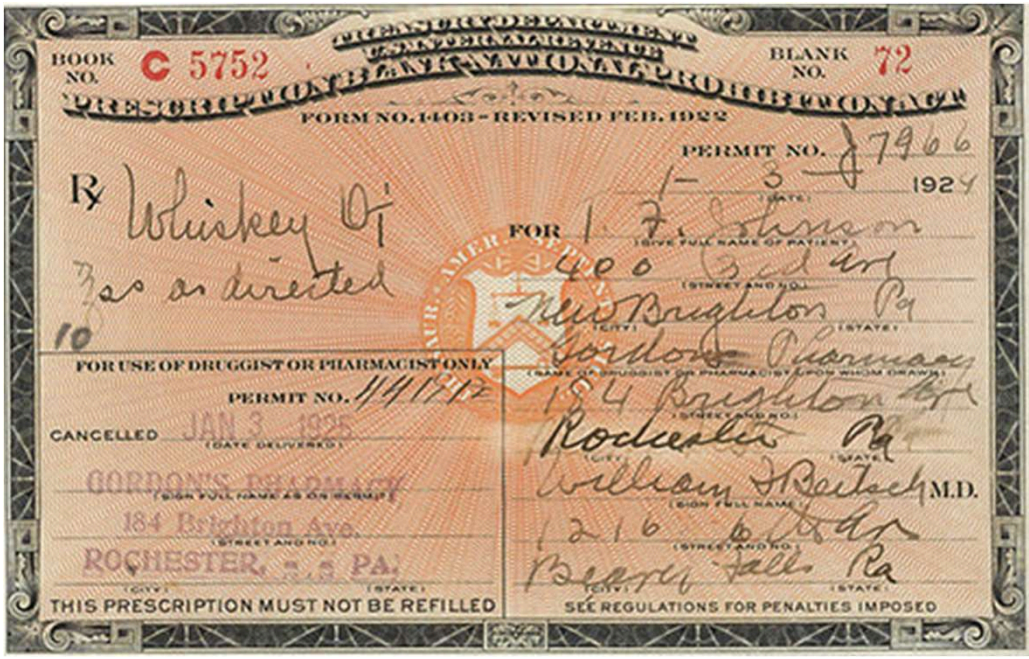
TTB FLAVOR UNFITNESS:
A REGULATORY PERSPECTIVE

March 2021

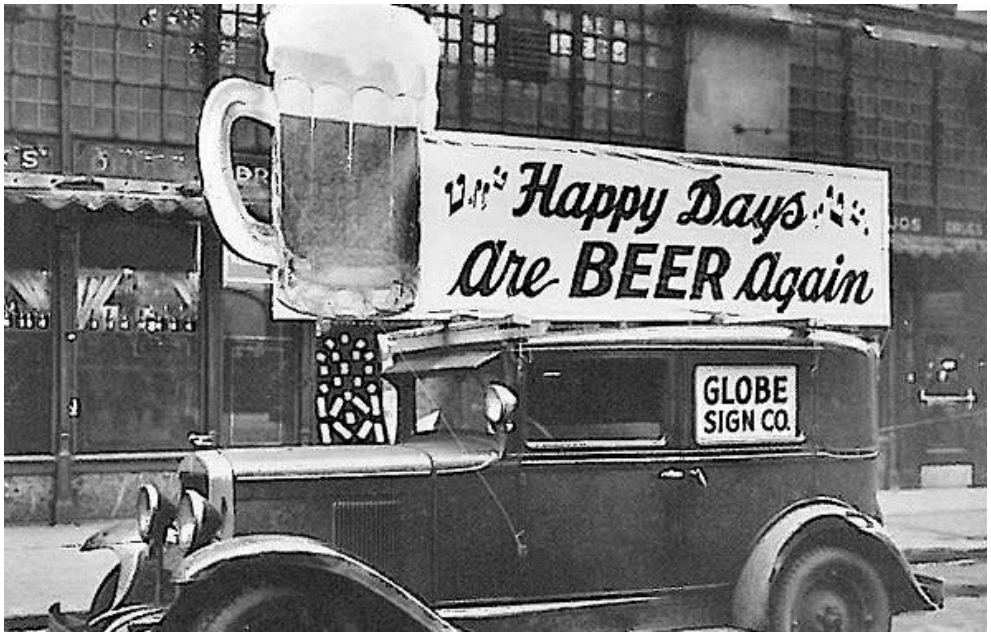
US TTB OVERVIEW:
PROHIBITION

Prohibition in the United States was a nationwide constitutional ban on the **production, importation, transportation, and sale** of alcoholic beverages from 1920 to 1933.

