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December 15, 2014

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

RE: FDA-2011-N-0920; RIN0910-AG-36- Revised "Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventative Controls for Human Food."

To Whom It May Concern:

New York Farm Bureau (NYFB), the State's largest general farm organization, appreciates this opportunity to provide comments regarding the revised "Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventative Controls for Human Food."
The Food Safety Modernization ACT (FSMA) is a major challenge and we appreciate the Food and Drug Administration (FDA) recognizing that farmer input is integral in ensuring food safety goals are met. We commend the FDA for issuing this Supplemental Notice of Proposed Rulemaking and are pleased to provide our perspective from the farm level on the modifications to the initial produce safety proposal. Moreover, we appreciate acknowledgement of concerns raised in New York Farm Bureau comments and the resulted modifications seen in the revised "Current Good Manufacturing Practice and Hazard Analysis and Risk Based Preventative Controls for Human Food" (Preventative Controls) rule.

General Food Safety
New York Farmers have a vital interest in how food safety is practiced, perceived and regulated. We believe that while our food production system is among the best in the world, science-based, collaborative improvement is always an important principle.

Food systems, by their nature, are biological and are not failsafe or ever "zero risk." However, recent improvements in reducing foodborne illness have occurred despite new challenges for food safety, such as changes in the typical American diet that include more imported foods and more food consumed away from home. The United Sates imports food from more than 150 different countries through more than 300 ports of entry. About half of the fresh fruits eaten in America are grown outside of the country, and these imports allow us to enjoy our favorite produce year-round. This exchange in food products permits a more varied and customized diet suited to today's consumer preferences and permits our farmers and other food producers to sell their goods abroad. It also means that food safety requires enhanced attention to the global food supply, and ***FDA must apply and enforce any new produce safety standards on imports in a manner similar to that for domestic producers*.**
Because of the complexity of the food system, it is critical for FDA to set forth science-based standards and distinguish between "farm" and "facility" within the Preventative Control Rule. Overall, New York Farm Bureau believes this revised Preventative Controls rule is a step in the right direction, but we still have concerns.

Facilities Regulated Under Preventative Controls Rule

We contend that the congressional intent of FSMA is met if registered facilities that handle, hold, pack or package raw, intact produce are covered by the relevant requirements of the Produce Safety rule instead of Preventative Controls. While it is clear that FDA intends a sharp division between "facilities" subject to Preventative Controls and "farms" subject to Produce Safety based on the section 415 registration regulations, it is an artificial restriction.

Definition of Farm

We commend FDA for expanding the definition of farm activities to include culling, conveying, sorting, waxing, storing, labeling, packing, packaging and shipping of raw, intact produce, and storing including crop maintenance activities that occur during storing like fumigation, pest control, sprout inhibition and atmosphere control for ripening or ripening inhibition. We continue to believe that any normal handling, holding or packing activity performed on raw, intact produce that results in no significant change in the produce shape or structure, and creates no significant change in the hazard analysis for the product, should be considered consistent with the "farm" definition, and operations that perform only such activities should be covered under this rule, rather than the Preventative Controls for Human Food rule.

<u>Under One Ownership</u>

The initial rule required that farms "harvesting" or "packing" or "holding" raw agricultural commodities (RACs) grown on a farm under different ownership would have been forced to register as a food facility, subject to extensive Preventive Controls for Human Food requirements. ***We commend FDA for recognizing that approach presented no added food safety benefit and eliminating this requirement for "packing" and "holding" and "harvesting" by now allowing farms to harvest, pack or hold RACs grown on another farm under a different ownership.*** This change improves workability of the rule, while recognizing typical farm practices.

However, we remain concerned that defining a farm as being "under one ownership" ignores important farmland ownership and management structures that exist today. According to USDA Economic Research Service, about 40 percent of U.S. farmland has been rented over the last 25 years. A definition of farm that does not take non-owner management of farmland into account would make complying with FSMA considerably more difficult and costly.

<u>One General Physical Location</u>

NYFB has concerns regarding the "one general physical location" requirement within the farm definition. As FDA accurate points out, farms generally consist of non-contiguous parcels of land in various geographical location, including different counties, states, regions, and countries. This reality must be contemplated in any interpretation of the "one general physical location" requirement.

NYFB does not see a benefit to including the "one general physical location" requirement. By limiting farms in that manner may cause duplication of requirements, recordkeeping, and costs. If this requirement is included it should be interpreted as broadly as possible. Farm size and structure vary due to regional factors, climatic conditions, production practices and marketing and distribution channels. For instance in New York the average farm spans over 228 acres and consists of several parcels of land, some contiguous – some non-contiguous – some that can cover multiple counties and even cross state borders into Pennsylvania, Vermont, Massachusetts and Connecticut.

NYFB appreciates the improvements FDA has made to the definition of "farm," however, we remain concerned about its overall workability. We support the American Farm Bureau Federation's definition as follows:

Farm means *an establishment where raw agricultural commodities are grown, harvested, packed and/or held, animals are raised (including seafood), or both and have a common, owner, operator(s) or agent in charge and are operated under a common food safety management scheme. The term "farm" includes establishments that, in addition to these activities:*

(i) Pack or hold processed food, provided that all processed food used in such activities is either consumed on that farm or another farm under the same ownership, or is processed food identified in paragraph (iii)(B)(1) of this definition; and

(ii) Manufacture/process food, provided that:

(A) All food used in such activities is consumed on that farm or another farm under the same ownership; or

(B) Any manufacturing/processing of food that is not consumed on that farm or another farm under the same ownership consists only of:

(1) Drying/dehydrating raw agricultural commodities to create a distinct commodity, and packaging and labeling such commodities, without additional manufacturing/processing; and

(2) Packaging and labeling raw agricultural commodities, when these activities do not involve additional manufacturing/processing.

