

HOW TO START A CREAMERY: Comprehensive Food Safety/Defense Program

How to Start a Creamery:  
Food Safety & Defense Plan  
NCR-SARE FNC13-918

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## Introduction

This manual is a guide to the first steps in creating a food safety and food defense plan for a starting creamery. Most of the information you will find in the document is from the FDA website, [www.fda.gov](http://www.fda.gov). Our goal is to inform one beginning a creamery on the different ways to navigate through the startup process.

When thinking and gathering information to create a sustainable farm by processing any type of human food product, development of the food safety/defense plan (food safety refers to accidental contamination and food defense refers to intentional contamination or adulteration of the food product) should be considered equal with development of the business plan, arranging finance, and all other aspects of the planning process.

An individual or team should be designated in the organization to be food safety/defense coordinator (s). This coordinator should be or should become educated in reliable food safety/defense. A food safety consultant may be complimentary but WARNING – make sure the information is reliable. This will take investment of time, effort, and money. This will be ongoing,; expect changes in regulations, continuous and ongoing staff education, and continuous monitoring and evaluation of the food safety/defense plan. And do not completely rely on a consultant-- this is your business, and it is your business to be knowledgeable about your food safety program! But a good consultant should be one who empowers by not only sharing knowledge but also provides guidance on identifying reliable resources, and inspires development of processes that will improve effectiveness of operations. A good consultant should enable you to grow in independence.

## 1. Food Safety/Defense Coordinator Training

### Basic Food Safety Training –

- a. [www.ServSafe.com](http://www.ServSafe.com) – National Restaurant Association. Can download printable Food Handler or for a fee online Food Service Sanitation Manager Certification Course.
- b. [www.nfsmi.org](http://www.nfsmi.org) – FREE- many training programs available. Recommend Serving It Safe for basic sanitation similar to ServSafe
- c. Free Subscription to Food Safety Magazine -  
<http://www.foodsafetymagazine.com/>
- d. Illinois Technical Institute has partnered with the Food and Drug Administration (FDA) to develop and make training for Food Safety Modernization Act (FSMA) for small and medium size food manufacturers -  
[http://www.iit.edu/ifsh/alliance/pdfs/FSPCA\\_TAN\\_At-a-Glance\\_11\\_20\\_2015\\_Final.pdf](http://www.iit.edu/ifsh/alliance/pdfs/FSPCA_TAN_At-a-Glance_11_20_2015_Final.pdf)
- e. Basic Foodborne Illness Microbiology  
<http://www.fda.gov/Food/FoodborneIllnessContaminants/FoodborneIllnessesNeedToKnow/default.htm>
- f. <http://www.marlerclark.com/> - A nationwide law firm representing victims of foodborne illness. This website reports failures of the food provider leading to foodborne illness in specific cases. Also provides general information about specific pathogenic microorganisms.
- g. Foodborne Illness Microbiology – Bag Bug Book  
<http://www.fda.gov/Food/FoodborneIllnessContaminants/CausesOfIllnessBadBugBook/default.htm>
- h. Food and Drug Administration (FDA) free publications -  
<http://www.fda.gov/downloads/Food/ResourcesForYou/UCM222258.pdf>
- i. FDA Overview of Food Business  
<http://www.fda.gov/Food/ResourcesForYou/Industry/ucm322302.htm>

- j. FDA Employee Health and Hygiene Interactive Training - <http://www.fda.gov/food/guidanceregulation/retailfoodprotection/industryandregulatoryassistanceandtrainingresources/ucm266434.htm>
- k. FDA Employee Health and Hygiene Workbook downloadable - <http://www.fda.gov/downloads/Food/GuidanceRegulation/RetailFoodProtection/IndustryandRegulatoryAssistanceandTrainingResources/UCM194575.pdf>
- l. More FDA training resources - <http://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/IndustryandRegulatoryAssistanceandTrainingResources/default.htm>
- m. Third party audit companies – useful but often very expensive

2. FSMA-Food Safety Modernization Act

A good starting point is to understand regulation. “The FDA, Food Safety Modernization Act (FSMA), the most sweeping reform of our food safety laws in more than 70 years, was signed into law by President Obama January 4, 2011. **It aims to ensure the US food supply is safe by shifting the focus from responding to contamination to preventing it.**”

