



PennState Extension

Richard Kralj, M. Ed., RDN, LDN

**Senior Extension Educator
Food Safety & Quality**



PennState Extension



FSMA For Food & Feed Grains



The Food Safety Modernization Act (FSMA)



- FSMA includes:
 - Produce Safety Rule
 - Preventive Controls for Human Food
 - Preventive Controls for Animal Food
 - Foreign Supplier Verification Programs
 - Accreditation of Third-Party Auditors/Certification
 - Sanitary Transportation of Human and Animal Food
 - Prevention of Intentional Contamination/Adulteration

Components of Good Manufacturing Practices (GMPs) Human Foods

- The regulation (21 CFR 117 Subpart B) lists these components that establish the conditions and practices the food industry must follow for processing safe food under sanitary conditions:
 - Personnel
 - Plant and grounds
 - Sanitary operations*
 - Sanitary facilities and controls
 - Equipment and utensils
 - Processes and controls*
 - Warehousing and distribution
 - Holding and distribution of human food by-products for use as animal food, and
 - Defect action levels

*Some components may be preventive controls based on hazard analysis

Components of Good Manufacturing Practices (GMPs) Animal Foods

- The regulation (21 CFR 507 Subpart B) lists these components that establish the conditions and practices the Animal Food industry must follow for processing safe food under sanitary conditions:
 - Personnel
 - Plant and grounds
 - Sanitation
 - Water supply & plumbing
 - Equipment and utensils
 - Plant operations
 - Holding and distributions
 - Holding and distribution of human food by-products for use as animal food, and

How Does FSMA Effect What I Do or Sell From My Farm

- It depends on who the targeted audience is for my product
- FDA has various regulations for making and selling human and/or animal foods
- Facilities that manufacture, process, pack or hold human food (§ 117.1) In general, facilities required to register with FDA under sec. 415 of the FD&C Act
- Farms generally exempt from requirements to register with FDA and compliance with FSMA PC rules
 - A farm mixed-type facility must register with FDA

Flow Chart

- <https://nam10.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.vermontlaw.edu%2Fsites%2Fdefault%2Ffiles%2F2021-08%2FUnderstanding-FSMA.pdf&data=04%7C01%7Crak15%40psu.edu%7C565cb145c2b049d38dd008d9d6c1bc87%7C7cf48d453ddb4389a9c1c115526eb52e%7C0%7C0%7C637776949840565223%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzliLCJBTil6Ik1haWwiLCJXVCI6Mn0%3D%7C3000&sdata=cl2DE%2BQz3uGG4JuVJeieTlh3TDpTqcKjZy0GbavveEw%3D&reserved=0>

Human Food

“Qualified” facilities (§ 117.5(a))

- Very small businesses (less than \$1 million in total annual sales of human food plus the value of food held without sale)

OR

- Food sales averaging less than \$500,000 per year during the last three years AND
- Sales to qualified end-users must exceed sales to others

Animal Food

“Qualified” facilities (§ 507.3(a))

- Very small businesses - definition >\$2,500,000
- **OR**
- Food sales averaging less than \$500,000 per year during the last three years AND
- Sales to qualified end-users must exceed sales to others

Exempt from hazard analysis and risk-based preventive controls when certain documentation is provided [GMP's Still apply](#)

FDA - Exemptions - “Qualified Facility”

Exemptions for Farms

- “Qualified” facilities (§ 507.3(a))
 - Very small businesses - definition >\$2,500,000
 - **OR**
 - Food sales averaging less than \$500,000 per year during the last three years **AND**
 - Sales to qualified end-users must exceed sales to others
- Exempt from hazard analysis and risk-based preventive controls when certain documentation is provided [GMP's Still apply](#)

Farms and the Preventive Controls Rule

- Making sure your operation meets the regulatory definition for “Farm”
 - Consider the range of your activities you conduct
 - The location of where these activities are carried out
- Processing grains - not part of “farm definition”
 - Limited exceptions include the following:
 - Packaging & labeling small quantities of whole grains directly to consumers

Additional processing steps may lead to a “Mixed-type Facility” subject to PCR.

