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Food Safety Solutions

A Guide to Food Safety Systems for Wineries as Required by FSMA

What is FSMA?

- Voluntary food safety practices are now laws under the **Food Safety Modernization Act**

- Seven Primary Rules:
  - Produce Safety Rule
  - Preventive Controls for Human Food
  - Preventive Controls for Animal Food
  - Foreign Supplier Verification Program
  - Accreditation of 3rd Party Auditors/Certifiers
  - Sanitary Transportation of Human and Animal Food
  - Prevention of Intentional Contamination/Adulteration

What is FSMA Preventive Controls About?

- Changes the FDA's focus from reactionary to preventive
- Requires companies to evaluate biological, chemical (including allergen) and physical hazards that could affect food safety in their:
  - Supply chain
  - Storage
  - Processing
- Companies must specify preventive steps and controls that will eliminate or minimize hazards and must maintain records of monitoring and corrective actions taken when problems occur
- Compliance dates based on company size:
  - Aug 30, 2016 if total employees > 500
  - Aug 30, 2017 if sales are greater than $1M
  - Aug 30, 2018 if sales < $1M (must apply for exemption)
  - Aug 30, 2019 if subject to PMO

The Law – 21 CFR Part 117

- Subpart A – General Provisions
  - Definitions
- Subpart B – Current Good Manufacturing Practices
  - cGMP
    - SSOP
    - SOP
- Subpart C – Hazard Analysis and Risk Based Preventive Controls
  - Exempt per 21 CFR 117.5 (i)(1)
  - Also exempt from Recall Plan per 21 CFR 117.139
- Subpart D – Modified Requirements
  - Not Applicable
- Subpart E – Withdrawal of a Qualified Facility Exemption
  - Not Applicable
- Subpart F – Record Keeping
- Subpart G – Supply Chain Program
  - Exempt per 21 CFR 117.5 (i)(1)

FSMA Operational Changes

- Requires all food related business to have Current Good Manufacturing Practices in place.
- Requires a formal written Food Safety Plan as defined in the law - Wineries are Exempt from this Requirement
- Requires evidence of science based mitigation for all identified Preventative Controls - Wineries are Exempt from this Requirement
- Mandatory record keeping for 24 months
- Mandatory FDA inspections
- Mandatory registration with the FDA – renewal every 2 years http://www.fda.gov/Food/GuidanceRegulation/FoodFacilityRegistration/default.htm

