



EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA); Scientific Opinion related to a notification from the International Organisation of Vine and Wine (OIV) on ovalbumin/egg white to be used in the manufacture of wine as clarification processing aids pursuant to Article 6, paragraph 11 of Directive 2000/13/EC – for permanent exemption from labelling

EFSA Publication

Link to article, DOI:
[10.2903/j.efsa.2011.2385](https://doi.org/10.2903/j.efsa.2011.2385)

Publication date:
2011

Document Version
Publisher's PDF, also known as Version of record

[Link back to DTU Orbit](#)

Citation (APA):
EFSA Publication (2011). *EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA); Scientific Opinion related to a notification from the International Organisation of Vine and Wine (OIV) on ovalbumin/egg white to be used in the manufacture of wine as clarification processing aids pursuant to Article 6, paragraph 11 of Directive 2000/13/EC – for permanent exemption from labelling*. Parma, Italy: European Food Safety Authority. the EFSA Journal, No. 2385 <https://doi.org/10.2903/j.efsa.2011.2385>

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SCIENTIFIC OPINION

Scientific Opinion related to a notification from the International Organisation of Vine and Wine (OIV) on ovalbumin/egg white to be used in the manufacture of wine as clarification processing aids pursuant to Article 6, paragraph 11 of Directive 2000/13/EC – for permanent exemption from labelling¹

EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA)^{2, 3}

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ABSTRACT

Following a request from the European Commission, the Panel on Dietetic Products, Nutrition and Allergies (NDA) was asked to deliver a scientific opinion related to a notification from the International Organisation of Vine and Wine on ovalbumin/egg white to be used in the manufacture of wine as clarification processing aids pursuant to Article 6, paragraph 11 of Directive 2000/13/EC – for permanent exemption from labelling. In earlier assessments, the Panel concluded that wines fined with egg products and albumin (egg white) may trigger adverse reactions in susceptible individuals under the proposed conditions of use based on the limited information provided on the characterisation of the fining agents, on the limitations of the methods used to quantify ovalbumin and other egg allergens in wine, and on the clinical studies presented, which reported allergic reactions in egg-allergic individuals following double-blind placebo controlled food challenges with wines fined with ovalbumin/egg white. This application refers to new analytical methods developed for the detection of egg allergens in the fining agent and the detection of ovalbumin in wine. There were no changes in the wine manufacturing process and no new clinical studies were provided. Taking into account the information provided on the characterisation of the fining agents regarding their content of egg proteins other than ovalbumin, the lack of standardisation of the wine manufacturing process, and that no new clinical data have been provided in the present application, the Panel concludes that wines fined with ovalbumin/egg white products may trigger adverse reactions in susceptible individuals under the proposed conditions of use. © European Food Safety Authority, 2011

KEY WORD

Wine, fining agents, ovalbumin, egg white, food allergy.

¹ On request from the European Commission, Question No EFSA-Q-2010-01024, adopted on 15 September 2011.

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³ Acknowledgement: The Panel wishes to thank the members of the Working Group on Allergy: Pagona Lagiou, Martinus Løvik, Rosangela Marchelli, Martin Stern, Stephan Strobel, Hendrik van Loveren, Jean Michel Wal for the preparatory work on this scientific opinion.

Suggested citation: EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA); Scientific Opinion related to a notification from the International Organisation of Vine and Wine (OIV) on ovalbumin/egg white to be used in the manufacture of wine as clarification processing aids pursuant to Article 6, paragraph 11 of Directive 2000/13/EC – for permanent exemption from labelling. EFSA Journal 2011;9(10):2385. [13 pp.] doi:10.2903/j.efsa.2011.2385. Available online: www.efsa.europa.eu/efsajournal

SUMMARY

Following a request from the European Commission, the Panel on Dietetic Products, Nutrition and Allergies (NDA) was asked to deliver a scientific opinion related to a notification from the International Organisation of Vine and Wine on ovalbumin/egg white to be used in the manufacture of wine as clarification processing aids pursuant to Article 6, paragraph 11 of Directive 2000/13/EC – for permanent exemption from labelling.

