



## **Understanding and Commenting on the Food Safety Modernization Act Proposed Rules**

By Vern Grubinger, vegetable and berry specialist, University of Vermont Extension

For many years, foods that pose significant food safety risks if not properly handled have been highly regulated, including dairy, meat and seafood. Fruits and vegetables don't pose nearly as much risk, so growers have not had to deal with food safety regulations aimed at fresh produce. True, some growers voluntarily complied with GAP (Good Agricultural Practices) in order to satisfy their markets, but for the most part the industry was left to take common sense precautions to keep their products safe.

The situation has changed with passage of the Food Safety Modernization Act (FSMA) by Congress. Once implemented, this Federal law will require many growers to spend a lot of time and resources on risk prevention. Even those growers exempted from the law are likely to be affected because, over time, food buyers will want documentation of similar food safety practices from all the farms they deal with.

Rationale. According to the Centers for Disease Control and Prevention about 48 million Americans get sick and 3,000 die each year from foodborne diseases. However, very little of this is due to fresh produce. For example, from 1996 to 2010 there were 131 produce-related outbreaks resulting in 14,350 illnesses and 34 deaths. Thus, fresh produce accounts for about one percent of all foodborne disease-related deaths. While this is tragic and growers agree that more can be done to reduce food safety risks on their farms, it should be recognized that millions of pounds of fresh produce are consumed every day with hardly any problems. That said, FSMA is now the law and growers will have to deal with its requirements aimed at making a small risk even smaller.

The Law and the Rules. The FSMA law provides the framework for new food safety regulations, called rules. These get written after a law is passed, and they provide the specifics of how it will work. FSMA put the U.S. Food and Drug Administration (FDA) in charge of regulating food safety on produce farms, rather than the USDA which has typically regulated farm practices. To its credit, FDA has held many public sessions to gather input while writing the FSMA rules. The last chance for providing input ends on November 15, the deadline for written comments.

There are a variety of different rules associated with FSMA, but two in particular specify what will actually be required of growers. These are the 'Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption' (a.k.a the Produce Safety rule) and 'Preventive Controls for Human Food' (a.k.a. Preventative Controls rule).

Helpful sites. The draft rules are long and complicated documents, but there are many summaries available on line. A good place to start is the FDA's website:

<http://www.fda.gov/Food/GuidanceRegulation/FSMA/>.

The National Sustainable Agriculture Coalition has a site with summaries of the different sections of the rule: <http://sustainableagriculture.net/fsma/>, as does the University of New Hampshire Extension: <http://extension.unh.edu/Food-Safety-Modernization-Act-FSMA> , and The New England Farmers Union: <http://www.newenglandfarmersunion.org/food-safety-modernization-act/>.

Don't miss the deadline for comments. The deadline to submit comments to FDA on the draft FSMA rules has been extended twice, to November 15, 2013. After that FDA will finalize the rules; it will take a few years till they are implemented but you'll have to live with them. So don't delay; spend some time now to learn how the rules will affect your farm and then submit your comments on-line or by mail so that the FDA knows what growers are concerned about, and why.

Below are some key concepts about the proposed rule that you should understand. In addition, I have listed some specific concerns and suggestions. These are my personal opinions, not those of any organization I work for. Take some time to develop your own views on these issues.

Farm vs. facility. The Produce Safety rule applies to farms that grow, harvest, pack or hold what is termed 'covered' produce, which is produce that is usually consumed raw. Produce that is normally cooked is not covered under this rule. The Preventive Controls rule applies to facilities that manufacture, process, pack or hold human food. and those that buy and resell products grown on other farms. These facilities must register with the federal government. If you only grow, wash, and trim off outer leaves, and if you only sell products you grow, then you run a farm and the Preventative Controls rule does not apply to you. But if you peel, chop, combine ingredients -- or if you buy and resell products from another farm -- you run a facility or a mixed farm-facility and you may be subject to this rule.

Facilities have to keep a written food safety plan, including a hazard analysis and they will be required to keep records of preventive controls, monitoring, corrective actions, and verification. However, there is still some confusion about what activities make a farm into a facility (such as how much of a vegetable can be trimmed until it is considered cutting). Further, the scale of production that triggers the definition of a facility and various requirements is not yet set; exemptions up to \$25,000 or even \$500,000 have been suggested but the FDA has not decided.

