WINE INSTITUTE

Robert P. Koch
President and Chief Executive Officer

December 26, 2006

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

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

Dear Mr. Manfreda:

Wine Institute is the trade association of California wineries with a membership of over 1,000 California wineries and affiliated businesses. WineAmerica is the national association of American wineries with over 800 members in 48 states. Both organizations are committed to sound public policy at all levels of government. and jointly submit these comments to Notice No. 62, in response to proposed regulations to mandate food allergen labeling for wines, distilled spirits and malt beverages. We appreciate the additional time that was granted earlier in response to Wine Institute's request for an extension of the comment period.

These comments are presented in three parts:

I. **Background** – legal, scientific, and international aspects of allergen labeling.

II **General Comments to Notice No. 62**

A. ***Proposed Revisions to 27 CFR 4.32a***. Suggested revisions and discussion. Our discussion begins on page 9.
B. ***Proposed Revisions to 27 CFR 4.32b***. Suggested revisions and discussion. Our discussion begins on page 14.
C. ***Discussion of the International Impact of the Proposed Rule.*** Our discussion begins on page 19.

III. **Responses to Specific Questions solicited in the NPRM**. Our discussion begins on page 20.

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I. BACKGROUND: The Current Status of the Law, Proposed Regulations, Science and International Efforts to Regulate Allergen Labeling

In this section of our comments, we summarize the legal, scientific, and international aspects of allergen labeling. TTB's proposal attempts to remain faithful to the letter of FALCPA, yet we note that the proposed regulations do not include the post-FALCPA exception based on "cross-contact" that has already been embraced by the Food and Drug Administration. We address ELISA kits and note that while there are very few performance-tested methods for evaluating the presence of allergens in finished foods, FDA has recognized and touted the value of testing with ELISA kits. We note recent clinical work on allergenic effects from wine fined with protein-based fining agents available from Australia, and similar work that is reaching a conclusion in Europe. The Australian study concludes that wines fined with egg white, isinglass, and non-grape tannins, present only an extremely low risk of anaphylaxis to fish, egg, and peanut-allergic consumers.

We identify putative sources of allergens in wine, based on TTB's winemaking regulations. We note that virtually all wines are clarified, racked, and filtered prior to bottling to remove sediment and processing aids.

TTB's proposed regulations require the "Contains" statement when an ingredient or wine fining agent that contains an allergen is ***used*** in wine production. We note that labeling based on use is inconsistent with existing and proposed international regulations in which the trigger for labeling is the presence of the allergen in the finished product.

A. FALCPA – The Statute

The Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA) begins with a statement of findings that estimate the number of allergy-susceptible individuals and the difficulty that parents have in deciphering ingredient labels to determine whether food products contain allergens. These findings suggest that the disclosure of allergens in foods should be based on the presence of such allergens in the finished food, as that is where allergic consumers would be exposed to the health risk. However, FALCPA requires that even flavorings, colors, or incidental additives that bear or contain a major food allergen are also subject to the allergen labeling requirements, FALCPA also provides for a procedure to exempt a product or ingredient from labeling, but only when it is shown through notice or petition that no allergenic material remains. Thus, under FALCPA, the event that triggers allergen labeling is the use of allergens in processing rather than their presence in the final product, but the basis for an exemption from allergen labeling is the absence of allergens in the ingredient or the final product.

The Food and Drug Administration explains that Congress passed the act to "make it easier for food allergic consumers and their caregivers to identify and avoid foods that contain major food

allergens."[1] While allergic reactions are caused by exposure of susceptible individuals to allergens, FDA follows the statute by taking an ingredient-by-ingredient approach to food products which conditions the labeling of an allergen in a finished product based on the presence in an ingredient. Further provisions allow ingredient manufacturers to submit either a petition or notification to the Food and Drug Administration to obtain an exemption from the Act's label disclosure provisions. Of the seven exemption notices submitted as of December 18, 2006, FDA has opposed six, with the status of the remaining notice pending.[2]

B. TTB's Proposal – The Proposed Rule

FALCPA is self-executing and took effect for all food products under FDA's jurisdiction on January 1, 2006. FDA does not have implementing regulations, instead relying on the familiarity of its policies on ingredient labeling, its past policies and procedures, and a series of publications available online to provide compliance information to food producers under the agency's jurisdiction. TTB, on the other hand, published its NPRM at the same time it published voluntary allergen labeling regulations[3] on July 26, 2006. It was on this date that alcoholic beverage producers learned of TTB's approach to FALCPA.

TTB's proposed regulations provide for labeling requirements as well as for an exemption procedure. As with the FDA petition and notice processes, the burden of qualifying for an exemption still remains on the petitioner, but TTB's proposed regulations authorize exemptions for product classes as opposed to the ingredient-by-ingredient, notice and petition approach that FDA has implemented. The proposed petition process affords TTB 180 days after the receipt of the petition to make a decision on the petition, but the petition is deemed rejected if TTB fails to make a written response within the 180 days.

Consistent with FDA's approach, TTB does not propose threshold levels for any of the allergens. Little is mentioned in the NPRM about the available analytical methods that are recognized as being reliable indicators for the presence of the controlled allergens. Likewise, nothing is mentioned about allergens that might end up in a finished product because of cross-contact.[4] In

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[1] FDA's web site contains a Consumer Qs and As at http://www.cfsan.fda.gov/~dms/alrgqa.html which further explains that 25% of sampled foods failed to list peanuts or eggs as ingredients on the food labels although the foods **contained** these allergens.

[2] See "Inventory of Notifications Received Under 21 USC 343(w)(7) for Exemptions from Food Allergen Labeling" at http://www.cfsan.fda.gov/~dms/falnoti.html

[3] T.D. TTB-53; Re: Notice No. 62. 71 FR 42260, July 26, 2006.

[4] FDA **[Added December, 2005] Is a major food allergen that has been unintentionally added to a food as the result of cross-contact subject to FALCPA's labeling requirements?**
No. FALCPA's labeling requirements do not apply to major food allergens that are unintentionally added to a food as the result of cross-contact. In the context of food allergens, "Cross-contact" occurs when a residue or other trace amount of an allergenic food is unintentionally incorporated into another food that is not intended to contain that allergenic food.

response to FALCPA, in July of 2006, FDA released a report to Congress analyzing ways that cross-contact with allergens can be reduced or eliminated with good manufacturing practices; the FDA released its cross-contact report in July of 2006.

C. The Federal Alcohol Administration Act

TTB's wine labeling regulations are based on the Federal Alcohol Administration Act's mandate in 27 USC 205(e). This section of the FAA Act authorizes TTB to develop regulations that will prohibit consumer deception and that will prohibit, irrespective of falsity, statements relating to scientific matters that are likely to mislead the consumer, and that will provide the consumer with adequate information as to the identity and quality of the products.

D. The "Cross-Contact" Exception to Allergen Labeling

Notwithstanding the "zero-threshold" restraints of FALCPA, FDA recognizes one exception to the allergen disclosure provisions. FDA's Final Guidance to Industry[5] describes FALCPA's "use"-based disclosure of allergens, but also notes that FALCPA's allergen disclosure requirements do not apply to major food allergens that are unintentionally added to a food as the result of cross-contact, regardless of their presence in finished foods. In the context of food allergens, "cross-contact" occurs when a residue or other trace amount of an allergenic food is unintentionally incorporated into another food that is not intended to contain that allergenic food. Cross-contact may result from customary methods of growing and harvesting crops, as well as from the use of shared storage, transportation, or production equipment. In other words, although an allergen might be present in a product through cross-contact, FDA's opinion is that FALCPAt does not require disclosure of the presence of the allergen.

E. Methods of Analysis for Testing for the Presence of Allergens: The State of the Science

There are very few performance-tested methods for evaluating the presence of allergens in finished foods. While FDA has collaborated with the Association of Official Analytical Chemists (AOAC) on peanut test kits, resulting in recognized methods for testing for peanuts, there are no such methods available to test for the presence of eggs, milk, wheat, or fish in wine. FDA has touted the virtues of such test kits, stating: "Organizations that have limited laboratory facilities such as research and industrial food operations are the likely users of these kits. For example, use

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Cross-contact may result from customary methods of growing and harvesting crops, as well as from the use of shared storage, transportation, or production equipment.

[5] "Questions and Answers Regarding Food Allergens, Including the Food Allergen Labeling and Consumer Protection Act of 2004 (Edition 3) – Guidance for Industry." This document is available at the FDA web site at http://www.cfsan.fda.gov/~dms/alrguid3.html . [The web site now contains "Edition 4".]

of these tests can assist organizations in rapidly determining whether their food processing operations are adequate to prevent the inclusion of peanut products in foods declared to be peanut-free. They can also use the tests to determine whether food processing plant cleanup operations are sufficient to avoid cross-contamination and whether the finished product is peanut-free."[6]

Enzyme-linked immunosorbent assay (ELISA) test kits exist for testing for egg, wheat, and milk. These tests are not yet AOAC-approved. ELISA test kits use a biochemical technique to detect the presence of protein from a given source in a sample (e.g. milk protein, egg protein). The kits depend on the use of antibodies raised to that protein but because the allergenic protein component is generally only one part of the total protein used for raising antibodies, it cannot be guaranteed that the kits will actually be sensitive to the allergenic protein itself. TTB's proposed exemption petition regulation requires that petitioners prove that a finished class of products does not contain ***allergenic protein*** derived from the identified sources of food allergens.[7]

TTB has recently reported on its evaluation of commercially available ELISA-based kits for protein fining agents in wine,. TTB stated that the results of its testing of ten wines known to have been fined with egg with three different ELISA test kits demonstrated that while the kits detected egg protein in control wine matrices spiked with a reference, the kits detected no egg protein ***in any of the wine samples fined with eggs.***

F. Status of Clinical Data

There is a dearth of clinical data regarding allergenic effects from wine fined with protein-based 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. Fining agents such as eggs and milk have been used in wine production for millennia with few, if any, substantiated complaints from allergy sufferers. We are aware, however, of a significant body of data that has been collected over the years by the Liquor Control Board of Ontario (LCBO) that TTB should not ignore.[8]

As indicated in Dr. Soleas' comments, the LCBO is one of the world's largest retailers of alcoholic beverages and imports products from over sixty countries, supporting a retail network of more than 800 stores in the province of Ontario, Canada. In 2005, sales totaled approximately $3.68 billion CDN. The LCBO, as part of its operations, also receives and investigates consumer

[6] FDA Talk Paper T03-72, October 30, 2003, "FDA Collaborates with AOAC To Gain Approval of Peanut Test Kits for Food Products," found at http://www.fda.gov/bbs/topics/ANSWERS/2003/ANS01258.html

[7] Interim section 27 CFR Section 4.32b and proposed 27 CFR Section 4.32b are virtually identical, requiring proof that the product or class of product requesting the exemption either (1) does not cause an allergic response that poses a risk to human health, or (2) does not contain allergenic protein derived from one of the foods identified in FALCPA.

[8] Specifically, please refer to TTB's public comment number 28 submitted by Dr. George Soleas.

complaints. Since 2000, the LCBO has recorded about 486,000 customer complaints. The LCBO investigated about 1,300 of these complaints, and, of these, 337 were of an alleged illness-related nature. Of the 337 investigated complaints, not one involved wine fining agents or production practices .

While FALCPA is only now being implemented in the United States, Australian legislation already requires the labeling of wines fined with potentially allergenic food proteins such as casein, milk, egg white, and isinglass if there are detectable residual levels of the allergen remain. This legislation prompted a scientific study at the Department of Immunology, Monash University, in Melbourne Australia (Nutrition 22 (2006) 882-888).[9] In a double-blind placebo-controlled trial to determine whether allergic reactions followed consumption of Australian commercial wines fined using one or more of the targeted food proteins, the researchers concluded that wines fined with egg white, or treated with isinglass or non-grape tannins presented only an extremely low risk of anaphylaxis to fish, egg, and peanut-allergic consumers. Additionally, the researchers concluded that consumption of milk protein-fined wine did not induce anaphylaxis in a milk-allergic subject, at the same time expressing their difficulty in locating milk-allergic consumers.

This double-blind, placebo-controlled challenge of sensitive individuals with wine fined with food proteins is, in the researchers' words, the "gold standard of diagnostic challenge for food sensitivity."[10]

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[9] "Potential food allergens in wine: Double-blind, placebo-controlled trial and basophile activation analysis," Jennifer M. Rolland, Ph.D, Effie Apostolou, M.Sc, Kirsten Deckert R.N., Maria P. de Leon,Ph.D., Jo A. Douglass,M.D., Ian N. Glaspole, Ph.D., Michael Bailey, Ph. D., Creina S. Stockley, M.Sc., M.B.A., and Robyn E. O'Hehir, Ph.D. Manuscript received December 8, 2005; accepted June 6, 2006. Nutrition 22 (2006) 882-888.

[10] The U.S. Department of Health and Human Services, National Institutes of Health, National Institute of Allergy and Infectious Diseases, recognizes double blind food challenge as the "gold standard." On page 14 of a public document that serves as an overview of food allergy and available at http://www.niaid.nih.gov/publications/pdf/foodallergy.pdf (NIH Publication No. 04-5518), the National Institute of Allergy and Infectious Diseases writes:

> "The final method health care providers use to diagnose food allergy is double-blind food challenge. This testing has come to be the "gold standard" of allergy testing."
>
> "The advantage of such a challenge is that if you react only to suspected foods and not to other foods tested, it confirms the diagnosis …"
>
> "In addition, this testing is difficult because it takes a lot of time to perform and many food allergies are difficult to evaluate with this procedure. Consequently, health care providers seldom do double blind food challenges."

The study represents the most recent and relevant clinical information on the allergenicity of wine fining agents, so we are including a copy of the study with these comments. We are aware that work of a similar nature is reaching a conclusion in Europe, and we understand that the results will confirm and supplement those from the work done in Australia. .

G. Putative Sources of Allergens in Wine: The State of the Product

Federal winemaking regulations authorize the use of certain materials and processes for the treatment of wine.[11] Among them, we have identified the following wine fining agents that are potential allergen sources:

Allergen	Authorized Material	Regulatory Provisions
Egg	Albumen (egg white): Fining agent	May be prepared in a light brine 1 oz. (28.35 grams) potassium chloride, 2 lbs (907.2 grams) egg white, 1 gal. (3.785 L) of water. Usage not to exceed 1.5 gallons. Of solution per 1,000 gals. of wine..
	Lysozyme: To stabilize wines from malolactic acid bacterial degradation	The amount used must not exceed 500 mg/L. FDA advisory opinion dated 12/15/93.
Milk	Milk products (pasteurized whole, skim, or half-and-half) is authorized as either a fining agent for grape wine or sherry or to remove off flavors.	The amount used must not exceed 2.0 liters of pasteurized milk per 1,000 liters (0.2 percent V/V) of wine. To remove off flavors, the amount used must not exceed 10 liters of pasteurized milk per 1,000 liters (1 percent V/V) of wine.
	Casein, potassium salt of casein: To clarify wine	GRAS per FDA opinions 02/23/60 and 08/25/61. 27 CFR 24.243.
Fish	Isinglass	GRAS per FDA advisory opinion dated 02/25/85.

Winemaking agents such as eggs, milk, and isinglass are not interchangeable. A winemaker makes a conscious decision to use a particular fining agent for the effect that it will have on the wine. There are no suitable alternatives to these agents. Alumino-silicates such as bentonite, for example, which is also authorized for the treatment of wine, are thus no substitute for milk or egg in wine production.

Virtually all wines are clarified, racked, and filtered before being bottled to remove sediment and processing aids.

