



Submitted via the Federal e-Rulemaking Portal

Alcohol and Tobacco Tax and Trade Bureau (TTB)
Attn: Amy Greenberg, Director
Regulations and Ruling Division
1310 G Street, N.W., Box 12
Washington, DC 20005

Re: TTB Notice No. 238, Major Food Allergen Labeling for Wines, Distilled Spirits, and Malt Beverages

Dear Director Greenberg,

I write on behalf of the Brewers Association (BA) to provide written input on TTB Notice No. 238, *Major Food Allergen Labeling for Wines, Distilled Spirits, and Malt Beverages*.¹ We appreciate the extension of the comment period for this notice and respectfully submit these written comments on behalf of America's small and independent brewers. We thank you in advance for your time and attention to these comments.

As you know, the Brewers Association is a 501(c)(6) not-for-profit trade association of brewers, for brewers and by brewers. We have approximately 5,000 U.S. professional brewery members and over 1,200 supplier members from throughout the beer supply chain. Our mission is to promote and protect American craft brewers and their beers.

The Brewers Association has long supported the concept of mandatory allergen labeling for malt beverages, along with other alcohol beverages. A consumer's ignorance about the presence of an allergen in a beverage can have serious, even life-threatening, health consequences. This distinguishes, in a fundamental way, allergen labeling from disclosures related to, for example, calories, carbohydrates, fat, or protein.

We now turn to our specific comments on Notice 238's proposed regulations.

¹ 90 Fed. Reg. 5763 (Jan. 17, 2025).

1. **Materials Not Present in the Finished Product Should Not Require Label Disclosure**

While the mandatory allergen labeling rules proposed by Notice 238 contemplate an exemption process, the Brewers Association believes that a rational rule must start with the premise that disclosures are required only if the finished product – the product reaching consumers – contains the allergen in question. After all, a malt beverage or other food that does not contain an allergen will not cause an allergic reaction among sensitive individuals.

In this regard, we wish to remind TTB that over-disclosure has costs for consumers. Individuals with allergies should have access to as wide a variety of food, including malt beverages, as safety permits. This consideration may explain the Food & Drug Administration's (FDA's) failure to mandate "may contains" allergen warnings (they are voluntary), as a mandate might encourage risk-averse food manufacturers to overuse such labeling as a simple way to avoid liability and careful testing. Warning a consumer away from foods that they can consume without an adverse health reaction deprives that consumer of choice and variety without a corresponding health benefit.

Notice 238 proposes including processing aids and other incidental additives in an allergen labeling rule, citing the approach of The Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA).² As TTB recognizes, however, while harmonizing with FDA standards under FALCPA is often beneficial, Congress clearly contemplated that TTB would depart from those standards where appropriate.³

TTB already has recognized that alcohol beverages will, at times, require a different approach. Most notably, Notice 238 proposes to codify existing TTB policy treating distilled spirits as not containing an allergen if the product has been subject to complete distillation that removes allergenic proteins.⁴

We urge TTB to take a similar approach in other instances when sound scientific evidence indicates the lack of allergenic proteins in a finished product. To take one example, the European Union, Australia and New Zealand have ruled that the fining agent isinglass can safely be used as a processing aid in beer and wine.⁵ While TTB, with FDA assistance, should undertake a review of the evidence and not rely blindly on other nations' conclusions, we commend to TTB the more flexible approach that does not result in over-warning sensitive individuals to allergens that are not, in fact, found in a finished product.

² See 90 Fed. Reg at 5770.

³ See H.R. Rep. No. 608, 108th Cong., 2d Sess., at 3 (2004).

⁴ See 90 Fed. Reg. at 5771.

⁵ See The EFSA Journal (2007) 536, 1-10, *Opinion of the Scientific Panel on Dietetic Products, Nutrition and Allergies on a request from the Commission related to a notification from Brewers of Europe and BFBi on isinglass used as a clarifying agent in brewing pursuant to Article 6 paragraph 11 of Directive 2000/13/EC – for permanent exemption from labelling* (July 6, 2007); Food Standards Australia New Zealand, *FINAL ASSESSMENT REPORT - APPLICATION A490 - EXEMPTION OF ALLERGEN DECLARATION FOR ISINGLASS* (March 20, 2009).

