



# TTB Boot Camp: Formulas

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# TTB Disclaimer

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 (TTB) 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 applicable laws and regulations for the most current requirements.

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



# Agenda

In this session we'll cover:

- Formula basics
- How to determine if your product requires a formula
  - Ingredients/processes that are exempt from formula approval
- Ingredients that require formula approval
  - Compounded flavors
  - Multi-component ingredients
  - Hemp ingredients
- How to apply for formula approval



# Formula Basics



# Common Formula Questions

- What is a formula?
- Why is a formula required?
- At what stage do I apply for formula approval?
- When is a formula required?
- How do I apply for formula approval?



# What is a Formula?

- A formula is the recipe for your beer/malt beverage
  - It must include a quantitative list of ingredients
  - It must include a description of how the product is produced
  - It must indicate a total yield or batch size
  - In some instances a sample of the product must also be submitted to TTB for laboratory analysis
- See [Formula Basics](#) page on TTB.gov



# Where is the Formula Requirement?

- TTB regulations contain the requirement that formula approval must be obtained for certain products
  - Domestic (27 CFR 25.55)
  - Imported (27 CFR 7.28)



# Why is a Formula Required?

- We use the information found in the formula to:
  - Determine whether the product is an IRC beer or malt beverage
  - 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





# At What Stage do I Apply for Formula Approval?

- **Domestic** - Formula approval (if required) must be obtained prior to producing the beer
- **Imported** – Formula approval may be requested prior to or in conjunction with an application for a certificate of label approval



# FDA Requirements

- FDA has authority over food and ingredient safety
  - Approved Food Additives
    - 21 CFR parts 170-186
  - Generally Recognized as Safe
    - Traditional use in food prior to 1958
    - Scientific determination
- Traditional medicines/dietary supplements are not necessarily GRAS
- Importer/producer is responsible for providing evidence that an ingredient is GRAS





# GRAS Ingredients

- **GRAS – Generally Recognized As Safe**
  - Under sections 201(s) and 409 of the Federal Food, Drug, and Cosmetic 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 to be safe
  - Using only GRAS ingredients does not impact whether or not a formula is required



# Prohibited and Limited Ingredients

- FDA maintains a list of prohibited ingredients at [21 CFR part 189](#)
- Certain non-prohibited ingredients may be used within prescribed limits
  - [TTB Limited Ingredients](#)



# How to Determine if Your Product Requires a Formula



# When is a Formula Required?

- Formula approval is required if the brewer uses any of the following ingredients or processes\*:
  - Flavors with alcohol
  - Compounded flavors
  - Colors
  - Artificial sweeteners
  - Food materials (unless exempted by [Attachment 1](#) of [TTB Ruling 2015-1](#))
  - The beverage is frozen and ice crystals are removed (e.g., [ice beer](#))

\*Not a complete list



# Ingredients and Processes that are Exempt from Formula Requirements

- [TTB Ruling 2015-1](#) exempts certain traditional ingredients and processes when used to make malt beverages
- [Attachment 1](#) specifies which ingredients and processes are exempt, for example:
  - Honey, vanilla beans
  - Barrel-aging



# Ingredients and Processes that are Exempt from Formula Requirements

- [TTB Ruling 2015-1](#) does not exempt extracts or flavors containing alcohol
  - Vanilla beans are exempt, but vanilla extract is not exempt
- At least 51% of the fermentable materials must consist of malt or substitutes for malt (rice, grain of any kind, bran, glucose, sugar, and molasses)
- TTB can still request a formula and samples for analysis at any time, even when exempt ingredients are used





# TTB Ruling 2015-1 | Attachment 1

## Exempt Ingredients and Processes Determined to be Traditional Under TTB Ruling 2015-1

TTB Ruling 2015-1  
Attachment 1

### Exempt Ingredients Under the Conditions of TTB Ruling 2015-1

*Industry members are responsible for ensuring that all ingredients, including any parts of fruit, used in the production of malt beverages or beer are wholesome products suitable for human food consumption and comply with applicable ingredient safety regulations of the Food and Drug Administration.*