[11] 27 CFR 24.246, Materials Authorized for the Treatment of Wine and Juice

H. International Efforts

In 1998, the Codex Alimentarius Committee on Food Labeling (CCFL) finalized proposed changes to the Codex General Standard for the Labeling of Prepackaged Foods and advanced them to the Codex Commission meeting in 1999 for adoption. At this meeting, the Codex Alimentarius Commission adopted the proposed changes to that standard to incorporate a recommendation that the **presence** of potentially allergenic substances in food should be indicated on the label.[12]

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 first set of regulations requiring the presence of allergens in wine to be indicated on the label was developed in Australia. Subsequently, provisions have been developed in the European Union and the United States of America. Canada is actively considering regulations also. The Australian[13] and EU[14] allergen labeling provisions condition disclosure on the **presence** of allergens in the finished product.

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[12] In the changes (worded as follows), those foods that were associated with the majority of allergic reactions were grouped into 8 categories - often referred to as the "Big 8":

"The following foods and ingredients are known to cause hypersensitivity and shall always be declared:

- Cereals containing gluten; i.e., wheat, rye, barley, oats, spelt or their hybridized strains and products of these;
- Crustacea and products of these;
- Eggs and egg products;
- Fish and fish products;
- Peanuts, soybeans and products of these;
- Milk and milk products (lactose included);
- Tree nuts and nut products; and
- Sulphite in concentrations of 10 mg/kg or more."

[13] See *The Australia, New Zealand Food Standards Code, Standard 1.2.3: Mandatory Warning and Advisory Statements and Declarations*, attached as Exhibit A, particularly Clause 4.
[14] See *The EU Food Labeling Directive, 2000/13*, attached as Exhibit B, which requires that food be labeled to indicate the **presence** of listed allergenic substances.

II. General Comments to Notice No. 62

This section is composed of three parts:

- **Part A** contains our comments and suggested revisions to proposed 27 CFR Section 4.32a;
- **Part B** contains our comments and suggested revisions to proposed 27 CFR Section 4.32b;
- **Part C** discusses the international impact of the proposed rule.

Wine Institute recognizes that FALCPA demands allergen labeling in conformity with its stated goals. We also acknowledge TTB's regulatory responsibility to issue regulations that incorporate the FALCPA goals into the alcoholic beverage labeling rules. However, we believe that the TTB regulations should recognize that FALCPA represents the rare instance where the requirements of the law are far ahead of the science that is available to address its provisions.

Generally, we suggest several changes to the proposed regulations, including:

- Requiring labeling only when it is demonstrated that a major food allergen used in the production of a wine remains in the finished wine;
- The codification of the "cross-contact" exception that has already been recognized by the Food and Drug Administration;
- The adoption of the "Processed With" statement for fining agents;
- For exemptions, the establishment of a standard of proof (preponderance of the evidence) based on the best and reasonably available scientific evidence and methods, and a statement of reasons for denial of a petition

We also discuss the international impact of the proposed regulations and specifically discuss the conflict that arises when reconciling the proposed regulations with the WTO Sanitary and Phytosanitary Agreement.

A. Wine Institute Proposed Revisions to Section 4.32a:

Our changes to Proposed Section 4.32a are set forth below:

§ 4.32a Major food allergens.

(a) *Definitions.* For purposes of this section the following terms have the meanings indicated.

(1) *Major food allergen. Major food allergen* means any of the following:

(i) Milk, egg, fish (for example, bass, flounder, or cod), Crustacean shellfish (for example, crab, lobster, or shrimp), tree nuts (for example, almonds, pecans, or walnuts), wheat, peanuts, and soybeans; or

(ii) A food ingredient that contains protein derived from a food specified in paragraph (a)(1)(i) of this section, except:

(A) Any highly refined oil derived from a food specified in paragraph (a)(1)(i) of this section and any ingredient derived from such highly refined oil; or

(B) A food ingredient that is exempt from major food allergen labeling requirements pursuant to a petition for exemption approved by the Food and Drug Administration (FDA) under *21 U.S.C. 343*(w)(6) or pursuant to a notice submitted to FDA under *21 U.S.C. 343*(w)(7), provided that the food ingredient meets the terms or conditions, if any, specified for that exemption.

(2) *Name of the food source from which each major food allergen is derived. Name of the food source from which each major food allergen is derived* means the name of the food as listed in paragraph (a)(1)(i) of this section, except that:

(i) In the case of a tree nut, it means the name of the specific type of nut (for example, almonds, pecans, or walnuts);

(ii) In the case of Crustacean shellfish, it means the name of the species of Crustacean shellfish (for example, crab, lobster, or shrimp); and

(iii) The names "egg" and "peanuts," as well as the names of the different types of tree nuts, may be expressed in either the singular or plural form, and the term "soy", "soybean", or "soya" may be used instead of "soybeans".

(b)* Cross-contact. *"Cross-contact" occurs when a residue or other trace amount of a food allergen is present on a food contact surface, production machinery, or is air-borne, and unintentionally becomes incorporated into a product not intended to contain the allergen.

~~(b)~~ ***(c)*** *Labeling requirements.* All major food allergens (defined in paragraph (a)(1) of this section) used in the production of a wine ***and that remain in the finished wine***, including major food allergens used as fining or processing agents, must be declared on a label affixed to the container, except when subject to an

approved petition for exemption described in § 4.32b. ***For major food allergens other than those used as fining or processing agent that remain in the finished wines,*** 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 **[*42342]** allergen is derived (for example, "Contains: egg")**.*For food allergens used as fining or processing agents that remain in the finished wine, the major food allergens declaration must consist of the word "Processed with" followed by a colon and the name of the food source from which each major food allergen is derived.***

(d) The labeling requirements set forth in (c) do not apply to major food allergens that are unintentionally added to food as a result of cross-contact..

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

(1) 4.32a(c): Allergen Labeling Should be Required Only When It is Demonstrated That a Major Food Allergen Used in the Production of a Wine Remains in the Finished Wine

We propose a change to the language in proposed 27 CFR Section 4.32a(c) so that labeling is required not simply based on use, but is based on the **presence** of the allergen in the finished wine. This change is supported by the language in FALCPA, the congressional record, and statements by the Food and Drug Administration.

FALCPA's congressional findings are based on the lack of adequate label information that would convey the presence of allergens in food. It is the exposure of consumers to potential allergens , and not simply the mere use of processing aids such as fining agents during production, that concerned Congress. As stated by Hon. Michael K. Simpson in the House of Representatives on July 22, 2004:

> "The Food Allergen Labeling and Consumer Protection Act will make it easier for people with food allergies to more easily identify a product's ingredients. By requiring food labels to list what, if any, of the eight major food allergens are **contained** in a product, the bill will protect people with food allergies from the risk of dangerous and even life-threatening reactions." (emphasis added).

The House Report (Report 108-608) on S. 741 is consistent with this view:

> Title II of S. 741 is the Food Allergen Labeling and Consumer Protection Act. It lays out a number of new requirements for the labeling of food in order to protect consumers with food allergies. Specifically, food that **contains** one of the eight

> major food allergens (milk, eggs, fish, Crustacean shellfish, tree nuts, peanuts, wheat, and soybeans) must list the food source from which the major food allergen is derived either immediately after the list of ingredients or in parentheses following an ingredient that contains a food allergen. (emphasis added).

The Senate Report on S. 741 (Calendar No. 431, Report 108-226), concurs, stating:

> The major purpose of this legislation is to ensure that the major food allergens are identified in plain English on food product labels. Members of this committee have worked in a bi-partisan fashion to ensure that this legislation will provide reliable, accurate, and clear allergen information on the food label. Title II of S. 741, ''The Food Allergen Labeling and Consumer Protection Act of 2003'' will assist food allergic consumers in identifying foods that **contain** major food allergens. (emphasis added).

Finally, the Food and Drug Administration, in its FAQs on FALCPA, states that Congress passed FALCPA "to make it easier for food allergic consumers and their caregivers to identify and avoid foods that **contain** major food allergens."[15] (emphasis added).

As indicated in other portions of our comments, requiring allergen labeling merely on the basis of use could lead to even further consumer confusion and would be inconsistent with existing and proposed international regulations on allergen labeling. Wine Institute believes that a wine product should have to contain an allergen to justify such a label declaration, and that requiring labeling merely on the basis of use is inconsistent with the letter and spirit of the Act..

We argue consistently throughout our comments that TTB's proposed regulation, which trigger labeling based on the mere use of an allergen, are unjustified, inconsistent, and unfair, especially when the purpose of the Act is to minimize exposure to allergens that are present in a finished product, and not allergens that may simply have been used during production but which do not remain in the finished product.

(2) 4.32a(b) and (d): TTB Regulations Should Codify a "Cross-Contact" Exception

As we discussed earlier, FDA recognizes an exemption for cross-contact exposures. As TTB moves ahead with rulemaking, we believe that the cross-contact policy of FDA should be embodied in TTB's allergen labeling regulations. FDA's recently released report to the Committee on Health, Education, Labor and Pensions of the US Senate and the Committee on Energy and Commerce of the US House of Representatives (July, 2006) identifies several points in the manufacturing process where cross-contact can occur. For beverages, FDA has identified

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[15] See FDA's "Information for Consumers: Food Allergen Labeling and Consumer Protection Act of 2004: Questions and Answers" found at http://www.cfsan.fda.gov/~dms/alrgqa.html, specifically FDA's response to Question 2, Why Did Congress pass this Act?

specific points and control practices. Cross-contact points identified are: filler, shared equipment, storage tanks, blending, pumps, lines, pasteurization, homogenization, liquefiers, batch tanks. Control practices used include: sanitation, scheduling, allergen testing, visual inspection, and flushing.

TTB's final regulations should acknowledge the results of this report, and include both a definition and exemption for cross-contact exposures.

(3) 4.32a(c): TTB Regulations Should Provide for a "Processed With" Statement for Fining Agents

The suggested changes to Section 4.32 include an alternative statement for processing aids and fining agents. Wine Institute recommends requiring the statement "Processed With:" rather than "Contains" because there may not be any processing aids remaining in the finished product after bottling. As discussed below, requiring "Contains" is potentially misleading and harmful to consumers.

FALCPA and the accompanying FDA guidance documents were not drafted to specifically address the production processes and techniques that are used to remove fining agents from wine. Wine fining agents are not intended to remain in the wine. Rather, they drop out of solution, taking with them the materials they are targeted to remove from the wine. While a winery may use a fining agent during wine production that might contain an allergen, the wine will subsequently undergo further production steps to remove the allergen before bottling.

In drafting the proposed allergen labeling regulations, it is clear that TTB did not make a distinction between presence and use.

> In response to the concerns expressed by some wineries that they would be required to conduct extensive and expensive laboratory analysis to determine allergen content, we note that mandatory allergen labeling does not necessarily require producers to conduct any chemical analyses of their products. Producers are aware of and usually keep extensive records of what materials, including major food allergens, go into the production of an alcohol beverage. The producers therefore would already know when the ***presence*** of a major food allergen ought to be declared. Thus, the adoption of mandatory labeling requirements for major food allergens in alcohol beverages would not require expensive laboratory tests of those alcohol beverages. 71 FR at 42333.

TTB's proposed regulations require that a wine that has been treated with material containing a target allergen must bear the appropriate allergen declaration that the wine "Contains" the allergen.[16] Yet, TTB's proposed regulations implementing FALCPA must be reconciled with TTB's existing regulations regarding false and misleading label statements. TTB's regulation at

[16] Proposed 27 CFR Section 4.23(d) states: "If a major food allergen as defined in Section 4.32a is used in the production of a wine, there shall be included on a label affixed to the container a statement as required by that section."

27 CFR Section 4.39 prohibits any false or untrue statement, or even any statement that tends to create a misleading impression irrespective of falsity.[17]

Many consumers misinterpret food intolerance as food allergy. In one account, it is stated that about 25% of the population believes that they are allergic to certain foods.[18] Still others estimate that about 33% of Americans believe that they have a food allergy,[19] Consequently, mislabeling wine as containing an allergen or allergens will have consequences beyond the very small number of wine-consuming adults that have genuine allergies to the possible allergens in fining agents.[20] It may result in perpetuating the myth and misunderstanding of food allergies rather than helping to convey useful information to those that need to read it. While it is convenient to suggest that wineries label their products with allergen disclosure statements so that those with allergies can make informed decisions, false information may unreasonably and unnecessarily restrict the already limited choices available to the allergenic individual, causing relatively large numbers of consumers who are at no risk to shy away from wine industry products.

This presents a major dilemma for wineries of all sizes. In order for a winery to be in compliance with the TTB regulations requiring "Contains" labeling and not mislead consumers, the winery not only must make the statement declaring the presence of an allergen, but must make sure that the statement is true. As a result, we respectfully disagree with TTB's belief that the proposed allergen labeling requirements would not require expensive laboratory tests of those alcohol beverages. A winery could not be sure that its allergen declaration is truthful unless it invested in analytical testing.

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[17] 27 CFR 4.39, in part, states:

> (a) Statements on labels. Containers of wine, or any label on such containers, or any individual covering, carton, or other wrapper of such container, or any written, printed, graphic, or other matter accompanying such container to the consumer shall not contain:
>
> (1) Any statement that is false or untrue in any particular, or that, irrespective of falsity, directly, or by ambiguity, omission, or inference, or by the addition of irrelevant, scientific or technical matter, tends to create a misleading impression.

[18] At FamilyDoctor.Org at http://familydoctor.org/340.xml : "FACT: Although 25 percent of people think they're allergic to certain foods, studies show that about only 8 percent of children and 2 percent of adults have a food allergy."

[19] From the International Food Information Council Brochure, *"Understanding Food Allergy"*: "Surveys show that about one-third of all adults believe they have food allergies. Yet true food allergy is estimated to affect less than two percent of the population."

[20] In Comment 22, Michael Muilenberg, an instructor and researcher for the Harvard School of Public Health, submits that "approximately 2% of the population … has verified food allergies." But Mr. Muilenberg's general figure includes the entire population and all food allergies. However, the more relevant data indicates that milk allergenic consumers represent about 0.3% of the adult population, egg allergy about 0.2%, fish allergy about 0.4%.

The proposed "Processed with" language is a more accurate description of the effect of fining agents on the allergenic content of wine. Sensitive consumers would still be alerted to the potential presence of an allergenic substance, and the distinction from "contains" would help all consumer understand that the fining agent is not intended to be part of the final product.

B. Wine Institute Proposed Revisions to Section 4.32b:

Our suggested changes to proposed Section 4.32b are set forth below:

§ 4.32b Petitions for exemption from major food allergen labeling.

(a) *Submission of petition.* Any person may petition the appropriate TTB officer to exempt a particular product or class of products from the labeling requirements of § 4.32a. The burden is on the petitioner to provide scientific evidence (including the analytical method used to produce the evidence) that demonstrates that the finished product or class of products, as derived by the method specified in the petition, either:

(1) Does not cause an allergic response that poses a risk to human health; or

(2) Does not contain allergenic protein derived from one of the foods identified in § 4.32a(a)(1)(i), even though a major food allergen was used in production. ***When demonstrating that a particular product or product class does not contain allergenic protein as required by this section, proof of nonpresence submitted based on the best and reasonably-available scientific method shall be deemed adequate for approval if substantiated by a preponderance of the evidence.***

(b) *Decision on petition.* TTB will approve or deny a petition for exemption submitted under paragraph (a) of this section in writing within 180 days of receipt of the petition. ~~If TTB does not provide a written response to the petitioner within that 180-day period, the petition will be deemed denied, unless a~~**A**n extension of time for decision ***beyond the 180 days prescribed may be***~~is~~ mutually agreed upon by the appropriate TTB officer and the petitioner. ***All denials shall be accompanied by a written statement that includes specific reasons for denial and issued within the prescribed time limits including any mutually agreed upon extensions.*** TTB may confer with the Food and Drug Administration (FDA) on petitions for exemption, as appropriate and as FDA resources permit. TTB may require the submission of product samples and other additional information in support of the petition; however, unless required by TTB, the submission of samples or additional information by the petitioner after submission of the petition will be treated as the withdrawal of the initial petition and the submission of a new petition. An approval or denial under this section will constitute a final agency action.

