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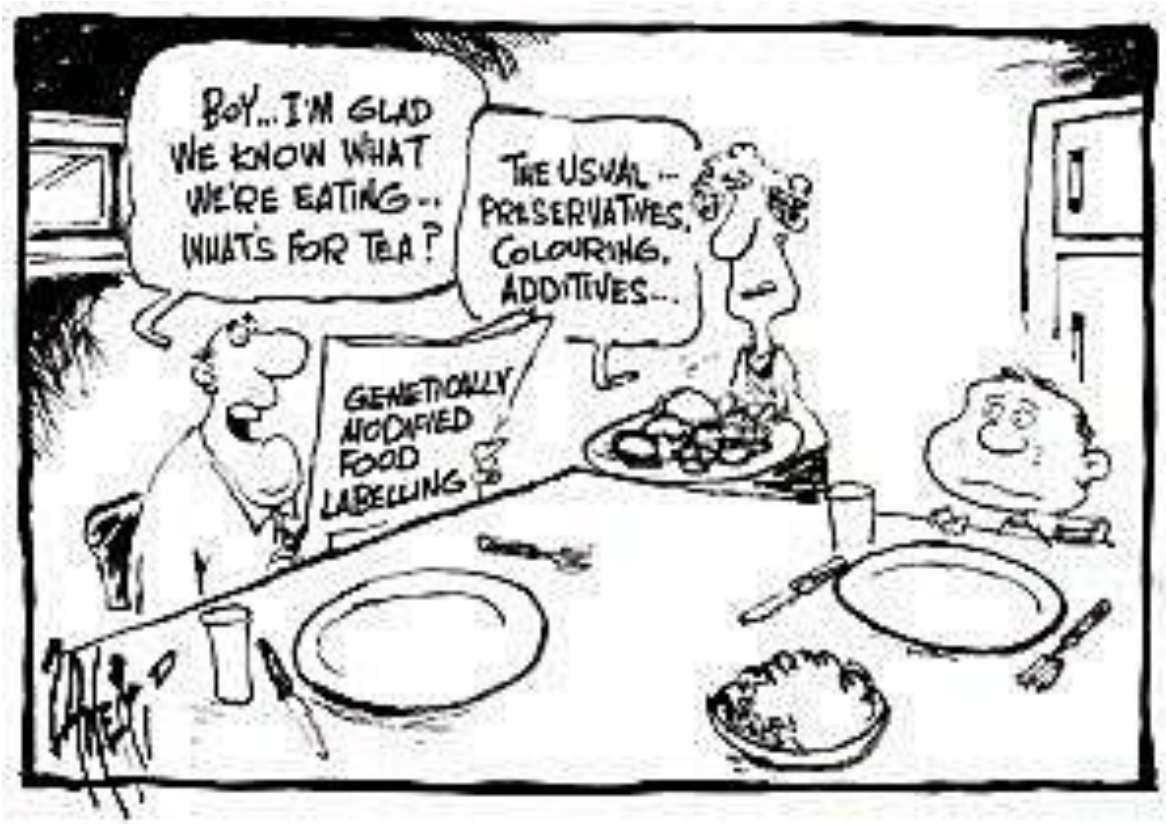
Where is allergen labelling at



Creina Stockley

Health and Regulatory Information Manager

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Background

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19% of the Australia population considers that they have a food allergy or intolerance.

In reality, however, egg, fish and milk and their products are associated with allergic reactions in only 4-8% of children and 1-2% of adults.

