

## Formulas and Labels for Beer/Malt Beverages

CALIFORNIA CRAFT BREWERS CONFERENCE DECEMBER 2, 2021



### Agenda

- Introduction
- Formulas
- Labels
- Questions



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.



## Formulas for Beer/Malt Beverages

STACEY COCHIARA FORMULA SPECIALIST



### **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 7.31(d))



### 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



# 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 (if required) must be obtained prior to applying for a certificate of label approval



### 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 <u>Attachment 1</u> of <u>TTB Ruling</u> <u>2015-1</u>)
  - 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

- <u>TTB Ruling 2015-1</u> exempts certain traditional ingredients and processes when used to make malt beverages
- <u>Attachment 1</u> specifies which ingredients and processes are exempt, for example:
  - Honey, vanilla beans
  - Barrel-aging



Ingredients and Processes that are Exempt from Formula Requirements

- <u>TTB Ruling 2015-1</u> does not exempt extracts or flavors containing alcohol
  - Vanilla beans are exempt, but vanilla extract is not exempt
- Exempt ingredients cannot comprise more than 49% of the fermentables
- 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

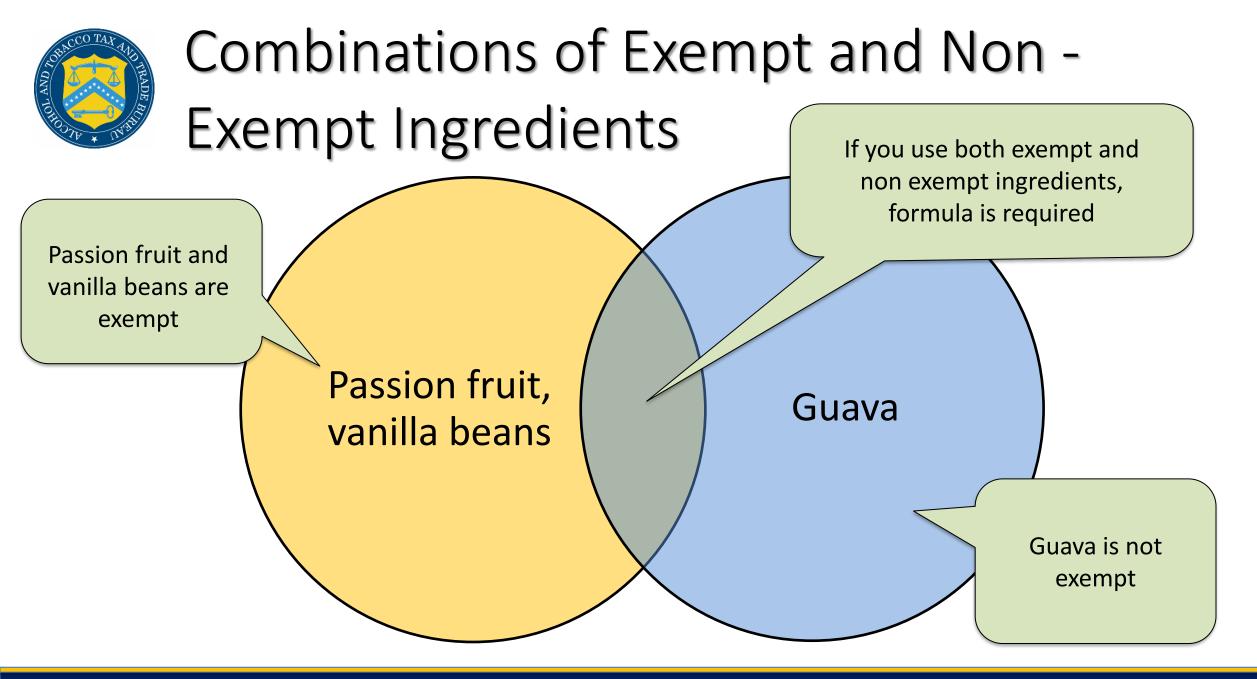
#### Exempt Ingredients and Processes Determined to be Traditional Under TTB Ruling 2015–1

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. <i>Does not</i> include extracts, essential
	oils, or syrups.
ALLSPICE	As outlined in FDA's GRAS listing at <u>21 CFR 182.10</u> . Spices may be whole or
	ground. Does not include extracts, essential oils, or syrups.
ANISE	As outlined in FDA's GRAS listing at <u>21 CFR 182.10</u> . Spices may be whole or
	ground. Does not include extracts, essential oils, or syrups.
APPLES	Whole, juice, puree, or concentrate. <i>Does not</i> include extracts, essential
	oils, or syrups.
APRICOTS	Whole, juice, puree, or concentrate. <i>Does not</i> include extracts, essential
	oils, or syrups.