(c) *Resubmission of a petition.* After a petition for exemption is denied under this section, the petitioner may resubmit the petition along with supporting materials for reconsideration at any time. TTB will treat this submission as a new petition for purposes of the time frames for decision set forth in paragraph (b) of this section.

(d) *Availability of information.* (1) *General.* TTB will promptly post to its public Web site, *http://www.ttb.gov*, all petitions received under this section as well as TTB's responses to those petitions. Any information submitted in support of the petition that is not posted to the TTB Web site will be available to the public pursuant to *5 U.S.C. 552*, except where a request for confidential treatment is granted under paragraph (d)(2) of this section.

(2) *Requests for confidential treatment of business information.* A person who provides trade secrets or other commercial or financial information in connection with a petition for exemption under this section may request that TTB give confidential treatment to that information. A failure to request confidential treatment at the time the information in question is submitted to TTB will constitute a waiver of confidential treatment. A request for confidential treatment of information under this section must conform to the following standards:

(i) The request must be in writing;

(ii) The request must clearly identify the information to be kept confidential;

(iii) The request must relate to information that constitutes trade secrets or other confidential commercial or financial information regarding the business transactions of an interested person, the disclosure of which would cause substantial harm to the competitive position of that person;

(iv) The request must set forth the reasons why the information should not be disclosed, including the reasons the disclosure of the information would prejudice the competitive position of the interested person; and

(v) The request must be supported by a signed statement by the interested person, or by an authorized officer or employee of that person, certifying that the information in question is a trade secret or other confidential commercial or financial information and that the information is not already in the public domain.

(1) 4.32b(a)(2): The TTB Regulation Should Establish a Standard of Proof and Should Recognize Best and Reasonably Available Scientific Evidence and Methods

To allow for new developments in the ever-expanding analytical sciences, as well as to accommodate wineries that are interested in submitting an exemption petition based on scientific facts, we suggest a change to the regulations that would allow petitions to be based on “best and

reasonably available scientific methods" and that the burden of proof when demonstrating the absence of allergens be established as the "preponderance of the evidence."

The standard of proof applicable to most disputed factual issues is the "preponderance of evidence" standard. FALCPA does not mention a standard of proof, and while Congress had the opportunity to set more stringent standards, it did not do so. Judicial decisions show that courts are reluctant to create standards of proof that are more demanding than the "preponderance of evidence" standard (See Huddleston v. United States, 485 U.S. 681 (1988)).

We assert that a standard of proof is essential and should be embodied in the final regulations, as much of the evidence submitted in support of allergen labeling for alcoholic beverages is anecdotal.

By including provisions that permit exemption petitions, Congress must have intended that food ingredient manufacturers would be able to meet their burden of proof using best and reasonably available scientific methods. Congress would not have intended exemption petitions to be futile scientific exercises that result in systematic agency denials based on findings of "insubstantial evidence." Thus, the TTB regulations should allow the "best and reasonably available scientific methods to be used to demonstrate non-presence of a potential allergen. This language would allow for the automatic adoption of approved methods as soon as they are approved so long as the testing method is reasonable and not beyond the reach of the wine industry.

We request this change because the current state of analytical science rests with ELISA test kits. However, current ELISA test kits are not necessarily sensitive specifically to the allergenic protein component in a given food such as egg. Wine Institute asserts that the absence of any detected protein with an ELISA kit should create the presumption that the allergenic component is absent, even if the kit may not be sensitive to that precise component of the total protein. If no protein is detected with an ELISA kit, in all probability the allergenic component must also be absent. In seeking this change to the regulation, we are asking TTB to accept the current state of scientific analysis. As we indicated earlier, FDA has recognized the utility of ELISA kits and implied that a negative ELISA test result indicates absence of contamination with a given potential allergen.

As with the sulfite disclosure regulation, and as TTB becomes comfortable with recognized scientific methods, the wine industry would accept changes to the regulations that incorporate AOAC-approved, reasonably available methodology and detection limitsdetectability levels. We would urge that TTB continue work on establishing threshold levels for allergens and revise their regulations accordingly.

In its discussion of the proposed regulations, TTB quotes Dr. Elizabeth TePas' position that allergens used as fining agents be disclosed:

> "While most food allergic individuals are not going to react to the minute amounts of allergen found in some alcoholic beverages, those who are extremely sensitive can have life-threatening reactions." She suggested that until thresholds are scientifically established and affordable and

> reliable testing is available, both allergens used as primary ingredients and allergens used as fining and processing agents should be disclosed on the label. 71 FR at 42335.

Wine Institute disagrees with the premise that one must label for the presence of an allergen based simply on the use of an allergenic fining agent until science and regulators "catch up" by developing thresholds and tests specific to each allergen. Based on FDA's longstanding efforts to develop ELISA kits for peanuts, the likely standardization of testing kits specific other allergens can be predicted and measured in terms of years rather than months. Threshold levels, as well, will rely on clinical data that may not be compiled for years to come, if at all.

As noted above, Wine Institute submits that wineries should be able to qualify for an exemption by using tests such as ELISA, even though the test is not specific to the allergenic component protein, Any other conclusion would render the exemption provisions devoid of meaning, a result that Congress must not have intended.

Wine Institute also submits that anecdotal evidence alone should not be sufficient to deny a petition for an exemption. TTB's NPRM, FALCPA's public comments, and the previous public comments to TTB are replete with anecdotal evidence. Anecdotal evidence is notoriously unreliable and in some cases is tantamount to hearsay. Such evidence is clearly unscientific, and uninvestigated claims of adverse reactions should be weighed accordingly. Costly labeling requirements cannot be justified based merely on such evidence.[21]

Anecdotal evidence of allergic reactions to wine runs counter to the stronger and more convincing historical evidence that the use of fining agents in wine production has resulted in no substantiated allergen complaints. Milk, eggs and isinglass have been used in winemaking for millennia. In 1675, Walter Charleton, describing the "Mystique of Vintners", recommends beaten whites of egg, milk and isinglass for fining. (http://home.btconnect.com/ntruman/wine/ancientcraft.html). Other references to this subject indicate that wine clarification practices were in use at the time of the Roman Empire. Consequently there are quite literally 2 millennia of experience in the use of these substances in winemaking and in all that time, no objectively validated instances are known of severe allergic reactions to wines treated with these materials.

Wine Institute believes that anecdotal evidence concerning allergic reactions to fined wines is unreliable. In light of the special burdens placed on wineries as well as others seeking an exemption from allergen labeling, anecdotal evidence should be dismissed in the presence of scientific evidence to the contrary. Anecdotal evidence may well contribute to the overestimation

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[21] 71 FR at 42333,for example: "A consumer explained that some beverages have caused her to break out in a mild rash, and she feels that knowing what ingredients are present in these beverages would help her know what drinks to avoid. A Canadian consumer commented that she has an anaphylactic allergy to eggs, and she stated that she considers it very dangerous to drink alcohol beverages at all due to the fact that no allergen information is currently identified on alcohol beverages."

of allergen-sensitive individuals in the United States, and should not outweigh scientific evidence or be the main basis for denial of an exemption petition.

As indicated earlier, peer-reviewed, stringent studies performed in Australia demonstrated that allergic individuals did not react to wines that had previously been fined with milk, eggs or isinglass according to good manufacturing practices (J. M. Rolland et al. Nutrition 22 (2006) 882–888). TTB's own studies with egg-detecting ELISA kits and further research studies that are about to be completed in the EU and in the USA will shortly add to the body of objective scientific data on this subject.

(2) 4.32b(b): TTB Should Provide A Statement of Reasons for Denial of a Petition for Exemption

We also suggest that the proposed regulation should require TTB to provide a written statement of its reasons for denial of an exemption petition. We support TTB's proposed provisions that allow for resubmission of an exemption petition, but such procedures only create a vicious circle of submission and resubmission unless the petitioner can be responsive to the reasons for the denial. We note, as well, that the FDA posts its written responses to ingredient manufacturer notices, so such a regulatory change in TTB's regulations would be consistent with FDA's actions to date of providing the reasons for Agency objections (see FDA's "Inventory of Notifications Received Under 21 U.S.C. 343(w)(7) for Exemptions from Food Allergen Labeling" at http://www.cfsan.fda.gov/~dms/falnoti.html.)

Since analytical chemistry is always developing, we are keenly aware that TTB may feel constrained to issue conditional approvals so that new analytical methods will trigger a review of the exemption. We are not opposed to a review of granted exemptions, but would expect that a similar burden of proof and standards of reasonableness apply in such situations.

C. International Impact of TTB Proposed Allergen Regulations

In evaluating TTB's proposed regulations, Wine Institute submits that TTB should consider whether they comply with the international obligations of the United States and their effect on the international competitiveness of domestically-produced wines.

The final TTB rules for allergen labeling must comply with the provisions of the Sanitary and Phytosanitary Agreement (SPS Agreement) of WTO (text of this agreement is available at http://www.wto.org/English/tratop_e/sps_e/spsagr_e.htm to which the US Government is a signatory. If the final rules do not comply with the SPS agreement, there is a risk that another WTO member country could challenge the final rule in a dispute settlement case in Geneva.

The SPS Agreement forms part of the 1994 Accords that established the WTO, which replaced the General Agreement on Tariffs and Trade (GATT). The agreement provides in part for *the protection of human or animal life or health within a territory from risks arising from additives, contaminants, toxins, or disease-causing organisms in food, beverages, or feedstuffs.*

To achieve its objectives, the WTO-SPS Agreement contains a set of substantive and procedural provisions. The substantive provisions are aimed at protecting human, animal, and plant health and life while preventing unjustifiable barriers to trade. The procedural provisions create a framework to improve communication between members regarding proposed SPS changes and to provide a forum for dispute settlement.

The WTO-SPS Agreement creates a framework for border protection and eradication measures while facilitating freer trade. The Agreement is based on the following five general principles:

1. Harmonization--encourages the adoption of measures that conform to international standards, guidelines, and/or recommendations of international agencies.
2. Equivalence--mutual recognition of different but equivalent measures to achieve international standards.
3. Non-discriminatory--treating imports no differently than domestic produce.
4. Transparency--notifying trading partners of changes in their SPS measures, especially when the measures differ from international standards.
5. Regionalization--allows continued exports from clean (disease-free) areas of affected countries.

The Agreement reaffirms the freedom of countries to choose the measures necessary to protect human, animal or plant life or health. However, when the measures do not conform to international standards, the importing country must scientifically investigate why the measures are needed and how they control risk. The main substantive provisions for this discussion are found in Article 5:

- **Article 5.1**, requires members (when possible and as appropriate) to base their SPS measures on risk assessment methodologies developed under the auspices of the appropriate relevant international organization.
- **Article 5.2** stipulates that countries should consider direct risk-related costs (e.g., potential production or sales losses or control and eradication costs) both in assessing and managing risks through the choice of an SPS measure to protect plant or animal health.
- **Article 5.5** states that each member is also obligated to avoid arbitrary or unjustifiable distinctions in the levels of protection it considers to be appropriate (if these distinctions would result in disguised restrictions on international trade) to achieve the objective of consistency in the application of SPS measures.

Under these provisions, TTB or another regulatory agency can impose restrictions and/or labeling requirements for the protection of the consumer. However, those restrictions should comply with the requirement to support the restriction with scientific evidence and risk

assessment developed under the auspices of the appropriate relevant international organization. Stated another way, should the final rule be contrary to the standards established by Codex Alimentarius and similar organizations, the U.S. runs the risk of violating its international obligations.

Other countries have determined that allergen labeling based on a "presence" rule gives a sufficient degree of protection and this appears to be more in line with the postion elaborated in Codex Alimentarius than the "use" regulation proposed by TTB.

In addition, TTB's proposal, if enacted, would hamper the competitiveness of U.S. wines due to the inevitable disparity of enforcement with foreign wines. Only domestic wineries would or could be subject to enforcement through the inspection of production records. Since TTB has no subpoena or administrative jurisdiction over foreign wineries, their enforcement envelope ends at the national border, and imported wines are quite likely to fall out of compliance with the allergen labeling rules because they will follow their own country rules that require labeling only for "presence".

III. Comments to Specific Questions Solicited by NPRM

After reviewing the proposed rule and the impact that it will have on U.S. wineries, we have concluded, for reasons we discuss in this section, that wineries of all sizes will be affected by the rule in virtually the same way. Therefore, we have combined our response to both Question 1 and Question 2. The remaining questions are addressed separately.

Question 1 & 2.

What would be the costs associated with mandatory allergen labeling to the industry and, ultimately, the consumer?

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.

General Comments on Cost Impact

As we indicated earlier, TTB's proposal 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. This important difference has implications in terms of the costs of compliance. It has been suggested that wineries can avoid costly analyses by simply labeling with the allergenic fining agents used. While this approach may relieve industry of some analysis costs, it imposes additional costs in areas that are less obvious at first sight.

Each fining agent available for use in winemaking has different effects on the sensory characteristics of the finished product. Therefore, they are not simply equivalent options for performing exactly the same function. Rather, they are distinct tools, and the winemaker uses his or her skill to select the right fining agent to optimize the particular wine being treated. Consequently, it is entirely possible for fining agents based on milk, eggs and/or fish to be used in different blending legs that are ultimately combined to make a final product. In addition, the precise combination of fining agents used might change from one final production blend of a given product to the next. This is therefore an extremely complicated situation. It is not easy to track the use of fining agents in these circumstances. The result of the TTB proposals is a complex labeling requirement in which stocks of several labels, differing only in their allergen warning statements, may have to be maintained in inventory and applied as appropriate to the final product, once the fining treatments applied to the various blending legs were definitively known. The label and administrative cost increases in this situation would be significant. Since potentially allergenic fining agents used in wine may be derived from milk, egg or fish protein, there are at least eight different permutations in the allergen declaration that would be required on the label, depending on which agents have or have not been used in the several blending legs of the final product, irrespective of their presence in the finished wine.

Because of these cost implications, the proposal may incline some producers to adopt one of the following compliance strategies:

1) Wineries might stop using potentially allergenic fining agents in their wines, so they have no allergen use to declare on the label. We are not aware of substitutes for these fining agents that would produce identical results, so the quality of the end product to the consumer would decrease significantly with the inherent costs of potential lost return purchases. Also, since the proposed regulations woule be difficult to enforce on imported wines, a loss of quality of U.S. wines versus imports may occur, resulting in a loss of domestic market share for U.S. wines.
2) Wineries might decide that it is simpler to use small quantities of all the implicated substances in all their products and then label all their products accordingly. This might be a lower cost option than dealing with the additional administrative burdens and label inventories that the proposal might otherwise engender. However, this approach would not help the allergic consumer, and in effect defeats the stated purpose of the proposal and of the Act.

3) Since it is virtually impossible to prove that cross-contamination could not have taken place, wineries may conclude that they must label every bottle of product with all known allergens in use in the winery. (See our proposal to include a definition and exemption for cross-contact exposures).

Again, this is because the zero-risk option (or precautionary principle) has been adopted in the draft regulations, in which the use of the substance, rather than its presence in the final product, is the trigger for labeling.

