



# FSMA Implementation Challenges

*Kathy Gombas*

# Challenges

- Rule exemptions are complicated
- Don't know where to start
- Struggle with supply chain requirements
- Need “affordable” and “timely” resources
- Outreach challenges



# FSMA Implementation Resources

- Training (Alliances)
- Guidance Documents (FDA, Industry)
- Tools (model plans, templates, plan builders)
- Technical Assistance (States, TAN experts, Academia, Trade Associations)





# Produce Safety Rule

*David Gombas*

# The Good News

“90%” of the rule aligns with well established Good Agricultural Practices (GAPs)

- Emphasis on same 5 major potential vectors of contamination: water, animals, manure, workers, and food contact surfaces.
- Concentrates on practices, not on recordkeeping
- Farms already complying with private sector GAP standards should have little difficulty complying with the rule



# The Challenges

## Fear and Confusion

- Water testing
- Produce Safety or Preventive Controls?
- Exemptions
- Foreign suppliers
- The Devil's in the Details
- Who will enforce and how?





# Hot Topics in Food Safety

Craig Wilson  
Costco Wholesale

- FDA/FSMA Angst
- The Role of Auditors, Certifications, and Challenges for Small Suppliers
- The Elephant in the Room ??
- Ongoing Support from the FDA and FSIS
- Recalls and the Consumer







Jeffrey Steger  
Senior Counsel  
Consumer Protection Branch  
U.S. Department of Justice

- For more than 40 years, Consumer Protection Branch (CPB) has worked to protect the health, safety, and economic security of the American consumer.
- CPB leads the Justice Department's efforts to enforce consumer protection statutes throughout the United States.

*The views expressed are the author's and do not necessarily represent the views of the Department of Justice or any other agency.*



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## FDA inspections – what to expect “Routine” and “For Cause”

What you need to know about observations that trigger  
Form 483s and Warning Letters  
Pathogen Control

How to avoid making operational  
mistakes that could result in criminal exposure  
“Smart Sampling” and “Root Source”



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