

# Obstacles and Opportunities for the Produce Industry: Implications for Research and Data Needs

David Gombas, Ph.D.  
United Fresh Produce Association  
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# Five FSMA Proposed Rules

- Produce Safety
- Preventive Controls for Human Food
- Foreign Supplier Verification
- Accredited Third Party Certification
- Preventive Controls for Animal Feed
- And more to come...

# Produce Safety proposed rule

- Applies to raw agricultural commodities, including fruits and vegetables, mushrooms, tree nuts, sprouts and mixes of intact fruits and vegetables
  - Applies to “farms”, domestic and foreign
  - Covers the edible portion (including peel)
  - Does not apply to “rarely consumed raw”
  - Does not apply to commercially processed produce
  - Does not apply to operations <\$25,000 total food sales

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# What's covered

- Worker training
  - Worker health and hygiene
  - Agricultural water
  - Animal-derived soil amendments
  - Animals (wildlife and domestic)
  - Transport, buildings, tools, equipment, other food contact surfaces, sanitation, plumbing, toilet/handwashing facilities, trash, pests
  - Recordkeeping
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# Monitoring and control...

## Health

- “Excluding any person...”
- “Instructing personnel to notify their supervisor...”

## Animal intrusion

- “Must monitor” during growing season and immediately prior to harvest
- If intrusion occurs, evaluate whether to harvest

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# So what are the issues?

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# Agricultural water

“Whiskey is for drinking and water is for fighting”

- <235 generic E. coli/100 mL (single sample) and <126/100 mL (5 samples rolling geometric mean)
  - Direct water application during growing
- Testing:
  - Everyone: Beginning of growing season and every 3 months
  - Untreated surface water NOT subject to runoff: monthly
  - Untreated surface water subject to runoff: every 7 days

# Animal-derived soil amendments

- 9 month “interval” for use of untreated amendment that contacts produce
- Compost standards for *L. monocytogenes*, *Salmonella*, *E. coli* O157:H7 and fecal coliform
  - No interval if meets all standards
  - 45 day if meets *Salmonella*/fecal coliform standard and may contact produce
  - No interval if does not contact produce
  - No standards if not animal-derived
- Option for alternative standards



# Alternatives and Variances

- Alternatives can be established by individual operations, but...
  - Can apply to microbiological limits for agricultural water, compost process conditions, and minimum number of days before harvest that compost can be applied
  - Cannot apply to any other standards or provisions in the rule (e.g. frequency of water testing, organisms to be tested for)
- Variances can be established for any part of the rule, but...
  - Can only be submitted by foreign and state governments

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# Meanwhile, what about facilities?

Part 117 — *Current Good Manufacturing Practice And Hazard Analysis And Risk-based Preventive Controls For Human Food*

- Applies to operations that manufacture/ process, pack or hold food for sale in the U.S. (i.e., facilities required to register with FDA)
- Six subparts:
  - cGMPs (replaces part 110)
  - Hazard Analysis and Risk-Based Preventive Controls

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## Subpart C: Preventive Controls

- Written food safety plan
  - Written hazard analysis
  - Written preventive controls for identified hazards
  - Written monitoring procedures and frequencies
  - Written corrective actions
  - Written verification procedures, including validation of most preventive controls
  - Recall Plan
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## 117.3 Definitions

***Mixed-type facility*** means an establishment that engages in both activities that are exempt from registration under section 415 of the FFDCA and activities that require the establishment to be registered. An example of such a facility is a “farm mixed-type facility,” which is an establishment that grows and harvests crops or raises animals and may conduct other activities within the farm definition, but also conducts activities that require the establishment to be registered.

# Research and Data Needs

- Numerical standards – does one size fit all?
- If not, how to measure “equivalent public health protection”?
- When is an operation too small to matter?
- What is the cost of food safety? Is the cost of compliance really an issue?
- The details...
  - If not E. coli, then what to test for?
  - When is testing too soon to matter?
  - How much chlorine is “safe”?
  - How much animal intrusion is too much?

# **Obstacles and Opportunities for the Produce Industry: Implications for Research and Data Needs**

## **Questions?**

**[dgombas@unitedfresh.org](mailto:dgombas@unitedfresh.org)**

