

The Proposed FDA Produce Safety Rule: Brief overview for Pear Growers and Shippers

SACRAMENTO RIVER DISTRICT PEAR
RESEARCH MEETING
6 February 2013
Walnut Grove, CA



With input from David E. Gombas, Ph.D.
United Fresh Produce Association

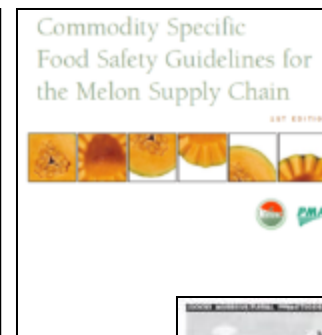
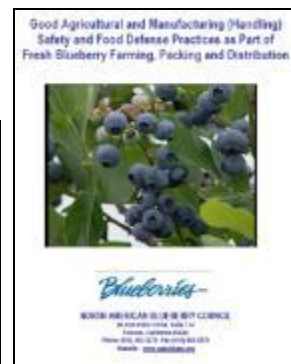
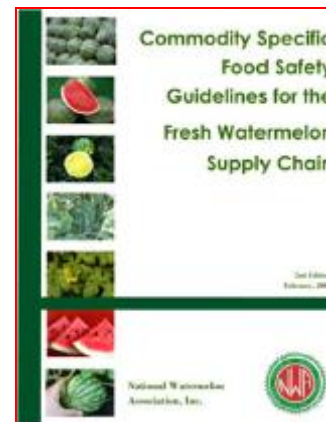
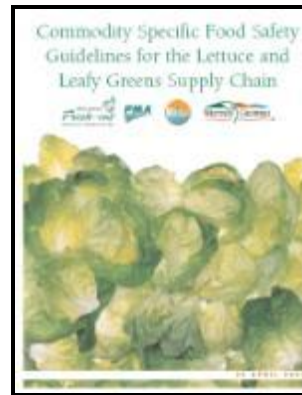
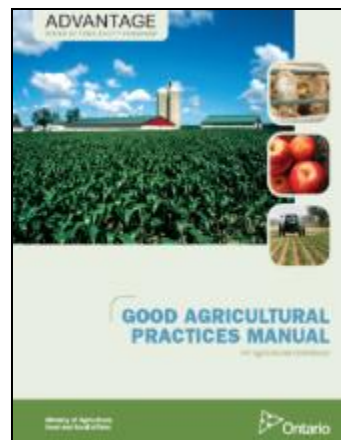


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Commodity-Specific GAPs and Food Safety Audit Checklists

- Melon
- Tomato
- Stone fruit
- Mushroom
- Lettuce & Leafy Greens
- Culinary Herbs
- Green Onions
- Sprouts
- Almond
- Citrus
- Strawberry
- Watermelon
- Blueberries
- Asparagus



