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Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm 1061
Rockville, MD 20582

Docket No. FDA-2011-N-0921, RIN 0910-AG35, Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption

Docket No. FDA-2011-N-0920, RIN 0910-AG36, Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food

Dear Sir or Madam:

Iowa Farmers Union (IFU) submits the following comments on two of the proposed rules implementing the Food Safety Modernization Act (FSMA): the proposed rule for Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption (Produce Rule) and the proposed rule for Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food (Preventive Controls Rule).

Since 1915, IFU members have worked together to strengthen the independent family farm through education, legislation and cooperation and to provide Iowans with sustainable production, safe food, a clean environment and healthy communities. Our membership includes hundreds of family farmers and ranchers from across the state of Iowa, as well as consumer members who value family farm agriculture and who support the mission of IFU.

Our farmer members represent a diversity of farm types: conventional row crops, small grains, hay and forage crops, livestock, dairy, fruits and vegetables, organic and direct market farms that sell directly to consumers. A large percentage of our beginning farmers, as well as a number of our more established farmers, rely on the retail model of agriculture that allows them to sell directly to consumers via community supported agriculture (CSA) shares, farmers markets, roadside stands, and farmer cooperatives and food hubs that aggregate products from a number of farms for sale on the local market. Retail agriculture allows farmers to make a living on a smaller number of acres, with a labor-intensive operation and relatively low input and equipment costs. This business model is crucial to the continued economic viability of family farms, particularly new farms, in an environment of historically high land prices and rising equipment and input costs. At the same time, consumers have placed increasing value on

knowing where food comes from and the details of the farming operation that produced it. Retail agriculture and the development of local and regional food systems have forged new connections between consumers and farmers, increased the basic knowledge of agriculture among urban consumers and introduced a renewed sense of community to our food system.

IFU grassroots policy strongly supports maintaining the safety of our food supply, and “safe food” is included as part of our organizational mission statement. For all of our farmer members, and in particular those with farms that sell directly to consumers, business reputation and economic success depend on the integrity of the food system and consumer trust and confidence in the food that they eat. We support FSMA as an important tool for overhauling an outdated system of food safety oversight and strengthening consumer confidence in the food that our farmers produce. We also appreciate that FSMA recognizes the value of small- to mid-sized farms and provides for flexibility in how best to attain high standards of food safety while continuing to support and grow family farms and local and regional food systems. The rules to implement FSMA need to be crafted to effectively achieve important benchmarks of food safety without jeopardizing the economic viability of family farms or reversing the development and growth of the local and regional food systems.

PRODUCE RULE

The \$25,000 gross sales exemption from the Produce Rule should be calculated based solely on sales of covered produce, rather than sales of all food.

The proposed Produce Rule would exempt farms with an average annual monetary value of \$25,000 or less of food sold during the previous three-year period. We support this exemption and agree that the small farms eligible for this exemption represent a tiny fraction of the overall food supply and should not be regulated under the Produce Rule. However, for the purpose of determining eligibility for the exemption, gross sales should be calculated based solely on the sales of produce covered by the Produce Rule and should not include the sales of other food not covered by the Produce Rule.

In our experience working with our members, it is fairly common for a beginning farmer trying to build an operation, or a conventional commodity farmer trying to diversify or transition an operation, to combine several types of cropping systems into one farm. For example, we have members who primarily grow corn and soybeans, while devoting several acres of farmland to fruit and vegetable production. This is a common model to diversify the income stream of the farm, to support a transition to organic production, or to provide a means of bringing a second generation into the family farming operation. The total gross annual sales from this type of farm in a given year easily would exceed \$25,000, even while the total gross sales of produce covered by the Produce Rule would fall well below the \$25,000 threshold. Despite the difference in total farm revenue, the food safety profile of the corn-soybean-vegetable farm, and the volume of covered produce finding its way into the food supply, is not materially different from that of a much smaller farm growing *only* a few acres of fruit and vegetables. Including the sales of non-covered food in the calculation of gross sales does not materially

enhance the food safety and risk mitigation goals of the Produce Rule. Therefore, gross sales should be calculated based solely on the sales of produce covered by the rule.

