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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: Docket No. FDA-2011-N-0921

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.

NYFB submitted comments during the first comment period on this proposed rule. We greatly appreciate FDA taking the time to review all the comments submitted and providing stakeholders a look at changes and the ability to respond during a second comment period. This is a complex rule and how it interacts with other rules under FSMA is important and we are pleased that FDA recognized this.

We further believe that the best way to implement this rule successfully—and to ensure the public's health—is by sticking to science-based protocols that do not unnecessary overburden farmers. To this end, we acknowledge and appreciate FDA making several significant changes to this rule, many in line with recommendations from NYFB. While I will note those below, it is also important to mention that some changes did not go far enough to ensure they are workable and practical for farmers to implement in the Northeast. I hope you will again take our comments into serious consideration as the agency

continues to improve this rule with the end goal of a thoughtful, meaningful and practical rule for our domestic food producers.

General Comments

We believe in the goal of improving food safety and have long supported research and education efforts to this end and hope that federal research monies will continue to support these types of efforts.

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 domestic produce provides the best way to ensure safe food 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 provided producers confidence in its international implementation going forward.

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.

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 condition, 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, including 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 (AFBF) 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 concerns raised above. First it, is inclusive of the various individuals that might be responsible for the operation of a "farm". The use of pronouns to refer to the "owner, operator or agent in charge" is appropriate. Second, we believe "one general physical location" is an irrelevant descriptor that cannot be clearly defined without being arbitrary or capricious. Hence, it should be removed from the definition of farm. It also allows packing and holding activities performed on RACs, as this allows for packing house operations to be considered "farm" establishments and be covered by the produce safety rule. This provides uniform and effective regulation of all packing activities irrespective of their physical location to be solely covered by the produce safety regulation.

Packing, Holding, & Harvesting

We further commends FDA for expanding the definitions of packing, holding, and harvesting. We generally support the updated versions of the definitions as provided in this supplemental proposal. Notwithstanding, there are other tasks that we want to draw attention to that should be contemplated in the definition of "holding" and "harvesting." We recognize that this is not an exclusive list, but we want to draw FDA's attention to a few other examples to better assist in future interpretation of harvest activities. One example is ripening of fruit. Ripening, whether by natural means over time or stimulated by introduction of ethylene for climacteric fruits, is done for the purpose of preparing a raw agricultural commodity for use as a food and hence should be defined as "harvesting" for the purposes of this regulation. Ripening is not a manufacturing or processing step as the RAC does not undergo any substantial transformation and is exactly the same food product being introduced into commerce both

before and after ripening. A second example that should be included in the definition of "holding" is fumigation. Fumigation of raw agricultural commodities is done for the safe effective storage of many fruits and vegetables and should be defined as "holding" for the purposes of this regulation.

Exemptions

As recommended in our initial comments, we appreciate FDA changing the farm sales exemption level calculation to include only the sales of produce, rather than all food. 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 commend FDA for making this change to implement the rule over covered produce in a fair manner and avoid unnecessary burden on producers.

Agricultural Water

NYFB commented strongly against the original proposal for the water quality standard and testing regime and we appreciate that FDA recognized how impractical this would be and made revisions. However, we still maintain that the water standard proposed by FDA is arbitrary and unreasonable. We do not support the use of quantitative generic *E. coli* levels as the criteria in the regulation to determine whether agricultural water is safe for use on farm.

Water Quality Standard

As stated in our previous comments, we continue to oppose FDA's use of the EPA recreational water standard as a food safety water quality standard. To justify the use of this standard, FDA still has not: 1) provided an adequate scientific basis for using this recreational water standard for general *E. coli*, 2) established a correlation between this standard and food safety, or 3) conducted the necessary research to establish an appropriate standard.

Our members fear that this arbitrary standard will not achieve the intended improvements in food safety, but could instead drive up compliance costs on the farm. For instance, there is no evidence that EPA's standards for generic E. coli numbers has any bearing on food safety when used in the common pre-harvest activities of irrigation or agricultural spraying. These activities, however, can be very important to the outcome of the crop in both yield and quality. Using this standard could remove the ability to irrigate or spray when necessary and undermine crop production under certain circumstances, which would not sacrifice the food safety of these same products.

Even with the added flexibility provided in the supplemental rule, which NYFB acknowledges, the standard will likely result in farms losing access to critical sources of water and could result in crop loss or extreme difficulty for some farms in obtaining water for agricultural practices. Without a scientific basis, we believe the EPA recreational water standard is unreasonable.

