



May 26, 2009

## Summary of Discussion Draft of the Food Safety Enhancement Act of 2009

Committee on Energy and Commerce

### Food Safety

- 1. Creates an up-to-date registry of all food facilities serving American consumers:** Requires all facilities operating within the U.S. or importing food to the U.S. to register with the FDA annually.
- 2. Generates resources to support FDA oversight of food safety:** Requires registered facilities to pay an annual registration fee of \$1,000 in order to generate revenue for food safety activities at the FDA; requires registered facilities to pay for FDA's costs associated with reinspections and food recalls; allows FDA to charge a fee to domestic firms requesting export certificates for exported food.
- 3. Prevents food safety problems before they occur:** Requires all facilities operating within the U.S. or importing food to the U.S. to implement safety plans that identify and protect against food hazards. FDA would have the authority to specify minimum food safety plan requirements and to audit food safety plans.
- 4. Requires safety plans for fresh produce:** Directs FDA to issue regulations for ensuring the safe production and harvesting of fruits and vegetables.
- 5. Increases inspections of food facilities:** Sets a minimum inspection frequency for all registered facilities. High-risk facilities would be inspected at least once every six to 18 months; low risk facilities would be inspected at least once every 18 months to three years; and warehouses that store food would be inspected at least once every three to four years. Refusing, impeding, or delaying an inspection is prohibited.
- 6. Improves traceability of food:** Enhances FDA's ability to trace the origin of tainted food in the event of an outbreak of foodborne illness. FDA would be required to issue regulations that require food producers, manufacturers, processors, transporters, or holders to maintain the full pedigree of the origin and previous distribution history of the food and to link that history with the subsequent distribution history of the food; and to establish an interoperable record to ensure fast and efficient traceback (current law permits facilities to hold a record in any format — paper or electronic — making efficient tracing of foods difficult for FDA). Prior to issuing such regulations, FDA would be required to conduct a feasibility study, public meetings, and a pilot project.
- 7. Enhances the safety of imported food:** As an additional layer of protection, FDA can require food to be certified as meeting all U.S. food safety requirements by the government of the country from which the article originated or by certain qualified third parties. Third party certifying entities must meet strict requirements to protect against conflicts of interest with the firm seeking certification.

8. **Expands laboratory testing capacity:** Requires FDA to establish a program to recognize laboratory accreditation bodies and to accept test results only from duly accredited laboratories. Gives FDA the ability to require laboratories to send test results to FDA.
9. **Provides strong, flexible enforcement tools:** Provides FDA new authority to issue mandatory recalls of tainted foods. Strengthens criminal penalties and establishes civil monetary penalties that FDA may impose on food facilities that fail to comply with safety requirements.
10. **Creates fast-track import process for food meeting security standards:** Permits FDA to develop voluntary security guidelines for imported foods. Importers meeting the guidelines would receive expedited processing.
11. **Enhances the safety of infant formula:** Enhances FDA’s ability to assure the safety of new infant formulas before they go on the market.
12. **Advances the science of food safety:** Directs the Secretary to include food in an active surveillance system to assess more accurately the frequency and sources of human illness. The Secretary is also directed to identify industry and regulatory approaches to minimize hazards in the food supply.
13. **Enhances FDA’s ability to block unsafe food from entering the food supply:** Strengthens FDA’s authority to administratively detain unsafe food products. Grants FDA “quarantine” authority under which the agency may restrict or prohibit the movement of unsafe food products from a particular geographic area.
14. **Directs FDA to assess the use of carbon monoxide in certain foods:** Requires FDA to conduct a safety review of the use of carbon monoxide in meat, poultry, and seafood products.
15. **Enhances transparency of GRAS program:** Requires posting on FDA’s website of documentation submitted to FDA in support of a “generally recognized as safe” (GRAS) notification.
16. **Requires country-of-origin labeling and disclosure:** Requires all processed food labels to indicate the country in which final processing occurred. Requires food manufacturers to identify the country of origin for all ingredients on their websites. Requires country-of-origin labeling for all produce.

### **General Provisions**

1. **Creates an up-to-date registry of importers:** Requires all importers of drugs, devices, and foods to register with the FDA annually and to pay a registration fee.
2. **Requires unique identification numbers for facilities and importers:** To enhance information about FDA-regulated entities, creates unique identification numbers for all drug, device, and food facilities and importers.

3. **Creates a dedicated foreign inspectorate:** Requires FDA to establish and maintain a corps of inspectors to monitor foreign facilities producing food, drugs, devices, and cosmetics for American consumers.
4. **Grants FDA new authority to subpoena records related to possible violations.**
5. **Provides protection for whistleblowers that bring attention to important safety information:** Prohibits entities regulated by the FDA from discriminating against an employee in retaliation for assisting in any investigation regarding any conduct which the employee reasonably believes constitutes a violation of federal law.