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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-0921 – Revised "Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption."

American Farm Bureau Federation (Farm Bureau) is the nation's largest general farm organization, representing approximately 6 million member families and growers of virtually every commodity. The implementation of the Food Safety and Modernization Act (FSMA) is a major challenge and we appreciate Food and Drug Administration (FDA) recognizing that farmer and rancher 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 present viewpoints from the farm level on the modifications to the initial produce safety proposal. Moreover, we appreciate clear acknowledgment of concerns raised in Farm Bureau comments dated November 21, 2013, and the resultant modifications seen in the revised Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption (Produce Safety) rule.

General Produce Safety Comments

Farm Bureau has a vital interest in how food safety is practiced, perceived and regulated. We believe that, while the U.S. food production system is among the best in the world, science-based, collaborative improvement is an important element in the system.

By their nature, food systems are biological and thus not failsafe nor ever "zero risk." 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 U.S. now imports food from more than 150 different countries through more than 300 ports of entry. About half of fresh fruits eaten in America are grown outside of the country, and these imports allow us to enjoy our favorite produce year-round. Trade in food permits a more varied and customized diet suited to today's consumer preferences. It permits farmers and other food producers to sell their goods abroad. But 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.

Adding to the complexity presented by increased food sources, the number of people involved in preparing the food we also consume has increased. Approximately 50 cents of every food dollar today is spent on foods prepared outside the home in places like restaurants, vending machines, and schools. This reality increases the need to ensure adequate training for food service workers across the country and to be vigilant against the potential of deliberate contamination of the food supply. As the supply

chain gets longer, the potential for both accidental and intentional introductions of public health threats increases.

Because of all these factors, it is critical for FDA to set forth science-based standards, accommodate the complexity of the food system, and recognize the unique farm structure within this rule. Overall, Farm Bureau believes this revised Produce Safety rule is a step in the right direction but we still have concerns. We appreciate the opportunity to voice these concerns in these comments.

Definition of Farm

In Farm Bureau's first set of comments, we raised numerous concerns within the definition of farm and mixed type facility. Congress did not contemplate safety standards for farms that would ignore the actual farm structure that exists in practice. In fact, FSMA states that the regulations should provide "sufficient flexibility to be *practicable* for all sizes and types of businesses" and "acknowledge differences in risk and minimize, as appropriate, the number of separate standards that apply to separate foods." FSMA § 105. 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. Farm Bureau believes 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.

Under One Ownership

Farm Bureau raised the concern that the original proposed definitions 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 Preventive Controls for Human Food requirements. We commend FDA for recognizing this 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 the 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.

One General Physical Location

Farm Bureau has concerns regarding the "one general physical location" requirement within the farm definition. As FDA accurately points out, farms generally consist of non-contiguous parcels of land in

various geographical locations, including different counties, states, regions, and countries. This reality must be taken into account in any interpretation of the "one general physical location" requirement.

FDA also rightly notes that a narrow interpretation could impact the amount of covered farms and the application of the produce safety standards. Farm Bureau believes food safety is size-neutral; all growers of covered produce should meet necessary standards. The expansion of exemptions that could arise due to a narrow interpretation may abdicate the overall goals of the rule. However, FDA must consider that the financial ability of growers to implement practices and systems to reduce or limit liability should not overburden smaller growers with unnecessary practices that would drive them out of business. We believe food safety regulations should be tailored to the size, type and capacity of the farm.

Farm Bureau does not see a benefit to including the "one general physical location" requirement. Limiting farms in that manner may cause duplication of requirements, record keeping, and costs. If this requirement is included, it should be interpreted as broadly as possible. Farm sizes and structure vary due to regional factors, climatic conditions, production practices, and marketing and distribution channels. In fact, the average farm spans over 434 acres and consists of several parcels of land, some contiguous and some not. Food safety regulations must be scale-appropriate, recognizing the wide variation in the needs of farmers based on farm size and scope. One size does not fit all, which is why definition "one general physical location" becomes extremely difficult. Because the detriment outweighs any potential benefit, we believe it should be deleted.

