

(2) The operator has not observed abnormal propeller vibration or abnormal engine vibration; and

(3) The operator has not observed any other abnormal operation from the engine or propeller; and

(4) The operator has not made earlier reports of abnormal propeller vibration, abnormal engine vibration, or other abnormal engine or propeller operations, that have not been addressed.

#### Related Information

(k) None.

#### Material Incorporated by Reference

(l) You must use McCauley Propeller Systems Alert Service Bulletin ASB252, dated June 6, 2006, to perform the inspections required by this AD. The Director of the Federal Register approved the incorporation by reference of this service bulletin in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Contact McCauley Propeller Systems, 7751 East Pawnee, Wichita, KS 67277, for a copy of this service information. You may review copies at the FAA, New England Region, Office of the Regional Counsel, 12 New England Executive Park, Burlington, MA; or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: <http://www.archives.gov/federal-register/cfr/ibr-locations.html>.

Issued in Burlington, Massachusetts, on July 18, 2006.

**Francis A. Favara,**

*Manager, Engine and Propeller Directorate, Aircraft Certification Service.*

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## DEPARTMENT OF THE TREASURY

### Alcohol and Tobacco Tax and Trade Bureau

#### 27 CFR Parts 4, 5, and 7

[T.D. TTB-53; Re: Notice No. 62]

RIN 1513-AB08

#### Major Food Allergen Labeling for Wines, Distilled Spirits, and Malt Beverages

**AGENCY:** Alcohol and Tobacco Tax and Trade Bureau, Treasury.

**ACTION:** Interim rule; Treasury decision.

**SUMMARY:** This interim rule, which parallels the recent amendments to the Federal Food, Drug and Cosmetic Act contained in the Food Allergen Labeling and Consumer Protection Act of 2004, adopts labeling standards for major food allergens used in the production of alcohol beverages subject to the labeling requirements of the Federal Alcohol Administration Act.

In addition, elsewhere in this issue of the **Federal Register**, we are publishing a notice of proposed rulemaking that proposes to make major food allergen labeling mandatory. That notice solicits comments from the public, including consumers and affected industry members, on the proposed labeling requirements and the time frame for making the requirements mandatory.

Under the interim regulations, producers, bottlers, and importers of wines, distilled spirits, and malt beverages may voluntarily declare the presence of milk, eggs, fish, Crustacean shellfish, tree nuts, wheat, peanuts, and soybeans, as well as ingredients that contain protein derived from these foods, in their products, but are not required to do so. The interim regulations, however, set forth rules that are mandatory for how industry members must undertake such labeling, should they choose to do so. The regulations also contain procedures for petitioning for an exemption from the standards imposed on those alcohol beverage producers who wish to make voluntary allergen statements on their product labels.

**DATES:** *Effective Date:* This interim rule is effective on July 26, 2006.

**FOR FURTHER INFORMATION CONTACT:** Lisa M. Gesser, Regulations and Rulings Division, Alcohol and Tobacco Tax and Trade Bureau, P.O. Box 128, Morganza, MD 20660; telephone (301) 290-1460.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

In recent years, the presence of food allergens in foods has become a matter of public concern. In response, Congress passed the Food Allergen Labeling and Consumer Protection Act of 2004 to require the declaration in labeling of major food allergens in plain, common language on the foods regulated under the Federal Food, Drug and Cosmetic Act. A House of Representatives committee report also noted that the committee expected the Alcohol and Tobacco Tax and Trade Bureau (TTB) to issue regulations on allergen labeling for alcohol beverage products under TTB's existing authority to regulate alcohol beverage labeling, working in cooperation with the Food and Drug Administration (FDA). In addition, TTB had earlier received a petition concerning ingredient and allergen labeling for alcohol beverages. In response, TTB is issuing these interim regulations regarding voluntary labeling of major food allergens used in the production of alcohol beverage products. TTB also is proposing mandatory major food allergen labeling

for alcohol beverage products in a notice of proposed rulemaking published elsewhere in this issue of the **Federal Register**.

##### A. FAA Act

TTB is responsible for the administration of the Federal Alcohol Administration Act, 27 U.S.C. 201 *et seq.*, (FAA Act), which governs, among other things, the labeling of wines containing at least 7 percent alcohol by volume, distilled spirits, and malt beverages in interstate and foreign commerce. These products are generically referred to as "alcohol beverages" or "alcohol beverage products" throughout this document.

In particular, section 105(e) of the FAA Act (27 U.S.C. 205(e)) gives the Secretary of the Treasury authority to issue regulations regarding the labeling of alcohol beverages to provide the consumer with adequate information concerning the identity and quality of such products, to prevent deception of the consumer, and to prohibit false or misleading statements. Section 105(e) also makes it unlawful for industry members "to sell or ship or deliver for sale or shipment, or otherwise introduce in interstate or foreign commerce, or to receive therein, or to remove from customs custody for consumption, any distilled spirits, wine, or malt beverages in bottles, unless such products are bottled, packaged, and labeled in conformity" with regulations prescribed by the Secretary. Regulations setting forth mandatory labeling information requirements for wine, distilled spirits, and malt beverages are contained, respectively, in parts 4, 5, and 7 of the TTB regulations (27 CFR parts 4, 5, and 7).

Most of the mandatory labeling requirements found in parts 4, 5, and 7 flow directly from the stated purpose of section 105(e) of the FAA Act, that is, to "provide the consumer with adequate information as to the identity and quality of the products, the alcoholic content thereof \* \* \*, the net contents of the package, and the manufacturer or bottler or importer of the product." Currently, the TTB labeling regulations contained in parts 4, 5, and 7 require the following information to appear on alcohol beverage labels: Brand name; product identity (class or type); the name and address of the bottler, packer, or importer; the net contents; and the alcohol content of distilled spirits, certain flavored malt beverage products, and wines over 14 percent alcohol by volume. Labels for wines with 14 percent alcohol by volume or less may contain either an alcohol content statement or the type designation

“table” wine or “light” wine (see 27 CFR part 4.36(a)). In addition, labels must note the presence of sulfites, FD&C Yellow No. 5, and in the case of malt beverages, aspartame. A health warning statement applicable to all alcohol beverages containing 0.5 percent or more alcohol by volume is required by the Alcoholic Beverage Labeling Act of 1988, codified at 27 U.S.C. 213–219 and 219a and implemented in the TTB regulations at 27 CFR part 16.

