

## **S. 510 Food Safety Modernization Act**

### **Healthy Local Foods Amendment – Senators Jon Tester and Kay Hagan**

The U.S. Senate is about to pass sweeping legislation providing Food and Drug Administration oversight over local processors processing local product for local markets, and small, direct market food producers offering fresh, wholesome local foods for farmers markets.

Senators Jon Tester and Kay Hagan are sponsoring two amendments that would remove these vital local food growers and processors from federal oversight, leaving them –as they currently are – within the existing regulatory framework of state and local health and sanitation laws and rules.

- All of the well-publicized incidents of contamination in recent years – whether in spinach, peppers, or peanuts – occurred in industrialized food supply chains that span national and even international boundaries. The food safety problems in this system can and should be addressed without harming the local food systems that provide an alternative for consumers.
- The growing trend toward healthy, fresh, **locally sourced** vegetables, fruit, dairy, and value-added products **improves** food safety by providing the opportunity for consumers to know their farmers and processors, to choose products on the basis of that relationship, and to readily trace any problems should they occur.
- Farmers and processors who sell directly to consumers and end users have a direct relationship with their customers that ensures quality, safety, transparency and accountability. In addition, small-scale food producers are already regulated by local and state authorities, and the potential risk their products pose is inherently limited by their size. For these farmers and processors, new federal requirements are unnecessary and would simply harm both the food producers and their consumers.

### **Questions and Answers**

**Q: Why shouldn't direct-marketing farmers have to comply with the same regulations as larger farmers who sell to Dole or Del Monte or other large food processors?**

**A:** Produce that is sold directly from the farm to consumers is inherently lower-risk than produce sold through long supply chains. When produce is sold to large companies, it is commingled with produce from many farms and changes hands as it is distributed, transported, stored, and marketed across long supply chains covering on average 1,500 miles and dozens of states. The commingling, processing, storage, and transport times all increase the risk posed by these products, in addition to the much larger number of people consuming such foods.

In contrast, direct-marketing farms sell small quantities of their products directly to consumers at places like local farmers markets very shortly after harvest, making their products lower risk. Moreover, because the consumer knows the farmer, the sales are inherently transparent and traceable, so that any problem can be immediately addressed.

**Q: Under the amendment, would small-scale processors and direct-marketing farms be exempt from all regulation?**

No. The amendments only exempt these small-scale and local food producers from specific new federal regulations. These food producers will still have to comply with the rules set forth by state and local health officials, in addition to any rules established by the farmers markets themselves. These small, local food producers have never caused a major foodborne illness outbreak, and there is simply no reason to impose extensive new federal regulations on them.

**Q: Doesn't S. 510 include provisions to protect small businesses from over-regulation?**

**A:** The current language of the bill provides no enforceable protections for small farms and food producers. While S. 510 does direct the agency to provide “flexibility” for “small businesses”, the bill contains a long list of highly prescriptive and specific requirements that contradict the “flexibility.” The bill’s complex and expensive regulations are inherently unnecessary and inappropriate for small businesses.

With respect to “facilities”, for example, the bill has a long list of specific requirements:

*Identify and evaluate known or reasonably foreseeable hazards; develop a written analysis of the hazards; identify and implement preventive controls; monitor the effectiveness of the preventive controls; establish procedures that a facility will implement if the preventive controls are found to be ineffective; verify that the preventive controls are adequate and the owner operator is conducting monitoring and is making appropriate corrective actions and that the preventive controls implemented are effectively and significantly minimizing or preventing the occurrence of identified hazards including the use of environmental and product testing and that there is documented, periodic reanalysis of the plan to ensure that it is still relevant; maintain for not less than 2 years records documenting the monitoring of the preventive controls, instances of nonconformance, testing results and other verification and corrective actions; prepare a written plan that documents and describes the procedures used by the facility to comply with the measurements of this section; and conduct a reanalysis whenever a significant change is made in the activities conducted at a facility or every 3 years whichever is earlier.*

With respect to farms raising produce, while the bill again directs FDA to provide “flexibility” for small business and diversified farms, there are no specific protections for these farms. Based on the existing Leafy Greens Marketing Agreement and statement made by FDA officials, the FDA regulations are expected to include provisions requiring vegetation-free buffer zones and protections against wildlife, even though such requirements have not been scientifically proven to increase food safety. For small, diversified farms that may raise over 100 different crops a year, these requirements directly contradict sustainable practices such as companion planting for pest control, buffer zones to encourage beneficial insects and water retention, and the incorporation of livestock for fertility. These regulations could be not only burdensome, but simply impossible. The bill’s language would not actually prevent FDA from imposing such requirements; only an exemption will truly protect small, sustainable farm practices.

**Q: Will the amendments open the doors to imports that threaten public health?**

**A:** The Tester-Hagan amendments will improve the safety of our food supply, not hurt it. First, by protecting small, local food producers, the amendments encourage decentralized domestic production instead of reliance on imports. Second, the amendments will not weaken S. 510’s provisions on imports. The direct farm-to-consumer exemption simply will not apply to importers, who sell their products through long supply chains. The exemption for small-scale processors only applies to businesses that gross under \$500,000 annually, an amount that would not allow large-scale importers to qualify. Large

importers who purchase from small companies to consolidate business will still have to comply with the bill's requirements, including addressing any risks that may derive from their supplies. Moreover, the small business exemption only applies to the requirements of Sections 103 and 204, which involve developing written plans and keeping records. These paperwork requirements are not the primary or best means for addressing contaminated imported food. For companies importing their products into the U.S., the key public health protection will be on-site inspections and inspections at the border. Exempting small US farms and facilities from S. 510 allows FDA to use its limited resources on inspecting the large facilities (both domestic and foreign) that pose the greater risk to public health.

**Q: What is a facility? Why are the provisions in S. 510 regulating facilities problematic for small-scale food producers?**

**A:** In the Bioterrorism Act of 2002, Congress amended the Food, Drug and Cosmetics Act to broadly define a food "facility" with the objective of registering every food processor, domestic or foreign, that sells its product in the U.S. regardless of size, for national security purposes. S. 510 uses that same definition of "facility" for a completely different purpose.

Pursuant to the Bioterrorism Act, FDA adopted guidance on what is and is not a facility. In general, anyone who holds, manufactures, or processes food is a facility. The exceptions include:

- Farms are not facilities, as long as they do not process the crops they grow; if the farmer processes the crops in any way (such as by making jams, cheeses, dried fruits, or other value-added products), they are facilities.
- Residences are not facilities. (Most state public health laws do not permit the commercial sale of products from home kitchens, however.)
- Retail food establishments are not facilities. The guidance around this exemption appears designed to establish that bakeries, delicatessens, and restaurants do not fall under the Food Drug and Cosmetics Act. The House bill incorporates part of that guidance into the statute.

There appears to be several misconceptions about what constitutes a facility. Some people have incorrectly stated that a farm that sells its value added products directly is exempt; however, the FDA's guidance specifically states that the value-added products are only exempt if they are **consumed** on the farm. If the farmer leaves the farm and sells the jam or jelly at a farmers market, then his or her operation is deemed a facility.

In the period since the Bioterrorism Act was adopted in 2002, thousands of facilities have registered, but there are still thousands more who have not yet complied. All of these small businesses, many of them very tiny, will now be the targets of the FDA and responsible for the rigorous and expensive requirements of Sec. 103 and 204 of the Act. In the House-passed version of the Food Safety Enhancement Act (H.R. 2749) every one of these facilities will need to pay a \$500 annual registration fee to underwrite the enforcement of this sweeping new law.

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