APPLICATION TO AMEND THE AUSTRALIA AND NEW ZEALAND FOOD STANDARD CODE FOR THE INCLUSION OF PECTIN AND CARRAGEENANS AS PROCESSING AIDS FOR WINE

Contents

3.1 GENERAL REQUIREMENTS

3.1.2 Applicant details

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3.1.3 PURPOSE OF THE APPLICATION

The intention of this application is to allow pectins and carrageenan as additives to wine *via* amendment of Standard 4.5.1. Pectin and carrageenans are polysaccharides that may be used as a processing aid to facilitate the removal of heat unstable wine proteins from wine. The application is related to Wine production requirements (Australia only) and is to address to the information requirements for Section 3.1 (General Requirements) and Sub section 3.3.2 (Processing Aids).

Pectins (INS 440) and Carrageenan (INS 407) are approved under Schedule 2 of Standard 1.3.1 as *Miscellaneous additives permitted in accordance with GMP in Processed Foods specified in Schedule 1* and therefore a permitted processing aid in food (Clause 3 of Standard 1.3.3).

3.1.4 JUSTIFICATION FOR THE APPLICATION

a) Need for the Proposed Change.

The proposal provides an alternative to using bentonite to heat stabilise wine. This process is required in white or rose wines because grape proteins that are present in the wine post-vinification can precipitate slowly post bottling to form an unsightly haze if the bottle of wine becomes heated during transportation or storage.

b) Advantages of the Proposed Change Over the Status Quo

Advantages of using pectin or carrageenan over bentonite are that these polysaccharides can be used to heat stabilise at natural separation points and could reduce the number of wine production processing steps. Sensory testing completed with expert winemaking panels indicates that any sensory impacts in using pectin and carrageenan are not unfavorable; thereby process efficiency will be improved without any negative quality impacts.

Pectin and carrageenan are plant-based materials and can therefore be sourced through sustainable agricultural practices as plants are a renewable bioresource. Carrageenan is produced from seaweed.

Pectin's are extracted primarily from citrus fruits. The current status quo of bentonite is an aluminum clay extracted from mining. Using a fining agent from a more sustainable source than mining lends to greener production.

In some cases these polysaccharides can heat stabilise at lower addition rate than that is required by bentonite for the same wine. The significance of this is that less waste is produced in the form of lees and more wine is recovered during separation of lees from the wine.

On the disadvantage side bentonite is much cheaper than pectin and carrageenan and this needs to be taken into account when considering the benefits of using the polysaccharides as an alternative fining agent.

c) Status of Similar Application made in other Countries

No applications are being made by the applicant to other national jurisdictions.

A. REGULATORY IMPACT INFORMATION

1. Costs and benefits

When wines develop a haze, the culprit is usually protein, particularly when the wines are exposed to high temperatures or after a long time in storage. Winegrapes contain proteins that persist throughout the winemaking process and, if not removed, they can produce an unsightly haze in white, rosé and sparkling wines. To remove the protein and prevent haze formation, most winemakers use bentonite fining. While bentonite itself is effective, this step in the winemaking process is not selective, as it removes all proteins, not just those that contribute to a haze. It also increases the time wines spend in tank; it can lead to loss of volume and quality; and it creates waste disposal challenges and costs. A recent study estimated the hidden cost of bentonite fining to be around $1 billion worldwide. These issues and costs have led researchers around the world to try to find an alternative

Any sensory impact from the use of pectin and carrageenan has been assessed as favorable or acceptable by wine experts.

a) Costs and benefits to the consumers

The use of pectins and carrageenan as wine fining agents are consistent with the increasing consumer expectations of achieving more sustainable industry practices and providing producers with a more sustainable alternative to bentonite.

b) Costs and Benefits to Industry and Business in General.

