



# TTB's Proposed Regulatory Change and its Effect on the Vanilla Industry

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# TTB Mission

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- **Collect** alcohol, tobacco, firearms, and ammunition excise taxes that are rightfully due
- **Protect** the consumer of alcohol beverages through voluntary compliance programs that are based upon education and enforcement to ensure a fair and even marketplace
- **Assist** industry members to understand and comply with Federal tax, product, and marketing requirements associated with the commodities we regulate



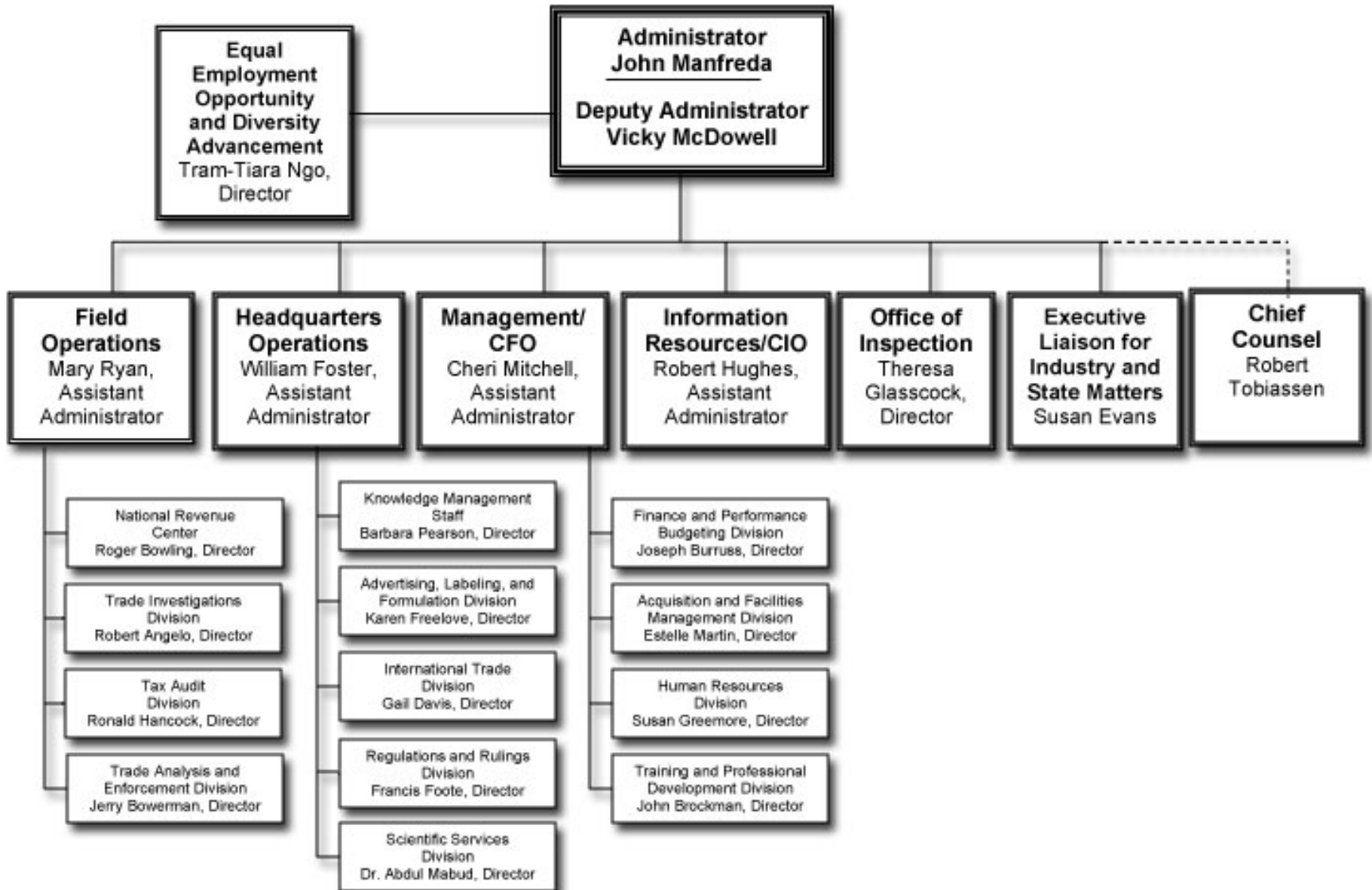
# Talk Objectives

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- Inform industry members of the proposed changes
- Discuss the effects on the vanilla industry
- Current regulations regarding the use and production of standard of identity vanilla extracts and other vanilla flavors
- TTB's position regarding sourcing of natural vanillin

