



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



**Produce Safety Rule vs.
Human Preventive Controls...
Which Rule Applies?**

**NC Produce Professionals Meeting
March 14, 2018**



Food Safety Modernization Act

FSMA

- Signed into law January 4, 2011.
- Focus on prevention through application of risk-based preventive controls.
- Provides new enforcement authorities.
- Strengthens authority to ensure safety of imported foods.



Final Rules: Issuance Dates

- **Preventive Controls for Human Food: Sep 17 2015**
- Preventive Controls -Food for Animals: Sep 17 2015
- **Produce Safety Rule: Nov 27 2015**
- Foreign Supplier Verification Program: Nov 27 2015
- Third Party Accreditation: Nov 27 2015
- Sanitary Transportation of food: Apr 6 2016
- Intentional Adulteration: May 27 2016



Produce Safety Rule

21 CFR Part 112 – Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption



Produce Safety Rule

Establishes science-based minimum standards for the safe growing, harvesting, packing and holding of fruits and vegetables for human consumption.

- Focus on routes of microbial contamination
- Risk-based, considers practices and commodities
- Includes provisions for alternatives and variances
- Includes exemptions and exclusions



Standards for Produce Safety

- Personnel qualifications and training
- Health and hygiene
- Agricultural water
- Biological soil amendments of animal origin
- Domesticated and wild animals
- Growing, harvesting, packing and holding activities
- Equipment, tools, buildings and sanitation
- Specific requirements for sprouts



Who is Covered?

- **Farms** that grow, harvest, pack or hold produce commonly consumed raw: Fruits , Vegetables, Mushrooms, Sprouts, Herbs and Tree Nuts
- Not covered:
 - Farms with annual produce sales under \$25,000
 - Produce for personal or on-farm consumption
 - Produce rarely consumed raw
 - Produce that will receive commercial processing



Does your farm grow, harvest, pack or hold produce?

Sections 112.1 and 112.3(c)
We define "produce" in section 112.3(c).

NO



Your farm is
NOT covered
by this rule.

YES

Does your farm on average (in the previous three years) have \$25k or less in annual produce sales?

Section 112.4(a)

YES



Your farm is
NOT covered
by this rule.

NO

Is your produce one of the commodities that FDA has identified as rarely consumed raw?

Section 112.2(a)(1)

If you grow, harvest, pack or hold more than one produce commodity, you must ask this question separately for each one to determine whether that particular produce commodity is covered by this rule.

YES



This product is
NOT covered
by this rule.

NO

Is your produce for personal/on-farm consumption?

Section 112.2(a)(2)

YES



This produce is
NOT covered
by this rule.

NO

Is your produce intended for commercial processing that adequately reduces pathogens (for example, commercial processing with a "kill step")?

Section 112.2(b)

YES



This produce is eligible
for exemption from the rule,
provided you make certain statements in documents
accompanying the produce, obtain certain written
assurances, and keep certain documentation, as per
Sections 112.2(b)(2) through (b)(6).

NO

Does your farm on average (in the previous three years) as per Section 112.5:

have < \$500k annual food sales,
AND

a majority of the food (by value) sold
directly to "qualified end-users"?

Section 112.3(c)

"Qualified End-User" as defined in
Section 112.3(c) means:

- the consumer of the food OR
- a restaurant or retail food establishment that is located—
 - (i) in the same State or the same Indian reservation as the farm that produced the food; OR
 - (ii) not more than 275 miles from such farm.

(The term "consumer" does not include a business.)

YES



Your farm is eligible for a
qualified exemption from this rule,
which means that you must comply with certain
modified requirements and keep certain
documentation, as per Sections 112.6 and 112.7.

NO

**YOU ARE COVERED
BY THIS RULE.**

STANDARDS FOR PRODUCE SAFETY Coverage and Exemptions/Exclusions for 21 PART 112

The Preventive Controls for Human Food rule clarified the definition of a farm to cover two types of farm operations, primary production farms and secondary activities farms. The same definition is used in the Produce Safety rule (section 112.3(c)). Below are basic criteria that determine whether an operation that meets the definition of "farm" is subject to the produce rule.



Preventive Controls for Human Food Rule (the PC Rule)

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



The PC Rule

- Updated Good Manufacturing Practices.
- 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 regulation of “farm mixed type” facilities.



Who is Covered?

