



Planning for the Food Safety and Management Act in Breweries

MBAA District Philadelphia

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At the end of this session you will



- Understand the basic bones of the new law
- Understand how the law affects brewers
- Understand how your brewery should prepare

- This presentation is NOT FSMA official training
- This presentation is NOT lawful advice, nor can I predict what your local regulators may ask.

Food Safety Modernization Act



- What is it
 - Sweeping new food safety regulation, first in 70 years
 - Signed into law 2011, Final Rule September 2015.
- Why it came to action
 - FDA thought there was too much risk still in food supply, HACCP was not required at all plants
 - Globalization
 - FDA needed to establish more regulatory authority in recalls



Interesting Changes

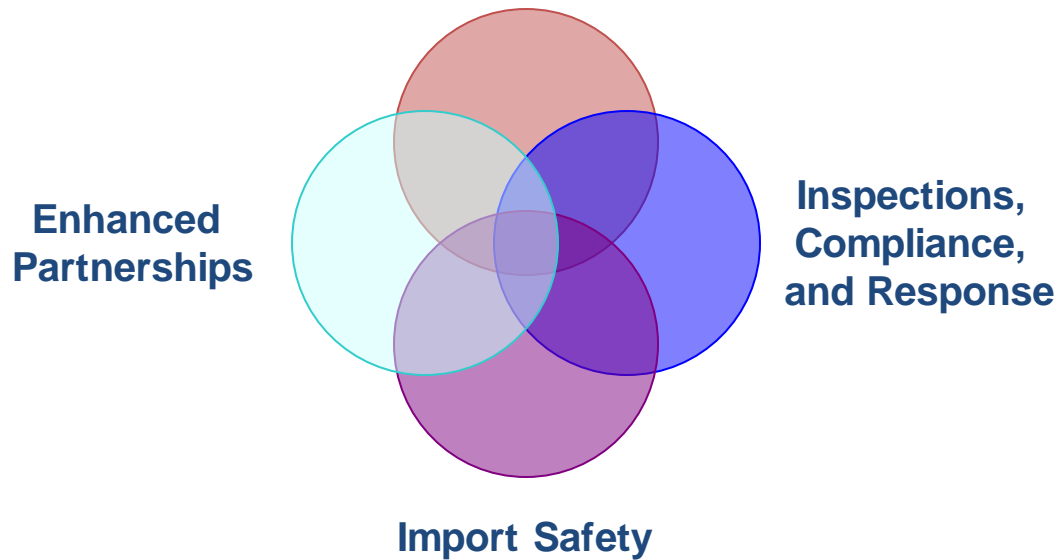


- Alcohol is defined as food
- Mandatory Prevention program (like HACCP) now for all food types (not just fruit juice, eggs, meat)
- FDA has more regulatory authority for recalls and closing plants down
- Mandatory inspections, testing and access to records
- Additional requirements for traceability
- GMPs explicit (no more “shall” instead used the word “must”)

Food⁶: Includes (1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article. Examples of food include fruits, vegetables, fish, dairy products, eggs, raw agricultural commodities used for food or as components of food, animal feed (including pet food), food and feed ingredients, food and feed additives, dietary supplements and dietary ingredients, infant formula, beverages (including alcoholic beverages and bottled water), live food animals, bakery goods, snack foods, candy, and canned foods. Does not include pesticides or food contact substances not intended to have any technical effect in the food.

Main Themes of the Legislation

Prevention



Major Components



- **Preventive Controls for Human Food** Final rule issued: Sept. 10, 2015.
- **Preventive Controls for Animal Food:** Establishes Current Good Manufacturing Practices and preventive controls for food for animals. Original rule proposed October 2013; supplemental rule to add provisions geared specifically to animal foods proposed September 2014. Final rule issued: Sept. 10, 2015.
- **Produce Safety**
- **Foreign Supplier Verification Program**
- **Third Party Certification**
- **Sanitary Transportation**
- **Intentional Adulteration**

Food safety and Preventative Controls (PC) for Human Food



- Brewers are exempt from PC but not CGMPs
- Preventative Control program
- CGMPs
- Supply Chain
- Allergen Control
- Sanitation Control
- Records



Food Safety Plan

Includes procedures for monitoring, corrective action, and verification
Requires Formal Training

