

Listeria monocytogenes
**Outbreak Investigations: FDA
Perspective**

Stic Harris, DVM, MPH

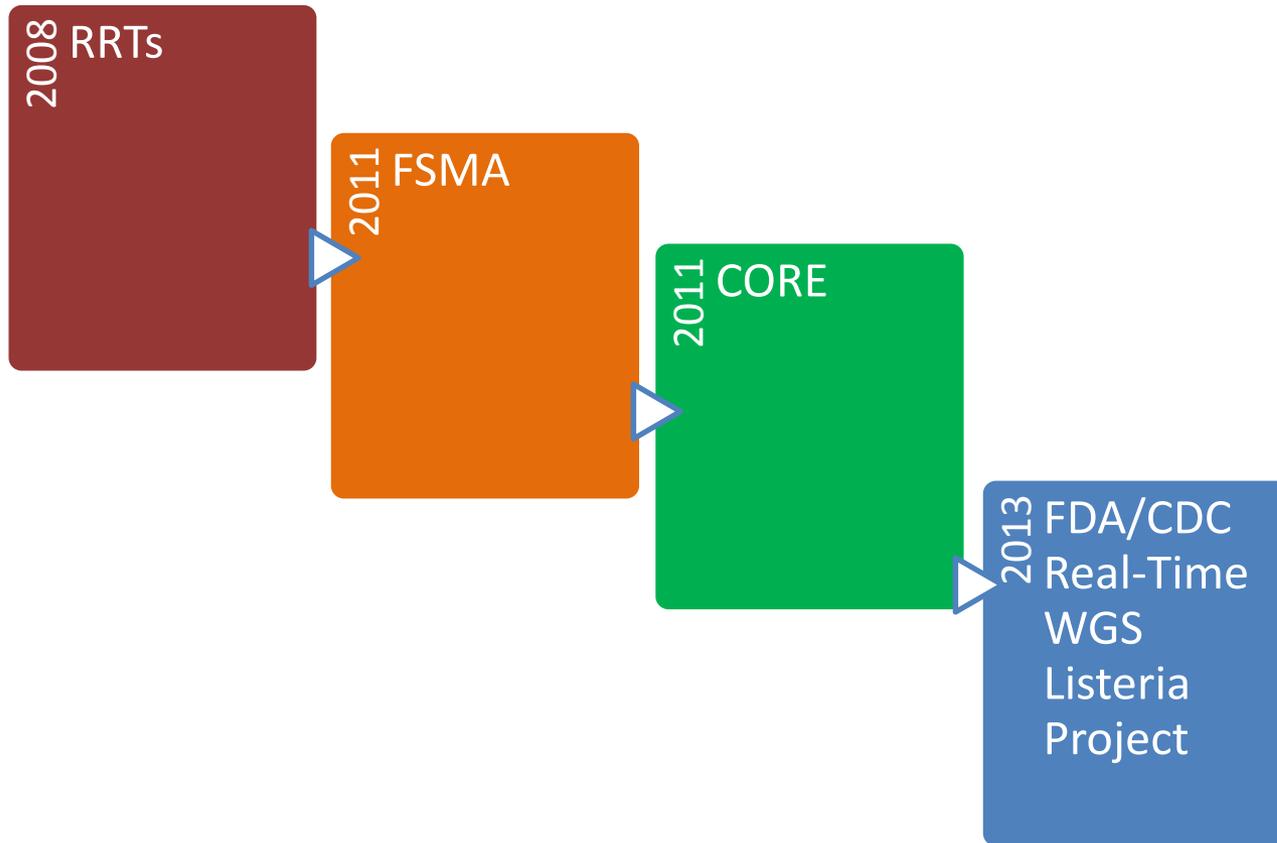
Director

Coordinated Outbreak Response & Evaluation Network (CORE)

