



# **BREWERY FOOD SAFETY**

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# DISCLAIMER

- 1.The information shared during this presentation was compiled from sources believed to be reliable and for informational purposes only.**
- 2.The information does not guarantee FSMA compliance**
- 3.Nor does it absolve alcohol beverage producers of the obligation to comply with all FSMA rules applicable to their individual operations.**



# WHAT WE'LL COVER TODAY

- Why is food safety important for breweries?
- Requirements and exemptions
- What's in a food safety plan?
- What to expect and how to be prepared for an inspection?
- Case study of inspection
- Formula approval
- Brewery food safety resources



# Why is food safety important for breweries?



## #1 It's the law

- Food Safety Modernization Act (FSMA)
- Signed into law January 4, 2011 [21 CFR.117]; rolled out gradually; all businesses must comply 9/17/18
- Resulted in alcohol producers being required to comply
- FDA permitted to inspect the facility at the times and in the manner permitted by the FD&C Act.
- Purpose is to shift focus from responding to prevention
- Carved out some exemptions for brewers

# Why is food safety important for breweries?



**#2 Food safety best practices have positive impacts on the quality of your beer**

- » Get everyone on the same page
- » Repeatable results
- » Minimize risks
- » Make better beer!

# Why is food safety important for breweries?

**#3 More retailers are requiring an annual GMP audit from their suppliers**



*“All facilities that manufacture consumable products for or supply consumable products to Costco are required to have an annual food safety (GMP) or GFSI certification audit.”*



# Exemptions

- In most cases, not required to perform Hazard Analysis or develop Risk-based Preventative Controls, except when...
  1. “Processing” spent grain (drying, pelletizing, etc.)
  2. Non-alc. soda production >5% of gross income
- Retail Food Establishments: businesses where at least 51% of gross income originates from sales direct to consumers vs. other businesses are exempt from registration and full FSMA compliance but not from GMP, training, and records requirements.
- Not required to develop and maintain a Supply Chain or Foreign Supplier Verification Program



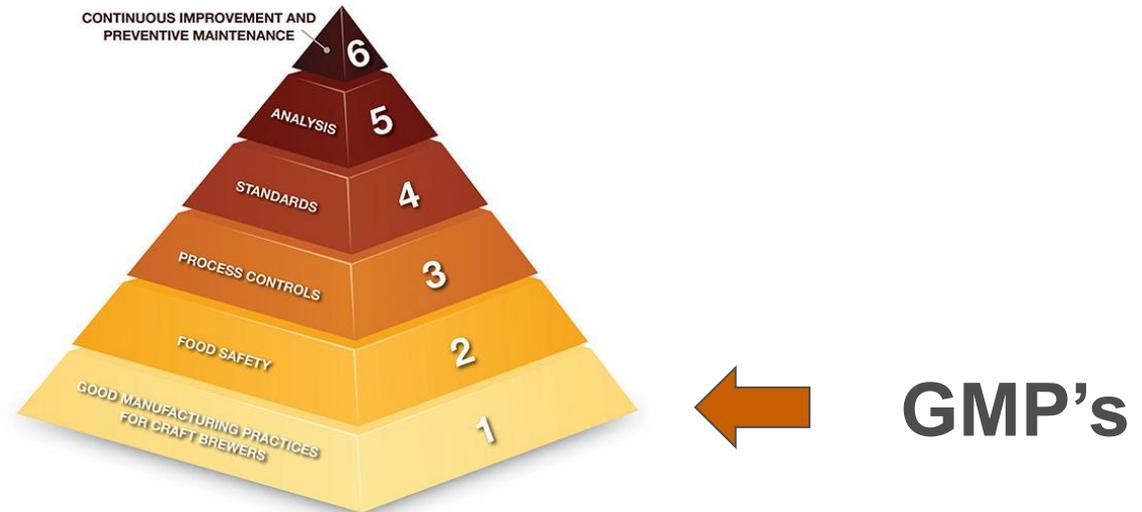
# Requirements

- Registration of food facilities with FDA + biennial renewal
- Implement Good Manufacturing Practices (GMPs)
  1. Good Manufacturing Practices for Craft Brewers (BA)
  2. Good Brewing Practices (MBAA)
- Provide adequate training for front-line staff
- Maintain relevant records



# Food Safety Requirement: GMPs

- Foundation for any brewery's quality assurance program.



