November 11, 2013

Dr. Samir Assar
Center for Food Safety and Applied Nutrition (HFS-317)
Food and Drug Administration
5100 Paint Branch Pkwy.
College Park, MD 20740

**Comments**
**Docket No. FDA-2011-N-0921**
**Regulatory Information Number RIN 0910-AG35**
*Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption*

**The comments within this document represent the collective, consensus views of 18 organizations representing North Carolina produce farmers. In writing below, the terms North Carolina produce farmers and North Carolina refer to this list of organizations.**

Dear Dr. Assar:

North Carolina's fruit and vegetable production and supply are proximate to the majority of the American population. Our state is a leading producer in season for a number of crops suitable to temperate climates such as blackberries, blueberries, tomatoes, cucumbers, bell peppers and squash to name a few. These comments are provided on behalf of a broad coalition of North Carolina produce farmers.

North Carolina produce farmers believe that producing food in a safe manner is of paramount importance. Our farmers produce wholesome, healthy produce consumed by in-state and out-of-state markets. Our farmers also recognize that the distribution chain, processors, retailers, food service/restaurants and the consuming public also play a crucial role in food safety. We believe that implementing the Food Safety Modernization Act well is vital to maintain the economic viability of our state's produce industry.

As a state, we have emphasized produce safety in a multitude of ways. Our NC Department of Agriculture & Consumer Services (NCDA&CS) regularly spotlights food

safety issues through annual meetings, press releases and food marketing efforts. In addition, the NCDA&CS Food & Drug Division has proactively reached out to farms and produce industry players to empower the farm to table continuum with information and technical assistance. This spring, NCDA C&S Food&Drug Division and partners hosted outreach meetings for our state's cantaloupe farmers in preparation for the upcoming melon season.

North Carolina (NCDA&CS and the NC Fresh Produce Safety Task Force) has hosted FDA and USDA officials on two formal occasions in Raleigh to facilitate dialogue surrounding produce safety as the agency works to develop produce safety regulations and implementation. During these meetings, FDA and USDA heard from dozens of farmers directly and toured farms in the Piedmont Triangle area.

## North Carolina Fresh Produce Safety Task Force

The greatest cooperative effort to focus on produce safety is the North Carolina Fresh Produce Safety Task Force (NCFPSTF), which brings together key players in North Carolina's produce industry: farmers, regulators, researchers, educators and public policy. Partnering institutions include North Carolina State University, North Carolina A&T State University, NC Cooperative Extension, the North Carolina Department of Agriculture & Consumer Services, US Food&Drug Administration, North Carolina Farm Bureau, producer commodity associations, fresh produce brokers/distributors, retail food chains and individual producers. The NCFPSTF has given voice to the needs of small, medium and large farms in North Carolina and the Southeast and empowered farms to learn from one another and to take a proactive stance regarding food safety. This cooperative effort can serve as a model in the nation.

The NCFPSTF has developed produce safety training curricula that are now available to NC State University and NCA&T University Cooperative Extension staff for delivery at the county and local level. This curriculum is called NC MarketReady Fresh Produce Safety—Field to Family Good Agricultural Practices Training. Tier 1 training provides basic level produce safety training in 6 modules for 7 hours. Tier 2, continuing training, offers 2 more modules and crisis communication training for an additional 7 hours. More than 120 extension agents and more than 750 farms have completed the training from NCFPSTF. Additionally, farmers have attended training at the local and county level provided by extension agents using the NCFPSTF curriculum.

Other training provided by NCFPSTF includes mock audit training and mock outbreak training to raise awareness of actual events during a food safety outbreak and investigation.

NCFPSTF members are frequent presenters at state, regional and national grower and food safety meetings. Task Force members are also frequently cited in local, state and regional press regarding various produce safety and food safety topics. The NCFPSTF website: www.ncfreshproducesafety.org and blog http://ncfreshproducesafety.wordpress.com are important hubs for information and connection among our state's farmers as they implement food safety on their farms.

The NCFPSTF has coordinated meetings with state level produce association executives and leadership to discuss the impact of FDA's Proposed Produce Safety Regulations on our state's produce farmers.

## Publish Revised Proposed Rules before Final Rules

**North Carolina produce farmers believe that the Proposed Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption Produce Safety Standards require significant revision to ensure the highest rate of compliance among the produce producers.** We believe that FDA should process the comments received from the Proposed Standards and prepare and publish a Revised Proposed Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption for public comment before making the rules final. Implementation of the rules by thousands of farmers and the produce industry at large will require significant investment. North Carolina produce producers believe FDA should ensure the production community's investment in produce safety by showing diligence in developing rules that will function as intended. **We strongly recommend that FDA work at a pace with the regulated community to ensure voluntary compliance.** By taking the time to develop rules that work, FDA will foster trust among the regulated community for high compliance rates.

## Areas where rules align with NC produce industry

There are several aspects of the proposed rules that align with the thinking among North Carolina's produce industry as developed through the NC Fresh Produce Safety Task Force:

- North Carolina supports an integrated approach to food safety on the farm. Our state's farms are highly diversified. High value crops such as fruits and vegetables are vitally important to the economic health of our state's farms. Because consumer demand is the driver of production for specialty crops, which includes fruit and vegetables, our farmers must be able to switch crops rapidly if needed. A commodity-specific approach to food safety would not allow the flexibility our farmers need to remain economically viable in a rapidly urbanizing state. Standards that enable farms to apply consistent food safety measures to multiple crops will positively affect produce safety outcome and better direct farm resources.
- Concurrent with support of an integrated approach to food safety, our farmers also believe it's important to focus on those facets of production where contamination of produce caused by agricultural practices or local circumstance is most likely. North Carolina produce farmers believe that focusing on risk to public health will help farms and produce growers as well as FDA and other regulatory agencies better employ limited resources.
- North Carolina produce farmers work with a wide range of state and federal agencies to manage their lands in ways that they as the landowner/manager deem important. North Carolina produce farmers believe that recognition of USDA NOP, USDA NRCS, US Fish&Wildlife, EPA standards, and others as well as state level environmental and health rules is important to successfully implementing the Proposed Produce Safety Rules.
- North Carolina's geography, geology, hydrology and biodiversity make our state one of the most diverse places worldwide; we believe that providing for variances is important to allow flexibility to our state's farmers.

- Our state's produce farmers know that alternative approaches to meeting standards will be important as the body of science to reference grows and as technology, society and cultural trends shape on-farm practices and food delivery practices.
- North Carolina farmers believe that voluntary compliance with produce safety standards will maximize the impact of FDA's staff time and limited resources, while minimizing on-farm disruptions.
- Our farmers believe that compliance with produce safety regulation should not require the use of outside, third parties to comply; however, we know that many farmers will require technical and financial assistance to meet the standards.

## Applying processing standards to farms

Our farmers need regulatory certainty regarding the rules and standards they are to meet. The farm support community also needs certainty regarding information to convey to our farmers. Training to date has focused on Good Agricultural Practices as this is the direction we believe has been conveyed by the Agency in the past. Microbial sampling and testing is not a part of GAPs nor should CGMPs be applied to farms.

It is our intent as a state to work together to implement FSMA rules. However at this time we are unclear as to what the standards for our state's farms will be. Based on experiences in our state this year, we are concerned that FDA is setting a precedent for routine farm level product and environmental microbial sampling even though Congress explicitly did not include microbial sampling in FSMA.

North Carolina produce farmers believe that farms that produce covered foods should be inspected only for cause, such as investigating a complaint that provides a reasonable basis to believe that a violation exists. To our knowledge, FSMA did not establish an inspection timetable for FDA to inspect farms. Our understanding is that Congress did not have intent for FDA to routinely inspect farms on a timetable or otherwise.

**North Carolina produce farmers seek clarification of how FDA believes farm level sampling and environmental swabbing is to interplay with the Proposed Produce Safety Rules and what circumstances will trigger routine FDA inspection and microbial sampling.**

## Providing clarity to regulated community: Registration

Defining a farm as a 'facility' in the definition of a farm in both the existing regulation and the proposed regulation may be a source of confusion as to which entities must register as facilities. On the one hand, a facility is a defined as "any establishment, structure, or structures under one ownership at one general physical location ..." in21 CFR § 1.227(b)(2). On the other hand a farm is an entity or a group of related entities that produce food and fiber. The regulations need to make this distinction clear. **We prefer language that provides clarity to the regulated community. Language in the suggested regulatory language below will improve clarity.**

There is a similar problem with the use of the word, 'facility,' in the proposed language of the 21 CFR § 1.227(b)(10) definition of restaurant, and in the existing language of 21 CFR § 1.226 'Who does not have to register under this subpart?'. It is our

hope that the rule drafters will take this opportunity to rewrite regulatory language in a manner that reduces confusion over the distinction between facilities that require registration, and entities and structures that do not. **A clarification of the language will improve compliance by improving understanding of obligations by members of the regulated community.**

**The sentence, "Washing, trimming of outer leaves of, and cooling produce are considered part of harvesting," in the existing regulations [21 CFR § 1.227(b)(3)] has been removed. We also propose that it be added back to distinguish normal farm activities from those of facilities required to register.**

## Definition of farm should reflect farming

The definition of a farm in the proposed regulation does not reflect farming as it is currently conducted in much of the United States. With about half of the farmed land in the United States leased or rented annually, the location of a farm is changing from year-to-year. Increasingly as farm land is partitioned into smaller and smaller parcels through estate divisions and for other reasons, farmers purchasing land find that they are rarely able to purchase adjacent parcels. Ownership structures of family-owned farms may also be quite complicated for a variety of reasons that include the allocation of management responsibilities among family members and the need to facilitate plans for intergenerational transfers of the farm business or businesses. For that reason we suggest that a farm be defined as any group of entities "owned by related parties as defined in 26 USC§267(b)" and located in one general area or region. The Internal Revenue Code §267(b) [26 USC§267(b)] is a related party rule used to treat multiple related entities as one for certain tax purposes. **Expanding the geographic scope of one farm more realistically reflects the way that farms operate.**

As an example, Mother (M) owns and operates the packing shed along with 100 acres of peaches as a limited liability company (LLC) of which she owns an 80% interest, with Daughter (D) owning 5% and serving as general manager. The remainder of the LLC is held in an irrevocable trust for Grandson (G) who is aged 3. The trust was set up under the terms of the will of G's father. The trust also owns an additional 500 acres of peach trees for the benefit of G. D owns 500 acres of peach trees that she inherited from her husband, G's father. Under the proposed rule, the packing shed would be a facility subject to registration because it packs peaches produced by the trust and the farm owned outside the LLC by D. Contrast this to the situation where all of the peach acreage is owned by the LLC - the packing shed would not be subject to registration as a facility. **As this example illustrates, the proposed rule produces a result dependent upon an accident of ownership structure, rather than any rational basis for distinguishing between registered facilities and farms not registered.**

| Current definition of a farm | Proposed definition of a farm | Comment - proposed changes |
|---|---|---|
| 21 CFR § 1.227(b)(3) Farm means a facility in one general physical location devoted to the growing and harvesting of crops, the raising of animals (including seafood), or both. Washing, trimming of outer leaves of, and cooling produce are considered part of harvesting. The term "farm" includes:<br><br>(i) Facilities that pack or hold food, provided that all food used in such activities is grown, raised, or consumed on that farm or another farm under the same ownership; and<br><br>(ii) Facilities that manufacture/process food, provided that all food used in such activities is consumed on that farm or another farm under the same ownership. | Farm means a facility in one general physical location devoted to the growing and harvesting of crops, the raising of animals (including seafood), or both. The term "farm" includes:<br><br>(1) Facilities that pack or hold food, provided that all food used in such activities is grown, raised, or consumed on that farm or another farm under the same ownership; and<br><br>(2) Facilities that manufacture/process food, provided that all food used in such activities is consumed on that farm or another farm under the same ownership. | **Farm means an establishment in one general area or region devoted to the growing, harvesting and marketing of crops, the raising of animals (including seafood), or both. Washing, trimming of outer leaves of, and cooling produce are considered part of harvesting. The term "farm" includes:**<br><br>**(1) Structures for packing or holding food, provided that all food used in such activities is grown, raised, or consumed on that farm or another farm owned by related parties as defined in 26 USC§267(b) ; and**<br><br>**(2) Structures for manufacturing or processing food, provided that all food used in such activities is consumed on that farm or another farm, owned by related parties as defined in 26 USC§267(b).** |

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## Mandated facilities registration

Some retail food buyers have required that many of our state's farms register as food facilities in order to sell to these buyers, even though by law the farms are exempted from the registration requirement in 21 CFR 1.226. Additional farms have registered because of misinformation or lack of understanding of the law. To date we do not understand how to instruct our state's farmers to "unregister" once they have erroneously registered as a food facility because they did not understand the law or were mandated to do so by a buyer.

