

ISGA Sprout Safety Workshop

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FDA Regulatory Perspective

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Presentation Overview

- Background
 - Sprout guidance documents
- Observations re: Implementation
 - Outbreak investigations
 - 2010 Sprout Assignment
- Proposed Produce Regulation in context of the Food Safety Modernization Act

Background – A Few Milestones

- Sprouts identified as a problem by CDC in 1995
- Mid- to late 1990s - Sprout work groups to identify and implement interventions for seeds and sprouts, public mtg, sprout summit....
- 1999 FDA Sprout Guidance docs
- 2005 Sprout Public Meeting
- 2009 Sprout Technical Day
- 2011 ISGA Sprout Workshop

FDA's Sprout Guidance

October 25, 1999

1. Reducing Microbial Food Safety Hazards for Sprouted Seeds
2. Sampling and Microbial Testing of Spent Irrigation Water During Sprout Production

<http://vm.cfsan.fda.gov/~dms/sprougd1.html>

<http://vm.cfsan.fda.gov/~dms/sprougd2.html>

Broad Sprout Guide

Everyone has a responsibility:

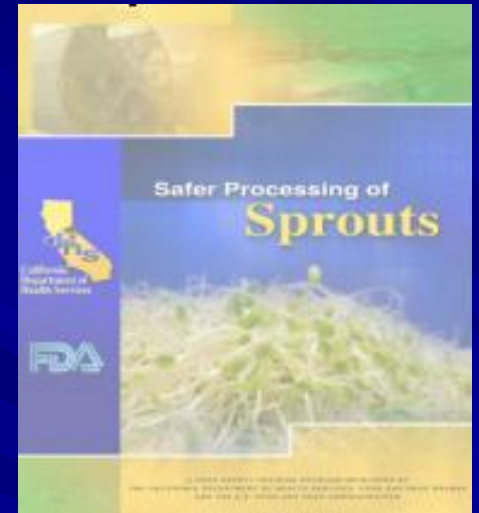
1. **Seed production** - Good Agricultural Practices (GAPs)
2. **Seed handling & distribution** - minimize contamination
3. **Sprout production** - GMPs should be standard operating procedure
4. **Seed treatment** - apply one or more approved treatments shown to reduce pathogens prior to sprouting
(SUCH AS 20,000 ppm calcium hypochlorite)
5. **Microbial testing** – test spent irrigation water from each batch of sprouts for pathogens before sprouts enter the food supply - *Salmonella* and *E. coli* O157:H7

“Safer Processing of Sprouts”

- Educational video produced by the CDPH – FDB and the FDA in cooperation with industry and academia.

- Now available on YouTube

<http://postharvest.ucdavis.edu/Pubs/video-library.shtml#Sprouts>



- After 1999 sprout guidance, the number of outbreaks, and the number of illnesses in an outbreak, appeared to decline.
- No reported sprout outbreaks in 2005, 2006, or 2007.

However...

- In late 2008, there was one sprout-associated *Salmonella* outbreak.
- In 2009, an ongoing *Salmonella* outbreak resulted in more than 200 illnesses
- In 2010, sprouts contaminated with *Salmonella* Newport infected 44 people in 11 states
- In June 2011, sprouts contaminated with *Salmonella* Enteritidis sickened 21 people in 5 states
- Sprouts have also been linked to *Listeria* illnesses and positive sample findings.

Adequacy of Current Guidance

Recent outbreaks and positive sample findings have led FDA to question:

- Consistent and Appropriate application of recommended practices in current guidance?
- Adequacy of current guidance?