# Which Beers Require Formula Approval?

 Use our online tool <u>Which Alcohol Beverages Require Formula</u> <u>Approval?</u> or check the list in <u>TTB G 2016-1A</u> 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:







Start

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



# 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



### Flavor Ingredient Data Sheet (FID Sheet or FIDS)

- 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 <u>TTB G 2017- 4</u> for additional information and examples



### 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
  - 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



### 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

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### **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

- <u>Limited Ingredient Calculation Worksheets</u> 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 <u>TTB G 2017-6</u> 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 the malt base
  - no more than 49 percent of the alcohol in the final product can come from the flavor and other nonbeverage materials



### 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

<sup>27</sup> CFR 7.11 & 22(a)(5), 27 CFR 25.15



Ingredient Specification Sheet (Spec Sheet or Technical Data Sheet)

- 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 <u>TTB G 2017-3</u> for additional information and examples



### 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 <u>21 CFR part</u> <u>189</u>
- Certain non-prohibited ingredients may be used within prescribed limits
  - TTB Limited Ingredients



### 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>



### 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



### Formulas Online Helpful Hints

• Ensure that ingredients are considered GRAS (generally recognized as safe) by the FDA before you submit

 Make sure you've uploaded all the applicable supporting documents, e.g., FIDS, Spec Sheet, etc., based on your list of ingredients





### Formula Resources

OTV * INVERT		
Beer Resources		
TTB Beer Rulings	Alcohol Beverage Formula Approval Guidance	
www.ttb.gov/beer/rulings	<u>https://www.ttb.gov/formulation</u>	
TTB Beer Industry Circulars	Does my Beer/Malt Beverage Require a Formula?	
www.ttb.gov/beer/industry-circulars	www.ttb.gov/formulation/mbev	
TTB Beer Frequently Asked Questions (FAQs) www.ttb.gov/beer/beer-faqs	TTB G 2016-1A –Beer/Malt Beverages Requiring Formula Approval or Laboratory Sample Analysis Chart <u>www.ttb.gov/public-guidance/ttb-g-2016-1a</u>	
Formula Approval with Laboratory Sample Analysis	Determine If and How Ingredients May be Used in Your	
https://www.ttb.gov/formulation/formula-approval-	Beverage	
with-laboratory-sample-analysis	<u>https://www.ttb.gov/formulation/determining-if-and-how-ingredients-may-be-used-in-your-beverage</u>	



## Labels for Malt Beverages

NICOLE CANDELORA QUALITY ASSURANCE COORDINATOR



- In this session we'll cover:
  - Mandatory label information
  - Keg collars
  - Prohibited labeling practices



# Mandatory Label Information



# Mandatory Label Information

### Must be on the Brand Label:

- Brand name (27 CFR 7.23)
- Class (27 CFR 7.24)
- Name and address (Domestic) (27 CFR 7.25)
- Net contents (27 CFR 7.27)
- Alcohol content (for malt beverages containing alcohol derived from added flavors or other nonbeverage ingredients (other than hops extract)) (27 CFR 7.22)