#### *B. Current Health-Risk Ingredient Disclosure on Alcohol Beverage Labels*

Our predecessor agency, the Bureau of Alcohol, Tobacco and Firearms (ATF), proposed on several occasions to adopt mandatory ingredient disclosure requirements for alcohol beverages. In each case, ATF ultimately decided not to adopt full ingredient labeling requirements. (See Notice No. 41, 70 FR 22274, April 29, 2005, for a more complete history of those ingredient labeling regulatory initiatives.)

These rulemaking actions included publication of T.D. ATF–150 (48 FR 45549, October 6, 1983), which rescinded the ingredient disclosure regulations that had been published in T.D. ATF–66 (45 FR 40538, June 13, 1980), but never implemented. T.D. ATF–150 did, however, mandate the disclosure of one ingredient, FD&C Yellow No. 5, on alcohol beverage labels. In the preamble to T.D. ATF–150, ATF stated:

\* \* \* there is no clear evidence in the record that any other ingredient besides FD&C Yellow No. 5 poses any special health problem. The Department will look at the necessity of mandatory labeling of other ingredients on a case-by-case basis through its own rulemaking initiative, or on the basis of petitions for rulemaking under 5 U.S.C. 553(e) and 27 CFR 71.41(c).

In conformity with that case-by-case review policy, ATF subsequently issued regulations requiring the disclosure on labels of sulfites in alcohol beverages (T.D. ATF–236, 51 FR 34706, September 30, 1986), because it was determined that the presence of undeclared sulfites in alcohol beverages posed a recognized health problem to sulfite-sensitive individuals.

In 1987, ATF entered into a Memorandum of Understanding (MOU) with FDA. See 52 FR 45502 (November 30, 1987). In the MOU, ATF made a commitment to consult with FDA regarding the necessity of requiring labeling statements for ingredients in alcohol beverages that pose a recognized public health problem and to initiate rulemaking proceedings to require disclosure of such ingredients where

appropriate. The pertinent portion of the MOU states:

ATF will be responsible for the promulgation and enforcement of regulations with respect to the labeling of distilled spirits, wine, and malt beverages pursuant to the FAA Act. When FDA has determined that the presence of an ingredient in food products, including alcoholic beverages, poses a recognized public health problem, and that the ingredient or substance must be identified on a food product label, ATF will initiate rulemaking proceedings to promulgate labeling regulations for alcoholic beverages consistent with ATF's health policy with respect to alcoholic beverages. ATF and FDA will consult on a regular basis concerning the propriety of promulgating regulations concerning the labeling of other ingredients and substances for alcoholic beverages.

Pursuant to the policies set forth in the MOU, ATF subsequently issued regulations requiring a declaration on labels when aspartame is used in the production of malt beverages (T.D. ATF–347, 58 FR 44131, August 19, 1993). It should be noted that FD&C Yellow No. 5, sulfites, and aspartame are not considered food allergens because they do not cause IgE (Immunoglobulin E)-mediated responses, but they may cause health problems in certain individuals.

#### *C. Petition From Dr. Christine Rogers*

On April 10, 2004, Christine A. Rogers, PhD., a senior research scientist in the Exposure, Epidemiology and Risk Program at the Harvard School of Public Health, petitioned TTB to change the regulations to require labeling of all ingredients and substances used in the production of alcohol beverages.

Dr. Rogers stated that she is allergic to egg protein and that she has had allergic reactions to egg in wine. For that reason, she expressed particular concern with the labeling of allergenic substances in alcohol beverage products. Dr. Rogers noted that allergic symptoms in consumers can include tingling or itching in the mouth, salivation, swelling of tissues, hives, abdominal cramps, vomiting, diarrhea, rapid loss of blood pressure, and death. She explained that allergic reactions to food vary based upon an individual's sensitivity to a particular allergen. The most sensitive allergic individuals are required to carry epinephrine with them for emergency use in the case of exposure to an offending allergen.

#### *D. Enactment of FALCPA*

On August 2, 2004, the President signed into law the Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA) (see title II of Pub. L. 108–282, 118 Stat. 905). FALCPA

amends portions of the Federal Food, Drug and Cosmetic Act (FD&C Act, 21 U.S.C. 301, *et seq.*) to require a food that is, or contains an ingredient that bears or contains, a major food allergen to list this information on its label using plain, common language. For example, instead of merely listing “semolina,” the label must also list “wheat”, and instead of merely listing “sodium casein,” the label must also list “milk.” The FALCPA amendments define “major food allergens” as milk, egg, fish, Crustacean shellfish, tree nuts, wheat, peanuts, and soybeans, as well as most ingredients containing proteins derived from these foods.

The effect of the FALCPA amendments is to add additional allergen information to the food label. The FALCPA amendments provide two ways for a manufacturer to disclose major food allergens on the label:

- The label can show the name of the food source from which the major food allergen is derived within parentheses in the ingredient list, for example, “Ingredients: Water, wheat, whey (milk), albumen (eggs), and peanuts”; or
- The label can list the name of the food source from which the allergen is derived in summary form after, or adjacent to, an ingredient list, for example: “Ingredients: Water, sugar, whey, and albumen. Contains: Milk and egg.”

Section 202 of FALCPA contains a number of congressional findings regarding the health risk posed by allergens. Congress found that approximately 2 percent of adults and 5 percent of infants and young children in the United States suffer from food allergies. Each year, roughly 30,000 individuals require emergency room treatment and 150 individuals die because of allergic reactions to food.

Congress found that the eight foods or food groups identified in FALCPA account for 90 percent of all food allergies. Since there is currently no cure for food allergies, a food-allergic consumer must avoid the food to which he or she is allergic. Congress further found that many consumers may not realize that a labeled food ingredient is derived from, or contains, a major food allergen. The FALCPA amendments fill this gap by ensuring that the food source from which a major food allergen is derived is clearly labeled in plain language.

