Association of Food and Drug Officials

2550 Kingston Road, Suite 311, York, PA 17402
Telephone (717) 757-2888 ● Fax (717) 650-3650
E-Mail: afdo@afdo.org ● Internet: www.afdo.org

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Department of Health and Human Services
Food and Drug Administration

RE: Comments from the Association of Food and Drug Officials
Docket No. FDA-2011-N-0921, "Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption Proposed Rule"

The Association of Food & Drug Officials (AFDO) is a national organization that represents state, local, and federal food, drug, and medical device safety regulatory officials. AFDO is well known for promoting uniformity and cooperation among the regulatory community and has helped to foster numerous collaborative projects to advance these objectives. Among the national projects AFDO was active in developing and promoting are the Seafood HACCP Alliance, National Food Safety System (NFSS) project, States Helping States project, the International Food Protection Training Institute (IFPTI), the Manufactured Food Regulatory Program Alliance, and FoodSHIELD. Additionally, AFDO has developed a host of model codes that states utilize in promulgating their own specific regulations. AFDO model codes such as our "Cured Salted and Smoked Fish GMP's", "Guidelines for Juice Manufacturers", "Produce Safety Model Code", "Retail Meat & Poultry Processing at Retail Guidelines" and "Reduced Oxygen Packaging at Retail" were authored following outbreaks and specific food safety concerns associated with these types of food products. A number of federal and state standards and regulations have been developed in part from the information contained within these model codes. Because of AFDO's strong association with state food safety programs, the organization is in a unique position to promote food safety projects and efforts that we feel will help to advance a national integrated food safety system that we have advanced for over 15 years.

While AFDO strongly supports the enactment of the proposed rule, we also recognize that it will take an active partnership and an integrated government effort to meet the demands of the proposed rule in terms of inspection and enforcement. **The proposed rule will only be effective if government agencies actively enforce it in a well-coordinated fashion.**

Many of the outbreaks associated with fresh fruits and vegetables were investigated by a number of our members and following each of these outbreaks questions were raised as to the current effectiveness of government activities in the fresh produce arena. Our comments to FDA are provided with the understanding that government must address the food safety concerns associated with fresh fruits and vegetables in an integrated manner that can begin in a similar progressive fashion as was conducted for fishery products, meat & poultry, shell eggs, and vegetable juices.

AFDO has members active in the Produce Safety Alliance Steering Committee and the various Working Groups that address the various components of produce safety and Good Agricultural Practices (GAPs). At this time AFDO will provide comments that relate to the proposed rule in general.

Additionally AFDO is providing comments and working with the National Association of State Departments of Agriculture [NASDA] on more specific comments relating to the various Subparts of the proposed rule. We are supportive of NASDA specific comments for agricultural water, soil amendments, animal control, sprouts, variances, and definition clarification.

AFDO general comments are as follow:

1) Communication with State Partners and other State/Federal Agencies

FDA must foster regular communication and information exchange with state partners and other state and federal agencies. Further development and implementation of the Produce Safety Rule will require a coordinated effort from FDA and its state partners. Because state agriculture agencies work closely with farmers, they are acutely aware of the challenges producers will face. It is essential that FDA establish regular and open communication with state organizations such as AFDO in addition to communicating directly with states by answering questions, addressing individual concerns, and listening to input from its partners. While AFDO applauds FDA's intent to provide a better food safety framework, if State and Federal agencies fail to effectively implement FSMA, or farmers are unable to comply, the rules will fail. FDA must continue to facilitate more dialogue with stakeholders and state governments prior to issuing the final Produce Safety Rule. AFDO also recommends that standardized mechanisms of communication between FDA and state governments be established before, during and after final rulemaking to ensure well-coordinated implementation. FDA participation in forums or question and answer panels at AFDO and AFDO affiliate meetings attended by state policy and program managers is recommended.

2) Exemptions

As required by Congress, farms would be partially exempt from the proposed rule if they meet two requirements. First, they must have food sales averaging less than $500,000 per year during the last three years (adjusted for inflation). Second, their sales to qualified end-users must exceed their sales to others during the same period. A qualified end-user is either a consumer (in any location) or a restaurant or retail food establishment located in the same State as the farm or not more than 275 miles away from the farm. However, FDA may withdraw this partial exemption if the farm is directly linked to an outbreak, or if FDA determines it is necessary to protect the public health and prevent or mitigate an outbreak based on conditions or conduct that create the potential for the farm's produce to cause an outbreak.

