



# The **Brighter** Future of the NPL

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# Objectives

- **Discuss the challenges under the current regulations and identify the need for new regulations**
- **Outline the proposed new regulations**
- **Suggest interim solutions**

# Industry Challenges

- **Condensed time for production of flavored alcoholic beverages**
- **Beverage industry's demand for TTB approved formulas**
- **Increasing requests for "rush" approvals**
- **Formulas submitted vs. products manufactured**

# Internal Challenges

- **Increasing workload over the past few years**
- **Staffing levels have not met the increased demand**
- **Increasing difficulty to meet the established 10 day turnaround time**
- **Decrease in job satisfaction of NPL chemists**

# Our Goals

- **Minimize NPL's burden on industries' business opportunities**
- **Meet the established turnaround time for formula approval**
- **Provide better tools for industry members**
- **Improve NPL employee morale**

# Business Process Re-engineering

- **Contractor hired to do a thorough review of the current process**
- **Contractor evaluated other Federal agencies with similar missions**
- **Proposed recommendations for nonbeverage processes**

# Proposed Recommendations

- **Allow manufacturers of nonbeverage products (MNBPs) to certify drawback formulas that meet TTB's standards**
- **Allow products to be certified based on organoleptic results when they do not meet the standards**

# The Result: New NBA Regulations

- **Consists of two parts:**
  - **0.1% and 1% Solution General Use Formulas**
  - **Certification**



# 0.1% and 1% Solutions

- **Natural and artificial flavor ingredients known to make alcohol unfit for beverage use**
- **Concurrent publication of General Use Formulas (TTB Publication 5154.1)**
- **To be added to the formulas allowed by 27 CFR 17.132**
- **Solutions may be manufactured without submission of TTB Drawback Form 5154.1**
- **Manufacturers will be allowed to claim drawback by submitting a drawback claim to the National Revenue Center (NRC)**

# Certification

- **Three categories of certified formulas:**
  - **Certified as unfit without a taste panel**
  - **Certified as unfit with a taste panel**
  - **Certified as fit for beverage use**

# Certified As Unfit Without a Taste Panel

- **Product contains an ingredient in Pub. 5154.1 at the required level without mitigating ingredients (glycerin, high fructose corn syrup, etc.)**
- **Product contains an ingredient from the “guidelines for nonbeverage product formulation” at the required level without mitigating ingredients**
- **Product meets the standards for sauces, syrups, brandied fruits, or candies as specified in the current regulations (27 CFR 17.133)**

# Certified As Unfit Without a Taste Panel, Cont'd.

- **Product meets the standards for vanilla extract, concentrated vanilla extract, vanilla flavoring, concentrated vanilla flavoring, vanilla-vanillin extract, or vanilla-vanillin as specified in FDA's regulations (21 CFR)**

*Exception: Vanilla extracts less than 3-fold with an alcohol content above 45% by volume*

- **Product contains less than 0.5% alcohol by volume, or no alcohol**

# Certified As Unfit Without a Taste Panel, Cont'd.

- **Certified formulas will be submitted to NPL at the time of sale or concurrently with drawback claim**
- **Appropriate canned statement will be included in item #18 on TTB Form 5154.1**
- **Applies to domestic and imported flavors as well as, "No Action" formulas**
- **Drawback claims for domestic products will be submitted to the National Revenue Center (NRC)**

# Certified As Unfit Without a Taste Panel, Cont'd.

- **NPL will log formulas into database and make formulas available to NRC for processing claims, but will not take any action on or mail copies to NRC or manufacturers**
- **Manufacturers will be required to retain samples for a period of time**
- **NPL will randomly request samples to verify that products are in agreement with the certified formulas**

# Certified As Unfit With a Taste Panel

- **Product does not meet TTB's standards based on any single ingredient, but does contain one or more ingredients that the manufacturer believes makes the product unfit for beverage use**
- **Product contains an ingredient that may appear to mitigate the impact of the flavoring ingredient, but the manufacturer believes that the product is unfit for beverage use**

# Certified As Unfit With a Taste Panel, Cont'd.

- **Manufacturer must subject product to a 6 member taste panel (parameters will be provided)**
- **4 out of 6 panelists must agree that product is unfit for beverage use**
- **Manufacturer must submit formula with the results of taste panel results to NPL**
- **Appropriate canned statement will be included in item #18 on TTB Form 5154.1**



# Certified As Unfit With a Taste Panel, Cont'd.

- **NPL will not take action on the formula but will log formulas into database and make formulas available to NRC for processing claims. It will not mail copies to NRC or manufacturers**
- **Applies to domestic and imported flavors as well as, "No Action" formulas**
- **Drawback claims for domestic products will be submitted to the NRC**