**North Carolina produce farmers believe FDA should use its discretion to prohibit companies or certifiers from mandating that farms register as food facilities when they have been specifically exempted and that FDA should develop and publish a procedure for farms that are exempted from facilities registration requirements to "unregister" as food facilities.**

## Definition of farm and processing

When Congress passed the Bioterrorism Act of 2002 (BTA), it confirmed the common understanding that farms, restaurants, and retail food establishments are not food processing facilities.

The BTA, 21 USC Sec. 350(d)(1), states: The term "facility" includes any factory, warehouse, or establishment (including a factory, warehouse, or establishment of an importer) that manufactures, processes, packs, or holds food. Such term does not include farms; restaurants; [or] other retail food establishments […].

FDA should ensure that its proposed rules implementing Secs.102, 103 and 104 of the Food Safety Modernization Act (FSMA) are consistent with the plain language of the BTA. The current proposed rules do not meet this standard:

- The proposed regulations at 21 CFR Secs. 1.227, 112.3(c), and 117.3 and state a farm is "a facility in one general physical location devoted to the growing and harvesting of crops, the raising of animals."
- The proposed rules invent the term 'farm-mixed type facility' in 21 CFR Secs. 1.227, 112.3(c), and 117.3 to cover farms that engage in many traditional value-added marketing activities, and regulates these farms as facilities.
- FSMA instructs FDA to explicitly classify sales through roadside stands, farmers markets, community supported agriculture and other 'direct sales platform[s]' as direct-to-end-user sales for the purposes of establishing if a business is a 'retail food establishment.' The proposed rules do not implement that mandate.
- The proposed regulations at 21 CFR Secs. 1.227, 112.3(c), and 117.3 include in their definitions of 'manufacturing/processing' a wide range of activities traditionally carried out by farms in preparing their crops for market that never have been commonly understood as 'manufacturing' because they do not change the nature of the intact crop. The proposed regulations include this over-broad definition of 'manufacturing/processing' even though FDA acknowledges in Table 1 of the Preamble to the Produce Rule that washing, waxing, fumigating, coloring, drying for the purpose of storage or transportation, hydro-cooling, packing, refrigerating, removal of leaves, stems and husks, shelling, conducting activities designed only to isolate or separate the commodity from foreign objects or other parts of the plant, and otherwise treating crops in their unpeeled natural

state are activities that do not in fact change the status of a crop as a raw agricultural commodity.

The examples cited above create confusion among farms and food industry participants.

FDA's definition of a 'farm' in the five 'organizing principles' outlined in Produce Rule's preamble assumes that farms exist simply to grow crops, and that getting those crops to market is something that 'farms' don't do. The reality is that a farm can't stay in business without marketing its crops.

North Carolina produce farmers cannot recall a time when it was not common industry practice to buy small amounts of produce from neighboring farms to meet market demand. The fresh market produce industry is highly volatile, especially to the effects of uncontrolled weather events. Farms serving markets must be able to meet customer needs to remain economically viable. From time to time it may be necessary to bring in a minimal amount of product to do that.

**FDA can resolve confusion in its Proposed Produce Standards and Preventive Controls rules by:**

- **Amending the rules to conform to Congress' plain directive that 'farms', 'retail food establishments' and 'restaurants' are not 'facilities', not subject to registration under the BTA, nor to the FSMA Preventive Controls rules. In other words, the definitions applicable to these types of establishments under the FDC&A should not use the term 'facility.'**
- **Restoring the definitions of food manufacturing/processing to the common-sense understanding of the term. This should be accomplished by excluding from the definitions of 'manufacturing/processing' at 21 CFR Secs. 1.227, 112.3(c), and 117.3 the basic packing, handling and storing activities that farms have traditionally performed in preparing intact fruits and vegetables for marketing. Examples of such activities include packing, packaging, labeling, shelling/husking, trimming, washing, waxing, fumigating, coloring, drying for the purpose of storage or transportation, hydro-cooling, refrigerating, conducting activities designed only to isolate or separate the commodity from foreign objects or other parts of the plant, and otherwise treating crops in their unpeeled natural state.**
- **Defining sales through roadside stands, farmers markets, buying clubs, and CSAs as direct-to-end-user sales for the purposes of determining if a business qualifies as a 'retail food establishment' that is not subject to registration under the BTA nor to the FSMA Preventive Controls rules.**
- **Clarifying that roadside stands and farmers markets are businesses that qualify as retail food establishments.**
- **Eliminating the term 'farm-mixed type facility' and recognizing that farms that perform value-added processing predominantly using their own crops are not facilities. This would not preclude application of GMPs to such on-farm value-added processing, but it would protect farms from facility registration and HARPC requirements.**

- **Providing a de minimis threshold for a farm's handling of raw agricultural commodities produced on another farm without triggering application of GMPs under the proposed 21 CFR 117.**

## Prescriptive benchmarks

North Carolina producers have concern that some portions of the Proposed Produce Safety Rules (such as the Agricultural Water Standards) are so prescriptive that upon implementation scores of farms will immediately be out of compliance. Further we are concerned that as science evolves many pieces of these sections of the regulations that are so prescriptive will be out of date.

## Technical oversight

**North Carolina producers believe that FDA should develop a review process that provides an opportunity to amend the rules at regular intervals to keep pace with technology, industry practice and science. We believe that a stakeholder advisory group with farmer representation should be established to provide oversight of this process.**

## Guidance documents

**North Carolina producers believe that FDA should seek and heed input from stakeholders regarding Guidance Documents that are prepared and updated for FSMA Produce Safety Rules implementation. A stakeholder oversight and advisory group that includes strong producer representation should be developed to ensure that industry norms and on-farm practices are included in the process. Guidance should remain within the authority of the rules and proposed FDA Guidance documents should be presented for a public comment period.**

**Finally, North Carolina producers strongly believe that FDA, not outside contractors, should be responsible for writing guidance. We also believe that it is not advisable, nor in the best interest of the public to write guidance before rules are finalized.**

## Cost

We question whether or not the approach FDA has chosen to take with the Proposed Produce Safety Rules will be cost effective. The North Carolina farming community understands that FDA has developed the rules based on the agency's understanding of the science available, but we ask if the agency has considered that the rules, once adopted, will impact future farm viability? We are especially concerned regarding the impact over time of the standards for water. Has the agency incorporated likely outcome in the rule making process? Our state's farmers will be diverting money that could have been invested to expand and/or diversify their farm business into meeting a new regulatory regime.

The long-term opportunity cost to communities and regional and state economies will be significant. **We believe FDA should develop a way to measure the benefits of safer food to regulatory costs and the costs of implementation. Included should be opportunity costs to farms. Our farmers ask the question, could lower-cost procedures and solutions in fact provide greater public health benefits than the proposed rules?**

## Funding education and outreach

As FDA points out in many instances in the preamble to the Proposed Produce Safety Rules, education and outreach are critical to successful implementation. North Carolina producers are concerned that a central premise underlying the success of implementation of the proposed rules is that Cooperative Extension will handle training of farmers and that technical assistance will be readily available.

In North Carolina our produce farmers strive to produce fruit and vegetables in a safe manner, taking advantage of the information and tools that have been and are available to them so they can do the best job possible.

FSMA Produce Safety Rule implementation will require massive education and outreach, and such an effort takes resources, people and a structure within which to operate. We have the structure and trained people in the form of NCSU, NCA&T, NC Cooperative Extension, NCDA&CS and a range of producer associations, however we need funding to conduct outreach efforts. In the past, the NC Fresh Produce Safety Task Force, NCSU, NCSU/NCA&T Cooperative Extension, NCDA&CS, the Carolina Farm Stewardship Association and many other producer organizations have leveraged grant funds from organizations such as the Tobacco Trust Fund and the Agricultural Advancement Consortium to help train our state's farmers on basic GAPs and food safety. However, these funds are no longer available. Meanwhile, the greatest food safety training need ever is coming in implementation of the Produce Safety Rules.

**We strongly urge FDA to include funding for education and outreach in its budget and to set up a program for states to receive monies to help the agency achieve education and outreach goals. We also encourage FDA to reach out to USDA to encourage that agency to fully fund federal cooperative extension efforts aimed at food safety education and outreach.**

## Farm registration

At the Chicago Listening Session, FDA asked the question: "Should we require that farms producing covered food be registered with FDA? " We understand that regulating the nationwide produce production community is a large undertaking. **North Carolina producers do not believe that farms should register with FDA for purposes of implementing the Produce Safety Rules or other reasons.** FDA has many state and federal partners to assist in reaching out to the produce production community. Additionally, there are existing industry resources that capture producer lists, such as the Bluebook or the Redbook.

## Training of FDA inspectors

One of the most important ways FDA can demonstrate commitment to implementing the Proposed Produce Safety Standards in a way that shows partnership with our nation's produce farmers is through developing world-class training programs for its own staff.

Training relevant FDA staff at all levels regarding production of horticultural crops for sale as food crops will be critical to ensuring that Produce Safety Standards work as they are intended and to protect our nation's vital fruit and vegetable production infrastructure.

**We believe FDA must develop rigorous training programs with on-farm modules to educate inspectors on the multitude of ways covered raw agricultural commodities (RACS ) are produced.** Diligence and long term effort by the agency in adhering to on-going education and updating guidance documents as crop production practices evolve will engender confidence in the regulated community.

Applying regulations against a background of understanding of typical and routine horticultural production, harvesting and handling methods is vitally important to ensure uninterrupted supply of healthy fruit and vegetables into our nation's food supply.

