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December 4, 2014
Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

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

Dear Food and Drug Administration officials:

Community Involved in Sustaining Agriculture (CISA) appreciates this second opportunity to comment on behalf of our 385 farm and food business members and 860 community members on the proposed rules under the Food Safety Modernization Act (FDA-2011-N-0921 and FDA-2011-N-0920). Since 1993 CISA has been working to strengthen farms and engage the community to build the local food economy in the Massachusetts Pioneer Valley. Our signature program, "Be a Local Hero, Buy Locally Grown,"® is the longest running "buy local" program in the country and has helped build a thriving local food system in western Massachusetts. Over the past decade local food sales in our area have grown tremendously - census data indicates that the inflation-adjusted value of farm products sold direct to consumers in our region has increased by 133%, with total fruit and vegetable sales increasing by 128%.

CISA's Board of Directors is made up of 16 members of our local community from all walks of life, united in their commitment to sustaining local agriculture here in the Valley. Our staff is comprised of 12 committed employees with a strong background in agriculture, marketing, development, management and community building. Our 385 business members include 251 farms, 56 restaurants, 36 retailers, 19 institutions, 18 specialty food producers, and 5 landscape & garden centers, all of whom support and directly benefit from our campaign to build demand for locally grown farm products. Our 860 community members are local residents and consumers who support our efforts to strengthen local farms and improve access to local food.

CISA, our members, and our stakeholders commend the FDA for its efforts to listen to and address comments received during the first public comment period in 2013. The FDA's proposed changes to the original rules indicate that our concerns were taken seriously, and include several positive changes to the rules. We continue, however, to have deep concerns about many aspects of the proposed rules. The rules as written would still disproportionately harm the small family farms in western

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Massachusetts, consequently driving many local farms out of business and reducing consumers' access to local food. We believe further changes must be made to the proposed rules to avoid losing a large number of farms in our region. The demise of these farms would not improve the safety of our food, and would be a devastating loss to our diets, our economy, our culture, and our sense of place.

Our specific concerns and requests are outlined as follows:

Both Rules: FDA-2011-N-0921 & FDA-2011-N-0920

1. **We support the FDA's proposal to include the packing and storing of Raw Agricultural Commodities (RACs) from other farms within its definition of "farm" activities.**

We strongly support the changes the FDA made to clarify that activities like packing and holding raw agricultural commodities (RACs) are included in its definition of "farm" activities, even when these RACs are produced on another farm. The farming culture in Western MA is deeply rooted in traditions of cooperation between neighboring farmers. The vast majority of farms in our region occasionally handle produce from other farms to supplement their own produce, and these farms should not be subject to additional regulations. Such community cooperation is crucial to the viability of local farms, allowing them to mitigate risk of crop failure and take advantage of economies of scale.

2. **We ask that the FDA revise their definitions of "farms" and "facilities" so that neither a farm's precise location nor the level of cooperation between farms will arbitrarily trigger more costly food safety requirements.**

We believe that the definition of a "farm" in the proposed regulations remains arbitrary. The rules should be changed further to clarify that they include in the definition of "farm" farmer cooperatives and other farmer-owned and -operated businesses that are engaged in farm activities. The FDA should remove the phrase "under one ownership" from the definition of a farm in light of the fact that local farm marketing cooperatives and food hubs are key to expanding consumer access to local produce, do not increase risk, and should not be inhibited by costly regulations. In addition, the FDA should remove the language "in one general physical location" from the definition of a farm. In western Massachusetts, an area with high land pressure, it is common for any given farm to have fields and buildings in multiple locations – this fact alone should not trigger more costly "facility" standards.

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3. **We ask that the FDA set size thresholds for regulation under these rules based upon sales of "covered produce" under the Produce Rule and on "covered human food" under the Preventive Controls rule.**

Congress' intent in passing this Act was not to give the FDA authority to regulate the production and handling of all types of food, but only of the types of food covered under the Act. Thus, it is inappropriate for the rules to use "total gross sales" or even "total gross produce sales" as the metrics for setting thresholds for how the rules should apply. In addition to exceeding the FDA's regulatory scope, both of these metrics would arbitrarily inhibit crop and income diversification, without accurately reflecting actual increased risk to consumers.