Taking into account the numerous and well documented reports of allergic individuals reacting to egg albumin (ovalbumin, egg white) and that the prevalence of such allergy to egg proteins has been reported to be around 0.3 % in adults, it is appropriate for the Panel to assess the likelihood of adverse reactions in allergic individuals consuming products where ovalbumin/egg white has been added during the manufacturing process.

Two applications submitted for permanent exemption from labelling were the basis for earlier EFSA assessments of egg products and albumin (egg white) used as fining agents in wine. The Panel concluded that wines fined with egg products and albumin (egg white) may trigger adverse reactions in susceptible individuals under the conditions of use stated by the applicants. The conclusion was based on the limited information provided on the characterisation of the fining agents, on the limitations of the methods used to quantify egg allergens other than ovalbumin in wine, and on clinical studies which reported allergic reactions in egg-allergic individuals following double-blind placebo controlled food challenges (DBPCFC) with wines fined with ovalbumin/egg white.

This application contains new information and data mainly with regard to the analytical methods developed for the detection of egg allergens in the fining agent and the detection of ovalbumin in wine. There were no changes in the wine manufacturing process and no new clinical studies were provided.

Hen's egg white albumin is in the form of either fresh or frozen egg white, or as freeze-dried powder of egg white or purified ovalbumin. Two types of preparation exist: one without added lysozyme, the other with lysozyme as a preservative. Lysozyme as an antimicrobial stabilising agent/additive is not dealt with in the present application. The commercial preparations of ovalbumin/egg white fining agents sold as "ovalbumin" may contain other proteinaceous materials in addition to ovalbumin. Egg allergens other than ovalbumin were found in every "ovalbumin" fining product tested. The Panel notes that "ovalbumin/egg white" fining agents contain other egg proteins in addition to ovalbumin, and that no quantitative information about their content in the fining agents has been provided.

Egg white albumin is particularly used for the clarification of red wines rich in tannins. The Panel notes that the recommended amounts of egg albumin/egg white to be added to wine as a fining agent, as well as the manufacturing process and steps recommended to decrease residual allergens in wine, are very variable, and that according to the applicant no changes in the manufacturing process have been introduced since the last application.

Two reports on the detection of ovalbumin in wine were provided. The Panel notes that in the new analytical studies provided by the applicant, ovalbumin was detected in trace amounts (0.2 mg/L) in one (out of four) experimental white wines fined at the excess dosage, and that the results from one study which showed no detectable amounts of ovalbumin in any of the altogether 77 commercial wines tested cannot be extrapolated to a random sample of commercial wines due to the varying use of non-mandatory manufacturing practices (microfiltration, bentonite treatment) applied to most of the wines, which may have affected proteinaceous fining agent residues in the wine. The Panel also notes that these studies do not exclude the presence in wine of other egg allergens contained in egg white, for which the ability (and limit of detection) of the analytical methods used was not reported, and that the difficulties in measuring residual fining agents in (particularly red) wine with the ELISAs

(because of interference with the wine matrix) may affect the reliability of the data provided. The Panel considers that although the sensitivity and performance of the methods used for the detection of ovalbumin in wine have improved relative to the previous applications, the studies provided by the applicant do not provide sufficient information about the levels of residual ovalbumin or other egg white allergens which may be found in commercial wines fined with ovalbumin/egg white under the proposed conditions of use.

Taking into account the information provided on the characterisation of the fining agents regarding their content of egg proteins other than ovalbumin, the lack of standardisation of the wine manufacturing process, and that no new clinical data have been provided in the present application, the Panel considers that the improvement on the methods used for the detection of ovalbumin in wine, and the new analytical studies provided, are insufficient to change its previous conclusion about the likelihood of adverse reactions triggered in susceptible individuals by the consumption of wines fined with ovalbumin/egg white products.

The Panel concludes that wines fined with ovalbumin/egg white products may trigger adverse reactions in susceptible individuals under the conditions of use proposed by the applicant.

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BACKGROUND AS PROVIDED BY THE EUROPEAN COMMISSION

Article 6, paragraph 11 of Directive 2000/13/EC⁴ establishes the cases and conditions for amending Annex IIIa to that Directive, which includes a list of food ingredients or substances known as likely to trigger allergic reactions in sensitive individuals. It also sets up a procedure for exempting from labelling, under certain conditions, derivatives of these ingredients.