The presence of these materials in the final product is an alternative criterion for a labeling requirement and one which has been followed by all other governments internationally that have contemplated or implemented allergen labeling provisions. In this case, a simple positive or negative test result would indicate whether or not to label for the allergen. This would solve the previously mentioned potential problem of blanket labeling of products for allergens. As we have noted, this is the approach preferred by Wine Institute. However, there are some possible difficulties with this approach that have already been noted:

- Notwithstanding the safety in use data spanning literally millennia, there has historically been a lack of objective scientific evidence as to whether a negative test result also indicates that the product is certain to be safe for sensitive individuals to consume. The recent regulatory activity in this area has stimulated significant research that will help to answer this question in the near future.
- Currently analytical test kits do not guarantee to detect the allergenic component of the protein to which they are sensitive. Though a non-detect result creates a strong likelihood that the allergenic component is also present at levels below the limit of detection for the kit.
- Analytical methods continually improve and "presence" would therefore be constantly re-defined according to the sensitivity of the analytical method used (but see our earlier comment about reasonable availability of scientific methods and review of the regulations).
- The approach imposes a burden of analysis costs on wineries – though this would obviously be dependant on how often the fining practices were actually required to be used in production.

In terms of the quality costs, the winemakers' decisions will be based on a balancing act, with the added costs of the fining process in time and materials on one end against the possibility of a loss of consumer appeal in the marketplace on the other. There are alternatives to the use of the allergenic protein derived fining agents, but these are not equivalent substitutes and often do not address the specific quality issue, or are too broad in the effect of use.

- The clays, organic-non-proteinaceous and inorganic fining agents often strip wines of desirable elements such as color, aroma and flavor
- Filtration with charged filter media can remove target elements, but leave behind unwanted smells or remove desired characteristics.
- Time and cooperage can also remove target elements, but add cost in inventory carry-over and the cost of the cooperage.

Removing allergenic protein-derived fining materials from the winemakers' pallet of tools would greatly hamper the creation of fine wines with the desired characteristics which appeal to consumers – taste, look and mouth feel.

Good Manufacturing Process for fining can be found in Wine Analysis and Production by Zoecklein, Fugelsang, Gump and Nury, Aspen/Kluwer 1999, p.245.

A last consideration for cost is the degradation of flexibility that producers will have in making their wines for the market. Though most producers have a good working knowledge of the blend components available to them in their cellars, the final blends often require some adjustment as components do age differently from year to year, depending on myriad factors. Further, fining most frequently occurs just prior to bottling, and lastly, forecasting invariably changes in the years between when grapes are harvested and when wines are bottled. All three of theses criteria will affect labeling as it applies to allergens, which will in turn affect lead-time for production and COLA submission. Current labeling requirements would almost never affect the label as a result of late processing, but allergen labeling requirements will very likely affected the label. These new requirements will necessitate either increased lead-times or increased label inventory to accommodate all anticipated possibilities for processing. The ramifications for not doing so would be loss of processing options at blending. In either case the cost would be high.

Forced Overlabeling and Cost Impact

TTB states that it is important to provide consumers with clear information on the presence of major food allergens in beverages that it regulates. The proposed mandatory allergen labeling does not require producers to conduct any chemical analyses of their products. They only need to know when a major food allergen is used in production and, therefore, should be declared regardless of whether traces of the allergen are present in the final product. Assuming that TTB provides amnesty for potentially false label statements, the impact of this "no-testing" approach on wineries will be a necessity to label in a very broad and inclusive way to capture all of the possible combinations of fining agents and processing aids used which are considered to be food allergens. In addition to providing little, if any, information of value to at-risk consumers, this "over" labeling will certainly negatively impact sales to this particular group of consumers.

The proposed mandatory allergen labeling would result in negative and significant impacts on all wineries regardless of size.

According to winery trade association figures, as of 2006 there are 4,280 wineries in the 50 states of which 4,000 are small wineries that typically produce less than 5,000 cases per year. Approximately 1,400 commercial wineries in California are also predominantly family-owned and operated. However, even the large US wine companies are often structured so that some or all of their brands or facilities are operated in the same manner as a smaller winery would. For

this reason, the economic and logistical problems imposed by a mandatory allergen labeling rule would affect the data collection, allergen reporting, label production and tracking activities of wineries of all sizes.

All wineries produce a range of products that may require the use of a specific type of fining agent or processing aid.

All wineries produce wines made from many different varietals, from grapes grown in different years and with a variety of style blends. Each of these different wines may require the use of a specific type of fining agent or processing aid. Most wineries use one or another of the available fining agents prior to filtering and think of fining only as a clarifying treatment when consistent with 27 CFR Part 24. While that is the main purpose for fining any wine, fining is also authorized for several other reasons including modification of color, odor, flavor and enhanced stability.[22] Generally, milk, evaporated milk, casein, potassium caseinate, and isinglass are used in the fining process to remove phenolic and tannin compounds from white wine and egg white is used to remove tannin compounds from red wine.

Blending, the combination of more than one grape varietal or grape source into a single bottle, occurs in virtually every wine-making country around the world to some degree or another. It can help to balance flavors, acid and tannin levels. Blending can also be used to adjust alcohol levels. As wine is an evolving, "living", product, winemakers do not know what type of fining agents or processing aids the final blends will require until the final stages of production. It is here that these agents are added and a determination of what specific product will be used takes place.

The many different varietals, blends and vintages and types of fining agents and processing aids used will require all wineries to continually redesign each of their labels on an ongoing basis.

The decision of what fining agents are to be used in a particular batch is often only made just prior to bottling. That sequence poses a very significant timing problem since labels must be designed, ordered and printed before the winery is likely to know which fining agent, if any, will be used. Therefore, an appropriate and practical statement would have to be more inclusive than necessarily definitive.

[22] 27 CFR Section 24.246 (a): "Materials used in the process of filtering, clarifying, or purifying wine may remove cloudiness, precipitation, and undesirable odors and flavors."

The costs of labeling redesign and production would present a significant burden to all wineries.

According to the US wine trade association, WineAmerica, mandatory label changes will generate very high costs for America's wineries. WineAmerica estimates that redesigning labels will involve one time costs of about $2,000 to $5,000 for each general label style. While some wineries only have one label style with different information depending on the type of wine, the majority have many more. Therefore, the label redesign costs could range from a low of $2,000 to a high of $15,000 for a winery with three different label styles. In many instances the label redesign will require the production of new dies for cutting labels in different shapes.

On an ongoing basis, some of the proposals for detailed mandatory information will require annual analysis and reprinting of labels in smaller and more frequent lots. In past assessments regarding nutrition and trans-fat labels for foods, FDA found that the cost of new labels per "stock keeping unit" or sku (a specific product sold in a particular size) was estimated to range from $1,100 to $2,600 per sku. Applying that to a winery selling five wines would yield a total cost between $5,500 and $13,000.A small winery with 15 labels would have to invest between $16,500 to $39,000.

Based on these figures, the first-year costs for mandatory allergen labeling including design and production could easily reach $54,000 even for a relatively small winery.

Additional labeling, tracking and administrative responsibilities will require additional winery staffing.

According to recent surveys of the California wine industry, salaries for administrative and technical staffing could average $30,000 or more per employee per year. With the addition of labeling, tracking and other administrative responsibilities related to compliance with the proposed regulations, additional staff will be required. Some of these duties will include handling label design with contractors, checking labels for appearance and accuracy, completing necessary documentation, updating and maintaining records related to compliance, and developing new procedures. Quality Assurance personnel may also be needed to provide technical review and analysis of all production documents to ensure compliance with all established procedures and specifications. These individuals will also review appropriate analytical data and work with laboratories and wine makers to determine the fining agents and processing aids used in the various wines being produced and may need to review batch record documentation from contract manufacturers to confirm Certificates of Analysis conform to established specifications. Some of the tasks we identify here can be outsourced, but we do not have cost information on such services.

The additional costs that wineries will incur may or may not be able to be passed on to the consumer depending on the competitive environment, type of wine, geographic region, market segment, etc.

Beyond the direct costs to wineries, consumers may also suffer from a lack of choice and be subjected to increased prices, as the direct costs will force wineries to limit or even shutdown some of their operations and possibly pass on some of these new input costs to the consumer. The net effect would make it more difficult for American wineries to compete with foreign imports, which already have a strong hold in many local markets.

Wine Institute believes that 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.

Question 3.

Are there ways in which the proposed regulations can be modified to reduce the regulatory burdens and associated costs imposed on the industry?

We have previously suggested changes to the regulation.

It is worth remembering the statement that the Industry Section of the World Wine Trade Group (WWTG, comprising representatives from the industries of 6 different countries) made in late 2003 to their respective Governments in that Organization (including the US):

> *"Several countries, including WWTG member countries, have introduced or are considering the introduction of labeling for potential allergens including, inter alia, fish, milk and egg products. The WWTG industry group recommends that any such labeling must be based on sound science.*
>
> *To date the scientific community has no evidence on the allergenic affects of these products in wine. Australia is currently undertaking extensive research in this area. Therefore, the WWTG industry group urges the WWTG governments to take full account of the scientific findings, expected within 12 months, in formulating or revising their labeling regulations in this area."*[23]

[23] See House Congressional Record, July 20, 2004, H6097.
See also http://www.wwtg-gmcv.org/EnglishPages/MeetingStatements/ConCon.htm.

In the light of these considerations, Wine Institute urges TTB 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. These results should be available by the end of 2007, giving TTB adequate opportunity to consider the results prior to publication of the final rule.

The results of this approach will be sound scientific evidence to foster reasonable, rather than subjective, guidance on allergen labeling that would be of true benefit to consumers. The alternative is a situation in which labels that are essentially misleading are placed on wine bottles and which could prevent consumers who have safely enjoyed identical products all their lives from continuing to do so.

Question 4.

The proposed rule allows industry members a great deal of flexibility in the placement of mandatory allergen labeling statements. Does this flexibility reduce the costs 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 labeling statements in addition to the requirements already applicable to all mandatory information on alcohol beverage 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 No. 5, sulfites, and aspartame?

Unlike other food products, alcoholic beverages have very specific type size and placement requirements 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. Wine Institute acknowledges that there are some perceived benefits to uniform allergen statements in uniform label locations, but we do not believe that a more rigid regulation is necessary based on the risk factors involved. TTB's regulations should be as flexible as possible.

Question 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 labeling requirement, for

example, a ''processed with'' labeling statement instead of a ''contains'' labeling statement? Would requiring a distinction between primary ingredients and fining and processing agents be informative to the consumer or would it mislead consumers? Would distinct labeling for processing and fining agents allow industry members to impart more specific information about the use of processing and fining aids?

As we indicated earlier in these comments, in the interest of providing accurate product information to the wine consumer, the use of a "processed with" statement instead of "contains" would allow for a more accurate description of a product treated with fining agents or processing aids during production.

The intentional use of fining agents in winemaking is based on millennia of practical experience and on an understanding of the chemistry of wine. The materials precipitate out of the wine during use, leaving minimal (if any), residues in the final product. In such circumstances, to place a statement on a label that indicates that the final product "Contains" the specific allergen would be potentially misleading and unhelpful to the consumer. On the other hand, "Processed with" is more specific information which acknowledges that the fining agent has been used during the production process but does not necessarily imply that there are quantifiable residues in the final product.

Question 6.

Should mandatory allergen labeling statements for alcohol beverages disclose the specific species of fish, or is it sufficient to merely label the allergen as ''fish,'' as TTB proposes?

In answering this request for comments, Wine Institute echoes and underlines two considerations that the TTB acknowledges in its interim rule and proposal: the declaration of fish species is technically impossible on the one hand and is unnecessary on the other.

Wineries may use isinglass, a protein derived from fish, as a fining agent. Wine Institute agrees with TTB that the indication of fish species on the label is impossible for the wine producer to ascertain. This is supported by both literature and practice. In the Extract from the Opinion of the Scientific Panel on Dietetic Products, Nutrition and Allergies on a request from the Commission related to a notification from Brewers of Europe and BFBi on isinglass used as a clarifying agent in brewing pursuant to Article 6 paragraph 11 of Directive 2000/13/EC - The EFSA Journal (2004) 149, 1-8:

> *Isinglass is a form of collagen derived from dried swim bladders of certain tropical and subtropical fish. The fish species used for isinglass production are all more primitive or*

> *physostomatous fish. It is stated that in these fish there is little adherence between the bladder and the body cavity wall so that swim bladders are readily detached and removed from the body of the fish without extraneous tissue. The swim bladders are shipped dried or frozen.*
>
> ***The production process varies**, according to the applicant, **between manufacturers. It consists of blending of swim bladders from different fish to meet quality, functionality, cost and supply criteria**. Then various steps follow including granulation, washing, sterilisation with dilute hydrogen peroxide and further washing.*
>
> *Isinglass powder, paste and "ready-to-use" liquids are tested empirically for functionality (clarification efficiency) by the isinglass industry to ensure consistent performance of the product. The customers purchase according to certain specifications, including hygienic (bacteria, heavy metals) and functionality (protein) parameters.*
>
> *Thus, there is a certain degree of uniformity in the production process of isinglass, **but also room for considerable variation among producers**.*
>
> (emphasis added)

From this it is clear that wineries have no way of discovering for labeling purposes which combinations of fish species may have been used in the production of the particular isinglass used, nor of knowing whether and how the combination of species changes from batch to batch for a given isinglass source or from brand to brand.

In addition, we have additionally queried several isinglass manufactures to validate our belief that fish species information is unascertainable, and have been informed by these manufacturers that they cannot produce such information. In this respect, please refer to the letter dated November 30, 2006, from Laffort Oenologie's Russell Robbins, enologist and manager for Laffort's North American operations, which accompanies our comments as Exhibit C. In the letter, Mr. Robbins states:

> "Because we purchase the raw material from various sources depending on quality, it is currently not possible to accurately identify which species of fish are found in the final product."

Further, labeling fish species is unnecessary because allergies to fish are not species-specific. On this score, Wine Institute agrees with the position on this issue taken in the submission already made to FDA by the Flavors and Extracts Manufacturers' Association (FEMA) in response to the Guidance on Compliance with the Food Allergen Labeling and Consumer Protection Act. In that submission, evidence was presented to show that individuals allergic to one species of fish are usually allergic to other species also (this was noted in both the TTB interim rule and the proposed rule).[24]

[24] "Allergens have been assessed in several species of fish. The major allergens of fish are parvalbumins, calcium-binding proteins which are known to be present in the muscles of all species of fish that have thus far been

This is apparently a widely acknowledged fact, since the draft report prepared by the CFSAN Threshold Working Group "Approaches to Establish Thresholds for Major Food Allergens and for Gluten in Food (http://www.cfsan.fda.gov/~dms/alrgn.html) states the following:

> "Allergenic cross-reactivity among fish species has been described in the clinical literature, but appears to be less common than among species of crustacea. Both Sicherer (2001) and Sampson (1999) estimate that there is a 50% probability that an individual allergic to one fish species will also react to at least one other fish species. Helbling et al. (1999) reported that 4 of 14 (29%) fish allergic patients reacted to two or more species in DBPCFC tests. Bernhisel-Broadbent et al. (1992) reported that 3 of 10 (30%) fish allergic patients responded to more than one fish species in oral challenges, but that skin prick tests were positive to multiple species for all of these patients. Similarly, Hansen et al. (1997) showed that eight cod allergic patients all had positive skin prick tests with two other fish species. The data presented in Pascual et al. (1992) suggest that at least 80% of a group of 79 fish allergic children had IgE antibodies to two or more fish species. In some cases, cross-reactivity has been shown to reflect the presence of one of more closely related allergenic proteins in different species (Pascual, 1992; Hansen et al., 1997; Leung et al., 1999; Hamada et al., 2003)."

It seems, then, from a practical point of view, that fish allergic individuals should avoid all fish in the diet, since there is a relatively high likelihood that they will react to several different species. It follows that to declare on a label the name of the fish species from which the isinglass used to fine the product was made would be giving an unnecessary and confusing level of detail, beyond that which is required to achieve the spirit and purpose of the allergen labeling proposals.

