What to Expect in a Distilled Spirits Plant Product Integrity Investigation

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Notice:

This information is being presented to help the public to understand and comply with the laws and regulations that the Alcohol and Tobacco Tax and Trade Bureau administers. It is not intended to establish any new, or change any existing, definitions, interpretations, standards, or procedures regarding those laws and regulations. In addition, this presentation may be made obsolete by changes in laws and regulations. Please consult the regulations for the most current regulatory requirements.

Sample documents (such as records, returns, and labels) are for illustrative purposes only and contain fictitious data.
Agenda

- Introduction
- Opening Conference
- Qualifying Documents
- Standards of Identity and Formula Compliance
- Label/Certificate of Label Approval (COLA) Verification
- Advertising
- Samples for TTB Lab Submission
- Closing Conference and Follow-Up
- Updates and Resources
TTB Overview

• Bureau within the Department of the Treasury
• Currently about 480 employees
• Headquarters are in Washington, DC
• Office of Permitting and Taxation is in Cincinnati, Ohio
• Field offices located across the country and Puerto Rico
• Laboratories located in Maryland and California
Our Mission

COLLECT the taxes on alcohol, tobacco, firearms, and ammunition

PROTECT the consumer by ensuring the integrity of alcohol products

ENSURE only qualified businesses enter the alcohol and tobacco industries

PREVENT unfair and unlawful market activity for alcohol and tobacco products
The Trade Investigations Division (TID) is responsible for ensuring industry members comply with the laws and regulations administered by TTB.

**TID investigators:**

- Ensure only qualified applicants are granted permits to engage in the production and distribution of alcohol and tobacco
- Investigate allegations of trade practice violations in the marketplace
- Examine Certificates of Label Approvals (COLAs) to deter unauthorized usage
- Prevent misleading labeling and advertising of alcohol beverages
- Respond to credible information suggesting a health-related contamination or adulteration of an alcohol product
Follow the TTB Path for Distillers

Apply for a permit and register as a Distilled Spirits Plant (DSP)

Apply for formula approval (if needed)

Produce distilled spirits products

Apply for label approval (or exemption)

Bottle/remove/sell

File tax return, pay taxes, file operational reports

Ongoing once your permit is approved:
1) Keep records of operations  
2) Report changes to your business to TTB
What Do We Look For?

Product integrity (consumer protection)

- Opening Conference
- Qualifying Documents
- Standards of Identity & Formula Compliance
- Label/Certificate of Label Approval (COLA) Verification
What Do We Look For?

Product integrity (consumer protection)

- Manipulated/Altered COLAs
- Advertising
- Proof and Fill
- Samples for TTB Lab Analysis
Opening Conference
The TTB investigator will:

• Tour the premises

• Identify and interview key personnel responsible for production, labeling, and lab analysis including alcohol and fill tests

• Identify COLAs, formulas, records, and reports needed for the investigation

• Identify operations conducted on bonded DSP premises
Qualifying Documents
Qualifying Documents

The TTB investigator will:

• Examine qualifying documents from the original application that relate to the DSP operations
• If necessary, advise of procedures to amend your permit/registration
• Verify that only authorized persons sign documents submitted to TTB
Qualifying Documents: Common Issues and Solutions

Not reporting changes in the business operations to TTB

- Must report changes in officers / directors within 30 days
- Must report changes in control / ownership within 30 days
- New consultants / employees need Power of Attorney or Signing Authority to submit on your behalf

Failure to File for altered business premises

- New buildings, tanks, rooms, labs, etc. must be reported to TTB and approved before construction or addition
Standards of Identity and Formula Compliance
Standards of Identity

The TTB investigator will:

• Verify the permittee's records accurately identify the class and type of spirits produced and/or received in bond (imported and domestic)

• Determine whether the kinds of spirits are properly identified according to the materials from which they are produced

• When applicable, examine additional documents necessary to remove specific products from Customs custody
  ◦ Certificates of origin for Scotch, Irish, and Canadian Whiskey;
  ◦ Certificates of age for rum, brandy, and agave spirits; and
  ◦ Certificates of authenticity for Tequila and Cognac
Standards of Identity: Common Issues

Proof Issues
• Vodka must be bottled at or above 80 proof
• Whisky (at the time of distillation) must be made at less than 190 proof

Ingredient Issues
• Corn whisky must be made with not less than 80% corn
• Straight whisky may not have sugar added
• Bourbon whisky must use charred new oak barrels
• Rum must be made with sugar cane or sugar cane products
TTB Approved Formula

• Ensure DSP has TTB-approved formulas for all products produced and bottled that require them.

