FOOD SAFETY DOCUMENT DEVELOPMENT FOR SMALL FOOD PROCESSORS

This training is made possible by funding from the USDA's Food Safety Outreach Program and from contribution to key project personnel:

Abby Snyder, Ph.D.
Assistant Professor

Erin DiCaprio, Ph.D.
Assistant Extension Specialist

Olga Padilla-Zakour, Ph.D.
Professor

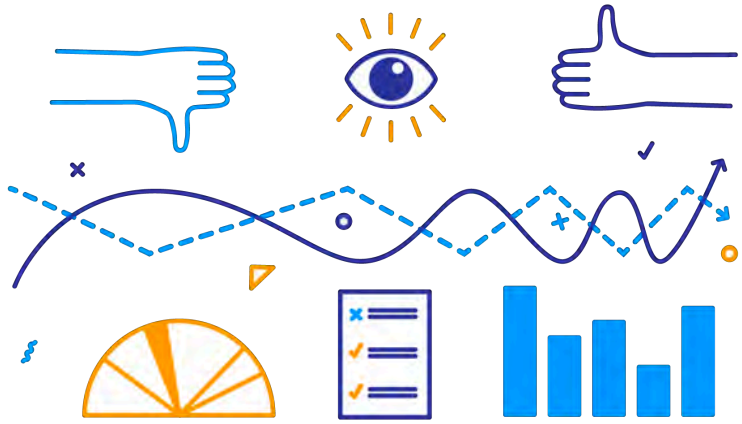
Bruno Xavier, Ph.D.
Senior Extension Associate

Shiyu Cai, M.S.
Graduate Research Assistant

Contents

FOOD SAFETY DOCUMENT DEVELOPMENT FOR SMALL FOOD PROCESSORS

PCHF RULE QUALIFIED EXEMPTION-ELIGIBLE FOOD FACILITIES



PRE-COURSE EVALUATIONS

LOGISTICS

- Restroom location
- Power outlets
- WiFi
- Breaks given, but feel free to step out if needed
- Be respectful of other learners if you need to take a call
- Plan to wrap-up before lunch

INTRODUCTIONS

- Name
- Business and food safety responsibilities
- Types of products
- Previous experience
- What you hope to get out of the course

COURSE OBJECTIVES

Participants will:

- Understand food safety hazards and be able to identify those relevant to your product and facility
  - Increased emphasis on allergens
- Identify and develop documents needed for compliance with the Human Food Rule of FSMA for qualified facilities
- Develop a plan for employee training and the associated record keeping
- Review process for conversion of existing food safety programs into a food safety plan
  - Future business growth resulting in loss of exemption

REGULATIONS WE ARE DISCUSSING

FDA FOOD SAFETY MODERNIZATION ACT

- How does this pertain to smaller food processors?
  - Who is subject to what aspects of the regulation
- What programs need in place to be compliant?
- What documentation needs to be in place to be compliant?

WHO REGULATES FOOD?

FDA

- Most food
- Seafood
- Dairy
- Shell eggs
- Juice
- Acidified and low acid canned foods

USDA

- Meat
- Poultry
- Egg products

- State level inspectors
- Cottage food

PRODUCT EXAMPLE – WHAT ARE THE REGULATIONS?

FSMA?

Acidified foods?

Cottage foods?

PRODUCT EXAMPLE – WHAT ARE THE REGULATIONS?

FSMA?

Low Aw food?

Cottage foods?

WHAT DO I HAVE TO DO?

It Depends!

- Product type
- Facility size (value of food produced)

- Compliance requirements depend on what regulations you're subject to

- The regulations you're subject to depend on aspects of your business

BUSINESS ASPECTS THAT MODIFY REQUIREMENTS

Food safety risks (severity and likelihood of illness or injury to consumers) influenced by:

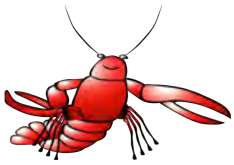
- Types and sources of ingredients
- Packing and distribution
- Consumers
- **Facility size**

You may be subject to one or more regulations with different requirements, basis for exemption, and documentation requirements.

RISK-BASED FOOD SAFETY PROGRAMS

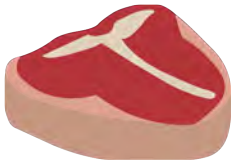
US Space program

Low-acid canned food regs



FDA Seafood HACCP regs

FDA Juice HACCP regs



USDA HACCP regs

Codex HACCP Annex

NCIMS Dairy HACCP

FOOD SAFETY MODERNIZATION ACT

Subpart A – General Provisions

Subpart B – Current Good Manufacturing Practice

Subpart C – Hazard Analysis and Risk-based Preventive Controls

Subpart D – Modified Requirements

Subpart E – Withdrawal of a Qualified Facility Exemption

Subpart F – Requirements Applying to Records That Must be Established and Maintained

Subpart G – Supply-chain Program

- **Human Food**
- Produce Safety
- Animal Feed and Pet Food
- (etc…)

FOOD SAFETY MODERNIZATION ACT

Subpart C – Hazard Analysis and Risk-based Preventive Controls

- Written hazard analysis
- Process preventive controls
- Sanitation preventive controls
- Allergen preventive controls

Subpart G – Supply-chain Program

- Supply chain preventive controls

- Human Food
- Produce Safety
- Animal Feed and Pet Food
- (etc…)

PREVENTIVE CONTROLS FOR HUMAN FOOD

Subpart A – General Provisions

Subpart B – Current Good Manufacturing Practice

Subpart D – Modified Requirements

Subpart E – Withdrawal of a Qualified Facility Exemption

Subpart F – Requirements Applying to Records That Must be Established and Maintained

FDA FOOD SAFETY MODERNIZATION ACT

- Human Food
- Produce Safety
- Animal Feed and Pet Food
- (etc…)

PRODUCT EXAMPLE – WHAT ARE THE HAZARDS?

People

Environment

Ingredients

PRODUCT EXAMPLE – WHAT ARE THE HAZARDS?

People

Environment

Ingredients

HOW DO WE START TO MITIGATE THESE ISSUES?

- What practices mitigate these different hazards?
- What are the best practices for mitigating these hazards, and what are the regulatory requirements?
- What documentation is useful and what is required?

GROUP BREAKOUT

- Review your company description within your group
- What regulations might be relevant to these companies?

Brainstorm what regulations might be relevant to the following businesses. Consider whether or not they are exempt from preventive controls (Subparts C and G), GMPs, HACCP (juice, seafood), or canned food rules (acidified food, water activity controlled, low acid canned food), or are producing under cottage food laws.

1. You are a cookie manufacturer and you employ 10 people and sell $5 million in cookie products each year.

2. You make cookies in your home and sell them at the local farmers' market.

3. You are a juice manufacturer who sells apple cider and green juices at the local farmers' market.

4. You are a sauerkraut processor who sells $700k in product every year.

5. You are a pickle processor who sells $1.2 million in product each year.

FOOD SAFETY AND HAZARDS

OBJECTIVES

By the end of the module participants will be able to:

- Identify hazards relevant to their product, ingredients, and facility
  - Bacterial pathogens that cause foodborne disease
  - Undeclared allergens that cause reactions in sensitive populations
- Evaluate the risk these hazards pose to the safety of their products

A REVIEW OF SOME TERMS

- **Food Safety** – programs or activities that serve to prevent illness or injury that results from eating food
- **Hazards** – the things that cause illness or injury
- **Risk** – the likelihood of illness or injury occurring

Different food safety programs (and regulations) address the issues of hazard and risk in different ways. Our goal in this module is to: (1) identify pertinent hazards specific to you and (2) consider relevant food safety activities to manage those risks outside of Preventive Controls

HAZARDS

Has the potential to cause illness or injury in the absence of an appropriate control

Types of hazards:

- Biological

- Chemical

- Physical

IMPACTS

- Contaminated food that makes you sick
- Foodborne illness, foodborne disease, or food poisoning
- **48 million cases of foodborne disease**
  - 1:6 people in the US each year
  - Quality of life
- **3,000 deaths**
- **128,000 hospitalizations**
- **Economic burden**
  - Missed work days
  - Recalled product
- Caused by biological hazards: pathogenic bacteria, viruses, and parasites

Scallen, 2011

BIOLOGICAL HAZARDS

- Bacteria
- Viruses
- Parasites

INFECTIONS AND INTOXICATIONS

Foodborne infection

- Pathogen invades the body after consumption of contaminated food
- Growth in the food may not be necessary to cause illness
- Examples
  - Pathogenic *E. coli*
  - *Salmonella*
  - *Listeria monocytogenes*
  - All viruses and parasites

Foodborne intoxication

- Pathogen growth in the food produces a toxin that causes illness when consumed
- No growth in food = No toxin = No illness
- Examples
  - *Staphylococcus aureus*
  - *Clostridium botulinum*
  - *Bacillus cereus*

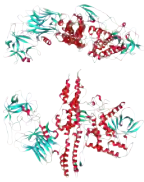
INFECTION EXAMPLE

- Caused by the ingestion of live pathogenic bacteria which grow and establish themselves in the human intestinal tract

What product and pathogen combinations relevant to your facility cause illness through infection?

INTOXICATION EXAMPLE

- Caused by the ingestion of food containing toxins made by bacteria during growth



What product and pathogen combinations relevant to your facility cause illness through intoxication?

FACTORS THAT INFLUENCE BACTERIAL GROWTH

- Food – a nutrient source
- Temperature and time
- pH – acidity or alkalinity measure
- Water
- Proper atmosphere
  - Atmospheric oxygen, reduced oxygen, no oxygen
- Microbial competition
- Preservatives

Reducing growth reduces risk but may not eliminate it!

Canned Sauerkraut – what factors are relevant here?

FACTORS THAT INFLUENCE BACTERIAL GROWTH

- Food – a nutrient source
- Temperature and time
- pH – acidity or alkalinity measure
- Water
- Proper atmosphere
  - Atmospheric oxygen, reduced oxygen, no oxygen
- Microbial competition
- Preservatives

Reducing growth reduces risk but may not eliminate it!

Bread – what factors are relevant here?

FOODBORNE VIRUSES

- Do not grow in food
- Do not spoil food
- Foodborne pathogenic viruses survive freezing
- Transmitted by people, contaminated food and contaminated water and environmental surfaces
- Cause illness by infection

METHODS TO PREVENT VIRAL TRANSMISSION

- Proper practices
  - Good personal hygiene practices by food handlers
  - Exclusion of ill food handlers
  - Proper disposal of human feces
  - Elimination of insufficiently treated sewage to fertilize crops
  - Proper treatment of sewage
  - Cleaning and disinfection of restroom facilities
- Cooking

SPOILAGE/QUALITY – NOT TYPICALLY A HAZARD

CHEMICAL HAZARDS

ALLERGENS

MYCOTOXINS

ALLERGENS

- Certain foods cause an immune reaction in some consumers
- Symptoms including rash, vomiting, difficulty breathing, and even death
- How many allergens MUST be labeled in the US? Can you name them?
- Why were these selected? Can other foods cause allergic reactions
- Are other countries labeling requirements the same?

DOES ANYONE KNOW SOMEONE WITH A FOOD ALLERGY?

- "An estimated 4 percent of adults and 5 percent of children in the United States have food allergy, a condition in which the immune system reacts abnormally to a component of a food," according to a news release from NIH.

FALCPA* REQUIRED FOOD ALLERGEN LABELING

- Milk
- Egg
- Peanut
- Tree nuts (species specific)
- Fish (species specific)
- Crustacean shellfish (species specific)
- Wheat
- Soy

* Food Allergen Labeling and Consumer Protection Act

Photo Sources: Microsoft Clip Art and KMJ Swanson (soybeans)

IMPACTS

Two die because of reactions to undeclared allergen ingredients

By Joe Whitworth on October 10, 2018

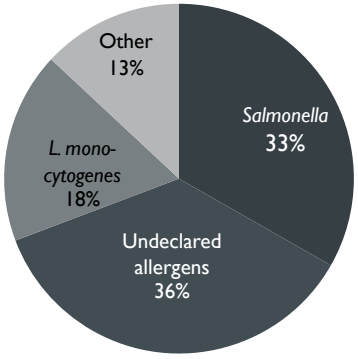
Two people in England died after having allergic reactions linked to eating at Pret A Manger in different incidents.

Celia Marsh, 42, from Wiltshire, died in December 2017 after eating a "super-veg rainbow flatbread" which should have been dairy free.

Natasha Ednan-Laperouse, 15, died after eating a baguette from the sandwich chain in July 2016. She had a sesame allergy and the product was not listed with allergen information.

REPORTABLE FOOD REGISTRY IDENTIFIES CONCERNS

Reportable Food Registry Reports 2009-2013



- Electronic portal for industry to report foods when use is reasonably likely to cause illness, injury or death
- Biological hazards in foods are reported most frequently
- Undeclared allergens represent about 1/3 of reports

ARE ALLERGENS USED IN YOUR FACILITY?

DO YOU KNOW?

HOW WE CAN MANAGE ALLERGENS IN FOOD PROCESSING

1. Preventing allergen cross-contact
   - Clean shared equipment – potential sanitation controls
   - Properly manage rework
   - Avoid in-process or post-process allergen cross-contact
2. Accurate allergen labeling of finished food
   - Ensure labels are correct – potential supply-chain program
   - Ensure the correct label or package is used

- Human error can be involved – training is essential!

VERIFICATION OF ALLERGEN CLEANING

Visually clean

No residue, film or sheen

Tests

Non-specific tests, e.g., ATP and protein

- May not be sensitive enough to detect some allergens

Allergen test kits

- Follow manufacturer's instructions!

Complex tests

- Special situations

SCHEDULING OR RUN SEQUENCING

- Minimize changeovers
- Run dedicated or designated systems as much as possible
- Schedule appropriate sanitation activities
- Control allergen addition

ALLERGENIC INGREDIENT CONTROL

- Develop a master list of allergenic ingredients used in the facility
  - Letters of guarantee from suppliers on the presence or absence of allergenic ingredients
  - Accessibility of master list at receiving dock
  - Use common names of allergens
- Apply careful handling at receiving to avoid allergen cross-contact
- Identify allergens with icons

STORAGE OF INCOMING GOODS

- Separate allergenic ingredients from non-allergenic ingredients to prevent allergen cross-contact
  - Control traffic patterns also
- Use signage in areas used to store allergens
  - Maintain consistent allergen identifiers – color or image
- Store allergens in sealed, intact containers, as appropriate
- Do not store allergens above non-allergens on racks or pallets
- Store allergens with "like" allergens
- Have documented clean up procedures available

ALLERGEN LABELING CONSIDERATIONS

- Label accuracy
  - Accurate printing of allergen ingredients on the label
  - The right label on the package
- Receiving ingredients
  - Do you check ingredient labels?
  - What if you change brands?

"MAY CONTAIN" LABELING

- "May Contain" or similar labeling is NOT a substitute for appropriate GMPs
- Carefully consider label implications for ingredients with precautionary labels (e.g., "May Contain")

BREAKOUT!

- Brainstorm what hazards are relevant to your product(s)
- What kind of mitigation strategies do you have in place to control these hazards – how do you prove/verify that you are actually doing these things?
  - Be prepared to share with the group!

Question1: Describe your product and how you make it, briefly

Question 2: What potential hazards are relevant to your product and facility?

- Biological

- Chemical

- Physical

Question 3: What risk mitigation strategies might you use to manage these hazards?

GOOD MANUFACTURING PRACTICES – PRELIMINARY STEPS

OBJECTIVES

By the end of this module participants will:

- Be familiar with basic practices associated with health and hygiene in food production
- Have received training on updates to Good Manufacturing Practices
- Be able to identify key strategies used to prevent environmental cross-contamination (pathogens) and cross-contact (allergens)

GMPS ARE REQUIRED

- The current federal GMP regulation specifically applies to all food products regulated by FDA.
- It outlines the basic sanitary controls that are required for all food processing plants, wholesale or food distribution firms and food storage facilities that handle, store or process FDA-regulated food. This GMP regulation also provides a framework for the specific state regulations that may apply to these firms.