- Establish clear guidelines for the hygiene and cleanliness of workers and their workplace.
- Dramatically decrease the food safety risk for the brewery's customers



# Food Safety Requirement: GMPs

## **1. Personnel**

*Illness, Cleanliness, Clothing, Hand washing, Jewelry, Hair restraint, Food consumption*

## **2. Brewery and Grounds**

*Building materials, Equipment storage, Lighting, Water drainage, Pest management*

## **3. Sanitary Operations**

*Building maintenance, Chemical storage, Sanitary surfaces*

## **4. Sanitary Facilities and Controls**

*Water supply, Plumbing, Floor drainage, Hand-washing facilities*

## **5. Equipment and Utensils**

*Food-safe equipment surfaces, lubricants, and compressed air; Instrument maintenance*

## **6. Production and Process Controls**

*Raw material inspection and handling, Allergen management, Temperature controls*

# Food Safety Requirement: GMPs

## Good Manufacturing Practices (GMPs)

Describe how  
to perform  
tasks

SOPs  
SSOPs  
Protocols

Data  
collection  
docs

Logbooks  
Batch  
Logs  
Maint.  
Records

Traceability  
system

SOP#  
Form #  
Batch #  
Yeast #  
Lot #

Compiled  
data files

Equip.  
History  
Product  
Specs  
Training  
Records



# Food Safety Requirement: GMPs

## Assessing Food Safety Risk in a Brewery

- BA GMP Checklists
- Identify gaps
- Target future efforts

No	Sub	Inspection Criteria	Yes	No
10		Are all brewery utensils and equipment constructed of adequately cleanable materials and suitable for their intended uses?		
	a	Are there no wooden or soft metal utensils?		
	b	Are connections between process vessels and utilities supplies well insulated and sealed with cleanable jacketing?		
		<b>Best Practice</b> - All process vessel construction uses appropriate stainless steel alloys (no plastic fermenters!)		
11		Is the equipment designed and used in a manner that precludes contamination with lubricants, contaminated water, metal fragments, etc.?		
	a	Are grease and oil seals in good condition?		
	b	Are wearable bushings or other metal-to-metal contact surfaces in good condition?		
	c	Are shutoff valves free from leaks?		
		<b>Best Practice</b> - Visually inspect oil seals on a regular basis.		
		<b>Best Practice</b> - Replace leaky hose bibbs to prevent mold growth.		
12		Is the equipment installed and maintained so as to facilitate the cleaning of equipment and adjacent areas?		
	a	Is there a minimum of 18" between vessels, equipment, and walls?		
	b	Is there adequate clearance underneath process vessels to reach the floor and vessel underside with cleaning tools?		
	c	Are motors, solenoid valves, and other electrical components washdown rated?		
		<b>Best Practice</b> - Ensure that electrical power is safely installed to withstand overspray from cleaning of brewing equipment and vessels.		



# Food Safety Requirement: GMPs

## Low-Hanging Fruit

- Food in the Brewery
- Hair/Beard Nets
- Wooden Utensils
- Cell Phones/Ear Buds
- Pets



# Food Safety Requirement: GMPs

## Low-Hanging Fruit

- Use food grade lubricants
- Remove glass from brewery
- Keep external doors closed
- Label & segregate spent grain containers

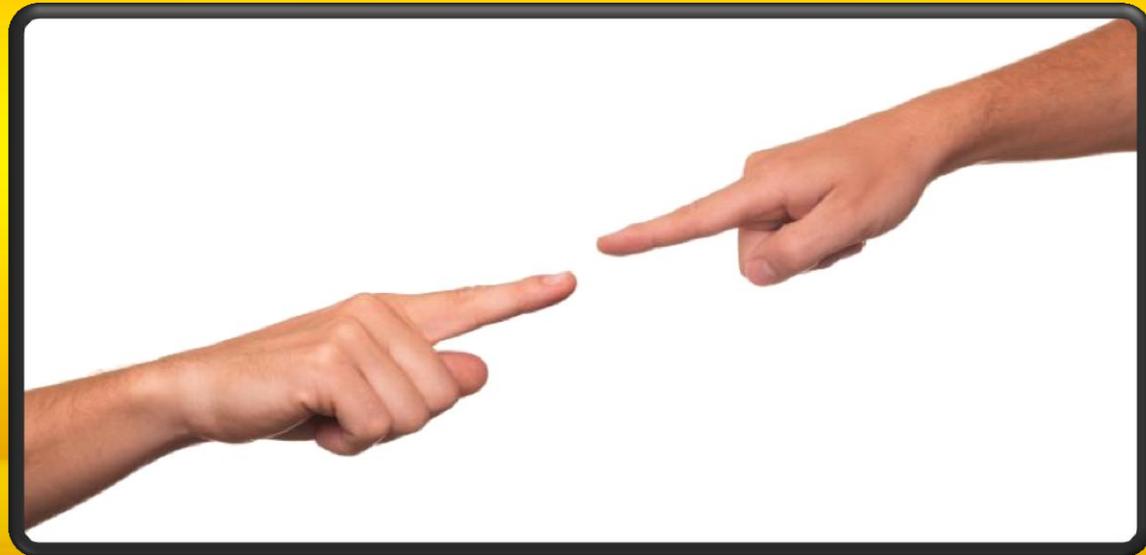


# What's in a food safety plan?

## Who is responsible?

– *Designated individual*

1. *Familiar with all facets of operation*
2. *Knows food safety*
3. *Aware of exemptions*