The use of pectin and carrageenan as fining agents and as alternatives to bentonite by wineries will be entirely voluntary. Individual wineries will consider the benefits in sustainability, process efficiencies, wine recovery and waste decrease against the additional cost of these polysaccharides per kg relative to bentonite. In the short term there are unlikely to be savings costs, but the use of pectins and carrageenans provide the producer with the opportunity to strengthen their sustainability credentials and increase markets and potential price as a result.

c) Costs and Benefits to Government.

There will be no increased regulatory or enforcement costs for the government.

2. Impact on International Trade

There will be no impact on imported wines as pectins and carageenans are already permitted processing aids (under Standard 1.3.3) (see section 3.1.3).

3.1.5 INFORMATION TO SUPPORT THE APPLICATION

1. General

(a) There are no negative public health implications. The application is consistent with FSANZ obligation to public health because pectins and carrageenan are found throughout the food supply as an additive sourced from naturally occurring plant components. Pectins and carrageenan are also consumed as natural components of plants including fruit, vegetables and seaweed.

(b) Consumer Choice Issues

The application will enable an alternative to benonite as a fining agent and increase consumer choice in sourcing a more sustainable fining agent.

(c) Evidence of General Food Industry or Specific Company Support

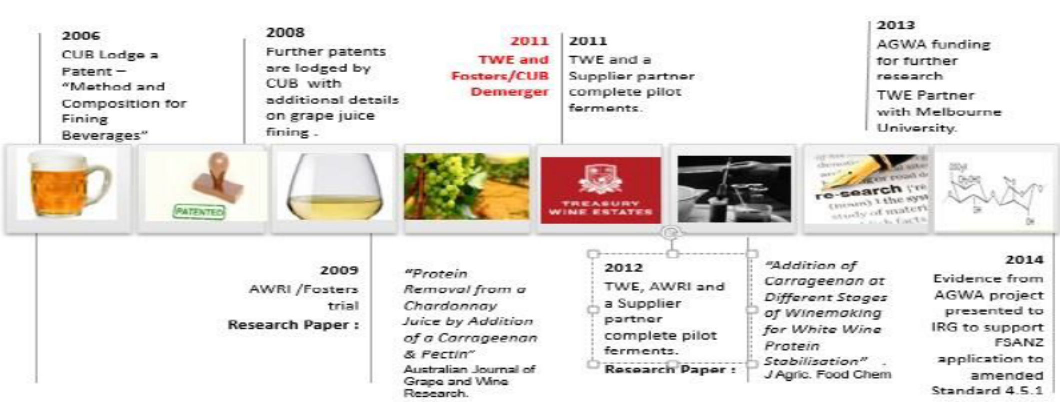
Pectins and carrageenans have been used to clarify beer as a replacement for isinglass (animal protein). and research of their use in winemaking in addition to brewing were initiated by Carlton and United Brewing (CUB) a division of Foster's. The outcomes of this research were first published in 2008.

A demerger between Fosters and its wine division Treasury Wine Estates (TWE) resulted in a research application focused solely on the use of these polysaccharides in wine and was supported by the Australian Wine Research Institute.

An Australian Grape and Wine Association (AGWA) - funded secondary project to comprehensively screen suitable polysaccharides and their characteristics which would make them ideal candidates for bentonite alternatives was led by TWE with the support of Melbourne University School of Botany. This research has the support of an Industry Reference Group and the peak industry body, Winemakers Federation of Australia is sponsoring approval to be legalise pectin and carrageenan as wine processing additives.

The accumulation of this research has resulted in a number of research publications (Attachment 1) and a time line of events is illustrated below.

TIMELINE OF EVENTS



A. Technical Information on the Processing Aid

1. Information on the type of processing aid

Pectin and carrageenans are plant-based polysaccharides used to fine wine, thus falling in category (d) – *Permitted decolourants, clarifying, filtration and adsorbent agents* in Standard 1.3.3.

Pectin and carrageenans are both present in the Codex Alimentarius Commission General Standard for Food Additives under the functional classes emulsifier, Gelling agent, glazing agent, stabilizer and thickener.

