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.
How are Mead (Honey Wine) Products Classified?
How are Honey Wine Products Classified?

Depending on how they are made, wines made by fermenting honey are either:

• Standard Agricultural (honey) wine
• Other than standard wine
Production of Domestic Standard Honey Wine

• Honey must be the sole fermentable ingredient
• The following may be added:
  ◦ Water to facilitate fermentation, provided the density of the honey and water mixture is not reduced below 13 degrees Brix
  ◦ Hops in quantities not to exceed one pound for each 1,000 pounds of honey
  ◦ Pure, dry sugar or honey for sweetening
    ◦ Sugar may be added only after fermentation is completed
• After complete fermentation or complete fermentation and sweetening:
  ◦ May not exceed 14% ABV
  ◦ May not have a total solids content that exceeds 35 degrees Brix

27 CFR 24.200, 24.203, 4.21(f), TTB Ruling 2016-2

Formula approval is not required for standard honey wine
Production Limitations for Domestic Standard Honey Wine

• No wine spirits/honey spirits/brandy may be added
• No coloring or flavoring materials (e.g., fruit juices, spices, or other flavoring materials) may be added
  ◦ Exception: hops may be added to honey wine
• Cannot be the product of blending honey wine with wine made from fruit or any other agricultural commodities

Note: Grain, cereal, malt, or molasses are never allowed in the production of wine, and may not be received on bonded wine premises

27 CFR 24.200, 24.203, 4.21(f)
Label Designations for Domestic Standard Honey Wine

Standard honey wine may be labeled as:

• Honey wine
• Mead

• If the product contains more than 0.392 gram of CO₂ per 100 milliliters:
  ◦ Sparkling honey wine/mead
  ◦ Carbonated honey wine/mead

27 CFR 4.21(f)
Other than Standard/Wine Specialty

Other than standard wine made from honey includes wine made:

- With sugar, water, or sugar and water beyond the limitations prescribed for standard honey wine
- By blending honey wine with wine made from fruit/other agricultural products
- With sugar other than pure dry sugar, liquid pure sugar, and invert sugar syrup
- With materials not authorized for use in standard honey wine
  - Flavors (other than hops), e.g., spices, fruit juice
  - Colors
  - Wine spirits

Formula approval is always required for other than standard wine

27 CFR 24.218
Other than standard wine includes honey wine:

- Produced below 13° Brix
- Finished above 14% ABV
- Where sugar is added before fermentation
- Where fruit juice, spices, or other flavoring materials are added

**Note:** Grain, cereal, malt, or molasses are never allowed in the production of wine, and may not be received on bonded wine premises.
Label Designations for Domestic Other than Standard Wine/Wine Specialties

• Wine specialty products may **NOT** be labeled simply as “honey wine” or “mead”

• Wine specialty products **must be** labeled with **truthful and adequate statements of composition**

• TTB provides a suggested statement of composition during formula review
  • TTB’s suggestion is general - you may choose to be more specific
Formula Basics
What is a Formula?

Think of a formula as a recipe – it includes:

- Quantitative list of ingredients
- Method of manufacture
  - Describes the steps you take to create your product
  - Must include each ingredient mentioned on the ingredients list
- Total yield, or batch size
Where is the Formula Requirement?

TTB regulations under the IRC require formulas for certain types of domestic wine. (27 CFR 24.200)

TTB regulations under the FAA Act authorize TTB to require formulas for certain domestic and imported wines. (27 CFR 4.38(h))
When are Formulas required?

In general, formula approval is required if a wine is made with:

- Flavors, (with or without alcohol) including compounded flavors, essences, and extracts
- Coloring materials
- Excess sugar
- Excess water
Why is a Formula Required?

We use the information found in the formula to:

• Classify the product for tax and labeling purposes
• Ensure that the product does not contain any prohibited ingredients
• Determine if limited ingredients are used within prescribed limitations or if they will impact labeling
• Provide a suggested statement of composition for labeling purposes
Who Applies for Formula Approval and When?

Formulas, when required, are submitted by:

- **Domestic:** the producer (BW proprietor)
- **Imported***: U.S. importer (holder of an Importer’s Basic Permit)

Formulas must be obtained:

- **Domestic:** before product is produced and before applying for label approval (if needed)
- **Imported***: before applying for label approval and before product is removed from customs custody

* Formula requirements do not apply to imported wine with under 7% ABV
Which Alcohol Beverages Require Formula Approval?

