

# Food Safety Enhancement Act (HR2749)

## General Structure

### ◆ Background Info

- e.g., does not preempt states, does not cover USDA-regulated animals or alter FDA/USDA jurisdiction

### ◆ Title I - Food Safety

- Subtitle A - Prevention
- Subtitle B - Intervention
  - ◆ Surveillance, public education, research
- Subtitle C - Response
  - ◆ e.g., criminal and civil monetary penalties

### ◆ Title II – Miscellaneous

- e.g., GRAS, COOL, importer & broker registration, subpoena authority

# Subtitle A - Prevention

- ◆ Facility Registration
- ◆ Hazard Analysis and Preventive Controls, Food Safety Plan, Testing, Food Defense
- ◆ Performance standards for contaminants
- ◆ Safety Standards for produce etc.
- ◆ Risk-Based Inspection Schedule
- ◆ Records Access
- ◆ Traceability
- ◆ Notification, Non-Distribution, Recall
- ◆ Reportable Food Registry, Exchange of information

# Facility Registration

- Annual
- \$500/facility, \$175,000 cap
- Contact info, business activity, trade names, unique identifier

# Hazard Analysis and Preventive Controls, Food Safety Plan, End Product Testing, Food Defense

- Developed by facility
- Includes procedures to ensure safety of incoming ingredients
- FDA can specify hazards and controls, industry has flexibility in adopting controls
- Testing, per regulation after pilot programs, for high risk facilities; reporting of positives posing severe adverse health risk

# Performance and Safety Standards

- ◆ **Performance Standards:** e.g., tolerances for most significant food-borne contaminants, as determined through epidemiology etc.
- ◆ **Safety Standards:** In coordination with USDA, develop regs for safe growing, processing, packing etc. of specific types of raw produce, nuts, mushrooms, as needed based on risk.

# Risk-Based Inspection Schedule

- Category 1 (high risk; manufactures or processes) 6-12 months
- Category 2 (low risk; manufactures, processes, packs, or labels) 18 – 36 months
- Category 3 (holds food) 5 years

# Records Access

## ◆ During inspection

- ◆ reasonable times, limits, manner.
- ◆ All records (manufacturing, processing, transporting, etc.) bearing on whether food may be adulterated or misbranded.
- ◆ Does not include recipes; financial, pricing, personnel, research, or sales data (other than shipment data regarding sales)

## ◆ Remote Access

- ◆ In emergencies (reasonable belief that food presents threat of serious adverse health consequence); or
- ◆ Relating to food safety plans

# Traceability

- Through notice and comment regulation, after public meetings, pilot project, assessment of cost-benefit and feasibility for different industry sectors
- Enable tracing entire food chain w/in 2 business days
- Does not mandate specific technologies
- Directs FDA to identify technologies and methodologies for consideration that enable maintenance of full food chain pedigree and are interoperable with other systems.
- Exemptions
  - ◆ farms direct to consumers, restaurants, groceries (only requires 1 up or 1 down)
  - ◆ sales by fishing vessels
  - ◆ "Grains" from farm to initial warehouse



# Notification, Non-Distribution, Recall

- **Notify FDA** when have reason to believe a food in commerce is adulterated or misbranded in a manner presenting reasonable probability of threat of serious adverse health consequences
- **Cease distribution order** if may cause serious adverse health consequence
  - ◆ 24 hours to request hearing
  - ◆ if requested, must occur w/in 5 days
- **Mandatory recall** after hearing opportunity
- **Emergency recall** – prior to hearing if credible information of imminent threat

# Reportable Food Registry, Exchange of information

- ◆ In addition to facilities, farms, restaurants and importers would have to report food when reasonable probability will cause serious adverse health consequences
- ◆ Provides FDA with authority to share info with state, local and foreign governments and the public, under specified conditions, as needed to protect public health.

# Subtitle C - Response

- ◆ Seizure (procedural change)
- ◆ Detention (changes in standards and procedures)
- ◆ Restrict movement of food within a state
- ◆ Criminal penalties
  - up to 10 years for knowing violation
- ◆ Civil monetary penalty for any food prohibited act
  - Separate penalties for knowing and unknowing violations. Max in 1 proceeding:
    - ◆ Unknowing: \$50K/individual, \$1 mill/company
    - ◆ Knowing: \$100K/individual, \$7.5 mill/company
  - (Existing law: only for pesticide violations, \$500K max, individual or company, knowing or not)
- ◆ Improper import Entry Filings – prohibited act

# Title II - Miscellaneous

- ◆ GRAS
- ◆ COOL
- ◆ Export Certificates
- ◆ Importer and broker registration
- ◆ Unique Identifiers
- ◆ Prohibition against delaying inspections
- ◆ False or misleading reporting
- ◆ Subpoena authority