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Regulations and Ruling Division Alcohol and Tobacco Tax and Trade Bureau 1310 G Street NW. Box 12 Washington, DC 20005

Comment on Proposed Rule: Major Food Allergen Labeling for Wines, Distilled Spirits, and Malt Beverages (Docket No. TTB-2025-0003)

The Center for Science in the Public Interest (CSPI) respectfully submits the following comments on the Alcohol and Tobacco Tax and Trade Bureau's (TTB's) proposed rule on major food allergens for the labeling of wines, distilled spirits, and malt beverages. CSPI is a non-profit consumer education and advocacy organization that has worked since 1971 to improve the public's health through better nutrition and safer food. CSPI publishes *Nutrition Action* and is supported by the subscribers to *Nutrition Action*, individual donors, and foundation grants. CSPI is an independent organization that does not accept any corporate donations.

CSPI commends TTB for issuing a proposed rule that would greatly improve transparency and protect consumers with food allergies by requiring labeling of the top nine major food allergens that does not exempt processing aids. We would support a variety of wording options for phrasing the disclosure (e.g. "Contains..."), provided that TTB adopts a specific required phrasing to ensure uniformity. Most importantly, we urge TTB to finalize the proposed rule as expeditiously as possible; U.S. residents have already waited more than long enough for this information.

However, the final rule should be strengthened by:

- Specifying where the allergen disclosure should appear.
- Outlining specific formatting requirements.
- Requiring species-specific disclosure for the labeling of finfish.
- Adjusting the proposed 5-year compliance period to a 3.5-year compliance period, striking a better balance between giving consumers access to the information they need and want while still minimizing cost to industry.
- Explicitly requiring the allergen disclosure to appear on-package and never solely via electronic means (e.g., via QR code), as this would place a barrier between consumers and this vital information.

1) Background

When Congress passed the Food Allergen Labeling and Consumer Protection Act (FALCPA) of 2004, the associated House report documented the expectation that TTB would "determine how, as appropriate, to apply allergen labeling of beverage alcohol products and the labeling requirements for those products." It has been over 20 years since that bill was passed, but TTB has never issued final regulations applying allergen labeling requirements to alcohol. CSPI has a long history of advocating for transparency to protect consumers with food allergies, including ingredient and major food allergen labeling. In 2003, CSPI, the National Consumers League (NCL), Consumer Federation of America (CFA), and 66 other health and consumer organizations filed a citizen petition calling on TTB to require a standardized label including ingredients on all beer, wine, and distilled spirits, with an emphasis on the importance of listing common allergens.² In 2005, TTB requested public comments on alcohol labeling,³ and in 2006, TTB issued a proposed rule for mandatory allergen labeling, 4 but this rule was never finalized. Instead, an interim rule from 2006 allows voluntary allergen labeling.⁵ In October 2022, CSPI, NCL, and CFA filed a lawsuit demanding a long-overdue response to our 19-year-old citizen petition.⁶ In November 2022, in a letter responding to our lawsuit, TTB stated that it would engage in new rulemakings on nutrient and alcohol content labeling, ingredient labeling, and major food allergen labeling.⁷

The present proposed rulemaking was issued in January 2025 and would require all TTB-regulated alcoholic beverages to label the top nine food allergens using the statement "Contains Major Food Allergen(s)" followed by a colon and the name of the food source(s) from which the food allergen(s) present is/are derived (i.e., milk, eggs, fish, shellfish, tree nuts, wheat, peanuts, soybeans, and sesame). Unlike FDA regulations, the species of finfish is not required for fish ingredients. The proposed rule also applies to fining or processing agents, which are additives used in the production of alcohol. The rule allows for some exemptions, including for ingredients that are incorporated prior to the distillation process, in a manner such that no allergenic protein exists in the final product. The rule does not include any type size, formatting, or presentation requirements for the disclosure.

2) Public Health Importance of Allergen Labeling

Requiring allergen labeling on alcohol is a commonsense approach to ensuring consumers with food allergies have all the information they need to make informed purchases and stay safe when drinking alcohol. We commend TTB for proposing a strong mandatory allergen disclosure rule that does not exempt processing agents.