# Certified As Fit for Beverage Use

- **Domestic manufacturer knows that the product is fit for beverage use and intends to use it as an intermediate product in a nonbeverage product eligible for drawback**
- **Foreign manufacturer wants to use a product fit for beverage use in an alcoholic beverage manufactured outside of the U.S.**

# Certified As Fit for Beverage Use, Cont'd.

- **Formulas will be submitted to NPL at the time of manufacture for sale**
- **No taste panel is required**
- **Appropriate canned statement will be included in item #18 on TTB Form 5154.1**

# The Road to the New Regulations

- **Regulations are currently being drafted for a temporary rule**
- **Several levels of review required before final draft is submitted for publication in Federal Register**
- **Voluntary basis**

# The Road to New Regulations, Cont'd.

- **1<sup>st</sup> NPRM will be published concurrently with temporary rule in Federal Register**
- **Comment period**
- **Revision**
- **2nd NPRM will be published later proposing to make the temporary rule permanent**
- **Final rule**

# NPL's Role After New Regulations

- **Enhanced NPL website, including tutorial**
- **Seminars**
- **Provide advice and training to TTB auditors and investigators**
- **Develop analytical methods**
- **Goal – To expand the guidelines so everything can be certified based on guidelines to remove subjectivity**

# Interim Solution

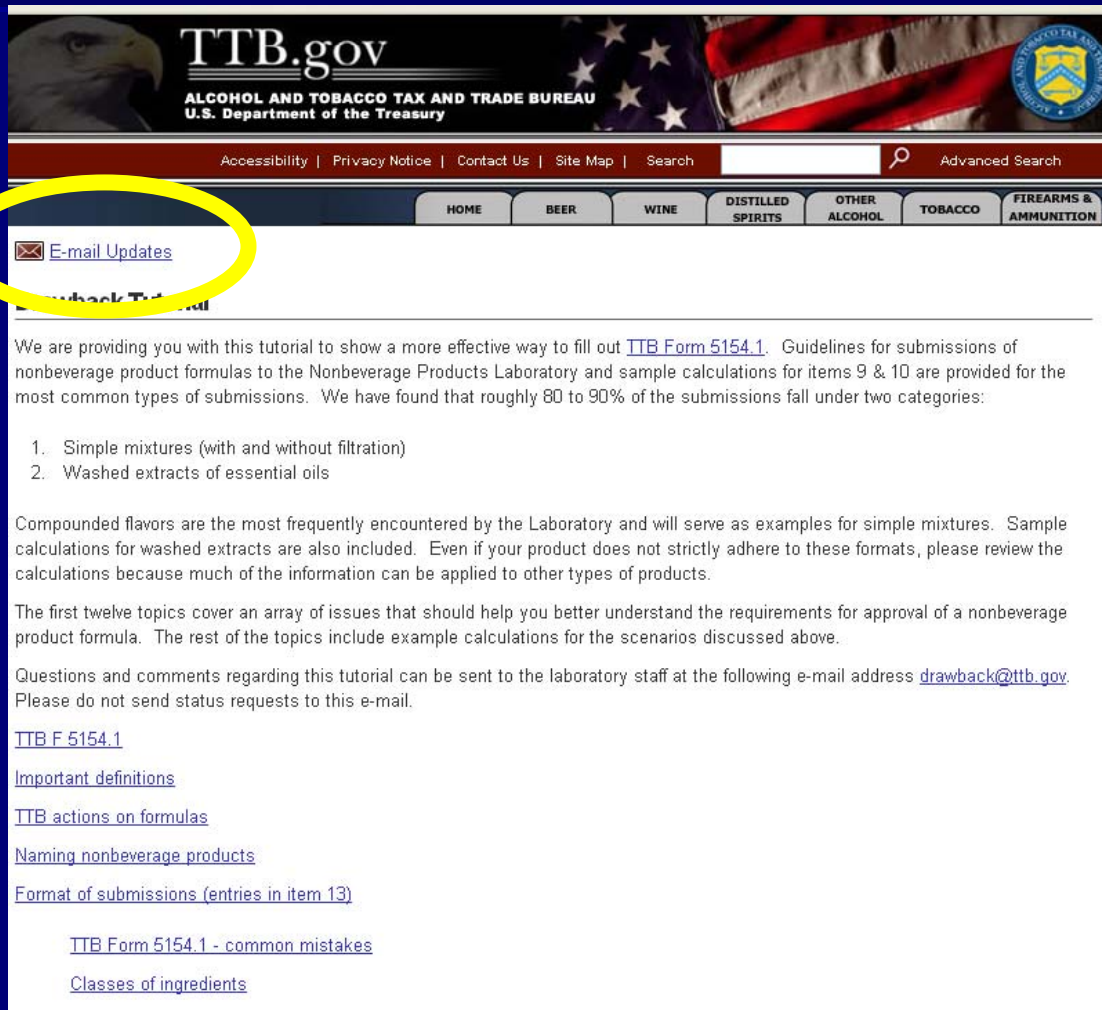
**Provide complete information on the formula**

