CISA
community involved in sustaining agriculture
20 years of strengthening farms and communities

November 14, 2013

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; RIN 0910-AG35
Preventive Controls Rule: FDA-2011-N-0920; RIN 0910-AG36

Dear Food and Drug Administration officials:

Community Involved in Sustaining Agriculture (CISA) appreciates this opportunity to comment on behalf of our over 360 farm and food business members and 650 community members on the proposed rules under the Food Safety Modernization Act (FDA-2011-N-0921/RIN 0910-AG35 & FDA-2011-N-0920/RIN 0910-AG36).

Since 1993 CISA has been working to strengthen the connections between local farms and the community in the Massachusetts Pioneer Valley, by creating and running programs that link farmers, community members, and markets. Our signature program, *"Be a Local Hero, But Locally Grown,"*® is the longest running "buy local" program in the country and has helped build a thriving local food system in Western Massachusetts. Just since 2007, the number of farmers' markets in our region has more than doubled and the number of CSA farms selling farm shares has more than tripled.

CISA's Board of Directors is made up of 17 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 361 business members include 229 farms, 56 restaurants, 32 retailers, 23 institutions, 15 specialty food producers, and 6 landscape & garden centers, all of whom support and directly benefit from our campaign to build demand for locally grown farm products. Our 674 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 have deep concerns about many aspects of the proposed rules. We are alarmed by the prospect that, as written, these rules will disproportionately harm the small family farms in Western Massachusetts, consequently driving many local farms out of business and reducing consumers' access to local food. We believe it is crucial that changes be made to the proposed rules so that their impact is equitable across regions and across farms of different scales, in proportion to risk. Losing a large number of farms in our region 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. It is unacceptable for our federal government to implement regulations that could bring this to pass.

One Sugarloaf Street
South Deerfield
Massachusetts
01373

Phone 413.665.7100
Fax 413.665.7101

www.buylocalfood.org

Our specific concerns and requests are outlined as follows:

Both Rules: FDA-2011-N-0921; RIN 0910-AG35 & FDA-2011-N-0920; RIN 0910-AG36

1. **We request that the FDA strengthen and expand the exemptions for small farms based on the lower risk they pose to consumers, so that they are not unfairly disadvantaged.**

The overwhelming majority of foodborne illnesses originate in food handling practices after food leaves the farm, or on the very large farms that dominate our food system – NOT on small farms that market locally. Federal government regulations and resources should thus focus on these very large farms that sell their product nationally. These farms grow the vast majority of our country's food, and food from these farms is often commingled with food from many other farms, bagged, and shipped throughout the country. Clearly, when an outbreak occurs originating with these very large farms, it is much harder to identify and address the source of contamination, since it may have occurred in a wide variety of locations in the supply chain.

As Congress mandated, both rules include a qualified exemption or modified requirements for farms with gross food sales averaging below $500,000 who market more than half of their produce to local consumers, retailers, restaurants and other qualified end users. These exemptions are crucial, but the exemption can and should go further.

CISA requests that the FDA redefine "food sales" as the sale of human food covered under these rules, not the sale of all food and animal feed raised on a farm. The FDA's overly broad definition of "food sales" would unfairly penalize farms with the majority of their operation geared toward producing animal feeds like hay or corn silage, and would make it cost prohibitive for these farms to market even a small amount of fruit or vegetables to customers on the side.

CISA requests that the scale at which farms are exempted from both rules be increased. It is important to note that many farms and "mixed-type facilities" grossing over $500,000 in our region net only a tiny fraction of that. One of our farmer members who grows 80 acres of vegetables in Whately, MA commented that an annual cost of $30,000 to implement these rules would easily cut his farm's profit in half, limiting his ability to reward his farm workers, or consider a mortgage on new farm property or set up a college education fund. Farms like his clearly still qualify as "small farms" by many measures, and still pose relatively low risk to consumers due to a short supply chain and the ease of tracing products back to the farm.

Congress authorizes the FDA to exempt or modify the requirements for small farms that are low risk. We strongly agree that produce from small farms marketing locally (i.e. in state or within 275 miles) poses a low risk to consumers, and thus should be exempted from the high costs of compliance. The FDA's current multiple definitions of "small" and "very small" businesses are described in a confusing manner in the proposed rules – especially the Preventive Controls rule. In the case of HA/PC exemptions for low-risk activities, "small

businesses" are defined as those with <500 employees – very large by Massachusetts standards. However, in all other cases in these rules the FDA's definitions of "small" or "very small" farms and facilities are exponentially more limited. The FDA specifically asked for comment on its definition of "very small business" in the Preventive Controls rule: We support including businesses in this definition that have gross food sales up to at least $1,000,000. Similarly, we request that farms with gross food sales up to at least $1,000,000 be exempt from the Produce Rule.

