

Update 2017 Unified Agenda of Federal Regulatory and Deregulatory Actions Identifies Two Rule-Making Priorities for TTB



By
Richard M. Blau
GrayRobinson's Nationwide Alcohol Industry Team

The Office of Information and Regulatory Affairs, a part of the federal government's Office of management and Budget, recently published the Updated 2017 Unified Agenda of Federal Regulatory and Deregulatory Actions. The Unified Agenda provides an updated report on the administrative rulemaking actions that federal agencies plan to undertake in the near and long term. "Long-Term Actions" are items under development but for which the agency does not expect to have a regulatory action within the 12 months after publication of the Unified Agenda.

The 2017 unified Agenda identifies two Long-Term Actions that TTB intends to pursue regarding changes to the labeling and advertising requirements of alcohol beverage products regulated by the agency: (i) Expanded labeling and advertising disclosures for wines, distilled spirits, and malt beverages; and (ii) Major food allergen labeling for wines, distilled spirits, and malt beverages.

TTB has long required certain labeling, such as brand name, class and type, alcohol content (in the case of wines containing more than 14 percent alcohol by volume and distilled spirits) and net contents. In recent years, TTB also has published updated standards for the use of carbohydrate and calorie claims. Over the last several years, the agency has received petitions to mandate additional information, including ingredient, allergen, alcohol, calorie, and carbohydrate content. TTB also has received requests by a number of industry members to use labels with at least some of that additional information on a voluntary basis under existing rules,

TTB believes it is now appropriate to consider revising the alcohol beverage labeling and advertising regulations to mandate disclosure to consumers of all or some of this additional information. According to the recently published *Updated 2017 Unified Agenda of Federal Regulatory and Deregulatory Actions*, TTB will seek additional public comment to assist the

agency in formulating specific regulatory proposals for final rulemaking in two areas. The two primary areas of focus are (i) mandatory allergen disclosures, and (ii) expanded mandatory labeling of certain consumer information relating to a statement of a product's alcohol content as well as adoption of a standardized "Serving Facts" panel for each product's label.

1. MANDATORY ALLERGEN LABELING

Notice No. 62, *Major Food Allergen Labeling for Wines, Distilled Spirits and Malt Beverages*, is a notice of proposed rulemaking originally published in the Federal Register on July 26, 2006; TTB published Notice No. 62 in the Federal Register (71 FR 42329). That notice of proposed rulemaking concerns the adoption of **mandatory labeling standards for major food allergens** used in the production of alcohol beverages subject to the labeling requirements of the Federal Alcohol Administration Act. The rulemaking process remains ongoing, as notice and comment periods have been extended repeatedly.

The proposed rule defines a "major food allergen" as:

"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 (i) above.

That said, the scope of what constitutes a food allergen is replete with specified exceptions, such as "highly refined oils" derived from any of the food products identified in the definition of "major food allergen."

The impetus for this proposed rule crystalized when Congress passed and President George W. Bush signed the Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA) 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 (FD&C Act). A House of Representatives committee report associated with the FD&C Act specifically noted that the committee expected TTB to issue regulations on allergen labeling for alcohol beverage products under the agency's existing authority to regulate alcohol beverage labeling, working in cooperation with the Food and Drug Administration (FDA). In addition, TTB earlier had received a petition concerning ingredient and allergen labeling for alcohol beverages. Based on this predicate, TTB issued Notice No. 62.

The alcohol regulatory agency derives statutory authority to require mandatory labeling from parts 4, 5, and 7 of the Federal Alcohol Administration Act; these statutory provisions in turn relate back to the stated purpose of section 105(e) of the FAAA, which 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 of the

FAAA 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.

FALCPA mandated the inclusion of additional allergen information to the food label. FALCPA provides 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.”

Although the FDA is responsible for promoting and protecting the public health through enforcement of federal food laws such as the Federal Food, Drug and Cosmetic Act, TTB has the responsibility to issue regulations with respect to the labeling of wine, distilled spirits, and malt beverages under the FAA Act. 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.

Based on Congressional and public comment input, TTB concluded 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 are empowered to make informed decisions as to whether consumption of a particular beverage may pose a risk of an allergic reaction. Accordingly, the agency proposed mandatory labeling of major food allergens in the Federal Register through the publication of Notice 62 on July 26, 2006 .

In order to make allergen labeling standards applicable to alcohol beverages at the earliest practicable date, and before the public comment procedures associated with formal rulemaking were completed, TTB determined that the best approach was to adopt voluntary regulatory standards for major food allergen labeling through an interim rule. Accordingly, the agency published standards in Notice 62 in Federal Register Vol. 71, No. 143, that became effective immediately for voluntary compliance, to accommodate industry members who wanted to provide allergen-related information on their product labels.

This interim rule presented in Notice 62 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, TTB 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.

Areas addressed by the allergen-related disclosure rules include:

- ***Labeling of Fish Species***;
- ***Identification of Processing and Fining Agents***;
- ***No Threshold Levels for Labeling*** (all major food allergens and proteins derived from the major food allergens used in production must be declared on the beverage label without exception for minimum quantities, unless the product or class of products is covered by an approved petition for exemption);
- ***Exceptions from Disclosure*** –
 - *Highly Refined Oils*
 - *Ingredients already exempted under the FD&C Act.*

The full text of Notice No. 62 is accessible and can be online and can be downloaded at: <https://www.regulations.gov/document?D=TTB-2007-0046-0001>

According to the recently-published *Update 2017 Unified Agenda of Federal Regulatory and Deregulatory Actions*, it is TTB's intent to convert the interim rule announced by Notice 62 into a final agency rule.

2. EXPANDED MANDATORY CONSUMER INFORMATION

Notice No. 73, *Labeling and Advertising of Wines, Distilled Spirits, and Malt Beverages*, a notice of proposed rulemaking published in the Federal Register on July 31, 2007; TTB proposes to amend its regulations to require a **statement of alcohol content**, expressed as a percentage of alcohol by volume, on all alcohol beverage products. This statement may appear on any label affixed to the container. TTB also proposes to require a **Serving Facts panel** on alcohol beverage labels, which would include a statement of calories, carbohydrates, fat, and protein. Industry members may also choose to disclose on the Serving Facts panel the number of U.S. fluid ounces of pure alcohol (ethyl alcohol) per serving as part of a statement that includes alcohol content expressed as a percentage of alcohol by volume.

The proposed regulations would also specify **new reference serving sizes for wine, distilled spirits, and malt beverages** based on the amount of beverage customarily consumed as a single serving. However, TTB is not defining a standard drink in this document.

TTB proposes to make these new requirements mandatory three years after the date of publication of the final rule in the Federal Register. The agency is proposing these amendments to ensure that alcohol beverage labels provide consumers with adequate information about their product. The full text of Notice No. 73 is accessible online and can be downloaded at: <https://www.regulations.gov/document?D=TTB-2007-0062-0001>

The TTB contact for these initiatives is **Lisa Gesser**. Her contact information is as follows:

Lisa M. Gesser
Program Manager
Department of the Treasury
U.S. Alcohol and Tobacco Tax and Trade Bureau
P.O. Box 128,
Morganza, MD 20660
Phone: (202) 453-1039
Fax: (202) 453-2662
Email: lisa.gesser@ttb.gov

If you would like more information regarding the TTB's Long-Term Actions, or if you are interested in providing public comment on either or both of these initiatives, please contact GrayRobinson's *Nationwide Alcohol Industry Team* via telephone at **(866) 382-5132** or via e-mail at beveragelaw@gray-robinson.com