egg accounts for approx. 1.3% of the total allergic population

fish accounts for approx. 1.6% of the total allergic population

milk accounts for approx. 1 % of the total allergic population

Mechanism of an IgE-mediated allergic reaction

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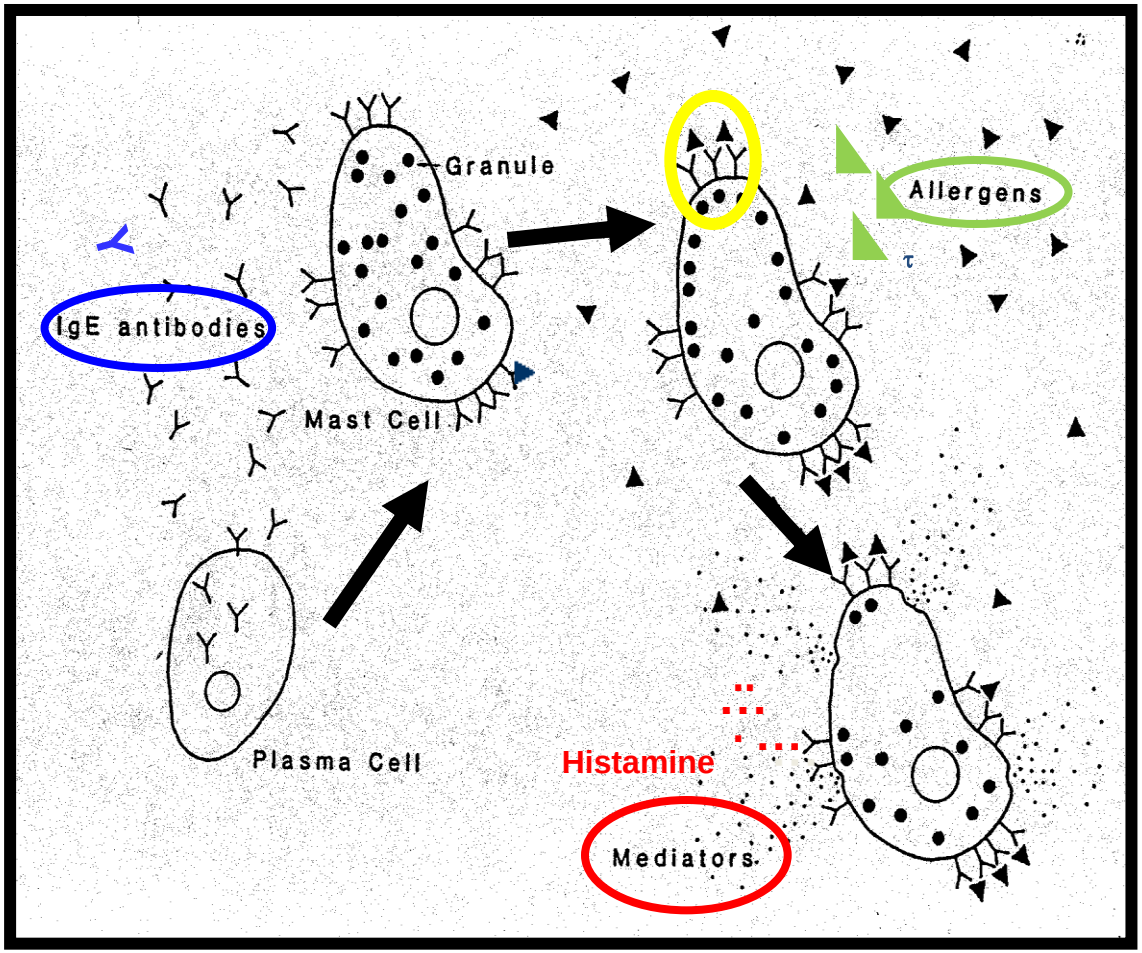

(Taylor 1992)

