The ABCs of the FSMA: The Food Safety Modernization Act and Wineries

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Background

- M.S. and Ph.D in industry microbiology
- Designed and implemented QA/QC program for a brewery
- Performs sanitation reviews for wineries and offers custom troubleshooting for sanitation issues

Outline

- Overview of FSMA
- FSMA and Wineries
- FDA Inspections
- Good Manufacturing Practices (GMPs)
- Implementing GMPs in the Winery
- HACCP and HACCP-like programs
- Sanitation Reviews
- Questions

What is the FSMA

- Food Safety Modernization Act - Signed into law Jan 4th, 2011
- Key Authorities and Mandates:
  - Prevention
  - Inspection and Compliance
  - Response
  - Imports
  - Enhanced Partnerships

Prevention

- Mandatory Preventative Controls for Food Facilities
  - This applies to all facilities required to register
    - Alcoholic beverage production is exempt from some of the requirements
- Mandatory Produce Safety Standards
  - Applies to growing, harvesting, packing, and holding of produce
    - Produce that will undergo further processing is exempt
- Authority to prevent intentional contamination

Prevention cont…

- Changes are made to cGMPs (current good manufacturing practices)
  - These changes apply to alcoholic beverage production
- Food safety plans are required
  - HACCP and HACCP-like plans
  - Alcoholic beverage production is exempt

Inspection and Compliance

- FSMA established a mandated inspection frequency.
  - All food facilities must be inspected by 2018.
- FDA will be provided access to all records for a facility including there food safety plans. Documentation of how these plans are implemented is also necessary.
- Certain types of food testing will need to carried out by accredited laboratories.

Response

- The FDA will have the authority to perform mandatory recalls on products that they consider unsafe and fail to be voluntarily recalled by a company.
- The FSMA allows the FDA to perform administrative detention. This is the procedure FDA uses to keep suspect food from being moved.
- The FDA can suspend registration of a facility if it determines that the food poses a reasonable probability of serious adverse health consequences or death.
- The FDA is charged with developing a program to better trace the distribution of food products.
- High risk food producers will have additional recordkeeping requirements.

Imports

This provides the FDA the authority to ensure that imported products meet U.S. standards and are safe for U.S. consumers through:

- Importer accountability
- Third party certification
- Certification for high risk foods
- Voluntary qualified importer program
- Authority to deny entry

Enhanced Partnerships

- The FDA in required to develop strategies to enhance food safety and defense capacities of State and local agencies.
- The FDA must provide a plan for foreign governments and their industries to be trained in US food safety requirements.
- The FDA will rely heavily on inspections of other Federal, State and local agencies to meet its increased inspection mandate for domestic facilities.

FSMA and Wineries

- Winery Requirements:
  - Wineries are exempt from the majority of the law (if they are required to have a permit or register with the Department of Treasury as per the Federal Alcohol Administration Act and are also required to register with FDA).
    - Registration of facility (this has been a requirement since the Bioterrorism act of 2002)
    - Mandatory recalls and administrative detention
    - Import controls
    - Inspections Authority

FDA Registration

- Required for facilities engaged in:
  - Manufacturing/Processing
  - Packing
  - Holding
- Renewal required every 2 yrs.
- Registrations is required for:
  - Wine making operations
  - Wine bottling operations
  - Truck-mounted bottlers

FDA Inspections

- Key things to remember
  - Wineries are consider food plants and therefore they must register with the FDA
  - Wine is an “acid food”
  - Food plants must follow current Good Manufacturing Practices (GMPs)
  - Record keeping is expected

Good Manufacturing Practices

GMP refers to a set of guidelines for practices and processes required for the safe manufacture of any product.