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examined. Parvalbumins have been identified as cross-reacting allergens in several fish species and are clinically relevant in fish allergic individuals (Wild and Lehrer, 2005). Parvalbumins have been specifically identified as the major fish allergen in all fish species examined thus far including two types of cod, carp, salmon, three types of mackerel, and several types of tuna (Taylor et at., 2004). Several minor fish allergens have also been identified in a few species but the clinical significance of these allergens remains to be determined (Taylor et al., 2004).

"Clinical and scientific evidence supports the concept that fish-allergic individuals will react adversely to all species of fish. Studies have demonstrated IgE cross-reactivity in 8 adult codfish-allergic individuals tested using double-blind placebo-controlled food challenge, skin prick tests, histamine release tests, specific IgE sodium dodecyl sulfate- polyacrylamide gel electrophoresis, immunoblotting, and RAST to 4 species of fish: cod, mackerel, herring, and plaice (Hansen et al., 1997). Similar clinical evidence has been obtained in other studies (see Taylor et al., 2004 for a summary). Although cross- reactivity among all fish species has not been specifically confirmed by clinical investigations, fish-allergic individuals are believed to be potentially reactive to all species of fish (Taylor et al. 2004). Experts in fish allergy have concluded that advising fish-allergic subjects to avoid all fish species should be emphasized until a species can be proven safe to eat by provocative challenge (Helbling et al., 1999). This cross-reactivity is one reason organizations such as the Food Allergy & Anaphylaxis Network recommend that individuals who have a reaction to one species of fish avoid all fish.

"The high likelihood of reaction to multiple fish for those with a fish allergy suggests that the requirement to label specific species of fish does not often offer additional risk management information and may result in a fish allergic individual consuming a food with a particular fish species the individual considers acceptable even though disparate species of fish seem to share a common allergen (Bush et. al., 1995)."

Taking the first and second points together, Wine Institute maintains that it would be technically impossible and (most importantly) of no additional benefit to fish-allergic consumers to go beyond use of the word, "fish" in allergen labeling for wines.[25]

[25] Additional references:

- Bernhisel-Broadbent, J., Scanlon, S. M., Sampson, H. A. (1992). Fish hypersensitivity. I. In vitro and oral challenge results in fish-allergic patients. *J Allergy Clin Immunol*, 89(3):730-737.
- Bernhisel-Broadbent, J., Strause, D., Sampson, H. A. (1992). Fish hypersensitivity. II: Clinical relevance of altered fish allergenicity caused by various preparation methods. *J Allergy Clin Immunol*, 90(4 Pt 1):622-629.
- Bush, R.K., Taylor, S.L. and Hefle, S.L. 1995. Seafood allergies. IN: Management of Wilderness and Environmental Emergencies, 3rd edition. Auerbach, P.C. (ed.), Macmillan, New York, pp. 1392-1 398.
- Hamada, Y., Tanaka, H., Ishizaki, S., Ishida, M,, Nagashima, Y., Shiomi, K. (2003). Purification, reactivity with IgE and cDNA cloning of parvalbumin as the major allergen of mackerels. *Food Chem Toxicol*, 41(8):1149-1156.
- Hansen, T. K., Bindslev-Jensen, C., Skov, P. S., Poulsen, L. K. (1997). Codfish allergy in adults: IgE cross-reactivity among fish species. *Ann Allergy Asthma Immunol*, 78(2):187-194.
- Helbling, A., Haydel, R. Jr., McCants, M. L., Musmand, J. J., El-Dahr, J., Lehrer, S. B. (1999). Fish allergy: is cross-reactivity among fish species relevant? Double-blind placebo-controlled food challenge studies of fish allergic adults. *Ann Allergy Asthma Immunol*, 83(6 Pt 1):517-523.
- Leung, P. S., Chen, Y. C., Chu, K. H. (1999). Seafood allergy: tropomyosins and beyond. *J Microbiol Immunol Infect*, 32(3):143-154.
- Pascual, C., Esteban, M. M., Crespo, J. F. (1992). Fish Allergy: Evaluation of the importance of cross-reactivity. *J of Pediatrics*, 121(5:2)S29-S34.
- Sampson, H. A. (1999). Food allergy. Part 1: Immunopathogenesis and clinical disorders. J Allergy Clin Immunol, 103(5):717-728.
- Sicherer, S. H., Noone, S. A., Koerner, C. B., Christie, L., Burks, A. W., Sampson, H. A. (2001). Hypoallergenicity and efficacy of an amino acid-based formula in children with cow's milk and multiple food hypersensitivities. J Pediatr, 138:688-693.
- Taylor, S.L., Kabourek, J.L. and Hefle, S.L. Fish allergy: fish and products thereof. 2004. J of Food Science 69 (8): 175-180.
- Wild, L.G. and Lehrer, S.G. Fish and shellfish allergy. 2005. Current Allergy and Asthma Reports 5:74-79

Question 7.

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

Wine Institute seeks a delay to the implementation of these proposals where final regulations would be mandated commencing with wines bottled three years after the date of publication of the final rule.. Such a period of time is necessary to provide an orderly transition to provide industry with the opportunity to prepare, develop the testing protocols, hold clinical trials, and submit the results in the form of exemption petitions to TTB, while also allowing TTB sufficient time to reasonably entertain such petitions.

Many producers hold bottled inventory anywhere from a few weeks to a few years. If lead-times for TTB label approval and packaging procurement are taken into account, some producers — especially the smaller ones—could reasonably request as much as thirty-six months lead time to be able to comply with regulations while minimizing disruption to their operations.

More importantly, Wine Institute particularly wants to avoid the needless costs to industry that would occur if wineries gear up to comply with an early implementation date for 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.

We point out that the Federal Register of December 21, 2006, contained a Food and Drug Administration Final Rule that establishes January 1, 2010, as the uniform compliance date for food labeling regulations that are issued between January 1, 2007, and December 31, 2008.[26] As stated in the FDA's final rule:

> "Use of a uniform compliance date provides for an orderly and economical industry adjustment to new labeling requirements by allowing sufficient lead time to plan for the use of existing label inventories and the development of new labeling materials. This policy serves consumers' interests as well because the cost of multiple short-term label revisions that would otherwise occur would likely be passed on to consumers in the form of higher prices." 71 FR at 76599.

With the added burdens of possible exemption petitions and Certificate of Label Approval applications, we believe that a 3-year time period is reasonable and is consistent with the interests expressed by FDA when it issued its final rule on uniform compliance dates.

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[26] 71 FR 76599; December 21, 2006. Final Rule,m Uniform Compliance Date for Food Labeling Regulations, U.S. Food and Drug Administration.

Thank you for allowing us to submit these comments. We would be glad to respond to any questions these comments may raise.

Respectfully submitted,

Robert P. Koch
President, Wine Institute

WINE INSTITUTE
THE VOICE FOR CALIFORNIA WINE

Bill Nelson
President, WineAmerica

WineAmerica
The National Association of American Wineries

Attachments to
Wine Institute / WineAmerica Comments to
Notice No. 62:

Exhibit A	*The Australia, New Zealand Food Standards Code, Standard 1.2.3: Mandatory Warning and Advisory Statements and Declarations*
Exhibit B	*The EU Food Labeling Directive, 2000/13*
Exhibit C	*Letter from Russell Robbins, Enologist and Manager, Laffort Oenologie, Dated November 30, 2006*

STANDARD 1.2.3

MANDATORY WARNING AND ADVISORY STATEMENTS AND DECLARATIONS

Purpose

This Standard sets out mandatory advisory statements and declarations which must be made in relation to certain foods or foods containing certain substances.

Table of Provisions

Clauses

1 Deleted

2 Mandatory advisory statements and declarations

(1) The label on a package of food listed in column 1 of the Table to this clause must include the advisory statement listed in relation to that food in column 2 of the Table.

(2) Where a food listed in column 1 of the Table to this clause is not required to bear a label pursuant to clause 2 of Standard 1.2.1, the advisory statement listed in relation to that food in column 2 of the Table, must be –

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

Editorial note:

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

Table to clause 2

Column 1	Column 2
Food	**Advisory Statement**
Bee pollen presented as a food, or a food containing bee pollen as an ingredient as defined in Standard 1.2.4	Statement to the effect that the product contains bee pollen which can cause severe allergic reactions
Cereal-based beverages, where these foods contain no more than 2.5% m/m fat and less than 3% m/m protein, or less than 3% m/m protein only.	Statement to the effect that the product is not suitable as a complete milk replacement for children under the age of five years.
Evaporated and dried products made from cereals, where these foods contain no more than 2.5% m/m fat and less than 3% m/m protein, or less than 3% m/m protein only, as reconstituted according to directions for direct consumption.	Statement to the effect that the product is not suitable as a complete milk replacement for children under the age of five years.
Evaporated milks, dried milks and equivalent products made from soy or cereals, where these foods contain no more than 2.5% m/m fat as reconstituted according to directions for direct consumption.	Statement to the effect that the product is not suitable as a complete milk food for children under the age of two years.
Food containing aspartame or aspartame-acesulphame salt	Statement to the effect that the product contains phenylalanine
Food containing quinine	Statement to the effect that the product contains quinine
Food containing guarana or extracts of guarana	Statement to the effect that the product contains caffeine
Foods containing added phytosterol esters	Statements to the effect that – 1. when consuming this product, it should be consumed as part of a healthy diet; 2. this product may not be suitable for children under the age of five years and pregnant or lactating women; and 3. plant sterols do not provide additional benefits when consumed in excess of three grams per day.
Foods containing added tall oil phytosterols	Statements to the effect that – 1. when consuming this product, it should be consumed as part of a healthy diet; 2. this product may not be suitable for children under 5 years and pregnant or lactating women; and 3. plant sterols do not provide additional benefits when consumed in excess of three grams per day.
Kola beverages containing added caffeine, or food containing a kola beverage containing added caffeine as an ingredient as defined in Standard 1.2.4.	Statement to the effect that the product contains caffeine
Milk, and beverages made from soy or cereals, where these foods contain no more than 2.5% m/m fat.	Statement to the effect that the product is not suitable as a complete milk food for children under the age of two years.

Table to clause 2 (continued)

Column 1	Column 2
Food	**Advisory Statement**
Propolis presented as a food, or food containing propolis as an ingredient as defined in Standard 1.2.4.	Statement to the effect that the product contains propolis which can cause severe allergic reactions
Unpasteurised egg products	Statement to the effect that the product is unpasteurised
Unpasteurised milk and unpasteurised liquid milk products	Statement to the effect that the product has not been pasteurised

Editorial note:

'Milk' is defined in Standard 2.5.1. – 'dried milks' and 'evaporated milks' are defined in Standard 2.5.7.

The term 'reconstituted' in the Table to clause 2 means, in relation to evaporated milks and dried milks, reconstituted to the original level of hydration.

Aspartame-acesulphame salt (INS 962) is specified in the Table to clause 2 because it is a food additive which is distinct from mixtures of aspartame and acesulphame K.

3 Mandatory warning statements and declarations

(1) The label on a package of food listed in column 1 of the Table to this clause must include the warning statement listed in relation to that food in column 2 of the Table.

(2) Where a food listed in column 1 of the Table to this clause, is not required to bear a label pursuant to clause 2 of Standard 1.2.1, the warning statement listed in relation to that food in column 2 of the Table, must be displayed on or in connection with the display of the food.

Table to clause 3

Column 1	Column 2
Food	**Warning Statement**
Royal jelly when presented as a food; or Food containing royal jelly as an ingredient as defined in Standard 1.2.4	This product contains royal jelly which has been reported to cause severe allergic reactions and in rare cases, fatalities, especially in asthma and allergy sufferers

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) The presence of the substances listed in the Table to this clause must be –

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

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

Editorial note:

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

Table to clause 4

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

Editorial note:

1. Clause 4 can be complied with by listing those substances in the Table in the ingredient list.

2. Any exemptions in relation to ingredient listing do not override the requirement to declare the presence of the substances listed in the Table to clause 4.

3. Manufacturers occasionally substitute one ingredient for another within the same class of foods. Where this involves a substance listed in the Table to clause 4 there must be an indication on the label that the substance is in the food. Manufacturers may indicate in the ingredient list that the product contains one substance or another (e.g. brazil nuts or cashew nuts) in cases where substitutions occur regularly.

4. Expressions such as 'egg and egg product' or 'crustacea and their products' include all products derived from the substance listed in the Table to clause 4.

5. Sulphites should be declared in the same manner as other food additives.

6. Coconut is the fruit of the palm (*Cocos nucifera*) and is not generally considered to be a tree nut.

5 Advisory statement in relation to foods containing polyols or polydextrose

(1) The label on a package of food must include an advisory statement to the effect that excess consumption of the food may have a laxative effect, where the food contains any of the substances –

(a) listed in Table 1 to this clause, either singularly or in combination at a level of or in excess of 10 g/100 g; or
(b) listed in Table 2 to this clause, either singularly or in combination at a level of or in excess of 25 g/100 g; or
(c) listed in Table 1 in combination with any of the substances listed in Table 2 at a level of or in excess of 10 g/100 g.

(2) Where food containing any of the substances referred to in subclause (1) is not required to bear a label pursuant to clause 2 of Standard 1.2.1, an advisory statement to the effect that excess consumption of the food may have a laxative effect, must be –

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

Editorial note:

Paragraph 5(2)(b) allows the retailer of a food to provide the information specified in the Table to clause 2 verbally or in writing.

Table 1 to clause 5

Substance
Lactitol
Maltitol
Maltitol syrup
Mannitol
Xylitol

Table 2 to clause 5

Substance
Erythritol
Isomalt
Polydextrose
Sorbitol

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►B 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)

Amended by:

		Official Journal		
		No	page	date
►M1	Commission Directive 2001/101/EC of 26 November 2001	L 310	19	28.11.2001
►M2	Directive 2003/89/EC of the European Parliament and of the Council of 10 November 2003	L 308	15	25.11.2003

Amended by:

►A1	Act concerning the conditions of accession of the Czech Republic, the Republic of Estonia, the Republic of Cyprus, the Republic of Latvia, the Republic of Lithuania, the Republic of Hungary, the Republic of Malta, the Republic of Poland, the Republic of Slovenia and the Slovak Republic and the adjustments to the Treaties on which the European Union is founded	L 236	33	23.9.2003

Corrected by:

►C1 Corrigendum, OJ L 124, 25.5.2000, p. 66 (2000/13/EC)

▼B

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

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 95 thereof,

Having regard to the proposal of the Commission,

Having regard to the opinion of the Economic and Social Committee ([1]),

Acting in accordance with the procedure laid down in Article 251 of the Treaty ([2]),

Whereas:

(1) Council Directive 79/112/EEC of 18 December 1978 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs ([3]) has been frequently and substantially amended ([4]). Therefore, for reasons of clarity and rationality, the said Directive should be consolidated in a single text.

(2) Differences between the laws, regulations and administrative provisions of the Member States on the labelling of foodstuffs may impede the free circulation of these products and can lead to unequal conditions of competition.

(3) Therefore, approximation of these laws would contribute to the smooth functioning of the internal market.

(4) The purpose of this Directive should be to enact Community rules of a general nature applicable horizontally to all foodstuffs put on the market.

(5) Rules of a specific nature which apply vertically only to particular foodstuffs should be laid down in provisions dealing with those products.

(6) The prime consideration for any rules on the labelling of foodstuffs should be the need to inform and protect the consumer.

(7) That need means that Member States may, in compliance with the rules of the Treaty, impose language requirements.

(8) Detailed labelling, in particular giving the exact nature and characteristics of the product which enables the consumer to make his choice in full knowledge of the facts, is the most appropriate since it creates fewest obstacles to free trade.

(9) Therefore, a list should be drawn up of all information which should in principle be included in the labelling of all foodstuffs.