2. **The FDA should add to the rules a process for protecting the exempt status of small farms not covered by the rules, and a process for reinstating exemptions that are removed by the FDA.**

As written, the rules give the FDA broad powers to remove small farms' exempt status without due process. Before removing the exempt status of a farm, the FDA should be required to give the farm a "warning letter" so that the farm has an opportunity to fix the identified issues. In order to remove a farm's exemption, the FDA should be required to prove, with specific scientific information, why the farm's practices pose unacceptable risk of a foodborne illness outbreak. A farm must then be given an opportunity to appeal the FDA's decision to remove its exemption, and the FDA should describe an achievable standard of record-keeping that a farm could keep in order to be able to challenge a withdrawal notice. The FDA should also outline a process for reinstating exemptions, describing the steps a farm must take to reinstate its exempt status.

3. **The rules should outline an enforcement structure that minimizes redundancy, reduces the paperwork burden on farms, and utilizes inspectors familiar with local farm practices.**

The proposed rules do not specify how they will be enforced. The Massachusetts Department of Agricultural Resources (MDAR) coordinates existing food safety certification programs in Massachusetts – the Commonwealth Quality Program, Good Agricultural Practices (GAP) and Good Handling Practices (GHP) audit programs. We request that MDAR be granted enforcement responsibility, given their familiarity with local farm practices and experience in conducting existing food safety certifications. We believe this will result in less redundancy with other certification systems, certifiers who understand food safety in the context of local farm practices, and a higher compliance rate on the part of farms.

Our member farms are concerned that complying with FSMA standards will add a new layer to their already complex and time-consuming food safety-related paperwork and certifications. For example, one of our member farmers growing 180 acres of produce in Hadley, MA reported that he expects to have to hire an extra full-time employee to handle all of the paperwork accompanying FSMA certification, in addition to existing harmonized GAP, HACCP, and Commonwealth Quality Program standards. Because his existing employees are not fluent in English, he cannot easily delegate food safety record-keeping to existing employees, and has very limited time to devote himself to these tasks. Even though his farm

has already made substantial capital investments to comply with food safety standards, he is concerned that the added time and cost burden of FSMA will harm his farm business.

We believe that the existing food safety certification programs in Massachusetts like GAP and Commonwealth Quality (which is accessible to smaller-scale farms) should be recognized as means of complying with FSMA rules. Similarly, it is unreasonable to expect that dairy farms already in compliance with the stringent Pasteurized Milk Ordinance (PMO) should separately comply with FSMA rules, which are largely redundant with the PMO; dairy farms should not be covered under the Preventive Controls rule.

Produce Rule: FDA-2011-N-0921; RIN 0910-AG35

1. **It is crucial that the rule provide low-cost alternatives to complying with food safety regulations that are appropriate for small farms.**

The high costs that the proposed rule would impose on our small family farms in Massachusetts are unacceptable. The FDA estimates that complying with these rule would cost very small farms about $4,700 per year (about 6% of gross sales), small farms about $13,000 per year (about 4% of gross sales), and large farms over $30,000 per year (about 1% of gross sales on average, or more for farms that gross just over the $500,000 threshold).

The FDA's estimates likely underestimate the true costs of compliance in MA. For example, they significantly underestimate the number of months our small farms are in operation (it is common for our local vegetable farms to market for 8 months or more). Furthermore, the FDA underestimates the additional first-year costs of this rule, which are estimated at about $3,500 for very small farms and $7,500 for small and large farms alike. These estimates do not take into account the full costs of the many capital expenditures and management changes required on many small farms in our region to comply with this rule.

Western Massachusetts is a region made up of small family farms. According to the 2007 NASS Ag Census, only 4 farms (0.05% of farms) in Massachusetts gross over $5 million, compared to 1,365 farms (almost 2% of farms) in the country's leading fresh market vegetable producing state, California. Margins are tight on Massachusetts farms, and our farms would be disproportionately impacted – and, to be sure, driven out of business – by this rule. The average profit margin of MA farms is significantly lower than the national average, and to add to this disparity, MA farm operators and their families put in a far greater number of unpaid hours of labor than the national average. Given that the FDA's own analysis indicates that smaller farms would suffer disproportionately from the high costs of implementing this rule, nearly every one of our farms would be put at a strong competitive disadvantage by this rule when matched with the large farms in California and elsewhere that compete with local producers to supply Massachusetts markets.