Notice 238 proposes to exempt the need to identify a particular fish species where a Federal Alcohol Administration Act (FAA Act)-regulated product may contain fish.⁶ As already noted, we question whether the most likely reason for such a disclosure – use of the fining agent isinglass – should trigger an allergen disclosure. In any case, if a disclosure of fish is required, the Brewers Association agrees that the identification of fish species should not be required in the case of fish-derived processing aids.

Notice 238 proposes to permit the label of a food made with a processing aid derived from one of the major allergens to optionally identify a material as a “processing aid” on the label.⁷ As already noted, the Brewers Association does not agree that a processing aid whose material does not remain in a finished food should require disclosure. But if TTB mandates such disclosure, we would support providing the option of identifying the allergen as a “processing aid.”

2. For an Exemption System to Work, TTB Must Establish Sensible Thresholds

The Brewers Association supports the development of tolerance thresholds, as any exemption system becomes otherwise unstable and untenable as detection technology improves.

Notice 238 indicates that TTB, deferring to FDA, will not adopt any tolerances for allergens in FAA Act-regulated products.⁸ But without a threshold on what trace amounts of a material are permitted, advances in detection technology will require constant updates to recognized exemptions. Of course, such thresholds should be based on sound science. But as detection technology improves, even trace amounts of a material, perhaps naturally occurring and from multiple sources, might become detectable.

TTB regulations should create certainty, not require the industry to “chase technology.” In the case of the exemption process contemplated by TTB, better detection technology would require it to amend the regulations as soon as advancing detection technology can identify minute levels of an exempted material in a finished product. This burden of technology “moving the goalposts” would put a strain on both government and industry resources.

⁶ See 90 Fed. Reg. at 5770.

⁷ See *id.*

⁸ See 90 Fed. Reg. at 5770-71.

3. “Contains” Should be Sufficient (instead of “Contains Major Food Allergens”)

The Brewers Association believes that the statement preceding a mandatory allergen disclosure should simply say “contains,” and not the wordy and unnecessary “contains major food allergens” as proposed in Notice 238.⁹

To any reasonable consumer with a known allergen sensitivity, the word “contains” plus an identification of the allergen(s) present will give that individual the information they need. A person sensitive to gluten, for example, would instantly recognize that a product labeled “Contains: Wheat” could trigger an allergic reaction. Adding “major food allergens” does not add any useful information. If the individual does not yet know they suffer from an allergic reaction to a particular material, then identifying that material as a “major food allergen” does nothing to alert that individual to a possible health reaction.

Given that TTB proposes to defer to FDA on quite a few policy matters tackled by Notice 238, the Brewers Association does not understand why it ignores FDA when it comes to the wording of the proposed mandatory allergen statement. Under the Food, Drug, and Cosmetic Act (FD&C Act) administered by FDA, the word “contains” is sufficient for the labels of foods falling under FDA’s primary labeling jurisdiction.¹⁰ The Brewers Association does not perceive any need for a different approach with respect to FAA Act-regulated products.

The Brewers Association also urges TTB to consider regulatory burden when choosing the wording of its disclosure. “Contains major food allergens” is unnecessarily wordy, taking valuable labeling space – a scarce resource on a typical malt beverage label.¹¹ Keeping mandatory wording short where, as here, the benefit to the consumer of added words is unclear strikes a better balance between consumer protection and avoiding unnecessary burdens on the industry.

Finally, using the term “major allergens” erroneously assumes that the typical consumer understands what this means. It strains credulity to believe that consumers know the legal distinction between “major” allergens (those in FALCP and the Food Allergy Safety, Treatment, Education, and Research [FASTER] Act) and other allergens. Once again, the only conclusion is that the added information would do little to assist consumers make smart choices.

⁹ See 90 Fed. Reg. at 5768-69.

¹⁰ See 21 U.S.C. § 343(w).

¹¹ A standard twelve-ounce beer can with a full-wrap label has just 3.625” times 8” of total labeling space available.

4. A New Major Allergen Disclosure Should Incorporate Existing Disclosures for FD&C Yellow No. 5, Cochineal Extract or Carmine, Sulfites, and Aspartame

The Brewers Association encourages TTB to adopt a final rule that groups all allergen information in a single place. Existing TTB regulations require the label disclosure of FD&C Yellow No. 5, Cochineal Extract or Carmine, Sulfites, and Aspartame,¹² all due to the possibility of allergic reactions to these materials. Folding the disclosure of such material into the disclosure of major food allergens makes eminent sense.