### May be on Any Label:

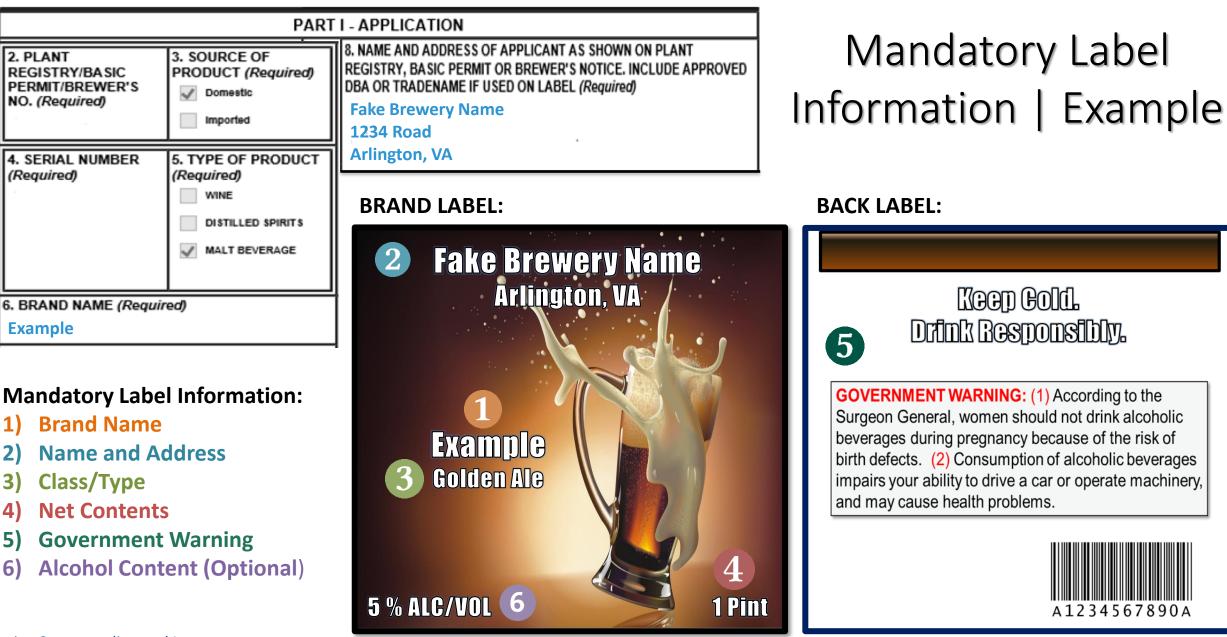
- Government Health Warning (27 CFR 16.21-22)
- Name and address (Imported) (27 CFR 7.25)
- Country of origin (Imported)
- **Declaration of certain ingredients** (when used): (27 CFR 7.22)
  - Aspartame
  - Sulfites
  - FD&C yellow #5
  - Cochineal extract or carmine



### Mandatory Label Information General Requirements

- Must be readily legible under ordinary conditions, and must appear on a contrasting background
- Other than the brand name, must be in English, with exceptions for malt beverages bottled for consumption in Puerto Rico
- For information about type size requirements, refer to
  - 27 CFR 7.28 General Requirements, or

- TTB Malt Beverage BAM (Beverage Alcohol Manual)



Creative Commons-licensed Image

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1)

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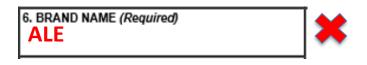
5)

6)



### Mandatory Label Information Brand Name

- Name under which the malt beverage is marketed
- If you do not identify a brand name, then the name of the bottler or importer is considered the brand name
- Common Mistakes:
  - Brand name on the label is not correctly entered on the application
  - Class/type is entered in the brand name field on the application
    - Example:





### Mandatory Label Information Name and Address

- City and state of bottler/packer
- Trade name or DBA (doing business as) is allowed
- Principal place of business of the producing brewer may be used in lieu of listing all brewing locations when owning multiple brewing locations



# Name and Address | Common Mistakes

- Name and address are missing from the label
- City and state on label do not match the address on the Brewer's Notice
- Contract brewer/producer has not added the contractee's DBA/trade name to their Brewer's Notice
- Label contains name and address of the contractee and not the contract brewer/producer



## Mandatory Label Information

Net Contents

- Must use English units of measure (fluid ounces, pints, quarts, gallons)
- May show both metric and English units on the label
  - 1 pint 9.4 fl. oz. (750 mL)

