GR

ORIGINAL SUBMISSION

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RICHARD M. GAHAGAN
Regulatory Consultant – Beverage Alcohol

October 18, 2005

Linda S. Kahl, Ph.D.
Regulatory Policy Branch
Office of Premarket Approval (HFS-200)
U.S. Food and Drug Administration
Center for Food Safety and Applied Nutrition
200 C St., SW
Washington, DC 20204

REC'D OCT 26 2005

Re: GRAS Notification for Plant Proteins in Winemaking

Dear Dr. Kahl:

Enclosed please find our notice of a claim for GRAS exemption based on a GRAS determination regarding the use of wheat and pea protein as a processing aid in winemaking. Our claim consists of a one page GRAS Exemption Claim and an extensive document describing in detail the outcome of the scientific procedure undertaken to determine GRAS eligibility.

These documents have been sent to you in triplicate by U.S. mail as directed in the guidelines. An electronic copy is also enclosed in a CD format.

Pursuant to the guidelines, we expect to receive notification of the receipt of these documents within 30 days of receipt by your branch. Further, we expect to be advised within 90 days if you or your scientific advisors consider this GRAS claim to be unsubstantiated. Although we understand we may not receive a subsequent notification if the GRAS claim is satisfactory, we respectfully request such notification as the U. S. Bureau of Alcohol and Tobacco Tax and Trade Bureau requires documentation from FDA before any material, including plant protein, may be used in commercial winemaking in the United States.

Please let me know if you have any questions, or desire additional information.

Sincerely yours,

Richard M. Gahagan
ATF Enrolled Practitioner #43

Cc: Alain MARTIN, Project Manager, Martin Vialatte

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P.O. Box 8569 Fresno, California 93747 U.S.A. Tel: 559-251-1759 Cell: 559-333-0551 Fax: 559-272-5259
Email: rmg@richardgahagan.com Website: www.richardgahagan.com

Notice of a Claim for GRAS Exemption Based on a GRAS Determination

Notification by:	Martin Vialatte
Address:	Martin Vialatte Attn: Alain MARTIN 79, ave. A. THEVENET BP 1031 – Magenta 51319 Epernay Cedex
Project Manager:	Alain MARTIN
Name of Substance for which GRAS eligibility is sought:	Wheat and pea Plant Proteins
Use for substances from witch GRAS eligibility is sought:	Removal of harsh, bitter tannin material in wine by forming an insoluble protein-tannin complex which precipitates from wine.
Types of food substance to be used:	Wine
Determination method for GRAS eligibility:	Through scientific procedure. All documentation cited in support of GRAS eligibility will be provided to FDA upon request.

GRAS Notification Plant Proteins for use in Winemaking

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Notification

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Contact:	Richard M. Gahagan Regulatory Consultant P.O. Box 8569 Fresno, CA 93747 rmg@RichardGahagan.com 559-251-1759

This notification is a self GRAS affirmation filed under the provisions of the Food and Drug Administration's proposed regulation 21 CFR § 170.36 (62 *Federal Register* 18938); April 17, 1997; Substances Generally Recognized as Safe (GRAS).

This notification covers the use of proteins derived from wheat and peas as an aid in the production of wine and such use of theses plant proteins is exempt from the premarket approval requirements of the Food, Drug and Cosmetic Act because we have determine such use is GRAS through scientific procedures.

The common or usual name of this material is "Plant Protein." The raw materials entering the formulation of plant proteins are manufactured by great European cereal industry whose products in conformity with the Codex Alimentarius are intended for agroalimentary industry. The assembly of these raw materials is then carried out in Epernay, France by Martin Vialatte.

1. Plant Protein – process, product and application in winemaking

The wheat protein is a hydrolyzed wheat gluten (*Triticum Sp.s*) and the pea protein is an isolate (*Pisum sativum*). These proteins are used in powder or aqueous form.

Protein "fining" treatment is applied to clarify wine and to reduce astringency. In this process, tannin natural to grapes and wine, which is responsible for astringency and haze in beverages including wine and beer, interact with "fining" proteins to form an insoluble complex which precipitates from the wine.

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The protein fining agents currently authorized for use in winemaking in the United States are all derived from animals and include: gelatin, egg white, casein, milk, and isinglass. (see 27 CFR § 24. 246)

Plant Proteins provides an alternative to animal derived proteins in winemaking.

2. Basis for GRAS Determination

This notice for a claim for GRAS Determination for isolated plant protein is made, first, following the outcome of a scientific process involving direct scientific data relating to the physical and chemical nature of plant protein and their function as in winemaking and, second, based on the intended use of plant proteins, there is no increase in dietary exposure to plant proteins in the human diet for wine consuming adults..

The data and information that are the basis for our GRAS determination are available for the Food and Drug Administration's (FDA) review and copying at reasonable times at the address specified or such data and information will be sent to FDA upon request.

3.Identity and Composition of Isolated Plant Proteins

Protein patterns and molecular weights of proteins were established using Sodium dodecyl sulfate polyacrylamide gel electrophoresis (SDS-PAGE). Most proteins in the wheat hydrolyzate were approximately 13k Daltons. The molecular weight of the pea proteins is higher. There are two major groups of pea protein; the first has a molecular weight of between 360 and 400 K Daltons and the second the molecular weight of the second group of pea protein is between 160 and 200 K Daltons.

The amino acid composition of the plant proteins was established using high performance liquid chromatography (HPLC). The major amino acids in the wheat proteins are glutamic acid/glutamine and proline, whereas those in pea are glutamic acid/glutamine and aspartic acid/asparagine.

As determined from the amino acid composition, the protein content of pea protein was 90% on a dray basis, while the amino acid composition of the hydrolyzed wheat gluten was higher 94% on a dray basis.

(see section 4.4.1 for analytical methodologies)

4. The Scientific Process forming the basis of the GRAS Determination for Plant Proteins as a Fining Agent in Winemaking

Data has been gathered indirectly from literature and common experience, and directly by physical and chemical analysis. This information has been considered with respect to any potential hazard to human health that may result from contact with or consumption of wine fined with Plant Proteins.

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The data analysis has been directed towards the raw material, processing conditions, product composition and use and these are considered below under the following headings:

Natural origin of wheat and peas
Manufacturing Process
Similar Products
Biological and Chemical Specifications for Plant Proteins
Intended technical use and benefit

4.1 Natural origin of wheat, peas and lupin

4.1.1 Wheat

Wheat is a wild grass (*Gramineae* family) native to arid countries of western Asia. Its use as a food goes back to the stone ages and remains an important food in Europe, the eastern Mediterranean region, the western part of Asia and North America. Wheat has become the leading cereal crop as bread, especially leavening varieties, has become an important part of the daily diet. Wheat is the only grain suitable for leavening bread. About 600 million tons of wheat are produced and consumed around the world each year. Furthermore, the United States Food and Drug Administration has previously determined wheat gluten as GRAS when used according to good commercial practice conditions. (see 21 CFR §184.1322).

4.1.2 Peas

Peas (*Pisum sativum*) are cultivated for the fresh green seeds, tender green pods, dried seeds and foliage. Green peas are eaten cooked as a vegetable, and are marketed fresh, canned, or frozen while ripe dried peas are used whole, split, or made into flour. In some parts of the world, dried peas are consumed split as dahl, roasted, parched or boiled. Green peas are the number one processed vegetable specifically in UK and USA. The protein content of peas range from 15.5 – 39.7%.

4.2 Manufacturing Processes

4.2.1 Processing Chemicals

All chemicals used to process wheat gluten or pea protein meet the recognized standards of performance and quality for their application as specified in Food Chemical Codex 4th Ed (1996). Food chemicals are handles according to standards of "good manufacturing practice."

4.2.1.1 Wheat gluten

The wheat gluten, thanks to its aggregative properties, is obtained directly by selective extraction of proteins as they are not soluble. Thus no chemical or enzyme necessary to

accomplish this step. In the second step, a protease enzyme protease is used for the hydrolysis of the extracted wheat gluten.

4.2.1.2 Pea protein

No chemical, acid or enzymes are necessary for the manufacture of the pea protein isolate we use.

4.2.2 Method of Manufacture/Processing Procedure

4.2.2.1 Wheat

Gluten, which is not soluble with a neutral pH, is recovered from wheat flour by initially forming an aqueous dough which is subsequently thinned and washed to remove soluble granules including starch and other irrelevant materials (this is the lixiviation process). Gluten is then dried by atomization at rather low temperatures of 50°C so that it preserves its physicochemical properties.

4.2.2.2 Pea

The pea protein used in the formulation of fining product is a pea isolate. The isolate result from two successive steps. The first consists in putting the pea flour in suspension to solubilize the proteins in an aqueous medium (the proteins are soluble with neutral pH) and separating them from the insoluble substances (starch, parietal components) by centrifugation, for example.

The second step consists in recovering these proteins in a way which is as selective as possible by excluding the other soluble elements (small molecules, non protein nitrogenized components, soluble sugars, polyphenols, and salts). Ultrafiltration is used to accomplish this step. In this, the non protein soluble molecules of low molecular size cross the membrane and constitute the permeate. The retentate, consisting of proteins, thus purified and concentrated, is dried directly.

4.3 Similar Products

4.3.1. Wheat

The gluten can then be modified to give hydrolyzed gluten. The wheat gluten is hydrolyzed enzymatically (protease). It is then dried by atomization and after having passed controls of conformity, it is filtered then packaged.

The reduction of the size of the polypeptide chains of the gluten increases their solubility and creates new functionalities.

4.3 Products arising from variation in the processing conditions of

4.3.1 Wheat

The enzyme nature, concentration, pH, processing temperature and duration are the major variables which may be used to achieve desired specific differences in the functionality of the gluten. This variable is not considered significant to change the GRAS status of the wheat protein hydrolyzate.

4.3.2 Pea

Temperature and pH are the major variables which may be used to achieve desired specific differences in the functionality of the pea protein. This variable is not considered significant to change the GRAS status of the pea protein isolate.

4.4 Chemical and biological Specification for Plant Proteins

The isolated plant protein is available as a whitish, beige or yellowish powder. It is totally of partially soluble in water depending on pH.

4.4.1 Identification tests

4.4.1.1 Protein

Protein patterns and molecular weights of isolated plant proteins were established using Sodium dodecyl sulfate polyacrylamide gel electrophoresis (SDS-PAGE), using concentration gradient gels (9 to 19% acrylamide), was performed as previously described elsewhere [13]. Protein were then stained using Coomassie blue G-250.

4.4.1.2. Amino acid determination

The amino acid composition of the protein preparations was determined by the Kjeldahl method for total nitrogen multiplied by the factor of 6.25.