Some states may be interested in developing their own state-wide food safety program that would be more inclusive and promote more of a complete preventative food safety program. Some states and regions structure of food production consists of small scale diversified farms distributing their local agricultural products to conveniently accessible markets. This production structure is uniquely affected by the proposed rules. AFDO recommends that FDA allow the states to promulgate regulations that cover producers who fall under the $25,000 exemption and between the $25,000-$500,000 exemptions.

In relation to exemptions, AFDO has always opposed them on the grounds that they are typically unenforceable. How will determinations be made to assure a farm has food sales averaging less than $500,000 per year during the last three years? Will there be a process for establishing and removing exemptions? Who will verify that sales are located in the same state and are not more than 275 miles away? The limited inspection resources that currently exist should not be devoted to determining the annual sales of a grower or the miles they distribute from their location.

Exemptions can also have a huge impact on national uniformity. An illustration of this can be clearly seen with

USDA/FSIS exempt poultry processing facilities. Some states license and inspect the exempted facilities while others do not, the result of which is non-uniform oversight.

We have learned from the past that an entire industry can be negatively impacted by the smallest of operations. Exempting small grower operations is unwise, in our view. FDA notes, however, that exempted farms are and will continue to be covered under the adulteration provisions of the FD&C Act, whether or not they are included within the scope of this proposed rule. These adulteration provisions, however, are reactive forms of compliance and not preventive, which is the primary focus of all proposed FSMA rules. The adulteration provisions of the FD&C Act are regulatory responses which are generally taken after an episode has already happened.

Furthermore, we do not believe it is unreasonable to expect commercial fruit and vegetable growers or packers of produce that will be consumed by humans to be required to conduct an operational assessment and food safety plan for their operation to provide food safety assurance. The idea that one establishment is exempted from this rule until such time that their products have been linked to an outbreak or has been posted on the *Reportable Food Registry* does not make good sense from a public health perspective. Does FDA have a proposal on how food safety plans can be incorporated into the Produce Safety Rule to provide some degree of prevention/protection for producers technically exempt from inspection/regulatory coverage under the exemption provisions of the Tester Amendment? Could FDA please share their thoughts or rationale on why they did not include/require Food Safety Plans in the rule?

AFDO does support, however, the ranking of produce commodities by risk for determining the need for inspection and consideration of inspection frequency.

AFDO also supports the categorization of farms as “Very Small Businesses”, “Small Businesses”, and “Other Businesses” to provide added time for the smaller operations to come into compliance with the proposed rule.

And finally, exemptions create an uneven playing field and places more of a burden on retailers and consumers who receive products from exempted firms.

3) Role of the States

Currently, some State agriculture food safety programs have experience in conducting farm growing and packing evaluations through inspections for Good Agricultural Practices (GAPs). There are also State health agencies which have experience at the grower level in conducting investigations following illness outbreaks. We believe these agencies can play a major role in conducting inspections and performing enforcement actions that will result from enactment of the proposed rule. We envision that contracts or cooperative agreements with these state agencies to conduct produce safety work could be assigned. FDA must first clarify; however, what they believe is the appropriate role of the states. Until this point, only conceptual discussions between current state and federal food safety personnel have occurred regarding the potential institutional relationships that may be needed to implement FSMA. Even though FDA has not yet spelled out what FDA believes is the appropriate role of the states, it is clear that FDA intends to have states involved. Reference is made to the following pages in the proposed rule:

Section V The Proposal, Q Subpart Q – Compliance and Enforcement, Subsection 4. Inspections:

- Page 392 of the Federal Register version of the preamble “...FDA intends to work collaboratively with our federal and state regulatory partners to use available inspection resources...”
- Page 392 of the Federal Register version of the preamble “....We expect to continue to cooperatively

leverage the resources of federal, state, and local government agencies...."

- Page 393 of the Federal Register version of the preamble "...States may choose to adopt requirements modeled after the provisions of a final produce safety rule and may choose to perform inspections under their own authorities..."

Section V The Proposal, Q Subpart Q – Compliance and Enforcement, Subsection 5. Comments Related to the Proposed Provisions:

- Page 394 of the Federal Register version of the preamble "...funding should be provided to states to hire and train auditors..."
- Page 394 of the Federal Register version of the preamble "...FDA intends to work collaboratively with our federal, state, territorial, tribal, and local regulatory partners to use available resources to conduct risk-based inspections of farms for compliance with the final regulation..."

