- 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 Australia and New Zealand Food Regulation Ministerial Council (Ministerial Council).

The specific objective of this assessment is to assess the technological justification and safety of the agarose based ion exchange resin and determine whether it is appropriate to amend the Code to permit its use to stabilise beer.

5. Key Assessment Questions

In assessing this Application, FSANZ considered the following questions:

- 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

6. Risk Assessment Summary

6.1 Safety Assessment

A safety assessment 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. The assessment was based on data on the chemistry, impurity profile, toxicity of potential impurities and intended use pattern of agarose ion exchange resin provided by the Applicants and obtained from the scientific literature.

The Safety Assessment Report **(Attachment 2)** concluded that there are no safety concerns 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, this resin does not generate any detectable impurities in beer under normal processing or abuse conditions.

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

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

- Contact time between beer and the 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.

6.2 Technological need for agarose ion exchange resin

The agarose ion exchange resin was 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 adsorbs (binds) the following listed polyphenols in order of increasing adsorption; catechin, Procyanidin B_3 and Prodelphinidin B_3.
Haze sensitive proteins are also adsorbed 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 Food Technology Report **(Attachment 3)** concluded that the use of the 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.

6.3 Dietary Exposure Considerations

No dietary exposure or nutritional issues were identified 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.

RISK MANAGEMENT

7. Options

FSANZ is required to consider the impact of various regulatory (and non-regulatory) options on all sectors of the community, which includes consumers, food industries and governments in Australia and New Zealand.

Processing aids used in Australia and New Zealand are required to be listed in Standard 1.3.3. 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 agarose ion exchange resin as a processing aid for beer stability treatment in Standard 1.3.3.

Under this option, the *status quo* would be maintained and there would be no changes to the Code.

Option 2 Amend Standard 1.3.3 by permitting the agarose ion exchange resin as a processing aid for beer stability treatment.

Under this option, an amendment to the Code would be required to permit agarose to be used in the manufacture of beer, with the function being as an adsorbent to remove specific proteins and polyphenols during beer manufacture.

If option 2 is successful the Applicants have asked that the approval for the resin be added to the Table to clause 14 (Permitted processing aids with miscellaneous functions) of Standard 1.3.3 and only allow its use in beer. Accepting option 2 also requires a specification for the agarose resin to be added into Standard 1.3.4, 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 affected by this Application are: **consumers** of beer in Australia and New Zealand, the beer **industry** who intend to use this as an alternative processing aid to stabilise their beer and potentially produce higher quality, clear beer, with good shelf life and possibly more economically; **suppliers** of alternative beer stabilisation technologies, who will have competition; and the **Governments** of Australia and New Zealand in terms of enforcing the requirements of the Code.

8.2 Benefit Cost Analysis

In developing food standards for Australia and New Zealand, FSANZ is required to consider the impact of all options (including non-regulatory options) on all sectors of the community, including consumers, the food industry and governments in both countries. The regulatory impact assessment identifies and evaluates, though is not limited to, the costs and benefits of the proposed regulation, including the likely health, economic and social impacts.

This Final Assessment has considered the potential costs and benefits of the two regulatory options on the parties identified as being affected by the regulatory decision. This has been based on information on the agarose ion exchange resin supplied by the Applicants, information gained from submissions to the Initial and Draft Assessment Reports, and on knowledge gained from the previous assessments of similar ion exchange resins permitted in the Code.

8.2.1 Option 1: Not permit the agarose ion exchange resin as a processing aid for beer stability treatment in Standard 1.3.3

8.2.1.1 Consumers

It is likely that maintaining the *status quo* will have minimal impact on consumers of beer. Consumers will continue to have access to quality beer, as the majority of haze forming proteins and polyphenolic compounds can be readily removed with the current range of processing aids.

8.2.1.2 Industry

For industry, maintaining the *status quo* has disadvantages by the loss of cost savings that could potentially occur with greater variety and competition in the range of beer processing aids. This may limit the potential financial returns they could receive on their products.

