



Center for Agricultural  
and Shale Law

Food Safety Modernization Act  
Jacqueline K. Schweichler, Esq.

## Recent Developments in the Implementation of the Food Safety Modernization Act

The Ag & Food Law Webinar Series  
The Agricultural and Food Law Consortium  
Wednesday, October 17, 2018



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## Penn State Agricultural Law Blog

A research and education program of the Center for Agricultural and Shale Law (CASL)

Agricultural Law Blog | Shale Law Blog

Thursday, October 4, 2018

### Agricultural Law Weekly Review – October 4, 2018

Written by:  
Deanna Smith - Research Assistant  
Jackie Schweichler - Education Programs Coordinator

The following information is an update of recent local, state, national, and international legal developments relevant to agriculture.

**International Trade: United States-Mexico-Canada Agreement replaces NAFTA**  
On September 30, 2018, the United States and Canada came to an agreement to replace the North American Free Trade Agreement (NAFTA) with the United States-Mexico-Canada Agreement. The new agreement, which Mexico agreed to in August of this year, includes greater access to Canada's milk market, provisions on rules of origin of automotive goods, and provisions on digital trade and intellectual property. USMCA will utilize the same dispute resolution system as was used under NAFTA. In a *Joint Statement from United States Trade Representative Robert Lighthizer and Canadian Foreign Affairs Minister Chrystia Freeland*, both the U.S. and Canada claim the agreement "will strengthen the middle class, and create good, well-paying jobs and new opportunities for the nearly half billion people who sell North American goods." The agreement will come into effect after it is approved by the U.S. Congress as well as legislatures in Canada and Mexico. For more information, the Office of the U.S. Trade Representative has published several fact sheets on the USMCA agreement.

#### Right to Farm: Pennsylvania Supreme Court Denies Appeal of Neighbors in Hog Farm Nuisance Lawsuit

On September 18, 2018, the Supreme Court of Pennsylvania denied a *Petition for Allowance of Appeal* filed by landowners involved in a lawsuit against owners of a concentrated animal feeding operation (*Burlingame v. Depogtin*, No. 296 MAL 2008). Will-O-Bett Farm originally operated as a dairy farm, then as a beef farm, and eventually was converted to a swine operation in 2005. A few years later, the farm began spreading liquid swine manure on its fields, and several neighboring landowners filed suit against the farm alleging that the resulting odor constituted a nuisance. Will-O-Bett Farm filed for summary judgment, arguing that it was protected from suit under Pennsylvania's Right to Farm Act (RTFA) (17 P.S. §§ 913-917). The trial court agreed, finding that the farm's application of liquid swine manure had been addressed in an approved nutrient management plan. The Pennsylvania Superior Court affirmed the trial court's order, and now the Pennsylvania Supreme Court has declined further appeal.

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### The Agricultural Law Brief

OCTOBER 2018

A research and education program of the Center for Agricultural and Shale Law

#### RECENT LEGAL DEVELOPMENTS

##### Right to Farm: Pennsylvania Supreme Court Denies Appeal of Neighbors in Hog Farm Nuisance Lawsuit

On September 18, 2018, the Supreme Court of Pennsylvania *granted a Petition for Allowance of Appeal* filed by landowners involved in a lawsuit against owners of a concentrated animal feeding operation (*Burlingame v. Depogtin*, No. 296 MAL 2008). Will-O-Bett Farm originally operated as a dairy farm, then as a beef farm, and eventually was converted to a swine operation in 2005. A few years later, the farm began spreading liquid swine manure on its fields, and several neighboring landowners filed suit against the farm alleging that the resulting odor constituted a nuisance. Will-O-Bett Farm filed for summary judgment, arguing that it was protected from suit under Pennsylvania's Right to Farm Act (RTFA) (17 P.S. §§ 913-917). Under the RTFA, an agricultural operation is protected from a nuisance claim so long as it has been in operation for at least one year and the conditions complained of have not changed during that one-year period. Where the agricultural operation has undergone an expansion or substantial alteration, the one-year time period, within which a lawsuit can be filed, is effectively eliminated if the changes were addressed in a nutrient management plan. Ruling in favor of Will-O-Bett Farm, the *Supreme Court* found that the farm's application of liquid swine manure had been addressed in an approved nutrient management plan. As such, the RTFA provided a defense to the nuisance lawsuit. The Pennsylvania Superior Court *affirmed* the trial court's order, and now the Pennsylvania Supreme Court has declined further appeal.

