



# TTB Formula Approvals

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# TTB Disclaimer

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- 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.



# Agenda: You'll learn if you need to get your formula approved by TTB and how to apply

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What "TTB formula approval" means

2

How to determine if you need formula approval

3

How to apply



# Formula Basics

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## **Not all cider/perry products require formula approval**

Whether or not you need formula approval is based on:

- Ingredients
- Manufacturing methods

Formula requirements are **NOT** connected to:

- Alcohol content
- Eligibility for Hard Cider tax rate
- Whether or not the product will require TTB label approval



# Formula Basics

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## What is a formula?

- A complete, quantitative list of all ingredients used to make the product
- A step-by-step description of how it's made (AKA: method of manufacture)



# Formula Basics

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## **Formula approval, when required, 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

## **Formulas are submitted by:**

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

\*Only imported cider/perry products with 7% or more alc. by vol. are subject to formula requirements

# When is Formula Approval Required?





# When is a Formula Required?

## Imported Cider/Perry Products

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- Formulas may be required for imported cider/perry product as part of the COLA approval process
- Only imported cider/perry products with 7% or more alc. by vol. are subject to formula requirements
- Types of imported cider/perry products that require formula approval mirror those for domestic cider/perry products, for example:
  - Added flavors
  - Blending two kinds of wine
  - Extra sugar or water





# When is a Formula Required?

## Domestic Cider/Perry Product

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Formula approval is NOT required if you are producing:

- Natural apple or pear wine (cider/perry), or
- Any other “natural” fruit wine, even if the wine is fermented from the juice of different fruits, such as fermenting apple juice and blueberry juice together

TTB regulations DO require formulas for:

- Special Natural wine
- Other than Standard wine

[27 CFR 24.80 – 24.82](#)



# Fruit-Based Wine Classifications in Part 24

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- For production purposes, part 24 subdivides wine into **Standard wine** and **Other than Standard wine**
- Cider/perry products may be either, depending on how they are made
- Cider/perry products that are **Standard wine** may be either
  - **Natural wine**
  - **Special Natural wine**



# Is My Cider/Perry Product a Natural Fruit Wine?

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## “Natural” wine is:

- The product of the juice or must of sound, ripe fruit; and
- Made with any cellar treatment authorized by subparts F and L of 27 CFR part 24, and containing not more than 21% by weight of total solids

***Natural fruit wine DOES NOT require formula approval***

27 CFR 24.10



# Is My Cider/Perry Product a Natural Fruit Wine?

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Production of **natural** cider (apple wine) or perry (pear wine):

- Only malic acid may be added to cider to correct natural acid deficiencies. Only malic acid or citric acid may be added to perry to correct natural acid deficiencies. See 27 CFR 24.182 for further restrictions
- See 27 CFR part 24, subpart F for the conditions and limitations under which fruit juice concentrate may be used in juice or wine made from the same kind of fruit (i.e., apple juice for cider and pear juice for perry) for the purposes of chaptalizing or sweetening

27 CFR 24.10



# Is My Cider/Perry Product a Natural Fruit Wine?

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Production of **natural** cider (apple wine) or perry (pear wine):

- Sugar (which means only pure dry sugar, liquid pure sugar, or invert sugar syrup) may be added to chaptalize or sweeten a fruit wine, within the limits set out in 27 CFR part 24, subpart F
- See 27 CFR 24.178 for rules about the amelioration of natural fruit wines

27 CFR 24.10



# Is My Cider/Perry Product a Natural Fruit Wine?

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Examples of cider/perry products that are **Natural Fruit wine**:

- Made only from apple/pear concentrate, or apple/pear juice, with or without added CO<sub>2</sub>
- Made by fermenting apple juice and raspberry juice together

27 CFR 24.10



# Is My Cider/Perry Product Special Natural Wine?

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## Special Natural wine is:

- A flavored wine made from a base of natural wine
- The flavoring may be natural herbs, spices, fruit juices, natural aromatics, natural essences, or other natural flavorings, subject to conditions outlined in 27 CFR part 24 subpart H

***Special Natural wine requires formula approval***

27 CFR 24.10  
27 CFR 24.80



# Is My Cider/Perry Product Special Natural Wine?

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Examples of cider/perry products that are Special Natural wine:

- Made from apple juice and flavored with hops
- Made from apple concentrate and flavored with citrus peel
- Made from pear juice and flavored with honey

