U.S. FOOD & DRUG ADMINISTRATION

# American Spice Trade Association

# Regulatory Workshop

**Stephen Ostroff, Deputy Commissioner for Foods and Veterinary Medicine**

**October 19, 2016**

*"The future ain't what it used to be."*

- Yogi Berra

# Great Moments in History

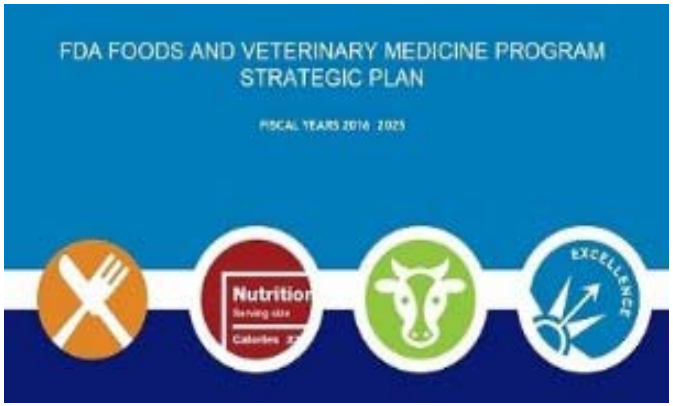
- 1906 – establishment of the Food and Drug Administration

- 1907 – establishment of the American Spice Trade Association
- 1908 – last world series win by the Chicago Cubs

# Topics

- Spice safety
- Food Safety Modernization Act
- FSMA Education and Training
- Other Food Safety Activities
  - GRAS
  - Recalls
  - WGS

Our mission is to promote public health by preventing foodborne illness, fostering good nutrition, and improving the safety and efficacy of animal health products




Food Safety – Provide resources to support industry efforts ensuring clean, safe spice and utilize global alliances to reach the entire supply chain

# Challenges with Spice Safety

- 2013 FDA risk profile:
  - presence of pathogens, such as *Salmonella*
  - filth is a systemic challenge
- Problem relates in part to poor or inconsistent use of appropriate controls to prevent contamination
- In U.S., important to distinguish safety at import vs. at retail
- Shipments from 79 countries at import were examined for *Salmonella*
  - 37 (47%) of the 79 countries had *Salmonella*-contaminated shipments

