

Title: FSMA on Small and Mid-sized Farms: Compliance, Enforcement, and Beyond

Program Description: Thousands of small and mid-sized farms must comply in some part with the Food Safety Modernization Act (FSMA). FDA and state regulatory agencies are now verifying that these diverse businesses are complying with the Produce Safety Rule and Preventive Controls Rule. Yet, countless farmers do not know how these rules are being enforced, who is enforcing them, or what they must do to comply. Based on our research, publications, and work with farms, we will discuss how these rules affect such farms, how these rules have been enforced, and what the future of these rules may look like.

Presentation Outline:

- I. Implementing and Enforcing the FSMA Produce Safety Rule
 - A. State vs. FDA inspections
 - B. State authority vs. credentialing
 - C. State agency conducting inspections
 - D. Relevant state statutes and regulations for PSR implementation and enforcement

Relevant state statutes and regulations for PSR implementation and enforcement			
State	State or FDA Conducting Inspections	Relevant State Agency	Relevant State Law
Alabama	State (Under State Authority)	Dep't of Agriculture and Industries	Ala. Code § 20-1-3; Ala. Admin. Code 80-1-22.49
Alaska	State (Credentialed)	Dep't of Env. Conservation	N/A
Arizona	State (Under State Authority)	Dep't of Agriculture	Ariz. Rev. Stat. §§ 3-525 to -535.08
Arkansas	State (Under State Authority)	Dep't of Agriculture	Ark. Code Ann. §§ 2-16-201 to - 214; Proposed Rule (Mar. 2020)
California	State (Credentialed)	Dep't of Food and Agriculture	Cal. Food & Agric. Code §42653

Colorado	State (Under State Authority)	Dep't of Agriculture	Colo. Rev. Stat. §§ 35-77-101 to -111; 5 Colo. Code Regs. § 1002-84
Connecticut	State (Under State Authority)	Dep't of Agriculture	Conn. Gen. Stat. § 22-39g; Proposed Rule (Feb. 2020)
Delaware	State (Credentialed)	Dep't of Agriculture	Del. Code Ann. tit. 3 §§ 101(1), (3), (6); 3-300-302 Del. Admin. Code §§ 1.0 - 9.0
Florida	State (Credentialed)	Dep't of Agriculture and Consumer Services	N/A
Georgia	State (Under State Authority)	Dep't of Agriculture	Ga. Code Ann. §§ 26-2-440, 441; Ga. Comp. R. & Regs. 40-7-20
Hawaii	State (Under State Authority)	Dep't of Agriculture	Haw. Rev. Stat. §§ 145-31 to -39
Idaho	State (Under State Authority)	Dep't of Agriculture	Idaho Code Ann. §§ 22-5401 to -5407; Idaho Admin. Code r. 02.05.01
Illinois	FDA	N/A	N/A
Indiana	State (Under State Authority)	Dep't of Health	Ind. Code §§ 16-42-3.5, 3.5-1
Iowa	FDA	N/A	N/A
Kansas	State (Credentialed)	Dep't of Agriculture	N/A
Kentucky	State (Credentialed)	Dep't of Agriculture	N/A

Louisiana	State (Under State Authority)	Dep't of Agriculture and Forestry	La. Rev. Stat. Ann. §§ 3:921-928
Maine	State (Credentialed)	Dep't of Agriculture, Conservation, and Forestry	N/A
Maryland	State (Under State Authority)	Dep't of Agriculture	Md. Code Ann., Agric. §§ 16-101 to -111
Massachusetts	State (Under State Authority)	Department of Agriculture and Conservation	Mass. Gen. Laws ch. 128, § 124
Michigan	State (Under State Authority)	Dep't of Agriculture and Rural Development	Mich. Comp. Laws § 289.7112
Minnesota	State (Under State Authority)	Dep't of Agriculture	Minn. Stat. § 31.101 Subd. 8
Mississippi	State (Under State Authority)	Dep't of Agriculture and Commerce	Miss. Code Ann. § 69-1-56
Missouri	State (Credentialed)	Dep't of Agriculture	N/A
Montana	State (Under State Authority)	Dep't of Agriculture	Mont. Code Ann. §§ 80-3-301 to -306
Nebraska	State (Credentialed)	Dep't of Agriculture	N/A
Nevada	State (Credentialed)	Dep't of Agriculture	N/A
New Hampshire	State (Under State Authority)	Dep't of Agriculture, Markets and Food	N.H. Rev. Stat. Ann §§ 426-A:1-6; N.H. Code Admin. R. Ann. Agr 3900.01-.06
New Jersey	State (Credentialed)	Dep't of Agriculture	N/A