##### Antimicrobial Use: FDA Releases Five-Year Plan for Antimicrobial Stewardship

On September 14, 2018, the U.S. Food & Drug Administration (FDA) Center for Veterinary Medicine (CVM) released its five-year plan, *Accelerating Antimicrobial Stewardship in Veterinary Settings*. In the *plan*, *announcement* of the plan on July 31, 2018, FDA explained that overuse of antimicrobial drugs can promote development of antimicrobial-resistant bacteria. In order to slow the growth of resistant bacteria, CVM will be encouraging judicious use of antimicrobial drugs in food-producing animals. Under CVM policy, "medically important antimicrobial drugs should only be used when necessary to treat, control, or prevent disease." CVM requires each animal drug to go through a pre-approval review, and CVM conducts post-approval surveillance and monitoring. The key goals of the plan include aligning antimicrobial drug use with the principles of antimicrobial stewardship, bolstering stewardship in veterinary settings, and enhancing the monitoring of antimicrobial resistance. One of the anticipated changes set forth in the plan includes the revision of conditions for antimicrobial use approval in food-producing animals. CVM also will develop and implement a strategy to promote antimicrobial

##### Hydraulic Fracturing: Three Pennsylvania State Senators Allowed to Intervene in Litigation Challenging Delaware River Basin Commission Moratorium

On September 17, 2018, the U.S. District Court for the Middle District of Pennsylvania *granted the motion* of three Pennsylvania state senators – Joseph B. Scarnati, Lisa Baker, and Gene Yee – to intervene in court proceedings initiated by the Wayne Land and Mineral Group (Wayne, LLC), challenging the Delaware River Basin Commission's (DRBC) moratorium on hydraulic fracturing in the Basin (Wayne Land and Mineral Group LLC v. Delaware River Basin Commission, No. 13-16-cv-00987-ADJ). On November 30, 2017, the Commission published draft regulations prohibiting high-volume hydraulic fracturing within the Basin. Wayne has filed suit to contest the Commission's jurisdiction to revise and approve natural gas projects located in the Delaware River Basin and thus its authority to prohibit hydraulic fracturing operations. The U.S. District Court for the Middle District of Pennsylvania originally dismissed Wayne's complaint, but on July 2, 2018, the U.S. Court of Appeals for the Third Circuit remanded the case back to the District Court. In their Motion to Intervene, the three senators argued that they have a "significant protectable interest" in the proceedings as they are a "contracting party" to the *Delaware River Basin Compact* and, more particularly, because they "have a cognizable property interest in the subject matter of this action; the Commission's moratorium is not confined to private property, but also extends to Commonwealth-owned property that is part of the Trust, over which the Senators and other elected officials have trustee obligations."


##### Biosecurity: White House Announces New Federal Biodefense Strategy

On September 18, 2018, the White House released the *Presidential Memorandum on the Support for National Biosecurity*. The Memorandum establishes the Cabinet-level Biodefense Steering Committee (Committee) which will be led by the Secretary of Health and Human Services (Secretary). The Committee will monitor, share information, coordinate, and evaluate the implementation of the National Biosecurity Strategy (Strategy). The purpose of the Strategy is to improve understanding and response to biological threats which can include disease and biological attacks. The National Security Advisor will review biological threats and annually prioritize defensive actions. In addition, the Secretary must establish a Biodefense Coordination Team (Team). The Team will assist the Committee in implementing the Strategy and will identify opportunities to increase coordination with non-federal partners and international organizations. The Team will prepare an annual Biodefense Assessment to identify any problems with the implementation and execution of the Strategy. Using this information, joint policy guidance will be prepared annually regarding the priority areas of biosecurity. According to a *statement* by the White House, the Strategy will address biological threats that are naturally occurring, deliberate, and accidental.

