FDA Agency Report

Conference for Food Protection
Virtual Meeting 2021
Mark Moorman, Ph.D.
Partnering Forward on the Road to Retail Food Safety
2020 AND BEYOND: PLANNING FOR THE FUTURE
Welcome to FDA’s New Era of Smarter Food Safety

- Tech-enabled Traceability
- Smarter Tools and Approaches for Prevention and Outbreak Response
- New Business Models and Retail Modernization
- Food Safety Culture
Core Element 2

1. Invigorate Root Cause Analyses
2. Strengthen Predictive Analytics Capabilities
3. Domestic Mutual Reliance
4. Inspection, Training, and Compliance Tools
5. Outbreak Response
6. Recall Modernization

Smarter Tools and Approaches for Prevention and Outbreak Response
Core Element 3

1. Ensure Safety of Food Produced or Delivered Using New Business Models
2. Modernize Traditional Retail Food Safety Approaches
NEW ERA OF SMARTER FOOD SAFETY

FDA Public Meeting

New Era of Smarter Food Safety Summit on E-Commerce: Ensuring the Safety of Foods Ordered Online and Delivered Directly to Consumers

SAVE THE DATE

Three-Day Virtual Event

October 19-21, 2021
The Road Ahead: Priorities for Core Element 3.0 in 2021 to 2023

3.1 Plan and Convene **New Business Model Summit** – Targeted for October 2021

3.2 Coordinate the Design and Launch of the **Independent Review of Traditional Retail Food Program Approaches**

3.2 Work with Stakeholders:
- **Food Code Adoption** Strategy & Tool Kit
- **Food Safety Management Systems** with retail food establishments
- Risk Based inspection methods and root cause analysis
- Intervention Strategies that positively **impact behavioral change**
- **State of the Art** – Facility and Equipment Design
2020 AND BEYOND: CURRENT AGENCY and CFSAN/OFS PROGRAM INITIATIVES
Vision for Prevention: and Challenge Statements to Address

• More foodborne illness outbreaks detected due to enhanced disease attribution capabilities

• We need a structured process as we transition from outbreak to prevention

• We have an opportunity to bring clarity and collaboration to prevention activities
After the Outbreak

What is our vision for prevention after the outbreak?

We lead and execute a systematic approach for:

• identifying gaps in understanding
• identifying activities to resolve gaps
• engaging experts and making connections during the prevention process (FDA, CDC, States, academia, and industry)
• executing an influence and communication strategy for every outbreak

• FDA offices and state partners lead execution of identified deliverables
After the Outbreak

**What is our vision for prevention after the outbreak?**

What is a prevention strategy and what’s in it?

- Affirmative, deliberate approach to limit or prevent the occurrence of a root cause that led to an outbreak or adverse incident.

- Strategy may incorporate recommendations for:
  - Research
  - policy development
  - publications/communications
  - industry influence
  - industry training
  - compliance activities
  - regulator training
  - rule-making
  - guidance development
FDA Outlines 2020 Action Plan to Help Advance the Safety of Leafy Greens

Key Areas of Focus
- Prevention
- Response
- Knowledge Gaps
Leafy Green Shiga-toxin producing E. coli (STEC) Action Plan

2021 Update

- Renewed emphasis on actions to prevent contamination stemming from activities on adjacent land
- Announces new actions that build on the accomplishments and learnings from the 2020 plan
- Renews our commitment to completing certain actions that were difficult to accomplish in 2020 due to challenges presented by the COVID-19 pandemic.
- New webpage also describes progress made under 2020 plan
Leafy Green STEC Action Plan: Adjacent and Nearby Land Use

- Increase awareness and address concerns by providing education and technical assistance
- Collaborate with partners, research organizations and industry stakeholders to understand current practices, and opportunities and barriers to implementation
FASTER Act – Sesame as MFA

• In Oct. 2018, FDA statement noted sesame allergies may be a growing concern in the U.S. and new effort to consider labeling for sesame to help sesame allergic consumers.