2. Information on the identity of the processing aid

<u>Pectin</u>

- Other names - Pectic polysaccharides
- INS Number - In the International Numbering System (INS), pectin has the number 440. In Europe, pectins are differentiated into the E numbers E440 (i) for non-amidated pectins and E440 (ii) for amidated pectins.
- CAS Number 9000-69-5
- EINEC Number 232-533-0

<u>Carrageenan</u>

- Other names - *Chondrus crispus* (Irish Moss) seaweed
- INS Number - E-number E407 or E407a when present as "processed eucheuma seaweed".
- CAS Number 11114-20-8.
- EINEC Number - 232-524-2

3. Information on the chemical and physical properties of the processing aid

<u>Pectin chemical and physical properties.</u>

Pectin consists mainly of the partial methyl esters of polygalacturonic acid in an alpha (1-4) chain and their sodium, potassium, calcium and ammonium salts. Commercially processed pectin is available in the three primary types of pectin structures which are low methoxy pectin (less than 50 % esterfied), high methoxy pectin (greater than 50 % esterfied) and amidated pectin. Pectin may naturally contain acetate or other ester groups. The molecular weight of commercial pectins are typically between 60–130,000 Da.

Dry powdered pectin, when added to water, has a tendency to hydrate, and rapidly, form gels. Pectin is therefore typically used in food manufacturing as a gelling agent, thickening agent or stabilizer.

<u>Carrageenan chemical and physical properties.</u>

Carrageenans are highly sulfated galactans. Carrageenans are divided into three major families according to the position of sulfate groups in their 1, 3- and 1, 4-linked disaccharide galactose residues. Kappa (κ) carrageenan contains one sulphate per disaccharide, iota (ί) Carrageenan two sulphates per disaccharide lambda and (λ) Carrageenan contains three sulphates per disaccharide. Commercial carrageenan may occur as the Na^+ K^+, Ca^{2+} or NH_4 salt.

Carrageenans have large molecular weights of 200,000–800,000 Da. Carrageenans are large, highly flexible molecules that curl forming helical structures. This gives them the ability to form a variety of different gels at standardized temperatures. Gelling properties are also related to their chemical structure. *Kappa* carrageenans have low negative electric charge and form strong rigid gels. *Iota* carrageenans have medium negative electric charge and form soft gels. *Lambda* carrageenans have high negative electric charge and are non-gelling. The primary differences influencing the gelling properties of kappa, iota, and lambda carrageenan are the number and position of the ester sulfate groups on the repeating galactose units. Higher levels of ester sulfate either lower the solubility temperature of the carrageenan and produce lower strength gels or contribute to gel inhibition as is the case of *lambda* carrageenans.

Solubility of carrageenan is also related to chemical structure. All carrageenans are soluble in hot water; in cold water, the *lambda* form is soluble. *Kappa* and *iota* carrageenans are only soluble in cold water as their sodium salts.

Given the gelling properties described carrageenans are widely used in the food and other industries as thickening and stabilizing agents.

Physical properties of carrageenan and pectin in beer.

In beer carrageenan and pectin have been used as a possessing aid and as a fining agent to bind and remove proteins or tannins.

4. Manufacturing process

Pectin Manufacture

Pectin is obtained by extraction into an aqueous medium from appropriate edible plant material, usually the peel of citrus fruits or apples. No organic precipitants shall be used other than methanol, ethanol and isopropanol. In some types a portion of the methyl esters may have been converted to primary amides by treatment with ammonia under alkaline conditions.

Carrageenan Manufacture

Carrageenan manufacturing begins with the dried seaweed which is mechanically ground and sieved to eliminate impurities such as sand and salt. Following an extensive washing step, the seaweed undergoes a hot extraction process with alkali solution to separate the carrageenan from the extraneous plant fiber which is mostly cellulose. Further cellulose is removed from the carrageenan by centrifugation and filtration. The carrageenan solution is then concentrated by evaporation to accommodate the removal of water.

