



To: Division of Dockets Management (HFA-305), Food and Drug Administration

Re: Preventive Controls Rule: FDA-2011-N-0920, Produce Standards Rule: FDA-2011-N-0921

**“Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food” and “Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption.”**

Date: November 11, 2013

The Institute for Agriculture and Trade Policy (IATP) is a nonprofit, 501(c)(3) nongovernmental organization, headquartered in Minneapolis, Minnesota, with an office in Washington, D.C. Our mission states, **“The Institute for Agriculture and Trade Policy works locally and globally at the intersection of policy and practice to ensure fair and sustainable food, farm and trade systems.”** To carry out this mission, IATP engages in research and advocacy activities.

With over 25 years of experience in the fields of agriculture and trade, IATP has significant experience working with food producers, processors, distributors, retailers and consumers on a variety of scales. This experience has afforded the organization an appreciation of the impact—both positive and negative—Food and Drug Administration (FDA) policy and regulation can have on efforts to maintain a fair and sustainable food and agriculture system. As such, we are **concerned about the impact that FDA’s proposed Food Safety Modernization Act (FSMA) rules** will have on family farmers, sustainable and organic farming practices, and the availability of fresh, local food within all communities.

IATP encourages the FDA to review the new regulations and ensure that they do not create undue, unfair or unnecessary burdens for family farms and the facilities that support them. While we have long championed approaches that encourage a safe and wholesome food supply, we feel that the policies and regulations to ensure farm-to-fork safety **must use a “precision” approach** that is appropriate to application **rather than the “general application” approach outlined in the proposed Rules**. Such a general approach may pose impediments to on-farm conservation, protection of wildlife and organic farming practices; unfairly target local food and limits opportunities for farmers; lack due process and raise costs for farmers and consumers. With **“precision” regulations and requirements that are tailored to different types and sizes of operations**, we can achieve a flexible food safety system that is fair for everyone.

Specifically, our concerns with the proposed Rules and our suggested changes are as follows:

- Produce Standards Rule: FDA-2011-N-0921
  - The proposed Produce Standards Rule standards for the use of manure and compost create undue waiting period barriers for the use of such natural, sustainable fertilizers, despite the fact that this is adequately regulated by established federal organic standards, thus encouraging the increased use of

chemical, unsustainable fertilizers that create human and ecological health concerns. *These standards for manure and compost must be aligned with the National Organic Program (NOP) regulations, i.e., the interval between application of untreated manure and harvest should not exceed the interval required by NOP; the interval requirement between application and harvest for compost treated consistently with NOP or other approved composting standards should be removed as there is no food safety risk associated with compost; and the requirement that insulation of compost be included in any acceptable treatment process for compost should also be removed.*

- The proposed Produce Standards Rule does not protect or encourage on-farm conservation practices aimed at protecting soil, water and/or wildlife habitat and places unnecessary restrictions on the proven best practices of grazing livestock into farm fields. Such practices have benefit for agricultural and ecological services vital for long-term viability. Without explicit protection, conservation and integration practices—despite being safely managed by and of benefit to the producer—are discouraged by default and vulnerable to forceful removal. *The proposed Produce Standards Rule should incorporate stronger, explicit support for on-farm conservation that supports food safety as well as natural resource and wildlife habitat protection. Specifically, the FDA should: explicitly support on-farm conservation efforts and explicitly prohibit their destruction as a condition of compliance with food safety rules; include requirements in the Produce Rule to train on-farm personnel on how conservation practices support food safety goals; not treat grazing like manure application, nor restrict grazing through unrealistic intervals; and should conduct a full Environmental Impact Statement for the purpose of incorporating the findings into the proposed rules.*
- The proposed Produce Standards Rule places unfair and scientifically unjustified standards for irrigation water that have a significant financial impact on producers in the form of water testing and treatment requirements. The frequency of weekly water testing, the indicators of generic *E. coli* pathogen presence, and remediation requirement for up-stream pollutants are unfair, not supported by science and unachievable, creating an unnecessary burden on small-to-medium scale producers. *The proposed Produce Standards Rule should be amended to take a reasonable, risk-based approach to agricultural water that enables farmers to manage risks in their own water systems. Specifically, the FDA should: only include region-appropriate numerical thresholds for presence of pathogens or pathogen indicators with the backing of significant research findings; remove the requirement for weekly water testing and replace it with a requirement for producers to collect monthly baseline information about their water systems in the first growing season and to base future actions and testing frequencies on those results; and should not encourage or allow the treatment of irrigation water with chemicals, as such chemicals pose persistent human and ecological health concerns.*
- Preventive Controls Rule: FDA-2011-N-0920
  - The proposed Preventative Controls Rule unfairly treats farmers adding value to their crops through low-risk processing under the same regulations as high-risk processors. While the initial list of low-risk value-added processing activities is a good start, it must be expanded as to not unfairly and inappropriately target certain activities considered low-risk by many states. *The FDA should expand the*