8.2.1.3 Government

The impact of maintaining the *status quo* on the Australian and New Zealand Governments is likely to be minimal with respect to monitoring and enforcement of the processing aids used in beer manufacture.

8.2.2 Option 2: Amend Standard 1.3.3 by permitting the agarose ion exchange resin as a processing aid for beer stability treatment

8.2.2.1 Consumers

The use of a wider variety of treatments to remove haze forming proteins and other compounds as processing aids could give beer manufacturers greater scope to produce beers of higher quality, and therefore allow consumers to have increased access to quality beer products.

8.2.2.2 Industry

An amendment that allows a processing aid that removes specific haze forming proteins and other compounds during beer manufacture could have substantial benefits for industry by providing greater variety and competition in the range of beer processing aids available.

There is the potential for cost savings in the manufacture of beer, due to greater competition in the market for processing aids to be used by beer manufacturers.

The use of the agarose ion exchange resin as a processing aid in the manufacture of beer does not impose any additional/discernable costs to the industry. This is reflected in the Business Cost Calculator Report, in accordance with the Office of Best Practice Regulation (OBPR) guidelines which is found at **Attachment 5**.

8.2.2.3 Government

The use of the agarose ion exchange resin as a processing aid in the manufacture of beer is unlikely to result in additional/discernable costs to Government.

8.3 Comparison of Options

Industry stakeholders are the group most affected by the regulatory options. Option one rejects a technologically justified processing aid as an alternative treatment to the currently permitted and used processing aids and processes. There are potential benefits for the beer manufacturing industry under Option 2. Such benefits are most likely to be derived from improvements to selective removal of specific haze forming proteins and polyphenolic compounds.

By accepting option two to permit the use of the agarose ion exchange resin, beer manufacturers will have an alternative beer stability treatment they can use to reduce the formation of beer haze and particulates in their beer.

No significant adverse costs have been identified with either option for consumer and government stakeholders. Overall, the benefits outweigh the costs.

COMMUNICATION AND CONSULTATION STRATEGY

9. Communication

FSANZ has applied a basic communication strategy to Application A600. This involved advertising the availability of assessment reports for public comment in the national press and making the reports available on the FSANZ website. The Applicants, individuals and organisations that made submissions on this Application were notified at each stage of the Application. If the FSANZ Board approves the draft variations to the Code, FSANZ will notify its decision to the Ministerial Council. The Applicants and stakeholders, including the public, will be notified of the gazetted changes to the Code in the national press and on the website.

10. Consultation

FSANZ invited public submissions on the Initial Assessment Report between 21 March 2007 and 2 May 2007. Four submissions were received; three supported the Application pending the outcome of the safety assessment and one stated no position indicating further comment would be made after the Draft Assessment was released for comment.

FSANZ invited public comment on the Draft Assessment Report between 8 August 2007 and 19 September 2007. Six submissions were received during this period. All six submitters supported the incorporation of the agarose ion exchange resin into Standard 1.3.3. One submitter wanted the approval to reflect that agarose was only to be used as a processing aid for beer stability treatment. The Application and the draft variation to the standard specifies that the agarose ion exchange resin is only permitted as a processing aid in beer. All submitters accepted the specification for the agarose ion exchange resin will be added to the Schedule to Standard 1.3.4.

Submissions received during the first and second rounds of public comment are summarised in **Attachment 4**.

10.1 Issues raised in submissions

An issue relating to cost was raised in regard to the Draft Assessment Report submission from Queensland Health which noted that the Draft Assessment Report stated that ‘no additional costs to Government have been identified’.
The Submission suggested that there was a potential cost to government if their laboratories are required to develop methods for analysing low level concentrations of potential contaminants that may be present from the use of the agarose ion exchange resin.