Carrageenan can then recovered by one of two processing methods. In one method, the concentrated carrageenan solution is deposited into a solution of chloride salt. This raises the gelling temperature so that the filtrate will gel immediately. The gel is then frozen and compressed while thawing to remove excess water.

In an alternative method, the concentrated carrageenan solution is precipitated by a strong alcohol solution. As carrageenan is insoluble in alcohol, the filtrate turns into a coagulum of carrageenan, alcohol and water. The coagulum is compressed to remove the liquids and vacuum dried to completely remove the alcohol. The dried coagulum is then ground to specification.

Different carrageenan extractions may be blended to meet the finished product's exact specifications.

5. Specification for identity and purity

Pectin Purity and identity

The commercial product is normally standardized with sugars, and may be buffered with suitable food grade salts. The IPPA (IPPA International Pectin Producers Association) outlines the following for pectin product purity

Parameter	Specification
Loss on drying	Not more than 12.0% (105°C, 2 h)
Sulphur dioxide	Not more than 50 mg/kg
Acid-insoluble ash	Not more than 1.0%
Insoluble materials	Not more than 3.0% in alkali plus sequestrant
Free methanol, ethanol and isopropanol	Not more than 1.0% singly or in combination
Nitrogen content	Not more than 2.5% after washing with acid and ethanol
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Cadmium	Not more than 1 mg/kg
Mercury	Not more than 1 mg/kg
Heavy Metals (as lead)	Not more than 20 mg/kg
Galacturonic acid	Not less than 65% calculated on the ash-free and dried bases
Degree of amidation	Not more than 25%, of total carboxyl groups of pectin

In addition the general specification and testing methods for pectin product preparations used in food processing has been established by the joint Expert Committee of Food Additives of the (Guide to JEFCA Specifications), FNP 5/ Rev. 2 (1991) (Attachment 3:

http://www.fao.org/ag/agn/jecfa-additives/specs/monograph7/additive-306-m7.pdf)

Carrageenan Purity and identity

Semi-refined carrageenan forms an opaque gel and contains high cellulose and fiber levels. Refined carrageenan should not contain either cellulose or plant cell wall material.

Parameter	Specification
Loss on drying	Not more than 12.0% (105°C, 2 h)
Sulphate	Not less than 15 % and not more than 40% (as SO4) on the dried basis
Total Ash	Not less than 15 % and not more than 40 % on the dried basis
Acid-insoluble ash	Not more than 1 %
Acid Insoluble matter	Not more than 2.0%
Residual Solvent	Not more than 0.1% of ethanol, isopropanol or methanol, singularly or in combination.
Low molecular weight carrageenan (Molecular weight fraction below 50 kDa):	Not more than 5 %
Arsenic	Not more than 3 mg/kg

Lead	Not more than 5 mg/kg
Cadmium	Not more than 1 mg/kg
Mercury	Not more than 1 mg/kg

Microbiological criteria

Total plate count:	Not more than 5 000 colonies per gram.
Yeast and mold	Not more than 300 colonies per gram.
Escherichia coli	Absent in 5g
Salmonella spp	Absent in 10 g

The above level of purity and the addition the general specification and testing methods for carrageenan product preparations used in food processing has been established by at the 68th JECFA (2007) and published in FAO JECFA Monographs 4 (2007), superseding specifications prepared at the 57th JECFA (2001), published in the Combined Compendium of Food Additive Specifications (Attachment 4).

http://www.fao.org/ag/agn/jecfa-additives/specs/monograph4/additive-117-m4.pdf

6. Analytical method for detection

Pectin Identification Tests

Enzyme Degradation	Degraded by pure pectate lyase with generation of conjugated unsaturation detectable by UV absorption at 235 nm. A suitable pectate lyase and test kit are available from Megazyme at www.megazyme.com.
Test for amide group	Amidated pectins converted to the free acid form react positively by liberation of ammonia with cold alkali

