FDA U.S. FOOD & DRUG ADMINISTRATION

The New Era of Smarter Food Safety

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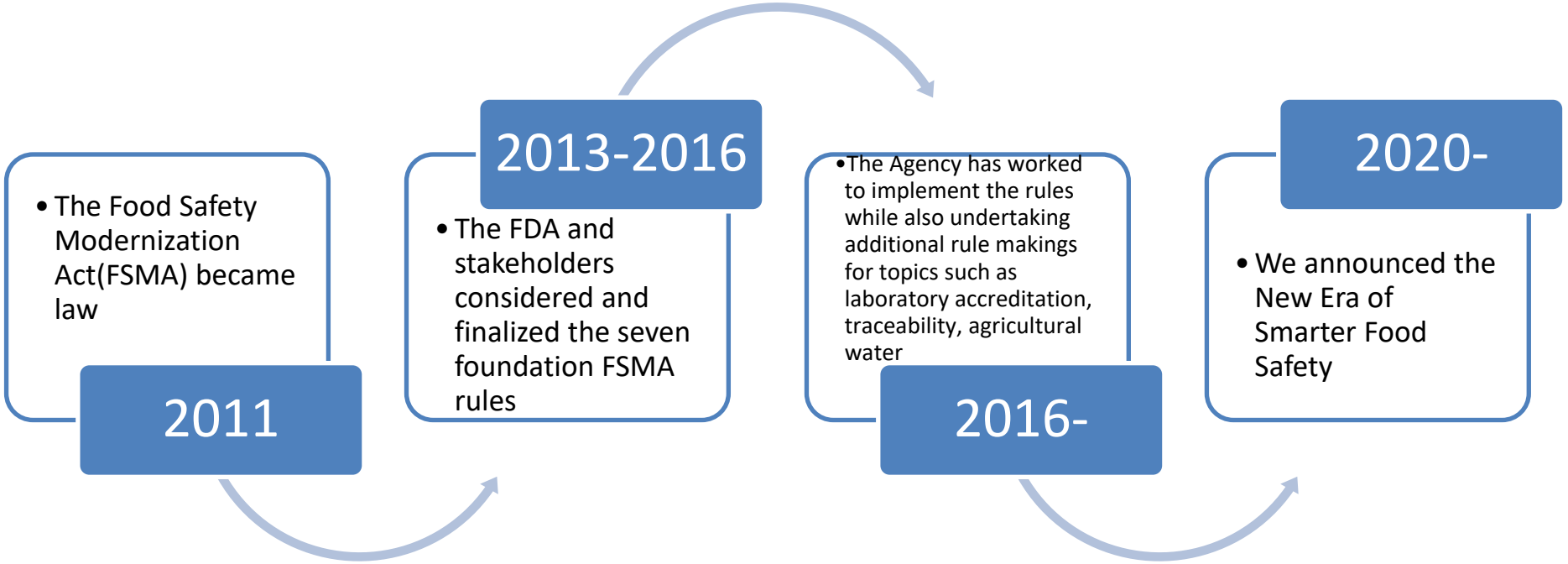
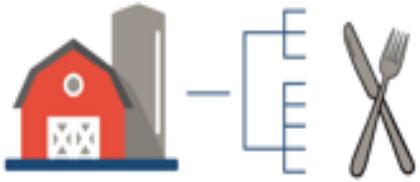
FSMA to New Era



NEW ERA OF SMARTER FOOD SAFETY

Core Element 1

Tech-Enabled Traceability will create a harmonized system of traceability from farm to fork that will help protect consumers from unsafe food.



Core Element 2

Smarter Tools and Approaches for Prevention and Outbreak Response will help regulators and industry leverage new data sources, improve analytic capabilities, and adopt new technologies and processes that prevent food safety problems and enhance responses to food safety problems.

Core Element 3

New Business Models and Retail Modernization will improve the safety of food produced using new technologies and delivered using e-commerce while also ensuring the safety of foods sold at restaurants and other retail establishments.

Core Element 4

Food Safety Culture will address how those that produce, regulate, and consume food think about food safety, strengthening their commitment to this goal and influencing human behavior to make improvements that reduce the burden of foodborne illness.