While we do believe FDA has made improvements to the definition of "farm," as noted above, Farm Bureau remains concerned about its overall workability. Therefore, we suggest an alternate 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 which has a common, owner, operator(s) or agent in charge and which is 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

As stated above, Farm Bureau 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." Farm Bureau recognizes 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 such example is seed conditioning, which is the act of cleaning seed, including removal of leaves, stems, and husks, in order to prepare it for marketing. The conditioning is done as a harvest activity prior to any transformation of the RAC. The act of seed conditioning, to the extent that seed enters the food or feed chain, should be considered a harvest activity subject to this rule rather than the preventive controls for human food or preventative control for animal feed rules. A second example is ripening (artificial or natural) 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 third 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.

Farm Bureau notes that "packaging" (when used as a verb) should be considered "packing." Packaging activities should not be considered under the term "processing" as they do not "substantially transform" a RAC into a "processed food." Simply by placing raw agricultural commodities in a container that directly contacts the food and that the consumer receives does not transform the product, nor does it impact food safety any differently than "packing." As such, "packaging" of RACs should be considered within the definition of "packing."

Exemptions:

As stated above, Farm Bureau believes food safety is size-neutral and all growers of covered produce should meet necessary standards. Further, FDA must consider the financial ability of growers to implement practices and systems to reduce or limit liability; moreover, smaller growers should not be overburdened with unnecessary practices that would drive them out of business. We believe food safety regulations should be tailored to the size, type and capacity of the farm rather than simply creating threshold exemptions.

In prior comments, Farm Bureau noted our belief that the number of farms exempt due to having less than $25,000 in sales and qualified exemptions had been overestimated. *Farm Bureau Comments: Appendix 1 Economic Analysis.* This was primarily because the sales threshold includes all agricultural products sales, not just horticultural product sales. We noted that small farms tend to be highly diversified, with fruit and vegetable production in addition to livestock and row crops in order to improve cash flow. We appreciate FDAs recognition that diversity is a key risk management practice and support changing the exemption only to include "produce" sales, rather than including all food sales.

FDA also requests comment on whether it should include only "covered produce" sales, rather than all "produce" sales. Farm Bureau supports including only "covered produce" sales, rather than all "produce" sales in order to more fully embrace growers' diversification efforts. Farm Bureau also supports considering "covered produce" sales rather than all food sales within the definitions "very small" and "small" farms.

We continue to urge FDA to reconsider "covered produce" standards that take into account the relative risks and comparative benefits associated with individual commodities. FDA should initially propose regulations for only those commodities with a history of microbial contamination. If these regulations can be successfully implemented and enforced, it may be appropriate at that point to consider whether there is a net public health benefit to be gained from expanding regulations to cover other commodities. If FDA takes the more targeted approach, including only those commodities with a history of microbial contamination, it would be necessary to examine the loss of public health benefits that could occur from excluding those farms with less than $25,000 "covered produce" sales.

Agricultural Water

Farm Bureau commends FDA for recognizing the unworkability of the initial proposed water quality standard and testing regime, but Farm Bureau maintains that FDA applies an arbitrary and unreasonable water quality standard and does not support the use of quantitative generic *E. coli* levels as the criteria in the regulation to determine when agricultural water is not of safe and of adequate sanitary quality.

Water Quality Standard

Farm Bureau opposes FDA's use of EPA's recreational water standard. FDA still has not provided an adequate scientific basis for continuing using the EPA recreational water standard for general *E. coli*, nor has it established a correlation between EPA's recreational water standard and food safety, nor has FDA conducted the research necessary to develop an appropriate standard. This standard will not achieve improvements in food safety but will require extremely high compliance costs at the farm level. Moreover, even with added flexibility, the standard will likely result in farms losing access to critical sources of irrigation water and experience crop losses. Multiple farms will not have the financial or technical means to use the water treatment and testing schedule that would be necessary under the proposed or even the supplemental rule. Therefore, its use as a binding FDA regulatory standard is completely arbitrary and unreasonable.

We recommend that FDA utilize this standard as a voluntary measure, along with the flexibility provided within this supplemental rule, until such time the FDA develops an appropriate standard. In

the meantime, if an agricultural water standard must be used, it should be no more restrictive than the current World Health Organization's (WHO) recommended standard. Without sound scientific justification for enacting a standard more restrictive than the international standard, the United States risks running afoul of its World Trade Organization (WTO) obligations.

