# National Organic Coalition

July 12, 2010

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

RE: **[Docket No. FDA–2010–N–0085]**
**Preventive Controls for Fresh Produce**

On behalf of the member organizations of the National Organic Coalition (NOC), I am submitting these written comments to provide feedback on the questions posed by the agency with regard to produce food safety. These comments summarize and augment the comments provided during the conference call discussion held on May 11, 2010 between FDA produce food safety staff and NOC member organizations on the same topic.

**• Role of the Good Agricultural Practices (GAP) guidelines entitled ''Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables"**

Many of the food safety challenges with regard to produce farms are educational. A number of NOC member organizations have been holding conversations with their members and farmers for a number of years regarding (GAP) guidelines. Much of the urgency of these discussions has been driven by "super metric" requirements by private produce buyers, such as food service providers and grocery store chains.

Maine Organic Farmers and Gardeners Association (MOFGA) has 6000 members and certifies 5 percent of the farms in Maine. MOFGA has been holding food safety conversations with its member farmers for the past three years, and has reached 30% of its certified growers with food safety training of 3-4 hours.

The Northeast Organic Farming Association-Vermont (NOFA-Vermont) is organizing workshops, and will be having on-farm discussions and developing videos for farmers regarding food safety/GAP guidelines. 25 percent of produce farms in Vermont are certified organic.

Organically Grown Company (OGC) is an Oregon-based organic produce wholesaler which sources product from 400 suppliers; 160 of which are regional growers, mostly located in Oregon and Washington. OGC has hired a food safety consultant to consult with Northwest leafy green growers, conducted food safety training workshops for organic producers in conjunction with the Center for Risk Management at Washington State University, and is coordinating food

safety efforts with organic produce wholesalers across the country with a goal of identifying key risk factors and cost effective controls in the production, handling and distribution of organic produce. OGC believes that it has a stewardship responsibility on behalf of its customers to help mitigate food safety risk in the organic produce supply chain.

The USDA GAP guide is not designed for diversified farming operations, because of its requirements for separation of livestock and crops, and for manure handling. The FDA GAP guide is not written in a manner that is easily understood by farmers. In fact, most farmers are not aware that that the guide exists.

FDA should work closely with USDA and NGOs to translate GAP guides into language and educational materials that are more readily used by farmers and growers, and more applicable to their operations. For example, Cornell University has done a good job of putting together GAP publications that are very farmer friendly.

It remains unclear which GAP guidelines apply to whom, since there are so many public and private GAP standards with which growers are being asked to comply. In addition, it is very unclear how the FDA produce regulations relate to FDA facility registration requirements. These questions should be clarified.

- **Identification and prioritization of risk factors**

To identify risk factors, FDA should:

1) Start with sound scientific research that is data-driven and focused on preventing the introduction and proliferation of human pathogens in the food supply;

2) Evaluate the cost effectiveness of achieving a specific target reduction in human pathogens as a function of the volume of food grown and distributed.

3) Conduct applied research that will exploit the positive biological interactions and dynamics that exist on organic farms or that could be engineered into farming systems. Research needs to consider impact of soil nutrient levels, sources of nutrients, water sources, irrigation methods and innate physiological and plant defense resources.

4) Test for presence and source of pathogens through the farm-to-consumer value chain including small, medium scale and large farms that market locally, regionally, nationally and internationally. This will help identify most important risk factors and associated control points (e.g. impact of co-mingling product, packaging, pushing for extended harvest-to-consumption shelf life, etc.)

5) Conduct or sponsor research over a number of years and under various circumstances through the whole value chain from farm, processing, distribution through retail/foodservice.

6) Analyze outbreak incidence data to determine trends and patterns of contamination. For example, FDA's own pathogen outbreak incident data suggests a greater level of risk for processed produce such as fresh-cut or shredded produce, relative to the fresh product. During USDA's Monterey hearing on the National Leafy Greens Marketing Agreement proposal,

testimony was presented based on FDA data showing the history of foodborne pathogen outbreaks in leafy greens where two or more people were sickened. The data, which was gathered via a Freedom of Information Act request to FDA, show that since 1999, when FDA started tracking the distinction between fresh and fresh-cut product, every outbreak was attributed to a processed/fresh cut product, not a fresh product. (Testimony of Dave Runsten, Monterey NLGMA hearing, 2nd day, exhibit 33A, http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5079854) This data raises the question of whether the "pietrie dish" effect of placing produce in sealed bags for extended periods of time has the effect of exacerbating pathogen problems.

