WINE LAW

INFORMATION

7 December 2011
6 of 2011
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1 CANADA ALLERGEN LABELLING

Wine Law 4 of 2011 included a trade letter by the Liquor Control Board of Ontario (LCBO), which indicated that wines labelled with a vintage date of 2012 or earlier will be exempt from the labelling for allergens. During the October 2011 meeting of the World Wine Trade Group (WWTG) we, however, were reliably informed by officials of the Canadian Federal Government that the exemption will probably only apply to wine showing a vintage date of 2011 and earlier - also see section highlighted in yellow in the attached document

The attached document by the Comité Européen des Entreprises Vins (CEEV) provides an excellent summary of the current position regarding allergen labelling in Canada. It also gives good technical information relating to best fining practices for wine.

2 USE OF AMMONIA

We are aware that it is not standard wine making practice in South Africa to use ammonia (as such or as a solution in water). However, since we received a query in this regard, we thought it prudent to point out that ammonia is not allowed for exports to the European Union. The following are allowed: diammonium phosphate (DAP), ammonium sulphate, ammonium bisulphite, ammonium sulphite and, only by virtue of our wine agreement with the EU, ammonium phosphate.

ANDRÉ MATTHEE
DIRECTOR: REGULATORY SERVICES
WINE AND SPIRIT BOARD
Tel: 022 423 8692 **Fax:** 021 807 6003 **Email:** matthee@wo.org.za

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De : Comité Vins [mailto:ceev@ceev.be]
Envoyé : mercredi 2 novembre 2011 09:45
À : ceev
Objet : CEEV/MINT-21/11-02/11: Allergens labelling- policy developments in Canada and possible impact in the EU

MINT-21/11-02/11

To: Directors

INFORMATION & ACTION

Subject: Allergens labelling- policy developments in Canada and possible impact in the EU.

Dear all,

Following our notes COMEX-08/11 on the new obligation of allergens labelling of wines in **Canada** as from August 2012 and our note MINT-18/11 confirming the **EFSA's** unfavourable scientific opinions on the exemption of allergens labelling in wine in the EU, we participated at the last **FIVS Wine Committee** meeting in Santiago de Chile (17-19 October) where we had the occasion to exchange information on latest developments on allergens labeling at international level.

I. Update on the latest policy developments in Canada:

1.1. The Canadian legislation- like the EU one- imposes allergens to be declared when present in the final product. For this reason, allergen labelling will be required whenever a fining agent from milk, fish or egg has been used as part of the processing only if the process used leaves behind some protein from the food allergen in the wine. We have got confirmation that **Health Canada** (the Canadian Health and Food safety authority) intends to follow the **line of interpretation** below:

- Food allergens must be declared on the label when protein from the specified food allergens is present in the finished product.

- Some food allergen derived fining agents are used in the manufacture of wines, however the use of a food allergen derived fining agent would only pose a risk to allergic consumers if protein from the food allergen is left behind in the wine at the end of the process

- For this reason, allergen labelling will not be required whenever a fining agent from milk, fish or egg has been used as part of the processing, but only if the process used leaves behind some protein from the food allergen in the wine.

- It is understood that under normal conditions of use, the fining agents are added at the lowest level required to achieve the purpose of clarifying the wine, and that a filtration process is normally used at the end to separate the fining agents from the clarified wine. Also, when these kinds of best practices are followed, no protein from the food allergen is left behind in the wine. However, where best practices are not followed, such as where larger amounts of fining agents are used, or less rigorous methods are used at the end to separate the fining agent from

the wine, then protein from the food allergen could be present in the wine and labelling could be required.

- Wine producers will have to be aware of the process they are using to fine their wines and whether or not this process can result in protein from a food allergen being present in a wine.

- While the regulations do not provide a specific threshold level, typical test methods for food allergens can detect in the low parts per million (ppm) range and if these methods did not detect any protein from the food allergen in the wine, then it could be considered that no protein was present.

1.2. Taking the above into consideration, **Health Canada has announced its willingness to provide for a Draft Guidance to develop national rules which would allow to exempt all wines which have followed the approved fining practices guidelines**. **These guidelines are expected to be approved and made public before the end of 2011.**

For this purpose, the Canadian Vintners Association (CVA) have completed a Guidance Document relating to "Best Fining Practices for Wine" built on the basis of *FIVS Good Fining Practice Guidelines for Wine* and submitted this proposal to Health Canada. Based on scientific evidence, CVA expects that Health Canada will use this science-based document to develop the national rules which would exempt all wines which have followed the approved fining practices.

➔ You will find enclosed the dossier sent by Canadian Vintners Association's (CVA) to help Health Canada develop this guidance. This includes:

1.2.1. Annex 1: Fining Agents - Technical Aspects
1.2.2. Annex 2: FIVS Good Fining Practice Guidelines for Wine
1.2.3. Annex 3: Historical and empirical evidence concerning the risks together with a letter to the TTB
1.2.4. Annex 4: Summary of scientific data documenting the risks associated with the consumption of fined wines by allergic individuals.
1.2.5. Annex 5: Summary of data indicating that residual protein is negligible using routine and readily available test methods in commercial wines.

1.3. Our colleagues in the Canadian Vintners Association's (CVA) have also informed about existing **data from the LCBO (Ontario Liquor Board) which would show no evidence of any allergen problems with any consumers over past ten years based on hundreds of millions of bottles of wine sold.**

➔ We are waiting for further information on this LCBO data and will keep you posted.
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1.4. The Canadian regulations did not provide any exemption for vintage wines. However, CVA has being arguing with Health Canada that the 18-month implementation period is insufficient for wine products which can have much longer shelf-lives than other pre-packaged foods and remain in circulation for many years. Health Canada could accept this arguments on the basis that the new labelling requirements would require millions of bottles of wine to be re-labelled and re-packaged, and has confirmed it is currently investigating the possibility of amendment which would exempt vintage wines with a vintage year of 2011 and earlier from the requirement for labelling of food allergens. CVA expects that Health Canada could accept the following line (to be confirmed yet):

o All vintage wines dated 2011 and earlier will be exempt from the new allergen regulations until stocks are depleted.

o All vintage wines dated 2012 and later will have to meet the new allergen labelling regulations.

o All wine and wine products without a vintage date, such as bag-in-box, non-vintage sparkling and non-vintage liqueur wines will have to comply with the new allergen labelling regulations effective August 4, 2012.

➔ Further information on this should be available in the near future.

II. Possible impact on the EU standpoints.

These Canadian authorities' interpretation and announced guidelines, if confirmed, will be the last chance for us to overcome the position of the DGSANCO.
Therefore we are contacting the relevant EC interlocutors (AGRI and SANCO) to support the 'Canadian approach' and explore the possibilities for the EC to take them into full consideration.

ACTION

-> Please do not hesitate to share with us any comment or remark on this, and confirm your agreement on CEEV definitely lobbying for such approach vis-à-vis the EU.
-> CEEV secretariat is liaising with the Canadian Vintners Association (CVA) and Health Canada on this issue. We are inviting the Canadian wine industry to attend our seminar on 23rd November;
-> CEEV Secretariat is contacting DG AGRI and SANCO at appropriate levels on this issue in advance to our Seminar on Allergens next 23rd November.