Concern: Many farms buy-in and re-sell products from other farms, which is a mutually beneficial practice. Quite a few farms lightly process vegetables (cutting carrots, peeling winter squash) or do on-farm value-added processing (making cider, jams, pies, salsa, etc.). Even a minimal amount of additional paperwork will deter farms from engaging in these activities, which have been encouraged as ways to strengthen local food systems. Only farms that conduct these activities with large volumes of produce, over \$1 million of sales to wholesale markets, should be regulated as facilities. Buying fresh produce in clearly labeled containers from other farms that have their own food safety plan does not increase food safety risks enough to warrant the buying farm coming under the Preventative Control rule.

'Covered' produce is generally eaten raw, such as leafy greens, melons, tomatoes, etc. The Produce Safety rule does not apply to a long list of produce that is usually cooked, such as asparagus, beets, potatoes, pumpkins, sweet corn, winter squash, etc. It also does not apply to produce grown for personal consumption or consumption on the farm.

Concern: Buyers are not likely to distinguish between covered and non-covered produce, and will want to see evidence of food safety risk management on all farms they purchase from. Further, since most farms grow, harvest and pack a mixture of covered and non-covered produce these categories complicate the rule without providing significant regulatory relief to most farms. The rule requires careful separation of covered and non-covered produce. It would be a lot simpler for the marketplace, and for diversified farms, if FSMA simply applied to fresh produce.

Cost to growers. The FDA developed estimates for the cost of FSMA implementation. On farms with total food sales between \$25,000 and \$250,000 the cost may be about \$5,000 per year; on farms with food sales between \$250,000 and \$500,000 the cost may be about \$13,000 per year; on farms with food sales over \$500,000 the cost may be about \$30,000 per year.

Concern: these are large expenses for small and medium size farms, especially when you consider that food sales include ALL types of food, while the costs are incurred only for covered produce, which may be a just a fraction of a farm's total food sales. For example, a \$5,000 annual FSMA cost for a small wholesale vegetable farm with \$50,000 in sales is not appropriate or affordable. Many farms in my area gross just over \$500,000 in food sales, and their covered produce accounts for perhaps half of that. A ten or twenty or thirty thousand dollar hit will take a large part of their net revenues.

These high costs, in combination with the management burden of compliance, are likely to drive many small and medium growers out of the fresh produce business. It will be simpler to not grow fruits or vegetables, and just have a store that sells other farms' products. Even though many farms that sell retail or direct-to-retailers will be exempt from FSMA, they are likely to have similar costs if their customers, or insurance agents, demand analogous food safety documentation. These added costs will harm the ongoing development of local food systems that provide economic development, food security and access to fresh food for communities across the nation.

Key Parts of the Produce Safety Rule. In a nutshell, this rule establishes standards for:

**Agricultural Water:** farmers have to make sure that water likely to contact covered produce or food-contact surfaces is safe and of adequate sanitary quality, with water system inspection and periodic testing requirements.

**Biological Soil Amendments of Animal Origin:** The use of compost and manure is spelled out in terms of treatments to reduce pathogens, methods of application, and time intervals between application and crop harvest.

Domesticated and Wild Animals: Farmers must keep domestic animals out of produce handling areas and monitor for wildlife intrusion. They cannot harvest produce visibly contaminated with animal feces. After grazing domesticated animals a waiting period is needed before crop harvest.

Equipment, tools, and buildings: There are sanitary requirements for equipment and tools that come into contact with produce, and for building construction where produce is handled.

Health and Hygiene: Farm personnel have to follow hygienic practices, including hand washing, not working when sick, and maintaining personal cleanliness.

Training: Training is required for supervisors and farm personnel who handle covered produce.

Exemptions. Some farms will be exempt from the Produce Safety Rule. Those that don't grow any covered produce are exempt; for example, a sweet corn or a potato farm. Other farms are exempted based on their level of food sales – this is *total* food sales, not just covered produce sales. In other words, all human and animal foods including eggs, hay, meat, milk, pickles and all covered and non-covered fruits and vegetables. Farms that sell less than \$25,000 of all foods per year averaged over three years are not required to comply with this rule. Farms that sell between \$25,000 and \$500,000 of food are exempt only if over half of all their food sales are to direct to consumers, restaurants and certain retailers within 275 miles of the farm. These farms must still comply with certain labeling practices.

Concerns: There are numerous concerns with exemptions. First is the use of all food rather than covered produce as a basis for determining an exemption. This definition is in the FSMA law, not the draft rule, so FDA cannot change it, but you should let them know if you think it needs to be changed, and copy your federal legislators. This definition will create situations where farms that sell only a small amount of fresh produce will have to comply with the law. For example, a dairy farm that sells a lot of milk or a lot of hay, or a grower with a farm stand that sells a lot of sweet corn and pumpkins would be required to follow the rule even if they sell hardly any covered produce. Exemptions should be based on annual sales of (covered) produce only. Also, it is not clear how farmers working together in cooperatives or food hubs would be affected; this rule could deter farmers from working together to market their crops if it puts them over the threshold for exemption.