It is a fallacy for the FDA to assume that farms not covered under this federal rule will escape the high costs of compliance. Inevitably, the high cost of complying with these FDA regulations would not only impact covered farms, but would also impact countless "exempt"

farms that would be required by buyers to comply with the regulations in order to access wholesale markets. There is a long track record of this occurring with existing food safety standards like GAP and HACCP – small growers throughout New England have had to incur the costs of certification in order to sell their produce to grocery stores, institutions, and other buyers. Thus, it is crucial that these regulations include fair alternatives that can enable growers of all scales and in all regions to comply without being driven out of business by the high costs of compliance. Any national standards will serve as a model for private and regional standards, so they must set a standard for flexibility that treats farms of all scales fairly.

We recognize that the rule makes limited allowance for farmers and farm service providers to establish science-based alternatives or apply for variances to some portions of the rule. While flexibility of this type is essential, we emphatically believe that the burden of research and proof in developing affordable alternatives should not be placed on the small under-resourced growers of our region. Our farm service providers are similarly ill-equipped to take on the sole responsibility of developing such alternatives; in contrast to many other parts of the country that still retain county-based Extension services, there are only a handful of agricultural Extension agents serving produce growers in all of New England.

Our local farms lack the resources needed to comply with the proposed rule, or the resources to research and advocate for alternatives. This is unacceptable – it is the FDA's responsibility to provide equitable and research-based food safety regulations.

2. **We request that the rule be changed to maximize their net benefit to society, while taking into account both the rule's direct costs to small farms and the public, and also the indirect costs to society due to negative environmental impacts and reduced access to local produce.**

CISA is concerned that the FDA's Preliminary Regulatory Impact Analysis is based on assumptions that likely overestimate the benefit of this rule, and overlook many direct and indirect costs. As a result, we are concerned that the rule would not maximize the net benefits to society in reducing foodborne illness as intended, and would unnecessarily harm small local farms and the local food system.

There are several reasons to expect that the Preliminary Regulatory Impact Analysis overestimates the benefit of the rule to society in reducing foodborne illness. The baseline data the FDA used to estimate the numbers of foodborne illness due to produce is 5 years out of date, so it does not take into account the impact of major food safety initiatives in recent years. Moreover, the years this baseline data is drawn from (2003-2008) had an unusually high percentage of illnesses associated with produce compared to the adjacent years.

Even more critical, the FDA's estimates of how effective the rule would be in reducing foodborne illness are not science-based, because, as the FDA stated, science-based "information on the effectiveness of preventive measures was scarce." Thus, these estimates were instead determined through a survey of FDA staff, in which FDA staff members were interviewed about their expectations regarding how effective the measures would be in the

specific context of the leafy greens and tomato industry. This has two problems: first, it is likely that these responses would not generalize to the entire produce industry; and second, these responses are subjective and prone to positive bias, given that those responsible for regulating food safety have clear incentive to overestimate their own efficacy.

We also believe the FDA's Preliminary Regulatory Impact Analysis represents a narrow view of the costs of the regulation. It does not adequately consider enforcement costs, or indirect costs to the public, such as lost farms, reduced access to fresh local produce, and negative environmental impacts. Interestingly, the FDA's own (limited) analysis indicates that the net benefits of the rule would be maximized if small farms with gross food sales under $100,000 were exempted from the rule, and yet in its proposed rule, the FDA has instead chosen to set the small farm exemption level at $25,000. At this level, the FDA states that the net benefits of the rule, framed economically, are actually *minimized* compared to all other options. We request that the FDA completely exempt small farms with gross food sales up to at least $100,000.

We believe that the FDA should be more transparent in presenting its Regulatory Impact Analysis so that the extent of uncertainty is clearer to stakeholders and policy-makers. We also request that the FDA take into account the full costs to small farms, the full costs to taxpayers, and the full indirect costs of the rule when considering how to maximize the net benefit to society in the final rule.

3. **We support the FDA's decision to use an integrated approach to regulating different crops, while exempting low-risk crops that are rarely consumed raw.**

We agree that the FDA's list of exempt crops should remain exempt from this rule, given that these crops are overwhelmingly cooked before consumption and thus pose a far lower level of risk to consumers. While there are differences in the levels of risk posed by the crops that are covered under this rule, and there may be additional crops that should be exempt from this rule due to extremely low risk, we support the FDA's integrated approach to regulating covered crops. The burden of complying with different regulations for each covered crop would be untenable for our diversified produce farms in Western Massachusetts, so maintaining an integrated approach is crucial to their ability to comply.

