**OVERVIEW**

**Food Safety Modernization Act (FSMA)**

About48 million people (1 in 6 Americans) get sick, 128,000 are hospitalized, and 3,000 die each year from foodborne diseases, according to recent data from the Centers for Disease Control and Prevention. This is a significant public health burden that is largely preventable. FSMA aims to ensure the U.S. food supply is safe by shifting the focus from responding to contamination to preventing it.

If you manufacture your products you are required to file for a State Manufacturers License, register with the Food and Drug Administration (FDA) and be FSMA compliant, (see exemptions below). If you get any ingredients from outside your state and/or your products sell/ship across state lines you are required to be FSMA compliant; expect an FDA inspection.

Compliance clarification:

* + Retail store that sell ONLY direct to consumers are exempt.
  + However, if a Retail Store manufactures their products at a separate location/facility from the store, the exception does not apply and they are required to be FSMA compliant.
  + “Farm-Operated Business” may sell direct to consumers via roadside stands, farmers markets, etc. are exempt. (By “farm-operated business,” FDA means a business that is managed by one or more farms and that conducts manufacturing/processing not on the farm(s).
  + In general, domestic and foreign food facilities (facilities that manufacture, process, pack, or hold food, as defined 21 CFR 1.227, for human or animal consumption in the U.S.) that are required to register with section 415 of the Food, Drug, & Cosmetic Act must comply with the requirements for risk-based preventive controls mandated by the FDA Food Safety Modernization Act (FSMA) as well as the modernized Current Good Manufacturing Practices (cGMPs) of this rule (unless an exemption applies).

Small Business defined as less than 500 full time employees:

* Compliance required by September 18, 2017

Very Small Business defined as less than $1 million sales/year:

* Maintain records supporting Qualified Facility Status\* by 1/1/16
* Compliance required by September 17, 2018

\* A Qualified Facility MUST submit qualifying notifications to FDA during the same two year timeframe that the facility is required to update its Facility Registration.

To simplify, the overall FSMA distinction is if you are a Manufacturer that Wholesales your product, you are required to be FSMA compliant. (Think a little bit pregnant.) The Rationale behind FSMA Retail vs. Wholesale:

**Example: Fresh Banana**

* Retail: Eat a fresh banana immediately. No time delay, which doesn’t allow for growth of pathogen.
* Wholesale: Fresh Banana is an ingredient in finished product. However, the finished product doesn’t freeze immediately, it takes time ….. temperature and time allow for pathogen growth and risk.

However, regardless of the Size and Scope of your Operation and whether or not you are technically required under FSMA, it is incumbent on you, the Business Owner, to take proper steps to insure your product is safe!

**Steps to Developing a Food Safety Plan**

**Specific for your Company**

1. **Food Safety Plan Manual:**

**Table of Contents**

**Chapter 1:**  **Introduction**

Begin with a **Welcome letter** to provide information on the scope of operations of your Company, your Quality Control Programs, and your compliance with FDA Food Safety Modernization Act (FSMA). We recommend your Welcome Letter describes your business, who you are, what you do, your team, key players, customer base, products and overall scope of your operation, a floor plan, and if you have received any special certifications, training, or third party audits. See sample Welcome Letter Template.

**Chapter 2: Core Programs –** Core programs are **steps or procedures, including Good Manufacturing Practices (GMPs) and Sanitation Standard Operating Procedures (SSOPs),** which control the operational conditions within your Company and promote environmental conditions that are favorable for the production of safe food.