Symptoms of an IgE-mediated allergic response

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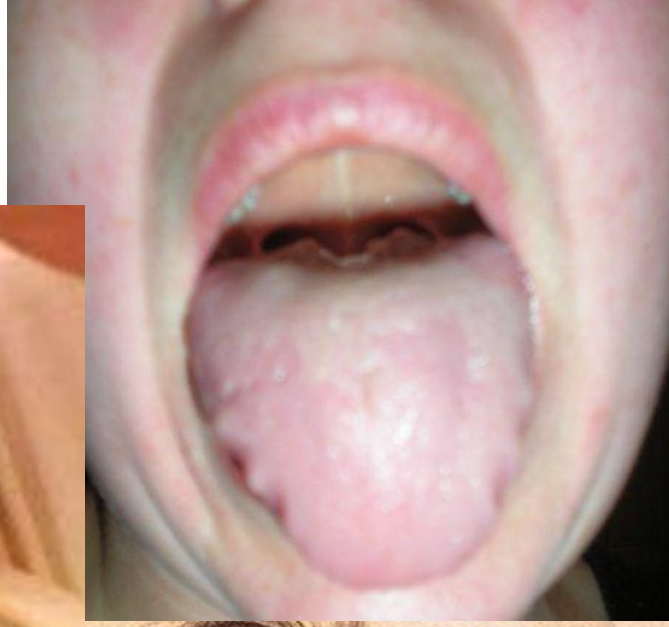
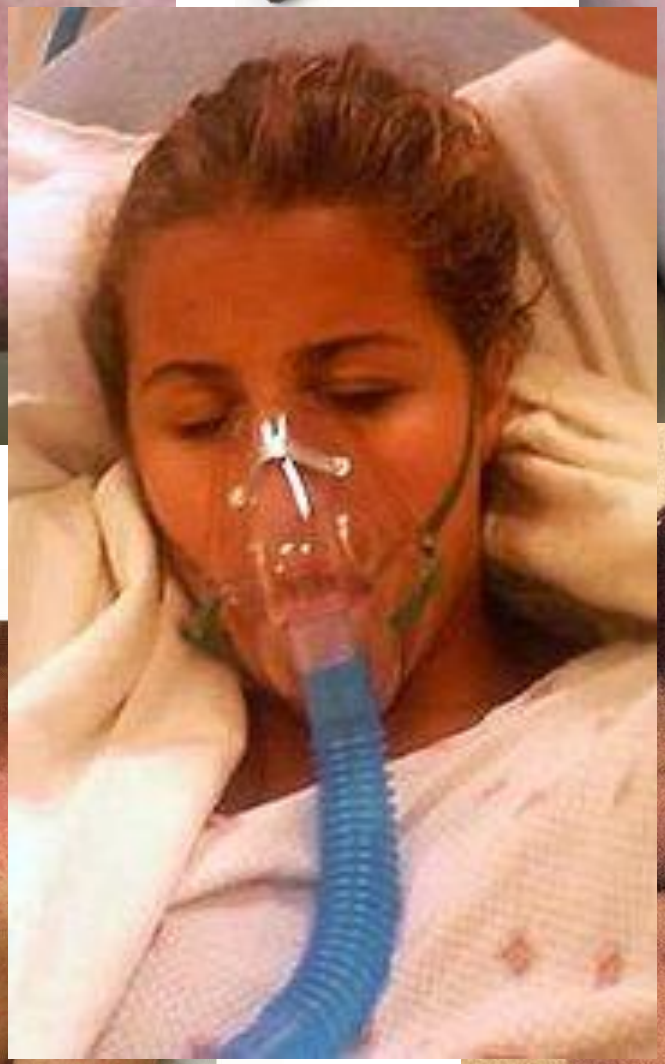
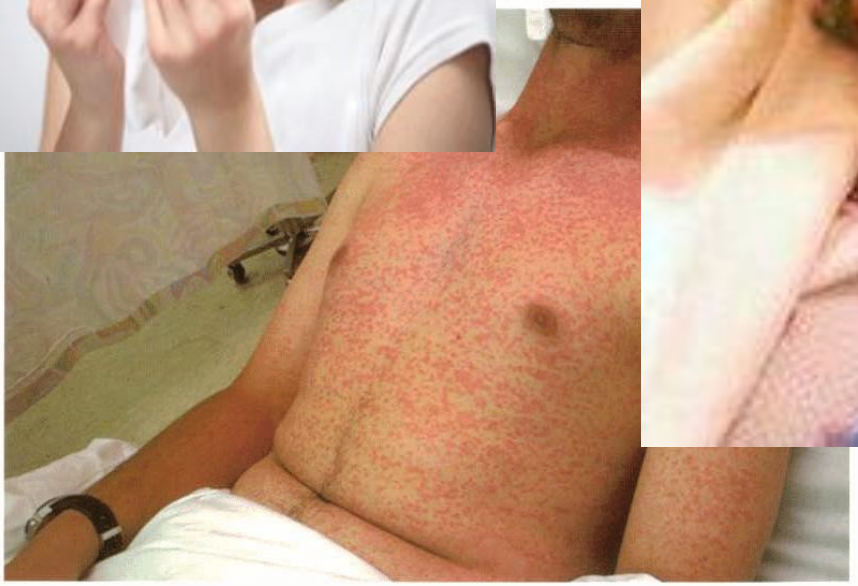
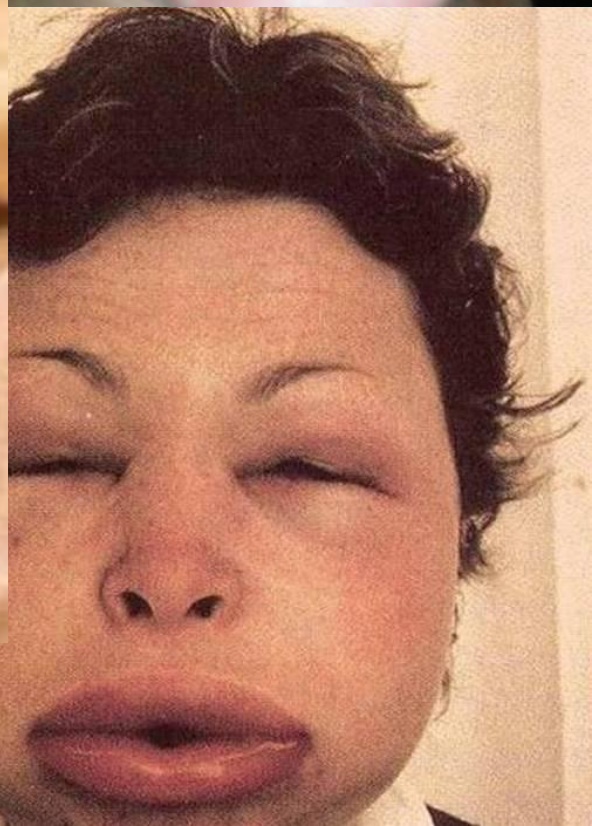
Symptom	Manifestation
Respiratory	runny nose difficulty breathing constriction of throat
Cutaneous	hives rash swelling
Gastrointestinal	stomach cramps diarrhoea nausea vomiting
Systemic	cardiac/respiratory shock









