



National Organic Coalition

1301 Hancock Avenue, Alexandria, VA 22301
703-519-7772 email: steveetka@gmail.com

January 4, 2010

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

DOCKET NUMBERS: FDA-2009-D-0346
 FDA-2009-D-0347
 FDA-2009-D-0348

Thank you for the opportunity to provide comments on following draft guidances:

Guide to Minimize Microbial Food Safety Hazards of Tomatoes. (FDA-2009-D-0346)
Guide to Minimize Microbial Food Safety Hazards of Melons (FDA-2009-D-0347)
Guide to Minimize Microbial Food Safety Hazards of Leafy Greens (FDA-2009-D-0348)

In General

The three commodity-specific guidances are broad and general in nature. As described in the introductory language common to all three guidances:

“.. each firm from the farm level through the retail or foodservice level [is encouraged] to assess the recommendations in this guidance and then tailor its food safety practices to its particular operations by developing its own food safety programs based on the assessment of the potential hazards and its operations.”

We recognize that these documents are not to be viewed as an action plan for any specific operation, but rather a starting point for each operation to assess the food safety risks on their farms and facilities. In general, we appreciate the flexibility of this approach, which is one strategy to avoid a one-size-fits-all set of food safety metrics that would be counterproductive and burdensome to small scale, organic and diversified farming operations.

However, each of these guidances also state that:

“FDA will continue to evaluate how best to measure the extent to which the recommendations in this and other federal guidance, as well as industry standards and practices, are being implemented and are effective in reducing microbial contamination in [leafy greens, melons, and tomatoes]. In particular, we are considering the extent to which more specific measures, including metrics, should be utilized to help verify the implementation and efficacy of the federal recommendations and industry practices.”

In other words, these guidelines cannot be viewed in a vacuum. This is acutely true now. Currently, Congress is in the process of considering food safety reform legislation, the U.S. Department of Agriculture is in the midst of a multi-year regulatory process for the development of industry-led food safety regulations for leafy greens, and a plethora of produce buyers have established their own commodity-specific food safety “super-metrics” with which many fruit and vegetable farms must comply in order to sell their product.

Therefore, we believe it is important to provide the Agency with a broad outline of the principles we are espousing in the context of all of these intertwined and overlapping food safety discussions, and the science to back up those principles.

General Food Safety Policy Principles

Regulation Should Target the Areas of Greatest Risk, and Those Risks Should be Scientifically Determined

Part of the analysis of risk should also be recognition that scale and type of operation plays a role in determining risk. For example, when there is a large-scale spinach or lettuce farming operation, with a centralized washing facility co-mingling product from thousands of acres and bagging that produce for distribution to retail stores in 20 states, the potential for widespread contamination and trace back difficulties is much higher than there would be in a small scale operation cutting fresh greens from a 100-acre field, washing it, and delivering it un-bagged to a restaurant, farmers market, or natural food cooperative later that same day. Commonsense would dictate that these two types of operations should be treated differently when it comes to addressing food safety risks.

For leafy greens, we argue that large-scale operations distributing fresh-cut or ready-to-eat greens in sealed bags to retail stores in multiple states should be the focus of greatest scrutiny with regard to food safety regulations. Compelling evidence compiled from FDA foodborne illness outbreak data associated with lettuce or spinach and E.coli 0157:H7 for the period of 1993-2008 was presented at the Monterey, California National Leafy Green Marketing Agreement (NLGMA) hearing on September 24, 2009 by the California Alliance with Family Farms (CAFF).¹

¹ <http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELPRDC5079854>.
NOC Comments on FDA Guidances
Tomatoes, Melons, Leafy Greens

These data show that most of the documented cases of E. coli 0157:H7 illness outbreaks for lettuce or spinach during this time were associated with bagged/fresh-cut product, not fresh whole head or bunched product. In some cases, the source of the contamination was not known. Unless FDA has further evidence to contradict this incidence data, we believe that food safety regulation for leafy greens should target the bagged/fresh-cut market as the area of highest risk.