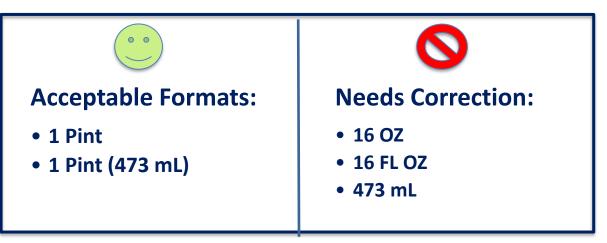
		1	
		EXAMPLES	
CONTENTS OF	NET CONTENTS MUST BE SHOWN IN	CONTAINER SIZE	LABEL NET CONTENTS STATEMENT MUST BE
Less than 1 pint	Fluid ounces or fractions of a pint	8 ounces	8 fluid ounces (fl. oz.) or ½ pint (pt.) or 0.5 pint (pt.)
1 pint	Pints	16 ounces	1 pint (pt.)
More than 1 pint but less than 1 quart	Pints and fluid ounces or fractions of a quart	20 ounces	1 pint (pt.), 4 fluid ounces (fl. oz.) or 5/8 quart (qt.) or 0.63 quart (qt.)
1 quart	Quarts	32 ounces	1 quart (qt.)
More than 1 quart but less than 1 gallon	Quarts, pints and fluid ounces or fractions of a gallon	60 ounces	1 quart (qt.), 1 pint (pt.), 12 fluid ounces (fl. oz.) or 15/32 gallon (gal.) or 0.47 gallon (gal.)
1 gallon	Gallons	128 ounces	1 gallon (gal.)
More than 1 gallon	Gallons and fractions of gallons	166 ounces	1 ¼ gallons (gals.) or 1.25 gallons (gals.)

27 CFR 7.27



### Net Contents | Common Mistakes

- Stating just oz. instead of fl. oz.
- Stating 16 fl. oz. instead of 1 pint (may list both)



- Not converting measurements into pints and fluid ounces (22 fl. oz. vs. 1 pint 6 fl. oz.)
- Showing only metric units (750 mL)



### Mandatory Label Information Alcohol Content

#### Alcohol By Volume:

- Mandatory if any alcohol is derived from added flavors or other added nonbeverage ingredients (other than hops extract) containing alcohol
- Otherwise, it is optional (unless required by state law)
- Alcohol By Weight:
  - You may optionally include alcohol by weight together with the statement of alcohol by volume

Approved Formats:				
Alcohol By Volume:	Alcohol By Weight:			
Alcohol (ALC)% by Volume (VOL)	Alcohol (ALC)% by Weight			
Alcohol (ALC) by Volume (VOL)%	Alcohol (ALC) by Weight%			
% Alcohol (ALC) by Volume (VOL)	% Alcohol (ALC) by Weight			
% Alcohol (ALC)/Volume (VOL)	% Alcohol (ALC) / Weight			



# Alcohol Content | Common Mistakes

- Using an incorrect format
  - ABV and ABW are not permitted you must spell out the words or use the abbreviations allowed by 27 CFR 7.71(b)(3)
    - Example: 🗱 5% ABV vs. 🗹 5% ALC/VOL
- Leaving off part of the phrase or the percent symbol (%)
- Not listing alcohol content on the label for products that contain added alcohol from a flavor



### Mandatory Label Information Health Warning Statement

- Must be readily legible under ordinary conditions and on a contrasting background
- Must be separate and apart from all other label text
- The words **GOVERNMENT WARNING** must appear in capital letters and bold type

**GOVERNMENT WARNING:** (1) According to the Surgeon General, women should not drink alcoholic beverages during pregnancy because of the risk of birth defects. (2) Consumption of alcoholic beverages impairs your ability to drive a car or operate machinery, and may cause health problems.