FALCPA amends food labeling requirements in the FD&C Act. Pursuant to authority delegated to it by the Secretary of Health and Human Services, FDA is responsible for promoting and protecting the public health through enforcement of the FD&C

Act and for ensuring that the nation's food supply is properly labeled. However, it is TTB's responsibility to issue regulations with respect to the labeling of wine, distilled spirits, and malt beverages under the FAA Act. See the 1987 ATF-FDA MOU and *Brown-Forman Distillers Corp. v. Mathews*, 435 F. Supp. 5 (W.D. Ky. 1976).

The allergen labeling requirements in FALCPA apply to any food, as that term is defined in section 201(f) of the FD&C Act, other than raw agricultural commodities. As reflected in the 1987 MOU with FDA, TTB is responsible for the promulgation and enforcement of regulations with respect to the labeling of distilled spirits, wines, and malt beverages pursuant to the FAA Act. The House of Representatives Committee on Energy and Commerce called for TTB to work with FDA to promulgate appropriate allergen labeling regulations for alcohol beverages labeled under the FAA Act and TTB regulations, consistent with the 1987 MOU with FDA. The committee report accompanying FALCPA stated:

The Committee expects, consistent with the November 30, 1987 Memorandum of Understanding, that the Alcohol and Tobacco Tax and Trade Bureau (TTB) of the Department of Treasury will pursuant to the Federal Alcohol Administration Act determine how, as appropriate, to apply allergen labeling of beverage alcohol products and the labeling requirements for those products. The Committee expects that the TTB and the FDA will work together in promulgation of allergen regulations, with respect to those products. (H.R. Rep. No. 608, 108th Cong., 2d Sess., at 3 (2004); hereafter "House committee report.")

Congress thus recognized TTB's longstanding policy of consulting with FDA in determining what ingredients in alcohol beverages should be disclosed on labels, and called on TTB to work with FDA to promulgate appropriate allergen labeling regulations for alcohol beverages. The clear intent reflected in the House committee report is that TTB issue regulations similar to the FALCPA standards, pursuant to the policies expressed in the MOU with FDA and the authority of the FAA Act.

Under the MOU, the two agencies have over the years collaborated on many food safety issues and continue to exchange a wide variety of information, including relevant consumer complaints concerning the adulteration of alcohol beverages. The agencies consult regularly concerning the use and labeling of potentially harmful ingredients and substances in alcohol beverages. The laboratories of FDA and TTB regularly exchange information

concerning methodologies and techniques for testing alcohol beverages.

Consistent with the expectations expressed in the House committee report, TTB consulted with FDA prior to issuing this interim rule. However, it should be emphasized that while this interim rule is promulgated in response to, among other things, the expectations set out in the legislative history of FALCPA, TTB's legal authority to establish this rule is based on the FAA Act.

FDA is the agency authorized to implement FALCPA with regard to foods. The House committee has set forth its expectation that TTB will implement allergen labeling for alcohol beverages, as appropriate, and will work with FDA in this effort. While TTB has generally strived to be consistent with FDA's interpretation of FALCPA, the implementation of regulations regarding major food allergen labeling for alcohol beverages under the FAA Act will necessarily differ in some respects from the requirements of FALCPA.

Accordingly, this interim rule reflects TTB's interpretation of its authority under the FAA Act, as guided by the language in the committee report. This regulation does not necessarily represent the views of FDA with regard to allergen labeling or the requirements of FALCPA.

## II. Rulemaking History and Summary of Comments

On April 29, 2005, TTB published in the *Federal Register* (70 FR 22274) Notice No. 41, an advance notice of proposed rulemaking (the ANPRM). The notice was entitled "Labeling and Advertising of Wines, Distilled Spirits and Malt Beverages; Request for Public Comment." We provided a 60-day period for comments from consumers, interest groups, trade associations, industry, and other members of the public on several alcohol beverage labeling issues, including calorie and carbohydrate claims on labels, "serving facts" labeling, "alcohol facts" labeling, ingredient labeling, allergen labeling, and composite label approaches.

In the ANPRM, we invited comments on specific issues related to allergen labeling, including: Whether our regulations should require allergen labeling to be part of or adjacent to a list of ingredients, similar to the FALCPA requirements; whether an allergen must be labeled in an allergen statement even when the allergen name already appears in the product name; how processing or fining agents should be labeled; whether we should consider threshold levels in allergen labeling; what costs industry may incur from new labeling

requirements; and how consumers might benefit from allergen labeling. We also invited submission of any other relevant information on the subject of allergen labeling.

During the 60-day comment period, we received several requests from alcohol beverage industry representatives and organizations to extend the comment period for an additional 60 to 90 days beyond the original June 28, 2005, closing date. In support of the extension requests, industry members noted that some of the questions posed in the notice were broad and far reaching from a policy standpoint while others were very technical, requiring research and coordination within the affected industries. In response to these requests, we extended the comment period for an additional 90 days. See Notice No. 48, 70 FR 36359, June 23, 2005. The extended comment period for the ANPRM closed on September 26, 2005.

We received more than 18,000 comments in response to the ANPRM, approximately 50 of which specifically addressed the subject of allergen labeling. Based on the clearly expressed congressional interest in allergen labeling, the particular risks that allergens pose to human health, FALCPA's effective date of January 1, 2006, and the relatively small number of comments submitted on allergen issues, we have decided to separate the allergen labeling rulemaking from the other issues discussed in the ANPRM. We will review the comments submitted on the other ANPRM issues, with a view to determining whether to proceed with future rulemaking action in those areas, separately from our action on allergen labeling. Accordingly, this document only addresses allergen issues, including the approximately 50 comments on allergens submitted in response to the ANPRM.

We note that of the comments we received on allergens, the vast majority favored mandatory labeling of the major food allergens. Industry members as well as consumer and public health advocates commented in support of major food allergen labeling.

The major trade associations representing the alcohol beverage industry expressed their support for mandatory labeling of major food allergens. The Beer Institute, the Brewers Association, the Distilled Spirits Council of the United States (DISCUS), the National Association of Beverage Importers (NABI), the Presidents' Forum, Spirits Canada, Wine America, and the Wine Institute submitted a consolidated comment, in which they stated that they fully

supported the purpose and objectives of FALCPA and stood ready to work with TTB in the implementation of allergen labeling. In a separate comment, the Brewers Association stated that “mandatory rules regarding the disclosure of major allergens are necessary because certain types of allergens, or at least when present above scientifically determined harmful levels, can pose a significant threat to consumer health.”

