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# Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food

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# Who is Covered by Part 117?

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- In general, facilities required to register with FDA under Sec. 415 of the FD&C Act
  - Facilities that manufacture, process, pack or hold human food
  - Not farms or retail food establishments
- Applies to domestic and imported food
- Some exemptions and modified requirements apply

# Exemptions from CGMP requirements

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- Farms
- Fishing vessels that do not have to register with FDA
- Establishments solely engaged in holding and/or transportation of one or more raw agricultural commodities
- Activities of farm mixed-type facilities that fall within the “farm” definition
- Establishments solely engaged in hulling, shelling, drying, packing, and/or holding nuts

# Exemptions from Hazard Analysis and Preventive Controls

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- Qualified facilities: modified requirements apply
- Foods subject to Hazard Analysis and Critical Control Point (HACCP) regulations (i.e., seafood, juice)
- Dietary supplements
- Alcoholic beverages
  - Additionally, food that is not an alcoholic beverage at such a facility if the food is prepackaged such that there is no direct human contact with the food, and constitutes  $\leq 5\%$  of the overall sales of the facility

# Exemptions from Hazard Analysis and Preventive Controls

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- Facilities solely engaged in storing unexposed packaged food: modified requirements if time-temperature control required for safety
- Small or very small businesses only conducting certain low-risk manufacturing/processing, packing, and holding activities on farms on specific foods
  - E.g. On-farm grinding, cracking, and crushing hops without additional manufacturing/processing

# Food Safety Plan

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- Hazard analysis
- Preventive controls
- Preventive control management components
  - Procedures for monitoring
  - Corrective action procedures
  - Verification procedures
- Supply-chain program
- Recall plan

# Preventive Controls Qualified Individual (PCQI)

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- 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
- Oversees preparation and implementation of the food safety plan

# Food Safety Plan: Hazard Analysis

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- Hazard identification must consider known or reasonably foreseeable biological, chemical (including radiological) and physical hazards
  - Naturally-occurring, unintentionally introduced, or intentionally introduced for economic gain
- Must consider severity of illness/injury and probability of occurrence in absence of preventive controls



# Food Safety Plan: Preventive Controls

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- Measures required to ensure that hazards are significantly minimized or prevented, including:
  - Process controls
  - Food allergen controls
  - Sanitation controls
  - Supply-chain controls
  - Recall plan

# Food Safety Plan: Preventive Control Management Components

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- Monitoring
- Corrective actions & corrections
- Verification
  - Includes (as appropriate to the facility, food and nature of the preventive control):
    - Validation of preventive controls (process PCs)
    - Verification of monitoring and corrective actions
    - Calibration of process monitoring and verification instruments
    - Product testing, environmental monitoring
    - Records review

# Circumstances in which you might not implement a preventive control

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- You determine that the type of food could not be consumed without application of an appropriate control and document that determination
- You rely on your customer to control the hazard or ensure that an entity further downstream will control the hazard and you:
  - Disclose in documents accompanying the food that the food “is not processed to control [identified hazard]”
  - Written assurance requirements: FDA intends to exercise enforcement discretion

