

Analysis of S. 510, the Food Safety Modernization Act

8/20/2010

OVERVIEW

On August 12, 2010, Senators Durbin, Harkin, Enzi, Burr, Gregg and Dodd released the “Managers’ Package” of S.510, the Food Safety Modernization Act. The Managers’ Package is a new version of the bill that replaces the one passed by the Senate Health, Education, Labor and Pensions (HELP) Committee in November 2009.

The Managers’ Package includes some new provisions that provide FDA with the ability to address the concerns of small farms and on-farm processors. But almost all of these provisions either explicitly commit the issues to the FDA's discretion or have language that, in practice, leaves FDA with significant discretion. There are very few enforceable protections for small-scale producers and farmers.

The Managers’ Package does not include the Tester-Hagan Amendments. These amendments remain under negotiation, but (if adopted), they would provide an exemption for small direct-market farms and facilities from the new HACCP-type requirements and on-farm produce standards. The amendments only address the new requirements that FDA can impose under S.510; they do not exempt small farms and processors from existing state and local health requirements.

Particularly given FDA’s track record of favoring large industry over small-scale and sustainable producers, the Tester-Hagan amendments are vital to ensuring that local food producers can continue to provide healthy and safe food for consumers.

KEY PROVISIONS of S.510

I. Food Facilities – these provisions apply to any place that engages in “manufacturing, processing, packing, or holding food for consumption in the United States.”

A. Registration (Sec. 102): Facilities already have to register under 21 USC 350d(1). S.510 authorizes FDA to mandate electronic registration in 5 years. (p.9)

B. Hazard Analysis and Risk-Based Preventative Controls (“HARPC”) (sec. 103)

1. HARPC requirements are very similar to the Hazard Analysis and Critical Control Point plans (HACCP) plans required under the House version of the bill. Every facility would be required to develop a HACCP-type plan that identifies and evaluates potential hazards, develops preventative controls, monitors the effectiveness of the controls, takes corrective actions, and provides verification. The facility owner must also keep records documenting all of this and periodically reanalyze the plan. The plan is subject to FDA approval and inspection. (pp.11-16)

2. The requirements specifically cover **on-farm processing**. (p.18) A farm is considered a facility if it does any processing of foods (such as making maple syrup, sun-dried tomatoes, or jams) unless the food is consumed on the farm. (p.22)
3. FDA is directed to “provide sufficient flexibility to be practicable for all sizes and types of facilities” including small businesses. (p.18) These are undefined terms and, in practice, largely unenforceable.
4. FDA has discretion to choose to exempt or modify requirements for on-farm processing “as the Secretary deems appropriate.” This discretionary authority of the FDA only applies to small facilities and low-risk activities. (pp.23-24)
5. Small business have more time to comply. The HARPC provisions go into effect 18 months after enactment in general, but small businesses will have 24 months to comply and very small businesses will have 36 months to comply. (p.27-28)
6. FDA is directed to review existing programs, including specifically the Grade A Pasteurized Milk Ordinance, to “ensure that such regulations are consistent, to the extent practicable, with applicable domestic and internationally-recognized standards in existence” at the time the regulations are promulgated. (p.19)

C. Inspections (Sec. 421) (pp. 90-93)

1. After an initial extended implementation phase, high-risk facilities must be inspected every 3 years and non-high-risk facilities must be inspected every 5 years. (p.92)
2. Foreign facilities are inspected, starting with just 600 per year and gradually increasing to approximately 19,000 foreign facilities annually over a 6-year period. Based on FDA’s estimate of 210,000 foreign facilities (www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/RegistrationofFoodFacilities/ucm175995.htm), it will take 15 years for FDA inspect each foreign facility just **once** under S. 510. Yet the bill calls for a domestic high-risk facility to have been inspected at least **four** times in that same time period, and a low-risk facility (such as a local baker or jam-maker) to have been inspected at least **twice** during that same time period.

