New York Farm Bureau • 159 Wolf Road P.O. Box 5330 • Albany, New York 12205 • (518) 436-8495 Fax: (518) 431-5656

November 15, 2013

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

Re: Docket No. FDA-2011-N-0921 and RIN 0910-AG35

To Whom It May Concern:

As New York State's largest general farm organization, representing nearly 25,000 members, New York Farm Bureau (NYFB) appreciates the opportunity to comment on the Food and Drug Administration (FDA) proposed "Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption." Our members grow a large variety of commodities, represent all size farms and represent the large variety of production methods from organic to conventional and everything in between. Food safety is of utmost importance to our food system in the U.S. so implementing the Food Safety Modernization Act (FSMA) in a way that is meaningful and effective for both farmers and consumers is essential to our members and to our country at large.

Farmers in New York are already committed to food safety and participate in both voluntary Good Agricultural Practices (GAPs) and retailer-developed food safety programs. It is nearly impossible to be a produce grower in our state without being involved in some type of food audit program that takes into account food safety.

Also, because so many growers in New York have direct contact with their consumers—through farm markets, farm stands, Community Supported Agriculture (CSA) structures, direct restaurant sales and other innovative and modern local food distribution systems, farmers are directly accountable to these customers who know them by face and may even visit their farm. Therefore, on-farm food safety protocols are already key to the reputation and success of the business.

We believe—and can see from the nearly inexistent data on food safety outbreaks in our state due to the many of the types of unprocessed farm products covered in this rule—that New York produce farmers are already doing a good job at protecting public health. So placing undue burden on these producers, driving up their production costs and/or driving them out of business without evidence that provisions of the proposed rule will be effective in improving public health, is irresponsible and goes against the Congressional intent of the Food Safety

Modernization Act. In these comments we will endeavor to highlight the areas that should be reconsidered by the agency in order to avoid the overregulation of farmers to the detriment of our overall food system in an effort to improve this rule.

Second Stakeholder Comment Period

This rule, combined with the simultaneously proposed "Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food" rule, are part of a significant expansion of FDA authority onto farms. FDA does not have previous experience regulating farms and we do recognize and appreciate the hard work of the agency to understand what goes on in agricultural production by holding listening sessions and conducting farm visits throughout the country. In particular, we thank agency staff for visiting a number of farms on Long Island in advance of writing the proposed rule and talking with our farmers and local production specialists about the safeguards already in place and the challenges they face. However, based on the number of comments submitted, it is apparent there will be many suggestions offered to the agency and we also agree that some areas of the proposed rule need to be adjusted and re-thought. We anticipate that significant changes to the rule will be made.

Without the opportunity for farmers and other stakeholders to respond and comment on these changes before the rule is finalized, it is possible there may be unforeseen consequences that are unworkable for farmers. ***Therefore, we strongly urge FDA to publish a second draft of the rule and allow public comment before the final rule is promulgated.*** This will allow adequate stakeholder input into a complex rule and help ensure the regulatory process ends in a sound and operable program that can be successfully implemented.

General Comments

Our food system is, by its nature, a biological system that can never be failsafe or "zero risk," despite all our best and most diligent efforts. We believe in the goal of improving food safety and have long supported research and education efforts to this end. But it is fair to say that farmers are not the last stop on the safety path from field to plate. Consumers and food preparers also have responsibilities in ensuring the safety of food—including common sense washing, cooking and storing of food items—and educational efforts on this front must continue. Produce may be touched by several hands and have several potential contaminant points long after it leaves the farm. Everyone involved in the food system plays a role and the cost burden should not lie disproportionately on farmers.

The United States food production system is among the best in the world and we hear too often about major food safety breaches in other countries. ***It should be a priority of FDA and the U.S. Department of Agriculture to ensure that domestic production of fruits and vegetables is able to continue, as we believe this is the best way to ensure food safety to consumers.*** Although this rule clearly and fairly imposes the same standards on off-shore food producers who export food to the U.S., it is hard to see where the resources to enforce standards at the same level as in the U.S. will come from. Inspection of imported food at our borders is already a very small 1 percent of the total and FDA hasn't adequately explained how

it plans to inspect all the foreign farms shipping to the U.S. in a way that provides producers confidence in its international implementation.

