

# TTB Webinar: Domestic Malt Beverage Formulas

#### Presented November 2017



## **TTB Disclaimer**

#### 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 (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.



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### **Common Formula Questions**

- What is a formula?
- Why is a formula required?
- When is a formula required?
- How is a formula submitted?



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### What is a Formula?

- A formula is a recipe.
- It must indicate a Total Yield, or Batch Size.
- It must have a quantitative list of ingredients.
- It must include a description of how the product is produced.

Formula Basics - https://www.ttb.gov/formulation/index.shtml



* Type: O Percentage	e 🖲 Volume/W	/eight 🕕	* Units: 🔿 English 💿 Motric 🕕
Yield Summary			
		-	
* Total Yield: 1000.0	x Liters V	0	
* Total Yield:  1000.0	× Liters ✓ High	Unit	
"Low			
	High	'Unit	

#### Ingredients List

List ALL ingredients to be used in formulating a batch of the product. Please enter the ingredients in production order. Ingredient List Examples

Draft Lemon Pale Ale	990.0 - 995.0 I. AbV: 5.5% - 5.5% PaD: <not entered=""> TTB Formula ID: <not entered=""></not></not>	Finished Alcohol	1
Flavor Group 1: Natural Mango flavor	1.2 - 5.0 I. TTB Company Code: WL5 TTB Drawback #: 25	Flavor (Compounded)	0 🖬
Flavor Group 1: Natural Jablanica Mint flavor	4.0 - 5.0 I. TTB Company Code: WL5 TTB Drawback #: 3	Flavor (Compounded)	0 🖬
Flavor Group 2: Natural and Artificial Pineapple flavor	3.5 - 5.0 I. TTB Company Code: WL5 TTB Drawback #: 55	Flavor (Compounded)	0 🖬
Flavor Group 2: Natural and Artificial Balkan Coffee flavor	1.0 - 5.0 I. TTB Company Code: WL5 TTB Drawback #: 1	Flavor (Compounded)	<i>®</i> 🛍
Flavor Group 3: Natural and Artificial Tropical Fruit flavor	0.25 - 5.0 I. TTB Company Code: WL5 TTB Drawback #: 59	Flavor (Compounded)	@ 🛍
Flavor Group 3: Natural Blablar Blueberry flavor	1.0 - 5.0 I. TTB Company Code: WL5 TTB Drawback #: 19	Flavor (Compounded)	<i>®</i> 🛍
FD&C Blue #1	40.0 - 45.0 ml.	Color	莭
Titanium Dioxide	25.0 - 100.0 g	Color	莭
Sodium benzoate	500.0 - 800.0 g	Other	莭
> Caramel	100.0 - 110.0 ml.	Color	莭

+Add Ingredient... Which category should I choose?

#### Method of Manufacture

Describe in sequence each step used to produce this product.

This can be done in a format similar to a recipe, for instance providing the sequence of steps in either a list or paragraph format to describe how your product is made.

See Method of Manufacture Examples for some indications of the level of detail that TTB looks for when evaluating formula submissions.

Description:	M	ethod of Manufacture De	ocuments			
<ol> <li>Use approved flavored malt beverage as base for new product. Base is produced according the 2015-1 Ruling.</li> </ol>	~	Туре		NAME	DATE	ACTION
2.) Add to this base beverage one of the three flavor groups. Flavor groups are marked as Group 1, 2, or 3 in the ingredient list. Products are seasonal beers and the flavor palate will change during the year.	0	Add Attachment	)			
3.) Add Sodium benzoate as preservative, use rate no greater than .1%						
4.) Add FD&C Blue #1, Caramel, and Titanium Dioxide and blend.						
5.) Bottle and package.						
« Previous Save as Draft	t Vi	alidate	Next »			



### Why is a Formula required?

- Regulation requirement -27 CFR 25.55-58
- Formula review finds a "home" for a product and assigns it a particular classification.
- A <u>Statement of Composition</u> describes the product in a generic fashion, example "Malt Beverage with Natural Flavors and Certified Colors."



