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SUBMITTED ELECTRONICALLY

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Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

**Docket No. FDA-2011-N-0920; Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food**

**Docket No. FDA-2011-N-0921; Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption**

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On behalf of the members of the Iowa Farmers Union (IFU), thank you for the opportunity to submit written comments to the Food and Drug Administration (FDA), regarding the proposed implementing rules for the Food Safety Modernization Act (FSMA):

- Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food (Preventive Controls Rule); and
- Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption (Produce Standards Rule).

Since 1915, IFU members have worked together to strengthen the independent family farm and to provide lowans with sustainable production, safe food, a clean environment and healthy communities. Our farm families operate farms ranging from less than 2 acres to more than 2,000 acres, producing a diverse array of agricultural products, including corn, soybeans, small grains, livestock, dairy, fruits and vegetables, organic and specialty crops, and value-added agricultural goods.

Our members share a strong commitment to producing safe, high quality, sustainably produced food for consumers. For all of our farmers, and in particular those that sell directly to consumers, business reputation and economic success depend on the actual and perceived integrity of the food system and consumer trust and confidence in the food that they purchase for their families. We generally are supportive of FSMA as an important tool for modernizing and improving our system of food safety oversight and strengthening consumer confidence in the food that our family farms produce.

At the same time, we recognize that much of the economic opportunity for small- to mid-scale family farms and beginning farmers currently comes from diversified, small scale production and the retail model of agriculture that allows farmers to sell directly to consumers via community support agriculture (CSA) shares, farmers markets, road side stands, local food cooperatives, food hubs that aggregate products for sale in local and regional markets, as well as a variety of on-farm value-added

ventures. This model of agriculture allows family farmers to succeed in a climate of historically high land prices, costly inputs, and price volatility for conventional commodities. Diversified, small- to mid-scale retail farms also contribute to a diverse and healthy food supply, improved ecological health, and more economically vibrant rural communities.

We greatly appreciate the revisions that the FDA already has made to both proposed rules in light of public comments submitted in 2013, but additional changes are required in order to preserve the economic viability of the small- to mid-scale retail farming model that is so crucial to the overall success of our current generation of family farms. The final Preventive Control and Produce Standards Rules need to strike the appropriate balance between achieving important benchmarks for food safety without jeopardizing the economic viability of family farms or reversing the development and growth of local and regional food systems.

## **GENERAL COMMENTS**

The following comments are generally applicable to both the proposed Preventive Controls Rule and the proposed Produce Standards Rule.

### **Definition of “Farm”**

Whether and how the proposed rules apply to a business depends in part on whether the business qualifies as a “farm” or a “facility.” We support a definition of “farm” in the final rules that allows genuine farm operators to carry out growing, harvesting, packing and holding activities that facilitate and add value to the farm business - without opening loopholes for non-farm packing and processing enterprises. The difference between “farm” and “facility” should be based on risk-based distinctions with a clear connection to food safety. Including a requirement for contiguity in the definition of “farm” is not a risk-based distinction, and should not be included in the definition in the final rules. It is very common for farms of all sizes to be located on non-contiguous parcels of land. Even in the case of very small operations, the current system of land tenure - high land prices, high levels of competition to rent or purchase available land, fewer parcels with homesteads and outbuildings - frequently forces farmers to piece together a farm by renting or purchasing a small parcel here, a small parcel there, and the end result will be a patchwork of land in multiple locations. Defining a farm as being in “one general physical location” is not realistic for the current generation of farms.

The final rules also should clarify that CSA farms, farmers markets and other farmer-owned direct-to-consumer enterprises fall under the definition of “retail food establishment” and are not “facilities for the purposes of these rules.

### **All Food vs. Covered Food**

Whether and how the proposed rules apply to a business also depends in part on a calculation of sales. The proposed rules calculate sales in different ways in different parts of the rules - based on all food sales, based on produce sales, based on human food sales - without creating a single, consistent standard. The final rules should calculate sales using a clear and consistent standard is risk-based and clearly connected to food safety. In particular, we propose that regulatory thresholds in both rules should be based on sales of the regulated product or products. For the Preventive Controls Rule, this would mean calculating sales based on total sales of “covered human food”; for the Produce Standards Rule, this would mean calculating sales based on total sales of “covered produce.” This is particularly

important for retail farms that rely on a diversified farming model as a basis for economic viability and risk mitigation. For example, if a diversified farm has a small organic dairy herd, as well as several acres of fruits and vegetables, that farm would have fairly high sales from the dairy portion of the operation, while having perhaps only modest sales from the fruit and vegetable portion of the operation. The presence of the dairy cows does not impact the safety of the fruit and vegetable operation, and vice versa. If a stand-alone fruit and vegetable operation of the same size would not be regulated, an identical fruit and vegetable operation should not come under regulation merely because the farmer also owns a dairy herd, or has several hundred acres in commodity production, or other income sources that do not impact the overall safety of the covered food products.

## **PREVENTIVE CONTROLS RULE**

### **Supplier Verification Program**

The proposed Preventive Controls Rule includes a supplier verification program that would require an annual on-site third-party audit “when a hazard in a raw material or ingredient will be controlled by the supplier and is one for which there is a reasonable probability that exposure to the hazard will result in serious adverse health consequences or death to humans.” This program would essentially require on-farm third-party audits for all farms selling produce destined for a covered manufacturing or processing facility and contradicts language in FSMA that expressly bars the FDA from requiring these types of third-party audits. The Supplier Verification Program, and the requirement for on-site audits, should be struck from the final rule.