An Entity Does Not Have To Grow & Harvest Crops To Be Considered A Farm

- Secondary active farms
 - Majority of grain cleaned, dehulled or stored must come from a farm, or multiple farms, or cooperatives that have a majority ownership interest in the operation

The Facilities and the Preventive Control Rules

- Farm-Mixed Types
 - Small or very small farms may qualify for certain exemptions under PCR for low risk processing
 - Farms that do low risk processing but also engage in other processing not identified as low risk are not eligible for exemption and would be subject to PCR
- Example of low risk processing
 - Milling grains, baking bread from milled grained products, flaking oats, making popcorn, and making ronal or trail mix from grain products such as oat flakes

All Facilities

- To comply with the PCR, All facilities, including mixed-type-facilities doing low-risk processing on farm and storage must
 - Register as a food facility with FDA
 - Follow employee training requirements in Subpart A
 - Implement cGMP'S as outlined in Subpart B
 - Follow record keeping requirements as outlined in Subpart F

Qualified Facilities

- To comply with the PCR, All facilities, including mixed-type-facilities doing low-risk processing on farm and storage must
 - Register as a food facility with FDA
 - Submit biennial attestation to FDA
 - Follow employee training requirements in Subpart A
 - Implement cGMP'S as outlined in Subpart B
 - Follow record keeping requirements as outlined in Subpart F

Farm mixed-type facilities that conduct processing beyond what is identified in the low-risk activity may be qualified facility and not subject HARPC and Supply chain program requirements

Fully Covered Facilities

- To comply with the PCR, All facilities, including mixed-type-facilities doing low-risk processing on farm and storage must
 - Register as a food facility with FDA
 - Follow employee training requirements in Subpart A
 - Implement all provisions of PCR, including HARPC and Supply-Chain program
 - Implement cGMP'S as outlined in Subpart B
 - Follow record keeping requirements as outlined in Subpart F

Farm mixed-type facilities that conduct processing beyond what is identified in the low-risk activity may be qualified facility and not subject HARPC and Supply chain program requirements

Facilities that pack, hold, or process alcoholic beverages

- To comply with the PCR, All facilities, including mixed-type-facilities doing low-risk processing on farm and storage must
 - Register as a food facility with FDA
 - Follow employee training requirements in Subpart A
 - Implement cGMP'S as outlined in Subpart B
 - Follow record keeping requirements as outlined in Subpart F

Farm mixed-type facilities that conduct processing beyond what is identified in the low-risk activity may be qualified facility and not subject HARPC and Supply chain program requirements

Operations such as breweries and distilleries that manufacture, process, pack, or hold alcoholic beverages must register with FDA as facilities. Such operations are exempt from HARPC and supply chain program