10.1.1 FSANZ response

FSANZ considered the possibility of low level concentrations of potential contaminants during the assessment of this Application and concluded that the presence of potential contaminants was identified as a theoretical possibility but it is expected in practice that the levels of any contaminants would be extremely low. The Safety Assessment indicates that the majority of the potential impurities are already permitted as processing aids or food additives and as such, methods for their analysis are likely to already exist. Additionally, the Safety Assessment indicates that there were no detectable levels of extractants of concern even under abuse conditions of use. Therefore it is unlikely that there will be any additional cost to Government.

The New South Wales Food Authority submission envisaged that there would be no significant cost to government by approving the agarose ion exchange resin as a processing aid in the manufacture of beer.

10.2 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.

This Application requested 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 was 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

11. Conclusion and Decision

There is likely to be an overall benefit to consumers, the beer industry and manufacturers and suppliers of alternative beer stabilisation technologies from the approval of Agarose ion exchange resin. There is unlikely to be a significant impact on government compliance agencies as a result of the use of the agarose ion exchange resin.

The draft variations to Standards 1.3.3 and 1.3.4 are in **Attachment 1**.

Decision

Approval is given to amend Standard 1.3.3 – Processing Aids to include the agarose ion exchange resin in the Table to clause 14 – Permitted processing aids with miscellaneous functions, as a processing aid for beer stability treatment. The specification for the agarose ion exchange resin will be added to the Schedule to Standard 1.3.4 – Identity and Purity.

11.1 Reasons for decision

The proposed draft variations to the Code are consistent with the section 18 objectives of the FSANZ Act. FSANZ recommends the draft variations to the Code for the following reasons:

- The 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 Draft Assessment identifying any risks associated with the proposed approval of the agarose ion exchange resin.
- Agarose ion exchange resin has desirable qualities that are of interest to the beer manufacturing industry.
- The regulation impact analysis concluded that the benefits of permitting the use of the agarose ion exchange resin outweigh any associated costs.
- To achieve what the Application seeks, there are no alternatives that are more cost-effective than a variation to Standards 1.3.3 and 1.3.4.

12. Implementation and Review

It is proposed that the draft variations come into effect on the date of gazettal.

ATTACHMENTS

1. Draft variation to the *Australia New Zealand Food Standards Code*
2. Safety Assessment Report
3. Food Technology Report
4. Summary of issues raised in submissions in the first and second rounds
5. Business Cost Calculator Report

Attachment 1

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

Standards or variations to standards are considered to be legislative instruments for the purposes of the Legislative Instruments Act (2003) and are not subject to disallowance or sunsetting.

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 5, and the temperatures of water and food passing through the resin bed shall not exceed 2˚C. pH and temperature restrictions do not apply to cleaning processes.

(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 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 sulphate. 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[2] from the CSS Adsorber were either: (1) estimated from elemental analysis of carbon, nitrogen, sulphur 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, sulphur 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.

[2] 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]	In accordance with Good Manufacturing Practice (GMP)
Glycerol	Food additive 422 (Standard 1.3.1, Schedule 2)	In accordance with GMP
Sodium acetate	Food additive 262 (Standard 1.3.1, Schedule 2)	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)]	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)	In accordance with GMP
Sodium bicarbonate	Food additive 500 (Standard 1.3.1, Schedule 2)	In accordance with GMP
Ethanol	Processing aid [Standard 1.3.3, clause 3 (Generally permitted processing aids)]	At a level necessary to achieve function during manufacture
Toluene	Processing aid [Standard 1.3.3, clause 13 (permitted extraction solvents)]	1 mg/kg
Trimethylamine	Constituent in other ion exchange resins [Standard 1.3.3, clause 8 (permitted ion exchange resins)]; 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)]	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)]	30 mg/L
Epichlorohydrin	Constituent in other ion exchange resins (Standard 1.3.3, clause 8)	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 in spa treatments as an antimicrobial/algicide agent. It is no longer used in human medicine. Inorganic bromide was 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 in vitro 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).