Consumer and public health interest groups also submitted comments in support of mandatory labeling of major food allergens. The National Consumers League (NCL) submitted a comment supported by several groups, including the American Public Health Association and the American School Health Association. This comment urged TTB to adopt a uniform, mandatory labeling regime for all alcohol beverages that includes, among other things, an ingredient declaration listing each ingredient by its common or usual name and identifying any major food allergens present in the product. The Center for Science in the Public Interest (CSPI), a nonprofit health education and advocacy organization, submitted a comment in support of the adoption of a mandatory allergen disclosure policy for alcohol beverages consistent with the FALCPA requirements for food and the FDA policies implementing FALCPA.

We also received comments in support of allergen labeling from the American Medical Association; the American Academy of Allergy, Asthma and Immunology; the American College of Allergy, Asthma and Immunology; the Food Allergy and Anaphylaxis Network; the American Council on Science and Health; the American Society of Addiction Medicine; the American Dietetic Association; the American Nurses Association; Shape Up America; and several other public health organizations and health professionals.

Only a few comments questioned the usefulness of requiring allergen information on alcohol beverage labels. Furthermore, there were some disagreements among the commenters about the allergen labeling implementation issues that we raised in the ANPRM.

### III. Interim Regulatory Changes

After careful consideration of the comments on this issue, TTB has determined that it should propose rules for the mandatory labeling of major food allergens used in the production of alcohol beverages. Consistent with the guidance expressed in the House

committee report and our statutory mandate under the FAA Act to promulgate regulations ensuring that consumers receive adequate information about the identity and quality of alcohol beverages, we believe that alcohol beverage labels should provide consumers with sufficient information about the use of major food allergens in the production of alcohol beverages so that allergic consumers may make an informed decision as to whether consumption of a particular beverage may pose a risk of an allergic reaction. Accordingly, we are proposing mandatory labeling of major food allergens elsewhere in this issue of the **Federal Register**.

As explained below, we are issuing this interim rule to provide immediate guidance to industry members who wish to place allergen statements on alcohol beverage labels on a voluntary basis. The interim regulations also allow for the immediate filing of petitions for exemptions from the standards imposed on those producers who wish to make voluntary allergen statements on their labels.

#### A. Voluntary Labeling Approach

We note that in response to the ANPRM, some commenters urged TTB to require labeling of major food allergens for products labeled on or after January 1, 2006, which is the effective date of the FALCPA amendments. One commenter suggested that consumers will expect to see allergen information on alcohol beverage products at the same time that such information begins appearing on food labels under FALCPA, and that they may be misled by the absence of such information on labels of products that in fact contain major food allergens. Other commenters, recognizing that it may take some time before a final rule is issued, suggested that TTB allow voluntary labeling of major food allergens pending the completion of rulemaking.

In this regard, it should be noted that the congressional committees involved with FALCPA had different expectations of FDA and of TTB. The report of the Senate Committee on Health, Education, Labor, and Pensions, S. Rep. No. 226, 108th Cong., 2d Sess., at 10 (2004) (hereafter “Senate committee report”), states:

The committee intends the requirements of section 403(w) to be self-implementing. FDA will not be required to issue regulations to implement section 403(w). FDA may issue guidance, should the agency find that guidance would assist manufacturers or distributors, particularly small businesses, to comply with the requirements in this legislation.

On the other hand, as previously noted, the House committee report specifically stated its expectation that TTB would promulgate regulations, in consultation with FDA, to apply allergen labeling requirements to alcohol beverages, as appropriate. Given that the TTB regulations must be amended in order to implement allergen labeling, we believe it is appropriate to allow the public, including affected industry members, the opportunity to comment on allergen labeling standards before making them mandatory.

Accordingly, in order to make allergen labeling standards applicable to alcohol beverages at the earliest practicable date, and before the public comment procedures can be completed, TTB has determined that the best approach is to adopt voluntary regulatory standards for major food allergen labeling through an interim rule. TTB agrees with those commenters who suggested that producers of alcohol beverages be given immediate guidance with respect to the voluntary use of allergen labeling statements on labels. We have already received inquiries from industry members about the voluntary use of allergen statements on alcohol beverage labels. Because industry members may wish to begin providing allergen information to consumers on a voluntary basis right away, we are publishing standards that are effective immediately.

The interim rule also gives industry members an opportunity to file petitions for exemption from the standards imposed on those alcohol beverage producers who wish to make voluntary allergen statements on their product labels.

This interim rule amends parts 4, 5, and 7 of the TTB regulations to include specific requirements for those who choose to place voluntary declarations of major food allergens on labels. The amendments include the addition of new sections 4.32a, 5.32a, and 7.22a, which set forth specific format requirements for the voluntary labeling of major food allergens. In addition, we have added new sections 4.32b, 5.32b, and 7.22b, which allow any person to petition TTB for an exemption from the labeling standards that apply if voluntary major food allergen labeling is undertaken. A detailed discussion of the specific provisions within the interim regulations follows.

In consideration of the requirements for prior public notice and comment procedures under the Administrative Procedure Act, we are proposing the adoption of mandatory labeling standards in a separate document, Notice No. 62, which is published in the

Proposed Rules section of this issue of the **Federal Register**. The voluntary standards adopted in this interim rule document will remain in place until they are replaced by final action on the proposal for mandatory standards.

### B. Labeling of Major Food Allergens

#### 1. Definitions

Consistent with the FALCPA amendments, the interim regulations provide that when allergen labeling is undertaken, the product must be labeled "Contains:" followed by the name of the food source from which each major food allergen is derived, as set forth in the definition of "major food allergen."

The definition of the term "major food allergen" is consistent with the statutory definition in FALCPA. The interim regulations define the term "major food allergen" as any of the following: "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." The term as defined also includes any food ingredient that contains protein derived from one of these eight foods or food groups, subject to certain exceptions explained below.

It should be noted that, consistent with guidance provided by FDA to the food industry, the interim regulations allow the terms "soybean," "soy," and "soya" as synonyms for the term "soybeans," as used in the statute. Furthermore, also consistent with FDA guidance, the singular term "peanut" may be substituted for the plural term "peanuts," and singular terms (for example, almond, pecan, or walnut) may be used in place of plural terms to describe the different types of tree nuts.