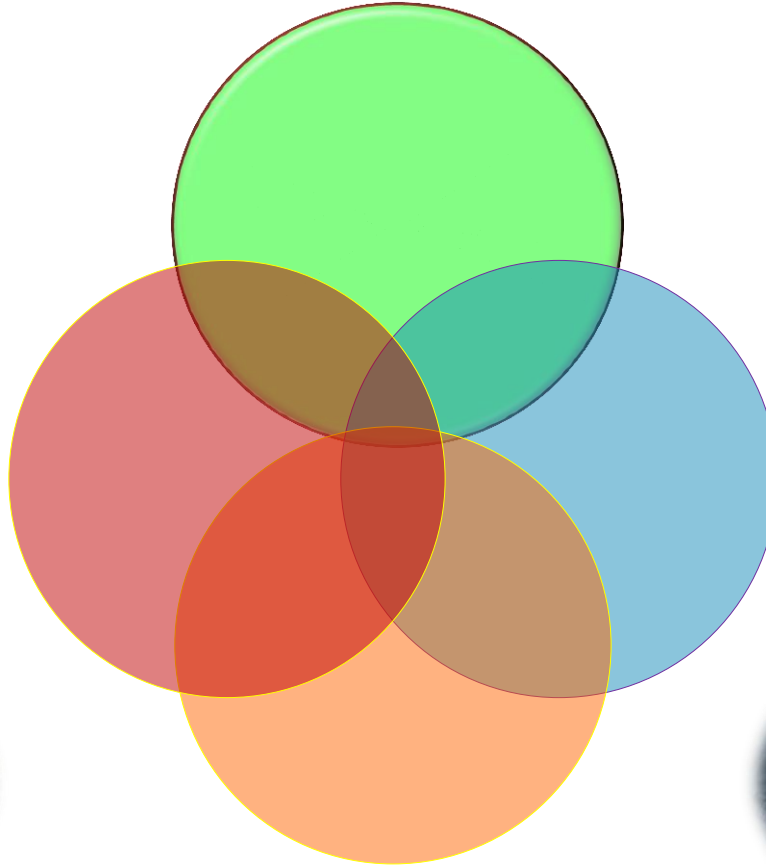
Main Themes of the FDA Legislation

Prevention

**Enhanced
Partnerships**

**Inspections,
Compliance,
and Response**

Import Safety



FSMA-Prevention

FDA has legislative mandate to require **science-based preventive controls** across the food supply

Mandatory preventive controls (implementation of a written preventive control plan)

- Hazard evaluation
- Preventive steps or controls to minimize or prevent the hazards
- Monitoring and verification of preventive controls
- Specify corrective actions

FSMA- Key Fact

FDA now has mandatory recall authority for all food products



FDA Releases Produce Safety Rule

Jan 16, 2013...120 day Comment period

Comments submitted to Docket by May 16, 2013



Five FSMA Proposed Rules

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

Part 112: Standards For The Growing, Harvesting, Packing, And Holding Of Produce For Human Consumption

- 547 pages, as published on FDA website
 - First 435 pages are “preamble”
 - Explains FDA’s thought process
 - Discusses industry perspectives on commodity-based risk
 - Discusses FDA perspective on practice-based risk
 - Asks specific questions, soliciting comment on what they have/have not proposed
- Actual proposed rule is last 66 pages
 - 14 Subparts

What's covered, what's not

- Applies to raw agricultural commodities, including fruits and vegetables, mushrooms, tree nuts, sprouts and mixes of intact fruits and vegetables
 - Applies to domestic and imported produce
 - Covers the edible portion (including peel) but not the rest of the plant
 - Exhaustive list of “rarely consumed raw” not covered
 - Does not apply to produce that is commercially processed (must have records of who processed it)
- No mention of “high risk” commodities
- No exclusion of “low risk” commodities

***Subpart A**

Who's covered, who's not

- Applies to “farms” as defined in 21 CFR part 1.227
 - Including “farm” portion of mixed-type operations
- Does not apply to operations <\$25,000 total food sales (3 year average)
- Small or very small operations, with majority of food sold to consumers (retail) in-state/275 miles, qualify for exemption from most requirements
 - Package or Point-of-Service labeling of “where grown” required
 - Qualified exemption can be withdrawn

***Subpart A**

Applies to all Covered Produce

- Proposed § 112.112 would require that farms take all measures reasonably necessary to identify and not harvest covered produce that is visibly contaminated with animal excreta.
(pg.195)



Covered risk factors

- Worker health and hygiene
- Agricultural water (that contacts the produce or food contact surfaces)
- Animal-derived soil amendments (reasonably likely to contact the produce or food contact surfaces)
- Animals (wildlife and domestic)
- Facilities and food contact surfaces (equipment, tools, instruments and controls, transport)
- Subpart M: specific requirements for sprouts

Worker health and hygiene

■ Training

- All personnel, including temporary, part time, seasonal and contracted, who handle covered produce or food-contact surfaces
- Additional requirements for harvest crew
- **“At least one supervisor or responsible party”
standardized curriculum recognized by FDA**
- Records of training



***Subpart C**

PSA National GAPs and GHPs Curriculum

- Cooperative Agreement between Cornell, FDA, and USDA
- Outreach and Education
- FSMA Produce Regulation Support targets small-scale farms
- Workgroups initiated Oct. 1, 2010
- 3 year program