Core Element 1

Tech-Enabled Traceability

1. Develop Foundational Components
2. Encourage and Incentivize Industry Adoption of New Technologies
3. Leveraging the Digital Transformation

New Era of Smarter Food Safety

Low- or No-Cost Tech Enabled Traceability Challenge Winners

ATMA.IO

WHOLECHAIN

FARMTABS

TAGONE

FRESHLY

RFIDER

HEAVYCONNECT

ROAMBEE/GSM/
WILIOT

KEZZLER

PRECISE

MOJIX

OPSSMART

Core Element 2

Smarter Tools and Approaches for Prevention and Outbreak Response

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**

Foodborne Outbreak Response Improvement Plan

- Tech-enabled product traceback
- Root cause investigations
- Analysis, dissemination of outbreak data
- Operational improvements

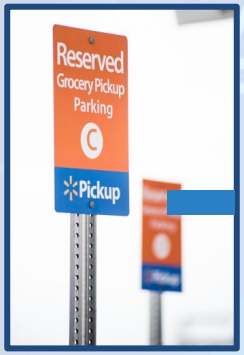
Core Element 3

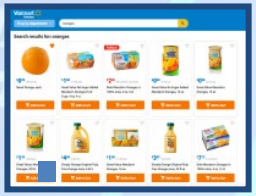
New Business Models and Retail Modernization

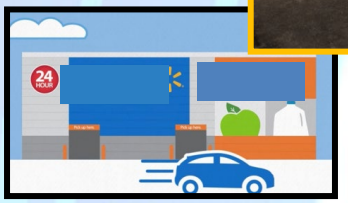
1. **Ensure Safety of Food Produced or Delivered Using New Business Models**
2. **Modernize Traditional Retail Food Safety Approaches**

E-Commerce Summit

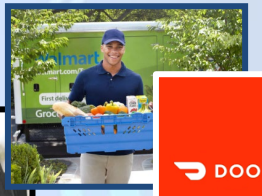
Grocery Pick-Up







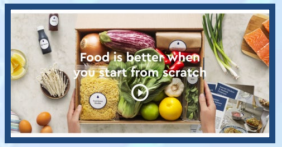
Home Delivery



DOORDASH

Novel Delivery

Home Shipping & Meal Kits



Core Element 4

Food Safety Culture

1. Promote Food Safety Culture **Throughout the Food System**
2. Further Promote Food Safety Culture **Throughout the Agency**
3. Develop and Promote a Smarter Food Safety **Consumer Education Campaign**

Let’s get into some examples of work in Core Element 2…

Core Element 2

Smarter Tools and Approaches for Prevention and Outbreak Response

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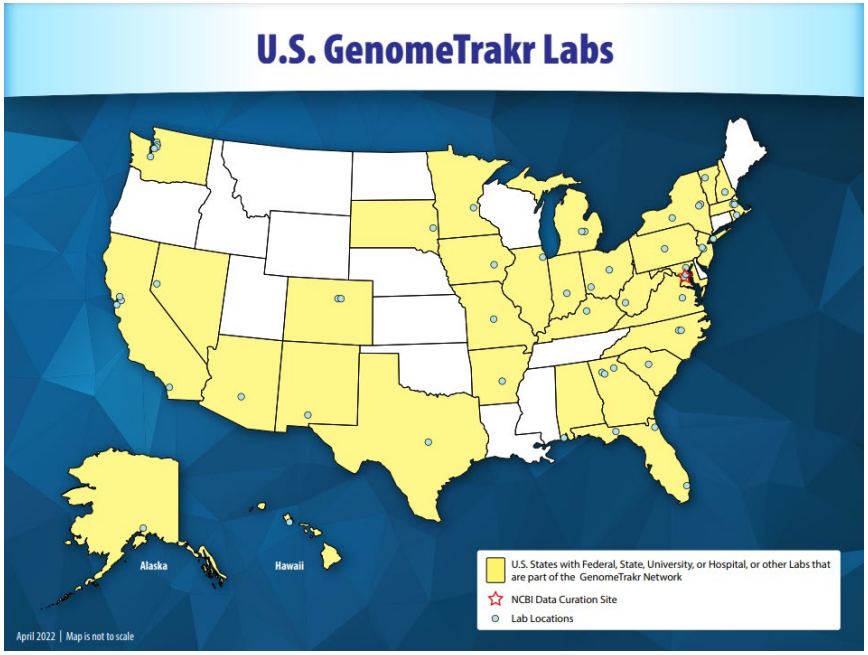
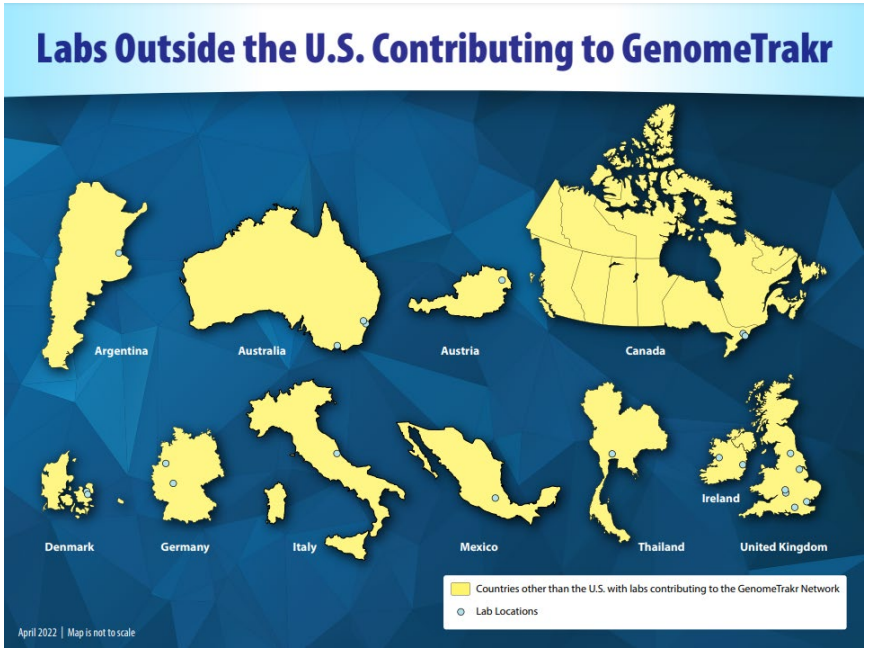
6. **Recall Modernization**