- Inspection Criteria:
  - Personnel
  - Plants and Grounds
  - Equipment and Utensils
  - Sanitary Facilities and Controls
  - Sanitary Operations
  - Processes and Controls

Personnel

- All employees should maintain good personal hygiene and training should be provided
- Personnel should have the necessary training and experience to perform their assigned functions (i.e. from vineyards through production, bottling, warehousing, and distribution)

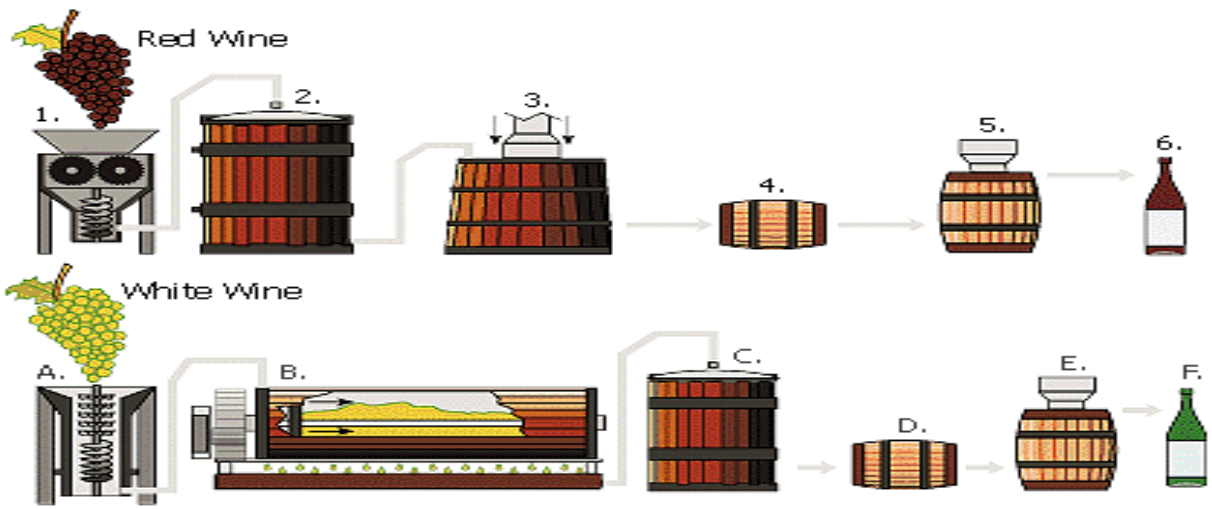


Image courtesy of:
www.theworldwidewine.com/Wine_trivia/How_wine_production.php

Personnel

- Personnel should wear clean uniforms and protective equipment were necessary
- Avoid wearing anything that could easily fall into production materials or loose fitting clothes that could get caught in the equipment

Body Part	Type of PPE	Uses
Eyes	Safety glasses, goggles, and face shields	General eye protection and working with chemicals that my splash
Ear	Hearing protection	Around machinery in the winery or vineyard and on the bottling line
Hands	Gloves (dependent on the use)	Work Gloves – working in storage areas, handling garbage, or landscaping. Chemical-resistant gloves – handling and working with chemicals Cut-resistant gloves – vineyard work and handling broken glass
Feet	Non-slip footwear (rubber boots)	Working in and around tanks
Body	Seat belts	In vehicles (including tractors and fork lifts)

Personnel

- All health and safety procedures should be followed
- Personnel are responsible for the cleanliness of their work space
- Personnel should be free of of cuts/open wounds and infections
  - Medical dressings should be secure.
- All contractors should be aware of onsite policy and procedures

Plants and Grounds

- Grounds and premises need to be free of debris and potential breeding places for pests
- Ground should have adequate drainage to prevent areas of standing water.
- Sufficient storage space for equipment and materials
- Floors, walls, and ceilings easy to clean and in good repair
- Processing areas are separate from other area of production
- Air quality is sufficient enough to prevent contamination by dust
- Plant takes precautions to prevent pest infestations

Picture courtesy of : andamansaravanan.blogspot.com/2010/09/madhavaram-poor-drainage-system-puts.html

Equipment and Utensils

- Equipment should be in good condition and easy to clean
- Equipment designed to prevent contamination by lubricants, metal fragments, etc…
- The equipment is placed to allow all areas of the plant to be cleaned

Sanitary Facilities and Controls

- Water supply needs to be adequate in both quantity and quality
- Water temperature and pressure must be at suitable levels for its intended use