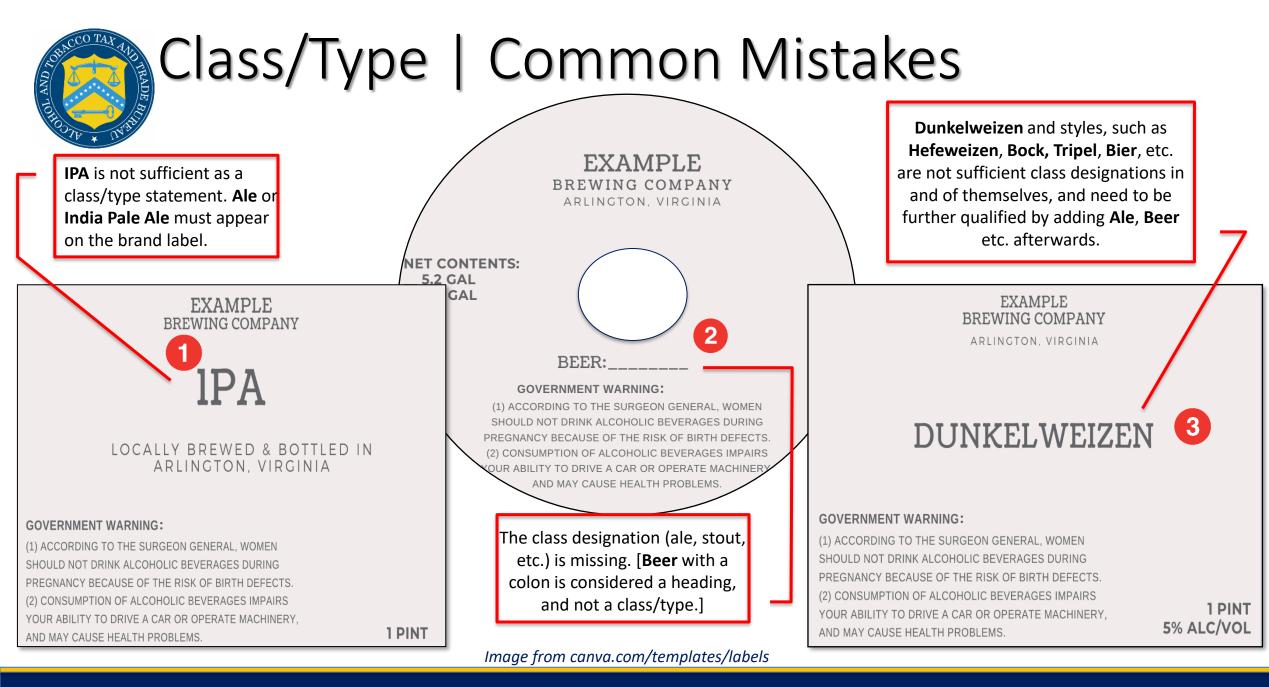
27 CFR part 16



### Mandatory Label Information Class and Type - General

- The specific identity of a malt beverage
- The designation of malt beverages is based on trade understandings of the characteristics generally attributed to the particular malt beverage
  - Ale, Beer, Malt Liquor, Stout, Ice Beer, Porter, and India Pale Ale are all acceptable as the class designation of a malt beverage

27 CFR 7.24



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Mandatory Label Information Class and Type – Malt Beverage Specialty Products

- Products not known to the trade under a particular designation are commonly called malt beverage specialty products
- MB specialty products require formula approval prior to applying for label approval, unless they have been specifically exempted from formula approval

27 CFR 7.24(a)



Mandatory Label Information Class and Type – Formulated Specialty Products

• If formula approval is required, the product must be labeled with a distinctive or fanciful name, together with an adequate and truthful statement of the composition



27 CFR 7.24(a)



# MB Specialties that Require Formulas | Common Mistakes

- Fanciful name is missing on the label and/or application
- Statement of composition does not accurately reflect the flavoring materials in the product as per the formula
- Statement of composition is missing the base beer
  - For example, Made with Vanilla Extract vs. Ale with Vanilla Extract