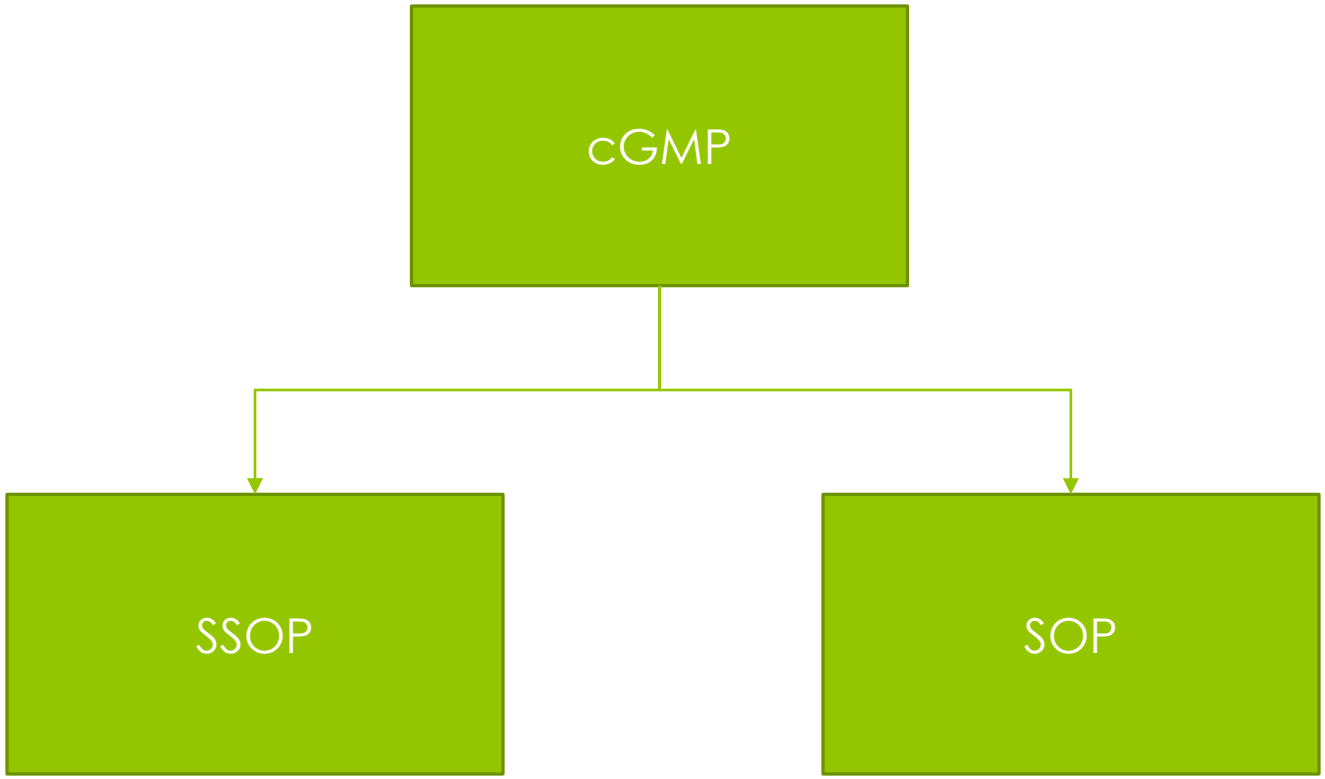
Important Changes for Wineries

- FDA now has authority to:
  - Recall "adulterated" food
  - Close a business making "adulterated" food
  - Bring criminal charges against operators of businesses making "adulterated" food
- 21 CFR 117.1 says "adulterated" food is:
  - Section 402(a)(3) - "food that has been manufactured under such conditions that it is unfit for food…"
  - Section 402 (a)(4)"food that has been prepared, packed or held under insanitary conditions whereby it may have been contaminated…"

FSMA Requirements for Wineries

1. Current Good Manufacturing Practices (cGMP) document is required
2. Sanitation Standard Operating Practices (SSOP) must be in place and properly documented
3. Standard Operating Practices (SOP) must be in place and properly documented
4. Record Keeping Systems must be in place and records must be held for 2 years after last lot shipped

FSMA Food Safety System for Wineries



current Good Manufacturing Practices

define your practices regarding:

- Personnel
- Plant and Grounds
- Sanitary Operations
- Sanitary Facilities
- Equipment and Utensils
- Processes and Controls
- Warehousing and Distribution
- Traceability and Recall Program
- Record Keeping

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Sanitation Standards Operating Practices

- Define how your company goes about meeting the sanitation points outlined in the Current Good Manufacturing Practices (cGMP)
  - What are your systems
  - How do you monitor your systems

SSOP Examples:

- Testing for safe water
- Preventing cross contamination
- Employee hygiene and health
- Cleaning food contact surfaces
- Pest management
- Preventing product adulteration
- Management of toxic compounds in plant

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Standard Operating Practices

- Define how your company goes about meeting the operational points outlined in the Good Manufacturing Practices (GMP)
  - What are your systems
  - How do you monitor your systems

SOP Examples:

- Employee hiring procedures and screening
- Vendor screening and acceptance process
- Manufacturing processes
- Shipping and receiving procedures

Implementation Procedures

- What is being monitored
- How is it being done
- When is it being monitored
- Who is doing the monitoring
- Where is it being recorded

- Who is the auditor and how frequently is the system being audited

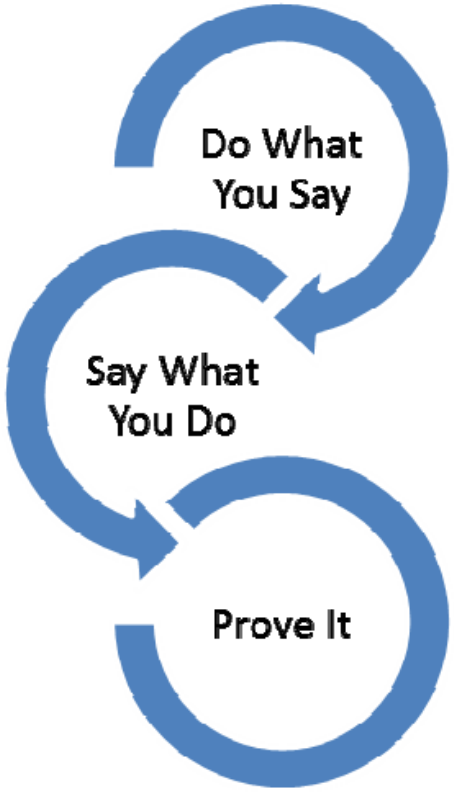
Example:
Bottling Table Sanitization

- WHAT – Bottling table is being cleaned and sanitized
- HOW - Per the standards defined in the SSOP
- WHEN – Occurs at the end of each shift
- WHO – Production employee performs the task
- WHERE RECORDED – A cleaning log is used to record the cleaning

- AUDIT CONTROL – Operations manager reviews cleaning and log a verifies SSOP is being met

Food Safety System for Wineries

- Current Good Manufacturing Practices (cGMP)
- Sanitation Standard Operating Practices (SSOP)
- Standard Operating Practices (SOP)
- Implementation Records



Questions?

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