

DEPARTMENT OF THE TREASURY
ALCOHOL AND TOBACCO TAX AND TRADE BUREAU
Supporting Statement -- Information Collection Request
OMB Control Number 1513-0121

Information Collection Request Title:

Labeling of Major Food Allergens and Petitions for Exemption.

Information Collections Issued under this Title:

- Labeling of Major Food Allergens.
- Petitions for Exemption from Major Food Allergen Labeling.

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.

Section 105(e) of the Federal Alcohol Administration Act (FAA Act; 27 U.S.C. 205(e)), authorizes the Secretary of the Treasury to prescribe regulations for alcohol beverage products introduced into interstate commerce in the United States, other than wines containing less than 7 percent alcohol by volume. The FAA Act provides that these regulations should, among other things, prohibit consumer deception and the use of misleading statements on labels and ensure that labels provide consumers with adequate information as to the identity and quality of alcohol beverage products. 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, codified at 6 U.S.C. 531(d). The Secretary also has delegated various authorities to administer and enforce the FAA Act to the TTB Administrator through Treasury Department Order 120-01.

The Federal Food, Drug and Cosmetic Act, 21 U.S.C. 301, *et seq.*, as amended by the Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA; Title II of Public Law 108-282, 118 Stat. 905) requires disclosure of major food allergens on the labels of food and beverage products subject to the jurisdiction of the Food and Drug Administration (FDA), which includes wines under 7 percent alcohol by volume. However, while the FALCPA amendments do not apply to alcohol beverages labeled under the FAA Act and the TTB regulations, the House of Representatives Committee on Energy and Commerce in its report on FALCPA called for TTB to work with the FDA to promulgate appropriate allergen labeling regulations for alcohol beverages subject to the FAA Act pursuant to TTB's Memorandum of Understanding with the FDA (see H.R. Rep. No. 108-608, 108th Cong., 2d Sess., at page 3 (2004)).

In response to this Congressional request, TTB issued regulations under its FAA Act authority allowing for the voluntary disclosure of major food allergens used in the production of alcohol beverages labeled under TTB's jurisdiction. These regulations are found at 27 CFR 4.32a for wine, 27 CFR 5.32a for distilled spirits, and 27 CFR 7.22a for malt beverages. Under these regulations, major food allergens are defined as milk, egg, fish, crustacean shellfish, tree nuts, wheat, peanuts, and soybeans, or a food ingredient that contains protein derived from those foods. These regulations also provide that if one major food allergen is declared, then all such allergens used in the production of the alcohol beverage, including those used as fining or processing agents, must be declared, except when an allergen is covered by a petition for exemption from major food allergen labeling approved by TTB. In addition, these regulations state that the allergen declaration must consist of the word "Contains" followed by a colon and the name of the food source from which each major food allergen is derived (for example, "Contains: egg").

The regulations regarding the submission and approval of petitions for exemption from major food allergen labeling are found at 27 CFR 4.32b for wine, 27 CFR 5.32b for distilled spirits, and 27 CFR 7.22b for malt beverages. Under these TTB regulations, a petition for exemption must describe the scientific evidence, including the analytical method used to produce the evidence, demonstrating that the finished product, or class of products, either: (1) does not cause an allergic response that poses a risk to human health or (2) does not contain allergenic proteins derived from a major food allergen even though that allergen was used in the product's production. In addition, under these regulations, a petitioner may request that TTB give confidential treatment to trade secrets or commercial or financial information provided in a petition, but the regulations also state that a failure to request confidential treatment at the time the information in question is submitted to TTB constitutes a waiver of confidential treatment.

The voluntary label disclosure of major food allergens used in the production of alcohol beverage products allows consumers sensitive to such allergens to identify and avoid allergen-containing products. In addition, approved petitions for exemption allow alcohol beverage producers to avoid consumer confusion by exempting from disclosure allergens that, while used in a product's production, are not present in the finished product at levels that would pose a risk to human health.

This information collection is aligned with —

- Line of Business/Sub-function: Law Enforcement/Substance Control.
- IT Investment: None.

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

The voluntary label disclosure by alcohol beverage producers of major food allergens used in the production of such products serves as a public health warning and allows consumers sensitive to such allergens to avoid them. In addition, petitions for exemption submitted by alcohol beverage producers and subsequently approved by TTB allow alcohol beverage producers to avoid consumer confusion by exempting from disclosure allergens that, while used in a product's production, are not present in the finished product at levels that would pose a risk to human health.

Together, the voluntary major food allergen labeling and petition for exemption elements of this information collection assist TTB in enforcing its statutory responsibility under the FAA Act to provide consumers with adequate information regarding the identity and quality of alcohol beverage products while avoiding consumer confusion regarding 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?