US TTB OVERVIEW:
PROHIBITION



US TTB OVERVIEW:
21ST AMMENDMENT



AUTHORITY TO REGULATE ALCOHOL

Federal Alcohol Administration Act (1935)

26 U.S.C Internal Revenue Code

U.S. TTB Overview

BACKGROUND

Alcohol and Tobacco Tax and Trade Bureau

Department of Treasury

Established under the Homeland Security Act of 2002

Formerly the Bureau of Alcohol, Tobacco, Firearms and Explosives (BATF)

Responsible for enforcing the laws regulating **alcohol production, importation,** and wholesale businesses; tobacco manufacturing and importing businesses; and **alcohol labeling and advertising** in accordance with the Federal Alcohol Administration Act (27 U.S.C. Chapter 8).

U.S. TTB Overview

FLAVORINGS

≥0.5% ABV

The United States defines alcoholic beverages as products which contain **greater than half a percent** alcohol by volume that are **potable***.

NONBEVERAGE PRODUCTS

Flavorings are classified as **Non-beverage products** which are excluded from the definition of alcohol beverage as long as they are **unfit for beverage**.

UNFIT FOR BEVERAGE

Unfit for beverage means the average person could not mistake the product for an alcoholic beverage—it is **not drinkable**.

*Potable = Drinkable = “Fit for beverage”

27 CFR § 17.134

U.S. TTB Overview

UNFITNESS

The TTB has guidelines to determine potability of flavorings containing ethanol.

PRIMARY GUIDELINES

Commonly used ingredients at certain usage levels

FLAVOR UNFITNESS WORKSHEET

Feranoli ‘s usage levels

ORGANOLEPTIC ANALYSIS

Protocol for tasting

U.S. TTB Overview

FLAVORING UNFITNESS

1% Flavor Chemicals	**1% by weight @ 95% v/v ethanol** **Artificial Flavor Materials** **Natural Flavor Materials**
2% Total Flavor Chemicals	**2% by weight @ 95% v/v ethanol** % by weight of any combination of materials listed on the 1% list of Artificial Flavor Materials or Natural Flavor Materials is unfit for beverage purposes, even if mitigating materials are present in the formulation.

Ingredient	Amount
Anise Oil	4.4% by weight at 95% alcohol
Black pepper powder	3.6 g/100 ml @ 95% v/v ethanol
Citric acid	If ethanol ≤ 30% v/v - acid must be ≥ [0.1 × ethanol % + 0.5] (g/100mL) If ethanol > 30% v/v - acid must be ≥ [0.1 × ethanol %] (g/100mL)
Cocoa nibs	10.6 lbs/gal @ 95% v/v ethanol
Essential oils	Most essential oils are unfit at 3.2% by weight in 95% v/v ethanol for **simple mixtures**. Some oils are on the 1% list.
Ethyl acetate	2.1% by volume @ 95% v/v ethanol
Ethyl maltol	5.3% by weight @ 95% v/v ethanol
Ethyl vanillin	1.3 av. oz./gal @ 95% v/v ethanol
Fennel Oil	4.4% by weight at 95% alcohol
Fusel Oil	1.6 g/100 ml @ 95% v/v ethanol
Lactic acid	9.5% by volume @ 95% v/v ethanol
Maltol	5.3% by weight @ 95% v/v ethanol

Ingredient	Amount
Malic acid	If ethanol ≤ 30% v/v - acid must be ≥ [0.14 × ethanol % + 0.5] (g/100mL) If ethanol > 30% v/v - acid must be ≥ [0.14 × ethanol %] (g/100mL)
Propylene glycol	Equal amounts by volume of ethanol and propylene glycol
Quassia powder	20.8 ppm @ 95% v/v ethanol
Quinine	950 ppm @ 95% v/v ethanol
Salt (sodium chloride)	6.8 g /100 ml @ 95% v/v ethanol
Tannic acid	1.6% by weight @ 95% v/v ethanol
Tartaric Acid	If ethanol ≤ 30% v/v - acid must be ≥ [0.13 × ethanol % + 0.5] (g/100mL) If ethanol > 30% v/v - acid must be ≥ [0.13 × ethanol %] (g/100mL)
Triacetin	2.5% by weight @ 95% v/v ethanol
Triethyl citrate	2.5% by weight @ 95% v/v ethanol
Vanillin	3.2 av. oz./gal @ 95% v/v ethanol
Washed Extracts of Essential Oils	6.33% by weight (amount of oil initially, before extraction) at 95% v/v ethanol ***for single oil only**

U.S. TTB Overview

FLAVORING UNFITNESS

Unfitness based on the **Feranoli's** average maximum usage levels.

