

Food Safety Enhancement Act Numbered Summary of Key Requirements

This is a numbered summary of the key requirements in the four sections of The Food Safety Enhancement Act of 2009, entitled Prevention, Intervention, Response and Miscellaneous.

Subtitle A – Prevention

- 1) Manufacturers need to register with FDA (name, address, food category, contact) – 2010 annual fee of \$500/facility.
- 2) Manufacturers need to develop a risk based preventive controls such as HACCP (including allergen controls).
- 3) Manufacturers required to verify suppliers of incoming ingredients to good agricultural practices – may include on site audits and testing of ingredients.
- 4) Manufacturers required to have a recall procedure.
- 5) Manufacturers required to have a procedure for tracing distribution history of articles of food to assure a secure supply chain.
- 6) **Compliance effective date – 18 months after Enactment of Act for most companies but longer times for “small” and “very small” manufacturers.’**
- 7) FDA to develop in 18 months safety standards for product/raw agricultural commodities – good agricultural practices.
- 8) FDA inspections
 - Category 1 – manufacturers or processors of raw products of animal origin - 6-18 month inspection time frame.
 - Category 2 – manufacturers that process/pack/label – 18-36 month inspection time frame.
 - Category 3 – facility that hold food such as distribution centers – 36 months to 48 month’s inspection time frame.
- 9) FDA to establish a tracing system for distribution history of food.
- 10) Food imported in compliance with Act – certification by country agency or accredited body.
- 11) FDA has authority to require a recall.

Subtitle B – Intervention

- 1) FDA required to build surveillance system to assess frequency/source of human illness associated with food consumption.
- 2) FDA to develop public education program on food safety.
- 3) FDA to develop rapid method for detection of contaminants in food.

Subtitle C - Response

- 1) FDA to have product seizure authority for “reason to believe” rather than “credible evidence” of food safety.
- 2) Civil and criminal penalties for violations relating to aspects of the Act.
- 3) FDA has the authority to quarantine food if there is the threat of serious adverse health consequences.

Title II - Miscellaneous

- 1) FDA posting notice of a substances GRAS status.
- 2) Food misbranded if food label fails to identify the country in which final food processing occurs.
- 3) Food misbranded if importer fails to register and pay a fee.
- 4) Whistleblower protection.