

DEPARTMENT OF THE TREASURY

ALCOHOL AND TOBACCO TAX AND TRADE BUREAU

Supporting Statement — Information Collection Request

OMB Control Number 1513–0121

Labeling of Major Food Allergens and Petitions for Exemption

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 (the Secretary) 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 and beer that is not made with both malted barley and hops. The FAA Act provides that those 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 TTB 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 and beer that is not made with both malted barley and hops. 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 requested that TTB coordinate with the FDA to promulgate appropriate allergen labeling regulations for alcohol beverages subject to the FAA Act (see H.R. Rep. No. 108–608, 108th Cong., 2d Sess., page 3 (2004)).

In response to that 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. Those regulations define major food allergens as milk, egg, fish, crustacean shellfish, tree nuts, wheat, peanuts, and soybeans, or a food ingredient that contains protein derived from those foods. The TTB regulations also provide that if one major food allergen is declared, then all such allergens used in the production of the alcohol beverage must be declared,

including those used as fining or processing agents, 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 those 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: Health/Consumer Health and Safety.
- 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, industry members apply such labeling at their business premises, and they may use automated, electronic, mechanical, or other technologies of their choice to meet the 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, TTB considers it 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 public, TTB published a "60-day" comment request notice for this information collection in the Federal Register on November 3, 2020, at 85 FR 69680. 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?

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 respondent submits the information in question 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?

Estimated Respondent Burden: Based on recent data, the estimated annual burden for this information collection request is as follows:

Information Collection	Number of Annual Respondents	No. of Responses / Respondent	Total Annual Responses	Hours per Response	Total Annual Burden Hours
Allergen Labeling	695	1	695	0.67	466
Exemption Petitions	5	1	5	20.0	100
Totals	700	1	700	0.817	566

Estimated Respondent Labor Costs: TTB estimates the annual per-respondent and total respondent labor costs for this information collection as follows:

NAICS 312100 - Beverage Manufacturing – Management Occupations Fully-loaded Labor Rate/Hour¹ = \$82.50*						
Information Collection	Avg. Time / Response	Labor Cost / Response	Responses / Respondent	Labor Costs / Respondent	Total Responses	Total Labor Costs
Food Allergen Labeling	0.67 hour	\$55.28	1	\$55.28	695	\$38,419.60
Exemption Petitions	20 hours	\$1,650.00	1	\$1,650.00	5	\$8,250.00
TOTALS					700	\$46,669.60

* Labor costs rounded to the nearest cent.

Respondent Record Retention: There is no specific record retention requirement prescribed for this information collection because it involves the third-party disclosure of food allergen information to the public on alcohol beverage labels or the submission of food allergen labeling exemption petitions to TTB, which TTB subsequently posts to its website.

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)?*

In general, the labeling of alcohol beverage products is a usual and customary practice undertaken by alcohol beverage bottlers during the normal course of business to identify their products to consumers. Regarding the addition of food allergen information to such labels, TTB believes that bottlers have only minimal one-time costs when making minor adjustments to certain product labels to incorporate the voluntary disclosure of food allergen information on those labels. As for food allergen labeling exemption petitions, respondents incur estimated mailing costs of no more than \$10.00 for each of the 5 exemption petitions submitted annually to TTB, totaling \$50.00.

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

Regarding voluntary major food allergen labeling for alcohol beverages, there are no costs to Federal Government associated with such for third party disclosures. As for petitions for exemption from such labeling, TTB estimates the annualized costs to the Federal Government as follows:

¹ Private Sector Fully-loaded Labor Rate = Hourly wage rate x a factor of 1.44 to account for benefit costs. Based on the most recent U.S. Department of Labor, Bureau of Labor Statistics (BLS), hourly wage data for National Industry-Specific Occupational Employment and Wage Estimates for NAICS 312100—Beverage Manufacturing, the average fully-loaded labor rate per hour for Management Occupations (occupation Code 11–0000) is \$82.50 (\$57.29 in wages plus \$25.21 in benefit costs). This labor cost estimate is a maximum as wage rates for other employee categories that might respond to this collection, such as Food Scientists and Technologists, are lower than that for Management Occupations. See the BLS website at https://www.bls.gov/oes/current/naics4_312100.htm#19-0000.

Labor Costs for Evaluation of Allergen Labeling Exemption Petitions by TTB Personnel*					
Position	Fully-loaded Labor Rate/Hour ²	Processing Time per Response	Labor Costs per Response	Total Responses	Total TTB Labor Costs
GS-13, Step 5, Specialist or Chemist	91.79	4 hours	\$367.16	5	\$1,835.80
GS-14, Step 5, Supervisor	\$108.46	1 hour	\$108.46		\$542.30
TOTALS	\$95.12	5 hours	\$475.62	5	\$2,378.10

* Labor costs rounded to the nearest whole cent.

There are no annualized printing, distribution, or other costs 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, TTB is increasing the estimated annual burden associated with the allergen labeling portion of this collection, from 645 respondents and responses to 695, and from 427 hours to 466. These increases are due to an increase in the number of alcohol beverage producers making voluntary food allergen labeling disclosures. The estimated annual burden for the exemption petition portion of this collection remains the same (5 respondents and responses and 100 hours). TTB is also adjusting the costs previously reported for this collection to reflect only the annualized non-labor costs associated with this information collection (see question 13 above). Respondent labor costs are correctly reported in question 12 above.

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

The voluntary disclosure of major food allergens on alcohol beverage labels is a third-party disclosure made to the public by industry members. As for petitions for exemption for allergen labeling, 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 such confidential treatment when an industry member submits an exempt petition constitutes a waiver of confidential treatment.

² Federal Government Fully-loaded Labor Rate = Hourly wage rate x a factor of 1.63 to account for benefit costs. Per the most recent Office of Personnel Management (OPM) wage data, the fully-loaded labor rates for employees in the Washington, DC pay are: (1) GS-13, step 5 = \$91.79/hour (\$56.31 in wages plus \$35.48 in benefit costs), and (2) GS-14, step 5 = \$108.46/hour (\$66.54 in wages plus \$41.92 in benefit costs). See the OPM website at https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2021/DCB_h.pdf.

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?*

There are no prescribed TTB forms or standardized information collection instruments for voluntary food allergen labeling on alcohol beverages or petitions for exemption from such labeling. As such, there is no medium for TTB to display this collection's 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 information collection does not employ statistical methods.