NCLS Agriculture Task Force
Food Safety Modernization Act Update

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Why FSMA?

• Series of large, high profile outbreaks
  – Peanut butter, peppers, spinach, etc.
• Large burden of foodborne illness in US
  – CDC estimates
  – Economic burden
• Changing food supply
  – Increasing import volume and diversity
  – Changing consumer preferences
Percent change in incidence of culture-confirmed human infections, 2006-08 vs 2016, CDC FoodNet

MMWR, Apr 21, 2017;66:397-403
# 2015 Food Safety Report

Measuring progress toward Healthy People 2020 goals

<table>
<thead>
<tr>
<th>Pathogen</th>
<th>Healthy People 2020 Target Rate</th>
<th>2015 Rate</th>
<th>Change Compared with 2006-2008</th>
</tr>
</thead>
<tbody>
<tr>
<td>Campylobacter</td>
<td>8.5</td>
<td>12.97</td>
<td>9%</td>
</tr>
<tr>
<td>E. coli O157*</td>
<td>0.6</td>
<td>0.95</td>
<td>-30%</td>
</tr>
<tr>
<td>Listeria</td>
<td>0.2</td>
<td>0.24</td>
<td>No change</td>
</tr>
<tr>
<td>Salmonella</td>
<td>11.4</td>
<td>15.89</td>
<td>No change</td>
</tr>
<tr>
<td>Vibrio</td>
<td>0.2</td>
<td>0.39</td>
<td>34%</td>
</tr>
<tr>
<td>Yersinia</td>
<td>0.3</td>
<td>0.29</td>
<td>No change</td>
</tr>
</tbody>
</table>

*Per 100,000 population

*Culture-confirmed infections per 100,000 population

*2006-2008 were the baseline years used to establish Healthy People 2020 targets

*Shiga toxin-producing Escherichia coli O157
FSMA Central Tenets

• Prevent problems rather than simply react
• Build on best practices
• Domestic and import parity
• High rates of compliance crucial to success
• Educate before and while regulating
• Critical role of partnerships
  • Other federal agencies
  • Integrated food safety system (states and local)
  • Foreign partnerships
Seven foundational rules finalized Sept 2015-May 2016

- Preventive controls for human food
- Preventive controls for animal food
- Produce safety rule
- Foreign supplier verification programs
- Accredited third-party certification
- Sanitary transportation
- Intentional adulteration (food defense)

Staggered implementation by rule and facility size
FSMA Compliance Dates Reached

- **September 19 2016**: PC - Human and Animal Food
  - Modified Good Manufacturing Practices (GMPs)
  - Risk-Based Preventive Controls for Human Food
  - Current Good Manufacturing Practices (GMPs)
- **January 26, 2017**: Produce Safety rule
  - Sprouts only
- **April 6, 2017**: Sanitary Transportation
- **May 30, 2017**: Foreign Supplier Verification Programs
- **June 21, 2017**: Third Party Accreditation website opened
Approaching FSMA Compliance Dates

- Compliance dates on previous slide apply to largest operations
  - Smaller operations fast-forward by a year
- September 18, 2017: Preventive Controls for Animal Food
- January 27, 2018: Produce Safety Rule
  - All other covered commodities
- July 26, 2019: Intentional Adulteration
Produce Safety Compliance Dates

- Jan 2018 – large farms ($>500k 3-year avg)
- Jan 2019 – small farms ($250-499k)
- Jan 2020 – very small farms ($25-249k)
Produce Safety Rule
Addresses risk-based routes of contamination

Water Quality
Biological soil amendments
Worker hygiene
Animal encroachment
Farm buildings
Farm equipment
Agricultural Water

- Agricultural water known source of contamination
- Feedback on microbial quality standards: Too complex to understand & implement
- Considering how to simplify the standards while still protecting public health
- We announced our intention to extend the compliance date
- FR notice forthcoming
Compliance Extensions
Aug 2016

- Written customer assurances
- Packinghouses
- Secondary activities farms
- Coloring raw agricultural commodities
- Cotton ginning facilities
- Importers of food contact substances
FSMA Produce Safety Resources

- Training alliances up and running
  - Joint FDA & USDA FSMA Collaborative Training Forum
- Academic Partnerships
- Produce Safety Network
- Guidance
- The FSMA Technical Assistance Network (TAN) up and running
  - https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm459719.htm
Produce Safety Network

- FDA produce experts in each region of the country
  - Combines staff from the Office of Regulatory Affairs (ORA) and the Center for Food Safety and Applied Nutrition (CFSAN)
- Outreach, education, and technical assistance
- Inspections and outbreak response
- Working with NASDA on the On-Farm Readiness Review program
Produce Safety Training

• The Produce Safety Alliance (Cornell University)
• The National Coordination Center and four Regional Centers, created in a partnership with USDA’s National Institute of Food and Agriculture
  – NCC – Intl Food Protection Training Institute – Battle Creek
  – Northeast region – University of Vermont
  – Southern region – University of Florida
  – North Central region – Iowa State University
  – Western region – Oregon State University
• The National Farmers Union Foundation – local food producers
• The University of Arkansas-Fayetteville - tribal
• Joint Institute for Food Safety and Nutrition (JFSAN) – University of Maryland – international partners
State Produce Implementation
Cooperative Agreement Program (CAP)

• Cooperative Agreement with NASDA
• State support
  – Year 1: $21.8 million to support 42 states
  – Year 2: $30.9 million to support 43 states
• The cooperative agreement provides states with the resources to formulate a multi-year plan to implement a produce safety system, hire staff, develop and provide education, outreach and technical assistance, and develop programs to address the specific and unique needs of their growers.
State Produce Implementation CAP Awardees

Competition A Only & Competition A / B Map

- **Competition A** includes Infrastructure, Education, Technical Assistance, and Inventory Program.
- **Competition A/B** includes Competition A components AND an Inspection, Compliance and Enforcement Program.

June 2017
“I’ve read the last page of the Bible. It’s all going to turn out all right.”

- Rev. Billy Graham