José Ramón Fernandez
Secretary General

CEEV-Comité Européen des Entreprises Vins
Comité Vins
Vins, Vins Aromatisés, Vins Mousseux, Vins de Liqueur et Autres Produits
Av. des Arts 43
B-1040 Bruxelles.
ceev@ceev.be
www.ceev.be
www.wineinmoderation.eu
Tel: (0032 2) 230 99 70
Gsm: (0032) 0495 28 18 72
Fax: (0032 2) 513 02 18

WINEinMODERATION.eu
Art de Vivre

GUIDANCE FOR THE FINING OF WINE AND THE LABELLING OF FINED WINES

Table of Contents

1 PURPOSE

This document details the regulatory background to labelling requirements for use of food additives and processing aids that are, or contain food allergens. It then outlines guidance on internationally agreed best fining practices for winemaking, together with the validation procedures, scientific and empirical data that have been used to demonstrate that the use of these practices removes from the final wine product residual levels of egg, fish, milk proteins used as fining agents in winemaking.

This guidance is required to address situations where (based on the best available scientific information) eggs, fish and milk used as fining agents in the winemaking process are not present in the final product at levels which pose risk to consumers with food allergies.

2 REGULATORY BACKGROUND

In Canada, the *Food and Drugs Act* ("the Act") is the basis for the regulatory oversight of all substances used in food processing and manufacture. Under the Act, the *Food and Drug Regulations* ("the Regulations") require the labelling of food allergens, gluten sources and added sulphites that are present in food.

Under the new allergen labelling provisions announced February 4, 2011, standardized alcoholic beverages will not be required to provide a list of ingredients, but will require a "Contains:" statement to identify any common food allergens present in the product. When the statement "Contains:" appears on the label (either by choice or because it was triggered by the presence of food allergens in the product) this statement must be complete and must identify all common food allergens in the prepackaged product.

2.1 Distinguishing between Food Additives and Processing Aids

2.1.1 Food Additive

"Food additive" is defined in section B.01.001 of the Regulations as *"any substance the use of which results, or may reasonably be expected to result, in it or its by-products becoming a part of or affecting the characteristics of a food."*

Fining agents are not automatically excluded from the Food and Drug Regulations as a "food additive". While the action of a fining agent in wine is consistent with that of a processing aid, whether it is regarded as such or as a food additive under the Regulations depends on the residue(s) of the agent (if any) in the finished product.

2.1.2 Processing Aid

A food processing aid is a substance that is used for a technical effect in food processing or manufacture, the use of which does not affect the intrinsic characteristics of the food and results in no or negligible residues of the substance or its by-products in or on the finished food. Processing aids fall outside the regulatory definitions of "food additive" and food "ingredient". As a result, processing aids are not required under the Food and Drug Regulations to be declared on prepackaged food labels.

2.1.3 Decision Tree for Distinguishing Between Food Additives and Processing Aids

Figure 1 shows a decision tree that can be used to distinguish between food additives and processing aids, based on the regulatory definition of "food additive". The questions in the tree should be answered by following the principles outlined under "Principles for using the decision tree".

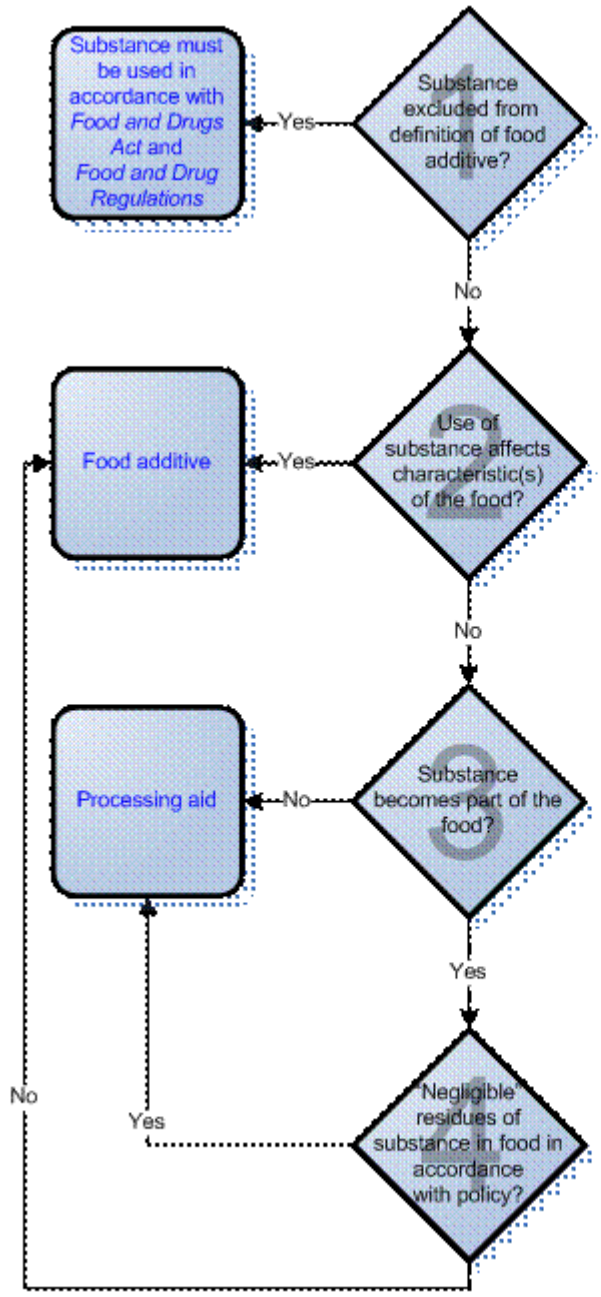

Figure 1 - Decision tree to distinguish between food additives and processing aids, based on the regulatory definition of "food additive".

2.1.4 Principles for Using the Decision Tree in the Case of Wine Fining Agents

Question 1: Does the definition of "food additive" exclude the substance?
Principle1: Egg, fish and milk fining agents are defined as processing aids under the Regulations B.02.100 (Wine) but are not specifically excluded from the definition of "food additive".

Question 2: Does use of the substance affect one or more characteristics of the food?
Principle 2: A substance is a "food additive" if the presence of the substance continues to have a technological function on the finished wine. Thus eggs, milk and fish products used as fining agents would be viewed as processing aids rather than additives provided there are negligible (if any) residues of the fining agent or its by-products in the finished wine.

Question 3: Does the substance become part of the wine?
Principle 3: A substance is a "food additive" if it or its by-product(s) become part of the wine, which they do, unless it can be demonstrated that any residues of the substance in or on the finished wine are "negligible".

