

August 15, 2025

Director

Regulations and Ruling Division

Alcohol and Tobacco Tax and Trade Bureau

1310 G Street NW, Box 12

Washington, D.C. 20005

[Submitted electronically on https://www.regulations.gov]

Re: ACSA Comments on Notice of Proposed Rulemaking re: Major Food Allergen Labeling for Wines, Distiller Spirits, and Malt Beverages, Notice No. 238

INTRODUCTION

Almost two decades ago, TTB issued an interim rule addressing voluntary labeling of major food allergens. Some craft spirits producers followed suit and began adding additional information for the consumer. TTB's current proposal, which seeks to make a voluntary program mandatory, is generally accepted by the American Craft Spirits Association (ACSA) for the reasons set forth below. If the focus is to notice the consumer of ingredients most often associated with food allergies, however, ACSA suggests an approach led by "The simpler the better".

Allergen Statements

A. Labeling of Major Food Allergens and other Mandatory Disclosures

- 1. Wording of the Labeling Statement and Other Mandatory Disclosures
 - 1.1. Should TTB adopt the proposed wording of the major food allergen statement ("Contains major food allergen(s)" followed by a colon and the name of the food source from which each major food allergen is derived)? Alternately, should TTB require or allow alternative formats, including the following:
 - 1.1.1. "Contains" followed by a colon and the name of the food source from which each major food allergen is derived; or
 - 1.1.2. A heading such as "Major Food Allergen Information" followed by "Contains:" or other language and the name of the food source from which each major food allergen is derived.

All of these options effectively communicate the desired information. We encourage TTB to allow the briefer options, such as "Contains: Nuts"

A consumer who needs this information will know what to do with it. They don't need to be told that this is major allergen information- they know they're allergic to nuts.

1.2. Should TTB allow the inclusion of major food allergens within a voluntary ingredient statement on labels as an alternative to a separate major food allergen statement?

Yes.

1.3. If mandatory ingredient labeling is ultimately adopted, should TTB allow the inclusion of major food allergens in the list of ingredients as an alternative to a separate major food allergen statement? If mandatory ingredient labeling is ultimately adopted, should TTB use the "Contains" statement for major food allergens, consistent with FDA's approach? Should TTB limit the use of the "Contains" statement only for major food allergens?

Yes, if the information is communicated.

1.4. Should other ingredients that are required to be disclosed under current TTB regulations (FD&C Yellow No. 5, cochineal extract or carmine, sulfites, and aspartame) be required to be listed in one statement on the label? If so, should the other ingredients be included in a "Contains" statement that includes the major food allergens? (For example, "Contains egg and sulfites"). Or should the major food allergens be identified as such, and the other ingredients listed separately (for example, "Contains Major Food Allergen: egg. Contains sulfites")? Should another statement be used for ingredients that are required to be disclosed under current TTB regulations

(FD&C Yellow No. 5, cochineal extract or carmine, sulfites, and aspartame) to differentiate from the "Contains" statement for major food allergens?

All required disclosure of ingredients should be in a single statement for simplicity.

1.5. Would requiring all mandatory disclosures to be in one place on the label, including the proposed major food allergen statement, make it easier for consumers to find this information? Would such a requirement impose additional costs or regulatory burdens on industry members as compared to allowing the mandatory disclosures to appear separately?

All required disclosure of ingredients should be in a single statement for simplicity.

1.6. Should TTB mandate specific placement, type size, and presentation requirements for major allergen 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? Or, to the extent practicable, should TTB mandate formatting consistent with FDA requirements for major allergen labeling?

TTB should keep the requirements consistent with those already existing for other mandatory information. Minimum type size and legibility requirements have been sufficient to communicate alcohol content- we see no reason they wouldn't be sufficient in this case. A box should not be required.

2. Definition of Major Food Allergen

2.1. **N/A**

3. Labeling of Fish Species

3.1. TTB solicits comments on whether labeling alcohol beverages produced using finfish protein merely as containing "fish," rather than with the name of the fish species, provides adequate information to consumers. TTB also seeks comments on whether there are alternative approaches to this issue that would provide consumers with adequate information regarding the use of finfish protein in the production of alcohol beverages.

"Fish" should be sufficient.