Sanitary Facilities and Controls

- Sewage disposal systems must be adequate
- Plumbing systems must be designed to prevent contamination
- Toilets must be provided and maintained
- Hand washing and sanitizing facility must be provided were appropriate
- Garbage must be stored properly

Sanitary Operations

- The facility must be kept clean and in good physical repair
  - General Maintenance
  - Sanitation Plans
- Cleaning of the facilities and equipment must be conducted in such a manner to avoid contamination of products

Sanitation Operations

- A sanitation plan should be developed that includes methods for:
  - cleaning - removal of debris from surfaces
  - sanitation - reduction and control of unwanted microorganisms
  - sterilization-elimination of all microorganisms
- Sanitation plans should also include detailed methods for the procedures and chemicals used through out the winery
- If carried out properly a good sanitation plan can limit the build-up of organic debris that can allow microbial proliferation and reinfection of products

Sanitary Operations

- Cleaning supplies must be used in a safe and effective manner and proper documentation (MSDSs) must be on site

- Processing areas must be maintained free of insects, rodents, and other pests
- Equipment must be sanitized at intervals frequently enough to avoid contamination of products
  - Develop and cleaning and sanitation schedule to have on hand to show the inspectors

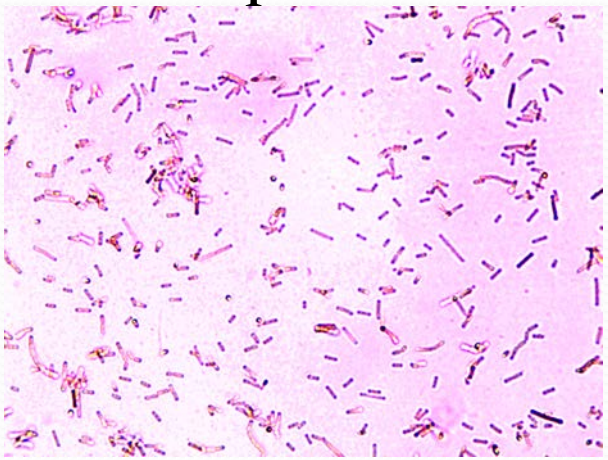
Process and Controls

- **The responsibility of overall plant sanitation should be specifically assigned to an individual (i.e. Winery Sanitarian)**
  - Winery Sanitarian
    - Should have a basic understanding of wine making process.
    - Should have some (formal) education and training in Food/Fruit processing plant sanitation. The knowledge could be acquired through an academic degree or various workshops and short courses.
    - Ability to detect existing and potential unsanitary conditions in the winery and have the necessary knowledge to correct the problem.
    - Ability to develop an applicable winery sanitation program and train other employees on the importance of such a plan
    - A basic knowledge of federal, state and local laws and regulations relating to the winery operation should understand the inspection process and be knowledgeable about implementing the recommendations following inspection.
    - Should possess a good aesthetic sense of environmental sanitation values as related to winery operation.
  - This person would be responsible for conducting in house inspections at appropriate time intervals. They should also make note of the current conditions and submitting issues with recommendations to management as well as coordinating with key personnel to address and correct problems

Modified from the Importance of Cleaning and Winery Sanitation (M. Dharmadhikari)

Process and Controls

- Processing should be conducted in a manner to prevent contamination and microbiological growth
- Testing procedures for chemical and microbial issues should be in place and used when necessary
- Laboratory methods should be adequate to ensure declared quantities



Process and Controls

- Raw materials and ingredients should be inspected and stored to ensure quality products
  - Identify raw materials used in production (i.e. grapes, juice, yeast, additives, etc…)
- Use only additives approved for food
- Packaging and process materials should prevent contamination
- Products should be properly coded and a record should be keep of their existence
- Labels need to be in compliance (TTB regulates this still for alcoholic beverages)
- Finished products need to be stored and shipped under conditions that prevent contamination or deterioration

