

**DEPARTMENT OF THE TREASURY  
ALCOHOL AND TOBACCO TAX AND TRADE BUREAU**

**Supporting Statement — Information Collection Request**

**Formula and Process for Domestic and Imported Alcohol Beverages**

**OMB Control Number 1513–0122**

Information Collection Instruments Issued under this Title:

- Formula and Process for Domestic and Imported Alcohol Beverages (TTB F 5100.51).
- Formulas Online (FONL) — Formula and Process for Domestic and Imported 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.*

General Legal Authority

The Alcohol and Tobacco Tax and Trade Bureau (TTB) administers chapter 51 (distilled spirits, wine and beer) of the Internal Revenue Code of 1986, as amended, (IRC, 26 U.S.C.), as well as the Federal Alcohol Administration Act (FAA Act, 27 U.S.C. chapter 8), pursuant to section 1111(d) of the Homeland Security Act of 2002, as codified at 6 U.S.C. 531(d). Additionally, the Secretary of the Treasury (the Secretary) has delegated certain IRC and FAA Act administrative and enforcement authorities to TTB via Treasury Department Order 120–01.

In general, provisions of chapter 51 of the IRC govern the production, classification, and taxation of alcohol products, and the IRC at 26 U.S.C. 5555 authorizes the Secretary to issue regulations requiring persons subject to the alcohol excise tax to, among other things, keep such records and render such statements as the Secretary may prescribe by regulation. The FAA Act at 27 U.S.C. 205(e) prohibits consumer deception in alcohol beverage labeling and advertising, and it requires alcohol beverage labels to provide consumers with adequate information as to the identity and quality of alcohol beverages. That FAA Act section also authorizes the Secretary to issue regulations regarding alcohol beverage labeling and advertising.

The TTB regulations issued under the authority of the IRC that govern operations by proprietors of domestic distilled spirits plants, wineries, and breweries are found in 27 CFR parts 19, 24, and 25, respectively. The TTB regulations issued under the FAA Act that govern the labeling of wine, distilled spirits, and malt beverages are found in 27 CFR parts 4, 5, and 7, respectively. IRC and FAA Act-based formula submission requirements

also appear in 27 CFR part 26, which contains regulations related to alcohol products brought into the United States from Puerto Rico and the Virgin Islands.

Under those TTB regulations, proprietors generally do not need TTB preapproval to manufacture traditional or standard alcohol beverage products. However, if a proprietor wishes to manufacture a non-standard distilled spirit, wine, beer, or malt beverage product, the TTB regulations may require that such proprietors submit a formula, which also may require submission of samples and/or a statement of process, before beginning production. Such formulas allow TTB to determine that the product in question is properly classified for excise tax purposes under the IRC and that it is properly labeled under the FAA Act.

#### Use of TTB F 5100.51 and FONL as an Alternate Method:

The TTB regulations prescribe the use of different, commodity-specific forms or letterhead notices for the submission of distilled spirits, wine, or beer/malt beverage formulas, which are approved under various other OMB control numbers.<sup>1</sup> However, under this OMB control number, 1513–0122, proprietors may substitute form TTB F 5100.51, Formula and Process for Domestic and Imported Alcohol Beverages, or its electronic web-based equivalent in TTB's Formulas Online (FONL) system for those prescribed commodity-specific information collections. TTB has issued these two comprehensive information collection instruments to simplify the formula submission process and to provide a more consistent means of information collection across all commodity areas for both domestic and imported products.

TTB intends to pursue regulatory changes that will replace the various commodity-specific information collections currently set forth in the TTB regulations with this information collection. Until those regulatory changes occur, proprietors may voluntarily use TTB F 5100.51 or FONL as an authorized alternate method or procedure for submitting any required alcohol formulas.