FOOD SAFETY MODERNIZATION ACT

Subpart A – General Provisions

Subpart B – Current Good Manufacturing Practice

Subpart C – Hazard Analysis and Risk-based Preventive Controls

Subpart D – Modified Requirements

Subpart E – Withdrawal of a Qualified Facility Exemption

Subpart F – Requirements Applying to Records That Must be Established and Maintained

Subpart G – Supply-chain Program

FDA FOOD SAFETY MODERNIZATION ACT

- **Who has to have GMPs in place?**

COMPONENTS OF GOOD MANUFACTURING PRACTICES (GMPS)

- The regulation (21 CFR 117 Subpart B) lists these components that establish the conditions and practices the food industry must follow for processing safe food under sanitary conditions:
  - Personnel
  - Plant and grounds
  - Sanitary operations
  - Sanitary facilities and controls
  - Equipment and utensils
  - Processes and controls
  - Warehousing and distribution
  - Holding and distribution of human food by-products for use as animal food, and
  - Defect action levels

TRAINING

- Individuals **must** be qualified by education, training, or experience to manufacture, process, pack or hold food
- Individuals **must** receive food hygiene and food safety training
- Supervisors responsible for ensuring compliance must have appropriate knowledge, training or experience

PERSONNEL

- Restricting persons with illness or open wounds
- Proper handwashing and sanitizing
- Adequate personal cleanliness
- Suitable gloves maintained in satisfactory condition
- Suitable outer garments
- Jewelry removed
- Hair restraint
- Personal items stored away from production areas
- No eating, drinking or tobacco use in production area

PLANT AND GROUNDS

- Removal of debris, unused equipment and uncut vegetation
- Proper drainage of grounds
- Proper waste disposal
- Adequate space for operations and cleaning
- Proper separation of operations to prevent cross-contamination and allergen cross-contact
- Cleanable walls, floors and ceilings kept in good repair
- Prevent drip or condensate from contaminating the product
- Adequate lighting
- Guard against glass breakage
- Adequate ventilation that does not contaminate the product
- Screened openings to the outside

WHAT'S WRONG WITH THIS PICTURE? WASTE DISPOSAL AND DRAIN AREA

Improper waste disposal and drainage

- Exterior drain clogged with food waste.
- Potential source of contamination of food by seepage, foodborne filth, and a breeding place for pests.

WHAT'S WRONG WITH THIS PICTURE? CEILING LIGHT FIXTURE

- Broken light bulb in raw material storage area
- Hit by fork lift driver with a full load of incoming product

SANITARY OPERATIONS

- Plant maintained in good state of repair
- Cleaning operations not a source of contamination
- Cleaning and sanitizing compounds safe and free from contamination
- Unnecessary toxic chemicals not stored
- **Toxic chemicals properly identified, stored and used**
- **Pest control safe and effective**
- **Food-contact surfaces cleaned and sanitized before use and after interruptions**
- Non-food-contact surfaces cleaned as necessary
- Single service articles protected from contamination
- Recontamination of portable equipment and utensils prevented

WHAT'S WRONG WITH THIS PICTURE? WHITE AND BROWN SUGAR AT A BAKERY

- Improper storage of chemicals
- Even when properly labeled, these chemicals do not belong in a food preparation area to prevent accidental use

SANITARY OPERATIONS

CONDITION AND CLEANLINESS OF FOOD-CONTACT SURFACES

- Food-contact surfaces must be:
  - Smooth and easy to clean
  - Cleaned and sanitized as necessary to protect against allergen cross-contact and cross-contamination of food
- Potentially hazardous situations that may require Food Safety Plan documentation include:
  - Allergen cross-contact
  - Environmental pathogen harborage sites
  - Sanitation frequency to prevent pathogen growth

WHAT'S WRONG WITH THIS PICTURE?

CLEANING AND SANITATION

- Apron "cleaning" on the floor and over a floor drain, which is a potential contamination source!
- Employee is focused on cleaning but needs training on potential sources of contamination.

SANITARY FACILITIES AND CONTROLS

- **Adequate potable water supply**
- **Proper plumbing**
- Adequate floor drainage
- Proper sewage disposal
- **Adequate, accessible, sanitary toilet facilities**
- **Convenient hand-washing and sanitizing facilities**
- Proper trash and waste disposal

WHAT'S WRONG WITH THIS PICTURE?
WAREWASHING SINK

Inadequate water supply

- Leaky faucet
- Open holes are potential contamination sources

WHAT'S WRONG WITH THIS PICTURE?

EMPLOYEE TOILET

- Inadequately cleaned toilet
- Soiled toilet may contain bacterial and viral pathogens that can aerosolized when the toilet is flushed

WHAT'S WRONG WITH THIS PICTURE?

HANDWASHING SINK

- Hand sink must be dedicated to handwashing
- A tofu firm inappropriately used the handwashing sink to store the colander used to collect soy curds for pressing.
- Also note the bar of soap, which is not sanitary and should not be used in food facilities.

EQUIPMENT AND UTENSILS

- Cleanable and maintained food-contact and non-food-contact areas
- Preclude adulteration
- Corrosion resistant and nontoxic food-contact surfaces
- Compressed gases properly filtered
- Freezers and coolers have temperature indicating devices and automatic temperature control or alarm
- Properly maintain accurate process control instruments

PROCESSES AND CONTROLS

- General
  - Appropriate quality control procedures employed
  - Overall sanitation under the supervision of competent individuals
  - Adulterated foods must not enter commerce
- Raw materials and ingredients
- Manufacturing operations

PROCESSES AND CONTROLS
RAW MATERIALS AND INGREDIENTS

- Comply with FDA requirements for pests, extraneous material or undesirable microorganisms, as assured by testing, supplier certification or heat treatment
- Inspect for suitability
- Store and handle to prevent contamination and deterioration
- Properly identify rework and prevent contamination, allergen cross-contact and deterioration

PROCESSES AND CONTROLS
MANUFACTURING OPERATIONS

- Prevent microbial growth through:
  - Cooking, time/temperature control, water activity control, pH etc.
- Use clean and sanitized equipment, utensils and finished product containers
- Manufacture ice from potable water in a sanitary manner
- Prevent cross-contamination and allergen cross-contact

Prerequisite Worksheet

Prerequisite #	Title
Purpose	

Identify specific tasks to be accomplished. Define purpose of each with a brief description.
1.
2.
3.
4.

Summary of Required Monitoring Documentation

Monitor *(What & Who)*	Frequency of monitoring	Monitoring Document/Record	Verification *(Who & Frequency)*	Retention *(Where & How Long)*
Procedure 1				
Procedure 2				
Procedure 3				
Procedure 4				
Corrections				

Company Name _____ Telephone Number _____
Address _____ Email/Website _____
Version/Date _____ Supersedes _____
Approved by (print name) _____ Title _____
Approval Signature _____ Date Signed _____

MODEL DOCUMENT FOR USE IN YOUR FACILITY

WHAT'S WRONG WITH THIS PICTURE?
POLY BAGS CONTAINING OF PITA CHIPS

- Pita chips may become contaminated because of numerous tears in poly bags.
- Need for rigid containers to protect the product.

HOW HAVE GMPS BEEN MODERNIZED

Increased emphasis on allergen management

- This includes issues relating to sanitation and cleanliness to prevent cross-contact
- Transfer of allergens from shared utensils and equipment
- Order of food produced in the facility
- Receipt and storage of allergens
- If you're in a shared-use facility, how do you manage risks posed by others? If you use a co-packer, do you know their policies on allergen management?

WHY IS DOCUMENTATION NEEDED?

- Only documentation *required* is for training
- Other components of your pre-requisite program do not require written plan or implementation records
- However, what possible benefits are there to documentation GMP?
  - How do you know if your employees did what they said they would do?

BREAKOUT!

- Assign each person in your group one of the specified areas for GMPs
  - Personnel
  - Plant and grounds
  - Sanitary operations
  - Sanitary facilities and controls
  - Equipment and utensils
  - Processes and controls
  - Warehousing and distribution
  - Holding and distribution of human food by-products for use as animal food, and
  - Defect action levels
- Have each person develop a written plan for documentation
- What worked well? What didn't

Business Name: _____ Issue Date:_____

Address:_____

NAME OF GMP PLAN:

Purpose:

Procedure:

Who is responsible?

Associated Records:

Corrective Actions:

Business Name: _____ Issue Date:_____

Address:_____

NAME OF MONITORING RECORD:

DATE						
11/3/18						
11/4/18						
11/5/18						
11/6/18						
11/7/18						
11/8/18						
11/9/18						

EMPLOYEE TRAINING

OBJECTIVES

By the end of this module, participants will:

- Have identified the requirements for employee training
- Developed a documentation system for managing those records
- Received sufficient training and records following this course
- Be aware of available resources for ongoing employee training in their facilities

WHAT IS THE GOAL

Why train?

- Employees are the "boots on the ground" for implementing food safety and GMPs
- GMPs may not be immediately obvious and previous experiences may vary among employees
- Employee turnover
- Employees should have training appropriate for their role and responsibilities

REGULATION

Subpart A – General Provisions

21 CFR 117.4 Qualifications of individuals who manufacture, process, pack or hold food

- (a) *Applicability.* (1) The management of an establishment must ensure that all individuals who manufacture, process, pack, or hold food subject to subparts B and F of this part are qualified to perform their assigned duties.
- (2) The owner, operator, or agent in charge of a facility must ensure that all individuals who manufacture, process, pack, or hold food subject to subpart C, D, E, F, or G of this part are qualified to perform their assigned duties.
- (b) *Qualifications of all individuals engaged in manufacturing, processing, packing, or holding food.* Each individual engaged in manufacturing, processing, packing, or holding food (including temporary and seasonal personnel) or in the supervision thereof must:
- (1) Be a qualified individual as that term is defined in 117.3--*i.e.,* have the education, training, or experience (or a combination thereof) necessary to manufacture, process, pack, or hold clean and safe food as appropriate to the individual's assigned duties; and
- (2) Receive training in the principles of food hygiene and food safety, including the importance of employee health and personal hygiene, as appropriate to the food, the facility and the individual's assigned duties.

REGULATION

Subpart A – General Provisions

21 CFR 117.4 Qualifications of individuals who manufacture, process, pack or hold food

- (c) *Additional qualifications of supervisory personnel.* Responsibility for ensuring compliance by individuals with the requirements of this part must be clearly assigned to supervisory personnel who have the education, training, or experience (or a combination thereof) necessary to supervise the production of clean and safe food.

WHAT MAKES TRAINING HARD?

- One of the more difficult challenges for many smaller businesses is to convert the general conditions and practices described in the GMP regulation into routine or periodic procedures that will ensure compliance.
  - 25,785 establishments involved in food manufacturing
  - 33,867 wholesale establishments of grocery and related products
  - 6,754 wholesale establishments of farm product raw materials
  - 1,883 refrigerated or farm product warehouse or storage facilities
- These firms employed over 2.3 million individuals. These statistics underscore the scope of the challenges associated with development and delivery of effective training to ensure food safety.

Ken Gall, Food Safety Magazine

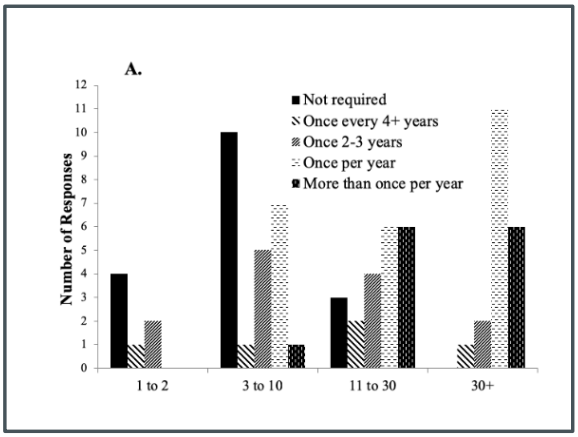
WHAT ARE FEATURES OF HIGH QUALITY EMPLOYEE TRAINING?

- Employees are trained in a timely manner
- Content is specific to job/facility
- Appropriate weight is given to relevant hazards and high risk scenarios
- Employees are engaged during training
- Learning is assessed following training
- But, a simple test may not sufficiently evaluate an employee's knowledge retention and application
- Employee training is a continuous process

WHO NEEDS TO BE TRAINED?

- All individuals who manufacture, process, pack, or hold food
- May include the following roles:
  - Equipment operators
  - QA/QC
  - Sanitation crew
  - Warehouse manager
- How does employee turnover impact training efficacy?
- When a new employee is hired, how long until they receive food safety training?

HOW FREQUENTLY DO THEY NEED TO BE TRAINED?



- Regulation only states that they must be qualified and receive training, does not establish frequency for refresher training
- Optional rule of thumb:
  - Whenever an employee's responsibilities change
  - Whenever an issue solvable by training is identified
  - At least once a year

WHAT TYPE OF TRAINING SHOULD THEY RECEIVE

- Receive training in the principles of food hygiene and food safety, including the importance of employee health and personal hygiene, as appropriate to the food, the facility and the individual's assigned duties.
- Could be delivered by:
  - Instruction by supervisor
  - Extension courses
  - Online classes
- Tradeoffs regarding cost, time, and quality of instruction exist for each training method and options
- Resources for GMP training provided in subsequent slides

DOCUMENTATION

***Records.* Records that document training required must be established and maintained.**

- What information is useful to keep on a training log?
  - Title of the record, facility name, etc.
  - Name of the employee trained
  - Date of the training
  - Signature or initials of trainer or supervisor
  - Type or content of the training (e.g. GMPs, HACCP, thermal processing, etc.)

EXAMPLE DOCUMENTATION

Facility Name: ABC Food Company
Record Title: Employee Training Log
Last updated: December, 2018

Employee Name	Title	Date of Training	Training Type	Supervisor Signature
Bob Jones	Shift manager	November 2018	PCQI	B Jones
Candace Doe	Line operator	December 2018	GMPs	B Jones
Sheryl Cutter	Warehouse supervisor	December 2018	GMPs	B Jones
Jerome Cup	Pasteurizer operator	December 2018	GMPs	B Jones
Lisa Marie	Business owner	December 2018	GMPs	B Jones
Travis Mark	QA Technician	December 2018	GMPs	B Jones

WHAT CONTENTS NEEDS TO BE INCLUDED IN TRAINING?

- Receive training in the principles of food hygiene and food safety, including the importance of employee health and personal hygiene, as appropriate to the food, the facility and the individual's assigned duties.
- Subpart B
- § 117.10 - Personnel.
  - § 117.20 - Plant and grounds.
  - § 117.35 - Sanitary operations.
  - § 117.37 - Sanitary facilities and controls.
  - § 117.40 - Equipment and utensils.
  - § 117.80 - Processes and controls.
  - § 117.93 - Warehousing and distribution.
  - § 117.95 - Holding and distribution of human food by-products for use as animal food.
  - § 117.110 - Defect action levels.

RESOURCES - ONLINE

- https://instituteforfoodsafety.cornell.edu/trainings/good-manufacturing-practices-registration/

- Module 1: GMP Regulation & Training
- Module 2: Food Safety: Microbes & Allergens
- Module 3: Personnel: Health & Hygiene
- Module 4: Plant Grounds & Pest Control
- Module 5: Plant Construction & Design
- Module 6: Sanitary Facilities: Water, Plumbing & Toilets
- Module 7: Sanitary Operations: Cleaning & Sanitizing
- Module 8: Equipment & Utensils
- Module 9: Plant Operations & Raw Materials
- Module 10: Manufacturing Operations: Process Controls
- Module 11: Warehousing, Food Disposition & Defects
- Module 12: Building Sanitation Procedures

- Various online certificate programs
- Can be completed over multiple sessions from remote locations

INTERNAL TRAINING DEVELOPMENT

WHAT TO INCLUDE?

REMAINING SLIDES ARE REFERENCES FOR INTERNAL USE

- Questions?