# What's in a food safety plan?

## Description of business

- *Food facility registration*
- *Brewers notice*
- *Business license*
- *Hours of operation*
- *List of products*
- *List of ingredients*
- *List of customers*
- *Examples of labels*
- *Overview of process*

## OPENING HOURS

MONDAY	9.00 - 5.30
TUESDAY	9.00 - 5.30
WEDNESDAY	9.00 - 5.30
THURSDAY	9.00 - 5.30
FRIDAY	9.00 - 5.30
SATURDAY	9.00 - 12.00
SUNDAY	CLOSED



# What's in a food safety plan?



## Who must be trained?

- *“Qualified Individual” is a person who has the training, education, or combination of those needed to manufacture, process or hold food.*
- *Not everyone has to be qualified to do everything, but individuals have to be qualified when it comes to doing their job as it pertains to food safety.*
- *There is a regulatory requirement that the business provide individuals adequate training in food safety, hygiene, and the specific duties of their job. They also must generate and maintain documentation to support that they did this.*



# What's in a food safety plan?

## How do you identify + control hazards?



Hazards	Controls
CIP	titration
Rinse water pH	pH meter or strips
Glass, plastic, rubber	-Screens -Glass breakage SOP -Replacement schedule
Light bulbs	Containment tubes
Metal	Magnets

# What's in a food safety plan?

## Brewery Process Flow



# What's in a food safety plan?



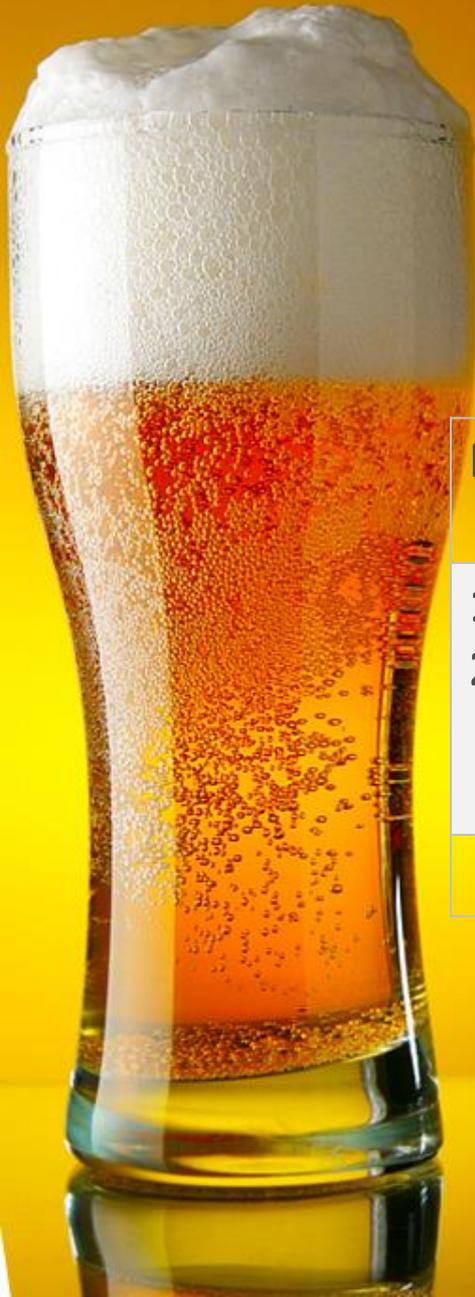
Name of Company	Title of SOP
STANDARD OPERATING PROCEDURE FOR DEPT:	Brewing 02-Cellar
Issue Date: 9/30/2016	Supersedes: 9/4/2015
Plant: Production Brewery	Document # 02-001
<b>Purpose:</b> To ensure...	<b>Safety Equipment:</b> Gloves, safety glasses, boots, hearing protection, etc.
<b>Items Needed:</b> Equipment such as brew hose, clamps, chemicals, etc.	<b>Notes:</b> List any important considerations or hints. May also list reference material to further explain certain items.
<u>Title of Procedure</u>	
1.Step 1 1.Sub steps for clarification	
2.Step 2 1.Sub Steps for clarification Page 1 of 1 (Footer)	

# What's in a food safety plan?

## Record of SOP Changes

- Provides a history of why changes were made

Date	Change made by	Approved by	Description of Change and Why
1/26/2019	Head Brewer	Head Brewer, Quality Manager	Updated to show new procedure due to brew house modification.