##### Contributors Include:

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In 2011, the United States Congress passed the Food and Drug Administration (FDA) Food Safety Modernization Act (FSMA). FSMA, which represents the first major overhaul of United States food safety law since the passage of the Food Drug and Cosmetic Act in 1938, requires FDA to create final rules addressing various food safety topics including produce safety, hazard analysis, preventive controls, and sanitary transportation of food. These final rules are to be designed to shift the focus of food safety regulations away from contamination response to contamination prevention.

This guide is intended to represent a collection of legal resources relating to FSMA and FDA food safety regulations. While the Center for Agricultural and Shale Law makes every effort to maintain and update the content furnished in this guide, no warranty or other guarantee is made regarding the timeliness or accuracy of any information provided.

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Authors - Jackie Schweichler and Mary Webber

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Don't forget to check out our October Events Calendar! There are a lot of great agricultural & shale events between now and Halloween! 🍂🍁  
@NAROut @PennAgIndustry @MarcellusGas @AmAgLaw  
#Agriculture #shale #Fall #October #events

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**October 2018 Events Calendar**

**October 3, 2018**  
Penn State Law, PA  
National Association of Agricultural Business - Ag Business Center Day

**October 15, 2018**  
Agriculture & Food Law Consortium - Ag & Food Law Webinar Series  
Webinar: Regs. Sep. 2017  
Penn State Center for Agricultural and Shale Law  
Recent Legal Developments with the Food Safety Modernization Act: Jackie Schweichler

**October 17-18, 2018**  
Energy & Mineral Law Foundation - Kentucky Mineral Law Conference  
Lexington, KY

**October 19, 2018**  
National Association of Royalty Owners - 39th National NARO Convention  
Denver, CO  
Penn State Center for Agricultural and Shale Law presentation - *Asset Pile*

**October 23, 2018**  
Schuylkill County Coalition - Environmental Rights Amendment Seminar  
Pottsville, PA  
Penn State Center for Agricultural and Shale Law presentation  
What Other States Should Be Considered in the State of the Supreme Court Decision - *Asset Pile*

**October 23/24, 2018**



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October 12 at 3:03 PM  
The CASL Ledger  
Coming Events  
On Wednesday, October 17, 2018, Center Education Programs Coordinator Jackie Schweichler will be

**Penn State Center for Agricultural and Shale Law**  
October 5 at 2:33 PM  
The CASL Ledger  
The Agricultural Law Brief  
This week, the Center published the October Agricultural Law Brief! If you're interested in

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## Introduction

- Federal Food, Drug, and Cosmetic Act – 1938
  - Gives FDA authority to oversee safety of food, drugs, cosmetics
- Food Safety Modernization Act – 2011
  - Focus on *preventing* food safety problems, rather than reacting
  - Gives FDA “prevention-based controls”

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## FSMA – Seven Pillars

1. [Accreditation of Third-Party Certification Bodies to Conduct Food Safety Audits and to Issue Certifications](#)
2. [Current Good Manufacturing Practices and Hazard Analysis and Risk-Based Preventive Controls for Human Food](#)
3. [Current Good Manufacturing Practices and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals](#)

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## FSMA – Seven Pillars

4. [Foreign Supplier Verification Program \(FSVP\)](#)
5. [Mitigation Strategies to Protect Food Against Intentional Adulteration](#)
6. [Sanitary Transportation of Human and Animal Food](#)
7. [Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption](#)

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## Accredited Third-Party Certification