Question 4: Are residues of the substance in the wine "negligible" in accordance with this policy?
Principle 4: Negligible in the case of eggs, fish and milk fining agents used in winemaking means that there are no residues of public health significance in the finished wine, and that any residues that are present are at levels too low to exert a technical effect in or on the product (i.e. less than 1 mg/L). The data presented in Annexes 3-6 provide the scientific and technological basis for this threshold.

The Winemaker should determine, on a case-by-case basis, whether residues are, or are likely to be, negligible in quantity (and thus in public health significance) and in technical effect in the wine that will be offered for sale. Supporting evidence to assist in making this evaluation might include:

(1) The unit processes to which the product will be exposed after fining that will serve to reduce or eliminate residues of fining agents or their by-products from the wine (e.g. the filtration processes, blending steps, etc.);

(2) Data from analytical tests showing that the residue levels are at or below a level of 1 mg/L; and/or

(3) Information from scientific literature and practical experience showing that residue levels are too low to have any technical effect in, or on the finished wine. In practice, this will always be the case at levels of 1 mg/L or lower for the fining agents in the purview of these Guidelines.

2.2 Labelling of Wine Fining Agents under Allergen Labelling Regulations

Wine which is fined in accordance with internationally agreed best practices (See Section 3) contains negligible (if any) amounts of residual fining proteins that can be detected using routine and readily available analytical methods sensitive to mg/L. Therefore the fining agents are functioning as processing aids in the wine and will not be required to be indicated (e.g. as eggs, milk or fish) in a "Contains:" statement on the label.

3 GOOD FINING PRACTICE GUIDELINES FOR WINE[1]

Fining is the winemaking process either before and/or after the fermentation process to remove unwanted insoluble particles and undissolved microscopic particles (colloidal material) from the juice or wine.

Fining involves the addition of adsorptive or reactive material in order to reduce or eliminate the presence of certain less desirable wine components. Fining agents are added to modify a wine's clarity, colour, texture or flavour or to ensure a wine remains in a particular stable state for a given period of time. Fining materials serve no ongoing purpose in the finished product and indeed are designed to be entirely removed from the treated wine as part of the fining process.

The effectiveness of a given fining agent depends on the agent, its method of preparation and addition, the levels of addition, together with characteristics of the wine such as pH, metal content, temperature, presence of CO_2 and prior wine treatments.

In addition to the steps outlined below for good fining practices, winemakers should give attention to maintaining traceability throughout the wine production process by recording the batch from which each sample of fining material is drawn, and to obtaining documented evidence from suppliers of the fining agents used, in keeping with the normal requirements of traceability.

[1] Adapted from the FIVS "Good Fining Practice Guidelines for Wine" (2007, see Annex 2), taking account of information such as that presented in Annex 1, "Fining Agents - Technical Aspects".

1. Fining agents shall be free from undesirable taints and shall conform to all applicable regulations. They should be stored in a cool, dry environment in sealed containers, or in other recommended storage conditions.

2. It is strongly recommended that laboratory scale trial runs be conducted prior to treatment of wine in the cellar.

3. The laboratory trial runs should also duplicate as far as possible the treatment to be conducted in the cellar, giving attention to the batch of fining agent to be used, the method of its preparation and addition to the wine, and the temperature of the laboratory sample with respect to that of the bulk wine to be fined. Hydration protocols for protein fining agents should be consistent between laboratory and cellar.

4. A minimal volume of distilled, de-ionised or other suitably pure drinking water should be used in order to dissolve or disperse the fining agent without overly diluting the wine (applicable regulations must be observed).

5. The quantity of fining agent used should always be the smallest amount needed to achieve the desired result as stipulated by winemaker sensory and/or analytical evaluation, and in no case shall the amount used exceed any applicable regulatory limits.

6. Thorough and adequate mixing of the fining agent into the juice or wine should be ensured, and sufficient time should be allowed for the material to react prior to immediate racking and/or subsequent filtration.

7. Industry recognized best practice filtration methods (including passing the wine through a fine powder filtration process and/or pre-bottling filtration through a 0.65 µm or smaller filter, or performing treatments of equivalent effect) should be used to remove insoluble protein fining agents. Where the treated wine is simply racked off the lees remaining from the fining treatment, or where a less rigorous filtration or other technique for removal of the lees is applied, and it is desirable to confirm that there is only negligible (if any) residual fining agent, a laboratory test should be conducted to confirm this at some stage prior to bottling.

8. Routine, periodic monitoring of the fining process shall be conducted. In general, this will entail analysis of a sample of fined wine using a sufficiently sensitive method of analysis for the fining agent in question. The frequency of sampling should be adequate to give confidence that the fining processes are being conducted in such a way as to negligible (if any) fining agent residues in the treated wine.

   Analysis shall <u>always</u> be conducted on fined wines that are intended to be bottled without filtration, to ensure that no residues of fining agents may be detected. Corrective action must be taken where the analysis of such wines indicates the presence of residual fining agents, or the product labels must reflect that presence in a “Contains:” statement.

9. Verification should be conducted at regular intervals, and should consist of a review designed to ensure that monitoring is occurring carefully and consistently, at a frequency that is adequate to give confidence that the fining processes are being conducted in such a way as to leave only negligible (if any) fining agent residues. Verification should also ensure that adequate and timely corrective actions are taken where evidence is obtained that indicates the potential for the presence of residual fining agents in a treated wine (e.g. through false positive results).

4 FOOD SAFETY CONTROL MEASURES FOR WINE FINING[2]

A study has been conducted on the available scientific and empirical data to determine whether internationally agreed best practices for the fining of wine do indeed present a sufficiently robust control measure to ensure there are negligible (if any) residual fining agents in treated wines and thus that they are not present in the final product at levels which pose risk to consumers with food allergies. This section of the document presents the method followed in this evaluation, together with the outcome.

4.1 VALIDATION STEPS

4.1.1 Pre-validation Tasks Undertaken.

a. Hazard: The presence of residual allergenic protein in wines fined with milk, eggs and fish and their products.

b. Food safety outcome required: Negligible (if any) levels of residual fining agents (using routine and readily available test methods) in wines fined according to internationally agreed best practices (i.e., the FIVS "Good Fining Practice Guidelines for Wine" presented in Annex 1 or a derivative with at least equivalent provisions relating to filtration of the fined product).

c. Control measure to be validated: The fining and filtration processes applied to wines

4.1.2 Approach

Historical empirical data and recent scientific studies allow the control measure to be validated without the need for additional studies (see Annexes 3-6).

4.1.3 Parameters and Decision Criteria:

a. Parameters:

i. The amount of protein used to fine a wine should be determined to be the minimum amount required to produce the desired outcomes.

ii. Wines should be fined according to internationally agreed best practices.

b. Decision Criteria:

i. The control measure for fined wines will be validated if negligible (if any) allergenic protein can be determined (generally by using routine and readily available test methods with adequate sensitivity) in a wine fined according to internationally agreed best practices.