We do not believe the additional justification provided in this supplemental rule meets the required standards. When promulgating a rule, the agency "must examine the relevant data and articulate a satisfactory explanation for its action including a rational connection between the facts found and the choice made." *Motor Vehicle Assn. v. State Farm Mut.*, 463 U.S. 29, 43 (1983). In this case, the water standard, which focuses solely on generic *E. coli*, is wholly uncorrelated with the human pathogens of concern that have caused produce outbreaks and recalls such as E. coli O157:H7, Salmonella enterica, Listeria monocytogenes, and the recent outbreak organism Cyclospora cayatenensis.

In support of its proposal, FDA cites the fact that some industry groups have adopted the generic *E. coli* component of the EPA recreational water standards for certain uses of agricultural water, as well as the fact that British Columbia. Canada has also announced its intention to use this standard. What the agency fails to acknowledge, however, is that USDA researchers question the effectiveness of these very industry standards. *See* Daniel Shelton, Jeffrey Karns, Cary Coppock, Jitu Patel, Manan Sharma, & Yakov Pachepsky, *Comparison of Generic E. coli vs. Pathogenic E. Coli Virulence Factors in an Agricultural Watershed: Implications for Irrigation Water Standards and Leafy Green Commodities*, 74 J FOOD PROTECT 18 (2011).

USDA researchers noted in 2011 that all of the reported cases of fresh produce contamination from irrigation waters were due to cattle, and generic *E. coli* are excreted by wildlife and waterfowl, the vast majority of which are not pathogenic to humans. Thus, the adequacy of the generic *E. coli* standard was determined to be unclear. Moreover, in their study, the researchers analyzed water samples for both generic *E. coli* and virulence factors associated with pathogenic *E. coli* from a predominately agricultural watershed. While there were relatively high concentrations of *E. coli* and prevalence of virulence factors, the agency researchers were unable to establish any relationship between the two, suggesting that generic *E. coli* may not be a reliable indicator of irrigation water quality. *See id.*

Further evidencing the lack of a rational connection between the scientific realities and the FDA proposal is the fact that the EPA recreational water standards were not only developed over two decades ago, but were founded on epidemiological studies that correlated the risk of gastrointestinal illness to exposure to marine and freshwater swimmers. As even FDA points out, "the risk of adverse health outcomes resulting from full body contact in contaminated water may be different than risks associated with consuming produce irrigated with contaminated water, given the differences in expected routes of infection and pathogen mortality rates in different environments (bodies of water for the EPA recreational water standards; soil, plants, and produce for this proposed rule)." 78 Fed. Reg. 3569. In reality, the link between EPA's epidemiological studies and produce safety is attenuated at best.

FDA's conclusion that the recreational water standards would "serve to minimize a risk of unknown or reasonably foreseeable hazards" is clearly not an expert-driven decision. Moreover, the agency has failed to give adequate consideration to the relevant data and provide reasoned explanations to support its decision. Just because FDA acknowledges the limitations of the recreational water standards does not make it an acceptable proposal. In fact, the agency's acknowledgment only serves to illuminate the

inappropriateness of the standards further. To finalize this proposal without adequate justification – and none is provided in the preamble to the proposal – would be arbitrary and capricious.

Water Quality Flexibility Proposals:

In an attempt to make an unrealistic water quality standard workable, FDA does create flexibility in the application of this standard. We commend FDA for revising the single maximum requirement and providing parameters for die off rates as few, if any; surface irrigation systems could meet the EPA's recreational contact water standard as was originally proposed. We do note that because of the complexity of the testing regime we support placing this in guidance for adaptability in the future.

In regard to the single maximum level of generic E.Coli revision, Farm Bureau still believes that focusing solely on generic *E. coli*, is wholly uncorrelated with the human pathogens of concern that have caused produce outbreaks and recalls.