* **Pre-Requisite Program**, which includes:
  + Premises:
    - Outside Property – Describe desired condition of exterior of building, example free of debris and refuse to prevent harborage of pests, no roof leaks, etc.
    - Building – describe desired condition of and features in place to promote Food Safety, such as maintained in good repair to prevent access by pests, prevent contamination and adequate space for all operations, production areas separated from other operations to prevent contamination, positive pressure maintained in production areas, restrooms self-closing doors, hand washing stations available in production areas and wash hand signs are posted in restrooms and break areas, etc.
    - Water Supply – detail type of water and biological testing utilized, frequency, records retention, example: are hose equipped with anti-backflow devices
    - Ice Supply – detail bacteriological testing frequency, record retention and how water treated.
* Receiving and Storage – Detail key ingredients receiving protocols, such as letter of guarantee, certificates of analysis, record retention, all ingredients and packaging meet the requirements and regulations promulgated by the FDA, as well as local and State law. Detail receiving and storage procedures and how ongoing compliance monitored.
* Equipment Maintenance Program
  + Equipment Calibrations
  + Preventative Maintenance
* Personnel Training – new hire, ongoing training sessions, topics and frequency
* Sanitation – detail for cleaning of all equipment, utensils, overhead structures, floors, shoes, walls, drains, pallets, door knobs, production keyboards, key pads, sinks, water fountains, A/C filters, pipes and lines, drip gutters, uniforms, dolleys, hand trucks, jacks, grease traps, dumpster slab, phones, refrigerators, conveyors, air curtains, fans, crates, etc.
* Recall Program – detail that a recall program is in place outlining the procedure to ensure that any food can be removed from the market efficiently and completely.
* Allergen Control Program – ensure there is an Allergen Control Program in place to make sure allergenic ingredients do NOT find their way into products for which they are not intended. Refer them to applicable Chapter/Section of Food Safety Plan Manual for complete Allergen Control Program.
* **Good Manufacturing Practices** (GMPs): (helpful to prepare in both English and Spanish) – see sample templates
  + Apply to your company the following policies:
    - Proper Hand Washing Procedures
    - Pallet Cleaning Policy
    - Plastic Crate Cleaning Policy
    - Shoe Policy
    - Uniform Policy
    - Visiting Contractor Policy
    - Tote Cleaning Policy
    - Confined Space
    - Lot Code / Traceability Policy /Product Labeling
* **Sanitation Standard Operating Procedures (SSOP),** which should include procedures for:
  + Preparation of cleaners and sanitizers
  + Clean in Place (CIP) or Clean Out of Place (COP) cleaning procedure for applicable equipment
* **Allergen Control Program –** see sample template
* **Supplier Verification Program** – see sample templates

Note: If you are regularly getting a specific ingredient from a Grocery Store, Bulk Warehouse, etc. make sure you Register with that Company for the specific ingredient so they will timely notified in the event of a recall.

* **Transporting / Delivering Standard Operating Procedures** – see sample template
* **Hold and Release Policy –** detail Company policy and procedure
* **Recall Program** – see Sample template

Note: Mock Recall to be covered in Separate Manual for Foods Safety Plan Supporting Documents – see Sample Templates

**Chapter 3: Flow Chart**

* **Flow Chart –** this will need to be developed specific to your Company to document the flow of each type of ingredient received (i.e., refrigerated ingredients, frozen ingredients, pasteurized frozen ingredients, bulk liquid sugar {applicable for Mix Manufacturing only}, Dry non-dairy ingredient, dry ingredient, pasteurized liquid ice cream mix, frozen cultures, spray dried cultures, packaging, etc.) all the way through your process (i.e, specific storage handling, blending, holding tanks, compressed air, flavor vats, ice cream freezing, fruit feeder, ripple pump, inclusion staging, artisan ladling, package filling, package labeling, metal detector, hardening, freezer storage, etc.) to finished product and distribution.

**Chapter 4: Hazard Analysis**

* **Hazard Analysis –** this will document each step in the Flow Chart, identify what potential Hazards exist and what Preventative Controls you will apply to minimize the Hazard. - see sample Hazard Analysis Worksheet

**Chapter 5:**  **Hazard Analysis Summary of Critical Control Points – this is only applicable if you are making Mix. If you are receiving Ice Cream Mix this chapter is not applicable.**

* **Hazard Analysis Summary –** this details any Critical Control Points (CCP) - see attached Hazard Analysis Summary Template

**Chapter 6: Record Keeping**

* **Record Keeping** – detail your record keeping, list forms, timeframe, location of each applicable record. In addition, create a Hazard Analysis – Specific Control Measure Record Keeping Log – see attached sample template.

