

Public Hearing on Safety of Fresh Produce

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9am-5pm

College Park, MD

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Overview

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



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 ~ 72 reported outbreaks associated with ~ 20 fresh produce commodities



Outbreak History

1998-2006

~ 72 outbreaks with FDA involvement

~ 20 fresh produce commodities identified

24 Leafy greens

12 Tomatoes

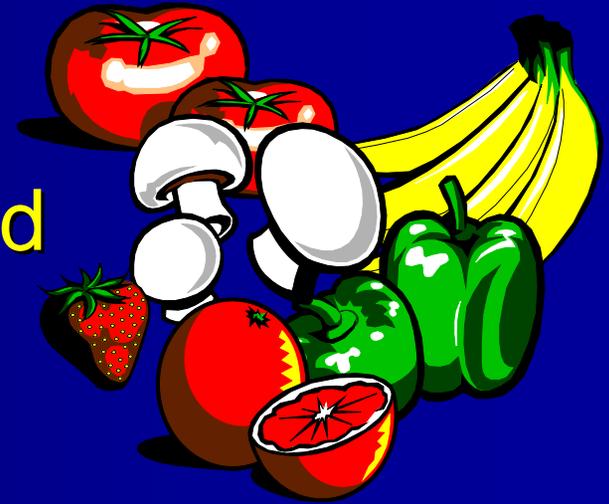
11 Melons

47 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

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



2004 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



Challenge/Opportunity

1998 GAPs guide

- Voluntary – Not a regulation
 - “recommend”
 - “encourage”
- Broad scope – Tailor to fit operation

Risk of microbial contamination results from the interaction of several factors

- Characteristics of the commodity
- Production environment and practices



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



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

Several examples in FR Notice

- *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