- [Accreditation of Third-Party Certification Bodies to Conduct Food Safety Audits and to Issue Certifications, 80 FR 74,569](#)
  - Published: Nov. 27, 2015
  - Creates program for 3<sup>rd</sup> party certification groups/auditors
  - Can be used to establish eligibility for [Voluntary Qualified Importer Program](#)
    - Allows expedited entry of food

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## Accredited Third-Party Certification

- [Amendments to Accreditation of Third-Party Certification Bodies To Conduct Food Safety Audits and To Issue Certifications To Provide for the User Fee Program](#), 81 Fed. Reg. 90,186
  - Published: Dec. 14, 2016
  - Establishes reimbursement or ‘user fee’ program
  - Fees apply to accreditation bodies

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## Preventive Controls for Human Food

- Current Good Manufacturing Practices and Hazard Analysis and Risk-Based Preventive Controls for Human Food, [80 FR 55,907](#)
  - Published: Sept. 17, 2015
  - Applies to facilities that are required to register with FDA
  - Requires a food safety plan with a hazards analysis and risk-based preventive controls



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## Preventive Controls for Human Food

- [Draft Guidance for Industry: Hazard Analysis and Risk-Based Preventive Controls for Human Food, 81 FR 57,816](#)
  - Published: Jan. 25, 2018 - incomplete
  - General guidance for the rule
  - Contains 16 chapters and 4 appendices
    - 7 chapters and 3 appendices are complete
    - The most recent chapter, *Chapter 15: Supply-Chain Program for Human Food Products*

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## Preventive Controls for Human Food

- Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food ([83 FR 46,104](#))
  - Published: Sept. 12, 2018
  - Final rule; partial withdrawal
  - According to the FDA: “this action will serve to correct an obvious oversight made in the compliance date final rule”
  - Extends old regulations until new regulations come into effect

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## Preventive Controls for Food for Animals



- Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals ([80 FR 56,169](#))
  - Final Rule Published: Sept. 17, 2015
  - Establishes requirements for animal feed
    - Applies to establishments that register with FDA as a food “facility”
    - Facilities must have food safety plan and hazards analysis
    - Must follow Current Good Manufacturing Practice (CGMP)
    - Must establish food safety system

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## Preventive Controls for Food for Animals

- Draft Guidance, Hazard Analysis and Risk-Based Preventive Controls for Food for Animals: Supply-Chain Program [83 FR 27,999](#)
  - Draft Guidance Published: June 15, 2018
  - Comments Close: Dec. 12, 2018
  - Helps receiving facility understand supply-chain requirements



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## Foreign Supplier Verification Program

- Foreign Supplier Verification Programs for Importers of Food for Human and Animals (FSVP), [80 FR 74225](#)
  - Publication: Nov. 27, 2015
  - Importers must verify:
    - Food meets hazard analysis & risk-based preventive controls
    - Food is not adulterated
    - Food is not misbranded (food allergens)

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## Foreign Supplier Verification Program

- [Draft Guidance for Industry: Foreign Supplier Verification Programs for Importers of Food for Humans and Animals, 83 FR 3,445](#)
  - Published: Jan. 25, 2018
  - Explains how to analyze hazards in food
  - Evaluate foreign suppliers' performance & risk posed by food
  - Conduct appropriate foreign supplier verification activities



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## Foreign Supplier Verification Program

- [Guidance for Industry: Foreign Supplier Verification Programs for Importers of Food for Humans and Animals: What You Need to Know About the FDA Regulation; Small Entity Compliance Guide, 83 FR 3,442](#)
  - Published: Jan. 25, 2018
  - The regulation has standard requirements for larger importers & modified procedures for small importers
  - Clarifies actions that small entity must take to comply with the rule

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## Foreign Supplier Verification Program

