Submission / CEEV
USA ALLERGENS LABELLING

Comment 33

Director, Regulations and Rulings Division
Alcohol and Tobacco Tax and Trade Bureau
Notice n°62
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RE : Notice No. 62 – Major Food Allergen Labelling for Wines, Distilled Spirits and Malt Beverages (Fed. Reg. Vol 71. n° 143 – July 26, 2006)

The Comité Vins (CEEV – Comité Européen des Entreprises Vins) is the professional association representing the European wine industry and commerce. It is made up of 24 national associations representing more than 7000 companies mainly of medium and small size. Jointly these account for more than 90% of annual exports with a value of over 4.5 billion €.

CEEV welcomes the opportunity to present its views regarding the above referenced notice.

I. GENERAL COMMENTS

1. We support the TTB in its determination that full ingredient listing for wines should not be included with its rule making on major food allergen labelling and that a decision on this issue has been deferred.

We do not support any move towards full ingredient listing for wine. This is a complex issue which is the subject of considerable debate at a global level. As a result, we fully concur with trade opinion outside the EU that states that a substantial transformation of the raw materials takes place during the fermentation process in the production of wine, i.e. there is no simple and direct relationship between the initial ingredients and the contents of the finished product. Therefore, full ingredient listing for wines would be largely meaningless to the consumer.

2. CEEV shares the goal of TTB of providing consumers with meaningful and sometimes critical information on allergens through labelling (eg sulphite labelling), but only to the extent that (i) the allergenic risk is clearly established (ii) the allergenic substance for which a risk threshold has been established is indeed present in the final product.

Mandatory allergen labelling without solid scientific evidence would only raise unnecessary concern among the consuming public and possibly negatively impact the consumption of wines. Any regulation on that issue should indeed not contribute to consumer deception.

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3. CEEV would like to stress the importance of preventing different allergen labelling approaches and rules for wines that would erect unnecessary burdens on international trade, given the existence of analogous allergen labelling requirements in other nations.

In that sense it is important to seek for harmonization of wine regulations, including ingredient allergens labelling requirements, between major producing countries/regions in the world. For that reason, CEEV strongly suggests that this issue should also be tackled within the framework of the recently signed Wine agreement between the EU and the USA.

4. TTB's proposal actually requires that the **use** of potentially allergenic materials in winemaking be declared on the label of the finished product. This contrasts with the approach taken elsewhere in the world, where only **presence** of the substances in the finished product triggers a labeling requirement. The TTB proposal actually adopts the precautionary principle whereas all other countries in the world are using an evidence-based approach[1].

The proposed regulations should take into account the approaches, efforts and solutions being adopted in the rest of the world, as well as the state of the science, to bring scientific evidences to this issue.

5.In Europe, the EU Directive 2003/89/EC (the "Allergen Labelling Directive") which came into force on 25 November 2004 amended the Directive 2000/13, so that from 25 November 2005 EU member states were obliged by law to prohibit the sale of products containing any of the 12 listed allergenic ingredients which did not comply with the new labelling rules. However, this Directive provided for the possibility of excluding categories of products that are produced and/or processed in a similar manner.

The European Commission, after receiving notice of several scientific studies and after consultation with the European Food Safety Authority (EFSA), provisionally excluded the labelling in case of eight uses of major food allergens in beverage alcohol products until November 25, 2007[2]. Amongst those eight uses there are the following concerning wine:

-lysozyme (egg);

-albumen (egg white) used as a fining agent;

-fish gelatin or isinglass used as a fining agent;

-milk (casein) products used as fining agents;

This provisional temporary derogation was subject to the completion of scientific research showing that no allergen remained in the final product in a form that could cause an allergic reaction, in order to be confirmed as a permanent exemption.

[1] In 1998 the Codex Alimentarius Commission modified the Codex General Standard on Food Labeling to incorporate a recommendation that the **presence** of potentially allergenic substances in food should be indicated on the label. Member Governments of the Codex Alimentarius have since been working to incorporate these recommendations into their national laws for labeling of foods, usually including alcoholic beverages. The Australian and EU allergen labeling provisions condition disclosure on the **presence** of allergens in the finished product.

[2] European Commission Directive (2005/26/EC).

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6. In the EU, considerable effort is being made through scientific analysis to ascertain whether there is any residual protein at all remaining in the final product after processing in a form that could cause an allergic reaction.

