

Entrepreneurs & Their Communities Monthly Webinar Series

Best Practices for Food Safety in Value-Added Foods

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Outline

- Why is food safety important?
- Regulatory overview
- Good Manufacturing Practices
- Other Food Safety Best Practices



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Foodborne Illness (FBI)

- Each year, CDC estimates 1 in 6 people get sick from foodborne illness
 - ~48 million get sick
 - ~128,000 are hospitalized
 - ~3,000 deaths
 - Highly under-reported
- Many recent outbreaks in various products
- **Can happen to all sizes of producers



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Persons of interest

- Young- day care facilities
- Old
- Pregnant
- Sick- chronic illness, immune disorder



Which Food Regulations??

- If selling in state, need to meet state regs
- Out of state: federal requirements
 - Meat and poultry: USDA
 - Basically all other foods and animal feed: FDA
 - Waiting on FSMA rules
- Selling to restaurants, grocery stores/coops, distributors- check with buyer!
- Farmers Markets- varies by state



HACCP plans

- Currently a regulatory requirement for:
 - Meat and poultry (USDA)
 - Juice (FDA)
 - Seafood (FDA)
 - Some vacuum packaged foods (FDA)
- FSMA will require “food safety plans”
 - GMPs and pre-requisites even more important
- Increasingly required by buyers
- Tool to strengthen safety of product



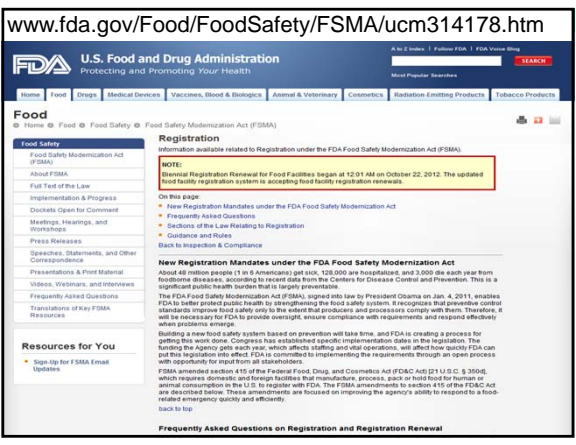
Registering with FDA

- Obtain licensing from relevant state agency first
- Register (free) on-line every two years
 - Must re-register before Dec 31, 2012
- FDA may inspect your facility
- Must meet GMPs




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www.fda.gov/Food/FoodSafety/FSMA/ucm314178.htm



Registration
Information available related to Registration under the FDA Food Safety Modernization Act (FSMA).

NOTE:
Biannual Registration Renewal for Food Facilities began at 12:01 AM on October 22, 2012. The updated food facility registration system is accepting food facility registration renewals.

On this page:

- New Registration Mandates under the FDA Food Safety Modernization Act
- Frequently Asked Questions
- Sections of the Law Relating to Registration
- Guidance and Rules

Back to Inspection & Compliance

New Registration Mandates under the FDA Food Safety Modernization Act
About 80 million people in the U.S. depend on get our 120,000 are regulations, and 2,000 the each year from foodborne diseases, according to recent data from the Centers for Disease Control and Prevention. This is a significant public health burden that is largely preventable.

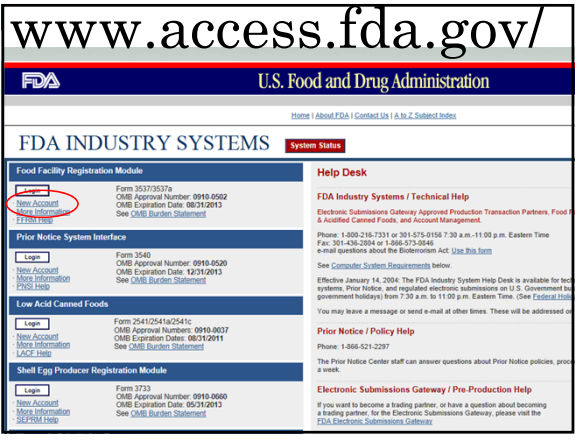
The FDA Food Safety Modernization Act (FSMA), signed into law by President Obama on Jan. 4, 2011, enables FDA to better protect public health by strengthening the food safety system. It recognizes that preventive control standards improve food safety only to the extent that producers and processors comply with them. Therefore, it will be necessary for FDA to provide oversight, ensure compliance with requirements and respond effectively when problems emerge.