4.4.2 Specifications of Plant Proteins

4.4.2.1 **Fungal derived toxins**:

Aflatoxin B1, B2, G1, and G2	<5.0 µg/kg

4.4.2.2 **Toxic Metal Concentration**

Lead	<0.5 mg/kg
Cadium	<1 mg/kg
Copper	<35 mg/kg
Zinc	<50 mg/kg
Chromium	<10 mg/kg
Arsenic	<3 mg/kg
Mercury	<1 mg/kg

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Antimony	<0.5 mg/kg

4.4.2.3 **Microbiological Specification**

Total viable micro-organisms	<5.1 x 10^4 cfu/g
Yeasts	<1,000 cfu/g
Moulds	<1,000 cfu/g
Coliforms	<100 cfu/g
E. coli	<1.0 cfu/g
Sulfite reducing anaerobes	<30 cfu/g
Salmonella	0 in 25 g
Staphylococcus:	<100 cfu/g
Total aerobic mesophiles	<50,000/g

4.5 **Intended technical use and benefit**

Protein fining agents have a selective affinity for wine poly-phenols, i.e., tannin. The mechanism of interaction is by hydrogen bonding between the phenolic hydroxyl and the carbonyl oxygen of the peptide bond of the protein. This tannin – protein complex is insoluble and precipitates from the wine.

The plant proteins are added to wine to remove harsh and bitter tannin. The usage rate of plant protein is pretty much wine specific. This being the case, the usage rate is determined by conducting laboratory scale trials to determine the minimum quantity of plant protein necessary to achieve the desired effect. The maximum quantity of plant protein used in any single wine will not exceed 0.5 g/L.

A body of generally available and acceptable scientific literature relating to the role of vegetable protein in wine making includes the following:

Maury, *et. al.*, (2003) reports plant proteins do not precipitate simple phenolic compounds but selectively precipitate condensed tannin. Amino acid composition was not found to be a major factor in the affinity for condensed tannin. The hydrolyzed wheat glutens were selective in precipitating highly polymerized and highly galloylated tannin. Initial results showed that plant proteins can be used as fining agents in enology (winemaking)." [3]

Lefebvre, *et. al.*, (2003) reported gluten react like gelatins in fining wines. The monomeric phenols were not eliminated while tannin with high mean degree of polymerization and highly gallolytes were selectively eliminated. The quantity of tannin precipitated using plant protein was less than with gelatin. Sensory data shows wines treated with plant protein are less astringent than non treated wine. [4]

Lefebvre, Sandrine (2004) reported results of trials using three vegetable proteins; wheat gluten, pea and lupin. Nineteen trials were carried out in France and 2 in Switzerland. The results showed that in most trials the vegetable proteins have an equivalent action, if not better, that the animal proteins used as a reference. [5]

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Anonymous (2004) The OIV resolves recommending approval of the use of protein mater of plant origin for the fining of wines in order to improve their clarity, stability and gustatory properties. [2]

Anonymous (2004) The OIV resolves recommending approval of the use of protein mater of plant origin for the fining of musts (crushed grapes) in order to improve their clarity, stability and gustatory properties. [1]

5.0 Data, information, methods, or principles the notifier relies on to establish safety

The notifier relies on FDA's GRAS status of wheat gluten (21 CFR 184.1322); Codex Alimentarius General Guidelines for the Utilization of Vegetable Protein Products in Foods (CAC/GL 4-1989); Codex General Standard for Vegetable Protein Products (Codex STAN 174-1989); Codex Standard for Wheat Protein Products including wheat gulten (CODEX STAN 163-1987, Rev. 1-2001); International Office of Wine and Vine resolutions number 7/2004 and 8/2004; the body of scientific literature summarized in section 4.5 of this notification; the fact these vegetables are already part of the human diet; and the fact the vegetable protein precipitates out of the wine with condensed tannin.

6.0 Reports of investigation or other information which may appear to be inconsistent with GRAS determination

No reports of investigations or other information were found that may appear to be inconsistent with this GRAS determination.

7.0 Consensus of Experts Plant Protein is safe under the intended conditions of use.

The International office of Wine and Vine (OIV), headquartered in Paris, France, has given a favorable "admitted" recommendation for the use of Plant Protein in winemaking.[1,2]. The membership of the OIV, an intergovernmental body (IGO), includes the governments of 39 wine producing and wine consuming countries, and 9 observer status countries. The OIV is an observer to the Codex Alimentarius.

In order for a new wine making material to be recognized by the OIV, it must be studied by the relevant "expert groups." The "expert groups" consist of scientific delegates of member countries as well as invited experts. The experts include academics as well as government scientists, including public health officials. The Plant Protein project was evaluated for 3 years by the expert groups "Wine Technology," "Food Safety," and "International Code of Oenological Practice," as well as the "Sub-commission on Methods of Analysis."

Based on the favorable recommendation of the OIV, it is clear there is consensus among winemaking scientists, public health officials, and the governmental policy level officials of 39 countries that Plant Proteins are not harmful when used under the conditions intended.

8.0 Self limiting feature

If excess plant protein is use, such wines will develop "protein haze." Such haze appears with time and is accelerated by incidental warming of the wine.

9.0 Dietary Exposure

The use of plant protein in winemaking results in the protein reacting with the tannin in the wine forming an insoluble protein-tannin complex which precipitates; therefore, there is no increase in dietary exposure to consumers of wine processed with Plant Protein.

10.0 Labeling

The following indication should appear on the label of the packaged plant protein: (1) plant origin of the protein, (2) minimal protein content, (3) safety and storage conditions, and (4) expiration date.

We thank you very much for your careful consideration of the plant protein GRAS notification. Should you have any questions or desire additional information, please contact me.

Sincerely yours,

Richard M. Gahagan
Regulatory Consultant – Beverage Alcohol

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Selected References

1. Anonymous, International Office of Wine and Vine Resoltuion Oeno 7/2004: *Must – Fining using Proteins of Plant Origin*, Paris, France (2004).

2. Anonymous, International Office of Wine and Vine Resoltuion Oeno 8/2004: *Wine – Fining using Proteins of Plant Origin*, Paris, France (2004).

3. Maury, C., Sarni-Manchado, P., Lefebvre, S., Cheynier, V., and Moutounet, M., *Influence of Fining with Plant Proteins on Proanthocyanidin Composition of Red Wine*, Am. J. of Enol & Vitic. 54:2 (2003)

4. Lefebvre, S., Maury, C. Scotti, B., Sarni-Manchado, P., Cheynier, V., and Moutounet, M., *Study of Phenolic Composition in Red Wine with Vegetal Protein*, Vinidea.net (Wine internet technical journal) N. 3 (2003)

5. Lefebvre, Sandrine, *Summary – Trials Carried Out Vegetable Proteinaceous Material for Must and Wine Fining*, Report of Research, Martin Vialatte Oenology, Epernay, France (2004)

SUBMISSION END

RICHARD M. GAHAGAN
Regulatory Consultant – Beverage Alcohol

AM

November 26, 2005

Edmundo Garcia, Ph. D.
Food and Drug Administration
Washington, DC

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Via e-mail

Re: GRAS Notice No. 000182 – wheat and pea proteins in winemaking

Dear Dr. Garcia:

Per our telephone conversation of October 27, 2005, the following is a summary of the data supporting our GRAS conclusion that plant proteins when used as indicated are safe and pose no health or safety risks to wine consumers.

This summary follows:

The United States Food and Drug Administration

The United States Food and Drug Administration has by regulation declared wheat glutin to be GRAS as a food ingredient. (21 CFR § 184.1322)

In a GRAS letter dated December 16, 1999, the United States Food and Drug Administration advised a GRAS notifier the agency has no questions at that time regarding the notifier's conclusion that isolated wheat protein is GRAS under the intended conditions of use and an ingredient in baking. (9)

The International Office of Wine and Vine

The International office of Wine and Vine (OIV), headquartered in Paris, France, has given a favorable "admitted" recommendation for the use of Plant Protein in winemaking. (2, 3).

The membership of the OIV, an intergovernmental body (IGO), includes the governments of 39 wine producing and wine consuming countries, and 7 observer status countries. The OIV is an observer to the Codex Alimentarius.

In order for a new wine making material to be recognized by the OIV, it must be studied by the relevant "expert groups." The "expert groups" consist of scientific delegates of member countries as well as invited experts. The delegates and experts include academics as well as government scientists, including public health officials. The Plant Protein project was evaluated for 3 years by the expert groups "Wine Technology,"

P.O. Box 8569 Fresno, California 93747 U.S.A. Tel: 559-251-1759 Cell: 559-333-0551 Fax: 559-272-5259
Email: rmg@richardgahagan.com Website: www.richardgahagan.com

"Food Safety," and "International Code of Oenological Practice," as well as the "Sub-commission on Methods of Analysis."

The Food Safety Expert group consisted of public health officials from the 39 member governments. The United States was a member of the OIV withdrawing *circa* 2001. Leslie Bluhm, Ph.D.; Director, Division of HACCP Programs, FDA, CFSAN was the United States delegate to the Food Safety group of the OIV and served as the group's Vice-Chairman.

A listing of OIV member and observer countries follows:

OIV MEMBER COUNTRIES

South Africa	Greece	Norway
Algeria	Hungary	Peru
Germany	Ireland	Portugal
Australia	Israel	Czech Republic
Austria	Italy	Romania
Belgium	Luxemburg	Russia
Bulgaria	FYR Macedonia	Serbia-Montenegro
Chile	Malta	Slovakia
Cyprus	Morocco	Slovenia
Croatia	Mexico	Sweden
Spain	Moldavia	Switzerland
Finland	Netherlands	Turkey
France	New Zealand	Uruguay

OIV OBSERVER COUNTRIES

Argentina	Georgia	Tunisia
Bolivia	Lebanon	Ukraine
Brazil		

The favorable recommendation of the OIV shows there is consensus among winemaking scientists, public health officials, and the governmental policy level officials of 39 countries that plant proteins are not harmful when used under the conditions intended.

<u>The Food Standards Of Australia and New Zealand</u>

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The Food Standards Of Australia and New Zealand (2004) concluded, in their final assessment of plant proteins (including wheat and peas) as wine processing aids, concludes "that plant proteins derived from traditional food sources can be considered as alternative wine processing aids for clarifying wine. These products have a technological

. Box 8569 Fresno, California 93747 U.S.A. Tel: 559-251-1759 Cell: 559-333-0551 Fax: 559-272-5259
Email: rmg@richardgahagan.com Website: www.richardgahagan.com

justification and do not raise any public health and safety concerns beyond the current permission for foods as processing aids." (3)

Other Investigations Supporting Our Claim that Vegetable Proteins are GRAS

Cattaneo, A., *el. al.*, (2003) found no detectable residual protein in red wines clarified with lupin, pea or a mixture of pea and lupin proteins or in white wines clarified with pea proteins using immunoreactivity to specific rabbit anti-lupin and anti-pea polyclonal antibodies in treated wines as determined by SDS-PAGE and immunoblotting. (4).

Cattaneo, A., *el. al.*, (2003) found no residual immunoreactive gluten in treated wines as assessed by SDS-PAGE and immunoblotting. (5).