# *Standards*

## Subpart A

North Carolina fruit and vegetable farmers support focusing resources on areas of highest risk. Under the definition of covered farms, at its discretion, FDA has determined that farms with less than $25,000 in food sales should not be regulated. **We believe that FDA should use its discretion to revise this definition to farms that produce less than $25,000 in "Covered Foods."** It is our experience that our state's farmers diversify their production mix from time to time for economic reasons, market demand or personal circumstance. For example, farms that primarily raise larger acreages of grain crops or another agricultural commodity that falls into the very broad definition of "food" within the Proposed Produce Safety Rules may also produce a smaller amount of a crop like tomatoes, sweet corn or cucumbers from time to time. Including these farms in the Proposed Produce Safety Rules on the basis of the value of their overall food production, rather than the "Covered Foods" they produce would do little to increase food safety while placing significant burden on support infrastructure such as Cooperative Extension, for outreach and training.

## Farms with non-regulated food crops

Some North Carolina produce farmers will need more time to comply than spelled out under the definition of small farms. We have farms with significant production of non-FDA regulated crops that fall into the food definition as outlined. However, just because they may be defined as "large" in a financial sense does not mean these farms have resources to bring to bear to meet the Proposed Produce Safety Standards. For example, a farm with several hundred acres of grain production, but a minor amount of produce will

fall into the "large" farm category. Such a farm is highly automated for the grain crops they produce, which are exempted from the Proposed Produce Safety Standards. This type of farm is commonly a one-person operation.

North Carolina has a number of farms with grains, oilseeds, dry beans, and dry peas sales of >$500,000 but who also produced some fruits, tree nuts, and berries and/or vegetables, melons, potatoes, and sweet potatoes. For 13 of these farms, the fruit/nut and vegetable production combined was $250,000 or less annually, according to USDA NASS. Six of the North Carolina farms with grains, oilseeds, dry beans, and dry peas sales of >$500,000 have fruit/nut and vegetable production combined that was $25,000 or less annually.

These farms will fall within the large farm definition, yet they do not have significant infrastructure or resources for fruit/vegetable/nut production. As already stated, these farms are highly automated for the non-regulated food crops they produce. The types of covered RAC crops that are produced by such farms commonly include pick-your-own strawberries, blueberries, or peaches or a truck crop such as watermelons. While small in number, the economic diversification that produce adds to these farms is vitally important to their economic health.

Language within FSMA instructs FDA to focus resources by placing emphasis on those areas to make the biggest impact. **North Carolina requests that FDA use its discretion to revise the definitions of small and very small farms to base the definition on covered food.** This will help to minimize the impact of the rules on farms participating in short supply chains such as those farms participating in farm-direct sales.

**Summary of Proposed Qualifications (on a rolling basis, average annual monetary value of food sold during the previous three-year period)**

- **Small Business: Above $250,000 in covered food and no more than $500,000 in covered food.**
- **Very Small Business: Above $25,000 in covered food and no more than $250,000 in covered food.**
- **Excluded from coverage: $25,000 or less in covered food.**

**We also request clarification that crops harvested but not placed into commerce are not counted in the value of food produced. Such crops may include crops gleaned from fields by volunteers for alleviating hunger in underserved populations and/or crops removed during the production cycle and discarded.**

## Covered food

North Carolina producers support the approach FDA is taking by separating Produce into Covered food and Produce not covered. **We request addition of additional crops that are rarely consumed raw to the "Produce not covered" category:**

- **Ramps, *Allium triccoum***
- **Greasy beans, Fava beans**
- **Hubbard squash, and all hard-skinned winter squash**

- **Creasy greens, mustard greens, turnip greens, chard**
- **Leeks**
- **Celery root, salsify and sun chokes (Jerusalem artichokes)**
- **Chestnuts**

**North Carolina produce farmers also request that FDA include culled produce as not covered produce for purposes of the Produce Safety Rules.** Farmers may remove and discard some crops such as strawberries, muscadine grapes, apples, peaches, watermelons, or others. In such instances they are removing disease infested berries or thinning a crop. Such product is not placed into commerce, but is generally discarded or composted.

**North Carolina produce farmers request clarification of covered food regarding produce that is gleaned from fields by volunteers to alleviate hunger in underserved populations. Note: This produce is not placed into commerce.**

## Definition of processing

North Carolina produce farmers want to ensure regulatory certainty, clarity and transparency as FSMA is implemented through the Proposed Produce Safety Rules. **We ask that additional language specific to activities that are routinely conducted on a farm to prepare an RAC for use as food be included in the Produce Safety Rules.**

The preamble includes charts and explanation that includes language such that when a farm labels or packages their own RAC that activity is not considered manufacturing or processing. The Rule includes language regarding commonly accepted post-harvest practices on the farm such as separating the edible from non-consumable portions of the produce (preparing the produce for use as food) and that activity (such as shelling, etc.) does not constitute processing.

Our farms must see a bright line between processing and routine on-farm harvesting activities. North Carolina produce farmers request that language specific to the activities that are part of the normal routine operations of a produce farm when done on a farm be placed into the Produce Safety Rules, thereby codifying the language that appears in the preamble of the Proposed Produce Safety Rules for activities that are part of harvesting. These include:

- Application of pesticides (including by washing, waxing, fumigation, or packing);
- Coloring;
- Drying for the purpose of storage or transportation;
- Hydro-cooling;
- Otherwise treating fruits in their unpeeled natural form;
- Packing;
- Refrigeration;
- Removal of leaves, stems, and husks;
- Shelling of nuts;
- Washing;

- Waxing; and
- Activities designed only to isolate or separate the commodity from foreign objects or other parts of the plant

## Packing

To ensure clarity in the regulated community. **North Carolina produce farmers request that FDA clarify that harvesting/packing includes labeling produce with sticker identification and field packing into a clamshell, other container or placing leafy greens into food grade plastic bags.** Increasingly our farms are required by produce retailers and buyers to have a PLU identification sticker on each unit. These food-grade stickers are applied at the harvest/packing stage. Additionally, to encourage materials and labor efficiency, many of our farmers pack produce directly into clamshells or other containers (such as sleeves for greens) in the field. These activities are normal, routine activities that should be clearly included in packing to provide regulatory certainty to our farms.

## Harvest cuts

As the rules are currently written, anything beyond an initial field harvest cut would be considered processing and bring the farm into different regulations. However, a number of crops are commonly recut on the farm as a routine post-harvest practice prior to sale. This additional harvest cut that prepares the item/bunch for use as food should not be categorized as a processing activity. The following activities are common: re-cutting harvested heads of cabbage prior to shipping; trimming the tops of bunches of harvested allium crops such as leeks, chives or garlic or root crops such as carrots, beets, turnips, parsnips, etc. to prepare them for sale; and trimming the lower stems of harvested herb crops such as parsley, basil, or cilantro or the lower stems of leafy greens such as chard, kale, collards or mustard. These activities that prepare an RAC for use as food when done by a farmer on an RAC produced on their farm should not be considered processing. **North Carolina produce farmers request that FDA clarify the Produce Safety Rules so that activities such as these that prepare an RAC for use as food when done by a farmer on an RAC produced on their farm should not be considered processing. We also specifically request that FDA clarify that a harvest cut is not defined as processing.**

## 112.5 Exemptions

**North Carolina produce farmers seek FDA guidance on what records regarding food sales are needed to meet requirements for the qualified exemption.** While many state-level rules allow farms to prove they meet financial thresholds by providing their Schedule F income tax return on request, the scenario and requirements to meet the qualified exemption within the Proposed Produce Safety Rule is more complex than total farm sales.

**North Carolina produce farmers request that FDA provide a template for how to track information on sales to qualified end users.** North Carolina believes that many records kept in the normal course of business such as invoices, crop insurance

or FSA records, etc. should be acceptable. **We recommend that FDA deem such records kept in the normal course of conducting business as adequate. In determining mileage distance, North Carolina believes FDA should measure miles in a radius surrounding the farm. In the event of the doubt of distance, the issue should be resolved to the benefit of the farmer.**

North Carolina produce farmers seek clarification on what constitutes "sales to qualified consumers end users." **We believe that any sale direct to a consumer should be considered to a qualified end user, including internet sales, or mail order sales.**

## Subpart C Standards Directed to Personnel Qualifications & Training

We believe that implementation of the Produce Safety standards requires far reaching, accurate, consistent and well-rounded training programs with skilled trainers providing the same information to growers, processors and distributors. Training materials should have addendums to reflect the differences among the varied growing regions, commodities and production practices and processes.

**North Carolina produce farmers request that FDA develop approved curricula for the training programs for Subpart C.**

The North Carolina Fresh Produce Safety Task Force has developed training programs for multiple levels within our states produce industry—farm level for personnel, operator/owner level, and extension agent level. It is our intent to maintain and update that training as new information is developed. It is also our intent to ensure our training modules meet any requirements mandated by FDA for approved curricula.

**North Carolina seeks clarification on training and record keeping responsibility for various scenarios for Subpart C.**

- Work crews that perform many jobs for produce farms. It is the experience of our farmers that different sets of workers may perform different farm activities related to the production of the crop. Employees performing non-harvest activities during crop production may be farm employees, contracted labor or unpaid family or volunteers. During winter months, pruning, crop sanitation and clean-up is performed. Later, crews may remove and discard disease infested berries or fruit, or thin fruit in an orchard. **Since this product will not be placed into commerce for consumption, do we assume those workers performing this function do not require training for the purposes of the Produce Safety Rules?**
- North Carolina produce farmers make varied arrangements for crop harvest. In addition to hiring their own employees, it is common for some farms to contract their harvest operations. The farmer then receives the harvest for packing and marketing. **Our farmers believe that it is the responsibility of the crew leader to ensure the contract harvest crew is trained and that documentation provided to the farmer that the crew has received approved training should be deemed acceptable for proof of training for the Produce Safety Rules.**

- Commercial harvest followed by U-pick. Some farmers harvest the bulk of their produce for wholesale commercial sales, and then open their fields to pick your own customers. **North Carolina produce farmers believe that maintaining records to demonstrate separation by time of commercially harvested crops from pick-your-own crops should be adequate to demonstrate that the later stages of the crop was harvested by pick-your-own customers. Also see comments under Pick Your Own Farms below.**
- Entities that harvest remnant crops in fields following the main harvest. These may be contract purchases (ownership of the crop transferred prior to harvest) by a third party who harvests and removes the crop from the farm and markets it into commerce sometimes called "scrappers." **Our farmers believe that it is the responsibility of the entity purchasing ownership of the crop to ensure the harvest crew is trained and that documentation provided to the farmer that the harvesters have received approved training should be deemed acceptable for proof of training for the Produce Safety Rules.**
- Gleaners. Many farmers allow non-profit organizations to harvest remnant crops following the main harvest. In North Carolina, we typically call these organizations "gleaners." For example, the Society of St. Andrews is one such non-profit. These non-profit organizations are an important partner with our state's produce growers to alleviate food insecurity and provide healthy fresh produce to our state's network of food banks and kitchens. Typically gleaners rely on volunteers to do the labor of removing remnant crops from the field. **For the purposes of the Proposed Produce Safety Rules, we believe that volunteer gleaners should be considered visitors and not personnel for the purposes of Subpart C. Further, since this produce is not placed into commerce, we request clarification of whether or not the produce is covered food. We also request clarification that crops harvested but not placed into commerce are not counted in the value of food produced.**
- Pick-your-own customers. **North Carolina produce farmers request clarification in the Rules and in Guidance that customers harvesting at a pick-your-own farm are considered visitors and not personnel for the purposes of Subpart C.**

## 112.32

Section 112.32 includes language under "Hygienic practices for personnel. (2) "Avoiding contact w/animals other than working animals….and minimizing likelihood of contamination…when in direct contact w/working animals."