DSP Processing Batch Records

• Compare product batch records to TTB-approved formula.
• Ensure ingredients match approved formula.
• Ensure all quantities and ranges of ingredients are within compliance.
DSPs producing products without an approved formula

DSPs not adhering to an approved formula:

• Quantities and ranges must match your approved formula
• Statement of process must match your actual production process
• Must amend / resubmit formulas if you wish to change the ingredient list
Labels/COLA Verification
The TTB investigator will:

• Verify permittee has either certificates of label approval (COLA) or exemption from label approval for labels on all bottled spirits in inventory

• Verify labels on bottled spirits include all mandatory information and avoid prohibited practices (27 CFR Parts 5 and 19)

• Verify trade names appearing on labels are identical to trade names listed on permittee's basic permit
Label/COLA Verification

- For COLAs granted conditional or use-up approval:
  - Verify product labels comply with restrictions, including expiration date, listed in the **Qualifications** section
  - Verify adequate controls are in place to ensure new labels will be in compliance and expired COLAs are not used beyond expiration date

- Verify Government Health Warning Statement meets requirements of 27 CFR part 16

- Request DSP surrender any COLAs that are inactive, obsolete, or terminated
COLAs: Common Issues

- No COLA
- Making unallowable change to product label without obtaining new COLA
- Incorrectly formatted Government Health Warning Statement
  - **Government Warning** is not bold and does not stand out from rest of warning
- Exceeding requirements for conditionally-approved COLA or per a TTB-approved use-up approval
Advertising
Advertising

The TTB investigator will:

• Review all advertising material on the DSP website and social media accounts

• Review any point of sale (POS) materials for violations, such as:
  • Sales pamphlets
  • Posters
  • Promotional displays, or
  • Written, printed, or graphic materials in stock
Advertising: Common Issues

• Missing mandatory statements
• Health claims
• Advertising is inconsistent with label
• Class/Type issues
Proof and Fill

CAPTAIN JOHN'S SPICED RUM
RUM WITH NATURAL FLAVORS ADDED

20% ALCOHOL BY VOLUME (40 PROOF)

2020
50 ml
100 ml
200 ml
375 ml
750 ml
1.00 L
1.75 L

2021
50 ml
100 ml
200 ml
375 ml
700 ml
720 ml
750 ml
900 ml
1.00 L
1.75 L
1.80 L
Proofing

The TTB investigator will:

• Verify DSP proofing procedures
• Observe plant personnel conduct proofing test
• Verify all measuring devices used for proofing are correctly calibrated
• Review required proofing records
  • Records must include all information showing DSP is compliant with requirements/regulations at 27 CFR 19.188, 19.600, and 19.356
Proofing: Common Issues

- Not using properly calibrated equipment
- Not distilling samples with high solids before proofing
- Not correcting for temperature
- Not following consistent steps in proofing
- Not maintaining accurate proofing logs
Fill Testing

The TTB investigator will:

• Verify DSP fill procedures
• Observe plant personnel conducting fill test
• Verify all measuring devices used for fill are correctly calibrated
• Review fill records required
  • Records must include all information showing DSP is compliant with requirements/regulations at 27 CFR 19.188, 19.600, and 19.356
Fill: Common Issues

• Calibration and Testing
  • Correcting for the temperature of the liquid
  • Must use calibrated equipment (thermometer, hydrometer, graduated cylinders, etc.)
  • Not checking each fill head on bottling line and making adjustments if necessary

• Records
  • No fill test records, or corrections shown on fill test record
  • No calibration records
  • No proofing records
Samples for TTB Lab Submission
Samples for TTB Lab Submission

The TTB investigator will:

• Pull several samples from bonded inventory
  • Samples will be of various sizes and products

• Send samples to TTB lab for analysis and check for proof and fill compliance (27 CFR 19.356)

• Follow up with DSP as to the results of lab analysis
Lab Samples: Common Issues

- Product is under/over proof
- Product is under filled
- Headspace, more than 8% of container

➤ See 27 CFR 5.202(b), 19.356(c), and 19.356(b)
Closing Conference and Follow-Up
Closing Conference

The TTB investigator will:

• Hold closing conference with DSP and explain results of investigation

• Advise proprietor of the results from samples submitted to the TTB lab for analysis which may require corrective action

• Issue written summary of violations and, if needed, advise proprietor of corrective action
Adverse Action