Carrageenan Identification Test

Carrageenan infrared absorption spectra to identify carrageenan is and method to prepare sample described in a method published in the FAO JECFA (Attachment 5)
http://www.fao.org/ag/agn/jecfa-additives/specs/monograph4/additive-117-m4.pdf

Wave number (cm^{-1})	Molecular Assignment	Absorbance relative to 1050 (cm^{-1})		
		Kappa	Iota	Lambda
1220-1260	ester sulfate	0.3-1.4	1.2-1.7	1.4-2.0
928-933	3,6-anhydrogalactose	0.2-0.7	0.2-0.4	0-0.2
840-850	galactose-4-sulfate	0.2-0.5	0.2-0.4	-
825-830	galactose-2-sulfate	-	-	0.2-0.4
810-820	galactose-6-sulfate	-	-	0.1-0.3
800-805	3,6-anhydrogalactose-2-sulfate	0-0.2	0.2-0.4	-

B. Information Related to the Safety of a chemical processing aid

1. General Information on the Industrial use of this chemical

Industrial Use of Pectin

Pectin occurs naturally in the grape berry. During ripening, pectin is hydrolyzed by naturally occurring pectolytic enzymes, which renders the berry softer as it ripens. In winemaking as juice is extracted from the grape berry, the pectin causes cloudiness by holding the particles of grape pulp in suspension. To allow the suspended solids to settle and clarify the juice, commercial preparations of pectolytic enzymes are often used.

Pectin is traditionally used as a gelling agent in a wide range of fruit-based products, such as jams, marmalades, jellies, fruit preparations for yoghurts and desserts and fruit fillings for bakery products. Pectin can be used to improve the mouth-feel and the pulp stability in juice based drinks and as a stabilizer in acidic protein beverages. Pectin also reduces syneresis in jams and marmalades and increases the gel strength of low calorie jams. Pectin is used in confectionery jellies to give a good gel structure and a clean bite. The typical dosage of pectin in food applications is between 0.5 - 1.0%.

Industrial Use of Carrageenan

Carrageenans are widely used in the food industry, for their gelling, thickening, and stabilizing properties. Main applications of carrageenan in food are in dairy and meat products, due to their strong binding to food proteins. Common examples of their use in foods include as gelling agents in, ice cream, cream, milkshakes, salad dressings, sweetened condensed milks, and sauces to increase product viscosity.

Pâtés and other processed meats such as ham use a carrageenan as an ingredient to substitute for fat, increase water retention or improve slicability.

Carrageenans may be added to soy and other plant-based milk to emulate the consistency of whole milk. Carrageenan is also used as a clarifier in beer to remove haze-causing proteins. Carrageenan can be used in infant milk formulas to retain nutrients in the liquid.

Carrageenan is a vegetarian and vegan alternative to gelatin, in some instances it is used to replace gelatin in confectionery.

Carrageenan is a common constituent in toothpaste to prevent separation of ingredients.

2. General information on the use of the chemical as a food processing aid in other countries

Pectin and carrageenans have been used as processing aids in the production of alcoholic fermentable beverages such as beer, lager, ale and cider. Purpose for this use include removal of calcium, tannins and proteins.

3. Data on the toxicokinetics and metabolism of the chemical processing aid, and if necessary its metabolites

Toxiokinetic Metabolism of Pectin

When ingested, pectin is degraded by fecal bacteria in the colon. Very low levels of methanol are released by this degradation. Studies involving human subjects on large quantities of pectin for extended periods have not resulted in methanol poisoning (Attachment 6: *Am J Clin Nutr. 1988 May;47(5):848-51. Methanol production from the degradation of pectin by human colonic bacteria. Siragusa RJ1, Cerda JJ, Baig MM, Burgin CW, Robbins FL.)*

Toxiokinetic Metabolism of Carrageenan

Oral feeding studies with laboratory animals indicate dietary carrageenan is excreted quantitatively and is not accumulated in body organs such as either the liver or colon. Carrageenan is inert to hydrolysis by intestinal enzymes in both humans and monogastric animals.