4.1.4 Relevant validation information and the need for further studies.

a. Historical and empirical evidence concerning the risks associated with consumption of fined wines by allergic individuals are summarized in Annex 3. They show that such risks are very small, based on literature reviews, emerging information on tolerance of allergic individuals to small amounts of allergenic protein, the experience of allergy clinics, clinical trial data and consumer complaints information received by retailers and other organizations over many years.

b. Scientific data documenting the risks associated with consumption of fined wines by allergic individuals are summarized in Annex 4. They show that none of the 49 subjects in clinical trials had a clinically significant or life-threatening adverse reaction to a protein-fined wine -- only one of 49 subjects had a mild skin condition adverse reaction.

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[2] Based on the Codex Alimentarius Commission " Guidelines For The Validation Of Food Safety Control Measures" - CAC/GL 69 - 2008

c. Information to demonstrate that the proteinaceous wine fining agents casein and egg white used according to GMP in winemaking guarantee that there will only be residues of casein and ovalbumin below 0.07 and 0.002 mg/L (ppm), respectively, in the final wine product are presented in Annex 5. Such levels are not likely to trigger adverse reactions in milk or egg allergic individuals, respectively, which comprise approximately 1% or less of the adult population.

The available scientific literature and data relating to fining of wine has been reviewed to determine their pertinence to the internationally agreed best practices. The information is believed to be sufficient to validate the control measure without the need for further studies.

4.1.5 Analysis of results.

a. Data acquired on the ability of the fining procedures elaborated in internationally agreed best practices to consistently achieve the desired outcomes. The results of this analysis are presented in Annex 6.

4.1.6 Documents and decisions supporting the validation of the control measure.

All analyses, data, and decisions are presented in the Annexes to this text.

4.1.7 Conclusion

a. Data from scientific studies, as well as historical and empirical evidence, indicate that fining wine according to internationally agreed best practices leaves negligible (if any) residual levels of protein from fish, eggs or milk food allergens in the finished wine product.

b. These data can be used to establish a program of monitoring for residual fining agents in treated wines.

4.2 MONITORING STEPS

Routine, periodic monitoring of the fining process shall be conducted. In general, this will entail analysis of a sample of fined wine using a sufficiently sensitive method of analysis for the fining agent in question. The frequency of sampling should be adequate to give confidence that the fining processes are being conducted in such a way as to leave negligible (if any) fining agent residues in the treated wine.

Analysis should always be conducted on fined wines that are intended to be bottled without filtration, to ensure that no residues of fining agents may be detected. Corrective action must be taken where the analysis of such wines indicates the presence of residual fining agents, or the product labels must reflect that presence in a "Contains:" statement.

4.3 VERIFICATION STEPS

Verification should be conducted at regular intervals, and should consist of a review designed to ensure that monitoring is occurring carefully and consistently, at a frequency that is adequate to give confidence that the fining processes are being conducted in such a way as to leave negligible (if any) fining agent residues in the treated wine. Verification should also ensure that adequate and timely corrective actions are taken where evidence is obtained that indicates the potential for the presence of residual fining agents in a treated wine (i.e., through false positive results).

5 Annex 1 - Fining Agents - Technical Aspects

The purpose of adding a fining agent to wine can be three-fold: to "soften" or reduce its astringency and/or bitterness; to clarify and remove proteins capable of haze formation; and/or to stabilize and reduce the colour by the adsorption and precipitation of polymeric phenolic compounds and tannins. The fining agent reacts with wine components either chemically or physically, to form a new complex that can be separated from the wine.

Fining agents may bind with substances either through:

- Electrical interaction – the fining agent and substance(s) to be removed are of opposite charge and come together forming larger particles which settle in wine;
- Bond formation – the chemical bond is formed between the substance(s) to be removed and the fining agent;
- Absorption and adsorption – the substance(s) to be removed are either caught within the structure of the fining agent, or bind on the surface of the fining agent.

Test Sampling

Fining should be carried out only when necessary and using lower rather than higher levels of fining agent addition, as it is possible to remove desirable aroma and flavour characteristics from the wine with excessive additions. It is important, however, that sufficient fining agent is added when the prime purpose of fining is to achieve stability and/or to remove undesirable sensory characteristics.

Different fining agents react differently with different wines[3], and even with the same wine. Therefore, sample testing, which involves adding varying amounts of a fining agent to small wine samples, is strongly recommended to determine the outcome of the specific fining material used and the optimum dosage to avoid over- or under-fining. The test samples are assessed for organoleptic quality, and the treatment is scaled up proportionately for the larger, production batch of wine.

Mixing

Powdered fining agents should be rehydrated in water before addition to wine, and the added fining agents must be thoroughly mixed throughout the wine. This can be achieved by constant stirring and slow addition, or incorporating the fining agent addition into a racking procedure for larger wine batches.

Addition of Fining Agents to White and Red Wine

According to international research concerning the presence of residual potentially allergenic proteinaceous fining agents in wine, it could be concluded that if residual fining agent cannot be detected using an analytical method with a limit of quantification of 1 mg/L, those agents are not present in the final product at levels which pose risk to consumers with food allergies (see Annexes 3, to 6). In such circumstances an individual consuming 2 glasses of wine (284 mL) would ingest 0.284 mg of potentially allergenic protein.

[3] Every wine is different in composition and will react differently to the same fining agent. The effectiveness of a fining agent will depend on the agent used, the preparations, the method of addition to the wine, the dosage, the wine's pH and metal content, the temperature, the dissolved CO2 level, and any previous wine treatment.

Type of Wine	Fining Agent	Typical Addition (Mg/L)	Characteristics
White Wine	Isinglass	10-25[4] 20-50[4] 6-10[5]	Good clarity. Intensifies yellow colour. Light flakes, bulky, settles slowly
	Milk, Casein, sodium and potassium caseinate.	50-500[8]	Good clarification. Treats and prevents oxidation. No over-fining. Mainly used before alcoholic fermentation
Red Wine	Egg derived products	30-150[8]	Very good fining agent for tannic wines with some age. Tends not to remove protective colloids.
	Milk, Casein, sodium and potassium caseinate.	50-250[8]	Good clarification. Treats and prevents oxidation. No over-fining.

Milk, Casein, sodium and potassium caseinate

Because wines differ in their composition, there is no set recommendation on the amount of casein to be used in fining. From the winemaker's perspective, it is important that little of the protein remains in the wine after the fining/ clarification, as the presence of relatively large amounts of residual fining agent will lead to visual protein precipitates that necessitate further remedial processes. Excessive casein fining can also cause milky/cheesy aromas. Therefore, most fining processes are based on laboratory trials of individual batches of wine.

Casein is difficult to mix into the juice/wine as it is relatively insoluble in acidic solutions and should be mixed in water with a pH value above 8 or made alkaline prior to mixing. Potassium caseinate is usually used in preference to casein itself, as it can be dissolved directly in water. Either form is less effective when stirred into wine directly. Casein binds to the material to be removed from the wine before flocculating and precipitating quickly in the acidic environment. Slow and thorough mixing is important. Casein is often introduced to the bottom of the vessel at fining and the wine is then agitated. This prevents clumps forming on the surface of the wine. After the fining agent has settled, the wine is either racked or preferably filtered.