New Mexico	State (Credentialed)	Dep't of Agriculture	N.M. Stat. Ann. § 76-1-2(N)
New York	State (Under State Authority)	Dep't of Agriculture and Markets	N.Y. Agric. & Mkts. Law § 214-B; N.Y. Comp. Codes R. & Regs. tit. 1, § 273.1
North Carolina	State (Under State Authority)	Dep't of Agriculture and Consumer Services	N.C. Gen. Stat. § 106-139; 02 N.C. Admin. Code 09b .0116(o)(51)
North Dakota	FDA	N/A	N/A
Ohio	State (Under State Authority)	Dep't of Agriculture	Ohio Rev. Code Ann. § 3715; Ohio Admin. Code 901:3-12
Oklahoma	State (Under State Authority)	Dep't of Agriculture, Food, and Forestry	Okla. Stat. tit. 2, § 2-2- 4(A)(2); Okla. Admin. Code §§ 35:37-17-1 to -5
Oregon	FDA	N/A	N/A
Pennsylvania	State (Credentialed)	Dep't of Agriculture	N/A
Rhode Island	State (Under State Authority)	Dep't of Environmental Management - Division of Agriculture	R.I. Gen. Laws § 2-1-10; 250-40 R.I. Code R. § 00-2
South Carolina	State (Under State Authority)	Dep't of Agriculture	S.C. Code Ann. §§ 39-26-10 to - 170
South Dakota	FDA	N/A	N/A
Tennessee	State (Under State Authority)	Dep't of Agriculture	Tenn. Code Ann. §§ 53-1- 301 to - 303; Tenn. Comp. R. & Regs 0080-04-15.01

Texas	State (Under State Authority)	Dep't of Agriculture	Tex. Agric. Code Ann. § 91.009; 4 Tex. Admin. Code §§1.11.1 - .43
Utah	State (Under State Authority)	Dep't of Agriculture and Food	Utah Code Ann. §§ 4-5-103(1)(l), 104(9), 105; Utah Admin. Code r. 70-530-1 to -3
Vermont	State (Under State Authority)	Agency of Agriculture, Food and Markets	Vt. Stat. Ann. tit. 6, §§ 851 - 857
Virginia	State (Under State Authority)	Dep't of Agriculture and Consumer Services	Va. Code Ann. §§ 3.2-5146 to -5156
Washington	State (Under State Authority)	Dep't of Agriculture	Wash. Rev. Code §§ 15.135.010 - .900
West Virginia	State (Credentialed)	Dep't of Agriculture	N/A
Wisconsin	State (Credentialed)	Dep't of Agriculture, Trade and Consumer Protection	N/A
Wyoming	FDA	N/A	N/A

E. Enforcement challenges

1. Farm definition & when multiple separate LLCs might be considered part of a single farm operation subject to the rule
2. Cleaning vs. Sanitizing. Harvest tools should be cleaned and sanitized when necessary, and harvest tools also need a plan to be cleaned while in the field. According to **21 C.F.R. 112.123(d)(1)** you must inspect, maintain, and clean and, when necessary and appropriate, sanitize all food contact surfaces of equipment and tools used in covered activities as frequently as reasonably necessary to protect against contamination of covered produce.
 - a) Issue: "when reasonably necessary" only applies to sanitizing, NOT cleaning