North Carolina's fruit and vegetable production community is highly diverse. More than 1,470 farms produce both livestock and fruit/vegetables. On a highly diverse farm it is impossible for farmers to avoid livestock. However it is possible to maintain separation of livestock from fruit/vegetable operations or to take steps to mitigate contact of livestock with fruit and vegetable production. **We request that FDA changes language as follows "(2) *Minimizing* contact w/animals other than working animals and taking appropriate steps to minimize the likelihood of contamination of covered produce when in direct contact with working animals."**

## 112.33 Visitors

North Carolina produce farmers seek clarification from FDA related to visitors. Our produce farmers do not believe that all visitors to the farm should require training. For instance, visitors who are restricted to the office area only, or visitors to service areas of the farm, but who do not enter fields, work areas of the packing house or otherwise do not have contact with edible portions of the crop. These may include such visitors as office visitors, service and delivery providers, agricultural sales representatives, law enforcement officers, regulators, visiting dignitaries or elected officials or family and friends of workers. **Visitors who enter the farm with owner's permission who do not enter fields or working areas of the packing house and who do not come into contact with produce should not require training under Subpart C. Further, we do not believe that proof that any visitors have been trained or that records of any training for any visitor should be required for the Produce Safety Rules.**

## Pick your own farms

Pick your own farms are an important farm income diversification for our state's farmers. North Carolina ranks 3rd in the nation in the value of its strawberry production and almost all of these farms offer part or all of the crop to the public to "pick your own." These farms are a vital part of our state's agritourism and are a tradition for tens of thousands of our state's families and school children. Some farms may receive 3,000 visitors on a busy Saturday to harvest strawberries at the height of the season.

In addition, pick-your-own blueberries, blackberries, raspberries, peaches, apples and some vegetables to name a few, are a popular way for our state's citizens to enjoy the outdoors while engaging in a wholesome family-oriented activity that connects them to the land. Pick-your-own is also an economically profitable option for many farms, as it allows farms without a harvest labor force to be viable and because direct-to-consumer sales can provide a greater level of profit than wholesale markets.

**North Carolina produce farmers believe that pick-your-own customers should be considered visitors to farms for the purposes of the Produce Safety Standards.**

**North Carolina produce farmers believe that each pick your own farm should share their farm safety policy with their pick-your-own customers prior to customers entering fields and that signage instructing pick-your-own customers of the basic food safety practices of that farm during harvest should be deemed sufficient training. We ask that FDA provide guidance regarding language that should be used on signage while recognizing the voluntary, recreational and non-contractual nature of the pick-your-own relationship.**

**North Carolina produce farmers believe that pick-your-own visitors should not have to register when they come to the farm, nor should the farmer be required to keep a list of pick-your-own visitors. FDA Guidance for Subpart C should clarify these points.**

## Subpart E Agricultural Water

North Carolina produce farms appreciate FDA's recognition that farm, state, regional or produce commodity groups may approach water management differently. However, North Carolina's farmers do not believe that the proposed produce safety standards have adequately taken the economic expense of water source for the farmer into account.

We also believe that as proposed, Subpart E greatly oversimplifies water in general and as it is used on the farm. Water resources are highly complex across geography in their hydrology and geology. Additionally, the regulatory infrastructure is a web of federal, state, regional and local law. This framework provides perspective for the myriad of crops farms grow and the multitude of ways that a crop can be irrigated.

North Carolina's produce farmers often employ multiple sources of water, sometimes for the same crop. Our 2010 Produce Safety Small Farm Listening Sessions were conducted in 42 counties. About 238 growers attended. A survey conducted of the attendees found the following sources of water employed for fruit/vegetable production: Wells 56%; Streams/Rivers 34%; Ponds 22%; Municipal/County Water 17%; and Springs 1%.

Our farmers' choice of water sources for crop irrigation is dependent on factors beyond their control. Individual farmers may be limited to a single water source due to economic, geographical/geological or other constraints. As one listening session participant said, "My water source is a great asset; I have to make it feasible."

In Western North Carolina, surface waters (rivers/streams) are the most important source for small farms to use for fruit/vegetable irrigation. Surface water withdrawals are a necessity for the viability of mountain fruit/vegetable farms. Wells are cost prohibitive, and in some areas of the mountains, may not provide enough water at any depth. In Eastern North Carolina, wells and/or farm ponds are the most used irrigation water source. While in the Piedmont participants employ a mix of irrigation water sources.

However, while some farmers may choose from multiple water sources, many more are restricted to one sole source of water, be it from a stream, river, lake, pond impoundment or well. Also see comments below under Single Water Source.

We believe it's problematic that the Proposed Produce Safety Rules have been written with the paradigm that waters pulled from ground sources are lower risk than surface waters without regard to depth, soil/substrate profile or geographic location. This broad stroke assumption is likely to be an economically limiting factor for our vegetable farms in the future as they must simultaneously deal with mitigating their own risk through securing long term water availability in a shifting regulatory climate through the lens of FDA Produce Safety Rules water standards and individual FDA inspectors who will interpret rules.

Hydrology in North Carolina is complex. Our state encompasses 17 major water basins and 38 subbasins. Deep aquifers in Eastern North Carolina are confined, with the deepest dating back to the Triassic era. Our Piedmont and Mountains have unconfined aquifers with water tables that fluctuate with elevation. Groundwater discharge feeds our state's rivers and streams. While many farms have access to below ground water resources, others do not.

**Language in the Proposed Produce Safety Standards is vague regarding aquifers/ground water. Our farmers Believe FDA should craft a definition of ground water using reliable sources such as the USGS and NRCS.**

North Carolina, like many states, is closely examining future water resources. It is possible that ground water withdrawals will be regulated and perhaps even allocated in the future. Farmers are taking steps to mitigate their own risk by installing irrigation and water retention ponds and/or rain water catchment systems such as large cisterns/water storage tanks. These impoundments may be charged by ground water at times, by surface waters at other times and by rainfall.

**North Carolina believes that FDA should fund research on the best methods farmers can use to ensure the safety of surface water sources that are used to irrigate produce crops.**

**We believe that bias in the rules toward ground water sources is not beneficial to the long term economic viability of our state's produce industry.** We believe that surface water is a valuable resource to be stewarded.

## Cost

The Agricultural Water Standards within the Proposed Produce Safety Rules will require many of our state's vegetable farmers to make on-farm capital investments to meet standards. Common grower discussion for various produce crops grown within North Carolina is that installing a water-efficient irrigation system such as drip tape or drip emitters for most produce crops will cost a ballpark of $20,000 per acre. Even a small farmer that begins to irrigate crops will likely spend $5,000 just for a pump, filters and a small water delivery system.

North Carolina produce farmers question whether or not FDA has adequately taken this expense into account for the impact of the Proposed Produce Safety Rules.

## Agricultural water in field situations

North Carolina farmers seek clarity in the rules regarding standards for water. It is our understanding that there are two primary types of water in the proposed rules: 1) agricultural water that directly contacts the crop, employees' hands, food surfaces or is made into agricultural tea. It is our understanding that this water has a zero detectable generic *E. coli* tolerance (presence/absence or quantitative test) and 2) water that is used to irrigate crops during production, but that does not contact the edible portion of the crop.

It is our further understanding that there are 2 standards for testing: 1) agricultural water from ground sources and 2) surface agricultural waters. We further understand another category for surface sources of agricultural water 1)waters likely to be impacted by runoff and 2) those less likely to be impacted by runoff.

**It is our understanding that there are no standards for indirect contact of the edible portions of the crop and therefore this water is not subject to testing. We support this approach.**

## Single water source

Currently, many NC farmers effectively have only a single source of irrigation water that can be used for their crops. Many times, this is a surface water source and the only alternate source of water might require the construction of a new groundwater well. For many of our state's farmers, constructing a new well is often geologically or economically impossible. Therefore, if the current water source that is being used is not "of adequate sanitary quality for its intended use," the farmer will be forced to treat, or mitigate, their current agricultural water under proposed § 112.43.

As written § 112.43, which outlines guidance for mitigation of agricultural water, is vague. § 112.43 does not outline the level of microbial reduction that must be met (< 235 cfu/100 ml, <126 cfu/100 ml, or no detectable E. coli/100 ml), nor does it outline some standard measure of reduction that must be met by the treatment intervention (i.e. 2 log10 reduction, 99%, etc.), nor does it outline a defined interval for monitoring the water treatment process and resulting water quality.

§ 112.44 states that, if a farmer chooses to mitigate their water, "any chemicals used in such treatment would require registration under the Federal Insecticide, Fungicide, and Rodenticide Act before they can be lawfully used." The proposed Rule further goes on to say that "at the present time, no such registration for chemical treatment of irrigation water exists." **If this is the case (i.e. there are no "approved" chemicals for irrigation water treatment), then North Carolina farmers would like instruction from FDA on how farmers can treat/mitigate their water to comply with the Proposed Produce Safety Rules.**

§ 112.50 outlines the requirements for documentation that farmers will need to maintain if they choose to treat/mitigate their water. Proposed § 112.50(b)3 would require maintaining documentation of "*scientific data or information that you rely on to support the adequacy of a method used to satisfy the requirements of § 112.43(b) and (c)1*." There is scientific evidence to support some chemical disinfectants for treatment of drinking water; however, there is very little evidence to support the use of these same chemical disinfectants for treatment of irrigation water. Furthermore, many of the alternate treatment/mitigation strategies do not have documented information for efficacy in treating irrigation water at field scale. **North Carolina produce farmers recommend that FDA fund research to document common chemical disinfectants, as well as other alternative disinfectants such as ultraviolet light, for their efficacy in specifically treating irrigation water that may be considered agricultural water under the definition outlined in this proposed rule.**

The proposed rule acknowledges the difficulty in treating/mitigating irrigation water that will be applied to the harvestable portion of a crop. It points out that there will be different "*frequencies for maintenance of well and surface water sources, distribution, and holding systems*." However, the rule does not give specific information that farmers might be able to use to address the individual situations that may be present on their farms. Most North Carolina produce farmers lack background and knowledge in water treatment and mitigation practices that are implied by the proposed rule, the resources for equipment used to treat and/or monitor water treatment efficacy, or the time to implement such an involved program. Furthermore, many times the factors that may impact the efficacy of treatment are dictated by the physical characteristics of the water. And many times these factors, such as rainfall, turbidity, organic content, and so forth are

*highly* variable and beyond the control of many farmers based on the time and resources that they may have available.

**North Carolina requests clarification and instruction from FDA of how farmers are to comply with the Proposed Produce Safety Standards for water applied to the harvestable portion of the crop given the complexity and variability of the water sources and environmental conditions we find in our state. Our farmers find that the Water Standards as presented have insufficient detail to enable compliance. This situation is exacerbated for all of our farmers who find that a single water source is their only option.**

**Freeze protection**

A critical crop management technique used by North Carolina fruit producers and others around the country employs the use of overhead water application for freeze protection on berry crops such as strawberries and blueberries or orchard crops such as peaches. In these situations the water may protect the bud, the blossom, or newly formed fruit, depending on the timing of the freeze event. For most of these farmers, freeze application is the only time they use water that may meet the definition of agricultural water. Due to the volumes of water that must be applied overhead in a short period of time to provide adequate freeze protection, ground water sources may not be feasible. Most farms pump from a farm pond or other surface source.