As described by California leafy greens grower Dale Coke at the Monterey NLGMA hearing, growing, handling and marketing procedures for bagged/fresh-cut/ready-to-eat leafy greens products is significantly different, and riskier from a food safety context, than those harvested and sold as fresh, whole-head or bunched product, and present many more opportunities for pathogen contamination.²

Food Safety Regulations Should Recognize the Benefits of Diversified, Conservation-Oriented Farming Operations, and Avoid Imposing Unnecessary Burdens on Them

It would be unfortunate and ironic if regulations intended to enhance food safety were to create incentives for farmers to move away from sustainable farming systems, which are designed to reduce toxic loads in the water, soil and air, and to instead promote the use of large scale, monocultural farming systems that we believe to be of higher risk.

Research backed up our claims about the food safety benefits on diversified, conservation-oriented farming operations.

For example, research from USDA's Agricultural Research Service shows that vegetative buffers such as filter strips, constructed wetlands, and contour buffer strips can retard, retain, and metabolize pollutants. Buffers restrict pollution by reducing drift, increasing sedimentation, increasing uptake by plants, and increasing microbial activity. Vegetated ditches and constructed wetlands can process pollutants in runoff.³

Similarly, in 2006, University of California- Davis researchers tested the effectiveness of vegetated buffers at filtering E. coli in runoff from cattle grazing lands in California. They found that even narrow vegetative buffers can filter between 95% and 99.99% of total E. coli. These results support the assertion that grassland buffers are an effective method for reducing animal agricultural inputs of waterborne E. coli into surface waters.⁴

Food safety regulations should recognize the benefits of practices used on diversified and organic farms with regard to pathogen reduction, including the benefits of wildlife habitat, such

² <http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5079734>

³ **Title:** Integrated management of in-field, edge-of-field, and after-field buffers.
Author: Dabney, S.M., Moore, M.T., Locke, M.A. (USDA ARS)
Journal of the American Water Resources Association. 42(1): 15-24, 2006)

⁴ **Title:** Significant Escherichia coli Attenuation by Vegetative Buffers on Annual Grasslands
Authors: Kenneth W. Tate, Edward R. Atwill, James W. Bartolome and Glenn Nader (from UC Davis and the UC School of Veterinary Medicine) J Environ Qual 35:795-805 (2006)
NOC Comments on FDA Guidances January 4, 2010
Tomatoes, Melons, Leafy Greens

as filter strips and vegetated buffer zones, to filter out pathogens and to encourage beneficial insects as a pest control mechanism.

Therefore, such regulations and/or metrics should be developed in a manner that will avoid discrimination against diversified, organic, and/or small scale farming operations, by NOT:

- 1) creating inflexible, one-size-fits-all requirements biased toward large scale operations;
- 2) penalizing farms that promote wildlife habitat and natural pest and pathogen control through conservation practices, such as vegetated buffer zones and filter strips, based on false assumptions of pathogen risk from deer, frogs and other wildlife, which has been unsupported by scientific research;
- 3) creating barriers to the use of basic farming practices required for organic certification, such as biodiversity promotion measures and organic pest control measures.
- 4) creating a general bias toward a sterilization model of farming, where synthetic pesticides kill all microbial activity in the soil, and where synthetic fertilizers must be used to add back the nutrients needed for plant growth, which is ultimately counterproductive from both a food safety and an environmental standpoint.

Food Safety Regulations Should Support a Whole-Farm Approach, and NOT require each Farmer to Follow Separate Food Safety Protocols for Each Specific Crop

We strongly support a whole-farm approach to food safety. Asking diversified farms, which may raise 40-60 different crops during a growing season, to follow 40-60 different guidance documents is a recipe for disaster, both from the farmer's perspective and from that of prospective regulators. Guidances should encourage whole farm food safety strategies, and then provide guidance on specific activities that have documented high risks (e.g., bagging mixed greens from multiple farms.)

Federal and State Agencies Must Avoid Costly and Counter-productive Duplication

All federal and state agencies must work in concert when developing food safety regulations, guidelines and outreach efforts. The potential for imposing unnecessary, burdensome, and ineffective food safety requirements on farmers and industry is exacerbated if agencies work at cross purposes or duplicate efforts. For example, to the greatest extent possible, FDA and USDA should work together closely on the development and enforcement on food safety standards.