Investigational Findings:

- Seed most likely source of contamination in most if not all sprout outbreaks, though conditions at the facility can exacerbate conditions (1999 Sprout Guides)
- Recent “contributing factors” show exceptions to the rule
 - *Listeria* positives on equipment and in sprouting facility
 - Facility practices and conditions, matching *Salmonella* outbreak strain in compost run-off

2010 Sprout Assignment

Objectives:

- Conduct comprehensive inspections to assess current industry practices (GMPs)
- Determine the extent of adoption of FDA Sprout guidance (Sprout Checklist)
- Sample spent irrigation water & finished product for *Salmonella*, *E. coli* O157:H7, and *Listeria monocytogenes*
- Document conditions & take regulatory action of firms operating under insanitary conditions

2010 Sprout Assignment

- Follow-up to May 1, 2009 Letter to seed and sprout industry
- Observations & information from this assignment will enhance our ability to prevent future outbreaks associated with contaminated sprouts,
- Support future policy development, education/outreach and
- Inform rulemaking efforts (proposed produce rule)

Preliminary Results

- More than 60 firms identified for inspection, sample collection and checklist data
- Timing of assignment: checklist data from about 1/3 of firms
- No positive sample findings

General Observations

- Many operations were taking steps to implement at least some of the recommendations in the Sprout Guides, though this effort was not universal across sprout farms visited nor was it across all current recommendations within a single operation.
- Some observations at one or more sprout farms (not necessarily sprout specific) included: issues with equipment and facility design, sanitation and hygienic practices

Preliminary Data: Checklist

- All firms stored seed in clean dry areas
 - many in closed covered containers, most stored seed off the floor and some away from walls.
- About half reported looking for seed w/ GAPs
- About half report testing spent irrigation water
 - Fewer had SOPs for testing (sample size or frequency) logs of results
 - About 1/3 reported environmental testing for *Listeria*

What's Next?

- Proposed Produce Rule, including Sprouts
 - In Context of FSMA
 - Current thinking
- Opportunities for continued engagement

Food Safety Modernization Act

FSMA directs us, in coordination with USDA and states, in consultation with other agencies, to:

Establish science-based minimum standards for the safe production and harvesting of those types of fruits and vegetables (RACs) where we determine that such standards minimize the risk

In addition, FSMA provides specific directions for

- Content of the proposed rule - minimum standards related to select issue areas, including: soil amendments, worker hygiene, animal presence and water quality,
- Sufficient flexibility to apply to various types of entities growing and harvesting fruits and vegetables that are RACs, including small businesses and entities that sell directly to consumers, and
- Appropriate to the scale and diversity of the production and harvesting of such commodities

Context

- FSMA focuses on prevention
- Major preventive control rules:
 - Food preventive controls (GMP modernization)
 - **Produce safety**
 - Feed preventive controls
 - Prevention of intentional contamination
 - Sanitary transportation
 - Foreign supplier verification