Roughly 11% of U.S. adults have food allergies. To help consumers with food allergies avoid allergic reactions, FDA-regulated food and beverages are required to clearly disclose the nine

most common food allergens using their common name either in the text of the ingredient list (in parentheses if not already listed by the common name) or after using a "contains" statement. Currently, TTB-regulated products are not required to disclose these allergens. Insufficient allergen and ingredient labeling puts millions of Americans with food allergies at risk of reactions ranging from mild to deadly.

Without proper labeling, consumers may be unaware that alcoholic beverages often contain major food allergens. This includes wheat in many beers, shellfish in some micheladas (Mexican beverages with beer, lime juice, and sometimes clam juice), 10,11 milk in liqueurs such as Baileys Irish Cream, and tree nuts in liqueurs such as Amaretto, Frangelico, and Nocello. 12 Additionally, additives authorized by federal regulations for use in winemaking include ingredients derived from fish, milk, and eggs. 13

Consumers with food allergies rely heavily on labels to help them avoid allergens. A recent study found that 71% of those with food allergies check labels for allergens every time they purchase a product, highlighting the importance of on-package labeling. ¹⁴ In recognition of the importance of ensuring consumers have access to allergen information, Australia, New Zealand, ¹⁵ Canada, ¹⁶ and the EU¹⁷ already require allergen disclosure for at least some alcoholic beverages.

A March 2024 poll commissioned by CSPI found that consumers do not have all the information they desire from alcohol labels. ¹⁸ Big Village's CARAVAN U.S. Online Omnibus Survey was administered to a nationally representative sample of U.S. adults, demographically balanced to represent the U.S. Census on age, sex, geographical region, race, and ethnicity. Of the 1,924 respondents, 1,509 (78%) reported consuming a drink containing alcohol in the past year. Respondents answered questions about their level of support and perceived importance of alcohol labeling. An analysis of those respondents who had at least one drink in the past year found that 65% support required labeling of allergens on alcohol and 79% would find allergen information at least somewhat helpful when making purchasing decisions about alcoholic beverages.

In addition to major allergen labeling, full ingredients labeling is important for the many consumers who have non-major food allergies. Over 170 foods are known to cause allergic reactions. ¹⁹ To ensure the safety of consumers with all types of food allergies, separately TTB should also publish the pre-rule on ingredients, which was previously sent to the Office of Management and Budget (OMB)²⁰ and call for mandatory ingredient labeling on all alcohol.

Below, we provide input on the questions posed by TTB in the proposed rule, with an emphasis on the importance of mandatory, on-package allergen disclosure, with consistent formatting.

3) Wording and Format

As already noted, TTB proposed the language: "Contains major food allergen (s):_____" and seeks comment on the content and placement of the disclosure. So long as the disclosure is mandatory, CSPI would support a variety of options for content and placement of the allergen disclosure, provided all ingredient disclosures on the label are required to be located in close proximity to each other. We also encourage TTB to move forward with mandatory ingredient labeling, on which the agency has not yet produced a proposed rule, as this will help consumers identify additional allergens beyond the top nine.

a. Wording

While the proposed language "Contains major food allergen (s):____" is useful, a more straightforward "Contains:" statement is also appropriate for major allergen disclosure. This is the wording consumers are likely accustomed to as this is the format often used for major allergen disclosure on FDA-labeled products.

While TTB has not yet proposed requiring full ingredient disclosure for alcohol, certain specific ingredients are already required to be disclosed on-label. These include sulfites, FD&C Yellow No. 5, and carmine or cochineal extract.^{21–23} Additionally, a beer or distilled liquor that contains aspartame is required to disclose "PHENYLKETONURICS: CONTAINS PHENYLALANINE." Some of these ingredients, including FD&C Yellow No. 5 and carmine or cochineal extract, are also allergens. TTB has sought comment on whether such ingredients should be included with the allergen disclosure.