Notwithstanding this opposition, using a testing method of multiple samples and using Statistical Threshold Values (STV) and Geometric Means (GM) is a much more workable model. This model provides assurances that growers will not lose access to a critical water source due to a higher single test result as long as the average does not exceed 126 CFUs. Farm Bureau supports the implementation of the die off mechanisms that allow farmers to continue use of irrigation water that does not meet the desired standard. Both die off standards applying between last irrigation and harvest and harvest and end of storage, provide more flexibility and workability. However, Farm Bureau does have some concern that ceasing irrigation may be detrimental to production. The end of season irrigation water can be critical to overall yields, and FDA must be mindful of that when establishing the die-off rate. Every hour that a grower is unable to apply water is critical and as such Farm Bureau seeks more guidance on implementation of the .5 log per day die-off rate. It is unclear whether FDA interprets "per day" to be a 24-hour cycle or if the desired quality can be met within some portion of the 24 hours period if that would meet the standard. To clarify - FDA gives two numerical examples of situations where a grower could meet the microbial standard requirements by utilizing the die off standard. In the first example, FDA shows that if the grower utilized the 0.5 log per day, 1-day time interval he could meet the microbial standard because the GM and STV values would be reduced to 76 CFU per 100 mL and 182 CFU per mL, respectively. However, our calculations reveal that the grower could meet the microbial standard after 14 hours, still utilizing the 0.5 log per day interval. After 14 hours, the GM would be 123 CFU per 100 mL and the STV would be 294 CFU per 100 mL. In the second example, FDA shows that if the grower utilized the 0.5 log per day, over a three day time interval he could meet the microbial standard because the GM and STV values would be reduced to 8 CFU per 100 mL and 145 CFU per mL, respectively. However, our calculations reveal that the grower could meet the microbial standard after 51 hours, still utilizing the 0.5 log per day interval. After 51 hours, the GM would be 20 CFU per 100 mL and the STV would be 398 CFU per 100 mL.

Generally, Farm Bureau supports maximum flexibility within the die-off rates. We support allowing the 0.5 log per day die-off rate to be applied per hour rather than 24hour 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 the sale of that covered produce.

Water Testing

Farm Bureau appreciates FDA recognizing the original testing requirements were not only unreasonable but incredibly costly with no added food safety benefit. Generally, Farm Bureau believes 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 much more cost effective and workable testing model. We again note that we support providing these regulations in guidance for adaptability in the future. Farm Bureau supports testing as close to harvest as practical and allowing that time to be determined by the farmer. 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 also support allowing the use of annual survey data set for verification and do not believe any circumstances warrant changing water practices in season. If there is a significant change in testing results, food safety will be protected by the die-off rates that particular season.

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 with varying 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.

Farm Bureau strongly supports allowing the sharing of water testing data. Surface water irrigators often use the same source and sharing of information would substantially decrease costs. This also may provide opportunities for water resource districts and cooperatives to assist and provide testing as a benefit to their members.

Biological Soil Amendments

Farm Bureau supports FDA's implementation of the current accepted standard of 120 days between application of soil amendments and harvest and eliminating the 45 day minimum compost application period rather than the 9 month requirement used in the original rule.

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, if such an assessment warrants changing the application period. It would be unworkable for such a standard to change in a growing season where biological amendments may have already been applied.

Domestic and Wild Animals

Farm Bureau would like to thank FDA for its 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. We also appreciate that FDA does not require covered farms to take measures to exclude animals from outdoor growing areas. Any such requirement would be completely unworkable.

We suggest that food safety practices be developed only to address the highest risk areas of wildlife intrusion.

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 proposed 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.

Withdrawal and Reinstatement of Qualified Exemption

Farm Bureau supports the modified requirements required prior to withdrawing a qualified exemption. We raised concerns in our original comments that a farm would not have the opportunity to take corrective actions before having its 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. Farm Bureau appreciates FDA's recognition of the farms due process rights within the supplemental rules.

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

Recordkeeping

Farm Bureau wants to reiterate that records and other documentation necessary to implement these rules should not increase production costs for diversified farmers, most of whom operate small businesses. Farmers currently maintain a plethora of records, yet most farms do not have the technical or financial resources available to make their record-keeping systems interoperable with government or others in the food chain.