To help achieve these goals, FDA staff should be in contact with Dr. Charles Benbrook of the Organic Center, who can provide an update on the current state of food safety science, especially with respect to organic agriculture. In addition to his expertise with regard to state of the current science, Dr. Benbrook has also submitted a grant proposal to USDA's Organic Research and Extension Initiative (OREI) to do a farm and consumer food safety assessment of small-medium-large farms. The study would look at food safety risks through the whole supply chain – not just on the farm. For example, it would analyze the effects of co-mingling and packaging as well.

To prioritize risk factors, FDA should:

1) Evaluate opportunities to bring about the greatest risk reduction in a manner that is most cost effective and minimally intrusive to operators. Absent this level of empirical research, the private sector is likely to err on the side of standards that push costs back to the original producers. This will result in overly complex, costly and potentially detrimental GAPs.

2) Ensure that GAPs do not undermine the biological and ecological interactions upon which organic agriculture depends. For example, Dr. Trevor Suslow and others have performed research that shows that biologically active soil is more effective at controlling proliferation of pathogenic bacteria than soils that are less biologically diverse. [See T.V. Suslow, *et al*, "Production Practices as Risk Factors in Microbial Food Safety of Fresh and Fresh-Cut Produce," in Comprehensive Reviews in Food Science and Food Safety, Vol 2 (supplement), 2003; pp 38-77, particularly section 2.1.2.3, page 44]

3) FDA and USDA should consider pathogens as one component of an overall food safety regimen that also considers the health impacts of chemical exposures and loads. If farmers are forced to avoid use of animal manure composts and remove vegetation near their fields, they may be required to rely on commercial fertilizers and pesticides, further exacerbating environmental degradation and the toxic loads.

- **Coordination of produce food safety practices and sustainable and/or organic production methods**

FDA and USDA should communicate clearly and often regarding the interplay between organic standards and food safety requirements. We are very concerned about food safety requirements that would directly interfere with or contradict organic standards. Without clear coordination between FDA and USDA's National Organic Program, such conflicts could arise unintentionally.

For example, vegetation in road and riparian areas is critical to organic farming systems for biodiversity and pathogen filtration. In fact, organic standards require organic farmers to include wildlife habitat and other biodiversity measures into their farm plans. Yet some public and private GAP standards have led to the destruction of non-crop vegetation, filter strips and wildlife habitat based on a general assumption that wildlife is a significant pathogen risk, and that bare, sterile ground reduces risk. Not only are these assumptions in conflict with organic standards, but they are not well grounded in science.

A great deal of testimony was heard on this topic during the field hearings held by USDA's Agricultural Marketing Service (AMS) during the fall of 2009 regarding the Proposed Leafy Greens Marketing Agreement (LGMA). Much of the testimony, particularly at the Monterey, California hearing location, focused on how the food safety metrics established under the California LGMA, and their interpretation by auditors, have placed pressure on leafy green growers to remove wildlife habitat, in conflict with organic standards and good conservation standards. The LGMA experience will be discussed further below.

Farming systems that combine crops and livestock, as is common on organic farms particularly in the Northeast and Midwest, is another aspect to biodiversity. Scientific studies show that grass-fed animals are significantly less risky than confined animals with regard to *E.coli* 0157:H7 and other pathogen contamination. There is a growing body of science regarding the pathogen reduction benefits of biologically active soils and diversified farming system can help foster those soil structures.

While organic standards are not food safety standards per se, many of the standards have positive food safety implications, and care should be taken not to undermine those beneficial standards. For example, organic standards have strict standards for the application of manure to farm fields. Raw manure is prohibited from application to soil within 90 or 120 days of harvest, depending on the type of crop, unless composted under strict standards before it is spread on fields. Compost teas and manure teas have the same waiting periods as raw manure.

FDA should be aware of these standards before issuing any blanket regulations discouraging the use of manure on farms. Such regulations would have the effect of moving farmers away from the soil-building, organic practices have been shown to be beneficial from a food safety standpoint, and toward the use of chemical fertilizers as an alternative to manure or compost.

FDA and USDA should work closely with the NGOs that are doing the outreach with farmers on these issues.

- **Coordination of produce food safety practices and environmental and/or conservation goals or practices;**

Similar to the above discussion about the need to coordinate food safety standards with organic and sustainable farming systems, the same holds true with regard to coordination with environmental and/or conservation goals or practices. Coordinating with and building upon conservation measures already underway on many farms can enhance the effective ecosystem services provided by a healthy growing environment while ensuring the safe growing of food.