# Food Safety Plan: Supply-Chain Program

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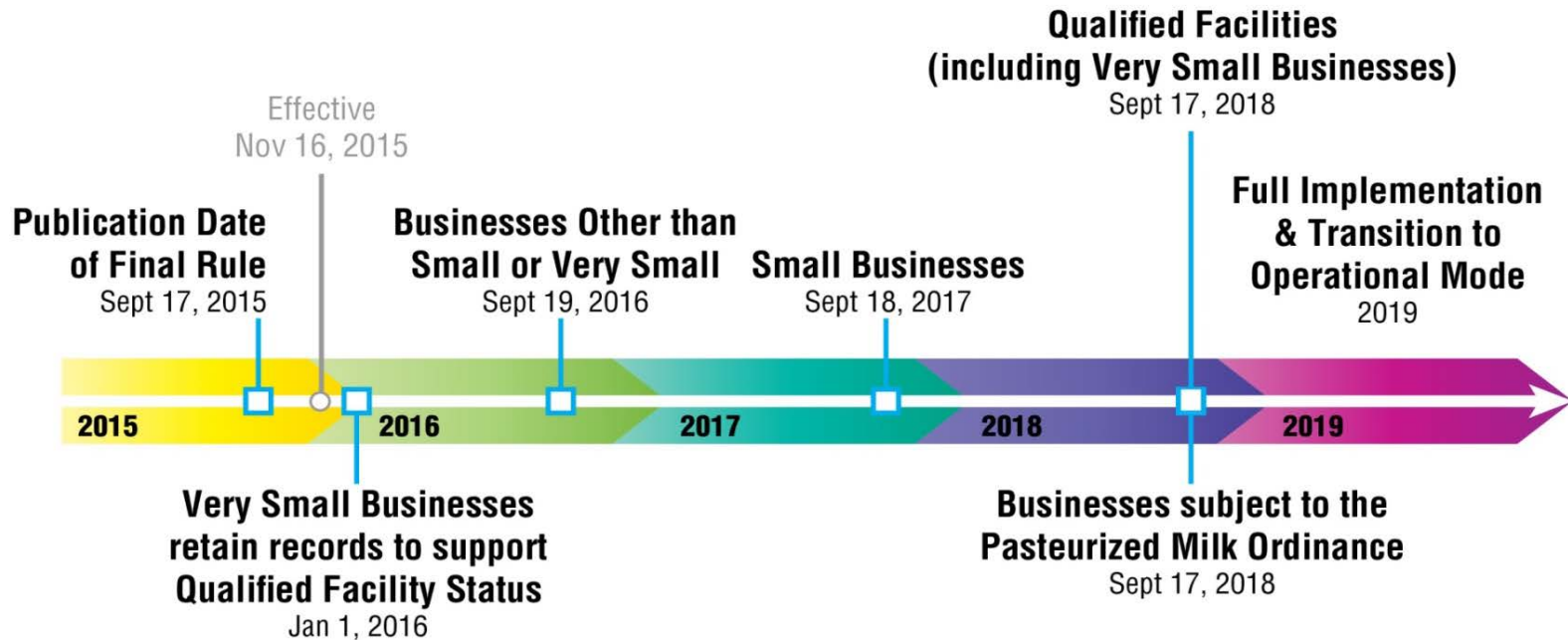
- Receiving facilities (manufacture/process a raw material or other ingredient) must ensure that the foods receiving a *supply-chain-applied control* are sourced from approved suppliers
- Establish written procedures for receiving raw materials and ingredients
- Determine appropriate supplier verification activities
- Conduct and document supplier verification activities
- When applicable, assess documentation of verification by another entity

# Food Safety Plan: Supplier Verification Activities

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- Sampling and testing of the raw material/ingredient
- Review of supplier's relevant food safety records
- Onsite audits
  - Annual audits are the appropriate verification activity for hazards that may cause serious adverse health consequences or death to humans (SAHCODH)
  - Other verification activities or less frequent auditing may provide adequate assurance that hazards are controlled
- Others based on supplier performance and risk associated with the raw material/ingredient, as appropriate

# Compliance Dates for Businesses



Small Businesses – business with fewer than 500 full-time equivalent employees

Very Small Businesses – average less than \$1M per year in sales of human food plus the value of such food manufactured, processed, packed or held without sale

\*Compliance dates for supply-chain program may differ.

# FDA's Food Safety Plan Builder

Food Safety Plan Builder - DPPB food safety plan\*

File Edit View Tools Help

Facility Information Preliminary Steps GMP & Other Prerequisite Programs Hazard Analysis & Preventive Controls Determination Process Preventive Controls Food Allergen Preventive Controls Sanitation Preventive Controls Supply-Chain Preventive Controls Recall Plan Reanalysis of

1. Product 1: Product Description

1a. Describe the full name of the finished product, including important food safety characteristics.

Comments:

Supplementary Information:

Include descriptors like Ready-To-Eat (RTE), frozen, the processing method(s), assembly, and the family of products included in the category. If it is relevant to product safety, then include intrinsic properties like water activity and pH.

Back Next

Detailed description of the software interface: The screenshot shows a web-based application window titled "Food Safety Plan Builder - DPPB food safety plan\*". The window has a standard menu bar (File, Edit, View, Tools, Help) and a toolbar with icons for file operations. Below the toolbar is a horizontal tabbed interface with several tabs: "Facility Information", "Preliminary Steps", "GMP & Other Prerequisite Programs", "Hazard Analysis & Preventive Controls Determination", "Process Preventive Controls", "Food Allergen Preventive Controls", "Sanitation Preventive Controls", "Supply-Chain Preventive Controls", "Recall Plan", and "Reanalysis of". The "Hazard Analysis & Preventive Controls Determination" tab is active, showing a tree view on the left and a main content area on the right. The tree view shows a hierarchy: "Describe the Product, Distribution, Intended Use and Consumption" (with a sub-item "Enter/Add Product Name"), "Product 1", "1. Product Description" (highlighted with a green arrow), "2. Intended Use, Intended Consumers, and Labeling Information", and "3. Flow Diagram Process Steps" (with sub-items "3a. Enter Product/Process Name and Steps From Each Flow Diagram" and "3b. Verify the Flow Diagram(s)"). The main content area is titled "1. Product 1: Product Description" and contains a form for "1a. Describe the full name of the finished product, including important food safety characteristics." with a text input field and a "Comments:" text area. To the right of the main content area is a "Supplementary Information:" section with a text area and "Zoom(-)" and "Zoom(+)" buttons. At the bottom of the main content area are "Back" and "Next" buttons.

