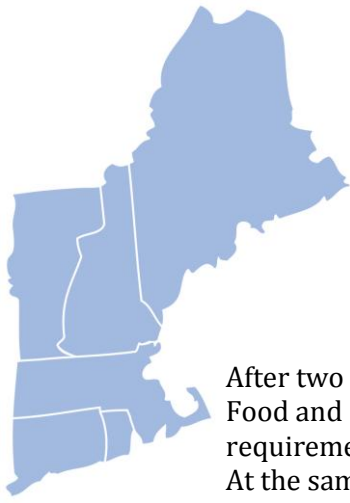


The Food Safety Modernization Act

What do the new laws mean for small farms and food producers?



After two years of wrangling, Congress has passed, and President Obama has signed into law, the Food and Drug Administration (FDA) Food Safety Modernization Act. The new laws impose a set of requirements on food producers, and grant broad powers to the FDA to enforce those requirements. At the same time, there are exemptions for many farms and small-scale food producers. The laws are very complex, and many of the details of how they will be enforced have yet to be worked out. This sheet is meant to serve as a general overview of the Act.

What new requirements does the Act impose?

- Food processing facilities must document a hazard analysis plan and preventative controls.
- The FDA has broad authority to demand access to records and to impose requirements for traceability for sales and inputs.
- The FDA has new authority to impose mandatory recalls.
- The FDA has new authority to oversee the testing and handling of imported foods.

The Bioterrorism Act of 2002 granted the FDA administrative detention authority over food items if there is credible evidence or information that indicates the food presents a threat of serious adverse health consequences or death to humans or animals. The new law broadens that authority, allowing for administrative detention based on 'reason to believe' that the food item has been 'misbranded or adulterated' and thus violates a legal standard for the product.

The Act imposes no new fees on producers. The law will not affect meat inspections or other U.S. Department of Agriculture (USDA)-inspected food products.

What about small farms?

At the last minute, before the Senate passed what would ultimately be the final version of the bill, an amendment was added to exempt small farms from many of the requirements. Co-sponsored by Sens. Jon Tester, D-Mont., and Kay Hagan, D-N.C., the amendment exempts farms from the new requirements if they meet two criteria:

- Less than \$500,000 in annual gross sales; and
- More than half of the product sold is sold to 'qualified end users,' defined as consumers and restaurants or retailers either in-state or within 275 miles of the farm or facility.

Farms meeting these criteria are exempt from the produce safety standard regulations and will not be subject to any new inspections. Facilities (food processors and manufacturers, including on-farm) meeting these criteria are exempt from the preventative control and hazard analysis requirements, but will still be required to undergo inspections under the new law. Such inspections will require that the operation demonstrate that it has identified potential hazards and is implementing preventive controls.

But if a farm is a 'retail food establishment,' meaning it sells more than half of its products directly to customers, the farm is also exempt from inspections, and the criteria requiring less than \$500,000 in gross annual sales does not have to be met. The Tester-Hagan amendment is somewhat more expansive, in that it says that such direct-to-consumer sales may occur on the farm itself, at a farmers' market, or at local stores or restaurants that purchase from the farm. Sales to distributors or wholesalers would not qualify as direct-to-consumer sales.





Some examples:

- If a farm grows fruits and/or vegetables and sells less than \$500,000 worth of food and more than half of it is sold to 'qualified end users,' that farm is exempt from the produce safety standard being drafted by the FDA. There is no registration or paperwork required.
- If a farm processes or manufactures food products on-site — and this can be anything from making maple syrup to cutting up vegetables to making preserves or baked goods — and more than half of those products are sold on the farm, at a farmers' market, or at another location controlled by the farm owners, directly to consumers, the farm is classified as a retail food establishment and is exempt from the new requirements.
- If a farm processes or manufactures food products and sells less than half of its products to individual consumers but more than half to a combination of those customers, local restaurants and stores, and the gross sales are less than \$500,000, the farm is still required to register with the FDA under the Bioterrorism Act of 2002 (which requires any facility that holds, stores, processes or manufactures foods to register with the FDA. Retail stores and restaurants are exempt from this requirement, as are farms that sell direct to consumers). The farm operators also must demonstrate that they have identified potential hazards and are implementing preventive controls, OR demonstrate to FDA that they are in compliance with state or local food safety laws plan.

The act grants the FDA the authority to withdraw any exemption if they deem it necessary: "In the event of an active investigation of a foodborne illness outbreak that is directly linked to a facility or farm exempted under this section, or if the Secretary determines that it is necessary to protect the public health and prevent or mitigate a foodborne illness outbreak based on conduct or conditions associated with a facility or farm that are material to the safety of food, the Secretary may withdraw the exemption provided to such facility under this section."

Other amendments to the law instruct the FDA to minimize the number of different standards that apply to separate foods, prohibit the FDA from requiring farms and other food facilities to hire outside consultants to write food safety plans, and establish a USDA-delivered competitive grant program for food safety training for farmers, small processors and wholesalers, with a priority for small- and mid-scale farms.

It is worth noting that the law is somewhat unclear on where the burden lies in claiming exemptions. There is nothing explicit that indicates that farms or facilities will have to file for exemptions and show proof in the form of a years' worth of records, but the advent of this law serves as a good reminder of how important comprehensive recordkeeping can be.

What's next?

Now that the Act is in place, the FDA must begin the rulemaking process to codify how they intend to enforce the new laws. Public comment periods are required during rulemaking, and it will be critical for farmers and friends of farmers to engage in this process to ensure that small farms are treated fairly. Even after the rulemaking process is complete, it will likely be some time before the FDA is fully equipped to enforce the new laws. The agency estimates that it will need at least 1,000 more inspectors and \$1.4 billion over the next five years, and it is not a certainty that Congress will appropriate such funds, given the current economic climate and calls for spending cuts and smaller government.

The addition of the Tester-Hagan amendment came about as a result of significant advocacy efforts from New England Farmers Union and many other organizations that are fighting to ensure that small farms are not over burdened with regulations intended to address foodborne illnesses caused by industrial-produced food. This victory is evidence of how important it is that we continue to stay engaged as the voice calling for policies that protect and strengthen family farms.

Action Items

- Join New England Farmers Union (NEFU) in order to stay informed about food safety and other issues. See www.newenglandfarmersunion.org for details.
- Review NEFU's policy on food safety and offer comments or suggestions. Our policy book can be found at newenglandfarmersunion.org/policybook.html
- Contact your state's department of agriculture to learn about food safety regulations in your state.
- Contact NEFU if you have questions or want to be a part of our effort to take action during the rulemaking process. Contact us at 413-625-3051 or info@newenglandfarmersunion.org.

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