The standard is arbitrary as the presence of generic E. coli has not be demonstrated to be a reliable indicator of the presence of pathogens that actually lead to food-borne illnesses in humans. So, FDA is imposing a standard on American farmers that does not correlate to improved food safety results for consumers and could be overlooking more appropriate indicators of food-borne illnesses.

NYFB recommends that FDA utilize this standard as a <u>voluntary</u> measure, along with the flexibility provided within this supplemental rule, until such time as the FDA can develop an appropriate standard. However, if FDA does implement this standard against recommendation, it should <u>include a mandatory sunset provision</u> of three to five years so that research into an appropriate food safety

standard for water quality can be hastened and completed to provide a reasonable, science-based standard to replace this recreational standard.

Water Quality Flexibility Proposals

In spite of using an unreasonable water quality standard, we do appreciate that FDA creates flexibility in the application of this standard. We commend FDA for revising the single maximum requirement and providing parameters for die off rates. We do note that because of the complexity of the testing regime, we support American Farm Bureau Federation's (AFBF) recommendation to place this in guidance for adaptability in the future.

NYFB supports the implementation of the die off mechanisms that allow farmers to continue use of irrigation water that does not meet the desired standard and we believe this is still supports the safety of the food. We also support allowing the 0.5 log per day die-off rate to be applied per hour rather than 24-hour period to allow the maximum irrigation opportunity. We also support the implementation of allowing die-off rates, so long as farmers provide adequate scientific data. Additionally, for covered produce that is stored after harvest, we support the using an "appropriate" microbial die-off rate taking into consideration other activities that may be conducted before a sale.

Water Testing

We commented strongly and appreciate that FDA recognized the original testing requirements were not only unreasonable but incredibly costly to farmers, with no added food safety benefit. Generally, we believe the tiered approach, including the baseline survey, annual verification testing, and requirements to develop new water quality profiles, sampling requirements, and reduced frequency of testing is a much more cost effective and workable testing model. We again note that we support AFBF's suggestion of providing these regulations in guidance for adaptability in the future.

We support the "testing as close to harvest as practical" as being determined by the farmer, as harvest times vary from crop to crop and farm to farm and some flexibility here is needed. We believe this to be a better model than implementing an arbitrary time period that may not reflect certain conditions of that growing season or needs of that commodity.

We still believe testing frequency of all sources of water is required too frequently and could be cost prohibitive for farms that include multiple locations and multiple sources of water. FDA seeks comment on whether increased testing should be required for highly variable water sources. We would oppose this action, considering most if not all surface water would qualify as a "moving water body." This inclusion would defeat the purpose of a more adaptable testing model.

Given the possible costs of this testing for some farms, and the need to reduce redundancy in the system, we strongly support allowing the sharing of water testing data. Farmers using surface water access the same source and sharing of information would substantially decrease costs and burden on farmers.

However, the testing requirements and calculations still remain confusing for farmers and FDA should be mindful of providing either greater clarity in the final rule or providing guidance that will answer the questions farmers will have. This part of the rule will likely be the most problematic and most difficult for farmers to understand and ensure they are complying with correctly. To avoid unintended violations, it is important that FDA work closely with stakeholder groups, educators and the state regulators we

anticipate will be carrying out this rule so that growers receive a thorough understanding of what is expected and how to carry it out as the rule pertains to water quality standards.

Biological Soil Amendments

FDA's proposed minimum application period in the original proposal for untreated biological soil amendments of 270 days before harvest (if the covered product is reasonably likely to contact soil after application) would have been very difficult for many growers to meet in the Northeast and we commend the agency for removing this requirement until a more appropriate time interval can be determined.

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. In determining a more appropriate timeline, FDA should also consider the impact on environmental regulations and the comprehensive nutrient management plans that either the state or federal government have already approved for some of our farms. These plans specifically outline nutrient application amounts and times and we would not want to push farmers to apply nutrients during more environmentally sensitive times. Instead, any standard should take into account the short growing season in the Northeast and the need to serve both food safety and environmental concerns at the same time.

We appreciate that FDA will specifically not force growers already complying with USDA's National Organic Program standards to make changes from using a 120-day interval for raw manure application to crops prior to harvest. This practice has not led to a higher incidence of food-borne illnesses in organic produce over conventional and the produce safety regulations were clearly not intended to include any requirement that conflicts with the National Organic Program.