We encourage FDA to create risk management assessment standards that allow for the co-management of food safety and conservation. USDA spends billions of taxpayer dollars annually on programs to pay farmers to implement wildlife and water quality conservation practices on farms. By building co-management into the produce standards, FDA will not create conflicts with the Endangered Species Act, Federal and State water quality mandates such as the Clean Water Act, the National Organic Program rule, or the Conservation Stewardship Program and other programs of USDA's Natural Resources Conservation Service (NRCS) which administers over $4 billion each year for Farm Bill programs. USDA's overall proposed conservation budget for fiscal year 2011 is $5.9 billion.

Many organic farmers are active participants in NRCS cost share programs, for example. Indeed, under provisions of the 2008 Farm Bill the agency administers a separate Environmental Quality Incentives Program known as the EQIP Organic Initiative for technical and financial assistance to transitioning and organic farmers to implement conservation practices on their land that specifically relate to certified organic practices.

However, as mentioned above, under the California Leafy Greens Marketing Agreement (LGMA) program, in the name of food safety, auditors have pressured farmers to rip out, bulldoze and otherwise destroy many of these same conservation projects that were designed and funded through multi-year contracts with various governmental specialists and agencies. In response to the Agricultural Marketing Service's formal hearings on a proposed National Leafy Greens Marketing Agreement that were held across the country in 2009 – the National Organic Coalition (NOC), Northeast Organic Farming Association (NOFA), Food and Water Watch and many other organizations and individuals provided detailed testimony and comments in opposition to the proposal -- and we are pleased that FDA has accepted the complete LGMA hearing record into the FDA Guidance docket for review and consideration. It is critical that FDA consider small scale farmers' testimony on the adverse impacts of the LGMA that was presented at the USDA hearings.

When it comes to considering coordination with time-honored conservation practices, we urge a verifiable science-based approach. As opposed to the suppositions that are behind the metrics and "supermetrics" that were adopted by industry in response to the California LGMA, there is a growing body of evidence that wildlife and their habitat are in fact a low food safety risk. In addition, there is considerable evidence that the conservation and restoration of grasses and wetlands that filter *E. coli* pathogens, and the promotion of diverse soil microorganisms that are antagonistic to these pathogens, increase the safety of food. Not to mention the potential for hedgerows and natural, vegetative barriers to minimize the spread of airborne pathogens.

Under water quality protections that are mandated by the Clean Water Act, for instance, California farmers are specifically required to address runoff by the State Water Resources Control Board. Conservation practices typically used for water quality benefits include grassing ditches, using native shrubs and trees along waterways to stabilize soils, and installing sediment basins to capture runoff before it leaves the field. Yet in the Salinas Valley alone, under the California LGMA, food safety auditors pressured farmers to remove conservation practices for water quality and wildlife habitat on over 30,000 acres, including 30-foot bulldozed bare earth buffer zones around produce fields.

However, grass and wetlands are known to filter out 70-99% of *E. coli* so that it does not spread throughout the landscape. And since *E.coli* O157:H7 can also be carried on dust, conservation measures such as hedgerows and windbreaks are important practices that can better filter dust and reduce pathogen transfer. The billions of dollars spent by USDA NRCS's and others' on farm conservation should augment FDA standards, not be at odds with them.

Further, it is not just large government expenditures that are involved in conservation installations. Many of these are cost share projects where farmers bear some of the cost. Any mandates that modify or remove these improvements represent a financial loss to the farmers, taxpayers, as well as the farm environment.

**• Microbial testing**

As discussed above with regard to the question about risk identification and prioritization, we encourage FDA to support research to test for presence and source of pathogens through the farm-to-consumer value chain including small, medium scale and large farms that market locally, regionally, nationally and internationally. This will help identify most important risk factors and associated control points (e.g. impact of co-mingling product, packaging, harvest-to-consumption shelf life, etc.)

This research should be conducted or sponsored over a number of years and under various circumstances through the whole value chain from farm, processing, distribution through retail/foodservice.

In addition, FDA should be mindful of the costs of microbial testing for small producer. Who will do the testing, and who will pay for it? The cost can be significant.

**• Records and other documentation that would be useful to industry and regulators in ensuring the safety of fresh produce**

There is a great deal of documentation built into the organic system. FDA should fully understand the recordkeeping requirements with which organic producers must already comply, and mine that system for pieces of recordkeeping that can be used to address food safety data needs.

There should be no electronic recordkeeping requirement for farmers, which can be quite burdensome for smaller scale farmers. Nor should farmers be required to keep separate records for each crop, which can place an overwhelming burden on diversified farming operations with many different crops. Instead, a whole-farm approach to food safety and recordkeeping is far more practical, and also more effective from a food safety perspective, as it may catch interactions between crops that may not be evident in a more myopic crop-by-crop focus.