Standards for agricultural water proposed in the Produce Rule do not have an adequate scientific basis, place an undue economic burden on small- to mid-sized fruit and vegetable farms, and should be significantly revised.

The proposed Produce Rule would mandate that farms covered by the rule conduct weekly testing of surface water and monthly testing of ground water to ensure that all water used in the farming operation meets the Environmental Protection Agency (EPA) standard for recreational water, and to stop using or to chemically treat water that fails to meet the standard. We oppose adopting the EPA recreational water standard for agricultural water, as well as the onerous testing and treatment requirements of the proposed rule.

The proposed rule fails to offer an adequate scientific basis for adopting the EPA recreational water standard as a necessary measure to maintain food safety. The EPA recreational water standard was developed based on studies of the risk of gastrointestinal illness in humans exposed to marine or freshwater during swimming. The FDA now proposes to simply transfer this standard to agricultural water in the absence of any more appropriate standards. Without adequate scientific evidence or quantitative risk assessment specific to agricultural water and the risk of food-borne illness related to agricultural water, the FDA has no statutory authority to mandate the kind of prescriptive requirements now proposed. A relevant and adequate body of scientific evidence should pre-date attempts to impose inflexible numerical standards and expensive testing and treatment requirements for agricultural water.

The proposed testing requirements would impose an unreasonable financial burden on our members. Many of our farmers operating small- to mid-sized fruit and vegetable farms rely on multiple sources of surface and groundwater to service multiple sites within the same farming operation. The costs of either weekly or monthly testing for each of those sources could easily amount to thousands of dollars per farm per growing season and would be financially unsustainable for many of our farmers.

It is also important to understand that the EPA recreational water standard would be, in practice, completely unworkable for many Iowa farms. With watersheds across Iowa inundated by agricultural runoff, many sources of surface water in the state currently are rated for most or all of the growing season as unsuitable for recreational purposes. Having already incurred the expense of frequent water testing, many Iowa farms would then face the additional expense of either losing one or more sources of water altogether, or paying to have the water treated. Despite the fact that many of our fruit and vegetable farmers have long relied on and made regular use of this surface water in their operations, Iowa has not experienced related outbreaks of food-borne illness.

Even where adequate treatment options exist that are legal, technologically and economically feasible, and not prohibited by a farm's organic or other certification – all of which are

important obstacles to note – farmers engaged in local retail agriculture who are required to add chemical treatments to on-farm water sources will suffer damage to their business reputation with urban consumers who place high value on sustainable production practices. Farms that sell produce locally via CSA shares, farmers markets, farmer cooperatives or food hubs typically make available to consumers detailed information about the type of practices used in the farming operation, in particular the use of any synthetic chemicals or fertilizers that may come in contact with the produce. The consumers that our farmers deal with and rely on for their market share are highly likely to object to produce soaked in chemically treated water, as well as the environmental and public health consequences of adding more farm chemicals to the watershed. Consumers often support local food systems specifically to avoid those types of harmful impacts to the ecosystem from our system of food production.

In reality, the safety of food exposed to agricultural water depends on a variety of factors, including the type of water source, climate and weather conditions, timing and method of application, the type of produce involved and a variety of other factors. All of these factors should be accounted for in the rule to provide small- to mid-sized farms with the flexibility they need to operate and stay in business. A uniformly applicable numerical standard is neither practicable nor merited. The rule suggests that farmers could propose alternative regimes for testing and treatment, provided there is an adequate supporting body of scientific evidence to show that the alternative would maintain the same level of safety in the food supply. Given that the proposed rule itself fails to set forth an adequate scientific basis for the standard being proposed, it would be unreasonable and inequitable to shift the burden of proof to individual farmers. If this rule goes into effect as written, many of our beginning farmers and small- to mid-sized fruit and vegetable farms would be out of business before anyone could demonstrate a more reasonable set of standards or more cost effective alternatives.