### **Compliance Costs**

The costs of complying with the proposed environmental and product testing requirements are substantial and will be especially burdensome for independently owned small-scale growers and processors. Inevitably, these costs will force some farmers and food facilities out of business, prevent beginners from entering farming, and force farmers to support their farm businesses by taking on extra jobs to supplement income. Many of these small farming operations may be relatively healthy in terms of equity and net worth, but not in terms of cash flow. There is not a lot of wiggle room to remain in business while complying with expensive new regulations that may exceed \$28,000 per year in costs. To the extent that proposed standards for environmental and product testing create inflexible requirements for farms and food facilities, the FDA should identify ways to maximize flexibility and lessen the cost burden of compliance for small and very small farms that are not positioned to easily absorb significant new costs. One way to achieve this would be to include environmental and product testing standards in guidance for public comment, rather than in the regulations

## **PRODUCE STANDARDS RULE**

### **Agricultural Water**

The proposed Produce Standards Rule includes costly, non-science-based standards for testing and treatment of agricultural water. While we appreciate that agricultural water used prior to, during or after harvest may pose a food safety risk to some crops, farmers should not be required to comply with testing and treating protocols that created undue financial burdens without reasonable contributing to increases in food safety. Some precautions related to water quality are reasonable. For example,

farmers can reasonably take responsibility for agricultural water under their control to prevent contamination from sources also under the farmers' control: trash, debris, animal waste, etc. A farmer can control how and when water is used on certain crops, including how and when water is applied in relation to timing of harvest and/or sale to the consumer. However, many small- to mid-sized retail farms in Iowa would be overly burdened by the frequent testing, treatment protocols and numeric standards contained in the proposed rule. Iowa is home to a diverse array of farm types, and some sectors of Iowa agriculture are a significant source of contamination for the state's watersheds. It would be inequitable and economically unfeasible to ask a 5-acre fruit and vegetable operation to bear the regulatory cost of pollution being dumped into Iowa waterways by industrial-scale animal confinements and other major sources of water pollution that are ubiquitous across the state. In the final Produce Standards Rule, the FDA should:

- Reduce the required frequency of testing, as the current proposal is overly burdensome and without scientific justification;
- Align testing requirements to USDA Good Agricultural Practices (GAPs) standards, limiting testing to three (3) samples per growing season;
- Provide farmers with increased flexibility to determine the number of tests needed to establish the baseline and water quality profile of a water source, particularly where a consistently impaired water source is outside the farmer's control, or where the water source is consistently in compliance with the proposed standard;
- Allow farmers to rely on credible, existing sources of water quality monitor data, in lieu of conducting separate tests at the farmer's expense; and
- Defer setting numerical water quality standards until the FDA has completed a full risk assessment for agricultural water, and implement standards through flexible guidance that contains a mechanism to re-adjust periodically to reflect new science or new data.

## **Manure and Compost**

We greatly appreciate the FDA's adjustments to the proposed rules for manure and compost from animal origins in response to public comments filed for the 2013 proposed rules. In particular, aligning requirements with National Organic Program (NOP) guidelines for the use of treated compost is an important step in the right direction. We also appreciate that the FDA has chosen to defer guidelines for the application of raw manure until a full risk assessment has been completed. Both of these changes are critical to creating a risk- and science-based framework for the use of biological soil amendments, a common and important component of many organic and diversified horticultural farms. As the FDA moves forward with its risk assessment of raw manure and promoting increased use of compost, the sustainable agriculture and organic communities must be fully engaged in process. We support:

- Including representatives from the sustainable agriculture and organic communities on advisory bodies overseeing the process and science of the risk assessment;
- Aligning standards with current best management practices in order to encourage increased use of compost, including removing any requirement that compost must be insulated; and
- Allowing farmers to continue to follow NOP standards for raw manure application until such time as a risk assessment is completed, a new standard is proposed, and the FDA has allowed for an adequate public comment period on the new standard.

Whatever standard is identified for the application of raw manure, the final rules should not discourage on-farm animal grazing by treating it like manure application. Grazing animals on cover crops or other field cover in the off-season is a common, environmentally beneficial practice. It does not carry the

same risk factors as raw manure application, and a nine month interval between grazing and harvest is neither reasonable nor necessary.

## **CONCLUSION**

Family farms and diversified small- to mid-scale retail farms that rely on direct consumer relationships and value-added enterprises are essential to ensuring the diversity, health and security of our nation's food supply. While our farmer members fully support FSMA's underlying principle of crafting a food safety framework that preserves and strengthens consumer safety and confidence, we also feel strongly that maintaining the health and viability of the family farms at the center of a safe food supply should be of paramount concern. If the final rules put in place to implement FSMA drive family farmers out of business or prevent new family farms from making a successful start, the ultimate goal of creating a safe and secure food supply will only be undermined. We appreciate the progress made by the FDA in response to the original public comment period in 2013, and we hope that by taking into full account the input from local food consumers and the farming community in the second comment period, the final rules will reflect a common-sense balance that both promotes food safety and protects the family farms that form the vital core of a safe and healthy system of food production.

Thank you for your consideration of these comments.

Sincerely,

A handwritten signature in black ink, appearing to read 'J.M. Linderman', with a long horizontal flourish extending to the right.

Jana M. Linderman  
President