Lower limit?

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What the exact lower limit is for the concentration below which the risk of an adverse allergenic reaction is minimal is difficult to identify due to the numerous factors involved including

individual sensitivity, age, gender, genetic constitution, dietary habits and, as yet, largely unidentified environmental factors.

HOWEVER

in children

known thresholds for allergic reactions to raw egg white are <u>1-2 mg</u>
= 0.24 mg dried egg white + 0.007 mg lysozyme

and

known thresholds for allergic reactions to milk protein are <u>105-130 mg</u>
= 90 mg casein.

Studies suggest that to guarantee the safety of 95% of food allergic consumers, and on the basis of consumption of 100 g/100 mL of a food,

the detection limit of analytical methods should be <10 mg/L for egg

and

the detection limit of analytical methods should be <30 mg/L for milk proteins

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Resolution OIV-OENO 427-2010

Criteria for the methods of quantification of potentially allergenic residues of fining agent proteins in wine

as written into EU law:

LOD ≤

0.25 mg/L for both egg and milk residues

OIV
Organisation Internationale de la Vigne et du Vin

Consumption of wine

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When 1 L of wine is consumed,
the quantity of total protein ingested = approx. 1 mg.

From the NHMRC Australian alcohol guidelines
of 2 standard drinks/day for men and for women,
when 0.2 L of wine is consumed,
the quantity of total protein ingested = approx. 0.2 mg.

Australian Government
National Health and Medical Research Council

N H M R C

Australian allergen labelling requirements

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introduced December 2002 for egg, fish and milk and their products

but

in May 2009 was repealed for fish and fish products

FOOD STANDARDS Australia New Zealand

Te Mana Kounga Kai – Ahitereiria me Aotearoa

Standard 1.2.3
Mandatory warning labels and advisory statements and declaration

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Clause 4. Mandatory declaration of certain substances in food

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

(a) an ingredient; or

(b) an ingredient of a compound ingredient; or

(c) a food additive or component of a food additive; or

(d) a processing aid or component of a processing aid.