• In Nov. 2020, FDA issued draft guidance for industry on voluntary disclosure of sesame when added as flavoring or spice.
  – Recommended manufacturers to voluntarily declare sesame following the spice or flavor.
  – Recommended sesame to be voluntarily included in parentheses following the ingredient, such as tahini, when sesame is not in the common name of food.

• In April 2021, the FASTER Act was signed into law, declaring sesame as the 9th major food allergen. Effective on Jan. 1, 2023.

• Beginning Jan. 2023, sesame allergen labeling required under FALCPA and controls (cross-contact and label) required under FSMA.
2020 AND BEYOND: CURRENT RETAIL PROGRAM INITIATIVES
### FDA National Retail Food Team’s Strategic Goal & Objectives

**GOAL:** Reduce the occurrence of foodborne illness risk factors in food establishments

(Metric: FDA Foodborne Illness Risk Factor Study & State, Local, Tribal, & Territorial (SLTT) Risk Factor Studies)

<table>
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<tr>
<th>1. Increase uniformity, consistency, and capacity of SLTT retail food protection programs</th>
<th>2. Promote industry’s active managerial control of foodborne illness risk factors &amp; promote a culture of food safety</th>
<th>3. Maintain a strong NRFT workforce</th>
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<tr>
<td>• Promote adoption of Science based guidance</td>
<td>• Increase use of Food Safety Management Systems</td>
<td>• Optimize resource allocation</td>
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<td>• Drive progress &amp; conformance with Program Standards</td>
<td>• Encourage/support development of new technology and interventions</td>
<td>• Attract, retain, and optimally deploy a highly skilled workforce</td>
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<td>• Maximize implementation of Standardization</td>
<td>• Monitor emerging managerial practices, food safety culture and behavioral science in relation to evolving business models.</td>
<td>• Advance the professional development and technical expertise of staff</td>
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<td>• Provide Tech Assistance &amp; Training</td>
<td>• Monitor and assess industry compliance</td>
<td>• Promote a value-based organizational culture</td>
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<td>• Build capacity for better FBI Surveillance &amp; Response</td>
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<td>• Create new &amp; strengthen Partnerships</td>
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ANALYSIS OF CFP ISSUES AND RECOMMENDATIONS TO AMEND THE FOOD CODE AND PROGRAM STANDARDS

CFSAN uses a retail food policy analysis framework to support decision-making.
RETAIL FOOD POLICY ANALYSIS FRAMEWORK

1. Identify, understand, and clarify the proposition
   - Understanding and clarifying the policy proposition and arguments
   - Identify and link the four stock issues (Problem – Cause – Solution – Consequence)
   - Map the arguments
   - Tool: Toulmin Model
   - Tool: Bowtie Method
   - Tool: Logic Models

2. Evaluate the proposition and arguments
   - Evaluating the policy arguments
   - Evaluate the reasons, evidence, and claims of the stock issues
   - Specifying and evaluating alternative solutions
   - Identify and consider alternative solutions

3. Justify a conclusion about the proposition
   - Estimating or predicting the impact (outcomes) of all solutions
   - Tool: Bowtie Method
   - Consider the consequences
   - Estimating or predicting the risk of “concurring” or “not concurring” with the policy proposition
   - Compare proposed solution(s)
   - Tool: Multi-Criteria Decision Analysis
The CFP Cycle for the Retail Food Policy Team

Prior to CFP
- Identify the proposition(s)
- Identify and evaluate claims and key arguments ("stock issues")
- Identify assumptions, evaluation criteria, and logical fallacies
- Identify evidence and clash points

During CFP
- Gain clarity and inform debate on the proposition(s), claims, key arguments, assumptions, evaluation criteria, and evidence.
- Inform the debate on alternative solutions
- Understand the intent and rationale of final recommendations

