FDA Update

American Cheese Society Annual Meeting

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Presentation Topics

- ACS best practices guide
- Raw milk cheese assignment results
- Environmental monitoring assignment results
- Status of generic *E. coli* criteria
- Status of 60-day aging requirement review
- A brief update on FSMA Implementation

ACS Best Practices Guide

- FDA commends ACS efforts to develop the guide
- Thank you for giving FDA the opportunity to provide technical input
- Technical input on chapters 1-5 on 12/2/15
- Technical input on chapters 6-11 and glossary on 7/7/16 and 7/13/16
- FDA looks forward to continued collaboration with ACS

Raw Milk Cheese Sampling

An Overview, in Brief:

- Assignment conducted FY14 to FY16
- Employed new sampling model, centering on large data set(s)
- Tested1,606 samples, primarily softer types as their greater moisture content can be conducive to the growth of *Lm*, if present.
- About 30% of samples were domestic; 70%, import.

Raw Milk Cheese Sampling

Key Objectives:

- To determine the prevalence of *Salmonella*, *Listeria monocytogenes* and Shiga toxin-producing *E. coli* (primarily *E. coli* O157:H7) in raw milk cheese.
- To determine if there are common factors associated with positive findings (such as origin, variety or manufacturing practice).
- To take appropriate regulatory action when positive findings are observed.