For certain distilled spirits, beers/malt beverages, and wines, TTB must evaluate the ingredients and production process before the product can be made or imported, and before you can submit your labels to TTB (if required). In some cases we also analyze a sample of the product in our laboratory while reviewing the formula.

Select your commodity, then answer a few questions about your product and we’ll tell you whether it needs formula approval:

- Distilled Spirits
- Malt Beverage (Beer)
- Wine/Cider

https://www.ttb.gov/formulation/which-alcohol-beverages-require-formula-approval
A Deeper Dive into Formulas
Compounded Flavors

For this purpose, a compounded flavor includes any flavor, cloudifier, or blender that consists of multiple ingredients that are combined to produce a particular taste characteristic (e.g., artificial strawberry flavor or natural pecan flavor)

If you’re using a compounded flavor that was purchased from a flavor manufacturer, you should submit a FID sheet with your formula
A **FID Sheet** is a document that includes information about certain ingredients used to make a compounded flavor.

Submit one FID Sheet for each compounded flavor used in your product.

See [TTB G 2017-4](#) for additional information and examples.
Flavor Ingredient Data Sheet (FIDS)

- Flavor manufacturer supplies to the producer
- FID based on exchange between flavor producer and TTB Nonbeverage Laboratory
- It lists concentration of limited ingredients in PPM
- Lists any colors used in flavor
- States alcohol content of flavor
- This information, combined with the use rate, determines classification of flavor
**Flavor Ingredient Data Sheet**

**Flavor Producer Information**
- **TTB Co. Code**: WA-2112
- **Company Name**: WinCo Winery
- **Address**: 6052 Hannah Lane
  Bellevue, WA 98006
- **Name & Title**: WinCo Winery
- **Phone**: 360-454-7015
- **Fax**: 360-454-7120

**Flavor Name**: Chardonnay ND-1007
- **TTR Batch Number**: ND-1007
- **Alcohol Range by Volume**: 11.5% to 13.5%
- **Flavor Product Number**: ND-1007

**Classification**
- **Natural**: Yes
- **Non-NRA**
- **Non-Top Note**: Yes
- **Top Note (including synthetic vanilla, ethyl vanillin, synthetic maltol, and ethyl maltol)**: Yes

**Flavor Component**

<table>
<thead>
<tr>
<th>Additive</th>
<th>TTB Concentration in Finished Product</th>
<th>Amount of Additive or Aged Percent in Flavor</th>
<th>Maximum Use Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Synthetic vanilla</td>
<td>40.0 ppm</td>
<td>40.0 ppm</td>
<td>- ppm</td>
</tr>
<tr>
<td>2. Ethyl Vanillin</td>
<td>10.0 ppm</td>
<td>10.0 ppm</td>
<td>- ppm</td>
</tr>
<tr>
<td>3. Synthetic Maltol</td>
<td>250.0 ppm</td>
<td>250.0 ppm</td>
<td>- ppm</td>
</tr>
<tr>
<td>4. Ethyl Maltol</td>
<td>100.0 ppm</td>
<td>100.0 ppm</td>
<td>- ppm</td>
</tr>
<tr>
<td>5. Ethanol</td>
<td>10.0 ppm</td>
<td>10.0 ppm</td>
<td>- ppm</td>
</tr>
<tr>
<td>6. NO</td>
<td>1.0 ppm</td>
<td>1.0 ppm</td>
<td>- ppm</td>
</tr>
<tr>
<td>7. Sodium Bisulfite</td>
<td>1000.0 ppm</td>
<td>1000.0 ppm</td>
<td>- ppm</td>
</tr>
<tr>
<td>8. Corn Maltodextrin</td>
<td>200000.0 ppm</td>
<td>200000.0 ppm</td>
<td>- ppm</td>
</tr>
<tr>
<td>9. Propylene Glycol</td>
<td>50000.0 ppm</td>
<td>50000.0 ppm</td>
<td>NO LIMIT ppm</td>
</tr>
<tr>
<td>10. Stevia</td>
<td>(0.5% Essential Oil)</td>
<td>check/flushed</td>
<td>check/flushed</td>
</tr>
<tr>
<td>11. Natural Acid</td>
<td>1000.0 ppm</td>
<td>1000.0 ppm</td>
<td>- ppm</td>
</tr>
<tr>
<td>12. <strong>Total Sugar</strong></td>
<td>- ppm</td>
<td>- ppm</td>
<td>- ppm</td>
</tr>
<tr>
<td>13. <strong>Total Additives</strong></td>
<td>40.0 ppm</td>
<td>40.0 ppm</td>
<td>- ppm</td>
</tr>
<tr>
<td>14. <strong>Total Maltol</strong></td>
<td>250.0 ppm</td>
<td>250.0 ppm</td>
<td>- ppm</td>
</tr>
</tbody>
</table>