#### 2. Labeling of Fish Species

FALCPA provides that in the case of tree nuts, the label must list the name of the specific type of nut (for example, almonds, pecans, or walnuts). In the case of Crustacean shellfish, the label must list the name of the species of shellfish (for example, crab, lobster, or shrimp). Finally, in the case of fish, the FALCPA amendments provide that the name of the species of fish (for example, bass, flounder, or cod) must appear on the label.

The interim regulations are consistent with the FALCPA amendments with respect to the labeling of tree nuts and Crustacean shellfish. However, for the reasons explained below, the interim regulations set forth in this document do not require labeling of the specific fish species when an industry member chooses to provide major food allergen

information. The regulations instead require simply listing "fish" when any type of finfish protein is used in the production of an alcohol beverage.

Isinglass and fish gelatin are often used to clarify wines and beers. Isinglass is a substance obtained from the swim bladders of sturgeon and other fish. Fish gelatin is obtained from the skin of a fish. Fish gelatin most often is made from cod skins but can be made from any species of fish.

Vintners and brewers, when purchasing isinglass or fish gelatin from a manufacturer for fining purposes, often do not know, and have no way of easily finding out, which particular species of fish was used to make the product. Moreover, it may be difficult for industry members to determine by chemical analysis which particular fish species was the source of the isinglass or fish gelatin.

On August 1, 2005, the Flavor and Extract Manufacturers Association of the United States (FEMA) submitted a request to FDA for guidance concerning the labeling of fish species under the FALCPA amendments. In its request for guidance, FEMA asked FDA to allow for use of the term "fish" for labeling "non-nutritive fish ingredients" used in flavors. FEMA cited clinical and scientific evidence in support of its argument that many fish-allergic individuals will react adversely to more than one species of fish.

TTB recognizes that FALCPA requires the labeling of the particular species of fish used as an ingredient in a food product. However, it is our responsibility to implement allergen labeling regulations that are appropriate for alcohol beverages. It is likely that declarations of the use of fish in the production of alcohol beverages will generally involve the use of isinglass or fish gelatin as a processing aid. Because of the particular difficulty faced by the producer in determining the specific species of fish used in producing the isinglass or fish gelatin, and because at least some consumers may be allergic to more than one species of fish, TTB is persuaded that requiring labeling with the name of the specific type of fish would impose a difficult fact-finding burden on the alcohol beverage industry without offering consumers who may be allergic to more than one species of fish any significant additional information to help them avoid the risk of an allergic reaction. Accordingly, we believe that the goal of the FALCPA amendments with respect to alcohol beverages is adequately met if alcohol beverages produced using finfish protein are labeled merely with "fish," rather than with the name of the fish species.

We would note that the data on this matter are not conclusive, and we are specifically inviting comments on this issue in our notice of proposed rulemaking. However, for purposes of the guidance provided in this interim rule for industry members who wish to make voluntary allergen labeling statements, we believe that there is a basis for concluding that a reference to "fish" on the label will provide adequate information to consumers about the presence of finfish protein in certain alcohol beverages.

#### 3. Processing and Fining Agents

FALCPA amends the FD&C Act to require that, notwithstanding any other provision of law, a flavoring, coloring, or incidental additive that is or bears or contains a major food allergen must conform to FALCPA's labeling requirements. See 21 U.S.C. 343(w)(4). The FDA regulations define the term "incidental additive" to include, among other things, processing aids. See 21 CFR 101.100(a)(3). Therefore, if alcohol beverage industry members choose to make major food allergen declarations, the interim regulations treat major food allergens used as fining or processing agents in the same way as any other major food allergen used in the production of the alcohol beverage.

#### 4. Threshold Levels

The FALCPA amendments, which took effect for foods labeled on or after January 1, 2006, require allergen labeling for foods regulated by FDA without the establishment of any threshold levels for labeling. Furthermore, pursuant to our authority under the FAA Act to ensure that labels provide consumers with adequate information about the identity and quality of alcohol beverage products, the interim regulations provide that if an industry member chooses to label for any major food allergen, all major food allergens and proteins derived from the major food allergens used in production must be declared on the beverage label, unless the product or class of products is covered by an approved petition for exemption. Accordingly, TTB is not setting thresholds in this interim regulation.

TTB believes that this position will ensure that consumers have adequate information about the potential presence of even trace amounts of major food allergens in alcohol beverage products. As more accurate scientific data become available in the future, we may revisit the threshold issue as appropriate.

### C. Exceptions From Allergen Labeling Requirements

The interim regulations contain three exceptions from major food allergen labeling. Two of these exceptions are provided within the definition of "major food allergen," and the third is an exemption through a TTB petition process.

#### 1. Highly Refined Oil

The FALCPA amendments exclude from the definition of "major food allergen" any highly refined oil derived from one of the eight foods or food groups listed in that definition and any ingredient derived from such highly refined oil. The Senate committee report at page 7 indicates that the exception for highly refined oils was intended to apply to refined, bleached, deodorized (RBD) oils. Both the House committee report at page 16 and the Senate committee report at page 7 specifically identify peanut oil as one of the highly refined oils covered by the exception. We believe this exception from labeling for highly refined oils is also appropriate in the case of alcohol beverages, and we therefore have included this as an exception from the definition of a major food allergen in the interim regulatory texts.

#### 2. Exemptions Under the FD&C Act

FALCPA added two processes to the FD&C Act at 21 U.S.C. 343(w)(6) and (7) by which any person may obtain an exemption from the allergen labeling requirements imposed by the statute.

Subsection (w)(6) allows any person to petition the Secretary of Health and Human Services to exempt a food ingredient from the allergen labeling requirements. Under its delegated authority, FDA performs the function of the Secretary in this area. In this situation, the burden is on the petitioner to provide scientific evidence (including the analytical method used to produce the evidence) that demonstrates that the food ingredient, as derived by the method specified in the petition, does not cause an allergic response that poses a risk to human health. FDA must approve or deny any such petition within 180 days of receipt or the petition will be deemed denied, unless an extension is mutually agreed upon by FDA and the petitioner.

