
Legislative Update on Federal Food Safety Policy

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Federal Food Safety Policy

General Observations

- Was a major focus of our public policy efforts in 2009
- Produce is an extraordinarily safe and healthy food
 - Over 1 billion servings of produce are consumed daily in the U.S., without issue
- Focus must be to ensure public trust in a system of food protection that:
 - Maintains confidence in eating healthy fresh fruits and vegetables
 - Can deal with rare problems without destroying public confidence
 - Doesn't kill the industry or sweep all products into same bucket

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- **Food Safety Enhancement Act (FSEA, H.R. 2749)**
 - *Sponsored by John Dingell (D-MI)*
 - *Introduced June 2009, fast-tracked and passed in House by voice vote in July*
 - *Specifically affects FDA-regulated facilities*
 - *We had strong play in shaping this bill to be the best it could be*

Food Safety Enhancement Act

Facility Registration

- a food is misbranded if manufactured, processed, packed, or held in a facility that is not registered
- requires annual registration of food facilities and directs the Secretary to collect an annual fee for registration
- suspend the registration of any food facility for a violation that could result in serious adverse health consequences or death to humans or animals

Food Safety Enhancement Act

Food Safety Plan

- Requires the owner, operator, or agent of a food facility to: (1) conduct a hazard analysis; (2) identify and implement effective preventive controls; (3) monitor preventive controls; (4) institute corrective actions as necessary; (5) conduct verification activities; and (6) maintain records.
- Requires facility to implement a food safety plan
- Authorizes the Secretary to require the submission of finished product test results
- Requires the facility to implement a food defense plan

Food Safety Enhancement Act

Fresh Produce

- Requires the Secretary to establish scientific and risk-based food safety standards for the growing, harvesting, packing, sorting, transporting, and holding of raw agricultural commodities: (1) that are a fruit, vegetable, nut, or fungus; and (2) for which the Secretary has determined that such standards are reasonably necessary to minimize the risk of serious adverse health consequences or death to humans or animals

Food Safety Enhancement Act

Traceability

- Requires the Secretary to establish a tracing system that enables the Secretary to quickly identify each person who grows, produces, manufactures, processes, packs, transports, holds, or sells such food.
- Requires the refusal of admission of articles that have not complied with the requirements of the food tracing system.

Food Safety Enhancement Act

Recall Penalties

- Requires the Secretary to assess fees on each food facility in a fiscal year that: (1) commits a violation of the Federal Food Drug and Cosmetic Act relating to food and so requires additional inspections by the FDA; or (2) has been subject to a food recall.

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Summary of FSEA.....**The Good**

- Strengthened commodity-specific approach to produce
- Ensured that FDA would work with USDA, state departments of agriculture
- Enhanced the ability of fresh processors to develop individual HACCP programs without rigid one-size fits-all mandates;
- Exempted produce from any duplicative requirements for country of origin labeling
- Assured equal treatment of imported and domestic produce in food safety standards

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Summary of FSEANeeds work

- Kept a mandate for traceability across all foods, but without prescriptive dictates that could have set back work on our current Produce Traceability Initiative
- Ensured tighter control of potential FDA geographic quarantine authority, requiring an imminent threat to take such action and coordination with USDA
- Capped registration fees for both facilities and importers
- Does not mandate FDA to establish “Fast-Lane” requirement for imports

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Summary of FSEA**The Ugly**

- Registration fees need to be targeted to specific FDA activities related to food safety
- Developing in law “categories of risk” is dangerous with trading allies and consumer confidence
- Eliminate Finished Produce Testing Provision
- Create stronger outbreak management structure within FDA and throughout government
- Geographic Quarantine provision is overkill

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- **FDA Food Safety Modernization Act (S. 510)**

- *Sponsored by Richard Durbin [D-IL]*
 - *Co-sponsored by Saxby Chambliss [R-GA], John Isakson [R-GA] and 12 other Senators*
- *Introduced March 2009, recommended by Health, Education, Labor and Pensions (HELP) Committee in November for full Senate consideration*
- *Specifically affects FDA-regulated facilities*

H.R. 2749 and S. 510

Similarities

- Both would require mandatory standards for produce
- Would require food facility to re-register with FDA while unregistered facilities would be prohibited from introducing food into interstate commerce
- Would require a written and implemented food safety plan
- Would establish new industry fees

H.R. 2749 and S. 510

Similarities

- Would grant mandatory recall authority, administration detention (reason to believe) assess civil fines, suspension authority
- New regulatory requirements for imported food
- Only tests conducted by Federal labs or accredited non-federal labs could be used for regulatory purposes, and would require lab test results to be sent directly to FDA

H.R. 2749 and S. 510

Differences

- House bill would require annual re-registration and fee. Durbin bill is bi-annual registration and no fee.
- House bill requires tracing system for food. Durbin has no similar provision.
- House bill would require importers and custom brokers to register with FDA and importers to pay registration fee annually. Durbin bill would not require importers or custom brokers to register but would require importers to pay fees sufficient to cover FDA administrative cost for Voluntary Qualified Importer Program.

H.R. 2749 and S. 510

Differences

- House bill authorizes Geographic Quarantine Program. Durbin bill does not have this provision.
- House bill assesses civil penalties for each prohibited act. Durbin bill authorizes FDA to assess civil fines only for failure to comply with recall order.

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- Senate is up next
 - S. 510 has passed major hurdle with passage out of the Senate HELP committee
 - Floor time will be dictated by health care debate but most likely between January and April of this year
- Key policy areas to consider in Senate bill
 - Produce Specific Requirements
 - Traceability
 - Outbreak Investigation and Recovery
 - **Hot Button issues:** Quarantine Authority, Finished Product Testing, Small farm exemptions

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Questions?