
SMALL FOOD PROCESSOR

PREPAREDNESS: FSMA COMPLIANCE AND
QUALIFIED EXEMPTIONS FOR VERY SMALL FOOD
BUSINESSES

**PCHF RULE QUALIFIED EXEMPTION-
ELIGIBLE FOOD FACILITIES**



REGULATORY LANDSCAPE

- Just because we're focusing on COVID-19 preparedness, doesn't mean the existing regulations matter less
- During times of uncertainty and potential disruption in food production chains, production of safe product that complies with regulations is even more important
- Many of the practices that support COVID-19 preparedness (GMPs, business continuity plans) also enhance preparedness and compliance with food safety regulations
- More purchasing of retail sales, interest in local foods. For new and existing businesses, now is a valuable time to strategize about what you need to do to bring new products to market. This means identifying the steps to get food safety documentation in place and training completed.

WHO REGULATES FOOD?



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



- Meat
- Poultry
- Egg products

- State level inspectors
- Cottage food



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...)**



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



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PREVENTIVE CONTROLS FOR HUMAN FOOD

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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



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



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



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



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



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?



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.**



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



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



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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	<i>B Jones</i>
Candace Doe	Line operator	December 2018	GMPs	<i>B Jones</i>
Sheryl Cutter	Warehouse supervisor	December 2018	GMPs	<i>B Jones</i>
Jerome Cup	Pasteurizer operator	December 2018	GMPs	<i>B Jones</i>
Lisa Marie	Business owner	December 2018	GMPs	<i>B Jones</i>
Travis Mark	QA Technician	December 2018	GMPs	<i>B Jones</i>



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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, and UCD to help small food businesses achieve compliance with FSMA through USDA supported programming.
- Come to the next session to learn more