- **Facilities** that manufacture, process, pack or hold human food.
- Required to register with FDA under sec. 415 of the FD&C Act.
- Applies to domestic and imported facilities.
- Some exemptions and modified requirements for certain business sizes and types of manufacturing processes.



Which Regulation Applies?

- Is it a Farm?
 - Do they conduct a covered activity on covered produce?
- Is it a Facility?
 - Do they manufacture/process food?
- Is it both?



Is it a Farm?

Defined in the regulation at §112.3

- Primary Production Farm-
 - Growing crops, harvesting crops, raising animals or any combination of activities, includes:
 - ✦ Pack or Hold RACs
 - ✦ Pack or Hold Processed food for on-farm consumption
 - ✦ Manufacture/Process food under specific conditions



Is it a Farm?

- Secondary Activities Farm-
 - Not located on primary production farm, includes:
 - ✦ Harvesting, Packing and/or Holding RACS.
 - The primary production farm(s) that grows, harvests, and/or raises the majority of the raw agricultural commodities owns, or jointly owns, a majority interest in the secondary activities farm.
 - Includes same additional activities as a primary production farm.



Is it a Facility?

Defined in the regulation at §§117.3 and 1.225

- Required to register with FDA.
- Manufacture, process, pack or hold food for consumption in the US.
- Manufacture/process means making food from one or more ingredients.
- Farms, retail operations and restaurants are not facilities.



Is it Both?

- Farm mixed type facility.
- Conduct activities of a farm and a facility.
- Subject to both Produce Safety and PC Rules.



Guidance

- Draft Guidance for Industry: Classification of Activities as Harvesting, Packing, Holding, or Manufacturing/Processing for Farms and Facilities – August 2016.
- Small entity Compliance Guide: Guidance for Industry: Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption: What You Need to Know About the FDA Regulation - Small Entity Compliance Guide – September 2017.



Next Steps

- Farm definition: FDA Commissioner Scott Gottlieb, NASDA Winter Policy Conference, January 31, 2018
“FDA understands the need to reexamine the definition of a farm, along with several other challenges in the FSMA rules.”
- Enforcement discretion: Guidance for Industry: Policy Regarding Certain Entities Subject to the Current Good Manufacturing Practice and Preventive Controls, Produce Safety, and/or Foreign Supplier Verification Programs.



Impact on NC Agribusiness

- Cost of Compliance-facility upgrades, food safety plans
- Employee Training
- Potential changes in routine business practices
- Impact of multiple audits
- Increased cost of production





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

[Preventive Standards under the FSMA Main Page](#)

Generally, domestic and foreign food facilities that are required to register with section 415 of the Food, Drug, & Cosmetic Act must comply with the requirements for risk-based preventive controls mandated by the FDA Food Safety Modernization Act (FSMA) as well as the modernized Current Good Manufacturing Practices (CGMPs) of this rule (unless an exemption applies). It is important to note that applicability of the CGMPs is not dependent upon whether a facility is required to register.

Final Rule

- [Federal Register Notice](#)
- [Docket Folder **FDA-2011-N-0920**](#)
- [Questions & Answers](#)
- [Clarification of Compliance Date for Certain Food Establishments](#)
- [Fact Sheet \(PDF: 138KB\)](#)

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[Produce Safety Standards under the FSMA Main Page](#)

View the Final Rule Contents in the Federal Register Notice

Below is a fact sheet provided by FDA.

In this fact sheet:

- [Introduction](#)
- [Key Requirements](#)
- [Exemptions](#)
- [Variances](#)
- [Compliance Dates](#)
- [Environmental Impact Statement](#)
- [Assistance to Industry](#)

About the Final Rule

- [Federal Register Notice](#)
- [Docket Folder **FDA-2011-N-0921**](#)
- [Questions & Answers](#)
- [Coverage and Exemptions/Exclusions Flowchart \(Color PDF: 95KB\)](#)
- [Coverage and Exemptions/Exclusions Flowchart \(Black & White PDF: 67KB\)](#)



How do I find the Rules?

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Rules and Guidance for Industry related to the FDA Food Safety Modernization Act (FSMA).

- [Rules](#)
- [Guidance for Industry & Others](#)



In Conclusion

Determining which rule applies is
complicated...

**I may not have answered all your questions
but probably questioned all your answers....**



NORTH CAROLINA

DEPARTMENT OF AGRICULTURE & CONSUMER SERVICES

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Thank you!

Anita.macmullan@ncagr.gov

Questions?