Marchal, R., and co investigators (2003) found, using an ELISA immunotechnique, gluten antibodies were not able to recognize their antigens in the Muscat juice treated with 20 g/hL gluten. They concluded this result clearly indicates the absence of residual deamidated gluten proteins in the treated juice (< 1mg/L limit of detection.) (6).

Marchal, R., *et. al.* (2001) Using the a noncompetitive dot-blot technique, conducted a control experiment using antisera containing deamidated gluten polyclonal antibodies yielded no positive cross-reaction with the undiluted control wine and the undiluted control wine treated with deamidated gluten 5. Further, using the same dot-blotting technique, these workers found the gluten-antibodies obtained were not able to recognize their antigens in wine treated with 12 g/hL gluten. They concluded, this work clearly indicates that if there were residual gluten proteins in wine, their concentration was lower than 0.25 g/hL (2.5 mg/L). 7).

Restani, P., and co-workers, (2002) evaluated the presence of gluten in treated wine using SDS-PAGE and its immunoreactivity was evaluated using immunoblotting. A small amount of protein was found in treated wine but this produced no significant immunochemical reaction. Further, under the most restrictive tests of the presence of gluten in the wine, the predicable residue of gluten was safe for celiac subjects. (8).

Please let me know if you have any questions or desire additional information.

Sincerely yours,

/s/ Richard M. Gahagan

Richard M. Gahagan
Regulatory Consultant

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Enclosures

. Box 8569 Fresno, California 93747 U.S.A. Tel: 559-251-1759 Cell: 559-333-0551 Fax: 559-272-5259
Email: rmg@richardgahagan.com Website: www.richardgahagan.com

References and Attachments

1. Anonymous, OIV Resolution OENO 7/2004, **Musts**- Fining using proteins of plant origin; International Office of Wine and Vine, Paris France, July 30, 2004.

2. Anonymous, OIV Resolution OENO 8/2004, **Wines**- Fining using proteins of plant origin; International Office of Wine and Vine, Paris France, July 30, 2004

3. Anonymous, Final Assessment Report, Application A482, Plant proteins as wine processing aids, Food Standards Australia and New Zealand, 18 February 2004.

4. Cattaneo, A.; Ballabio, C.; Restani, P.; Bertelli, A .A.; Bernardini, R.;.Novembre, E.; Vierucci, A.; Assessment of residual immunoreactivity in red or white wines clarified with pea or lupin extracts. Int. J. Tissue React. 2003, 25(4), 157- 165.

5. Cattaneo, A.; Ballabio, C.; Bertelli, A .A.; Fiocchi, A.; Galli, C. L.; Isoardi, P.; Terracciano, L.; Restani, P. Evaluation by immunoreactivity in red and white wines clarified with gluten and gluten derivatives. Int. J. Tissue React. 2003, 25(2), 57-64.

6. Marchal, R.; Lallement, A.; Jeandet, P.; Establet, G. Clarification of muscat musts using wheat proteins and the flotation technique, J. Agric. Food Chem. 2003, 51, 2040-2048.

7. Marchal, R.; Marchal-Delahaut, L.; Lallement A.; Jeandet, P. Wheat gluten used as clarifying agent of red wines, J. Agric. Food Chem. 2002, 50, 177-184.

8. Restani, P.; Beretta, B.; Ballabio, C.; Galli, C.L.; Bertelli, A.A. Evaluation by SDS-PAGE and immunoblotting of residual antigenicity in gluten-treated wine: a preliminary study, Int. J. Tissue React. 2002, 24(2), 45-51.

9. Rulis, Alan, GRAS Notice #000026, Director, Pre-market Approval, FDA, December 16, 1999.

. Box 8569 Fresno, California 93747 U.S.A. Tel: 559-251-1759 Cell: 559-333-0551 Fax: 559-272-5259
Email: rmg@richardgahagan.com Website: www.richardgahagan.com

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Washington, DC 20204

December 16, 1999

Dr. R. John Pearce
Manildra Group
P.O. Box 123 Nowra
N.S.W. Australia 2541

Re: GRAS Notice No. GRN 000026

Dear Dr. Pearce:

The Food and Drug Administration (FDA) is responding to the notice, dated June 30, 1999, that you submitted in accordance with the agency's proposed regulation, proposed 21 CFR 170.36 (62 FR 18938; April 17, 1997; Substances Generally Recognized as Safe (GRAS)). FDA received this notice on July 8, 1999 and designated it as GRAS Notice No. GRN 000026.

The subject of your notice is isolated wheat protein. The notice informs FDA of the view of the Manildra Group that isolated wheat protein is GRAS, through scientific procedures, for use as a food emulsifier, foam stabiliser, water retention agent, thickening and gelling agent, microencapsulation aid, film formation aid, adhesion aid and stretchability agent in powdered shortenings in baked goods, milk-like beverages, beverage whiteners, cheese analogues, manufactured meat and fish products, whole muscle cooked meats, soups, sauces and marinades, mousses and meringues, and edible films and coatings at a level of use ranging from 1 to 50 grams per kilogram.

The Manildra Group prepares isolated wheat protein from a commonly consumed food substance, i.e., wheat gluten (which is affirmed as GRAS as a direct human food ingredient, 21 CFR 184.1322). According to your notice, dietary exposure to isolated wheat protein at this use level would be substantially equivalent to the present dietary exposure of gluten and gluten derivatives.

The notice provides information about the identity, characterizing specifications, method of manufacture, and conditions of use of isolated wheat protein. In an electronic mail message dated November 25, 1999, you informed FDA of one additional specification for isolated wheat protein - i.e., a lead specification of less than 0.5 mg/kg.

The Office of Premarket Approval consulted with the Office of Food Labeling (OFL) regarding the Manildra Group's proposal to declare the presence of isolated wheat protein by the common or usual name "wheat protein." OFL advises that the proposed name

"wheat protein" would sufficiently describe the ingredient and would alert consumers who are allergic to wheat to the presence of a wheat-derived ingredient.

Based on the information provided by Manildra Group, as well as other information available to FDA, the agency has no questions at this time regarding the Manildra Group's conclusion that isolated wheat protein is GRAS under the intended conditions of use. The agency has not, however, made its own determination regarding the GRAS status of the subject use of isolated wheat protein. As always, it is the continuing responsibility of the Manildra Group to ensure that food ingredients that the firm markets are safe, and are otherwise in compliance with all applicable legal and regulatory requirements.

FDA consulted with the Labeling and Additives Policy Division (LAPD) of the Food Safety and Inspection Service (FSIS), United States Department of Agriculture, regarding the use of isolated wheat protein in meat or meat-type products. With the exception of the implications of meat product standards, LAPD did not identify any concerns regarding the suitability of the intended use of isolated wheat protein in meat or meat-type products. LAPD requested that we advise you to seek regulatory guidance regarding whether the use of isolated wheat protein in meat or meat-type products requires rulemaking under the statutes that FSIS implements. You should direct your inquiry to Dr. Robert Post, Director, LAPD, Office of Policy, Program Development and Evaluation, Food Safety and Inspection Service, 300 12th Street, SW, Room 602, Washington, DC 20250-3700. The telephone number for LAPD is (202) 205-0279 and the FAX number is (202) 205-3625.

In accordance with proposed 21 CFR 170.36(f), a copy of the text of this letter, as well as a copy of the information in your notice that conforms to the information in proposed 21 CFR 170.36(c)(1), is available for public review and copying on the Office of Premarket Approval's homepage on the World Wide Web.

Sincerely,
/s/
Alan M. Rulis, Ph.D.
Director
Office of Premarket Approval
Center for Food Safety and Applied Nutrition

cc: Dr. Robert Post, Director, LAPD
Office of Policy, Program Development and Evaluation
Food Safety and Inspection Service
300 12th Street, SW, Room 602
Washington, DC 20250-3700

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

1-04
18 February 2004

FINAL ASSESSMENT REPORT

APPLICATION A482

PLANT PROTEINS AS WINE PROCESSING AIDS

BEST ORIGINAL COPY

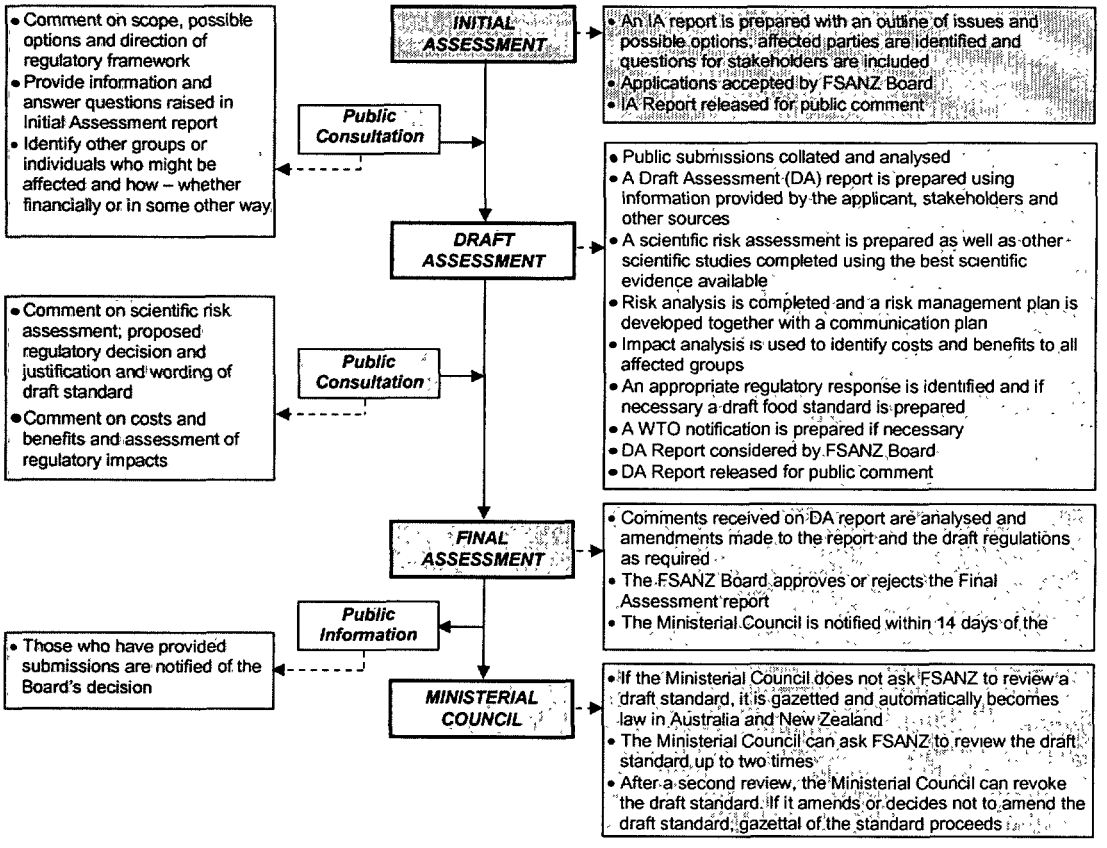
FOOD STANDARDS AUSTRALIA NEW ZEALAND (FSANZ)

FSANZ's role is to protect the health and safety of people in Australia and New Zealand through the maintenance of a safe food supply. FSANZ is a partnership between ten governments: the Commonwealth; Australian States and Territories; and New Zealand. It is a statutory authority under Commonwealth law and is an independent, expert body.