Subsection (w)(7) allows any person to file a notification containing scientific evidence demonstrating that an ingredient "does not contain allergenic protein." The scientific evidence must include the analytical method used to produce the evidence that the ingredient, as derived by the

method specified in the notification, does not contain allergenic protein. Alternatively, the notification may contain a determination from FDA under a premarket approval or notification program provided for in section 409 of the FD&C Act (21 U.S.C. 348) that the ingredient does not cause an allergic response that poses a risk to human health. FDA has 90 days to object to a notification. Absent an objection, the food ingredient is exempt from the FDA labeling requirements for major food allergens.

Many ingredients and food additives used in the production of foods regulated by FDA are also used in the production of alcohol beverages regulated by TTB. Under the two exemption processes described above, certain ingredients and food additives may be exempted from the allergen labeling requirements of the FD&C Act. We believe it is appropriate to allow alcohol beverage industry members to rely on the exemptions from major food allergen labeling requirements allowed under the FD&C Act and FDA procedures. We have therefore included in the definition of "major food allergen" an exception for uses of food ingredients that are exempt pursuant to 21 U.S.C. 343(w)(6) or (7).

It is important to note in this regard that alcohol beverage industry members must consider two issues when determining whether an ingredient exempted under the FD&C Act is also not subject to TTB allergen labeling requirements. First, the ingredient they used or intend to use in a product must be the same ingredient that is exempt under the FD&C Act. Second, the proposed use must be consistent with any conditions of use in the FD&C Act exemption for the ingredient.

#### 3. Petitions for Exemption From TTB Regulations

We also recognize that major food allergens are used in alcohol beverage production in ways that may differ from the way they are used in the production of foods regulated by FDA. For this reason, new sections 4.32a, 5.32a, and 7.22a refer in each case to an exception for a product covered by a petition for exemption approved under new section 4.32b, 5.32b, or 7.22b. A petition may pertain to the use of a major food allergen in the production of one specific alcohol beverage product or it may pertain to a class of products using a particular process involving a major food allergen.

As stated above, TTB's jurisdiction extends to the labeling of wines, distilled spirits, and malt beverages. Accordingly, we only will accept a

petition seeking an exemption from the labeling of a major food allergen when the material in question is used in the production of an alcohol beverage product regulated by TTB. If an exemption from the FD&C Act allergen labeling requirements is also desired, the interested party must submit a petition or notification to FDA under 21 U.S.C. 343(w)(6) or (7), rather than submit a petition under the applicable TTB regulation.

The use of the TTB petition process is similar to that of the petition and notification processes provided for at 21 U.S.C. 343(w)(6) and (7), except that the TTB petition procedure focuses on products instead of ingredients. The TTB petition process may be used:

- When it is asserted that the product or class of products, as derived by the method specified in the petition, does not cause an allergic response that poses a risk to human health; or
- When it is asserted that the product or class of products, as derived by the method specified in the petition, does not contain allergenic protein, even though a major food allergen was used in production.

The interim TTB regulations provide for only a petition procedure, rather than both the petition procedure and the notification procedure provided for in the FALCPA amendments to the FD&C Act. We believe that having one petition procedure, rather than separate petition and notification procedures, will simplify the process for industry, and will allow our personnel adequate time to review the evidence presented in each request for an exemption. TTB is not in a position to administer a 90-day notice procedure similar to the notification procedure in subsection (w)(7) of the statute. The interim regulation petition procedure is therefore similar to the petition procedure in subsection (w)(6) of the statute in that the regulation places the burden on the petitioner to provide evidence in support of the exemption and gives TTB 180 days to respond.

The interim regulations provide that a petition for exemption from major food allergen labeling must be submitted to the appropriate TTB officer. The appropriate TTB officer to whom petitions must be submitted is the Assistant Administrator, Headquarters Operations. The petition should be sent to the Alcohol and Tobacco Tax and Trade Bureau, 1310 G Street NW., Suite 200E, Washington, DC 20220 and should bear the notation: "Attention: Petition for Exemption from Major Food Allergen Labeling" to ensure prompt processing.

In addition, the interim regulations provide that if TTB does not approve or deny the petition for exemption within 180 days of receipt, the petition is deemed denied, unless an extension of time is mutually agreed upon by TTB and the petitioner. The regulations also provide that a determination under this section constitutes a final agency action and that even though a petition is deemed denied because no action was taken within the 180-day period, the petitioner may resubmit the petition at any time. A resubmitted petition will be treated as a new petition.

As a result of FDA's implementation of FALCPA and our establishment of this interim rule, TTB and FDA will both be regulating allergen labeling, with TTB overseeing labeling for alcohol beverages and FDA the labeling for all other products that are foods under the FD&C Act. As noted, TTB and FDA are parties to an MOU signed in 1987. That MOU provides that FDA and TTB will exchange information generally about appropriate labeling for, and the adulteration of, alcohol beverages, including information about methodologies and techniques for testing such beverages. Consistent with these general MOU provisions and both agencies' recognition that, generally, the regulation of allergen labeling should be consistent for alcohol beverages and all other foods, TTB intends to confer with FDA, as appropriate and as FDA resources permit, on petitions submitted under this interim rule.

Consistent with FALCPA, the interim rule places the burden on the petitioner to provide adequate evidence in its initial petition submission to justify an exemption from labeling. TTB may require the subsequent submission of product samples and other additional information in support of a 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.

FALCPA provides that FDA shall promptly post to a public site all petitions within 14 days of receipt and shall promptly post the Government's response to each. Our interim regulations are consistent with FALCPA's requirement to make petitions and responses available to the public, but may go beyond the requirements of FALCPA in some respects. The interim regulations provide that petitions submitted to TTB, and TTB's response to those petitions, will be posted to the TTB Web site (<http://www.ttb.gov>). However, TTB will

not post lengthy materials submitted in support of a petition on its Web site; we will, instead, make such materials available to the public in accordance with the procedures set forth in the Freedom of Information Act, 5 U.S.C. 552.

A person who provides trade secrets or other confidential commercial or financial information in either a petition for exemption or in any supporting documentation submitted in connection with such a petition may request that TTB give confidential treatment to that information. The interim regulations set forth the standards for making such a request. A failure to request confidential treatment at the time the information in question is submitted to TTB will constitute a waiver of confidential treatment.