- b) You should evaluate and establish cleaning frequencies for both food contact and non-food contact surfaces, as well as sanitizing frequencies for food contact surfaces, as necessary and appropriate. You should schedule cleaning and sanitizing of equipment and tools with food contact surfaces after storage, after relevant production cycles (e.g., daily or between shifts), or as otherwise necessary to protect against contamination of covered produce. In some cases, you could determine that cleaning for both the non-food contact surfaces and the food contact surfaces of equipment and tools should occur at the same frequency. (**Produce Safety Rule Draft Guidance, page 108,** <https://www.fda.gov/media/117414/download>).
- c) Solution: Prove your cleaning harvest tools sufficiently by:
1. Create an SOP on when to clean harvest tools, and record every day the SOP was followed.
 2. Make sure there is a SOP and that the SOP is followed each day, and it is documented that the SOP is followed everyday that includes that "when employees take a break during harvest, their tools are going onto a clean surface, and then if they observe the tools needs cleaning, they will clean it (recommended that if dry environment, dry cleaning takes place, i.e. - paper towel or brush used on item, and SOP also includes how you will keep the brush clean-- as introducing water into field might increase other risks).
 - d) "Yes, a once a day cleaning frequency could be sufficient, although I would ask how the farm accounts for contamination that might happen during the day. For instance: What happens when the harvester sticks their knife in the dirt during a break? What happens when the harvester harvests fresh produce with a tool that they then realize has animal fecal matter on it? What happens when the harvest process results in the accumulation of soil on the equipment/tools throughout the day? What happens when the harvester crew moves from one commodity to another commodity, such as from an RCR commodity to a covered commodity, or from a covered commodity to another covered commodity? There are other questions that could be asked also. The bottom-line though is that in 112.123, FDA does not prescribe a required frequency, recognizing that there are many factors which may influence the necessary cleaning frequency (commodity, harvest method, type of equipment)."
3. Qualified Exemption- can a state come and inspect my farm if I'm qualified exempt?

- a) **Farm and Ranch Freedom Alliance v. Texas Department of Agriculture.** <http://farmandranchfreedom.org/wp-content/uploads/2019/12/Final-Petition-FARFA-v-TDA-et-al.pdf>
- b) Argues this is in violation of the 4th Amendment because the farm has a right to be free from unreasonable and warrantless searches and claims it also violated their due process 14th amendment rights because the Department is permitted to inspect an exempt farm if there is an “egregious” condition.

II. Implementing and Enforcing FSMA Preventive Controls Rule (PCR) on Farms
(Brian)

- A. Introduction to PCR (**21 U.S.C. § 350g; 21 C.F.R. parts 117, 507**)
 - 1. Rule is about controlling food safety throughout supply chain of processed foods
 - 2. Built on existing regulations and voluntary standards
 - 3. Regulating Human Food vs. Animal Food
- B. Farm vs. Farm Mixed Type Facility (FMTF)
 - 1. Overview of “food facility” — processing, manufacturing, packing, holding food for consumption in the United States (**21 U.S.C. § 350d**)
 - a) If activities of farm cause it to be considered a “food facility” → FMTF (PCR applies to those activities) (**21 C.F.R. § 117.3**)
 - b) Activities-based definition — delineation between growing/harvesting (PSR may apply) and manufacturing/processing (PCR may apply)
 - (1) Examples of growing/harvesting (*draw from Sophia’s presentation*)
 - (2) Examples of manufacturing/processing (e.g., **FDA Draft Guidance: Classification of Activities**)
 - 2. FDA definition of “farm” (primary production and secondary activities) (**21 C.F.R. § 117.3; draw from Kelly’s portion**)
 - 3. FDA enforcement discretion
- C. Exemptions vs. Partial Exemptions vs. No Exemptions
 - 1. Totally exempt farms — no manufacturing/processing, packing, or holding
 - 2. Partially exempt activities — low-risk activities (**21 C.F.R. § 117.5**)
 - 3. Partially exempt — PCR activities conducted, but FMTF is Qualified Facility (QF or QFE)
 - a) Generally based on sales and value of food (**21 C.F.R. § 117.3**)
 - b) Attestation (**21 C.F.R. § 117.201**)
 - c) Withdrawal of qualified facility exemption (**21 C.F.R. §§ 117.251 - 117.287**)