The states may not have available inspection resources to take on this entirely new sector of previously unregulated industry, and FDA should not assume all states will conduct FDA contract inspections or adopt the pending rule. In our opinion, funding must be provided to the states to support the hiring and training of auditors in the form of a permanent funding stream. FDA should work closely with the Produce Safety Alliance, AFDO and the International Food Protection Training Institute to assure state officials are provided the necessary training and are fully prepared to meet the mandates of the proposed rule. Inspections should be uniform and consistent among federal and state officials conducting food safety assessments at the farm level, and this can be accomplished through appropriate training.

Specifically, AFDO supports the National Association of State Departments of Agriculture's [NASDA] recommendation for establishing a grant funding program to issue awards to state food safety agencies, to develop the infrastructure, capacity, and capability to conduct inspections at farms subject to the Produce Safety Rule. Under this grant, funding would be provided for eligible agencies to develop and maintain a regulatory inspection and compliance program necessary to conduct produce safety inspections in accordance with the Produce Rule. Funding under this program would be utilized to:

- Obtain training for inspection, compliance and management personnel;
- Develop a comprehensive produce inspection program that includes provisions for compliance and enforcement;
- Collaborate with FDA to develop an inventory of farms subject to the Produce Safety Rule;
- Obtain appropriate authority to conduct inspections either through federal credentials or through statutory authority to conduct inspections under state credentials;
- Develop a process of supervision and regulatory inspections of farms to encourage voluntary compliance;
- Develop enforcement actions to be taken, when appropriate, in response to inspectional observations;
- Develop a process for product sampling and analysis to be employed as necessary to support and document inspectional observations; and,
- Facilitate the sharing of educational and outreach material with both exempt and nonexempt firms subject to the FSMA produce rules.

Eligible entities that submit responsive applications and that are selected for funding would receive a base level of funding for a mutually agreed upon period of time, e.g., three calendar years, as established by a grant. Funding awarded to successful applicants is intended to cover entirely the cost of on-farm inspections conducted pursuant to the Produce Safety Rule.

In addition to the base level funding established by a grant, additional funding would be made available to grant recipients under annual administrative supplements based on metrics to consider the following parameters:

- Active participation in grant activities;
- Number of farms in the state;
- Number of inspections conducted;
- State population;
- Population density; and
- At risk population.

Inspections conducted under the grant will be coordinated with FDA. Inspectional activities will require:

- Coordination of inspection priorities and work-planning between FDA and the grantee.
- Grantees to share inspection reports, including compliance and enforcement actions with FDA and relevant participating state agencies.
- Coordination of compliance and enforcement actions to ensure optimal usage of respective agency authorities. AFDO will not support, however, the establishment of a FDA Cooperative Program such as which currently exists for retail food, shellfish, and Grade A dairy products for the purpose of leveraging state resources with this proposed rule.

AFDO believes FDA will need to clarify what their position on acceptable compliance efforts will be, being mindful that state agencies commonly use educational methods in their compliance efforts. AFDO would suggest that FDA not rule out using educational methods for gaining compliance. State agencies can provide supportive data for using education for compliance in other regulated areas. Furthermore, it is unclear whether FDA or the states will conduct the compliance efforts and whether there will be graduated sanctions applied when necessary. AFDO requests clarification on this matter.

4) Implementation

FDA must activate groups and organizations that can help them deliberate how to best implement the proposed rule. Implementation will be a huge challenge and AFDO recommends the process begin now. FDA FSMA Operational Teams must include state participation and input while outreach through industry and government associations can be conducted to keep industry and government officials updated and informed. FDA must foster regular communication and information exchange with state partners and other state and federal agencies. Further development and implementation of the Produce Safety Rule will require a coordinated effort from FDA and its state partners.

Up until this point, only conceptual discussions between current state and federal food safety personnel had occurred regarding the potential institutional relationships that may be needed to implement FSMA. State-level agencies need to have discussions with FDA about the state-federal relationship in terms of delegation of authority and who will be responsible for enforcement once the rules are in force.

Depending on the number and types of facilities that fall under this rule, and depending on what FDA delegates to states, the states question their capacity to carry out the inspections and the environmental microbial testing that may be required by this rule.

FDA is seeking information on the availability of inventories that may exist for fruit and vegetable growers and packers. AFDO may be able to assist FDA in obtaining this information from state agriculture program managers. State Agriculture agencies typically work with and exchange information with the USDA National

Agricultural Statistics Service (NASS) and information may be available through this agency.

