



Implications of the 2011 FDA Food Safety Modernization Act on Direct Farm Marketers and Value-Added Producers

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Disclaimer

This publication is for educational purposes only and does not constitute legal advice nor is it intended to be a substitute for the services of a competent legal professional.

Changes in legislation and regulations can be common. The implications summarized here reflect an understanding of the legislation at the time of this publication's preparation. Additional details of this legislation will be forthcoming as regulations for the act are developed.

Introduction

The FDA Food Safety Modernization Act (FSMA) was signed into law on January 4, 2011 with the intent to modernize an outdated U.S. food safety system and issue a call for the government to improve its ability to decrease food-borne illness outbreaks. It pursues a food safety system that "is based on science and addresses hazards from farm to table."ⁱ The law provides the Food and Drug Administration (FDA) and the Secretary of Health and Human Services greater regulatory authority.ⁱⁱ

The FSMA will likely impact all players in the U.S. food industry, including farmers who market directly to consumers and value-added agriculture producers in various ways. This fact sheet provides a brief overview of some major points of the FSMA and their potential implications for direct farm marketers and value-added agriculture producers as understood based on information available at the time of publication.

A complete understanding of implications of the law is not known at this time. There are still steps that must be taken within the FDA before the FSMA can or will be implemented. Forthcoming regulations from the FDA will determine the specific guidelines by which food industry players will be required to meet the mandates of this new legislation. These regulations will be issued within two years after the act's passage, with some being issued in as soon as 180 days from passage. After the regulations are

written, there will be an additional period of time for food businesses to reach compliance.ⁱⁱⁱ Another area of uncertainty for the FSMA is the current U.S. federal budget situation. As of this publication, the budget for fiscal year 2011, including funding of the FSMA, was still being negotiated by Congress.

Regulations are often developed through a rulemaking process called “notice and comment.” This process allows for those stakeholders, including producers, who could be directly affected by a law to participate in public hearings and submit written comments relating to the law’s final regulations. Information and news about the comment period and public hearings may be obtained by monitoring the related FDA websites listed below.

The FDA maintains a website dedicated to the FSMA at
<http://www.fda.gov/Food/FoodSafety/FSMA/default.htm>

The full text of the act is available at
<http://www.gpo.gov/fdsys/pkg/PLAW-111publ353/pdf/PLAW-111publ353.pdf>

Some Major Points of the FSMA and Implications for Direct Farm Marketers and Value-Added Agriculture Producers

Direct farm marketers and value-added agriculture entrepreneurs are involved in the production, handling and distribution of food, and could thus be subject to the FSMA. This is largely due to these producers selling raw produce and/or food intended for consumption. With some exceptions, such as imported foods and seafood, the FSMA is not anticipated to have significant, direct effects on producers of commodity crops and meat animals for live sale.

1. Who will be affected by FSMA?

Most players in the U.S. food industry, including food manufacturers, processors and retailers, will be affected by the Food Safety Modernization Act. The act includes language that:

- Establishes mandatory preventive controls for food facilities and mandatory produce safety standards determined by science-based methodology^{iv}
- Addresses food safety issues for imported foods
- Increases the authority of the FDA to regulate food safety
- Improves collaboration across various government agencies for regulating and responding to food safety issues

Potential Implications for Farms and Direct Farm Marketers

Under the FSMA, food facilities (including some farms) could be subject to requirements to evaluate food safety hazards, implement and monitor possible sources of contamination, and establish a plan for corrective action.^v The act also gives the FDA the authority to:

- Establish standards regulating the safe production and harvest of fruits and vegetables
- Inspect food facilities for compliance to new regulations

“Food facilities” are referred within the act as those facilities manufacturing, processing, packing, receiving or holding food.^{vi} Although this definition could apply to many direct farm marketers, such as those manufacturing food products in on-farm kitchens, the language of the act also exempts many such producers from fulfilling the requirements of the act. It is currently unclear how rigorously this definition of food facilities will be applied to farms that may not meet the exception language.

2. Who may be exempted?

The FSMA provides for some exemptions to its requirements, including exemptions for some fruit and vegetable growers and value-added producers.