#### When are Formulas required?

- TTB Industry Circular 2007-4
- A formula is required if:
  - Flavors with alcohol are added
  - Compound flavors are added
  - Colors are added
  - Artificial sweeteners are added
  - Agricultural products not listed in TTB Ruling 2015-1 are used

For unique processes:

 The beverage is frozen and ice crystals may be removed (i.e., ice beer)



#### When are Formulas required?

- A formula is required if (cont.):
  - The alcohol is less than 0.5% or the alcohol is completely removed (i.e., non-alcoholic malt beverage or alcohol free malt beverage)
  - A TTB employee requests it
  - A small percentage will require lab review
- A formula is not required for:
  - Barrel aging
  - Addition of an agricultural product listed under TTB Ruling 2015-1 (e.g., cherries)



# Are Formulas required for all products?

#### -<u>TTB Ruling 2015-1</u>

https://www.ttb.gov/rulings/ttb-ruling-2015-1-maltbeverage-formulas.pdf https://www.ttb.gov/rulings/ttb-ruling-2015-1-attachment-1.pdf https://www.ttb.gov/rulings/ttb-ruling-2015-1-attachment-2.pdf

#### -TTB Industry Circular 2007-4

https://ttb.gov/industry\_circulars/archives/2007/07-04.html https://ttb.gov/industry\_circulars/archives/2007/precola\_eval\_beer\_updated.pdf



#### **Malt Beverage Formula Tool**



Alcohol and Tobacco Tax and Trade Bureau

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TTB Audiences Resources



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#### Which Alcohol Beverages Require Formula Approval?

#### Beer and Malt Beverage Products

Beer, under the Internal Revenue Code of 1986 (IRC) and the TTB regulations, means beer, ale, porter, stout and other similar fermented beverages (including sake' and similar products) containing one-half of one percent or more of alcohol by volume, brewed or produced from malt, wholly or in part, or from substitutes for malt. Only rice, grain of any kind, bran, glucose, sugar, and molasses are substitutes for malt.



Malt beverage, under the Federal Alcohol Administration Act (FAA Act) and the TTB regulations, means a beverage, which may be alcoholic, non-alcoholic, or alcohol-free, made by the alcoholic fermentation of an infusion or decoction, or combination of both, in potable brewing water, of:

- · malted barley and hops (or their parts or products) AND, with or without:
- · other malted cereals;
- unmalted or prepared cereals;
- · other carbohydrates (or products prepared therefrom);
- · carbon dioxide; and
- · other wholesome products suitable for human food consumption.

NOTE: In order for a brewery product to fall within the definition of a "malt beverage" under the FAA Act, it must be a fermented beverage made from both malted barley and hops, or their parts, or their products. A fermented beverage that qualifies as a "beer" under the IRC but that is made without both malted barley and hops is not a malt beverage under the FAA Act. For more information see TTB Ruling 2008-3.

Tell us about your product or browse the lists of beers and malt beverage products that require formula approval or formula approval and laboratory sample analysis.

Source

O Domestic O Imported

CONTINUE



#### How to Submit a Formula

- Electronic Submission Formulas Online
- Paper Submissions use <u>TTB F 5100.51</u> and mail to TTB.



#### **Common Return Reasons**

- Please upload a specification sheet or an image of the label clearly showing the list of ingredients for the following item(s). Specification sheets are typically available from the ingredient manufacturer.
- Please complete and attach a Beverage Alcohol Limited Components Calculation sheet for the purchased flavors and/or blenders you are using. This will aid us in our review of the use rates for any limited ingredients (e.g.vanillin and propylene glycol) contained in these ingredients.
- Please upload a Flavor Ingredient Data (FID) Sheet for each compounded flavor specified in your ingredients list. You can obtain FID sheets from the flavor manufacturer.
- The method of manufacture (MoM) should be a detailed, step-by-step guide that describes how the product is made and includes all ingredients. Please revise your MoM accordingly.



#### **Reasons Continued**

- This malt beverage product does not require formula review nor sample
- analysis because it is composed of exempt ingredients or processes. You may proceed to Labeling.
- A malt beverage must contain hops or their parts. Please clarify if hops are being added.
- To help us evaluate your formula, in the Submitter Remarks section below, please provide the information that is being requested regarding the following ingredient(s)
- Please provide a copy of the GRAS Notification and number (Generally Recognized as Safe) for the ingredient. GRAS notifications are issued by the U.S. Food and Drug Administration (FDA).
- Quantities were not provided for all ingredients. Please update the list of ingredients to specify the amount of each.