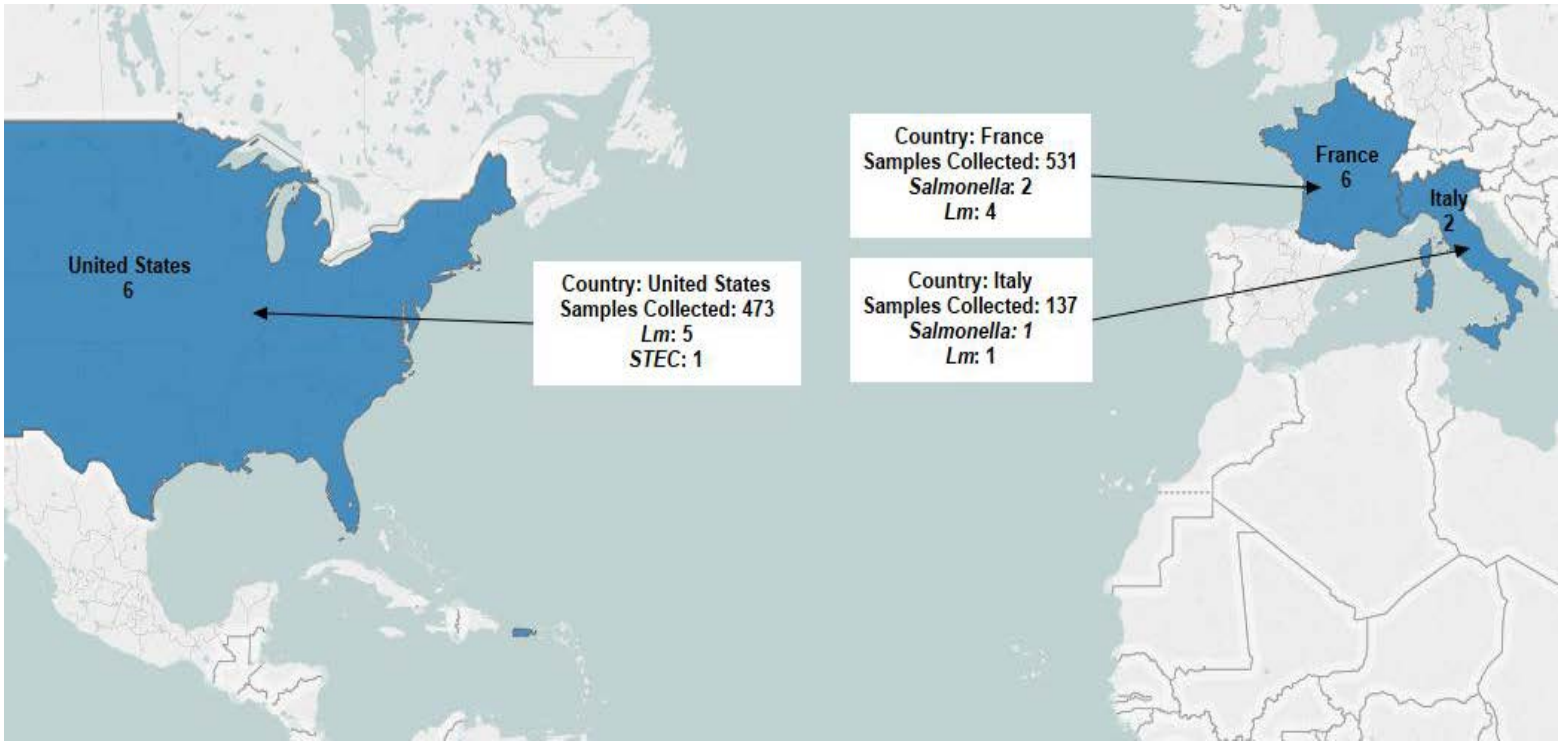
Raw Milk Cheese Sampling

Findings: Pathogens

- The contamination rate for each target pathogen was less than 1%.
  - ❑ *Salmonella*: 0.19% prevalence (3 samples positive)
  - ❑ *Listeria monocytogenes*: 0.62% prevalence (10 samples positive)
  - ❑ *E. coli* O157:H7: No samples positive
  - ❑ STEC: 0.68% prevalence (11 samples positive)
  - ❑ Pathogenic STEC (*E. coli* O111:H8 serotype): 0.06% prevalence (1 sample positive)