According to USDA's National Agricultural Statistics Service (NASS), 70 percent of farms have access to a computer, 68 percent own or lease a computer and 40 percent of U.S. farms used a computer for farm business in 2013. NASS also concludes that two-thirds of U.S. farms have Internet access, but some farms still rely on dial-up access. Therefore, if recordkeeping is determined necessary, there must be acceptable, basic alternatives to an electronic format.

The privacy and confidentiality of individual farm businesses must be considered in the development of new regulations. Any recordkeeping requirements must be accompanied by assurance that information accessed by federal government authorities in regards to food safety protocols will remain confidential and that a system of records is developed in accordance with the Privacy Act.

Implementation, Compliance, and Enforcement

Regulatory Consultation and Coordination - Implementation

Institutional relationships between state and federal food safety personnel will need to be developed to successfully implement FSMA. We encourage FDA to heavily consult state and local food regulatory agencies that are willing to participate in the implementation of FSMA and integration of state and federal food safety systems, and to pursue mutually workable strategies for future collaboration. State Departments of Agriculture are a valuable resource that should be utilized in any contact with, outreach to or education for rural areas.

Compliance and Enforcement

One of the most important ways FDA can demonstrate commitment to implementation and workability of these rule is by developing world-class training programs for inspection staff. The supplemental rules provide for much flexibility and to ensure workability and proper compliance inspectors must be thoroughly trained in a manner that is consistent and uniform, such that all inspectors are able and willing to enforce rules competently and fairly.

It is imperative that FDA inspectors understand that a farm is vastly different from a food manufacturing facility. FDA must train inspectors to understand routine and acceptable on-farm practices. Training relevant FDA staff at all levels will be critical to ensuring that the Preventive Controls rule functions as intended. As a preferred alternative to the expenditure of considerable FDA resources to establish qualified inspection personnel, we urge FDA to utilize partnerships with existing well-trained regulators already knowledgeable about these practices. In particular, we encourage more cooperative agreements with state departments of agriculture that are closer to the farm level and have a strong history of largely successful inspection processes.

We have heard concerns from state partners about the lack of information FDA has provided on the nature of future cooperation. Exactly how inspections will be carried out, and the structure of state-federal relationships must be established as soon as possible in order to ensure uniform enforcement among states.

Specifically, we request that FDA answer the following questions to provide a framework for transparent and reasonable expectations:

- What mechanisms will FDA use to delegate authority to the states?
- Will FDA create commissions or credentialing of state personnel to conduct inspections?
- If a state is unable to actively support one or more FSMA requirements, will FDA chose to implement the rules with its own inspectors?

Outreach

Communication and coordination with growers and others in the produce industry is essential. We commend FDA for continuing stakeholder discussions exemplified by issuing the supplemental rules. FDA should continue to work with stakeholders to clearly define education and outreach needs. FDA must provide substantive training, guidance and scientific information to both industries and local

regulators. The implementation of any new rule in the absence of appropriate guidance and support will lead to negative unintended consequences for growers and will impede the progress of protecting public health as intended by FSMA. Education should come before regulation to increase the ultimate likelihood of successful adoption of any new food safety standards.

FDA must include robust funding for education and outreach in its budget for FSMA. Additional resources are by far the greatest component needed to create a more thorough educational delivery system. The federal-state-local scope of USDA's National Institute for Food and Agriculture, agricultural universities and extension professionals offer excellent infrastructure, but the budgets of these entities are insufficient to take on new efforts. We strongly encourage FDA to direct FSMA funding to this partnership and others like it that are already well-suited and ideally positioned to disseminate educational programming and curriculum.

Research

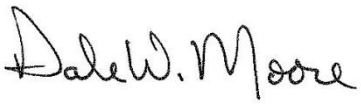
Additional FDA resources are needed to fund produce safety research. In particular, water used in production and post-harvest handling of produce requires more data to inform on-farm actions. Additionally, further research is needed for the following specific areas:

- 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 about 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.

Conclusion

We are committed to improving produce safety in a targeted, scientific, and risk-based manner. We look forward to continuing our working partnership with FDA to promote the safety of fresh produce.

Sincerely,



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