SMALL FOOD PROCESSOR PREPAREDNESS: DOCUMENTATION AND RECORD KEEPING REQUIREMENTS AND RECOMMENDATIONS

PCHF RULE QUALIFIED EXEMPTION-ELIGIBLE FOOD FACILITIES

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?

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 FOR HUMAN FOOD

Subpart A – General Provisions

Subpart B – Current Good Manufacturing Practice

Subpart D – Modified Requirements

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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.

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

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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 _____

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Approved by (*print name*) _____ Title _____

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WHY IS DOCUMENTATION NEEDED?

- 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?

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.

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

FOOD SAFETY MODERNIZATION ACT

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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

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)

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)

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)

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

FOOD SAFETY DOCUMENTATION REQUIREMENTS (FOR VERY SMALL FOOD BUSINESSES)

Required

- Training records
- Documentation supporting qualified exemptions

Suggested

- Monitoring and verification of critical food safety systems
- "Make sheets" for traceability by batches
- Checksheets for COVID-19 practices

MONITORING AND VERIFICATION OF CRITICAL FOOD SAFETY SYSTEMS

- Consider product and process-specific hazards
  - Pathogens like *E. coli, Salmonella,* and *Listeria*
  - Allergens
  - Depending on the product (i.e. acidified foods) you may already have additional record keeping requirements
- Determine what activities you use to control these hazards
  - Cook step, refrigeration, allergen labeling, etc.
- Implement simple record keeping practices to document control over these hazards at established time intervals
  - Record time/temperature information, check every batch of product labels for allergen declaration statements

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MAKE SHEETS FOR TRACEABILITY BY BATCHES

- Records can be prepared by activity (e.g. cooler monitoring log) or by batch (e.g. make sheets)
- Make sheets allow small processors to record all batch-specific information on one form
  - Time/temperature for processing
  - pH
  - Type of label used and that the allergen statement was present
  - Visual inspection of cleanliness following sanitation
  - Visual check on employees following GMPs
  - Lot numbers for ingredients
  - Batch numbers of finished product

CHECKSHEETS FOR COVID-19 MITIGATION ACTIVITIES

LIST OF FREQUENTLY TOUCHED SURFACES

Suggested cleaning procedure based on the equipment or surface

Bucket and Brush/ Sanitizing Spray

- ☐ Stainless table tops, production
- ☐ Main Dairy doors handles, in and out
- ☐ Tank room door handles, in and out
- ☐ COP tub Handle
- ☐ Case Hooks
- ☐ Domestic water hose handles
- ☐ Step ladder rails, dry ingredients
- ☐ Garbage bag frame holders
- ☐ Long bed cart handles
- ☐ Delivery truck back door handles
- ☐ Wheelers handles
- ☐ Garbage lid in cooler

CHECKSHEETS FOR COVID-19 MITIGATION ACTIVITIES

Disposable Cleaning and Sanitizing wipe

- ☐ Light switches to ingredient cooler and freezer
- ☐ Ingredient cooler pull cord, in and out
- ☐ Ingredient freezer pull cord, in and out
- ☐ Handicap accessible push buttons, in and out of main door
- ☐ Break room door handles, in and out
- ☐ Office door handles, in and out
- ☐ Door handles to concrete hallway by cooler, in and out
- ☐ "Man- door" to cooler, in and out
- ☐ Light switch to main cooler
- ☐ Exit door by truck loadout, in and out
- ☐ Plant lavatory door handles, in and out
- ☐ Dry ingredients pull cord, in and out
- ☐ Tool box drawers
- ☐ Cooler, pad lock, pull handle and exit
- ☐ Markers on white production schedule board
- ☐ Federal filler operation control buttons
- ☐ Control buttons for conveyors in bottle room
- ☐ Personal phone screens
- ☐ Mouse and keyboards located in lab/ control room
- ☐ Lactoscope
- ☐ Chart recorder handles
- ☐ Arms of office chair
- ☐ Ball point pens
- ☐ phone chargers
- ☐ Cell phones
- ☐ Truck gear shift
- ☐ Delivery truck steering wheel
- ☐ Driver door handle
- ☐ Controls for hot / cold dashboard of truck
- ☐ Truck keys
- ☐ Metal invoice clipboard of truck

CHECKSHEETS FOR COVID-19 MITIGATION ACTIVITIES

- Develop a protocol for WHEN you or an employee contracts COVID-19
  - Inform other workers in the facility (do not need to identify by name)
  - Perform intensive cleaning and sanitation of employee workspace, personnel locker, other high touch areas, and food contact surfaces
  - Use sanitizing products from List N of EPA-registered disinfectants effective against COVID-19
  - Identify other works who are in close contact with the ill individual within the last 48 h while maintaining privacy of the individual – as a rule of thumb, works who spent more than 15 minutes within 6 ft of the individual who did not wear a facemask. If possible, send these workers home until the results of tests are known.
  - When possible, monitoring of temperatures and request for disclosure of contact with sick individuals and symptoms
  - Determine who can backfill responsibilities in the case of illness or quarantine at all levels of the food business

COVID-19 PREPAREDNESS

If you're out of production, use this time to get your ducks in a row for when you re-open

If you're in production, beef up your GMPs and develop a continuity plan so you can stay in production

ADDITIONAL RESOURCES

- Abby Snyder – Cornell University, collaborating with Purdue, OSU, UCD to help small food businesses achieve compliance with FSMA through USDA supported programming.