POLICIES AND PRACTICES

- Where do employees eat lunch? Where can they take a smoke break?
- Are there changing rooms and what are the rules on clothing, aprons, and gloves?
- Can employees keep food and drinks on-site, where?
- How do you handle trash disposal?
- How do employees wash their uniforms?

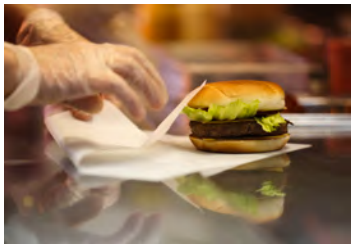
HAZARDS

- Discuss the three types of hazards: biological, chemical, and physical
- What hazards are relevant to your facility?
- Do employees know what practices control these hazards or enhance the risk?
- What allergens are in your facility?
- How are allergen-containing ingredients and products stored? What are the labeling requirements? Do you use dedicated equipment and utensils?

JOB-SPECIFIC PRACTICES

- What equipment does the employee need to know how to operate?
- Are there operational specifications the equipment must adhere to?
- Does he or she know who to contact and what to do if an issue with the equipment occurs?
- Under what circumstances should the employee stop the process?
- What records should the employee be responsible for?

EMPLOYEE HEALTH AND HYGIENE



- How should employees contain an on-the-job injury?
- Under what circumstances should an employee stay home to prevent spreading illness?
- When should employees wash their hands? How should employees wash their hands?
- What are the rules on hair restrains and jewelry?
- How should employees address cuts and open sores?

EQUIPMENT AND UTENSILS

- What hazards can be spread by equipment and utensils?
- Are dedicated utensils assigned for certain functions in production and sanitation? Are these color coded?
- How are utensils stored to prevent cross-contamination?
- What surfaces on equipment are in contact with food?
- Do parts of the equipment need removed for cleaning to prevent contamination?

CLEANING AND SANITATION

- What is the cleaning schedule for your facility?
- Who is responsible for cleaning and sanitizing what equipment?
- What detergents and sanitizers are used on what surfaces? At what concentrations?
- How do you know when a surface is clean?
- What are the consequences of doing a poor job cleaning and sanitizing?

RE-WORK, IN-PROCESS, ON HOLD PRODUCT

- At what points in your process might product be separated for re-work or put on hold?
- How is this product stored or held? What would mishandling this product do to food safety risks?
- Are allergens present in re-work? If so, how are they identified? Are they added back into non-allergen containing products?

PESTS AND PREVENTATIVE MAINTENANCE

- What types of pests are relevant to your facility and what threat to food safety do they represent?
- What measures are in place to control pests in food production and storage areas?
- What should you do if you see a rodent? A cockroach? Flies?
- How often should you check equipment and utensils for damage or wear-and-tear?
- What should be done if damage is found on equipment?

IN CASE OF EMERGENCY

- Emergency procedures for crises and disasters
- Consider employee safety, food safety assurance, and business continuity
- Review procedures, roles, and important contacts

QUALIFIED FACILITIES - FSMA DOCUMENT DEVELOPMENT

OBJECTIVES

By the end of this module, participants will:

- Understand the requirements for a qualified exemption
- Complete the documentation for a qualified facility attestation to be compliant with the PCHF rule
- Recognize remaining food safety needs and considerations

REGULATION CANNOT BE ONE SIZE FITS ALL

- No food facility is exempt from the responsibility to produce safe food
- However, different scales and types of supply chains pose varying levels of risk to public health
- One of the parts of this risk-based, scale-sensitive approach was a provision that set forth modified requirements for very small businesses

PCHF REQUIREMENTS FOR A QUALIFIED FACILITY

- Subject to modified requirements in 21 CFR Part 117.201 of the Preventive Controls for Human Food Rule
- These modified requirements require the business to submit a form to FDA, attesting to its status as a qualified facility

WHAT DOES A PREVENTIVE CONTROL PLAN ENTAIL?

- Subpart C and G
- Written hazard analysis
- As relevant, preventive control programs for:
  - Process Preventive Controls
  - Allergen Preventive Controls
  - Sanitation Preventive Controls
  - Supplier Preventive Controls

ELIGIBILITY TO BE A QUALIFIED FACILITY

1. "Very Small Business"
   - Less than $1 million in annual sales (or the value of food you hold, manufacture, or distribute) of human food, OR
2. Less than $500,000 in annual gross sales (adjusted for inflation) over a previous three-year period AND sells the majority of the food directly to a "qualified end-user"
   - "Qualified end-user": i.e., a consumer, or a restaurant or retail food establishment (e.g., a grocery store) that is located in the same state as the facility or not more than 275 miles from the facility)

QUALIFIED FACILITIES ARE SUBJECT TO 5 PARTS OF THE PCHF RULE

1. General provisions
2. Current Good Manufacturing Practices
3. Modified requirements that apply to a qualified facilities
4. Certain recordkeeping requirements
5. Withdrawal of modified requirements that apply to qualified facilities

1. GENERAL PROVISIONS

- Food facilities are prohibited through pre-existing law from selling adulterated food
- Definition of adulterated food?

2. CURRENT GOOD MANUFACTURING PRACTICES

- Facilities will be required to follow updated cGMPs in Subpart B

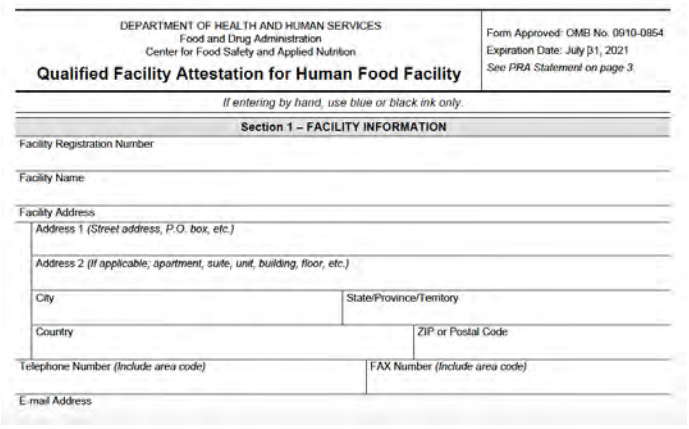
3. DOCUMENTATION REQUIRED FOR QUALIFIED FACILITIES

- Under the modified requirements, qualified facilities must submit two types of documentation to FDA:

1. A statement from the qualified facility certifying that it is a qualified facility
2. Either:
    1. Documentation showing that the facility has identified hazards, is implementing preventive controls, and is monitoring to ensure the effectiveness of the preventive controls; OR
    2. Documentation that the facility is complying with applicable non-Federal food safety law (e.g., state, local, or county)

FDA BIOTERRORISM REGISTRATION (BT REGISTRATION)

- BT registration requirements existed prior to FSMA – you may already be registered!
- If you are not required to BT register, you are not subject to subpart C and G of the PCHF rule
  - Still subject to GMPs either way
- If you do BT register, the business size calculation may qualify you for an exemption from subparts C and G
- Who does not have to BT register?
  - Farms
  - Food service
  - Retail establishments
- To register, use Form FDA 3537 available through the same portal as the qualified facility attestation through the "FDA Industry Systems" https://www.access.fda.gov/



DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration
Center for Food Safety and Applied Nutrition

Qualified Facility Attestation for Human Food Facility

Form Approved: OMB No. 0910-0854
Expiration Date: July 31, 2021
See PRA Statement on page 3.

If entering by hand, use blue or black ink only.

Section 1 – FACILITY INFORMATION

Facility Registration Number

Facility Name

Facility Address

Address 1 *(Street address, P.O. box, etc.)*

Address 2 *(If applicable; apartment, suite, unit, building, floor, etc.)*

City | State/Province/Territory

Country | ZIP or Postal Code

Telephone Number *(Include area code)* | FAX Number *(Include area code)*

E-mail Address

COMPLETING THE ATTESTATION FORM

(FDA 3942A)

Section 2 – TYPE OF NOTIFICATION

a. ☐ Initial Submission (21 CFR 117.201(c)(2)(i)) – Complete Sections 3, 4 and 5 only.

b. ☐ Biennial (Renewal) Submission (21 CFR 117.201(c)(2)(ii)) – Complete Sections 3, 4 and 5 only.

c. ☐ Status Change (21 CFR 117.201(c)(3)) – Complete Section 6 only.

COMPLETING THE ATTESTATION FORM

(FDA 3942A)

Section 3 – QUALIFICATION FOR MODIFIED REQUIREMENTS *(Fill out only if Section 6 does not apply.)*

Human food facilities may be exempt from the preventive controls regulations in 21 CFR part 117, primarily in subparts C and G, with associated requirements in subparts A, D, E, and F, under 21 CFR 117.5(a). Check the appropriate box to indicate the reason why your facility is a qualified facility.

When including the sales by any subsidiary; affiliate; or subsidiaries or affiliates, collectively, of any entity of which the facility is a subsidiary or affiliate:

☐ The above-named facility qualifies for the exemption as a "very small business" as defined in 21 CFR 117.3 because, during the preceding three calendar years, the facility (including any subsidiaries and affiliates) averaged less than $1,000,000, adjusted for inflation, per year, in sales of human food plus the market value of human food manufactured, processed, packed, or held without sale (e.g., held for a fee).

☐ The above-named facility qualifies for the exemption as a "qualified facility" as defined in 21 CFR 117.3 because:

(1) during the preceding three calendar years, the average annual monetary value of the food manufactured, processed, packed, or held at the facility that was sold directly to qualified end-users (as defined in 21 CFR 117.3) exceeded the average annual monetary value of the food sold by the facility to all other purchasers; **and**

(2) the average annual monetary value of all food sold during the preceding three calendar years was less than $500,000, adjusted for inflation.

COMPLETING THE ATTESTATION FORM

(FDA 3942A)

Section 4 – COMPLIANCE WITH 21 CFR 117.201 *(Fill out only if Section 6 does not apply.)*

Check the box to indicate how your facility is in compliance with 21 CFR 117.201(a)(2).

☐ I, as the owner, operator, or agent in charge of the above-named facility, (1) have identified the potential hazards associated with the food being produced, (2) am implementing preventive controls to address the hazards, **and** (3) am monitoring the performance of the preventive controls to ensure that such controls are effective. (21 CFR 117.201(a)(2)(i).) I understand that I am required to maintain records to support this attestation, but that I am not required to submit those records with this attestation. (21 CFR 117.201(f).)

☐ The above-named facility is in compliance with State, local, county, tribal, or other applicable non-Federal food safety law including relevant laws and regulations of foreign countries. This is based on my knowledge, as the owner, operator, or agent in charge of the above-named facility, of the facility's licenses, inspection reports, certificates, permits, credentials, certification by an appropriate agency (such as a State department of agriculture), or other evidence of oversight. (21 CFR 117.201(a)(2)(ii).) I understand that I am required to maintain records to support this attestation, but that I am not required to submit those records with this attestation. (21 CFR 117.201(f).)

COMPLETING THE ATTESTATION FORM

(FDA 3942A)

Section 5 – ATTESTATION STATEMENT*(Fill out only if Section 6 does not apply.)*

I attest that, to the best of my knowledge and belief, the information provided in this Qualified Facility Attestation is true, accurate and complete and that the above-named facility qualifies for the exemption requested. I understand that, as the owner, operator, or agent in charge of the above-named facility, I must maintain those records relied upon to support these attestations (21 CFR 117.201(f)) and make those records promptly available to a duly authorized representative of the Secretary of Health and Human Services for official review and copying upon oral or written request (21 CFR 117.320). I also understand that under 18 U.S.C. 1001, anyone who knowingly and willfully makes a materially false, fictitious, or fraudulent statement to the U.S. Government is subject to criminal penalties.

Signature	Date

Printed Name and Title:

Please check one option below that best describes your relationship to the facility.

☐ Owner ☐ Operator ☐ Agent in Charge

Please provide your contact information below if it differs from the facility information provided in Section 1.

Contact Address

Address 1 *(Street address, P.O. box, etc.)*

COMPLETING THE ATTESTATION FORM

(FDA 3942A)

4. RECORD KEEPING REQUIREMENTS

- A qualified facility must maintain records that support the documentation required
  - Examples: financial records, GAP audit records, hazard analysis, SOPs and associated monitoring documentation, etc.
- These records must:
  - Be accurate and legible
  - Be retained at the facility for at least two years after the date they were prepared
  - Records >6 months old can be stored offsite (must be retrievable in 24 hours)

5. FDA CAN REVOKE QUALIFIED FACILITY STATUS

- FDA can withdraw a qualified exemption under certain broad circumstances:

1. Foodborne illness outbreak linked to a qualified facility
2. Necessary to protect the public health and prevent or mitigate a foodborne illness outbreak
   - FDA discretion following an inspection
   - Based on conduct or conditions associated with the facility

WILL THE FDA DETERMINE IF MY FACILITY IS A QUALIFIED FACILITY?

NO

- You are responsible for determining whether your business meets the definition of a qualified facility
- Subject to verification by FDA

CALCULATION TO DETERMINE QUALIFIED FACILITY STATUS

- How often do I need to do this calculation?
  - Each year
  - No later than July 1 of each calendar year (21 CFR 117.201(c)(1)).

CALCULATION TO DETERMINE QUALIFIED FACILITY STATUS

- Include ALL human food
- Regardless of whether the human food is subject to the PCHF Rule
  - Foods subject to HACCP regulations
    - juice, seafood
  - Food subject to other regulations
    - low acid canned foods, dietary supplements
  - Raw Agricultural Commodities (RACs)
    - produce, grains, milk, eggs
  - USDA regulated products
    - meat, poultry

HOW DO I CALCULATE MY AVERAGE ANNUAL SALES?

- Determine which three years to include in the average
- Determine annual sales and market value of food manufactured, processed, packed, or held without sale for each of the three years
- Adjust annual sales and market value for each year for inflation
- Calculate the inflation-adjusted average annual sales and market value

WHAT YEARS DO I USE IN MY CALCULATION?

- Average is based on the 3-year period preceding the applicable calendar year
- The applicable calendar year is the current year
- If the current year is 2019, the three preceding calendar years would be 2016, 2017 and 2018

WHAT IF I DO NOT HAVE 3 YEARS OF FINANCIAL RECORDS FOR MY CALCULATION?

- The compliance date for you to keep records to support your status as a qualified facility is January 1, 2016
  - The compliance date for you to begin complying with the modified requirements for a qualified facility is September 17, 2018.
  - FDA intends to accept records for the preceding 2 calendar years as adequate to support status as a qualified facility.
- If you begin operations between January 1, 2017, and September 17, 2018, your applicable financial records would not cover even 2 calendar years by September 17, 2018.
  - FDA intends to accept records for the preceding one or two years as adequate to support your status as a qualified facility until you have been in operation long enough to provide three years of records.
- If you begin operations after January 1, 2018, you can rely on a projected estimate of revenue (or market value) at the time you begin operations.
  - FDA intends to evaluate the credibility of the projected revenue (or market value) based on such factors as your number of employees

HOW DO I DETERMINE ANNUAL SALES OF HUMAN FOOD?

- Determine your annual sales using resources such as:
  - Tax Forms, e.g. Gross Receipts or Sales (Line 1A) from Internal Revenue Service (IRS) Form 1120;
  - Accounting documents, e.g. Total Sales or Revenues from an Income Statement; or
  - Invoices and bills of lading.
- Do not adjust the total sales for the year to include the cost of the sales – for example, you should not adjust total sales for the cost of labor

DO I SUBTRACT THE SALES FROM "QUALIFIED END USERS"?

- No
- The definition of very small business is based on average annual sales plus market value and is not adjusted for sales to a qualified end-user

HOW DO I ADJUST ANNUAL SALES PLUS MARKET VALUE OF HUMAN FOOD PRODUCTS FOR INFLATION?