[www.fda.gov/Food/GuidanceRegulation/FSMA](http://www.fda.gov/Food/GuidanceRegulation/FSMA))

3. FDA Inspection Guidelines

To gain awareness of expectations through an FDA inspection:

FDA Inspection Guidelines for Dairy Products:

<http://www.fda.gov/ICECI/Inspections/InspectionGuides/ucm074974.htm>

And Interstate Milk Shippers List

<http://www.fda.gov/Food/GuidanceRegulation/FederalStateFoodPrograms/ucm2007965.htm>

#### 4. Food Facility Registration

The Public Health Security and Bioterrorist Preparedness and Response Act of 2002 directs the FDA... to take steps to protect the public from a threatened or actual terrorist attack on the U.S. food supply and other food related emergencies.

(<http://www.fda.gov/Food/GuidanceRegulation/FoodFacilityRegistration/default.htm>) To carry out this direction the FDA requires

manufacturing begins the business must be registered on the Food Drug Administration “Food Facility Registration” on the internet website -

<http://www.fda.gov/Food/GuidanceRegulation/FoodFacilityRegistration/ucm073728.htm>. A step by step Guidance tool is available to assist in completing the Food Facility Registration. The registration may be completed as of January 1, 2016 and must be completed online. To actually fill in the online Food Facility Registration for go to -

<http://www.fda.gov/Food/GuidanceRegulation/FoodFacilityRegistration/default.htm>. Registration must be renewed each even numbered years from October 1 through December 31. Maintain a copy of the completed Food Facility Registration in your facility which contains the facility’s Registration number and pin number used to log on to an account created for future updates. Renewal is also required when a facility changes ownership.

**WARNING** – There are companies that will complete the registration for you for a fee and send you a plaque with your information on it to display. They will offer to register your facility every year. This is **not** a regulatory requirement,; it is costly. I recommend your facility identification number be kept in private documentation and not displayed to the public. The FDA requires you to register your facility on the even number years (e.g. 2016, 2018).



## 5. Prerequisite Programs (PPs) or Standard Operating Procedures (SOPs)

To assure that expected practices are continuously in practice, procedures on everyday tasks are developed. “Prerequisite programs (PPs) are universal procedures used to control the conditions of the plant environment that contribute to the overall safety of the product.” (Dairy HACCP- NCIMS HACCP Pilot Program <http://www.fda.gov/Food/GuidanceRegulation/HACCP/ucm120907.htm> )

Pasteurized Milk Ordinance -

<http://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/milk/ucm301297.htm>

PPs recommended to include (but be specific to your facility’s needs):

- Good Manufacturing Practices -  
<http://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/ucm238182.htm>
- Personnel Practices
- Customer Complaint
- Chemical Control
- Cleaning
- Preventive Maintenance
- Transportation and Storage
- Integrated Pest Management
- Receiving
- Allergen Control
- Approved Supplier

All staff are trained on PPs. Be sure to keep training documentation on all training completed. PPs are approved initially by the facility’s governing body or designated individual, reviewed at least annually and updated as necessary throughout the year. PPs address any usual task in the facility.

6. Develop Hazardous Analysis Critical Control Points(HACCP) Plan or Hazardous Analysis Risk-based Preventive Control (HARPC) Plan. Resources include:

a. Differences in HACCP and HARPC are explained simply in Food Safety Magazine Article:

<http://www.foodsafetymagazine.com/magazine-archive1/december-2015january-2016/how-food-companies-can-modify-their-existing-haccp-plans-into-an-all-encompassing-food-safety-plan/> . FDA regulation for HARPC has not been finalized at this time but to progress food safety program to HARPC is recommended.

b. Guidebook for the Preparation of HACCP Plans

<http://www.fsis.usda.gov/wps/wcm/connect/3ec95930-e7fe-4e61-90ad-675e6b483591/HACCP-1.pdf?MOD=AJPERES>

c. Dairy HACCP- NCIMS HACCP Pilot Program

<http://www.fda.gov/Food/GuidanceRegulation/HACCP/ucm120907.htm>

\*Use these guides to critically specifically review each step of the process.

Note: One individual must receive certified training in HACCP planning. Keep this certification with HACCP Plan for regulatory review. This could be a consultant who is not an employee of the facility but who has assisted in development of the HACCP Plan and who reassesses and modifies the HACCP Plan as necessary.