**Chapter 7: Corrective Action**

* **Corrective Action –**
  + **Hazard Analysis Critical Control Point (HACCP) / Food Safety Plan Review Schedule –** see sample template
  + **Critical Control Point (CCP) Deviation Records** – in the event there is a CCP Deviation, it is recommended you have a pre-made form to consistently address and document corrective action. See attached sample template. (This is not applicable if you are not making Mix).
  + **Policy Deviation Records -** in the event there is a Policy Deviation, it is recommended you have a pre-made form to consistently address and document corrective action. See attached sample template.

**Chapter 8: Third Party Certification**

* **Third Party Certification**

**Chapter 9: Environmental Monitoring Program –** to be reviewed and implemented AFTER you have developed a culture in your Company that prioritizes Food Safety and your Food Safety Plan Manual is complete and actively in place. An environmental Monitoring Program is the validation step to confirm the effectiveness of your Company’s Sanitation Program and further validate that the policies and procedures in your Food Safety Plan are successful in eradicating conditions conducive to the growth of pathogens. It is recommended that prior to implementing an Environmental Monitoring Program your Company should already be conducting and obtaining good results from the following Microbiological methods:

* Standard Plate Count
* Coliform Count
* Yeast and Mold Count
* Sampling Procedures
* Microbiological Specifications
* Pre-Operational Swabs
* Refractometer - only applicable if you are receiving liquid sugar {applicable for Mix Manufacturing only}

We will cover this section in greater detail at the end of this program.

* **Environmental Monitoring Program**
  + **Environmental Monitoring Program**
  + **Listeria Corrective Action Form**
  + **Listeria Environmental Monitoring Program (LEMP) Decision Tree**
  + **Third Party Finished Product Testing**
  + **Production Room(s) Zone Map(s)**

**Don’t let the task at hand feel daunting;**

**FOCUS ON CORE PRINCIPLES OF PATHOGEN CONTROL:**

* Principle # 1: Separate Raw from Ready –to-Eat
* Principle # 2: Good Manufacturing Practices (GMP’s) and Controlled Conditions
* Principle # 3: Sanitary Facility and Equipment Design
* Principle # 4: Effective Cleaning and Sanitation Procedures and Controls
* Principle # 5: Environmental Pathogen Monitoring
* Develop a culture of Food Safety! Food Safety needs to be EVERY Employee’s PRIORITY, not just the employees in the Production Area.

1. **Supplementary Food Safety Plan Supporting Documents:**

The Food Safety Manual is your Company’s policies, procedures and protocols. Whereas the Supporting Document Manual details by Department or Area the actual steps you take on a daily, weekly, monthly, semi-monthly or annual basis to ensure that you are doing what your Food Safety Manual states. It is comprised of the supporting documentation. Remember, “If you didn’t document it, it didn’t happen. And if you did document it, that’s exactly the way it did happen.” Joseph Levitt, Partner, Hogan Lovells US, LLP

**Table of Contents**

**Chapter 1: Mix Room –** If your Company produces Mix, the type of documentation in this area consists of:

* + Sanitation and Cleaning Logs
  + Daily Operating Procedure Log
  + Overhead Pipe Cleaning and Foam Walls Log
  + Monthly Valve Cleaning and Inspection Log
  + Tool Cleaning Policy
  + Hose Cleaning and Sanitation Procedure Log
  + Fan Cleaning Procedure Log
  + Quaternary Ammonia Fogger Procedure and Log
  + Sugar Pump Filter Cleaning Log
  + Holding Tank Temperature Log
  + Monthly Plug Valve Inspection Chart
  + Bag Lot Number Log
  + Etc.