How A Winery Can Adopt GMPs

- Train the employees and make sure they follow the wineries policies
- Develop a sanitation plan and follow it
  - Evaluate the effectiveness of your sanitation plan
- Keep good records!!!
  - Sanitation records
  - Source of raw materials
  - Final product recording (location/destination)

Summary – FSMA and GMPs

- Wineries as “food plants” must comply with the FSMA
- They are exempt from the majority of the regulations
  - They must register with the FDA, comply with inspections, can be subjected to mandatory recalls and administrative detention, and import controls
- GMPs are an important part of passing a FDA inspection
- GMPs can easily be adopted and implemented by wineries

HACCP-like programs in the Winery

- GMPs - bare minimum
  - Just requirements
  - No direction on how to achieve them
- HACCP programs provide the answers to:
  - Why cleaning and sanitation procedures are performed
  - Why each chemical or microbial analysis is performed
  - What role these test play in overall wine quality
  - When in the process you need certain results
  - What the specific range for each result is
  - What to do if the results are not within specifications

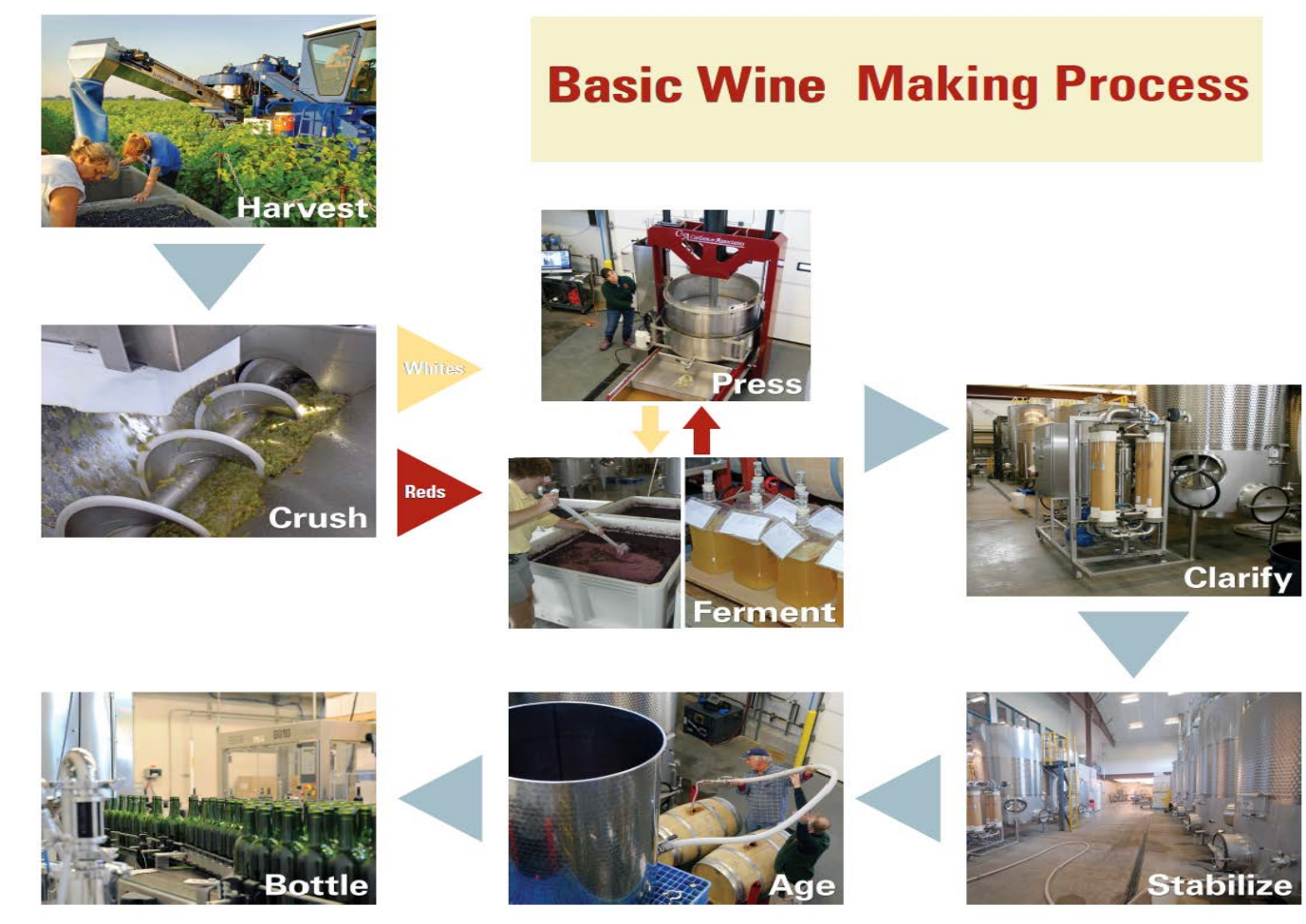
HACCP-like programs in the Winery

- As a producer your determine when, why and how wines should be evaluated by chemical, microbiological and sensory analysis.
- HACCP plans don't have to involve just sanitation.
- HACCP and HACCP-like systems are individual and based on your parameters.
- Wine "Quality" is how you – or your customer - define it.

HACCP-like programs in the Winery

- Seven Step Program
  - Step 1. Develop a flow diagram
  - Step 2. Identify critical control points
  - Step 3. Establish limits for your control points
  - Step 4. Develop monitoring procedures
  - Step 5. Establish corrective actions
  - Step 6. Verification and validation
  - Step 7. Record keeping

Develop a Flow Diagram



Identify Critical Control Points

- For each step in the flow chart, identify potential areas that may adversely impact quality – these are your critical control points (CCPs)
- The CCP's should be ranked by what quality factors must be controlled
  - Quality Factors
    - Physical (packaging materials or cork pieces bottled wine)
    - Microbiological (High VA, off flavors, and off-aromas)
- Establish protocol(s) for monitoring quality factor. These should be in the wineries SOPs