### Class and Type | Formulated MB Specialty Product

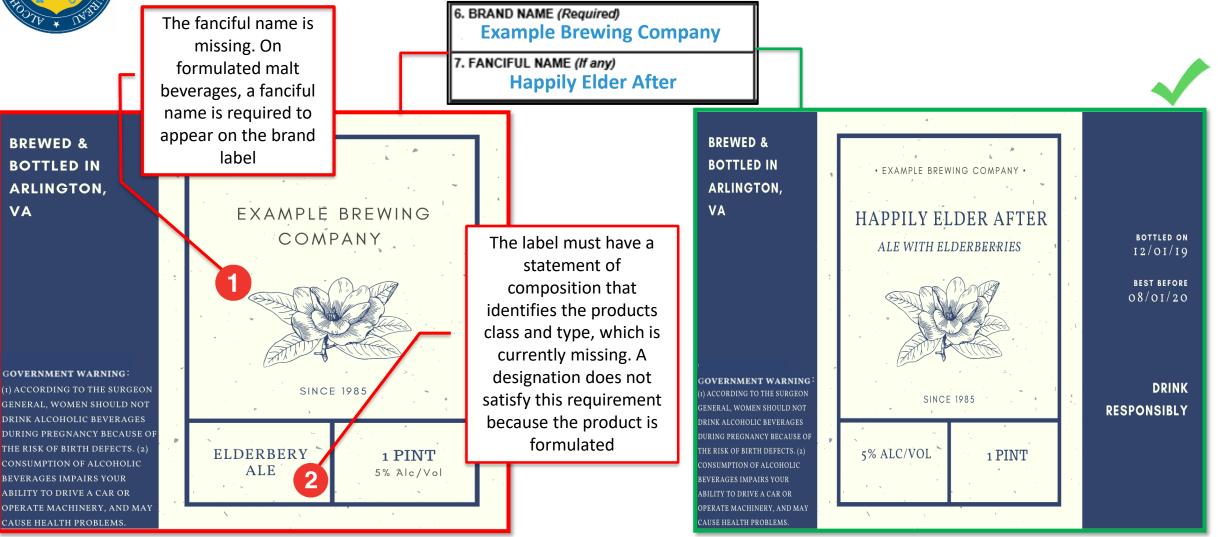


Image from canva.com/templates/labels



# Mandatory Information

Class and Type – Formula Exempt MB Specialties

- Specific malt beverage ingredients and processes are exempt from formulas under <u>TTB Ruling 2015-1</u>
- The process of aging beer is exempt, however DS or wine barrels, woodchips, or staves should have no discernible quantity of spirits or wine
- Labeling Requirements:
  - Class/type may be stated as either a
     Designation or Statement of
     Composition
  - Fanciful Names are not required
  - Aging of a product does not need to be called out as part of the Class/type

Flavoring Ingredient used:	Raspberry puree	
Is a formula required?	NO (exempt under 2015-1)	
<ul> <li>Labeling options:</li> <li>in accordance with trade understanding</li> </ul>	Fruit Ale Raspberry Ale	
Statement of Composition	Ale with Natural Flavor Ale with Raspberries	



# 2015-1 Examples of Designations – Attachment 2

Examples of Adequate and Inadequate Designations in Accordance with Trade Understanding

Description of product	Examples of statements of composition that will continue to be allowed as designations in accordance with trade understanding under this ruling.	Examples of adequate designations in accordance with trade understanding.	Examples of inadequate and misleading designations.* (Examples of inadequate designations are in black and misleading designations are designated as such and appear in red.)
Beer brewed with cherry juice	<ul> <li>Beer brewed with cherry juice</li> <li>Malt beverage fermented with natural flavor</li> <li>(Kriek may be added as optional additional information.)</li> </ul>	<ul> <li>Fruit beer</li> <li>Cherry beer</li> <li>(Kriek may be added as optional additional information.)</li> </ul>	<ul> <li>Cherry delight</li> <li>Kriek</li> <li>Bob's Beer</li> <li>Beer</li> <li>Malt beverage</li> </ul>
Beer with cherry juice added after fermentation	<ul> <li>Beer flavored with cherry juice</li> <li>Malt beverage with natural flavor added</li> <li>(Kriek may be added as optional additional information.)</li> </ul>	<ul> <li>Fruit beer</li> <li>Cherry beer</li> <li>(<i>Kriek</i> may be added as optional additional information.)</li> </ul>	<ul> <li>Cherry delight</li> <li>Kriek</li> <li>Bob's Beer</li> <li>Misleading designation:</li> <li>Beer brewed with cherry juice</li> </ul>