INGREDIENT	DESCRIPTION/LIMITATION
AGAVE	Whole, juice, puree, or concentrate. <b>Does not</b> include extracts, essential oils, or syrups.
ALLSPICE	As outlined in FDA's GRAS listing at <a href="#">21 CFR 182.10</a> . Spices may be whole or ground. <b>Does not</b> include extracts, essential oils, or syrups.
ANISE	As outlined in FDA's GRAS listing at <a href="#">21 CFR 182.10</a> . Spices may be whole or ground. <b>Does not</b> include extracts, essential oils, or syrups.
APPLES	Whole, juice, puree, or concentrate. <b>Does not</b> include extracts, essential oils, or syrups.
APRICOTS	Whole, juice, puree, or concentrate. <b>Does not</b> include extracts, essential oils, or syrups.



# Combinations of Exempt and Non - Exempt Ingredients

Passion fruit and  
vanilla beans are  
exempt

Passion fruit,  
vanilla beans

If you use both exempt and  
non exempt ingredients,  
formula is required

Guava

Guava is not  
exempt



# When is a Formula Required?

- **FAQ B13**: Am I exempt from formula requirements if I sell my malt beverage only at my brewpub or only within my state?
  - No
  - If a brewer is required to obtain formula approval for a product then approval of the formula must be obtained prior to production, even if the product will be sold only at the brewer's brewpub or otherwise sold only within the state in which it is produced
  - Formula requirements also apply regardless of whether the product is sold on tap at the brewer's brewpub or is bottled, canned, or kegged



# Which Beers Require Formula Approval?

- Use our online tool [Which Alcohol Beverages Require Formula Approval?](#) or check the list in [TTB G 2016-1A](#) to learn which beers require formula approval

## Which Alcohol Beverages Require Formula Approval?

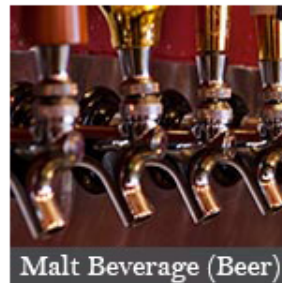
For certain distilled spirits, beers/malt beverages, and wines, TTB must evaluate the ingredients and production process before the product can be made or imported, and before you can submit your labels to TTB (if required). In some cases we also analyze a sample of the product in our laboratory while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

Start



Malt Beverage (Beer)

Start



Wine/Cider

Start



# What TTB Looks For When Reviewing Formulas

- Have you used the correct designation (class and type)?
- Is the base produced according to the stated standard?\*
- What is the GRAS (Generally Recognized As Safe) status of certain ingredients?

\*See 27 CFR 7.1, 7.141-7.147, and 25.15



# What TTB Looks For When Reviewing Formulas (Cont.)

- Have you used any limited or prohibited ingredients?
- Did you submit all the correct supporting documents needed for certain ingredients?
  - Ingredient Specification Sheet (Spec Sheet)
  - Flavor Ingredient Data Sheets (FIDS)
  - Limited Ingredient Calculation Worksheet



# Ingredients that Trigger Formula Requirement





# Compounded Flavors

- If you're using a compounded flavor that was purchased from a flavor manufacturer, you should submit a FID sheet with your formula
- 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)





# Flavor Ingredient Data Sheet (FID Sheet or FIDS)

- 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 (Cont.)