Building a new food safety system based on prevention will take time, and FDA is creating a process for getting this work done. Congress has established specific implementation dates in the legislation. The funding the agency gets each year, which affects staffing and other operations, will affect how quickly FDA can put this legislation into effect. FDA is committed to implementing the requirements through an open process with opportunity for input from all stakeholders.

FSMA amended section 419 of the Federal Food, Drug, and Cosmetic Act (FFDCA) 21 U.S.C. § 3509, which requires domestic and foreign facilities that manufacture, process, pack, or hold food for human or animal consumption in the U.S. to register with FDA. The FSMA amendments to section 419 of the FFDCA are described below. These amendments are focused on improving the agency's ability to respond to a food-related emergency quickly and efficiently.

Frequently Asked Questions on Registration and Registration Renewal

www.access.fda.gov/



FDA INDUSTRY SYSTEMS System Status

| | |
|---|---|
| Food Facility Registration Module Log In New Account Forgot My Account Forgot My Password | Form 3537/3537a OMB Approval Number: 0910-0592 OMB Expiration Date: 08/31/2013 More Information See OMB Burden Statement |
| Prior Notice System Interface Log In New Account Forgot My Account Forgot My Password | Form 3540 OMB Approval Number: 0910-0520 OMB Expiration Date: 12/31/2013 More Information See OMB Burden Statement |
| Low Acid Canned Foods Log In New Account Forgot My Account Forgot My Password | Form 294102541a/2941c OMB Approval Number: 0910-0037 OMB Expiration Date: 09/30/2011 More Information See OMB Burden Statement LISC Link |
| Shell Egg Producer Registration Module Log In New Account Forgot My Account Forgot My Password | Form 3733 OMB Approval Number: 0910-0660 OMB Expiration Date: 09/30/2013 More Information See OMB Burden Statement |

Help Desk
 FDA Industry Systems / Technical Help
 Electronic Submissions Gateway Approved Production Transaction Partners, Food & Acidified Canned Foods, and Account Management
 Phone: 1-800-218-7331 or 301-575-0156 7:30 a.m. - 11:00 p.m. Eastern Time
 Fax: 301-426-2084 or 1-866-573-2646
[Email Questions](#)
 See [Computer System Requirements](#) below
 Effective January 14, 2014, The FDA Industry System Help Desk is available for two systems: Prior Notice, and regulated electronic submissions on U.S. Government (no government holidays) from 7:30 a.m. to 11:00 p.m. Eastern Time. (See [Federal Hours of Operation](#))
 You may leave a message or send e-mail at other times. These will be addressed or a work.

Prior Notice / Policy Help
 The Prior Notice Center staff can answer questions about Prior Notice policies, process a work.
 Phone: 1-866-521-2297

Electronic Submissions Gateway / Pre-Production Help
 If you want to become a trading partner, or have a question about becoming a trading partner, for the Electronic Submissions Gateway, please visit the [FDA Electronic Submissions Gateway](#)

Good Manufacturing Practices (GMPs or cGMPs – 21 CFR 110)

The basic sanitary and processing requirements necessary to ensure production of wholesome food.

- Facilities and grounds
- Equipment and utensils
- Personnel
- Raw materials
- Process control



Good Manufacturing Practices Buildings and Facilities

- Grounds – free of weeds, good drainage.
- Facilities – cleanable surfaces, good ventilation and lighting, chemical control.
- Well-maintained handwashing and restroom facilities.
- Water – potable, backflow prevention.



Germ Farm





Good Manufacturing Practices Equipment and Utensils

- Sanitary design: constructed of adequately cleanable materials, food-grade, suitable for intended use, precludes contamination
- Equipment installed and maintained to facilitate cleaning of equipment and adjacent areas
- Use only food-grade lubricants



Good Manufacturing Practices Personnel

- Disease Control
 - No sick workers
 - Prevent contamination (open sores, wounds).
- Hygienic Practices
 - Handwashing and personal cleanliness.
 - Hair restraints, no jewelry or loose articles.
 - No eating, drinking, tobacco products in production.
 - Proper attire (gloves, aprons, uniforms).