- D. **Fees.** While S. 510 does not impose a registration fee on facilities (unlike its companion bill, HR 2749), it does make a facility liable for the costs of re-inspection. (p.46).

II. On-Farm Regulation: “Standards for Produce Safety” (Sec. 105) (pp. 29-41)

- A. FDA is authorized to establish standards for how fruits and vegetables are grown and harvested, including standards for “soil amendments, hygiene, packing, temperature controls, animals in the growing area, and water.” (pp.30&32) This does not

- authorize FDA to set standards for meat, eggs, or dairy, although farmers who have both livestock and produce could face problems based on the requirements about “animals in the growing area.”
- B. Produce standards shall provide "sufficient flexibility" and be "appropriate to the scale of diversity" of the farms. (p.31) These are undefined terms and, in practice, largely unenforceable.
 - C. The requirements specifically **include** farms that sell directly to consumers (p.31)
 - D. FDA **may** exempt or modify requirements for small or very small businesses that grow low-risk crops. (p.30-31) The decision is left to FDA’s discretion.
 - E. Standards cannot conflict with **certified organic** regulations for certified organic producers. (p.32) This does not protect the practices of non-certified sustainable producers, however, and the FDA can impose **additional** standards even on certified producers.
 - F. Standards shall “take into consideration, consistent with ensuring enforceable public health protection, conservation and environmental practice standards and policies established by Federal natural resource conservation, wildlife conservation, and environmental agencies.” (p.32) Having considered these policies, FDA is not legally obligated to protect natural resources or wildlife.
 - G. Small businesses have an additional year to comply with regulations and very small businesses have an additional 2 years to comply. (p.34)

III. Tracking of Food and Recordkeeping (Sec. 204) (pp.108-129)

- A. FDA is directed to conduct pilot projects for rapid traceback.
- B. FDA shall establish a product tracing system. (p.111)
- C. FDA shall issue regulations requiring facilities to keep additional records for high-risk foods. (pp.112-117)
- D. FDA is to consider the impact on farm-to-school or farm-to-institution programs and shall modify the traceback requirements “as appropriate” to avoid “undue burdens.” (p.118)
- E. Food that is produced and packaged on a farm, and for which the packaging “maintains the integrity of the product and prevents subsequent contamination”, and is labeled with the farm’s information, is exempt from traceback requirements. (p.119) This is often referred to as “identity preserved” items.

- F. Food that is sold from a farm directly to a consumer is exempt from the traceback requirements. (p.122-123)
- G. Additional requirements may be imposed on farms during an investigation of an outbreak. (p.125-129)

IV. Miscellaneous

- A. Small entity compliance policy guide.** Throughout the bill, the agency is directed to prepare a “Small Entity Compliance Policy Guide” after it adopts new rules, which sets forth in “plain language” the requirements of the new regulations.
- B. Not explicitly require a consultant.** In both the facilities hazard analysis and risk prevention section and the farming produce standards sections, the bill states that regulations “not require a facility to hire a consultant or other third party to identify, implement, certify, or audit preventive controls.” This provision only prevents FDA from explicitly requiring a facility to hire a consultant. In practice, small businesses and farms may need to hire consultants in order to understand and comply with FDA’s requirements.
- C. Reduces standard for administrative detention of food.** Currently, FDA must have credible evidence that the food presents a threat of serious adverse health consequences or death in order to detain food. S. 510 would allow the agency to detain food if it has a “reason to believe” that the food “is adulterated or misbranded.” (p.148) This could include things that do not pose a health threat, such as failing to have complied with the various filing and paperwork requirements.
- D. Provisions for specific industries:**
 - 1. Dairy farms are subject to the "protection against intentional adulteration" requirements, although other farms are exempt. (p.43)
 - 2. Regulates new dietary ingredients that may contain analogues of anabolic steroids. (p.83-84)
 - 3. Requires FDA to submit to the HELP Committee any proposed guidance documents or regulations relating to post-harvest processing of raw oysters prior to issuing them. (p.85-87)

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