



The Food Safety Modernization Act 2013 News

In December 2010, Congress passed a food safety bill that significantly expands FDA's authority. The bill gives FDA mandatory recall power and directs the agency to inspect facilities at least every 5 years. But the bill does **not** to ensure that FDA will use that recall or inspection authority responsibly. The Act does not address the revolving door between the agency and industry, epitomized by Michael Taylor's current position as FDA's food czar following his work for Monsanto. Nor does it address the underlying causes of most foodborne illness, namely the industrialized agriculture production and processing systems. These fundamental flaws mean that the bill will most likely do very little to actually improve food safety.

The Tester-Hagan Amendment

The Farm and Ranch Freedom Alliance (FARFA) was one of the leading organizations working to protect local food producers from unnecessary and burdensome regulations. We succeeded in passing the Tester-Hagan amendment, which exempts small-scale local producers from the new burdens of hazard analysis plans (HACCP-type plans) and produce safety standards.

Even with the amendment, the bill poses problems for the local foods movement because of the new regulations on medium-scale producers and FDA's increased power to administratively detain food. But the amendment succeeded in carving out a sphere of protection for the most vulnerable small-scale businesses, keeping them alive to fight the next fight.

The Tester-Hagan amendment sets an important precedent: local food producers selling directly to consumers are different, and should be regulated differently, from the mainstream conventional food system. This is the first time this fact has been recognized by Congress. The importance of this precedent can be seen in Agribusiness' reaction; major industry organizations that had supported the food safety bill for over a year opposed it as soon as the Tester-Hagan amendment was included.

FDA's Proposed Rules

On January 16, 2013, the FDA issued proposed regulations to implement the major provisions of the Act. FARFA is coordinating with a coalition of organizations to analyze the proposed rules and develop sample comments for producers and consumers. Public comments are due by May 16, 2013, and we will have more information posted on our website by the end of February.

It is vital that local producers and supporters of local foods speak up during the comment period. Agribusiness' control of Congress and the agencies developed over the course of several decades, as more and more family farmers were lost to consolidation and consumers became more disconnected from the source of their food. It will take a lot of time and work for the local foods movement to reverse this trend.

For more information, visit www.FarmAndRanchFreedom.org
or call 254-697-2661

Frequently Asked Questions – see the back of this flyer

Disclaimer: These FAQs are NOT legal advice. The exact application of the Act in practice will be significantly impacted by the FDA's rulemaking process.

Q: I sell grass-fed beef/ grass-fed lamb/ pastured pork. Will I face new regulations under the Act?

A: No. The Act applies to FDA, not the USDA. Meats are regulated by USDA.

Q: I have a backyard garden where I grow food for myself and my family. Will I be regulated by FDA?

A: No. If you do not sell any food, you are not subject to the Act. [Note: FDA theoretically has power over even non-commercial activities, due to the Supreme Court's decision in *Wickard v Filburn*. But this Act does not apply to that level.]

Q: I grow and sell fruits and vegetables. What new regulations will I face?

A: If you do **not** qualify for the Tester-Hagan amendment, you will be subject to the produce safety standards that FDA will develop.

To determine if you qualify for the Tester-Hagan amendment, answer these questions:

1. Do you gross under \$500,000 annually from the sale of food products? (Note: the gross sales limit is averaged over three years, and will be adjusted for inflation)
2. If yes, do you sell more than half of your products to some combination of:
 - a. Individual consumers (regardless of where they are located);
 - b. Restaurants that are in the same state as your farm or within 275 miles of it; and/or
 - c. Retailers (such as co-ops, health food stores, and grocery stores) that are in the same state as your farm or within 275 miles of it.
 - i. Note: both the restaurants and the retailers must in turn sell directly to consumers. In other words, your farm is no more than 1 step removed from the consumer.
3. If you answered yes to both questions, you are exempt from the produce safety standards.

Q: I make value-added products such as jams, jellies, breads, cheeses, dried fruits, lacto-fermented vegetables. What new regulations will I face?

A: Answering this question requires a multi-step process

Step 1: Do you sell more than half your products directly to individual consumers? The sale can occur either at the same location where you make the food or through a farmers market, farm stand, or CSA. If yes, then you are a "retail food establishment." Retail food establishments do **not** have to register with the FDA **nor** are they subject to the new HACCP-type requirements. You still may face inspections by FDA if you engage in interstate commerce, as was the case even before the Act.

Step 2. If you are not a retail food establishment, the next question is whether you are a "qualified facility."

Answer questions 1 & 2 above, in the section on fruits & vegetables

- a. If the answer to both questions is "yes," then you are a "qualified facility." You still must register with the FDA due to the requirements of the 2002 Bioterrorism Act. But instead of having to do a HARCP (see next), you may instead provide (1) documentation showing you meet the elements for a qualified facility; and (2) proof that you comply with applicable state and local laws. This could include such things as your commercial kitchen or food handlers' license. If you choose, or if absolutely no local or state laws apply, then you must submit a simplified hazard analysis plan.

Step 3: If you are neither a retail food establishment nor a qualified facility, you will have to comply with the FDA's new regulations for **Hazard Analysis and Risk Control Plans (HARCP)**. You will have to develop a written analysis of known or reasonable hazards; identify and implement preventative control; establish alternative correct procedures; verify through documents, periodic monitoring and reanalysis; and keep records to document the monitoring, compliance, testing results, corrective action, efficacy. The HARCP is subject to FDA review and approval.