Pursuant to the procedure referred to above, a list of ingredients or substances derived from ingredients listed in Annex IIIa has been adopted by the Commission and is included in the Annex to Commission Directive 2007/68/EC⁵ of 27 November 2007, amending Annex IIIa to Directive 2000/13/EC of the European Parliament and of the Council as regards certain food ingredients. Applicants who are seeking the exclusion of a given product from Annex IIIa have to submit a request, completed with the results of relevant scientific studies.

Therefore, in the context of the permanent labelling exemption procedure, the European Food Safety Authority is asked to provide scientific opinions on submissions in accordance with the present terms of reference.

TERMS OF REFERENCE AS PROVIDED BY THE EUROPEAN COMMISSION

In accordance with Article 29(1)(a) of Regulation (EC) N° 178/2002, the European Commission requests the European Food Safety Authority to evaluate the scientific data submitted by the International Organisation of Vine and Wine (OIV) in the framework of the procedure laid down in Article 6, paragraph 11 of Directive 2000/13/EC. On the basis of that evaluation, EFSA is requested to issue an opinion on the information provided, and in particular to consider the likelihood of adverse reactions triggered in susceptible individuals by the consumption of the following ingredients/substances used under the conditions specified by the applicant: ovalbumin/egg white to be used in the manufacture of wine as clarification processing aids.

⁴ Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs. OJ L 109, 6.5.2000, p. 29–42.

⁵ Commission Directive 2007/68/EC of 27 November 2007 amending Annex IIIa to Directive 2000/13/EC of the European Parliament and of the Council as regards certain food ingredients. OJ L 310, 28.11.2007, p. 11–14.

ASSESSMENT

Taking into account the numerous and well documented reports of allergic individuals reacting to egg albumin (ovalbumin, egg white), and that the prevalence of such allergy to egg proteins has been reported to be around 0.3 % in adults (EFSA, 2004; Sampson, 2004; Sicherer and Sampson, 2010; Vierk et al., 2007), it is appropriate for the Panel to assess the likelihood of adverse reactions in allergic individuals consuming products where ovalbumin/egg white has been added during the manufacturing process.

Applications submitted by Deutscher Weinbauverband (DWV) and the Office National Interprofessionnel des Fruits, des Légumes, des Vins et de l'Horticulture (VINIFLHOR), and by the Winemakers' Federation of Australia (WFA) and the Australian Wine Research Institute (AWRI), to the European Commission pursuant to Article 6, Paragraph 11 of Directive 2000/13/EC as amended by Directive 2003/89/EC⁶ for permanent exemption from labelling were the basis for earlier assessments of egg products and albumin (egg white) used as fining agents in wine by the Panel on Dietetic Products, Nutrition and Allergies (NDA) (EFSA, 2007a, 2007b). The Panel concluded that wines fined with egg products and albumin (egg white) may trigger adverse reactions in susceptible individuals under the conditions of use stated by the applicants. The conclusion was based on the limited information provided on the characterisation of the fining agents, on the limitations of the methods used to quantify egg allergens other than ovalbumin in wine, and on clinical studies which reported allergic reactions in egg-allergic individuals following double-blind placebo controlled food challenges (DBPCFC) with wines fined with ovalbumin/egg white.

The present opinion is based on a dossier from the International Organisation of Vine and Wine (OIV), with an application for permanent exemption. This application contains new information and data mainly with regard to the analytical methods developed for the detection of egg allergens in the fining agent and the detection of ovalbumin in wine. There were no changes in the wine manufacturing process and no new clinical studies were provided.