Weiner ML (1988) Intestinal transport of some macromolecules in food. Fd Chem Toxicol 26:867-880

*Pittman, KA; Golberg, L; Coulston, F (1976). "Carrageenan: the effect of molecular weight and polymer type on its uptake, excretion and degradation in animals". Fd Cosmet Toxicol **14**: 85–93. doi:10.1016/s0015-6264(76)80249-0.*

*Weiner, ML; Nuber, D; Blakemore, WR et al. (2007). "A 90-day dietary study of kappa carrageenan with emphasis on the gastrointestinal tract". Fd Chem Toxicol **45**: 98–106. doi:10.1016/j.fct.2006.07.033.*

C. ***Information on the*** **toxicity of the chemical processing aid and, if necessary, its major metabolites.**

Toxicity *in vitro* studies of Pectin

Pectins occur naturally and widely in fruits especially citrus fruits and apples and are part of the cell walls. They are therefore part of the normal diet and have also been administered intravenously at high levels to humans without acute toxic effects (see for example, Attachment 7 Seventeenth Report of the Joint FAO/WHO Expert Committee on Food Additives, Wld Hlth Org. techn. Rep. Ser., 1974, No. 539; FAO Nutrition Meetings Report Series, 1974, No. 53).

Toxicity *in vitro* studies of Carrageenan

Carrageenan has been tested as a food ingredient for more than 40 years. It has been used globally for more than 600 years. The substance has been reviewed for safety and toxicology by the global authoritative body, the Joint FAO/WHO Expert Committee on Food Additives (JECFA), multiple times to date. JECFA's conclusion following each review is that carrageenan is safe as consumed in foods.

A recent toxicity/toxicokinetic swine-adapted infant formula feeding study was conducted in Domestic Yorkshire Crossbred Swine from lactation day 3 for 28 consecutive days during the preweaning period at carrageenan concentrations of 0, 300, 1000 and 2250 ppm under GLP guidelines. No treatment-related adverse effects at any carrageenan concentration were found on any parameter. The high dose in this study, equivalent to ~430 mg/kg/day, provides an adequate margin of exposure for human infants, as affirmed by JECFA at their 79th meeting and supports the safe use of carrageenan for infants ages 0-12 weeks and older and infants with special medical needs (Attachment 9:CCFA (2015) Matters of interest arising from FAO and WHO and from the 79th meeting of JECFA (CX/FA 15/47/3))

5. Safety assessment reports prepared by international agencies or other national government agencies if available

A. Food safety of pectin

Under the American Food and Drug Administration (FDA) designation has been assigned "GRAS" generally recognized as safe.

Pectins have been given an acceptable daily Intake (ADI) of "not specified" by the FAO/WHO Joint Expert Committee on Food Additives (JECFA), and are listed on that basis in the Codex General Standard for Food Additives. Pectins were evaluated in 1981. The latest JECFA monograph was published in JECFA Monographs 7 in 2009 (Attachment 8).

B. Food safety of carrageenans

In 1978, the Scientific Committee for Food (SCF) endorsed the Acceptable Daily Intake (ADI) of 0 - 75 mg/kg be established for carrageenan by the Joint FAO/WHO Expert Committee on Food Additives (JECFA, 1974; SCF, 1978). JECFA reviewed carrageenan again in 1984 and allocated an ADI "not specified" for refined non-degraded carrageenan (JECFA, 1984a) (attached).

In 2003 an EU commission conducted a committee report that concluded that the current information on carrageenan as an additive for general food use did not provide any reason to alter the ADI of 0 - 75 mg/kg established previously. The Committee noted that human consumption intakes are considerably below the ADI (Attachment 10: Opinion of the Scientific Committee on Food on Carrageenan report (2003) http://ec.europa.eu/food/fs/sc/scf/out164_en.pdf) .