Freeze protection is the most important risk mitigation many of our fruit producers can take to ensure a successful season. In 2007 blueberry growers who did not have freeze protection lost 90 percent of their crop. If our berry producers are not able to rely on this practice to protect their investment, they will be significantly economically harmed.

Strawberry plants are put in the ground (generally in raised beds covered with plastic) the fall before harvest (May of the following year). Plants are nurtured through the winter. While strawberry plants are not highly sensitive to freezing temperatures, flowers and fruit are sensitive to freezing temperatures. By April (harvest generally occurs from May to June), the farm has invested all expenses but labor to harvest in the crop. A loss at this time is economically devastating.

While some strawberry farmers use row covers to protect from frost, this method has many drawbacks: Cost of labor to pull them, wind can dislodge them and row covers can create cultural conditions that result in insect problems. Strawberries are cropped for one season only. The farmer begins with new plants again in the fall.

By April, a blueberry farmer also has significant investment in the crop. Unlike strawberries, blueberry plants may be cropped for 15 years or more. However, like strawberries, the farmer has most of his annual production expenses tied up in the crop by April. A late frost on buds, flowers or newly formed fruit is devastating and can affect that farm's ability to market product in Eastern US wholesale markets for years.

**Our produce farmers believe that water applied to produce crops prior to the presence of the harvestable portion of the crop should not be considered agricultural water. It is our understanding that no outbreaks have been connected to water used for frost protection when no fruit is on the plants.**

**We are seriously concerned that if all overhead water application is categorized as agricultural water from the start in regulations, then there will be**

**no reason to research the area. We recommend that FDA make research of application of water for frost protection a priority.**

Our farmers must be able to protect their crop investments if needed with overhead application of water for freeze protection. Most of them are currently accessing farm ponds or streams to do so. It is our understanding that no outbreaks have been connected to water used as frost protection when no fruit is on the plants.

We cannot overstate the importance for North Carolina's farmers to be able to protect their crops from late freezes by using overhead water applications.

## Irrigation

Many vegetable farmers in North Carolina use multiple ways to irrigate their crops depending on the crop, the time of year, cultural and physiological requirements and equipment availability. It's not uncommon for one cycle of production of the same crop to be irrigated at different times with overhead irrigation, drip irrigation and/or no irrigation. Production conditions also play a role in how crops are irrigated. Each farm adopts irrigation management systems appropriate for their crop, their farm and the specific environmental conditions of the time period of production. Farmers must constantly shift to meet changing production conditions.

**North Carolina produce farmers do not believe FDA has adequately accounted for the myriad of ways our farmers employ to irrigate crops in the Proposed Water Standards.**

### Fruit and produce young plants/seasonality

Some farms produce vegetable transplants from seed in "plugs" that are planted in the field. These plug seedlings are generally grown in controlled environment conditions such as in a greenhouse. Most of the time, these seedlings are produced on growing media (artificial mix of peat moss, perlite, vermiculite, fertilizer charge, and wetting agents). Irrigation is primarily accomplished with overhead boom sprinklers or breakers on the end of a hose. These plug seedlings may be germinated in a closed germination chamber prior to being moved to the greenhouse.

A similar type greenhouse culture system may be used for grafted seedling crops such as melons or tomatoes. Grafted crops require tight environmental controls immediately following the grafting process to allow the rootstock to join the scion to ensure a good union and healthy plants. Generally grafted crops start in a greenhouse under timed mist irrigation. Grafted plants are an important way for producers of high value produce crops to reduce pesticide applications as a desirable scion may be grafted onto a disease tolerant rootstock.

Additionally, rooting cuttings for perennial crops such as blueberries or brambles, or producing tree seedlings may also be grown in controlled greenhouse conditions as described above or in outdoor nursery conditions. These crops are generally sold based on their age, 1-year, 2-year, etc. They may be sold in containers as rooted in plants, in grow tubes or sold as bare root plants.

The produce farmer may produce their own plug transplants, rooted cuttings, trees or strawberry plants. However, it's more common for the producer to buy in their vegetable and fruit starter seedlings, plants or trees.

When these starter plants are placed in the field often they are irrigated with overhead irrigation systems to help with establishment. For crops that are sown in the field such as beets, carrots, lettuce, and others, overhead irrigation is the only effective means to germinate seed and nurture new seedlings. When appropriate for the crop being grown, farmers may switch to more water-efficient methods to irrigate such as drip tape or even no irrigation.

The purpose of providing the background on the multitude of ways various produce crops may be propagated is to point out the wide variety of production methods produce farmers routinely employ to meet their specific conditions or the requirements of the crop.

**The Proposed Produce Safety Standards do not distinguish between plant stage and irrigation requirements.**

**North Carolina farmers request that water used during the crop establishment phase not be deemed agricultural water. For seed grown crops this would be through emergence of the second set of true leaves on seedlings.** Applying water during the seedling establishment phase of a crop seeded in the field, when the edible portion of the crop is not present, is low risk.

**We do not believe FDA should deem irrigation water applied to crops during their propagation stage agricultural water use.** North Carolina produce farmers request that FDA fund research to understand whether or not irrigation water applied to crops such as grafted cuttings, grafted seedlings or other vegetative methods of plant propagation in a controlled environment (such as a greenhouse or germination chamber) is a risk when the edible portion of the fruit is *not* present.

**Growing season**

The Water Standards state that farmers are to organize their water testing around the season of the crop however; it's unclear from the rules when the crop season actually begins. **North Carolina produce farmers would like clarification around the statement defining "growing season." We believe the season begins when the harvested portion of the crop is present. We recommend that FDA works with USDA to establish the season for all covered crops.**

Many of our farms produce a multitude of covered crops. **We believe that an informational table provided in guidance that highlights the season of covered crops will improve compliance for produce farms.** Our farms must see regulatory clarity if they are to comply with the Proposed Water Safety Standards. **North Carolina farmers believe that water testing should correlate with the use of the water as agricultural water.**

## Spray water

Currently many mountain producers use stream water to mix sprays for use in fields. As with much horticultural production that takes place in mountainous regions, our North Carolina mountain horticultural crop production takes place on small plots that are generally not contiguous. A large field may be just 10 or 15 acres. Our farmers rely on water sources proximate to the field for filling spray tanks.

To meet the Water Standards in the Proposed Produce Safety Rules North Carolina's 300 apple growers producing 10,000 acres of apples will incur tens of thousands of dollars in additional expense and time in traveling to and from fields with spray tanks that are

prepared at a central location. Many sprays are applied to trees when there is no fruit present. However the new produce safety standards require either treatment of spray water or water testing without regard to the stage of the crop.

**North Carolina fruit and vegetable producers believe that water used to apply sprays to perennial fruit when the harvestable portion of fruit is not present should not fall under the definition of agricultural water.**

## Benchmark standards for water

North Carolina produce farmers question why Proposed Produce Safety Rule Standards for testing waters defined as agricultural waters use tests for generic *E. coli*. It is our understanding that generic *E. coli* is not the most reliable indicator.

While it is important to measure and understand the "sanitary quality" of water that may come into contact with the edible portion of plants cultivated for human consumption, it is unclear which microbial indicator organism is most appropriate.

It is our understanding that for more than a century, municipal water providers have strived to develop the "ideal indicator" organisms. As most enteric pathogens are spread through the fecal-oral route, experts sought to use organisms that are quick and economical to test for, are in concentrations higher that the pathogens of interest, and whose numbers correlate with the risks that one might expect from exposure as being "indicative" of the relative safety of that water. Further, it is our understanding that the indicator organism concept revolves around the fact that the organism is present when fecal contamination is present and therefore, there is an increased probability that pathogenic organisms will be present. Our understanding is that none of the indicator organisms were intended to be indicative of any single pathogenic organism but rather as an index of whether a water is impacted by fecal contamination and the associated risk potential for fecally derived pathogenic organisms as a whole from contact or ingestion of that water.

Over the past 25 years, many different indicators have been proposed, ranging from total coliform bacteria *(currently used to measure "potable" water in the US; US, California, 1978, <2.2 TC/100 ml)*, fecal coliform bacteria *(WHO, 1989, <1000 FC/100 ml; Canada, 2002, <1000 TC/100 ml and < 100 FC/100 ml; Australia/New Zealand, 2000, <10 FC/100 ml)*, to *E. coli* bacteria *(Belgium, 2009, <1,000 EC/100 ml; Spain, 2010, <100 EC/100 ml; Sweden, <100 EC/100 ml, but also <1 EC/100 ml within 48 hours of harvest)*. Internationally, the most recommended indicator organism is generic *E. coli,* as this bacteria tends to be more indicative of fecal contamination than any of the other indicators currently proposed (total or fecal coliform bacteria).

**However, North Carolina farmers question how Recreational Water Quality standards, which are based on Quantitative Microbial Risk Assessment (QMRA) models for swimmers, equate to consumer risks for water applied and used for growing fresh produce in an agricultural setting.** Currently, the US Recreational Water standards are for waters to have a 5 sample geometric mean of less than 126 EC/100 ml, with a statistical threshold value (STV) of 410 EC/100 ml. The STV is a statistically generated microbial concentration derived from risk values for which no more than 10% of the total water samples collected and tested can exceed.

**North Carolina produce farmers believe mandating use of generic *E. coli* in the Standards will make changing to a more reliable indicator in the future more difficult.**

## Water testing

Testing water defined as "agricultural water" in the Proposed Produce Safety Rules will require significant expense, time and potential delays in cropping cycles for North Carolina produce farmers.

**Our farmers ask FDA to clarify the adequacy of science that demonstrates a direct relationship between contaminated irrigation water and a positive crop contamination due to irrigation water. Our farmers strongly request that FDA fund research to show how time, application method and environmental factors interact to subsequently cause crop contamination. Our farmers request that FDA fund study on how field environmental conditions affect the longevity and efficacy of pathogens of concern. This information needs to be commodity specific, recognizing that different commodities use irrigation water differently and those practices change over the season. Our farmers believe that metrics employed for the implementation of FSMA through the Proposed Produce Safety Rules need to be based on good science, be real time and dynamic in their scope to accommodate the changing production environment.**

North Carolina produce farmers have many questions regarding water testing. The Proposed Produce Safety Rules mandate that if water is untreated and subject to runoff, it must be tested every 7 days. **Our farmers question whether or not this testing frequency represents the risk of using the water source as agricultural water that contacts the harvested portion of the crop. We believe this area requires much more research and that FDA should make funding the issue of testing frequency and risk a priority.**

The Proposed Produce Safety Rules provide no explanation of standardized testing protocol at the farm. Our farmers ask for clarity about the relationship of sample size/volume and use of the water being tested for irrigation. **FDA should develop standardized water sample collection protocol for our farms that includes detailed instructions on how to collect samples, holding times allowed, shipping conditions and chain of custody requirements. We also believe that FDA should make funding the issue of sample size as it relates to irrigation water use a priority.**

It is our understanding that some public water systems may pool water from various sources for testing. However, there is no indication in the Proposed Produce Safety Rules that such a practice would be allowed for produce farms. **We request that FDA develop protocol for farms that may share water sources—such as a common stream, river or impoundment. FDA should allow farms to pool water samples and use the same water testing results when it is warranted.**

**Our produce farmers also seek clarification on laboratory requirements/ accreditations and what appropriate water tests might be.** We also seek clarity regarding Bacteriological Analytical Manual (BAM), is this the protocol laboratories are to follow for standardized tests? **Our farmers specifically ask FDA: Are water testing laboratories to be accredited? If they are to be accredited, what accreditation bodies are acceptable? What specific tests and protocols should our farmers**

**request in order to generate testing results that show they are in compliance with the Proposed Produce Safety Standards?**

North Carolina farmers are also highly concerned regarding test result delays. Obtaining test results requires a turn-around time. **We seek clarification on how FDA believes the 7-day testing cycle will work.**

**North Carolina farmers believe that FDA needs to facilitate laboratories.** We are highly concerned that North Carolina does not have enough laboratories to test to the level required or for the volume of water samples that will be generated based on our understanding of the Water Standards.