This definition addresses all of the concerns raised above: it is inclusive of the various individuals that might be responsible for the operation of a "farm"; it removes the use of "one general physical location" as it is an irrelevant descriptor that cannot be clearly defined without being arbitrary or capricious; and lastly, it allows packing and holding activities performed on RACs.

Packing, Holding & Harvesting

NYFB commends FDA for expanding the definitions of packing, holding, and harvesting, as mentioned above. We support the inclusion of activities performed incidental to storage of food in the definition of holding of RACs – other than fruits and vegetables. The activities articulated in the supplemental rule do not alter the nature of the RAC and are, therefore, rightfully included as farming activities. Again, we commend FDA's recognition of these incidental activities as part of the farming process and not subjecting these farms to Preventative Controls.

Product Testing and Environmental Monitoring

Product Testing

NYFB recommends against the inclusion of product testing – whether incoming raw material or finished product, regular or periodic, regardless of the size of the operation – as a requirement in Preventative Controls. This option considers the limited technology available to do testing of fresh produce, the added cost of implementing a product testing process, and the limited time available due to the

perishable nature of the commodity. Generally, we believe that the established preventative control and monitoring go further to protect safety, without the added cost of sampling.

Environmental Monitoring:
NYFB does not support the inclusion of environmental monitoring tools in the rule. Rather, we encourage monitoring to be conducted through facility specific food safety plans. The risk associated with certain exposures of a ready to eat food depends on multiple factors that must be considered in any environmental monitoring tool. Further, any regulatory requirement will soon be outdated as products change and science improves. Food safety plans, rather than regulation, provides the flexibility necessary to monitor any risk successfully.

Withdrawal and Reinstatement of Qualified Exemption
NYFB supports the modified requirements required prior to withdrawing a qualified exemption. In our original comments, we raised concerns that farmers would not have any opportunity to take corrective actions before having its exempt status fully withdrawn. We are supportive of FDA's proposal to require FDA issuance of a warning letter, recall, administrative detention, refusal of food offered for import, seizure, and injunction. This would provide an intermediary step prior to a full withdrawal; further providing the farm has an opportunity to respond to any alleged problems identified by the FDA and allow FDA to consider the farm's response prior to issuing an order to withdraw the exemption. We appreciate the recognition of a farms due process rights within the supplemental rules.

Furthermore, we support the FDA's addition of a process to reinstate a qualified exemption. This process is critical where an alleged outbreak is not directly link to the farm or mixed-type facility and also recognizes that farms and mixed-type facilities can manage a food safety risk and return back into compliance.

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 routine and acceptable 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. If FDA is not able to invest in this type of training, we encourage the agency to utilize the networks of well-trained inspectors who are already familiar with these practices through our state department of agriculture. These inspectors are already familiar with acceptable farming practices, are familiar with types of activities performed on our farms and have a strong history of successful inspection processes. However, this would require adequate funds made available to these regulators to perform this function.

However, we repeat from our previous comments that ***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.

Outreach
FSMA will only be successful if farmers are able to understand its requirements and efficiently implement any needed changes, so communication and coordination with grower and others in the produce industry is key. FDA has already done an admirable job of reaching out to stakeholders, including a visit to farms on Long Island in preparation of drafting this rule, but the agency must continue to identify education and outreach needs and provide a plan for meeting these. We anticipate that substantial training, guidance and scientific information will need to be provided to both industry and regulators in advance of this rule being implemented. We feel strongly that education should come before regulation and enforcement to increase the success of these new food safety rules.

To this end, FDA must include robust funding for education and outreach in its budget for FSMA. Right now our growers are clamoring for educational material and while our land-grant Cornell University and excellent Cooperative Extension have helped immensely, they will need even more resources to provide the best information to our farmers. These entities do not have budgets that can easily take on the new efforts that FSMA training will require, so we strongly encourage FDA to earmark FSMA funding for partnerships like these (including the Produce Safety Alliance and produce stakeholder organizations) which will be able to deliver educational programming.

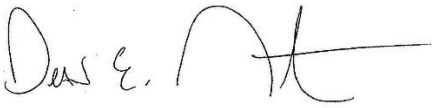
Data Privacy and Recordkeeping Requirements
Farmers are concerned about the privacy of their personal information and proprietary information regarding their farm business. ***FDA must take measures to ensure data privacy and confidentiality of individual farm businesses and their proprietary information.*** 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.

Furthermore, the records and other documentation necessary to implement these rules should not increase production costs for our farms, many of which are small businesses that cannot afford to

purchase data programs or hire an additional staff member to maintain complicated records. Recordkeeping requirements should be flexible enough to allow farmers to integrate into their current system with limited burden.

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. In fact, according to a 2013 farm computer usage survey conducted by the U.S. Department of Agriculture, 69 percent of farms in New York have internet access. This leaves 31 percent of our farms—or more than 11,000 operations—that do not currently have internet access.
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 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.

Conclusion
Once again, thank you for providing the opportunity for us to comment on the revised rule. NYFB remains committed to improving produce safety in a targeted, scientific, and risk-based manner. We look forward to continuing or working partnership with the FDA to promote the safety of fresh produce.
Sincerely,



Dean Norton
President