

## **The First Year of FSMA Produce Safety Rule Inspections: Top Legal Issues**

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1. Intro: Survey the Room
  - a. How many are familiar with FSMA and PSR?
  - b. Have you been to a training or had a client with an issue? Or had a client with an issue? Have you had a client ask you does this apply to me and how?
  - c. What have you heard are the top concerns and issues after the first year of produce safety rule inspections?
2. Overview of Inspections (Socrates)
  - a. At the outset, it is important to understand the relationship between the FD&CA and FSMA.
    - i. FSMA did not modify the FD&C A and it is still applicable, such as FD&CA 402(a).
    - ii. FSMA has 7 Foundational Rules (21 C.F.R. Parts 11, 16, and 12) which are the following:
      1. Produce Safety (21 C.F.R. Part 112)
      2. Preventive Controls for Human Food (21 C.F.R. Part 117)
      3. Preventive Controls for Food for Animals (21 C.F.R. Part 507)
      4. Foreign Supplier Verification Program (21 C.F.R. Part 1.500)
      5. Third Party Accreditation (21 C.F.R. Part 1.600)
      6. Intentional Adulteration (21 C.F.R. Part 121)
      7. Sanitary Transportation of Food (21 C.F.R. Part 1.900)
  - b. A 101 overview on the Rule & Ag Water
    - i. The Produce Safety rule is now final, and the earliest compliance dates for some farms begin one year after the effective date of the final rule.
    - ii. The rule establishes, for the first time, science-based minimum standards for the safe growing, harvesting, packing, and holding of fruits and vegetables grown for human consumption.
    - iii. This rule was first proposed in January 2013.
    - iv. In response to input received during the comment period and during numerous public engagements that included public meetings, webinars, listening sessions, and visits to farms across the country, the FDA issued a supplemental notice of proposed rulemaking in September 2014. The proposed revisions were designed to make the originally proposed rule more practical, flexible, and effective.
    - v. Final comment period closed on December 15, 2014 after Extensive stakeholder outreach and input, four public meetings; various outreach efforts. About 36,000 submissions were received, including over 15,000 unique comments, in response to both 2013 and 2014 documents. Inputs from various sectors of the stakeholder community.

- vi. The final rule is a combination of the original proposal and revisions outlined in the supplemental proposal, with additional changes as appropriate.
    - c. The Produce Safety Rule focuses on conditions and practices identified as potential contributing factors for microbial contamination. The following are the main components of the Rule:
      - i. Agricultural water (21 C.F.R. Part 112, subpart E)
      - ii. Biological soil amendments of animal origin (21 C.F.R. Part 112, subpart F)
      - iii. Worker health and hygiene (21 C.F.R. Part 112, subpart D)
      - iv. Equipment, tools, buildings and sanitation (21 C.F.R. Part 112, subpart L)
      - v. Domesticated and wild animals (21 C.F.R. Part 112, subpart I)
      - vi. Growing, harvesting, packing and holding activities (21 C.F.R. Part 112, subpart K)
      - vii. Records (21 C.F.R. Part 112, subpart O)
    - d. Since finalizing the Produce Safety Rule, FDA has received feedback that some of the standards outlined in Subpart E, which include numerical criteria for pre-harvest microbial water quality, may be too complex to understand, translate, and implement. In response to these concerns, the FDA is exploring ways to simplify the microbial quality and testing requirements for agricultural water while still protecting public health.
      - i. Larger farms are now required to comply with the agricultural water requirements by January 26, 2022, while small farms have until January 26, 2023 and very small farms until January 26, 2024. This rule does not change the compliance dates for sprout operations. (March 18, 2019, 84 FR 9706)
    - e. What did year 1 look like for produce farms?
      - i. The first major compliance date for large farms subject to the Produce Safety Rule, other than sprout operations, arrived on January 26, 2018 (Large farms sell an average of more than \$500,000 a year in produce). (Nov. 27, 2015, 80 FR 74353)
      - ii. However, FDA Commissioner Scott Gottlieb, M.D., conveyed in a previous announcement that routine inspections associated with the rule would not begin until Spring 2019.
      - iii. This action was intended to allow FDA and its state partners to provide additional opportunities for education and outreach, such as through the On-Farm Readiness Review program.
3. Top Legal Issues: (15 minutes)
- a. Who has the authority to conduct an inspection? (Socrates)
    - i. The answer to his question depends on whether the state in question has passed its own version of the Produce Safety Rule on the state level. If a state has its own Produce Safety Rule program, the inspections will be conducted by state inspectors. In states that have not passed their own Produce Safety Rule program (currently there are 6) the U.S. FDA will conduct the inspections.
  - b. What state laws may have additional requirements? (Kelly)
    - i. First, as mentioned 46 states have a cooperative agreement to conduct inspections on behalf of FDA. However, not all of those state Departments of Agriculture will enforce the rule if there are violations found during an inspection. Only

states that have adopted the Produce Safety Rule and the authority to regulate it into their state administrative code or law will be able to enforce a violation of the produce safety rule. (See, e.g. A.R.S. §§ 3-525 – 3-525.08; Idaho Code § 22-5404; Miss. Code Ann. § 69-1-56; Tex. Agric. Code § 91.009; Va. Code Ann. §§ 3.2-5146 – 3.2-5156; 6 V.S.A. §§ 851- 857; Rev. Code Wash. §§ 15.135.010 – 15.135.900).