- Use the U.S. Bureau of Economic Analysis' Implicit Price Deflators for Gross Domestic Product (GDP)
  - Adjust using the 2011 Implicit Price Deflator as the baseline

$$\frac{\text{Annual sales + market value of food held} \times \text{2011 implicit price deflator index number}}{\text{Current year implicit price deflator number}} = \text{Inflation-adjusted sales plus market value}$$

HOW DO I CALCULATE THE THREE-YEAR AVERAGE OF THE INFLATION-ADJUSTED ANNUAL SALES PLUS MARKET VALUE OF HUMAN FOOD?

$$\frac{\text{Annual Sales + Market Value Adjusted for Inflation (Previous Year 3)} + \text{Annual Sales + Market Value Adjusted for Inflation (Previous Year 2)} + \text{Annual Sales + Market Value Adjusted for Inflation (Previous Year 1)}}{3}$$

RECORDS NEEDED TO SHOW YOUR BUSINESS IS AN ELIGIBLE QUALIFIED FACILITY

- Records to support the attestations you make on Form FDA 3942a
- Records that you use for your calculations of annual sales
- Records of the actual calculations that you make
  - e.g., calculations of inflation-adjusted annual sales plus market value and the three-year average of inflation-adjusted annual sales plus market value

WHAT IF I SUPPLY INGREDIENTS TO A PROCESSOR WHO IS NOT A QUALIFIED FACILITY?

- Do you control a hazard for that processor?
  - For example, you sell chocolate to a granola bar manufacturer. The granola bar manufacturer does not apply a baking step to kill pathogens and relies on you to ensure the chocolate does not contain *Salmonella*.
- The receiving facility (granola bar manufacturer) must obtain written assurance that a supplier is a qualified facility before first approving the supplier for an applicable calendar year, and on an annual basis thereafter, by December 31 of each calendar year, for the following calendar year (21 CFR 117.430(c)(1)). Note that the receiving facility must obtain other written assurances from the supplier every two years.

FORM FDA 3942A RESUBMISSIONS

- Must re-submit Form FDA 3942a to FDA every 2 years
  - Beginning 2020
- During the food facility biennial registration renewal period beginning on October 1 and ending on December 31

DO FARMS NEED TO SUBMIT FORM FDA 3942A?

NO

WHAT OTHER EXEMPTIONS FROM C AND G EXIST?

- Alcoholic beverages
- Retail/food service
- 501 3C
- Description can be found in 21 CFR 117.5
  - https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=117.5

HOW TO MANAGE THINGS OUTSIDE OF PC PLAN IF EXEMPT

What type of systems do you use to ensure food safety if you don't use a preventive control food safety plan?

HOW TO MANAGE THINGS OUTSIDE OF PC PLAN IF EXEMPT

- Time/temperature measurements if critical for safety
- pH measurements
- Employee training
- Measuring sanitizer concentration
- Visual inspections of cleanliness by a supervisor following sanitation
- Checking allergen declaration statements on each batch of product
- Reviewing allergen statements on incoming ingredients
- Working with kitchen managers, if in a shared use facility, to understand and manage the use of allergens by other clients in shared spaces

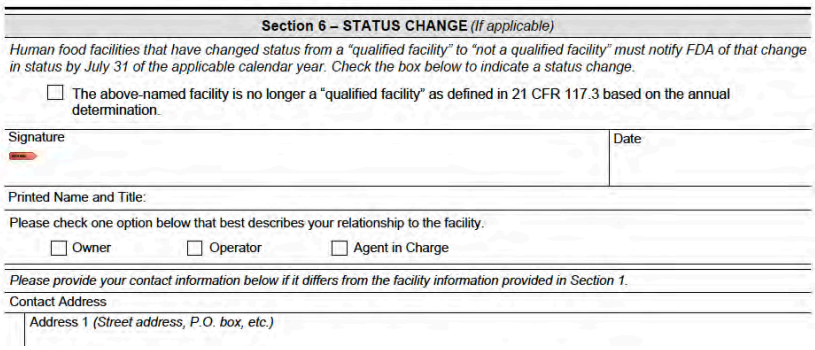
OPTIONAL RECORD KEEPING

- Make sheets that include processing and lot code information
- Time/temperature logs
- Traceability records
- pH calibration and measurement records
- Records documenting sanitation inspections and sanitizer concentrations
- Check-sheets for allergen labels for employees

- *What record is not optional?

WHEN MUST I SUBMIT FORM FDA 3942A TO FDA IF MY FACILITY'S STATUS CHANGES FROM "QUALIFIED FACILITY" TO "NOT A QUALIFIED FACILITY"?

- Submit Form FDA 3942a notifying FDA of that change in status by July 31 of the applicable calendar year



Section 6 – STATUS CHANGE *(If applicable)*

Human food facilities that have changed status from a "qualified facility" to "not a qualified facility" must notify FDA of that change in status by July 31 of the applicable calendar year. Check the box below to indicate a status change.

☐ The above-named facility is no longer a "qualified facility" as defined in 21 CFR 117.3 based on the annual determination.

Signature | Date

Printed Name and Title:

Please check one option below that best describes your relationship to the facility.

☐ Owner ☐ Operator ☐ Agent in Charge

Please provide your contact information below if it differs from the facility information provided in Section 1.

Contact Address

Address 1 *(Street address, P.O. box, etc.)*

COMPLETING THE ATTESTATION FORM

(FDA 3942A)

BREAKOUT!

- Complete qualified facility exemption form
  - This can be used as the template for completing your electronic submission at https://www.access.fda.gov/
- Discuss with your group how you will manage your food safety hazards, either within or outside of a preventive controls food safety plan

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration
Center for Food Safety and Applied Nutrition

Qualified Facility Attestation for Human Food Facility

Form Approved: OMB No. 0910-0854
Expiration Date: July 31, 2021
See PRA Statement on page 3.

If entering by hand, use blue or black ink only.

Section 1 – FACILITY INFORMATION

Facility Registration Number

Facility Name

Facility Address

Address 1 *(Street address, P.O. box, etc.)*

Address 2 *(If applicable; apartment, suite, unit, building, floor, etc.)*

City | State/Province/Territory

Country | ZIP or Postal Code

Telephone Number *(Include area code)* | FAX Number *(Include area code)*

E-mail Address

Section 2 – TYPE OF NOTIFICATION

a. ☐ Initial Submission (21 CFR 117.201(c)(2)(i)) – Complete Sections 3, 4 and 5 only.

b. ☐ Biennial (Renewal) Submission (21 CFR 117.201(c)(2)(ii)) – Complete Sections 3, 4 and 5 only.

c. ☐ Status Change (21 CFR 117.201(c)(3)) – Complete Section 6 only.

Section 3 – QUALIFICATION FOR MODIFIED REQUIREMENTS *(Fill out only if Section 6 does not apply.)*

Human food facilities may be exempt from the preventive controls regulations in 21 CFR part 117, primarily in subparts C and G, with associated requirements in subparts A, D, E, and F, under 21 CFR 117.5(a). Check the appropriate box to indicate the reason why your facility is a qualified facility.

When including the sales by any subsidiary; affiliate; or subsidiaries or affiliates, collectively, of any entity of which the facility is a subsidiary or affiliate:

☐ The above-named facility qualifies for the exemption as a "very small business" as defined in 21 CFR 117.3 because, during the preceding three calendar years, the facility (including any subsidiaries and affiliates) averaged less than $1,000,000, adjusted for inflation, per year, in sales of human food plus the market value of human food manufactured, processed, packed, or held without sale (e.g., held for a fee).

☐ The above-named facility qualifies for the exemption as a "qualified facility" as defined in 21 CFR 117.3 because:

(1) during the preceding three calendar years, the average annual monetary value of the food manufactured, processed, packed, or held at the facility that was sold directly to qualified end-users (as defined in 21 CFR 117.3) exceeded the average annual monetary value of the food sold by the facility to all other purchasers; **and**

(2) the average annual monetary value of all food sold during the preceding three calendar years was less than $500,000, adjusted for inflation.

Section 4 – COMPLIANCE WITH 21 CFR 117.201 *(Fill out only if Section 6 does not apply.)*

Check the box to indicate how your facility is in compliance with 21 CFR 117.201(a)(2).

☐ I, as the owner, operator, or agent in charge of the above-named facility, (1) have identified the potential hazards associated with the food being produced, (2) am implementing preventive controls to address the hazards, **and** (3) am monitoring the performance of the preventive controls to ensure that such controls are effective. (21 CFR 117.201(a)(2)(i).) I understand that I am required to maintain records to support this attestation, but that I am not required to submit those records with this attestation. (21 CFR 117.201(f).)

☐ The above-named facility is in compliance with State, local, county, tribal, or other applicable non-Federal food safety law including relevant laws and regulations of foreign countries. This is based on my knowledge, as the owner, operator, or agent in charge of the above-named facility, of the facility's licenses, inspection reports, certificates, permits, credentials, certification by an appropriate agency (such as a State department of agriculture), or other evidence of oversight. (21 CFR 117.201(a)(2)(ii).) I understand that I am required to maintain records to support this attestation, but that I am not required to submit those records with this attestation. (21 CFR 117.201(f).)

Section 5 – ATTESTATION STATEMENT *(Fill out only if Section 6 does not apply.)*

I attest that, to the best of my knowledge and belief, the information provided in this Qualified Facility Attestation is true, accurate and complete and that the above-named facility qualifies for the exemption requested. I understand that, as the owner, operator, or agent in charge of the above-named facility, I must maintain those records relied upon to support these attestations (21 CFR 117.201(f)) and make those records promptly available to a duly authorized representative of the Secretary of Health and Human Services for official review and copying upon oral or written request (21 CFR 117.320). I also understand that under 18 U.S.C. 1001, anyone who knowingly and willfully makes a materially false, fictitious, or fraudulent statement to the U.S. Government is subject to criminal penalties.

Signature	Date

Printed Name and Title:

Please check one option below that best describes your relationship to the facility.

☐ Owner ☐ Operator ☐ Agent in Charge

Please provide your contact information below if it differs from the facility information provided in Section 1.

Contact Address

Address 1 *(Street address, P.O. box, etc.)*

Address 2 *(Apartment, suite, unit, building, floor, etc.)*

City	State/Province/Territory

Country	ZIP or Postal Code

Telephone Number *(Include area code)*	FAX Number *(Include area code)*

E-mail Address

Section 6 – STATUS CHANGE *(If applicable)*

Human food facilities that have changed status from a "qualified facility" to "not a qualified facility" must notify FDA of that change in status by July 31 of the applicable calendar year. Check the box below to indicate a status change.

☐ The above-named facility is no longer a "qualified facility" as defined in 21 CFR 117.3 based on the annual determination.

Signature	Date

Printed Name and Title:

Please check one option below that best describes your relationship to the facility.

☐ Owner ☐ Operator ☐ Agent in Charge

Please provide your contact information below if it differs from the facility information provided in Section 1.

Contact Address

Address 1 *(Street address, P.O. box, etc.)*

Address 2 *(Apartment, suite, unit, building, floor, etc.)*

City	State/Province/Territory

Country	ZIP or Postal Code

Telephone Number *(Include area code)*	FAX Number *(Include area code)*

E-mail Address

If section 6 applied to you, refer to the FDA return address noted beneath Section 6.

Return your completed Form FDA 3942a to the following FDA address:

U.S. Food and Drug Administration
(HFS-681)
5001 Campus Drive
College Park, MD 20740

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

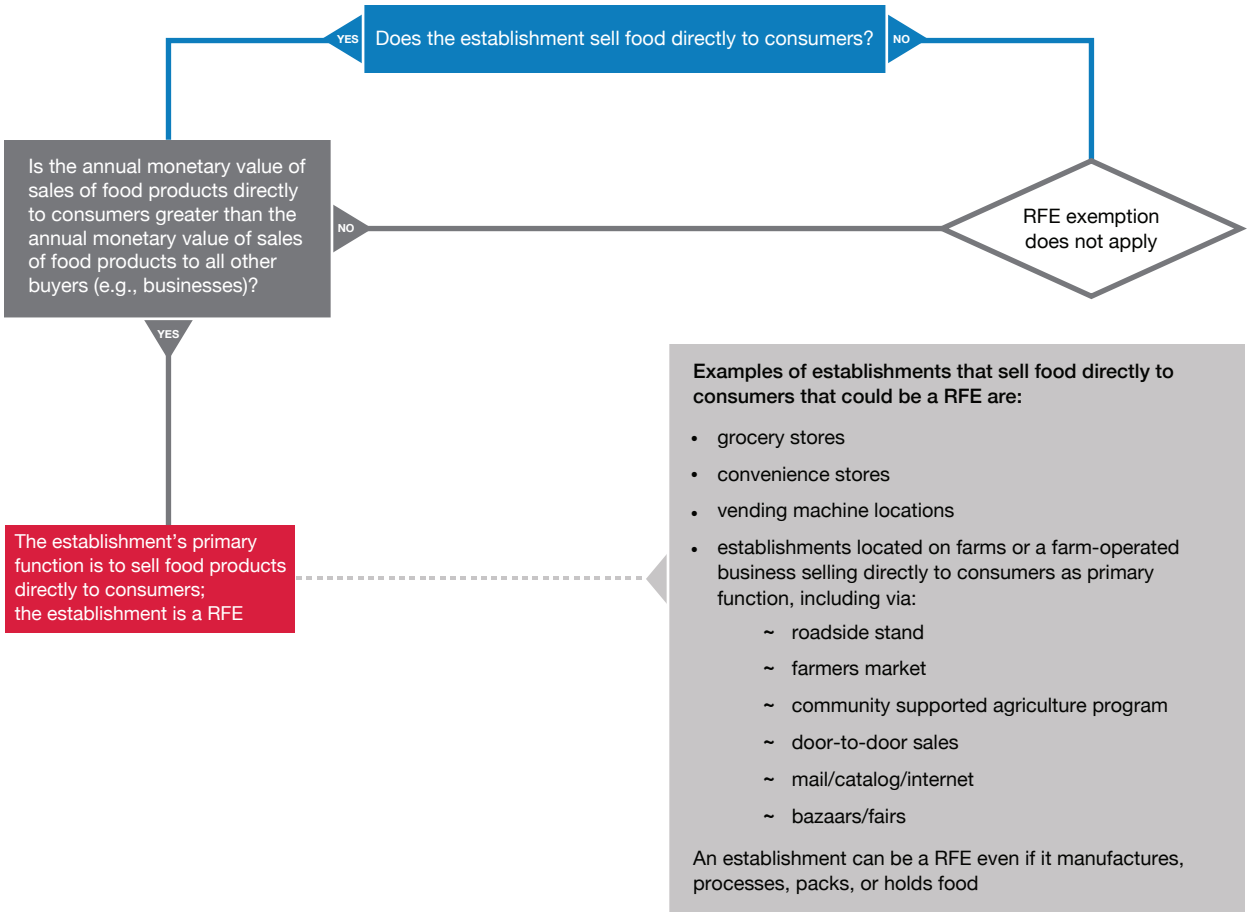
The burden time for this collection of information is estimated to average 30 minutes per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Operations
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Retail Food Establishment Exemption Flowchart

Facilities that manufacture/process, pack, or hold food for human or animal consumption in the United States must be registered unless the facility satisfies one of the exemptions in 21 CFR 1.226. One of the exemptions is for "retail food establishments" (RFEs), as defined in 21 CFR 1.227. This chart describes the definition for RFEs.



Retail food establishment means an establishment that sells food products directly to consumers as its primary function. The term "retail food establishment" includes facilities that manufacture, process, pack, or hold food if the establishment's primary function is to sell from that establishment food, including food that it manufactures, processes, packs, or holds, directly to consumers. A retail food establishment's primary function is to sell food directly to consumers if the annual monetary value of sales of food products directly to consumers exceeds the annual monetary value of sales of food products to all other buyers. The term "consumers" does not include businesses. A "retail food establishment" includes grocery stores, convenience stores, and vending machine locations. A "retail food establishment" also includes certain farm-operated businesses selling food directly to consumers as their primary function.