## (FID Sheet or FIDS)

- Flavor manufacturer supplies it to the brewer
- 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 the flavor



# Flavor Ingredient Data Sheet (Cont.)

## (FID Sheet or FIDS)

- The FID Sheet allows TTB to:
  - Ensure that the compounded flavor has been evaluated by the TTB Nonbeverage Products Laboratory
  - Verify that your beverage does not contain any ingredients in excess of the limits prescribed by TTB or by FDA
  - Ensure the appropriate labeling of your product, including any added colors
  - Ensure your product complies with TTB restrictions governing how much of the alcohol in your beverage may be derived from flavors and other nonbeverage ingredients containing alcohol



# TTB Limited Ingredients

- TTB allows 4 artificial flavor materials to be present at certain levels in alcohol beverages without affecting the label declaration:
  - Synthetic maltol
  - Ethyl maltol
  - Synthetic vanillin
  - Ethyl vanillin
- If these limits are exceeded, a **natural flavor** is treated as an **artificial flavor** in the product



# Limited Ingredient Calculation Worksheets

- [Limited Ingredient Calculation Worksheets](#) are used to calculate the total amounts of ingredients that have limits on their use per TTB and FDA requirements
- Complete and submit one for each malt beverage made with one or more compounded flavors



# Limited Ingredient Calculation Worksheets (Cont.)

- Also useful as a product development tool
  - Allows you to confirm that new product formulas are in compliance with limited ingredient requirements, and whether a flavor will be labeled as artificial prior to submitting the formula
- See [TTB G 2017-6](#) for additional information and examples



# Beer/Malt Beverages with Flavors that Contain Alcohol

- If final ABV is **less than or equal to 6 percent**:
  - at least 51 percent of the alcohol in the final product must come from ingredients fermented at the brewery
  - no more than 49 percent of the alcohol in the final product can come from the flavor(s) and other nonbeverage material(s) containing alcohol

27 CFR 7.5, 7.63(a)(3), and 25.15



# Beer/Malt Beverages with Flavors that Contain Alcohol (Cont.)

- If final ABV is **greater than 6 percent**:
  - no more than 1.5 percent of the volume of the malt beverage can consist of alcohol from flavors and other nonbeverage ingredients containing alcohol
- An alcohol content statement must appear on the label if any alcohol in the malt beverage was derived from added flavors or other added nonbeverage ingredients (other than hops extract) containing alcohol

27 CFR 7.5, 7.63(a)(3), and 25.15





# 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



# Ingredient Specification Sheet (Cont.)

## (Spec Sheet or Technical Data Sheet)

- Should not be used for compounded flavors (use FID sheet)
- See [TTB G 2017-3](#) for additional information and examples



# Hemp and Hemp Derivatives



# Allowable Hemp Ingredients

- Three hemp seed ingredients have been the subject of an evaluated GRAS notification:
  - Hulled hemp seed
  - Hemp seed protein powder
  - Hemp seed oil
- No other cannabis-derived ingredients have been the subject of a food additive petition, an evaluated GRAS notification, or have otherwise been approved for use in food by FDA



# Cannabidiol (CBD)

- CBD has not been the subject of a food additive petition, an evaluated GRAS notification, or have otherwise been approved for use in food by FDA
- After enactment of the 2018 Farm Bill, FDA stated that it is unlawful under the FD&C Act to introduce into interstate commerce any food to which CBD has been added (FD&C Act Section 301(l))
- [See also: FDA Regulation of Cannabis and Cannabis-Derived Products, Including Cannabidiol \(CBD\)](#)



# Terpenes and Botanical Extracts

- **Terpene** refers to a class of organic chemical compounds that may be sourced from plants or synthesized in a laboratory
- FDA has issued regulations that authorize individual synthetic terpenes for use in food (see, e.g., [21 CFR 182.60](#))



# Terpenes and Botanical Extracts (Cont.)

- Many forms of botanical extracts are authorized for use in food in specific FDA regulations
  - botanical extracts from cannabis (hemp) are not included in these regulations
- FDA has advised that alcohol beverage industry members interested in using botanical extracts containing mixtures of terpenes sourced from hemp, or any other plant, should consider submitting a GRAS notice



# Alcohol Beverage Formulas for Products Containing Hemp Ingredients

- TTB regulations require formula approval for alcohol beverages to which hemp ingredients have been added, even if the product is sold only intrastate
- Based on FDA's public statements and TTB's ongoing consultations with FDA, TTB will return for correction any formula applications including hemp ingredients other than the three ingredients derived from hemp seeds
- See [TTB Industry Circular 2019-1](#) for additional information