DPPB food safety plan

# Guidance

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- FDA guidance
  - Hazard analysis and risk-based preventive controls for human food
  - Juice HACCP and FSMA, Seafood HACCP and FSMA, Low-acid canned foods and FSMA
  - Control of *Listeria monocytogenes* in Ready-to-Eat Foods
  - Application of the “Solely Engaged” exemptions in Part 117 and 507
  - Classification of Activities as Harvesting, Packing, Holding, or Manufacturing/processing for Farms and Facilities
  - Small entity compliance guide



# FSMA Frequently Asked Questions

## Frequently Asked Questions on FSMA

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### Questions & Answers on the Food Safety Modernization Act

- [Preventive Controls Rules: Human Food and Animal Food](#)
- [Final Rule for Preventive Controls for Human Food as it Relates to Dairy Products Produced under the Pasteurized Milk Ordinance \(PMO\)](#)
- [Dietary Supplements](#)
- [Produce Safety Rule](#)
- [Enforcement](#)
- [FSVP Rule](#)
- [Accredited Third-Party Certification](#)
- [Voluntary Qualified Importer Program](#)
- [Sanitary Transportation of Human and Animal Food](#)
- [Intentional Adulteration](#)
- [Recalls](#)
- [Administrative Detention](#)
- [Records and Records Access](#)
- [Registration](#)

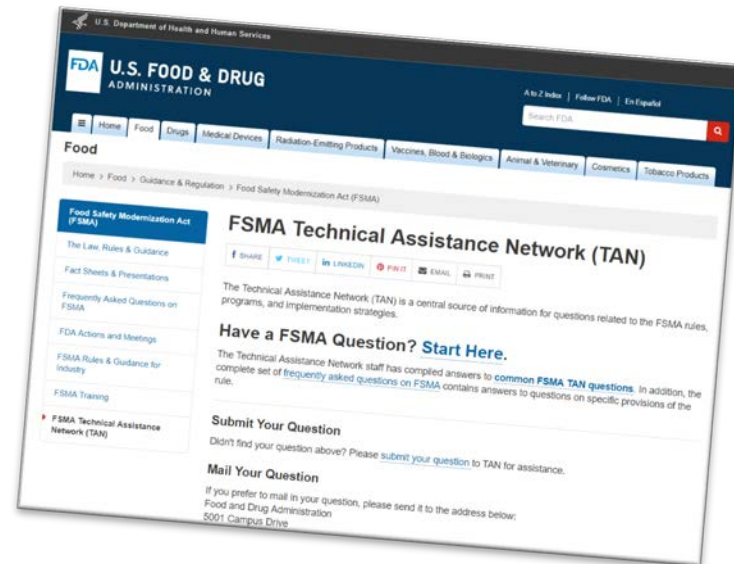
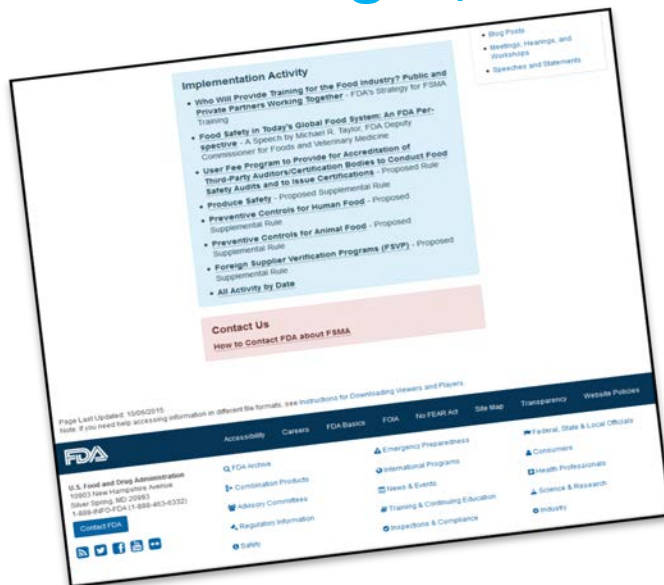
#### Additional Resources

- [Common Technical Assistance Network \(TAN\) Questions](#) (PDF: 146KB)
- [Contact TAN for Assistance](#)

<https://www.fda.gov/food/guidance/eregulation/fsma/ucm247559.htm>

# Contact FDA

- Web site: [www.fda.gov/fsma](http://www.fda.gov/fsma) (subscription feature available)
- To submit a question about FSMA, visit [www.fda.gov/fsma](http://www.fda.gov/fsma) and go to [Contact Us](#)



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Questions?