



**North Carolina Department of  
Agriculture & Consumer Services  
Steve Troxler, Commissioner**

**21 CFR Part 117 – Current Good  
Manufacturing Practice, Hazard  
Analysis, and Risk-Based Preventive  
Controls for Human Food**

**The Final Rule**

**AFDOSS Fall 2015 Educational  
Conference**



# **Food Safety Modernization Act Proposed Rules**

- **Produce Safety**
- **Preventive Controls for Human Food**
- **Preventive Controls for Food for Animals**
- **Foreign Supplier Verification Program**
- **Third Party Accreditation**
- **Intentional Adulteration**
- **Sanitary Transportation of food**



## **21 CFR Part 117**

**Final Rule announced on September 10, 2015**

- **Will be officially published in the Federal Register on September 17, 2015**
- **Current “unpublished version” = 930 pages!**  
**(The rule starts on page 834)**



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Public Inspection: Rule

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

An unpublished Rule by the Food and Drug Administration on 09/17/2015



This document has not been published and is only available in PDF format.

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This document is unpublished, but on 09/17/2015 it is scheduled to be published and available on this page. Until then, you can download the [pre-publication PDF version](#).

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This document is scheduled to be published in the Federal Register on 09/17/2015 and available online at <http://federalregister.gov/a/2015-21920>, and on [FDsys.gov](http://FDsys.gov)

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

21 CFR Parts 1, 11, 16, 106, 110, 114, 117, 120, 123, 129, 179, and 211

[Docket No. FDA-2011-N-0920]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.



# **Preventive Controls for Human Food**

## **21 CFR Part 117**

- Applies risk-based preventive principles to the manufacturing, processing, packing and holding of food for humans
- Facilities, unless otherwise exempt, would be required to implement a written food safety plan that focuses on preventing hazards in foods
- Includes updated Good Manufacturing Practices



# Hazard Analysis and Risk-Based Preventive Controls

- Process controls
- Food allergen controls
- Sanitation controls
- Recall plan





## **Subparts:**

- A. General Provisions**
- B. Current Good Manufacturing Practice**
- C. Hazard Analysis and Risk-based Preventive Controls**
- D. Modified Requirements**
- E. Withdrawal of a Qualified Facility Exemption**
- F. Requirements Applying to Records That Must Be Established and Maintained**
- G. Supply-Chain Program \***





## **Overview of Changes:**

- New, revised, removed definitions
- Revised low risk food/activity combinations for on-farm mixed type facility exemptions
- New Sections in Subparts A, C and F
- Supplier verification now is in separate Subpart and is renamed “Supply-Chain Program”
- Redefinition of farm in 21CFR1.227
- By-products (for animal food) not addressed in this rule, but are addressed in the Animal PC Rule.



## **21CFR1.227 – Farm Definition:**

- Revised to include two designations:
  - Primary Production Farm and
  - Secondary Activities Farm
- Addresses “ownership” and “one general location” issues
- Replaces the term “establishment” with “operation”



## **21CFR1.227 – Farm Definition:**

(1) Primary production farm. A primary production farm is an operation under one management in one general (but not necessarily contiguous) physical location devoted to the growing of crops, the harvesting of crops, the raising of animals (including seafood), or any combination of these activities.



## **21CFR1.227 – Farm Definition:**

(2) Secondary activities farm. A secondary activities farm is an operation, not located on a primary production farm, devoted to harvesting (such as hulling or shelling), packing, and/or holding of raw agricultural commodities, provided that the primary production farm(s) that grows, harvests, and/or raises the majority of the raw agricultural commodities harvested, packed, and/or held by the secondary activities farm owns, or jointly owns, a majority interest in the secondary activities farm.