(10) However, the horizontal nature of this Directive does not allow, at the initial stage, the inclusion in the compulsory indications of all the indications which must be added to the list applying in principle to the whole range of foodstuffs. During a later stage, Community provisions should be adopted, aimed at supplementing the existing rules.

([1]) OJ C 258, 10.9.1999, p. 12.
([2]) Opinion of the European Parliament of 18 January 2000 (not yet published in the Official Journal) and Council Decision of 13 March 2000.
([3]) OJ L 33, 8.2.1979, p. 1. Directive as last amended by Directive 97/4/EC of the European Parliament and of the Council (OJ L 43, 14.2.1997, p. 21).
([4]) See Annex IV, Part B.

▼B

(11) Furthermore, in the absence of Community rules of a specific nature Member States should retain the right to lay down certain national provisions which may be added to the general provisions of this Directive, nevertheless these provisions should be subject to a Community procedure.

(12) The said Community procedure must be that of a Community decision when a Member State wishes to enact new legislation.

(13) Provision should also be made for the Community legislator to derogate, in exceptional cases, from certain obligations that have been fixed generally.

(14) The rules on labelling should also prohibit the use of information that would mislead the purchaser or attribute medicinal properties to foodstuffs. To be effective, this prohibition should also apply to the presentation and advertising of foodstuffs.

(15) With a view to facilitating trade between Member States, it may be provided that, at stages prior to sale to the ultimate consumer, only information on the essential elements should appear on the outer packaging and certain mandatory particulars that must appear on a prepackaged foodstuff need appear only on commercial documents referring thereto.

(16) Member States should retain the right, depending on local practical conditions and circumstances, to lay down rules in respect of the labelling of foodstuffs sold in bulk; in such cases, information should nevertheless be provided for the consumer.

(17) With the aim of simplifying and accelerating the procedure, the Commission should be entrusted with the task of adopting implementing measures of a technical nature.

(18) The measures necessary for the implementing of this Directive should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission ([1]).

(19) This Directive should be without prejudice to the obligations of the Member States concerning the time limits for transposition of the Directives set out in Annex IV, Part B,

HAVE ADOPTED THIS DIRECTIVE:

Article 1

1. This Directive concerns the labelling of foodstuffs to be delivered as such to the ultimate consumer and certain aspects relating to the presentation and advertising thereof.

2. This Directive shall apply also to foodstuffs intended for supply to restaurants, hospitals, canteens and other similar mass caterers (hereinafter referred to as ‘mass caterers’).

3. For the purpose of this Directive,

(a) ‘labelling’ shall mean any words, particulars, trade marks, brand name, pictorial matter or symbol relating to a foodstuff and placed on any packaging, document, notice, label, ring or collar accompanying or referring to such foodstuff;

(b) ‘pre-packaged foodstuff’ shall mean any single item for presentation as such to the ultimate consumer and to mass caterers, consisting of a foodstuff and the packaging into which it was put before being offered for sale, whether such packaging encloses the foodstuff completely or only partially, but in any case in such a way that the contents cannot be altered without opening or changing the packaging.

([1]) OJ L 184, 17.7.1999, p. 23.

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Article 2

1. The labelling and methods used must not:

(a) be such as could mislead the purchaser to a material degree, particularly:

(i) as to the characteristics of the foodstuff and, in particular, as to its nature, identity, properties, composition, quantity, durability, origin or provenance, method of manufacture or production;

(ii) by attributing to the foodstuff effects or properties which it does not possess;

(iii) by suggesting that the foodstuff possesses special characteristics when in fact all similar foodstuffs possess such characteristics;

(b) subject to Community provisions applicable to natural mineral waters and foodstuffs for particular nutritional uses, attribute to any foodstuff the property of preventing, treating or curing a human disease, or refer to such properties.

2. The Council, in accordance with the procedure laid down in Article 95 of the Treaty, shall draw up a non-exhaustive list of the claims within the meaning of paragraph 1, the use of which must at all events be prohibited or restricted.

3. The prohibitions or restrictions referred to in paragraphs 1 and 2 shall also apply to:

(a) the presentation of foodstuffs, in particular their shape, appearance or packaging, the packaging materials used, the way in which they are arranged and the setting in which they are displayed;

(b) advertising.

Article 3

1. In accordance with Articles 4 to 17 and subject to the exceptions contained therein, indication of the following particulars alone shall be compulsory on the labelling of foodstuffs:

(1) the name under which the product is sold;

(2) the list of ingredients;

(3) the quantity of certain ingredients or categories of ingredients as provided for in Article 7;

(4) in the case of prepackaged foodstuffs, the net quantity;

(5) the date of minimum durability or, in the case of foodstuffs which, from the microbiological point of view, are highly perishable, the ‘use by’ date;

(6) any special storage conditions or conditions of use;

(7) the name or business name and address of the manufacturer or packager, or of a seller established within the Community.

However, the Member States shall be authorised, in respect of butter produced in their territory, to require only an indication of the manufacturer, packager or seller.

Without prejudice to the notification provided for in Article 24, Member States shall inform the Commission and the other Member States of any measure taken pursuant to the second paragraph;

(8) particulars of the place of origin or provenance where failure to give such particulars might mislead the consumer to a material degree as to the true origin or provenance of the foodstuff;

(9) instructions for use when it would be impossible to make appropriate use of the foodstuff in the absence of such instructions;

(10) with respect to beverages containing more than 1,2 % by volume of alcohol, the actual alcoholic strength by volume.

▼B

2. Notwithstanding the previous paragraph, Member States may retain national provisions which require indication of the factory or packaging centre, in respect of home production.

3. The provisions of this Article shall be without prejudice to more precise or more extensive provisions regarding weights and measures.

Article 4

1. Community provisions applicable to specified foodstuffs and not to foodstuffs in general may provide for derogations, in exceptional cases, from the requirements laid down in Article 3(1), points 2 and 5, provided that this does not result in the purchaser being inadequately informed.

2. Community provisions applicable to specified foodstuffs and not to foodstuffs in general may provide that other particulars in addition to those listed in Article 3 must appear on the labelling.

Where there are no Community provisions, Member States may make provision for such particulars in accordance with the procedure laid down in Article 19.

3. The Community provisions referred to in paragraphs 1 and 2 shall be adopted in accordance with the procedure laid down in Article 20(2).

Article 5

1. The name under which a foodstuff is sold shall be the name provided for in the Community provisions applicable to it.

(a) In the absence of Community provisions, the name under which a product is sold shall be the name provided for in the laws, regulations and administrative provisions applicable in the Member State in which the product is sold to the final consumer or to mass caterers.

Failing this, the name under which a product is sold shall be the name customary in the Member State in which it is sold to the final consumer or to mass caterers, or a description of the foodstuff, and if necessary of its use, which is clear enough to let the purchaser know its true nature and distinguish it from other products with which it might be confused.

(b) The use in the Member State of marketing of the sales name under which the product is legally manufactured and marketed in the Member State of production shall also be allowed.

However, where the application of the other provisions of this Directive, in particular those set out in Article 3, would not enable consumers in the Member State of marketing to know the true nature of the foodstuff and to distinguish it from foodstuffs with which they could confuse it, the sales name shall be accompanied by other descriptive information which shall appear in proximity to the sales name.

(c) In exceptional cases, the sales name of the Member State of production shall not be used in the Member State of marketing when the foodstuff which it designates is so different, as regards its composition or manufacture, from the foodstuff known under that name that the provisions of point (b) are not sufficient to ensure, in the Member State of marketing, correct information for consumers.

2. No trade mark, brand name or fancy name may be substituted for the name under which the product is sold.

3. The name under which the product is sold shall include or be accompanied by particulars as to the physical condition of the foodstuff or the specific treatment which it has undergone (e.g. powdered, freeze-dried, deep-frozen, concentrated, smoked) in all cases where omission of such information could create confusion in the mind of the purchaser.

▼B

Any foodstuff which has been treated with ionising radiation must bear one of the following indications:

▼A1

— in Spanish:
‘irradiado’ or ‘tratado con radiación ionizante’,
— in Czech:
‘ozářeno’ or ‘ošetřeno ionizujícím zářením’,
— in Danish:
‘bestrålet/…’ or ‘strålekonserveret’ or ‘behandlet med ioniserende stråling’ or ‘konserveret med ioniserende stråling’,
— in German:
‘bestrahlt’ or ‘mit ionisierenden Strahlen behandelt’,
— in Estonian:
‘kiiritatud’ or ‘töödeldud ioniseeriva kiirgusega’,
— in Greek:
‘επεξεργασμένο με ιονίζουσα ακτινοβολία’or ‘ακτινοβολημένο’,
— in English:
‘irradiated’ or ‘treated with ionising radiation’,
— in French:
‘traité par rayonnements ionisants’ or ‘traité par ionisation’,
— in Italian:
‘irradiato’ or ‘trattato con radiazioni ionizzanti’,
— in Latvian:
‘apstarots’ or ‘apstrādāts ar jonizējošo starojumu’,
— in Lithuanian:
‘apšvitinta’ or ‘apdorota jonizuojančiąja spinduliuote’,
— in Hungarian:
‘sugárkezelt vagy ionizáló energiával kezelt’,
— in Maltese:
‘ittrattat bir-radjazzjoni’ or ‘ittrattat b'radjazzjoni jonizzanti’,
— in Dutch:
‘doorstraald’ or ‘door bestraling behandeld’ oder ‘met ioniserende stralen behandeld’,
— in Polish:
‘napromieniony’ or ‘poddany działaniu promieniowania jonizującego’,
— in Portuguese:
‘irradiado’ or ‘tratado por irradiação’ or ‘tratado por radiação ionizante’,
— in Slovak:
‘ošetrené ionizujúcim žiarením’,
— in Slovenian:
‘obsevano’ or ‘obdelano z ionizirajočim sevanjem’,
— in Finnish:
‘säteilytetty’ or ‘käsitelty ionisoivalla säteilyllä’,
— in Swedish:
‘bestrålad’ or ‘behandlad med joniserande strålning’.

▼B

Article 6

▼M2

1. Ingredients shall be listed in accordance with this Article and Annexes I, II, III and IIIa.

▼B

2. Ingredients need not be listed in the case of:

(a) — fresh fruit and vegetables, including potatoes, which have not been peeled, cut or similarly treated,

▼B

— carbonated water, the description of which indicates that it has been carbonated,

— fermentation vinegars derived exclusively from a single basic product, provided that no other ingredient has been added;

(b) — cheese,

— butter,

— fermented milk and cream,

provided that no ingredient has been added other than lactic products, enzymes and micro-organism cultures essential to manufacture, or the salt needed for the manufacture of cheese other than fresh cheese and processed cheese;

(c) products comprising a single ingredient, where:

— the trade name is identical with the ingredient name, or

— the trade name enables the nature of the ingredient to be clearly identified.

3. In the case of beverages containing more than 1,2 % by volume of alcohol, the Council, acting on a proposal from the Commission, shall, before 22 December 1982, determine the rules for labelling ingredients.

▼M2

3a. Without prejudice to the rules for labelling to be established pursuant to paragraph 3, any ingredient, as defined in paragraph 4(a) and listed in Annex IIIa, shall be indicated on the labelling where it is present in beverages referred to in paragraph 3. This indication shall comprise the word 'contains' followed by the name of the ingredient(s) concerned. However, an indication is not necessary when the ingredient is already included under its specific name in the list of ingredients or in the name under which the beverage is sold.

Where necessary, detailed rules for the presentation of the indication referred to in the first subparagraph may be adopted in accordance with the following procedures:

(a) as regards the products referred to in Article 1(2) of Council Regulation (EC) No 1493/99 of 17 May 1999 on the common organisation of the market in wine [1], under the procedure laid down in Article 75 of that Regulation;

(b) as regards the products referred to in Article 2(1) of Council Regulation (EEC) No 1601/91 of 10 June 1991 laying down general rules on the definition, description and presentation of aromatised wines, aromatised wine-based drinks and aromatised wine-product cocktails [2], under the procedure laid down in Article 13 of that Regulation;

(c) as regards the products referred to in Article 1(2) of Council Regulation (EEC) No 1576/89 of 29 May 1989 laying down general rules on the definition, description and presentation of spirit drinks [3], under the procedure laid down in Article 14 of that Regulation;

(d) as regards other products, under the procedure laid down in Article 20(2) of this Directive.

▼B

4. (a) 'Ingredient' shall mean any substance, including additives, used in the manufacture or preparation of a foodstuff and still present in the finished product, even if in altered form.

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[1] OJ L 179, 14.7.1999, p. 1. Regulation as last amended by Commission Regulation (EC) No 1795/2003 (OJ L 262, 14.10.2003, p. 13).

[2] OJ L 149, 14.6.1991, p. 1. Regulation as last amended by Regulation (EC) No 2061/96 of the European Parliament and of the Council (OJ L 277, 30.10.1996, p. 1).

[3] OJ L 160, 12.6.1989, p. 1. Regulation as last amended by Regulation (EC) No 3378/94 of the European Parliament and of the Council (OJ L 366, 31.12.1994, p. 1).

▼B

(b) Where an ingredient of the foodstuff is itself the product of several ingredients, the latter shall be regarded as ingredients of the foodstuff in question.

(c) The following shall not be regarded as ingredients:

(i) the constituents of an ingredient which have been temporarily separated during the manufacturing process and later reintroduced but not in excess of their original proportions;

(ii) additives:

— whose presence in a given foodstuff is solely due to the fact that they were contained in one or more ingredients of that foodstuff, provided that they serve no technological function in the finished product,

— which are used as processing aids;

(iii) substances used in the quantities strictly necessary as solvents or media for additives or flavouring;

▼M2

(iv) substances which are not additives but are used in the same way and with the same purpose as processing aids and are still present in the finished product, even if in altered form.

▼B

(d) In certain cases Decisions may be taken in accordance with the procedure laid down in Article 20(2) as to whether the conditions described in point (c)(ii) and (iii) are satisfied.

5. The list of ingredients shall include all the ingredients of the foodstuff, in descending order of weight, as recorded at the time of their use in the manufacture of the foodstuff. It shall appear preceded by a suitable heading which includes the word ‘ingredients’.

However:

— added water and volatile products shall be listed in order of their weight in the finished product; the amount of water added as an ingredient in a foodstuff shall be calculated by deducting from the total amount of the finished product the total amount of the other ingredients used. This amount need not be taken into consideration if it does not exceed 5 % by weight of the finished product,

— ingredients used in concentrated or dehydrated form and reconstituted at the time of manufacture may be listed in order of weight as recorded before their concentration or dehydration,

— in the case of concentrated or dehydrated foods which are intended to be reconstituted by the addition of water, the ingredients may be listed in order of proportion in the reconstituted product provided that the list of ingredients is accompanied by an expression such as ‘ingredients of the reconstituted product’, or ‘ingredients of the ready-to-use product’,

▼M2

— where fruit, vegetables or mushrooms, none of which significantly predominates in terms of weight and which are used in proportions that are likely to vary, are used in a mixture as ingredients of a foodstuff, they may be grouped together in the list of ingredients under the designation ‘fruit’, ‘vegetables’ or ‘mushrooms’ followed by the phrase ‘in varying proportions’, immediately followed by a list of the fruit, vegetables or mushrooms present; in such cases, the mixture shall be included in the list of ingredients in accordance with the first subparagraph, on the basis of the total weight of the fruit, vegetables or mushrooms present,

▼B

— in the case of mixtures of spices or herbs, where none significantly predominates in proportion by weight, those ingredients may be listed in another order provided that that list of ingredients is accompanied by an expression such as ‘in variable proportion’,

▼M2

— ingredients constituting less than 2 % of the finished product may be listed in a different order after the other ingredients,

— where ingredients which are similar or mutually substitutable are likely to be used in the manufacture or preparation of a foodstuff

▼M2

without altering its composition, its nature or its perceived value, and in so far as they constitute less than 2 % of the finished product, they may be referred to in the list of ingredients by means of the phrase 'contains … and/or …', where at least one of no more than two ingredients is present in the finished product. This provision shall not apply to additives or to ingredients listed in Annex IIIa.