Fruit and Vegetable Growers

The Tester Amendment of the FSMA contains an “Exemption for Direct Farm Marketing” of produce crops.^{vii} Farms growing fruits and vegetables may be exempted from the FSMA if the farm meets **each** of these two conditions:

1. The majority of the farm’s entire income from food over a three-year period comes from direct marketing activities to qualified end-users; **and**
2. The average monetary value of all food sold is less than \$500,000 annually

“Qualified end-users” are defined as:

1. The food consumer, **OR**
2. A restaurant or retail food establishment that is
 - a. Located in the same state, or within 275 miles, of the farm or food facility **and**
 - b. Purchasing food for direct sale to the consumer

Value-Added Producers

“Value-added” producers are those who change or transform their farm products into a more valuable state. When applied to food crops, many value-added activities can result in producers operating a “food facility” that could fall under the regulation of the FDA as the result of the FSMA. However, there are also exemptions in the act that will apply to some value-added producers. These include:

- Facilities that are already in compliance with a HACCP (Hazard Analysis Critical Control Points) program. Facilities operating with a HACCP program often include those making juice/cider, low-acid foods and seafood products.
- Firms that are “Very Small Businesses.” The act specifies that small entities will be defined by the FDA within 180 days of the signing of the FSMA.

- A firm meeting the “Limited Annual Monetary Value of Sales.” Similar to the exemption language for fruit and vegetable growers, this exemption stipulates that the average annual sales during a three-year period prior to the calendar year must be:
 - greater for direct-marketed food products than for wholesale food products, **and**
 - less than \$500,000

Value-added producers who are “exempt” must still meet some minimum requirements of the act. Refer to question 4, “What will the FSMA require?” for details.

3. Who will not be exempted?

All fruit and vegetable farms and value-added producers failing to meet the exemptions of the FSMA will be responsible for meeting the requirements of the law. Two examples of operations that apparently will not meet the exemption language are:

1. Farms generating over \$500,000 in annual income from food (by definition, this includes animal food)
2. Farms selling produce to wholesale intermediaries (brokers, produce auctions, etc.)

This would seem to indicate that a farm selling more than \$500,000 in food crops (including row crops such as corn, soybeans and wheat) that is also direct marketing produce would be need to follow the requirements of the FSMA. Produce auctions, or other wholesale intermediaries, also appear to fail to meet the requirements of a “qualified end user.” Farms selling to such wholesale markets will apparently be required to meet the stipulations of the FSMA.

4. What will the FSMA require?

The FSMA will require food producers and/or manufacturers to develop food safety plans and provide written documentation of all potential hazards in their farms and/or facilities. These requirements include, but are not limited, to:

- Developing a written analysis of safety hazards in a food facility
- Identifying and implementing critical controls as defined by FDA
- Monitoring the food safety plan’s effectiveness
- Undertaking corrective actions in cases of safety failures
- Verifying that these measures have been taken through inspections including independent audits and/or testing by accredited laboratories
- Maintaining written records of all safety for a two-year period

The forthcoming regulations will provide specific guidelines for how all written records should be prepared. Recordkeeping requirements will be phased in over a period of time to ease the transition burden on food producers with special attention given to ease the burden on small food producers and

manufacturers. A specific compliance manual for small businesses will be made available six months after the FDA issues a final rule for recordkeeping requirements.

Requirements for “Exempt” Value-Added Producers

Although the FSMA language appears to exempt many value-added producers, those exempted producers must still provide one of two sets of documentation. Value-added producers must provide either:^{viii}

- Documents verifying that the facility is in compliance with all State, local, country, or other non-Federal food safety laws, OR
- Written documentation demonstrating that the “owner, operator, or agent in charge of the facility has identified potential hazards associated with the food being produced, is implementing preventive controls to address the hazards, and is monitoring the preventive controls to ensure that such controls are effective”^{ix}

Furthermore, the manufacturer/producer is required to provide an adequate label (including the name and business address where the food was manufactured and processed).^x

Current Recommendations for Direct Farm Marketers

Regulations will be published within the next two years that will stipulate exactly how the FSMA will affect farm marketers, value-added producers and others in the food industry. Some producers may decide to participate in the public notice and comment rulemaking process that occurs as the FSMA regulations are written. All producers may start proactive management decisions in preparation for the phase-in of this legislation. These decisions may include the following:

1. Review Operation’s Current Regulatory Compliance

Direct marketers and value-added producers are already subject to a range of licensing and regulatory requirements from local and state agencies. Producers should periodically review existing licenses to ensure that they continue to meet local and state requirements for their enterprise. Submission of such licenses and other documentation will apparently be required for exempted firms under the FSMA.