If TTB adopts a simple "Contains" statement, in the absence of a mandatory ingredient list, TTB may consider allowing all ingredients that are allergens requiring disclosure to be combined in one "Contains" statement (e.g., "Contains allergen(s):_____," or simply "Contains:_____,"), with the exception of aspartame which requires more specific wording and should remain in the current required format (i.e., PHENYLKETONURICS: CONTAINS PHENYLALANINE), as this may help to signal the presence of the ingredient to consumers with phenylketonuria for whom allergy is not a specific issue.

b. Location

All mandatory ingredient and allergen disclosures for alcohol should be required to appear in close proximity to each other, ideally directly adjacent to the proposed "Alcohol Facts" panel. A 2021 analysis of the allergen labeling of products labeled for European Union regulation found that lack of a standard location for allergen information can make it harder to identify this information on the label.²⁴ Including additional ingredient information (e.g., other required ingredient disclosures) nearby would further improve the ability of consumers to note any

important health and safety information and prevent them from having to search through other material on the label.

If TTB mandates ingredient labeling, TTB should also mandate that the "Contains" statement appear below, or immediately adjacent to the ingredients list, which ideally would be required to appear directly under or adjacent to the mandatory "Alcohol Facts" panel. This would align with how consumers are accustomed to finding this information on FDA labels, which requires allergen information to be either within, after, or adjacent to the ingredients list. If the allergen labeling requirement is finalized in the absence of a mandatory "Alcohol Facts," the allergen information should be offset by a box to aid consumers in locating it.

c. Within ingredient list allergen disclosure

TTB is soliciting feedback on potentially allowing major allergen disclosure within a mandatory or voluntary ingredients list. FDA allows for disclosure of major allergens within the ingredient list provided the common or usual name for the allergen is used (or is present in parentheses next to the ingredient if the common or usual name of the allergen is not clearly in the ingredient name). However, TTB should require that a separate "Contains" statement be present directly below the "Alcohol Facts" panel, regardless of whether a full ingredients list is mandatory. The separate statement, in either scenario, would most clearly signal to consumers when a major food allergen is present and avoid the risk that consumers will wrongly infer the absence of such allergens when such separate statements do not appear.

d. Format

Allergen information should be subject to the same general requirements that apply to all mandatory information on alcohol beverage labels including that the information is readily legible, on a contrasting background, and appear as text at least 1 millimeter in height for smaller containers and 2 millimeters in height for larger containers. ^{26–28} The word "Contains" should appear in bold.

4) Considerations for Finfish

TTB is not proposing to require the name of the fish species when finfish is present in a product, instead allowing for the simple disclosure of "fish." However, many people with a finfish allergy are able to consume one or more different species of finfish²⁹ and solely labeling "fish" may lead consumers with specific fish allergies to unnecessarily avoid products. TTB should instead require that specific types of finfish be declared. This would align with FALCPA, which covers all FDA-regulated foods and requires that the species of fish also appear on the label.²⁵

In the proposed rule, TTB cites concerns that vintners and brewers using isinglass and fish gelatin as a fining agent often do not know what species of fish was used to make the product. While the burden of finding this out should not be on the alcohol producer, the problem could be

solved if manufacturers of this product simply started disclosing the type of fish from which their products are derived. Notably, some products used for fining alcohol already have FALCPA compliant allergen disclosures (*see Figure 1*). In any event, asking vintners and brewers to ascertain exactly what fish is in their product does not seem like a major burden.

Figure 1. Fish gelatin powder with FALCPA-compliant label noting tilapia as the source



Source: Amazon.com, https://www.amazon.com/Pure-Gelatin-Powder-Kosher-Certified/dp/B00CWJMX2U

5) Distillation Exemption

TTB is soliciting feedback on the proposal to exempt allergenic ingredients that have undergone distillation from allergen disclosure given that no protein remains after the distillation process. TTB would require producers to be prepared to substantiate the absence of major food allergens only if ingredients containing protein are added to the product post distillation. We agree with this exemption.

