U.S. FOOD & DRUG ADMINISTRATION

Preventive Controls Update for Maple Producers

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http://www.fda.gov/fsma

FDA FOOD SAFETY MODERNIZATION ACT

THE FUTURE IS NOW

Objectives

- Do I have to Register with the FDA?
- What is the Preventive Control Rule?
- What parts of the Rule am I subject to?

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Food Facility Registration Background

BIOTERRORISM ACT OF 2002: The owner, operator, or agent in charge of a domestic or foreign facility engaged in manufacturing/processing, packing, or holding food for consumption by humans or animals in the United States is required to register the facility with FDA

- Food facilities must be registered before such operations begin
- The owner, operator, or agent in charge of a facility that is required to register may authorize an individual to register the facility on its behalf

FSMA Requirements

- The e-mail address for the contact person of the facility or, in case of a foreign facility, the email address of the U.S. Agent for the facility
- Assurance that FDA will be permitted to inspect the facility at the times and in the manner permitted by the FD&C Act
- Updated food category information, as determined appropriate by FDA
- Biennial Renewal
- Suspension of Registration

Food Facility Registration Exemptions

- Retail Food Establishments
- Farms
- Restaurants
- Nonprofit Food Establishments in which food is prepared for, or served directly to, the consumer
- Certain fishing vessels not engaged in processing;
- Facilities regulated exclusively, throughout the entire facility, by the U.S. Department of Agriculture (USDA) under the Federal Meat Inspection Act (21 U.S.C. 601, et seq.), the Poultry Products Inspection Act (21 U.S.C. 451, et seq.), or the Egg Products Inspection Act (21 U.S.C. 1031, et seq.).

Registration FAQ for Maple Producers

- **Are maple syrup producers "farms" and, thus, exempt from registering?**

- Gathering sap is a harvesting activity = farm = exempt from registering
- concentrating sugar maple sap by heating is a form of "manufacturing/processing" (21 CFR 1.227) = required to register, unless all of the concentrated sap is consumed on the farm or another farm under the same management, or another exemption applies.

Registration FAQ for Maple Producers

- **If a person has a business in his or her home that involves manufacturing, processing, packing, or holding food, does that person need to register that private residence as a food facility?**

- No. A private residence is not a facility as defined in 21 CFR 1.227. Thus, a private residence that meets customary expectations for a private residence that is also used to manufacture, process, pack, or hold food need not be registered.

Registration FAQ for Maple Producers

A number of maple sugar makers operate from their own property, on which their private residence is also located. Are these maple sugar makers required to register the facility that is on their property and used for maple sugar production?

- A private residence must meet **customary expectations** for a private home and does not otherwise include commercial facilities in which a person also happens to reside.

- If a separate building located on the real property of the private residence site is used as a maple sugar manufacturing or processing facility and does not have a use as **customarily expected** for a private residence, that facility must be registered, unless that facility qualifies for another exemption

If I register, will I be inspected by the FDA?

Registration of Food Facilities and Other Submissions

FDA Industry Systems

Login / Create Account

Content current as of: 09/20/2019

Regulated Product(s): Food & Beverages

The **Public Health Security and Bioterrorism Preparedness and Response Act of 2002** (the Bioterrorism Act) directs the Food and Drug Administration (FDA), as the food regulatory agency of the Department of Health and Human Services, to take steps to protect the public from a threatened or actual terrorist attack on the U.S. food supply and other food-related emergencies.

To carry out certain provisions of the Bioterrorism Act, FDA established regulations requiring that:

- Food facilities register with FDA, and
- FDA be given advance notice on shipments of imported food.

These regulations became effective on **December 12, 2003.**

The **FDA Food Safety Modernization Act (FSMA)**, enacted on January 4, 2011, amended section 415 of the Federal Food, Drug, and Cosmetic Act (FD&C Act), in relevant part, to require that facilities engaged in manufacturing, processing, packing, or holding food for consumption in the United States submit additional registration information to FDA, including an assurance that FDA will be permitted to inspect the facility at the times and in the manner permitted by the FD&C Act. Section 415 of the FD&C Act, as amended by FSMA, also requires food facilities required to register with FDA to renew such registrations every other year, and provides FDA with authority to suspend the registration of a food facility in certain circumstances. Specifically, if FDA determines that food manufactured, processed, packed, received, or held by a registered food facility has a reasonable probability of causing serious adverse health consequences or death to humans or animals, FDA may by order suspend the registration of a facility that:

1. Created, caused, or was otherwise responsible for such reasonable probability; or
2. Knew of, or had reason to know of, such reasonable probability; and packed, received, or held such food.