▼B

6. Ingredients shall be designated by their specific name, where applicable, in accordance with the rules laid down in Article 5.

However:

— ingredients which belong to one of the categories listed in Annex I and are constituents of another foodstuff need only be designated by the name of that category.

Alterations to the list of categories in Annex I may be effected in accordance with the procedure laid down in Article 20(2).

However, the designation 'starch' listed in Annex I must always be complemented by the indication of its specific vegetable origin, when that ingredient may contain gluten,

— ingredients belonging to one of the categories listed in Annex II must be designated by the name of that category, followed by their specific name or EC number; if an ingredient belongs to more than one of the categories, the category appropriate to the principal function in the case of the foodstuff in question shall be indicated.

Amendments to this Annex based on advances in scientific and technical knowledge shall be adopted in accordance with the procedure laid down in Article 20(2).

However, the designation 'modified starch' listed in Annex II must always be complemented by the indication of its specific vegetable origin, when that ingredient may contain gluten,

— flavourings shall be designated in accordance with Annex III,

— the specific Community provisions governing the indication of treatment of an ingredient with ionising radiation shall be adopted subsequently in accordance with Article 95 of the Treaty.

7. Community provisions or, where there are none, national provisions may lay down that the name under which a specific foodstuff is sold is to be accompanied by mention of a particular ingredient or ingredients.

The procedure laid down in Article 19 shall apply to any such national provisions.

The Community provisions referred to in this paragraph shall be adopted in accordance with the procedure laid down in Article 20(2).

8. In the case referred to in paragraph 4(b), a compound ingredient may be included in the list of ingredients, under its own designation in so far as this is laid down by law or established by custom, in terms of its overall weight, provided that it is immediately followed by a list of its ingredients.

▼M2

The list referred to in the first subparagraph shall not be compulsory:

(a) where the composition of the compound ingredient is defined in current Community legislation, and in so far as the compound ingredient constitutes less than 2 % of the finished product; however, this provision shall not apply to additives, subject to paragraph 4(c),

(b) for compound ingredients consisting of mixtures of spices and/or herbs that constitute less than 2 % of the finished product, with the exception of additives, subject to paragraph 4(c),

(c) where the compound ingredient is a foodstuff for which a list of ingredients is not required under Community legislation.

▼B

9. Notwithstanding paragraph 5 the water content need not be specified:

(a) where the water is used during the manufacturing process solely for the reconstitution of an ingredient used in concentrated or dehydrated form;

(b) in the case of a liquid medium which is not normally consumed.

▼M2

10. Notwithstanding paragraph 2, the second subparagraph of paragraph 6 and the second subparagraph of paragraph 8, any ingredient used in production of a foodstuff and still present in the finished product, even if in altered form, and listed in Annex IIIa or originating from an ingredient listed in Annex IIIa shall be indicated on the label with a clear reference to the name of this ingredient.

The indication referred to in the first subparagraph shall not be required if the name under which the foodstuff is sold clearly refers to the ingredient concerned.

Notwithstanding paragraph 4(c)(ii), (iii) and (iv), any substance used in production of a foodstuff and still present in the finished product, even if in altered form, and originating from ingredients listed in Annex IIIa shall be considered as an ingredient and shall be indicated on the label with a clear reference to the name of the ingredient from which it originates.

11. The list in Annex IIIa shall be systematically re-examined and, where necessary, updated on the basis of the most recent scientific knowledge. The first re-examination shall take place at the latest on 25 November 2005.

Updating could also be effected by the deletion from Annex IIIa of ingredients for which it has been scientifically established that it is not possible for them to cause adverse reactions. To this end, the Commission may be notified until 25 August 2004 of the studies currently being conducted to establish whether ingredients or substances, derived from ingredients listed in Annex IIIa are not likely, under specific circumstances, to trigger adverse reactions. The Commission shall, not later than 25 November 2004, after consultation with the European Food Safety Authority, adopt a list of those ingredients or substances, which shall consequently be excluded from Annex IIIa, pending the final results of the notified studies, or at the latest until 25 November 2007.

Without prejudice to the second subparagraph, Annex IIIa may be amended, in compliance with the procedure referred to in Article 20(2), after an opinion has been obtained from the European Food Safety Authority issued on the basis of Article 29 of Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002, laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety ([1]).

Where necessary, technical guidelines may be issued for the interpretation of the list in Annex IIIa, in compliance with the procedure referred to in Article 20(2).

▼B

Article 7

1. The quantity of an ingredient or category of ingredients used in the manufacture or preparation of a foodstuff shall be stated in accordance with this Article.

([1]) OJ L 31, 1.2.2002, p. 1. Regulation as amended by Regulation (EC) No 1642/2003 (OJ L 245, 29.9.2003, p. 4).

▼B

2. The indication referred to in paragraph 1 shall be compulsory:

(a) where the ingredient or category of ingredients concerned appears in the name under which the foodstuff is sold or is usually associated with that name by the consumer; or

(b) where the ingredient or category of ingredients concerned is emphasised on the labelling in words, pictures or graphics; or

(c) where the ingredient or category of ingredients concerned is essential to characterise a foodstuff and to distinguish it from products with which it might be confused because of its name or appearance; or

(d) in the cases determined in accordance with the procedure laid down in Article 20(2).

3. Paragraph 2 shall not apply:

(a) to an ingredient or category of ingredients:

— the drained net weight of which is indicated in accordance with Article 8(4), or

— the quantities of which are already required to be given on the labelling under Community provisions, or

— which is used in small quantities for the purposes of flavouring, or

— which, while appearing in the name under which the food is sold, is not such as to govern the choice of the consumer in the country of marketing because the variation in quantity is not essential to characterise the foodstuff or does not distinguish it from similar foods. In cases of doubt it shall be decided by the procedure laid down in Article 20(2) whether the conditions laid down in this indent are fulfilled;

(b) where specific Community provisions stipulate precisely the quantity of an ingredient or of a category of ingredients without providing for the indication thereof on the labelling;

(c) in the cases referred to in the fourth and fifth indents of Article 6(5);

(d) in the cases determined in accordance with the procedure laid down in Article 20(2).

4. The quantity indicated, expressed as a percentage, shall correspond to the quantity of the ingredient or ingredients at the time of its/their use. However, Community provisions may allow for derogations from this principle for certain foodstuffs. Such provisions shall be adopted in accordance with the procedure laid down in Article 20(2).

5. The indication referred to in paragraph 1 shall appear either in or immediately next to the name under which the foodstuff is sold or in the list of ingredients in connection with the ingredient or category of ingredients in question.

6. This Article shall apply without prejudice to Community rules on nutrition labelling for foodstuffs.

Article 8

1. The net quantity of prepackaged foodstuffs shall be expressed:

— in units of volume in the case of liquids,

— in units of mass in the case of other products,

using the litre, centilitre, millilitre, kilogram or gram, as appropriate.

Community provisions or, where there are none, national provisions applicable to certain specified foodstuffs may derogate from this rule.

The procedure laid down in Article 19 shall apply to any such national provisions.

2. (a) Where the indication of a certain type of quantity (e.g. nominal quantity, minimum quantity, average quantity) is required by

▼B

Community provisions or, where there are none, by national provisions, this quantity shall be regarded as the net quantity for the purposes of this Directive.

Without prejudice to the notification provided for in Article 24, Member States shall inform the Commission and the other Member States of any measure taken pursuant to this point.

(b) Community provisions or, where there are none, national provisions may, for certain specified foodstuffs classified by quantity in categories, require other indications of quantity.

The procedure laid down in Article 19 shall apply to any such national provisions.

(c) Where a prepackaged item consists of two or more individual prepackaged items containing the same quantity of the same product, the net quantity shall be indicated by mentioning the net quantity contained in each individual package and the total number of such packages. Indication of these particulars shall not, however, be compulsory where the total number of individual packages can be clearly seen and easily counted from the outside and where at least one indication of the net quantity contained in each individual package can be clearly seen from the outside.

(d) Where a prepackaged item consists of two or more individual packages which are not regarded as units of sale, the net quantity shall be given by indicating the total net quantity and the total number of individual packages. Community provisions or, where there are none, national provisions need not, in the case of certain foodstuffs, require indication of the total number of individual packages.

Without prejudice to the notification provided for in Article 24, Member States shall inform the Commission and the other Member States of any measure taken pursuant to this point.

3. In the case of foodstuffs normally sold by number, Member States need not require indication of the net quantity provided that the number of items can clearly be seen and easily counted from the outside or, if not, is indicated on the labelling.

Without prejudice to the notification provided for in Article 24, Member States shall inform the Commission and the other Member States of any measure taken pursuant to this paragraph.

4. Where a solid foodstuff is presented in a liquid medium, the drained net weight of the foodstuff shall also be indicated on the labelling.

For the purposes of this paragraph, 'liquid medium' shall mean the following products, possibly in mixtures and also where frozen or quick-frozen, provided that the liquid is merely an adjunct to the essential elements of that preparation and is thus not a decisive factor for the purchase: water, aqueous solutions of salts, brine, aqueous solutions of food acids, vinegar, aqueous solutions of sugars, aqueous solutions of other sweetening substances, fruit or vegetable juices in the case of fruit or vegetables.

This list may be supplemented in accordance with the procedure laid down in Article 20(2).

Methods of checking the drained net weight shall be determined in accordance with the procedure laid down in Article 20(2).

5. It shall not be compulsory to indicate the net quantity in the case of foodstuffs:

(a) which are subject to considerable losses in their volume or mass and which are sold by number or weighed in the presence of the purchaser;

(b) the net quantity of which is less than 5 g or 5 ml; however, this provision shall not apply to spices and herbs.

▼B

Community provisions or, where there are none, national provisions applicable to specified foodstuffs may in exceptional cases lay down thresholds which are higher than 5 g or 5 ml provided that this does not result in the purchaser being inadequately informed.

Without prejudice to the notification provided for in Article 24, Member States shall inform the Commission and the other Member States of any measure taken pursuant to this paragraph.

6. The Community provisions referred to in paragraphs 1, second subparagraph, 2(b) and (d) and 5, second subparagraph, shall be adopted in accordance with the procedure laid down in Article 20(2).

Article 9

1. The date of minimum durability of a foodstuff shall be the date until which the foodstuff retains its specific properties when properly stored.

It shall be indicated in accordance with paragraphs 2 to 5.

2. The date shall be preceded by the words:

— 'Best before …' when the date includes an indication of the day,

— 'Best before end …' in other cases.

3. The words referred to in paragraph 2 shall be accompanied by:

— either the date itself, or

— a reference to where the date is given on the labelling.

If need be, these particulars shall be followed by a description of the storage conditions which must be observed if the product is to keep for the specified period.

4. The date shall consist of the day, month and year in uncoded chronological form.

However, in the case of foodstuffs:

— which will not keep for more than three months, an indication of the day and the month will suffice,

— which will keep for more than three months but not more than 18 months, an indication of the month and year will suffice,

— which will keep for more than 18 months, an indication of the year will suffice.

The manner of indicating the date may be specified according to the procedure laid down in Article 20(2).

5. Subject to Community provisions imposing other types of date indication, an indication of the durability date shall not be required for:

— fresh fruit and vegetables, including potatoes, which have not been peeled, cut or similarly treated. This derogation shall not apply to sprouting seeds and similar products such as legume sprouts,

— wines, liqueur wines, sparkling wines, aromatised wines and similar products obtained from fruits other than grapes, and beverages falling within CN codes 2206 00 91, 2206 00 93 and 2206 00 99 and manufactured from grapes or grape musts,

— beverages containing 10 % or more by volume of alcohol,

— soft drinks, fruit juices, fruit nectars and alcoholic beverages in individual containers of more than five litres, intended for supply to mass caterers,

— bakers' or pastry cooks' wares which, given the nature of their content, are normally consumed within 24 hours of their manufacture,

— vinegar,

— cooking salt,

— solid sugar,

— confectionery products consisting almost solely of flavoured and/or coloured sugars,

— chewing gums and similar chewing products,

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— individual portions of ice-cream.

Article 10

1. In the case of foodstuffs which, from the microbiological point of view, are highly perishable and are therefore likely after a short period to constitute an immediate danger to human health, the date of minimum durability shall be replaced by the 'use by' date.

2. The date shall be preceded by the words:

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— in Spanish:
'fecha de caducidad',
— in Czech:
'spotřebujte do',
— in Danish:
'sidste anvendelsesdato',
— in German:
'verbrauchen bis',
— in Estonian:
'kõlblik kuni',
— in Greek:
'ανάλωση μέχρι'
— in English:
'use by',
— in French:
'à consommer jusqu'au',
— in Italian:
'da consumare entro',
— in Latvian:
'izlietot līdz',
— in Lithuanian:
'tinka vartoti iki',
— in Hungarian:
'fogyasztható',
— in Maltese:
'uża sa',
— in Dutch:
'te gebruiken tot',
— in Polish:
'należy spożyć do',
— in Portuguese:
'a consumir até',
— in Slovak:
'spotrebujte do',
— in Slovenian:
'porabiti do',
— in Finnish:
'viimeinen käyttöajankohta',
— in Swedish:
'sista förbrukningsdag'.

▼B

These words shall be accompanied by:

— either the date itself, or

— a reference to where the date is given on the labelling.

These particulars shall be followed by a description of the storage conditions which must be observed.

3. The date shall consist of the day, the month and, possibly, the year, in that order and in uncoded form.

4. In some cases it may be decided by the procedure laid down in Article 20(2) whether the conditions laid down in paragraph 1 are fulfilled.

▼B

Article 11

1. The instructions for use of a foodstuff shall be indicated in such a way as to enable appropriate use to be made thereof.

2. Community provisions or, where there are none, national provisions may, in the case of certain foodstuffs, specify the way in which the instructions for use should be indicated.

The procedure laid down in Article 19 shall apply to such national provisions.

The Community provisions referred to in this paragraph shall be adopted in accordance with the procedure laid down in Article 20(2).

Article 12

The rules concerning indication of the alcoholic strength by volume shall, in the case of products covered by tariff heading Nos 22.04 and 22.05, be those laid down in the specific Community provisions applicable to such products.

In the case of other beverages containing more than 1,2 % by volume of alcohol, these rules shall be laid down in accordance with the procedure provided for in Article 20(2).

Article 13

1. (a) When the foodstuffs are prepackaged, the particulars provided for in Articles 3 and 4(2) shall appear on the prepackaging or on a label attached thereto.

   (b) Notwithstanding point (a) and without prejudice to Community provisions on nominal quantities, where prepackaged foodstuffs are:

   — intended for the ultimate consumer but marketed at a stage prior to sale to the ultimate consumer and where sale to a mass caterer is not involved at that stage,

   — intended for supply to mass caterers for preparation, processing, splitting or cutting up,

   the particulars required under Articles 3 and 4(2) need appear only on the commercial documents referring to the foodstuffs where it can be guaranteed that such documents, containing all the labelling information, either accompany the foodstuffs to which they refer or were sent before or at the same time as delivery.

   (c) In the case referred to in point (b), the particulars referred to in Article 3(1) point 1, 5 and 7 and, where appropriate, that referred to in Article 10, shall also appear on the external packaging in which the foodstuffs are presented for marketing.

2. The particulars mentioned in Article 3 and Article 4(2) shall be easy to understand and marked in a conspicuous place in such a way as to be easily visible, clearly legible and indelible.

They shall not in any way be hidden, obscured or interrupted by other written or pictorial matter.

3. The particulars listed in Article 3(1), points 1, 4, 5 and 10 shall appear in the same field of vision.

This requirement may be extended to the particulars provided for in Article 4(2).