FSANZ is responsible for developing, varying and reviewing standards and for developing codes of conduct with industry for food available in Australia and New Zealand covering labelling, composition and contaminants. In Australia, FSANZ also develops food standards for food safety, maximum residue limits, primary production and processing and a range of other functions including the coordination of national food surveillance and recall systems, conducting research and assessing policies about imported food.

The FSANZ Board approves new standards or variations to food standards in accordance with policy guidelines set by the Australia and New Zealand Food Regulation Ministerial Council (Ministerial Council) made up of Commonwealth, State and Territory and New Zealand Health Ministers as lead Ministers, with representation from other portfolios. Approved standards are then notified to the Ministerial Council. The Ministerial Council may then request that FSANZ review a proposed or existing standard. If the Ministerial Council does not request that FSANZ review the draft standard, or amends a draft standard, the standard is adopted by reference under the food laws of the Commonwealth, States, Territories and New Zealand. The Ministerial Council can, independently of a notification from FSANZ, request that FSANZ review a standard.

The process for amending the *Australia New Zealand Food Standards Code* is prescribed in the *Food Standards Australia New Zealand Act 1991* (FSANZ Act). The diagram below represents the different stages in the process including when periods of public consultation occur. This process varies for matters that are urgent or minor in significance or complexity.



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Final Assessment Stage (s.36)

FSANZ has now completed two stages of the assessment process and held one round of public consultation as part of its assessment of this Application. This Final Assessment Report and its recommendations have been approved by the FSANZ Board and notified to the Ministerial Council.

If the Ministerial Council does not request FSANZ to review the draft amendments to the *Australia New Zealand Food Standards Code* (the Code), an amendment to the Code is published in the *Commonwealth Gazette* and the *New Zealand Gazette* and adopted by reference and without amendment under Australian State and Territory food law.

In New Zealand, the New Zealand Minister for Food Safety gazettes the food standard under the *New Zealand Food Act (1981)*. Following gazettal, the standard takes effect 28 days later.

Further Information

Further information on this Application and the assessment process should be addressed to the FSANZ Standards Liaison Officer at one of the following addresses:

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

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

Assessment reports are available for viewing and downloading from the FSANZ website www.foodstandards.gov.au or alternatively paper copies of reports can be requested from FSANZ's Information Officer at info@foodstandards.gov.au including other general enquiries and requests for information.

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000026

Executive Summary and Statement of Reasons

FSANZ received an application on 18 November 2002, from Scorpex Wine Services to amend the *Australia New Zealand Food Standards Code* (the Code) to permit the use of plant proteins as processing aids during production of wine. The Application is being progressed as a Group 3 (cost-recovered) application. The Applicant requested that Standard 4.1.1 – Wine Production Requirements (Australia only) be amended accordingly.

The purpose of the Application is to permit the use of plant proteins as alternative wine clarifying agents. The most widely used clarifying agents are sourced from animals. For example, gelatine, which is the most commonly used clarifying agent is sourced from cattle. Interest in clarifying agents from non-animal sources has been stimulated by concerns about the safety of products derived from cattle. Such plant derived products would also be suitable to produce wine that is acceptable for vegan and vegetarian consumers.

The objective of this assessment is to determine whether the Code should be amended to permit the use of plant proteins derived from traditional food sources as processing aids for wine production in Australia.

The Application indicates that plant proteins may be produced from wheat, rice, peas, lupins and maize, though this would not be an exclusive or final list. The products are usually obtained as brown or yellow water soluble powders from a variety of processing techniques that includes milling, extraction, toasting, grinding, washing and ultrafiltration.

The proposed plant proteins are foods or food ingredients and meet the Codex Alimentarius Standard 174-89 for Vegetable Protein Products. They are already used in the food industry as an alternative to gelatine in a variety of food products. These plant proteins are considered to be traditional foods and foods already have approval as processing aids under Standard 1.3.3 – Processing Aids, and can therefore be used to produce wine under Standard 2.7.4 – Wine and Wine Product. However, wine produced in Australia must also comply with the wine production standard, Standard 4.1.1 – Wine Production Requirements (Australia only) which currently does not provide permissions for the use of foods as processing aids.

Clause 4 of Standard 1.2.3 requires the mandatory declaration of certain substances if they are present in food. Plant protein products that may be affected by this Standard are cereals containing gluten, tree nuts, sesame seeds, peanuts and soybeans.

FSANZ progressed the Application under section 36 of the FSANZ Act as it believed the Application raised issues of minor complexity. Therefore FSANZ did not request any public comments on the Initial Assessment Report. Public comment on the Draft Assessment Report was sought from 16 July to 27 August 2003 (with one late supplementary submission received 22 September 2003). Eighteen submissions were received with 10 supporting the Application while eight objected due to concerns about residual gluten (from gluten derived plant proteins) remaining in the wine for people with Coeliac disease. Their concerns are addressed by mandatory labeling provisions of the Code (clause 4 of Standard 1.2.3), which require mandatory declaration of certain allergenic substances if present in the final food.

The Final Assessment Report concludes that plant proteins derived from traditional food sources can be considered as alternative wine processing aids for clarifying wine. The use of such plant proteins as processing aids in wine is technologically justified and does not raise any new public health and safety concerns.

Statement of Reasons

The draft variation to Standard 4.1.1 – Wine Production Requirements (Australia only) of the Code to permit plant proteins derived from traditional food sources as processing aids for the production of wine in Australia is agreed for the following reasons.

- In general there are no public health and safety concerns with using plant proteins derived from traditional food sources as processing aids for wine. However, wine remains subject to general labelling requirements in Standard 1.2.3 that require mandatory declaration of certain substances in food including gluten and known allergens.

- Plant proteins derived from traditional food sources are technologically justified as non-animal replacements for currently used wine clarification processing aids from international research and trials.

- As concluded by the regulatory impact analysis conducted, the costs that would arise from a variation to Standard 4.1.1 to permit plant proteins as processing aids for wine do not outweigh the direct and indirect benefits to the community, government or industry that would arise from the variation.

- The proposed draft variation of the Code is consistent with the section 10 objectives of the FSANZ Act. FSANZ is protecting public health and safety by ensuring the use of only those plant proteins which are derived from traditional food sources are permitted as wine processing aids in Standard 4.1.1. FSANZ is also ensuring consistency with international wine standards and the promotion of fair trading in wine.

- A majority of submitters were supportive of the Application. A number had concerns about the impact on consumers with Coeliac disease. These concerns are addressed by the mandatory labelling provisions of the Code.

- To achieve what the Application seeks, namely permission to use plant proteins as processing aids for wine produced in Australia, there are no alternatives that are more cost-effective than a variation to Standard 4.1.1.

1. Introduction

FSANZ received an application on 18 November 2002, from Scorpex Wine Services to amend the Code to permit the use of plant proteins as processing aids during production of wine. The Application is being progressed as a Group 3 (cost-recovered) application. The Applicant requested that Standard 4.1.1 – Wine Production Requirements (Australia only) be amended accordingly.

The purpose of this Application is to permit the use of plant proteins as alternatives to currently used wine clarifying agents that are sourced from animals, such as gelatine (cattle), isinglass (fish), milk and milk products (milk) and egg white (egg) with proteins derived from plant matter. Gelatine is the most widely used clarifying agent. With the recent concerns about the safety of products derived from contaminated cattle due to the Bovine Spongiform Encephalopathy (BSE) agent there has been greater interest in developing non-animal derived alternatives to gelatine. Such products would also be available to produce wine that is acceptable for vegan and vegetarian consumers.

2. Regulatory Problem

The regulatory problem is that Standard 4.1.1 does not permit the use of plant proteins as processing aids. However these same plant proteins are currently permitted for use in wine made in accordance with Standard 2.7.4 – Wine and Wine Product, because they are considered as traditional foods and thus are generally permitted for use as processing aids as provided by clause 3(a) to Standard 1.3.3, which states:

The following processing aids may be used in the course of manufacture of any food at a level necessary to achieve a function in the processing of that food –

(a) foods, including water;

Standard 2.7.4 was developed during the review as the joint wine standard that applies to wine produced in New Zealand and wine imported into Australia and New Zealand. It is a minimally prescriptive standard which defines wine and wine product and provides permissions for the addition of certain specified foods during the production of wine.

Standard 4.1.1 is an Australia-only standard which was developed in order to underpin the 1994 *Agreement between Australia and the European Community (EC) on Trade in Wine and Protocol* (Australia – EC Wine Trade Agreement). This agreement relies on Australian wine being recognised as wine of designated quality and origin (e.g. *appellation controllé*, DOC, *qualitätswein*, etc). It contains many provisions which are not appropriate in a joint wine standard and the permissions in Standard 1.3.3 do not apply. All wine produced in Australia must comply with Standard 4.1.1. Therefore in order to permit Australian wine producers to use plant proteins, a variation is required to Standard 4.1.1. Clause 4 of Standard 4.1.1 contains a positive list of permitted processing aids. Only the substances listed in clause 4 of Standard 4.1.1 are permitted to be used as processing aids in Australian produced wine.

3. Objective

The objective of this assessment is to determine whether it is appropriate to amend the Code to permit the use of plant proteins derived from traditional food sources for use as processing aids during wine production in Australia.

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

- the protection of public health and safety;
- the provision of adequate information relating to food to enable consumers to make informed choices; and
- the prevention of misleading or deceptive conduct.

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

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

Public health and safety is protected by ensuring that any plant proteins which are approved for the purpose of wine clarification are safe. The promotion of consistency with international wine standards and the promotion of fair trading in wine is also addressed in assessing this Application.

4. Background

A number of proteinaceous materials derived from animal products are permitted by the Code for use to clarify grape juice and wine. These proteinaceous materials irreversibly bind with phenolic structures extracted from grapes to form insoluble precipitates, which are removed by techniques such as filtration. Commonly used proteinaceous clarifying materials include gelatine, skim milk powder, isinglass (fish collagen) and egg white.

The most common and widely used clarifying product is gelatine, which is derived from cattle. The emergence of variant Creutzfeldt-Jakob disease (vCJD) has caused worldwide concern about the use of bovine materials from Bovine Spongiform Encephalopathy (BSE) infected animals in the production of food for human consumption. BSE, commonly known as "mad cow disease", is a chronic degenerative disease affecting the central nervous system of cattle. Recently with the concerns of potential transmission of the BSE agent to humans from contaminated cattle products there has been greater interest in replacing products derived from cattle. This is the case in the wine industry where there have been moves, prompted by consumer concerns, to replace the use of gelatine with a product not derived from cattle (or animals).