4. **We support the FDA's decision to include a procedure for reinstatement of a farm's qualified exemption and we ask for stronger language ensuring due process and consistency with regard to withdrawing and reinstating exemptions.**

To ensure farms are treated fairly, we support the FDA's inclusion in the rules of a process for reinstating a qualified exemption after it is withdrawn, and request the following changes: 1) The FDA should add to the rules that "credible and substantial evidence" must be presented to justify a withdrawal; 2) The FDA should clarify its use of the term "material conditions," to ensure this term refers only to scientifically measurable traits that can clearly be identified in individual cases, and *cannot* be applied by conjecture to a whole class of operations or a broad description of food being produced; 3) The FDA should include a specific statement of the reasons for withdrawal in the notice of revocation, with facts unique to that business, so the producer can respond to the specific issues of concern; 4) The FDA should guarantee a hearing before a farm's exemption is revoked and provide adequate time for producers to submit the facts and documentation to contest the revocation; 5) The FDA should provide at least one year for a previously exempt farmer or producer to come into compliance with the rules after revocation; 6) The FDA should state that any reinstatement of exemptions would occur within a reasonable period of time; and 5) To avoid confusion, the process for withdrawing and reinstating a qualified exemption should be the same under both rules.

5. **For farms that pack or hold produce from other farms, we ask that the FDA require retention of transactional records for no more than one year, and that the FDA accept paper or electronic records used in the ordinary course of business, such as an invoice, to satisfy record-keeping requirements.**

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Produce Rule: FDA-2011-N-0921

1. **We strongly support the FDA's decision to defer its requirement of an excessive waiting period between manure application and harvest until additional research and a thorough, fair analysis of the relative costs and benefits is conducted.**

We agree with the FDA's decision not to implement a nine-month waiting period between manure application and harvest, which would more than double the interval that is currently recommended in the National Organic Program (NOP) regulations and as the "best practice" in our region. In addition, we ask that the FDA clarify that the deferral of the manure standard also means that the nine-month interval between grazing a field and harvesting a crop mentioned in the preamble to the proposed rule does not apply. While we do not oppose a shorter waiting period, a nine-month interval would strongly conflict with traditional farming practices in our region, and would result in negative impacts on the environment, soil fertility, and farm economics. The FDA appropriately has acknowledged that far more research weighing the costs and benefits must be conducted before an interval with such significant impact could be required. To facilitate this process of researching the appropriate interval, we ask that the FDA form two research advisory boards – one that advises the process and one that reviews the science. Both boards should include representatives of working farms, including diversified conventional and organic farms. The environmental impact assessment must also be seriously considered before finalizing the manure application interval.

2. **We ask again that the FDA not require insulation of compost as part of acceptable compost treatment. The existing research does not justify this requirement, which would inhibit compost use and does not align with current best practices.**

Conversations with local compost producers suggest that none could meet the FDA's costly requirements for compost production. To align with current best management practices, insulation of compost piles should not be required. Local compost producers in our region do not insulate their compost windrows, and the high cost of doing so puts it out of reach for many small on-farm compost operations. The FDA should change this rule so that compost produced according to strict NOP standards qualifies as "compost," and compost use regulations are consistent with NOP guidance. Otherwise, this requirement will inhibit compost use, which consequently will negatively impact both the environment and food safety.

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3. **We commend the FDA for clarifying that the rules should not inhibit conservation of endangered species and wildlife. We ask that the FDA further strengthen its language supporting co-management of conservation and food safety goals.**

Given the fact that other food safety regulations have had frequent unintended negative impacts on wildlife and conservation goals, we ask that the FDA clearly specify in the regulations that co-management of conservation and food safety is an activity that is encouraged by the rules. Furthermore, we ask the FDA to include requirements to train its personnel on how conservation practices like planting habitat, cover crops, and riparian buffers can support food safety goals.