**Confidential Information Not Shown (CIS)**
- **Check if container is formula**: No
- **Check if CIS was previously submitted**: No

**Beverage Manufacturer / Importer**

- **Formula # / Serial #**: 
  - **Name**: [Name]
  - **Date**: [Date]

**Beverage Alcohol Manufacturer / Importer**

- **Formula # / Serial #**: 
  - **Name**: [Name]
  - **Date**: [Date]

**Signature of Alcoholic Beverage Representative**: [Signature]
Limited Ingredients Section

<table>
<thead>
<tr>
<th>TTB/FDA Limited Ingredients</th>
<th>TTB/FDA Limitation in Finished Product</th>
<th>Amount of Additive or Agent Present in Flavor</th>
<th>Maximum Use Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Synthetic Vanillin</td>
<td>40.0 ppm</td>
<td>___ ppm</td>
<td>- %</td>
</tr>
<tr>
<td>2. Ethyl Vanillin</td>
<td>16.0 ppm</td>
<td>___ ppm</td>
<td>- %</td>
</tr>
<tr>
<td>3. Synthetic Maltol</td>
<td>250.0 ppm</td>
<td>___ ppm</td>
<td>- %</td>
</tr>
<tr>
<td>4. Ethyl Maltol</td>
<td>100.0 ppm</td>
<td>___ ppm</td>
<td>- %</td>
</tr>
<tr>
<td>5. Ester Gum</td>
<td>100.0 ppm</td>
<td>___ ppm</td>
<td>- %</td>
</tr>
<tr>
<td>6. BVO</td>
<td>15.0 ppm</td>
<td>___ ppm</td>
<td>- %</td>
</tr>
<tr>
<td>7. Sodium Benzoate</td>
<td>1,000,000 ppm</td>
<td>5,000 ppm</td>
<td>20.00 %</td>
</tr>
<tr>
<td>8. Gum Arabic/Acacia</td>
<td>200,000.0 ppm</td>
<td>___ ppm</td>
<td>- %</td>
</tr>
<tr>
<td>9. Propylene Glycol</td>
<td>50,000.0 ppm</td>
<td>___ ppm</td>
<td>- %</td>
</tr>
<tr>
<td>10. BHA</td>
<td>(&lt;0.5% Essential Oil)</td>
<td>check if contained</td>
<td></td>
</tr>
<tr>
<td>11. Acetic Acid</td>
<td>1,500.0 ppm</td>
<td>___ ppm</td>
<td>- %</td>
</tr>
<tr>
<td>12. _____________</td>
<td>___ ppm</td>
<td>___ ppm</td>
<td>- %</td>
</tr>
<tr>
<td>13. _____________</td>
<td>___ ppm</td>
<td>___ ppm</td>
<td>- %</td>
</tr>
<tr>
<td>14. _____________</td>
<td>___ ppm</td>
<td>___ ppm</td>
<td>- %</td>
</tr>
<tr>
<td>15. Total Vanillin</td>
<td>40.0 ppm</td>
<td>___ ppm</td>
<td>- %</td>
</tr>
<tr>
<td>16. Total Maltol</td>
<td>250.0 ppm</td>
<td>___ ppm</td>
<td>- %</td>
</tr>
</tbody>
</table>
There are 4 flavor materials that TTB allows to be present at certain levels in alcoholic beverages without affecting the label declaration:

• Synthetic maltol
• Ethyl maltol
• Synthetic vanillin
• Ethyl vanillin

If these limits are exceeded, the flavor must be labeled as an “artificial flavor” in the product.
Ingredient Specification Sheet
(Spec Sheet or Technical Data Sheet)

A **spec sheet** is a document or label that lists or describes the contents of an ingredient that is made from more than one component.