(2) Any substance required to be declared by subclause (1) must be —

(a) declared on the label on a package of the food;…

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Te Mana Kounga Kai – Ahitereiria me Aotearoa

Table to Clause 4

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

The Australian wine industry must label for:

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casein

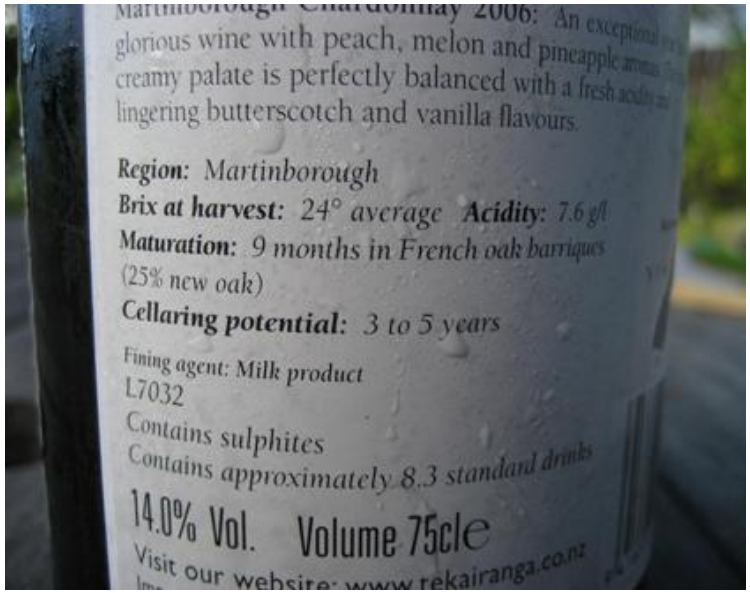
potassium caseinate

egg white

lysozyme

isinglass

milk and evaporated milk



Appropriate wording

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Following discussions with government and industry, the Winemakers Federation of Australia advised that the following options are deemed accurate in all jurisdictions:

Produced with milk

Contains/produced with milk product

Produced with milk. Traces may remain

Produced with milk products. Traces may remain.

The use of the word “may” is acceptable in these contexts (that is, in conjunction with the words “produced with”) as it is difficult to determine the presence of some substances at low levels and available detection methodologies produce inconsistent results.

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

HARDYS

BRUT RESERVE

Established in 1853, Hardys is one of Australia's most respected and highly awarded winemakers. Hardys Brut Reserve is a stylish Australian sparkling wine ideal for any occasion. Carefully blended and matured to produce a wine with rich fruit, soft full flavours and complex, yeasty characters. Serve chilled.

BOTTLED BY THOMAS HARDY & SONS

CONTAINS SULPHITES AND MILK PRODUCTS

APPROX 7.1 STANDARD DRINKS

WARNING: THIS WINE IS STORED UNDER PRESSURE. TAKE CARE NOT TO SCRATCH OR DAMAGE THIS BOTTLE AS IT MAY CAUSE IT TO EXPLODE. TO OPEN, POINT BOTTLE AWAY FROM SELF & OTHERS. DO NOT USE A CORKSCREW TO REMOVE THE CORK.

Canadian allergen labelling requirements

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2011 Health Canada
Amendments to the Food Allergen Labelling Regulations

Health Canada

Question 20.

Will the new regulations require food allergens to be declared for beer, wine, and other standardized alcoholic beverages that do not need a list of ingredients?

Answer 20.

Although standardized alcoholic beverages such as beer and wine are not required to have a list of ingredients, if they contain a food allergen then the food allergen will need to be declared somewhere on the label in the statement called "Allergy and Intolerance Information - Contains:".

However, milk, egg and fish will not have to be declared when fining agents derived from these allergens are used in the manufacture of standardized alcoholic beverages or bourbon whiskey. Health Canada may reconsider this position should there be available scientific evidence suggesting that residues of these fining agents remain in the final beverage products that could cause a health risk to susceptible individuals.