North Carolina's fruit and vegetable producers are located in all 100 of our state's counties. Many of them are in remote locations. We have serious concerns regarding the availability of water testing labs that are able to conduct the tests. It is our understanding that samples for some tests must move expediently to the lab in order to receive valid test results. **We have additional concerns that the flow of samples for testing may take valuable time and resources, diverting personnel to make "water test runs" as they strive to meet the Proposed Produce Safety Rules. Our farmers ask, what is FDA doing to increase water testing lab capacity?**

**We do not believe that FDA should enforce these rules unless the agency can assure the produce farming community there is sufficient laboratory capacity and that the records generated by the labs will provide the farmer with records that provide the farmer proof of compliance with the Water Standards.**

It is our understanding that water test results are one factor for the farmer making a decision such as to irrigate or not irrigate. North Carolina produce farms cannot be in a position to wait to irrigate based on a test result. **We support FDA's approach that test results are not a decision making tool when regarded on an individual basis, but that a positive result may be an indicator of potential contamination.**

**North Carolina produce farmers request clarification and instruction from FDA on what actions they must take in the event of a positive test result in order to show compliance with the Proposed Water Standards.**

**Surface water: Impoundment and catchment systems**

Many of our medium-sized and larger farms have irrigation water impoundments (farm ponds). Additionally, many of our produce farmers that employ irrigation use multiple sources of surface water sources depending on the crop, the time of year and occurrence of rainfall events. As written, the Proposed Produce Safety Rules would require weekly samples from every source throughout the production season if the water is used in a manner defined as agricultural water.

Additionally, the proposed rules affect our farmer's ability to fully leverage capital investments over their useful life. Many North Carolina fruit and vegetable farms have made significant investments in irrigation systems, impoundments and other water equipment. For instance, one small Sandhills region tobacco farmer who diversified into vegetable production has invested $20,000 in center pivot irrigation to ensure uniform crop yields and quality. The requirement to test and/or treat agricultural waters as proposed in the regulations will add several thousand dollars annually to this farm's production costs with no anticipated higher income as a result.

Some surface systems, such as covered catchment basins or covered ponds that may be charged with ground water are not subject to the same external forces that a natural stream or lake would be. However, there is no accommodation within the Proposed Produce Safety Rules for impounded waters that may not be fully exposed to external forces.

Rainwater catchment systems are becoming more popular as farmers seek to mitigate their water supplies. Water from building or greenhouse roofs may be captured and stored in cisterns or rain barrels.

**We recommend that FDA research ways to reduce risk for water holding systems. We recommend that study of water conservation systems should be a priority. We also believe that as FDA implements the Proposed Produce Safety Rules, it must be done in a way that does not prohibit innovative water reuse or catchment systems.** North Carolina's produce farmers must be able to act on their own behalf by securing water resources for the future. In our state that will generally be through impoundments and other surface water systems.

## Alternatives

North Carolina produce farmers would like clarification regarding what kind of information should be maintained as documentation for alternative methods under this section. It is our understanding that research into the area of water quality and produce safety is emerging.

**We believe FDA should establish criteria for how information supplied in support of alternatives will be evaluated. We support the use of industry generated scientific data conducted through accredited or university laboratories. We also believe that data sets, methodology and analysis should be shared so that other groups can access and leverage results. We believe that information doesn't need to be published in a peer reviewed journal.** Guidance should spell out what kind of information/support documentation is acceptable.

**North Carolina farmers believe that a stakeholder group should be established to review variances and alternatives.**

## 112.46 Water during harvest/packing/holding

North Carolina would like to ensure FDA knows that many of our farmers will be required to make financial investments to ensure that a 10°C difference between water temperature and fruit core temperature is maintained. Our markets and production climate dictate that most of our crops be washed as a routine activity during on-farm harvest and post production practices.

North Carolina produce farmers who grow multiple crops would like clarification. Some of our farmers use water during postharvest activities on a crop that does not require agricultural water (such as sweet potatoes). **To comply with the Produce Safety Standards, do these farmers need to maintain records of when they harvest/pack a crop that does not require agricultural water vs. those that do? Or, can they document in their Food Safety Plan/Standard Operating Procedures that they use agricultural water for all crops?** If someone uses the same line or

same pack line and one crop is covered and one crop is not, is it sufficient to document a clear sanitation break between crops is sufficient? **We believe that if covered product processed first, a clean break should not be required.**

## Subpart F Biological Soil Amendments of Animal Origin

North Carolina supports FDA's integrated approach to focus on highest risk practices and a whole farm approach rather than commodity specific measures.

**North Carolina's highly diverse agriculture**

Two-thirds of North Carolina's agricultural economy is comprised animal livestock production and processing, primarily swine and poultry. Our state's ability to safely and responsibly handle waste from these agricultural sectors is critical to our agricultural economy and to maintaining a calorie dense food supply for the American public. Currently swine and poultry waste is applied at agronomic rates to field crops such as corn or soybeans, or in forestry plantations. Trials of composted chicken litter have been conducted on other crops, but it is our knowledge that its use is not widespread due to economic considerations. Our produce industry farmers do not access Confined Animal Feeding Operation waste streams for use as fertilizer on fruit and vegetable crops.

North Carolina's agricultural production base is highly diversified. Many of our state's medium sized and small farmers produce livestock *and* fruit and vegetable crops. More than 1,470 of North Carolina's agricultural producers grow both. This number represents about 8% of all North Carolina fruit and vegetable farmers and 3% of all North Carolina's farmers. The most common livestock on farms with produce is cattle, which is mostly pasture raised and sold as feeder cattle to locations out of state.

However a dedicated group of farms in the state, while economically a small proportion, intensively manage their land by combining livestock and food production in an integrated production system. The farmers engaged in this type of farming say they receive multiple benefits: Maximized nutrient cycles, balanced production systems, economic diversification, land clearing, and weed control, etc. using a rotation that involves livestock, cover crops and fruit/vegetable production.

Livestock used in these systems can include goats, sheep, cattle, pigs, turkeys and chickens. Among some of the rotations they employ: Hogs or goats to clear land, followed with a cover crop, then planting fruit/vegetables. Some follow pasture raised hogs with poultry, then with a cover crop or cut flowers before planting fruit/vegetables. Free-range chickens contained by fence and housed in a mobile coop, may be moved every three to four weeks in the season before planting a fruit/vegetable crop on the same land. Free-range broiler chickens may be followed by a cover crop such as rye, clover or buckwheat, before planting fruit/vegetables. Hogs may be pastured under perennial fruit trees. Cattle may be grazed on fruit/vegetable crop residue in the fall, followed by a winter rye cover crop, and then fruit/vegetables on the same plot. There are many other scenarios as well.

While economically small to agriculture as a whole, this type of production provides very important income to these farm families and vital tax base to our state's rural communities. The Proposed Produce Safety Rules will greatly impact this sector. However, at this point the extent to which their practices must be altered and the resulting economic impact that will have is unclear.

**General comments**

Meeting the composting requirements may require significant investment from the farmer, perhaps not in equipment, but in terms of additional time to cover piles for curing and to prevent animal encroachment. North Carolina produce farmers seek clarification on many parts of the compost requirements.

**North Carolina produce farmers seek clarification in the rules for compost sources of animal origin vs. plant origin. We also request clarification regarding vermicomposting, will vermicompost be regarded as biological soil amendment of animal origin?**

There is no mention of incorporation of manure or compost into the soil in the Proposed Produce Safety Rules. In practice, most farmers incorporate manure or compost into fields by turning it in. North Carolina produce farmers using compost and manure question the nine-month window required for non-processed compost or manure in the Proposed Produce Safety Rules. This time period conflicts with the National Organic Program. It is our understanding that the plain language of the statute instructs FDA to develop rules that are not in conflict with other programs, therefore mandating a 9-month period is inconsistent with instruction from the statute.

**The rules state a nine-month waiting period prior to the crop for untreated manure. North Carolina produce farmers seek clarity on what time period the time frame correlates to: Before the crop is planted? Harvested?** It is our understanding that other groups and states will comment on existing research that demonstrates a time period of 120 days is a sufficient waiting period where the harvestable portion of the crop comes into contact with the soil.

**North Carolina produce farmers seek clarification in the Produce Safety Rules that dropped covered produce does not include produce that accidentally falls to the ground when it is harvested.**

**Compost standards/tests**

In 112.54, FDA states that processes for treating biological soil amendments of animal origin must meet benchmark microbial metrics for *L. monocytogenes*, *Salmonella sp*., and *E. coli* 0157:H7. The implication of these standards is that our state's composters will be required to routinely test their product to provide our state's farms with documentation that can be retained in records.

**North Carolina produce farmers seek clarification from FDA regarding sampling procedures and protocol for compost that is produced on the farm as well as compost that is purchased from suppliers. What are FDA's expectations for sampling? What standards for compost processing are acceptable for purposes of the Produce Safety Standards? What verification program for compost suppliers is acceptable FDA? What is a valid certificate of performance? Does FDA seek a validated process(es) for a specific pathogen(s)? Which pathogen(s)? What laboratory accreditations are acceptable to FDA for purposes of compost tests?**

We do not believe that FDA should enforce these rules unless the agency can assure the farming community there is sufficient laboratory capacity and that the records generated by the labs will provide the farmer with the documentation required to be in compliance with the Produce Safety Standards.

**Agricultural tea**

Proposed rules mandate that bio-materials used to make agricultural tea must be processed, and that the water used for the tea must be clean as defined in the agricultural water section. However, if the water is used to subirrigate the crop, then it is not by definition agricultural water. **If the compost has been processed, then an agricultural tea made with the compost and applied using methods that minimize or do not contact edible portions of the crop should be allowed using non-ag water. North Carolina produce farmers request that FDA clarify this point in the rules.**

## 112.116 Food packing/food packaging material

North Carolina's produce farmers use a variety of containers for harvesting crops, such as: reused durable waxed or heavy duty unwaxed cardboard boxes for harvesting vegetables in the field; single purpose new containers that may be plastic, cardboard or woven wooden baskets; "bulb crates" (rigid PVC plastic mesh, roughly square, about 6-8" tall); burlap sacks (new or used); polyethylene sacks for cabbage, sweet corn and/or potatoes; plastic tubs, peach baskets (wooden of domestic origin), canvas picking bags for apples and restaurant bus pans in addition to others. This equipment represents a significant investment by the farm and is not easily replaced.