4. No exemption/Full compliance
 - a) Too big for QFE
 - b) Withdrawal of QFE
- D. Degrees of Compliance
 1. Modified Requirements (QFE and certain storage facilities) (**21 C.F.R. §§ 117.201, 117.206**) / Requirements that apply to enumerated activities, e.g., thermally processed low-acid foods in hermetically sealed containers, seafood, alcohol regulated by TTB, etc. (**21 C.F.R. § 117.5**)
 - a) Current Good Manufacturing Practices (**21 C.F.R. §§ 117.10 - 117.110**)
 - b) Record-keeping requirements (**21 C.F.R. § 117.301 - 117.335**)
 2. Hazard Analysis and Risk-Based Preventive Controls Rule (HARPC) + Supply Chain Program
 - a) Subpart C basics (e.g., HARPC, preventive control, hazard, food safety plan) (**21 C.F.R. §§ 117.126 - 117.190**)
 - b) Subpart G basics (e.g., Supply Chain Program, receiving facility, supply chain preventive control) (**21 C.F.R. §§ 117.405 - 117.475**)
- E. Overview of FDA violations for PCR
 1. Warning Letters
 2. Citations database
 3. Enforcement challenges for QFE FMTFs (**build on Sophia's last section here -- PSR inspections (mostly states) vs. PCR inspections (all FDA)**)

III. FSMA Future (Kelly)

- A. Traceability Rule — FDA said they will still release this by the end of the year / court ordered Sept. 2020 deadline
 1. After a recent lawsuit, FDA is required to now draft and implement a new proposed rule related to FSMA, the High Risk Foods Proposed Rule, by September 2020. **Center for Food Safety v. Sharpless, Case no. 3:18-cv-06299 (N.D. Cal. June 7, 2019)**.
 - a) The rule requires FDA to create a list of high risk rules and then implement certain record keeping requirements around that rule to ensure FDA is able to effectively trace the produce in the event of a foodborne illness outbreak.
- B. Produce Safety Rule inspections have been delayed due to COVID-19. <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-focuses-safety-regulated-products-while-scaling-back-domestic>
- C. FDA also included some new flexibility for the Qualified Exemption because of COVID-19. FDA does not intend to enforce the requirement in **21 CFR 112.5(a)(1)** that a majority of sales be to qualified end-users for a farm to be eligible for the qualified exemption under the Produce Safety

Rule. This policy applies to any calendar year COVID-19 is a public health emergency. <https://www.fda.gov/media/138316/download>

- D. Food Safety Outreach Program Requests for Applications Review: Who's eligible and why your client, Dept. of Ag, etc. should consider applying? **7 U.S.C. 7625.**
- E. FDA states they will revise the ag water rule and farm definition but COVID19 delayed that progress so might be another year or two. <https://www.fda.gov/media/110052/download>

Biographies:

Sophia Kruszewski is an Assistant Professor of Law at Vermont Law School, where she serves as the Center for Agriculture and Food Systems Clinic Director. She holds a JD from Vermont Law School and a BS from the University of Michigan.

Kelly Nuckolls is a policy specialist at the National Sustainable Agriculture Coalition, where she translates complex regulatory issues to farmers and food businesses. She frequently presents on the Food Safety Modernization Act, sustainable agriculture, and local food systems to audiences ranging from farmers and food businesses to state and regional community-based organizations to government agencies and lawyers. She has been the lead project coordinator for the Produce Safety Rule Alternate Curricula for Small Diversified Farm Operations at NSAC. Kelly holds an LL.M. in Agricultural and Food Law from the University of Arkansas Law School, a J.D. from Drake University Law School, and a B.A. in Political Science from Fort Hays State University. She previously worked at the University of Maryland and with the University of Delaware Cooperative Extension, where she helped farmers manage legal risks and understand federal and state laws that impact their operations. Kelly also is an adjunct professor of Food Law and Policy at George Mason University's Law School, where she teaches second and third year law students.

Brian Fink is an attorney at Danow, McMullan & Panoff, P.C., where he represents food and beverage businesses. His practice focuses on compliance with state and federal regulations, particularly those enforced by Food & Drug Administration, U.S. Department of Agriculture, and Alcohol and Tobacco Tax and Trade Bureau. Published by National Farmers Union, Brian wrote *FSMA on the Farm*, a legal handbook intended to assist farm businesses understand how Food Safety Modernization Act Preventive Controls Rule applies to their value-added product operations. He also co-authored a legal guide for Connecticut farm and food businesses and a legal guide for Massachusetts community kitchens. Brian has presented on the regulation of food safety, regulatory enforcement, and food-system policy to lawyers, businesses, and government agencies. He holds a J.D. from University of California, Los Angeles (UCLA) School of Law and a B.A. from University of Washington.