Guides and Tutorials

- Food Facility Account Management
- User Guides for Online Registration of Food Facilities
- Guide to Biennial Registration Renewal
- Cancellation by Paper (Mail or FAX)
- System Status

Quick Links

U.S. FOOD & DRUG ADMINISTRATION

Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food (21 CFR 117)

Implications for Maple Syrup Producers and Packers in the US

21 CFR part 117

- Modernizes longstanding current good manufacturing practice (CGMP) requirements
- Establishes new requirements for hazard analysis and risk-based preventive controls (HA/PC requirements)

21 CFR 117 Subparts

- A: General Provisions
- B: Current Good Manufacturing Practice
- C: Hazard Analysis and Risk-Based Preventive Controls
- D: Modified Requirements
- E: Withdrawal of Qualified Facility Exemption
- F: Records
- G: Supply Chain Control Program

21 CFR 117 Subparts

- A: General Provisions
- B: Current Good Manufacturing Practice
- C: Hazard Analysis and Risk-Based Preventive Controls
- D: Modified Requirements
- E: Withdrawal of Qualified Facility Exemption
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Good Manufacturing Practices*

Personnel must:

- be free of illness and wounds (or appropriately covered)
- wear suitable outer garments
- wash hands thoroughly (and sanitize if necessary)
- remove unsecured jewelry

* See 21 CFR 117 subpart B for full GMPs

Good Manufacturing Practices

Plant and Grounds must:

- be maintained in a way that protects food from contamination
- be of suitable in size, construction, and design to facilitate maintenance and sanitary operations for food-production purposes

Good Manufacturing Practices

Sanitary Operations

- Buildings, fixtures, and other physical facilities of the plant must be maintained in a clean and sanitary condition and kept in good repair.
- Pest Control
- Food contact surfaces must be cleaned as frequently as necessary to protect against contamination of food
- Toxic material must be held in a manner which prevents contamination

Good Manufacturing Practices

Sanitary Facilities and Controls

- Adequate, readily accessible toilet facilities
- Adequate hand-washing facilities
- Appropriate rubbish storage and removal

Good Manufacturing Practices

Equipment and Utensils

- Designed and of such material and workmanship as to be cleanable, and held in sanitary conditions, and that it protects from adulteration

Good Manufacturing Practices

Process and Controls

- Ensure that production procedures do not contribute to contamination from any source
- Adulterated food must be rejected
- Raw materials and ingredients are clean and suitable for processing into food

Good Manufacturing Practices

Warehouse and Distribution

- Store and transport food in such a manner that protects it from contamination

Holding and distribution of human food by-products for use as an animal food

- Human food by products to be used as animal food must be labeled and held in a manner that prevents contamination

Qualifications of Individuals

- Must have the education/ training/ experience necessary to manufacture, process, pack, or hold clean and safe food as appropriate to the individual's assigned duties

- Must receive training in the principles of food hygiene and food safety, as appropriate to the food, the facility and the individual's assigned duties

Hazard Analysis and Preventive Controls

- In general, firms that must register are subject to both the cGMP and HA/PC provisions of the rule

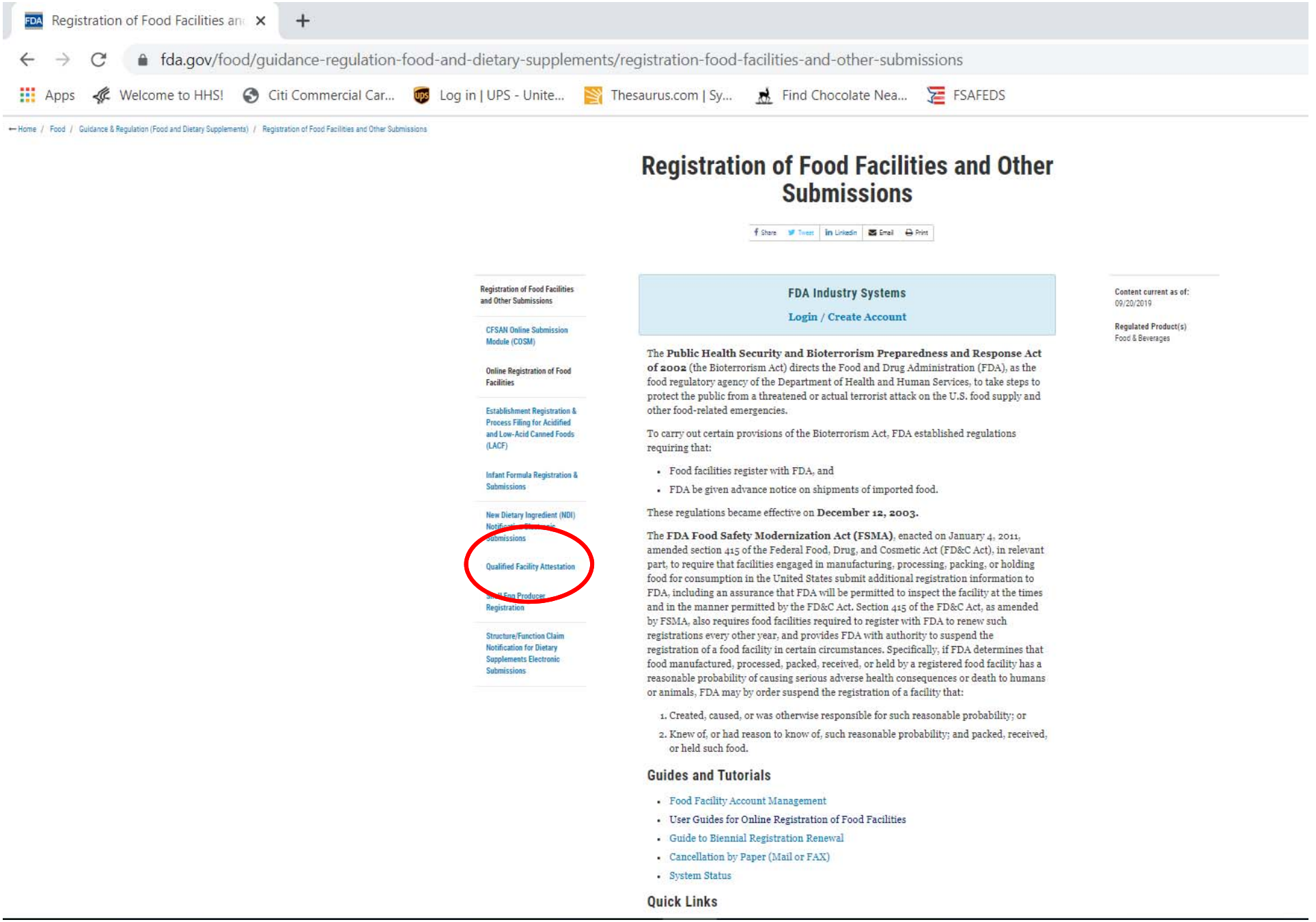
- However, there are exceptions to the HA/PC provisions, and many of these exceptions may be applicable to maple producers.