Concern: a system that lets some growers do nothing, and requires others to do more than necessary does not make sense. Food safety would be better protected by a simpler method of tiered compliance, as is used in many other areas of risk management regulation, from water supplies (home, community and municipal standards) to airplane safety (private, regional and commercial airline standards.) All farms should have a food safety plan, and for the vast majority of farms (which are small farms) this should be simple and highly practical. For example, all farm employees should wash their hands before handling produce and raw manure should not be applied on any farms without a reasonable delay before harvest.

Small farms could have a checklist-type of plan that assures they employ the most critical food safety practices. It's the largest farms that warrant a more complicated approach like that proposed in the draft rules. Large farms pose most of the fresh produce food safety risk given the volume of produce they sell and its wide geographic distribution. The smallest tier of farms, under \$100,000 in annual sales of fresh produce, should be required to have a simple food safety plan on file at the farm; farms from there up to \$1 million in sales of fresh produce should be regulated by state agencies that can provide them with locally-appropriate food safety plan templates such as those already developed by Cooperative Extension in some states.

Only farms selling a million dollars or more of fresh produce into wholesale food channels should be required to comply with FSMA. This is a much more realistic approach in terms of implementation cost and it will be much more effective in protecting food safety since it would help all growers identify and act on the most important food safety risks on their farms, rather than tying them up with recordkeeping. This approach will also assure that the effort required, and cost, is proportional to the risk. Further, it will provide assurance to buyers that all growers have a food safety plan.

Agricultural Water is water that's intended to contact covered produce. It includes water used for overhead irrigation, crop sprays and for washing, wetting or icing during harvesting, packing and holding. Water that does not have potential to come in direct contact with covered produce is not subject to this rule, including subsurface drip irrigation water. Agricultural water from streams, lakes, rivers, must be tested at least every seven days for generic E. coli; it cannot be used if the average of 5 samples exceeds 126 colony forming units (CFU) per 100 ml water or if 1 sample is above 235 CFU.

Concerns: the testing requirements for surface waters are unreasonable. Testing every week is excessive especially many weeks in advance of harvest, when food safety risk is low; testing should only be required when risks are higher, as when irrigating two or three weeks prior to harvest, unless research proves more time is needed. Constant testing is expensive and existing surface water data from recreational water monitoring programs shows that E. coli levels are erratic from week to week over a season and often higher than the allowed levels for irrigation. Rather than prohibit overhead irrigation when E. coli levels exceed the threshold, the focus should be on the period immediately before harvest as most E. coli will die off after exposure to the elements. Drip irrigation water does not require testing but it is not practical on large acreages, and there is no practical method of sanitizing the large volumes of water needed for overhead irrigation.

Agricultural water must be potable (zero coliforms) at the start of produce washing, but it is not clear if this is required throughout the washing procedure. Wash water contacts produce directly just prior to packing and sale; it can create a cross contamination risk if one piece of produce has pathogens on it. There is no easy way to test wash water as it is being used, however, my on-farm research suggests that double or triple washing is very effective in reducing E.coli levels in wash water, and so is the use of commercially available sanitizer (conventional as well as organically-allowed products.) While the rule requires growers to have a schedule of water changing, there should also be a requirement to suppress microbial populations in wash water, using either multiple rinses or the addition of sanitizer.

**Biological Soil Amendments.** The draft rule does not regulate chemical soil additives or those of non-animal origin. Untreated soil amendments of animal origin (e.g. manure) must be applied so they do not contact covered produce during application, and after application there is a 9 month waiting period to harvest. Composting can be used to treat manure so it can be applied with only a 45 day waiting period until harvest (so long as it does not contact produce). Composting includes static systems that maintain aerobic conditions at 131 °F for 3 days followed by curing, or turned systems that maintains aerobic conditions at a minimum of 131 °F for 15 days, with at least five turnings, followed by curing. Recordkeeping of compost measurements is required and a certificate of conformance is necessary for compost producers.

**Concerns:** A 9-month wait from spreading manure to crop harvest is not practical. This would require manure application in the fall of the year before harvest, a practice that has long been discouraged since it can lead to loss of nitrogen and poses a threat to water quality. The current manure management standards in both GAP and the National Organic Program are workable and provide a reasonable wait of 120 days from manure applications to harvest. A 45-day wait until harvest after compost application conflicts with the National Organic Program standards which doesn't require any waiting period.