We believe the FDA, as the lead federal food safety agency for produce, has the relevant scientific food safety expertise whereas USDA has the more practical knowledge with regard to the application of that science in a manner that is practical and enforceable in the agriculture sector. The potential for the agencies to duplicate and contradict the other's efforts is high, and a tight collaboration must be instituted to avoid that outcome.

For example, the U.S. Department of Agriculture's Agriculture Marketing Service (AMS) is in the midst of a major rulemaking to consider a proposal from the leafy greens produce industry to

establish a National Leafy Greens Marketing Agreement (NLGMA). The proposal would establish a process for an industry-dominated Board to take the lead on establishing food safety standards for leafy greens, for endorsement by the Secretary of Agriculture, in the context of produce promotion and marketing. This is despite a clear lack of food safety standards authority or expertise on the part of AMS. This controversial and exhaustive process, which included over 4800 pages of testimony gathered over 11 days at 7 different locations across the country, has taken place at the same time as FDA is seeking comments on its own approach to addressing food safety standards for leafy greens. Much of the testimony at the NLGMA hearing focused on differing opinions about the appropriateness of two federal agencies simultaneously developing leafy greens food safety standards.

It is very burdensome for farmers, non-profit organizations, and small businesses to try to provide comment and feedback on both agencies' efforts, especially when no clear statement has been made by either agency about how their respective rulemakings are related, if at all.

We strongly urge FDA to include the entire NLGMA hearing transcript as comments on the Guide to Minimize Microbial Food Safety Hazards of Leafy Greens, given the direct relevance to the subject.⁵

With regard to food safety standards for organic farms, there are many aspects of federal organic standards, such as manure composting and handling standards, recordkeeping and audit procedures, and biodiversity requirements, which have direct and positive implications from a food safety standpoint. By working directly with the National Organic Program on the development of produce food safety standards and their enforcement for certified organic farms, FDA can avoid unnecessary duplication and leverage scarce resources and expertise.

FDA should coordinate closely with the AMS' National Organic Program (NOP) in developing food safety regulations to assure that both the regulations and their interpretation by growers, handlers, and buyers do not result in unintended conflict with the organic standards.

Training and Education is Critical to Effective Implementation of Food Safety Protocols for Small-to-Medium Scale Farms, and Small Processors and Handlers

FDA, in coordination with USDA, should sponsor regional training and education programs to help small processors and handlers, as well as small-and-medium scale farmers, address food safety concerns in their operations. Training should also be provided to help food safety auditors understand the unique needs and attributes of these operations.

Senator Debbie Stabenow has introduced legislation enumerating one approach to addressing this need⁶, though other approaches should be considered as well.

⁵ The NLGMA transcript can be found on the "Industry Marketing and Promotion" section of the AMS website: <http://www.ams.usda.gov/AMSV1.0/ams.fetchTemplateData.do?template=TemplateA&navID=Proposed-LeafyGreensMarketingAgreement&rightNav1=Proposed-LeafyGreensMarketingAgreement&topNav=&leftNav=&page=LeafyGreensProposal&resultType=&acct=fvmktord>

⁶ S. 2758, <http://thomas.loc.gov/cgi-bin/bdquery/D?d111:34:./temp/~bdKb9R:./bss/>

Food Safety Must be Viewed from a Holistic Perspective, Not Narrowly Focused on Pathogens Alone

Pathogens are just one piece of the food safety equation. If pathogen risk is addressed in a vacuum, the outcome will be to create incentives for farmers to sterilize their soils and crops with pesticides whose residues can be harmful to human health, or to remove wildlife habitat and filter strips which filter out incoming pathogens and pesticide residues and harbor beneficial insects that serve as a non-chemical method of pest management.

Well Managed, Biodiverse Soils are Part of the Solution to Both Pathogen and Chemical Residue Risks

Science has shown that organically managed soils with vibrant microbial activity provide great benefits in terms of reducing pathogens in the soil and impeding their uptake by the crop. Yet this beneficial microbial activity is itself hampered if the soil is exposed to synthetic pesticide and fertilizers.