***Special Natural wine requires formula approval***

27 CFR 24.10  
27 CFR 24.80





# Is My Cider/Perry Product Other Than Standard Wine?

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## **Other than Standard wine is:**

- Made with sugar and/or water beyond the limitations for standard wine
- Made by blending wines produced from different kinds of fruit
- Made with sugar other than pure dry sugar, liquid pure sugar, and invert sugar syrup
- Made with materials not authorized for use in standard wine, e.g., spirits derived from fruit other than primary winemaking material, coloring material and artificial flavors

***Other than standard wine requires formula approval***

27 CFR 24.218



# Is My Cider/Perry Product Other Than Standard Wine?

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Examples of cider/perry products that are **Other than Standard Wine** include wine made by:

- Blending apple wine with rhubarb wine
- Coloring with grape skin extract
- Sweetening with raw sugar
- Flavoring with raspberry spirits

***Other than standard wine requires formula approval***

27 CFR 24.218



# Wine Formula Tool

<https://www.ttb.gov/formulation/which-alcohol-beverages-require-formula-approval>

You may also use our **Wine Formula Tool** on **TTB.gov**

## Which Alcohol Beverages Require Formula Approval?

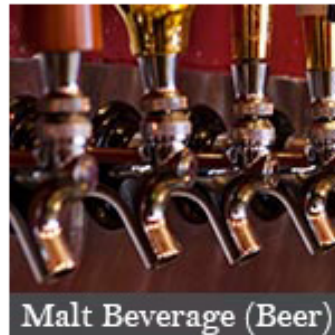
For certain distilled spirits, beers/malt beverages, and wines, TTB must evaluate the ingredients and production process before the product can be made or imported, and before you can submit your labels to TTB (if required). In some cases we also analyze a sample of the product in our laboratory while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



# Compounded Flavors

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Are one of the following:

- All natural
- Natural and artificial containing up to 0.1% artificial content topnote
- Natural and artificial containing greater than 0.1% artificial content topnote
- All artificial
- Non-flavor: product is not flavor (e.g., Cloud Emulsion)

Submitted to TTB Nonbeverage Lab for Review

May contain colors



# TTB Limited Ingredients

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There are 4 artificial flavor materials that TTB allows to be present at certain levels in alcoholic beverages without affecting the label declaration:

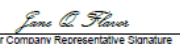
- Synthetic maltol
- Ethyl maltol
- Synthetic vanillin
- Ethyl vanillin

If these limits are exceeded, a “natural flavor” is treated as an “artificial flavor” in the product



