

Mead Formulas

MEADCON 2022
AUGUST 22-23, 2022
CHRISTIAN FAY, SENIOR FORMULA SPECIALIST



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

Formula approval is not required for 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



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 Specialty Product

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

27 CFR 24.218



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

27 CFR 4.34



Formula Basics



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:



Start



Start



Start

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 <u>FID Sheet</u> 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

- 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									
Company Nam	e: Flavors-R-Us LLC		Contact Person:	Jane Q. Flavor					
Addres	ss: 123 Nonexistant Street		Phone:	202-555-5555					
	Any City, State USA 00000		Fax:	202-555-5554					
			Check Appropria	ite Box:					
Flavor Nam	Flavor Name: Natural Poppin' Pecan Supreme			Approved for Drawback (DrB)					
TTB Drawback Number: 123456			Approved as No Action (N/A)						
Alcohol Range by Volum	Alcohol Range by Volume: 50.0 - 54.0			Fit for Beverage Purposes (Fit)					
Flavor Product Number: 7891011			Submitted for TTB Approval						
		Not Yet Submitted for TTB Approval							
		Classification							
Natural 🗸	N&A ≤ 0.1% Topnote	N&A > 0.1% Topnote	Artificial	Non-Flavor					
Total Artificial	Flavor Content:	ppm (Excluding Synthetic Vanillin	, Ethyl Vanillin, Synthetic I	Maltol, and Ethyl Maltol)					
		Flavor Components							
	TTB/FDA Limitation in	Amount of Additive or	Maximum Use	Coloring Additives and Other					
TTB/FDA Limited Ingredien	rits Finished Product	Agent Present in Flavor	Rate	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					
2. Ethyl Vanillin	16.0 ppm	ppm	96	2. FD&C Yellow #6					
3. Synthetic Maltol	250.0 ppm	ppm	- %	3. FD&C Blue #1					
4. Ethyl Maltol	100.0 ppm	ppm	- %	4. FD&C Blue #2					
5. Ester Gum	100.0 ppm	ppm	- %	5. FD&C Green #3					
6. BVO	15.0 ppm	ppm	- %	6. FD&C Red #40					
7. Sodium Benzoate	1,000.0 ppm	5,000 ppm	20.00 %	7. Grapeskin Extract					
8. Gum Arabic/Acacia	200,000.0 ppm	ppm	- %	8. Caramel Color					
9. Propylene Glycol	50,000.0 ppm	10,000 ppm	NO LIMIT %	9. Annatto					
10. BHA	(<0.5% Essential Oil)		NO EMILI	10. Elderberry Extract					
11. Acetic Acid	1,500.0 ppm	check if contained	- %	11. Beet Extract					
		ppm							
12	ppm	ppm	%						
13	ppm	ppm	%	13. Carmine/					
14	ppm	ppm	%	Cochineal Extract					
de Tatal Va-::::-	40.0		- %	14					
15. Total Vanillin	40.0 ppm	ppm		15					
16. Total Maltol	250.0 ppm	ppm	96						
	Confident	tial Limited Ingredients Not	Shown (CLI)						
	Check if contained in formula	Check if CLI was	previously submitted						
	Payaraga Manufashirar / I	A.F.							
	Beverage Manufacturer / Importe Formula # / Serial								
	romula # / Senai	m							
Lanc Q. Flavor Title: Supervisory Chemist Date: 30-Sep-17									
Flavor Company R	epresentative Signature								
<u> </u>									