1. Characterisation of the fining agent

In previous submissions (EFSA, 2007a, 2007b), egg white albumin used as a fining agent was characterised by the applicant using SDS-PAGE electrophoresis and, in parallel with Coomassie blue staining, different protein bands were revealed by western blotting using sera from egg allergic patients and from non-allergic controls. Sera from allergic patients were incompletely characterised. Tests were also performed using sera of rabbits or mice immunized with egg white albumin. Purified rabbit IgG recognized a total of 14 bands; not all could be visualised by Coomassie blue staining. The bands identified, i.e. at 40-55, 11-17 and 80 kDa, could correspond to ovalbumin, lysozyme and ovotransferrins respectively, but there were also bands not corresponding to identifiable components of egg proteins. Human IgE recognized three bands at around 31, 67 and 80 kDa. These observations implied that bands not corresponding to pure egg white proteins may be related to degradation or aggregation products, or other immunoreactive proteins in the starting materials. Thus, the egg white albumin which was used as a fining agent may contain residual amounts of other proteins.

In the present application, product sheets of fining agents sold as "egg albumin", as well as SDS-PAGE and immunoblotting studies, have been submitted. The product sheets generally give no information with regard to protein purity. The applicant claims that the commercial preparations of the fining agent used in the manufacturing of wine comply with the International Oenology Codex standards.

⁶ Directive 2003/89/EC of the European Parliament and of the Council of 10 November 2003 amending Directive 2000/13/EC as regards indication of the ingredients present in foodstuffs. OJ L 308, 25.11.2003, p. 15–18.

Hen's egg white albumin is in the form of either fresh or frozen egg white, or as freeze-dried powder of egg white or purified ovalbumin. Powdered egg white can be dissolved in a potassium carbonate solution. Two types of preparation exist: one without added lysozyme, the other with lysozyme as a preservative. Lysozyme as an antimicrobial stabilising agent/additive is not dealt with in the present application. Further, the commercial preparations of the fining agent may contain other added organic (e.g. gelatine, milk proteins) and non-organic (e.g. E558 bentonite or similar clay, E1202 polyvinylpyrrolidone (PVPP)) materials.

In the present application, different oenological fining agents based on ovalbumin/egg white were investigated. In a study (Paschke et al., 2011, unpublished) using SDS-PAGE and immunoblot as described in Weber et al. (2007), all of the eight "ovalbumin" products tested were found to contain other egg proteins (e.g. conalbumin and lysozyme) in addition to ovalbumin as indicated on the product label. Similarly, in a study performed by Restani (2011, unpublished), six commercial "ovalbumin" fining agents were analysed by SDS-immunoblotting, demonstrating the presence of conalbumin, lysozyme, ovomucoid and ovotransferrin in addition to ovalbumin. Weber et al. (2007) point out the importance of using antibodies capable of detecting all egg allergens in addition to ovalbumin in the assessment of residual egg allergens in fined wines. The Panel agrees with this statement and notes that the application does not provide quantification of egg white proteins other than ovalbumin finally present in the commercial fining preparations sold as "egg albumin", and therefore possibly also in the wine.

The Panel notes that "ovalbumin/egg white" fining agents contain other egg proteins in addition to ovalbumin, and that no quantitative information about their content in the fining agents has been provided.

2. Conditions of use

Egg white albumin is particularly used for the clarification of red wines rich in tannins.

In previous submissions (EFSA, 2007a, 2007b), applicants described the winemaking process for different wines (red, white and rosé wines) that are produced in different European regions. The winemaking process could vary according to the region, vintage and colour of the wine, as well as the skill of the winemaker, and fining is decided upon after evaluation of each particular batch of wine. However, wine manufacturing was claimed to follow the professional guidance documents, namely *Référentiel des pratiques oenologiques intégrées* (ITV, 2001) and *Guide des bonnes pratiques hygiéniques filière vins* (ONIVINS, 2000). The amount of egg white albumin added to wine usually ranges from 50 to 150 mg/L according to DWV and VINIFLHOR, and from 20 to 100 mg/L according to WFA and AWRI.

In the present application, the criteria and guidance documents set by the OIV regarding materials and procedures to be used in wine production were provided. Egg white is the source of albumin commonly used in red winemaking. Specifications for albumin in egg were set in 2000 (OIV, 2000). The applicant states that the amount of egg albumin added to red wine usually ranges from 30 to 150 mg/L (Ribéreau-Gayon et al., 2000). According to the applicant, for fresh egg whites doses range from 1-5 (or 2-8) egg whites per barrel of 225 L (one egg white corresponds to about 30 mg/L ovalbumin). Dried egg white powder or frozen egg whites can also be used at 100 to 200 mg/L (or 50-150 mg/L), and dried albumin can be used at 30-70 mg/L.