(1) Sale of food directly to consumers from an establishment located on a farm includes sales by that establishment directly to consumers:

(i) At a roadside stand (a stand situated on the side of or near a road or thoroughfare at which a farmer sells food from his or her farm directly to consumers) or farmers' market (a location where one or more local farmers assemble to sell food from their farms directly to consumers);

(ii) Through a community supported agriculture program. Community supported agriculture (CSA) program means a program under which a farmer or group of farmers grows food for a group of shareholders (or subscribers) who pledge to buy a portion of the farmer's crop(s) for that season. This includes CSA programs in which a group of farmers consolidate their crops at a central location for distribution to shareholders or subscribers; and

(iii) At other such direct-to-consumer sales platforms, including door-to-door sales; mail, catalog and Internet order, including online farmers markets and online grocery delivery; religious or other organization bazaars; and State and local fairs.

(2) Sale of food directly to consumers by a farm-operated business includes the sale of food by that farm-operated business directly to consumers:

(i) At a roadside stand (a stand situated on the side of or near a road or thoroughfare at which a farmer sells food from his or her farm directly to consumers) or farmers' market (a location where one or more local farmers assemble to sell food from their farms directly to consumers);

(ii) Through a community supported agriculture program. Community supported agriculture (CSA) program means a program under which a farmer or group of farmers grows food for a group of shareholders (or subscribers) who pledge to buy a portion of the farmer's crop(s) for that season. This includes CSA programs in which a group of farmers consolidate their crops at a central location for distribution to shareholders or subscribers; and

(iii) At other such direct-to-consumer sales platforms, including door-to-door sales; mail, catalog and Internet order, including online farmers markets and online grocery delivery; religious or other organization bazaars; and State and local fairs.

(3) For the purposes of this definition, "farm-operated business" means a business that is managed by one or more farms and conducts manufacturing/processing not on the farm(s).

TRANSITIONING TO A FOOD SAFETY PLAN

OBJECTIVES

By the end of this module, participants will:

- Have an understanding of requirement changes for businesses >$1 million/year
- Be able to convert acidified food scheduled processes into process preventive control plans
- Understand additional preventive control programs potentially necessary to manage food safety

BUSINESS GROWTH > $1 MILLION

- Your food business is very successful – great!
- What happens when you exceed sales of $1 million/year – how does that change your regulatory requirements regarding food safety?

FOOD SAFETY MODERNIZATION ACT

Subpart A – General Provisions

Subpart B – Current Good Manufacturing Practice

Subpart C – Hazard Analysis and Risk-based Preventive Controls

Subpart D – Modified Requirements

Subpart E – Withdrawal of a Qualified Facility Exemption

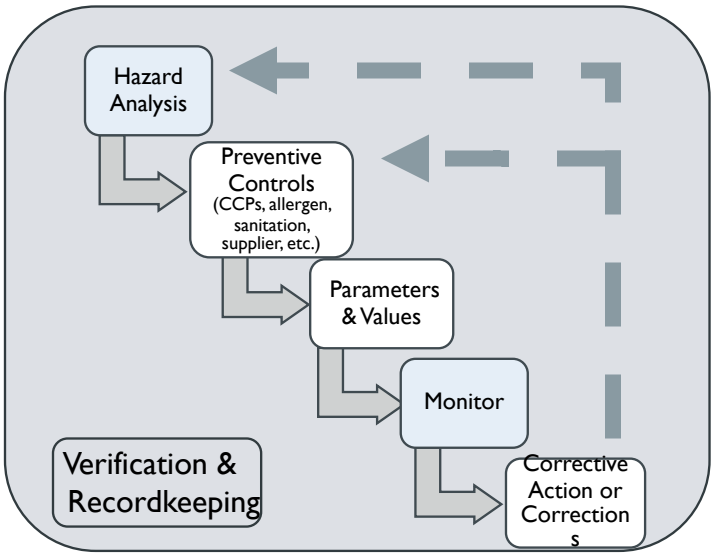
Subpart F – Requirements Applying to Records That Must be Established and Maintained

Subpart G – Supply-chain Program

FDA FOOD SAFETY MODERNIZATION ACT

- **Human Food**
- Produce Safety
- Animal Feed and Pet Food
- (etc…)

PREVENTIVE CONTROLS INCLUDE MORE THAN HACCP



EXAMPLE HACCP PLAN

Critical Control Point (CCP)	Hazard(s)	Critical Limits	Monitoring				Corrective Action	Verification	Record Keeping
			What	How	Frequency	Who			
Screening	Metal	Screen intact	Screen integrity	Visual	Daily, before and after production	Operator	Isolate affected product, reprocess or destroy, determine source of metal	Review all records within one week of preparation, annually measure the gage of the screen (<7 mm)	Screen integrity log, screen calibration log Corrective action log

CONVERSION OF A SCHEDULED PROCESS OR HACCP PLAN INTO A PREVENTIVE CONTROL PLAN

HACCP/Scheduled Process

- Critical Control Points (CCPs) – e.g. microbial kill step and controls for metal
- Critical factors for safety and stability – e.g. hot-fill hold temperature and time, pH, water activity

*Changes documentation requirement →

Preventive Controls Food Safety Plan

- Process Preventive Controls
  - CCPs or critical factors
- Sanitation Preventive Controls
  - Post-processing contamination where product is exposed to the environment
- Allergen Preventive Controls
  - Shared food processing equipment
  - Labeling
- Supplier Preventive Controls
  - If you do not control the hazard in-house

CONTENTS OF A FOOD SAFETY PLAN

Required

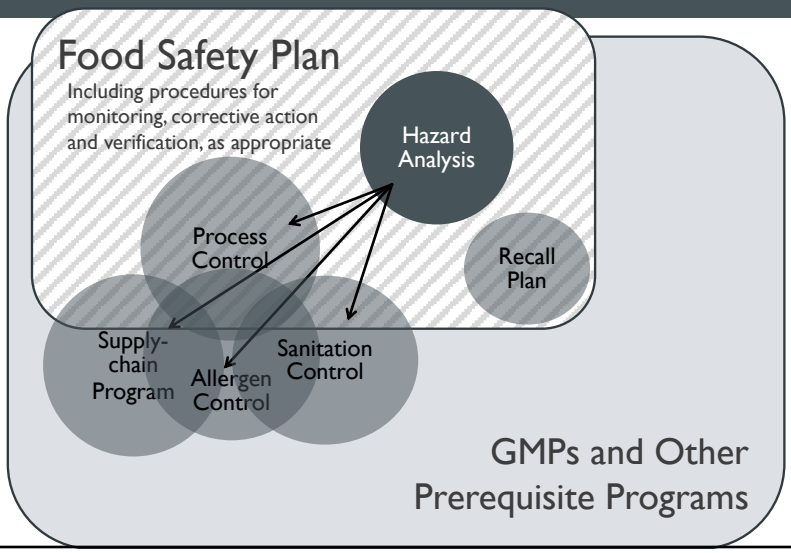
- Hazard analysis
- Preventive controls*
  - Process, food allergen, sanitation, supply-chain and other
  - Recall plan*
- Procedures for monitoring, corrective action and verification*

Useful

- Facility overview and Food Safety Team
- Product description
- Flow diagram
- Process description

* Required when a hazard requiring a preventive control is identified

PREVENTIVE FOOD SAFETY SYSTEMS



PROCESS TO IDENTIFY HAZARDS AND CONTROLS

1. List process steps and ingredients
2. Identify **known or reasonably foreseeable** (i.e., potential) **food safety hazards**
3. Determine if the hazard **requires a preventive control**
   - Severity and probability in the absence of control
4. Justify the decision
5. Identify preventive controls for significant hazards

Hazard Analysis	PRODUCT:					PAGE X of Y	
PLANT NAME					ISSUE DATE	mm/dd/yy	
ADDRESS					SUPERSEDES	mm/dd/yy	
(1) Ingredient/ Processing Step	(2) Identify potential food safety hazards introduced, controlled or enhanced at this step	(3) Do any potential food safety hazards require a preventive control?		(4) Justify your decision for column 3	(5) What preventive control measure(s) can be applied to significantly minimize or prevent the food safety hazard? *Process including CCPs, Allergen, Sanitation, Supply-chain, other preventive control*	(6) Is the preventive control applied at this step?	
		Yes	No			Yes	No
	B						
	C						
	P						

Hazard Analysis Form Example -
other formats may be used

PREVENTIVE CONTROLS MAY INCLUDE:

- Process preventive controls
- Food allergen preventive controls
- Sanitation preventive controls
- Supply-chain program

Described in PCQI training

POTENTIAL PREVENTIVE CONTROL EXAMPLES

Biological hazards

- Process controls that kill pathogens
  - E.g., cooking
- Process controls that prevent growth; e.g.,
  - Time/temperature controls
  - Checking formulation
- Supply-chain programs for sensitive ingredients used without a kill step
- Sanitation controls that prevent recontamination

Chemical hazards

- Supply-chain programs
- Allergen labeling
- Sanitation controls to prevent allergen cross-contact

Physical hazards

- Process controls such as
  - Filtering, metal detection, X-ray devices

BLANK PROCESS CONTROL FORM

PRODUCT: PAGE I of X
PLANT NAME: ISSUE DATE mm/dd/yy
ADDRESS: SUPERSEDES mm/dd/yy

Process Control	Hazard(s)	Critical Limits	Monitoring				Corrective Action	Verification	Records
			What	How	Frequency	Who			

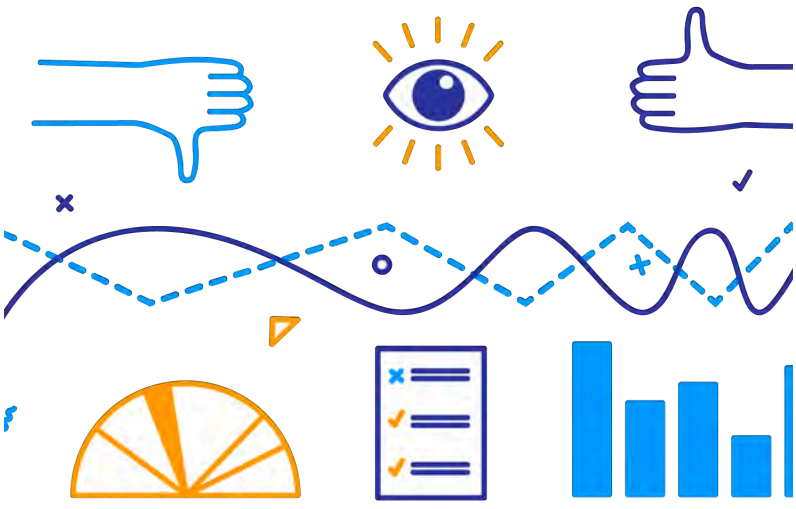
Pepper Jack Example

PRODUCT: Pepper Jack Cheese – Ready-to-Eat — PAGE 1 of X

PLANT NAME: Wisconsin Cheese Company — ISSUE DATE mm/dd/yy

ADDRESS: 123 Main Street, Monterey, USA — SUPERSEDES mm/dd/yy

Process Control	Hazard(s)	Critical Limits	Monitoring				Corrective Action	Verification	Records
			What	How	Frequency	Who			
Milk Pasteuriz-ation	Biological – pathogens	≥ 161 °F ≥ 15 secs	Milk temperature	Recording thermometer and chart recorder	Continuous monitoring of Mag Flow/Temperature at end of holding tube	Certified or trained pasteurizer operator	Flow divert, recirculate and Pasteurize Broken Seal Report – phosphatase every 4 hours Hold finished product for further disposition Determine cause of temperature deviation and correct. Document corrective action.	State timed & sealed record; Review of chart, Seal checks, Daily cut in/cut out, Recorder vs. indicating thermometer and signed by PCQI or designee within 7 working days;	HTST Chart and Deviation Reports Hold records Validation record as per 21 CFR Part 131.3(b) legal definition of pasteurization



POST-COURSE EVALUATIONS

PLANT NAME	ISSUE DATE	PAGE
ADDRESS	SUPERSEDES	PRODUCT CODE

Process Preventive Controls – Landscape Layout

Records			
Verification			
Corrective Action			
Monitoring	Who		
	Frequency		
	How		
	What		
Parameters, values or critical limits			
Hazard(s)			
Process Controls			

Contains Nonbinding Recommendations

Determination of Status as a Qualified Facility Under Part 117: Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food And Part 507: Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals

Guidance for Industry

Additional copies are available from:
Office of Compliance
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5001 Campus Drive
College Park, MD 20740
(tel) 240-701-5986
http://www.fda.gov/FoodGuidances

Policy and Regulations Staff (HFV-6)
Center for Veterinary Medicine
Food and Drug Administration
7500 Standish Place
Rockville, MD 20855
https://www.fda.gov/AnimalVeterinary/default.htm

You may submit electronic or written comments regarding this guidance at any time. Submit electronic comments to https://www.regulations.gov. Submit written comments on the guidance to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number FDA–2016–D–1164.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Food Safety and Applied Nutrition and Center for Veterinary Medicine

September 2018

OMB Control No. 0910-0854
Expiration Date: The current expiration date can be found in Form FDA 3942a and Form FDA 3942b.
See additional PRA statement in Section V of this guidance

Table of Contents

Determination of Status as a Qualified Facility Under Part 117: Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food And Part 507: Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals Guidance for Industry[1]

This guidance represents the current thinking of the Food and Drug Administration's (FDA or we) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA Food Safety Modernization Act Technical Assistance Network by submitting your information at https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm459719.htm.

I. Introduction

The FDA Food Safety Modernization Act (FSMA) establishes requirements for hazard analysis and risk-based preventive controls for facilities that produce food for humans and animals. We have issued two regulations to implement these requirements. The first regulation is established in 21 CFR part 117 and is entitled "Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food" (published in the *Federal Register* on September 17, 2015, 80 FR 55907). In the remainder of this guidance we refer to this regulation as "part 117." Subparts A, B, and F of part 117 include current good manufacturing practice (CGMP) requirements for domestic and foreign facilities that manufacture, process, pack, or hold human food. Subparts A, C, D, E, F, and G of part 117 include requirements for domestic and foreign facilities that are required to register under section 415 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 350d) to conduct a hazard analysis and implement risk-based preventive controls for human food (the human food preventive controls requirements). The second regulation is established in 21 CFR part 507 and is entitled "Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals" (published in the *Federal Register* on September 17, 2015, 80 FR 56170). In the remainder of this guidance we refer to this regulation as "part 507." For domestic and foreign facilities that are required to register under the FD&C Act, subparts A, B, and F of part 507

[1] This guidance has been prepared by the Office of Food Safety in the Center for Food Safety and Applied Nutrition in cooperation with the Office of Surveillance and Compliance in the Center for Veterinary Medicine at the U.S. Food and Drug Administration.

include CGMP requirements and subparts A, C, D, E, and F of part 507 include requirements to conduct a hazard analysis and implement risk-based preventive controls for animal food (the animal food preventive controls requirements).

A facility that meets the definition of a "qualified facility" in part 117 or part 507 is subject to CGMP requirements as well as the modified requirements described in 21 CFR 117.201 or in 21 CFR 507.7, respectively. These modified requirements include the requirement that the facility submit a form to FDA, attesting to its status as a qualified facility. Section II of this guidance explains how to determine whether your facility meets the definition of "qualified facility" under part 117 and how to submit Form FDA 3942a attesting to your status as a qualified facility that is subject to the modified requirements in 21 CFR 117.201. Section III of this guidance explains how to determine whether your facility meets the definition of "qualified facility" under part 507 and how to submit Form FDA 3942b attesting to your status as a qualified facility that is subject to the modified requirements in 21 CFR 507.7. The modified requirements also include a requirement that the facility attest to certain food safety practices. See 21 CFR 117.201(a)(2); 507.7(a)(2).

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe our current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in FDA guidances means that something is suggested or recommended, but not required.

II. Frequently Asked Questions About Requirements for Qualified Facilities That Manufacture, Process, Pack, or Hold Human Food

A. Definition of Qualified Facility Under Part 117

1. How does part 117 define "qualified facility"?

Part 117 defines a qualified facility as (when including the sales by any subsidiary; affiliate; or subsidiaries or affiliates, collectively, of any entity of which the facility is a subsidiary or affiliate):

- A facility that is a very small business (see definition in Question II.A.2); or
- A facility to which both of the following apply:
    - During the 3-year period preceding the applicable calendar year, the average annual monetary value of the food manufactured, processed, packed, or held at such facility that is sold directly to qualified end-users (see definition in Question II.A.5) during such period exceeded the average annual monetary value of the food sold by such facility to all other purchasers; and

- The average annual monetary value of all food sold during the 3-year period preceding the applicable calendar year was less than $500,000, adjusted for inflation.