Core Element 2

2.5 Outbreak Response

Whole genome sequencing - discovering more outbreaks that would previously have gone undetected





Core Element 2

Smarter Tools and Approaches for Prevention and Outbreak Response

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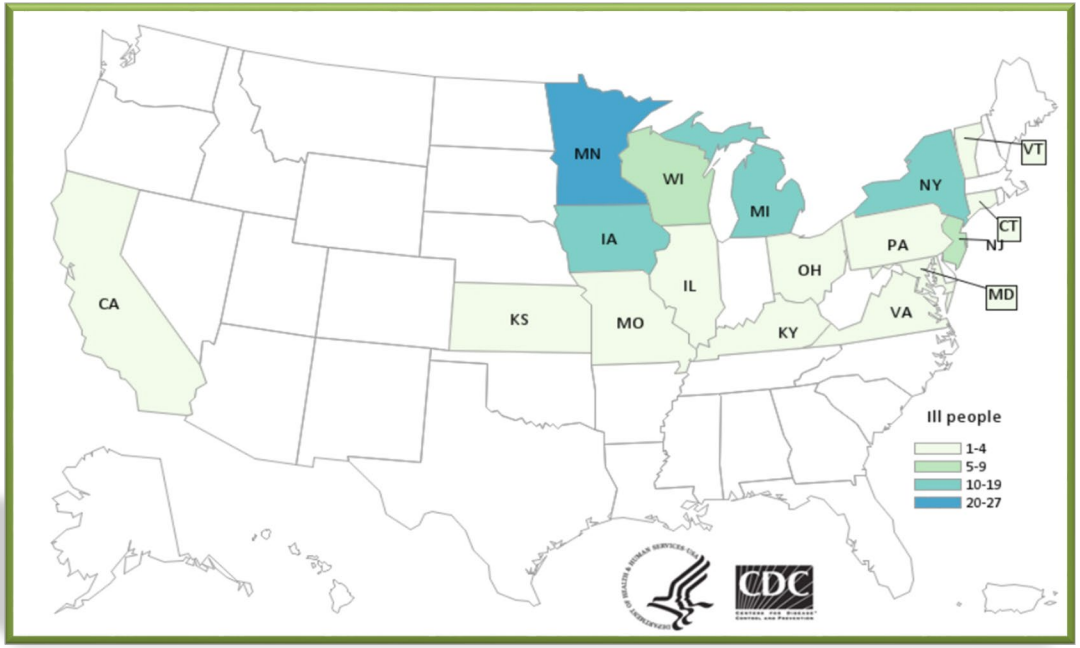
Peaches- *Salmonella* Enteritidis Outbreak Background (2020)