For these reasons, it is our opinion that overburdening farmers with a produce safety rule that has expensive provisions that have not been scientifically shown to provide additional protection to the food system, will suffocate our domestic produce farmers and drive production overseas to locations that are much harder to regulate and where FDA's enforcement is much more difficult and expensive. FDA must consider the negative impact that implementing these rules as written could have on our domestic food production and the long-term food safety effects of shifting our production overseas. ***Therefore, it is essential that all requirements placed on farmers by this rule are based in sound, proven science and the cost to farmers can be justified.***

Additionally, as noted above, many farmers already meet food safety standards set in the private sector by retailers and handlers. Farmers in some cases are suffering from "audit fatigue" due to the bevy of requirements already in place, often varying from retailer to retailer. ***For this regulation to have the best possible result, we strongly encourage FDA to work extensively with the retail community to promote the adoption of any final produce safety rule as a uniform standard.*** FDA must help our farmers ease the burden of implementing this regulation by making every effort to gain the acceptance from the marketing chain for a standardization of produce safety regulations and third-party audits. This will help prevent growers from facing additional and sometimes contradictory rules and duplicative paperwork that goes along with multiple food safety standards set by a variety of marketing outlets. FDA could provide invaluable assistance to farmers by taking the lead on streamlining food safety standards with retailers and making produce safety a non-competitive issue, as it should be.

Covered Produce

We are disappointed that in developing this rule, FDA did not stick with the intent of Congress, which directed FDA to concentrate FSMA rulemaking on the commodities and commodity groups that have been associated with human foodborne illness. These foods are well known to FDA. Instead, we believe this rule is unnecessarily broad and far-reaching without taking into account the relative risks and comparative benefits associated with individual commodity groups.

We urge you to reconsider this type of approach and only initially propose regulations for those commodities and packaging methods (ie: bagged salad mixes) with a history of microbial contamination. If these regulations are successfully implemented and enforced, it would then be appropriate at that time to consider whether there is a net public health benefit from expanding regulations to other commodities.

We see this regulation as a one-size-fits-all approach to food safety that does not take into consideration the fact that different crops (ie: those grown off the ground), different growing practices (ie: drip irrigation) and different growing regions all contribute to the potential for a

food item to cause a health risk. With this said, we do recognize and support FDA's exemption of grains, produce that is rarely consumed raw, produce that is intended for commercial thermal processing and produce for personal and on-farm consumption. These are appropriate exemptions that should be part of the final rule.

Farm Exemptions

New York Farm Bureau does support exempting some farms due to their size as they both lack the resources (financial and personnel) necessary to comply and have not demonstrated a widespread risk to food safety.

The $500,000 farm sales exemption level set by FSMA for producers selling at least half direct to qualified buyers (consumer, retailer, restaurant), includes the sales of products not covered by the rule. ***We recommend that the calculation of the farm sales exemption level be revised to include only the sales of commodities subject to the rule.***

For example, Farmer A primarily growing potatoes (not a covered commodity) with annual sales of $476,000, who has a small sideline strawberry patch that generates $24,000 in sales annually, would be subject to the regulation as it is written. However, neighboring Farmer B selling $24,000 worth of strawberries and nothing else would not be subject to the rule. Obviously the potential risk of contamination of Farmer A's strawberries is not increased by the fact that he also grows potatoes. Because the inclusion of commodities not subject to the rule in this sales figure does not seem to have a basis in food safety risk, we strongly encourage FDA to change this in order to implement the rule over covered produce in a fair manner and avoid unnecessary burden on producers.

Agricultural Water

This standard as published does not recognize the realities of farming and FDA has not described the scientific basis for these requirements. In particular, the numeric generic E. coli criteria for surface water and weekly testing requirement are not backed by sound food safety testing. There is no evidence that EPA's "recreational contact" number for generic E. coli, which FDA used in this rule, has any bearing on food safety when used in irrigation or for spraying.

For example, surface water used early in the season to irrigate before the edible portion of a plant is exposed would pose no threat. Also, depending on the time before harvest and weather, the survival of E. coli even if it does come into contact with the edible portion of the plant decreases significantly over time. Drip irrigation water applied to a plant which has the edible portion growing about the ground also would not be placed at risk. These factors are not adequately considered in the standards. Nor is the fact that generic E. coli is not necessarily indicative of a human health risk.