Alternative clarifying products, sourced from plants, could also be used to produce wine suitable for vegan and vegetarian consumers.

Trials have been carried out in Europe evaluating the efficacy of using plant proteins as an alternative for gelatine during wine production. Initial results have been promising and form the basis for this Application. The Applicant requests that these plant proteins can be used as alternatives for animal-derived clarifying agents.

5. Relevant Issues

5.1 Nature of the Products

The plant proteins proposed for use are foods or food ingredients. They are composed of hydrolysed proteins derived from cereals and legumes. The plant proteins proposed for use comply with the Codex Alimentarius Standard 174-89 for Vegetable Protein Products. Such products are prepared by various separation techniques from vegetable sources. The Codex Standard applies to products that are used during food manufacturing of foods that require further processing.

The sources of the plant proteins which have been evaluated in trials by the wine industry and which have potential for commercial use include cereals (rice, wheat, barley, maize), legumes (peas, soya, lupin, haricot), oilseeds (rape, sunflower, sesame), tubers (potato, beetroot) and foliage crops (lucerne). The final products can undergo a variety of processing techniques including, milling, extraction, concentration, toasting, grinding, washing and ultrafiltration. Such plant proteins may be flours, concentrates, isolates, protein isolates or enzymatic or chemical hydrolysates. They are usually dried powders of a brown or yellow colour, which are soluble in water. The production of plant proteins is explained in more detail in the Food Technology Report (**Attachment 2**).

Based on these trials, the products having the best potential for development as commercial products have been obtained from wheat, rice, peas, lupin and maize, though this is not an exclusive list.

5.2 Technological Need

Wine makers in several countries have initiated production trials to evaluate the effectiveness of the plant proteins as alternatives to gelatine for the clarification of wine and musts. Results to date from such trials, included in the Application, have been positive indicating that different products and different treatments can be used to give similar performance compared to gelatine. From the information in the Application it would seem that individual wine makers would need to evaluate the performance of the products for their individual wines to determine the optimal treatment required.

Industry support for this Application is shown by letters from two major Australian wine producers included in the Application. Both these companies expressed support to have an alternative to animal products for wine clarification and phenolic adjustment to their wines. They have indicated interest in trialling such products on their wines.

It would appear that there are no dietary or nutritional implications of using plant proteins as wine processing aids since the proteinaceous materials added as clarifying agents react with components in the wine to form insoluble precipitates which are subsequently removed by filtration, racking or centrifugation.

5.3 Safety Assessment

A safety assessment has not been conducted on the plant proteins proposed to be used since they are derived from traditional foods. The plant proteins also meet the Codex Alimentarius Standard 174-89 for Vegetable Protein Products.

Such plant proteins are currently used in the food industry as an alternative to gelatine in cherry candies and fruit chews, in products derived from meat or fish, in soups and sauces, dietary products and children's foodstuffs.

In order to ensure the safety of plant proteins used as wine processing aids, it is necessary to specify which plants will be used as a source of proteins. To that end FSANZ has written the proposed draft variation to Standard 4.1.1 to allow only those plant proteins that are derived from traditional food sources to be approved as processing aids for wine production. This has been done by linking the permission back to the relevant subclause (subclause 3(a) of Standard 1.3.3) that allows foods to be considered generally permitted processing aids. The proposed draft variation is listed in Attachment 1.

5.4 International Regulatory Standards

Plant proteins are not currently used as processing aids for wine in other countries. The Applicant has provided two documents from the Office International de la Vigne et du Vin (OIV) showing trials are underway to evaluate the use of plant proteins for wine through the OIV process. The Applicant believes that approval from the OIV is likely in 2004. An application to allow the use of plant proteins as wine clarifying agents has also been made to the EU and the Applicant believes permission may occur in early to mid 2004.

The Italian government has authorised the Asti Instituto Sperimentale di Enologia to conduct plant trials where over 500,000 litres of grape juice, and white and red wine has been treated with plant proteins.

5.5 Labelling Issues – Cereals Containing Gluten

A number of recent Australian wines have labels which indicate that the wine has been treated by isinglass (a fish product). This is not saying that there is definitely isinglass residues in the final treated wine, just that it has been used. Examples of labels statements which are used in Australia (information obtained from the Winemakers' Federation of Australia) are:

- Produced with isinglass (fish product)
- Contains / produced with fish product
- Produced with isinglass (fish product). Traces may remain.
- Produced with fish products. Traces may remain.

There is no data indicating that this has caused any consumer concern or negative response. A similar reaction may be expected for the use of plant proteins containing gluten used to treat wine. Such advisory labelling would be useful information for people with Coeliac disease.

The presence of gluten-containing cereals and their products in the final wine will evoke mandatory labelling requirements (clause 4 of Standard 1.2.3 – Mandatory Warning and Advisory Statements and Declarations).

The relevant section of clause 4 of Standard 1.2.3 is printed below.

4 Mandatory declaration of certain substances in food

1) The presence in a food of any of the substances listed in the Table to this clause, must be declared in accordance with subclause (2), when present as -

(a) an ingredient; or
(b) an ingredient of a compound ingredient; or
(c) a food additive or component of a food additive; or
(d) a processing aid or component of a processing aid.

(2) Any substances required to be declared by subclause (1) must be –

(a) declared on the label on a package of the food; or
(b) where the food is not required to bear a label pursuant to clause 2 of Standard 1.2.1 -

(i) displayed on or in connection with the display of the food; or
(ii) provided to the purchaser upon request.

Editorial note:

Paragraph 4(2)(b) allows the retailer of a food to provide the information specified in the Table to clause 2 verbally or in writing.

Table to clause 4

Cereals containing gluten and their products, namely, wheat, rye, barley, oats and spelt and their hybridised strains other than where these substances are present in beer and spirits standardised in Standards 2.7.2 and 2.7.5 respectively
Crustacea and their products
Egg and egg products
Fish and fish products
Milk and milk products
Peanuts and soybeans, and their products
Added Sulphites in concentrations of 10 mg/kg or more
Tree nuts and sesame seeds and their products

Evidence from recent research papers that have evaluated the efficacy of plant proteins (including gluten based) that have used ELISA (enzyme-linked immunosorbent assay) have failed to detect residual gluten in the final treated wine to the detection limit of these tests.[1,2]

If these products were to be used commercially the onus would be on manufacturers to determine whether cereals containing gluten and their products are present in the wine and, if so, to label accordingly.

Clause 4 of Standard 1.2.3 requires mandatory declaration of certain substances if they are present in food. These substances require mandatory declarations because they may cause severe adverse reactions in susceptible individuals. In addition to cereals containing gluten and their products, wine containing plant proteins sourced from tree nuts and sesame seeds and their products; and peanuts and soybeans and their products would also require these declarations if they are present in the final wine.

[1] Marchal, R.; Marchal-Delahaut, L.; Lallement A.; Jeandet, P. Wheat gluten used as clarifying agent of red wines, *J. Agric. Food Chem.* 2002, 50, 177-184
[2] Marchal, R.; Lallement, A.; Jeandet, P.; Establet, G. Clarification of muscat musts using wheat proteins and the flotation technique, *J. Agric. Food Chem.* 2003, 51, 2040-2048

5.6 Issues Addressed from Submissions

5.6.1 Gluten issue

There were eight submissions that objected to the Application because of concerns of residual gluten from the plant proteins remaining in the final wine which they believe will cause serious health concerns for those consumers that have Coeliac disease (which is an intolerance to gluten).

One of these submitters was the Coeliac Society of Australia which sent their submission to the review of the gluten labelling requirements (P264 – Review of Gluten Claims with Specific Reference to Oats and Malt). FSANZ staff discussed the issue with the submitter and then formally responded to their submission with legal advice to correct the submitter's interpretation. The submitter's interpretation of clause 4 of Standard 1.2.3 was that labelling of the final food is required if processing aids derived from gluten containing cereals are used in the production of the food rather than when present in the final food.

The other seven submissions that objected to the Application were from private citizens that also have a concern about the use of gluten products to clarify wine and the possibility of residual gluten remaining in the wine affecting the health of wine consumers who have Coeliac disease. A number of these submitters were from overseas and said they would not consume Australian wine if this Application is successful. A number of submissions stated that various other non-gluten products such as mineral type filter media are suitable for wine clarification and filtration.

These submissions contend that to allow the use of gluten to clarify wine raises issues of public health and safety concerns for people with Coeliac disease who wish to consume wine. It will reduce their choice of beverages.

There a number of points to be made to address these concerns.

1. The Application is not only about the use of gluten containing plant proteins as wine clarifying agents. Possible plant protein products that may be used for this purpose could include those derived from various non-gluten containing cereals and plants including but not limited to rice, peas, lupins and maize.

2. There are technological differences associated with the use and the action of mineral type filtration agents such as bentonite, diatomaceous earth, activated carbon and kaolin compared to clarifying agents such as gelatine, isinglass and plant protein products. They can act in concert with each other but they can not completely replace one with the other. Clarifying agents aid in settling very fine particulate matter found in freshly fermented wine and musts by aggregating these to larger particles which can settle out. This is explained in more detail in Attachment 2 – Food Technology Report. Mineral filtration agents are very porous materials which form a complex physical barrier that absorb particulates and are used to filter precipitates from the wine. Very fine haze particles that have not been fined to produce larger aggregates can pass through filter beds and then form unacceptable hazes or precipitates in the aged wine.

3. Research work has been undertaken to investigate the effectiveness of replacing gelatine with plant proteins as wine clarifying agents. Researchers analysed for gluten residues in the final treated wine and have not found any to the limits of the very sensitive analytical methods (section 5.5 above). This indicates that the gluten added has been bound to particulates from the wine, settled out, filtered and removed from the final bottled wine to below the level of detection in wine. Individual winemakers will need to do their own analyses on their treated wine to ensure this is the case for their processes if they use gluten based plant proteins as clarifying agents.

4. The mandatory labelling requirements (clause 4 of Standard 1.2.3) for the presence of gluten-containing cereals and their products in the final wine, means that consumers who have Coeliac disease will be able to identify these wines and avoid them if they wish. There will be many other wines that do not have declarations for plant proteins (gluten) for these consumers to choose from.

5. It is expected that winemakers in Europe and possibly other regions will also soon have approval to use plant proteins as wine clarifying agents.

6. Winemakers may decide to label that they have used gluten products in the production of the wine in an analogous way many are now indicating the use of fish collagen (isinglass). This would be added information for wine consumers, especially those with Coeliac disease.

5.6.2 Editorial note, linking approval to mandatory labelling for gluten

New Zealand Food Safety Authority (NZFSA) made a suggestion in its submission that an editorial note be written linking the approval for plant proteins as a processing aid to the mandatory labelling requirements for gluten if present in the final food (clause 4 of Standard 1.2.3). This is to ensure that Australian winemakers would be aware of the labelling requirements in Standard 1.2.3.