### What TTB Looks For

- Correct designation (Class and Type) Is the base produced according to the stated standard?
- Colors, flavors, and artificial sweeteners.
- Flavors and Flavor Ingredient Data (FID) sheets.
- GRAS (generally recognized as safe) ingredients.
- Restricted and Prohibited Ingredients.



### **Helpful Hints**

- Supply a quantitative list of ingredients.
- Provide a complete method of manufacture.
- Indicate at what stage flavors are added to the product.
- Flavor Ingredient Data Sheets (FIDS) should include a TTB number, a Flavor Product Number, and the TTB Approval status (Nonbeverage Lab Approval).
- Provide the common name and scientific name (genus and species) for any unusual herbal ingredients. Ensure that ingredients are GRAS (generally recognized as safe).



# Flavors



### **Compounded Flavors**

- Are classified as:
  - All natural
  - Natural and artificial containing not more than 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



#### Flavor Ingredient Data Sheet (FIDS)

- Flavor Manufacturer supplies form to the Producer.
- FID based on exchange between Flavor Producer and TTB Nonbeverage Laboratory.
- It lists concentration of Limited Ingredients in PPM.
- Any colors used in flavor.
- States alcohol content of flavor.
- This information, combined with the use rate, determines classification of flavor.

			Flavor Producer Informati	on	
	Company N	Code: WLOVE lame: We Love Flavors Iress: 6000 Ammendale Rd		Date: Contact Person: Phone:	5/28/2014 Martha Washington 240-555-1212
		Beltsville, MD 20705		Fax:	240-5551213
		2		Check Appropria	ate Box:
	Flavor N	ame: Nat. Chocolate WONF		Approved for Drav	
	TTB Drawback Nu			Approved as No A	
A		ume: 63.5 +/- 3.5%		Fit for Beverage P	
	Flavor Product Nu	mber: X1257		Submitted for TTE Not Yet Submitted	B Approval
			Classification		
	Natural 🗹	N&A ≤ 0.1% Topnote	N&A > 0.1% Topnote	Artificia	I Non-Flavor
	Total Artific	tial Flavor Content:	0 ppm (Excluding Synthetic Vanillin	n, Ethyl Vanillin, Synthetic	Maltol, and Ethyl Maltol)
			Flavor Components		
	Additive	TTB Limitation in Finished Product	Amount of Additive or Agent Present in Flavor	Maximum Use Rate	Beverage Label Information based of functionality (theck of tel label ingredients that affect the beverage table)
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	1000.0 ppm	ppm	- %	7. Grapeskin Extract
8.	Gum Arabic/Acacia	200000.0 ppm	ppm	- %	8. Caramel Color
9.	Propylene Glycol	50000.0 ppm	30,000 ppm	NO LIMIT %	9. Annatto
10.	BHA	(<0.5% Essential Oil)	check if contained		10. Elderberry Extract
11.	Acetic Acid	1500.0 ppm	ppm	%	11. Beet Extract
12.		ppm	ppm	- %	12. Oak Extract
13.		ppm	ppm	%	13
14.		ppm	ppm	%	14
15.	Total Vanillin	40.0 ppm	ppm	%	
16.	Total Maltol	250.0 ppm	ppm	%	
		Check if contained in formula Beverage Manufacturer / Importe	r:	s previously submitted	
_		Formula # / Serial a	#:		
	Flavor Compa	Title	e:	?	Date:
			age Alcohol Manufacturer /		
		facturer / Importer:		Formula # / Se	
	F	lavor Approved on:	Notified by:		As: Approved No Action Export Only



