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

## Supporting Statement — Information Collection Request

#### OMB Control Number 1513–0122

# Formula and Process for Domestic and Imported Alcohol Beverages

# **Changes Since Last Approval**

In this Supporting Statement, TTB is updating the information in the following Questions:

- In Question 1 and 12, TTB is updating the 27 CFR parts 5 and 7 regulatory sections cited due to the publication of a final rule revising and recodifying those parts issued in 2022. That final rule did not affect the requirements or burden of this information collection.
- In Question 8, TTB is updating the 60-day notice publication information related to this information collection.
- In Questions 12, 13, 14, and 15, TTB is updating, respectively, the estimated respondent burden and labor costs, respondent non-labor costs, Federal Government costs, and adjustments associated with this information collection.

#### 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.

## 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.) and 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). The Secretary of the Treasury (the Secretary) also 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, which may vary based on the type of product and its alcohol content. In addition, the IRC at 26 U.S.C. 5555 authorizes the Secretary to issue regulations requiring persons subject to alcohol excise tax to, among other things, keep records and render statements as the Secretary prescribes 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

<sup>&</sup>lt;sup>1</sup> See T.D. TTB–176, Modernization of the Labeling and Advertising Regulations for Distilled Spirits and Malt Beverages, published in the Federal Register on February 9, 2022, at 87 FR 7526. A copy of this final rule may be viewed via the TTB website at <a href="https://www.ttb.gov/rrd/treasury-decisions">https://www.ttb.gov/rrd/treasury-decisions</a>.

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 governing distilled spirit, wine, and beer operations, including formula submissions, are found in 27 CFR parts 19, 24, and 25, respectively. The TTB regulations governing alcohol beverage labeling for wine, distilled spirits, and malt beverages issued under the FAA Act, including formula submissions, are found in 27 CFR parts 4, 5, and 7, respectively. IRC and FAA Act-based formula 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, respondents generally do not need TTB preapproval to manufacture traditional or standard alcohol beverage products. However, if a respondent wishes to bottle or import a non-standard distilled spirit, wine, beer, or malt beverage product, the regulations provide that TTB may require submission of a formula approval request and may also require submission of a statement of process and/or a product sample before beginning production or importation. Such requirements allow TTB to determine that a formula product is properly classified for excise tax purposes under the IRC and that the product is properly labeled under the FAA Act.

#### Use of TTB F 5100.51 or 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 other OMB control numbers. However, under this control number, OMB No. 1513–0122, proprietors may substitute form TTB F 5100.51, Formula and Process for Domestic and Imported Alcohol Beverages, or its electronic equivalent in TTB's Formulas Online (FONL) system for the prescribed commodity-specific formula approval requests. TTB issued F 5100.51 and FONL to simplify the formula submission process and to provide a more consistent means of information collection across all commodity areas for domestic and imported alcohol beverage products.

In the future, TTB intends to replace the various commodity-specific information collections currently set forth in its 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 beverage formula approval requests.

Commodity-specific Statues and Regulations Related to This Information Collection

## Distilled Spirits:

The IRC, at 26 U.S.C. 5201 requires persons to conduct all operations at distilled spirits plants under the regulations the Secretary prescribes. 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 brought into the United States in bulk containers. In addition, the FAA Act at 27 U.S.C. 205(e) authorizes the Secretary to issue regulations regarding the labeling of distilled spirits to prohibit consumer deception and to

<sup>&</sup>lt;sup>2</sup> See OMB No. 1513–0010, Formula and Process for Wine; OMB No. 1513–0046, Formula for Distilled Spirits under the FAA Act; and OMB No. 1513–0118, Formulas for Fermented Beverage Products.

provide the consumer with adequate information as to the identity and quality of the products. That FAA Act section also allows the Secretary 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 those statutory authorities, the TTB regulations in 27 CFR parts 5 and 19 require distilled spirits bottlers and importers to submit a formula, listing the ingredients and process used to make a product, whenever they intend to blend, mix, purify, refine, compound, or treat distilled spirits in a manner that changes the character, composition, class, or type of the spirits, and they 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. These regulations are found specifically at 27 CFR:

5.28	5.192	5.193	5.194	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 5.192 and 5.193.

#### 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 to submit formulas when they intend to produce special natural wine, agricultural wine, other than standard wine, or nonbeverage wine. 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 and 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, and 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. In addition, the FAA Act at 27 U.S.C. 205(e) authorizes the Secretary to issue regulations regarding the labeling of malt beverages to

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prohibit consumer deception and to provide the consumer with adequate information as to the identity and quality of such products.

Under its 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. TTB also requires formulas for fermented products to which producers will add nonbeverage ingredients, nontraditional coloring, natural or artificial flavors, fruit, fruit juice or concentrate, herbs, spices, honey, maple syrup, or other food materials. Additionally, brewers must submit formulas for any saké they produce, including flavored and sparkling saké. Under its FAA Act authority, under the TTB regulations in 27 CFR part 7, TTB may require a bottler or importer to submit a formula, the results of laboratory testing of the malt beverage, or a sample of any malt beverage or ingredients used in producing a malt beverage prior to or in conjunction with the filing of a certificate of label approval (COLA) for the product.<sup>3</sup> Specifically, TTB prescribes formula requirements for fermented products in 27 CFR:

7.28 25.53 25.55 25.56 25.57 and 25.58.