FSANZ considers that a cross reference is not necessary. The Australian wine industry is generally aware of the requirements for mandatory labelling of allergenic substances. Further, if the course of action suggested by NZFSA was followed, this would set a precedent for a large number of consequential amendments for which there is not sufficient justification. It is FSANZ's view that the appropriate vehicle for addressing the concerns of NZFSA is through the relevant user guides to the Code and these will be amended to address this issue when they are next updated. Finally, FSANZ has before it an Application (A480) to limit mandatory labelling requirements to the substances listed in the Table to clause 4 of Standard 1.2.3 and their protein containing derivatives. If the course of action suggested by NZFSA was followed it may indicate pre-judgement of the outcome of A480.

5.6.3 Incorporate plant protein specifications within the Code

One submission suggested that the specifications for plant proteins (which are listed within the Food Technology Report (**Attachment 3**)) should be included in the Code. There is no justification for the inclusion of specifications for materials that are considered foods within the Code. This course of action would set a precedent for a number of other processing aids that are also foods.

6. Regulatory Options

Plant proteins which are foods or food ingredients already have approval as general processing aids and can be used during wine manufacture under Standard 2.7.4 – Wine and Wine Product (but not for wine produced in Australia under Standard 4.1.1).

The two regulatory options available for this situation are:

1. Not approve the use of plant proteins derived from traditional food sources as processing aids for wine production in Australia under Standard 4.1.1;

2. Approve the use of plant proteins derived from traditional food sources for wine production in Australia under Standard 4.1.1, which duplicates their current approval for use in wine made in accordance with Standard 2.7.4.

Plant proteins not derived from traditional food sources would not be considered to be foods. They would need to be assessed as novel foods under Standard 1.5.1 – Novel Foods.

7. Impact Analysis

The affected parties to this Application are:

1. wine producers and suppliers to wine producers in Australia;

2. consumers of Australian wine; and

3. Commonwealth, State and Territory regulatory departments that enforce food regulations in Australia. There should be no impact in New Zealand since the proposed amendment is an Australia only standard.

Option 1

There are no perceived benefits to the Australian wine industry, consumers or government agencies if this option is taken.

There are disadvantages to the Australian wine industry if this option is taken since they would have less choice in which clarifying agents they can use. They would not have access to a non-animal derived clarifying agent. This limits the ability of Australian wine-makers to produce wine for vegan and vegetarian consumers, as well as consumers that have a concern about the use of gelatine.

It also puts Australian wine producers at a disadvantage because wine may soon be produced overseas using plant proteins as clarifying agents. These wines could be sold in Australia since they would meet Standard 2.7.4, but Australian wine producers could not use plant proteins.

Option 2

There are advantages to the Australian wine industry, giving them a choice of using a non-animal derived clarifying agent that they can use to appeal to a broader range of wine consumers.

There are benefits for wine consumers who are vegan and vegetarian and do not wish to purchase wine made using animal derived products. Also it would satisfy consumers who have health concerns about using gelatine (derived from cattle) in wine manufacture.

There should be minimal costs for such changes to wine producers. One possible cost for wine producers would be new labelling if there is the presence of any of the substances that require mandatory declarations required by clause 4 of Standard 1.2.3 in the final wine, caused by the use of plant proteins.

There should be no added costs or concerns for food regulators.

The Applicant states that the EU currently does not allow the use of plant proteins for use in winemaking but it is probable that they will provide regulations for plant proteins in wine in 2003.

Representatives of the Australian Wine and Brandy Corporation, Winemakers' Federation of Australia, and the Department of Agriculture, Fisheries and Forestry - Australia have advised the Applicant that they consider the proposed permission for the use of plant protein processing aids in Standard 4.1.1 will have no impact on the Australia - EC Wine Trade Agreement.

There should also be no issues with trade with other signatories to the Mutual Acceptance Agreement on Oenological Practices (including New Zealand, USA, Canada and Chile) since there are no consumer health or deception issues associated with the permission in Standard 4.1.1.

8. Consultation

8.1 Public Consultation

FSANZ did not request any public comments on the Initial Assessment Report. The Applicant requested the Application to be progressed under section 36 of the FSANZ Act, since it raises issues of minor complexity.

Public comment on the Draft Assessment Report was sought from 16 July to 27 August 2003 (with one late supplementary submission accepted on 22 September 2003). Eighteen submissions were received. **Attachment 3** summarises the submissions received. Of the eighteen submissions received 10 supported the Application while eight objected. The eight submitters who objected to the Application all had concerns about the use of gluten as a clarifying agent and possible gluten residues in the final treated wine which may cause serious health concerns to people with Coeliac disease. This issue is addressed within section 5.5 (labelling issues – cereals containing gluten) and section 5.6 (issues addressed from submissions) of this report.

NZFSA suggested that an editorial note linking permission to use plant proteins as wine processing aids, with the mandatory labelling requirements of clause 4 of Standard 1.2.3, if residual gluten is present in the final wine. This is to make Australian wine makers aware of their labelling obligations. The issue is addressed in section 5.6.2 above of this report.

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8.2 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.

Plant proteins comply with the Codex Alimentarius General Standard for Vegetable Protein Products Codex Stan 174-1989 for use as foods and food ingredients. This Codex standard does not provide specific approval for use in wine. However, FSANZ understands approval is being sought through the OIV.

Additionally, it is not expected that permitting the use of plant proteins for wine production in Australia and/or New Zealand would have any significant effect on international trade. This is because the overall market for wine clarification agents (gelatine) is relatively small (100 tonnes at AUD $1.2M per annum). Approval would only provide wine producers with an optional alternative to gelatine and displacement of this market is not expected to be rapid or significant.

Any amendment to Standard 4.1.1 – Wine Production Requirements applies only to wine produced in Australia. For the above reasons FSANZ did not recommend relevant agencies notify the WTO.

9. Conclusion and Approval

The Final Assessment Report concludes that plant proteins derived from traditional food sources can be considered as alternative wine processing aids for clarifying wine. These products have a technological justification and do not raise any public health and safety concerns beyond the current permission for foods as processing aids.

The draft variation to Standard 4.1.1 – Wine Production Requirements (Australia only) of the Code to permit plant proteins derived from traditional food sources as processing aids for the production of wine in Australia is agreed for the following reasons.

- In general there are no public health and safety concerns with using plant proteins derived from traditional food sources as processing aids for wine. However, wine remains subject to general labelling requirements in Standard 1.2.3 that require mandatory declaration of certain substances in food including gluten and known allergens.

- Plant proteins derived from traditional food sources are technologically justified as non-animal replacements for currently used wine clarification processing aids from international research and trials.

- As concluded by the regulatory impact analysis conducted, the costs that would arise from a variation to Standard 4.1.1 to permit plant proteins as processing aids for wine do not outweigh the direct and indirect benefits to the community, government or industry that would arise from the variation.

- The proposed draft variation of the Code is consistent with the section 10 objectives of the FSANZ Act. FSANZ is protecting public health and safety by ensuring the use of only those plant proteins which are derived from traditional food sources are permitted as wine processing aids in Standard 4.1.1. FSANZ is also ensuring consistency with international wine standards and the promotion of fair trading in wine.

- A majority of submitters were supportive of the Application. A number had concerns about the impact on consumers with Coeliac disease. These concerns are addressed by the mandatory labelling provisions of the Code.

- To achieve what the Application seeks, namely permission to use plant proteins as processing aids for wine produced in Australia, there are no alternatives that are more cost-effective than a variation to Standard 4.1.1.

ATTACHMENTS

1. Draft Variation to the *Australia New Zealand Food Standards Code*
2. Food Technology Report
3. Summary of Submissions

ATTACHMENT 1

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

To commence: on gazettal

[1] ***Standard 4.1.1*** *of the Australia New Zealand Food Standards Code is varied by –*

[1.1] *inserting in the* Table to clause 4 –

Plant proteins permitted as processing aids under clause 3(a) to Standard 1.3.3

[1.2] *inserting after the* Table to clause 4 –

Editorial note:

Clause 3(a) to Standard 1.3.3 permits the use of foods, including water as processing aids. Therefore, plant proteins that are foods are permitted under that Standard, and would also be permitted under this Standard.

ATTACHMENT 2

Food Technology Report

A482 – Plant Proteins as Wine Processing Aids

Introduction

An Application has been received from Scorpex Wine Services (acting on behalf of Esseco S.p.A., Italy) to amend the *Australia New Zealand Food Standards Code* to allow the use of certain plant proteins to be used as approved processing aids for the production of wine in Australia.

These products would be used as alternative non-animal derived products for currently used wine clarifying agents derived from animal sources, such as gelatine (cattle), isinglass (fish), milk protein and egg albumin.

The Applicant requests to have their plant proteins added to the approved positive list of processing aids within Standard 4.1.1 – Wine Processing Requirements (Australia only).

Discussion of the products, how produced

The products covered by this Application for use by the wine industry comply with the Codex Alimentarius General Standard for Vegetable Protein Products (Codex Stan 174-1989). The scope of that Standard states:

> *This standard applies to vegetable protein products (VPP) intended for use in foods, which are prepared by various separation and extraction processes from proteins from vegetable sources other than single cell protein.*

These products are currently used as ingredients in the food industry, due to their rheological properties where they are used as food integrators or emulsifying agents. They have been used as gelatine replacements in cherry candies and fruit chews, in products derived from meat or fish, in soups and sauces, dietary products and children's foodstuffs.

The protein products this Application refers to have been sourced from wheat, rice, peas, lupin and maize but would not be limited to just these plants. The Applicant states that other possible sources could be barley, sesame, soya, haricot, rape seeds, sunflower seeds, potato, beetroot and lucerne. A wide range of products sourced from different materials have been investigated for possible use as wine clarifying agents. It would be anticipated in the future that new plant proteins would also be evaluated for their effectiveness.

The plant proteins would have undergone a range of processing steps including milling, extraction, concentration, toasting, grinding, washing and ultrafiltration. The products may be flours, concentrates, isolates, protein isolates, enzymatic or chemical hydrolysates. They are usually cream, brown or yellow water-soluble powders.

Fig. 1 contains a schematic for the production of the plant proteins.

Specifications

The specifications for the products are listed in Table I and II.