Additionally, we are not aware of FDA and EPA-approved treatment options for surface water in order to remedy any water source that does not meet the standard. FDA has not provided a sufficient alternative to using this surface water for agricultural purposes. Using alternate water sources may not be possible on a farm depending on the location; may require permitting from

state or local authorities, which could take 30 days or more; could be subject to restrictions, such as during drought conditions when irrigation water is needed most; or could place unexpected strains on municipal water sources. FDA has not considered the environmental impacts of farmers using alternative water sources (ie: shifting from surface to groundwater) and has not been able to show that these impacts would be offset by sufficiently increased food safety for the end consumer.

Also, testing laboratories are not always located in close proximity to farms. The regulation requires all surface water sources to be tested on a weekly basis. The cost and lost work hours to drive a sample to a laboratory or the cost to ship samples in a timely manner on such a frequent basis could become quite expensive for a farm, especially one that must use multiple water sources. This testing standard must be reconsidered and amended to become reasonably achievable for growers.

We strongly urge FDA to rescind the E. coli standard for surface water in this rule, which is based on EPA recreational use, and develop a standard based on food safety science. FDA is also urged to revise the irrigation standards to address the real contamination risks of spray and irrigation water, acknowledging that alternatives may be untenable for farm businesses or impact other environmental or community concerns.

Biological Soil Amendments

FDA's proposed minimum application period for untreated biological soil amendments of 270 days before harvest (if the covered product is reasonably likely to contact soil after application) will be very difficult for many growers to meet and does not recognize the length of the growing season in the Northeast.

Manure is indeed a source of nutrients (and a cost-effective and environmentally friendly one if applied in coordination with good management practices) for a large number of producers. Not every farm is in the position to compost or treat manure before application, although some certainly do. This timeline can seriously interfere with our environmental regulations and the comprehensive nutrient management plans that either the state or federal government have already approved for these farms, which outline nutrient application amounts and times. Spreading manure in January on frozen ground in order to harvest produce from that field in September, may not be good for the farmer or good for the environment if those nutrients are not absorbed.

The conflict of environmental regulations that are already in place, including Concentrated Animal Feeding Operations (CAFO) and comprehensive nutrient management plans, was not considered in this requirement. Additionally, the short growing season of the Northeast is not accommodated in these standards.

The reason for FDA setting this 270-day standard is unclear and we are not aware of any science that supports this interval. Also, it is in obvious conflict with the National Organic Program (NOP) regulations in 7 CFR 205.203(c)(2) when the produce safety regulations were

clearly not intended to include any requirement that conflicts with the National Organic Program.

We recommend FDA change the rule to allow a 120-day interval between application of untreated biological soil amendments and harvest.

USDA already accepts a 120-day standard in the NOP. If this application period posed an increased safety risk we would see evidence of greater food safety outbreaks related to organic produce, but this is clearly not the case. It seems that the more than 10 years since this standard has been included in the NOP offers sufficient evidence of its appropriateness, given the lack of science supporting the 270-day standard.

Wild Animals

The wildlife requirements show a lack of understanding about the environment that Northeast farmers work in. Farmers already work to exclude wildlife from fields because animals can destroy crops and introduce a potential for contamination, but it is an impossible task in some areas to exclude all wildlife despite the best efforts. In addition, several federal and state conservation programs actually encourage practices that provide habitat to wildlife near agricultural fields. The rule as written would effectively prevent the harvest of many fields of completely safe produce.

Farmers and their employees already avoid harvesting produce they have reason to suspect is contaminated and that remains the most effective way to deal with this type of threat. The proposed rule must acknowledge that the presence of an animal in a field does not mean food has been contaminated and that should not prevent the harvesting of the entire field. ***We urge FDA to re-write this section with a risk-based approach that recognizes the true threats of animals in produce fields (ie: actual presence of waste).*** Right now the language seems to be overreactive to the presence of animals and very difficult for farmers to comply effectively. Making this change will also serve to protect farmers with strong food safety records from overzealous inspectors and the unnecessary waste of healthy food.