- TTB# or ingredient data sheets for intermediate flavors**
- Identify and quantify all sources of ethanol**
- Identify and quantify limited ingredients**
- Disclose what makes a product unfit!!!**

# TTB Drawback Tutorial

<http://www.ttb.gov/ssd/drawbacktutorial.shtml>

- Link through the Laboratory's Webpage
- Google: "Drawback Tutorial"
- Add to Your Favorites



The screenshot shows the TTB.gov website header with the TTB logo and navigation menu. The 'E-mail Updates' link is circled in yellow. Below the header, the main content area contains a paragraph about the tutorial, a list of two categories, and several links for more information.

**TTB.gov**  
ALCOHOL AND TOBACCO TAX AND TRADE BUREAU  
U.S. Department of the Treasury

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[✉ E-mail Updates](#)

[Drawback Tutorial](#)

We are providing you with this tutorial to show a more effective way to fill out [TTB Form 5154.1](#). Guidelines for submissions of nonbeverage product formulas to the Nonbeverage Products Laboratory and sample calculations for items 9 & 10 are provided for the most common types of submissions. We have found that roughly 80 to 90% of the submissions fall under two categories:

1. Simple mixtures (with and without filtration)
2. Washed extracts of essential oils

Compounded flavors are the most frequently encountered by the Laboratory and will serve as examples for simple mixtures. Sample calculations for washed extracts are also included. Even if your product does not strictly adhere to these formats, please review the calculations because much of the information can be applied to other types of products.

The first twelve topics cover an array of issues that should help you better understand the requirements for approval of a nonbeverage product formula. The rest of the topics include example calculations for the scenarios discussed above.

Questions and comments regarding this tutorial can be sent to the laboratory staff at the following e-mail address [drawback@ttb.gov](mailto:drawback@ttb.gov). Please do not send status requests to this e-mail.

[TTB F 5154.1](#)

[Important definitions](#)

[TTB actions on formulas](#)

[Naming nonbeverage products](#)

[Format of submissions \(entries in item 13\)](#)

[TTB Form 5154.1 - common mistakes](#)

[Classes of ingredients](#)



# Pay.gov

For username and password please contact Edward Limowski

The screenshot shows the Pay.gov website in a Microsoft Internet Explorer browser window. The browser's address bar displays the URL <https://www.pay.gov/paygov/>. The website header includes the Pay.gov logo and the text "Provided by the US Department of the Treasury".

The main content area is divided into several sections:

- Login:** A section with input fields for "Username:" and "Password:", a "Login" button, and a link for "Forgot Your Password?".
- Find Public Forms:** A section with links for "by Form Name" and "by Agency Name", a "Search Public Forms" input field with a "Go" button, and a "Searching Help" link.
- Public Resources:** A section with links for "Resources", "Accessibility Statement", "Notices & Agreements", "Privacy & Security Policy", and "Public Reports".
- What is Pay.gov?:** A section with an American flag icon and text stating: "Pay.gov can be used to make secure electronic payments to Federal Government Agencies. Payments can be made directly from your bank account or by credit/debit card."
- How Do I Make a Payment?:** A section with a \$20 bill icon and text stating: "Find the Agency Form you need to fill out. Complete the required information and submit the Form. Enter payment information and Submit your payment."
- What Federal Agencies Can I Pay?:** A section with a classical building icon and a link for "Agency List".
- Information for Government Agencies:** A blue-bordered box with a link for "Information for Government Agencies".
- Frequently Used Forms:** A section with a link for "SBA Payments" and text: "Borrower and Lender Payments." Below this is a link for "US Customs and Border Protection" and text: "Pay Excise Taxes, apply for CDSOA Distribution." At the bottom of this section is a link for "US Courts" and text: "Pay a violation notice received on Federal..."

The Windows taskbar at the bottom shows the Start button, several open applications (Inb..., http..., TTB..., Roc..., Micr..., Pay...), and the system tray with the time 4:57 PM.

# **Thank You!**

Questions?

Phone: 240-264-1663