Health Canada

2011 Amendments to the Food Allergen Labelling Regulations in Canada Gazette, Part II (CGII)

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...enhanced labelling requirements are only triggered under the Regulations if the protein, or a modified protein, including any protein fraction, from an allergen source is present in the finished product....

... the use of allergen-derived fining agents does not normally result in any appreciable amount of protein from food allergens remaining in the wine, particularly when usual manufacturing practices such as filtration steps are employed.

...the use of food allergen-derived fining agents in wine production, following good manufacturing practices, is thus not expected to produce wine that would pose a risk to egg, milk, or fish allergic consumers.

Health Canada

2011 Amendments to the Food Allergen Labelling Regulations in Canada Gazette, Part II (CGII)

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From 4 August 2012,
new allergen labelling regulations should continue to apply to all non-vintage wines and vintage wines with a year date of 2012 and later, but that vintage wines with a year date of 2011 and earlier can continue to be sold with their original labels.

If the wine contains sulfites in an amount > 10 ppm, this must be declared on the label either in the ingredients or "contains ..." statement.

If the wine contains any significant amount of residual protein from the use of egg (ovalbumin), fish (isinglass) or milk (casein) products as a fining agent, then this must be declared on the label either in the ingredients or "contains ..." statement.

Health Canada

LOD < 1.0 mg/L egg and milk residues in wine

"Elisa-based methods with detection limits in the range of 1–5 mg/L should be sufficient to prove the absence of these fining agents".

EU allergen labelling requirements

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Directive 2003/89/EC

an amendment to the general food labeling *Directive 2000/13/EC*

EUROPEAN COMMISSION

List of potential allergenic ingredients to be labelled (Annex IIIa to Directive 2003/89/EC)

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Cereals containing gluten and products thereof

Crustaceans and products thereof

Eggs and products thereof

Fish and products thereof

Peanuts and products thereof

Soybeans and products thereof

Milk and dairy products (including lactose)

Nuts and nut products

Celery and products thereof

Mustard and products thereof

Sesame seeds and products thereof

Sulphur dioxide and sulphites at concentrations of more than 10 mg/kg or 10 mg/L expressed as SO2 (mandatory labeling since 2005)

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List of allergen derivatives that are temporarily exempted (Annex to Directive 2005/26/EC)

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Ingredients	Products thereof provisionally excluded
Gluten-containing cereals	Wheat based glucose syrups including dextrose
	Wheat based maltodextrins
	Glucose syrups based on barley
	Cereals used in distillates for spirits
Eggs	Lysozyme (produced from egg) used in wine
	Albumin (produced from egg) used as fining agent in wine and cider
Fish	Fish gelatin used as carrier for vitamins or carotenoid preparations and flavors
	Fish gelatin or isinglass used as fining agent in beer, cider and wine
Soybean	Fully refined soybean oil and fat
	Natural mixed tocopherols (E306), natural D-alpha tocopherol, natural D-alpha tocopherol acetate, natural D-alpha tocopherol succinate from soybean sources
	Vegetable oils derived phytosterols and phytosterol esters from soybean sources
	Plant stanol ester produced from vegetable oil sterols from soybean sources
Milk	Whey used in distillates for spirits
	Lactitol
	Milk (casein) products used in fining agents in cider and wines
Nuts	Nuts used in distillates for spirits
	Nuts (almonds, walnuts) used (as flavor) in spirits
Celery	Celery leaf and seed oil
	Celery seed oleoresin
Mustard	Mustard oil
	Mustard seed oil
	Mustard seed oleoresin

EUROPEAN COMMISSION

Timelines and exemptions...

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In 2003,

EFSA established list of food ingredients likely to cause adverse reactions in susceptible individuals to be indicated on the label of foodstuffs.

A temporary exemption was granted to enable scientific studies to be conducted and evaluated until 25/11/2007.

In 2007,

EFSA granted isinglass a permanent exemption from mandatory allergen labeling for beer and wine.

A temporary exemption extended until 31/12/2010.

