

WHAT TO EXPECT IN A DISTILLED SPIRITS PLANT PRODUCT INTEGRITY INVESTIGATION



TTB Disclaimer



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.



Trade Investigations Division (TID)



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 <u>trade practice</u> 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



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







Product integrity (consumer protection)

- Manipulated/Altered COLAs
- Advertising
- Proof and Fill
- Samples for TTB Lab Analysis

Opening Conference

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Opening Conference



- 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

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Qualifying Documents



- 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



- 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



Formula Compliance



TTB Approved Formula

 Ensure DSP has TTBapproved 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



Formula Compliance: Common Issues



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

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Label/COLA Verification



- 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

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Advertising



- 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

For questions about TTB's advertising requirements, contact the Market Compliance Office at **202-453-2251 (option 4)** or by e-mail at <u>Market.Compliance@ttb.gov</u>

Proof and Fill





Proofing



- 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



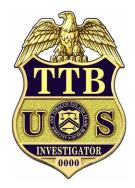
Proofing: Common Issues



- 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



- 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

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Samples for TTB Lab Submission



- •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

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Closing Conference



- 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



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
 - <u>https://www.ttb.gov/images/industry_circulars/archives/2004/04-05.html</u>
- Submit your voluntary disclosure here:
 - <u>https://www.ttb.gov/contact-nrc</u>

Resources

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TTB Trade Investigations Contacts



Western I District Field Office

21143 Hawthorne Blvd #461 Torrance, CA 90503-4615 513-684-2481

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

Western II District Field Office

5050 NE State Hwy 303 #103, PMB #206 Bremerton, WA 98311 513-684-2491

NOTE: This is a mailing address **ONLY**. This is not a physical address. Please direct all inquiries to: 513-684-2491

Mountain District Field Office

100 S. 1St Street #582331 Minneapolis, MN 55458 513-684-3608

NOTE: This is a mailing address **ONLY**. This is not a physical address. Please direct all inquiries to: 513-684-3608

Northeast District Field Office

425 Hurffville-Cross Keys Road, #8669 Blackwood, NJ 08012 202-453-3144

NOTE: This is a mailing address **ONLY**. This is not a physical address. Please direct all inquiries to: 202-453-3144

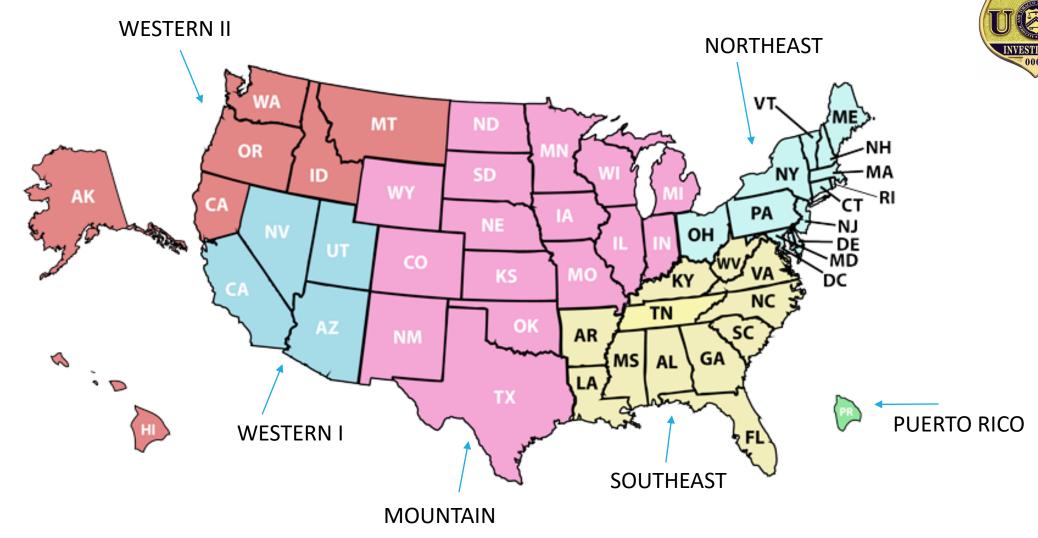
Southeast District Field Office

4300 West Cypress Street, Suite 340 Tampa, FL 33607 202-453-3117

Puerto Rico District Field Office

Torre Chardon 350 Ave Carlos Chardon, Suite 310 San Juan, PR 00918 202-453-3164

TTB Trade Investigations District Map





Internet Resources



Websites

- •www.ttb.gov
- •www.fda.gov
- •www.ecfr.gov
 - 27 CFR parts 1, 5, 16, 19
- •<u>Distilled Spirits Beverage</u> <u>Alcohol Manual</u>

Key Search Words

- •Formula
- •BAM
- Beverage Alcohol Manual
- Distilled Spirits Rulings
- •eCFR
- •COLA

*If searching on TTB.gov, begin each search with 'TTB' to return results on TTB site.







Alcohol Beverage Formula Approval Home Page https://www.ttb.gov/formulation/index.shtml

Subscribe to automatically receive the weekly TTB Newsletter

https://public.govdelivery.com/accounts/USTTB/subscriber/ new

Permits Online Help Center

https://www.ttb.gov/ponl/permits-online-help.shtml







Laws, Regulations, and Public Guidance: https://www.ttb.gov/distilled-spirits/laws-regulations-andpublic-guidance

CBMTRA page: <u>https://www.ttb.gov/alcohol/craft-beverage-modernization-and-tax-reform-cbmtra</u>

TTB Federal Register Publications: https://www.ttb.gov/what-we-do/regs-guidance/federalregister-publications







List of Allowable Changes to Approved Labels: https://www.ttb.gov/labeling/allowable-revisions

Formula Approval Tool: https://www.ttb.gov/formulation/which-alcohol-beveragesrequire-formula-approval

Proofing Video Series: <u>https://www.ttb.gov/distilled-</u> <u>spirits/proofing-tutorial</u> Thank you for attending this presentation! Please take few minutes to provide feedback on this session:

https://www.ttb.gov/survey



