

## S. 510, the Food Safety Modernization Act: Regulation of “Facilities”

### Background:

When Congress passed the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, it set into place a federal requirement for all food “facilities” to register with FDA. As of July 15, 2009, 156,489 facilities have registered in the U.S. FDA believes that approximately 37,000 additional facilities have not yet registered.

The impetus and rationale for such a sweeping federal reach into the smallest of food facilities was national security and bioterrorism. But S. 510 superimposes a significant regulatory burden on all of those facilities, regardless of the need from a food safety perspective. Small-scale producer and facilities that sell direct to consumers are inherently transparent and accountable and do not require federal oversight. Such facilities are already sufficiently regulated by state and local authorities.

### Current Compliance Guidelines Exceptions:

There are some limited exceptions to the existing registration requirement under Sec. 415 of the Food, Drug, and Cosmetic Act for farms, retail food establishments, and private residences. The terms were not defined in the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, but have been adopted by FDA through compliance guidelines.

- “Retail food establishments” that sell food directly to consumers as their primary function, including those that manufacture, process, pack, or hold food, are exempt from registration if the annual sales of food products to consumers exceeds the annual sales of food products to all other buyers. For purposes of the exemption, businesses are not consumers, so a small processor that sells directly to an end user such as a hotel, restaurant, or institution is not exempted.
- A farm selling raw agricultural commodities directly to consumers is not required to register as a facility.
  - A farm that does any “processing”, such as making jam or boiling sap into syrup, would have to register unless all the food is consumed on the farm (in other words, the farm could not sell any such products). *See* Q 2.15: <http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/FoodDefenseandEmergencyResponse/ucm082703.htm>

The current guidance documents are unclear whether a “farm” could also be a “retail food establishment,” leading to the potential that farmers who add value to their potatoes by making potato salad to sell directly to consumers could be subject to greater FDA regulation than the local deli that buys the same farmer’s potatoes and makes potato salad. Moreover, the current guidance document could be changed without even a notice and comment rulemaking, leading to significant uncertainty for farmers and food processors.

As currently written, S. 510 would require that all facilities that are required to register under Section 415 would **also** have to meet the requirements below under Section 103, Hazard

Analysis and Risk-Based Preventative Controls. If S. 510 passes as currently written, **every** facility will be liable for federal penalties and subject to the following regulatory regime:

- Hazard analysis: Identify and evaluate known or reasonable hazards and develop written analysis of the hazards.
- Preventive Controls: Identify and implement preventive controls, to provide assurances that hazards identified will be significantly minimized and prevented.
- Monitor effectiveness of the preventive controls.
- Establish procedures that a facility will implement if the preventive controls are found to be ineffective through monitoring.
- Verify that
  - The preventive controls are adequate.
  - Monitoring is in accordance with 103(d).
  - The owner is making appropriate decisions about corrective actions under 103(e).
  - The preventive controls are effectively and significantly minimizing or preventing the occurrence of identified hazards, including the use of environmental and product testing programs.
  - There is documented, periodic reanalysis of the plan to ensure that it is still relevant.
- Recordkeeping: Maintain, for not less than 2 years, records documenting the monitoring of the preventive controls implemented, instances of nonconformance, the results of testing, instances of corrective actions, and the efficacy of preventive controls.
- Written plan and documentation: Prepare a written plan that documents and describes the procedures used by the facility to comply with the requirements of this section, including analyzing the hazards under subsection 103(b) and identifying the preventive controls adopted under subsection 103(c) to address those hazards.