Egg-derived products

Egg white is used for fining (when necessary) when the wine is in barrel or prior to bottling. The resulting coagulum settles over the days following treatment and is separated from the wine by racking or preferably filtration.

[4] Ribéreau-Gayon et al. (2000).
[4] Wine Australia (2008)
[5] New Zealand Winegrowers (2008)
[8] Results of new studies to evaluate the potential allergenicity of wine made using proteinaceous processing aids (OIV 2010)
[8] Results of new studies to evaluate the potential allergenicity of wine made using proteinaceous processing aids (OIV 2010)
[8] Results of new studies to evaluate the potential allergenicity of wine made using proteinaceous processing aids (OIV 2010)

Isinglass

Isinglass is a pure form of collagen, which is derived from the dried swim bladders of certain tropical and subtropical fish. Only minimal residual amounts of the allergenic fish protein, parvalbumin, have been detected in commercially produced isinglass, as it is not a component of the swim bladder and adventitious parvalbumin tends to be removed in the production process.

In the wine production process, isinglass is added prior to fermentation to remove phenolic compounds from white juice, or immediately post fermentation to remove yeast, phenolic and tannin compounds from white wine. The typical usage level is 10-25 mg/L for white wines, and the protein is subsequently removed by sedimentation and filtration. Isinglass is seldom used to fine red and rosé wines.

Annex 2 - FIVS Good Fining Practice Guidelines for Wine[9]

Fining involves the addition of adsorptive or reactive material in order to reduce or eliminate the presence of certain less desirable wine components. Fining agents are added in order to modify a wine's clarity, colour, texture or flavour or in order to ensure a wine remains in a particular stable state for a given period of time. Fining materials serve no ongoing purpose in the finished product and indeed are designed to be entirely removed from the treated wine as part of the fining process.

The effectiveness of a given fining agent depends on the agent, its method of preparation and addition, the levels of addition, together with characteristics of the wine such as pH, metal content, temperature, presence of CO2 and prior wine treatments.

In addition to the steps outlined below for good fining practices, winemakers should give attention to maintaining traceability throughout the wine production process by recording the batch from which each sample of fining material is drawn, and to obtaining documented evidence from suppliers of the fining agents used, in keeping with the normal requirements of traceability.

1. Fining agents should be free from undesirable taints and must conform to all applicable regulations. They should be stored in a cool, dry environment in sealed containers, or in other recommended storage conditions.

2. It is recommended that laboratory scale trial runs be conducted prior to treatment of wine in the cellar.

3. The laboratory trial runs should also duplicate as far as possible the treatment to be conducted in the cellar, giving attention to the batch of fining agent to be used, the method of its preparation and addition to the wine, and the temperature of the laboratory sample with respect to that of the bulk wine to be fined. Hydration protocols for protein fining agents should be consistent between laboratory and cellar.

4. A minimal volume of distilled, de-ionised or other suitably pure water should be used in order to dissolve or disperse the fining agent without overly diluting the wine (applicable regulations must be observed).

5. The quantity of fining agent used should always be the smallest amount needed to achieve the desired result as stipulated by winemaker sensory and/or analytical evaluation, and in no case should the amount used exceed any applicable regulatory limits.

6. Thorough and adequate mixing of the fining agent into the juice or wine should be ensured, and sufficient time should be allowed for the material to react prior to immediate racking and/or subsequent filtration.

7. Industry recognized best practice filtration methods (including passing the wine through a fine powder filtration process and/or pre-bottling filtration through a 0.65 µm or smaller filter, or performing treatments of equivalent effect) should be used to remove insoluble protein fining agents. Where the treated wine is simply racked off the lees remaining from the fining treatment, or where a less rigorous filtration or other technique for removal of the lees is applied, and it is desirable to confirm the absence

[9] FIVS is a worldwide organization for all sectors of the alcohol beverage industry, including wine, beer, and spirits. Its members include producers, distributors, importers, exporters, and trade associations. FIVS is a non-governmental organization (NGO) that gathers and disseminates information related to activities of interest to its members and advocates consensus positions to international organizations. Founded in July 1951, FIVS has its headquarters in Paris, France.

of detectable residual fining agent, a laboratory test should be conducted to confirm this at some stage prior to bottling.

March 7, 2007

Annex 3. Historical and empirical evidence concerning the risks associated with consumption of fined wines by allergic individuals.

The literature is almost completely lacking reports of genuine allergic reactions following the ingestion of wine. A comprehensive literature search identifies only a few case reports of severe adverse reactions to wine ingestion largely anecdotally attributed to biogenic amines such as histamine, salicylates or sulphites, and an alcoholic fermentation wine yeast, *Saccharomyces cerevisiae* (Clayton or Busse 1980, Littlewood et al. 1988, Clayton and Busse, 1989, Alibrandi et al. 1990, Kortekangas-Savolainen et al. 1994, Vally et al., 1999 and 2000, Kanny et al., 2001, Borghesan et al., 2004), in addition to grape proteins (Pastorello et al. 2003, Borghesan et al. 2004, Kalogeromitros et al. 2005). Concerning Vally et al. (1999 and 2000), however, there was not a significant and independent association between adverse reactions to wine and IgE-mediated allergies to eggs, fish or milk in the Asthma Foundations of Australia survey, which were asked as separate questions (personal communication with Dr Hassan Vally, PhD MAppEpid, on 31 January 2005), while Borghesan et al. (2004) suggest grape protein as the probable allergen given that the individual did not have a history of egg, fish or milk allergies but did have a history of IgE-mediated adverse reactions to red and white grapes. While IgE-mediated adverse reactions to grape proteins have been described in the literature these are, however, extremely uncommon.

The question of a reaction due to fining agents has not, however, been specifically considered in the literature and there is no published literature available on the concentration of these processing aids in the finished wine. If, however, the dose of a proteinacous processing aid used in winemaking ranges between 1–50 mg/L (Ribéreau-Gayon et al. 1998) and is followed by further fining or clarification, it is likely that only ng–µg/L of a processing aid would reside in the finished wine. This level is 100–1000-fold less than the doses eliciting a reaction in previously conducted clinical trials (Hourihane et al. 1997b, Sicherer et al. 2000, Hourihane 2001). The 'gold standard' or definitive test for determining whether a patient is allergic to a particular product is a double-blind placebo-controlled food challenge (DBPCFC) (Bock et al. 1988).

There is also accumulating evidence to suggest that the majority of allergic individuals can tolerate small amounts of allergy-causing protein, although the threshold amount or dose varies among individuals and also among sources of the same protein/allergen (Hourihane 2001, Hefle and Taylor 2002, Taylor et al. 2002). For example, for sulfur dioxide, usually the threshold dose is considered to be 10 mg/L in sensitive individuals, which reflects existing Australian and international legislation (Vally and Thompson 2001). It has been clinically demonstrated, however, that sulfur dioxide will generally only elicit an adverse reaction in sulphite-sensitive asthmatics, which comprise approximately 1.7% of all asthmatics. Steroid-dependent asthmatics are most at risk of an adverse reaction (Vally and Thompson 2001). In a challenge study to determine a peanut protein threshold in sensitive individuals, the lowest dose to elicit a mild, non-threatening adverse reaction was observed to be 2 mg, although 50% of subjects could tolerate up to 50 mg (Hourihane et al. 1997b).