While it is possible to maintain harvest devices in a clean and sanitary manner, our farmers do not believe it is possible to sanitize all harvest containers.

**North Carolina produce farmers seek clarity and guidance on reuse of harvest containers such as wooden bins/boxes and canvas bags. What constitutes "cleanable" and what constitutes sanitizable to FDA?**

North Carolina produce farmers would like FDA to understand the significant economic expense that will be required to either change harvest containers to those made from materials that can be sanitized, or to purchase single-use liners or to purchase liners that may be cleaned and sanitized. Liners in crates also present postharvest issues. Air circulation is critical to maintaining crop quality and to reducing spoilage during storage. Any type of liner placed within a crate will reduce air flow and thus increase crop loss.

North Carolina produce farmers routinely store and move durable harvest containers through the year. During harvest, our farms operate at a rapid pace. It is common for some farms to place harvest containers in fields prior to harvest—perhaps the night before or early the morning of harvest or just a couple of hours prior to harvest.

When not used for harvest, these containers may be stored in multiple ways depending on the farm: Under a pole barn, inside a closed warehouse or barn, or outdoors on paved or unpaved surfaces. **North Carolina produce farmers request that the Proposed Produce Safety Rules accommodate these common practices for handling harvest containers that are widely employed.**

North Carolina's produce farmers who sell directly to the public also request clarification on a variety of containers that are widely employed for sale of produce at retail. Many of our state's farmers that sell at farmers markets or farm stands place produce in various containers to display it for sale. These containers may be wooden or plastic baskets, wooden or plastic boxes, pulp or plastic cups (covered or open) or decorative containers that enhance point of sale presentation. Greens may be sold in

plastic bags (closed or open), or loose in bulk. Sometimes the consumer purchases the container with the produce, other times the produce may be treated as bulk purchase when the farmer places the fruit or vegetables that were in a container into a plastic or paper bag at sale and reuses the display container. **North Carolina produce farmers request that FDA clarify that placing their produce in containers for display or sale at retail is not considered packaging.**

## Harvest or packing material not owned by the farmer

**North Carolina produce farmers request that FDA deem any harvest or packing material that a farmer does not own as part of their production system be excluded from the definition of food packing/food packaging.** The farmer has no control over packing or packaging containers used by customers or by third parties who may have purchased the right to a crop or groups that will donate production (gleaners) from fields.

Many customers at pick-your-own farms bring their own containers for harvesting crops; likewise, some restaurants also supply containers. Increasingly, environmentally conscious purchasers reuse containers they own. We believe that the Proposed Produce Safety Rules should not hinder the efforts of groups that chose to reduce waste.

## Subpart L Equipment, Tools, Buildings and Sanitation

North Carolina's fruit and vegetable farms have significant investment in their existing packing sheds and other farm outbuildings and most of them are of wood construction. Expecting that our farms rebuild their infrastructure because of the Produce Safety Rules is impractical and would drive many farms out of the production of produce.

North Carolina produce farmers are highly concerned that FDA recognize and be clear about the difference between the definition of sanitary and sanitizable in rules and language within Subpart L. Covered farms can have clean and sanitary equipment, tools and buildings. However, it is impractical for covered farms to have sanitizable equipment, tools and buildings. Surfaces that don't touch the edible portion of the crop do not present big risk. **FDA should clarify distinctions within Subpart L where sanitizable is required and restrict use of the term sanitizable to only those tools and surfaces that come into direct contact with covered produce. The proposed rules should clearly distinguish between food contact surfaces and other surfaces using a model such as is demonstrated in the definition of agricultural water within the Proposed Produce Safety Standards in Subpart E.**

North Carolina fruit and vegetable farmers would like FDA to be aware that many, if not all covered farms, have made significant capital outlays in equipment appropriate to the scale of their operations—they are not in an economic position to retrofit or upgrade because of the rules. Specifying, for example, that seams must be smoothly bonded implies significant expense in retrofitting existing infrastructure, which most farms cannot afford to do.

**North Carolina produce farmers request that FDA grandfather capital equipment for an additional seven years.** This should be added to the stepped in compliance schedule. Such a stepped in schedule will allow farms to replace older equipment with equipment that can meet benchmarks as they update. For many farmers,

their non-land net worth lies with the equipment they use. The economic reality of most farms prohibits them from a full re-outfit or even major retrofit. The Proposed Rules for Produce Safety Subpart L, Equipment, Tools and Buildings, requires all produce farms to reexamine their physical plant/production-packing equipment. Providing an additional seven years for farms to retrofit/re-outfit will allow them time to replace old equipment on a normal schedule.

Like farmers in many other states, North Carolina produce farms utilize many partially enclosed buildings for covered RACs for only a short period of the year. In these cases, the covered farm generally cleans the area before its use and maintains it during use for the work cycle. **However, we do not believe the farm should be required to maintain standards when the building is not in use for covered RACs.**

**Protected environment production**

**North Carolina produce farmers request that within FDA terminology, it is clear that protected environment production areas such as greenhouses or germination chambers used to germinate seedlings for crop transplants are not facilities.**

Greenhouse vegetable production is a growing area within North Carolina. Nationally, Rabobank N.A. expects that greenhouse vegetable production will reach $4 billion in sales by 2020. Greenhouse production may occur in high tunnels, in freestanding Quonset houses, in cold frames, under gutter-connected polyethylene structures, in glass houses (with wooden or metal glazing supports), or in movable single poly hoop houses. Structures may be heated or unheated. They may be used for vegetable production year-round, for only a portion of the year, or rotated with other crops such as cut flowers or flowering potted plants. These structures are used to produce crops in an intensive fashion that generally allows the farmer to increase yields on a per area basis.

Greenhouses may include sophisticated computer controlled or manual ventilation and heating systems. Greenhouse vegetable growing systems may be in ground beds, raised beds or on artificial substrates such as bagged rice hulls, rockwool, peat blocks, etc. They may include sophisticated or homemade interior benching systems. Once a crop is put in place, it is generally not moved until the harvest/crop cycle is completed. Irrigation systems may be complex, recirculating hydroponics systems with inline EC (measure of soluble salts concentrations) and pH meters, or hand held hose. Most farms use drip emitter, tube or tape irrigation systems.

Condensation from the greenhouse roof can be greatly managed through temperature control and use of anti-condensate films. There may be times when temperatures change so dramatically outside that condensation may form and drip downward from structural members rather than sheeting down sides. However, it's highly improbable that a pathogen of public health significance would find its way onto a greenhouse covering.

It is impractical to sanitize the interior of a greenhouse. However, maintaining clean and sanitary production conditions is the norm to reduce insect and disease losses and maximize yields. Greenhouse growers work to maintain a clean environment to control plant diseases and insects. Greenhouse sanitation is typical at the beginning of the season for that crop, before the crop is in place. Some farmers sanitize again at the end of the

season when the crop has been removed. Generally the structure is closed and temperatures are allowed to increase through solar radiation (a process called solarization). Some plant pathogens may require sanitizing of hard surfaces with Clorox or other products developed for greenhouse sanitation.

**North Carolina produce farmers request that FDA add greenhouses and other forms of protected environment production to the definitions within the Proposed Produce Safety Rules. Protected environment production should not be subject to Subpart L. We suggest that the agency works with the National Greenhouse Manufacturers Association to craft a definition (NGMA, 4305 North Sixth Street, Suite A, Harrisburg, PA 17110, 800-792-NGMA, 717-238-4530).**

Likewise, FDA should craft a definition for germination chamber for vegetable crops that ensures farms producing plug seedling transplants are not confused with sprouts producers. American plug producers grow several billion plug seedlings annually. While most of these are used for the flowering plant industry, one quarter or more are used for vegetable bedding plants sold to consumers or commercial farms.

Germination chambers are used for a brief period of time to germinate seed. The chamber allows the farmer to strictly control light, humidity and temperature to optimize seed germination and increase production efficiency. Seed is sown into a plug tray and placed within a germination chamber for a period of time—a day, to several days. Once seed is germinated, (radical emergence and cotyledon development) trays are immediately moved out and placed on greenhouse benches for growing on.

Using germination chambers allows farms to increase efficiency of their capital (greenhouse and equipment) and crop inputs (seed).

A germination chamber can take many forms, from small homemade structures that fit onto a greenhouse bench, to a retrofitted cooler, or a custom designed and constructed room. Germination chambers should not be confused with sprout production chambers.

**We recommend that FDA reach out to the American Horticulture Association to craft a definition of germination chamber to ensure that farms utilizing them are not confused with sprouts facilities. Germination chambers employed to germinate seed for the purposes of starting produce crops planted in a field or greenhouse should not be subject to Subpart L. (American Horticulture Association (formerly OFA/ANLA), 614-884-1145, 2130 Stella Court, Columbus, OH 43215-1033, www.ofa.org).**

**Rodent infestation**

Preventing rodent infestations in stored product may not be possible in all situations. **Contamination that is limited to a pallet or bin should not mean that the entire stored crop must be destroyed, just the affected storage unit (boxes/bins).**

## 112.129 Requirements for toilet facilities

**Many of North Carolina's small produce farms use the bathroom facilities in the residence of the farmer as the toilet facilities for the farm. We request that FDA guidance for the Produce Safety Rules clarify that this practice is allowed.**

Some North Carolina produce farms seek to reuse and steward all water resources. Our produce farms seek FDA guidance on acceptable ways to reuse rinse water from hand washing stations. For example, some would like to redeploy the water to irrigate crops. North Carolina allows farmers to dispose of up to 1,000 gallons of water from on-farm processing per day on the farm without special permits provided the water is land applied in a manner that does not violate the state's water quality protection laws. **We believe that rinse water from hand washing stations should be allowed to be land applied provided that it is used in a way so that it would not be deemed agricultural water.**

## Subpart P Variances

**North Carolina produce farmers ask that FDA use its discretion to allow other entities in addition to states and countries to request a variance.**

**We believe FDA should establish criteria for how information supplied in support of variances will be evaluated. We support the use of industry generated scientific data conducted through accredited or university laboratories. We also believe that data sets, methodology and analysis should be shared so that other groups can access and leverage results. We believe that information doesn't need to be published in peer reviewed journals.**

**North Carolina farmers believe that a stakeholder group should be established to review variances and alternatives.**

## Subpart Q Compliance and enforcement

**Inspector training critical**

North Carolina produce farmers are concerned that FDA inspectors may walk onto a production farm or into a produce farm packing shed and may apply food facility processing/manufacturing standards. **It's imperative that FDA train inspectors to understand routine acceptable on-farm practices. Consistency in training inspectors including on-farm modules that shows typical production and packing scenarios for that region of the country, and regular refresher courses will be vitally important.** A farm is not a food processing facility.

**We request that when FDA inspectors arrive to inspect a farm that they clearly articulate they are there to inspect a farm, so that all parties are clear which rule the inspector will be applying. We also request that FDA develop separate inspection guidelines for farms and for food facilities. When an inspector travels to a farm, those guidelines and documents would be used and only those guidelines and documents. Clarity of the inspector's intent is paramount.**

**Verification of compliance**

Overwhelmingly the No. 1 concern expressed among North Carolina's produce farms is of the added expense that Produce Safety Standards will entail.