# **Flavor Ingredient Datasheet**

			Floor Development of the Physics				
			Flavor Producer Information	n			
	TTB Co. Code:	WLOVE		Date:	5/28/2014		
		We Love Flavors		Contact Person:	Martha Wa	shington	_
		6000 Ammendale Rd		Phone:	240-555-1212		
		Beltsville, MD 20705		Fax:	240-55512	13	_
				Check Appropri	ate Box:		
	Flavor Name:	Nat. Chocolate WONF		Approved for Drav			
	TTB Drawback Number:			Approved as No A		<b>v</b>	
Al	cohol Range by Volume:	63.5 +/- 3.5%		Fit for Beverage F	Purposes (Fit		
	Flavor Product Number:	X1257		Submitted for TTE	3 Approval		
				Not Yet Submittee	for TTB Ap	proval	
			Classification				
٢		I&A ≤ 0.1% Topnote	N&A > 0.1% Topnote	Artificia			
	Total Artificial FI	avor Content:	0 ppm (Excluding Synthetic Vanillin	, Ethyl Vanillin, Synthetic	Maltol, and Et	hyl Maltol)	
			Flavor Components				
	Additive	TTB Limitation in Finished Product	Amount of Additive or Agent Present in Flavor	Maximum Use	Be	verage Label Infor based of function	
		Finished Product	Agent Present in Flavor	Rate	che	ck or list label ingredients the boverage label;	
1. 1	Synthetic Vanillin	40.0 ppm	ppm	- %	1	FD&C Yellow #5	E
	Ethyl Vanillin	16.0 ppm	ppm	- %	2	FD&C Yellow #6	
	Synthetic Maltol	250.0 ppm	ppm	- %		FD&C Blue #1	Г
	Ethyl Maltol	100.0 ppm	ppm	- %		FD&C Blue #2	
	Ester Gum	100.0 ppm	ppm	- %		FD&C Green #3	Ē
	BVO	15.0 ppm	ppm	- %		FD&C Red #40	
	Sodium Benzoate			- %		Grapeskin Extrac	_
	Sodium Benzoate Gum Arabic/Acacia	1000.0 ppm	ppm	- %		. Grapeskin Extrac . Caramel Color	
		200000.0 ppm	ppm			Annatto	
	Propylene Glycol	50000.0 ppm	30,000 ppm	NO LIMIT %			_
	BHA	(<0.5% Essential Oil)	check if contained			Elderberry Extra	
	Acetic Acid	1500.0 ppm	ppm	%		. Beet Extract	
-		ppm	ppm	%		Oak Extract	
13.		ppm	ppm	%	13		_
14		ppm	ppm	%	14	·	
15.	Total Vanillin	40.0 ppm	ppm	%			
16. 1	Total Maltol	250.0 ppm	ppm	%			
	Be	Confide Check if contained in formu verage Manufacturer / Impo Formula # / Seria	ter:	Shown (CLI) s previously submitted		-	
	Flavor Company Rep	resentative Signature	itle:		Date:		_
		Beve	rage Alcohol Manufacturer /	Importer			
	Beverage Manufactu	rer / Importer:		Formula # / S	erial #:		
	Flavor	Approved on:	Notified by:		As:	Approved No Action	



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## **FID Header**

#### **Flavor Ingredient Data Sheet**

#### Flavor Producer Information

TTB Co. Code:	WLOVE		Date:	5/28/2014	
Company Name:	We Love Flavors		Contact Person:	Martha Washingto	'n
Address:	6000 Ammendale Rd		Phone:	240-555-1212	
	Beltsville, MD 20705		Fax:	240-5551213	
			Check Appropri	ate Box:	
Flavor Name:	Nat. Chocolate WONF		Approved for Drav	wback (DrB)	
TTB Drawback Number:	1510		Approved as No A	Action (N/A)	$\checkmark$
Alcohol Range by Volume:	63.5 +/- 3.5%		Fit for Beverage F	Purposes (Fit)	
Flavor Product Number:	X1257		Submitted for TTE	3 Approval	
			Not Yet Submittee	d for TTB Approval	
		Classification			
Natural 🗸 N	&A ≤ 0.1% Topnote	N&A > 0.1% Topnote	Artificia	I Non-	Flavor 🗌
Total Artificial Fl	avor Content:	0 ppm (Excluding Synthetic Vanil	lin, Ethyl Vanillin, Synthetic	Maltol, and Ethyl Malto	(Ic
					Saleco TAX AND
					INV TO BE AND A
				20	THE THE PARTY OF T