The HACCP plan must include:

Product Description

Process Flow Diagram

Question Checklist of Hazard Analysis Process

Identification of Hazard/Preventive Measures

Hazard Analysis for each product

HACCP Plan Development Form: Monitoring Procedures and Frequency

HACCP Plan: for each product identify critical limits, monitoring procedures and frequency, HACCP Records, Verification Procedures and Frequency and Corrective Actions for each step in the production process including receiving raw ingredients through storage of the finished product.

Record Keeping

Validation, Verification, and

Reassessment of the effectiveness of the HACCP Plan

Continuous and ongoing staff training

## 7. Recall/Traceability Program

You can incorporate your Recall and Traceability Program with our HACCP program to expand toward a Hazardous Analysis Risk Preventive Control (HARPC) Program. Although the regulation for HARPC has not been finalized the concept maybe incorporated.

### - Traceability Program

<http://www.fda.gov/downloads/Food/GuidanceRegulation/UCM341810.pdf>

- Identification of ingredients including lot numbers, manufacturer name and address so that all product produced can be traced back to its origin
- Identification of all products produced so that all products can be traced to consumer.

### - Recall Program

[http://www.fsis.usda.gov/shared/PDF/RecallPlanBooklet\\_0513.pdf](http://www.fsis.usda.gov/shared/PDF/RecallPlanBooklet_0513.pdf)

- This is a two part proactive program.
  - Part 1 includes delegating tasks to staff such as: Primary Recall Coordinator, Alternate Recall Coordinator, Consumer Representative, Public Affairs Representative with written description of tasks each designation would achieve during a recall. Establishing criteria when a recall would be necessary, determination of implications of a recall (why would your company consider a recall), identifying specific records to be kept that would be essential and those that would be helpful in the event of a recall, development of several scenarios in which a recall might occur, identifying and prioritizing communications in the event of a recall, specifics of content of recall communications, specifies responsibility of the recipient of recall communications, identifies process to notify public of the recall with sample notification recall letter and press releases for various scenarios, defines specific checks of effectiveness in the recall process,

determination of returned product and disposition, and development of a plan of recall simulations.

Regulations require two mock recalls with records of mock recalls annually.

- Part 2 includes the actual recall communication samples – press releases and recall letters for various scenarios, Recall Plan Forms – identifying recall team members and contact information,
- <http://www.fda.gov/ICECI/Inspections/IOM/ucm122545.htm>  
FDA guidance for Recall Classification.

8. Consumer Complaint Program

A facility must have a Consumer Complaint Program in place. This can be a file with a specific form that has a series of questions for the customer filing the complaint. The form should include basic information (name, date, product complaining about). Be sure to include questions related to time of onset, was there a medical professional involved and the details, symptoms, etc.

<http://www.fda.gov/downloads/iceci/inspections/iom/ucm123515.pdf>

Online Voluntary Reporting for Serious Food/Beverage Allergic Reactions -

<https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home>

See Appendix A

## 9. Food Defense Plan

### a. Food Defense training

<http://www.fda.gov/Food/FoodDefense/ToolsEducationalMaterials/ucm353774.htm>

- Provides Food Defense training for Food Defense Coordinator with a printable certificate to be maintained in facility training records
- Provides Food Defense training for all staff

### b. Food Defense Builder

<http://www.fda.gov/Food/FoodDefense/ToolsEducationalMaterials/ucm349888.htm>

-Provides a downloadable online database to create individualized and printable Food Defense Program.

### c. Vulnerability Assessment-Identifying Greatest Threats

<http://www.fda.gov/Food/FoodDefense/ToolsEducationalMaterials/ucm295900.htm>

- Provides downloadable online software to create individualized and printable program. The software provides questions to be answered about the facility and process to help identify vulnerable areas by considering what type of attack is the greatest threat and whether a biological or chemical agent might be used in an attack. The intent is that by conducting a vulnerability assessment of the food production facility and process, the user can then better focus resources on protecting the most susceptible points.