**Domestic and Wild Animals.** The proposed rule requires risk- prevention measures if there is a reasonable probability that animals will contaminate covered produce. For example, if animal intrusion occurs in a field, a farmer must not harvest produce that is visibly contaminated by animal feces or urine (duh!). The rule does not require animal fencing. Evidence of animal intrusion includes observing significant quantities of animals, animal feces, or crop destruction due to grazing. If domestic animals are grazed in a field, then an "adequate waiting period" is needed between grazing and harvest. The rule does not specify a length of time but the preamble to the rule states that FDA would expect the waiting period to exceed nine months (which is the same interval proposed between the application of raw manure and harvest).

**Concerns:** this section does not pose serious concerns. However, the waiting period to harvest produce after grazing ruminants should be no more than 120 days, as suggested for manure. For pigs a longer period is warranted. This would allow flexible use of fields for integrated livestock and crop production while still reducing risk. Recordkeeping regarding monitoring of wildlife intrusions could be burdensome.

**Personnel.** The rule requires permanent as well as temporary, part time, seasonal and contracted personnel who handle covered produce, and their supervisors, to receive training appropriate to the person's duties. Training occurs upon hiring, at the beginning of each growing season (if applicable), and periodically thereafter. A trainer on the farm staff must go through a certified program in order to train other farm employees.

**Concerns:** It is not clear exactly how much training is necessary. On farms with many employees of different types that come and go during the season, providing multiple trainings could be a significant expense. Having a trainer on staff is impractical for small farms with limited full-time personnel, and it is not clear where or how these people would be trained.

Health and Hygiene Training. Everyone must wash their hands, and must stay home if they are ill. Workers may not go to the bathroom in the fields. This is reasonable.

Equipment, Tools and Buildings. This section of the rule requires that equipment and tools be kept reasonably clean and that buildings be constructed so that floors, walls, ceilings, fixtures, ducts, and pipes can be adequately cleaned and kept in good repair. Steps should be taken to prevent contamination of covered produce, food-contact surfaces, or packing materials in covered produce processing and storage areas. This is reasonable, except if greenhouses and high tunnels are considered buildings.

Recordkeeping. The proposed rule establishes both general recordkeeping, and specific recordkeeping requirements to show compliance. General recordkeeping includes: name and location of the farm; values and observations collected during monitoring activities; description of the produce applicable to the record (crop, variety, or other identifier such as a lot number); location of the growing area; and date and time that an activity was performed or observed. Records must be taken at the time an activity is performed or observed, and must be dated and signed by the person doing the activity. Records to show compliance with the standards in the rule include documentation of: Personnel qualifications and training; agricultural water; manure and compost; equipment, tools, buildings, and sanitation. Actions taken when a standard is not met must also be documented and a supervisor or responsible party must sign records documenting testing, monitoring, sanitizing, and corrective actions.

Concerns: this is an inordinate amount of recordkeeping for small and medium size farms. It will place an unfair financial and management burden on them compared to larger farms that can better afford to assign or hire someone to focus on recordkeeping.

Submitting comments to FDA. It's a good idea to start with a brief description of your farm or your role working with farmers, and what you have already been doing to reduce food safety risks. Then describe the areas of the rule that would affect your farm and what you think the consequences would be for your business. Offer concrete suggestions and estimates of time and cost involved if you can. Comments on the two proposed rules must be submitted separately. You can use the same introduction but be sure to cite specific parts of each rule when describing concerns or suggestion.

Here's how to submit comments to the FDA online:

For the Produce Safety rule:

<http://www.regulations.gov/#!submitComment;D=FDA-2011-N-0921-0199>

For the Preventive Controls rule

<http://www.regulations.gov/#!submitComment;D=FDA-2011-N-0920-0188>

If submitting on-line, write your comments ahead of time and save them on your computer. There is a time limit when using the Federal Register System, and you don't want to lose what you've written. If your comment is less than one page, you can copy and paste it into the comment box. If it is longer, write 'see attached' in the box and upload a separate Word or PDF file with your comments. Be sure to click the 'submit' button! You should then see a new screen with a confirmation number.

To submit comments by mail, send them to: Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852. Include the docket number in your comments: Produce Rule is FDA-2011-N-0921 and the Facilities Rule is FDA-2011-N-0920. Mailed comments must arrive by the deadline so send them a week ahead just to be sure.

9-5-13