In an unique partnership between several European institutions, under the leadership of the German Wine Grower's Association, the Deutsche Weinakademie, the French VINIFLHOR (Office National Interprofessionnels des Fruits, des Légumes, des Vins et de l'Horticulture) and ITV France (Institut Technique de la Vigne et du Vin), an extensive Franco-German research project has now examined whether fined wines can elicit allergic reactions in allergic individuals.

Both the analytical and clinical aspects of the research were carried out by the Institute of Biochemistry and Food Chemistry of the University of Hamburg, the French Agricultural Institute of Paris-Grignon (Institut National Agronomique de Paris-Grignon), the hospital of the Technical University of Munich and French hospitals in Paris, Besançon, Grenoble and Montpellier. In addition to these highly specific laboratory trials, in a clinical study adults allergic to egg, fish and milk products were tested under the continuous supervision of a physician following the approval of an Ethical Committee.

The risk profile of these test wines – some of them with up to 5 times the standard dose of fining agents – for allergic individuals was examined in a double-blind placebo-controlled food challenge study where the test wines and the respective control wines were given to the same participant.

The clinical results showed that the consumption of wine that was treated with fining agents and subsequently filtered to separate the sediment, did not elicit any allergic reactions – even when the wines had been fined with 5 times the standard dosage of egg, milk and fish protein. After the consumption of a French wine fined with albumin (egg) but unfiltered, only one adverse reaction was observed. This case needs to be investigated further.

Based on their clinical experience, allergy experts confirm that the majority of food allergic individuals can tolerate small amounts of proteins, and therefore, they do not consider fined wines a risk for this particular group of patients. [3].

Based on their objective scientific evaluation of the allergen experts, the German Wine Growers' Association and VINIFHLOR have requested a permanent exemption for the above processing aids derived from proteins. The dossiers with the results of the study have been presented to the EU Commission which has allowed EFSA one year (until 25 November 2007) to examine and evaluate the data.

[3] Actually experts only became aware about this "theoretical" risk to allergic consumers only after the EU Directive (2000/13) was changed to incorporate processing aids derived from allergic substances: until then, there was no literature to show that there might be a risk to consumers. There is a dearth of clinical data regarding allergenic effects from wine fining agents. Unlike other food allergies that have been more widely studied, we surmise that the lack of even anecdotal data on adverse reactions to wine allergens is likely the reason for the lack of study. Wine fining agents such as eggs and milk have been used in wine production for millennia with few, if any, substantiated complaints from allergy sufferers.

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7. TTB should in particular take into account the timing of the European Scientific Panel on Dietetic Products, Nutrition and Allergies' review and determinations for usages of major food allergens in production processes that also are utilized by industry members in the United States, Europe and elsewhere.

To make decisions prior to EFSA's deliberations being finalized will not produce the best results to protect consumers. Ignoring the EU research and decisions could result in the exact same products being labelled as containing allergens in the U.S. and not in the EU[4]. In today's global marketplace, such a result will be misleading and confusing to the very consumers the allergen laws are designed to serve.

So we request TTB should provide for temporary exclusions from allergen labelling for the food allergen usages currently exempted by the EU and allow until at least the end of calendar year 2007 for the filing of appropriate exemptions under the Bureau's labelling schema, followed by reasonable periods of time to render decisions in these exemption petitions and for the implementation of new labelling requirements, if necessary.

This would allow for the completion of the work that currently is being conducted domestically and internationally, and, in terms of labelling, the sound scientific evidence presented therein will be of true benefit to consumers and to the trade.

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II. COMMENTS TO SPECIFIC QUESTIONS SOLICITED BY NPRM

1.- What would be the cost associated with mandatory allergen labelling to the industry, and , ultimately, to the consumer? ;

It is difficult to provide precise estimates on associated costs because of the complexity of blending and the consequent variation in costs experienced by different companies. Wines are often blended together to produce a final product with the desired style and attributes. Where successive final blends of the same product are created, it is possible that base wines that have been treated with different combinations of fining agents will be used.

Even if it is not easy to obtain precise figures, CEEV indeed considers that mandatory allergen labelling would entail major costs for label changes, stocks monitoring products traceability to meet every allergen contingency (milk, eggs, fish) that may result from this situation.

[4] For instance industry members who export their respective wines to the United States should label those products as containing allergens, though those industry members have a temporary exclusion from such labelling in the EU and most likely will obtain a permanent exemption. Conversely, precipitous action could result in the same products being labelled for the U.S. domestic market, with no such requirement for the EU and other markets.