		Flavo	or Ingredient Data	Sheet			
			Flavor Producer Information	on			
	TTB Co. Cor	te: WLOVE		Date:	5/28/2014		
(ne: We Love Flavors		Contact Person: Phone:	Martha Washington		
,					240-555-1212		
Address: 6000 Ammendale Rd Beltsville, MD 20705				Fax:	240-5551213		
		Deko tille, Ilio 20100		, arc	ZIO GOGIZIO		
				Check Appropri			
		ne: Nat. Chocolate WONF		Approved for Drawback (DrB) Approved as No Action (N/A)			
TTB Drawback Number: 1510				Approved as No Action (N/A) Fit for Beverage Purposes (Fit) Submitted for TTB Approval Not Yet Submitted for TTB Approval			
Alcohol Range by Volume: 63.5 +/- 3.5% Flavor Product Number: X1257							
Natural	V	N&A ≤ 0.1% Topnote	N&A > 0.1% Topnote	☐ Artificia	Non-Flavor		
	Total Artificial	Flavor Content:	ppm (Excluding Synthetic Vanillin	_			
			Flavor Components				
		TTP Limitation in	•		Reverses Label Information		
Ad	dditive	TTB Limitation in Finished Product	Amount of Additive or Agent Present in Flavor	Maximum Use Rate	Beverage Label Information based of functionality theck or list label ingredents that affect the		
					boverage label)		
. Synthetic		40.0 ppm	ppm	%			
. Ethyl Va	nillin	16.0 ppm	ppm	- %	2. FD&C Yellow #6		
. Synthetic	c Maltol	250.0 ppm	ppm	%	3. FD&C Blue #1		
. Ethyl Ma	iltol	100.0 ppm	ppm	- %	4. FD&C Blue #2		
. Ester Gu	ım	100.0 ppm	ppm	- %	5. FD&C Green #3		
B. BVO		15.0 ppm	ppm	- %	6. FD&C Red #40		
7. Sodium	Benzoate	1000.0 ppm	ppm	- %	_		
	abic/Acacia	200000.0 ppm	ppm	- %			
Propyler		50000.0 ppm	30,000 ppm	NO LIMIT %	9. Annatto		
). BHA	ie Giycoi			NO LIMIT 70	_		
		(<0.5% Essential Oil)	check if contained				
I. Acetic A		1500.0 ppm	ppm	%			
2		ppm	ppm	%			
3		ppm	ppm	- %			
	_	ppm	ppm	%	14		
. Total Va	nillin	40.0 ppm	ppm	%			
6. Total Ma	iltol	250.0 ppm	ppm	%			
	1	Confident Check if contained in formula Beverage Manufacturer / Import Formula # / Serial	er:	Shown (CLI) previously submitted			
_	Flavor Company R	eprosentative Signature Titl	le:		Date:		
		Bever	age Alcohol Manufacturer i	Importer			
Beve	erage Manufac	turer / Importer:		Formula # / S	erial #:		
			Notified by:		As: Approved No Action Export Only		
Signat	ure of Alcohol	Beverage Representative:			_		



Limited Ingredients Section

		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
2. Ethyl Vanillin	16.0 ppm	ppm	- %	2. FD&C Yellow #6
3. Synthetic Maltol	250.0 ppm	ppm	- %	3. FD&C Blue #1
4. Ethyl Maltol	100.0 ppm	ppm	- %	4. FD&C Blue #2
5. Ester Gum	100.0 ppm	ppm	- %	5. FD&C Green #3
6. BVO	15.0 ppm	ppm	- %	6. FD&C Red #40
7. Sodium Benzoate	1,000.0 ppm	5,000 ppm	20.00 %	7. Grapeskin Extract
8. Gum Arabic/Acacia	200,000.0 ppm	ppm	%	8. Caramel Color
9. Propylene Glycol	50,000.0 ppm	10,000 ppm	NO LIMIT %	9. Annatto
10. BHA	(<0.5% Essential Oil)	check if contained		10. Elderberry Extract
11. Acetic Acid	1,500.0 ppm	ppm	%	11. Beet Extract
12	ppm	ppm	%	12. Oak Extract
13	ppm	ppm	- %	13. Carmine/
14	ppm	ppm	%	Cochineal Extract
15. Total Vanillin	40.0 ppm	ppm	%	15
16. Total Maltol	250.0 ppm	ppm	%	_



TTB Limited Ingredients

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



A <u>spec sheet</u> 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

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)

<u>Substances Added to Food</u> (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?

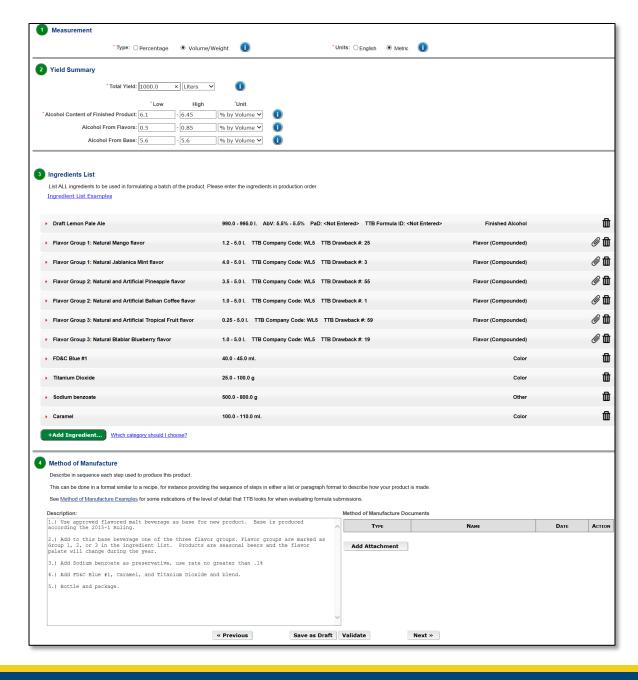
Formulas Online

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



Formulas Online Customer Page

See webinar presentation: <u>How to Register and Submit</u> <u>Formulas through Formulas Online</u>





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



Supporting Documentation: Flavor Ingredient Data Sheets

- 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

- 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?

- 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



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:

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