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) NTP 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.

WHO (1989) Pesticide residues in food (1988 evaluation) Part II – Toxicology, FAO Plant Production and Protection Paper 93/2. No 773
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 adsorbs the following listed polyphenols in order of increasing adsorption; catechin, Procyanidin B_3 and Prodelphinidin B_3. Haze sensitive proteins are also adsorbed 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. 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.

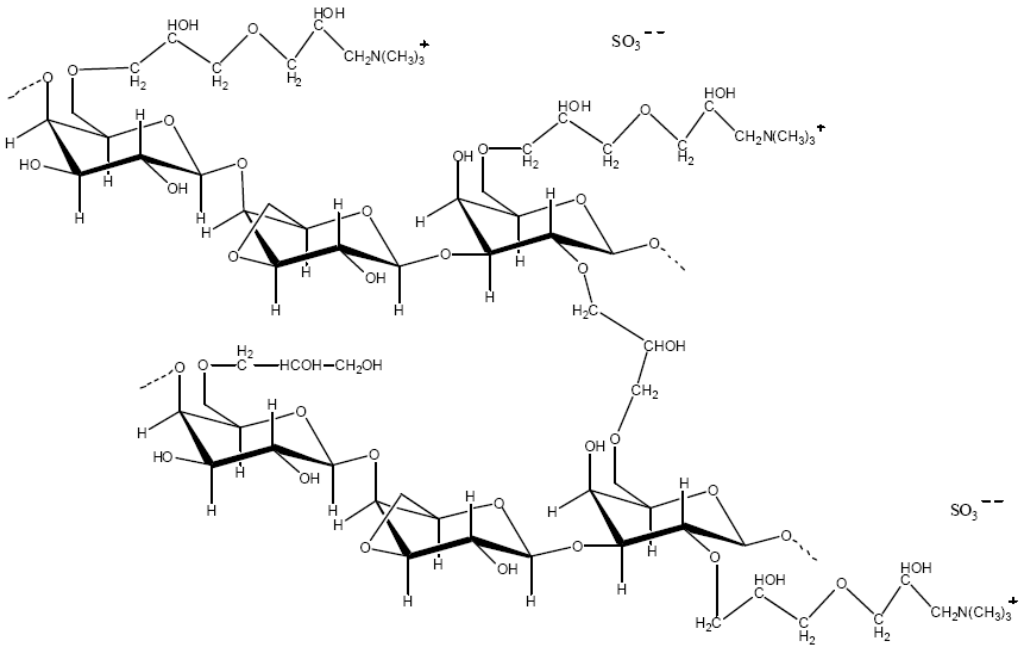

Figure 1: Structural representation of the agarose resin (copied from the Application)

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 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 (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 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.

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 two 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.

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

(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 5, and the temperatures of water and food passing through the resin bed shall not exceed 2°C. pH and temperature restrictions do not apply to cleaning processes; and

(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 issues raised in submissions in the first and second rounds

Round one – Initial Assessment

Submitter Organisation	Name
Food Technology Association Victoria Inc.	David Gill
New Zealand Food Safety Authority	Carole Inkster
Australian Food and Grocery Council (AFGC)	Kim Leighton
Queensland Health	Gary Bielby
New South Wales Food Authority (NSWFA)	Bill Porter

Submitter	Position	Comments
The Food Technology Association of Victoria Inc.	Supports	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	May comment at Draft Assessment.
Australian Food and Grocery Council (AFGC)	Supports	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. The AFGC indicated that the extremely low levels of residual agarose extractants that may be present in consumed beer will not pose a significant risk. 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.
Queensland Health	Tentative support	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.
NSW Food Authority	Supports	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.