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2.- Does the proposed rule adversely impact small businesses? If so, explain how. If you are a small business and you expect that the proposed rule would have an adverse impact on you, please provide us with specific data on the expected adverse impact.;

Once again, although data collection on real cost impact is really difficult to obtain. mandatory labeling would make the data collection, allergen reporting, label production and tracking a significant economic and logistical problem for large, mid-sized and small wineries, regardless of the size.

Wineries of all sizes would have significant and negative economic and operational impacts from the mandatory allergen labeling requirements as currently proposed by TTB in the NPRM Notice No. 62.

As this is a matter of public health, if mandatory allergen labelling requirements were imposed, we would not consider any exemption for Small and Medium-sized Enterprises (SMEs) on the basis of cost impact. All companies/producers should have an equal treatment while complying with regulations.

3.- Are there ways in which the proposed regulations can be modified to reduce the regulatory burdens and associated cost imposed on the industry?;

The proposed regulations should take into account the approaches, efforts and solutions being adopted, as well as the state of the science, in the rest of the world to bring scientific evidences to this issue.

The list of eight major allergens was initially drawn up by Codex Alimentarius so there is consistency at a global level as to exactly what they are. However, there is a major difference in approach to implementation between the EU and the US. The key difference is that the proposed regulation wishes to adopt the *precautionary principle* whereas the EU is using an evidence-based approach.

In the EU, considerable effort is being made through scientific analysis to ascertain whether there is any residual protein at all remaining in the final product after processing in a form that could cause an allergic reaction.

The relevant researches made in the EU (see point I.6) show that consumption of wine treated with fining agents and subsequently filtered to separate the sediment, did not elicit any allergic reactions – even when the wines had been fined with 5 times the standard dosage of egg, milk and fish protein.

The CEEV understanding is that there is also no evidence to suggest that anyone has ever suffered an allergic reaction to wine produced using a processing aid made from fish, eggs or milk. Because on a balance of probabilities it is highly unlikely that a consumer will suffer an allergic reaction from drinking wines processed with these substances in accordance with regulatory standards, it is hoped that the European Food Safety Authority will decide that it will not be necessary to label for them.

In the light of these considerations, CEEV urges TTB to accept an exemption without having to go through the petition process as stated in the proposed regulation, and in any case to delay the implementation date for the proposal to allow for the completion of the work that is currently being conducted domestically and internationally and whose results are expected to make a compelling case for exemption from labeling for these substances.

4.-The proposed rule allows industry members a great deal of flexibility in the placement of mandatory allergen labelling statements. Does this flexibility reduce the cost of compliance? Would this flexibility interfere with the consumer's ability to locate the allergen declaration? Alternatively, should TTB mandate specific placement, type size, and presentation requirements for these labelling statements in addition to the requirements already applicable to all mandatory information on alcohol beverages labels? For example, should the required allergen disclosure statement be set off by a box? Should the statement of major food allergens be combined with existing required disclosures of FD&C Yellow N° 5, sulfites, and aspartame?;

Any label change impacts adversely on businesses and is a disincentive to those attempting to enter new markets.

Placement of the Statement: Flexibility:

Unlike other food products, Wine is submitted to comprehensive regulations including very specific type size and placement requirements in the labels, that severely limit the expression of mandatory information on a wine label. Label space is finite, and as more mandatory information is required, it eliminates space that a winery might use for additional product information.

We would strongly support the notion of entire flexibility when labelling for allergens: we therefore oppose the idea of locating an allergen expression in a box on a fixed part of the label. Most consumers (98% adults) do not suffer from allergies and are therefore not interested in being told that a product contains allergenic material: it would be an added burden on business if it had to locate an allergen statement in an inappropriate part of the label designed *prima facie* to sell the product in a highly competitive environment. Therefore, we do not support any mandatory specific placement (main or so called "back label"), type size or presentation requirements, as on the contrary such obligations would create an unnecessary obstacle to trade.

5.- Do the proposed rules provide adequate information to consumers about the use of fining or processing agents ? Should processing or fining agents be subject to a different labelling requirement, for example, a "processed with" labelling statement instead of a "contains" labelling statement? Would requiring a distinction between primary ingredients and fining or processing agents be informative the consumer of would it mislead consumers? Would distinct labelling for processing and fining agents allow industry members to impart more specific information about the use of processing and fining aids ?;

We note that TTB has stated that it would welcome the submission of scientific evidence as part of its rule making process ' to show that fining agents are substantially altered during the production process, making it virtually impossible for an adverse reaction to occur '. This gives the EU wine trade some comfort.