#### IV. Notice of Proposed Rulemaking

In the Proposed Rules section of this issue of the **Federal Register**, we have published a notice of proposed rulemaking, Notice No. 62, to solicit public comment on our proposal to impose mandatory allergen labeling requirements on alcohol beverage products. That notice gives the public, including affected industry members, an opportunity to comment on the mandatory labeling of major food allergens, the time required by industry members to incorporate the required changes on their labels, and how to minimize any added compliance costs.

#### V. Regulatory Analysis and Notices

##### A. Executive Order 12866

We have determined that this interim rule is not a significant regulatory action as defined in Executive Order 12866. Therefore, a regulatory assessment is not required.

##### B. Regulatory Flexibility Act

Because this interim rule was not required to be preceded by a notice of proposed rulemaking, the provisions of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) do not apply.

##### C. Paperwork Reduction Act

This interim rule includes a new collection of information involving the declaration of major food allergens on an alcohol beverage label and the submission of petitions for exemption from allergen labeling. This collection is voluntary.

The collection of information has been reviewed and, pending receipt and evaluation of public comments, approved by the Office of Management and Budget (OMB) under 44 U.S.C. 3507(j) and assigned control number 1513-0121. An agency may not conduct

or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid control number assigned by OMB.

The collection of information is contained in §§ 4.32a, 4.32b, 5.32a, 5.32b, 7.22a, and 7.22b. The likely respondents are individuals and business or other for-profit institutions, including partnerships, associations, and corporations.

- *Estimated total annual reporting and/or recordkeeping burden:* 730 hours.
- *Estimated average annual burden per respondent/recordkeeper:* 1.46 hours.
- *Estimated number of respondents and/or recordkeepers:* 500.
- *Estimated annual number of responses:* 520.

Comments on this collection of information may be sent by e-mail to OMB at [Alexander\\_T.\\_Hunt@omb.eop.gov](mailto:Alexander_T._Hunt@omb.eop.gov), or by paper mail to Office of Management and Budget, Attention: Desk Officer for the Department of the Treasury, Office of Information and Regulatory Affairs, Washington, DC 20503. A copy should also be sent to TTB at one of the following addresses:

- P.O. Box 14412, Washington, DC 20044-4412;
- 202-927-8525 (facsimile); or
- [formcomments@ttb.gov](mailto:formcomments@ttb.gov) (e-mail).

Please reference the information collection's title and OMB number in your comment. If you submit your comment via facsimile, send no more than five 8.5 x 11 inch pages in order to ensure electronic access to our equipment.

Comments are invited on the accuracy of the burden. We also invite suggestions on how the burden may be reduced.

#### VI. Inapplicability of Prior Notice and Comment and Delayed Effective Date Procedures

It has been determined, pursuant to 5 U.S.C. 553(b)(B) and (d), that good cause exists to issue these regulations without prior notice and public procedure, and without a delayed effective date. Because the industry needs immediate standards for the placement of voluntary statements listing major food allergens on alcohol beverage labels, and because industry members may wish to begin immediately to submit petitions for exemptions, it is impracticable and contrary to the public interest to issue these regulations for prior notice and comment, and with a delayed effective date.

## VII. Drafting Information

The principal author of this document was Jessica M. Bungard, Regulations and Rulings Division, Alcohol and Tobacco Tax and Trade Bureau. However, other personnel participated in its development.

### List of Subjects

#### 27 CFR Part 4

Administrative practice and procedure, Advertising, Customs duties and inspection, Imports, Labeling, Packaging and containers, Reporting and recordkeeping requirements, Trade practices, Wine.

#### 27 CFR Part 5

Administrative practice and procedure, Advertising, Customs duties and inspection, Distilled spirits, Imports, Labeling, Packaging and containers, Reporting and recordkeeping requirements, Trade practices.

#### 27 CFR Part 7

Administrative practice and procedure, Advertising, Customs duties and inspection, Imports, Labeling, Malt beverages, Reporting and recordkeeping requirements, Trade practices.

### Amendments to the Regulations

■ For the reasons discussed in the preamble, TTB amends 27 CFR parts 4, 5, and 7 as follows:

#### PART 4—LABELING AND ADVERTISING OF WINE

■ 1. The authority citation for 27 CFR part 4 continues to read as follows:

**Authority:** 27 U.S.C. 205.

■ 2. A new § 4.32a is added to read as follows:

#### § 4.32a Voluntary disclosure of 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) *Voluntary labeling standards.* Major food allergens (defined in paragraph (a)(1) of this section) used in the production of a wine may, on a voluntary basis, be declared on any label affixed to the container. However, if any one major food allergen is voluntarily declared, all major food allergens used in production of the wine, including major food allergens used as fining or processing agents, must be declared, except when covered by a petition for exemption approved by the appropriate TTB officer under § 4.32b. The major food allergens declaration must consist of the word “Contains” followed by a colon and the name of the food source from which each major food allergen is derived (for example, “Contains: egg”).

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

■ 3. A new § 4.32b is added to read as follows:

#### § 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.

(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 an extension of time for decision is mutually agreed upon by the appropriate TTB officer and the petitioner. 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 a 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.

#### **PART 5—LABELING AND ADVERTISING OF DISTILLED SPIRITS**

■ 1. The authority citation for 27 CFR part 5 continues to read as follows:

**Authority:** 26 U.S.C. 5301, 7805, 27 U.S.C. 205.

■ 2. A new § 5.32a is added to read as follows:

##### **§ 5.32a Voluntary disclosure of 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) *Voluntary labeling standards.* Major food allergens (defined in paragraph (a)(1) of this section) used in the production of a distilled spirit product may, on a voluntary basis, be declared on any label affixed to the container. However, if any one major food allergen is voluntarily declared, all major food allergens used in production of the distilled spirit product, including major food allergens used as fining or processing agents, must be declared, except when covered by a petition for exemption approved by the appropriate TTB officer under § 5.32b. The major food allergens declaration must consist of the word “Contains” followed by a colon and the name of the food source from which each major food allergen is derived (for example, “Contains: egg”).