- [Guidance for Industry: Application of the Foreign Supplier Verification Program Regulation to Importers of Grain Raw Agricultural Commodities, 83 FR 3,443](#)
  - Published: Jan. 25, 2018
  - FDA will exercise enforcement discretion for grain importers
  - Applies to storage of grain



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## Foreign Supplier Verification Program

- [Guidance for Industry: Compliance with Providing an Acceptable Unique Facility Identifier for the Foreign Supplier Verification Programs Regulation](#)
  - Published: March 2018
  - How to identify yourself as an importer of a food at entry into the U.S.
  - Must obtain a Unique Facility Identifier (UFI)
    - Data Universal Numbering System (DUNS)
    - If DUNS is not obtained: importers may temporarily use “Unknown” (UNK)

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## Foreign Supplier Verification Program

- [Guidance for Industry: Application of the Foreign Supplier Verification Program Regulation to the Importation of Live Animals, 83 Fed. Reg. 12,483](#)
  - Published: March 22, 2018
  - In light of USDA oversight, FDA will exercise enforcement discretion
  - Certain live animals that are slaughtered and processed at USDA-inspected establishments are already subject to HACCP requirements

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## Intentional Adulteration Rule

- [Mitigation Strategies to Protect Food Against Intentional Adulteration, \(81 FR 34,165\)](#)
  - Published May 27, 2016
  - Applies to domestic & foreign food facilities
  - Smaller companies are exempt
  - Farms are exempt
  - Facilities must prepare food defense plan



## Intentional Adulteration Rule

- Draft Guidance for Industry: Mitigation Strategies to Protect Food Against Intentional Adulteration [83FR 28,651](#)
  - Published: June 20, 2018
  - Explains how to conduct vulnerability assessment
  - Explains how to identify & implement mitigation strategies

## Transportation Rule

- Sanitary Transportation of Human & Animal Food, [81 FR 20,091](#)
  - Published: April 6, 2016
  - applies to shippers, loaders, carriers by motor or rail vehicle, and receivers involved in transporting
  - Must use sanitary practices
    - Transportation vehicles/equipment must be cleanable & capable of maintaining temperatures
    - Safety measures
    - Carrier personnel must be trained
    - Must maintain records



## Produce Safety Rule

- Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption, [80 FR 74,353](#)



- Published: Nov. 27, 2015
- Establishes minimum safety standards - focuses on biological hazards
- does not apply to produce that is rarely consumed raw, produce for personal or on-farm consumption, or produce that is not a raw agricultural commodity



## Produce Safety Rule

- Proposed Rule: Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption; Extension of Compliance Dates for Subpart E, [82 FR 42,963](#)
  - Published: Sept. 13, 2017
  - Extension of compliance dates for agricultural water provisions
    - Will not apply to sprouts

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## Produce Safety Rule

- [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, 82 FR 42,031](#)
  - Published: Sept. 6, 2017
  - This guidance will assist small entities in complying with the Produce Safety Rule

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## Miscellaneous Rules and Guidance Documents



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## FSMA Final Rule

- Establishment, Maintenance, and Availability of Records: Amendment to Record Availability Requirements, [79 Fed. Reg. 18,799](#)
  - Published: April 4, 2014
  - FDA has access to records:
    - Where FDA reasonably believes the food to present a health threat
  - Rule expands FDA's access to food records
    - FDA may access records for other food that FDA reasonably believes is similarly affected

## FSMA Final Rule



- Registration of Food Facilities: Amendments to Food Facility Registration Requirements, [81 Fed. Reg. 45,911](#)

- Published: July 14, 2016
- New facility registration requirements
  - Must provide email address
  - Must renew registration every 2 years
  - Must permit FDA inspections

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## FSMA Guidance

- Registration of Food Facilities: What You Need to Know About the FDA Regulation; Small Entity Compliance Guide [83 FR 24,479](#)
  - Published: May 29, 2018
  - Explains new facility registration requirements for small facilities