Qualified Facilities

- Very small businesses are qualified facilities exempt from the requirements for hazard analysis and risk-based preventive controls (but have some modified requirements).
  - Average less than $1M per year in sales of human food plus the market value of human food manufactured, processed, packed or held without sale

Modified Requirements for a Qualified Facility

- Attestation that the facility is a qualified facility; AND
  - Attestation that hazards have been identified and that preventive controls have been implemented and are being monitored; OR
  - Attestation that the facility is in compliance with an applicable non-Federal food safety law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Infant Formula Registration & Submissions
New Dietary Ingredient (NDI)
Submissions
Qualified Facility Attestation
Registration
Structure/Function Claim Notification for Dietary Supplements Electronic Submissions
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09/20/2019
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Exemptions (from HA/PC)

- Small/very small businesses only conducting certain low-risk manufacturing/processing, packing, and holding activities on farms on specific foods are exempt from PCs
  - Making sugars and syrups from saps (e.g., maple sugar, maple syrup)
  - Making candy from saps (e.g., maple candy, maple cream)

Food Safety Plan

- Hazard analysis
- Preventive controls
- Procedures for monitoring the preventive controls
- Corrective action procedures
- Verification procedures
- Recall plan

PC Qualified Individual

- A qualified individual who has successfully completed training in the development and application of risk-based preventive controls at least equivalent to that received under a standardized curriculum recognized as adequate by FDA or is otherwise qualified through job experience to develop and apply a food safety system.

Food Safety Plan – Hazard Analysis

- Hazard identification must consider known or reasonably foreseeable biological, chemical and physical hazards.
  - These could occur naturally, be unintentionally introduced, or be intentionally introduced for economic gain.
- Hazard evaluation must consider severity of illness/injury and probability of occurrence in absence of preventive controls

Contains Non-binding Recommendations
Draft-Not for Implementation

Hazard Analysis and Risk-Based Preventive Controls for Human Food: Draft Guidance for Industry[1]

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (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 FDA's Technical Assistance Network by submitting the form available at http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm459719.htm.

Appendix 1: Potential Hazards for Foods and Processes

Appendix Organization

This appendix contains information on the potential biological, chemical, and physical hazards that are food-related and process related. The potential hazard information presented covers the following 17 food (including ingredients and raw materials) categories:

- Bakery
- Beverage
- Chocolate and Candy
- Dairy
- Dressings and Condiments
- Egg
- Food Additives
- Fruits and Vegetables
- Game Meat
- Grains
- Multi-Component Foods (such as a refrigerated entrée or a sandwich)
- Nuts

[1] This guidance has been prepared by the Office of Food Safety in the Center for Food Safety and Applied Nutrition

Food Safety Plan – Preventive Controls

- Measures required to ensure that hazards are significantly minimized or prevented. These include:
  - Process controls
  - Food allergen controls
  - Sanitation controls
  - Supply-chain controls
  - Other controls

Reanalysis of Food Safety Plan

- At least every three years
- Whenever there is a significant change that creates the potential for a new hazard or a significant increase in one previously identified
- When there is new information about potential hazards associated with a food
- When a preventive control is ineffective

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Public Information

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- To submit a question about FSMA, visit www.fda.gov/fsma and go to Contact Us