Substantial research is being carried out in the EU (see point I.6) and Australia to ascertain whether there actually is any residue of allergenic substances from the processing aid in the final product and if this eventual residue, if any, is in a form that could cause any allergic reaction The acidic and alcoholic wine matrix often results in a change in the structure of materials such as proteins, and in the absence of evidence to the contrary, it is questionable whether there is any residual protein at all in the final product which is in a form that could cause an allergic reaction. As far as we are aware, there have been no validated incidents of allergic reaction to processing aids used in wine: therefore in our view, the precautionary principle approach being taken by the FDA

and TTB on the strength of the assertion by one consumer (Dr Rogers) is hardly a good reason to inflict a major labelling change on a key industry. If the results of the ongoing international research show that on a balance of probability, the risk is negligible, then there should be no requirement to label for allergens.

"Contains" / "Processed with" labelling terms:

In the eventuality of allergens labelling requirements, we nevertheless cannot support the wording "contains" as it would give untrue and misleading information to consumer in the case where no residues of the fining or processing agent can be detected by analysis and would be more appropriate where such residues were present. Any remaining natural sediment in the wine would make a consumer believe that there is "some rests of a fish or an egg in the bottle…"

To avoid deceptive information for consumers, more appropriate wording such as "processed with" should be found where there is no detectable residue in a fined product on labels.

Nevertheless, we understand that accepting such potential wording (*processed with*) is without prejudice to the possibility of a total allergen labelling exemption, based on scientific evidence/research.

6.- Should mandatory allergen labelling statements for alcohol beverages disclose the specific species of fish, or is it sufficient to merely label the allergen as "fish", as TTB proposes ?; (*Is it necessary to mention the name of the fish specie or is it sufficient to simply list "fish" when any type of finfish protein is used?)*

We agree with US trade colleagues that winemakers when purchasing isinglass or fish gelatine from a manufacturer for fining purposes often do not know, and have no way of easily finding out, which particular specie (or species) of fish was used to make the product. Moreover, it is probably impossible to determine the specie (or species) by chemical analysis. Also, we agree with TTB that labelling for specific species of fish may not be beneficial to fish-allergic consumers, who are often allergic to more than one specie.

As said above, the mention "contains fish" would nevertheless give misleading information to consumer, making him believe that the producer has "put a fish in its bottle…"!

Therefore, in the event of having to label this substance, a reference to "isinglass" or "fish gelatine" should be true and sufficient to provide accurate information to consumers.

7. How much time does industry require to comply with mandatory food allergen labelling requirements? What delayed effective date would reduce burdens on affected industry members and at the same time ensure the protection of consumers?

CEEV seeks a significant delay to the implementation of these proposals of 3 years from the date of publication of the final rule.

It is hoped that no decision will be made in the US on labelling for processing aids derived from major allergens until the results of ongoing international research are available (EU and Australia). CEEV particularly wants to avoid the needless costs to industry that would occur if wineries gear up

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to comply with the proposed regulation but an exemption from labeling is then granted on the basis of the results from the current research on this subject. A suitably delayed implementation date in respect of the labeling of fining agents used in production of standard wine would be of great assistance in avoiding this situation.

In this regard, a minimum of (36) months from the date of publication of the final rule would be an appropriate time frame to allow for an informed decision regarding possible exemption to be made and also to allow for a transition to allergen labelling if an exemption is not possible.

Furthermore, to avoid any implementation difficulties, any new regulations should clearly be applied to wines produced after a specific vintage and not from a specific date, when there is vintage labelling.

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As a conclusion, CEEV shares the goal of TTB of providing consumers with meaningful and sometimes critical information on allergens through labelling (eg sulphite labelling), but only to the extent that (i) the allergenic risk is clearly established (ii) the allergenic substance for which a risk threshold has been established is indeed present in the final product.

Mandatory allergen labelling without solid scientific evidence would only raise unnecessary concern among the consuming public and possibly negatively impact the consumption of wines.

CEEV therefore recommends that TTB exempts wines from mandatory allergen labelling until further scientific datas and clinical evidence is available.

We thank you in advance in taking into consideration the above comments and remain at your disposal should you need more information.

Yours Sincerely,

Jose Ramon Fernandez
Sécretaire Général.
CEEV-Comité Européen des Entreprises Vins