### Class and Type | Formula Exempt MB Specialties

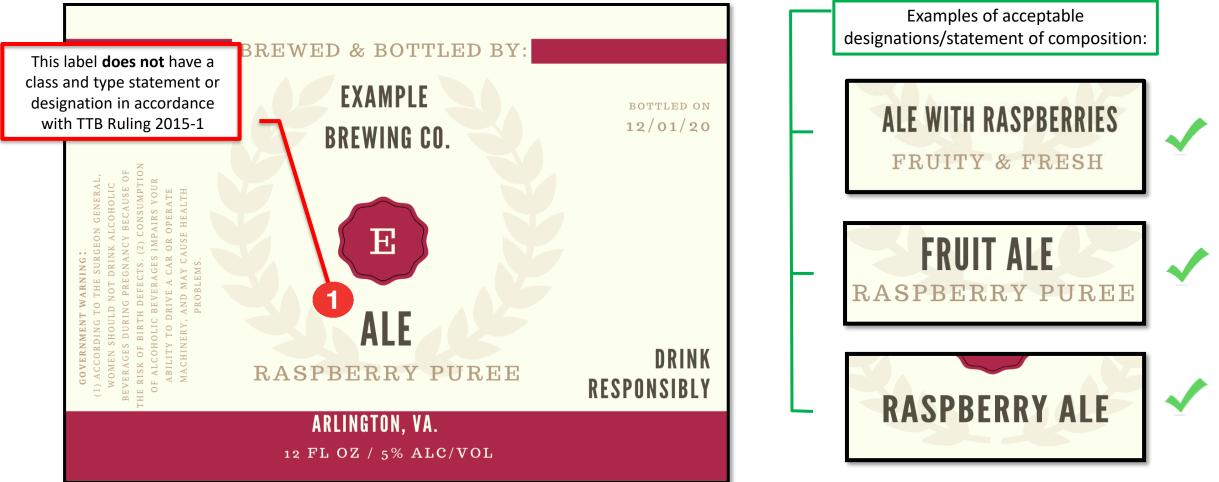


Image from canva.com/templates/labels



MB Specialties Exempt from Formulas | Common Mistakes

- Product ingredients are not sufficiently conveyed by the style's name, for example, as gose or wit
- Statement of composition or designation is missing
- Class designation of base product is missing in the statement of composition





### Geographical Names Class and Type

- Geographical names for distinctive types of malt beverages shall not be applied to malt beverages produced in any place other than the particular region indicated by the name unless qualified with text such as **STYLE** or **PRODUCT OF THE USA** or other text to indicate the true place of production
- Common Mistakes
  - India Pale Lager or India Session Ale appearing without qualifiers (such as Style or Product of USA)
  - Product of the USA does not appear in direct conjunction with the geographically significant reference (text or imagery)

27 CFR 7.24(f)-(h)



### Geographical Names of Distinctive Types Class and Type

Names that have lost geographic significance (no qualifier required)

- India Pale Ale
- Baltic Porter
- Bohemian
- Russian Imperial Stout
- Imperial Russian Stout
- Scotch Ale
- Scottish Ale

Examples of names that still have geographic significance\* (qualifier required)

- Belgian
- Berliner
- English
- Irish
- Kolsch
- Mexican
- Vienna
- New England
- West Coast (or similar) \*Not a Complete List



### Geographic Significance | Example

Unlike India Pale Ale, India Pale Lager has not lost its geographic significance



Geographically significant malt beverage styles produced in a country other than the one indicated must be properly qualified with **style** or a phrase such as **Product of USA** 