## **Subpart A:**

- Revised, added deleted definitions
- Added new sections
- Revised exemptions – particularly the low risk activity/food combinations for on-farm mixed type facilities



## **Subpart B:**

- **First revision of GMPs since 1986**
- **No new sections**
- **Removed nonbinding provisions (the “shoulds”) or made them requirements**



## **Subpart C:**

- Added in new sections (§§117.136 and 117.37) to describe circumstances where preventive controls are not required
- Retained product testing and environmental monitoring
- Supplier verification is a requirement of a food safety plan, but moved requirements to Subpart G Supply-Chain Program



## **Subpart G:**

- Receiving facility must establish and implement a risk-based supply chain program for raw materials and ingredients for which the receiving facility has identified a hazard requiring a supply-chain-applied control
- Addresses receivers that are also importers
- Addresses shell egg producers as suppliers





## Compliance Dates

Table 53.--Compliance Dates for the Requirements of Part 117 Other than the Requirements for a Supply-Chain Program (Subpart G)

Size of Business	Compliance Date
Qualified facility (including very small business) as defined in § 117.3	September 17, 2018, except that the compliance date for a facility to retain records to support its status as a qualified facility is January 1, 2016
Small business as defined in § 117.3	September 18, 2017
Businesses subject to the Pasteurized Milk Ordinance	September 17, 2018
All other businesses	September 19, 2016



# Compliance Dates

Table 54.--Compliance Dates for the Requirements of the Supply-Chain Program (Subpart G)

Situation	Compliance date:
A receiving facility is a small business and its supplier will not be subject to the human preventive controls rule or the produce safety rule	September 18, 2017
A receiving facility is a small business and its supplier is subject to the human preventive controls rule or the produce safety rule	The later of: September 18, 2017 or 6 months after the receiving facility's supplier of that raw material or other ingredient is required to comply with the applicable rule
A receiving facility is not a small business or a very small business and its supplier will not be subject to the human preventive controls rule or the produce safety rule	March 17, 2017
A receiving facility is not a small business or a very small business and its supplier will be subject to the human preventive controls rule or the produce safety rule	6 months after the receiving facility's supplier of that raw material or other ingredient is required to comply with the applicable rule



## **Additional Compliance Dates For qualified facilities:**

December 17, 2018—

- Initial attestation by a facility that it is a qualified facility per 117.201(a)(1) And
- Attestation regarding food safety practices per 117.201(a)(2)(i) **OR** that it is in compliance with non-Federal Food safety law per 117.201(a)(2)(ii)



## **One More Compliance Date For qualified facilities:**

January 1, 2020—

- Notification requirement per 117.201(e)(1) – notification to consumers for those facilities that are complying with applicable non-Federal food safety law.



## **21 CFR Part 117**

### **Overarching Concerns**

- Must ensure equal treatment of domestic and foreign producers in compliance and enforcement
- Extensive training and technical assistance for industry; must have education before regulation
- Resources are needed for State agencies to implement rules
- Technical assistance and guidance documents are needed before and during implementation



## Questions

- In the revised definition of farm...what is a “majority interest”?
- Following the completion of updates to the PMO, will Grade A facilities be regulated under the PMO or the PC rule? If under the PC rule, how will that be integrated into existing regulatory structure at the state level?
- When will guidance be issued?
- When will regulator training be available?



## **Next Steps:**

- Read, Read, Read – the devil is in the details
- Determine impact on industry
- Impact on regulatory program resources
- Identify Collaborations
- Funding

# Resources from FDA: Fact Sheets/Q&A:

## FSMA FACTS

FDA FOOD SAFETY  
MODERNIZATION ACT

THE FUTURE IS NOW

### Final Rule on Preventive Controls for Human Food

#### Summary

The FDA Food Safety Modernization Act (FSMA) Preventive Controls for Human Food rule is now final, and compliance dates for some businesses begin in September 2016.

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

- [General](#)
- [Preventive Controls Rules: Human Food and Animal Food](#)
- [Produce Safety Rule](#)
- [FSVP Rule](#)
- [Third-Party Accreditation](#)





## **Resources from FDA: Webinars:**

**Tuesday, September 15, 2015**

**Final Rules for Preventive Controls for Human and Animal Food:  
Who is Covered? What is the Definition of a Farm?**



**Wednesday, September 16, 2015**

**Final Rule for Preventive Controls for Human Food:  
Significant Provisions of the Rule**



**Thursday, September 17, 2015**

**Final Rule for Preventive Controls for Animal Food:  
Significant Provisions of the Rule**





# Resources from FDA: Public Meeting



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## FSMA Public Meeting: Preventive Controls for Human and Animal Food Final Rules

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### Save the Date

October 20, 2015 - 8:30 am to 5:30 pm

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540 North Michigan Ave.  
Chicago, IL 60611



**Thank you!**

**Anita MacMullan  
Food Administrator**





**Come visit us in Raleigh....  
October 15 - 25**