4. Processing and Fining Agents

4.1. TTB is proposing to require the disclosure of fining or processing agents that are or contain major food allergens, with the option of including the added parenthetical "(processing aid)" and is soliciting comments on this proposal. For example, if egg whites are used as a processing aid for wine, the industry member has the option of disclosing this on the label as follows: "Contains Major Food Allergen: egg (processing aid)." This is an option that industry members may choose to use, but they also may choose to list these agents without the parenthetical. TTB is not proposing parenthetical statements for other incidental additives besides processing aids.

TTB seeks comments on whether this proposal, which is generally consistent with FALCPA, will provide adequate information to consumers.

This seems sufficient.

5. Threshold Levels

5.1. **N/A**

6. Allergen Advisory Labeling

6.1. TTB's proposal does not specifically address allergen advisory labeling, such as statements that a product may contain a major food allergen, e.g., "May Contain (major food allergen)." TTB is concerned that allergen advisory labeling could be used as a substitute for adherence to current good manufacturing practices and could be misleading. TTB is soliciting comments on the use of allergen advisory labeling.

We believe TTB's requirements should be aligned with those for food, and if these statements on food do not undermine GMP, it should be sufficient for beverages.

In addition to aligning with food labeling practices, TTB should allow for consumers and producers some leeway to make the best decisions for themselves here. A producer may wish to disclose, out of an overabundance of caution, that equipment is shared between products that do and products that do not contain an often severe allergen, such as peanuts. A consumer with a particularly severe allergy may wish to know if equipment used to process a given product was also used to produce a product containing their allergen.

TTB is pursuing this allergen statement requirement due to its mission to provide consumers important information. Why, within that rule, should it disallow this potentially important disclosure of allergen information?

ACSA conducted a survey of its members, and found that some consumers are looking for more information about the allergens generally considered the most dangerous.

29% of respondents reported that consumers had asked them for info about allergen content. Of these, 83% reported that consumer inquiries focused on gluten content, while 11% had been asked about one of the "Big 9" allergens (milk, eggs, fish, shellfish, tree nuts, peanuts, wheat, soybeans, and sesame).

Despite most inquiries focusing on gluten, whose labeling in most distilled spirits produced under standard practices would be exempt under TTB's proposed rules in this NPRM, the number of inquiries about the Big 9 does indicate that some consumers of distilled spirits have severe allergies to major allergens, and willing distilleries should be able to choose to indicate their presence within the facility if they choose to do so.

B. Exceptions

- 1. Exceptions Found in Current Regulations
 - 1.1. N/A

2. Distillation

2.1. TTB is proposing to amend the distilled spirits regulations in proposed 27 CFR 5.75(b)(2) to specifically provide that the mandatory labeling requirements do not apply to major food allergens used in the production of a distilled spirits product if they have been completely distilled in such a manner that no protein remains in the distilled spirits. As needed, TTB will evaluate compliance by verifying the absence of protein in the distilled component using scientifically valid analytical methods that can reliably detect the presence or absence of protein or protein fragments in the finished product. If ingredients containing protein are added to the distilled spirits product after distillation, and no major food allergens are listed on the label, industry members must be prepared to substantiate, upon request, the absence of protein in the distillate, the absence of any major food allergens in the added ingredients, and the precautions taken to prevent cross-contact.

TTB is soliciting comments on whether this method of verifying compliance is adequate to protect consumers and whether there are better alternatives.

ACSA supports TTB's proposal to not require major food allergen labeling in spirits that use those allergen proteins only pre-distillation.

Yes, testing compliance through lab analysis on an as-needed basis is sufficient.

3. Compliance Date

3.1. TTB is proposing a compliance date of 5 years from the date that a final rule resulting from this proposal is published in the Federal Register to minimize the costs and burdens associated with the proposed new labeling information. TTB solicits comments on whether the proposed compliance date would suffice to limit the impact on small businesses and to reduce overall costs of compliance while ensuring that consumers are adequately informed. TTB also seeks comments on whether the use of a single compliance date for any new regulations on allergen, ingredient, or "Alcohol Facts" labeling would provide consumers with adequate information in a coherent and timely manner while also reducing costs and other regulatory burdens on industry.

If the additional allergen information is consistent with other mandated disclosures, a 5 year compliance date should be sufficient, even for affected small businesses. If the allergy disclosure is set off by a box, or requiring significantly larger physical space on the label, this could be burdensome.

Thank you for consideration of ACSA's comments. We appreciate the ability to respond and are happy to answer any questions you may have upon review.

Respectfully submitted,

Margie A.S. Lehrman, CEO

American Craft Spirits Association