*list of low-risk value-added processing activities in the proposed Rule to include: acidifying, pickling, and fermenting low-acid fruits and vegetables made in compliance with existing Good Manufacturing Practices; baking activities involving grain products; roasting grains for animal feed; extracting oils for seeds; extracting virgin olive oil; making molasses from sugarcane and sugar beets; and making syrups from sorghum, rice and malted barley.*

- The proposed Preventative Controls Rule does not clarify that Community Supported Agriculture (CSAs) and other direct-to-consumer businesses are not facilities subject to regulations for food facilities. This unfairly subjects these entities to regulations designed for industrial food facilities when they engage in light processing **or include another farm's produce in their CSA shares.** *The FDA should clarify that CSAs, roadside stands and other direct-to-consumer vendors fall under the definition of a "retail food establishment" and are not facilities that must register with FDA and, therefore, are not subject to the Preventive Controls Rule.*
- The proposed Preventative Controls Rule **does not establish a definition for "very small businesses"** and this lack of definition exposes a large number of already vulnerable operations, including farms, to regulations and related costs designed for large, industrial food manufacturers. *The FDA should adopt a higher threshold of at least \$1,000,000 in gross sales for a "very small business" definition and ensure that this threshold is based on regulated product value of a single "very small business," rather than the value of all food produced by that entity.*
- Both Produce Standards Rule: FDA-2011-N-0921 & Preventive Controls Rule: FDA-2011-N-0920
  - The proposed Produce Standards Rule and the Preventative Controls Rule make it difficult for mid-size farms, particular commodity producers, to diversify their production due to the way that the rules value farm production in relation to exemptions and modified regulations. By valuing everything produced (including commodity crops) on a mid-size farm when determining exemptions and modified regulations that must be applied to only a small portion of a diversified production (such as fresh fruit and vegetable production), producers are forced to comply with disproportionately high regulation for a small level of diversified production and are thus discouraged from diversifying their production long term. *The FDA should count the value of only the regulated product or produce and not all food when determining if the farm or facility is eligible for the modified requirements through the Tester-Hagan provisions. Further, an exemption from the Produce Rule should be provided for farms grossing less than \$25,000 and this should also be included in the definition of "very small businesses" in the Preventative Controls Rule.*
  - The proposed Produce Standards Rule and the Preventative Controls Rule provide the FDA with the power to treat family farmers and on-farm processors unfairly, without due process, and subject them to excessive costs. This authority to take away farm and facility exemptions and modified requirements without a burden of proof of problem, or process for reinstatement of revoked status reduces farm viability and raises costs for farmers and consumers. *The FDA should provide a fair regulatory framework for the qualified exemptions, specifically defining*

*“material conditions” as scientifically measurable and identifiable traits assessed on a case-by-case basis. These conditions must be backed by credible and substantial evidence to justify a withdrawal and there should be a fair and established process for reinstating a farm or facility’s status if that operation has had their exemption or modified requirement withdrawn.*

- The excessive compliance costs throughout the proposed Produce Standards Rule and the Preventative Controls Rule put a substantial and unfair burden on smaller growers, resulting in a loss of farm operations, diminished uptake of professional farming and increased dependence upon off-farm income sources. *The FDA should decrease the cost of compliance with the new rules, particularly for small and very small operations, and base all costs on realistic and flexible assumptions about growing season, farm net income and feasibility of water testing.*

We support the efforts of the Produce Standards Rule to acknowledge the importance of diversified farming systems by taking an integrated approach to standards that does not set separate requirements for different types of fruits and vegetables. This approach should be retained as a priority for encouraging farmers to produce a range of food without fear of laborious and unnecessary compliance rules.

Through precision policy that allows for the appropriate standards and regulations to be applied to the degree necessary to ensure safety, the proposed rules can ensure that farmers are encouraged, rather than discouraged, to use proven sustainable farming practices, to bring diversity and innovation to their operations, and to enjoy a fair process, without excessive costs.

Farms and food businesses, especially the very small to mid-scale, are a key components of a resilient and healthy food system. Too often, these crucial business and community members are burdened with policy and regulation designed for an industrial scale food system. It is this industrial system—too often the source of food and health safety concerns—that should bear the burden of high scrutiny of the proposed rules. By targeting the very small to mid-scale operations directly or indirectly, general application of industrial food policy and regulation can hinder the availability of fresh, local, sustainable foods for the communities that would benefit the most.

We ask that you reframe the proposed rules in light of our concerns and suggestions.

Thank you for your consideration,

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