**DEPARTMENT OF THE TREASURY**

**ALCOHOL AND TOBACCO TAX AND TRADE BUREAU**

**Supporting Statement –– Information Collection Request**

**OMB Control Number 1513–0084**

**Labeling of Sulfites in Alcohol Beverages.**

**A. Justification**

*1. What are the circumstances that make this collection of information necessary, and what legal or administrative requirements necessitate the collection? Also align the information collection to TTB’s Line of Business/Sub-function and IT Investment, if one is used.*

The Food and Drug Administration (FDA) has determined that sulfating agents can cause allergic reactions in humans, and, as such, the presence of sulfites in food may have serious health consequences for persons who are intolerant of sulfites, particularly asthmatics. To enable such persons to minimize their exposure to sulfites, the FDA regulations at 21 CFR 101.100(a)(4) require food labels to disclose the presence of sulfites if there are 10 parts per million or more of a sulfating agent in a finished product.

The Federal Alcohol Administration Act (FAA Act), 27 U.S.C. 205(e), directs the Secretary of the Treasury (the Secretary) to issue regulations that will provide consumers with “adequate information” as to the identity and quality of alcohol beverages. The Alcohol and Tobacco Tax and Trade Bureau (TTB) administers the FAA Act and its related regulations pursuant to section 1111(d) of the Homeland Security Act of 2002, as codified at 6 U.S.C. 531(d). The Secretary also has delegated various authorities to TTB to administer and enforce the FAA Act through Treasury Order 120–01.

Under its FAA Act authority, and consistent with FDA determinations and regulations, TTB has prescribed sulfite disclosure requirements in its alcohol beverage labeling regulations at 27 CFR 4.32(e) for wine, 5.32(b)(7) for distilled spirits, and 7.22(b)(6) for malt beverages. Those regulations require alcohol beverage labels to disclose the presence of sulfites in the labeled product if it contains 10 parts per million or more of a sulfating agent.

This information collection is aligned with ––

* Line of Business/Sub-function: Health / Consumer Health and Safety.
* IT Investment: None.

*2. How, by whom, and for what purpose is this information used?*

Sulfating agents can cause allergic responses in humans and, as such, their presence in food and beverages may have serious health consequences for persons who are intolerant of sulfites, particularly asthmatics. Persons who are or may be intolerant of sulfites use the mandated alcohol beverage label disclosure regarding the presence of sulfites to avoid consuming such products.

*3. To what extent does this collection of information involve the use of automated, electronic, mechanical, or other technological collection techniques or other forms of information technology? What consideration is given to use information technology to reduce burden?*

TTB believes that information technology is not a cost effective means for reducing burden, since this information collection is a third party disclosure that must appear on the labels of alcohol beverage products.

*4. What efforts are used to identify duplication? Can similar information already available be used or modified for use for the purposes described in Item 2 above?*

Efforts to identify duplication are not applicable to the collection of information for the purpose of disclosure to the general public through labeling or advertising.

*5. If this collection of information impacts small businesses or other small entities, what methods are used to minimize burden?*

All bottlers and importers, regardless of size, are required to disclose the presence of sulfites in alcohol beverages. Because this label disclosure is necessary for consumer protection, this third-party information collection’s burden cannot be reduced based on the size of the respondent’s business.

*6. What consequences to Federal program or policy activities and what, if any, technical or legal obstacles to reducing burden will occur if this collection is not conducted or is conducted less frequently?*

Respondents complete this information collection only as necessary to comply with the TTB regulations requiring a declaration of sulfites on alcohol beverage labels. If this collection was not conducted, consumers sensitive to sulfites would not be aware of their presence in alcohol beverage products that they might consume.

*7. Are there any special circumstances associated with this information collection that would require it to be conducted in a manner inconsistent with OMB guidelines? (See 5 CFR 1320.5(d)(2).)*

There are no special circumstances associated with this information collection that would require it to be inconsistent with OMB guidelines.

*8. What effort was made to notify the general public about this collection of information? Summarize the public comments that were received and describe the action taken by the agency in response to those comments.*

To solicit comments from the general public, TTB published a “60-day” comment request notice for this information collection in the Federal Register on May 21, 2019, at 84 FR 23157. TTB received no comments on this information collection in response.

*9. Was any payment or gift given to respondents, other than remuneration of contractors or grantees? If so, why?*

No payment or gift is associated with this information collection.

*10. What assurance of confidentiality was provided to respondents, and what was the basis for the assurance in statute, regulations, or agency policy?*

Assurances of confidentiality are not applicable for this third-party disclosure made on the labels of alcohol beverage products.

*11. What is the justification for questions of a sensitive nature? If personally identifiable information (PII) is being collected in an electronic system, identify the Privacy Impact Assessment (PIA) that has been conducted for the information collected under this request and/or the Privacy Act System of Records notice (SORN) issued for the electronic system in which the PII is being stored.*

This information collection contains no questions of a sensitive nature. In addition, this information collection is a third-party disclosure, and, as such, it does not collect personally identifiable information (PII) in an electronic system. Therefore, no Privacy Impact Assessment (PIA) or System of Records Notice (SORN) is required for this collection.

*12. What is the estimated hour burden of this collection of information?*

For this third-party disclosure of information, TTB estimates that there are 24,700 annual respondents, [[1]](#footnote-1) each making 1 response per year, for a total of 24,700 responses. TTB further estimates that each response requires 40 minutes, for an estimated annual total burden of 16,467 hours.

(24,700 respondents X 1 response each = 24,700 responses X 40 minutes per response = 988,000 minutes/60 minutes per hour = 16,467 hours.)

*13. What is the estimated annual cost burden to respondents or record keepers resulting from this information collection request (excluding the value of the hour burden in Question 12 above)?*

There are no additional costs to respondents associated with this information collection since the labeling of alcohol beverages is a usual and customary business practice.

*14. What is the annualized cost to the Federal Government?*

As a third-party disclosure made on alcohol beverage labels by industry members, there is no cost to the Federal Government associated with this information collection.

*15. What is the reason for any program changes or adjustments reported?*

There are no program changes associated with this information collection. As for adjustments, due to changes in agency estimates resulting from continued growth in the number of alcohol beverage bottlers and importers regulated by TTB, the number of respondents and annual responses to this information collection is increased from 19,197 to 24,700, and its estimated total annual burden is increased from 12,798 hours to 16,467.

*16. Outline plans for tabulation and publication for collections of information whose results will be published.*

TTB does not publish the results of this information collection, which is a third-party disclosure made on alcohol beverage labels by industry members.

17. If seeking approval to not display the expiration date for OMB approval of this information collection, what are the reasons that the display would be inappropriate?

This information collection is a third-party disclosure made on the labels of alcohol beverages that contain sulfating agents at 10 parts per million or more, and, as such, there is no prescribed TTB form for this collection. As such, there is no medium on which TTB can display this information collection’s expiration date.

*18. What are the exceptions to the certification statement?*

(c) See item 5 above.

(f) This is not a recordkeeping requirement.

(i) No statistics are involved.

(j) See item 3 above.

**B. Collections of Information Employing Statistical Methods.**

This collection does not employ statistical methods.

1. TTB has determined the affected respondents represent a portion of all alcohol beverage permittees, as follows: 1% of Distilled Spirits Plants, 5% of Brewers, 80% of Alcohol Beverage Importers, and 100% of Bonded Wineries. [↑](#footnote-ref-1)