A temporary exemption extended until 30/06/2012.

EUROPEAN COMMISSION

In March 2012,
OIV LOD and LOQ for egg and milk protein in wine are established at
≤ 0.25 and ≤ 0.5

In May 2012,
EFSA and EC accepts OIV LOD and LOQ limits for egg and milk protein in wine in legislation

EUROPEAN COMMISSION

Current EU

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Wines labelled with a vintage of 2011 and earlier are exempt from the mandatory labelling requirement.

Wine labelled with the 2012 vintage will only be exempt if labelled before 30 June 2012.

If milk or egg products have been used and the wine has not tested negative for the presence of residues using a technique with a detection limit of 0.25 mg/L, then the presence of allergens must be indicated.

The allergen indications may be in one of the following formats:

‘contains sulphites’ – ‘contains sulphur dioxide’

‘contains milk’ – ‘contains milk products’ – ‘contains milk casein’ – or ‘contains milk protein’

‘contains egg’ – ‘contains egg products’ – ‘contains egg protein’ – ‘contains egg lysozyme’ – or ‘contains egg albumin’

EUROPEAN COMMISSION

Current EU

If multiple allergens are present there is no need to repeat the word “contains”.
The phrase ‘contains sulphites, milk, egg’ would suffice if all 3 allergens were present.

Each EU member state has stipulated the language in which the allergen indication must be displayed. If wine is to be marketed in all 27 EU countries, it may be necessary to label in a minimum of 15 languages.

Pictorial logos may also be used in conjunction with the textual declaration.
The logos may be used in colour, gray scale or black and white.
No minimum print height has been advised.

US allergen labelling requirements

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The FDA adopted the *Food Allergen Labelling and Consumer Protection Act* in 2004

Notice No. 62 – Major Food Allergen Labelling for Wines, Distilled Spirits and Malt Beverages (Fed. Reg. Vol 71. n° 143 – July 26 2006)

Alcohol and Tobacco Tax and Trade Bureau, Treasury 27 CFR Parts 4, 5, and 7

Interim regulations

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Under interim regulations,

producers, bottlers, and importers of wines, distilled spirits, and malt beverages

may *voluntarily* declare the presence of milk, eggs, fish, crustacean shellfish, tree nuts, wheat, peanuts, and soybeans, as well as ingredients that contain protein derived from these foods, in their products.

The interim regulations set forth rules that are mandatory for how industry members must undertake such labeling, should they choose to do so.

PART 4—LABELING AND ADVERTISING OF WINE
§ 4.32a Voluntary disclosure of major food allergens

AWRI
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(b) *Voluntary labeling standards*

The major food allergens declaration must consist of the word "Contains" followed by a colon and the name of the food source from which each major food allergen is derived, for example, "Contains: egg".

c) *Cross reference*

For mandatory labeling requirements applicable to wines containing FD&C Yellow No. 5 and sulfites, see § § 4.32(c) and (e).

…we are proposing the adoption of mandatory labeling standards

…the voluntary standards adopted in this interim rule document will remain in place until they are replaced by final action on the proposal for mandatory standards.

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Results of
Australian, German, French and Italian research projects

Australian study - analytical

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153 commercially-available Australian wines

LOD = 8 ug/L casein, 1 ug/L ovalbumin, 1 mg/L isinglass

No casein protein

was detected in wines fined with up to 17 mg/L casein or 5550 mg/L milk

No ovalbumin protein

was detected in wines fined with up to 1000 mg/L egg white

No isinglass protein (collagen or parvalbumin)

was detected in wines fined with up to 4.5 mg/L isinglass

German + French study - analytical

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56 German and 400 French commercially-available wines

LOD = 400 ug/L casein, 400 ug/L ovalbumin, 5 ug/L lysozyme

Casein protein

was detected in 1% wines fined with casein or milk

Ovalbumin protein

was detected in 6% wines fined with egg white or lysozyme

These wines were over-fined and/or un-filtered

0.02 mg/L was found in 1 German egg-white fined wine which had been fined with 5x the recommended dosage.

9% of French wines that were organic (unfiltered after fining) where 13.5% contained residual protein compared with only 5.5% of the non-organic wines.