Table I
Specifications of the plant proteins from the Application

SPECIFICATIONS	DETAILS
CHEMICAL FEATURES	
Dried substance	94 % min
Proteins	70 % min
Fat materials	5 % min
Carbohydrates	10 % max
Ash	3 % max
Sodium	0.4 % max
Calcium	0.15 % max
Phosphorus	0.5 % max
Magnesium	0.2 % max
Potassium	0.5 % max
PHYSICAL FEATURES	
pH (10% solution)	6-8
Colour	powder cream
Odour	neutral
Taste	neutral
MICROBIOLOGY	
Total flora	<10,000/g
Yeasts and moulds	<200/g
Coliforms	<20/g
Pathogenic germs and salmonella	absent in 25 g

Table II
Extra Specifications from the Office International de la Vigne et du Vin (OIV) for Plant Proteins

SPECIFICATIONS	DETAILS
CHEMICAL	
Loss on drying	≤12 %
Total nitrogen	>10 % of dried powder (corresponds to approx. 65 % protein)
Ash	<8 %
Iron	<150 ppm
Chromium	<10 ppm
Copper	<40 ppm
Zinc	<100 ppm
Heavy metals	<10 ppm
MICROBIOLOGY	
Total viable micro-organism	$<5 \times 10^5$ cfu/g
Escherichia coli	absent in 1 g
Salmonella	absent in 25 g
Coliforms	<100/g
MYCOTOXINS AND PESTICIDES	
Aflatoxins B1 and B2	<4 ppb
Aflatoxin G1	<1 ppb
Aflatoxin G2	<1 ppb
Ochratoxin	<5 ppb
Organophosphorus residues	<10 ppm
Organochlorine residues	<0.1 ppm

Action of plant proteins as clarifying agents

Wine and musts (grape juice before fermentation is completed) contain naturally occurring insoluble material which can not always be removed by filtration or can form hazes at a later time, after filtration. Such insoluble material is mainly protein and polyphenol (tannins) compounds present in grape products, and enzymes and yeasts responsible for fermentation. Often these insoluble materials are very fine flocculants which have similar particle densities to the liquid and do not readily settle. Also electrical repulsion forces between the charged particles as well as diffusion phenomena results in very slow settling and clarification of wines. Hazes can form at a later date after initial clarification by filtration.

To improve wine quality, wine producers have historically used a variety of different products to assist in clarifying wines more rapidly. These are commonly called fining agents. The most commonly used fining agent in wine production is gelatine. Other commonly used wine fining agents are bentonites, tannins extracted from chestnuts, egg albumin, casein and silica gels. Isinglass, derived from fish swim bladders, is the most common fining agent used in beer production.

The primary reaction of protein finings is to form a complex between polyphenols in the wine and the added protein to produce larger particles which are less soluble and big enough to settle out of solution. The larger complexes between polyphenols and proteins are usually formed by hydrogen bonding between OH groups on polyphenol groups and keto-imide {C(O)NH} groups on the proteins.

There can also be protein–protein complexes formed to yield insoluble particles. For such reactions to occur, the two different types of proteins need to have different charges so they can form ionic bonds.

Formation of insoluble particles, which settle out, improves the clarity of the wine. They tend to settle out at the bottom of tanks to form wine lees. The resultant semi-clarified wine is subsequently filtered (or racked or centrifuged). Finings also remove some of the problem compounds which can flocculate with ageing of the produced wine therefore improving the quality of the bottled wine.

References

Cole, C.G.B., The use of gelatine in wine fining, *Proceedings of the 1st SAAFoST Technical Symposium, Emulsifiers, Stabilisers and Thickeners in the Food Industry 1*, Durban, South Africa, April 1986, Natal Technikon Printers.

Marchal, R.; Marchal-Delahaut, L.; Michels, F.; Parmentier, M.; Lallement, A.; Jeandet, P., Use of wheat gluten as clarifying agent of musts and white wines, *Am. J. Enol. Vitic.* 2002, 53(4), 308-314.

Sarni-Manchado, P.; Deleris, A.; Avallone, S.; Cheynier, V.; Moutounet, M., Analysis and characterisation of wine condensed tannins precipitated by proteins used as fining agent in enology, *Am. J. Enol. Vitic.* 1999, 50(1), 81-86.

Marchal, R.; Marchal-Delahaut, L.; Lallement A.; Jeandet, P. Wheat gluten used as clarifying agent of red wines, *J. Agric. Food Chem.* 2002, 50, 177-184.

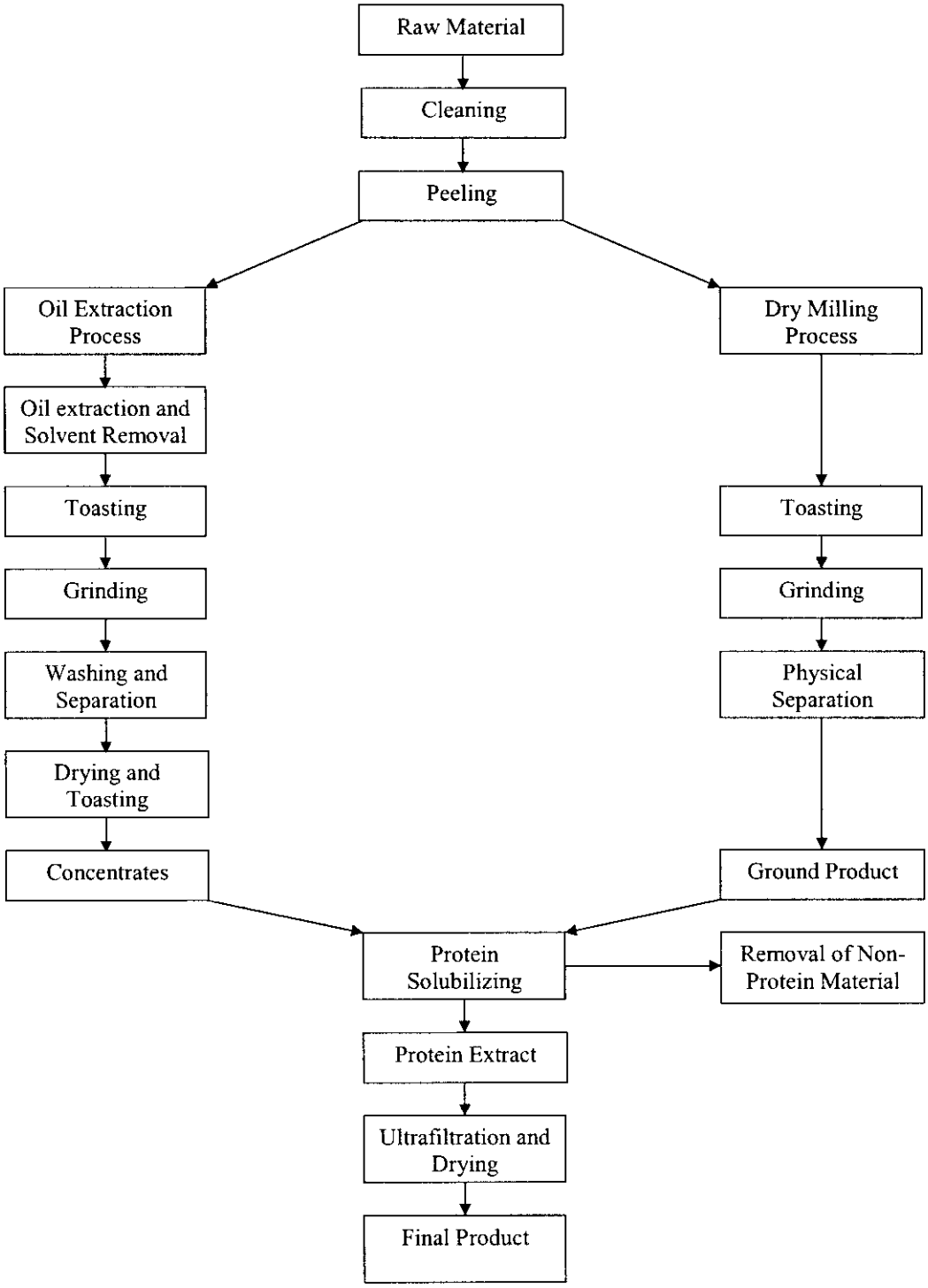
Marchal, R.; Lallement, A.; Jeandet, P.; Establet, G. Clarification of muscat musts using wheat proteins and the flotation technique, *J. Agric. Food Chem.* 2003, 51, 2040-2048.

Abstracts from the following:

Restani, P.; Beretta, B.; Ballabio, C.; Galli, C.L.; Bertelli, A.A. Evaluation by SDS-Page and immunoblotting of residual antigenicity in gluten-treated wine: a preliminary study, *Int. J. Tissue React.* 2002, 24(2), 45-51.

Fischerleitner, E.; Wendelin, S.; Eder, R. Effects of conventional and new protein containing fining agents on quality, composition and tolerance of wine, *Mitt. Klosterneuburg Rebe Wein*, 2002, 52 69-88.

Fig. 1
PLANT PROTEIN PRODUCTION SCHEMATIC



ATTACHMENT 3

Summary of Public Submissions

Submitters

#	Submitter Organisation	Name
1	Australian Food and Grocery Council	Tony Downer
2	The Coeliac Society of Australia Inc.	Graham Price
3	Food Technology Association of Victoria	David Gill
4	Winemakers' Federation of Australia	Tony Battaglene
5	Environmental Health Unit, Queensland Health	Gary Bielby
6	Agriculture, Fisheries and Forestry – Australia, Department of (Australian Quarantine and Inspection Service, AQIS)	Trent Brady Kerrie Boulton
7	New Zealand Food Safety Authority	Carole Inkster
8	Stephen and Liz Spain, York, UK	
9	Toby Anderson, Bournemouth, UK	
10	Stephen Rowe, Ferntree Gully, Victoria	
11	Constance Rieper-Estes, Australia	
12	Steve Cox, Huntington, UK	
13	Emma Wright	
14	David McIlfatrick	
15	Newton Che, student, Department of Food Science, University of Auckland	
16	Keren Ward, student, Department of Food Science, University of Auckland	
17	Mayank Joshi, student, Department of Food Science, University of Auckland	
18	Coles Myer Ltd (representing Liquorland)	Andrea Currie

Submitter	Position	Comments
Australian Food and Grocery Council	Supports	It supports the Application, including the approval of the use of plant proteins derived from traditional food sources, the impact analysis and the drafting. It also recommends that FSANZ considers including the specifications from Codex Alimentarius Standard 174-89 for Vegetable Protein Products into the Code. (FSANZ believes there is no reason to include specifications for materials that are considered foods within the Code. It would set a precedence for a number of other processing aids that are also foods. See section 5.6.3).
The Coeliac Society of Australia Inc.	Issue with gluten	It has an issue with section 5.5 – Labelling Issues – Cereals Containing Gluten of the report. It is their understanding that clause 4 of Standard 1.2.3 requires labelling of the final product if processing aids derived from gluten containing cereals are used in the production of the product rather than the presence in the final product. They have requested that FSANZ provide advice to clarify this situation and to review the interpretation. A meeting between the submitter and FSANZ has taken place as well as formal advice confirming that it is the presence of the processing aid in the final food that requires mandatory labelling.
Food Technology Association of Victoria	Supports	The committee agrees with option 2, to approve the Application. This would duplicate current approval for wine in accordance with Standard 2.7.4.