Establish Critical Limits

- Using the CCPs for your process identify how important these hazards are to quality of the wine and how controlled they should be
- A critical limit can be:
  - Process specs (i.e. temperature, agitation rates, etc.)
  - Measurements on a process or wine sample (VA, SO_2, alcohol, etc…)
  - Or a yes/no decision
  - For each analysis these factors need to be known:
    - Max. and Min. values
    - Acceptable values
    - Accuracy of the analysis.

Develop Monitoring Procedures

- Having a way to accurately test for items you measure
- For example, you are making sulfite free wine and require there to be less that 10 ppm SO_2 in the bottle. Are you capable of measuring that?
- It also needs to be established:
  - When, where, and by whom this will be monitored
  - Using your method can you verify the results, and if so how?

Establish Corrective Actions

- If there is a problem X the winery or winery personnel will take action Y.
  - Examples
    - Nitrogen level too low in juice. How and when will this be corrected?
    - VA is above the legal limit. How will this issue be handled?
    - Contamination is detected on the bottling line, what procedure will be used to clean it?
    - Bottle has a label misprint what corrective action will be taken?

Verification and Validation

- Procedures to ensure that control system is working and is effective
  - Record keeping with review
  - Use analysis methods different from monitoring methods (i.e. sugar by ^{o}Brix vs. enzymatic testing) or send samples to a 2nd party for analysis and conduct independent audits
  - Check in with staff to evaluate the program
  - Evaluate process and operations at CCPs

Record Keeping

- Be sure to establish documents for all procedures
  - Note potential hazards to the products or personnel
  - Record safety measures and corrective actions
  - Keep calibration records for instruments and know their specs.
  - Review these records

Summary- HACCP-Like Programs

- Analyze the production dangers to product quality, stylistic deviation, and /or worker safety
- HACCP-like programs provide the winery with a proactive method for identifying potential problems and what to do as a result
- Have an establish program like this allows you to deal with any compliance issues
- HACCP-like programs in the winery increase the probability of improving general wine quality

