Collaborative Implementation of FSMA Workshop

Root Cause Analysis

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One week in June...

- **First 24 hours (6/17/09)**
  - Customer inquiry on cookie dough
  - FDA, CDC provide briefing of investigation
    - Potential association of *E. coli* O157:H7 with the consumption of raw cookie dough
    - 63 cases in 26 states
One week in June...

- Second 24 hours (6/18 – 6/19/10)
  - FDA, CDC confirm association
    - No recovery from cookie dough
    - No ability to narrow scope to date or product type
  - Nestlé initiates recall
    - All refrigerated retail cookie dough on market
    - 47 products, 3.5 million packages
    - Largest, broadest scope recall in history of Nestlé USA
One week in June...

- Third 24 hours (6/20/10)
  - Arrival of FDA at Danville factory
  - Nestlé production halted after FDA review
What we knew...

- No past association of the consumption of raw cookie dough or it’s constituent materials with *E. coli O157:H7*
- Product had $a_w < 0.85$
- Product had validated cooking instructions, consumer labeling
- Epidemiological data suggested Multiple products and formats, multiple production lines
- No isolation of organism from retain or consumer units
- Large number of cases over a period of time
A novel vehicle for transmission of *Escherichia coli* O157:H7 to Humans: Multistate outbreak of *E. coli* O157:H7 infections associated with consumption of ready-to-bake commercial prepackaged cookie dough – United States, 2009
Investigation - Hypotheses

- Contaminated raw material
- Contamination from air / water
- Harborage in the factory / equipment
- Event lead to ingress
- Contamination from employee
- Cross contamination from Buitoni operation
Analytical tools

- No validated rapid method for *E. coli* O157:H7 detection in cookie dough or associated raw materials
- BAX *E. coli* O157:H7 MP assay
  - Recognized by Health Canada for a variety of matrices
- Commissioned a study in conjunction with Qualicon and Silliker laboratories
  - Validate the limit of detection for representative matrices:
    - Cookie dough
    - Wheat flour, sugar, egg powder, margarine, molasses, pecans, oats, cocoa powder, wheat flour, raisins, coconut, rice flour, chocolate morsels, peanut butter
- Evaluated compositing of cookie dough and wheat flour at 5 x 25g (125g) and 15 x 25g (375g)
Learnings: Issue and incident investigation

- Many times outbreak / issue investigations are conducted after the outbreak / issues is over
- Issue investigations are usually retrospective
- Analytical testing is statistically limited and often inconclusive
- Use of structured tools (eg Fishbone / 5 why) can help when organizing / sorting investigation findings and determining necessary corrective actions.

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Issue and incident management

- Often there is no "smoking gun" found
  - Need to identify all potential root causes and implement corrective / preventive actions
- Investigation / recall management requires resources across disciplines
- Co-operation, exchange of information with stakeholders (eg, supplier, customer, FDA / CDC / state health departments) is important to success