Line of Business and IT Investment:

This information collection is aligned with —

- Line of Business/Sub-function: General Government / Taxation Management.
- *IT Investment:* Formulas Online.
- 2. How, by whom, and for what purpose is this information used?

As required by statute or regulation, alcohol beverage producers and importers must submit formulas to TTB for certain distilled spirits, wine, beer, or malt beverage products, and TTB also may require such persons to submit a statement of process and/or a product sample for analysis. The collected information allows TTB to determine that the product in question is properly classified for excise tax purposes under the IRC and to ensure that nonbeverage wine, which is withdrawn free of tax under the IRC at 26 U.S.C. 5362(d), has been rendered unfit for beverage use, which is taxable. This collection also allows TTB to determine if a formula product is properly labeled under the FAA Act. In addition, Bureau personnel use this collection to determine if substances in formula products are approved by the Food and Drug Administration and TTB for use in the product and to verify that approved substances are within specified limitations on their 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?

<u>Electronic Submissions:</u> On TTB's website, respondents may electronically complete, sign, and file alcohol beverage formula submissions using the Formulas Online (FONL) system;

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<sup>&</sup>lt;sup>3</sup> See OMB No. 1513-0020, Application for and Certification/Exemption of Label/Bottle Approval.

see https://www.ttb.gov/formulation. FONL also allows respondents to attach any required supporting documents, and to track their formula approval applications.

<u>Paper Submissions:</u> Respondents also may complete and submit via postal mail a fillable-printable paper form, TTB F 5100.51, Formula and Process for Domestic and Imported Alcohol Beverages. This form is available to respondents on the TTB website at no cost; see <a href="https://www.ttb.gov/public-information/forms">https://www.ttb.gov/public-information/forms</a>.

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 collection, approved under OMB No. 1513–0122, gathers information that is pertinent to each respondent and applicable to their specific alcohol beverage product formula approval request. While other TTB information requests collect the same formula information based on the commodity in question, this collection is a substitute for those commodity-specific collections and is not a duplication.

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

As authorized by the IRC and FAA Act, TTB collects the required formula information to protect the revenue and to protect the public from mislabeled or unsafe alcohol beverage products. As such, TTB cannot waive this collection's requirements because of the size of a respondent's business. TTB notes that respondents only submit the collected information on an as-needed basis when regulations require approval of a new or revised formula for certain alcohol beverage products. As such, TTB believes that this information collection does not have a significant impact on a substantial number of small businesses.

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 certain non-standard or non-traditional alcohol beverage products are: (1) correctly classified for 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 public, TTB published a "60-day" comment request notice for

this information collection in the Federal Register on November 29, 2024, at 89 FR 94871. 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?

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 computer systems and file rooms 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 request contains no questions of a sensitive nature. In addition, this request does not collect personally identifiable information (PII) in an electronic system. Therefore, no Privacy and Civil Liberties Impact Assessment (PCLIA) or System of Records Notice (SORN) is required for this collection.

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

<u>Estimated Respondent Burden:</u> As provided under the TTB regulations, respondents submit formula applications only for certain alcohol beverage products. TTB estimates that 99.4 percent of all respondents electronically file formula approval requests via the FONL system. In addition, TTB estimates that only 3.65 percent of all formal applications require the submission of a product sample for TTB analysis. Based on recent data, TTB estimates the annual burden for this information collection as follows:

Collection Instrument	No. of Respondents	Average. Responses / Respondent	Annual Responses	Hours Per Response	Burden Hours
Formulas Online (FONL)	4,210	5.6	23,576	2 hours	47,152
TTB F 5100.51 (paper form)	20	7.0	140	2 hours	280
Sample Submission	(155*)	5.6	868	1 hour	868
Totals	4,230	(5.8118)	24,584	(1.9647)	48,300

<sup>\*</sup> The number of respondents submitting samples (155), is within the total number of respondents (4,230).

<u>Estimated Respondent Labor Costs:</u> TTB estimates respondent "fully-loaded" labor costs for this information collection as shown below.

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NAICS 312100 - Beverage Manufacturing – Food Scientists and Technologists, Fully-loaded Labor Rate/Hour⁴ = \$55.56*						
Avg. Time / Response	Labor Cost / Response	Responses / Respondent	Labor Costs / Respondent	Total Respondents	Total Labor Costs	
1.9647 hour	\$109.16	5.8118	\$634.42	4,230	\$2,683,173.60	

<sup>\*</sup> All labor costs rounded to the nearest whole cent.