Standards for biological soil amendments proposed in the Produce Rule conflict with the rules for the National Organic Program (NOP), are not feasible for many of Iowa’s organic and sustainably operated fruit and vegetable farms, and should be revised to comply with NOP standards and practices.

The proposed Produce Rule requires minimum intervals between the application of biological soil amendments and the harvest of produce, where there has been no contact with the produce during application and minimized potential for contact with the produce after application. For untreated soil amendments such as raw manure, the proposed interval is nine months, and for compost handled according to standards specified in the rule, the proposed interval is 45 days. The proposed rule would not require a waiting interval for soil amendments that have been treated with heat or chemicals.

In contrast, the National Organic Program (NOP) rules allow the application of raw manure as little as four months prior to harvest if the edible portions of the crop come into direct contact with the soil and three months if the edible portions of the crop do not come into direct contact with the soil. NOP rules do not require any interval between the application of compost and harvest, where the compost is handled consistent with NOP standards, and regardless of

whether edible portions of the crop come into contact with the soil. Iowa ranks 5th in the nation in total number of certified organic farms. NOP standards are well understood by our organic fruit and vegetable farmers, as well as many fruit and vegetable farmers who have chosen not to undergo the time and expense of organic certification but who nevertheless want to comply with certain sustainable production practices, such as refraining from the use of synthetic chemicals and fertilizers. Iowa has not experienced incidents of food-borne illness related to soil amendment practices that comply with NOP standards, and there is no evidentiary basis that a more stringent set of standards is necessary or would provide a measurable benefit in terms of increased food safety.

A nine-month interval between the application of raw manure and harvest is not a feasible standard for the Iowa farms that would be covered by this rule. Harvest season for the typical direct market fruit and vegetable farm in Iowa extends from early May through late October, with the potential to extend the outdoor growing season via high tunnels. Even for fall-harvested crops, the proposed rule would preclude spring application of raw manure for any crops to be harvested during the same calendar year. In the case of fall application of raw manure, the proposed rule would not permit harvest until near the end of the following summer, even where there is only minimal potential for contact with either edible or non-edible portions of the crop. To be clear, raw manure and other organic soil amendments get incorporated into the soil at the time of application, and growing crops typically would have no chance to come directly into contact with unincorporated raw manure. Depending on weather conditions and the date of the first frost, fall application is not always an available option in Iowa. The most likely outcome of the proposed rule would be to either force land out of production for an entire growing season to allow for manure application or to force farms to stop using raw manure as a source of organic fertilizer.

Similarly, the most common practice for applying compost as organic fertilizer would involve early spring application, depending on weather conditions and the dates of ground thaw and snow melt, with first harvests of produce occurring at the beginning of May. As a general rule, farmers do not apply fertilizer until snow has melted and the ground has dried out enough to ensure that nutrients will not run off or leach down into the water table. Even a 45-day interval would interfere with this schedule for application and harvest, and NOP standards do not require any interval between the application of properly prepared compost and harvest. The proposed rule also differs from NOP compost standards by requiring several months of “curing” or insulation of the compost prior to application, adding significantly to the time, expense and labor involved in using compost as a source of organic fertilizer.

The preferred practice for any type of fertilizer would be to time the application as close as possible to the period of active nutrient uptake by crops. Increasing the intervals from NOP requirements necessarily increases the amount of phosphorus and nitrogen leaching into the water table or running off of fields. Nutrient pollution has been identified as a serious environmental problem for Iowa watersheds. An unnecessarily long waiting interval for the application of organic fertilizer under the proposed rule would actively undermine current

efforts by the EPA and the State of Iowa to reduce nitrogen and phosphorus pollution in Iowa's waterways.

