

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

5

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

$\left[6\right)$

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?

- <u>Farms</u> that grow, harvest, pack or hold produce commonly consumed raw: Fruits, Vegetables, Mushrooms, Sprouts, Herbs and Tree Nuts
- Not covered:
 - o 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



(9)

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?
 - O Do they conduct a covered activity on covered produce?
- Is it a Facility?
 - O 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-
 - O 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

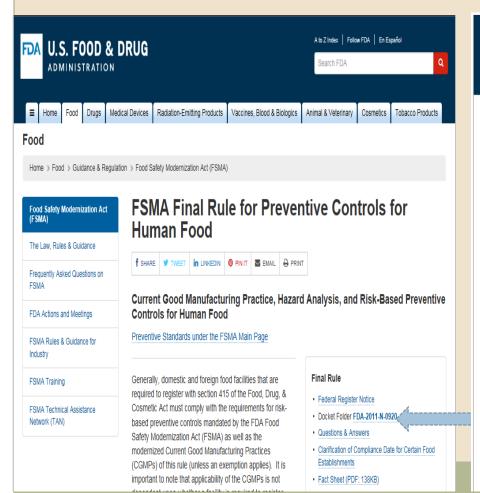


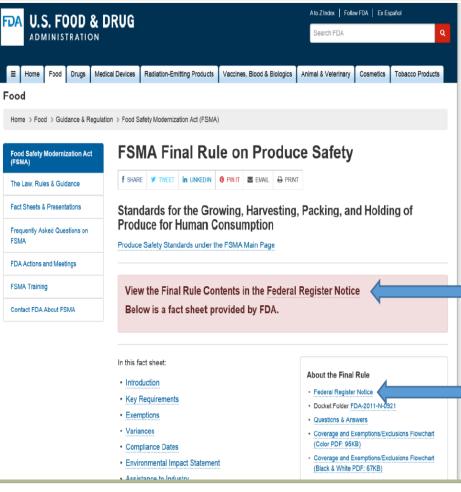


NORTH CAROLINA DEPARTMENT OF AGRICULTURE & CONSUMER SERVICES



How do I find the Rules?



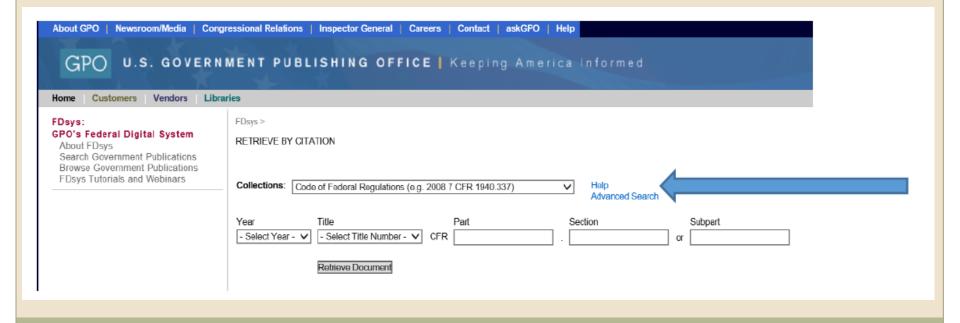


NORTH CAROLINA DEPARTMENT OF AGRICULTURE & CONSUMER SERVICES

21

How do I find the Rules?

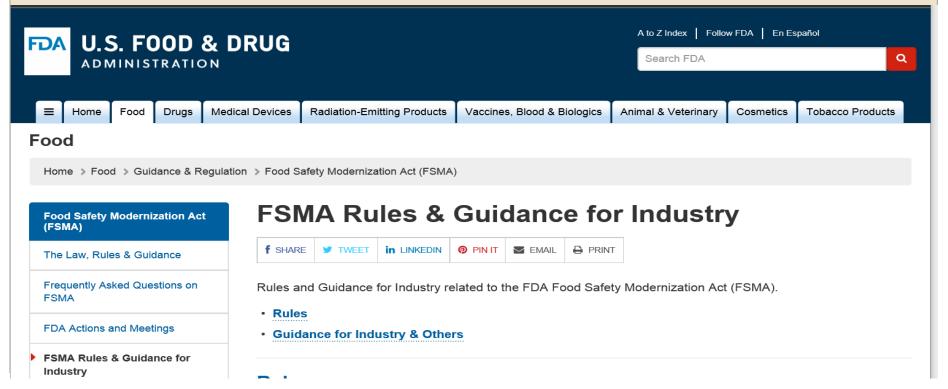
https://www.gpo.gov/fdsys/search/submitcitation.action?publication=CFR





How do I find FDA Guidance?

https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm253380.htm#guidance





In Conclusion

Determining which rule applies is complicated...

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



Thank you!

Anita.macmullan@ncagr.gov

Questions?