A material that is present at **>5 times** the Feranoli's maximum usage level, the product is deemed unfit for beverage.

Only valid in the **absence** of materials that will make the product more palatable (e.g., sugar, glycerin, high fructose corn syrup, etc.)

Extracts are not in scope

Flavor Unfitness Worksheet

Version 2019.1

Don't know how to use this worksheet? See the instructions below!

Formula Information:	
Total Weight	100
Alcohol content (high end of box #10)	82

Not all ingredients apply to this guideline. If you do not see a value in the Max Use Level box refer to this key:
NO GUIDELINE - There is no current NPL unfitness guideline for this material.
N/A - Information on this ingredient is not available
PRIMARY GDL - Refer to the Primary Guideline tabs below for the unfitness calculations.
SEE 1% LIST - To determine unfitness using this material, refer to the 1% guideline within the Primary Guideline tabs.
BOTANICAL EXT - Refer to the Botanical Extracts & Dietary Supplements tab for unfitness calculations.
*** See disclaimers below this table. ****

* guideline applies even if product contains mitigating ingredients

FEMA #	Ingredient	Limited (see key below)	Weight of ingredient	ppm in flavor	ppm @ 15% ABV	MAX Use Level	Factor higher MAX Use Level	Fit or Unfit? *	Remarks
2798	OCTANAL DIMETHYL ACETAL	-		0.0	0.0	7	-	-	-
2441	ETHYL LAURATE	-		0.0	0.0	4.17	-	-	-

U.S. TTB Overview

FLAVORING UNFITNESS

Tasting protocol: Performed under ambient conditions

1. Samples that contain more than 15% alcohol by volume are diluted to that level with tap water before taste paneling.

2. Samples that contain 15% alcohol by volume or less are tasted without dilution.

3. Six or more panelists are required for organoleptic analysis.

4. Two-thirds of the panelists must agree that the sample is unfit for beverage purposes.

Very subjective

Requires sample submission to TTB for analysis

U.S. TTB Overview

FLAVORINGS

FORMULA INFORMATION

Non-flavoring ingredients

All individual ingredients declared by weight.

*Volume is also needed for soluble ingredients when flavor is an extract

Added ethanol

Declare percent ethanol (v/v) or proof, the weight, and volume added to the formulation.

Ingredients that contain ethanol

Declare percent ethanol (v/v) or proof, the weight, and volume added to the formulation