### c. Mitigation Strategies – Identifying Preventive Measures

<http://www.fda.gov/Food/FoodDefense/ToolsEducationalMaterials/ucm295898.htm>

- Provides downloadable online database to create an individualized and printable program. Preventive measures are identified to protect the food in all stages of receiving ingredients, processing,

storage, packaging, transporting the product to protect against intentional adulteration.

d. CARVER Shock

<http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm094560.htm>

- CARVER is an acronym for the following six attributes used to evaluate the attractiveness of a target for attack:
- •Criticality - measure of public health and economic impacts of an attack
- •Accessibility – ability to physically access and egress from target
- •Recuperability – ability of system to recover from an attack
- •Vulnerability – ease of accomplishing attack
- •Effect – amount of direct loss from an attack as measured by loss in production
- •Recognizability – ease of identifying target
- 
- In addition, the modified CARVER tool evaluates a seventh attribute, the combined health, economic, and psychological impacts of an attack, or the SHOCK attributes of a target.



10. Third Party Audits

Considerations for Third Party Audits –

Many buyers like Whole Foods require a Third Party Audit. Third Party Audits are beneficial but can be costly. There are many companies that will offer an “Educational” audit before they will come in and complete the audit that will be on file. The Educational audit is very informative and usually will follow the FDA guidelines.

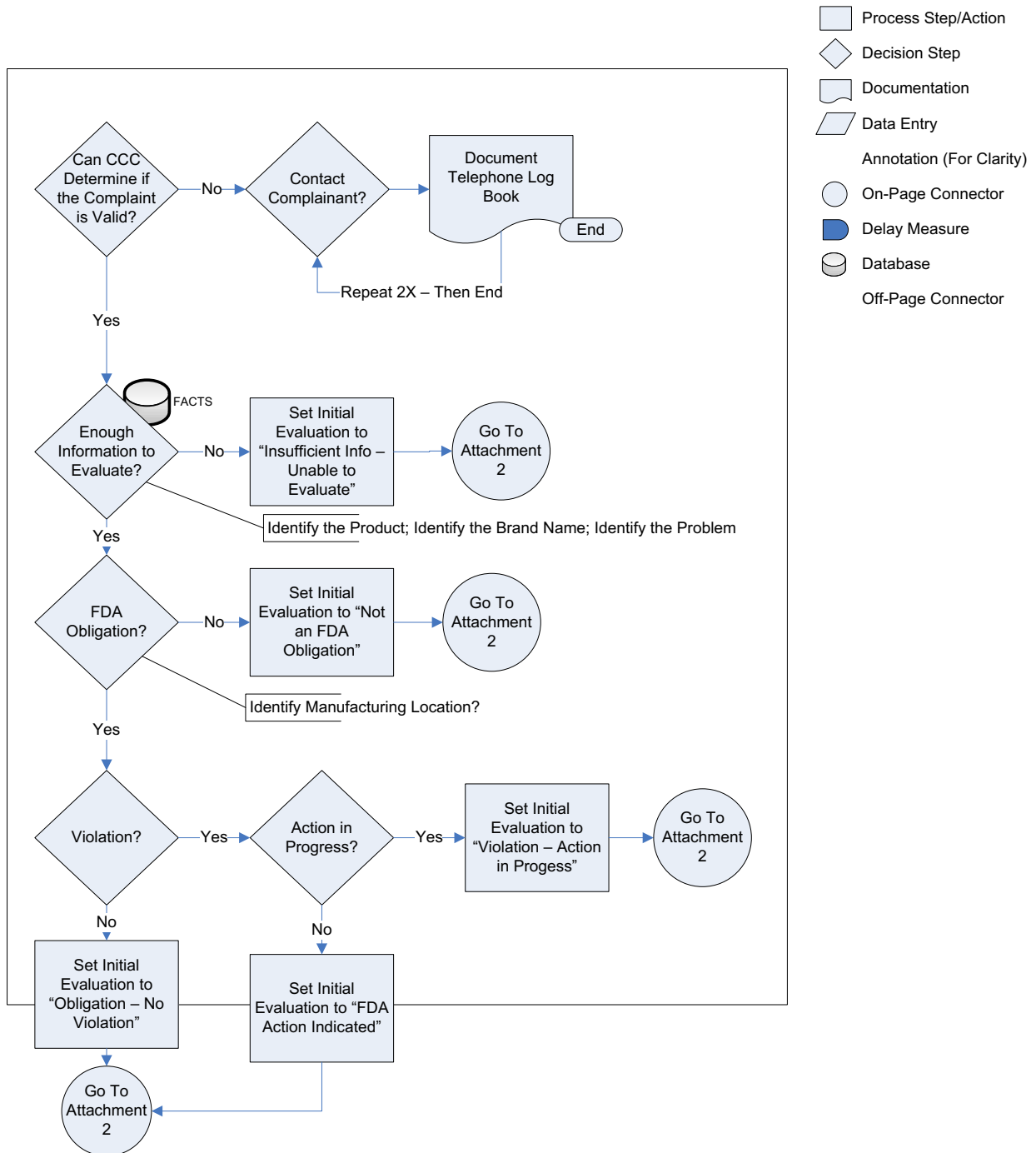
Here is a good resource for more information on third party audits.