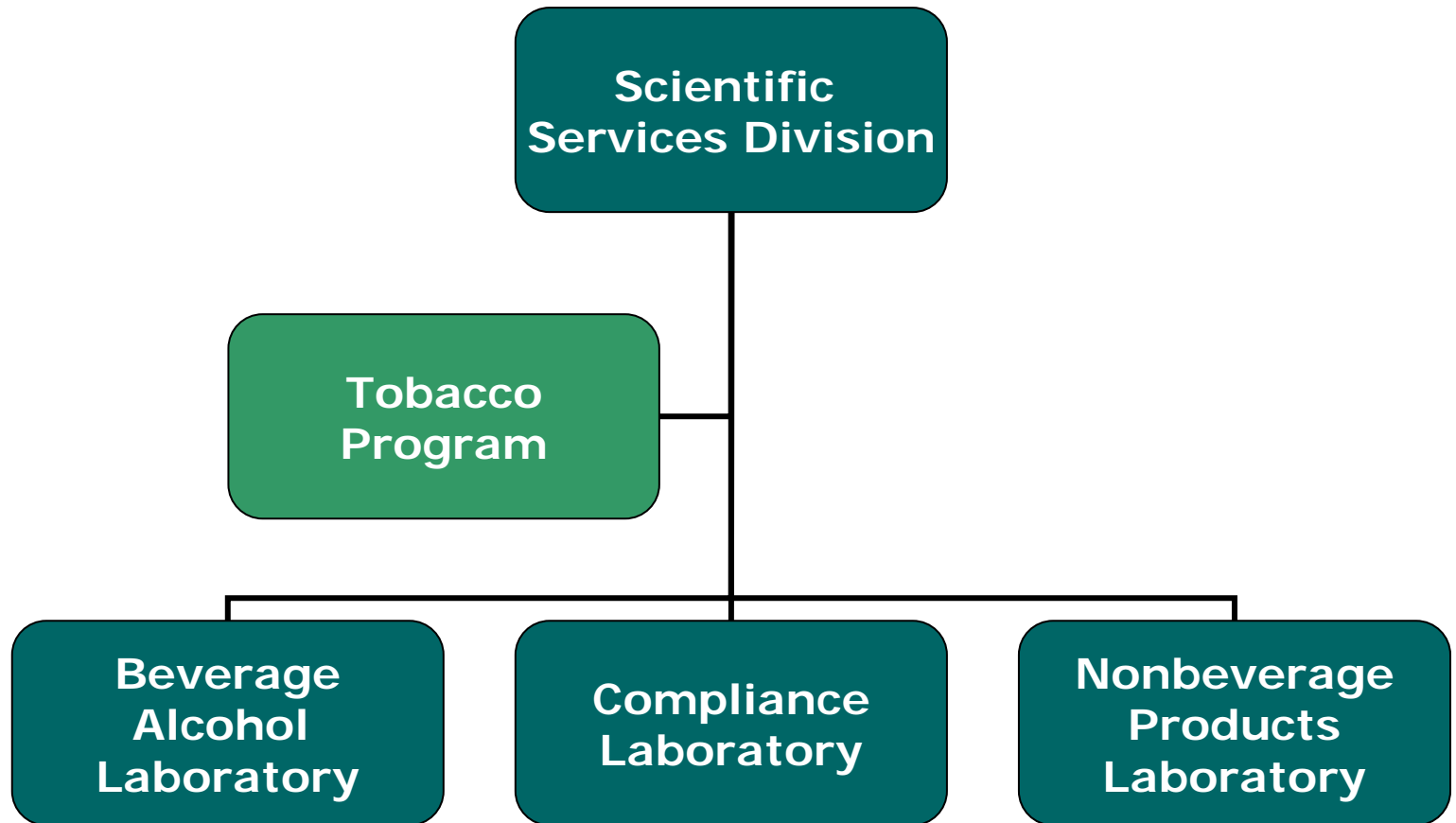
# The Alcohol and Tobacco Tax and Trade Bureau