2. Incorporate Management Practices with Food Safety in Mind

All firms, including those meeting the exceptions of the legislation, should always keep food safety in the forefront as they make management, production and handling decisions. These decisions can help protect consumers from unsafe food and producers from potential liability.

3. Firms at Upper End of Sales Thresholds May Consider Compliance

A farm or food manufacturer whose business levels may currently be exempted under the various \$500,000 thresholds, but whose sales are growing, may wish to develop or begin developing the written documentation required by the FSMA. This could prove especially useful should the business grow to exceed the income threshold for exemption.

Summary

The Food Safety and Modernization Act (FSMA) is far-reaching legislation that will impact all stakeholders, including producers, in the U.S. food industry. Although certain parts of the act may exempt some direct farm marketers and value-added producers from meeting the act's requirements, the exact effects upon farms remain unknown until the regulations are written and the legislation is phased in when and if implementation is funded in the federal budget. In the meantime, producers should remain diligent about using practices that promote food safety while monitoring the ongoing developments of this legislation.

Additional Resources

The resources listed below provide additional information about the FSMA and food safety. The FDA websites provide information directly from the government about the FSMA and forthcoming regulations. Other websites provide information about food safety for producers from respected sources. Producers should always verify that guidelines or recommendations are appropriate for their situation and local regulatory environment.

Complete Text of Food Safety Modernization Act

<http://www.fda.gov/Food/FoodSafety/FSMA/default.htm>

FDA Food Safety FSMA Website

<http://www.fda.gov/Food/FoodSafety/FSMA/default.htm>.

The Ohio State University Produce Safety

<http://www.producesafety.osu.edu/>

Iowa State Food Safety Website

<http://www.extension.iastate.edu/foodsafety/>

ⁱ "Food Bill Aims to Improve Safety." FDA Consumer Health Information / U.S. Food and Drug Administration. <http://www.fda.gov/downloads/ForConsumers/ConsumerUpdates/UCM238166.pdf>, p. 1. Viewed March 7, 2011.

ⁱⁱ *FDA Food Safety Modernization Act*, Public Law 111-353, H.R. Res. 2751, 111th Cong. (January 4, 2011). Viewed March 7, 2011 at <http://www.gpo.gov/fdsys/pkg/PLAW-111publ353/pdf/PLAW-111publ353.pdf>.

ⁱⁱⁱ *FDA Food Safety Modernization Act*, "Flexibility for Small Businesses," 204(i), 124 STAT. 3937.

^{iv} FDA, <http://www.fda.gov/Food/FoodSafety/FSMA/ucm239907.htm>, "Prevention." Viewed April 30, 2011.

^v FDA, <http://www.fda.gov/Food/FoodSafety/FSMA/ucm237934.htm>.

^{vi} *FDA Food Safety Modernization Act*, "Registration of Food Facilities," Sec. 102, 124 STAT. 3887.

^{vii} *FDA Food Safety Modernization Act*, "Standards for Produce Safety," Sec. 419, 124 STAT. 3903.

^{viii} *FDA Food Safety Modernization Act*, "Hazard Analysis and Risk Based Preventative Controls," Sec. 418(l)(2), 124 STAT. 3892.

^{ix} *FDA Food Safety Modernization Act*, Sec. 418(l)(2)(B)(i), 124 STAT. 3893.

^x *FDA Food Safety Modernization Act, Sec. 418(l)(7)(A) 124 STAT. 3894-95. "...prominently and conspicuously display, at the point of purchase, the name and business address of the facility where the food was manufactured or processed, on a label, poster, sign, placard, or documents delivered contemporaneously with the food in the normal course of business, or, in the case of Internet sales, in an electronic notice."*

Programs in agriculture and natural resources, 4-H youth development, family and consumer sciences, and resource development
University of Tennessee Institute of Agriculture, U.S. Department of Agriculture and county governments cooperating.
UT Extension provides equal opportunities in programs and employment.