<http://www.foodsafetymagazine.com/magazine-archive1/october-november-2009/third-party-audits-what-the-food-industry-really-needs/>

## Conclusion

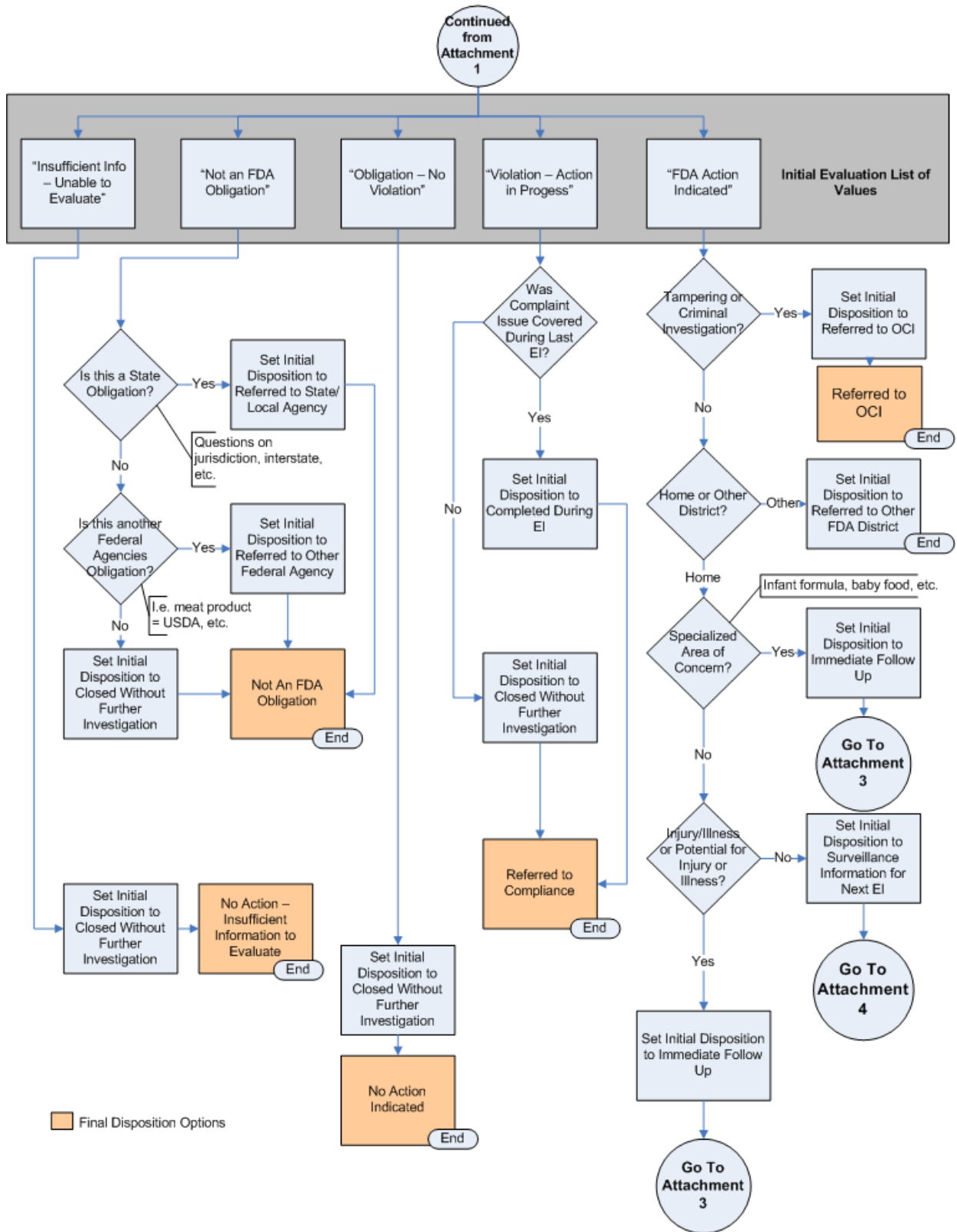
Developing a Food Safety and Food Defense program is essential to manufacturing food productions. To maintain an efficient and effective food safety program there must be ongoing practice, evaluation and education. **Food safety must be as actively pursued as any part of the business.**