# 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: <u>FLRUS</u>		Date: <u>1/1/2017</u>							
Company Name: <u>Flavors-R-Us LLC</u>		Contact Person: <u>Jane Q. Flavor</u>							
Address: <u>123 Nonexistent Street</u>		Phone: <u>202-555-5555</u>							
<u>Any City, State USA 00000</u>		Fax: <u>202-555-5554</u>							
<b>Check Appropriate Box:</b>									
Flavor Name: <u>Natural Poppin' Pecan Supreme</u>		Approved for Drawback (DrB)		<input type="checkbox"/>					
TTB Drawback Number: <u>123456</u>		Approved as No Action (N/A)		<input checked="" type="checkbox"/>					
Alcohol Range by Volume: <u>50.0 - 54.0</u>		Fit for Beverage Purposes (Fit)		<input type="checkbox"/>					
Flavor Product Number: <u>7891011</u>		Submitted for TTB Approval		<input type="checkbox"/>					
		Not Yet Submitted for TTB Approval		<input type="checkbox"/>					
Classification									
Natural	<input checked="" type="checkbox"/>	N&A ≤ 0.1% Topnote	<input type="checkbox"/>	N&A > 0.1% Topnote	<input type="checkbox"/>	Artificial	<input type="checkbox"/>	Non-Flavor	<input type="checkbox"/>
Total Artificial Flavor Content: _____ ppm (Excluding Synthetic Vanillin, Ethyl Vanillin, Synthetic Maltol, and Ethyl Maltol)									
Flavor Components									
TTB/FDA Limited Ingredients	TTB/FDA Limitation in Finished Product	Amount of Additive or Agent Present in Flavor	Maximum Use Rate	Coloring Additives and Other Additives that Affect the Beverage Label (check or list label ingredients that affect the beverage label)					
1. Synthetic Vanillin	40.0 ppm	_____ ppm	- %	1. FD&C Yellow #5 <input type="checkbox"/>					
2. Ethyl Vanillin	16.0 ppm	_____ ppm	- %	2. FD&C Yellow #6 <input type="checkbox"/>					
3. Synthetic Maltol	250.0 ppm	_____ ppm	- %	3. FD&C Blue #1 <input type="checkbox"/>					
4. Ethyl Maltol	100.0 ppm	_____ ppm	- %	4. FD&C Blue #2 <input type="checkbox"/>					
5. Ester Gum	100.0 ppm	_____ ppm	- %	5. FD&C Green #3 <input type="checkbox"/>					
6. BVO	15.0 ppm	_____ ppm	- %	6. FD&C Red #40 <input type="checkbox"/>					
7. Sodium Benzoate	1,000.0 ppm	5,000 ppm	20.00 %	7. Grapeskin Extract <input type="checkbox"/>					
8. Gum Arabic/Acacia	200,000.0 ppm	_____ ppm	- %	8. Caramel Color <input checked="" type="checkbox"/>					
9. Propylene Glycol	50,000.0 ppm	10,000 ppm	NO LIMIT %	9. Annatto <input type="checkbox"/>					
10. BHA	(<0.5% Essential Oil)	<input type="checkbox"/> check if contained	- %	10. Elderberry Extract <input type="checkbox"/>					
11. Acetic Acid	1,500.0 ppm	_____ ppm	- %	11. Beet Extract <input type="checkbox"/>					
12. _____	_____ ppm	_____ ppm	- %	12. Oak Extract <input type="checkbox"/>					
13. _____	_____ ppm	_____ ppm	- %	13. Carmine/ Cochineal Extract <input type="checkbox"/>					
14. _____	_____ ppm	_____ ppm	- %	14. _____ <input type="checkbox"/>					
15. Total Vanillin	40.0 ppm	- ppm	- %	15. _____ <input type="checkbox"/>					
16. Total Maltol	250.0 ppm	- ppm	- %						
Confidential Limited Ingredients Not Shown (CLI)									
Check if contained in formula <input type="checkbox"/> Check if CLI was previously submitted <input type="checkbox"/>									
Beverage Manufacturer / Importer: _____									
Formula # / Serial #: _____									
 Flavor Company Representative Signature		Title: <u>Supervisory Chemist</u>	Date: <u>30-Sep-17</u>						



# FDA Requirements

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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

# How to Apply for Formula Approval







# How Do I Apply for Formula Approval?

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## 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 Submitter Tips

## Before submitting a formula you should:

- Ensure that formula approval is required for your cider/perry product by using the [Formula Tool](#) on TTB's website
- Determine if your cider/perry product is a **Special Natural wine** or **Other than Standard wine**
  - If **Other than Standard wine**, determine the applicable subcategory, such as **Wine Specialty**
- Gather all pertinent information and documents about each ingredient used and your method of manufacture





# Supporting Documentation: Spec Sheets

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- 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



# Supporting Documentation: Flavor Ingredient Data Sheets

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- 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



# Supporting Documentation: Limited Ingredient Calculation Worksheets

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- 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



# Top 5 Reasons Wine Formulas are Returned for Correction

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- Ingredient Spec Sheet is missing
- FID Sheet is missing
- Clarification needed on a specific ingredient
- Ingredient quantity information is missing
- Limited Ingredient Calculation worksheet is missing



# Formula Resources

## Cider Resources

### Alcohol Beverage Formula Approval Guidance

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

### Does my Wine/Cider Require a Formula?

<https://www.ttb.gov/formulation/do-i-need-a-formula-wine>

### Flavor Ingredient Data Sheet: Guidance and Examples

[Flavor Ingredient Data Sheet: Guidance and Examples](#)

### Determine if and How Ingredients May be Used

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

### Ingredient Specification Sheet: Guidance and Examples

<https://www.ttb.gov/formulation/ingredient-specification-sheet-guidance-and-examples>

### Limited Ingredient Calculation Worksheet: Guidance and Examples

<https://www.ttb.gov/formulation/limited-ingredient-calculation-worksheet-guidance-and-examples>

### Formulas Online Customer Page

<https://www.ttb.gov/formulation/customer-support>

### Processing Times for Beverage Alcohol Formulas

<https://www.ttb.gov/formulation/fonl-processing-times>



# Contact Us

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## 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)