Hazard Analysis

Process Controls

Recall Plan and Records

Supply Chain Program

Allergen Control

Sanitation Control

GMPS and Other Pre-Requisite Programs

Exclusions – Beverage Alcohol



- No PCs – HOWEVER
 - If you have Non alcoholic beer, Gluten Free or Reduced Beer, it is highly recommended to follow this part of the law.
 - Allergen Control is part of GMPs, but depending on the risk, a full PC plan may be needed.
 - If you make soft drinks, you must have PC in place
 - This does not EXCLUDE breweries from GMP requirements

Subpart G - cGMPs

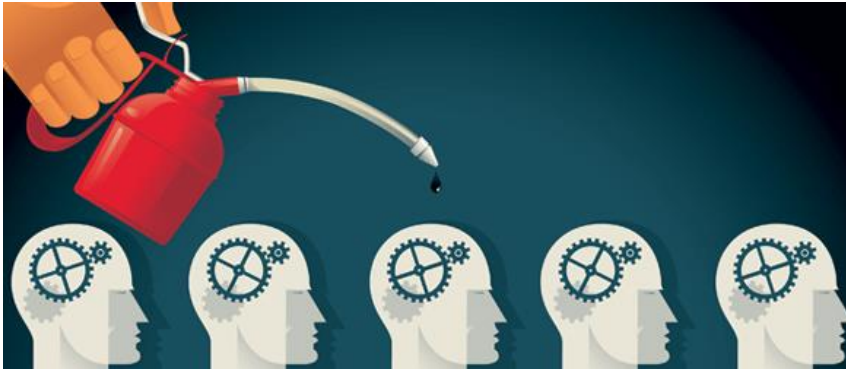


- No longer debate if breweries must comply with this portion of FDA's rule – you must
- GMP components
 - Personnel and Plant Management
 - Allergen Controls
 - Sanitation Controls
 - Supplier Management

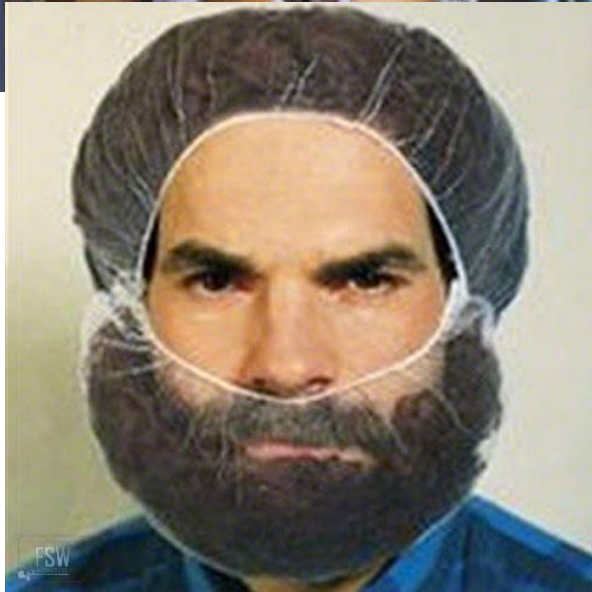
CGMP Training



- Employee training must be documented
- It must cover cleanliness, health requirements, and how to perform their job and how their work impacts food safety
- Supervisors must set a good example. They are responsible for ensuring compliance and must have appropriate knowledge, training or experience.



PERSONNEL



- Restricting personnel with illness or open wounds
- Proper handwashing
- No Jewelry
- Hair restraints where appropriate (and kept clean)
- No eating, drinking or tobacco use
- Adequate personal cleanliness, including clothing

Plant and Grounds



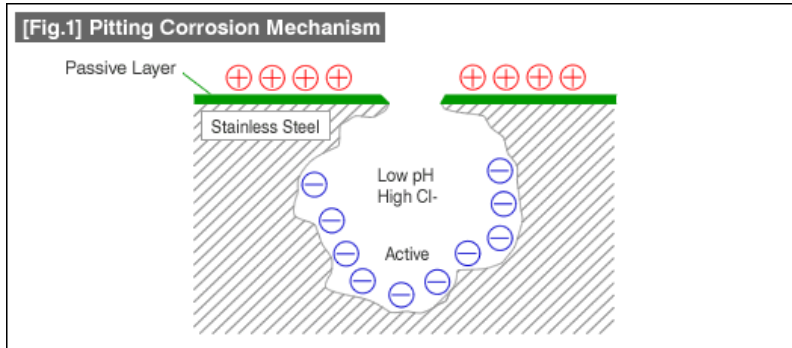
- Proper waste disposal
- Adequate lighting and space
- Guard against glass breakage
- Cleanable walls and floors
- Prevention of drip or condensate from contaminating the product
- Screened openings
- Adequate ventilation