<http://producesafetyalliance.cornell.edu/psa.html>

PSA Modules and Learning Objectives



PSA Conference (June 30–31: Orlando, FL)

[2011 PSA Conference Proceedings](#)

Presentations:

[Co-Management of Food Safety and Conservation Practices](#)

Laura Giudici Mills—Metz Fresh, LLC

[Farm-to-Table Food Safety for Colorado Produce Crops](#)

Marisa Bunning, Colorado State University

[Farming with Food Safety and Conservation in Mind](#)

Jo Ann Baumgartner — Wild Farm Alliance

[Florida Good Agricultural Practices \(GAPs\) Training Program](#)

Keith Schneider — University of Florida

[Food Safety for Local Growers](#)

Johnna Hepner — Produce Marketing Association

[Introduction to the Produce Safety Alliance](#)

Betsy Bihn and Robert Gravani — Cornell University

[Novel Approaches to GAPs Training, Tools, and Evaluation](#)

Ben Chapman — North Carolina State University

[Small Growers with an Emphasis on Organic/Sustainable Growers](#)

Chris Gunter — North Carolina State University

[The On Farm Food Safety Project: A Comprehensive Resource for Developing a Customized On-Farm Food Safety Plan](#)

Jim Slama — Family Farmed

Showcase Materials:



<http://producesafetyalliance.cornell.edu/psa-mat.html>

Showcase Materials:

[Arizona Leafy Greens Food Safety Committee](#)

Arizona Leafy Greens Products Shipper Marketing Agreement

[Farm to Table Food Safety – GAPs Webinars](#)

Colorado State University

[Farming with Food Safety and Conservation in Mind](#)

Wild Farm Alliance

[On-Farm Food Safety Program](#)

CanadaGAP

[Food Safety Practices for Strawberry Harvest Workers—flip chart](#)

California Strawberry Commission

[Food Safety Practices for Strawberry Harvest Worker—study guide](#)

California Strawberry Commission

[Rhode Island GAP – Training and Certification](#)

University of Rhode Island

[Texas AgriLife Food Safety Website](#)

Texas AgriLife Extension Service

[Texas GAPs and GHPs Food Safety Training Training Curriculum - Extension Publication B-6244](#)

Texas AgriLife Extension Service

[Vegetable Crops Online Resources Center – Food Safety](#)

Rutgers Cooperative Extension

Learning Objectives in Resource Flash Drive – Modules in 2013

Draft Curriculum Title: Produce Safety On-Farm Preventive Controls Training

Learning Objectives

Introduction to Preventive Controls

Objective 1: Describe how on-farm preventive controls provide a foundation for produce safety on fruit and vegetable farms through steps that include risk assessment, Good Agricultural Practices (GAPs), monitoring, corrective actions, and recordkeeping.

Objective 2: Identify the types of human pathogens that contaminate fresh produce resulting in foodborne illnesses and give an example of each.

Objective 3: Identify the five most common routes by which produce may be contaminated by human pathogens during production and postharvest handling.

Objective 4: Describe why preventing contamination is important for fresh produce safety.

Objective 5: Describe why commitment is the key to effectively evaluating risks and implementing food safety practices.

Agricultural water

- Inspect entire water system “under your control”: water source, distribution system, facilities and equipment
 - At beginning of growing season and “maintain”
 - “Immediately discontinue use” until...
- Testing:
 - Everyone: Beginning of season and every 3 months
 - **Untreated surface water subject to runoff: every 7 days**
 - Untreated surface water NOT subject to runoff: monthly



***Subpart E**

Agricultural water standards

- No *E. coli* in 100 mL, for
 - Directly contacts produce during/after harvest
 - Used to make treated “agricultural tea”
 - Food contact surfaces
 - Washing hands
- <235 *E. coli* /100 mL (single sample) and <126/100 mL (5 samples rolling geometric mean)
 - Direct water application during growing
- No standard for non-direct water application (drip)
- No testing if public water source or treated water
- Records of test results required
- Option for alternative standards

*Subpart E

A framework for developing research protocols for evaluation of microbial hazards and controls during production that pertain to the quality of agricultural water contacting fresh produce that may be consumed raw. J. Food Prot. 75: 2251-73

Harris, L.J., J. Bender, E. A. Bihn, T. Blessington, M.D. Danyluk, P. Delaquis, L. Goodridge, A. M. Ibekwe, S. Ilic, K. Kniel, J.T. LeJeune, D.W. Schaffner, D. Stoeckel, and T.V. Suslow.