+ TTB limited ingredients and supplier's TTB number

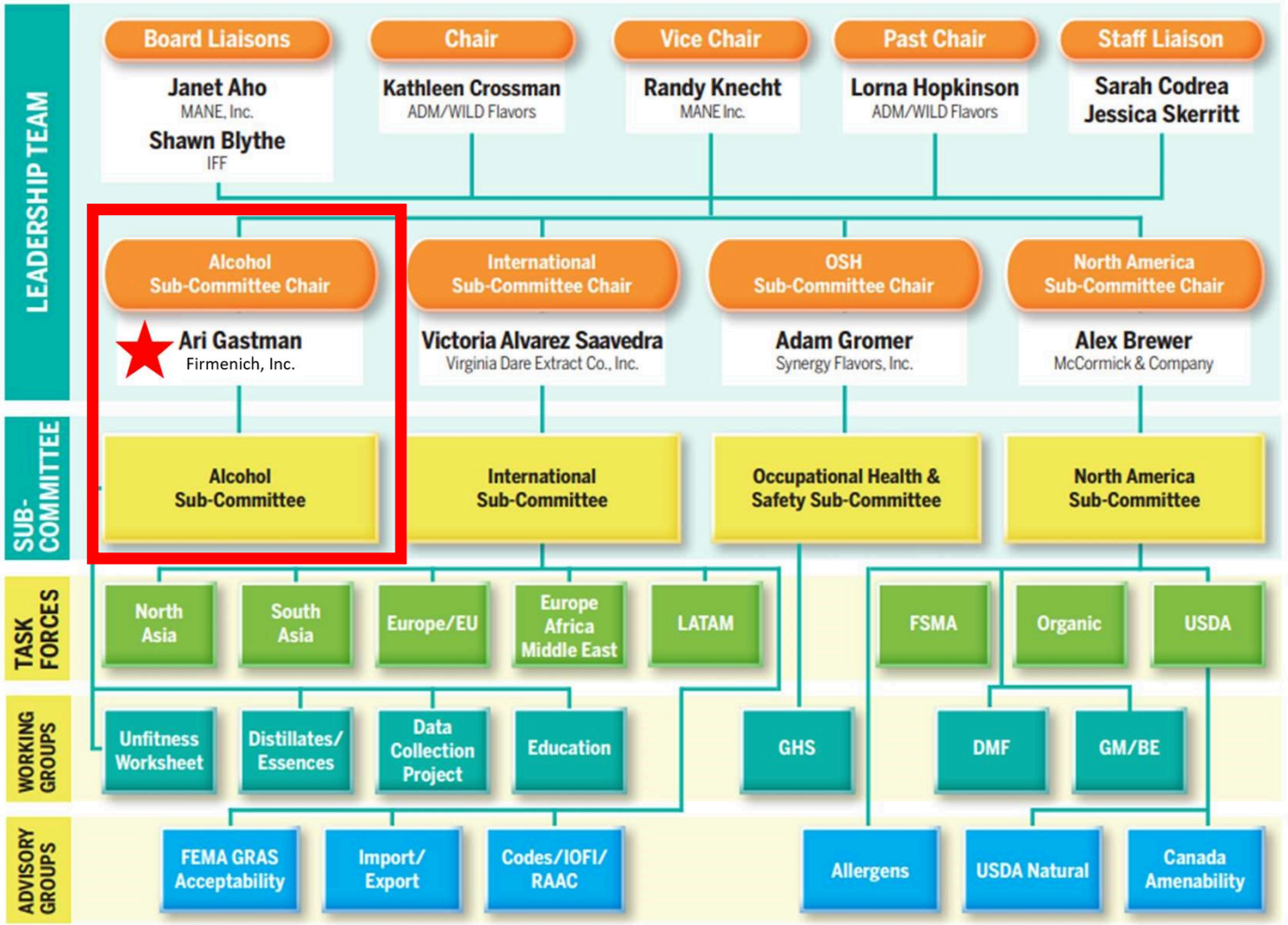
Flavorings

Flavorings can be grouped together with limited disclosure.

***If the group is <10% of the formula, at least 20% of the group must be identified and quantified.**
***If the group is >10% of the formula, at least 50% of the group must be identified and quantified.**

https://www.ttb.gov/scientific-services-division/dbmenu5sub3

REGULATORY AFFAIRS COMMITTEE



SCOPE:

- Regulations and procedures for tax drawbacks,
- Formula disclosure,
- Investigation and inspection procedures,
- Conflicts between agencies,
- Impact on wine and alcoholic beverage flavors and beverage ingredient labeling.

FEMA Alcohol Subcommittee

Washed Extracts working group

TTB UNFITNESS GUIDELINES FOR ESSENTIAL OILS

SIMPLE MIXTURES:

Most essential oils are unfit at 3.2% by weight in 95% v/v ethanol for **simple mixtures**. Some oils are on the 1% list.

EXTRACTS:

6.33% by weight (amount of oil initially, before extraction) at 95% v/v ethanol ***for single oil only**

PURPOSE:

Flexibility in unfitness criteria for blended oils for washed extracts, with primary focus on citrus oils.

Demonstrate that folded oils are needed at lower amounts for unfitness due to the concentrations of the oil.

FEMA Alcohol Subcommittee

Washed Extracts working group

***NOT A REAL FORMULA. FOR EXAMPLE ONLY

Component	Weight (lb)	Density (lbs/gal)	Volume (gal)
Ethanol (95%)	60	6.794	8.831
Water	35	8.345	4.194
Lime Oil	2		
Lemon Oil	3		

Volume alcohol x alcohol content = **8.389 gal Absolute EtOH**

Average Yield 95%

Density 7.25 lb/gal

ELIGIBLE ETHANOL

High range yield 97lbs / density =13.379 gal

Absolute gal EtOH / 13.379 gal x 100 = **62.70% EtOH (v/v)**

Low range yield 93lbs / density =12.828 gal

Absolute gal EtOH / 12.828 gal x 100 = **65.40% EtOH**

ABSOLUTE ETHANOL

Volume soluble ingredients = **13.025 gal**

Absolute EtOH / Volume soluble ingredients x 100 = **64.41 % EtOH (v/v)** **+/- 3.5%**