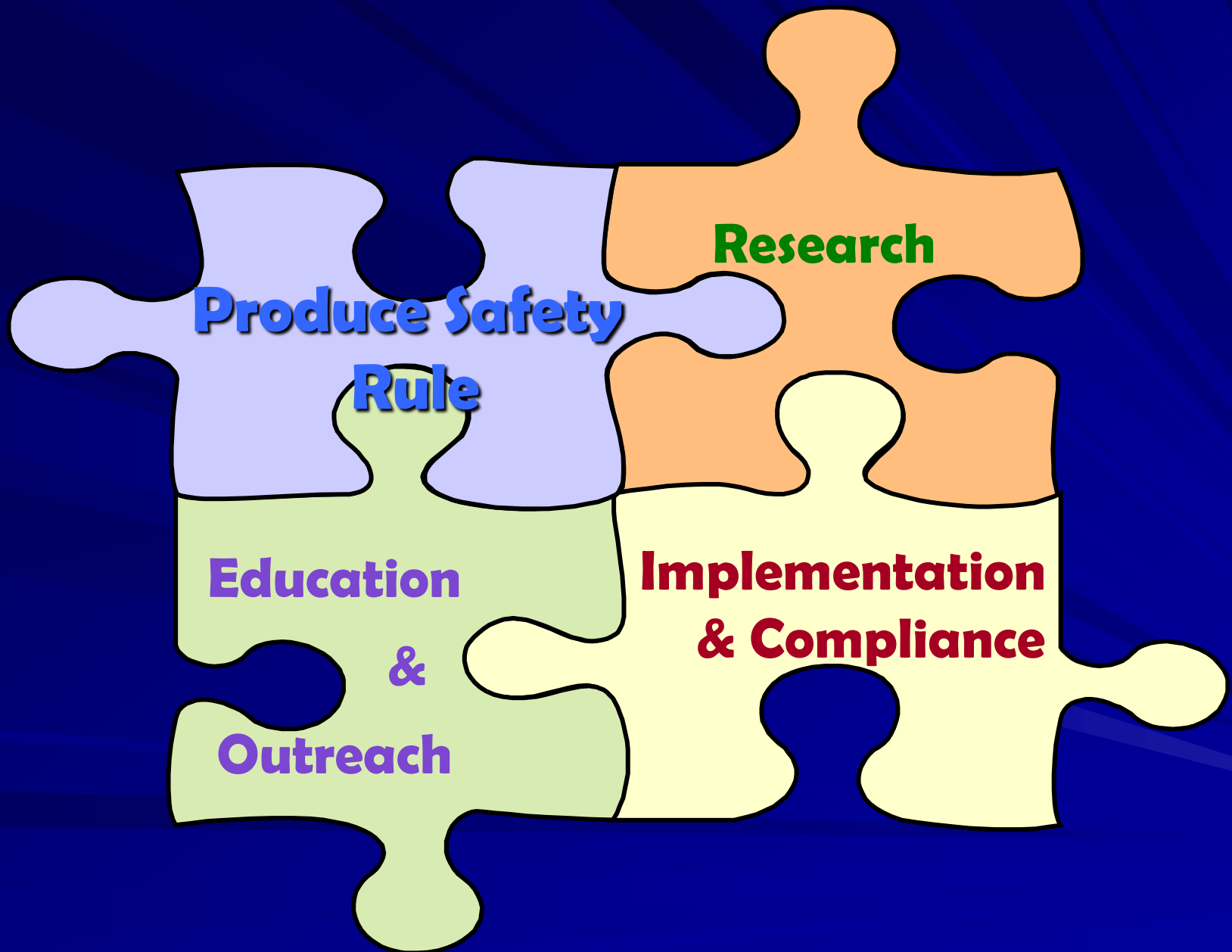
Context

Produce Safety Regulation

- Growing, harvesting, postharvest handling of produce (e.g., trimming & washing RACs)
- Packing of produce, where exempt from BT Act registration (on farm)

Food Preventive Controls Regulation (GMP Update)

- Processing of produce (e.g., fresh cut)
- Warehousing, shipping, receiving of produce
- Packing of produce, where subject to BT Act facility registration requirements



FDA's Current Thinking - Deliberative

Scope: Produce Safety Rule

In scope:

- Fresh fruit and vegetables
- Mushrooms
- **Sprouts**
- Peanuts and tree nuts

Scope

Tester Amendment - exempt if:

- Less than \$500,000 food sales, and
- Majority ($\geq 51\%$) of food sold to consumer, restaurant or retail establishment in same state or within 275 miles of farm
- Implementation date for covered firms tiered by size of firm

Regulatory Process: Next Steps

- Continuing review of public comments, existing programs & guidance
- Expert input and active engagement with other agencies, the produce industry and other stakeholders
- Proposed Rule anticipated early 2012, opportunity for more focused input

Collaboration

- What we do can only be as good as the information we have to work with
- Key to effectively implementing the Produce Safety Rule will be continued (and enhanced) collaboration with food safety partners, industry, universities and all our stakeholders

Additional Resources

- FDA Produce Safety Activities Page:

<http://www.fda.gov/Food/FoodSafety/Product-SpecificInformation/FruitsVegetablesJuices/FDAProduceSafetyActivities/default.htm>

- www.foodsafety.gov