Our state's produce farmers already have many non-regulatory produce safety metrics and benchmarks with which they must comply to meet buyer requirements. It is not uncommon for a farm selling into major produce supply chain markets have to comply with the requirements of two or more private food safety audits providers. It is our experience that private food safety audit firms do not coordinate their efforts, and North Carolina growers see that the duplication results in wasted time, resources and significant additional expense.

**North Carolina produce farmers request that FDA establish harmonized standards for third party auditors to reduce duplication and that FDA works with third party auditors to make sure that auditing standards they apply are in compliance with FSMA produce standards.** Our farmers collectively spend hundreds of thousands of dollars annually on third party audits; we want to ensure this expense results in verification that those farms are compliant with the Produce Safety Rules.

North Carolina produce farmers believe that FDA should recognize third party audits by private companies as verification of compliance when they meet the requirements of FSMA Produce Safety Standards. **Our farmers also believe that a USDA GAPS audit should be prima facie proof of compliance with FSMA, not an alternative.**

North Carolina produce farmers also believe that third party auditing companies should be liable for the audits they perform.

**Compliance should provide protection**

**North Carolina produce farmers request that FDA recognize a farm's compliance with the law in the event of an inspection or action. North Carolina produce farmers believe that compliance should provide them with a level of protection.**

North Carolina SESSION LAW 2013-265 (SENATE BILL 638) NC Farm Act of 2013 provides some protection for our state's produce farmers by entitling the producer to "a rebuttable presumption that the commodity producer was not negligent when death or injury is proximately caused by the consumption of the producer's raw agricultural commodity."

The North Carolina law states that the producer must be 1) Certified by the United States Department of Agriculture Agricultural Marketing Service Good Agricultural Practices and Good Handling Practices Audit Verification Program or another third party certification program designated by the Commissioner of Agriculture and Consumer Services; 2) Has a written food safety policy that complies with the certification program's standard and can provide evidence that the producer trains employees on the policy on an annual basis; 3) Has had no formal administrative findings or sanctions or legal judgments entered against the producer during the previous three years based on a claim that the commodity producer's negligence was the proximate cause of a plaintiff's death or injury; and 4) Has had no settlement agreements concluding litigation where the settlement exceeded twenty-five thousand dollars ($25,000), or in which the producer admitted liability, during the previous three years based on a claim that the commodity

producer's negligence was the proximate cause of a plaintiff's death or injury. The "presumption may be overcome only by clear and convincing evidence that the commodity producer's negligence was the proximate cause of the death or injury."

## 112.192 Failure to comply

Voluntary compliance will enable FDA to best direct limited resources to implement the Produce Safety Rules. We believe that FDA should add additional language to the Compliance section of the Proposed Produce Safety Rules to generate trust in the producer community and thus encourage voluntary compliance. For instance, our farmers want to know what to expect. There is no single place at which covered farms may access FDA's sequence of events in the instance that an inspector shows up at their farm. Farms should have understanding of what to expect for a routine inspection as well as for an outbreak investigation. We believe FDA should also work with state and federal stakeholders to develop training materials for farmers regarding on-farm inspection. It is our understanding that this tool is currently not available. Facilitating transparency in the process will allow regulated farms to comply and provide consistency while limiting individual interpretation.

On review of the Proposed Produce Safety Rules, we saw no distinction between violations that cause an immediate risk to public health and violations that are less serious. As the Proposed Produce Safety Rules are currently written, we read that a farm must meet all standards equally to be in compliance or they are in violation.

**North Carolina produce farmers do not believe that failure to comply with one section, or even portions of that section should equate to failure to comply with FSMA Produce Safety Rules unless there is an immediate public health risk.** When our farmers are audited by third party auditors, there is a grading system with points deducted based on the seriousness of the violation. **We would like to see the Produce Safety Rules follow a matrix similar to that used by the USDA GAPs program.** FDA has great experience with such an approach through the Food Code. **Just as FDA has crafted Produce Safety Rules based on risk, compliance violations should also be based on risk.**

**Voluntary compliance**

Voluntary compliance with the Produce Safety Standards will be possible provided that FDA shows diligence in developing a solid relationship with producers of fruit and vegetables and works with partners in states. Such an approach will help to ensure that limited federal resources are deployed in the most targeted ways to achieve positive outcome.

Voluntary compliance should have meaning to the farm that makes the significant investment in time, financial resources and manpower to comply with the Produce Safety Standards. FDA must provide assurance that if farmers meet the produce safety standards that they will be in compliance.

**When a farm demonstrates compliance, that fact should be a mitigating factor for FDA in the event of an outbreak investigation. Farms/farmers who have developed a food safety plan, keep mandated records and comply with the Produce Safety Rules demonstrate that they are taking steps to comply with the law. An audit performed by a third party that meets industry best practice should**

**be considered a mitigating factor in the event of an outbreak investigation. Enforcement actions for farms that are in compliance and/or who have demonstrated willingness to follow the law should be differentiated from enforcement actions for farms that have not shown effort to be in compliance.**

**Training**

We strongly encourage FDA in training to alert inspectors to the economic reality of produce farming. Fruit and vegetable farmers make the majority of their entire farm income in a brief period of time during harvest. Disruptions at harvest are potentially economically devastating. **We recommend that FDA inspector training include modules on the seasonality of production, so that in the event of an inspection while a farm is at the height of their yearly operations, it can be done in ways that facilitate FDA's needs while providing the least disruption consistent in providing an adequate inspection. We believe that such training will improve food safety because inspectors will understand the specific issues for various crops.**

**We also believe FDA should take extraordinary steps to ensure consistent application of rules with specialized training for inspectors that includes on-farm training at a variety of different type and scale of farms that may be encountered. Such training should be oriented to the geographic location where the inspector will be working as production practices and norms vary significantly across the country. Our producers believe that only inspectors with such on-farm training should be allowed to conduct on-farm produce safety inspections or to investigate complaints or outbreaks.**

**Farm inspection matrix**

As we stated above (Subpart Q Compliance and enforcement, Inspector training critical), we believe it is important for all parties that when an FDA inspector arrives to inspect a farm, that the intent of the inspector to inspect a farm should be clearly stated so that all parties are clear.

**North Carolina produce farmers believe that FDA should develop forms that are specific to farms to ensure consistent application of the Produce Safety Rules. We recommend that FDA develop a compliance matrix that inspectors can use during the inspection process.** We believe that the farm can learn from the inspection. **The inspector should review the completed matrix with the affected farm, leaving a copy of the matrix with the covered farm.** Where appropriate for areas of non-compliance, FDA officers should include the specific regulatory citation as well as citing specific available guidance documents for the topic. USDA GAPs audit forms would be a helpful reference for such a matrix.

North Carolina produce farmers have expressed concern regarding routine inspections by FDA and how those farms for routine and/or random inspection may be identified. It is our experience that some produce retailers have mandated their suppliers be registered as food facilities, even farms, which are exempted from the registration requirement. Some believe that a mandate to register as a food facility may be a backdoor effort to inspect or regulate farms that may not be covered by Produce Safety Rules or other regulatory schemes. Clearly the intent of Congress in enacting the Bioterrorism Rules and in enacting FSMA was that farms are exempted from food facility

registration requirements unless they are engaged in some activities that may require registration. **Simply that a farm may be registered as a food facility should not be a factor in whether or not that farm is selected for any type of routine or random FDA inspection. Our produce farmers believe that public good is best served by using federal funds to inspect those farms or other locations based on risk.**

## 112.193 Provisions for coordination

**North Carolina produce farmers would like to see detail provided in 112.193 to ensure that federal and state partners are included. We would like to see a list of who will work with FDA and a timeframe for how operations will be commenced.** Our state agencies and educational institutions such as the NCDA&CS Food&Drug Division, NC State University/NCA&T State University Cooperative Extension and non-profits will be valuable collaborators for FDA.

## Subpart R Withdrawal of Qualified Exemption

**North Carolina producers believe that FDA should develop a process for an exempted farm that loses exemption to regain exemption once issues are corrected. We seek guidance on how a farm that has a lost exemption be reinstated.**

**We also believe that NCDA&CS Food & Drug Division should be notified when a farm loses its exemption to the Produce Safety Rules.** Our state agencies such as the NCDA&CS Food&Drug Division, NC State University/NCA&T State University Cooperative Extension and non-profits are valuable resources in helping farms with compliance.

## Research

**North Carolina produce producers believe FDA should impress upon Congress the need to provide resources to fund research to inform growers of the best ways to produce fruit, vegetables and nuts in a safe manner.**

The area of water used in production and post-harvest handling of produce requires more data to inform on-farm actions.

North Carolina produce farmers have highlighted many areas for research in the comments above. Additionally, we highlight the following specific areas for which we believe further research is needed:

1. Alternative practices for agricultural water sanitation;
2. Assessing risk of using untreated water to protect fruit crops during freeze events;
3. Equipment design for sanitation; effective sanitizers and protocol for farm equipment;
4. Use of open water sources for spray applications and irrigation;
5. Development and use of alternative contamination indicator organisms

6. 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;
7. Impact of pesticide and nutrient/fertilizer residues on human pathogen survival, persistence and distribution in surface waters;
8. Sanitation of equipment used for irrigation;
9. Impact of dredging and construction/maintenance of water sources on human pathogen survival, persistence and distribution;
10. Suitability of generic E. coli as a predictive indicator of microbial contaminants and suitability of current action level (235 MPN/100 ml);
11. Uptake of different types of microbial contaminants by different types of produce;
12. Interactions of microbial pathogens on and in produce with the naturally occurring plant flora;
13. Quantitative Microbial Risk Assessment Model: Survival, persistence, transport of different microbial pathogens in pre- and post-harvest commercial production;
14. Post-harvest handling practices that may influence survival and persistence of microbial contaminants on produce;
15. Interactions of microbial contaminants with naturally occurring biofilms in irrigation systems;
16. Efficacy of currently deployed field hand washes stations used in conjunction with toilet facilities.

For further information or clarification on these comments, please contact Debbie Hamrick, Director, Specialty Crops, North Carolina Farm Bureau Federation and Chair, Group 3, NC Fresh Produce Safety Task Force, (919) 334-2977, debbie.hamrick@ncfb.org.

Sincerely,

**Appalachian Sustainable Agriculture Project**
**Carolina Farm Stewardship Association**
**North Carolina Apple Growers Association**
**North Carolina Commercial Blackberry & Raspberry Growers Association**
**North Carolina Blueberry Council Inc.**
**North Carolina Chapter of the United Produce Association**
**North Carolina Farm Bureau Federation**
**North Carolina Fresh Produce Safety Task Force**
**North Carolina Greenhouse Vegetable Growers Association**
**North Carolina Horticultural Council**
**North Carolina Peach Growers Society**
**North Carolina Pecan Growers Association**
**North Carolina Potato Association**

**North Carolina Strawberry Association**
**North Carolina SweetPotato Commission**
**North Carolina SweetPotato Commission Foundation**
**North Carolina Tomato Growers Association**
**North Carolina Vegetable Growers Association**