FEMA Alcohol Subcommittee

Washed Extracts working group

***NOT A REAL FORMULA. FOR EXAMPLE ONLY

Guidelines	High EtOH value	Ingredients for unfitness
Washed Extracts 6.33% oils by weight at 95% v/v ethanol	67.91% EtOH (v/v)	3 lb lemon oil (or 2 lb lime oil, guideline does not apply to combination of oil)

67.91% EtOH x 6.33%/95% EtOH= 4.52% oil needed (at 100% yield)

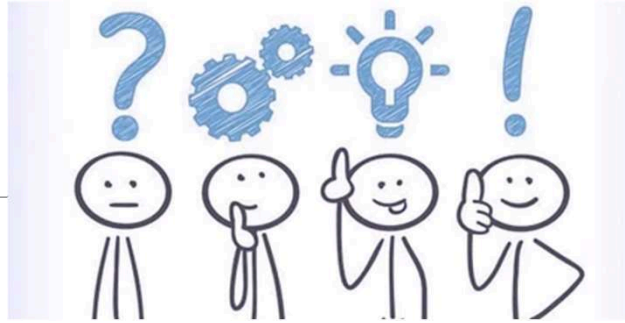
FIT FOR BEVERAGE

CURRENT OPTIONS:

- Organoleptic testing
- Reformulation

FEMA Alcohol Subcommittee

Washed Extracts working group



TTB policy currently allows only single oils to meet the 6.33% threshold for unfitness for washed extracts.

Component	Weight (lb)
Ethanol (95%)	60
Water	35
Lime Oil	2
Lemon Oil	3

FIT FOR BEVERAGE

Component	Weight (lb)
Ethanol (95%)	60
Water	35
Lemon Oil	5

UNFIT FOR BEVERAGE

FEMA Alcohol Subcommittee

Washed Extracts working group

Action:

Members are researching analytical data on citrus oils that demonstrates the similarities of the oils.

	Grapefruit Oil (1X)	Lemon Oil (1X)	Lime Oil (1X)	Mandarin Oil (1X)
FEMA No	2530	2625	2631	2657
CAS No	8016-20-4	8008-56-8; 8020-19-7	8008-26-2	8008-31-9
Relative density 20/20C	0.835 - 0.868	0.845 - 0.864	0.855 - 0.890	0.844 - 0.857
Refractive Index 20C	1.470 - 1.486	1.471 - 1.479	1.474 - 1.478	1.472 - 1.477
Optical rotation 20C	+88 - +95	+57 - +78	+31 - +47	+66 - +79
Typical GC Composition Markers (%)				
d-Limonene	91 - 96	59 - 80	36 - 52	65 - 77
Decanal	0.1 - 0.6			
B-Caryophyllene	<0.2			
Nootkatone	<1.0			
B-Pinene		8 - 17		
p-Mentha-1,4-diene (γ-Terpinene)		6 - 12	9 - 14	15 - 22
Citral		0.6 - 6		
a-Terpineol			6 - 9	
Eucalyptol (1,8-Cineole)			<3.0	
Linalool				
3-Carene				
Ethyl Butyrate				
Methyl-N-methyl anthranilate				0.3 - 0.9
a-Sinensal				0.2 - 0.5
% Composition by GC (ISO 3053:2004)				
a-Pinene	0.2 - 0.6	1.4 - 3.1	0.8 - 1.3	1.6 - 3
Sabinene	0.1 - 0.6	1.3 - 3.0	0.1 - 0.3	
B-Pinene	0.05 - 0.2	7 - 16.5	1 - 3	1 -2
Myrcene	1.5 - 2.5		1.1 - 1.5	1.4 - 2
Limonene	92 - 96	60 -80	36 - 46	65 - 75
n-Octanal	0.2 - 0.8			0.03 - 0.14
n-Nonanal	0.04 - 0.1			
n-Decanal	0.1 - 0.6			0.04 - 0.14
Neral	0.02 - 0.04	0.2 - 1.2		
B-Caryophyllene	0.2 - 0.5		0.4 - 0.8	

