



Non-toxigenic *E. coli* and other FDA Initiatives

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Non-toxigenic E. coli

- Traditionally used as an indicator of insanitation during processing
- Typically not in milk of a dairy animal
- Generally originate from animal or human feces
- Insanitary conditions may include poor employee hygiene practices, improperly sanitized utensils and equipment, or contaminated raw materials



Non-toxigenic E. coli

- FDA enforcing of non-toxigenic E. coli levels in raw milk cheese
- In 2010, FDA from the Compliance Program guideline (CPG) changed the standard for non-toxigenic E. coli from less than 10,000 to less than 10 MPN /gram
- However in 2009, FDA's own policy team recommended a level of 100 MPN/gram
- -FDA has been purchasing raw milk cheeses from distributors and testing them for pathogens. FDA is now visiting cheese facilities for a 3-day inspection.



Non-toxigenic E. coli

- FDA has paused its testing program for generic *E. coli* in cheese
- May need to revise 2010 Compliance Policy Guide and FDA documents



60-Day Aging Rule for Cheese

- Established in 1949
- Must be aged at a temperature of 35°F for not less than 60 days
- Not allowed for all cheeses
- Cheese must be manufactured under GHP, GMP and a food safety plan must be in place



60-Day Aging Rule for Cheese

- In 2009, FDA began an assessment. Still waiting for the outcome
- Scenarios that may occur:
 - Ban all raw milk/unpasteurized cheeses
 - Longer time frame based on scientific literature
 - May look at hygienic practices and animal health (European way)
 - Does nothing and leaves the 60 rule as is



FDA's Role

- Conducts inspections of both domestic and imported dairy firms
- Samples of finished products may be collected and tested for bacteria and filth and environmental samples may also be collected



FDA's Role

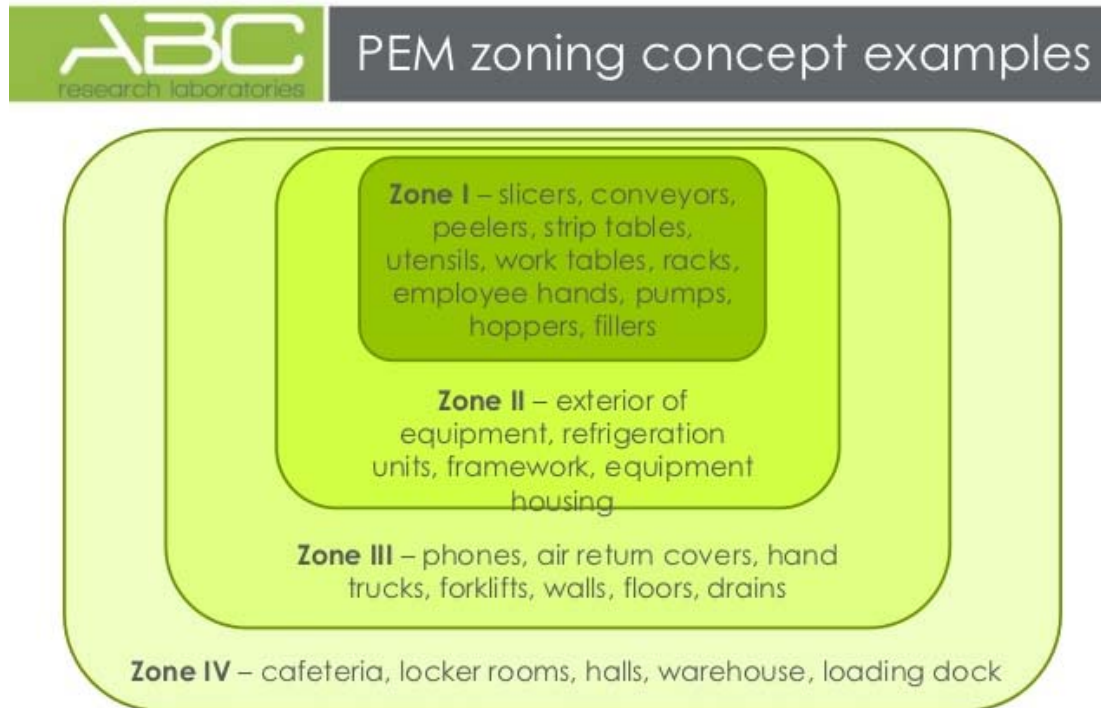
Each finished product sampling maybe analyzed for the following microorganisms:

- *Listeria monocytogenes*
- *Salmonella*
- *E. coli* 0157:H7 and STEC
- *Staph aureus* (>10,00 CFU/g)
- *Cronobacter sakazakii*



FDA's Role

FDA identifies four zones during sampling. These zones may contribute to product contamination





FDA's Role

Possible response may be a warning letter, regulatory meeting, seizure of adulterated lot, detention/refusal, injunction