See the definition of "qualified facility" in 21 CFR 117.3.

2. How does part 117 define "very small business"?

Part 117 defines "very small business" as a business, including any subsidiaries and affiliates, averaging less than **$1,000,000**, adjusted for inflation, per year, during the 3-year period preceding the applicable calendar year in sales of human food plus the market value of human food manufactured, processed, packed, or held without sale (e.g., held for a fee). See the definition of "very small business" in 21 CFR 117.3.

We believe the definition of a very small business will apply to most qualified facilities. As such, the focus of this guidance is on determining whether a facility meets the definition of a very small business, rather than on whether a facility meets the two-part definition based on sales to qualified end-users. If you have questions about sales to a qualified end-user that are not addressed in this guidance, please contact us as described in section IV of this guidance.

3. How does part 117 define "affiliate"?

Part 117 defines "affiliate" as any facility that controls, is controlled by, or is under common control with another facility. See the definition of "affiliate" in 21 CFR 117.3.

4. How does part 117 define "subsidiary"?

Part 117 defines a subsidiary as any company which is owned or controlled directly or indirectly by another company. See the definition of "subsidiary" in 21 CFR 117.3.

5. How does part 117 define "qualified end-user"?

Part 117 defines "qualified end-user" as the consumer of the food (where the term "consumer" does not include a business); or a restaurant or retail food establishment that:

- Is located:
  - In the same State or the same Indian reservation as the qualified facility that sold the food to such restaurant or establishment; or
  - Not more than 275 miles from such facility; and
- Is purchasing the food for sale directly to consumers at such restaurant or retail food establishment.

See the definition of "qualified end-user" in 21 CFR 117.3.

6. Who determines whether my facility meets the definition of a qualified facility under part 117?

You are responsible for determining whether your facility meets the definition of a qualified facility under part 117, subject to verification by FDA. We do not intend to review financial records supporting your status as a qualified facility during routine inspections. However, we may ask to review those financial records during inspections conducted "for cause" (e.g., during an inspection conducted because food produced at your facility is associated with an outbreak of foodborne illness or if we have reason to believe your facility does not meet the requirements to be a qualified facility).

7. Can a facility that is a subsidiary meet the definition of "very small business" under part 117 even if its parent company is not a very small business?

Yes. It is possible for a facility that is a subsidiary to be a very small business even if its parent company is not a very small business because not all human food sold or manufactured, processed, packed, or held without sale by the parent company is counted in a subsidiary facility's calculation of whether it is a very small business. Specifically, a subsidiary facility only includes operations of the parent company in the calculation if the parent company is an affiliate of the subsidiary facility. For example, a subsidiary may consist of Facility A with $300,000 in annual human food sales. The subsidiary's parent company may include Facility B, a manufacturer/processor with $600,000 in annual human food sales, and Farm C with $500,000 in annual human food sales. Facility A would include Facility B's sales in its calculation because Facility B is an affiliate of Facility A. Facility A would not include Farm C's sales in its calculation because Farm C is not an affiliate (it cannot be because farms are not facilities required to register) or a subsidiary (it is part of the parent company). Therefore, Facility A would determine that it has $900,000 ($600,000 + $300,000) in annual human food sales for its business. If the average over 3 years was less than $1,000,000 adjusted for inflation for the most recent of the three years, then Facility A would be a very small business.

Facility B's calculation to determine whether it is a very small business would be different. Facility B would include, in addition to its own sales ($600,000), Farm C's sales ($500,000) because Farm C is part of the same company. Facility B would also include Facility A's sales ($300,000) because Facility A is a subsidiary of the parent company that includes Facility B. Therefore, Facility B would determine that it has $1.4 million in annual human food sales for its business. (Note, in this example none of the entities have human food manufactured, processed, packed, or held without sale that must be included in the calculation.)

8. What does "food manufactured, processed, packed, or held without sale" mean in the definition of very small business in part 117?

Food manufactured, processed, packed, or held without sale means any food for human consumption that you manufacture, process, pack or hold at your facility and do not offer for sale. This does not include food that you will sell at a later date. Examples of food manufactured, processed, packed, or held without sale include food held for a fee (e.g., by a warehouse), food processed for a fee (e.g., by a contract processor (such as a facility that irradiates spices)), and food packaged for a fee (e.g., by a contract packager).

B. Calculations to Determine Status as a Qualified Facility Under Part 117

1. How often, and when, must I make the calculation to determine my status as a qualified facility under part 117?

You must make the calculation to determine your status as a qualified facility under part 117 on an annual basis no later than July 1 of each calendar year (21 CFR 117.201(c)(1)).

2. Which products do I include in, and which products do I exclude from, the calculation of annual sales plus market value to determine my status as a qualified facility under part 117?

Include all human food, including food manufactured, processed, packed, or held by all subsidiaries and affiliates, regardless of whether the human food is subject to part 117. For example, you would include products such as seafood, juice, low-acid canned foods, and dietary supplements. Likewise, you would include raw agricultural commodities (e.g., produce, grains, milk, and eggs) and products subject to the jurisdiction of the U.S. Department of Agriculture (e.g., meat products for human consumption), regardless of whether these products are subject to part 117. You do not need to include the value of food that you have processed but not yet sold.

Do not include animal food or other items not intended for human consumption.

3. Do I include human food sold in countries other than the United States in the calculation of total sales?

Yes. Include sales of all human food in the calculation of total sales, regardless of where the food is sold. For example, if you are a domestic facility that exports food to other countries, you would include sales of food for export in your calculation of total annual sales. If you are a foreign facility, you would include sales of human food in all countries, including sales in your own country, sales in the United States, and sales in other countries.

4. How do I include human food that is manufactured, processed, packed, or held without sale (e.g., because I am a warehouse, a contract processor, or a contract packager)?

Include human food that is manufactured, processed, packed, or held without sale, through calculations of market value (see Question II.B.9).

5. How do I determine whether my average annual sales plus market value of human food manufactured, processed, packed, or held without sale is under the inflation-adjusted cut-off?

We have outlined what we believe to be the simplest method below. We will accept other methods as well (e.g., deflating average annual sales to 2011-dollars) should you choose to use a different method.

The simplest method of determining whether your annual sales plus market value of human food manufactured, processed, packed, or held without sale is below the inflation-adjusted threshold for a "very small business" is to:

- Determine which three years to include in the average;
- Determine annual sales and market value of food manufactured, processed, packed, or held without sale for each of the three years;
- Calculate the average for the three years; and
- Compare to the three-year average value posted on FDA's website at: https://www.fda.gov/food/guidanceregulation/fsma/ucm554484.htm, to determine if your three-year average is less than $1,000,000 adjusted for inflation.

6. How do I determine which three years to include for the purpose of determining the average annual sales plus market value of human food?

The definition of a very small business specifies that the average is based on the 3-year period preceding the applicable calendar year. The applicable calendar year is the current year. If the current year is 2019, the three preceding calendar years would be 2016, 2017 and 2018. *Note that for the examples in this guidance, we use the years 2014, 2015, and 2016 in order to demonstrate the inflation adjustment.*

See question II.B.7 if you don't have three years of financial records to use for your calculations.

7. How do I determine average annual sales plus market value of human food if I don't have three years of financial records to use for my calculations?

The compliance date for you to keep records to support your status as a qualified facility is January 1, 2016, and the compliance date for you to begin complying with the modified requirements for a qualified facility is September 17, 2018. If you began keeping applicable financial records on January 1, 2016, you would only have such records for 2 previous calendar years by September 17, 2018. Therefore, it would be reasonable for you to make the calculation based on the 2 previous calendar years. If you have records for 3 previous calendar years, you could make the calculation based on the longer time period. If we ask to see your applicable financial records during inspection in 2018, we intend to accept records for the preceding 2 calendar years as adequate to support status as a qualified facility when you have records for the preceding 2 calendar years, but not for the preceding 3 previous calendar years.

If you begin operations between January 1, 2017, and September 17, 2018, your applicable financial records would not cover even 2 calendar years by September 17, 2018. During the first 3 years of your operation, you should make the calculation based on the records you have (i.e., for one or two preceding calendar years). If we ask to see your applicable financial records during the first 3 years of your operation, we intend to accept records for the preceding one or two years as adequate to support your status as a qualified facility until you have been in operation long enough to provide three years of records.

If you begin operations after January 1, 2018, you can rely on a projected estimate of revenue (or market value) at the time you begin operations. If we ask to see your applicable financial records

during your first year of operation, we intend to evaluate the credibility of the projected revenue (or market value) based on such factors as your number of employees. After you have records for one or two preceding years, you should make the calculation based on records you have (i.e., for one or two preceding calendar years). If we ask to see your applicable financial records during the next two years of your operation, we intend to accept records for the preceding one or two calendar years as adequate to support your status as a qualified facility in these circumstances.

8. How do I determine annual sales of human food?

Determine your annual sales using resources such as:

- Tax Forms, e.g. Gross Receipts or Sales (Line 1a) from Internal Revenue Service (IRS) Form 1120;
- Accounting documents, e.g., Total Sales or Revenues from an Income Statement; or
- Invoices and bills of lading.

Do not adjust the total sales for the year to include the cost of the sales – for example, you should not adjust total sales for the cost of labor.

Table 1 provides an example of determining annual sales for Business D for the years 2014-2016 based on tax documents. Business D does not process, pack, or hold human food without sale, and, thus, does not calculate market value. Business D consists of a facility (Facility D) that does not have any subsidiaries or affiliates.

Table 1: Determining Annual Sales of Human Food for Business D for the Years 2014-2016

Source	2014	2015	2016
Facility D: Gross Sales of Human Food (Item 1a, IRS Form 1120)	$800,000	$800,500	$900,000
Facility D: Market Value of Human Food Manufactured, Processed, Packed, or Held Without Sale	N/A*, **	N/A**	N/A**
Total Non-Inflation Adjusted Annual Sales + Market Value of Human Food Manufactured, Processed, Packed, or Held Without Sale	$800,000	$800,500	$900,000

*N/A = Not applicable

** There is no entry for market value of human food manufactured, processed, packed, or held without sale because Facility D does not manufacture, process, pack, or hold human food without sale.

Table 2 provides a more complex example of determining annual sales for Business E for the years 2014-2016 based on tax documents. Business E consists of Facility E and one affiliate (Affiliate E1), which produced and sold human and animal food. Neither Facility E nor Affiliate E1 manufactures, processes, packs, or holds human food without sale and, thus, neither Facility E nor Affiliate E1 calculates market value.

Table 2. Determining Annual Sales of Human Food for Business E (Facility E and its Affiliate) for the Years 2014-2016.

Source	2014	2015	2016
Facility E: Gross Sales of Human Food (Derived from Item 1a, IRS Form 1120)	$800,000	$800,500	$900,000
Facility E: Market Value of Human Food Manufactured, Processed, Packed, or Held Without Sale	N/A*	N/A*	N/A*
Affiliate E1: Gross Sales of Human Food (Item 1a, IRS Form 1120)	$190,000	$200,000	$200,000
Affiliate E1: Market Value of Human Food Manufactured, Processed, Packed, or Held Without Sale	N/A*	N/A*	N/A*
Affiliate E1: Gross Sales of Animal Food (Derived from Item 1A, IRS Form 1120) (Not included in calculation)	$50,000 (Not included in calculation)	$55,000 (Not included in calculation)	$60,000 (Not included in calculation)
Total Non-Inflation Adjusted Annual Sales + Market Value of Human Food Manufactured, Processed, Packed, or Held Without Sale	$990,000	$1,000,500	$1,100,000

*There is no entry for market value of human food manufactured, processed, packed, or held without sale because neither Facility E nor Affiliate E1 manufactures, processes, packs, or holds human food without sale.

9. How do I determine the market value of human food manufactured, processed, packed, or held without sale?

Use the value of the food, not the fee for the service (e.g., for holding, processing, or packing) to calculate the market value of food that you manufacture, process, pack or hold without sale. Determine the market value of human food manufactured, processed, packed, or held without sale by considering factors such as:

- The market value of incoming food obtained from the customer for whom the food is being manufactured, processed, packed, or held;
- The amount of insurance that a warehouse holds for its products;
- The value obtained by multiplying market price by volume of food manufactured, processed, packed, or held; or
- Assets on a balance sheet.

See Section II.D of this guidance for examples of how to determine market value for human food manufactured, processed, packed, or held without sale. The examples describe the calculation for a cold storage warehouse that holds human food. In one example (Question II.D.1), the warehouse calculates market value using the value of an insurance policy. In a second example (Question II.D.2), the same warehouse calculates market value using the market value of incoming food using information or accounting documents from the customer. In these examples, the warehouse reaches the same conclusion regardless of the method used to do the calculation.

10. What conversion rate should a foreign facility use when converting annual sales plus market value of human food to U.S. dollars?

A foreign facility should use the exchange rate in effect as of the ending date of the period during which it collected the reported receipts or sales. For example, for sales during 2016 a foreign facility would use the conversion rate in effect on December 31, 2016.

11. May I subtract sales of human food to qualified end-users from my annual sales of human food when determining whether my facility meets the definition of very small business under part 117?

No. The definition of very small business is based on average annual sales plus market value and is not adjusted for sales to a qualified end-user.

C. Other Questions About the Human Food Preventive Controls Requirements in Part 117

1. What records must I keep to demonstrate my facility's status as a qualified facility under part 117?

Part 117 requires that you keep records that you rely upon to support the attestations you make on Form FDA 3942a, but does not otherwise specify the types of records that you must keep (21 CFR 117.205(f)). You should keep the records that you use for your calculations of annual sales. See Question II.B.8 for examples of these records. You also should keep records of the actual calculations that you make – e.g., calculations of inflation-adjusted annual sales plus market value and the three-year average of inflation-adjusted annual sales plus market value. These records are subject to the requirements in subpart F of part 117 and must be produced upon request by a duly authorized representative of the Secretary of Health and Human Services (e.g., FDA) (21 CFR 117.201(f) and 21 CFR 117.320). We do not intend to ask to review these records during routine inspections. However, we may ask to review these records during inspections conducted "for cause" (e.g., during an inspection conducted because food produced

at your facility is associated with an outbreak of foodborne illness) or if we have reason to believe your facility does not meet the requirements to be a qualified facility.

The records you are required to keep to support your attestation as to food safety practices/compliance may vary depending on how you comply with 21 CFR 117.201(a)(2). The two options are as follows:

1. Option 1: You have identified potential hazards associated with the food being produced, are implementing preventive controls to address the hazards associated with the food being produced, and are monitoring the performance of the preventive controls to ensure that such controls are effective; or

2. Option 2: Your facility is in compliance with State, local, country, tribal, or other applicable non-Federal food safety law, including relevant laws and regulations of foreign countries.

When selecting Option 1, you must keep records documenting your identification of potential hazards, the preventive controls you are implementing to address those hazards, your implementation of your preventive controls, and your monitoring of your preventive controls. (21 CFR 117.201(f)(1)). For example, you could have a document identifying the hazards and the preventive controls you will implement to address those hazards, and batch records demonstrating your implementation and monitoring of the preventive controls. If some or all of the activities you conduct are activities that we have listed as a low-risk activity/food combination in 21 CFR 117.5(g) and (h), the records documenting your identification of hazards could be as simple as a reference to the applicable activity/food combination listed in the regulation.

When selecting Option 2, you must maintain records that document your compliance with the applicable non-Federal food safety law that you are following. (21 CFR 117.201(f)(1)). For example, you could keep a record of licenses, inspection reports, certificates, permits, credentials, certification by an appropriate agency or other evidence of oversight. If the applicable food safety law does not result in a license, inspection report, certificate, or permit, you could have a printed or electronic copy of the applicable food safety law.

