
SMALL FOOD PROCESSOR PREPAREDNESS: OVERVIEW OF THE FOOD SAFETY REGULATORY LANDSCAPE RELEVANT TO SMALL FOOD PROCESSORS

**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.



**FDA FOOD SAFETY
MODERNIZATION ACT**

REGULATIONS WE ARE DISCUSSING

- 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?



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



- Meat
- Poultry
- Egg products

- State level inspectors
- “Cottage food”



OHIO COTTAGE FOOD LAWS

- Cottage food rule specifically lists ~20 items
 - If you're not sure, ask
 - NOT all canned foods are cottage foods
- AND must be produced in a home kitchen
- "This Product is Home Produced"
 - 10 pt. font
- Comply with other labeling requirements
 - Product name
 - Contents
 - Ingredients
 - Business name and address



INDIANA HOME BASED VENDOR RULES

- Similar, must be home produced
- Limits sales location to farmers market and roadside stand
- Includes a broader range of Home-Based-Vendor (HBV) foods: baked goods, candy, whole produce, tree nuts, honey, traditional high acid fruit jellies, fermented vegetables not in an oxygen sealed container, temperature controlled for quality-only products
- Similar labeling requirements: “This product is home produced and processed and the production area has not been inspected by the State Department of Health”



CALIFORNIA COTTAGE FOOD LAW

All CFOs (cottage food operations) have to meet specified requirements pursuant to the California Health and Safety Code related to:

- Preparing foods that are on the approved food list
- Completing a food processor training course within three months of registering
- Implementing sanitary operations
- Establishing state and federal compliant labels
- Operating within established gross annual sales limits



If you're not sure, ask your state Extension specialist or food safety regulator

PRODUCT EXAMPLE – WHAT ARE THE REGULATIONS?



FSMA?

Acidified foods?

Cottage foods?



PRODUCT EXAMPLE – WHAT ARE THE REGULATIONS?



FSMA?

Low A_w (canned) food?

Cottage foods?



WHAT DO I HAVE TO DO?

It Depends!

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.



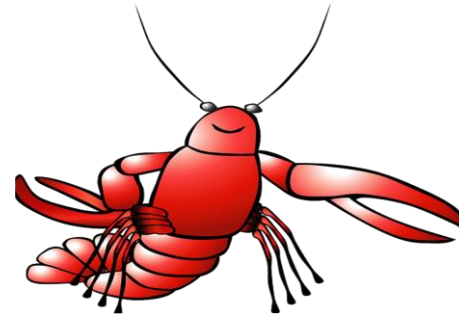
RISK-BASED FOOD SAFETY PROGRAMS



US Space program



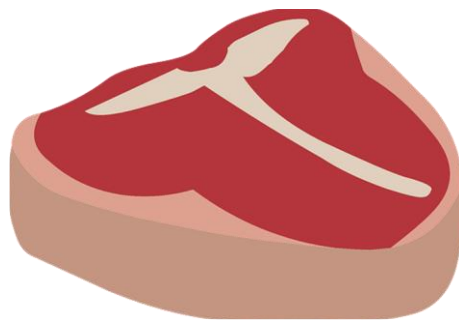
Low-acid canned food regs



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



**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



- 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...)**



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.



TEST YOUR KNOWLEDGE

DETERMINE THE REGULATORY
FRAMEWORK FOR THESE PRODUCTS

WHAT REGULATIONS APPLY?

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

WHAT REGULATIONS APPLY?

- You are a cookie manufacturer and you employ 10 people and sell \$5 million in cookie products each year.
- Preventive Controls Rule of FSMA

WHAT REGULATIONS APPLY?

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

WHAT REGULATIONS APPLY?

- You make cookies in your home and sell them at the local farmers' market.
- Cottage foods/home vendor

WHAT REGULATIONS APPLY?

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

WHAT REGULATIONS APPLY?

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

WHAT REGULATIONS APPLY?

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

WHAT REGULATIONS APPLY?

- You are a sauerkraut processor who sells \$700k in product every year.
- Preventive Controls Rule of FSMA
 - But, only subject to modified requirements

WHAT REGULATIONS APPLY?

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

WHAT REGULATIONS APPLY?

- You are a pickle processor who sells \$1.2 million in product each year.
- Preventive Controls Rule of FSMA

NEXT STEPS – PCHF RULE OF FSMA



**FDA FOOD SAFETY
MODERNIZATION ACT**

- Attend the next session on May 6th!
- GMP training and training documentation
- Depending on size, take the 2.5 hr PCQI course and develop written food safety plan
- OR document qualified exemptions through submission of the qualified exemption form

NEXT STEPS – ACIDIFIED FOODS



- 2-day Better Process Control School course
- Obtain a scheduled process
 - California – contact state
 - OH and IN, contact process authority:
 - Cornell Food Venture Center (bmx2@cornell.edu)

NEXT STEPS – COTTAGE FOODS

- Refer to state-specific regulatory requirements



NEXT STEPS – JUICE, SEAFOOD, DAIRY HACCP



- Enroll in product-specific HACCP courses
- Develop written HACCP plan

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