4. **The water testing requirements in the proposed rule are still excessive, costly and unscientific, and we ask that they be modified. We support the FDA's inclusion in the rule of practices known to promote pathogen die-off.**

We do not believe that the recreational water standard is an appropriate standard to use for testing irrigation water, and we ask that the FDA defer finalizing a numeric water quality standard until adequate research has been conducted to determine a standard that reflects actual risk. At that time the standard should be included in the FDA's guidance document, but not in the rule itself, to enable continued updating as further scientific advances are made in understanding risk. The FDA's proposed water testing requirements still far exceed current best practices, and it is premature to impose such costly requirements on small farms before even basic research has been conducted to quantify actual risks. Until better research-based recommendations are available, we ask that current GAP standards of testing surface water 3 times per year and well water 2 times per year should be followed. In addition, we ask that the rule focus on practices that research shows reduce risk by promoting microbial die-off, rather than on extensive testing. We support the FDA's proposal to allow farmers to use testing by third parties to monitor irrigation water sources, and ask that the FDA develop an MOU with the EPA to regularly publish the results of its water testing and make these available to farms.

5. **We ask that the sales threshold for farms with primarily wholesale markets to be excluded from the rule be raised from $25,000 to $250,000.**

The Tester-Hagan amendment exempts farms with no more than $500,000 in gross sales, provided that at least half are retail sales. Thus, under the current exemptions, a farm selling $250,000 wholesale would remain exempt from the rules as long as they also sold $250,000 retail; in contrast, a much smaller farm grossing only $26,000 –but with no

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retail sales – would not be exempt. This is an arbitrary distinction, and we ask that the FDA raise the $25,000 threshold for exclusion so as to equitably treat farms catering to different markets without posing different levels of food safety risk. Small farms should be allowed to develop simpler, scale-appropriate food safety plans monitored at the state level, rather than be driven out of business by costly federal standards not appropriate to the scale of their operations.

Preventive Controls Rule: FDA-2011-N-0920

1. **We ask again that the rules clarify that direct-to-consumer marketing platforms used by farms are exempt from this rule.**

We request for the second time that the FDA clearly state in the final rule that direct-to-consumer marketing venues – including (but not limited to) farm stands, farmers' markets, mobile markets and community supported agriculture (CSA) operations – fall under the definition of a "retail food establishment," meaning that they are not facilities and are not subject to this rule. Such direct market operations were explicitly exempted by Congress in the Food Safety Modernization Act, and though the FDA indicated it intended to add direct-marketing venues to the definition of "retailers," this still has not been clarified in the rule.

2. **We ask that the FDA comply with the directive of Congress and remove the on-site audit requirement from the supplier verification program.**

We are concerned that the entire supplier verification program will impose an unnecessarily burdensome second layer of regulation on produce farms that supply wholesale markets and processors. At minimum, the on-site audit requirement would be prohibitively expensive for some businesses and conflicts with the Congressional directive.

3. **To avoid putting family farms and facilities out of business, the FDA must remove the cost-prohibitive new requirement that businesses regularly test work surfaces and product for pathogens.**

The FDA's own estimates of the cost of the environmental and product testing provisions would be prohibitively high for family businesses, and the food safety benefits are unclear. The FDA estimates such testing would cost a small facility approximately $15,000 annually. Such costs would inevitably drive such farms and facilities out of business, particularly in the case of diversified farms and facilities producing

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multiple crops and food products. It is crucial that the FDA find ways to reduce the unfair costs of such testing through a more flexible approach to mitigating risk. At minimum, testing recommendations should be outlined in guidance documents as opposed to in the rules themselves.

4. **We support the FDA's decision to define "very small businesses" as a business with annual gross sales of under $1 million.**

This definition is consistent with Congress' intent, in addition to being appropriate to the low net income, margins, and food safety risk posed by such small businesses.

In conclusion, we commend the FDA for listening to the concerns expressed by CISA and hundreds of our stakeholders in November 2013, and we believe that some positive changes have been made to the rules. ***At the same time, we strongly believe that further changes are desperately needed to keep the high costs of these rules from driving our region's small family farms out of business.*** It would be unacceptable to cause such collateral damage to our thriving local food system, particularly since many of the proposed requirements are not supported by research. Instead, by threatening the future of local farms, these regulations will in fact reduce the safety of our food.

We wholeheartedly support federal regulations that improve food safety, and we look forward to seeing our input incorporated into final rules that will ensure both a safer food supply and a diverse and thriving local food system.

Respectfully,

Philip Korman
Executive Director

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