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## FSMA Guidance

- Questions and Answers Regarding Food Facility Registration (Seventh Edition) [83 FR 42,024](#)
  - Published: Aug. 20, 2018
  - guidance on registration requirements for domestic & foreign facilities that “manufacture, process, pack, or hold food for human or animal consumption”

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## FSMA Draft Guidance

- Draft Guidance: Supplemental Questions and Answers Regarding Food Facility Registration [83 FR 42,062](#)
  - Published: Aug. 20, 2018
  - Includes additional questions and answers
  - Clarifies who should register in situations involving more than 1 registrant
    - Ex: lessor and 1 or more lessees

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## FSMA Final Rule

- Extension and Clarification of Compliance Dates for Certain Provisions of Four Implementing Rules, [81 FR 57,784](#)
  - Published: Aug. 24, 2016
  - Extended compliance dates for:
    - Preventive Controls for Human Food
    - Preventive Controls for Food for Animals
    - Produce Safety Rule, and
    - Foreign Supplier Verification Program

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## FSMA Guidance

- Policy Regarding Certain Entities Subject to the Current Good Manufacturing Practice and Preventive Controls, Produce Safety, and/or Foreign Supplier Verification Programs: Guidance for Industry [83 FR 598](#)
  - Published: Jan. 5, 2018
  - (re: [August 2016](#) extended compliance dates)
  - Announced FDA intent not to enforce some requirements in 4 rules

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## FSMA Guidance

- Extension and Clarification of Compliance Dates for Certain Provisions of Four Implementing Rules: What You Need to Know About the FDA Regulation: Small Entity Compliance Guide [83 FR 22,193](#)
  - Published: May 14, 2018
  - (re: Aug. 2016 extended compliance dates & Jan. 2018 non-enforcement)
  - Intended to assist small entities with understanding extended compliance dates

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## FSMA Draft Guidance

- [Draft Guidance: Considerations for Determining Whether a Measure Provides the Same Level of Public Health Protection as the Corresponding Requirement in 21 CFR part 112 or the Preventive Controls Requirements in part 117 or 507, 83 FR 3,447](#)
  - Published: Jan. 25, 2018
  - How to determine “Same Level of Public Health Protection”

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## FSMA Guidance

- Determining the Number of Employees for Purposes of the “Small Business” Definition in Parts 117 and 507, [83 FR 12,143](#)
  - Published: March 20, 2018
  - “small business” means a business that employs fewer than 500 full-time equivalent employees
  - Explains how to determine the number of full-time equivalent employees



## FSMA Guidance

- Determination of Status as a Qualified Facility [83 FR 46,878](#)
  - Published: Sept. 17, 2018
  - explains how to determine whether your facility meets the definition of “qualified facility”
  - Explains how facility should submit forms to show status as qualified facility





## FSMA Proposed Rule

- Label Requirement for Food That Has Been Refused Admission Into the United States ([83 Fed. Reg. 49022](#))
  - Published: Sept. 28, 2018
  - Proposed rule withdrawing a proposed rule
  - The previous rule “directed owners or consignees to affix labels to physical documents such as invoices, packing lists, bills of lading, and any other documents accompanying refused food.”

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## FDA Funding for 2018/2019 [State Produce Cooperative Agreement Program](#)

- Announced: July 12, 2018
- New cooperative agreements: Hawaii, Kentucky, Mississippi
  - (46 states in total)
- Funding Totals:
  - Year 1 (9/2016 - 6/2017) = \$21.8 million
  - Year 2 (9/2017 - 6/2018) = \$30.9 million
  - Year 3 (9/2018 - 6/2019) = **\$32.5 million**

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## Resources

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  - [www. PennStateLaw.LibGuides.com/Food Safety](http://www.PennStateLaw.LibGuides.com/Food_Safety)
- U.S. Food & Drug Administration
  - <https://www.fda.gov/food/guidanceregulation/fsma/ucm253380.htm>
- Penn State Extension
  - <https://extension.psu.edu/fsma>

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