In the U.S., carrageenan is allowed under FDA regulations as a direct food additive and is considered safe when used in the amount necessary as an emulsifier, stabilizer, or thickener in foods, except those standardized foods that do not provide for such use. FDA also reviewed carrageenan safety for infant formula (Attachment 11 Generally Recognized As Safe 21 **CRF §182.7255** GRAS ID Code 9000-07-1 (1973) Federal Food, Drug, and Cosmetic Act 21 U.S.C. 350(a) **§412).** **(Attachment 11)**

Safety Assessment of Pectin as a food additive in other countries

European Union
Pectin (E440 (i)) and Amidated Pectin (E440 (ii)) have both been given an ADI "not specified" by the Scientific Committee for Food. Specifications are listed in Commission Regulation (EU) 231/2012 of 9th March 2012. Pectins may be used under "quantum satis" conditions in most foods in accordance with Regulation (EC) 1333/2008 of the European Parliament and of the Council of 16th December 2008 on food additives.

The European Union also approved carrageenan for food use in 1995 (E-407 as noted in Directive 95/2/EC and amendments).

United States
The FDA recognizes pectin as GRAS (generally recognized as safe). It may be used in all non-standardized foods. The pectin specification of the Food Chemical Codex is updated on a regular basis; the effective version can be found in the current edition.

Carrageenan was approved for use in foods by the U.S. Food and Drug Administration (FDA) in 1961; the FDA published amendments to its approval in 1995 (21 CFR 172.620).

F. Information Related to the Dietary Exposure to the Processing Aid.

1. A list of foods or food groups likely to contain the processing aid or its metabolites.

The use of pectin and carrageenan is proposed to be used as a processing aid in the fining of alcoholic beverages. As such, application in foodstuffs include wine, beer, lager or ale and cider.

Pectins and carageenans are naturally occurring in a variety of plants and seaweed respectively.

2. The levels of residues of the processing aid or its metabolites for each food group.

Following addition of the fining agent to the wine the beverage is racked off the lees and then filtered prior to bottling. Both the racking and filtration will reduce the pectin and carrageenan levels to undetectable. Pectin can also be degraded by pectinase enzymes. This is a current practice in winemaking producing sugar- based metabolites.

3. For food or food groups not currently listed in the most recent Australian or New Zealand national Nutrition Surveys (NNSs), information on the likely consumption.

Research has been conducted and published on the use of carrageenan and pectin to heat stabilise wine and it is predicted that up 2 g/L of fining agent may be required to heat stabilise wine varieties with very high levels of proteins. For use in juice and wine these pectin and carrageenan shall be substances that are added to a food for their purpose of removing heat unstable proteins in the processing but due to racking of lees solids or other form of separation shall be present in the finished food at insignificant levels and do not have any technical or functional effect in the wine.

4. **The percentage of the food group in which the processing aid is likely to be found or the percentage of the market likely to use the processing aid.**

The penetration percentage of pectin and carrageenan into the wine industry is difficult to predict as currently this industry uses bentonite to achieve heat instability at cost effect. Wineries may be tempted to use carrageenans and pectins due to their sustainable sourcing and to improve processing efficiencies. Heat stability is carried out predominantly on white and rose wine styles.

5. **Information relating to the levels of residues in foods in other countries.**

Pectin and carrageenan are a permitted food additive in many international markets. Both pectin and carrageenan are also naturally occurring in a wide range of foods and may be added to an extensive range of processed foods in international markets. The range and scope of use for these polysaccharides are extensive and limited by their achieving the desirable gelling and stability properties.

6. **For foods where consumption has changed in recent years, information on likely food consumption.**

n/a

3.1.6 Assessment Procedure

This application seeks the appropriate assessment procedure is **General Procedure Level 1.** The application extends the use of two common food additives to wine in which one of the food additive; pectin is a naturally present ingredient of wine.

3.1.7 CONFIDENTIAL COMMERCIAL INFORMATION

No confidential or commercial information is incorporated in this application.

3.1.8 EXCLUSIVE CAPTURABLE BENEFIT.

There is no exclusive capturable benefit to the applicant.