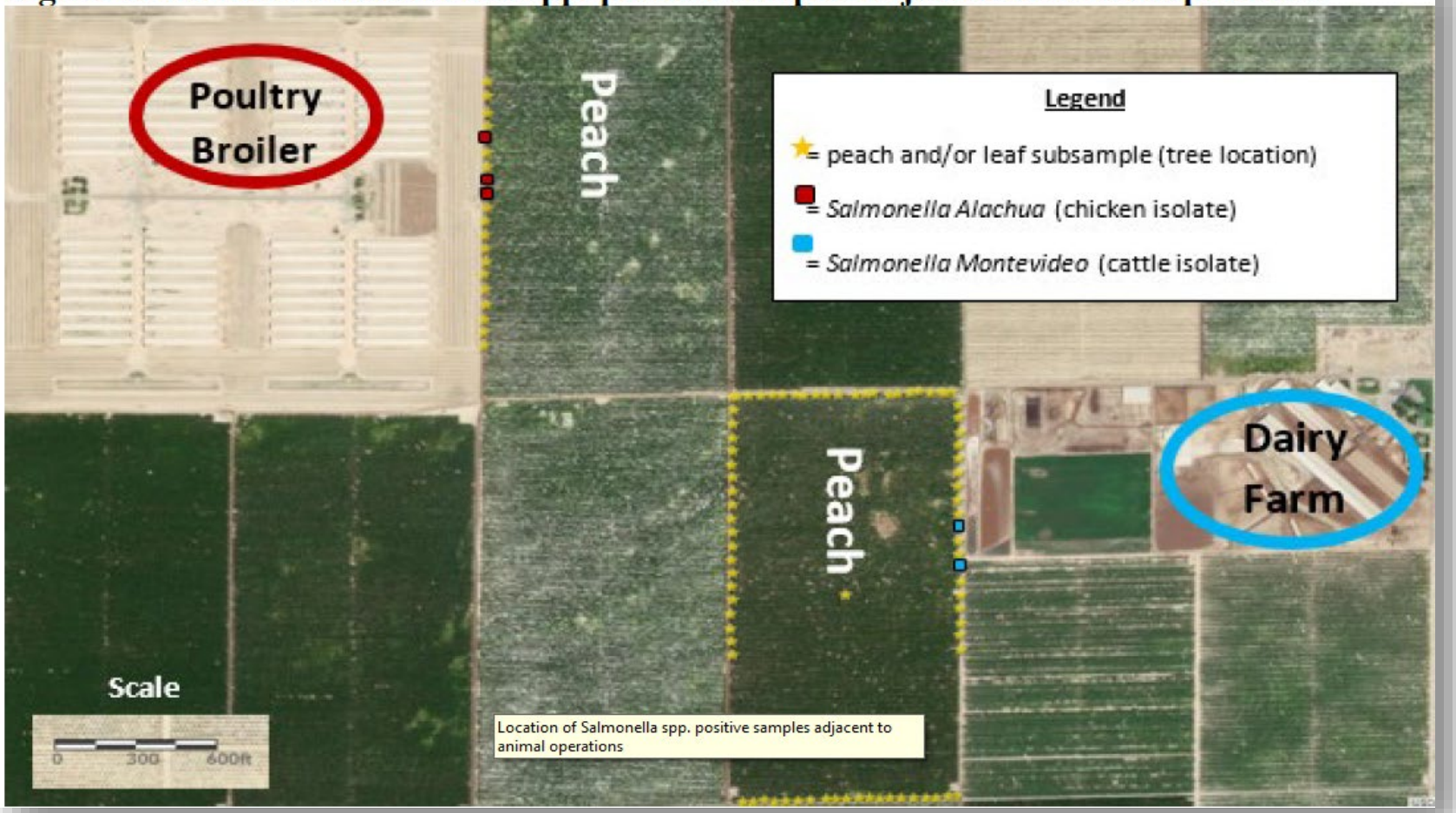
- Outbreak timeframe: 06/2020- 10/2020
- Case distribution across 17 states
- 101 individuals ill, 27 hospitalizations, 0 deaths
- Epidemiologic and traceback indicate peaches packed/suppled by Wawona



www.cdc.gov/salmonella/enteritidis-08-20/map.html
https://www.usatoday.com/story/money/2020/08/23/peach-recall-2020-salmonella-peaches-walmart-target-aldi-kroger/3424167001/

Positive *Salmonella* spp.

Figure 1: Location of *Salmonella* spp. positive samples adjacent to animal operations



Leading Hypothesis: contamination of the fruit in the orchard via fugitive dust, due to adjacent land use.