6) Allergen Disclosures need to appear directly on-package

Allergen information is critical for consumers who have food allergies and should be listed on the physical beverage container. TTB is seeking comments about whether there are alternatives to on-package allergen disclosure, such as a QR code leading to a website with the disclosure, that would still adequately inform consumers. CSPI does not support an option to provide allergen disclosures via QR code as it would create an undue burden on consumers with food allergies, who would need to spend excessive time scanning QR codes in-store just to figure out if they can or cannot consume a product. They will be more likely to simply not scan the product, depriving them of potentially critical information. Additionally, accessing QR codes requires a

smartphone, which not all consumers have, and internet access with good reception, which not all stores and drinking venues provide.

Barriers created by QR code disclosures would disproportionately affect consumers who are older or have lower incomes. In 2024, 84% of adults with annual household incomes less than \$30,000 owned smartphones compared to 96% of adults with annual household incomes over \$100,000.³⁰ These data show similar sized gaps in smartphone ownership by age, with 79% of adults aged 65 and older owning smartphones compared to 91 to 98% of adults in younger age groups.

Those living in rural or tribal areas would also be disproportionately impacted by lack of access to information if provided via QR code. A recent Federal Communications Commission (FCC) report, 31 which included data from 2022, shows a rural-urban gap for access to high-speed mobile internet (defined as 5G-NR with upload/download speeds at least 35/3 Mbps) with 64% access in rural areas versus 98% in urban areas. People living in tribal areas also face lower rates of access to reliable mobile internet (78%) compared to those living in urban areas. Even rates of "fixed terrestrial services" (i.e., fixed broadband services excluding fixed satellite service) deployments at all internet speeds differ for rural versus urban versus tribal areas, with especially large gaps in access to internet speeds of 100/20 Mbps (which FCC uses as a benchmark to assess progress towards the goal of ensuring all Americans have access to "advanced telecommunications capability.") While 98% of Americans living in urban areas have access to fixed terrestrial service speeds of 100/20 Mbps, only 72% of those living in rural areas and 76% of those living in tribal areas have access to this internet service speed.

In CSPI's March 2024 poll,¹⁸ adults who drank alcohol at least once in the past year were asked, "How would you prefer to learn about the ingredients, alcohol content, allergens, calories, and nutritional content of an alcoholic beverage?" Respondents could select one of four response options:

- 1. Read this information on the label of the container
- 2. Scan a QR code on the label
- 3. Visit a website address provided on the label
- 4. I do not want to learn this information

More than three quarters (76%) of respondents who drink said they would prefer to read information on the label of the container, while only 11% preferred to scan a QR code. The desire to see this information on-package was particularly strong among respondents living in suburban (79%) and rural communities (78%) compared to those living in urban communities (70%) and respondents over the age of 65 (83%) compared to younger respondents (71% of respondents ages 21-34) (Appendix A).

Because FDA mandates that this information appear on-package for all foods, supplements, and drugs it regulates, consumers are used to finding it on-package and therefore might not realize this information is even available if it is solely provided via QR code. For example, consumers might be accustomed to seeing "contains milk" on FDA-regulated products and then misinterpret the lack of an allergen disclosure on a TTB-regulated liqueur or canned cocktail containing milk to mean it is safe to consume.

Recently, the European Union updated its regulations for wine labeling to include mandatory ingredients, nutrition declaration, and allergen disclosure. While the new regulations allow for some information to be disclosed via QR code, they specify that allergen information is always required to also appear on-package.³²

7) Compliance date

TTB has proposed a compliance date of 5 years. This period is excessive and would further delay information that is vital for those with food allergies from appearing on alcohol products. An adjusted period of 3.5-years would better balance providing consumers with the information they need while minimizing cost to industry. According to FDA, food and beverage products tend to be voluntarily relabeled on a 2-5 year cycle, with most products undergoing voluntary label changes at least every 2-3 years.³³

Generally, the cost of label changes includes new labeling equipment (if needed), and any costs associated with label redesign, printing, and administration. While extra staff time for mandatory label-specific changes may add slight cost, when label changes for regulatory purposes coincide with changes the manufacturer would have made to their label in any case, the analysis estimates that there is minimal additional cost for the label design change to the manufacturer.