3.1.9 INTERNATIONAL AND OTHER STANDARDS

A. Codex Alimentarius Commission (Codex) Standards

Pectins and Carrageenans have been given an acceptable daily Intake (ADI) of "not specified" by the FAO/WHO Joint Expert Committee on Food Additives (JECFA), and are listed on that basis in the Codex General Standard for Food Additives.

B. Other National Standards

See above.

3.1.10 STATUTORY DECLARATION

Attached

3.1.11 CHECKLIST

Attached

Attachments

Attachment 1 Patent No WO 2006/032088 Methods and Compositions for Fining Beverages. Duan Weidong; Giandinoto Caroline; Goldsmith Mark; Hosking Peter; Lentini Aldo; Oliver Tony; Rogers Peter; Smith Peter; Bacic Antony; Liao Ming-Long; Pettolino Filomena.

Attachment 2 JECFA (2009) specification for Pectin, FAO JECFA Monographs 7 (2009).

Attachment 3 2001 IPPA International Pectin Producers Association **http://www.ippa.info/specification_for_pectins.htm**

Attachment 4 FAO Agar and Carrageenan Manual. Fao.org (1965-01-01). **http://www.fao.org/docrep/field/003/AB730E/AB730E03.htm**

Attachment 5 JECFA (2009) specification for Carrageenan, 68th JECFA (2007) and published in FAO JECFA Monographs 4 (2007)

Attachment 6 Am J Clin Nutr. 1988 May;47(5):848-51. Methanol production from the degradation of pectin by human colonic bacteria. Siragusa RJ1, Cerda JJ, Baig MM, Burgin CW, Robbins FL.

Attachment 7 Seventeenth Report of the Joint FAO/WHO Expert Committee on Food Additives, Wld Hlth Org. techn. Rep. Ser., 1974, No. 539; FAO Nutrition Meetings Report Series, 1974, No. 53 Pectins.

Attachment 8 Seventeenth Report of the Joint FAO/WHO Expert Committee on Food Additives, Wld Hlth Org. techn. Rep. Ser., 1974, No. 539; FAO Nutrition Meetings Report Series, 1974, No. 53 Carageenans.

Attachment 9: CCFA (2015) Matters of interest arising from FAO and WHO and from the 79th meeting of JECFA (CX/FA 15/47/3).

Attachment 10 Opinion of the Scientific Committee on Food on Carrageenan report (2003) http://ec.europa.eu/food/fs/sc/scf/out164_en.pdf)

Attachment 11 Generally Recognized As Safe 21 **CRF §182.7255** GRAS ID Code 9000-07-1 (1973) Federal Food, Drug, and Cosmetic Act 21 U.S.C. 350(a) **§412** **https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?fr=172.620 .**

Attachment 12 Protein removal from a Chardonnay juice by addition of carrageenan and pectin. M Marangon L Lucchetta, D Duan, VJ Stockdale, A Hart, PJ Rogers and EJ waters.. *Australian Journal of Grape and Wine Research* Volume 18, Issue 2, pages 194–202, June 2012.

Attachment 13 Addition of carrageenan at different stages of winemaking for white wine protein stabilization.

Matteo Marangon , Vanessa J Stockdale , Peter Munro , Timra Trethewey , Alex Schulkin , Helen E. Holt

, and Paul A. Smith. *J. Agric. Food Chem.*, June 11, 2013

Abbreviations

ADI	Acceptable Daily Intake
CAS	Chemical Abstracts Serial number
EEC	European Economic Community
EINECS	European Inventory of Existing Chemical Substances
FAO	Food and Agriculture Organization (of the United Nations)
FDA	Food and Drug Administration (of the USA)
GRAS	Generally Recognized As Safe
INS	International Numbering System (Codex Alimentarius numbers for food additives)
IPPA	International Pectin Producers Association
JECFA	Joint Expert Committee for Food Additives (FAO/WHO)
SCF	Scientific Committee for Food (the European Union expert committee)