Sanitary Operations

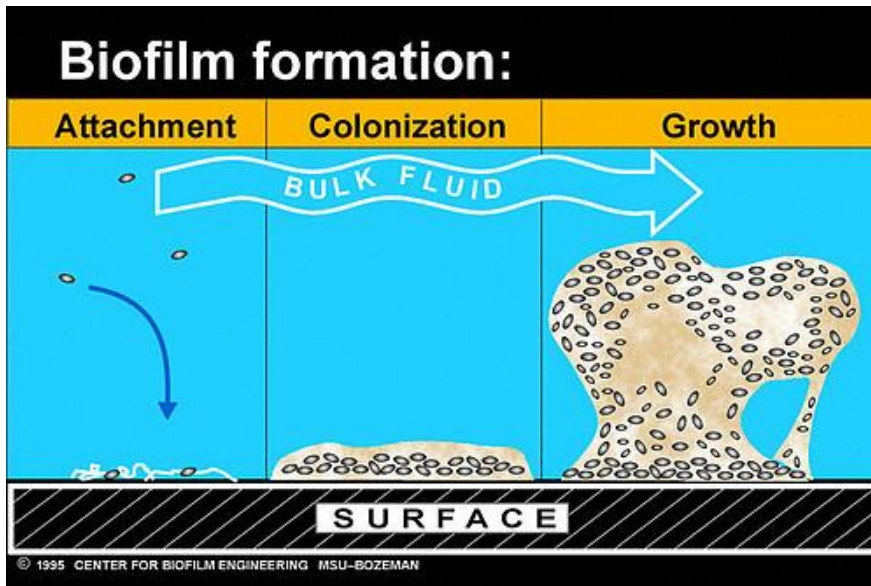


- Plant is maintained and cleanable
- CIPs not a source of contamination (test your chemicals)
- Toxic chemicals stored properly and identified
- Food grade lubes labelled
- Non food surfaces kept sanitary
- Pest control safe and effective

Conditions of Food Contact Surfaces



- Must be cleanable
- CIPs as necessary to protect against allergen cross contact or cross contamination
- Potentially hazardous situations that MAY require a Food Safety Plan include Allergen Cross Contact



SSOPs



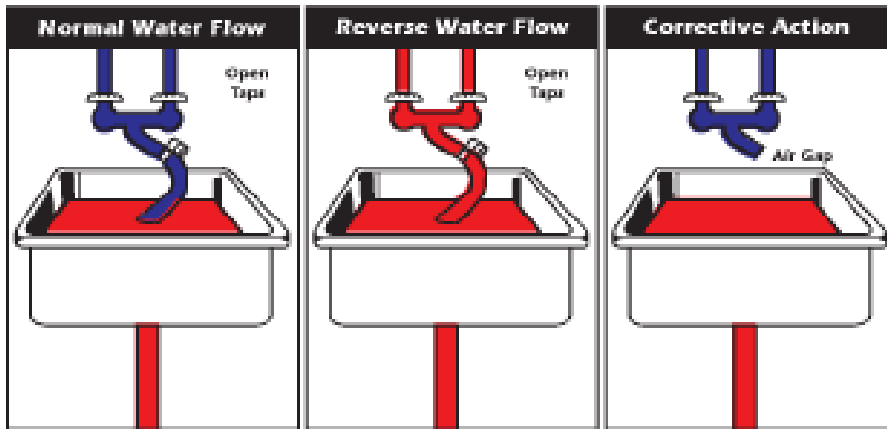
- Identify:
 - Purpose
 - Frequency
 - Who
 - Procedure
 - Monitoring
 - Corrections
 - Verification
 - Records
 - Other special conditions
- Standard Sanitation Operation Procedures (SSOPs) should be in place for critical equipment
 - CIPs
 - Packaging Hall equipment and environment
 - Spent grain handling
- Take note of allergens, alcohol cross contamination situations.
- Other standards (such as sweeping the floors) can be part of GMPs , and not detailed in SSOP.