2. If my facility supplies raw materials or other ingredients to a manufacturer/processor covered by the human food preventive controls requirements, and my facility is responsible for controlling the potential hazards, what information should I provide to the receiving facility regarding my status as a qualified facility, or any change in status from qualified to "not a qualified facility"?

In some circumstances, when a facility supplies a raw material or other ingredient to a manufacturer/processor that is covered by the human food preventive controls requirements, it is considered a "supplier" (see definition of "supplier" in 21 CFR 117.3). The manufacturer/processor is considered a "receiving facility." A receiving facility must establish and implement a supply-chain program for raw materials and other ingredients when a hazard identified by the receiving facility is controlled by a supplier. (See 21 CFR 117.405(a)(1)). The receiving facility may rely on certain written assurances from a supplier that is a qualified

facility (see 21 CFR 117.430(c)) rather than rely on other verification methods, like an onsite audit.

If you are a supplier to a receiving facility, the receiving facility must obtain written assurance from you that you are a qualified facility before first approving you as a supplier for an applicable calendar year, and on an annual basis thereafter, by December 31 of each calendar year, for the following calendar year (see 21 CFR 117.430(c)(1)). The receiving facility must also obtain other written assurance from you every two years that you are producing the raw material or ingredient in compliance with applicable FDA food safety regulations (or, when applicable, the food safety regulations of a country whose food safety system FDA has recognized as comparable or equivalent). This written assurance must include either:

1. a brief description of the preventive controls you are implementing to control the applicable hazards in the food; or

2. a statement that you are in compliance with State, local, county, tribal, or other applicable non-Federal food safety law.

(See 21 CFR 117.430(c)(2)).

If a receiving facility will rely on your written assurance that you are a qualified facility, you would provide the receiving facility with written assurance of your status as a qualified facility before the receiving facility approves you as a supplier, and on an annual basis thereafter. Because the human food preventive controls requirements require the receiving facility to obtain the written assurance by December 31 of each calendar year, a receiving facility has flexibility to work with you to determine the specific date within a calendar year for annual notification to the receiving facility. As a matter of a business agreement with the receiving facility, it is possible that you would provide the written assurance earlier than December 31 of each calendar year.

3. When must I submit my first attestation to FDA to comply with the modified requirements in 21 CFR 117.201?

You must submit your first attestation to FDA:

- By December 17, 2018, if your facility begins manufacturing, processing, packing, or holding food before September 17, 2018; or
- Before beginning operations, if your facility begins manufacturing, processing, packing, or holding food after September 17, 2018.

(21 CFR 117.201(c)(2)(i)).

4. How often, and when, must I re-submit Form FDA 3942a?

Beginning in 2020, you must re-submit Form FDA 3942a to FDA every 2 years during the food facility biennial registration renewal period beginning on October 1 and ending on December 31 (21 CFR 117.205(c)(2)(ii)). Note that you must also renew your facility registration at this time (21 CFR 1.230).

5. When must I submit Form FDA 3942a to FDA if my facility's status changes from "qualified facility" to "not a qualified facility"?

If your facility's status changes from "qualified facility" to "not a qualified facility" based on the annual determination, you must submit Form FDA 3942a notifying FDA of that change in status by July 31 of the applicable calendar year (see Reference 1: Qualified Facility Attestation Using Form FDA 3942a (for Human Food) or Form FDA 3942b (for Animal Food): Instructions for Submitting Your Attestation).

(21 CFR 117.205(c)(3)).

6. Do farms need to submit Form FDA 3942a?

No, provided that they meet FDA's definition of a "farm" (21 CFR 1.227). Submission of Form FDA 3942a is only required for businesses that are required to register with FDA as a food facility, and a farm is not required to register with FDA as a food facility.

7. Do farm mixed-type facilities need to submit Form FDA 3942a?

A farm mixed-type facility that meets the definition of "qualified facility" must submit Form FDA 3942a to FDA unless it is exempt from the preventive controls requirements in subparts C and G for another reason, such as it is only engaged in low-risk packing or holding activity/food combinations (21 CFR 117.5(g)) or low risk manufacturing/processing activity/food combinations (21 CFR 117.5(h)). In that case, we consider the mixed-type facility to be exempt from subparts C and G and the modified requirements for qualified facilities.

D. Examples of Calculations to Determine Market Value of Food Held Without Sale Under Part 117

1. How can I calculate market value of human food held without sale in my warehouse using the values in my insurance policy for the warehouse?

In this example, Warehouse F is a cold storage warehouse. Its inventory turns over approximately every two months. It has an insurance policy that covers the market value of food stored at any given time. Because the inventory turns over approximately every two months, Warehouse F could multiply the value of the insurance policy times six to arrive at an approximate value of the food stored for the entire year.

See **Table** 3 for an example of how Warehouse F could do its calculation of market value on an annual basis for the years 2014, 2015, and 2016. Warehouse F can then compare its three-year average market value to the inflation-adjusted value for the most recent year included in the average posted on FDA's website at: https://www.fda.gov/food/guidanceregulation/fsma/ucm554484.htm to determine if the three year average is less than $1,000,000 adjusted for inflation.

Table 3. Calculation of Market Value of Human Food Held Without Sale by Warehouse F Using the Value of an Insurance Policy

Item	2014	2015	2016
Value of Insurance Policy	$200,000	$225,000	$250,000
Number of time inventory turns over during the year	6	6	6
Total Market Value of human food manufactured, processed, packed, or held without sale	($2,000,000)(6) = $1,200,000	($2,250,000)(6) = $1,350,000	($2,500,000)(6) = $1,500,000

Warehouse F does not meet the definition of a very small business and is not a qualified facility because the three-year average value $1,350,000 is greater than $1,078,242 (inflation adjusted value of $1,000,000 in 2016).

Because an insurance policy may cover a slightly higher value than is in the warehouse at any given time, Warehouse F may decide to calculate the market value using information or accounting documents from their customer to determine the actual value of product received each year. See Question II.D.2 for an example of how one could calculate the market value using information or accounting documents from the customer.

2. How can I calculate the market value of human food held without sale as a contract processor using information or accounting documents from the customer?

In this example, Contract Processor G uses information on the value of the food received from the customer to determine the total market value of all food held without sale for each year. Using this method, Contract Processor G would add up the value of food for each shipment received throughout the year. Contract Processor G can then compare its three-year average market value to the inflation-adjusted value for the most recent year included in the average posted on FDA's website at: https://www.fda.gov/food/guidanceregulation/fsma/ucm554484.htm.

Table 4. Calculation of Market Value of Human Food Held Without Sale by Contract Processor F Using Information from the Customer to Determine the Value of Human Food for Each Shipment

Item	2014	2015	2016
Total Market Value of human food manufactured, processed, packed, or held without sale	$870,000	$1,030,000	$1,190,000

Contract Processor G does meet the definition of a very small business and is a qualified facility because the three year average value $1,030,000 is less than $1,078,242 (inflation adjusted value of $1,000,000 in 2016).

III. Frequently Asked Questions About Requirements for Qualified Facilities That Manufacture, Process, Pack, or Hold Animal Food

A. Definition of Qualified Facility Under Part 507

1. How does part 507 define "qualified facility"?

Part 507 defines a qualified facility as (when including the sales by any subsidiary; affiliate; or subsidiaries or affiliates, collectively, of any entity of which the facility is a subsidiary or affiliate):

- A facility that is a very small business (see definition in Question III.A.2.); or
- A facility to which both of the following apply:
    - During the 3-year period preceding the applicable calendar year, the average annual monetary value of the food manufactured, processed, packed, or held at such facility that is sold directly to qualified end-users (see definition in Question III.A.4) during such period exceeded the average annual monetary value of the food sold by such facility to all other purchasers; and
    - The average annual monetary value of all food sold during the 3-year period preceding the applicable calendar year was less than $500,000, adjusted for inflation.

See the definition of "qualified facility" in 21 CFR 507.3.

2. How does Part 507 define "very small business?"

Part 507 defines "very small business" as a business, including any subsidiaries and affiliates, averaging less than **$2,500,000**, adjusted for inflation, per year, during the 3-year period preceding the applicable calendar year in sales of animal food plus the market value of animal food manufactured, processed, packed, or held without sale (e.g., held for a fee or supplied to a farm without sale). See the definition of "very small business" in 21 CFR 507.3.

We believe the definition of a very small business will apply to most qualified facilities. As such, the focus of this guidance is on determining whether a facility meets the definition of a very small business, rather than on whether a facility meets the two-part definition based on sales to qualified end-users. If you have questions about sales to a qualified end-user that are not addressed in this guidance, please contact us as described in section IV of this guidance.

3. How does part 507 define "affiliate"?

Part 507 defines "affiliate" as any facility that controls, is controlled by, or is under common control with another facility. See the definition of "affiliate" in 21 CFR 507.3.

4. How does part 507 define "subsidiary"?

Part 507 defines a subsidiary as any company which is owned or controlled directly or indirectly by another company. See the definition of "subsidiary" in 21 CFR 507.3.

5. How does part 507 define "qualified end-user"?

Part 507 defines "qualified end-user" as the consumer of the food (where the term "consumer" does not include a business); or a restaurant or retail food establishment that:

- Is located:
    - In the same State or the same Indian reservation as the qualified facility that sold the food to such restaurant or establishment; or
    - Not more than 275 miles from such facility; and
- Is purchasing the food for sale directly to consumers at such restaurant or retail food establishment.

See the definition of "qualified end-user" in 21 CFR 507.3 and the definition of "restaurant" in 21 CFR 1.227.

6. Who determines whether my facility meets the definition of a qualified facility under part 507?

You are responsible for determining whether your facility meets the definition of a qualified facility under part 507, subject to verification by FDA. We do not intend to review financial records supporting your status as a qualified facility during routine inspections. However, we may ask to review those financial records during inspections conducted "for cause" (e.g., during an inspection conducted because animal food produced at your facility is associated with an outbreak of foodborne illness or if we have reason to believe your facility does not meet the requirements to be a qualified facility).

7. Can a facility that is a subsidiary meet the definition of "very small business" under part 507 even if its parent company is not a very small business?

Yes. It is possible for a facility that is a subsidiary to be a very small business even if its parent company is not a very small business because not all animal food sold or manufactured, processed, packed, or held without sale by the parent company is counted in a subsidiary facility's calculation of whether it is a very small business. Specifically, a subsidiary facility only includes operations of the parent company in the calculation if the parent company is an affiliate of the subsidiary facility. For example, a subsidiary may consist of Facility G with $300,000 in annual animal food sales. The subsidiary's parent company may include Facility H, a manufacturer/processor with $2 million in annual animal food sales, and Farm I with $500,000 in annual animal food sales. Facility G would include Facility H's sales in its calculation because Facility H is an affiliate of Facility G. Facility G would not include Farm I's sales in its calculation because Farm I is not an affiliate (it cannot be because farms are not facilities required to register) or a subsidiary (it is part of the parent company). Therefore, Facility G would determine that it has $2.3 million ($2,000,000 + $300,000) in annual animal food sales for

its business. If the average over 3 years were less than the inflation adjusted maximum for the most recent of the three years, then Facility G would be a very small business.

Facility H's calculation to determine whether it is a very small business would be different. Facility H would include, in addition to its own sales ($2 million), Farm I's sales ($500,000) because Farm I is part of the same company. Facility H would also include Facility G's sales ($300,000) because Facility G is a subsidiary of the parent company that includes Facility H. Therefore, Facility H would determine that it has $2.8 million in annual animal food sales for its business. (Note, in this example none of the entities have animal food manufactured/processed, packed, or held without sale that must be included in the calculation.)

8. What does "animal food manufactured, processed, packed, or held without sale" mean in the definition of very small business in part 507?

Animal food manufactured, processed, packed, or held without sale means any food for animal consumption that you manufacture, process, pack, or hold at your facility and do not offer for sale. This does not include animal food that you will sell at a later date. Examples of animal food manufactured, processed, packed, or held without sale include animal food being held for a fee (e.g., by a warehouse), animal food being processed for a fee (e.g., by a contract processor), animal food being packaged for a fee (e.g., by a contract packager), and animal food supplied by a feed mill (one which is required to register as a food facility), without sale, operating under contract farming agreements.

B. Calculations to Determine Status as a Qualified Facility Under Part 507

1. How often, and when, must I make the calculation to determine my status as a qualified facility under part 507?

You must make the calculation to determine your status as a qualified facility under part 507 on an annual basis no later than July 1 of each calendar year. (21 CFR 507.7(c)(1)).

2. Which products do I include in, and which products do I exclude from, the calculation of annual sales plus market value to determine my status as a qualified facility under part 507?

Include all animal food, including animal food manufactured, processed, packed, or held by all subsidiaries and affiliates, regardless of whether the animal food is subject to part 507. You do not need to include the value of animal food that you have processed but not yet sold.

Do not include food intended for consumption by humans or other items that are not animal food.

3. Do I include animal food that is sold in countries other than the United States, in the calculation of total sales?

Yes. Include sales of all animal food in the calculation of total sales, regardless of where the animal food is sold. For example, if you are a domestic facility that exports animal food to other

countries, you would include sales of animal food for export in your calculation of total annual sales. If you are a foreign facility, you would include sales of animal food in all countries, including sales in your own country, sales in the United States, and sales in other countries.

4. How do I include animal food that is manufactured, processed, packed, or held without sale (e.g., because I am a warehouse, a contract processor, a contract packager, or a feed mill that supplies the animal food to a farm without sale)?

Include animal food that is manufactured, processed, packed, or held without sale, through calculations of market value (see Question III.B.9).

5. How do I determine whether my average annual sales plus market value of animal food manufactured, processed, packed, or held without sale is under the inflation-adjusted cut-off?

We have outlined what we believe to be the simplest method below. We will accept other methods as well (e.g., deflating average annual sales to 2011-dollars) should you choose to use a different method.

The simplest method of determining whether your annual sales plus market value of animal food manufactured, processed, packed, or held without sale is below the inflation-adjusted threshold for a "very small business" is to:

- Determine which three years to include in the average;
- Determine annual sales and market value of animal food manufactured, processed, packed, or held without sale, or supplied to a farm without sale, for each of the three years;
- Calculate the average for the three years; and
- Compare to the three-year average value posted on FDA's website at: https://www.fda.gov/food/guidanceregulation/fsma/ucm554484.htm to determine if your three-year average is less than $2,500,000 adjusted for inflation.

6. How do I determine which three years to include for the purpose of determining the average annual sales plus market value of animal food?

The definition of a very small business specifies that the average is based on the 3-year period preceding the applicable calendar year. The applicable calendar year is the current year. If the current year is 2019, the three preceding calendar years would be 2016, 2017 and 2018. *Note that for the examples in this guidance, we use the years 2014, 2015, and 2016 in order to demonstrate the inflation adjustment.*

See question III.B.7 if you don't have three years of financial records to use for your calculations.

7. How do I determine average annual sales plus market value of animal food if I don't have three years of financial records to use for my calculations?

The compliance date for you to keep records to support your status as a qualified facility is January 1, 2017, and the compliance date for you to begin complying with the modified requirements for a qualified facility is September 17, 2019. If you began keeping applicable financial records on January 1, 2017, you would only have such records for 2 previous calendar years by September 17, 2019. Therefore, it would be reasonable for you to make the calculation based on the 2 previous calendar years. If you have records for 3 previous calendar years, you could make the calculation based on the longer time period. If we ask to see your applicable financial records during inspection in 2019, we intend to accept records for the preceding 2 calendar years as adequate to support status as a qualified facility when you have records for the preceding 2 calendar years, but not for the preceding 3 previous calendar years.

If you begin operations between January 1, 2018, and September 17, 2019, your applicable financial records would not cover even 2 calendar years by September 17, 2019. During the first 3 years of your operation, you should make the calculation based on the records you have (i.e., for one or two preceding calendar years). If we ask to see your applicable financial records during the first 3 years of your operation, we intend to accept records for the preceding one or two years as adequate to support your status as a qualified facility until you have been in operation long enough to provide three years of records.

