



USA Peanut Congress

June 18-22, 2011

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KNOWNS

Current Bill runs through 2012 crop

Budget stress

2012 is an ELECTION year

FY 2012 Ag Appropriations Bill



UNKNOWNNS

Everything else



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Having said that, let's speculate...



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H.R. 2751

FDA Food Safety & Modernization Act “FSMA”



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- Passed United States Senate December 19, 2010
- Passed United States House of Representatives December 21, 2010
- Signed by President Obama January 4, 2011
- FSMA is historic because it is the first time in over 70 years that the basic statutory tools for combatting food borne illness have been fundamentally changed

PARADIGM SHIFT

From

Reaction & response

Catching problems

To:

Prevention of
problems that made
people sick

Preventing problems
from happening in the
first place



FOCUS OF FSMA

- Record Keeping and Inspection of Records
- Registration of Food Facilities
- Hazard Analysis, Risk-Based Prevention Controls and Food Safety Plans
- Issuance of New Regulations and Guidance Documents
- FDA Reporting Requirements
- Inspections

FOCUS OF FSMA *(continued)*

- Lab Accreditation
- Traceability and Surveillance
- Recall Authority
- Administrative Detention
- State and Local Government Standards
- Reportable Food Registry (“RFR”)
- Imports

RECORD KEEPING & INSPECTION OF RECORDS

- Expands authority of FDA
- Allows access to records of products at issue AND related products

REGISTRATION OF FOOD FACILITIES

- Renew every 2 years beginning in 2012
- Allows suspension of registration by an FDA Commissioner
- Regulations are required BUT provisions are effective within 180 days of enactment
- Allows for development of electronic registration (after 5 years)

Hazard Analysis Risk-Based Controls & Food Safety Plans

- Develop a written risk based HACCP plan
- Update every 3 years
- Constantly monitor effectiveness

Hazard Analysis Risk-Based Controls & Food Safety Plans *(continued)*

- Maintain records for at least 2 years
- Regulations are required BUT provisions of the Act are effective within 18 months of enactment
- Regulations must be science based

REGULATIONS

- Must issue science based guidance documents every 2 years
- Priority given to fruits and vegetables that have been previously associated with recent food borne illness
- Within 18 months of enactment FDA must promulgate regulations to protect against intentional adulteration of food

ALLERGY GUIDELINES

- FDA to develop
- Voluntary
- Can provide grants to schools that implement

FDA Reporting Requirements

- FDA & USDA to submit to Congress “National Agricultural & Food Defense Strategy” within 2 years



INSPECTION

- Allocated on “risk profile”
- High risk = more inspections
- Foreign facilities will require massive manpower

TRACEABILITY & SURVEILLANCE

- Within nine (9) months of enactment, FDA is required to set up three (3) pilot programs for tracking processed food as well as fruits and vegetables, with a focus on at least three (3) different types of foods that have been associated with a significant outbreak in the last five (5) years

TRACEABILITY & SURVEILLANCE

(continued)

- Within eighteen (18) months of enactment, FDA will provide a report to Congress and provide recommendations for improving the tracing and tracking of food
- For high risk facilities, FDA must provide and publish a Notice of Proposed Rule Making to establish record keeping requirements for these facilities



LABORATORIES ACCREDITATION & TESTING

- This will serve to accredit food testing laboratories and adopt model accreditation standards that laboratories must meet

RECALL

- FDA now has mandatory recall authority
- Companies must keep FDA updated on progress of recall
- Companies must provide notice to consumers
- Provides for civil penalties
- Companies to pay recall costs

ADMINISTRATIVE DETENTION

- FDA standard now “reason to believe” replaces old “credible evidence” standard
- 1st New Rule-FDA can now administratively detain food it believes was produced under unsanitary or unsafe conditions

IMPORTS

- Foreign supplier verification program established
- 2nd New Rule-Must notify FDA if any country has refused entry for the same product