#### Commodity-specific Statutes and Regulations Related to This Information Collection

##### *Distilled Spirits:*

The IRC, at 26 U.S.C. 5201 requires proprietors to conduct all operations at distilled spirits plants under such regulations as the Secretary shall prescribe. Also, the IRC at U.S.C. 5222(c), 5223, and 5232 authorizes the Secretary to issue regulations regarding, respectively, the removal and addition of extraneous substances from distilled spirits, the redistillation of distilled spirits, and the import of distilled spirits imported or brought into the United States in bulk containers. In addition, the FAA Act at 27 U.S.C. 205(e) authorizes the Secretary of the Treasury to issue regulations regarding the labeling of distilled spirits to prohibit consumer deception regarding such products, to provide the consumer with adequate information as to the identity and quality of the products, and to require a statement of composition in certain cases of distilled spirits produced by blending or rectification or if neutral spirits were used in the production of a distilled spirits product.

Under these statutory authorities, the TTB regulations in 27 CFR parts 5 and 19 require proprietors to submit a formula, listing the ingredients and process used to make a product, whenever the proprietor intends to blend, mix, purify, refine, compound, or treat distilled

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<sup>1</sup> See 1513–0046, Formula for Distilled Spirits under the FAA Act, 1513–0010, Formula and Process for Wine; and 1513–0118, Formulas for Fermented Beverage Products.

spirits in a manner which results in a change in character, composition, class, or type of the spirits. The proprietor must receive approval of the formula before its use. Under the TTB regulations in 27 CFR part 26, persons in Puerto Rico and the Virgin Islands are required to submit formulas to TTB for distilled spirits products brought into the United States. Specifically, these regulations are found at 27 CFR:

5.26	5.27	5.28	5.33(g)	19.77	26.50(a)
26.53	26.54	26.197	26.220(a)	26.223 and	26.224.

In addition, 27 CFR 19.314 and 19.348 cross-reference 27 CFR 5.26 and 5.27.

*Wine*

For wine, the IRC contains a specific formula requirement in 26 U.S.C. 5386 for special natural wines, while 26 U.S.C. 5361, 5362(d), 5387, and 5388(b) authorize regulations governing the production of wines other than natural wines. In addition, the FAA Act at 27 U.S.C. 205(e) authorizes the Secretary to issue regulations regarding the labeling of wines to prohibit consumer deception and to provide the consumer with adequate information as to the identity and quality of such products.

In general, under those statutory authorities, the TTB regulations require proprietors intending to produce special natural wine, agricultural wine, other than standard wine, or nonbeverage wine to submit the formula by which the wine, or wine product made from wine, is to be made. The TTB regulations requiring the submission of such formulas are found in 27 CFR parts 4 and 24, and in 27 CFR part 26 for wine products produced in Puerto Rico or the Virgin Islands. Specifically, formula requirements for wine are prescribed at 27 CFR:

4.38(h)	24.80	24.81	24.82	24.86	24.87
24.192	24.195	24.196	24.198	24.201	24.211
24.214	26.50(b)	26.53	26.54	26.220(b)	26.223 and
					26.224.

*Beer (Malt Beverages)*

The IRC at 26 U.S.C. 5415 and 5555 requires brewers to file returns, reports, and statements as required by the regulations prescribed by the Secretary, while the IRC at 26 U.S.C. 7805 authorizes the Secretary to promulgate “all needful rules and regulations for the enforcement” of chapter 51 of the IRC, which includes the TTB beer-related regulations prescribed in 27 CFR part 25. In addition, under its FAA Act authority at 27 U.S.C. 205(e) to regulate alcohol beverage labeling, TTB has issued regulations requiring the submission of formulas for imported malt beverages in 27 CFR part 7.

Under those IRC authorities, prior to producing certain non-standard fermented brewery products, the TTB regulations in 27 CFR part 25 require brewers to submit formulas, including descriptions of any unusual production processes, to TTB for approval prior to beginning production. Such products include those that undergo nontraditional treatments (such as filtration that changes the product’s color, flavor or character, separation of beer

into different components, reverse osmosis, concentration, or ion exchange), and those to which nonbeverage ingredients, nontraditional coloring or natural or artificial flavors, or fruit, fruit juice or concentrate, herbs, spices, honey, maple syrup, or other food materials will be added. Brewers also must submit formulas for any saké they produce, including flavored and sparkling saké. Under its FAA Act authority, the TTB regulations in 27 CFR part 7 require certain importers to submit formulas for malt beverage products prior to or in conjunction with the filing of a certificate of label approval (COLA) for the product.<sup>2</sup> Specifically, formula requirements for fermented products are prescribed at 27 CFR:

7.31(d)      25.53      25.55      25.56      25.57 and      25.58.