The principle of fining is to mechanically remove insoluble and colloidal substances from wine. This aims to clarify and stabilize the wine, and to preserve and improve its flavour and taste. In the acidic environment of must and wine, albumin adsorbs phenolic compounds, particularly tannins, that may affect wine colour and taste, leading to precipitates which are removed by sedimentation, filtration and/or centrifugation. In the previous submissions (EFSA, 2007a, 2007b), applicants stated that

filtration may not be applied to certain wines. A wide variety of filtration materials and methods that may be used are described in the application. The applicant declared that no changes have been introduced in the manufacturing process with respect to previous applications.

The Panel notes that the recommended amounts of ovalbumin/egg white to be added to wine as a fining agent, as well as the manufacturing process and steps recommended to decrease residual allergens in wine, are very variable, and that according to the applicant no changes in the manufacturing process have been introduced since the last application.

3. Analysis of residual allergens in wine

In a previous submission (EFSA, 2007a), egg white albumin (about 0.200 mg/L) was detected in one wine fined with 200 mg/L egg white albumin. Six industrial test wines, provided by Union des Oenologues de France, and fined with egg white albumin (30 mg/L) were analyzed with a sandwich ELISA. The applicant stated that these wines were elaborated under industrial conditions but that the concentration of fining agent used was below the usual (i.e. 50-150 mg/L). Three out of the six industrial test wines were found to be positive for ovalbumin. Six wines experimentally fined with albumin (100 mg/L) were also found to contain detectable amounts of the fining agent. Finally, four hundred commercial French wines were analysed for the presence of egg white albumin using a sandwich ELISA. Fourteen wines were positive for albumin (>0.001 mg/L), most of which were red wines (12 out of 14, Lifrani et al., 2009).

Two reports were provided in the present application, one from Germany (Paschke et al., 2011, unpublished) and one from Italy (Restani, 2011, unpublished).

In the German report (Paschke et al., 2011, unpublished), one experimental German white wine was fined with two doses of ovalbumin/hen's egg white (1100 and 2200 mg/L) and thereafter passed through a flash pasteurization and/or filtering processes. Three different pasteurization and filtering processes were assessed: flash-pasteurization (72°C for 2 seconds), fine and sterile filtration, using pad filters ("Seitz" K-100 and EK, respectively), and filtration with diatomaceous earth (Kieselgur). The Panel notes that the dose of ovalbumin used was about 10-20 times higher than the doses normally used. Ovalbumin residues were investigated by an indirect ELISA with a claimed limit of detection (LOD) of 0.002 mg/L for ovalbumin. The limit of quantification (LOQ) was 0.003 mg/L and the working range 0.005-0.1 mg/L. No more information on the ELISA and the antibodies used was provided. No ovalbumin residues were detected in the wine fined with the lower dose of ovalbumin/hen's egg white. However, use of the higher dose resulted in detectable ovalbumin residues (1.49, 2.87 and 2.94 mg/L when filtration with diatomaceous earth, fine filtration, and flash pasteurization together with fine filtration were applied post fining, respectively). The Panel notes that the lowest dose of egg allergen capable of triggering an allergic reaction in a sensitive individual is highly uncertain, but that the lowest triggering dose of egg has been described to be as low as 0.13 mg for sensitive individuals (FDA, 2006). Further, the Panel notes the lack of information on the specificity of the antibody used (i.e. detection of other egg allergens apart from ovalbumin), the very large effect of doubling the dose of egg white used for fining on the residual amounts of ovalbumin in wine, and that only one experimental wine was used in this study.

Further, in the German report, 16 commercially available Australian white wines not allergen labelled (n=5) or labelled with "may contain milk and/or egg" (n=3 for 'egg, milk' or 'egg, milk, fish'; n=8 'milk' or 'milk, fish') (Paschke et al., 2011, unpublished) were examined with the same ELISA as above (LOD=0.002 mg/L). No ovalbumin residues were detected in any of the wines. The Panel notes that no information was provided on how these wines were selected for analysis. The Panel also notes that no information was provided about the manufacturing process (including doses of fining agent used) of these wines. The Panel considers that this study therefore provides information of only very limited value for use in the context of the present application.