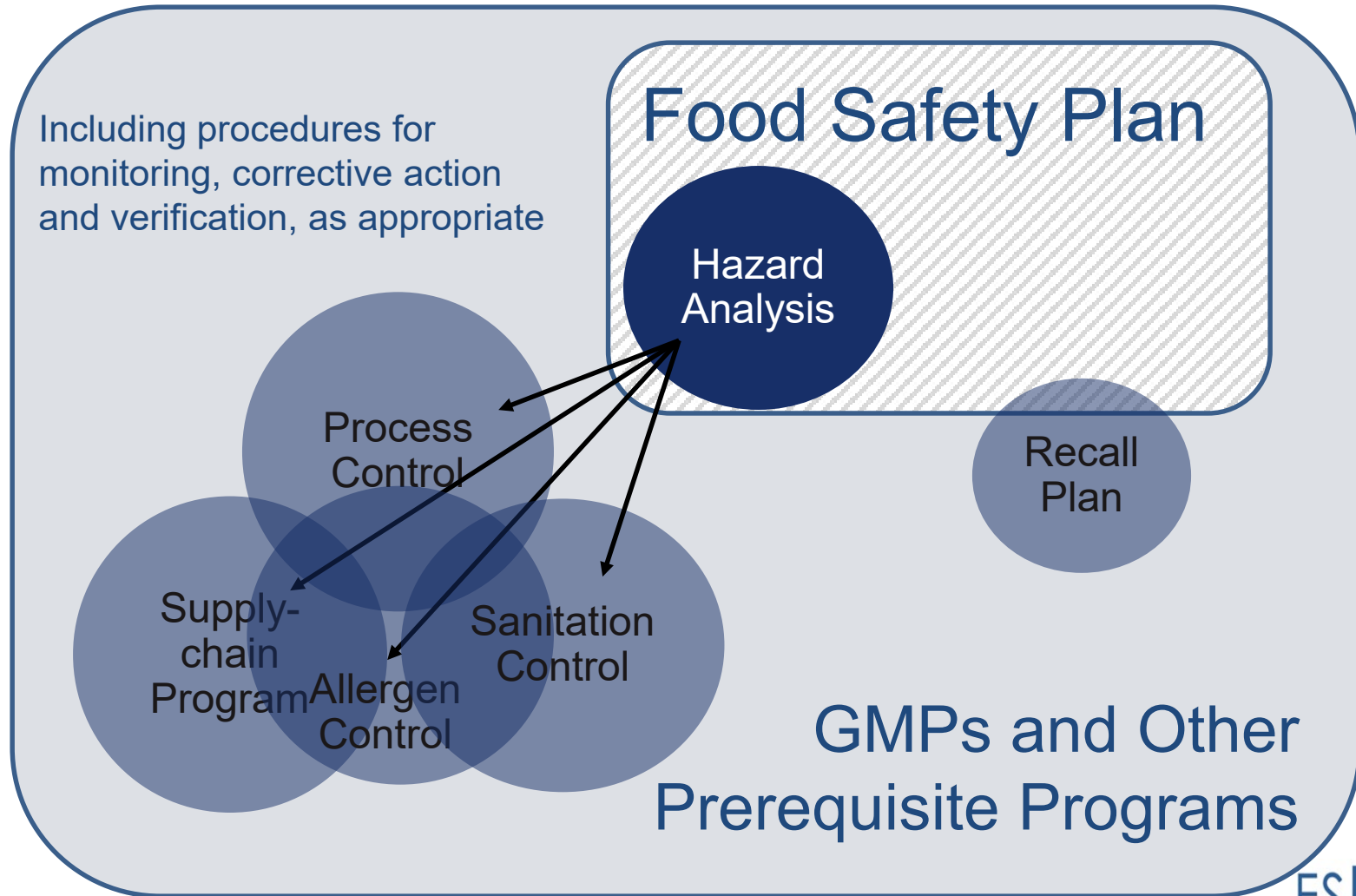
Developing a Food Safety Plan -

- A preventive controls systems may be needed to control identified risks
- All registered facilities must have cGMP's

Risk-based Preventive Controls

- Focus on what matters most for food safety
- Preventive, not reactive
- Work in conjunction with and supported by other programs like Good Manufacturing Practices
- Designed to minimize the risk of food safety hazards

PREVENTIVE FOOD SAFETY SYSTEMS



Current Good Manufacturing Practices (GMPs) -- Food Establishment Checklist* --

| FACILITY & GROUNDS (cont.) | | | Yes/No/NA |
|---------------------------------------|---------------|---|------------------|
| 26. | §117.20(b)(2) | Are food processing areas effectively separated (i.e. location, time, partition, etc.) from other operations which may cause contamination of food being processed or allergen cross-contact? | |
| 27. | §117.20(b)(3) | Are there proper precautions to protect food in outdoor bulk vessels? | |
| 28. | §117.20(b)(4) | Are floors, walls and ceilings constructed to facilitate adequate cleaning and repair? | |
| 29. | §117.20(b)(4) | Does drip or condensate from fixtures, ducts and pipes cause or potentially cause contamination of food, food contact surfaces or food packaging materials? | |
| 30. | §117.20(b)(4) | Are aisles and working spaces unobstructed and of adequate width to permit employees to perform their jobs and protect against contamination of food by clothing or personal contact? | |



PennState Extension