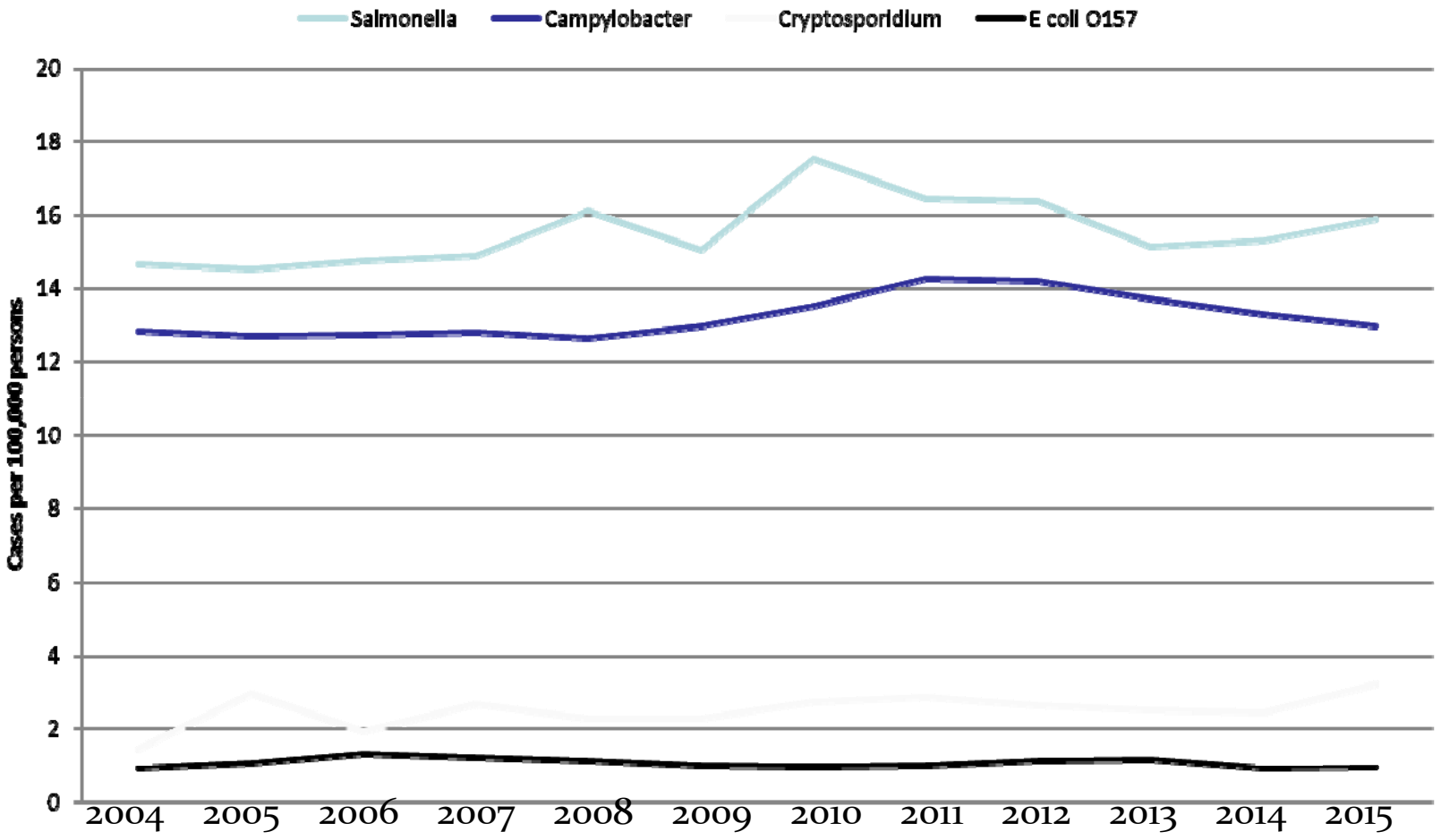
# Retail Sampling

- Spices at retail were part of a retail survey that included other foods
- Data now being fully analyzed
- Preliminary results show prevalence of *Salmonella* in spices at retail is lower, on average, than at import sites
- This likely reflects industry's use of process control to address the hazards found at import sites


# Journal of Food Protection

- Survey findings in FDA clearance
- Publish in the Journal of Food Protection
- Publication date not known but should be soon

# Incidence of Foodborne Illness
# CDC FoodNet 2004-2015





9

# 2015 FOOD SAFETY REPORT

Measuring progress toward Healthy People 2020 goals

| Pathogen | Healthy People 2020 Target Rate* | 2015 Rate† | Change Compared with 2006-2008§ | |
|---|---|---|---|---|
| *Campylobacter* | 8.5 | 12.97 | ↑ 9% |  |
| *E. coli* O157¶ | 0.6 | 0.95 | ↓ 30% |  |
| *Listeria* | 0.2 | 0.24 | No change |  |
| *Salmonella* | 11.4 | 15.89 | No change |  |
| *Vibrio* | 0.2 | 0.39 | ↑ 34% |  |
| *Yersinia* | 0.3 | 0.29 | No change |  |

U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

*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

# Food Safety Modernization Act

- Seven foundational rules finalized in May 2016
  - Preventive controls for human food
  - Preventive controls for animal food
  - Produce safety rule
  - Foreign supplier verification program
  - Third party accreditation
  - Sanitary transport
  - Intentional adulteration
- Staggered compliance dates by rule and size of operation
- Initial compliance date ---- Sept 19th PC Human

# Preventive Controls

- Sept 19th date
  - Larger firms must comply with the preventive controls and modernized CGMPs
  - These include both domestic and foreign firms, including those that produce spices
  - Larger animal food facilities must meet new CGMP requirements for animal food.
    - Extra year to meet preventive controls standards

# Preventive Controls

- Spice companies covered by the PC-Human food rule required to implement a food safety system that includes:
  - an analysis of hazards
  - risk-based preventive controls
  - verification controls are working

- Separate compliance dates established for the supply-chain program provisions
  - Food facility not required to comply with the supply-chain program provisions before its supplier is required to comply with PC human or the produce safety rule

# Compliance

- We will be entering this new territory together
- Primary focus will be on education, training and technical assistance
- Many larger companies already had HACCP plans
  - aspects of the preventive controls and CGMPs are very similar
- Focus will be on working with you to create the culture of food safety that is embodied in FSMA
  - However, FDA will act quickly if significant food safety hazards are identified