Submit a spec sheet for each ingredient that is made from more than one component, e.g., a fruit juice made from water, apples, and sugar.
Should not be used for compounded flavors (use FID sheet)

See TTB G 2017-3 for additional information and examples
GRAS Ingredients

According to the FDA website, Generally Recognized as Safe (GRAS) | FDA, “GRAS" is an acronym for the phrase Generally Recognized As Safe. Under sections 201(s) and 409 of the Federal Food, Drug, and Cosmetic Act (the Act), any substance that is intentionally added to food is a food additive, that is subject to premarket review and approval by FDA, unless the substance is generally recognized, among qualified experts, as having been adequately shown to be safe under the conditions of its intended use, or unless the use of the substance is otherwise excepted from the definition of a food additive.

- Using only GRAS ingredients does not mean a product is exempt from TTB formula requirements.
- TTB may ask for information regarding the GRAS status of additives in alcohol beverages
Food/Color Additives and Limitations on their Use

Food and color additives can be used in alcohol beverages assuming the ingredient is approved for its intended use, at appropriate use rates, by the FDA. See TTBGov - Determining If and How Ingredients may be used in Your Beverage

To find out if and how a food or color additive can be used, consult:

TTB’s list of limited flavoring substances, acceptable colors, and label implications
FDA’s Food Additive Status List
21 CFR Part 172 (Food Additives Permitted for Direct Addition to Food for Human Consumption)
Substances Added to Food (formerly “EAFUS” - FDA’s Everything Added to Food in the United States)
FDA’s Color Additive Status List
To learn more about GRAS requirements, see FDA’s:

- [Generally Recognized as Safe: Overview and Resources](#)
- [Frequently Asked Questions about GRAS](#)

**Contacting FDA**

For any questions regarding how GRAS determinations are made or the particular GRAS status of an ingredient, please [contact the FDA's Center for Food Safety and Applied Nutrition](#).
How to Apply for Formula Approval
How Do I Apply for Formula Approval?

Formulas Online
• Step-by-step guidance
• Data validation checks along the way
• Application status updates via email

Formulas Online Customer Page

See webinar presentation: How to Register and Submit Formulas through Formulas Online
Supporting Documentation: Spec Sheets

- An **ingredient specification sheet** (also called a **spec sheet** or technical data sheet) is a document (or copy of a product label) that lists or describes the contents of an ingredient used to make your alcohol beverage product.

- Include a **spec sheet** for each ingredient that is made from more than one component (excluding compounded flavors).

See [TTB G 2017-3](#) for additional information on **spec sheets**, including examples.
A Flavor Ingredient Data Sheet (also called FID sheet or FIDS) is a spreadsheet that includes information about certain ingredients.

Include a FID sheet if you're using a compounded flavor.

- A compounded flavor includes any flavor, cloudifier, or blender that consists of multiple ingredients that are combined to produce a particular taste characteristic.

See TTB G 2017-4 for additional information on FID sheets, including examples.
A Limited Ingredient Calculation Worksheet is used to calculate the total amounts of ingredients that have limits on their use per TTB and FDA requirements.

Submit the worksheet for products containing one or more compounded flavors.

See TTB G 2017-6 for additional information on Limited Ingredient Calculation Worksheets, including examples.
What Should I Do After My Formula is Approved?

1. Determine whether your product requires a Certificate of Label Approval (COLA)
   - **YES**: If wine product contains at least 7% alcohol by volume and will be sold in interstate commerce
   - **NO**: If it contains less than 7% alcohol by volume
   - **NO**: If it will only be sold only intrastate; you can instead apply for a Certificate of Exemption

2. If your product requires a COLA, find the statement of composition in the RESULTS tab of your approved formula
On the approved formula, TTB will provide a simple, general statement of composition for the product label, such as:

• *Honey Wine with Natural Flavors*

You can either use this generic statement of composition to meet the requirement for the class/type statement on the label, or create a more specific labeling statement that discloses the specific flavors as well as the coloring agent (if applicable), such as:

• *Mead with cherries, cinnamon, and vanilla*
What Should I Do After My Formula is Approved? (Cont.)

If a COLA is required, list your formula ID on your label application

More information can be found: TTBGov - Wine Example Formulas
Please take few minutes to provide feedback on this session:

https://www.ttb.gov/survey