

# Empire State Fruit & Vegetable Expo

January 25, 2012

## FSMA and Proposed Produce Safety Rule Update

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# Food Safety Modernization Act

## January 4, 2011

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 to this broad direction, FSMA provides specific requirements for

- Content of the proposed rule - minimum standards related to soil amendments, hygiene, packaging, temperature controls, animals in the growing area, and water,
- Sufficient flexibility to be applicable to various types of entities engaged in the production and harvesting of 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

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



# Context

## Foreign Supplier Verification Regulation

- Steps to assure compliance by foreign growers and shippers of produce

## Product tracing, includes pilots

- Product traceability important - not the subject of the produce rule



# Scope: Produce Safety Regulation

## In scope:

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



# Scope

## Out of scope or exempt from most provisions:

- “Tester Amendment”
- Usually cooked or “rarely consumed raw” (e.g., potatoes, sweet potatoes, artichokes)
- Produce destined for “kill step” processing (e.g., tomatoes for tomato paste)
- Agronomic crops (e.g., grain, canola, cottonseed, flaxseed, legumes, rice)



# Scope

**Tester Amendment** - exempt if:

- Less than \$500,000 food sales, and
- Majority of food sold to consumer, restaurant or retail establishment in same state or within 275 miles of farm



# Considerations: Size of Firm

- Many very small to medium sized farms exempted by Tester Amendment
- Implementation date tiered by size of firm
- Certain specific provisions may not apply to smallest firms (e.g., some records)



# Considerations: Products & Practices

- Very low risk products (cooked or processed) exempt from most provisions or out of scope
- Extent of prescribed standards and controls varies according to the risk of the practices employed (e.g., water application or soil amendment) and the appropriateness of standardization versus flexibility



# Considerations:

## Commodities & Outbreak History

Defining risk category for commodities by outbreak/illness data very challenging:

- Interplay of number, extent and severity of outbreaks
- Setting timeframes for baseline period
- Effect of consumption/exposure on illness data
- Effect of identifying food vehicle (or not) on illness data



# Considerations: Commodities & Sampling Data

Defining risk category for commodities by positive sampling data very challenging:

- Availability of contamination data by commodity highly variable
- Contamination testing driven, in part, by perceived risk
- Outbreak ranking not static: Could require moving commodities from one risk category to another based on new data



- Operations with multiple commodities in different risk categories but with similar practices and conditions could be subject to multiple standards and control regimes at a single farm



# Additional Challenges

- Risk associated with a given commodity varies depending upon practices employed (e.g., regional practices and conditions)
- Practices may change over time for a given commodity
- Higher burden associated with riskier practices provides incentive to move to lower risk practices, where options exist



# Engagement

We are committed to getting as much input as possible even before a proposed rule

- Listening sessions in 13 states across the country
- Open docket: over 800 comments

**FDA-2010-N-0085**

- Working closely with our food safety partners at the federal, state and local levels to ensure all perspectives and expertise are included



# Regulatory Process: Next Steps

- Expert input and active engagement with other agencies, the produce industry and other stakeholders
- Proposed Rule anticipated early 2012, opportunity for more focused input
  - Submit written comments
  - Regional public meetings
  - Other engagements



# To Facilitate Compliance

- “Hazards guide” to assist producers in designing preventive controls
- Reasonable time periods for implementation, taking into account firm size
- Cooperate with USDA, state & local extension, and industry-sponsored education efforts to foster understanding and implementation of the regulation
- Produce Safety Alliance out of Cornell



# To Facilitate Compliance

- Continue to cooperate with the industry and other food safety partners to identify and implement best practices
- Conduct and foster applied, problem-solving research to both better understand produce safety hazards and to develop the preventive controls needed to minimize them



# Additional Resources

- [www.foodsafety.gov](http://www.foodsafety.gov)

- FDA FSMA page:

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

- FDA Produce Safety Activities Page:

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