Post CFP
- Evaluate the final policy recommendation
- Determine if the policy recommendation is warranted.
  - If so, determine appropriate way to implement the recommendation.
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<tr>
<td>Journal of Food Protection</td>
<td>2017</td>
<td>Growth Kinetics of Listeria monocytogenes in Cut Produce</td>
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<td>2018</td>
<td>Advancing retail food policy debates: Estimating the risk of contaminated servings of food attributed to employee food handling practices in retail food establishments</td>
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<td>2019</td>
<td>Food Safety Management Systems, Certified Food Protection Managers, and Compliance with Food Safety Practices Associated with the Control of Listeria monocytogenes in Foods at Restaurants</td>
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<td>2020</td>
<td>Allergen Removal and Transfer with Wiping and Cleaning Methods Used in Retail and Food Service Establishments</td>
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<td>2020</td>
<td>Assessing Employee Health Policies for Reporting and Excluding Ill Food Employees in Restaurants within the United States</td>
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<td>Food Additives &amp; Contaminants: Part A</td>
<td>2020</td>
<td>Temperature and pH affect copper release kinetics from copper metal foil and commercial copperware to food simulants</td>
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<td>2020</td>
<td>A Matter of Time: Exploring Variation in Food and Drug Administration Food Code Adoption Among State Retail Food Regulatory Agencies</td>
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<tr>
<td>Journal of Agriculture, Food Systems, and Community Development</td>
<td>2020</td>
<td>Interventions and Compliance: How the Response to COVID-19 Reflects Decades of Retail Food Protection Efforts</td>
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SUMMARY
Food Safety Management Systems (FSMSs) and Out-of-Compliance Data Items (Food Safety Practices/Behaviors)

- Food Safety Management Systems were the strongest predictor of data item being Out-of-Compliance in both fast food and full-service restaurants
- Restaurants with well-developed FSMSs have significantly fewer food safety practices/behaviors Out-of-Compliance than did those with “less developed” FSMSs

For more information regarding the FDA Report on the Occurrence of Foodborne Illness Risk Factors in Fast Food and Full-Service Restaurants, please visit: https://www.fda.gov/food/retail-food-protection/retail-food-risk-factor-study
SUMMARY

Certified Food Protection Managers (CFPMs) and Food Safety Management Systems

• Restaurants that had a CFPM who was the person in charge at the time of the data collection had significantly better food safety management system scores that those restaurants that did not have a CFPM present or employed.
EXPANDING OUR BANDWIDTH THROUGH PARTNERSHIPS AND RESOURCES
Retail Program Standards Updates

- Research project on barriers associated with progression within the Retail Program Standards
- Online modules and F-2-F Self Assessment and Verification Audit Workshops (SAVA) in 2022
- Retail Future Funding Model (RFFM) funding opportunities
- FDA web-posted the SAVA tool in advance of Issue 2020-II-020 being deliberated to support local jurisdictions tracking their internal progress on the Retail Program Standards.
Expanding Bandwidth through Collaborations

“Working Together to Bend the Curve on Foodborne Illness”

CDC
AFDO
NFEDA
NACCHO

Retail Regulatory Association Collaborative

FDA Retail Food Safety Restaurant Partnership

FDA Retail Food Safety Retail Food Store Partnership
Retail Flexible Funding Model

- Reduce the occurrence of food borne illness risk factors
- Fully leverage SLTTs
- Move towards full conformance with the Retail Standards

FDA Funding through an association

Awards to SLTTs
Retail Flexible Funding Model

**Base Funding**
- Development
- Maintenance and Advancement

**Optional Add-Ons**
- Mentorship*
- Training/Staff Development and Program Standards Engagement
- Capacity Building
- Special Projects

*Applicants may be recommended for initial gateway into the mentorship program based on application review.*
QUESTIONS?
Mark Moorman, Ph.D.
Director, Office of Food Safety
mark.moorman@fda.hhs.gov
Retail Regulatory Association Collaborative

1. Develop Food Code adoption toolkit & develop/implement national strategy to promote adoption
2. Identify, assess, and promote intervention strategies (industry and regulatory)
3. Build on FDA’s VNFRPS technical assistance strategy
4. Assess application of risk-based inspection methods
5. Develop method to share info among stakeholders
6. Develop strategy to better tell our story
7. Issue joint recommendations on emerging issues

- Objectives support New Era Retail Food Initiatives
- Retail Regulatory Association Collaborative CAP – FY20
- $1.75M in funding awards