

Food Safety Legislation: There's a New Sheriff in Town

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Introduction



- Basic food laws enacted in 1906
- Technology, food processing, consumer expectations, and regulations have changed, but not fundamental legal requirements or government authority
- Food industry has developed and adopted effective food safety assurance systems – and food supply is safe
- Several newsworthy recalls in recent years
- Broad support for modernization of food safety laws
- Meanwhile, new Administration is regulating aggressively

Ripped from the Headlines...

- “Corned beef tainted with drug recalled”
 - Associated Press. May 23, 2010.
- “Romaine lettuce sickens people in four states”
 - United Press International. May 13, 2010.
- “USDA orders largest beef recall: 143.4 million pounds”
 - USA TODAY. Feb. 18, 2008.
- “Consumers Urged to Avoid Certain Tomatoes Amid Salmonella Scare”
 - Washington Post. Jun. 10, 2008.
- “Foodborne Illnesses Remain Constant in U.S.”
 - Washington Post. Apr. 10, 2008
- “Outbreaks prompt scrutiny of frozen chicken food labeling”
 - USA TODAY. Apr. 21, 2008.

And More

- “Meat Inspectors Can't Keep Up, Official Says”
 - Wall Street Journal. Apr. 18, 2008.
- “USDA Recommends That Food From Clones Stay Off the Market”
 - Washington Post. Jan.16, 2008; A03
- “Lawmaker: Nation's food system is collapsing”
 - CNN. May 14, 2008.
- “ConAgra: Peanut butter recall will cost \$50 million-\$60 million”
 - AP. Feb. 20, 2007.

The Political Climate

- Democrats control the White House and Congress
- U.S. Senate
 - 57 Democrats
 - 41 Republicans
 - 2 Independents (caucus with Democrats)
- U.S. House of Representatives
 - 256 Democrats
 - 178 Republicans
- Despite bipartisan claims, still party line bias
- Senate almost filibuster proof
- But time is running out as mid-term elections approach



Pending Legislation

Operations/Controls

- Mandatory food safety plans/preventive controls
- Mandatory food defense plans
- Supply chain management
- Added import controls
- Traceability requirements
- Product/environmental sampling/government access

Enforcement/Sanctions

- Mandatory recall
- Records Access
- Registration Suspension
- Civil penalties
- Increased criminal penalties
- User fees



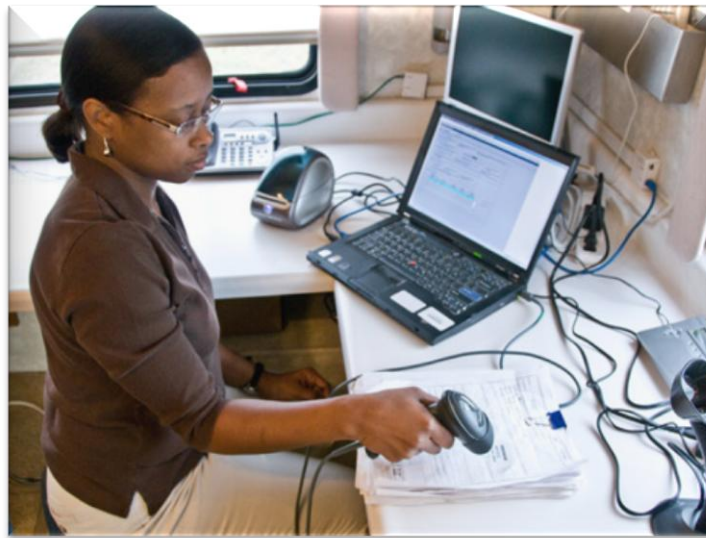
Legislation Will Pass, But Meanwhile

- Congress will act -- eventually
- Agencies under scrutiny and new leadership
- FDA increasing inspections
- USDA increasing inspection suspensions
- States increasing inspections
- States testing products
- Up and down the supply chain
- More recalls
- More enforcement actions
- And the burden of proof is shifting



Reporting Rules Mandated

- FDA – Reportable Food Registry
- USDA/FSIS -- Notification



Reportable Food Registry

- New food safety reporting requirement as of Fall 2009
- Only applies to products exclusively regulated by FDA
- Basic Requirement: A responsible party must file a report with FDA within 24 hours of determining that an article of food is a reportable food
- Failure to do so is a violation of the FFDCA

RFR: Scope

- You are only a responsible party as to any article of food manufactured, processed, packed, or held in your registered facility
- A reportable food is an article of food for “which there is a reasonable probability that the use of, or exposure to, such article of food will cause serious adverse health consequences or death to humans or animals” (Class I recall standard)

RFR: Timing and Exceptions

- 24-Hour clock does not run until determination is made
- After a food is determined to be a reportable food, you must report to FDA unless all of the following apply:
 - The adulteration originated with you
 - The food has not been transferred to another person
 - You correct the problem with the food or destroy it

RFR: Status

- RFR now in effect, and subject to FDA Q&A and varying (sometimes conflicting) interpretations
- New guidance just issued
- Document decisions!!!
- Records related to reports must be maintained for 2 years
- Reports filed with FDA are available to the public, excluding confidential business information

FSIS Notification

- Foods exclusively regulated by FSIS are not covered by the RFR, but
- 2008 Farm Bill mandated that an establishment shipping or receiving a misbranded or adulterated product report to FSIS
- Broader than RFR standard
- Proposed regulations implementing requirement are pending

Summary

- Food safety is in the news
- Basic laws have not been changed in a century
- Eventually, Congress will act
- The Administration is regulating aggressively
- The food industry – every segment – must focus on compliance and prepare for change
- There is a new sheriff in town!