Produce Safety Research RFP Announced



Feb 1, 2013

Center for Produce Safety

Announces Call for Research Proposals

\$3M in funds available to answer produce food safety questions

Partners in Research

2.1 The Washington Tree Fruit Research Commission and the fruit industry in the Pacific Northwest are interested in a research program to investigate the risk of pathogen contamination on fresh market tree fruit.

Animal-derived soil amendments

- Human waste prohibited, unless in compliance with 40 CFR part 503 (biosolids)
- 9 month “interval” for use of untreated amendment that contacts produce
- 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
- Option for alternative standards

*Subpart F

A Framework for Developing Research Protocols for Evaluation of Microbial Hazards and Controls During Production That Pertain to the Application of Untreated Soil Amendments of Animal Origin on Land Used to Grow Produce That May Be Consumed Raw

J. Food Protection *in press*

Linda J. Harris, Elaine D. Berry, Tyann Blessington, Marilyn Erickson, Michele Jay-Russell, Xiuping Jiang, Karen Killinger, Fredrick C. Michel, Jr., Pat Millner, Keith Schneider, Manan Sharma, Trevor V. Suslow, Luxin Wang, and Randy W. Worobo



FDA Position on Animal Intrusion

- **Wild Animals** - FDA recognizes that **it is impossible to keep all wild animals away from produce fields.** If the situation is out of control and there is a reasonable probability that wild animals can contaminate produce, **growers would be required to monitor their fields for signs of animals and take some kind of preventative measure** to keep them out or discourage them from entering.



Animals (wildlife and domestic)



Domestic/working animals

- “Adequate waiting period” after allowing animals to graze – **9 month rule for likely to contact...**
- “Measures to prevent” if animals allowed where crop has been planted

Animal intrusion

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

***Subpart I**

Soil to Shoes to Rungs to Hands to Fruit?

- Is this a significant risk?
- What could change your answer?



Meanwhile, what about facilities?

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

- 680 pages, as published on FDA website
- **Actual proposed rule pages 562-617**
- Many specific requests for comment, but entire document is open for comment

Six subparts:

A: Applicability, definitions and exemptions

B: cGMPs (replaces part 110)

C: **Hazard Analysis and Risk-Based Preventive Controls**
(written food safety plan, hazard analysis, monitoring,
corrective actions, validation...)

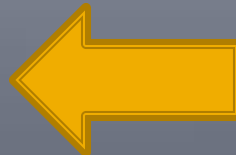
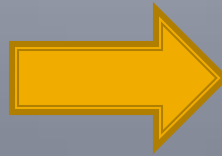
D: Modified Requirements (for qualified facilities and for facilities solely engaged in storage of packaged food not exposed to the environment)

E: Withdrawal of an Exemption

F: Records and Recordkeeping

How do you Clean & Sanitize?

How Often?



FDA Will Require Evidence for Effectiveness of Preventive Controls



- How effective?
- How do you know?

Rulemaking Process

- FDA publishes proposed rule in Federal Register (January 4, 2013)
- Public comment period: 120 days (May 16; subject to extension)
- FDA publishes final rule within 1 year after comments close (2013-'14)
- One year implementation (2015 likely first year of enforcement)
- Dates to be staggered for small (2 years) and very small (3 years) operations
- Plus 2 years for some water requirements

FSMA Proposed Rule for Produce: Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption

<http://www.fda.gov/Food/FoodSafety/FSMA/ucm261689.htm>Docket

Number: [FDA-2011-N-0921](#); comments due by May 16, 2013