Line of Business and I.T. Investment

This information collection is aligned with —

- Line of Business/Sub-function: General Government / Taxation Management.
- IT Investment: Regulatory Major Application System; Formulas Online.

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

In summary, the formula and process information collected through the submission of TTB F 5100.51 or FONL allows TTB to determine if the applicant meets the requirements for the production or importation of the described alcohol beverage product. TTB also uses the information in reviewing applications for label approval.

TTB reviews the information submitted on TTB F 5100.51 or FONL to determine:

- If the proposed ingredients are safe for human consumption (that is, all ingredients are U.S. Food and Drug Administration approved or Generally Recognized as Safe for food and beverage use);
- If approved production techniques are used;
- The applicable tax rate for the product;
- The proper class and type of the alcohol beverage and the appropriate label designation of the product; and
- In the case of nonbeverage wine (withdrawn free of tax under the provision of 26 U.S.C. 5362(d)), that the wine has been rendered unfit for beverage use.

*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?*

Electronic Submissions: After registering online for its use, respondents may electronically submit alcohol beverage formulas via the TTB website using TTB's fillable, fileable, signable Formulas Online (FONL) system; see <https://www.ttb.gov/formulation/fonl-main.shtml>. FONL allows respondents to draft, submit, and track formula approval applications for domestic and imported alcohol beverages. Respondents using FONL are no longer

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<sup>2</sup> See 1513-0020, Application for and Certification/Exemption of Label/Bottle Approval.

required to submit paper formula and pre-import applications in duplicate and supporting documentation is uploaded electronically as attachments to the FONL application.

In addition, with the integration of the FONL and COLAs Online systems, certificate of label approval (COLA) applicants no longer have to supply a paper copy of a formula as part of a COLA application, but may now select a product's formula from a drop-down menu in the related COLA application. As such, TTB labeling specialists are then able to obtain all necessary information about a particular label and formula submission using FONL and do not have to access paper records.

Although FONL offers electronic submission, respondents may not see a reduction in time to complete a given formula submission application, but they may see a decrease in the amount of time it takes for them to receive a TTB determination (approval or rejection) notification regarding their formula submission.

Paper Submissions: This information collection also is available as a fillable, printable paper form, TTB F 5100.51, Formula and Process for Domestic and Imported Alcohol Beverages, on the TTB website at <https://www.ttb.gov/forms/5000.shtml>.

*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?*

TTB F 5100.51 and FONL collect information that is pertinent to each respondent and applicable to their specific alcohol beverage product formula and/or process. As far as we can 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 alcohol beverage formula information collected by TTB under this approval request protects the revenue and protects the public from unsafe and mislabeled products. As such, this information collection's requirements cannot be waived due to the size of the respondent's business. TTB notes that respondents only submit this information collection on an as-needed basis when a new or revised formula submission is required by the TTB regulations. As such, TTB believes that this information collection does not have a significant impact on a substantial number of small businesses or other 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?*

If TTB did not collect the information contained in this collection, it could not evaluate whether alcohol beverage products are: (1) correctly classified for Federal excise tax purposes, (2) safe for consumption, (3) produced using approved processes and techniques, and (4) not labeled in a deceptive or misleading manner.

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 Wednesday, May 30, 2018, at 83 FR 24842. 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?*

The Paperwork Reduction Act Notice included on TTB F 5100.51 and in FONL states, “The information collected on this form must be considered confidential tax information under 26 U.S.C. 6103, and must not be disclosed to any unauthorized party under 26 U.S.C. 7213.” In addition, 5 U.S.C. 552 protects the confidentiality of proprietary information obtained by the Government from regulated businesses and individuals.

TTB maintains the collected information in secure file rooms and computer systems with controlled access.

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.