Food & Drug Administration

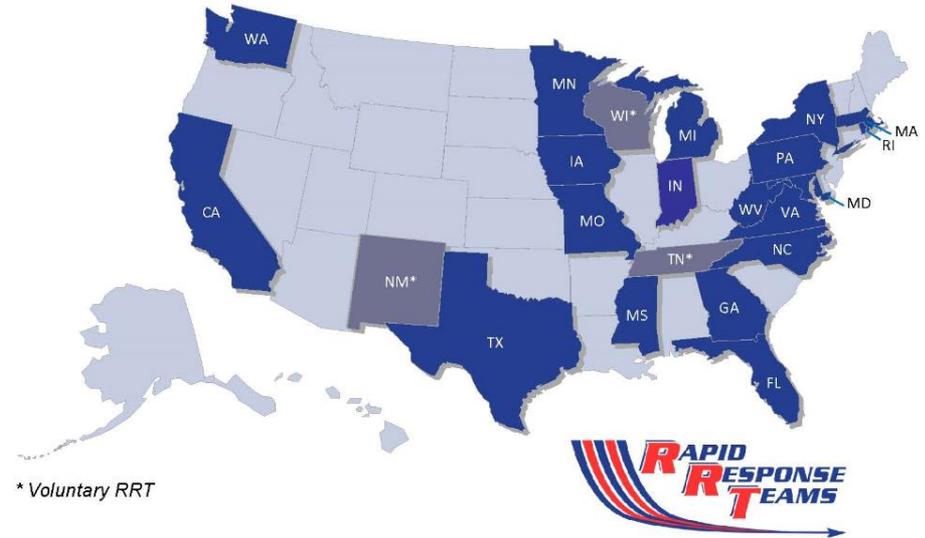
INFORM | 7 NOV 2017

Major Programmatic Changes at FDA in the past Decade

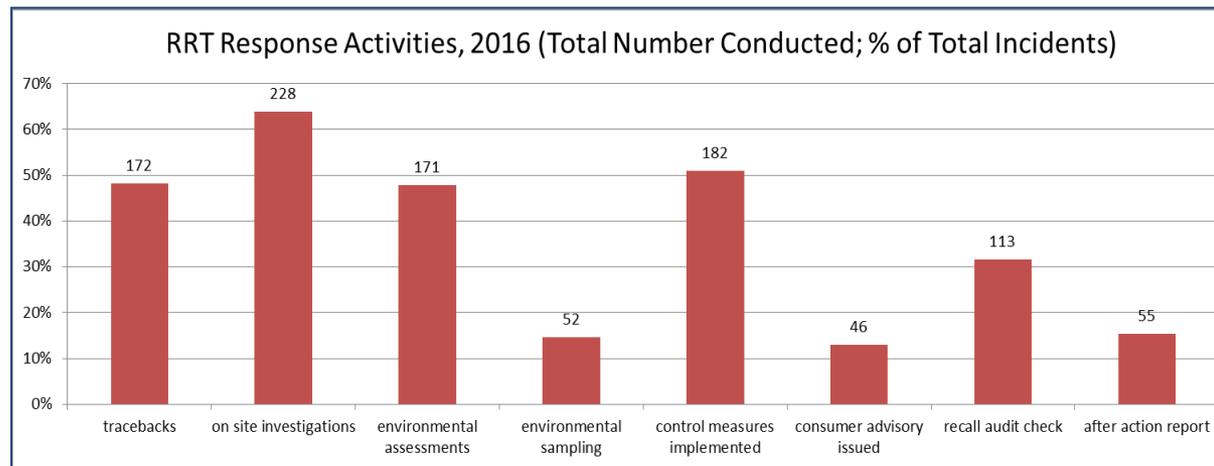


FDA RRT Program Highlights

- Started in 2008, the RRT program now includes 22 states*
- The RRT Program uses a cooperative agreement vehicle to support RRT development and maintenance (Total funding for FY18 is ~\$5,900,000)

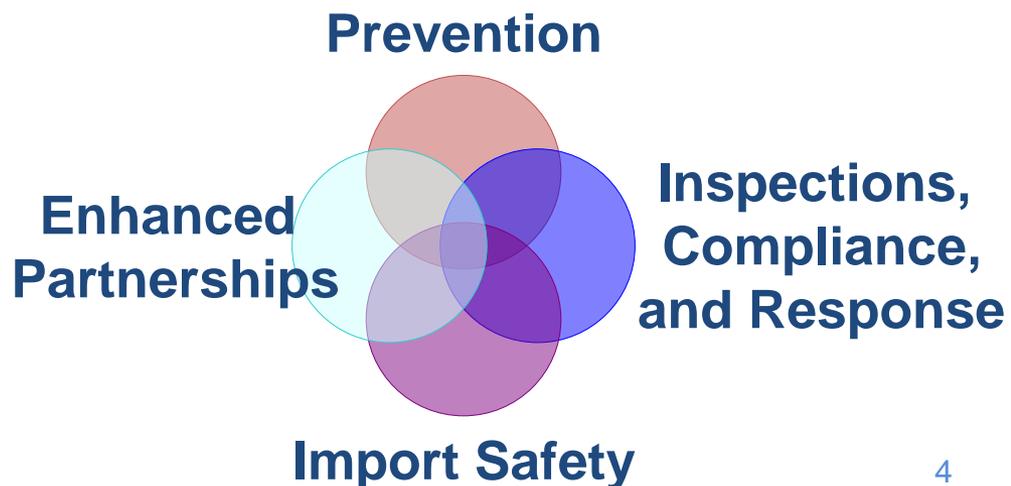


Goal of RRT program: to minimize the time between agency notification of a human or animal food contamination event and implementation of effective control measures