Appendix A: Customer Compliant Flow Chart

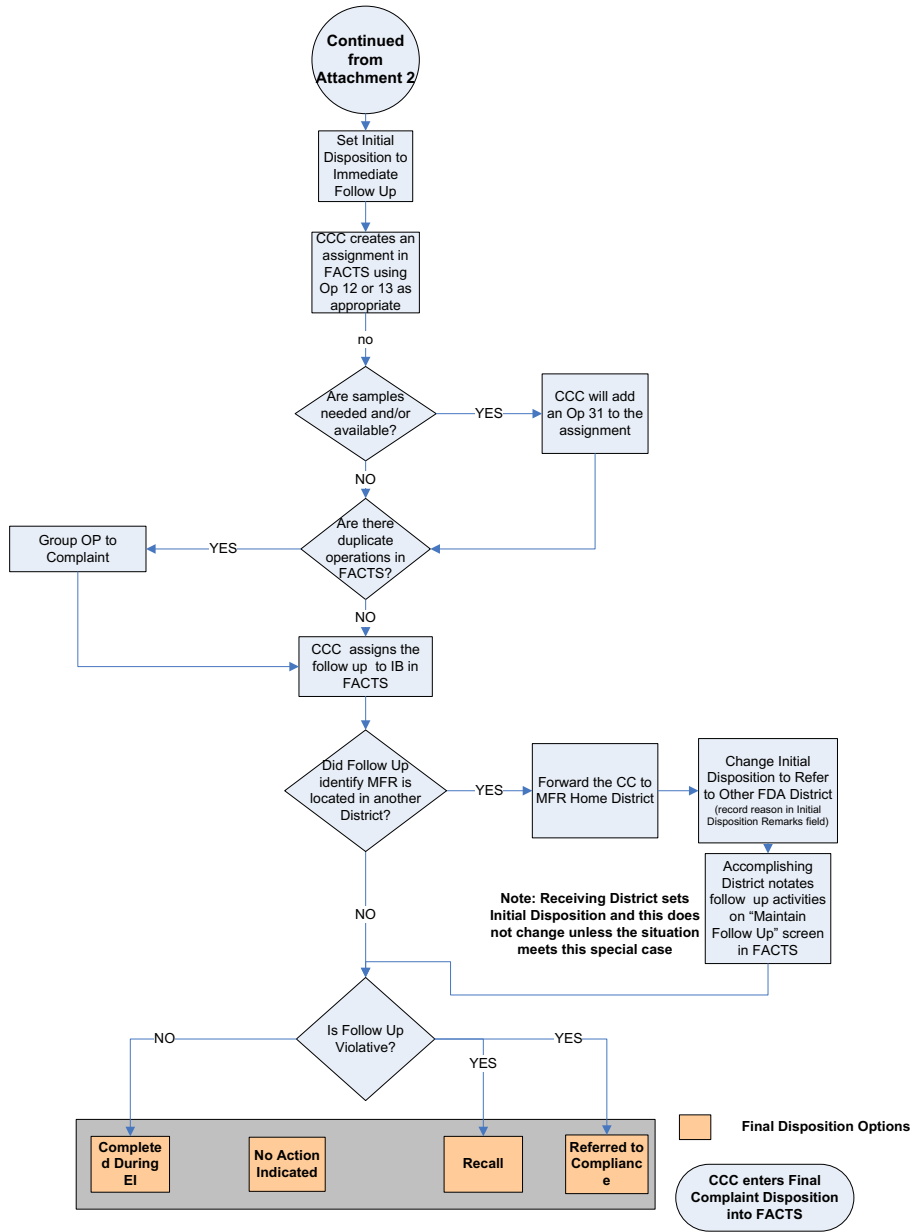


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