Privacy Impact Assessments (PIAs) have been conducted for information collected under this request under the Formulas Online system and as part of the Regulatory Major Application System. A Privacy Act System of Records notice (SORN) has been issued for those systems under TTB .001–Regulatory Enforcement Record System and published in the Federal Register on January 28, 2015, at 80 FR 4637. TTB’s PIAs are available on the TTB website at <https://www.ttb.gov/foia/pia.shtml>.

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

Based on recent data provided by the office that processes formula approval applications, TTB estimates that 2,937 respondents will each file an average of 4.932 formulas, for a total of 14,485 annual responses to this information collection. Of the 14,485 total responses to this information collection, 96.4 percent were submitted electronically using the FONL system. TTB further estimates that each response will require 2 hours to complete and submit, for an estimated total annual burden of 28,970 hours.

By commodity and submission method, the estimated annual burden for this information collection is as follows:

Commodity	FONL (Electronic)		F 5100.51 (Paper)		Total Respondents	Total Responses
	Respondents	Responses	Respondents	Responses		
Distilled Spirits	1,214	6,960	74	288	1,288	7,248
Wine	966	4,687	71	203	1,037	4,890
Beer (Malt Beverages)	588	2,310	24	37	612	2,347
TOTALS	2,768	13,957	169	528	2,937	14,485
Hours per Response		2 hours		2 hours		2 hours
TOTAL BURDEN HOURS		27,914		1,056		28,970

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 average cost to respondents resulting from this information collection as follows: \$2.00 per response in overhead and material costs, for a total of \$28,970 in such costs for this information collection. In addition, TTB estimates respondents have an average of \$50.00 in salary costs per response, for a total of \$724,250 in such costs for this information collection. Therefore, the total estimated total cost to respondents resulting from this collection is \$52.00 per response, for a total estimated cost of \$753,220 for this information collection request.

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

Estimates of annual cost to the Federal Government are:

Clerical costs	5,500
Other Salary costs (review, supervisory, etc.)	130,510
Overhead	100,000
<b>TOTAL COSTS:</b>	<b>\$ 236,010</b>

Printing and distribution costs to the Federal government have decreased to \$0.00 in TTB's cost estimate due to the electronic availability of this information collection's form on FONL and on the TTB website forms page at <https://www.ttb.gov/forms/5000.shtml>.

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

Program changes: TTB F 5100.51 and the FONL beverage alcohol submission application were previously reported as separate information collections. However, as a matter of agency discretion, TTB is now reporting TTB F 5100.51 and its FONL equivalent as two information collection instruments under the same information collection since the two instruments—one paper and the other electronic—collect the same information from the same universe of respondents, and the respondent may choose to respond to this information collection using either instrument.

Adjustments: As for adjustments, due to changes in agency estimates, TTB has increased the overall estimated number of annual respondents, responses, and burden hours associated with this information collection. This increase is due to continued growth in the number of alcohol beverage producers regulated by TTB and the resulting increase in the number of formula submissions made to TTB. However, because TTB recently has declared more alcohol beverage products that previously required formula approval to be standard products that do not required such approval, the average number of such products submitted for formula approval by each respondent has decreased from 5.2 to 4.932 per respondent. Also due to changes in agency estimates, TTB has also increased the Federal government and respondent costs associated with this information collection.

In addition, TTB is adding a Privacy Act Notice to form TTB F 5100.51.

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

TTB will not publish the results of this information collection.

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?*

As a cost-saving measure for both TTB and the general public, TTB requests approval to not display the expiration date for OMB approval of this information collection on the paper form or in FONL. By not displaying the expiration date of this collection on the form or in FONL, TTB will not have to update the expiration date on the FONL website pages or on the

paper form each time the information collection is approved. More importantly, this avoids confusion among respondents to this information collection when the OMB approval date may have passed but the form's approval continues under month-to-month approvals while the collection is under OMB review but before OMB has taken action. In addition, TTB-regulated businesses will not have to update their stocks of paper forms or alter electronic copies of the forms, including any versions of the forms produced by some businesses, at their own expense, for use with their electronic systems or for sale.

*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.

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

This collection does not employ statistical methods.