- ii. In the states that do not have the authority to enforce the Produce Safety Rule on farms, they will only be conducting inspections on behalf of FDA. FDA will then decide what to do in the event of a violation of the produce safety rule. See 21 C.F.R. pt. 112.
- iii. There are some key differences depending on the states vs. federal authority and how they are enforcing the produce safety rule.
  1. Key Differences (See, e.g. A.R.S. §§ 3-525 – 3-525.08; Idaho Code § 22-5404; Miss. Code Ann. § 69-1-56; Tex. Agric. Code § 91.009; Va. Code Ann. §§ 3.2-5146 – 3.2-5156; 6 V.S.A. §§ 851- 857; Rev. Code Wash. §§ 15.135.010 – 15.135.900):
    - a. Submissions of information to the State Dept. of Ag is different depending on states vs. FDA. For the states, some are requiring farms to fill out a survey or “register” to state their status as it relates to the produce safety rule.
    - b. Fines and Enforcement
      - i. Some states have written into their law the fines and enforcement measures they will take. For example, in some states a fine may a possible way to address violations of the rule, while in other a stop sale order or seizure of the produce is another enforcement mechanism.
    - c. Appeals Process
      - i. The appeals process will also differ depending on the state vs. federal authorities. In some states it would requiring an administrative hearing through that state’s department of agriculture.
    - d. Open Records Act Protections
      - i. Some states have added in protections for produce safety rule related documentation that is collected by the state, so these documents are protected and not subject to public disclosure.
  - c. How to approach/ appeal an adverse decision that the farmer disagrees with (Kelly)
    - i. Tips:
      1. Try and work with the regulating agency and a third party food safety consultant to work through the issue.
      2. The agencies are there to help you learn more about the rule and how to comply. So discuss Complaints and Concerns with the Agency, But

Remember If it is a State Law = **State's Decision, and if there is No State Law = FDA's Decision/**

3. For inspector and inspection related complaints at FDA, the best contacts are: Joann Givens, Program Director, Offices of Human and Animal Food Operations, at 301-796-7761, or Glenn Bass, Senior Advisor, Human and Animal Food Program, at 240-402-4894.
  4. For state inspector or inspection issues, contact your State Dept. of Ag.
  5. If you decide to appeal an adverse decision remember:
    - a. State Law = **State's appeals process;**
    - b. No State Law = **FDA's appeals process.**
- ii. Also, the FDA ORA Ombudsman will listen to complaints, questions, or comments about FDA inspectors. <https://www.fda.gov/about-fda/office-regulatory-affairs/ora-ombudsman>.
  - iii. Under FSMA, FDA now has Mandatory Recall Authority. 21 USC 350l. This means that the FDA can invoke authority to force farms to recall all of their products. In the context of a produce safety rule inspection, for egregious violations, this is a possible result. If the farmer has exhausted previously mentioned options, and still would like to appeal, there is an appeal's process specific to this authority.
    1. An Informal Hearing can be request 2 days after order is given to the farm to recall their products. 21 USC § 350l. Then, FDA will decide whether to amend the order or provide more details as to the recall, including determining whether there were adequate grounds for the order in the first place.
  - iv. If FDA action ends up in a Detention Order (21 USC 334(a)) you can appeal. <https://www.fda.gov/media/85381/download>. If FDA grants the hearing, the appeal will be heard within 2 days of filing for a hearing for perishable food. FDA must make a final decision within 5 days of the appeal filing.
    1. This is just the Expedited Decision Making process for Perishable Items.
  - v. Other Adverse Decisions:
    1. 21 C.F.R. 112.205-112.211. If the FDA decides to withdrawal a Qualified Exemption:
      - a. Farm has 15 days to appeal;
      - b. FDA must decide within 10 days of the appeal; and
      - c. \*Farms can request a hearing, which may extend the time period FDA has to make a decision.
  - vi. A hearing can be requested for other adverse decisions too. 21 CFR Pt. 16.
- d. Some produce growers fall into the Qualified Exempt (QE) category of the Produce Safety Rule (Sarah)
    - i. To be QE the average annual monetary value of all **food** the farm sold during the 3- year period preceding the applicable calendar year was less than \$500,000 (adjusted for inflation \$550,551, 2016-2018) and