# FSMA Compliance

- Just released Constituent Update (Oct. 13, 2016) on FDA.gov

"What to Expect Now that the First Big FSMA Compliance Dates Are Here"

Questions and Answers with Joann Givens

# Compliance Date Extension

August 2016

- FDA extended compliance dates for certain provisions in the preventive controls and other rules. These include:
  - Companies have an additional two years to comply with requirements for customer assurance that it will follow all applicable food safety requirements or sell only to someone who agrees to do so
  - We plan to take a closer look at the feasibility of these provisions during this time period

# Foreign Supplier Verification Program

- FSVP rule is particularly important to spice industry because of volume of imports
- FSVP requires importers verify that the foods they import are produced using processes and procedures that ensure the same level of safety as food produced in U.S.
- Importers that are also spice processors may be subject to the PC rule, including supply chain management provisions
  - If they meet the PC standards, they will largely be considered in compliance with FSVP

# Foreign Supplier Verification Program

- FSVP offers flexibility in meeting certain requirements
  - Importers can meet key requirements by relying on evaluations and activities performed by other entities in certain circumstances,
  - as long as those importers review and assess the corresponding documentation
- Compliance dates are staggered, depending on whether their suppliers are subject to PC or produce safety rule.

# Accredited Third-Party Certification

- Third pillar of FSMA for the spice industry
- Voluntary program for the accreditation of third-party certification bodies (auditors) to conduct food safety audits and issue certifications of foreign facilities and the foods they produce

# Accredited Third-Party Certification

- Accreditation body recognized by FDA could be a foreign government agency or a private third party
- Third-party certification bodies required to perform unannounced facility audits and to notify FDA upon discovering a condition that could cause or contribute to a serious risk to public health
- FDA intends to implement this rule as soon as possible after publication of final Model Accreditation Standards guidance and final rule on user fees.
  - These are expected early next year

# Education and Training

- FDA wants to “educate before and while we regulate,” especially for smaller businesses
- In August, FDA issued a draft guidance on ways to comply with the preventive controls in human foods requirements
- A guidance covering ways to comply with the FSVP provisions will be coming next year
- ASTA webinars for members on the FSMA rules, compliance and inspections are much appreciated

# Generally Recognized as Safe

- FDA recently issued a final rule detailing the criteria for concluding that the use of a substance in human or animal food is considered “GRAS”
  - Many spices and natural seasonings are considered GRAS
  - Unlike food additives, GRAS substances not subject to FDA pre-market approval
  - However, they must meet the same safety standards as approved food additives

# Generally Recognized as Safe

- Rule addresses :
  - types of scientific evidence that can be used to demonstrate safety
  - role of publications in evaluating whether the scientific evidence of safety is “generally available and accepted”
- Final rule formalizes the voluntary GRAS notification procedure originally established under an interim policy and pilot program for human food in 1997 and animal food in 2010
- Although notification is voluntary, FDA strongly encourages companies to inform us of GRAS conclusions through the finalized notification procedure


DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE OF INSPECTOR GENERAL

WASHINGTON, DC 20201


FDA

## *Early Alert: The Food and Drug Administration Does Not Have an Efficient and Effective Food Recall Initiation Process*

- Analysis of recalls conducted during 2013-2015
- Selected 30 "judgmental" recalls out of 1000s
- Alert focuses on 2 of these recalls in 2014
- OIG highlighted problems:
  - Lack of clear procedures and timeframes
  - Earlier use of FSMA tools