Factors Potentially Contributing to the Contamination of Peaches Implicated in the Summer 2020 Outbreak of Salmonella Enteritidis

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Executive Summary

Between August and October 2020, the U.S. Food and Drug Administration (FDA) and multiple state and federal partners investigated an outbreak of *Salmonella* Enteritidis infections linked to peaches packed or supplied by a large grower/producer. In total, in the U.S. there were 101 reported illnesses across 17 states. Based on the historical outbreak data, this multistate outbreak appears to represent a novel commodity/pathogen pair. The epidemiological and traceback investigation identified the large grower/producer's packinghouses, cooling facilities and/or orchards as a potential source of the peaches and helped prioritize investigational activities.

The investigation did not result in finding the outbreak strain (via whole genome sequencing (WGS)) in investigation samples, however, numerous *Salmonella* isolates were found in samples collected from the peach orchards. Multiple *Salmonella* isolates from product (peach) and peach tree leaf sampling activities conducted during this investigation genetically resembled historical chicken and cattle isolates not associated with this outbreak or any known foodborne illnesses. Geospatial analyses of the orchards that supplied fresh peaches during the period of interest, coupled with WGS analysis that

https://www.fda.gov/food/outbreaks-foodborne-illness/factors-potentially-contributing-contamination-peaches-implicated-summer-2020-outbreak-salmonella

Photo credits: https://www.canr.msu.edu/news/peaches_and_the_science_behind_them

Core Element 2

Smarter Tools and Approaches for Prevention and Outbreak Response

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Core Element 2

2.5 Outbreak Response

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, industry, competent authorities in other countries)
- developing a prevention strategy for ***every*** outbreak

- **FDA leads and drives alignment on prevention strategy**
- **Stakeholders lead execution of identified deliverables**

Core Element 2

2.5 Outbreak Response

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

- Affirmative, deliberate approach undertaken by the FDA 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, and guidance development.
  - Phase 1 – Communications and Stakeholder Engagement
  - Phase 2 – Targeted Regulatory and Research Activities
  - Phase 3 – Long-term Targeted Extension

- Goal: Prevention strategy for every outbreak - prioritize execution.

Imported Specialty Mushroom Prevention Strategy

Core Element 2

2.5 Outbreak Response

Imported Specialty Mushrooms

Phase 1 – Communications and Stakeholder Engagement

- Translations of the Produce Safety Rule and guidance
- Outreach on cultural differences in mushroom consumption
- Engagement with competent authorities in the Republic of Korea, China, Japan, Taiwan, and Canada

Phase 2 – Targeted Research and Regulatory Activities

- Targeted sampling of enoki mushrooms
  - FDA sampling at port of entry
  - State sampling via LFFM
- Research to better understand Lm and enokis

Phase 3 – Long-term Targeted Extension for the Mushroom Industry

- Facilitate the availability of training for enoki mushroom producers

Core Element 2

2.5 Outbreak Response

Onions *(Salmonella)*	**Sprouts** *(Salmonella & STEC)*	**Flour** *(STEC)*	**Tahini** *(Salmonella)*	**Leafy Green Action Plan** *(STEC)*
Melons *(Salmonella)*	**Imported Specialty Mushrooms** *(Salmonella and Listeria monocytogenes)*	**Hispanic Style Cheese** *(Listeria monocytogenes)*	**Imported Seafood** *(Salmonella)*	**Cyclospora Action Plan** *(C. cayetanensis)*
Ready to Eat Cereal *(Salmonella)*	**Avocados** *(Listeria monocytogenes)*	**Controlled Environment Agriculture** *(Salmonella)*	**Peaches** *(Salmonella)*	**Shell Eggs** *(Non SE)*

Hard Boiled Eggs *(Listeria monocytogenes)*	**Caramel Apples** *(Listeria monocytogenes)*	**Cashew Brie** *(Salmonella)*	**Frozen Pizza** *(STEC)*	**Mangoes** *(Salmonella)*	**Ground Bison** *(STEC)*

Core Element 2

Smarter Tools and Approaches for Prevention and Outbreak Response

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Core Element 2

2.5 Outbreak Response

Imported Specialty Mushrooms

Phase 1 – Communications and Stakeholder Engagement

- Produce Safety Rule now available in Korean and Japanese.
- Outreach on cultural differences in mushroom consumption
- Engagement with competent authorities in Japan and Canada

Phase 2 – Targeted Research and Regulatory Activities

- Targeted sampling of enoki mushrooms
  - State sampling via LFFM - 17 recalls (5/1/2021 through 3/18/2022)
  - FDA sampling at port of entry
- Research underway in CFSAN/OARSA to better understand Lm and enokis

Phase 3 – Long-term Targeted Extension for the Mushroom Industry

- (Pending) Facilitate the availability of training for enoki mushroom producers.

Questions?