From a review of DBPCFC undertaken over the past 30 years in milk allergic adults, the maximum dose of milk powder/casein at which was tolerated was 14.1 g of milk powder or *ca.* 3 g of casein (Bernstein et al. 1982). Other subjects could only tolerate a doses of 105 mg milk powder (*ca.* 90 mg casein) up to 50 g milk powder (*ca.* 1.5 g casein) (Olalde et al 1989, Pastorello et al. 1989, Norgaard et al. 1992, Lam et al. 2008).

In an extensive food challenge study to determine an egg and milk protein threshold in 267 and 117 sensitive individuals, respectively, while some subjects (11 and 25%, respectively) reacted to doses of 100 mg, the majority of sensitive individuals could tolerate this dose (Sicherer et al. 2000, Hourihane et al. 2001), which would contain approximately 3 g casein and approximately 5.51 mg ovalbumin. Indeed it has been suggested that the threshold dose eliciting an adverse reaction in 1 in 1 million subjects with egg allergy is 0.002 mg or 2 µg and 1 in 100 patients is 3.4 mg (Bindslev-Jensen et al. 2002).

Furthermore, no purported allergic reaction to the use of egg, fish or milk as a proteinaceous processing aids in winemaking has been recorded in the database of The Australian Wine Research Institute (AWRI) in the past 20 years. Approximately 250 information requests are recorded annually, and includes a record of all potential adverse effects reported to the AWRI's Health and Regulatory Information Manager from March 1991 to March 2011 by wine consumers and by wine companies on behalf of wine consumers. Similarly, The Alfred Hospital

allergy specialists have not encountered any patients with allergic reactions attributable to a proteinaceous processing aid consumed in wine (personal communication with Professor Robyn O'Hehir, FRACP PhD).

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These observations are further supported by date submitted by the Liquor Control Board of Ontario (LCBO) to the United States Alcohol and Tobacco Tax and Trade Bureau (TTB) in response to its Notice of Proposed Rulemaking No. 62 71 FR 42329 – July 26, 2006:

December 19, 2006

Mr. John Manfreda
Administrator
Alcohol and Tobacco Tax and Trade Bureau
U.S. Treasury
650 Massachusetts Avenue, NW
Washington, DC 20226

Dear Mr. Manfreda,

Re: Comments in Response to Notice No. 62 71 FR 42329 – July 26, 2006

We appreciate the opportunity to comment on the proposed regulations on “Major Food Allergen Labeling for Wines, Distilled Spirits and Malt Beverages”.

As the importer of record of beverage alcohol in the province of Ontario, we are concerned that the proposed regulations could mislead the consumer and will not provide the consumer with adequate information as to the correct identity and quality of the products.

The proposed labeling requirement for allergens is mandated of the fact that processing aids are used and designed to be absent from the final product, and if used and removed according to good manufacturing practice, the final concentration of these substances in the wine, if present at all, is likely to be extremely low due to the removal of precipitates through the clarification process.

There is no published literature available on the concentration of these proteinaceous fining agents in the finished wine; however, there are commercially available assays to measure their concentration in foods – ELISA and PCR. Unfortunately the lower level of sensitivity of both of these assays is generally at the mg/L

level, which is approximately 100-fold higher than the likely level of processing aid residue in wine when GMP is adopted.

Furthermore, there is no reliable scientific data on the human threshold limits to sensitivity of these potential allergens, other than the study published by J. M. Rolland, et. al., *Nutrition* 22 (2006), 882-885 from Monash University, Melbourne, Australia.

The justification for your proposed regulations relies heavily on anecdotal evidence of adverse allergic reactions. In this respect, we believe that we can provide you with substantial, objective information from our consumer complaint database regarding whether wine that we import poses an allergen risk.

The LCBO is a provincial government enterprise reporting to the Minister of Infrastructure Renewal. It is one of the world's largest retailers of beverage alcohol, importing products from over sixty countries world wide with a retail network of more than 800 stores in the province of Ontario, Canada. Net sales in 2005/06 were at $3.68 billion CDN which represented 51.2% of the Ontario beverage market share. Total volume sales for the same year were 388,733,000 litres of which 14% represented spirits, 29% wine, 49% beer and 8% ready to drink beverages. During this same period, more than $240 million of revenue was due to USA beverage alcohol sales, of which approximately 46% was from wine.

On a given year the LCBO retails either through its stores or through private stock/direct delivery/virtual offer programs more than 12,000 brands of beverage alcohol products of which approximately 75% represents wines, 10% spirits and the balance beer and ready-to-drink products. One of the primary reasons of this amazing selection of products is the demographics of our consumer base, which represents a multicultural society of more than 100 nationalities.

The LCBO is committed to retailing products of good quality, authentic and free of any contaminants, and as such all products listed by the LCBO are stringently evaluated for taste and appearance and chemically tested by its state-of-the-art Quality Assurance testing facilities.

Quality Assurance is also responsible for monitoring and investigating all customer complaints.

LCBO classifies customer complaints into two categories; complaints of a general nature and complaints requiring investigation. Complaints of a general nature are open bottles returned to an LCBO retail outlet for reasons of off taste, off odour, off colour, foreign matter or other, e.g., faulty package. The customer is issued a refund for their purchase and the complaint information is keyed into our Point of Sale (POS) system. Complaint data is transmitted nightly to our corporate mainframe and reconciled on a weekly basis. Statistical reports comparing the ratio of total complaints received, by Stock Keeping Unit (SKU), to the actual sales are generated and reviewed to identify possible product quality problems.

Complaints requiring investigation are complaints of alleged illness, personal injury or property damage. Retail staff notifies Quality Assurance immediately upon receipt of the complaint and arrangements are made to have the customer's sample forwarded for investigation. The steps taken to investigate the complaint are dependent on the nature of the complaint and the condition of the sample. Sensory evaluation, laboratory and packaging testing may be conducted. The customer is provided with a written report at the conclusion of the complaint.

In reviewing our Customer Complaint data base year-to-date since the year 2000, we have recorded 486,535 customer complaints. Of the total number of complaints, 1,344 (0.28%) were investigated by QA, of which 337 (0.07%) were of an alleged illness related nature.

One (1) complaint was specifically identified as an allergic reaction confirmed by a physician at a hospital emergency. The product consumed was a liquor type (Amaro Feltsina Ramazzotte). This product contains a mixture of several herbs, including "chinarinde", a source of quinine.

The possible side effects of quinine are well documented. The symptoms described by this customer, swelling of the lips & face and hives, are the classic symptoms of an allergic reaction to quinine.

Considering our total volume sales, the demographics of our customer base and the large selection of products we retail, we can postulate that the lack of any substantiated adverse allergic reactions to wine products in the

last approximately six years, provides strong evidence that legally permitted additives and processing aids for wine-making, present virtually no risk of severe adverse reaction such as anaphylaxis.