# What's in a food safety plan?

## Your Responsibilities During a Recall

In the event of a recall, the recall coordinator and their team will complete the following:

- Phone the local State Food and Drug Administration local recall coordinator (425-302-0467) ([orasearecalls@fda.hhs.gov](mailto:orasearecalls@fda.hhs.gov)) and let them know we must recall the products involved:
- Identity of product(s)
- Lot number(s) or date code(s)
- Other information that may help identify the affected product(s)
- Information on where the product was shipped or sold attached (list of distributors)
- Number of cases that were in the affected batch



# What's in a food safety plan?

## Recall Responsibilities Continued...

- Number of cases we have in our control (inventory)
- If advised to do so by the FDA, we will log the event on the FDA Reportable Food Registry.
- Take steps to separate and quarantine any of the affected product that is still in our control.
- Contact all distributors on list affected (sales or VP liaison).
- Contact the FDA if product entered interstate commerce.
- All phone, in-person, and/or e-mail contacts involved will be logged below
- Notes: additional info about recall
- Signature of recall coordinator



# What to expect and how to be prepared for an inspection?

- **Recommendations on how to treat your inspector**
  - Be welcoming!
  - Provide a tour
  - Give them your quality manual, copies of cleaning SOP's, and logs showing how you track activities



# Case Study of Inspection

## – Brief story of an actual inspection

- Inspector showed up unannounced
  - Request and verify credentials (WSDA or FDA)
  - They should produce form 482 (*Notice of Inspection*)
  - Find a quiet place for them to set up shop
  - Locate designated brewery food safety staff person
    - Have a back up!





## Case Study of Inspection

- **Brief story of an actual inspection**

- Inspector asked or requested:

- Tour of the facility followed by a meeting to fill out questionnaire. (FDA inspection form 2966)
- Can you provide copies of standard operating procedures of how you clean? Brew house, fermenters, bright tanks.
- SOP's backed up with CIP logs showing dates, chems, signed off by operator (archive logs for 2 years)
- Please provide a flowchart of your process. Include times and temperatures. Hint: PowerPoint works well for this (Example on Slide 19 "Brewery Process Flow")

# Case Study of Inspection

- **Brief story of an actual inspection**

- Inspector asked or requested:

- Where do you distribute?

- » Provide approximate percentage of product that goes to:

- » Each county in WA

- » Which states outside of WA





## Case Study of Inspection

### – Brief story of an actual inspection

- Inspector asked or requested:

- Do I smell root beer?

- » Separate inspection for non-alcoholic products.

- » Inspector will want to observe product being produced.

- » Will schedule to come back, if needed.

- » Wear appropriate food safety equipment:

- » Beard and hair nets

- » Gloves

- » Safety glasses

- » Should have a WA Food Processors license.

- » Shut the...bathroom door!

# Non-Traditional Processes or Ingredients



## Formula Approval Required for

- *Any fermented product to which flavors or other non-beverage ingredients (other than hop extract) containing alcohol will be added.*
- *Any fermented product to which coloring or natural or artificial flavors will be added.*
- *Any fermented product to which fruit, fruit juice, fruit concentrate, herbs, spices, honey, maple syrup, or other food materials will be added.*
- *Any fermented beverage using ingredients not on the exempted list (aka TTB Ruling 2015–1; Attachment 1)*

# Non-Traditional Processes or Ingredients



- *TTB's approval of the use of certain ingredients without submission of a formula does not exempt industry members from their obligation to ensure the safe use of these ingredients.*
- *It has always been, and it will remain, the responsibility of the industry member to use good commercial practices to ensure that the ingredients and production process result in the production of wholesome products suitable for human food consumption and that the ingredients and finished products comply with all applicable regulations of the FDA regarding ingredient safety.*

# Non-Traditional Processes or Ingredients

## Formula Approval...BEFORE beer is brewed

- *You may not produce a fermented product for which a formula is required until you have filed and received approval of a formula for that product.*

27 CFR § 25.55 *Formulas for Fermented Products*

- *A brewer may submit a request that TTB exempt from the formula requirement a particular coloring, flavoring, or food material for use in the production of beer.*