Winemakers' Federation of Australia	Supports	Their first submission: They do not have a formal position on the introduction of plant proteins as a processing aid for winemaking. They understand that internationally (especially Europe) there are moves to approve the use of plant proteins so they believe Australia should support the Application to prevent any future technical barrier to trade. They do not believe there would be any adverse political ramifications of such approval. A second late (supplementary) submission which FSANZ accepted: This submission was sent after the Application had been discussed by their Technical Advisory Committee. They still supported the Application but they raised two issues which they suggested FSANZ need to consider. 1. The Application is broad based and possible products may be derived from a number of sources. They also made comment about the rather low level of refinement and specification listed in the Report. They also mentioned possible allergen issues with other plant than those covered by the Code (such as favism with broad beans). (Unless there are issues of public health and safety the first point is a commercial decision winemakers can decide on. Favism is not covered by mandatory labelling requirements within the Code.) 2. They point out the issue of residual gluten for people with Coeliac disease, for those plant protein products that may be gluten based. (This issue has been raised by a number of other submitters and is addressed by mandatory labelling provisions within clause 4 of Standard 1.2.3 of the Code. It is discussed in section 5.6.1 of the report.)
Environmental Health Unit, Queensland Health	Tentative support (option 2)	They acknowledge there appears no obvious public health and safety implications in the Application. It would also allow the Australian wine industry greater choice to use non-animal derived clarifying agents. However they believe advice needs to be provided assuring there are no chemical residues remaining in the final hydrolysed protein products, or providing residue data on such. (The products would meet the specifications listed in Attachment 2, which gives specifications of chemical residues).
Agriculture, Fisheries and Forestry – Australia, Department of (Australian Quarantine and Inspection Service, AQIS)	Supports	They believe the Application will have no impact on AQIS imported food operations.
New Zealand Food Safety Authority	Supports	They support measures that harmonise Australia and New Zealand permissions. They suggest an editorial note linking the permission to use plant proteins as processing aids for wine to the mandatory labelling for gluten if present in the final food (clause 4 of Standard 1.2.3). (for discussion, see section 5.6.2 of the report. FSANZ decided that there was no justification for making a special case of plant proteins as processing aids since other products may also have mandatory labelling requirements. Industry need to be aware of all their obligations of the Code, including mandatory declarations. FSANZ also believes industry is quite aware of these requirements, from current experience and discussions.) They believe it would be expected that plant proteins would be filtered from the final wine but a reminder of the requirements for Australian winemakers should be made.

Stephen and Liz Spain	Object, issues with gluten, Coeliac disease	Concerned that allowing the use of plant proteins as processing aids for wine will cause residual gluten protein to remain in the final wine, which many people with Coeliac disease will no longer be able to consume. He states that he has stopped drinking beer (produced from malted barley, may contain gluten) because of he has Coeliac disease so drinks more wine. The Application would be a further restriction of foods that people with Coeliac disease could consume. He also believes there are other non animal wine clarifying alternatives that are not gluten based, such as products derived from rice, peas, lupins, maize (all of which are covered by this Application, since the Application is not just for gluten products) as well as mineral type filter media (such as bentonite, diatomaceous earth, carbon and kaolin). (for discussion see section 5.6.1)
Toby Anderson	Object, issues with gluten, Coeliac disease	He believes the Application raises issues of public health and safety if gluten is used in Australian wine because it will cause health concerns for people with Coeliac disease who inadvertently drink such wine. (for discussion see section 5.6.1)
Stephen Rowe	Object, issues with gluten, Coeliac disease	He believes the Application raises issues of public health and safety if gluten is used in Australian wine because it will cause health concerns for people with Coeliac disease who inadvertently drink such wine. (for discussion see section 5.6.1)
Constance Rieper-Estes	Object, issues with gluten, Coeliac disease	She believes the Application raises issues of public health and safety if gluten is used in Australian wine because it will cause health concerns for people with Coeliac disease who inadvertently drink such wine. (for discussion see section 5.6.1)
Stephen Cox	Object, issues with gluten, Coeliac disease	He believes the Application raises issues of public health and safety if gluten is used in Australian wine because it will cause health concerns for people with Coeliac disease who inadvertently drink such wine. (for discussion see section 5.6.1)
Emma Wright	Object, issues with gluten, Coeliac disease	She believes the Application raises issues of public health and safety if gluten is used in Australian wine because it will cause health concerns for people with Coeliac disease who inadvertently drink such wine. (for discussion see section 5.6.1)
David McIlfatrick	Object, issues with gluten, Coeliac disease	He believes the Application raises issues of public health and safety if gluten is used in Australian wine because it will cause health concerns for people with Coeliac disease who inadvertently drink such wine. (for discussion see section 5.6.1)
Newton Che	Supports	They supported the Application and provided justification for their position.
Keren Ward	Supports	They supported the Application and provided justification for their position. The one point of concern raised was about possible gluten residues in wine which people with Coeliac disease have concerns with. They have also provided a number of recent research articles indicating low gluten residues in treated wine.
Mayank Joshi	Supports	They supported the Application and provided justification for their position as well as a couple of references.
Coles Myer Ltd (representing Liquorland)	Supports	They believe the Application will give the wine industry greater choice for additional non-animal derived processing aids, appealing to a wider range of consumers.

OIV

RESOLUTION OENO 7/2004

MUSTS -FINING USING PROTEINS OF PLANT ORIGIN

The GENERAL ASSEMBLY,

In view of Article 2 paragraph iv of the Agreement of 3 April 2001 establishing the International Organisation of Vine and Wine

Considering the works of the experts group "Wine technology",

DECIDES:
Upon the proposal by Commission II "Oenology" to introduce in part II of the *International Code of Oenological Practices* the following oenological practices and treatments:

PART II

Chapter 2: Must

FINING USING PROTEINS OF PLANT ORIGIN

Objectives: Use of protein matter of plant origin for the fining of musts in order to improve their clarity, stability and taste.

Prescriptions:

1. The dose to be used is determined after a preliminary test trial. The maximum usage dose should be less than 50 g/hl. The dose retained corresponds to the sample which produces the sought after clarity and gives a better result for tasting.

2. Protein matter of plant origin can be used with other admitted products such as tannins, bentonite, silica gel...

3. Protein matter of plant origin must comply with the prescriptions of the *International Oenological Codex*.

Recommendations of the OIV:

Admitted.

Certified in conformity
Paris, 30th July 2004
The General Director of the OIV
Secretary of the General Assembly

Federico CASTELLUCCI

OIV

RESOLUTION OENO 8/2004

WINE - FINING USING PROTEINS OF PLANT ORIGIN

The GENERAL ASSEMBLY,

In view of Article 2 paragraph iv of the Agreement of 3 April 2001 establishing the International Organisation of Vine and Wine

Considering the works of the experts group "Wine technology",

DECIDES:
Upon the proposal by Commission II "Oenology" to introduce in part II of the *International Code of Oenological Practices* the following oenological practices and treatments:

PART II

Chapter 3: Wines

FINING USING PROTEINS OF PLANT ORIGIN

Objectives: Use of protein matter of plant origin for the fining of wines in order to improve their clarity, stability and gustatory properties.

Prescriptions:

1. The doses to be used are determined after a preliminary test trial. The maximum usage dose should be less than 50 g/hl. After racking, the wines are analysed (turbidity, colour, absorbance at 280nm) and tasted. The dose retained corresponds to the sample which clarifies the wine without excess and gives a better result for tasting.

2. Proteins of plant origin can be used with other admitted products such as tannins, bentonite, silica gel

3. Proteins of plant origin must comply with the prescriptions of the *International Oenological Codex.*

Recommendations of the OIV:

Admitted.

000050

Certified in conformity
Paris, 30th July 2004
The General Director of the OIV
Secretary of the General Assembly

Federico CASTELLUCCI

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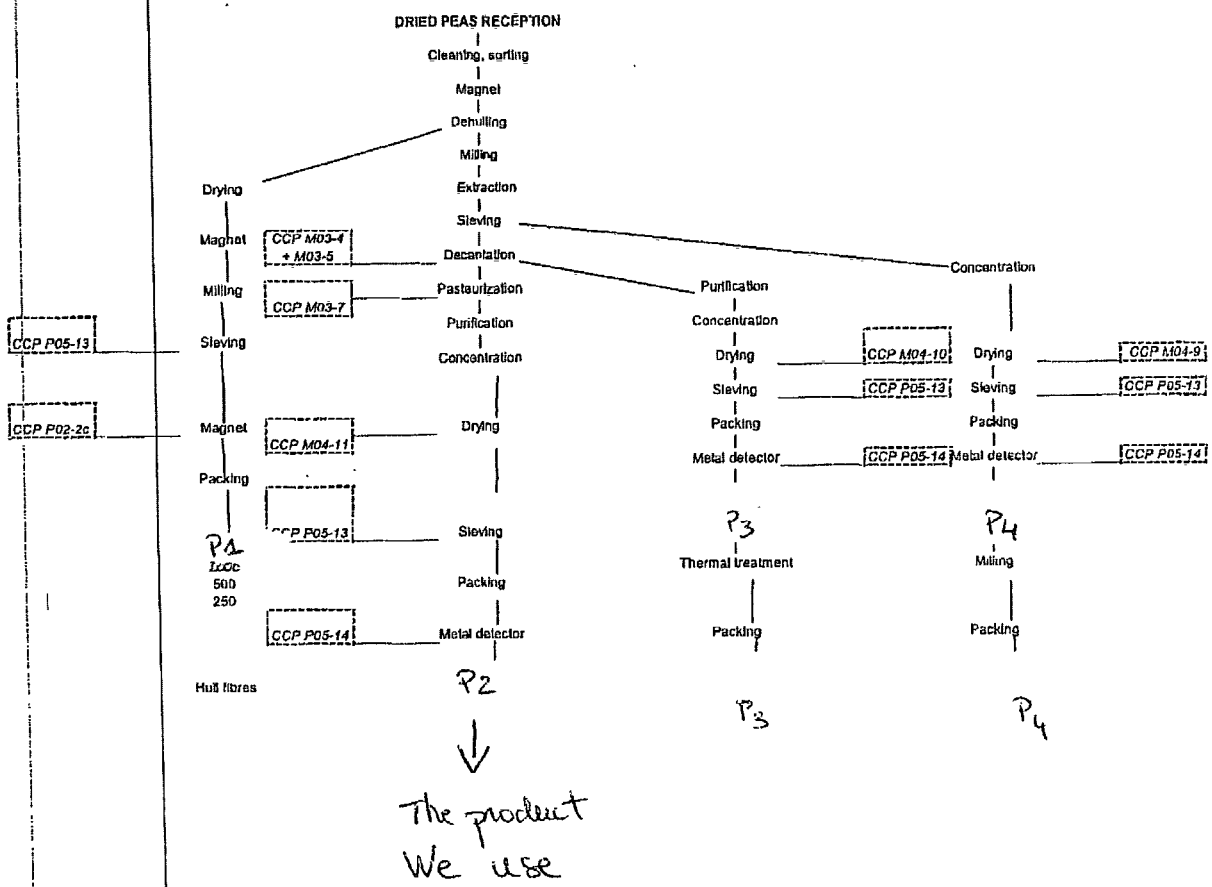

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Reference List for Industry Submission, GRN 000182

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NA- Not applicable