

# Public Hearing on Safety of Fresh Produce

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9am-5pm

Oakland, California

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# GAPs/GMPs, Produce Safety Action Plan, Opportunities and Challenges



# Overview

- Purpose of the Produce Hearings
- Outbreaks
- Background
  - 1998 GAPs/GMPs Guidance
  - 2004 Produce Safety Action Plan
- Opportunities & Challenges
- Where we are now
- Towards the future of produce safety



# Purpose of the Produce Safety Hearings

- Share information about recent outbreaks
- Solicit comments, data, other information to help inform FDA in potential future actions
  - Invited speakers
  - FDA panel - questions
  - Public comment



# Fresh Produce - Concerns

- Grown in a non-sterile environment
- Opportunities for contamination
- Likely to be consumed raw
- Presence of Pathogens is NOT the natural state of fresh produce –



practices can  
minimize risk



# Outbreak History

- 1973-1997 Foodborne illness outbreaks associated with fresh produce increased, both in absolute numbers and as a proportion of outbreaks w/ known vehicles
- 1998-2006 ~ 60 reported outbreaks associated with ~ 20 fresh produce commodities



# Outbreak History

1998-2006

~ 60 outbreaks with FDA involvement

~ 20 fresh produce commodities identified

17 Leafy greens

11 Tomatoes

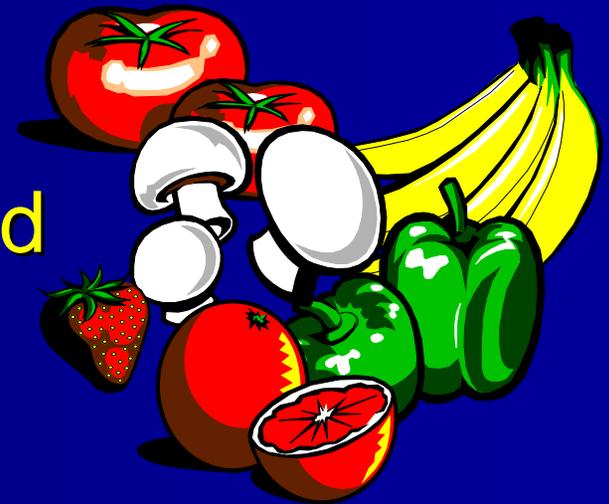
7 Melons

35 Outbreaks (more than half)



# The GAPs/GMPs Guide

- Broadscope - practices common to the growing and packing of most fresh produce consumed in the U.S.
- Risk reduction, not elimination
- Guidance, not a regulation



# Foodborne Illness Investigations - Findings

- In many cases – the most likely causes of contamination are preventable.
- Often, however, investigators are not able to identify a specific route of contamination.



# Produce Safety Action Plan

- Priority for CFSAN
- Builds upon existing programs and expertise
- Covers fresh fruits and vegetables from farm to table

<http://www.cfsan.fda.gov/~dms/prodpla2.html>



# Overarching Goal

Minimize foodborne illness  
associated with the  
consumption of fresh  
produce



# General Objectives

1. Prevent microbial contamination
2. Minimize public health impact when contamination occurs
3. Improve communication
  - w/ producers, preparers, consumers
4. Facilitate and support research relevant to fresh produce safety



# Implementing the Action Plan Accomplishments

- **Draft final guidance for fresh-cut produce**  
<http://www.cfsan.fda.gov/~dms/guidance.html#prod>
- **Leafy greens safety initiative**  
<http://www.cfsan.fda.gov/~dms/lettsafe.html>
- **Training for farm investigations – FDA, State and Foreign regulators**  
[http://www.fda.gov/ora/inspect\\_ref/igs/iglist.html](http://www.fda.gov/ora/inspect_ref/igs/iglist.html)



# Implementing the Action Plan Opportunities

- Communication with Research, Academia, Federal, and State, and Industry Partners
- Guidance - industry led, commodity specific supply chain guidance
- Research - develop coalitions to address specific issues



# Challenge/Opportunity

- 1998 GAPs guide - broad scope
- Risk of microbial contamination results from the interaction of several factors
  - Characteristics of the commodity
  - Production environment and practices



# Commodity Specific Guidance

Industry developed, commodity specific, supply chain guidance for

- melons,
- lettuce & leafy greens,
- tomatoes

<http://vm.cfsan.fda.gov/~tcjm/melonsup.html>

<http://vm.cfsan.fda.gov/~tcjm/lettsup.html>

<http://www.cfsan.fda.gov/~dms/tomatsup.html>



# Challenges

- Fresh produce outbreaks continue
- Globalization, complexity of distribution, variety of products
- Growing high risk population
- Practical limitations to investigations & information gained
- Traceback
- Identifying/promoting risk based preventive controls



# Our Starting Point

Measures outlined in the PSAP,  
GAPs/GMPs guide, and other public &  
private guidelines have or can be  
effective when properly implemented



# Foundation for Future Actions

## Outbreaks >>> Questions

- Extent of implementation ?
- Effectiveness when implemented properly ?
- What additional or different interventions might be appropriate to reduce future outbreaks ?



# Which Path to Take?

- Guidance?
- Regulations?
- Different or additional mechanisms?



# Foods Other Than Fresh Produce

## Examples in FR Notice of Public Hearing

- *21 CFR part 120 – Juice HACCP*
  - Training and other requirements for specific functions
  - Options for Importer verification
  - Records of implementation
- *Augmented with Hazards and Controls Guide; recognized training curriculum*



# Our Mission

Ensuring the safety of all domestic and imported fresh and fresh-cut fruits and vegetables consumed in the US

## Continuing themes:

- Increasing America's consumption of fruits and vegetables to achieve a healthier diet (consumer confidence)
- Improving the safety of fresh fruits and vegetables