## Bureau Organization



# Scientific Services Division

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# Nonbeverage Products Laboratory

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## Evaluates Formulas for Nonbeverage Products

- Flavors/Extracts
  - Medicines
  - Food Products
  - Perfumes
- **Should Drawback of Taxes be Paid on Distilled Spirits?**
  - **Are MNBPs Manufacturing According to Permit?**
  - **Are MNBPs Producing Products in Accordance with TTB & FDA Regulations?**



# Industry Pressures on NPL

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- **Condensed time for production of flavored alcoholic beverages (Conception to Market)**
- **Beverage industry's demand for TTB approved formulas**
- **Increasing requests for “rush” approvals**
- **Products submitted vs. products manufactured**

# Business Process Reengineering

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## Proposed Recommendations

- **Allow manufacturers of nonbeverage products (MNBPs) to certify drawback formulas that meet TTB's standards**
- **Allow organoleptic testing for those products that do not meet the standards**



# Certification

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

# Certification

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- **Three categories of certified formulas:**

- **Certified without a taste panel**
- **Certified with a taste panel**
- **Certified as fit for beverage use**



# Certified Without a Taste Panel

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- **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**



# Certified Without a Taste Panel

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- **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**
- **Drawback claims will be submitted to the National Revenue Center (NRC)**



# Certified Without a Taste Panel

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- **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**



# Benefits to Vanilla Industry

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- No Waiting Time for Formula Approval
- Reduced Waiting Time for Drawback Claim
- Reduced Burden on Manufacturers
- Greater Ability to Quickly Meet Customers' Needs



# New Regulations

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- **Regulations are currently being drafted**
- **Several levels of review required before final draft is submitted for publication in Federal Register**
- **Temporary Rule - Voluntary basis**
- **Notice of Proposed Rule Making (NPRM) Prior to Issuing a Final Rule**



# The Road to New Regulations

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- **Draft, review, and final draft of temporary rule to Main Treasury**
- **NPRM will be published in Federal Register at a later date**
- **Comment period**
- **Revision**
- **Final rule**



# TTB Laboratory Website

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

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

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## LABORATORY

**News and Events**

- [TTB Nonbeverage Formula Seminar Set for December 6 in Washington, DC](#) (11/01/06)
- **Natural Vanillin**  
FDA determines that the fermentation process for vanillin production submitted to them by Rhodia, Inc. is a natural process. [Read More.](#)
- **Drawback Tutorial for TTB Form 5154.1**  
We have developed a [tutorial](#) to help industry members complete Form 5154.1, Formula and Process for Nonbeverage Product. [Read More.](#)
- **Notice of Procedural Change**  
Effective November 13, 2006, the Nonbeverage Products Laboratory is implementing a change in procedure relating to the processing of TTB Form 5154.1 - "Formula and Process for Nonbeverage Product." [Read More.](#) (PDF Version)

**Information By Topic**

- [Drawback Tutorial](#)
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- [Limited Ingredients](#)
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- Forms
- Formulation
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# TTB Drawback Tutorial Website

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

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



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](#)

# TTB Drawback Tutorial Website

## Information Regarding Vanilla Extracts

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- Required Information
- Links to the CFR
- Basic Definitions
- Permitted Materials

### Vanilla Extracts and Vanilla Flavors

Vanilla extracts and vanilla flavors are covered within the U.S. Food and Drug Administration's regulations in [21 CFR 169.175 through 169.181](#). It is important to note that a standard of identity vanilla product must adhere to the criteria outlined in the CFR. If a product does not meet the standard of identity, it will be treated as any other flavor. A few key points regarding the standard of identity are listed below:

- **1 unit of vanilla beans:** 13.35 oz. of beans at 25% moisture
- **1X vanilla extract:** 1 unit per gallon of finished product with a minimum 35% ethanol by volume. The lower end of the range in item 10 defines the minimum.
- **vanilla flavor:** 1 unit per gallon of finished product (ethanol < 35% by volume)
- **concentrated vanilla extract:** 2 or more units per gallon with a minimum 35% ethanol by volume. The lower end of the range in item 10 defines the minimum.
- **concentrated vanilla flavor:** 2 or more units per gallon (ethanol < 35% by volume)

Other ingredients that may be used in a vanilla extract:

glycerin
propylene glycol (please quantify)
sugar (including invert sugar)
dextrose
corn syrup

If any other ingredients are used then the product does not meet the standard of identity.

### Two important tips:

- Information regarding moisture content of the beans, manufacturing yield, fold, extraction steps, recovered ethanol, and disposal of the spent beans must be included on your submission. We cannot process formula submissions with incomplete information.
- We subject 1 or 2 fold vanilla extracts to the organoleptic evaluation if they contain greater than 45% (by volume) alcohol. This is because the amount of alcohol is more than is necessary to extract all of the odorous and sapid materials from the vanilla beans.

# Vanillin: Natural vs. Artificial

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- Vanillin when Derived from Vanilla Beans is Considered Natural
- Vanillin is Considered Artificial when Derived from:
  - Turmeric
  - Clove
  - Eugenol
  - Lignin
- Rhovanil<sup>®</sup> Natural from Rhodia, Inc.
  - TTB Received Notification from the FDA
  - Natural Process → Natural Product



# Naming Guidelines for Vanilla Flavorings

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- Standard of Identity Products (CFR 21)
- Nat Vanilla Flavor (Non-Standard)
- Nat Vanilla Flavor WONF
- Nat Vanilla Type Flavor
- Nat & Art Vanilla Flavor
- Nat & Art Vanilla Type Flavor

# Standard of Identity vs. Non-Standard

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- Meets all requirements of CFR 21
  - Uses New Beans
  - Moisture Content
  - Above Minimum Alcohol Content for "Vanilla Extract"
  - Below Maximum Alcohol Content for "Vanilla Flavor"
  - Permitted Materials
- Dilution of Vanilla Concentrate to Meet Above Requirements
- Fails to meet one or more of the requirements of CFR 21
  - Uses Spent Beans
  - Less than a 1 Fold
  - Nonflavor Materials other than Glycerin, PG, Sugar, Corn Syrup are Used
  - Alcoholic Range Astraddles 35% ABV



# Nat Vanilla Flavor WONF

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- Nonstandard Vanilla Flavor
- Contains Vanilla Extract
- Contains Other Natural Flavors
- May Contain Rhovanil<sup>®</sup>
- No Specified Alcohol by Volume



# Nat Vanilla Type Flavor

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- Does Not Contain Vanilla Extract
- Contains Other Natural Flavors
- No Artificial Flavors
- May Contain Rhovanil®
- No Specified Alcohol by Volume





# Nat & Art Vanilla Flavor

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- Nonstandard Vanilla Flavor
- Contains Vanilla Extract
- May Other Contain Natural Flavors
- May Contain Artificial Flavors
- No Specified Alcohol by Volume



# Nat & Art Vanilla Type Flavor

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- Nonstandard Vanilla Flavor
- Does Not Contain Vanilla Extract
- May Contain Natural Flavors
- May Contain Artificial Flavors
- No Specified Alcohol by Volume



# Conclusion

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- New TTB Proposed Regulations Will Have a Positive Impact on Vanilla Industry
  - Production of Product
  - Payment of Drawback
  - Manufacturers Will Have an Easier Time Getting Their Products to Market
- Use of Natural Vanillin Allows Greater Flexibility in Flavor Industry
- Continued Need for Vanilla Extracts in Compounded Flavors



# Thank You!

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Questions?

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Phone: 240-264-1593

Website: <http://www.ttb.gov/ssd>