Weber et al. (2007) reported on four German white wines experimentally fined with 40 mg/L and 200 mg/L dried egg white (manufacturer's recommended dosage 40-160 mg/L). The wines were treated with lysozyme and bentonite, and cross-flow filtered (0.45 µm pore size). Antibodies were produced in rabbits against dried egg white. Positive results (0.2 mg/L undiluted wine) were observed for one of the wines with an amount equal to the limit of detection (0.02 mg/L, 1:10 dilution). The authors concluded that the consumption of about 1.2 L of egg white-treated wine would probably be necessary to trigger allergic reactions in patients with sensitivity equal to that described in a study by Morisset et al. (2003), but that allergic reactions to wines treated with lysozyme or egg white cannot be excluded. The Panel shares this opinion.

The report of an Italian study (Restani, 2011, unpublished) was also provided. Two experimental and 77 commercially available wines (42 from Italy, 20 from France, 11 from Australia, two from Spain and two from New Zealand), 76 of which were red and one of which was an Italian white wine. Experimental wines were fined with egg white/ovalbumin at doses of 30 and 100 mg/L with or without the use of bentonites, altogether in 16 different variants. Commercially available wines were fined with ovalbumin/egg white preparations at doses ranging from 30-200 mg/L, except for one wine fined with 400 mg/L, one fined with 500 mg/L, one with 660 mg/L, one with 1000 mg/L and five with unspecified doses. Bentonite was used for many of the Italian wines, but not for wines from other countries. Commercial wines were fined with 12 different commercial egg white/ovalbumin fining agents; one product also contained caseinate and one also lysozyme. Samples were filtered or microfiltered, except for two samples that were not filtrated, four were only centrifuged and no specifications were provided for six. Eight commercially available wines and 10 experimental unfined wine preparations were examined as negative controls. The Panel notes that microfiltration and bentonite treatment are not mandatory steps in wine processing as recommended by the applicant (OIV, 2009), and that these treatments may significantly affect the amount of residual fining agents in wine (Weber et al., 2009).

Three different methods were used to detect egg allergen residues in wine samples: ELISA, SDS-PAGE with silver staining (Gromova and Celis, 2006) and immunoblotting. A rabbit anti-total egg white antibody was characterized by, and used for, immunoblotting and ELISA. The antibody recognized the main egg white allergens (ovalbumin, ovotransferrin, ovomucoid, lysozyme). The ELISA, specifically developed for this project, was validated in an inter-laboratory (n=11) collaborative ring trial with 12 spiked or un-spiked samples of three Italian red wines (Restani et al., 2010; Università degli Studi di Milano et al., 2011, unpublished). Recovery in egg white spiked samples in the ELISA ranged between 81.3 % and 120.7 %. LODs for ELISA and immunoblotting were 0.056 mg/L and 0.024 mg/L, respectively. No allergenic residues were detected in any of the samples studied, neither with ELISA nor in the immunoblots. The Panel notes that for both the German and the Italian ELISAs, the ability of the antibodies used to detect egg allergens other than ovalbumin was not reported.

In summary, the Panel notes that, in the new analytical studies provided by the applicant, ovalbumin was detected in trace amounts (0.2 mg/L) in one (out of four) experimental white wines fined at the excess dosage (Weber et al., 2007), and that the results from an Italian study which showed no detectable amounts of ovalbumin in any of the altogether 77 commercial wines tested cannot be extrapolated to a random sample of commercial wines due to the varying use of non-mandatory manufacturing practices (microfiltration, bentonite treatment) applied to most of the wines, which may have affected proteinaceous fining agent residues in the wine. The Panel also notes that these studies do not exclude the presence in wine of other egg allergens contained in egg white, for which the ability (and limit of detection) of the analytical methods used was not reported, and that the difficulties in measuring residual fining agents in (particularly red) wine with the ELISAs (because of interference with the wine matrix) may affect the reliability of the data provided.