4. In the case of the glass bottles intended for reuse which are indelibly marked and which therefore bear no label, ring or collar and packaging or containers the largest surface of which has an area of less than 10 cm^2 only the particulars listed in Article 3(1) points 1, 4 and 5 need be given.

In this case, paragraph 3 shall not apply.

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5. Ireland, the Netherlands and the United Kingdom may derogate from Article 3(1) and paragraph 3 of this Article in the case of milk and milk products put up in glass bottles intended for reuse.

They shall inform the Commission of any measure taken pursuant to the first subparagraph.

Article 14

Where foodstuffs are offered for sale to the ultimate consumer or to mass caterers without prepackaging, or where foodstuffs are packaged on the sales premises at the consumer's request or prepackaged for direct sale, the Member States shall adopt detailed rules concerning the manner in which the particulars specified in Article 3 and Article 4(2) are to be shown.

They may decide not to require the provision of all or some of these particulars, provided that the purchaser still receives sufficient information.

Article 15

This Directive shall not affect the provisions of national laws which, in the absence of Community provisions, impose less stringent requirements for the labelling of foodstuffs presented in fancy packaging such as figurines or souvenirs.

Article 16

1. Member States shall ensure that the sale is prohibited within their own territories of foodstuffs for which the particulars provided for in Article 3 and Article 4(2) do not appear in a language easily understood by the consumer, unless the consumer is in fact informed by means of other measures determined in accordance with the procedure laid down in Article 20(2) as regards one or more labelling particulars.

2. Within its own territory, the Member State in which the product is marketed may, in accordance with the rules of the Treaty, stipulate that those labelling particulars shall be given in one or more languages which it shall determine from among the official languages of the Community.

3. Paragraphs 1 and 2 shall not preclude the labelling particulars from being indicated in several languages.

Article 17

Member States shall refrain from laying down requirements more detailed than those already contained in Articles 3 to 13 concerning the manner in which the particulars provided for in Article 3 and Article 4(2) are to be shown.

Article 18

1. Member States may not forbid trade in foodstuffs which comply with the rules laid down in this Directive by the application of non-harmonised national provisions governing the labelling and presentation of certain foodstuffs or of foodstuffs in general.

2. Paragraph 1 shall not apply to non-harmonised national provisions justified on grounds of:

— protection of public health,

— prevention of fraud, unless such provisions are liable to impede the application of the definitions and rules laid down by this Directive,

— protection of industrial and commercial property rights, indications of provenance, registered designations of origin and prevention of unfair competition.

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Article 19

Where reference is made to this Article, the following procedure shall apply should a Member State deem it necessary to adopt new legislation.

It shall notify the Commission and the other Member States of the measures envisaged and give the reasons justifying them. The Commission shall consult the Member States within the ►M2 Standing Committee on the Food Chain and Animal Health set up by Regulation (EC) No 178/2002 ◄ if it considers such consultation to be useful or if a Member State so requests.

Member States may take such envisaged measures only three months after such notification and provided that the Commission's opinion is not negative.

In the latter event, and before the expiry of the abovementioned period, the Commission shall initiate the procedure provided for in Article 20(2) in order to determine whether the envisaged measures may be implemented subject, if necessary, to the appropriate modifications.

Article 20

1. The Commission shall be assisted by the ►M2 Standing Committee on the Food Chain and Animal Health ◄ (hereinafter referred to as 'the Committee').

2. Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

The period referred to in Article 5(6) of Decision 1999/468/EC shall be set at three months.

3. The Committee shall adopt its rules of procedure.

Article 21

If temporary measures prove necessary to facilitate the application of this Directive, they shall be adopted in accordance with the procedure provided for in Article 20(2).

Article 22

This Directive shall not affect Community provisions relating to the labelling and presentation of certain foodstuffs already adopted on 22 December 1978.

Any amendments necessary to harmonise such provisions with the rules laid down in this Directive shall be decided in accordance with the procedure applicable to each of the provisions in question.

Article 23

This Directive shall not apply to products for export outside the Community.

Article 24

Member States shall ensure that the Commission receives the text of any essential provision of national law which they adopt in the field governed by this Directive.

Article 25

This Directive shall also apply to the French overseas departments.

Article 26

1. Directive 79/112/EEC as amended by the Directives referred to in Annex IV, Part A, is repealed, without prejudice to the obligations of

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the Member States in respect of the deadlines for transposition laid down in Annex IV, Part B.

2. The reference made to the repealed Directive shall be construed as references to this Directive and should be read in accordance with the correlation table set out in Annex V.

Article 27

This Directive enters into force on the 20th day following its publication in the *Official Journal of the European Communities*.

Article 28

This Directive is addressed to the Member States.

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ANNEX I

CATEGORIES OF INGREDIENTS WHICH MAY BE DESIGNATED BY THE NAME OF THE CATEGORY RATHER THAN THE SPECIFIC NAME

Definition	*Designation*
Refined oils other than olive oil	'Oil', together with — either the adjective 'vegetable' or 'animal', as appropriate, or — an indication of their specific vegetable or animal origin The adjective 'hydrogenated' must accompany the indication of a hydrogenated oil
Refined fats	'Fat', together with — either the adjective 'vegetable' or 'animal', as appropriate, or — an indication of their specific vegetable or animal origin The adjective 'hydrogenated' must accompany the indication of a hydrogenated fat
Mixtures of flour obtained from two or more cereal species	'Flour', followed by a list of the cereals from which it has been obtained, in descending order by weight
Starches, and starches modified by physical means or by enzymes	'Starch'
All species of fish where the fish constitutes an ingredient of another foodstuff and provided that the name and presentation of such foodstuff does not refer to a specific species of fish	'Fish'
All types of cheese where the cheese or mixture of cheeses constitutes an ingredient of another foodstuff and provided that the name and presentation of such foodstuff does not refer to a specific type of cheese	'Cheese'
All spices not exceeding 2 % by weight of the foodstuff	'Spice(s)' or 'mixed spices'
All herbs or parts of herbs not exceeding 2 % by weight of the foodstuff	'Herb(s)' or 'mixed herbs'
All types of gum preparations used in the manufacture of gum base for chewing gum	'Gum base'
All types of crumbed baked cereal products	'Crumbs' or 'rusks' as appropriate
All types of sucrose	'Sugar'
Anhydrous dextrose or dextrose monohydrate	'Dextrose'
Glucose syrup and anhydrous glucose syrup	'Glucose syrup'
All types of milk protein (caseins, caseinates and whey proteins) and mixtures thereof	'Milk proteins'
Press, expeller or refined cocoa butter	'Cocoa butter'

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All types of wine as defined in Council Regulation (EC) No 1493/1999 of 17 May 1999 on the common organisation of the market in wine [1]	'Wine'

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Definition	*Designation*

▼M1

Skeletal muscles (**) of mammalian and bird species recognised as fit for human consumption with naturally included or adherent tissue, where the total fat and connective tissue content does not exceed the values indicated below and where the meat constitutes an ingredient of another foodstuff. The products covered by the Community definiton of 'mechanically recovered meat' are excluded from this definition.

Maximum fat and connective tissue contents for ingredients designated by the term '… meat'.

Species	Fat (%)	Connective tissue (1) (%)
Mammals (other than rabbits and porcines) and mixtures of species with mammals predominating	25	25
Porcines	30	25
Birds and rabbits	15	10

(1) The connective tissue content is calculated on the basis of the ratio between collagen content and meat protein content. The collagen content means the hydroxyproline content multiplied by a factor of 8.

If these maximum limits are exceeded, but all other criteria for the definition of 'meat' are satisfied, the '… meat' content must be adjusted downwards accordingly and the list of ingredients must mention, in addition to the term '… meat', the presence of fat and/or connective tissue.

'… meat' and the name(s) (*) of the animal species from which it comes.

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(1) OJ L 179, 14.7.1999, p. 1.

►M1 (*) For labelling in English, this designation may be replaced by the generic name of the ingredient for the animal species concerned.

(**) The diaphragm and the masseters are part of the skeletal muscles, while the heart, tongue, the muscles of the head (other than the masseters), the muscles of the carpus, the tarsus and the tail are excluded. ◄

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ANNEX II

CATEGORIES OF INGREDIENTS WHICH MUST BE DESIGNATED BY THE NAME OF THEIR CATEGORY FOLLOWED BY THEIR SPECIFIC NAME OR EC NUMBER

Colour
Preservative
Antioxidant
Emulsifier
Thickener
Gelling agent
Stabiliser
Flavour enhancer
Acid
Acidity regulator
Anti-caking agent
Modified starch (1)
Sweetener
Raising agent
Anti-foaming agent
Glazing agent
Emulsifying salts (2)
Flour treatment agent
Firming agent
Humectant
Bulking agent
Propellent gas

(1) The specific name or EC number need not be indicated.
(2) Only for processed cheeses and products based on processed cheeses.

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ANNEX III

Designation of flavourings in the list of ingredients

1. Flavourings shall be designated either by the word 'flavouring(s)' or by a more specific name or description of the flavouring.

2. The word 'natural' or any other word having substantially the same meaning may be used only for flavourings in which the flavouring component contains exclusively flavouring substances as defined in Article 1(2)(b)(i) of Council Directive 88/388/EEC of 22 June 1988 on the approximation of the laws of the Member States relating to flavourings for use in foodstuffs and to source materials for their production ([1]) and/or flavouring preparations as defined in Article 1(2)(c) of the said Directive.

3. If the name of the flavouring contains a reference to the vegetable or animal nature or origin of the incorporated substances, the word 'natural' or any other word having substantially the same meaning may not be used unless the flavouring component has been isolated by appropriate physical processes, enzymatic or microbiological processes or traditional food-preparation processes solely or almost solely from the foodstuff or the flavouring source concerned.

([1]) OJ L 184, 15.7.1988, p. 61. Directive as amended by Commission Directive 91/71/EEC (OJ L 42, 15.2.1991, p. 25).

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ANNEX IIIa

Ingredients referred to in Article 6(3a), (10) and (11)

Cereals containing gluten (i.e. wheat, rye, barley, oats, spelt, kamut or their hybridised strains) 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 products thereof (including lactose)

Nuts i. e. Almond (*Amygdalus communis L.*), Hazelnut (*Corylus avellana*), Walnut (*Juglans regia*), Cashew (*Anacardium occidentale*), Pecan nut (*Carya illinoiesis (Wangenh.) K. Koch*), Brazil nut (*Bertholletia excelsa*), Pistachio nut (*Pistacia vera*), Macadamia nut and Queensland nut (*Macadamia ternifolia*) and products thereof

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/litre expressed as SO_2.

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ANNEX IV

PART A

REPEALED DIRECTIVE AND ITS SUCCESSIVE AMENDMENTS

(referred to by Article 26)

Council Directive 79/112/EEC (OJ L 33, 8.2.1979, p. 1)

Council Directive 85/7/EEC (OJ L 2, 3.1.1985, p. 22), only Article 1(9)

Council Directive 86/197/EEC (OJ L 144, 29.5.1986, p. 38)

Council Directive 89/395/EEC (OJ L 186, 30.6.1989, p. 17)

Commission Directive 91/72/EEC (OJ L 42, 15.2.1991, p. 27)

Commission Directive 93/102/EC (OJ L 291, 25.11.1993, p. 14)

Commission Directive 95/42/EC (OJ L 182, 2.8.1995, p. 20)

European Parliament and Council Directive 97/4/EC (OJ L 43, 14.2.1997, p. 21)

PART B

DEADLINES FOR TRANSPOSITION INTO NATIONAL LAW

(referred to by Article 26)

Directive	Deadline for transposition	Admission of market products according to this Directive	Prohibition of market products not in accordance with this Directive
79/112/EEC		22 December 1980	22 December 1982
85/7/EEC			
86/197/EEC		1 May 1988	1 May 1989
89/395/EEC		20 December 1990	20 June 1992
91/72/EEC		30 June 1992	1 January 1994
93/102/EC	30 December 1994	1 January 1995	30 June 1996
95/42/EC			
97/4/EC		14 August 1998	14 February 2000

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ANNEX V

CORRELATION TABLE

Directive 79/112/EEC	This Directive
Article 1	Article 1
Article 2	Article 2
Article 3(1), point 1	Article 3(1), point 1
Article 3(1), point 2	Article 3(1), point 2
Article 3(1), point 2a	Article 3(1), point 3
Article 3(1), point 3	Article 3(1), point 4
Article 3(1), point 4	Article 3(1), point 5
Article 3(1), point 5	Article 3(1), point 6
Article 3(1), point 6	Article 3(1), point 7
Article 3(1), point 7	Article 3(1), point 8
Article 3(1), point 8	Article 3(1), point 9
Article 3(1), point 9	Article 3(1), point 10
Article 3(2) and (3)	Article 3(2) and (3)
Article 4	Article 4
Article 5	Article 5
Article 6(1), (2) and (3)	Article 6(1), (2) and (3)
Article 6(4)(a) and (b)	Article 6(4)(a) and (b)
Article 6(4)(c)(i)	Article 6(4)(c)(i)
Article 6(4)(c)(ii), first indent	Article 6(4)(c)(ii)
Article 6(4)(c)(ii), second indent	Article 6(4)(c)(iii)
Article 6(4)(d)	Article 6(4)(d)
Article 6(5)(a)	Article 6(5)
Article 6(5)(b)	Article 6(6)
Article 6(6)	Article 6(7)
Article 6(7), first subparagraph	Article 6(8), first subparagraph
Article 6(7), second subparagraph, first and second indents	Article 6(8), second subparagraph, points (a) and (b)
Article 6(8)	Article 6(9)
Article 7	Article 7
Article 8(1) to (5)	Article 8(1) to (5)
Article 8(6)	—
Article 8(7)	Article 8(6)
Article 9(1) to (4)	Article 9(1) to (4)
Article 9(5)	—
Article 9(6)	Article 9(5)
Article 9a	Article 10
Article 10	Article 11
Article 10a	Article 12
Article 11(1) and (2)	Article 13(1) and (2)
Article 11(3)(a)	Article 13(3)
Article 11(3)(b)	—
Article 11(4)	Article 13(4)
Article 11(5)	—
Article 11(6)	Article 13(5), first subparagraph
Article 11(7)	Article 13(5), second subparagraph
Articles 12 and 13	Articles 14 and 15
Article 13a	Article 16
Articles 14 and 15	Articles 17 and 18
Article 16(1)	—
Article 16(2)	Article 19
Article 17, first paragraph	Article 20(1)
Article 17, second, third, fourth and fifth paragraphs	Article 20(2)
Article 18	—
Articles 19, 20 and 21	Articles 21, 22 and 23
Article 22(1), (2) and (3)	—
Article 22(4)	Article 24
Article 23	—

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Directive 79/112/EEC	This Directive
Article 24	Article 25
Article 25	—
Article 26	—
—	Article 26
—	Article 27
—	Article 28
Annex I	Annex I
Annex II	Annex II
Annex III	Annex III
—	Annex IV
—	Annex V

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To: Christopher Wirth
Research & Education
Wine Institute
425 Market Street, Suite 1000
San Francisco, CA 94105

November 30, 2006

Dear Chris

Laffort Oenologie is a producer of high quality purified isinglass for the wine industry. The basic raw material of isinglass are the air bladders of fish. A variety of fish species go into the production of isinglass and the actual species present in any particular isinglass product may vary from time to time according to availability.

Because we purchase the raw material from various sources depending on quality, it is currently not possible to accurately identify which species of fish are found in the final product.

To our knowledge there are no known instances of persons with fish allergies having any reaction to wine treated with insinglass including winemakers that have known sensitivities to fish.

Regards,

Russell Robbins
Enologist and Manager
Laffort Oenologie- North American Operations