5) System to Arbitrate Disputes

FDA must consider developing a review system to arbitrate disputes between industry and government officials over exemption and the content of a food safety plan. The system should be real-time so these matters can be resolved in a timely fashion. What may be challenging to growers and packers is the regulatory environment under which the rule will be implemented and managed. While the prevention concept is flexible, FDA and state regulators typically have their own set of biases about what constitutes a hazard in a specific growing and harvesting process and what type of documentation is appropriate to ensure compliance. There will be disputes and FDA should establish a system for responding to these in a prompt fashion.

A possible solution would be to establish an accessible technical center staffed by individuals who can quickly respond to issues which can arise.

6) Training

Any training programs for industry personnel and public or private sector inspection auditors should be recognized by FDA as appropriate to meet the requirements of the proposed rule. FDA should continue to work with the Produce Safety Alliance (PSA), IFPTI, and AFDO in establishing an approved training curriculum along with an appropriate recordkeeping and verification system for individuals who have successfully completed this course. Instituting a Train the Trainer program will be a critical first step in meeting the challenge of delivering the large number of programs that are anticipated. In our opinion, a training and training verification system similar to the current system in place for the Seafood HACCP Alliance (SHA) through AFDO should be used. Additionally, a program approval system for training provided outside the PSA will be needed and AFDO suggests IFPTI be designated for this purpose.

7) Operational Assessment of Farms

Under the proposed rule, FDA does not require all farms to conduct an operational assessment and develop a food safety plan. AFDO recommends that all covered farms should be required to perform operational assessments and/or develop a food safety plan. We also support registration of these farms with FDA which is most helpful during response activities associated with illness outbreaks and recalls.

8) Environmental Testing

The proposed rule would require testing the growing, harvesting, packing, and holding environment of sprouts for *Listeria* species or *L.* monocytogenes. FDA, however, did not propose to require environmental testing for any other covered produce. AFDO believes this should be reconsidered especially in view of a recent Listeria outbreak associated with cantaloupes. This is inconsistent and should be more uniformly implemented with produce implicated with outbreaks or which are known to harbor the organism.

Environmental testing may be the only way for addressing recognized hazards associated with certain produce commodities.

9) Imports

In our view, these proposed rules must be part of an overall food safety system that will include import regulations as well. AFDO supports the enactment of the Produce Safety Rule at the same time as the Import

rules so both domestic and foreign produced produce is impacted equally. Applying the proposed produce rules only domestically is unwise and unfair, in our view.

10) Variances & Alternatives

Under the proposed rules, alternatives may be granted to individual firms, but variances can only be applied for by states or foreign governments. Because alternatives appear to be very restrictive and must be scientifically established to provide equal protection to the provision in the rule, the states are concerned that variances will become the preferred means for industry to apply for any rule modification. In some states it is likely that state departments of agriculture will be the state agency that will inspect farms. If this responsibility is created through contract means – rather than the state providing statutory authority, who – among state agencies – can apply for variances?

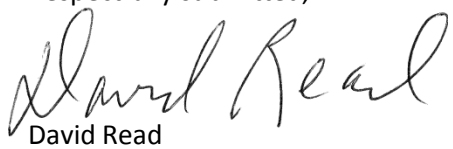
What will be the process for establishing a variance? Would the establishment of a national clearinghouse for approving variances be a preferred mechanism for creating uniformity and consistency in approving variance?

Resources will also be needed to support the alternative and variance processes. Although farms do not need initial approval from FDA to use an alternative, the industry will look to the state departments of agriculture for support and guidance on acceptable alternatives. There should be a system to ensure that states can provide the necessary support and the guidance does not contradict FDA enforcement.

State food safety agencies are very aware of the complexity associated with variances and the need for additional resources to handle variance requests. Since only states or foreign countries can submit variance requests to FDA, industry will submit requests to the states and the states will then have to filter the requests and determine what to submit to FDA. If a state does not have resources to administer this type of program, what legal obligations do they have to process industry variance requests?

The FDA Food Safety Modernization Act (FSMA) is the most sweeping reform of our food safety laws in more than 70 years. This proposed rule under FSMA should be as sweeping as the statute that has allowed it. AFDO is fully supportive of the proposed rule and energized to assist in any way we can to implement it fully. Creating exemptions and limiting the scope of the regulations, however, will only create gaps and weaken the food safety system we are trying so hard to create. This is a historic opportunity for food protection and FDA must take full advantage, in our view.

Respectfully submitted,



David Read
AFDO President