**Chapter 2: Ice Cream Production Room** – this is the Production Room your Company makes the finished product, and list below are some of the type of documentation needed to support your Food Safety Plan:

* Clean Up Check Off List Log
* Daily Sanitation Log
* Bucket Machine Cleaning Policy Log
* Monthly Checklist
* Quarterly Checklist
* Quarternary Ammonia Fogger Procedure and Log
* Monthly Butterfly Valve Cleaning and Inspection Log
* Bucket Part Lot Numbers
* Ingredient Lot Log
* Vat Ingredient Log
* Metal Detector Check Log
* Soft Serve Lot Log

**Chapter 3: Warehouse and Distribution** – again below are the types of supporting documents for this Department / area:

* Dock Receiving Form
* Warehouse / Sanitation Team Checklist
* Warehouse Weekly Plant Checklist
* Warehouse Monthly Checklist
* Warehouse Quarterly Checklist
* Color Identification Chart
* Weekend or After Hours Plant Checklist
* Truck Cleaning Log
* Returned Tote / Crate Cleaning Log
* Refrigerator Temperature Log
* Daily Trash Removal Log
* Daily Handle, Key Pad, Keyboard/Mouse clean and Sanitize Log
* Daily Drain and Refrigerator Door Clean
* Plant Inspection Map Sign off Log
* New of Used Equipment Cleaning Policy
* Pallet Jack Identification Numbers Cleaning Log
* Dolley Identification Numbers Cleaning Log
* Weekly Equipment Cleaning Log
* Grease Trap Cleaning Policy and Log
* Refrigerator / Freezer Temperature Log
* Etc.

**Chapter 4: Freezer** - again below are the types of supporting documents for this Department / area:

* Freezer Weekly Checklist
* Freezer and Warehouse Laundry Log
* Product Return Policy

**Chapter 5: Quality Control -** again below are the types of supporting documents for this Department / area:

* Quality Assurance Start-Up Checklist
* Start of Day QC Spot Inspection Checklist
* Weekly Plant Checklist
* Monthly Checklist
* Quarterly Check List
* Semi-Annual Plant Checklist
* Observations – AM and PM
* Annual Checklist

**Chapter 6: Customer Complaint Form**

**Chapter 7: Mock Recall** – see attached Sample Templates

**Chapter 8: Security**

* Plant and Personnel Security

**Chapter 9: Chemicals –**

* Chemical Handling Procedures
* Material Safety Data Sheets

**Chapter 10: Maintenance -** again below are the types of supporting documents for this Department / area:

* Maintenance Precaution Policy
* Emergency Maintenance Policy
* Periodic Daily Checklist – Maintenance
* Monthly Maintenance Checklist
* Monthly Bleach Condensate on Pumps and Lines
* Quarterly Checklist – Maintenance
* Semi-Annual Maintenance Checklist
* Annual Checklist – Maintenance
* Dehumidifier Filter Changing Procedure Form
* Compressed Air Policy
* Preventative Maintenance Equipment

**Chapter 11: Lab**

* Laboratory Testing Procedures
* Dilution Procedure Using 3M Plates
* Sterility Controls Using 3M
* Lab- Mix Room Sanitizer Cleaning Solution Concentration
* Lab- Ice Cream Production Room Cleaning Solution Concentration
* Sanitizer Concentration at Start-Up Mix
* Sanitizer Concentration at Start-Up Ice Cream Production Room
* Standard Plate Count and Coliform Check Log
* Environmental Swabs

**Chapter 12: Helpful Tools, Log Checklists, Misc. Signs**

* QC During Operation Spot Inspection Checklist
* Master Log Checklist by Frequency
* Master Log Checklist by Department
* QC Close of Day Spot Inspection Checklist
* Miscellaneous Signage / Notices for Plant