Key Legal Questions Associated with FSMA Produce Safety Rule Compliance

Speakers:
Sophia Kruszewski
Elizabeth Newbold

Produce Safety Educator’s Call #54
May 25, 2021
Instructions

- All participants are muted.
- There will be time for questions and discussion at the end of the meeting.
- This session will be recorded and the presentation will be shared via the listserv and on our website after the call.
Next Meeting

• Monday, June 21, 2021 at 2PM ET
• Becoming a PSA Lead Trainer: How to Build Your Foundation for Training Success

• Zoom link and registration to be shared shortly and posted on the website at:
  https://producesafetyalliance.cornell.edu/resources/educators-group/
FDA Food Safety Traceability Challenge

• June 1, 2021: FDA to launch Era of Smarter Food Safety Low- or No-Cost Tech-enabled Traceability Challenge
  • https://precision.fda.gov/challenges/14
  • Asking stakeholders, including technology providers, entrepreneurs, and innovators, to develop traceability tools that can be implemented in a scalable, cost-effective way for food operations of all sizes.
  • Submission window closes on July 30, 2021 at 5 PM ET
• Launched new quarterly podcast called TechTalk
Speaker Introductions

Sophia Kruszewski
Clinic Director
Center for Agriculture and Food Systems
Vermont Law School

Elizabeth Newbold
Assistant Director
Northeast Center to Advance Food Safety
University of Vermont Extension
FSMA Legal Resources

Produce Safety Educators Call

May 25, 2021
Presentation Overview

Introductions
Background
Intended Use
Intended Audience
Resources
Acknowledgments
Questions & Discussion
Introductions

Sophia Kruszewski  
Center for Agriculture & Food Systems at Vermont Law School  
[Link to website](www.vermontlaw.edu/cafs)

Elizabeth Newbold  
Northeast Center to Advance Food Safety (NECAFS)  
[Link to website](www.uvm.edu/extension/necafs)
Background

FSMA PSR is a significant development related to produce safety

- Project partners realized a need to explore some of the common legal questions and concerns being raised, nationally, by members of the produce community

Identified key legal questions through national survey

- 89 - total questions submitted
- 42% - growers
- 22% - educators
- 13% - regulator
- Remaining – consultants, buyers, industry, other

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Background

Legal topics identified by national survey

- Liability
- Business structure/operation
- Insurance
- Exemptions and Qualified Exemptions
- Audits vs inspections
- Enforcement
- Interaction between PSR and other state laws
- Variances/Alternatives
- Supplier verification & qualified exemption
- Federal policy process
- Privacy and TAN responses

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Intended Use

• Stand-alone and self-contained documents
• Some cross-referencing
• Date stamped
• Assumes a basic understanding of FMSA PSR & PCHF
• Not intended to provide legal advice
Intended Audience

Primary audience
- Educators
- Regulators
- Technical Service Providers

Secondary Audience
- Producers
- Processors
- Produce Buyers
FSMA PSR State Implementation Map

• Purpose:
  • The approach for implementing the PSR varies by state and this map consolidates that information into one location for side-by-side viewing.

• Takeaways:
  • Interactive Map with links
  • Illustrates state’s produce safety program specifics
  • Content also available in table
Produce Safety Rule Inspections and Third-Party Audits

• Purpose:
  • Growers have asked about the difference between an audit and a PSR inspection and this helps to distinguish between the two and how they may impact a producer’s liability.

• Takeaways:
  • History of audits
  • Differences between an audit and an inspection
  • Why producers may need both
FSMA PSR Coverage and Exemptions for Farms with Multiple Business Entities

Purpose:
- A farm may structure its operation into multiple business entities for various reasons. It is likely the day-to-day activities that determines PSR exemption status and not the legal business formation.

Takeaways:
- Factors to consider when determining sales from multiple business entities and exemption status
- Several examples are presented
- Description of day-to-day activities and how they can inform determination
Alternatives and Variances to the Produce Safety Rule

• Purpose:
  • There are unique and special state or regional attributes and interest in exploring alternatives and/or variances to address those. This factsheet explains the approval process for both.