# Applying 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](#)





# Formulas Online Helpful Hints



- Supply a quantitative list of ingredients
- Provide a complete method of manufacture
- Indicate at what stage flavors are added to the product
- Provide the common name and scientific name (genus and species) for any unusual herbal ingredients
- Ensure that ingredients are considered GRAS (generally recognized as safe) or are approved as food additives by the FDA before you submit



# Formulas Online Helpful Hints

- Make sure you've uploaded all the applicable supporting documents, e.g., FIDS, Spec Sheet, etc., based on your list of ingredients
- If a FID sheet is required, ensure it contains:
  - TTB-assigned company code
  - Flavor Product Number
  - Flavor classification (natural, artificial, etc.)
  - TTB Nonbeverage Lab approval status





# 5 Common Reasons Formulas Are Returned

1. [Ingredient Specification Sheet \(Spec Sheet\)](#) is missing for ingredients composed of more than one component
2. [Flavor Ingredient Data Sheet \(FIDS\)](#) is missing when compounded flavors are used
3. Clarification on whether hops are used in product
4. [Limited Ingredient Calculation Worksheet](#) is missing when compounded flavors are used
5. Formula approval is not required for this product because it is composed of exempt ingredients or processes (See [TTB Ruling 2015-1](#))



# What Should I Do After My Formula is Approved?

1. Determine whether your product requires a Certificate of Label Approval (COLA)
  - **YES:** If product contains both malted barley and hops **and** will be sold in interstate commerce
  - **NO:** If it does not contain both malted barley and hops
  - **NO:** If it will only be sold only intrastate
2. If your product requires a COLA, find the statement of composition in the RESULTS tab of your approved formula



# What Should I Do After My Formula is Approved? (Cont.)

- On the approved formula, TTB will provide a simple, general statement of composition for the product label, such as:
  - *Malt Beverage with Natural Flavors and Artificial Color*
- 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, such as:
  - *Malt beverage with coconut and cinnamon, coffee flavor, and caramel color*



# 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 - Malt Beverage Example Formulas TTB G 2017-7](#)





# Formula Resources

## Beer Resources

### TTB Beer Rulings

[www.ttb.gov/beer/rulings](http://www.ttb.gov/beer/rulings)

### Alcohol Beverage Formula Approval Guidance

<https://www.ttb.gov/formulation>

### TTB Beer Industry Circulars

[www.ttb.gov/beer/industry-circulars](http://www.ttb.gov/beer/industry-circulars)

### Does my Beer/Malt Beverage Require a Formula?

[www.ttb.gov/formulation/mbev](http://www.ttb.gov/formulation/mbev)

### TTB Beer Frequently Asked Questions (FAQs)

[www.ttb.gov/beer/beer-faqs](http://www.ttb.gov/beer/beer-faqs)

### TTB G 2016-1A –Beer/Malt Beverages Requiring Formula Approval or Laboratory Sample Analysis Chart

[www.ttb.gov/public-guidance/ttb-g-2016-1a](http://www.ttb.gov/public-guidance/ttb-g-2016-1a)

### Formula Approval with Laboratory Sample Analysis

<https://www.ttb.gov/formulation/formula-approval-with-laboratory-sample-analysis>

### Determine If and How Ingredients May be Used in Your Beverage

<https://www.ttb.gov/formulation/determining-if-and-how-ingredients-may-be-used-in-your-beverage>



# Contact Us

## Questions?

**Contact the Alcohol Labeling and Formulation Division at:**

- Toll Free at 866-927-ALFD (2533), OR
- Use our [Alcohol Labeling and Formulation Division \(ALFD\) Contact Form](#)

**Representatives are Available:**

8 a.m. to 4:30 p.m. ET Monday - Friday (except on federal holidays)