Additionally, we appreciate FDA eliminating the 45-day application interval for compost as this is, by its nature, a safe alternative to raw manure. Many of our produce farmers are already adopting the use of compost over raw manure applications and removing the 45-day application interval will encourage greater adoption of this practice.

In addition to this change, FDA suggests conducting a risk assessment on the safe use of raw manures in covered produce. While we believe that the history of the use of current standards shows there is no confirmed risk that would warrant such a risk assessment, if FDA goes forward we encourage strong stakeholder participation. We also encourage FDA to consider growing seasons and cycles, as mentioned above, if such an assessment warrants changing the application period. It would be unworkable on farms for such a standard to change during a growing season in which biological amendments may have already been applied. Any changes may need more than a year lead time.

Domestic and Wild Animals

Although the supplemental rule does clarify that farmers are not expected to exclude animals from outdoor growing areas or destroy animal habitat in an effort to remove animals, we still remain very concerned that the wildlife requirements show a lack of understanding about the environment that Northeast farmers work in. Some farmers already work to exclude wildlife from fields because animals can destroy crops and introduce a potential for contamination. Other farmers actually participate in federal or state conservation programs that encourage practices that provide habitat to wildlife near agricultural fields. Either way, this rule is still unclear as to the obligations of a farmer during harvest when it is reasonably likely that an animal has been in the field. As written originally and not amended,

this rule could effectively prevent the harvest of many fields of completely safe produce if clarity is not provided.

The rule currently states farmers must "take all measures reasonably necessary to identify, and not harvest, covered produce that is reasonably likely to be contaminated with a known or reasonably foreseeable hazard, including steps to identify and not harvest covered produce that is visibly contaminated with animal excreta."

Farmers and their employees already avoid harvesting produce they have reason to suspect is contaminated, so the "visibly contaminated" part of the rule is clear. Visual inspection by trained farm workers remains the most effective way to deal with this type of threat. However, what constitutes a "reasonably foreseeable hazard" is still ambiguous and could lead an overzealous inspector to force a farmer with a strong food safety record to unnecessarily waste healthy food. NYFB would still like to see the final rule acknowledge that the presence of an animal in a field does not mean food has been contaminated and that should not necessarily prevent the harvesting of the food unless a clear risk can be identified. New York farmers would like to see much clearer language on this issue.

Alternately, we appreciate FDA's continued consideration of the use of working animals in fields and its recognition of the need for this practice to remain available to those sectors of the industry that rely upon it—whether working horses, working oxen, working dogs or other animals that are working on the farm. However, we remain concerned that FDA may still be unclear on the use of working animals within fields and how it would be difficult, if not impossible, for farmers relying on working animals in the crop production to follow certain guidance presented in the proposed rule. For example, the rule suggests that farmers could use designated horse paths segregated from produce. When horses are used for plowing, treatment, picking and checking crops, it would be nearly impossible and certainly improbable to have a designated path that was completely segregated from growing produce at all times. We urge FDA to consider this before finalizing the rule so as not to make food production impractical for farmers using working animals.

Withdrawal and Reinstatement of Qualified Exemption

Furthermore, we support the modified requirements required prior to withdrawing a qualified exemption. In the original rule, farmers feared they would not have an opportunity to take corrective actions before having an exempt status fully withdrawn. We support FDA's proposal to require FDA issuance of a warning letter, recall, administrative detention, refusal of food offered for import, seizure, and an injunction. This would provide an intermediary step prior to a full withdrawal.

It is also critical that the farm has the opportunity to respond to any alleged problems identified by the FDA and for FDA to consider the farm's response prior to issuing an order to withdraw the exemption. We thank FDA for recognizing the farm's due process rights within the supplemental rule.

We also support FDA's addition of a process to reinstate a qualified exemption. This process recognizes that farms can manage a food safety risk and return to compliance. Moreover, this process is especially critical where an alleged outbreak is not directly linked to the farm at all.

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 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 both producer and state education and outreach, possible state staff, and other needs necessary to implement this rule*** 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

New York Farm Bureau appreciates FDA's efforts to improve this rule in response to farmer comments and we encourage the agency to continue its efforts as suggested above to ensure a targeted, science-based and risk-based approach. Produce farmers here in New York consider food safety a top priority and want to partner with FDA and our state Department of Agriculture and Markets to accomplish this. However, we remain committed to 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