FSMA (2011)

- The FDA Food Safety Modernization Act (FSMA), the most sweeping reform of our food safety laws in more than 70 years, was signed into law by President Obama on January 4, 2011. It aims to ensure the U.S. food supply is safe by shifting the focus from responding to contamination to **preventing** it.
- Major themes of FSMA include Prevention, Enhanced Partnerships, Inspections/Compliance/Response and Import Safety.
 - Prevention is the cornerstone of FSMA and FDA has developed rules that specifically address:
 - Comprehensive preventive controls for food and feed facilities
 - Produce safety standards
 - Intentional adulteration standards
 - Transportation
 - FSMA provided new tools for FDA to exercise regulatory authority:
 - Mandatory recall
 - Expanded records access
 - Expanded administrative detention
 - Suspension of registration
 - Enhanced product tracing
 - Third party laboratory testing





- Launched in 2011, CORE is responsible for coordinating FDA's activities related to foodborne outbreak detection, response and prevention
 - Three functional areas:
 - Signals and Surveillance – Find the outbreak
 - Response - Stop the outbreak
 - Post-Response - Prevent the next outbreak
 - Communications - coordinate/manage communications during an outbreak
- CORE's goals
- CORE Network Accomplishments (from 2011-2016):
 - CORE Signals evaluated >632 incidents
 - CORE Response teams coordinated responses to 173 outbreaks
 - CORE Post Response reviewed and implemented >710 recommendations

FDA/CDC Real Time *Listeria* Project (2013)

FDA



- Federal and state agencies committed to real-time whole genome sequencing of all *Listeria monocytogenes* isolates collected in the US
- Previously WGS was rarely used to guide public health action during an active outbreak investigation and never for routine surveillance
- By sequencing all LM isolates, public health partners:
 - Detected more LM illness clusters
 - Solved more LM outbreaks (linked illnesses to a likely food source)
 - Identified novel or unusual food vehicles capable of transmitting LM
 - Stopped LM outbreaks while they were still small
- The practices developed during this project have now become standard for LM outbreak detection and response in the US.

Transition in LM Vehicles: Not the Usual Suspects Anymore



Whole, uncut cantaloupe (2011)



Ice cream (2015)*+



Caramel Apples (2014)



Bagged lettuce (2016)*



Stone fruit (2014)*+



Frozen veggies (2016)*+



Sprouts (2014)*+



Soft cheeses (2012, 2013, 2014, 2015, 2017)

* Outbreaks in which WGS played a pivotal role in either detecting the outbreak and/or confirming the vehicle

+ Outbreaks that were detected via the retrospective pathway (began with product or environmental isolate)

WGS Impact on LM Outbreak Investigations

- Confluence of two key points: novel or unusual foods are causing LM illnesses in people, and because of WGS, we can now detect and attribute these outbreaks.
- From a regulatory and policy perspective, FDA is particularly interested in using WGS to:
 - Obtain more detailed information on the nature of LM in food production facilities (resident strains vs. pass through contaminants)
 - Identify more potential retrospective outbreak investigations (investigations that begin with a positive product or environmental sample that can be subsequently linked to cases with supporting epidemiologic information)
 - Enhance foodborne illness attribution and the implications for federal regulatory policy and guidance to industry as well as future research needs



Outbreak Investigations Matter: Impact on Policy and Research

- Each of these outbreak investigations with novel or unusual food vehicles expands our understanding of which foods can cause invasive listeriosis, and these findings play a role in developing the Agency's LM policy and guidance to industry
 - E.g. LM tolerance in non-growth, Ready-to-Eat foods
- They also identify areas for needed research to further understand the survivability of this organism in different food matrices, for e.g.:
 - Inoculation study by UW hypothesized that stick insertion into a caramel apple provides a mechanism for juice to enter the space between the skin and caramel, creating conditions favorable for LM proliferation

With Opportunity Comes Challenges...

- The use of WGS to characterize LM isolates has also yielded additional challenges in terms of guidance to industry on recalls:
 - How do we address situations in which the WGS strain is highly related to more than one facility?



- Since WGS can link sporadic cases of illness that span large time periods, when do we request a recall and how extensive does the recall need to be?

- While public health is paramount, how should we consider the risk of a food that is intended to be cooked or is past its intended shelf-life? And what does ready-to-eat really mean?



Acknowledgements

- Mickey Parish and Jenny Scott, US Food and Drug Administration/Center for Food Safety and Applied Nutrition
- Lauren Yeung, US Food and Drug Administration/Office of Regulatory Affairs/Office of Partnerships
- Jennifer Beal, CORE

Thank you