An effective allergen labeling rule will enable consumers to find all mandatory allergen information in one place. Placing such disclosures in two places – one for “major” allergens and a different place for other allergens – would risk a consumer seeing one statement and assuming that it conveys all mandatory allergen information. A single grouping after the word “contains” would best ensure that consumers find all the allergen information they need.

Moreover, dividing allergen disclosures into multiple separate statements based on the legal basis for the disclosure would elevate legal form over real-world substance. As already explained in Section 3, above, we do not believe consumers would recognize nor understand the distinction between FALCP-mandated allergen disclosures and those (such as sulfites) arising from prior TTB rulemaking action. Basing a consumer-protection rule on legal distinctions few consumers understand would not advance the informative purpose of allergen labeling.

5. A Linear Display on the Label is Sufficient and Gives Producers Flexibility

The Brewers Association agrees with Notice 238’s proposed approach of permitting an allergen disclosure via linear display. We see no reason to highlight allergens in a text box.¹³

Individuals with allergies already are familiar with FDA’s allergen disclosures, which do not require a specific text box or other highlighting of allergen information. Instead, FDA’s major allergen rule allows the “contains” statement as text within the Principal Display Panel.¹⁴ We are not aware of any problem with consumers finding the allergen information on FD&C Act-regulated products.

TTB must also recognize that the amount of space on a beer label is quite limited. For industry, this means that any loss of space to a text box deprives them of valuable branding room. More importantly, consumers interested in allergen information do not have a large area to scan in order to find an allergen statement.

¹² See 27 C.F.R. § 7.63(b).

¹³ See 90 Fed. Reg. at 5769.

¹⁴ See FDA Guidance Document, *Guidance for Industry: Questions and Answers Regarding Food Allergen Labeling* (Edition 5), FDA-2022-D-0099 (Jan. 2025).

Thus, we perceive little danger that a linear display without a text box or other highlighting will result in consumers not finding the allergen information they need.

Finally, permitting allergen information by linear display is consistent with TTB's position in Notice 237, proposing certain nutritional declarations on the labels of FAA Act-regulated products. We see no reason to treat allergen information differently.

6. The Compliance Date Should be the Same as Any Compliance Date for the Nutritional Labeling Rules in Notice 237 and any Compliance Date for FDA's Front-of-Package Labeling Rule

Small and independent brewers, along with most of the alcohol beverage industry, currently face the prospect of three new federal labeling mandates:

- The mandatory allergen disclosures contemplated by Notice 238;
- The nutritional, alcohol content, and possibly other disclosures contemplated by TTB Notice 237;¹⁵ and
- For alcohol beverages falling under FDA's primary labeling jurisdiction, a front-of-label packaging mandate contemplated by FDA Docket No. FDA-2024-N-2910.¹⁶

The prospect of implementing different labeling changes at different times is daunting to any industry member, but particularly to small producers. The Brewers Association accordingly supports Notice 238's suggestion¹⁷ that any implementation date be coordinated with the mandatory effective date of any final regulations flowing from TTB Notice 237.

The Brewers Association also supports Notice 238's suggestion¹⁸ that a final rule allow industry members to add a mandatory allergen labeling statement to labels without the need to apply for and obtain a Certificate of Label Approval (COLA) from TTB. This sensible approach will save considerable government and industry resources. Absent this accommodation, TTB would find itself inundated with hundreds of thousands of COLA applications as the compliance date for new regulations approaches.

Finally, we support a five-year compliance date as the default phase-in period for any new allergen labeling mandate. As explained in more detail in the Brewers Association's comments in connection with Notice 237, however, we do not believe the five-year period will spare all or perhaps even most small brewers from the need for a regulatory-mandated label change.

¹⁵ 90 Fed. Reg. 6651 (Jan. 17, 2025).

¹⁶ 90 Fed. Reg. 5426 (Jan. 16, 2025).

¹⁷ See 90 Fed. Reg. at 5772.

¹⁸ See *id.*

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We thank you for your careful consideration of these comments and look forward to working with TTB on this important topic.

Sincerely,

A handwritten signature in black ink that reads "Marc E Sorini". The signature is written in a cursive, flowing style.

Marc E. Sorini

Vice President of Government Relations, Brewers Association

Cc: Bart Watson, President & CEO, Brewers Association