



November 15, 2013

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, rm. 1061
Rockville, MD 20852

RE: Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption (FDA-2011-N-0921); and Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls For Human Food (FDA-2011-N-0920)

Dear Sir or Madam:

National Farmers Union (NFU) welcomes the opportunity to submit comments to the Food and Drug Administration (FDA) on implementation of the Food Safety Modernization Act (FSMA). Since 1902, NFU has advocated for the economic and social well-being and quality of life of family farmers and their communities through the sustainable production of food, fiber, feed and fuel.

NFU supported passage of FSMA, the first major overhaul of food safety legislation in more than 70 years. Our grassroots policy states that "it is imperative that we maintain the high quality of our food supply." Seeking to strengthen the trust consumers place in family farmers to produce reliably safe food, NFU works diligently to enact laws and regulations to protect that reputation and quality. NFU appreciates that FSMA moves the food safety system from reaction to prevention and places a greater emphasis on eliminating risk factors throughout the food chain. For far too long, FDA has not had the same degree of control over its jurisdiction as its sister agency does, the U.S. Department of Agriculture's (USDA) Food Safety and Inspection Service. Thanks to FSMA, FDA is now afforded greater authority to access records, mandate recalls, control imports through foreign supplier verification, and expedite review and entry for food products from qualified importers. FSMA also recognizes that small- to medium-sized farms provide unique benefits and should be allowed flexibility in how to best attain food safety standards. These are welcome objectives and NFU is grateful for the improvements included in FSMA. It is now a matter of establishing regulations to effectively achieve these goals without overreacting to recent outbreaks of foodborne illness in such a way that jeopardizes the livelihoods of family farmers.

Two of the pending rules for FSMA, the Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption (Produce Rule) and the Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls For Human Food (Preventive Controls Rule) have attracted the most attention from our family farmer members.

Definition of a Farm

Our very first concern with both rules stems from the definition of a farm. In the proposed rules, the definition used is drawn from the Bioterrorism Act of 2002, which defines farms as part of an exemption from the Act. This definition is not especially relevant to modern farming practices. The definition of a farm, as found in the FDA publication, “What You Need to Know About Registration of Food Facilities, (November 2003)” reads as:

“Facilities in one general location devoted to growing and harvesting crops (washing, trimming outer leaves, and cooling produce are part of harvesting) and/or raising animals (including seafood). The term ‘farm’ also includes facilities that manufacture/process, pack, or hold food, provided that all food used in those activities is grown, raised, or consumed on that farm or another farm under the same ownership.”

There are many instances of community-supported agriculture (CSA) farms that aggregate produce from other farms to provide their members with a steady variety and supply of fruits and vegetables. Food hubs, which have been promoted by USDA and other federal agencies as good examples of new marketing arrangements for farmers, could also be subject to these regulations. Many activities traditionally conducted on farms may now be considered an operation that will subject a farm to the restrictions of the Preventive Controls rule. Rather than work from an earlier definition of a farm, NFU suggests a more appropriate starting point to delineate what qualifies as a farm. FDA should clarify how the FSMA rules will impact farmer-owned cooperatives and other entities that provide marketing or other services to their members. Greater clarity should also be provided regarding the treatment under the rules of food hubs, CSAs that include more than one farm, and other aggregators. Furthermore, FDA should provide guidance about whether and when a farm that aggregates the produce of others for retail, including farm stands and CSA shares, will be subject to the Preventive Control Rules.

Exemptions

The twelve different exemptions contained in the Preventive Controls rule provide some degree of relief for lower-risk and smaller-scale producers. NFU appreciates the language in the rule that exempts facilities with less than an average of \$500,000 in sales annually, even though these facilities must notify FDA and be subject to a different set of still-burdensome requirements. Even if farms are exempted from the Preventive Controls rule, they may still need to register under the Bioterrorism Act. Including the sales of produce and commodities not covered by FSMA in the exemption calculations will penalize, rather than foster, diversified farming operations.