Research

We support the recommendations submitted by the American Farm Bureau Federation for the need of additional FDA resources to fund produce safety research. In particular, water used in production and post-harvest handling of produce requires more data to inform on-farm actions. Additionally, further research is needed for the following specific areas:

- Alternative practices for agricultural water sanitation;
- Assessing risk of using untreated water to protect fruit crops during freeze events;
- Equipment design for sanitation; effective sanitizers and protocol for farm equipment;
- Use of open water sources for spray applications and irrigation;
- Development and use of alternative contamination indicator organisms;
- Research and profile variability and risk of untreated surface water (impoundment/flowing stream, etc.) over time with regard to pathogens to inform guidance on water testing frequency;

- Impact of pesticide and nutrient/fertilizer residues on human pathogen survival, persistence and distribution in surface waters;
- Sanitation of equipment used for irrigation;
- Impact of dredging and construction/maintenance of water sources on human pathogen survival, persistence and distribution;
- Suitability of generic E. coli as a predictive indicator of microbial contaminants and suitability of current action level (235 MPN/100 ml);
- Uptake of different types of microbial contaminants by different types of produce;
- Interactions of microbial pathogens on and in produce with the naturally occurring plant flora;
- Quantitative Microbial Risk Assessment Model: Survival, persistence, transport of different microbial pathogens in pre- and post-harvest commercial production;
- Post-harvest handling practices that may influence survival and persistence of microbial contaminants on produce;
- Interactions of microbial contaminants with naturally occurring biofilms in irrigation systems; and
- Efficacy of currently deployed field hand washes stations used in conjunction with toilet facilities.

Resources for Training and Inspection

It is very important to growers that FDA ensure there are adequate resources for training of inspectors and for foreign inspections. It is important that inspectors are properly trained and familiar with agricultural practices and the true risks associated with various activities on a farm. Inspectors that are not adequately trained will not be able to implement the rule consistently and fairly across the U.S and would needlessly put some growers at a competitive disadvantage. This training must take into consideration the differences in crops, growing regions and growing practices.

However, it is also important that FDA have the resources to enforce these rules as stringently on foreign farms as on domestic farms. It is crucial that this rule is enforced internationally so our growers—already at an economic disadvantage due to labor costs, environmental regulations, higher tax and other business costs—don't have another inequity added that makes them less competitive compared to imported products. With only 1 percent of imported food inspected when it enters the country now, it is difficult for us to understand how FDA will have the resources to ensure equal compliance in the U.S. and abroad. It is critical that FDA does not disadvantage domestic growers in favor of foreign growers where compliance is much more difficult to monitor.

State Partner Cooperation

It is still unclear how FDA will cooperate with state partners to implement this rule. Exactly how inspections will be carried out and the structure of state-federal partnerships must be established as soon as possible in order to ensure uniform enforcement and enough time for state partners to prepare.

Furthermore, we support delegating inspection authority to state departments of agriculture as they are best prepared to conduct on-farm assessments and inspections and are already knowledgeable in farming practices. But this must be combined with adequate funding and other resources for education, staff, outreach and other needs necessary to implement this rule in the state so already stretched agencies can assist farmers and implement the rule fairly.

Data Privacy and Recordkeeping Requirements

Farmers are concerned about the privacy of their personal information and proprietary information regarding their farm business. ***FDA must take measures to ensure data privacy and confidentiality of individual farm businesses and their proprietary information.*** This must be considered in any information farmers will be required to submit to state or federal agencies and any information that inspectors or educators may collect.

Additionally***, recordkeeping requirements now and in the future must consider the fact that not all farmers have access to high-speed or broadband internet access.*** Many areas of New York State are rural and remote and do not permit growers to access the internet on a reliable and regular basis. For this reason, requirements like an email address in order to register as a food facility with FDA make it difficult for some farmers to comply. Email should not be the only communication method from FDA to communicate with a producer; rather a producer should be able to select a preferred communication and registration method that recognizes the hardship of internet access on some farms and for some of the farm community. Failure to do this will certainly undermine the effectiveness of this rule and ability of farmers to comply.

Economic Analysis

We do disagree with components of FDA's analysis of the cost and impact of this rule on farms and encourage the agency to carefully review the economic analysis submitted by the American Farm Bureau Federation.

Conclusion

New York Farm Bureau encourages FDA to continue its effort to improve this rule by using a targeted, science-based and risk-based approach. Produce farmers here consider food safety a top priority, but urge FDA to revise the proposed rule to incorporate a standard that can be scientifically supported, demonstrate real human health benefits and be reasonably attained by producers without inadvertently discouraging or disadvantaging domestic production.

Thank you in advance for considering these concerns.

Sincerely,

Dean E. Norton
President