- Violations may result in TTB taking administrative action against your permit
- Administrative action can range from a warning letter, up to and including, suspension or revocation of a permit
- Findings are made part of your official TTB file
- Additional administrative actions may be taken if violations continue
Voluntary disclosure of non-compliance

- TTB encourages industry members to voluntarily disclose violations upon discovery and take appropriate corrective action
- These disclosures may mitigate actions taken by TTB in response to violations
- See TTB Industry Circular 2004-5 for details
- Submit your voluntary disclosure here:
  - [https://www.ttb.gov/contact-nrc](https://www.ttb.gov/contact-nrc)
Updates and Resources
In 2018, we proposed to modernize the labeling and advertising regulations for:

- Wine (27 CFR part 4)
- Distilled spirits (CFR part 5)
- Malt beverages (CFR part 7)

**Goals of Proposed Rule:**

- Reorganize regulations
- Simplify and clarify regulatory standards
- Incorporate guidance documents and current policy
- Reduce regulatory burden on industry members where possible
On April 2, 2020, we published a rule known informally as Phase 1. This rule finalized proposals that could be implemented quickly and provide industry members greater flexibility.

Proposals for distilled spirits:

1. **Elimination of “Brand Label”**

   Mandatory information may appear anywhere on the label, as long as the brand name, class or type designation, and alcohol content appear in the same field of vision.
Labeling Modernization
Phase 1 Final Rule (cont.)

2. Increased alcohol content tolerance

TTB increased the alcohol content tolerance for distilled spirits to +/- 0.3%

3. Age statement changes

Previously, age statements were prohibited on many types of distilled spirits

Now, age statements may appear on any distilled spirits except vodka (which may not be aged)

• Age statements may account for the time spent in multiple barrels, which may be optionally separately stated on the label
4. Updates to Standards of Identity

- Vodka no longer must be “without distinctive character, aroma, taste, or color”
  - Incorporated rulings allowing for trace amounts of citric acid and sugar
- **Straight** for whisky is an optional designation
- **Agave spirits** was added as a class that includes Tequila and Mezcal, as well as domestic or imported agave spirits
On February 9, 2022, we revised the labeling and advertising regulations for:

- Distilled spirits (CFR part 5)
- Malt beverages (CFR part 7)

**Goals of Final Rule:**

- Improve the clarity and usability of the regulations
- Liberalize certain requirements, and
- Assist industry members in submitting compliant label and formula applications

- See [T.D. TTB-176](#), Modernization of the Labeling and Advertising Regulations for Distilled Spirits and Malt Beverages
Regarding distilled spirits specifically, the final rule:

1. Finalized a number of definitions, such as *container*, *distilled spirits*, *distinctive or fanciful name*, *American proof*, and *grain*

2. Provides clarity on what constitutes a label and what constitutes advertising material on a bottle

3. Provides specificity on name and address terms: **Blended by**, **Made by**, **Prepared by**, **Manufactured by**, and **Produced by**
4. Provides clarity on Standards of Identity
   - Reorganized the Standards of Identity so that each class appears in its own section
   - Clarified that a product may meet more than one standard of identity, but must only list one on the label
   - Created a class **Distilled Spirits Specialty Products**
   - Eliminated the concept of **recognized cocktails**
American Single Malt Whisky
TTB Proposal

Standard of Identity: Proposed New Type Within Whisky Class

• We are considering amending the regulations to include a new type of whisky called American Single Malt Whisky
  • To comment, see Notice No. 213

• Must be distilled entirely at one U.S. distillery, and be mashed, distilled, and aged in the United States (i.e., a distinctive product of U.S.)

• Would permit storage in any oak barrel not exceeding 700 liters

• If finalized, any COLA using term—but not meeting proposed standard of identity—would be revoked
TTB Trade Investigations Contacts

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513-684-2481

NOTE: This is a mailing address ONLY. This is not a physical address. Please direct all inquiries to: 513-684-2481

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**Internet Resources**

**Websites**
- [www.ttb.gov](http://www.ttb.gov)
- [www.fda.gov](http://www.fda.gov)
- [www.ecfr.gov](http://www.ecfr.gov)
  - 27 CFR parts 1, 5, 16, 19
- [Distilled Spirits Beverage Alcohol Manual](http://www.ttb.gov/distilled-spirits-beverage-alcohol-manual)

**Key Search Words**
- Formula
- BAM
- Beverage Alcohol Manual
- Distilled Spirits Rulings
- eCFR
- COLA
Resources on TTB.gov

Alcohol Beverage Formula Approval Home Page

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