• Takeaways:
  • Provisions that an alternative or a variance would apply to
  • Who is eligible to develop an alternative or variance
  • High burden of supporting either with credible scientific and technical evidence
FSMA Supply Chain Program Requirements for Processors and their Produce Suppliers

• Purpose:
  • Processors with a supply chain program are unsure of what documentation is required from exempt and qualified exempt farms to confirm their PSR status. This factsheet clarifies the processors responsibility under the PCHF.

• Takeaways:
  • Steps must be taken to approve farms as the supplier
  • There are alternative options available when sourcing from exempt and qualified exempt farms and from qualified farm mixed-type facilities.
Understanding the Relationship Between FDA Rules, Guidance, and Other Communications

• Purpose:
  • FDA releases information in various forms and producers are unsure of the legal effect of these forms of communication.

• Takeaways:
  • Describes that the PSR is legally binding
  • Describes that guidance, TAN responses, and PSN responses are informational and interpretive but non-binding
  • However, could be influential in court or in a regulatory decision
Produce Farms, Foodborne Illness, and Legal Liability

• Purpose:
  • A common misconception is that FSMA created liability for producers that did not previously exist. This factsheet outlines the nuance that FSMA adds to existing liability and how compliance can be helpful in the event of a lawsuit.

• Takeaways:
  • Describes the forms of legal liability
  • Compliance with FSMA PSR may help mitigate a producer’s financial or criminal responsibility in the event of a lawsuit
Using the FDA Technical Assistance Network and FOIA to Access Information about FSMA

• Purpose:
  • Whether any or all questions submitted to the FDA TAN and FDA’s subsequent responses could be made available to the public.

• Takeaways:
  • Privacy limits FDA’s ability to release TAN questions and answers
  • However, someone can seek access through a Freedom of Information Act (FOIA) request
  • Describes process for submitting a FOIA request
Resources

- All resources available at
  - elsi.necafs.org
  - Clearinghouse
- Currently 8 resources
- Additional resources coming
  - Market Intermediaries
  - PSR interaction with other state and federal laws
  - Liability white paper
  - PDF of state interactive map info
- Law journal articles
  - When a farm entity is considered separate or together
  - Alternative and variances
## Acknowledgements

Thank you to project advisors:

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<thead>
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Acknowledgements

Thank you to project advisors

Abbey Willard, Director of Agriculture Development Division at Vermont Agency of Agriculture, Food, and Markets

Trevor Suslow, Vice President of Produce Safety at the Produce Marketing Association

Atina Diffley, Owner and Consultant at Organic Farming Works, LLC.

Socrates Trujillo, served when he was a Consumer Safety Officer in the Produce Safety Network at Center for Food Safety and Applied Nutrition at the FDA

Leanne Skelton, served when she was the Liaison to FDA on FSMA-related issues at the USDA Agricultural Marketing Service, Specialty Crops Program

Tricia Kovacs, Deputy Administrator in Transportation & Marketing at the USDA Agricultural Marketing Service

Diane Ducharme, Consumer Safety Officer in the Produce Safety Network at Center for Food Safety and Applied Nutrition at the FDA
Acknowledgements

Thank you to student clinicians and interns

Sedona Chavez, JD ‘20
Bethany Towne, JD ‘20
Ella Farago, JD ‘20
Lexi Basile, MFALP ‘19
Samuel Ingraham, JD ‘20
Lizzie Fainberg, JD/MFALP ‘20
Lauren Wustenberg, JD/MFALP ‘21
Lindsay De May, JD/MFALP ‘21
Jessica Griswold, JD ‘21
Jessie Gittemeier, JD ‘21 (Lewis & Clark)
Acknowledgements

Factsheets designed by Kelly Collar, Mad River Creative

Web design by Pete Land, Tamarack Media Cooperative

Select Photos by Andrew Chamberlin, UVM Extension

This project is funded by the National Agricultural Library, Agricultural Research Service, U.S. Department of Agriculture
Questions & Discussion
The PSA Website

http://producesafetyalliance.cornell.edu/

En español: es.producesafetyalliance.cornell.edu