*Response by FDA*

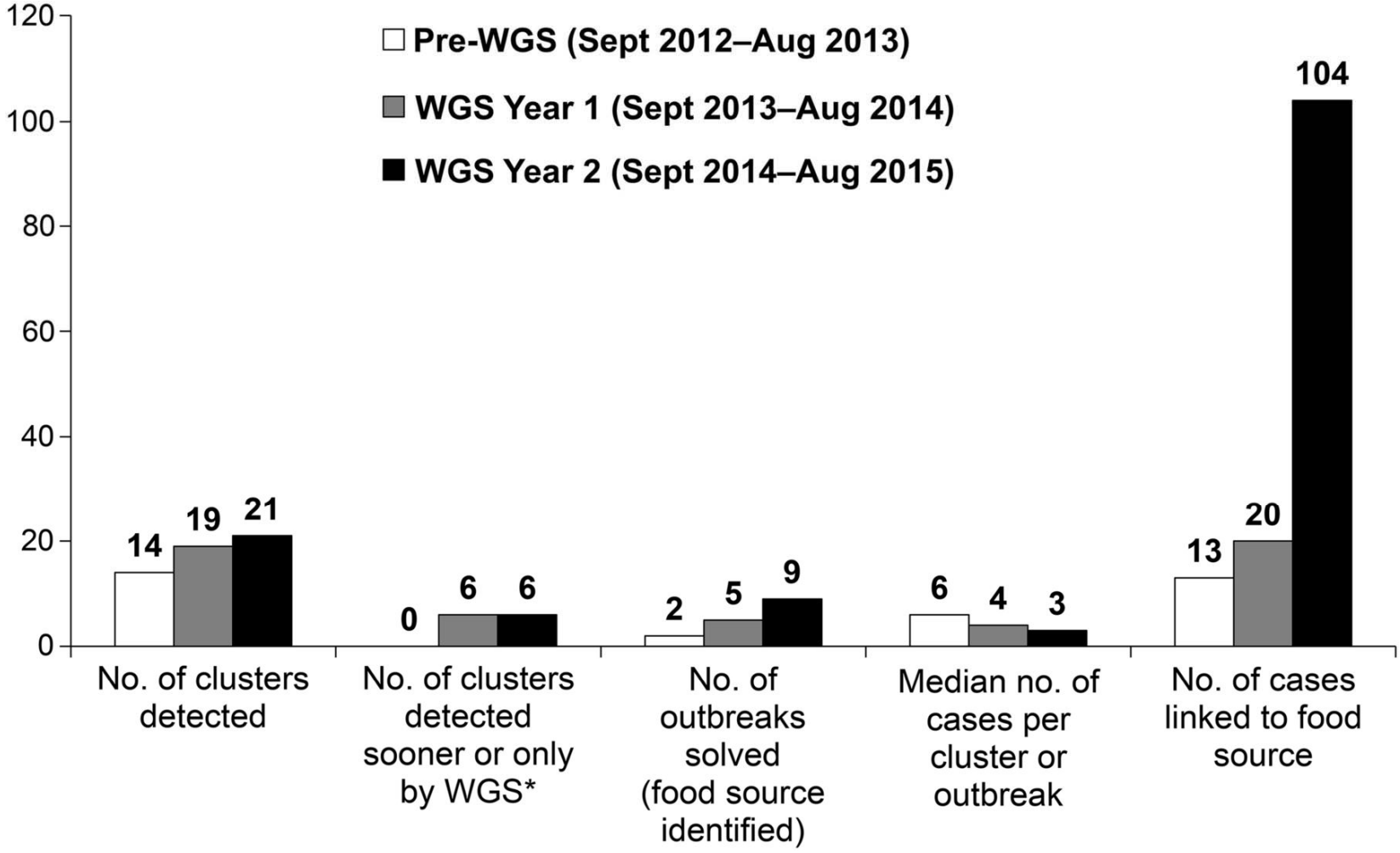
- SCORE (Strategic Coord. Outbreak Response & Evaluation)
- Routine application of whole genome sequencing
- Program alignment

# Whole Genome Sequencing

- Replacing PFGE as standard for molecular fingerprinting of pathogens
- Provides much more granular information
  - Pathogen/outbreak identification
  - Genetic relatedness
  - Resident pathogens
  - Antimicrobial susceptibility
- Cost has dropped considerably
- Multiagency 2013 Listeria initiative*
- Now used for other foodborne pathogens

* Clin Infect Dis 2016;63:380-6.