As with the proposed standard for agricultural water, it is not helpful to suggest that farmers could propose alternative science-based requirements for biological soil amendments. Given that the proposed rule itself fails to adequately explain either the scientific need or the statutory authority for deviating from existing NOP standards, it is wholly unreasonable to ask farmers to expend their own resources re-establishing the reasonableness and adequacy of NOP practices. The FDA should re-think this portion of the proposed rule and consider adopting the NOP standards that are already well understood and being effectively implemented by our farmers. The primary result of implementing the rule as proposed would be to remove organic fertilizer as a viable option for many small- to mid-sized fruit and vegetable farms and to push those farms toward less sustainable production practices and non-compliance with their organic certification.

PREVENTIVE CONTROLS RULE

The final Preventive Controls Rule should adopt a “very small business” threshold of at least \$1,000,000 in covered product.

The proposed Preventive Controls Rule has laid out three options for the definition of “very small business”:

1. a business that has less than \$250,000 in total annual sales of food, adjusted for inflation;
2. a business that has less than \$500,000 in total annual sales of food, adjusted for inflation; or
3. a business that has less than \$1,000,000 in total annual sales of food, adjusted for inflation.

Any facility meeting the definition of “very small business” would qualify for modified requirements under the rule and would be altogether exempt from the rule if the facility engages only in certain “low-risk” processing activities.

The primary concern of our members in establishing the higher \$1,000,000 threshold for a “very small business” is to limit the impact on “farm mixed-type” facilities that might otherwise fall under the full regulatory requirements of the Preventive Controls Rule. For our farmers who sell directly to consumers, operations more often than not will incorporate one or more low-risk, value-added processing component such as cooking and canning jams, jellies and preserves, making honey or fruit-based syrup or producing baked goods from grain grown on the farm. This type of low-risk valued-added processing activity is essential to the direct-to-consumer business model that allows these types of farms to be economically viable and can easily grow to be the largest portion of the farm's income stream. At the same time, facilities falling within the \$1,000,000 threshold account for less than 2 percent of all food produced in the United States.

Setting the threshold at \$1,000,000 in sales of *covered product* would also support the viability and flexibility of both new farms and established farms trying to diversify by incorporating a value-added processing component, while continuing to rely primarily on revenue from sales of food not covered by the proposed rule. It would be quite possible for this type of combined farming operation to exceed the \$1,000,000 threshold for total food sales, while having a significantly smaller dollar amount in sales of covered product. Sales of food not covered by the proposed rule would not materially contribute to raising the farm's risk profile and should not be used to calculate eligibility for the exemption.

The Preventive Controls Rule is designed to focus primarily on high-risk industrial food processing facilities. Setting the "very small business" threshold at \$1,000,000 in annual sales of covered product would help to maintain that focus and not place unnecessary compliance burdens on small- to mid-sized farms that make money through value-added processing.

The final Preventive Controls Rule should expand the list of low-risk on-farm processing activities and provide flexibility for future inclusion of new low-risk activities not contemplated at the time the rule was finalized.

The proposed Preventive Controls Rule includes a list of "low-risk" processing activities that smaller facilities, including farm mixed-type facilities, could engage in without being subject to the requirements of the rule. The items on the list are defined with a great deal of specificity, and the rule does not appear to allow for any deviation from the list. While some low-risk processing activities clearly are missing and should be added to the list in any final rule (producing baked goods from grain, extracting oil from seeds, pickling and fermenting low-acid fruits and vegetables), the list should not be conceived as a comprehensive, exhaustive enumeration of what activities qualify as "low risk" under the rule. Rather, the rule should set forth a general definition for what constitutes a low risk processing activity, followed by an illustrative list of sample activities that fall within the definition.