Raw Milk Cheese Sampling

All Pathogen Findings by Country of Origin



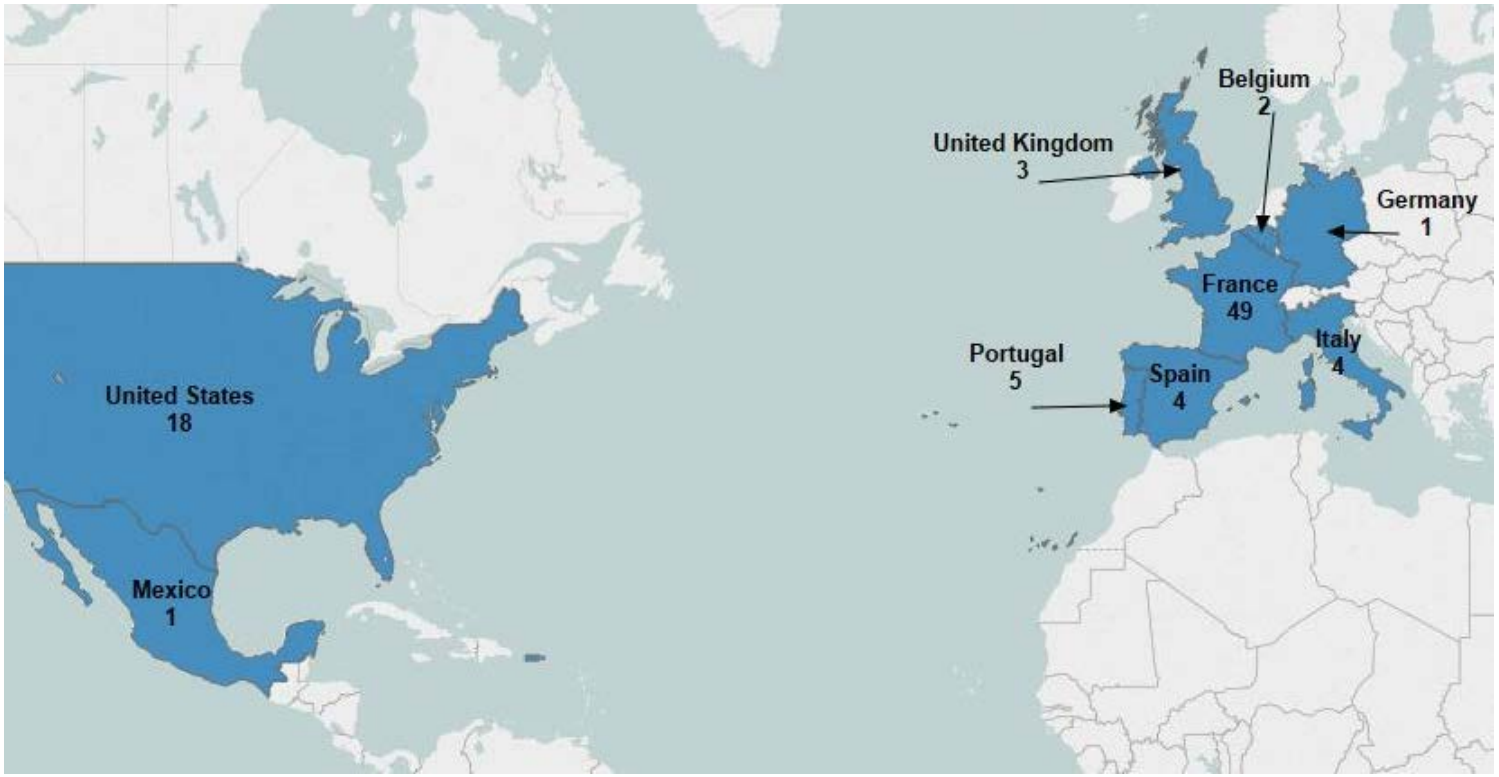
Raw Milk Cheese Sampling

Findings: Generic E. coli

- We detected violative levels of generic *E. coli* in 87 of the 1,606 samples tested, which makes for an overall contamination rate of 5.4 percent.
  - ❑ Domestic Samples: 3.8% prevalence (18 samples positive)
  - ❑ Import Samples: 6.1% prevalence (69 samples positive)
- FDA's criteria for determining violative levels of generic E. coli:
  - ❑ *n=5*, *c=2*, and *m=10 MPN/g* to *M=100 MPN/g*

Raw Milk Cheese Sampling

Generic *E. coli* Violative Samples by Country of Origin



Raw Milk Cheese Sampling

Generic E. coli Occurrence with Pathogens

- Of the 1,606 samples tested, we found one sample contaminated with both violative levels of generic *E. coli* and a pathogen (*Listeria monocytogenes*).

Chi Squared Table for Pathogens in Relation to Violative Samples of *E. coli*

	Negative for Pathogen(s)	Positive for Pathogen(s)
Not Violative for Generic *E. coli*	1506	13
Violative for Generic *E. coli*	86	1

Raw Milk Cheese Sampling

Conclusions, Next Steps:

- Less than 1% contamination rate in target pathogens
- Low frequencies limited our ability to discern patterns
- We took regulatory action in response to all violations identified
- We do not anticipate further, large-scale raw milk cheese sampling
- *Listeria monocytogenes* remains a concern, particularly as an environmental pathogen. Industry should focus on sanitation verification under the Preventive Controls for Human Food regulation through environmental monitoring programs.

Environmental Assessment

- Evaluate the potential for presence of *Listeria monocytogenes* at domestic manufacturers
  - Conduct GMP inspections
  - Collect environmental samples
  - Collect and document evidence to support the appropriate regulatory action when significant violations are observed
  - Determine if positive findings are linked to any outbreaks by using WGS

Environmental Assessment

- 2010 Results
  - 124 cheese manufacturers were inspected
  - 30 firms (24%) were found to have *Listeria monocytogenes* in their environments
  - Of the 124 firms, 41 were artisanal cheese manufacturers
  - 8 artisanal firms (22%) were found to have *Listeria monocytogenes* in their environments

Environmental Assessment

- 2012 Results
- 42 cheese manufacturers inspected
- 7 firms (16.6%) were found to have *Listeria monocytogenes* in their environment
- Zones 1 and 2

Environmental Assessment - next steps

- No plans to conduct additional environmental sampling specific to cheese – focus instead on RTE facilities generally
- Environmental sampling of cheese facilities for cause
  - Response to past signals or new signals; e.g. illness complaints, recalled or seized product, RFR report, previous inspection history, prior instances of environmental pathogens

Listeria monocytogenes – next steps

- Recent contamination events and outbreaks of listeriosis, internal FDA research and risk assessments have provided FDA with new information to consider with respect to *Listeria monocytogenes*
- We are looking at alternative approaches to the draft Lm CPG and draft guidance to industry on control of Lm in RTE foods, as well as a new draft guidance document on what constitutes a ready-to-eat food

Generic *E.coli* – background

- The criteria prior to 2010:
  - Analysis of the cheese or cheese product demonstrates that one or more units have *E. coli* levels greater than 1 x 10^4 (10,000) colony forming units (cfu) per gram (gm) of product and a recent inspection demonstrates the existence of significant insanitary conditions.