FEMA Alcohol Subcommittee

Washed Extracts working group

Unfitness for essential oils in simple mixtures does not account for concentration

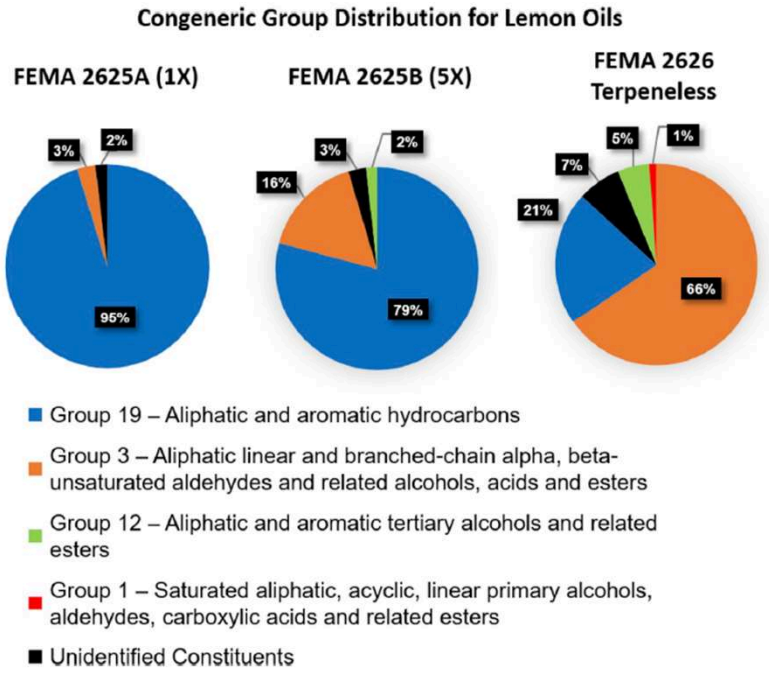


Fig. 3. Constituent profiles for 1X and 5X folds of Lemon Oil (FEMA 2625) and Lemon Oil, Terpeneless (FEMA 2626).

FEMA Alcohol Subcommittee

OTHER ACTIVITIES

Distillates & Essences Task Force

TTB over approximately the past 5 years began requiring a specification or proof of non-potability for any fruit essence or distillate containing >7% ABV.

Education Task Force

Provide education for FEMA members regarding specific issues with the TTB.

Voluntary returns collection project

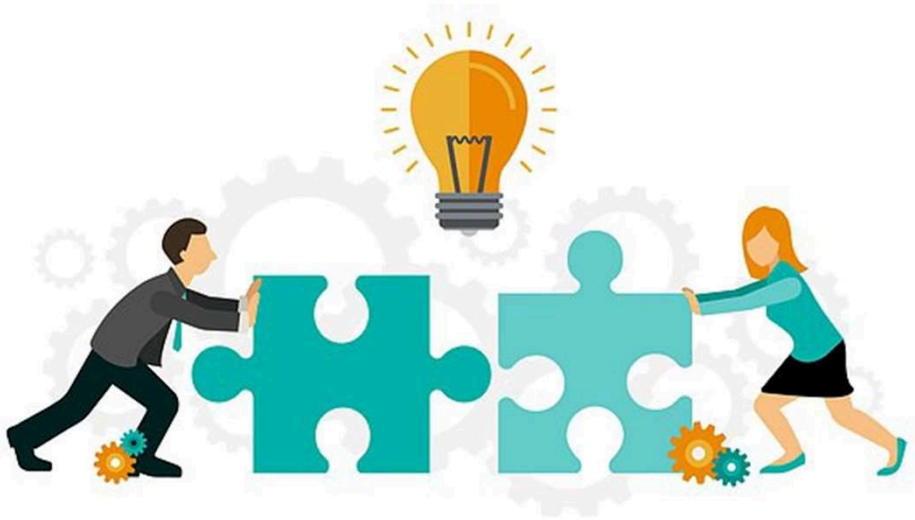
Collect & present statistical data regarding formula returns of FEMA members to TTB and to provide additional education to FEMA members.

< 15% ABV Working Group

Develop unfitness data for formulas with alcohol by volume (ABV) under 15%. Current guidelines require denaturing ingredients to be present at levels as if a formula contains 15% ABV. The working group will put together a proposal for the NPL to consider that would eliminate the need for excessive levels of denaturing ingredients.

WORKING TOGETHER

FLAVORIST + REGULATORY



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