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Good Manufacturing Practices Personnel

- Education and Training
 - Proper food handling for all employees
 - Education and experience in identifying sanitation failures or possible food contamination issues.
- Supervision
 - To assure compliance to personnel GMPs



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Sample Employee Training Record

| Name | Workshop/ Training Subject | Date Completed | Initials | Copy of certificate in file? Y/N | Supervisor signature | Date |
|------|-------------------------------|-------------------|----------|---|-------------------------|------|
| | | | | | | |
| | | | | | | |

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Raw Material/Supplier Control

Systems to check incoming raw materials, assure that suppliers have effective food safety programs.

- Written specifications are in place for ingredients, packaging, and chemicals.
 - Need food grade packaging, appropriate for use
- Inspection procedure for incoming loads.
- Procedures for handling and storage.
 - At proper temperature, clean conditions, etc.



Process control

- Use First In- First Out (FIFO)
- Date and log incoming products
- Store materials in safe manner
 - Written SOPs for handling and storage of raw materials, in-process product and finished product
 - Including time/temperature control



SSOPs – Sanitation Standard Operating Procedures

- SSOPs should be in place for the cleaning and sanitizing of all food processing equipment.
 - Need to document what you are doing!
- A Master Sanitation Schedule for verification of routine cleaning
 - Include areas needing periodic cleaning such as coolers and storage facilities



Allergen Control Program

System in place to control allergens

8 Major Allergens

- Peanuts
- Tree Nuts
- Milk (Dairy)
- Wheat
- Soy
- Fish
- Crustacean shellfish
- Eggs



Allergen Control Program

- Raw materials containing allergens are properly labeled and stored.
- Movement of allergen- containing ingredients within facility is controlled to not cause cross contamination.
- Sanitation procedures to ensure complete removal of allergens from equipment.
- Procedures to ensure the labeling of finished product and rework containing allergens.



Pest Control Program

An effective program that controls pests (ex. Insects, rodents, birds).

1. Prevent entry into facilities.
2. Deny them food and water sources.
3. Exterminate as necessary



Use of a licensed, insured PCO (Pest Control Operator) recommended.

Chemical Control Program

Cleaners, sanitizers, lubricants, pesticides, and all other non-food chemicals.

- Properly labeled- all containers.
- Properly stored- away from food.
- Properly used.
 - Put away food and packaging or cover before cleaning or using chemicals
 - Use according to label instructions



Glass Control Program

Program to control glass and glass-like (brittle plastic) foreign material.

- Cover glass light bulbs
- Monitor glass packaging and other glass in facility
 - Try to prevent or at least detect breakage



Foreign Material Sources

- Metal
 - Nuts, bolts, mixers, knives, thermometers, grinders
- Wood
 - Crates, pallets
- Plastic
 - Box bands, packaging, broom handles
- Hair, gum, jewelry, pens, cigarette butts, etc.
 - Poor personal hygiene



Foreign material control

- Visual inspection
 - Raw materials during receiving
 - In process- carefully add ingredients to products
 - Final product/ outgoing food
- Good personal hygiene
- Practice good housekeeping
 - watch for potential contaminants



Traceability and Recall

Need to know:

- Where your ingredients came from
- Which ingredients went into every batch of product
- Where your products are going

Needed in case of a recall (of ingredients or your product)



Traceability and Recall

Needed elements:

- Accurately documented receiving and tracking of ingredients through facility
- Lot coding system
 - May be one day of production, one batch, etc.
- Accurately documented distribution (next slide)
- Plan in place to conduct the recall process, verified with mock recall.
- Crisis response plan in place.

Distribution Record example

Product Name: _____ Finished Product Code: _____

| Buyer | # Cases | Bottles/ Case | Jar Size | Shipper | Shipping Parameters (2-day, refrigerated, etc.) | Date Sent | Initials |
|-------|---------|------------------|-------------|---------|--|-----------|----------|
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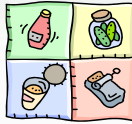
| | | | |
|----------|--|-------|--|
| Signed: | | Date: | |
| Reviewed | | Date: | |

Other Prerequisite Programs

Complaints – System to log, track, and trend consumer complaints for appropriate corrective action.

Labeling – System to ensure proper labeling.


Food defense/ Security- Prevention of intentional contamination of food.



Additional resources

- FDA Good Manufacturing Practices website
- UVM Extension Food Safety fact sheets:
www.uvm.edu/extension/food/?Page=food_safety.html
 - GMPs
 - Food Labeling
 - Farmers Market Food Safety
 - Other topics
- State Extension Services

Questions??



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Thank You!

Next month – January 10, 2013

Getting Action from Website Landing Pages

Jay Jenkins, UNL Extension