In regards to the labeling of major food allergens used in the production of alcohol beverage products, such labeling is performed by regulated industry members at their business premises, and they may use automated, electronic, mechanical, or other technologies of their choice to meet the allergen labeling requirements of this information collection. The petition for exemption element of this information collection, however, is not susceptible to the use of information technology to reduce burden due to such petitions being specific to a given product or class of products and due to the very limited number of such petitions submitted to TTB.

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?

This information collection discloses or contains information pertinent to each respondent and applicable to the specific issue of voluntary major food allergen labeling of alcohol beverages and petitions for exemption from such labeling. As far as TTB is able to determine, similar information is not available elsewhere.

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

The disclosure of major food allergens on the labels of alcohol beverage products labeled under the authority of the FAA Act, is voluntary, as is the submission of petitions for exemption. As such, TTB believes that this information collection does not have a significant impact on a substantial number of small entities. However, if such labeling is undertaken, all entities regardless of size, are required to meet the allergen labeling or petition for exemption requirements of the TTB regulations.

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?

This information collection requirement is voluntary and considered to be the minimum necessary to comply with the Congressional directive regarding major food allergen labeling for alcohol beverages labeled under the authority of the FAA Act.

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?

There are no special circumstances associated with this information collection.

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 July 13, 2017, at 82 FR 32441. 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 collection.

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

As a third-party disclosure to the public, no assurance of confidentiality is possible for the voluntary labeling of major food allergens used in the production of alcohol beverage products. For petitions for exemption, the TTB regulations at 27 CFR 4.32b (for wine), 5.32b (for distilled spirits), or 7.22b (for malt beverages) state that TTB will make public all such petitions and TTB’s responses to them unless the petitioner specifically requests confidential treatment of trade secrets or commercial or financial information provided in such a petition. The regulations also state that failure to request confidential treatment at the time the information in question is submitted to TTB constitutes a waiver of confidential treatment.

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 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?*

Currently, based on data provided by industry members and TTB personnel, TTB estimates that there are 645 annual respondents to this information collection, making one response each per year, at an estimated total annual burden of 527 hours. The burden for this information collection’s individual elements is as follows:

Information Collection	Number of Annual Respondents	No. of Responses per Respondent	Total Annual Responses	Hours per Response	Total Annual Burden Hours
Allergen Labeling	640	1	640	0.667	427
Petitions for Exemption	5	1	5	20.0	100
Totals	645	1	645		527

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)?*

TTB estimates the cost to respondents for allergen labeling disclosures and petitions for exemption from allergen labeling as follows:

- Allergen labeling, senior level preparation, 0.667 hours @ \$75.00 per hour = \$50.03 per response x 640 annual responses = \$32,019.20.
- Petitions for exemption, senior level research and preparation, 20 hours @ \$100.00 per hour = \$2,000 x 5 annual responses = \$10,000.
- Total cost to respondents for this information collection = \$42,019.20.

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

There is no cost to the Federal Government for third party disclosures such as major food allergen labeling of alcohol beverage products.

Regarding the evaluation of petitions for exemption of allergen labeling, estimates of the annual cost to the Federal Government are \$508.00 per petition and \$2,540.00 in total.

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

There are no program changes associated with this collection. As for adjustments, TTB is increasing the number of respondents and responses to the allergen labeling element of this information collection, from 500 to 640, due to an increase in the number of alcohol beverage producers making such disclosures. This results in an increase of 97 hours in annual burden (from 330 to 427 hours) for this element of this information collection. However, TTB is decreasing the estimated number of respondents and responses to the petition for exemption element of this information collection, from 20 to 5 annual responses, since TTB has, to date, received no such petitions. This results in a decrease of 300 hours in annual burden for this element of this information collection. Therefore, the overall estimated burden for this information collection has decreased from 730 hours to 527 hours, a decrease of 203 hours.

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

For major food allergen labeling of alcohol beverages: This element of this information collection is a voluntary third-party disclosure made by alcohol beverage producers on the labels of their products.

For petitions for exemption: The TTB regulations at 27 CFR 4.32b (for wine), 5.32b (for distilled spirits), or 7.22b (for malt beverages) state that TTB will make public all such petitions and TTB's responses to them unless the petitioner specifically requests confidential treatment of trade secrets or commercial or financial information provided in such a petition. The regulations also state that failure to request confidential treatment at the time the information in question is submitted to TTB constitutes a waiver of confidential treatment.

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 contains two elements: (1) the voluntary disclosure of major food allergens on alcohol beverage labels, which is a third-party disclosure, and (2) petitions for exemption from such labeling. As such, there are no prescribed TTB forms or standardized information collection instruments for this information collection requirement, and, thus, there is no medium for TTB to display the OMB approval 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.