Generic *E.coli* – background

- 2009 Proposed Compliance Policy Guide:
  - Raw milk products: n=5, c=1, m=100 MPN/g, M=1000 MPN/g
  - Pasteurized milk products: n=5, c=1, m=10 MPN/g, M=100 MPN/g
- 2010 Final Compliance Policy Guide:
  - All products: n=5, c=1, m=10 MPN/g, M=100 MPN/g

Generic *E. coli* – current status

- As of February 9, 2016, the FDA has paused its testing for generic *E. coli* in raw milk cheese as it considers implementation of the FSMA rules and what role generic *E. coli* should have in identifying and preventing insanitary conditions and food safety hazards for both domestic and foreign cheese producers.
  - The samples obtained under this assignment prior to the pause will be used by FDA as part of its deliberation on the role of testing for generic *E. coli* going forward.

Generic *E.coli* – next steps

- FDA's review of the role of generic E.coli in identifying and preventing insanitary conditions for both domestic and international cheese producers is currently ongoing. Effort includes:
  - Extensive review of the scientific literature on the subject
  - Consultation with external experts
  - Stakeholder dialogue
  - If warranted, re-issuance of a draft CPG for public comment

60-Day Aging of Cheeses – background

- FDA establishes food standards of identity, to promote honesty and fair dealings in the interest of consumers, under the authority set forth in section 401 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 341). Some of these standards of identity (e.g., the standard of identity for soft-ripened cheese in § 133.182 (21 CFR 133.182)) permit the manufacture of cheese from unpasteurized milk.

60-Day Aging of Cheeses - background

- The agency has long recognized that 60-day aging is not efficacious
- As a result, the agency is interested in identifying alternatives to pasteurization which are more effective than 60-day aging and amending the standards of identity for cheeses accordingly.

60-Day Aging of Cheeses - background

- Reitsma and Henning, in 1996, showed that pathogens such as *E. coli* O157:H7 can survive a 60-day aging period in a hard cheese such as Cheddar cheese.
- This work was later replicated by FDA; Schlesser, *et al*., 2006

60-Day Aging of Cheeses - background

- NACMCF advice to FDA in 1997:
  - "… literature shows that pathogenic organisms are found in raw milk….and can survive the 60-day aging process".
  - "The 60-day aging process for hard cheese is questionable as an effective measure in support of the public's health"
  - "Therefore the Cheese Subcommittee recommends that the FDA re-examine its current policy regarding the 60-day aging period for hard cheese made from raw milk".

60-Day Aging of Cheeses - background

- More recently, the results of the FDA/Health Canada quantitative assessment of risk of listeriosis from soft ripened cheese consumption in the US and Canada suggested that the 60-day aging period for soft ripened cheese may increase the risk of listeriosis from consumption of soft ripened cheeses by allowing more time for *Listeria monocytogenes*, if present, to multiply as cheese ages.

60-Day Aging of Cheeses – request for comments

- The agency issued a Federal Register notice on 8/3/2015 which requested comments and scientific data and information that would assist in identifying and evaluating intervention measures that might have an effect on the presence of bacterial pathogens in cheeses manufactured from unpasteurized milk.

60-Day Aging of Cheeses – request for comments

- We requested comments and scientific data and other information to:
  - Understand what (if any) aspects of the current regulatory framework for the production of cheese manufactured from unpasteurized milk act as an impediment to efficient and effective control measures to significantly minimize pathogens that may be present in unpasteurized milk.

60-Day Aging of Cheeses – request for comments

- To what extent do producers of cheese manufactured from unpasteurized milk solely rely on an aging period to significantly minimize pathogens that may be present in unpasteurized cheese?
- If such producers rely on control measures other than the aging process, what are those control measures and what is the prevalence of those control measures among such producers?
- How effective and practical are these control measures?