# Non-Traditional Processes or Ingredients

## Formula Approval & BARRELS

- The process of aging beer in barrels (or with woodchips, staves, or spirals from barrels) that were previously used in the production or storage of wine or distilled spirits is a traditional process and thus will no longer require a formula.
- This exemption from the formula requirement does not apply to the use of woodchips that have been soaked or infused with distilled spirits or wine for the sole purpose of use in the production of beer.
- Brewers must ensure that the use of barrels, woodchips, and part of barrels that were previously used in the production or storage of wine or distilled spirits will not add any discernible quantity of wine or distilled spirits to the beer



# Non-Traditional Processes or Ingredients

## Formula Approval Links/Process

- [TTB Ruling](#) about what is Beer vs Malt Beverage
- [List](#) of Allowed Ingredients
- Ingredients *Generally Recognized as Safe* = [GRAS](#)
- TTB Formula Approval [Resource](#)
- Formulas Online [Customer Page](#)
- [Processing Times](#) for Beverage Alcohol Formulas



# Food Safety Resources for Breweries

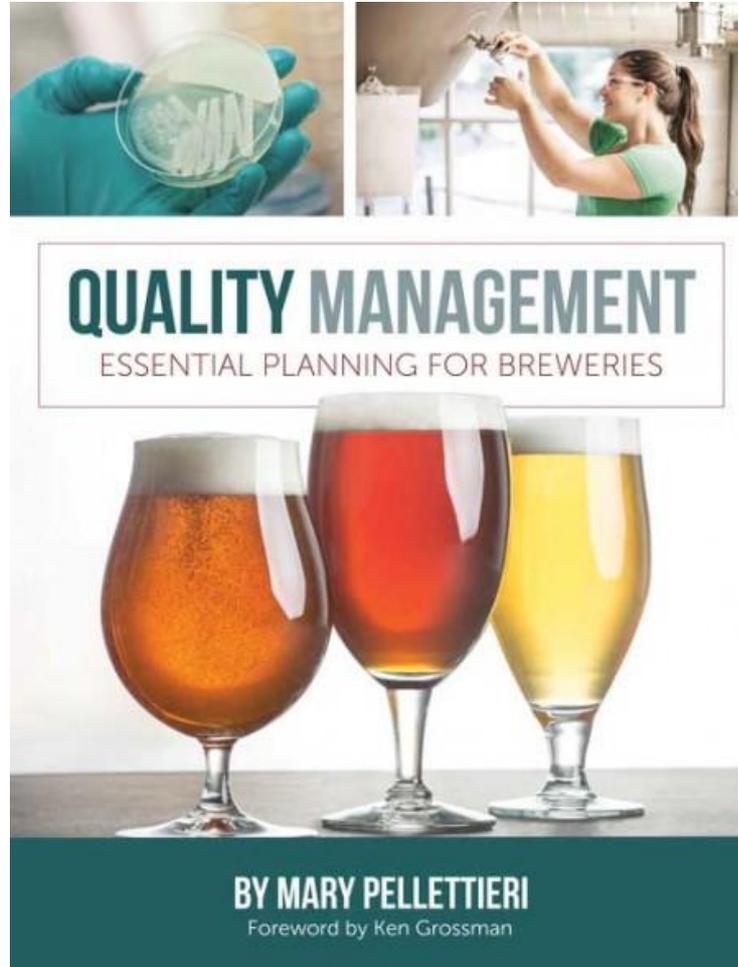
## – Brewers Association

- [Food Safety Plan & Hazard Templates](#)
- [Good Manufacturing Practices for Craft Brewers](#)
- [FSMA FAQs for Brewers](#)
- [Podcast: The FDA's Involvement in the Brewing Industry](#)
- Forthcoming comprehensive Food Safety Guide for Brewers



# Food Safety Resources for Breweries

## – Brewers Association



# Food Safety Resources for Breweries

## – Washington State University – Preventative Controls for Human Foods course

- *HINT: Some courses are subsidized, inquire about availability*
- [FSPCA PC Course Participant Manual](#)
- [Food Safety Plan Worksheets](#)
- [FSPCA Technical Assistance Network](#)





# Food Safety Resources for Breweries

## – Master Brewers Association

- [Food Safety Modernization Act: Insights for Breweries](#)
- [Why Should Breweries Be Concerned About Food Safety?](#)
- [Food Safety Decision Guide for the Brewing Industry](#)
- [Introduction to Good Brewing Practices](#)
- [Podcast: FSMA](#)



# THANKS!

## Questions?

Our  
Contact  
Information

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