German study - analytical

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German specifically-made wines
(maximum + double-maximum permitted doses of casein and egg white, racked, pasteurised and filtered with assorted agents)
+
24 commercially-available Australians

LOD = 70 ug/L casein, 2 ug/L ovalbumin

No casein protein detected in fined wines

No ovalbumin protein detected in fined wines

Traces of ovalbumin were found in wines fined with double-maximum doses of egg white

Italian study - analytical

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The Australian Wine Research Institute

63 commercially-available Italian wines + 24 commercially-available Australian wines
16 Italian specifically-made wines

LOD = 280 ug/L casein and ovalbumin

No casein or ovalbumin protein was detected in any fined wine

Double-Blind Placebo-Controlled Wine Challenge

Visit 1 → **≥ 7 days** → **Visit 2**

Baseline observations

- Blood pressure, pulse, respiratory rate
- Assessment of uvula, tongue and lips
- Assessment for any urticaria/angioedema
- Asculation of chest
- Lung function
- Data collection sheet filled in by subject (visual analogue score)

On one visit the subject was bled prior to challenge for laboratory tests

Subjects consumed 100 mL wine over 10 min

On one visit the relevant fined wine was consumed and on the other, the unfined wine.

Follow-up observations over 2 h @ 15 min intervals

- Symptoms
- Visual analogue score
- Physical examination
- Lung function

Australia: 23 specific IgE-allergic regular wine consumers + 25 controls
Germany: 26 specific IgE-allergic regular wine consumers + 26 controls

No subject experienced an IgE-mediated allergic reaction requiring medication treatment

No subject experienced anaphylaxis (laryngeal oedema)

1 egg-allergic subject had an adverse skin reaction to an egg-fined wine
1 egg-allergic subject had a subjective reaction to an egg-fined wine

Overall conclusions

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1.

No clinically significant adverse reaction to DBPC challenge of fined wines that could be attributed to residual food protein processing aids in wine made following GMP.

2.

Normal highly regulated and standardised (GMP) winemaking process presents an extremely low risk of an adverse reaction from relevant food protein allergens used during processing for adult egg or fish allergic consumers

3.

The rarity of IgE-mediated milk allergy in adults prevented a statistical analysis for milk-fined white wines, but this rarity makes potential allergic reactions to milk proteins in wine more a theoretical rather than an actual problem.

Overall conclusions

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Low levels (0.07 and 0.002 mg/L) in Australian wine are unlikely to trigger adverse reactions in milk or egg allergic individuals which comprise approximately 1% or less of the adult population.

Problems identified by EFSA

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- small sample size of IgE allergic subjects, unresolved allergy threshold for wine matrix and variation in validation of IgE allergy;
- an allergic reaction, albeit not life threatening, in several subjects allergic to eggs;
- variable consumption amounts and patterns, that is light, moderate or heavy amounts consumed occasionally, regularly or daily;
- detection of residual allergenic proteins in particular in unfiltered wines;
- uncertainty of, and variability with product integrity and specification; and
- variability in production protocols for wines.

efsa

European Food Safety Authority

Good fining practice guidelines

http://www.oiv.int/oiv/info/enguidesoiv

Good fining practice guidelines steps 1-9

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1. **Fining agents shall 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 as advised by the manufacturers.**

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

3. **The laboratory trial runs should also duplicate, as far as possible, the treatment to be conducted in the winery, 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 winery.**

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

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Good fining practice guidelines steps

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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 recommended typical addition rate.**

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 membrane 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 and bottled without filtration, or where a less rigorous filtration or other technique for removal of the lees is applied, an analysis must always be conducted at some stage prior to bottling.. However, it is recommended to conduct analysis of filtered and unfiltered wines to confirm that no residual fining agent(s) can be detected.**

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Good fining practice guidelines steps

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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 no detectable residue of fining agent remains in the treated wine.**

   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.

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 undetectable 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).**

If the fining guidelines above have been respected, it has been established from scientific studies that no residual fining agents will be detected in the wine.

OIV Organisation Internationale de la Vigne et du Vin