MSS



- Master Sanitation Schedule details;
 - What is cleaned
 - What frequency
 - By who
- Includes all environment
 - Floors
 - Overheads
 - Fans
 - EVERYTHING
- DO NOT NEED SSOP for every task
- Look at this list as a living document
- Add PMs to the list as they go hand in hand

Equipment and Water Supplies



- Corrosion resistant nontoxic food contact surfaces
- Compress gases properly filtered
- Maintain accurate process control of instruments (including temperature controls)
- Water supplies must be validated as Potable, checked against cross connections and tested

Other Areas



- Areas that the GMPs can cover under sanitary control, raw materials/supplier handling, process controls include;
 - Alcohol adulterations of barrel aged beers
 - Low alcohol beers/High Alcohol Beers
 - Fruit and all additions must be GRAS (no cherry pits for example)
 - Defect Action Levels, Mold
 - Processing aids handling and downstream filtration
 - Glass, Glass, Glass – during process and when breakage is an issue
 - Alcohol labeling – how it is done, how it is verified
 - Fill checks
 - Organic brewing
 - Gluten reduced beers – allergen control
 - Hold and release procedures
 - FIFO/Raw materials traceability

Supplier Management Purchasing and Manufacturing Specifications



- Write Purchasing Specifications for all raw materials
- Especially –
 - Glass defect action levels (<1 breakage / 100,000 btls)
 - Aflatoxin levels in malt
 - Pesticide residues in hops
 - If gluten free or gluten reduces, written requirements for suppliers

Human Foods or By Products sent to Animal Food



- Spent grain handling must comply with GMPs during holding and distribution
 - Ensure safety of containers
 - Avoid garbage
 - Identify material through labeling
- Must comply with PCs for animal food if being further processed (pizza dough etc)

Animal Food Component of Law (Spent Grain)



Though breweries are exempt from full PC portion, CGMPs must be in place

- Employees must be trained
- Management must be trained
- Bulk tanks must be sanitary
- Cleanable
- Waste must be controlled (no garbage)
- Toxic chemicals must be controlled
- Pests must be controlled (screens etc)
- Spent grain must be labelled for transport
- “Deterioration”

Recall Program



- Any large brewer should have a recall program in place specifically for glass issues
 - Written procedures to notify public and protect public health
 - Mock traceability audit
 - Appropriately dispose of the food

How your brewery should prepare



- Assign 1 person as point for cGMP compliance (Subject Expert)
 - Download lists from BA and other sources.
 - Get training on c GMPs if needed (note this is not as scripted as the “qualified individual” requirement for PCs, but is highly recommended FORMAL outside training is taken).
 - Audit current state.
 - Make a punch list of critical areas to address and timeline
 - Alter policy
 - Train on policy by a specific date
- Management
 - Make a commitment to the plant you will lead by example to change culture around GMPs
 - Implement policy as recommended by the Subject Expert
 - Follow-up with policy (audit frequently, add non-compliance events to employee records, support team if they comply fully with a party etc)

Dates to be aware of and Final Thoughts



- Very Small Business
 <\$2M
 9/18/18 – PC for Human Food
 9/18/19 – PC for Animal Food
- Small Business < 500
 Employees
 9/18/17 – PC for Human Food
 9/18/18 – PC for Animal Food
- Brewers are expected to comply with cGMPs for both beer and spent grain handling.
- Do your due diligence on your hazard potential (allergens, glass etc), and don't be afraid to implement a full Preventative Control plan, it will make you a better brewery.
- Start policy now, add to it as you grow

Resources



- www.fda.gov/Food/GuidanceRegulation/FSMA/
- www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM071343.pdf www.gpo.gov/fdsys/pkg/CFR-2011-title21-vol2/pdf/CFR-2011-title21-vol2-part110.pdf
- www.mbaa.com/brewresources/foodsafety/Pages/default.aspx
- <https://www.brewersassociation.org/educational-publications/good-manufacturing-practices-for-craft-brewers/>
- <https://www.ifsh.iit.edu/fspca/fspca-preventive-controls-human-food>