60-Day Aging of Cheeses – request for comments

- Understand the availability and feasibility of various treatments (*e.g.,* to achieve bacterial reductions of from 100- to 1,000,000-fold) that could reduce the risk of listeriosis and other foodborne illness from the consumption of all types of cheeses manufactured from unpasteurized milk.
  - We are aware of non-thermal control measures such as added substances (such as bacteriocins, lactoferrins, lysozyme, other enzymes, and salt), bactofugation, carbon dioxide, high hydrostatic pressure, microfiltration, microwave, pulsed electric field, pulsed light, ultrasound, and ultraviolet light.
  - However, we would like to receive additional data regarding the efficacy, on a consistent basis, of such treatments when used to minimize the broad spectrum of pathogens that may be present in unpasteurized milk.

60-Day Aging of Cheeses – request for comments

- Determine whether, consistent with modern international approaches to food safety, a performance objective (or standard) for *L. monocytogenes* should be used as a replacement for the 60-day aging requirement and whether a second performance standard for Gram-negative enteric pathogens should also be used. If a second performance standard is used for Gram-negative enteric pathogens, which Gram-negative pathogen should be specified?

60-Day Aging of Cheeses – request for comments

- Understand the prevalence of testing during manufacture (*e.g.*, testing for pathogens of each lot of cheese manufactured from unpasteurized milk and of bulk shipments of unpasteurized milk).
- If testing is not currently being used, how practical would such testing be? How much would it cost?

60-Day Aging of Cheeses

- Comment period closed on 11/2/2015.
- More than 70 substantive comments including data were received from a wide sector of stakeholders, including academia, industry - both domestic and foreign - and foreign governments.
- We thank all stakeholders for their input
- Comments and data are being collated and analyzed to chart what future directions FDA will take with respect to the 60-day aging requirement for certain cheeses.

FDA Food Safety Modernization Act

- Enacted Jan. 4, 2011
- Focus on detecting and preventing the hazards in domestic and imported foods that cause foodborne illness

FSMA Implementation
"*A Continuum*"

- Phase 1: Set Standards
  Develop regulations, guidance, policy

- Phase 2: Design Strategies to Promote and Oversee Industry Compliance
  Identify performance metrics to measure success

Phase 1: Standard Setting

Regulation	Proposal	Final
Preventive Controls (Human Food)*	Jan 16, 2013	Sept 17, 2015◊
Preventive Controls (Animal Food)*	Oct 29, 2013	Sept 17, 2015◊
Produce Safety*	Jan 16, 2013	Nov 27, 2015◊
Foreign Supplier Verification Program*	Jul 29, 2013	Nov 27, 2015◊
Third Party Accreditation	Jul 29, 2013	Nov 27, 2015◊
Sanitary Transport	Feb 5, 2014	April 6, 2016
Intentional Adulteration	Dec 24, 2013	May 27, 2016

* ***Supplemental proposals published September 2014***

What does the Preventive Controls for Human Food Rule Do?

- Establishes new requirements for hazard analysis & risk-based preventive controls

- Modernizes longstanding current good manufacturing practice (CGMP) requirements

Food Safety Plan

- Hazard analysis
- Preventive controls
- Supply-chain program
- Recall plan
- Procedures for monitoring
- Corrective action procedures
- Verification procedures

Technical Assistance Networks

- The FDA FSMA Technical Assistance Network will provide central, consistent sources of outreach and technical assistance for industry & regulators
  - Part 1: FSMA Rule Interpretation Questions
  - Part 2: Food Safety Regulatory Community

FSMA
TECHNICAL ASSISTANCE
NETWORK

Compliance Dates for Businesses
(Preventive Controls for Human Food)

- *Very small businesses:* (less than $1 million in annual food sales): Three years
- *Small businesses:* (a business with fewer than 500 full-time equivalent employees): Two years
- *All other businesses*: One year

Conclusion

- FDA is committed to working with ACS on cheese safety.
  - Best Practices Guide
  - Data sharing
  - Farm tours
  - Engaging in dialogue

Questions?

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