Respondent Record Retention: In general, under 27 CFR 4.40, 4.51, 5.27, 7.21(d) and 7.24(d), domestic bottlers and importers holding an original or duplicate Certificate of Label Approval (COLA) are required to present a copy of that COLA to any authorized TTB officer. As COLAs include the approval of any required formula, respondents must retain record copies of approved formulas submitted to and approved by TTB for as long as that formula and the resulting product's COLA are in use.<sup>5</sup>

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)?

The development, evaluation, and use of formulas to produce alcohol beverage products is a usual and customary practice undertaken during the normal course of business, and, as such, TTB believes that respondents have no capital, start-up, or ongoing maintenance costs for this information collection.

As for other costs, of the estimated 23,716 formula approval requests submitted to TTB annually (does not include the 868 formula sample submissions), TTB estimates that approximately 0.6 percent of all formula approval requests, 140, are submitted on paper (form TTB F 5100.51) via postal mail and incur postage and mailing supply costs, while responses filed via the FONL system have no such costs. In addition, TTB estimates that 3.65 percent of the 23,716 formula approval requests will also require the submission of a product sample to TTB for analysis, resulting in 868 sample submissions. Therefore, the total non-labor cost to respondents for this information collection are as follows:

<sup>4</sup> Private Sector Fully-loaded Labor Rate = Hourly wage multiplied by 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 estimated fully-loaded labor rate per hour for Food Scientists and Technologists (19–1012) is \$55.56, based on a mean hourly wage of \$38.58. See the BLS website at https://www.bls.gov/oes/curralcate/312100.htm.

<sup>&</sup>lt;sup>5</sup> The COLA-related record retention requirements are approved under OMB No. 1513–0020, Application for and Certification/Exemption of Label/Bottle Approval.

Item	Cost / Response	No. of Responses	<b>Total Postal Costs</b>	
Paper Submissions (TTB F 5100.51)	\$2.00	140	\$280.00	
Samples	\$30.00	868	\$26,040.00	
Totals	(\$26.1111)	1,008	\$26,320.00	

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

TTB estimates labor costs to the Federal government for this information collection as follows:

Labor Costs for TTB Personnel (Washington, DC Pay Area) for OMB No. 1513–0122*						
Position	Fully-loaded Labor Rate/Hour <sup>6</sup>	Processing Time per Response	Labor Costs per Response	Total Responses	Total TTB Labor Costs	
GS–12, Step 5, Formula Specialist	\$89.76	0.2 hour	\$17.95	23,716	\$425,702.20	
GS–13, Step 5 Sr. Formula Specialist	\$106.73	0.4 hour	\$42.69	(1,897**)	\$80,982.93	
GS–9, Step 5 Legal Instrument Examiner	\$61.89	0.2 hour	\$12.38	868	\$10,745.84	
TTB Chemists <sup>7</sup>	\$74.22	1.2 hours	\$89.06		\$77,304.08	
Totals	(\$84.7055)	0.2856	(\$24.1919)	24,584	\$594,735.05	

<sup>\*</sup> Labor costs rounded to the nearest whole cent unless otherwise noted.

TTB estimates that it has \$1.00 in overhead costs for each of the 23,716 formula approval requests submitted, and \$10.00 in laboratory supplies for each of the 868 samples submitted, resulting in a total of \$32,396.00 in overhead and supply costs for this information collection. As there is no TTB form associated with this collection, TTB has no printing or distribution costs for this collection. Therefore, the estimated total cost to TTB for this information collection is **\$627,131.05**.

those employees is \$74.22.

<sup>\*\*</sup> Due to complexities, approximately 8 percent of all formula approval request submissions require longer review by a senior specialist.

<sup>&</sup>lt;sup>6</sup> Federal Government Fully-loaded Labor Rate = Hourly wage rate x 1.63 to account for benefit costs. Per the most recent Office of Personnel Management (OPM) Federal hourly wage data, the fully-loaded labor rates for the Washington, DC wage area are: (1) GS–9, step 5 = \$61.89; (2) GS–11, step 5 = \$74.88; (3) GS–12, step 5 = \$89.76; and (4) GS–13, step 5 = \$106.73. See the OPM website at

https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2025/DCB\_h.pdf.

The TTB Beverage Alcohol Laboratory currently employs 3 GS-5 physical science technicians, and 6 GS-11, 2 GS-12, and 2 GS-13 chemists. The resulting average fully-loaded wage rate, rounded to the nearest cent, for

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

There are no program changes associated with this information collection at this time, and TTB is submitting it for extension purposes only. As for adjustments, due to changes in agency estimates, TTB is decreasing the overall estimated annual burden associated with this information collection. TTB is decreasing the estimated number of respondents from 4,325 to 4,230, the average number of responses per respondent from 6.6 to 5.8118, the number of annual responses from 28,545 to 24,584, the average time per response from 2 hours to 1.9647 hours, and total burden hours from 57,090 to 48,300 hours. TTB also notes that, due to changes in agency estimates resulting from more complete data, the estimated burden for this collection now includes an estimated 868 alcohol beverage sample submissions made under this collection.

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?

TTB will display the expiration date for OMB approval for this information collection on its related form, TTB F 5100.51.

- 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 information collection does not employ statistical methods.