November 11, 2013

Attention: United States Food and Drug Administration

RE: Preventative Controls Rule: FDA-2011-N-0920, Produce Standards Rule: FDA-2011-N-0921

Thank you for accepting comments on the draft Food Safety Modernization Act (FSMA). The Michigan Farmers Market Association is a statewide, member-based association located in East Lansing, Michigan. Our mission is to advance farmers markets to create a thriving marketplace for local food and farm products. We have been in existence since 2006 and work to support and represent Michigan farmers and farmers markets. We believe in short food supply chains that promote transparency and minimize risk through the reduction in handling, storage, and transportation.

We are writing today to ask for risk-based regulations that acknowledge the inherently lower risk of diversified, regional markets. Our association's leadership is concerned about the impact FDA's proposed FSMA rules will have on our members and more broadly Michigan farmers and farmers markets. Please ensure that new regulations do not put safe farmers out of business; harm farmers' soil, water and wildlife conservation efforts; or diminish the growth of healthy regional food systems.

At the same time, we are glad to see that the proposed rules take an integrated, instead of a commodity-specific approach. We believe that this approach acknowledges the importance of diversified farming systems – it's a good decision that should be retained!

Below we will describe the specific issues we have identified with the current draft. We urge you, the FDA, to publish a second draft of the rules for public comment before finalizing the produce safety and preventative controls regulations. The issues we are specifically concerned about are:

1. The Preventative Controls Rule fails to clarify that farmers markets, roadside stands, Community Supported Agriculture (CSA), and other direct farmer-to-consumer farms are not facilities subject to regulations for food facilities, despite clear instructions from Congress to do so (see Public Law 111-353: FDA Food Safety Modernization Act, 2011). Please clearly state in the second draft that farmers markets are **not** manufacturing facilities. In the Preventative Controls Rule farmers markets and farmers market vendors should fall under the definition of a retail food establishment and not as a facility that must register with FDA.

2. The rules as currently written do not treat farmers fairly. As proposed, FDA has broad authority to take away the exemptions and modified requirements certain farmers and facilities are eligible for and subject them to the full weight of the regulations if FDA thinks there may be a food safety problem on the farm. However, the rules do not require FDA to have proof of a problem, and there is no defined way to get that status back once FDA revokes it. We suggest that the second draft include a robust and fair regulatory framework for the qualified exemptions and modified requirements. FDA should specifically: (1) define "material conditions" as scientifically measurable traits that can be clearly identified in individual cases, and never by conjecture be applied to a whole class of persons, types of operations, or broad description of food being produced; (2) require credible and substantial evidence to justify a withdrawal of an exemption or modified requirement; and (3) establish a clear and fair process for reinstituting a farm or facility's status if that operation has had their exemption or modified requirement withdrawn.

3. In the current draft, FDA proposed three options for the definition of a "very small business." The definition that is finally adopted must be based on the product covered by FSMA and not the gross sales of all food, even products that are not processed. We also believe that FDA should adopt the $1,000,000 threshold for a very small business. This would focus the full regulations on big businesses that produce the vast majority of covered farm and food products, while focusing modified requirements on farms and businesses that represent the majority of producers but only the minority of product in the food supply.

4. Even though not all food produced on farms is subject to the proposed regulations, the current draft indicates everything produced on a farm counts when determining whether a farm is eligible for exemptions and modified regulations. Please clarify in the second draft that only crops covered by FSMA count towards the income eligibility test for modified requirements through the Tester-Hagan provisions, the exemption from the Produce Rule for farms grossing less than $25,000 and in the definition of "very small business."

5. We believe the list of low-risk, value-added products in the current draft is too narrow. Farmers adding value to their crops through low-risk value-added processing should not be subject to the same regulations as high-risk processing activities by large corporations. The rules should be comprehensive and include activities like acidifying, pickling and fermenting low-acid fruits and vegetables made in compliance with Good Manufacturing Practices; baking activities involving grain products; roasting grains for animal feed; extracting oils from seeds; extracting virgin olive oil; making molasses from sugarcane and sugar beets; and making syrups from sorghum, rice and malted barley.

6. The current draft regulations will create many barriers for farmers using manure or compost. In addition, the proposed standards are in direct contradiction with established federal National Organic Program (NOP) standards. The next draft of the FSMA produce safety rules should support, not conflict with, NOP. Three specific changes need to be made: (1) the interval between application of untreated manure and harvest should be four months, not nine as currently proposed; (2) there should be no interval between application and harvest for compost if the compost is treated consistently with NOP or similarly rigorous composting standards; and

(3) insulation of compost should not be required as part of an acceptable treatment process for compost.

7. The current FSMA draft requires excessive water testing on farms. Costly, burdensome, and unscientific standards for irrigation water should be removed from the next draft. FDA must take a reasonable, risk-based approach to agricultural water that allows farmers to respond to site-specific risks in their water systems. We specifically believe that: (1) FDA should not require weekly water testing, (2) FDA should not encourage the treatment of irrigation water with synthetic chemicals, and (3) FDA should include numerical thresholds in more flexible guidance documents after sufficient research indicates appropriate numerical standards by region; these numbers should not be in included in the FSMA rules.

8. The proposed Produce Rule should explicitly protect conservation practices that protect water, soil and wildlife habitat. FDA should state support for sustainable conservation practices in the final regulations and should prohibit the destruction of conservation practices as a condition of complying with food safety rules. We suggest that the FDA conduct a full Environmental Impact Statement to incorporate into the next draft of proposed rules.

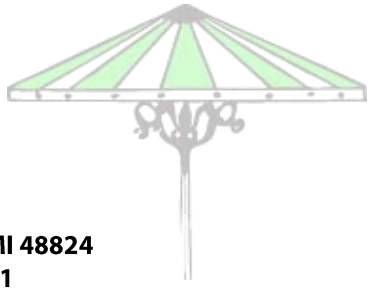
9. The cost of compliance will be substantial for farmers and will put an unfair burden on small farms. We are alarmed by your anticipation that farmers will go out of business, fewer people will start to farm, and more farmers will seek off-farm jobs to continue farming (see FDA Analysis of Economic Impacts – Standards for the Growing, Harvesting, Packing, and Holding of Product for Human Consumption, pages 313-314). The rule's requirements are too costly. FDA must find ways to decrease the costs of compliance with the new rules, especially for small and very small farms.

10. Ultimately, the successful implementation of the proposed FSMA rules will require extensive support by FDA in the form of outreach and education to regulatory staff at the federal, state, and local levels; agricultural support organizations; farmers and consumers. FDA must have a funding mechanism in place for this purpose.

On behalf of the Michigan Farmers Market Association, thank you for your careful consideration of our comments.

Sincerely,

Dru Montri, Ph.D.
Director
dru@mifma.org



480 Wilson Road, Room 172, East Lansing, MI 48824
Ph: (517) 432-3381 Fx: (517) 353-7961
www.mifma.org