As a consequence of the lack of data available on the residual of processing aids in wine and the inability to accurately and sensitively measure the residual at present as well as the lack of data on harm (human threshold limits to sensitivity), such regulations would be technically of no additional value to consumers and practically impossible to enforce at any level.

In order to avoid unnecessary expenses at all levels, we would suggest a delay in the implementation of such legislation until all of the above concerns are reasonably addressed.

Thank you for allowing us to submit our comments and we appreciate the granting of the extension on the comment period.

We would be happy to respond to any questions you may have as related to our comments.

Sincerely yours,

George Soleas, M.Sc., Ph.D., MCIC

Vice President, Quality Assurance

c.c. Mr. Bob Peter, President & Chief Operating Officer, LCBO
Mr. Bob Downey, Senior VP, Sales & Marketing, LCBO
Mr. John Salminen, Chief, Chemical Health Hazard Assessment Division, Health Canada
Ms. Carla Barry, National Manager, Fair Labelling Practices Program, CFIA

Mr. Dan Paszkowski, President, Canadian Vintners Association

Annex 4. Summary of scientific data documenting the risks associated with consumption of fined wines by allergic individuals

Research groups in Australia, France and Germany all undertook a complementary double-blind placebo-controlled clinical study to determine if egg/fish/milk-allergic consumers elicited a positive reaction on consumption of a wine made with any of these particular proteinaceous processing aids. The groups include the:

- Department of Asthma, Immunology and Respiratory Medicine, The Alfred Hospital (Victoria, Australia) and The Australian Wine Research Institute (South Australia, Australia)
- Technical University of Munich, Clinic of Dermatology and Allergology Biederstein and the University of Hamburg, Department of Chemistry, Institute of Food Chemistry (Germany)

Food related allergies affect 1–2% of the adult population as allergies to egg and milk observed in 6–8% of infants and children usually resolve by four years of age. This low adult prevalence of egg and milk allergies is reflected in the small number of subjects able to be recruited for the study in Australia, France and Germany. In total, only 26 Australian and 23 French/German allergic subjects could be recruited for the studies. This small size shows or suggests that the size of the potential problem is small. In particular, only one milk-allergic subject was recruited in Australia and only five egg-allergic subjects. In all countries, the diagnosis of IgE-mediated food allergy was confirmed by a clinical allergist based on a history of adverse reactions and anaphylaxis and corresponding demonstration of specific IgE to allergens of fish, egg and/or milk using, for example, the immunoCAP fluoroenzyme system and/or by skin-prick testing (wheal ≥4 mm in diameter).

No life-threatening adverse reactions such as asthma (constriction of bronchioles), laryngeal edema (swelling of the throat) and anaphylactic shock (blood pressure decrease, cardiac arrhythmia and multiple organ failure) were experienced by any of the subjects on consumption of protein fined-wine. Subjective, mild clinical symptoms were recorded by a small number of subjects. For example, in Australia, the one milk allergic subject gave a subjective 'lump or tickle in the throat' response to a milk-fined wine, one of the five egg allergic subjects had transient reduced lung function (22% and 11%, respectively, reduced FEV_1) which resolved immediately to both the egg-fined and the unfined control wine. Clinical assessment suggested that this subject had unstable asthma triggered by the spirometric manoeuvre, resulting in non-specific airway reactivity. No adverse reactions to casein-fined wine were observed in the six German milk-allergic subjects.

In Germany only one of the eight egg-allergic subjects had a skin condition adverse reaction to a French egg-fined wine, which resolved on treatment. Also, two egg-allergic subjects had a subjective adverse reactions – one 'laryngeal/pharyngeal discomfit' to an egg-fined wine although a subsequent skin prick test was negative and one oropharyngeal pruritis (itching) which was subsequently shown to contain residual egg white. In addition, one French egg allergic patient had a subjective reaction to a French egg-fined wine.

In the Australian clinical study, the subjects were challenged with 100 mL (one Australian standard drink) on two occasions, separated by at least 7 days; a fined wine and an unfined control wine. The subjects were then monitored for 2 h post challenge in the hospital and then by daily diary for a further 6 days for adverse reactions.

Similar to the Australian clinical study, in the French and German clinical studies, the subjects were challenged with protein-fined and unfined control wines on two occasions, separated by at least 2 days. On each occasion, however, successive doses from 1 drop to a total of 300 mL (three Australian standard drinks) for men and 200 mL (two Australian standard drinks) for women were administered in four steps at 30 min intervals. The challenge ceased immediately if any subjects experienced an adverse reaction. The subjects were then monitored for 2 h post

challenge in the hospital/research department, and then by daily diary for a further 2 days for adverse reactions. Subjects also underwent skin prick tests to casein and egg white and to the protein-fined and unfined control wines. One German egg allergic subject initially had an anaphylactic-related adverse reaction to the skin prick test with egg protein but on subsequent retesting with a German egg-fined wine, however, had no adverse reaction. Only one French egg allergic subject had a positive skin prick test with egg protein but on subsequent retesting with a French egg-fined wine, however, had no adverse reaction.

In summary, none of the 49 Australian and French/German subjects had a clinically significant or life-threatening adverse reaction to a protein-fined wine -- only one of 49 subjects had a mild skin condition adverse reaction. There is accumulating evidence to suggest that the majority of allergic individuals can tolerate small amounts of allergy-causing protein, although the threshold amount or dose varies among individuals and also among sources of the same protein/allergen (Hourihane 2001, Hefle and Taylor 2002, Taylor et al. 2002). In a challenge study to determine an egg and milk protein threshold in sensitive individuals, while some subjects (11 and 25%, respectively) reacted to doses of 100 mg, the majority of sensitive individuals could tolerate this dose (Sicherer et al. 2000, Hourihane et al. 2001). A recent literature review suggests that the threshold dose eliciting an adverse reaction in 1 in 1 million subjects with egg allergy was 0.002 mg or 2 µg and 1 in 100 patients was 3.4 mg (Bindslev-Jensen et al. 2002).

The highest amount of residual egg white protein in a German wine, which was actually fined with 5-times the amount of egg white recommended by the manufacturer, was only 0.02 mg/L. No residual milk protein was found in any of the Australia, French and German wines analysed.

Relevant references by the Australian, French and German research groups are:

Kirschner S, Belloni B, Kugler C, Ring J, Brockow K. Allergenicity of wine containing processing aids: a double-blind, placebo-controlled food challenge. J Investig Allergol Clin Immunol. 2009; 19(3):210-7.

Lifrani A, Dos Santos J, Dubarry M, Rautureau M, Blachier F, Tome D. Development of animal models and sandwich-ELISA tests to detect the allergenicity and antigenicity of fining agent residues in wines. J Agric Food Chem. 2009; 57(2):525-34.