# Keg Collars

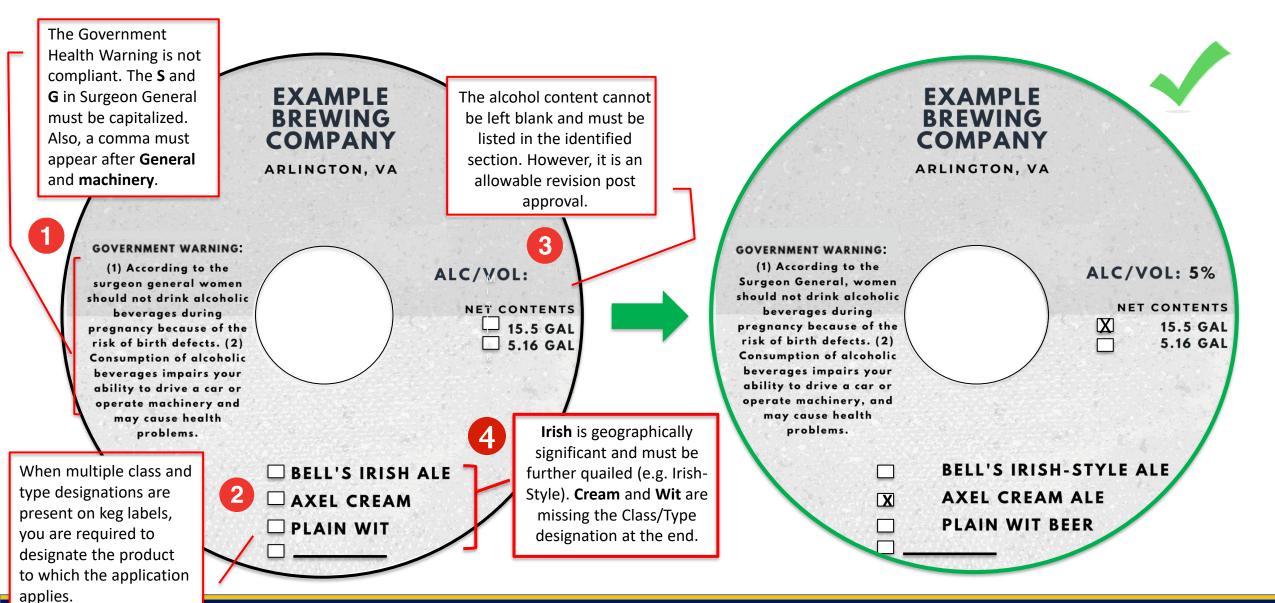




- Kegs are consumer containers, just like bottles or cans
- When a COLA is required, mandatory labeling requirements must be met
- Labels bearing mandatory information must be firmly affixed and may include:
  - Keg caps
  - Collars
  - Stickers
  - Combination of formats
- Information can be handwritten on the label
  - Except for GOVERNMENT WARNING



### Keg Label Common Mistakes | Example



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# Prohibited Labeling Practices



Examples of Things Prohibited from Appearing on Malt Beverage Labels

- Any statement that is false or untrue
- Any statement ... relating to any guarantee
- Any misleading information, such as:
  - Text that implies that the product is a distilled spirit or contains a distilled spirit
  - Misleading health-related claims
  - Implied government endorsements

27 CFR 7.29



# **Commonly Used Optional Information**

### **Rulings of Interest:**

- <u>2004-1</u> Caloric and Carbohydrate Representations
- <u>2020-2</u> Gluten Content Statements
- <u>2013-2</u> Voluntary Nutrient Content Statements

### **Frequently Asked Questions (FAQs) of Interest:**

- FAQs on TTB Ruling 2013-2 (Serving Facts Statements)
- FAQs on Sugar Content Statements
- FAQs on Major Food Allergen Labeling
- FAQs on Organic Labeling
- FAQs on Alcohol
- <u>FAQ [AF3]</u>: How do I calculate the number of servings per container?



### Labeling Resources

**Beer Resources** 

TTB Beer Rulings www.ttb.gov/beer/rulings

TTB Beer Industry Circulars www.ttb.gov/beer/industry-circulars Beer-Beverage Alcohol Manual (BAM) www.ttb.gov/beer/beverage-alcohol-manual

> **Do I Need a Formula? Tool** <u>www.ttb.gov/formulation/mbev</u>

TTB Beer Frequently Asked Questions (FAQs) 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

Allowable Revisions to Approved Labels www.ttb.gov/labeling/allowable-revisions Labeling Laws and Regulations www.ttb.gov/labeling/laws-and-regulations





### **Questions?**

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

- Toll Free at 866-927-ALFD (2533), OR
- Use our <u>Alcohol Labeling and Formulation Division (ALFD) Contact Form</u>

**Representatives are Available:** 

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



### Visit us at the TTB table!

Please take few minutes to provide feedback on this session:

https://www.ttb.gov/survey