We are concerned that under the currently proposed formulation, a final rule would inevitably miss some common low risk processing activities and unfairly subject an otherwise exempt farm-facility to the full requirements of the rule. However, a larger concern is that small- to mid-sized direct market farms rely heavily on entrepreneurial innovation, creativity and timely response to consumer demand. We could conduct a detailed poll of all our members, with a one hundred percent response rate, and use the data to create a comprehensive draft list of all the processing activities currently taking place on direct market farms in Iowa. However, this list would be different if we drafted it a year from now, two years from now or five years from now. In an evolving local food economy, on-farm practices are developing and changing every day with every new farm, and the rules should be crafted to recognize and allow for that flexibility.

GENERAL COMMENTS

Both the proposed Produce Rule and the proposed Preventive Controls Rule fail to define “farm” in a way that accurately reflects contemporary farming practices, particularly in the context of retail agriculture and local food economies.

The proposed Produce Rule and the proposed Preventive Controls Rule rely on an outdated and incomplete definition of “farm” drawn from the Bioterrorism Act of 2002 (quoting the 2003 FDA publication “What You Need to Know About Registering Food Facilities”):

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.

This definition is problematic in a variety of ways, particularly in the context of retail agriculture and local food economies. Our farmer members who grow food for the local market on a small number of acres understand that in order for small direct market farms to succeed, farmers must be cooperative as well as competitive. For example, farms often purchase food from neighboring farms to meet an order after an unexpected frost or sudden failure of the heating system in a greenhouse. Farms cooperate in transporting food to the point of purchase. Farms cooperate in collecting and boxing food for a CSA distribution. Farmer cooperatives and food hubs are premised on facilities being able to aggregate produce from a number of farms for sale and distribution to consumers at a central location.

In many of these instances, ownership of the food does not pass out of the hands of the original grower until reaching the hands of the consumer. However, the successful distribution and marketing of the food requires the participation of multiple farm owners, and sometimes a central, cooperatively owned facility. Two local food cooperatives in Iowa allow consumer-members to purchase food on-line directly from farmer-members; the co-op processes the transaction and co-op members organize the distribution, but ownership of the food passes directly from farmer to consumer. These types of arrangements and facilities are necessary components of local food systems that are providing expanded economic opportunities to family farmers while meeting increased consumer demand for locally sourced food.

Any final rules need to recognize that actual farming practices, particularly for small- to mid-sized farms, require a great deal of cooperative action among farms. The definition of “farm” should reflect that reality and allow for the types of practices that direct market farms and local food systems need to develop and to succeed.

The scope and magnitude of both the Produce Rule and the Preventive Controls Rule warrant promulgation of a second proposed rule and comment period.

Recognizing that any large-scale rulemaking process will uncover many unintended consequences during the implementation process, IFU urges the issuance of a second draft of the proposed Produce and Preventive Control Rules that takes into account the thousands of comments that have been submitted and that allows for a corresponding comment period. Particularly in the event that there are major revisions to the standards for agricultural water and biological soil amendments proposed under the Produce Rule, or to any of the other requirements in the proposed rules, our members and other stakeholders must be allowed the opportunity to review and respond to the changes in order to ensure the fair and effective implementation of the law. The FDA must exercise great care in finalizing regulations of this magnitude, particularly in light of the potential major impacts to the viability of family farms, local and regional food economies, and our system of food production in general.

CONCLUSION

As a grassroots farm organization dedicated to preserve and promote family farm agriculture, we recognize that much of the recent growth in our membership has come from small- to mid-sized family farms that depend on retail agriculture, organic and sustainable production, value-added on-farm processing and vibrant local and regional food systems. While we support the goals of FSMA in strengthening and maintaining the safety and integrity of our food system, we also place a high value on maintaining the economic viability of family farm agriculture and the local and regional food systems that play an increasingly important role in the success of our farmer members. We hope that the preceding comments will be considered in any final rulemaking, in the hopes that a well-founded push for modernizing food safety does not come at the expense of family farmers and consumer access to locally and sustainably produced food.

Sincerely,

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

Jana Linderman
President