

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

TTB Recordkeeping Requirement – 4.32a, 5.32a, 7.22a.

Petition for Exemption

TTB Recordkeeping Requirement - 4.32b, 5.32b, 7.22b.

A. JUSTIFICATION

1. What are the circumstances that make this collection of information necessary and what legal or administrative requirements necessitate the collection? Also include the following: Align the information collection to Treasury's Strategic Goals, Line of Business/Sub-function, and IT Investment, if one is used.

This collection of information involves voluntary labeling of major food allergens used in the production of alcohol beverages and includes a petition procedure to permit less than full allergen labeling. The information collection corresponds to the amendments to the Federal Food, Drug and Cosmetic Act (FD&C Act), 21 U.S.C. 301, *et seq.*, contained in the Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA), Title II of Public Law 108–282, 118 Stat. 905.

The allergen labeling requirements in the FALCPA do not directly apply to alcohol beverages subject to the labeling requirements of the Federal Alcohol Administration Act (FAA Act), 27 U.S.C. 201 *et seq.*, and TTB regulations. However, the House of Representatives Committee on Energy and Commerce called for TTB to work with FDA to promulgate appropriate allergen labeling regulations for these alcohol beverages pursuant to our MOU with FDA.

The Committee Report accompanying FALCPA stated:

The Committee expects, consistent with the November 30, 1987 Memorandum of Understanding, that the Alcohol and Tobacco Tax and Trade Bureau (TTB) of the Department of Treasury will pursuant to the Federal Alcohol Administration Act determine how, as appropriate, to apply allergen labeling of beverage alcohol products and the labeling requirements for those products. The Committee expects that the TTB and the FDA will work together in promulgation of allergen regulations, with respect to those products. (H.R. Rep. No. 608, 108th Cong., 2d Sess., at 3 (2004))

Regulations setting forth requirements for voluntary major food allergen labeling on alcoholic products are located in 27 CFR 4.32a, 5.32a, and 7.22a. Regulations setting forth requirements for filing a petition for exemption from voluntary major food allergen labeling on alcoholic products are located in 27 CFR 4.32b, 5.32b, and 7.22b.

Under 27 CFR 4.32a, 5.32a, and 7.22a, (b) *Voluntary labeling standards*, major food allergens (defined in §4.32a(a)(1), 5.32a(a)(1), and 7.22a(a)(1)) used in the production of wine, distilled spirits, and beer, respectively; may, on a voluntary basis, be declared on any label affixed to the container. However, if any one major food allergen is voluntarily declared, all major food allergens used in production of either alcoholic beverage, including major food allergens used as fining or processing agents, must be declared, except when covered by a petition for exemption approved by TTB under §4.32b, 5.32b, and 7.22b. The major food allergens 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").

A petitioner (for exemption) must provide scientific evidence (including the analytical method used to produce the evidence) that demonstrates that the finished product or class of products, as derived by the method specified in the petition, either: (1) Does not cause an allergic response that poses a risk to human health; or (2) does not contain allergenic protein derived from one of the foods identified in §4.32a(a)(1)(i), 5.32a(a)(1)(i), and 7.22a(a)(1)(i) even though a major food allergen was used in production.

A petitioner who provides trade secrets or other commercial or financial information in connection with a petition for exemption under §4.32b, 5.32b, and 7.22b may request that TTB give confidential treatment to that information. A failure to request confidential treatment at the time the information in question is submitted to TTB will constitute a waiver of confidential treatment. A request for confidential treatment of information under this section must conform to the standards in §4.32b(2)(i) through (iv), 5.32b(2)(i) through (v), and 7.22b(2)(i) through (v).

This information collection is aligned with:

Line of Business/Sub-function: Law Enforcement/Substance Control  
IT Investment: Regulatory Major Application Systems

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

The information collection will allow alcohol beverage producers to declare major food allergens on their product labels. This information will provide a health warning to allergic consumers. A producer who decides to engage in major food allergen labeling must declare all allergens used in production except when a petition for exemption from labeling has been granted for a particular allergen.

This information collection also helps TTB enforce our primary statutory responsibility under the FAA Act of providing the consumer with adequate information concerning the identity and quality of alcohol beverage 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 will approve, on a case-by-case basis, the use of improved technology for the maintenance of this information.

4. What efforts are used to identify duplication? Why can the agency not use or modify for use any similar information already available for the purposes described in Item 2 above?

No similar information is available from other sources.

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

The collection of information does not have a significant impact on a substantial number of small businesses or other small entities.

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 intent as announced in the FALCPA.

7. Are there any special circumstances associated with the information collection would require it to be conducted in a manner inconsistent with OMB guidelines?

The information collection is voluntary and does not require respondents to do any reporting.

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.

A 60-day Federal Register notice was published for this information collection on Friday, April 11, 2014, 79 FR 20305. The notice solicited comments from the general public. TTB received no comments.

9. What decision was made to provide any payment or gift to respondents, other than remuneration of contractors or grantees?

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?

Labeling information associated with this collection is maintained at the premises of the regulated individual. However, 18 U.S.C. 1905, and 5 U.S.C. 552 protect the confidentiality of proprietary or personal information obtained by the agency.

11. What justification is there 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 Privacy Act System of Records notice (SORN) that has been issued for the electronic system in which the PII is being stored.

We ask no questions of a sensitive nature. This collection is not associated with a PIA or SORN.

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

TTB estimates the number of allergen labeling respondents remains at 500. Each respondent prepares 1 allergen labeling response annually and takes 0.66 hour per response. These estimates were provided by industry and TTB field personnel. TTB also estimates the number of petition respondents remains at 20. Each respondent prepares 1 petition annually and takes 20 hours per petition response. These estimates are based on informal surveys of the industry and TTB laboratory personnel.

The estimated annual total burden remains at 730 hours.

Type of Respondent	Estimated Number of Respondents	Number of Responses Per Respondent	Annual Responses	Hours Per Response	Burdens
Allergen Labeling	500	1	500	0.66	330
Petition	20	1	20	20	400
<b>TOTALS</b>	<b>520</b>	<b>1</b>	<b>520</b>	<b>20.66</b>	<b>730</b>

13. What is the estimated total annual cost burden to respondents or recordkeepers resulting from this collection of information (excluding the value of the burden hours in Question 12 above)?

Total annual cost estimate associated with this paperwork requirement is allocated entirely to preparation and maintenance. Annual costs are allocated as follows:

Personnel time requirements:

Senior level preparation of 0.66 hours @ \$75.00/hour  
 per **allergen labeling respondent** = \$ 49.50  
 49.50 X 500 allergen label respondents = \$ 24,750

Senior level preparation of 20 hours @ \$100.00/hour per <b>petition respondent</b>	= \$ 2,000	
2,000 X 20 petition respondents		= <u>\$ 40,000</u>
Total industry cost burden for respondents		\$ 64,750

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

There is no cost to the Federal Government for 3<sup>rd</sup> party labeling.

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

There are no program changes or adjustments associated with this collection.

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

The results of this collection will not be published.

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?

We do not intend to display the expiration date of OMB approval for this collection because there is no appropriate medium for displaying it.

18. What are the exceptions to the certification statement?

- (c) See item 5 above.
- (f) This is not a recordkeeping collection so there is no retention period.
- (i) No statistics involved.
- (j) See item 3 above.

**B. COLLECTION OF INFORMATION EMPLOYING STATISTICAL METHODS**

This collection does not employ statistical methods.