If you begin operations after January 1, 2019, you can rely on a projected estimate of revenue (or market value) at the time you begin operations. If we ask to see your applicable financial records during your first year of operation, we intend to evaluate the credibility of the projected revenue (or market value) based on such factors as your number of employees. After you have records for one or two preceding years, you should make the calculation based on records you have (i.e., for one or two preceding calendar years). If we ask to see your applicable financial records during the next two years of your operation, we intend to accept records for the preceding one or two calendar years as adequate to support your status as a qualified facility in these circumstances.

8. How do I determine annual sales of animal food?

Determine your annual sales using resources such as:

- Tax Forms, e.g., Gross Receipts or Sales (Line 1a) from Internal Revenue Service (IRS) Form 1120;
- Accounting documents, e.g., Total Sales or Revenues from an Income Statement; or
- Invoices and bills of lading.

Do not adjust the total sales for the year to include the cost of the sales – for example, you should not adjust total sales for the cost of labor.

Table 5 provides an example of determining annual sales for Business J for the years 2014-2016 based on tax documents. Business J does not process, pack, or hold animal food without sale, and thus, does not calculate market value. Business J consists of a facility (Facility J) that does not have any subsidiaries or affiliates.

Table 5: Determining Annual Sales of Animal Food for Business J for the Years 2014-2016

Source	2014	2015	2016
Facility J: Gross Sales of Animal Food (Item 1a, IRS Form 1120)	$800,000	$800,500	$900,000
Facility J: Market Value of Animal Food Manufactured, Processed, Packed, or Held Without Sale	N/A*, **	N/A**	N/A**
Total Non-Inflation Adjusted Annual Sales + Market Value of Animal Food Manufactured, Processed, Packed, or Held Without Sale	$800,000	$800,500	$900,000

*N/A = Not applicable

** There is no entry for market value of animal food manufactured, processed, packed, or held without sale because Facility J does not manufacture, process, pack, or hold animal food without sale.

Table 6 provides a more complex example of determining annual sales for Business K for the years 2014-2016 based on tax documents. Business K consists of Facility K and one affiliate (Affiliate K1), which also produced and sold animal food. Neither Facility K nor Affiliate K1 manufactures, processes, packs, or holds animal food without sale and, thus, neither Facility K nor Affiliate K1 calculates market value.

Table 6. Determining Annual Sales of Animal Food for Business K (Facility K and its Affiliate) for the Years 2014-2016.

Source	2014	2015	2016
Facility K: Gross Sales of Food For Animals (Item 1a, IRS Form 1120)	$900,000	$1,200,000	$1,500,000
Facility K: Market Value of Animal Food Manufactured, Processed, Packed, or Held Without Sale	N/A*	N/A*	N/A*
Affiliate K1: Gross Sales of Animal Food (Item 1a, IRS Form 1120)	$900,000	$900,000	$1,100,000
Affiliate K1: Market Value of Animal Food Manufactured, Processed, Packed, or Held Without Sale	N/A*	N/A*	N/A*

Source	2014	2015	2016
Total Non-Inflation Adjusted Annual Sales Plus Market Value of Animal Food Manufactured, Processed, Packed, or Held Without Sale	$1,800,000	$2,100,000	$2,600,000

*There is no entry for market value of animal food manufactured, processed, packed, or held without sale because Facility K and Affiliate K1 do not manufacture, process, pack, or hold animal food without sale.

9. How do I determine the market value of animal food manufactured, processed, packed, or held without sale?

Use the value of the animal food, not the fee for the service (e.g., for holding, processing, or packing) to calculate the market value of animal food that you manufacture, process, pack or hold without sale. Determine the market value of animal food manufactured, processed, packed, or held without sale by considering factors such as:

- The market value of incoming animal food obtained from the customer for whom the animal food is being held;
- The amount of insurance that a warehouse holds for its products;
- The value obtained by multiplying market price by volume of animal food manufactured, processed, packed, or held; or
- Assets on a balance sheet.

See Section III.D of this guidance for an example of how to determine market value for animal food manufactured, processed, packed, or held without sale. The examples describe a warehouse facility holding animal food without sale and a contract manufacturer without sales.

10. What conversion rate should a foreign facility use when converting annual sales plus market value of animal food to U.S. dollars?

A foreign facility should use the exchange rate in effect as of the ending date of the period during which it collected the reported receipts or sales. For example, for sales during 2017 a foreign facility would use the conversion rate in effect on December 31, 2017.

11. May I subtract sales of animal food to qualified end-users from my annual sales of animal food when determining whether my facility meets the definition of very small business under part 507?

No. The definition of very small business is based on average annual sales plus market value and is not adjusted for sales to a qualified end-user.

C. Other Questions About the Animal Food Preventive Controls Requirements in Part 507

1. What records must I keep to demonstrate my facility's status as a qualified facility under part 507?

Part 507 requires that you keep records that you rely upon to support the attestations you make on Form FDA 3942b, but does not otherwise specify the types of records that you must keep. (See 21 CFR 507.7(f)(1)). You should keep the records that you use for your calculations of annual sales. See Question III.B.8 for examples of these records. You also should keep records of the actual calculations that you make – e.g., calculations of inflation-adjusted annual sales plus market value and the three-year average of inflation-adjusted annual sales plus market value. These records are subject to the requirements in subpart F of part 507 and must be produced upon request by a duly authorized representative of the Secretary of Health and Human Services (e.g., FDA). (See 21 CFR 507.7(f)(2) and 507.200(c)). We do not intend to ask to review these records during routine inspections. However, we may ask to review these records during inspections conducted "for cause" (e.g., during an inspection conducted because animal food produced at your facility is associated with an outbreak of foodborne illness) or if we have reason to believe your facility does not meet the requirements to be a qualified facility.

The records you are required to keep to support your attestation as to food safety practices/compliance may vary depending on how you comply with 21 CFR 507.7(a)(2). The two options are as follows:

1. Option 1: You have identified potential hazards associated with the animal food being produced, are implementing preventive controls to address the hazards associated with the animal food being produced, and are monitoring the performance of the preventive controls to ensure that such controls are effective; or

2. Option 2: Your facility is in compliance with State, local, county, tribal, or other applicable non-Federal food safety law, including relevant laws and regulations of foreign countries.

When selecting Option 1, you must keep records documenting your identification of potential hazards, the preventive controls you are implementing to address those hazards, your implementation of your preventive controls, and your monitoring of your preventive controls. (See 21 CFR 507.7(f)(1)). For example, you could have a document identifying the hazards and the preventive controls you will implement to address those hazards, and batch records demonstrating your implementation and monitoring of the preventive controls. If some or all of the activities you conduct are activities that we have listed as a low-risk activity/animal food combination in 21 CFR 507.5(e) and (f), the records documenting your identification of hazards could be as simple as a reference to the applicable activity/animal food combination listed in the applicable regulation.

When selecting Option 2, you must maintain records that document your compliance with the applicable non-Federal food safety law that you are following. (See 21 CFR 507.7(f)(1)). For

example, you could keep a record of licenses, inspection reports, certificates, permits, credentials, certification by an appropriate agency or other evidence of oversight. If the applicable food safety law does not result in a license, inspection report, certificate, or permit, you could have a printed or electronic copy of the applicable food safety law.

2. If my facility supplies raw materials or other ingredients to a manufacturer/processor covered by the animal food preventive controls requirements, and my facility is responsible for controlling the potential hazards, what information should I provide to the receiving facility regarding my status as a qualified facility, or any change in status from qualified to "not a qualified facility"?

In some circumstances, when a facility supplies a raw material or other ingredient to a manufacturer/processor that is covered by the animal food preventive controls requirements, it is considered a "supplier" (see definition of "supplier" in 21 CFR 507.3). The manufacturer/processor is considered a "receiving facility." A receiving facility must establish and implement a supply-chain program for raw materials and other ingredients when a hazard identified by the receiving facility is controlled by a supplier. (See 21 CFR 507.105(a)(1)). The receiving facility may rely on certain written assurances from a supplier that is a qualified facility (see 21 CFR 507.130(c)) rather than rely on other verification methods, like an onsite audit.

If you are a supplier to a receiving facility, the receiving facility must obtain written assurance from you that you are a qualified facility before first approving you as a supplier for an applicable calendar year, and on an annual basis thereafter, by December 31 of each calendar year, for the following calendar year (see 21 CFR 507.130(c)(1)). The receiving facility must also obtain other written assurance from you every two years that you are producing the raw material or ingredient in compliance with applicable FDA food safety regulations (or, when applicable, the food safety regulations of a country whose food safety system FDA has recognized as comparable or equivalent). This written assurance must include either:

1. a brief description of the preventive controls you are implementing to control the applicable hazards in the animal food; or

2. a statement that you are in compliance with State, local, country, tribal, or other applicable non-Federal food safety laws.

(See 21 CFR 507.130(c)(2)).

If a receiving facility will rely on your written assurances that you are a qualified facility, you would provide the receiving facility with written assurance of your status as a qualified facility before the receiving facility approves you as a supplier, and on an annual basis thereafter. Because the animal food preventive controls requirements require the receiving facility to obtain the written assurance by December 31 of each calendar year, a receiving facility has flexibility to work with you to determine the specific date within a calendar year for annual notification to the receiving facility. As a matter of a business agreement with the receiving facility, it is possible that you would provide the written assurance earlier than December 31 of each calendar year.

3. When must I submit my first attestation to FDA to comply with the modified requirements in 21 CFR 507.7?

You must submit your first attestation to FDA:

- By December 16, 2019, if your facility begins manufacturing, processing, packing, or holding animal food before September 17, 2019; or
- Before beginning operations, if your facility begins manufacturing, processing, packing, or holding animal food after September 17, 2019.

(See 21 CFR 507.7(c)(2)(i)).

4. How often, and when, must I re-submit Form FDA 3942b?

Beginning in 2020, you must re-submit Form FDA 3942b to FDA every 2 years during the food facility biennial registration renewal period beginning on October 1 and ending on December 31. (See 21 CFR 507.7(c)(2)(ii)). Note that you must also renew your facility registration at this time (21 CFR 1.230).

5. When must I submit Form FDA 3942b to FDA if my facility's status changes from "qualified facility" to "not a qualified facility"?

If your facility's status changes from "qualified facility" to "not a qualified facility" based on the annual determination, you must submit Form FDA 3942b notifying FDA of that change in status by July 31 of the applicable calendar year (see Reference 1: Qualified Facility Attestation Using Form FDA 3942a (for Human Food) or Form FDA 3942b (for Animal Food): Instructions for Submitting Your Attestation).

(See 21 CFR 507.5(c)(3)).

6. Do farms need to submit Form FDA 3942b?

No, providing they meet FDA's definition of a "farm" (see 21 CFR 1.227). Submission of Form FDA 3942b is only required for businesses that are required to register with FDA as an animal food facility, and a farm is not required to register with FDA as a food facility.

7. Do farm mixed-type facilities need to submit Form FDA 3942b?

A farm mixed-type facility that meets the definition of "qualified facility" must submit Form FDA 3942b to FDA unless it is exempt from the preventive controls requirements in subparts C and E for another reason, such as being engaged in only low-risk packing or holding activity/animal food combinations (see 21 CFR 507.5(e)) or low-risk manufacturing/processing activity/animal food combinations (see 21 CFR 507.5(f)). In that case, we consider the mixed-type facility to be exempt from subparts C and E and the modified requirements for qualified facilities in 21 CFR 507.7.

D. Examples of Calculations to Determine Market Value of Animal Food Held Without Sale Under Part 507

1. How can I calculate market value of animal food held without sale in my warehouse using the market value of the product?

There are several ways in which a facility could calculate the market value of animal food held without sale. For additional examples, see section II.D. In this example, Warehouse L holds soybean meal for a fee. There are several ways Warehouse L could calculate the market value for the soybean meal that is held. This example will show how Warehouse L could calculate the market value of soybean meal held in 2014 by using the commodity price. While Table 7 shows how to calculate the value for one year, Warehouse L would need to do the calculation for the three years preceding the applicable calendar year as part of its determination of the three-year average annual sales plus market value of animal food manufactured, processed, packed, or held without sale.

To determine the market value of the soybean meal held in 2014, Warehouse L determines the volume of soybean meal held each month, multiplies that volume by the commodity value for that month, and then calculates the total for the year.

Table 7. Calculation of Market Value of Soybean Meal Held by Warehouse L in 2014

Month	Soybean Meal Price (per Metric Ton)	Volume of Soybean Meal (Metric Tons)	Market Value (before adjustment for inflation)
January 2014	$473.75	11.2	$5,306.00
February 2014	$499.36	11.5	$5,742.64
March 2014	$506.69	12.3	$6,232.29
April 2014	$533.63	11.9	$6,350.20
May 2014	$442.78	12.2	$5,401.92
June 2014	$519.27	11.8	$6,127.39
July 2014	$451.02	12.5	$5,637.75
August 2014	$447.82	11.8	$5,284.28
September 2014	$409.10	12.4	$5,072.84
October 2014	$378.82	12.2	$4,621.60
November 2014	$423.25	11.9	$5,036.68
December 2014	$418.09	12.9	$5,393.36
2014 Market Value of Soybean Meal Held for a Fee	N/A*	N/A**	$66,206.93

*This column does not have an entry in the final row of the table because the entries in this column are for price per ton, not market value.
** This column does not have an entry in the final row of the table because the entries in this column are for volume, not market value.

2. How can I calculate the market value of animal food manufactured by a contract feed mill that does not sell the animal food?

In this example, Feed Mill M provides animal food to a contract farm, without sale of the animal food. Feed Mill M can determine the market value of animal food processed without sale by using the commodity price of the product (food for broiler chickens). Table 8 shows how the market value can be calculated based on the average price per ton of broiler feed and multiplying it by the volume of broiler feed provided to a contract farm. Feed Mill M would do the same calculation for 2015 and 2016. Feed Mill M can then compare its three-year average market value to the inflation-adjusted value for the most recent year included in the average posted on FDA's website at: https://www.fda.gov/food/guidanceregulation/fsma/ucm554484.htm to determine if the three-year average market value is less than $2,500,000 adjusted for inflation.

Table 8. Calculation of Market Value of Food for Broiler Chickens

Year	Average price per ton for broiler feed	Tons of broiler feed sent to contract farm	Market Value (before adjustment for inflation)
2014	$259.10	7,500	$1,943,250

IV. How to Contact FDA to Obtain Help with This Guidance

You can contact FDA with questions on this guidance using the FSMA Technical Assistance Network. Questions can be submitted online at https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm459719.htm.

You may also mail your questions to the address below:

Food and Drug Administration
5001 Campus Drive
Wiley Building, HFS-009
Attn: FSMA Outreach
College Park, MD 20740

V. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520).

The time required to complete this information collection is estimated to average 30 minutes per response, including the time to review instructions, search existing data sources, gather the data needed, and complete and review the information collection. Send comments regarding this burden estimate or suggestions for reducing this burden to:

5001 Campus Drive
Wiley Building, HFS-009
Attn: FSMA Outreach
College Park, MD 20740

This guidance also refers to previously approved collections of information found in FDA regulations. The collections of information in Part 117 have been approved under OMB Control No. 0910-0751 and the collections of information in Part 507 have been approved under OMB Control No. 0910-0789.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control number for this collection is 0910-0854.

VI. References

1. FDA 2016: Qualified Facility Attestation Using Form FDA 3942a (for Human Food) or Form FDA 3942b (for Animal Food): Instructions for Submitting Your Attestation. Accessible at: https://www.fda.gov/Food/GuidanceRegulation/FoodFacilityRegistration/default.htm

2. FDA 2017: Form FDA 3942a. Accessible at: https://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/ListFormsAlphabetically/default.htm

3. FDA 2017: Form FDA 3942b. Accessible at: https://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/ListFormsAlphabetically/default.htm

Certificate of Completion
Food Safety Document Development

THIS ACKNOWLEDGES THAT

HAS SUCCESSFULLY COMPLETED
TRAINING IN GMPS, EMPLOYEE TRAINING, AND FOOD SAFETY HAZARDS

ABIGAIL B. SNYDER

DATE