# Limited Ingredients Section

	Additive	TTB Limitation in Finished Product	Amount of Additive or Agent Present in Flavor	Maximum Use Rate	Beverage Label Information based of functionality (check or list label ingredients that affect the beverage label)
1. S	ynthetic Vanillin	40.0 ppm	ppm	%	1. FD&C Yellow #5
2. E	thyl Vanillin	16.0 ppm	ppm	- %	2. FD&C Yellow #6
3. S	ynthetic Maltol	250.0 ppm	ppm	- %	3. FD&C Blue #1
4. E	thyl Maltol	100.0 ppm	ppm	- %	4. FD&C Blue #2
5. E	ster Gum	100.0 ppm	ppm	- %	5. FD&C Green #3
6. B	VO	15.0 ppm	ppm	- %	6. FD&C Red #40
7. S	odium Benzoate	1000.0 ppm	ppm	- %	7. Grapeskin Extract
8. G	um Arabic/Acacia	200000.0 ppm	ppm	- %	8. Caramel Color
9. P	ropylene Glycol	50000.0 ppm	30,000 ppm	NO LIMIT %	9. Annatto
10. B	HA	(<0.5% Essential Oil)	check if contained		10. Elderberry Extract
11. A	cetic Acid	1500.0 ppm	ppm	- %	11. Beet Extract
12.		ppm	ppm	- %	12. Oak Extract
13.		ppm	ppm	- %	13.
14.		ppm	ppm	- %	14
15. T	otal Vanillin	40.0 ppm	ppm	%	
16. T	otal Maltol	250.0 ppm	- ppm	- %	



# **TTB Limited Ingredients**

#### - TTB has 4 limited ingredients:

- Synthetic maltol
- Ethyl maltol
- Synthetic vanillin
- Ethyl vanillin
- If these limits are exceeded, the "natural flavor" will be treated as artificial flavor in the product.



#### **Prohibited and Limited Ingredients**

- FDA maintains a list of prohibited ingredients at 21 CFR part 189.
- Other non-prohibited ingredients may be used within limits.
  - <u>http://www.ttb.gov/ssd/limited\_ingredients.s</u> <u>html</u>
- TTB does not approve formulas with directly added caffeine, vitamins, or minerals.



#### Certified Colors – 21 CFR Part 74 Subpart A

FD&C Blue #1	(Brilliant Blue FGF)	(E 133)
FD&C Blue #2	(Indigotine)	(E 132)
FD&C Green #3	(Fast Green FCF)	(E 143)
FD&C Red #40	(Allura Red AC)	(E 129)
FD&C Red #3	(Erythosine lake only)	(E 127)
FD&C Yellow #5*	(Tartrazine)	(E 102)
FD&C Yellow #6	(Sunset Yellow FCF)	(E 110)

\*Requires specific declaration on labels for finished alcohol beverages.



# Non-Certified Colors 21 CFR part 73 subpart A

- Annatto Extract
- Dehydrated beets (beet powder)
- Canthaxanthin
- Caramel Color
- Carmine (Cochineal Extract)\*
- Carrot oil

- β-Apo-8'-carotenal
- β-Carotene
- Fruit Juice
- Grape color extract
- Grapeskin Extract (Enocianina)

\*Requires specific declaration on labels for finished alcohol beverages. This is a partial list, see 21 CFR part 73 for complete list.



#### **FDA Requirements**

- FDA has authority over food and ingredient safety
- Generally Recognized as Safe
  - Specifically recognized in the regulations under 21 CFR parts 170-186
  - FDA will treat as a food substance.
  - Traditional medicine / dietary supplements are not necessarily GRAS
- Importer/producer is responsible for proving that an ingredient is GRAS.



#### **Treasury Decision 21**

- Effective January, 2006 See also 7.11
- If the final ABV is less than or equal to 6%, at least 51% of the alcohol in the final product must come from the malt base, no more than 49% of the alcohol in the final product can come from the flavor and other nonbeverage materials.
- If the final ABV is greater than 6%, no more than 1.5% of the volume of the malt beverage can consist of alcohol from flavors and other nonbeverage ingredients containing alcohol.
- An ABV statement must appear on the label if any alcohol in the malt beverage was derived from the added flavors. 27 CFR 7.22(a)(5)



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#### **Regulations & Resources**

- 27 CFR 7.10 Meaning of terms
- 27 CFR 7.24(a) Class and Type
- 27 CFR 25.11 Meaning of terms
- 27 CFR 25.15 Materials for the production of beer
- 27 CFR 25.55-58 Formulas
- TTB Industry Circular 2007-4
- TTB Ruling 2008-3 Classification of brewed products
- TTB Ruling 2015-1 Ingredients and processes not subject to formula requirements
- Beverage Alcohol Manual (BAM) for Malt Beverages



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# **Summary & Questions**