(c) *Cross reference.* For mandatory labeling requirements applicable to distilled spirits products containing FD&C Yellow No. 5 and sulfites, see §§ 5.32(b)(5) and (7).

■ 3. A new § 5.32b is added to read as follows:

##### **§ 5.32b 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 § 5.32a. 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 § 5.32a(a)(1)(i), even though a major food allergen was used in production.

(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 an extension of time for decision is mutually agreed upon by the appropriate TTB officer and the petitioner. 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 a 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.

## PART 7—LABELING AND ADVERTISING OF MALT BEVERAGES

- 1. The authority citation for 27 CFR part 7 continues to read as follows:

**Authority:** 27 U.S.C. 205.

- 2. A new § 7.22a is added to read as follows:

### § 7.22a Voluntary disclosure of 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); and

(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 name “soy”, “soybean”, or “soya” may be used instead of “soybeans”.

(b) *Voluntary labeling standards.* Major food allergens (defined in paragraph (a)(1) of this section) used in the production of a malt beverage product may, on a voluntary basis, be declared on any label affixed to the container. However, if any one major food allergen is voluntarily declared, all major food allergens used in production of the malt beverage product, including major food allergens used as fining or processing agents, must be declared, except when covered by a petition for exemption approved by the appropriate TTB officer under § 7.22b. The major food allergens declaration must consist of the word “Contains” followed by a colon and the name of the food source from which each major food allergen is derived (for example, “Contains: egg”).

(c) *Cross reference.* For mandatory labeling requirements applicable to malt beverage products containing FD&C Yellow No. 5, sulfites, and aspartame, see §§ 7.22(b)(4), (b)(6), and (b)(7).

- 3. A new § 7.22b is added to read as follows:

### § 7.22b 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 § 7.22a. 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 § 7.22(a)(1)(i), even though a major food allergen was used in production.

(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 an extension of time for decision is mutually agreed upon by the appropriate TTB officer and the petitioner. 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 a 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.

(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.

Signed: February 16, 2006.

**John J. Manfreda,**  
Administrator.

Approved: March 16, 2006.

**Timothy E. Skud,**  
Deputy Assistant Secretary (Tax, Trade, and Tariff Policy).  
[FR Doc. E6-11872 Filed 7-25-06; 8:45 am]  
BILLING CODE 4810-31-P

exemptions under the International Regulations for Preventing Collisions at Sea, 1972 (72 COLREGS), to reflect that the Deputy Assistant Judge Advocate General (Admiralty and Maritime Law) has determined that USS GRIDLEY (DDG 101) is a vessel of the Navy which, due to its special construction and purpose, cannot fully comply with certain provisions of the 72 COLREGS without interfering with its special function as a naval ship. The intended effect of this rule is to warn mariners in waters where 72 COLREGS apply.

**DATES:** *Effective Date:* July 17, 2006.

**FOR FURTHER INFORMATION CONTACT:** Commander Gregg A. Cervi, JAGC, U.S. Navy, Deputy Assistant Judge Advocate General (Admiralty and Maritime Law), Office of the Judge Advocate General, Department of the Navy, 1322 Patterson Ave., SE., Suite 3000, Washington Navy Yard, DC 20374-5066, telephone 202-685-5040.

**SUPPLEMENTARY INFORMATION:** Pursuant to the authority granted in 33 U.S.C. 1605, the Department of the Navy amends 32 CFR part 706. This amendment provides notice that the Deputy Assistant Judge Advocate General (Admiralty and Maritime Law), under authority delegated by the Secretary of the Navy, has certified that USS GRIDLEY (DDG 101) is a vessel of the Navy which, due to its special construction and purpose, cannot fully comply with the following specific provisions of 72 COLREGS without interfering with its special function as a naval ship: Annex I, paragraph 2(f)(i), pertaining to the placement of the masthead light or lights above and clear of all other lights and obstructions; Annex I, paragraph 2(f)(ii), pertaining to the vertical placement of task lights; Annex I, paragraph 3(a), pertaining to the location of the forward masthead light in the forward quarter of the ship, and the horizontal distance between the

forward and after masthead lights; and Annex I, paragraph 3(c), pertaining to placement of task lights not less than two meters from the fore and aft centerline of the ship in the athwartship direction. The Deputy Assistant Judge Advocate General (Admiralty and Maritime Law) has also certified that the lights involved are located in closest possible compliance with the applicable 72 COLREGS requirements.

Moreover, it has been determined, in accordance with 32 CFR parts 296 and 701, that publication of this amendment for public comment prior to adoption is impracticable, unnecessary, and contrary to public interest since it is based on technical findings that the placement of lights on this vessel in a manner differently from that prescribed herein will adversely affect the vessel's ability to perform its military functions.

**List of Subjects in 32 CFR Part 706**

Marine safety, Navigation (water), and Vessels.

■ For the reasons set forth in the preamble, amend part 706 of title 32 of the Code of Federal Regulations as follows:

**PART 706—CERTIFICATIONS AND EXEMPTIONS UNDER THE INTERNATIONAL REGULATIONS FOR PREVENTING COLLISIONS AT SEA, 1972**

■ 1. The authority citation for part 706 continues to read:

**Authority:** 33 U.S.C. 1605.

■ 2. Table Four, Paragraph 15 of § 706.2 is amended by adding, in numerical order, the following entry for USS GRIDLEY:

**§ 706.2 Certifications of the Secretary of the Navy under Executive Order 11964 and 33 U.S.C. 1605.**

\* \* \* \* \*

**DEPARTMENT OF DEFENSE**

**Department of the Navy**

**32 CFR Part 706**

**Certifications and Exemptions Under the International Regulations for Preventing Collisions at Sea, 1972**

**AGENCY:** Department of the Navy, DOD.

**ACTION:** Final rule.

**SUMMARY:** The Department of the Navy is amending its certifications and

Vessel	Number	Horizontal distance from the fore and aft centerline of the vessel in the athwartship direction
USS GRIDLEY .....	DDG 101 .....	1.86 meters.

■ 3. Table Four, Paragraph 16 of § 706.2 is amended by adding, in numerical

order, the following entry for USS GRIDLEY:

**§ 706.2 Certifications of the Secretary of the Navy under Executive Order 11964 and 33 U.S.C. 1605.**

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