4. **We request that changes be made to the rule to align standards for the use of manure and compost with current National Organic Program (NOP) regulations.**

The proposed nine-month waiting period between manure application and harvest more than doubles the waiting period that is currently recommended in the NOP regulations and as the "best practice" in our region. The field research supporting a nine-month waiting period does not currently exist. Only a small handful of studies have researched the links between manure application and persistence of pathogens in soil or on produce, and these studies have severe limitations which prevent conclusions from being made to support the strict application to harvest interval in these rule. Specifically, research identifying the time required for manure-

based pathogens to die off under field conditions is lacking. In light of this uncertainty, the inevitable economic and environmental costs are too great.

Conversations with several of our farmer members have indicated that the proposed rule would prevent their current manure use, which would have negative consequences both for soil fertility and the environment. Many farmers in our region apply dairy and poultry manure at the start of the growing season, and would have to cease using manure if a 9-month waiting period were required between application and harvest. In our region, such a long waiting period would require that farmers apply manure before the winter in most cases, which would cause pollution problems and significantly reduce the nutrient value of the manure. The other alternative would be to rotate a field out of production for an entire season, a luxury that our produce farmers rarely have given the high land costs of the region.

For farmers who use manure-based or food-waste-based compost in our region, this rule would also impose substantial new hurdles to compost use. The rule conflicts with the NOP compost production guidance and current best management practices by regulating compost production methods far more stringently, such that it would be impractical for local compost producers to meet the FDA's guidelines, in spite of the high quality of their product and low risk of pathogen contamination. Conversations with local compost producers suggest that none could meet the FDA's requirements for compost production. In particular, 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. It would also be impractical in many cases for compost piles to be maintained at a high temperature for the long period required in this rule. 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.

A closer look at the FDA's Preliminary Regulatory Impact Analysis reveals blatant oversights in the FDA's estimates of how much acreage would be impacted by these stringent compost and manure standards. For example, to determine the proportion of manure that is untreated, the FDA relies on data drawn from the USDA's report, "Fruit and Vegetable Agricultural Practices – 1999." In this report, the USDA's definition of "not treated" is barely relevant to the FDA's definition of "untreated." It excludes manure that has been aged or composted in any way, as well as manure treated with unspecified "other" methods, or manure for which the farmer doesn't know whether it was treated. It is likely that very little, if any, of the manure in these categories would comply with the FDA's stringent definition of "treated," so the vast majority should be considered untreated – certainly not only 18.5% as the FDA claims. We expect this is indicative of other substantial oversights with regard to the assumptions underlying this report, and request that the FDA redo the analysis to more accurately reflect impact.

Until better research-based recommendations are available, we request that the FDA follow current GAP and NOP recommendations for manure and manure-based compost use.

5. **The rule should explicitly state that farms will never be required to eliminate conservation practices to comply with the rule.**

The rule requires growers to monitor wildlife intrusion in crop fields and take action to prevent crop contamination from wildlife. Without explicit language in the rule to support conservation measures, it is likely these requirements will have unintended impacts on wildlife, penalizing growers who maintain wildlife habitat. Similar rules enacted in 2007 as part of the Leafy Greens Marketing Agreement in California led auditors to pressure farms to fence crop fields (fragmenting wildlife corridors) and remove habitat; these rules preceded a 13% loss in riparian habitat on farms and consequent decline in ecological diversity. Growers in the Northeast have reported similar pressure from GAP auditors to protect fields from wildlife by removing wildlife habitat.

The research linking wildlife to crop contamination is far from conclusive and sheds little insight on the magnitude of the risk posed by different types of wildlife. In light of this uncertainty, CISA requests that the FDA add language to the rule that clearly states that farmers will not be pressured to destroy wildlife, wildlife habitat or riparian buffers to comply with the rule. This will set a much-needed national example of co-management of conservation goals and food safety goals.

6. **The excessive water testing requirements in the proposed rule should be modified.**

As written, the water testing requirements are impractical for local farms to comply with and are of uncertain value in improving food safety, given that they are based on inadequate research. Conversations with our farmer members have indicated that many of our small farms use have over ten separate fields, often drawing from different water sources for each irrigated field. Requiring weekly testing of surface water irrigation sources would be time-intensive and cost-prohibitive for many of these farms, and the testing likely would not accurately reflect risk.

Indicator organism levels fluctuate constantly in running surface water, and high levels are most likely within 48 hours after heavy rain, when irrigation is not needed. Furthermore, the link between indicator organism levels and actual produce contamination risk is very poorly understood. The FDA's suggested levels draw upon recreational water standards and may well have little relation to the risks within the context of irrigating farm fields. A weekly water-testing frequency far exceeds current best practices, and it is premature to impose such costly requirements on small farms before even basic research has been conducted to quantify the actual risks. Until better research-based recommendations are available, current GAP standards of testing surface water 3 times per year and well water 2 times per year should be followed.