- ii. The average annual monetary value of the food sold directly to **qualified end-users** during the previous 3 year period exceeded the average annual value of the food sold to all other buyers during that period; (21 CFR 112.5(a))
      - 1. A qualified end user is the consumer of the food (an individual rather than a business, or a restaurant, a retail food establishment that is located either in same State/Reservation as the farm that produced the food, or not more than 275 miles from the farm. (21 CFR 112.3)
  - e. Some produce buyers are requesting FSMA compliance. (Socrates)
  - f. An update on any pending FSMA rules and FDA Guidance Documents (Kelly)
    - i. The Farm Definition impacts farms and farm activities that might fall under both the produce safety rule and the preventive controls rule for human food. 21 CFR 1.227; 21 CFR pts. 112, 117. The FDA is rewriting the definition to provide clarity for where farms might fall within either rule, depending on the activities they are doing, including businesses such as food hubs.
    - ii. 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).
    - iii. Agricultural Water Requirements are delayed until 2022. 21 CFR pt. 112, subpart E.
    - iv. Final Guidance on the Produce Safety Rule will be released at some point, but most likely will continued to be updated.
    - v. Rarely Consumed Raw Enforcement Discretion/ Guidance was issued by FDA in the federal register, and will also continue to be updated.  
<https://www.fda.gov/media/110052/download>.
- 4. Top FSMA PSR Tips (Sarah)
  - a. Farmers should consider taking advantage of an On-Farm Readiness Reviews (OFFR)
    - i. OFFRs are conducted by a team of regulatory and non-regulatory professionals who provide technical assistance and educational on-farm engagement prior to inspections.
    - ii. OFFRs prepare farmers for the implementation of the Produce Safety Rule.
    - iii. OFFRs are voluntary, free and are a non-regulatory review.
    - iv. Common non-compliance issues identified during OFFRs include:
      - 1. 21 CFR pt. 112.42(a): must inspect all of your agricultural water systems, to identify conditions that are likely to introduce hazards into or onto covered produce or food contact surfaces.
      - 2. 21 CFR pt. 112.21(a): all personnel who handle covered produce or food contact surfaces must receive adequate training, as appropriate to the person's duties.
      - 3. 21 CFR pt. 112.33: must make visitors aware of policies to protect covered produce and food contact surfaces from contamination and to ensure that they comply with these policies. Must also make toilet and hand washing stations available.

4. 21 CFR pt. 112.123(d)(1): must inspect, maintain, and clean and when necessary appropriate, sanitize all food contact surfaces of equipment and tools used in covered activities.
5. What is the future of Produce Safety Rule inspections? (Socrates)
  - a. Inspectors cannot make assumptions that the farmer understands the new regulations.
  - b. Discussions should take place with the farmer on how practices or conditions relate to regulatory concerns and possible points of contamination.
  - c. Time should be spent explaining how the regulatory process works from the inspections through compliance.
  - d. When inspectors find non-compliance they will explain the issue and seek voluntary compliance.
  - e. Farmers will be given an opportunity to voluntarily fix the issue. If the issue continues to occur, FDA will use a progressive regulatory approach
6. Resource Roundup Slide
  - a. Am I Affected Flowchart
  - b. English: [http://sustainableagriculture.net/wp-content/uploads/2016/02/2016\\_2-FSMA-Final-Rule-Flowchart-V3.pdf](http://sustainableagriculture.net/wp-content/uploads/2016/02/2016_2-FSMA-Final-Rule-Flowchart-V3.pdf)
  - c. Spanish: [http://sustainableagriculture.net/wp-content/uploads/2018/07/2018\\_05-FSMA-Flowchart-Spanish.pdf](http://sustainableagriculture.net/wp-content/uploads/2018/07/2018_05-FSMA-Flowchart-Spanish.pdf)
  - d. Overview of FDA's Draft Guidance: <http://sustainableagriculture.net/blog/fsma-guidance/>
  - e. Inspection Preview: <http://sustainableagriculture.net/blog/fsma-produce-safety-inspection-preview/>
  - f. Vermont Law School:
  - g. FSMA Legal Research Webinar:  
[https://www.youtube.com/watch?time\\_continue=1326&v=ztFohCnMI\\_M](https://www.youtube.com/watch?time_continue=1326&v=ztFohCnMI_M)
  - h. Food Safety Resource Clearinghouse:  
<https://www.uvm.edu/extension/necafs/clearinghouse/home>
  - i. FSMA Webinars (Draft Guidance and Inspections):  
<https://www.pma.com/events/webinars/2019/fsma>
  - j. FDA Inspection form for Produce Farms: <https://www.fda.gov/media/124867/download>
  - k. FDA Draft Guidance on the Produce Safety Rule:  
<https://www.fda.gov/media/117414/download>
  - l. Organic Farms and Food Safety Recordkeeping Tips Webinar:  
[https://www.ccof.org/sites/default/files/OrganicAndFoodSafetyRecordkeepingForProduceGrowers\\_2019.mp4](https://www.ccof.org/sites/default/files/OrganicAndFoodSafetyRecordkeepingForProduceGrowers_2019.mp4)
  - m. FSMA Fact Sheets and Food Safety Plan Templates in Spanish:  
<https://www.caff.org/programs/foodsafety/templates/>
  - n. Water Testing Requirements and the FSMA Produce Safety Rule:  
<https://vimeo.com/321329517>.
  - o. Worker Trainings and the FSMA Produce Safety Rule: <https://vimeo.com/314846825>.
  - p. I'm Qualified Exempt from the FSMA Produce Safety Rule – Now What?:  
<https://vimeo.com/309548944>.