Per the cost analysis explained in detail in the alcohol facts proposed rule (referenced in the allergen proposed rule),³⁴ TTB estimates that for brand name products, 100% of changes would overlap with a regularly scheduled change within 2 years. Private labels, which make up a smaller share of the market, would be able to coordinate 100% of their changes by the 3.5-year mark. Additionally, the model estimates that there are per-UPC cost reductions in extending the compliance period from 2 years to 3.5 years, but from 3.5 years onward the cost per UPC does not decrease further. Similarly, the total cost would not decrease further by extending the compliance period past 3.5 years.

Another metric used in TTB's analysis, the total cost using a 2% discount rate, similarly sees a dramatic decrease in the total cost of labeling changes when extending the deadline from 2 years to 3.5 years (\$323.4 million at 2 years down to \$259.5 million at 3 years and down to \$204.3 million at 3.5 years). However, the reduction in price is far smaller when extending from a 3.5-to a 5-year compliance period, which reduces the discounted total by only ~\$3 million more

(1.5%). Based on TTB's own analysis, a 3.5-year compliance period would be more than fair and strike a balance between minimizing cost to industry and providing consumers access to important and long overdue information in a timely fashion.

To further minimize costs, we recommend that TTB align the compliance dates for the two current proposed rules (allergens and alcohol facts). We do not recommend coordinating compliance with the ingredient labeling pre-rule, as this would likely take much longer than the other two rules to finalize and could mean significant delay of the other two rules.

8) Conclusion

In the two decades CSPI has been advocating for allergen disclosure on alcohol, consumers with allergens have been left without access to this basic information that is present on nearly all other foods and beverages.

Finalizing this proposed rule to require on-package disclosure of the top nine major food allergens on alcoholic beverages would be an important and commonsense step towards ensuring consumers with food allergies who choose to drink can do so safely. We hope that TTB will also move swiftly to publish and finalize the ingredient labeling rule to protect those with allergies to foods other than the top nine allergens.

Sincerely,

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Appendix A.

Consumers' preferred way to learn about the ingredients, alcohol content, allergens, calories, and nutritional content of an alcoholic beverage (n= 1,509 U.S. adults who drink alcohol)*

		Read this information on the label of the container	Scan a QR code on the label	Visit a website address provided on the label	I do not want to learn this information
Total		76%	11%	7%	6%
Sex	Male	74%	12%	8%	5%
	Female	77%	11%	6%	6%
Age (years)	21 to 34	71%	13%	10%	6%
	35 to 44	73%	15%	9%	4%
	45 to 54	74%	14%	6%	6%
	55 to 64	80%	11%	4%	5%
	65 and older	83%	5%	4%	8%
Region	North East	81%	9%	6%	4%
	Midwest	79%	11%	6%	5%
	South	74%	13%	8%	6%
	West	72%	12%	8%	8%
Race	Non-Hispanic White	79%	10%	6%	5%
	Non-Hispanic Black	70%	13%	13%	5%
	Hispanic (Any race)	67%	15%	8%	10%
Annual Household Income	Less than \$50,000	72%	11%	9%	8%
	\$50,000 - less than \$100,000	79%	10%	7%	4%
	\$100,000 or more	79%	13%	5%	4%
Children in Household?	No	78%	10%	6%	6%
	Yes	70%	15%	9%	6%
Education	High school grad or less	72%	11%	8%	9%
	Some college	73%	14%	7%	6%
	College grad or more	81%	10%	6%	3%
Type of Community	Urban	70%	14%	9%	8%
	Suburban	79%	10%	7%	4%
	Rural	78%	10%	6%	7%

^{*}Weighted sample by age, sex, geographic region, race, and education to ensure reliable and accurate representation of the total U.S. population 18 years and older. Results reported reflect an analysis of responses from the 1,509 respondents who indicated that they drank alcohol at least once in the past year.

Data source: 2024 CARAVAN survey conducted by Big Village among a sample of adults 21 years of age and older.

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