S. 510 Food Safety Modernization Act

Healthy Local Foods Amendment – Sen. Jon Tester

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.

Sen. Jon Tester is offering an amendment 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 small Farmers Market vendors have to comply with the same regulations as larger farmers who sell to Dole or Del Monte or other large food processors?

A: When produce is sold to large companies in a long industrial food chain, 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, farmers market vendors sell small quantities of their products directly to consumers very shortly after harvest, making their products lower risk.

In addition, even with the proposed exemption to S. 510, farmers market vendors still must comply with the rules set forth by the market managers, state and local health officials. They also deal directly with their customers, who do not have to wonder where the product they are purchasing came from – so there is inherent transparency and traceability in Farmers Market transactions.

It is overreaching and inappropriate for the federal government to insert itself into this simple local business transaction. Even if the worst case scenario were to unfold, in which a dangerous food borne pathogen were to contaminate the product sold in a farmers market, it is well within the capacity of local and state health officials to remedy the situation and address the problem.

Q: Doesn't S. 510 provide numerous provisions to protect small businesses from complex, expensive, burdensome and inappropriate regulations?

A: In Sec. 103, "Hazard Analysis and Risk-Based Preventive Controls", the Secretary of Health and Human Services may exercise flexibility when developing the rules under this section of the Act. However, Sec. 103 contains a long list of highly prescriptive and specific requirements that contradict the "flexibility."

The prescriptive and mandatory steps in the Act include the following:

> *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.*

In Sec. 105, "Standards for Produce Safety," new FDA rules clearly apply to all produce sold in the United States, including the produce marketed directly to consumers by small farmers and gardeners in farmers markets. The bill's language says that the rules "shall provide sufficient flexibility to be applicable for small businesses and entities that sell directly to consumers and be appropriate to the scale and diversity of the production and harvesting of such commodities." This means that the FDA will be writing rules governing the farming and harvesting practices of the small farms and gardeners who sell their products in farmers markets and local restaurants featuring fresh local produce. Again, it is well within the authority of local and state governments to address any problems that might arise from the direct market sale of produce in farmers markets or the direct farm-to-school, farm-to-restaurant or farm-to-institution programs that are increasingly being promoted and celebrated around the country.

In Sec. 204, there is language to allow farms covered by Sec. 105 to rely on their normal business records showing immediate subsequent recipients. There is also language that states that the Secretary cannot prescribe specific technologies for the maintenance of records.

Sen. Tester's amendment is needed because it clearly defines a scale of production and marketing for farms that does not have to comply with FDA farming and harvesting rules in Sec. 105; and for facilities that does not have to meet the rigorous and specific, expensive and burdensome list mandated by Sec. 103 and the traceback and record keeping mandates of Sec. 204.

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

A: First, importers will not be able to qualify for the exemption for direct marketing farms because they do not sell directly to consumers. Second, with respect to the exemption for small-scale processors, the exemption only addresses 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., whether raw agricultural commodities or products coming from facilities, the key public health protection will be the on-site inspection and verification that the FDA can bring to bear on the facilities and farmers in other countries. For that reason, bringing thousands of small U.S. farms and small local facilities under FDA's jurisdiction is counter productive because it diverts scarce public resources away from facilities and farms in other countries that should be inspected to ensure public health.

Q: What is a facility?

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. The exceptions include:

- Farms are not facilities, unless they are adding value to their produce, in which case 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. In July 2009, the FDA reported the number of facilities registered by state and by country. (See http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/RegistrationofFoodFacilities/ucm175995.htm

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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