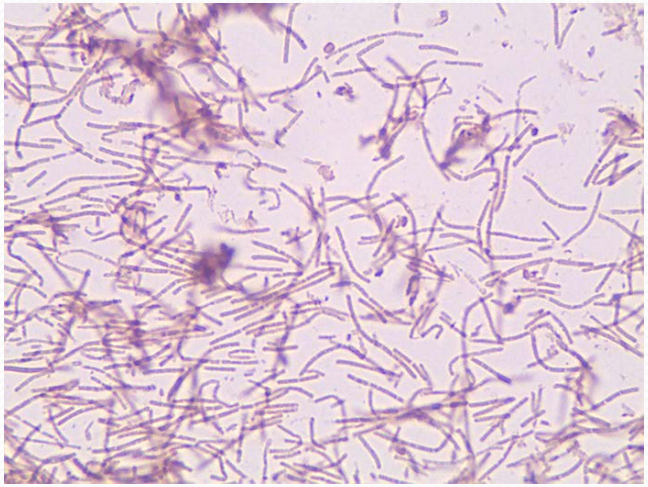
Sanitation Reviews at the MGWII

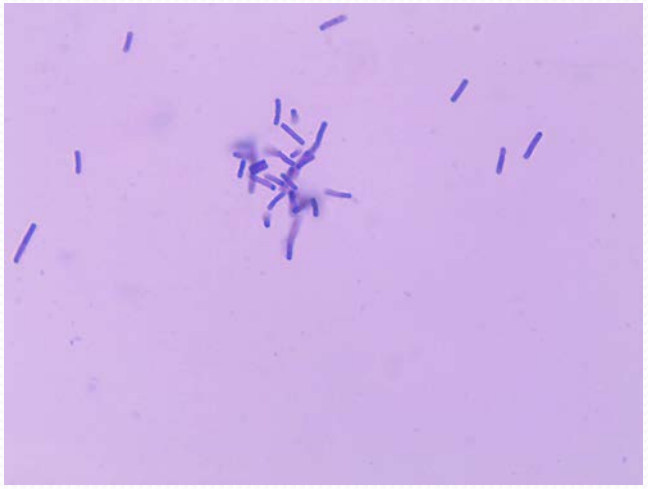
- Uses the FDA's "Food GMP Inspection Report" as a guideline for establishing areas to be tested
- The focus of the review is to evaluate the effectiveness of current winery sanitation practices
- A visual inspection of the grounds, production and cellar floors, equipment, and surfaces is conducted
- Microbial testing is conducted on identified control points
- Used both in HACCP and GMPs as validation methods

Sanitation Review Methods

- **Hygiene Testing**
  - Methods – ATP bioluminescence was used to test several surfaces that come in contact with the wine throughout the winery. These surfaces included fermentation tanks, valves, hoses, and the bottling line.
- **Microbial Swabbing and Plating**
  - Methods – Swabs (3M Quick Swabs) were taken from the surfaces and plated on selective media (3M petrifilms – Aerobic Count Plates and Yeast and Mold Plates). Differential media used for plating - Wallerstein Nutrient Media (WLN) and Wallerstein Differential Media (WLD).
- **Chemical Analysis of Wines**
  - Volatile acidity
  - Acetaldehyde
  - Off-aroma compounds

Common Winery Issues





Common Winery Issues

- Bottling line contamination
  - Cause: improper cleaning measures
  - Results: microbial instability in bottled wines
  - Corrective Action: Re-clean and sanitize the bottling line
  - Preventative Actions: Monitor the bottling line after cleaning (ATP-testing, swabbing, etc…)
- Fermenter Transfer Valve Contamination
  - Cause: Wine/juice build up on valve surface
  - Results: microbial contamination of wines
  - Corrective Action: Spray valves with alcohol thoroughly before and after use
  - Preventative Actions: Monitor fermentations/stored wine for contamination

Summary

- Winery's will have to comply with certain aspects of the FSMA
- As a result, they will be required to implement GMPs
- GMPs provide the bare minimum coverage, HACCP-like programs can both address compliance and potentially improve general wine quality
- Sanitation plans and testing there effectiveness through reviews can not only validate your processes but also identify areas of improvement

Questions