The Panel considers that although the sensitivity and performance of the methods used for the detection of ovalbumin in wine have improved relative to the previous applications, the studies

provided by the applicant do not provide sufficient information about the levels of residual ovalbumin or other egg allergens which may be found in commercial wines fined with ovalbumin/egg white under the proposed conditions of use.

4. Estimated level of exposure

The applicant indicates that 11 % of French wines and 2 % of German wines are fined with egg albumin.

In previous applications (EFSA, 2007a, 2007b), the applicants estimated the wine consumption in France to be around 60 L per person per year. In Germany the average consumption of wine was about 23 L per person in 2005. These and other published data on higher wine intakes (Weber et al., 2009) do not reflect the variability between individuals and geographic areas, nor the variations for a given individual over time. The Panel notes that intake on a single occasion may be more relevant regarding food allergic reactions than average daily or yearly intake. Further, the Panel notes that no generally applicable threshold levels of intake have been defined for food allergens (EFSA, 2004).

No estimate of exposure to egg white albumin or other egg allergen (e.g. lysozyme) residues through fined wines was provided by the applicant.

5. Evidence of non-allergenicity

5.1. History of non-allergenicity of wines fined with egg products

The applicant provides a general review on food allergens and particularly on egg allergens. Regarding egg products used as processing aids and the products under consideration, reference was made to historical reviews. The applicant states that in the medical literature there is no indication of an allergenic potential of wine that has been fined with egg products, but no justification for this statement is given. The strategy and the sources used for the literature search are not described. The Panel notes that reactions to wine, including allergic reactions, are well documented (Armentia, 2008; Vally and Thompson, 2003). Since consumers and health professionals may be unaware that egg products are used in the winemaking process, allergic reactions to albumin and other egg proteins have generally not been considered following allergic reactions to wine, and therefore underreporting of reactions caused by egg products after ingestion of wines may have occurred.

5.2. Animal studies

No new animal studies were provided. In the 2007 opinion (EFSA, 2007a), clinical reactions were observed in immunized mice after an intraperitoneal (i.p.) challenge with a decanted and filtered ovalbumin-fined wine. The Panel considered that the animal studies confirmed the presence of residual amounts of albumin in fined wines.

5.3. Clinical studies

Clinical studies which were provided in previous applications reported allergic reactions in egg-allergic individuals following double-blind placebo controlled food challenges (DBPCFC) with wines fined with ovalbumin/egg white (EFSA, 2007a, 2007b). No new clinical data are provided with the present application.

CONCLUSIONS

Taking into account the information provided on the characterisation of the fining agents regarding their content of egg proteins other than ovalbumin, the lack of standardisation of the wine manufacturing process, and that no new clinical data have been provided in the present application, the Panel considers that the improvement on the methods used for the detection of ovalbumin in wine, and the new analytical studies provided, are insufficient to change its previous conclusion about the likelihood of adverse reactions triggered in susceptible individuals by the consumption of wines fined with ovalbumin/egg white products.

The Panel concludes that wines fined with ovalbumin/egg white products may trigger adverse reactions in susceptible individuals under the conditions of use proposed by the applicant.

DOCUMENTATION PROVIDED TO EFSA

Dossier submitted by the International Organisation of Vine and Wine (OIV) to the European Commission pursuant to Article 6, paragraph 11 of Directive 2000/13/EC as amended by Directive 2003/89/EC, in March 2011.

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GLOSSARY / ABBREVIATIONS

AWRI	Australian Wine Research Institute
DBPCFC	Double-Blind Placebo Controlled Food Challenges
DWV	Deutscher Weinbauverband
ELISA	Enzyme-Linked Immunosorbent Assay
LOD	Limit of detection
LOQ	Limit of quantification
OIV	International Organisation of Vine and Wine
PVPP	Polyvinylpyrrolidone
SDS-PAGE	Sodium Dodecyl Sulfate Polyacrylamide Gel Electrophoresis
VINIFLHOR	Office National Interprofessionel des Fruits, des Légumes, des Vins et de l'Horticulture
WFA	Winemakers' Federation of Australia