

Vision for Prevention

*How do we bend the curve
on foodborne pathogen outbreaks?*

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Vision for Prevention

Challenge Statements

- 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 stakeholder clarity to prevention activities
- We have specific opportunities to make progress on Healthy People 2030

Vision for Prevention

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



Vision for Prevention

What happens after the outbreak?

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.

What's in the prevention strategy pipeline?

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)



Prevention Strategy for Soft Fresh Hispanic- Style Cheese

Goal: To prevent outbreaks of listeriosis associated with soft fresh Hispanic-Style Cheese

What are soft fresh Hispanic-Style Cheeses?

- Hispanic-Style Cheeses (HSC) refers to cheeses with origins in Mexico or Latin America.
- Hispanic-style cheeses comprise a large and diverse group.
 - Some cheeses are made in different countries and use same names, but the characteristics of the cheese may be different
 - Queso Fresco, Queso Blanco, Queso Panela, Queso Oaxaca and Requeson

What are soft fresh Hispanic-Style Cheeses?

- Soft fresh HSC have high moisture, low salt content, low acidity, a shorter shelf life than aged cheeses, and require refrigeration for safety
 - Support the growth of *Listeria monocytogenes*
- Often hand-crafted by small, artisan manufacturers, rather than mass-produced.
 - Employee handling, exposure to the environment
- HSC sometimes are made from raw milk (illegal for fresh cheese in the US)
 - Not the case in recent outbreaks of listeriosis



Historical Outbreaks and HSC



- There were 13 outbreaks of listeriosis in the US 1998–2014 associated with soft cheeses made from pasteurized milk
 - The majority of outbreaks (65%) were associated with HSC.
- Between 2011 and 2017 FDA conducted six outbreak investigations of listeriosis where the vehicle was confirmed as soft cheese.
 - Three of these outbreaks were linked to the consumption of HSC.

Get the Facts

Pregnant Hispanic women are **24 times more likely** than the general population to get *Listeria* infection.

Las mujeres hispanas embarazadas tienen **24 veces mayor** que la población general de contraer la infección por *Listeria*.

[Protect yourself and your baby](#)



Multistate outbreak of *listeriosis* linked to the consumption of HSC (2020/2021)

- 13 listeriosis illnesses in four states (CT, MD, NY, and VA)
- Isolation dates between Oct 2020 to Mar 2021.
- The CT Department of Public Health notified CDC that *L. monocytogenes* was isolated from a retail sample of El Abuelito Queso Fresco cheese.
- Whole Genome Sequencing (WGS) analysis concluded that the product isolate was genetically identical to the outbreak strain.
- CDC and FDA confirmed that Queso Fresco manufactured by Abuelito Cheese Inc. was the source of this outbreak.



Prevention Strategy

An Overview of Recommendations:

- Phase 1: Establish the Scope of the Strategy
- Phase 2: Conduct External Engagement and Education to Inform Domestic Stakeholders
- Phase 3: Consider External Engagement and Education to Inform Foreign Manufacturers about the Issue

Recommendations



Phase 1: Establish Scope of Strategy

- **Scope:** The target audience for external engagement is small and very small domestic manufacturers of soft fresh HSC, as well as consumers of HSC.
- Outreach will focus on raising awareness of *L. monocytogenes* as a hazard in soft fresh HSC, and resources available to manufacturers.
- **Rationale**
 - Limiting the target audience will aid in developing communication and outreach targeted to this niche industry segment, as well as the consumer
 - It is anticipated that large cheese-making companies are aware of the risk and are implementing appropriate controls.
- **Obstacles** Reaching this type of small firm is a challenge. We need to partner within FDA, as well as those outside of FDA, to identify existing or previously used channels of communication, as well as new ones if necessary. Also, identifying/naming the cheese is a challenge.

Recommendations

Phase 2: Industry Guidance, Outreach, and Training

Goal: Inspection of Manufacturers of Soft Fresh Hispanic-Style Cheeses

- There is a limited domestic inventory of firms that manufacture soft fresh HSC (~60 firms).
- Many of these firms were inspected in 2016 as part of a sampling assignment.
- It is recommended that FDA accelerate inspections for the industry.

Recommendations

Phase 2: Industry Guidance, Outreach, and Training



Goal: Publish an article detailing recent investigations of listeriosis linked to soft fresh HSC

- Detail recent investigations of listeriosis linked to HSC, as well as other soft cheeses.
- Publish in an accessible journal or trade magazine.
- Discuss the deficiencies that might have contributed to the outbreaks, lessons learned, and resources manufacturers can utilize.
- Spanish translation of abstract to share with stakeholders and Spanish media.

Recommendations

Phase 2: Industry Guidance, Outreach, and Training

Goal: Collaboration with States and Other Partners

- HSC firms are concentrated in a few states (e.g. WI, FL, TX, IL, NJ, NY and CA). A majority of recent cases have occurred in the Northeast, West and South regions of the US.
- Meet with:
 - State regulatory partners in these states or regions to propose collaboration on this issue.
 - Regional Centers for Food Safety Training, Outreach, and Technical Assistance/ University Extension



Recommendations

Phase 2: Industry Guidance, Outreach, and Training



Goal: Hispanic-Style Cheese Food Safety Fact Sheet

- Create a clear, concise and simple Fact Sheet that can be used to educate HSC manufacturers on *L. monocytogenes* in both English and Spanish.



Recommendations

Phase 2: Industry Guidance, Outreach, and Training



Goal: Facilitate Targeted Training for the Domestic Industry

- Provide training to artisanal and small cheese makers on food safety in collaboration with others.
- Spanish translation or be taught in Spanish.

Obstacles: Reaching this type of small firm is a challenge.

Recommendations

Phase 2: Develop Strategies for Reaching Vulnerable Populations

Goal: Work to raise consumer awareness on the risk of Listeriosis in soft Hispanic-Style Cheeses; update existing consumer messaging.

- Prepare a short article/paragraph/press release on listeriosis in fresh soft HSCs targeted to consumers, especially vulnerable populations, with a senior FDA leader as author.
- Update existing messaging, which is often not clear and is often confusing based on cheese type (e.g., raw milk cheese, soft cheese, etc.).

Preventing Listeriosis In Pregnant Hispanic Women in the U.S.



Spanish (Español)

Community Educator's Guide to a Serious Foodborne Risk

When pregnant women eat Mexican-style soft cheeses, they are putting their unborn babies at risk!

Questions?