Round 2 – Draft Assessment

Submitter Organisation	Name
The Food Technology Association Australia (formerly The Food Technology Association Victoria Inc.)	David Gill
New Zealand Food Safety Authority	Carole Inkster
Australian Food and Grocery Council (AFGC)	Kim Leighton
Queensland Health	Gary Bielby
Australasian Associated Brewers Inc	Terry Kavanagh
New South Wales Food Authority (NSWFA)	David Cusack

Submitter	Position	Comments
The Food Technology Association Australia (FTAA) (formerly The Food Technology Association Victoria Inc.)	Supports option 2	The FTAA 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 (NZFSA)	Supports option 2	The NZFSA supports Option 2 to amend Standard 1.3.3 – Processing Aids, and Standard 1.3.4 – Identity and Purity, to approve the use of agarose ion exchange resin as a processing aid to clarify and stabilise beer and provide a specification for this enzyme system. NZFSA is satisfied that there are no public health and safety concerns and the ion exchange resin is technologically justified
Australian Food and Grocery Council (AFGC)	Supports option 2	The AFGC 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. The AFGC noted FSANZ findings that agarose ion exchange resin poses no public health and safety concerns, is technologically justified and that there are benefits for industry and consumers in permitting its use. The AFGC supports the findings that the resin is able to selectively remove unwanted proteins and polyphenols, thereby improving the stability, quality and shelf life of beer.
Queensland Health	Supports option 2	Queensland Health 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. Queensland Health noted that the FSANZ Assessment did not identify any public health and safety concerns and the use of the enzyme is technologically justified as an alternative to currently used processing aids and processes. Queensland Health noted that the Draft Assessment report stated that there would be 'no cost' to government. Queensland Health noted that Queensland Health Scientific Services laboratories are not currently able to analyse the potential contaminants that may be present at low concentrations. Therefore there may be a cost to develop methods and therefore there would be some cost to government.
Australasian Associated Brewers Inc (AAB)	Supports option 2	The AAB 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 stabilisation. The Australasian Associated Brewers Inc represents major beer manufacturers in Australia and New Zealand. The AAB supports the approval for use of agarose ion exchange resin as an alternative processing aid for beer stabilisation as it poses no public health and safety issues.

Submitter	Position	Comments
New South Wales Food Authority (NSWFA)	Supports Option 2	The NSWFA supports this Application going to Final Assessment. The NSWFA's support for this application rests on it being progressed as a processing aid for beer only. NSWFA does not envisage any significant costs to the Authority arising from this application.

Attachment 5

Business Cost Calculator Report

A 600 – Agarose ion exchange resin as a processing aid for beer

Problem:	Currently there is no provision in the Code for agarose based ion exchange resin as a processing aid for beer. The application seeks to amend Standard 1.3.3 to approve agarose ion exchange resin as a processing aid for beer. It also seeks to include a specification for the resin in Standard 1.3.4
Objective:	To assess the safety and technological justification of agarose ion exchange resin as a processing aid for beer.

Policy Options

Option Name	**Quickscan Result**
Not list agarose ion exchange resin as a processing aid for beer stability treatment in Standard 1.3.3.	FALSE
Amend Standard 1.3.3 to include agarose ion exchange resin as a processing aid for beer.	FALSE

Compliance Cost Summary

Option Name:	Not list agarose ion exchange resin as a processing aid for beer stability treatment in Standard 1.3.3.
Businesses Affected:	N/A

Type	**Cost per Business**	**Total Cost of Regulation**
N/A	N/A	N/A

Option Name:	Amend Standard 1.3.3 to include agarose ion exchange resin as a processing aid for beer.
Businesses Affected:	N/A

Type	**Cost per Business**	**Total Cost of Regulation**
N/A	N/A	N/A

Caution should be used comparing options and interpreting results over time. The Business Cost Calculator does not estimate the future values of ongoing costs. Refer to the User Guidelines for further information. This report contains summaries of compliance costs only. An assessment on the compliance cost in itself does not provide an answer to which policy option is the most effective and efficient one. Rather, it provides information which needs to be considered alongside other relevant factors and issues when deciding between alternative policy options.