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Sabine Hildebrandt, Hartmut D. Kratzin, Raphaël Schaller, Rodolphe Fritsché, Hans Steinhart, and Angelika Paschke : In Vitro Determination of the Allergenic Potential of Technologically Altered Hen's Egg J. Agric. Food Chem., 2008, 56 (5), 1727-1733.

Annex 5. Summary of data indicating that residual protein is negligible using routine and readily available test methods in commercial wines fined according to internationally agreed best practices.

A systematic review of the scientific literature supports that the known thresholds for adverse reactions to egg white are approximately 1 to 2 mg and for milk protein (such as casein) are approximately 100 µg. Accordingly it has been suggested, that to guarantee the safety of 95% of allergic consumers, on the basis of 100 g of food (100 mL wine), the detection limits of any analytical methods should be equal to or exceed a sensitivity of 10 mg/L for egg white and 1 mg/L for milk proteins. In addition, considering consumption of 1 L of wine on a heavy drinking occasion, the quantity of total protein ingested would be approximately 1 mg. Most likely, however, the maximum ingestion of wine in short period of time would be limited to 500 mL corresponding to 0.5 mg of proteins.

Research groups in Australia and Germany have all undertaken complementary analytical and clinical research programs in order to determine the allergenic potential of protein fined-wine. The groups are:

- Monash University (Victoria, Australia) and The Australian Wine Research Institute (South Australia, Australia)
- Research Institute Geisenheim, Section of Enology and Wine Technology and the University of Hamburg, Department of Chemistry, Institute of Food Chemistry (Germany)

For example, each research group developed an analytical method such as a specific and sensitive ELISA to determine if there were residuals of the allergenic processing aids remaining in the final wine product. The wines analysed were either commercially available or made specifically for the studies with differing additions of processing aid. The German analytical and clinical studies were broadly based on the initial Australian study.

No residual processing aid was found in any of the 153 Australian wines analysed, however, a small amount of residual egg and milk processing aid was found in a small percentage (6 % and 1 %, respectively) of the 400 French and 56 German wines. Specifically, residual protein (approximately 0.02 mg/L or 20 µg/L) was found in one egg-white fined wine which had been fined with 5-times the recommended dosage and in seven wines treated with 25 or 50 g lysozyme; 50 g is twice the recommended dosage (Weber et al. 2007). Of the 9% of French wines that were organic, that is, where the wines were not filtered after fining, 13.5 % contained residual casein or egg white protein compared with only 5.5 % of the non-organic wines.

The commercially-available Australian wines were all made according to Good Winemaking Practice, that is, were fined and then filtered. The German wines were made like their commercially-available equivalents but had specific amounts of casein, dried egg white or lysozyme added at a dosage within the manufacturer's recommendation or up to five-times higher than recommended or twice for lysozyme. The wines were then further fined with bentonite and then filtered. The French wines were also commercially-available.

The lower limits of detection in the Australian-developed ELISA specific for the casein and ovalbumin proteins were 8 and 1 µg/L, respectively (Rolland et al. 2008). The lower limits of detection in the German-developed ELISA specific for the both casein and egg white proteins was 400 µg/L and the lower limit of detection for lysozyme was 5 µg/L.

These results suggest that adhering to a specific amount of addition for casein and egg white, followed by further fining with bentonite which absorbs positively charged proteins, and filtration are important for removing residual protein from wine. Alternatively or in addition, the wine tannins form cross links with protein leading to protein precipitation, such that precipitated proteins are readily removed by filtration.

In a subsequent but as yet unpublished study of German white wines treated with different fining agents and processes including casein and ovalbumin/hen's egg white were investigated by indirect ELISA. Analytical techniques such as sensitive indirect ELISA and immunoblotting methods are considered to be unequivocal measure of potentially allergenic protein residues.

No residues of casein and ovalbumin were detectable in the wines treated with common concentrations of these substances and by good manufacturing practice (GMP). Double doses of ovalbumin in the fining process, however, led to detectable residues of ovalbumin in the wine. The limit of detection of the analyses is 70 µg/L (70 ppb or 0.7 ppm) for casein and 2 µg/L (2 ppb or 0.002 ppm) for ovalbumin. These detection limits are much less than the proposed clinical threshold levels of the BfR paper (Statement No. 002/2010 des BfRof 29. July 2009) given at 100 ppm to 10 ppm allergenic food and 10 ppm to 1 ppm allergenic protein, respectively. The fining agents in this study were used at maximum doses according to legislation and at double the maximum doses as a worst case scenario: casein 40/80g/hL and hen's egg white 110/220g/hL. The fining agents remained 24 h in the wine before being racked. The wine then passed through pasteurization and filtering processes. In addition, different commercially-available Australian white wines labeled with "May contain" milk and/or egg or without labeling of allergens were also investigated by the indirect ELISA. No residues of casein and ovalbumin were detectable in the commercially-available white wines.

These results mean that the proteinaceous wine fining agents casein and egg white used according to GMP in winemaking guarantee that there will only be residues of casein and ovalbumin below 0.07 and 0.002 mg/L (ppm), respectively, in the final wine product. Hence they are not likely to trigger adverse reactions in milk or egg allergic individuals, respectively, which comprise approximately 1% or less of the adult population.

Relevant references from the Australian and German research groups are:

Rolland JM, Apostolou E, de Leon MP, Stockley CS, O'Hehir RE. Specific and sensitive enzyme-linked immunosorbent assays for analysis of residual allergenic food proteins in commercial bottled wine fined with egg white, milk, and nongrape-derived tannins. J Agric Food Chem. 2008; 56(2):349-54.

Weber P, Steinhart H, Paschke A. Investigation of the allergenic potential of wines fined with various proteinogenic fining agents by ELISA. J Agric Food Chem. 2007; 55(8):3127-33.

Weber, P., Kratzin, H., Brockow, K., Ring, J. Steinhart, H., Paschke, A. Lysozyme in wine: A risk evaluation for consumers allergic to hen's egg, Molecular Nutrition and Food Research 2009, (53): 1469-1477.

Weber, P., Steinhart, H., Paschke, A. Determination of the bovine food allergen casein in white wines by quantitative indirect ELISA, SDS-PAGE, Western-Blot and Immunostaining, Journal of Agricultural and Food Chemistry 2009; (57):8399-8405.

Weber, P., Steinhart, H., Paschke, A. Competitive indirect ELISA for the determination of parvalbumins from fish species in food gelatins and isinglass with PARV-19 anti parvalbumin antibodies, Journal of Agricultural and Food Chemistry 20090; (57): 11328-11334.

Weber, P., Steinhart, H., Paschke, A. Characterization, antigenicity and detection of fish gelatine and isinglass used as processing aids in wines, Food Additives and Contaminants 2010; (3): 273-282.

Weber, P., Steinhart, H., Paschke, A. Allergic potential of fining agent residues in German wines related to their dosage and an ordinary bentonite treatment, Agro Food industry High Tech 2007: 18 (5), 22-24.

Annex 6. The ability of the fining procedures elaborated in internationally agreed best practices to consistently achieve the desired outcomes.

A search for data is ongoing at present and will (if available) be appended in due course.