In addition, since the purpose of recordkeeping from a food safety perspective is to be able to trace a contaminated product back to its source, food that is sold directly to consumers and/or identity preserved should be exempt from additional food safety trace-back requirements.

**• The impact of scale of growing operations on the nature and degree of possible food safety hazards;**
**• Possible approaches to tailoring preventive controls to the scale of an operation so that the controls achieve an appropriate level of food safety protection and are feasible for a wide range of large and small operations;**

In August of 2009, FDA issued draft produce food safety guidances for melons, tomatoes and leafy greens. For smaller, diversified farming operations, which may have 40-60 crops, it is a real challenge to comply with guidance on a commodity-by-commodity basis. We encourage the FDA to follow the approach of an over-arching food safety plan with add-ons for specific identified food safety problems.

Buffer requirements are also a big issue for small farms. Typically a small, diversified farm will have multiple, very small fields whereas a large farm is more likely to have large fields. As a result, the percentage of plantable acres eliminated by buffers for a small farm can be significantly greater than would be true for a larger farm with large fields. Buffer requirements should be sensitive to scale of operation and field configuration.

For most small-scale farms, the farmer/producer is also the food safety person and the paperwork manager. Any rule should provide a framework for farmers who perform many functions.

Education and training should be the main focus of food safety related interaction with smaller-scale farms, and FDA and USDA should encourage the delivery of needed on-the-ground food safety information and training.

There should be a common-sense focus on the areas on the farm where there is the highest potential for problems, such as worker hygiene, potable wash water sourcing, and physical separation of washing/packing areas from livestock.

Scale of the farm operation can be a proxy for risk, in many cases, because practices used on smaller scale farms are in many cases different than those used on larger operations. For example, the practice of comingling produce of multiple farm operations to be cut, washed, and packaged in one common facility is much more commonly associated with large farms supplying produce for the large-scale marketing of products (such as bagged, fresh-cut or shredded leafy greens) that undergo some sort of additional processing. FDA's own pathogen outbreak incident data suggests a greater level of risk for processed produce such as this, relative to the fresh market. (See Testimony of Dave Runsten, Monterey NLGMA hearing, 2nd day, exhibit 33A, http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5079854)

It is not the large size of these farms *per se* that increases the risk, it is the higher-risk handling practices and extended shelf-life marketing strategies associated with produce from these farms that should raise the level of scrutiny. As discussed above in the section regarding risk identification and prioritization, further research can help expand the body of science regarding the relative risk of various practices, and how those correspond to various farm types and scales.

## Conclusion

From the perspective of farmers, consumers, and those organizations who work with them, the food safety debate has become extremely complicated, duplicative, confusing, and frenzied.

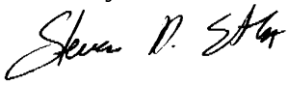
Congress is currently considering food safety legislation, FDA and USDA are both publicly contemplating their own produce food safety regulations, State governments (such as California, Arizona, and Florida) have already implemented their own produce food safety regulations, and private industry buyers are competing with each other to set their own food safety requirements for the farmers and wholesalers who supply them with produce. It is no wonder that farmers and consumers are overwhelmed and fatigued by the food safety debate.

As the lead produce food safety agency in the nation, it would be helpful for FDA's process to include a concerted effort to alleviate the audit fatigue that produce farmers are experiencing. We are not arguing for a heavy-handed, one-size-fits-all approach to produce food safety regulation. To the contrary, we are arguing for a system that establishes multiple tiers of food safety scrutiny based on verifiable levels of risk. But in moving in that direction, it is critical that FDA take the leadership in communicating with private buyers and the produce industry itself about the need to eliminate the overlapping and conflicting food safety metrics that farmers are confronting in their daily operations, and to alleviate the food safety audit frenzy in the marketplace. Safe food should be a baseline assumption for consumers, not the source of competition between products or brands.

At this moment, there is a sense that no one is in charge with regard of produce food safety. As a result, in the aftermath of very high profile pathogen outbreaks associated with produce, private buyers and the produce industry are establishing their own standards in an attempt to insulate themselves from litigation. Given the focus on liability avoidance rather than food safety science, many of these efforts are based more on establishing extreme farming and handling sterilization procedures than there are on understanding the full science of interaction between farming systems and pathogen and toxic chemical risk to humans.

It is our hope that FDA will bring some reason and order to the food safety frenzy in the marketplace, and we look forward to working with the agency in that process.

Sincerely,



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Attachment: Annotated List of Supporting Food Safety Research