**Listeriosis clusters detected and outbreaks solved before and after implementation of real-time whole-genome sequencing (WGS) of Listeria monocytogenes isolates from patients, food, and the environment, United States, September 2012–August 2015. *Cluster detection**



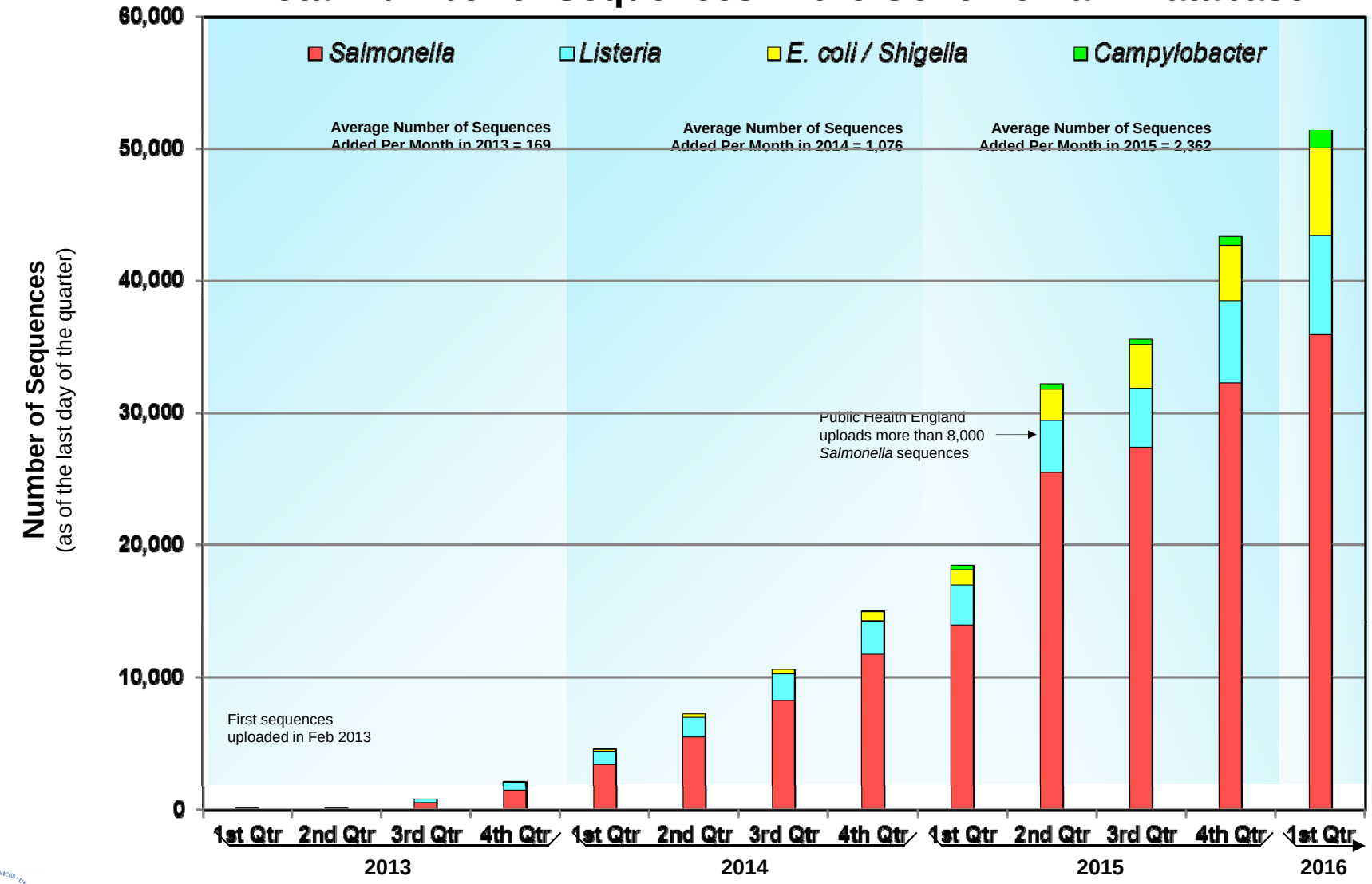

**Brendan R. Jackson et al. Clin Infect Dis. 2016;63:380-386**



Clinical Infectious Diseases

U.S. FOOD & DRUG ADMINISTRATION

# Total Number of Sequences in the GenomeTrakr Database



# Additional Items on the Plate

- FSMA – other rulemaking
  - Lab accreditation
  - Traceability
  - Reportable food registry
- Nutrition
  - Voluntary sodium reduction
- Labeling
  - Nutrition facts
  - Menu & vending machine
  - Healthy & natural
  - GMO
- Antimicrobial resistance

***If you ask me anything I don't know, I'm not going to answer."***