Many farms that also operate a processing facility will be classified as a farm mixed-type facility, which have their own exemptions from preventive controls. The list of low-risk food and activity combinations that qualify for an exemption from the Preventive Controls rule is very specific, and any deviation from that prescriptive list will result in that farm mixed-type facility being held to full compliance with the rule. NFU asks that greater flexibility be allowed in these exemptions, as many family farmers’ finances will

already be stretched thin in order to comply with the new food safety rules. FDA should be judicious in calculating gross sales figures and count only produce or food products covered by FSMA regulations.

Agricultural Water and Soil Amendments

When speaking with our members, some of the most frequently heard areas of concern with the Produce Rule are the standards for agricultural water and the corresponding testing requirements. The variety of agricultural water classifications in the rule—ranging from irrigation, to spraying, to washing, along with the various testing requirements based on water source—could be very onerous. Basing these requirements on Environmental Protection Agency standards for recreational water is not a relevant figure for the water that contacts produce throughout the growing season. If produce farmers are required to intensively test their water sources – up to once every 7 days for a river or lake – they will incur significant costs that will not be easily borne. We ask that these testing frequencies and water quality requirements be reconsidered and based upon realistic levels that are consistent with typical agriculture production methods.

Restrictions on biological soil amendments of animal origin, based on waiting periods described in the rule, will be problematic as currently written. While NFU appreciates that even more intensive requirements on non-biological soil amendments were not included in the rules, we are concerned by the potential incentive to increase farmers' dependence on petroleum-based fertilizers. We also feel there are significant problems with the minimum application intervals. Most notably, a 45-day interval between the application of a treated, animal origin soil amendment and harvest is more restrictive than the existing National Organic Program (NOP) regulations. Standards similar to NOP guidelines should be adopted for the next version of FSMA rules. Additionally, pasturing animals on fallow fields during the off-season for produce will be nearly impossible for some farmers. Beyond simply reducing the non-application interval, NFU suggests additional consideration for the effects of freezing temperatures on soil amendments.

Variations and Alternative Compliance Methods

Under the FSMA rules, farmers are allowed to establish alternatives for testing and other food safety considerations, with the understanding that “adequate scientific data” proves that the alternative will “provide the same level of public health protection” as the prescribed methods. State food safety agencies may also receive a variance for inspection of produce if it varies from the methods listed in the Preventive Controls rule, so long as the new method functions appropriately. How these alternative risk-prevention techniques will be evaluated is unknown, as FDA has not yet released the risk model it used to determine application intervals for biological soil amendments and water quality requirements. Credible, peer-reviewed scientific information to corroborate the rationale behind the rules must be disclosed so that consumers will have confidence in FSMA, alternative compliance arrangements can be made, and other requirements in the rule can be fully evaluated and understood.

Second Comment Period

As with any large-scale rulemaking process, the implementation of FSMA is likely to encounter many more unintended consequences. This is to be expected and is understandable. Because of the scope and breadth of the rules, especially the Produce and Preventive Controls rules, NFU urges the issuance of a second draft of the proposed rules and opening a corresponding comment period. We have heard that FDA officials have acknowledged there may well be major revisions to the proposed rules on water testing, biological soil amendments, and perhaps the definition of food as it applies to certain exemptions. Further research will be necessary in order to assess the impact of any changes to the current draft of the rule, and farmers must be able to respond with suggestions to ensure smooth implementation of the law. A second comment period for both the Produce and Preventive Controls rules could allow for comparison with the Foreign Supplier Verification Program and Accreditation of Third-Party Auditors rule, thereby improving interactions between them. Great care must be taken when finalizing regulations of this scale, and because of the importance of FSMA to the future of American agriculture, a set of revised rules should be published and made available for comments from stakeholders.

Conclusion

NFU policy states that, “programs that encourage sustainable agriculture through diversified production, improved marketing strategies, and enhanced value-added opportunities can be keys to reversing (the decline in the number of family-sized commercial farms).” Much of the recent growth in family farms has come from small- to medium-sized produce farms. While FSMA is a well-intentioned and important evolution of our food safety system, we ask that the aforementioned comments be considered before proceeding further in the rulemaking process, in the hopes that improvements to consumer confidence in the food supply not come at the expense of family farm agriculture.

Sincerely,



Roger Johnson
President