FDA's Role

Cheese/Ice Cream:

Recent outbreaks with *L. mono* in ice cream

Cheese inspections are conducted with this order: Soft/soft ripened, semi-soft, Hard cheeses, extra hard cheese



FDA's Assignments

- Ice cream facilities
- Mexican/Hispanic style cheeses (50). Started in late 2015 for the presence of *Salmonella* and *Listeria monocytogenes*
- Powder manufacturing facilities (25). Starting Spring 2016 for the presence of *Salmonella* in zones 1-4.
- Chemical Residue Monitoring is currently ongoing for the presence of glyphosate and 2,4-Dichlorophenoxyacetic acid pesticides



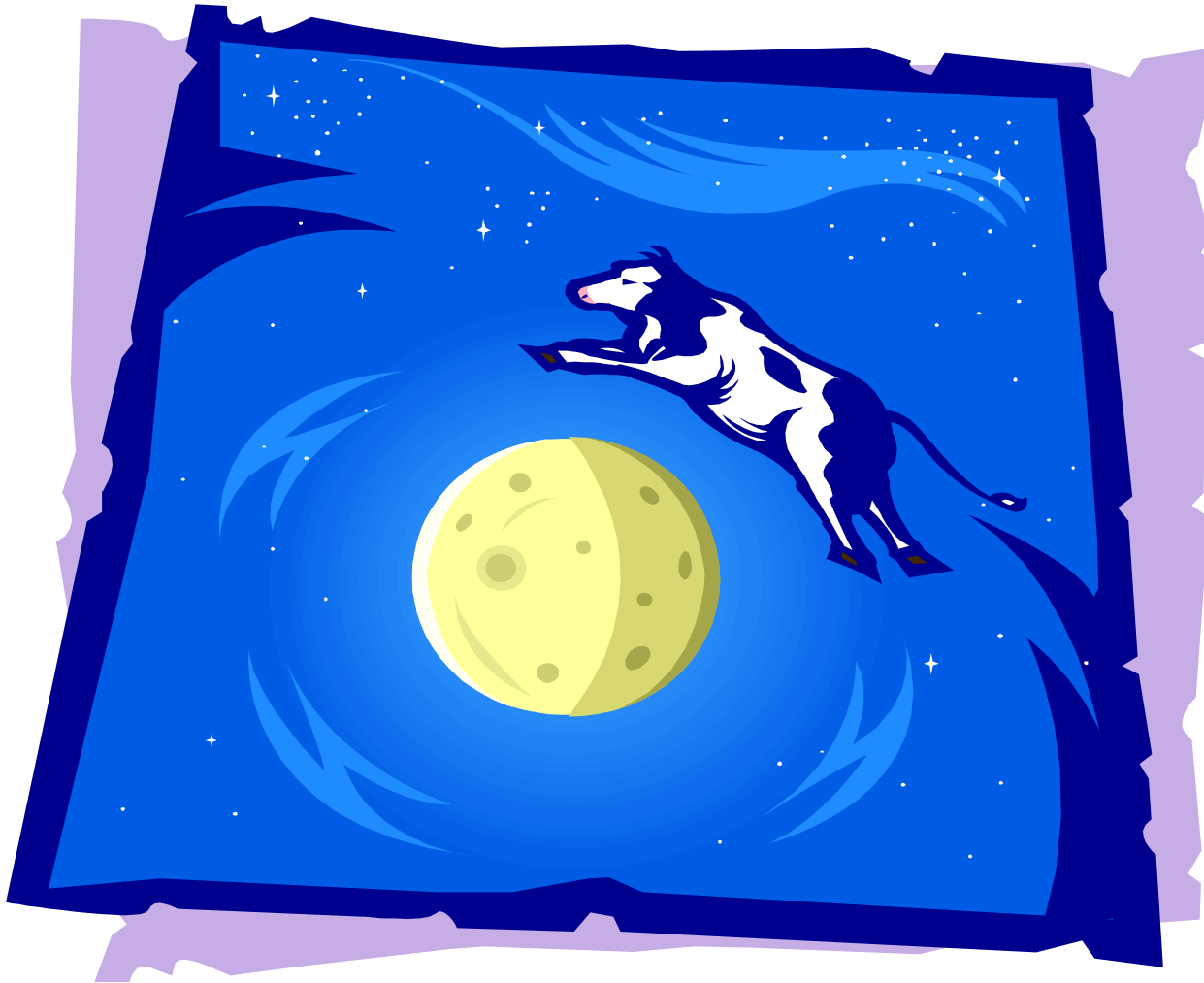
Things to Ponder?

Presence of pathogens in foods: Did you think the following would ever occur?

- *L. mono* in ice cream
- *E. coli* in flour

How do employees conduct themselves while manufacturing a food product? Have they been trained and retrained regarding food safety?

Have you re-assess your environment where you manufacture a food product?



Questions