7. **The rule should outline the nature of training and record-keeping required by this rule, and ensure that it is not overly burdensome for small farms.**

We support the FDA's decision not to require record-keeping of small farms that are subject to the modified requirements of the produce rule. We request that the record-keeping required of covered farms be streamlined so that it does not duplicate other record-keeping currently performed on farms subject to GAP, Commonwealth Quality or organic certification. In addition, we request that the final rule specify the nature of training required of all workers in food handling and hand washing – and that the required training should not be burdensome to small farms, including these on which the public performs some field operations like pick-your-own farms.

8. **The requirements for equipment, tools, buildings & sanitation in the rule should be modified to ensure that they are not costly and impractical for small farms.**

According to the FDA's own analysis, its regulations on equipment, tools, buildings and sanitation are the least cost-effective in reducing food safety contamination of all the measures in the rule, but we are concerned that these regulations may excessively impact small local farms. While the FDA leaves the precise requirements of the rule in this section vague, we are concerned that the implementation of these requirements as proposed would impose high capital costs on local farms. One of our farmer members based in Granby with 115 acres of produce is concerned that the regulations will require expensive equipment investments and will prevent them from utilizing local, sustainable materials like wood in their harvest totes and packing barn.

We are also concerned about parts of this section of the regulations that seem impractical – like the requirement that condensate not fall on produce in covered growing environments like greenhouses or tunnels. While low-drip plastic exists, the technology to completely eliminate condensate in greenhouses does not, nor is there research indicating that this is necessary.

9. **We request that the FDA comply with the federal mandate to fully incorporate conclusions from its belated environmental impact analysis into the final rule.**

This rule will have significant environmental impacts that must be weighed carefully. After the environmental impact analysis is conducted, it is crucial that the FDA use the results of this analysis to modify the final rule and reduce its negative impact on sustainable farming practices and the environment. The FDA should allow the public to comment on the resulting changes to the rules.

Preventive Controls Rule: FDA-2011-N-0920; RIN 0910-AG36

1. **The rule must clarify that farm stands, farmers' markets, mobile markets, CSAs and other direct-to-consumer marketing platforms used by farms are exempt from this rule.**

We request 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 – are not facilities and thus 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 has indicated it intends to add direct-marketing venues to the definition of "retailers," this should also be spelled out in the rule itself to prevent misinterpretation.

2. **The rule should be modified so that a farm can handle a reasonable amount of produce from other farms without being categorized as a "mixed-type facility."**

The farming culture in Western MA is deeply rooted in traditions of cooperation between neighboring farmers. This cooperation is crucial to the viability of our local farms and to making local food accessible to residents. The vast majority of farms in our region occasionally handle produce from other farms. These farms should not be subject to additional regulations. In particular, we request that low risk activities, such as packing and repacking produce and trimming outer leaves off produce, should not trigger the facility definition when performed on produce from neighboring farms.

3. **The FDA's list of low-risk activities should include baking of shelf-stable grain products.**

Baking of grain products that do not need refrigeration is widely recognized as posing low risk to consumers. Local regulators typically regulate the production of baked goods less stringently than other higher-risk processing activities, and we request that the FDA follow suit in this rule.

4. **Low-risk activities that occur off-farm on produce marketed locally, such as packing fresh produce at a small farm cooperative, should not be subject to strict HA/PC requirements.**

Small-scale farm marketing cooperatives and food hubs are key to expanding consumer access to local produce. This rule would impose substantial new regulations on farms that market cooperatively, even on a small scale, when the produce is packed off-farm. We believe such low-risk activities, when performed on a small scale on produce sold locally, are crucial to strengthening our local food system and should not subject farms to costly regulations.

In conclusion, we strongly believe that losing more of our small family farms in a quest to improve food safety is an unacceptable tradeoff, and will in fact reduce the safety of our food. As described above, major changes to these rules are needed so that they treat our local farms equitably. The analyses on which these rules are based must be modified to accurately reflect their uncertainty and to correct many oversights and false assumptions. The rules must then be changed accordingly – only then will their potential benefits be realized.

We wholeheartedly support federal regulations that improve food safety, and we are confident that this need not come at the expense of a strong local food economy. We appreciate the FDA's commitment to receiving stakeholder input on these rules through written comments and public hearings. We look forward to seeing this input incorporated into final rules that support both a safer food supply and a diverse and thriving local food system.

Respectfully,

Philip Korman
Executive Director

Risa Silverman
Chair, Board of Directors