A number of studies show that well-managed soil, such as that encouraged by organic production systems, can suppress pathogenic organisms. For example, a 2007 study in The Netherlands showed that soil with less biological complexity offers greater opportunities for invading microbial species, including *E. coli* 0157:H7, to establish and persist. More bio-diverse soils may suppress pathogens because beneficial microbes compete with pathogenic microbes for resources.⁷

In another study, researchers in the Netherlands in 2005 tested the survival of *E. coli* 0157:H7 added to manure from grass-fed cows and those fed a mixture of grass and corn silage. This manure was added to organic and conventional soils. *E. coli* levels declined fastest in the manure from grass-fed cows that had been mixed with organic soil; the slowest rate of decline was in manure from cows fed the grass/corn silage mixture that had been mixed with conventional soil. The researchers found that cattle diet and soil management are important factors affecting the survival of human pathogens in the environment.⁸

⁷ (**Title:** Survival of genetically marked *Escherichia coli* O157:H7 in soil as affected by soil microbial community shifts.

Authors: van Elsas JD, Hill P, Chronakova A, Grekova M, et al (Department of Microbial Ecology, Centre for Ecological and Evolutionary Studies, University of Groningen, Haren, The Netherlands)
ISME Journal (multidisciplinary journal of microbial ecology). 2007 Jul 1(3):204-14.)

⁸ **Title:** Effects of cattle feeding regimen and soil management type on the fate of *Escherichia coli* O157:H7 and salmonella enterica serovar typhimurium in manure, manure-amended soil, and lettuce.

Authors: Franz E, van Diepeningen AD, de Vos OJ, van Bruggen AH (Department of Plant Sciences, Wageningen University and Research Center, The Netherlands.) Appl Environ Microbiol. Oct;71(10):6165-74, 2005

Comments on the Specifics of the Guidances:

Leafy Green Guidance

V. Production and Harvest

A. Environmental Assessments and Risk Reduction Practices

“Practices FDA recommends to reduce the risk of microbial contamination of leafy greens in the production environment include:

- *Locating production sites (to the degree feasible) to minimize potential access by wildlife. For example, considering the proximity to water, wildlife harborage, open range lands, non-contiguous production lots or blocks, and urban centers.*
- *Controlling risks associated with production fields that are encroached upon by urban development.*
- *Considering risk factors including septic tank leaching and domestic animal fecal contamination of production fields and harvest equipment.*
- *Exercising care to reduce the potential for windborne soil, water or other media that may be sources of contamination to come into contact with the edible portions of leafy greens.*
- *Monitoring and minimizing domestic animal and wildlife activity in leafy greens fields and production environments (e.g., reducing potential harborage and standing water, and utilizing animal repellents and attractants).*
- *Considering whether or not to harvest any portions of a field affected by unusually heavy wildlife activity or evidence of wildlife activity (e.g., presence of wildlife feces).*
- *Assessing the field at the time of harvest to ensure that no new food safety risks have occurred.*
- *Using harvest practices such as removing outer soiled leaves and not harvesting whole soiled heads of leafy greens when excessive soil or mud builds up on leafy greens.*
- *Training harvest employees to recognize and report for appropriate action any evidence of wildlife activity or infestations (e.g., feces).” [underlined emphasis added]*

In the underlined text of this section, the microbial hazards of wildlife are presented as fact, in spite of the recent research from the California Department of Fish and Game showing that less than half of one percent of fecal samples from mammalian wildlife in the California Central Coast counties tested positive for E. coli 0157:H7. While this research is ongoing, it does draw into question the assumptions made about wildlife as being a significant vector for pathogen contamination of leafy greens and other produce.

Further, this section should point out the food safety benefits of vegetated buffer zones and filter strips, which help to filter out pathogens from nearby property and provide habitat for beneficial insects that help reduce or eliminate the need for use of synthetic pesticide sprays.

B. Water

Within this section, there needs to a recognition of the higher risks associated with co-mingling product from many different farms to be washed in one common facility. Under this scenario, the potential for rapid spread of any contamination is significantly heightened.

Language should also added to discourage against the use of rodent poisons in produce fields, because of high risk of these poisons being transferred to the soil and crop by water, wind, or other vectors. This problem was highlighted during the September 23, 2009 NLGMA hearing in Monterey, California.⁹

In addition, in the section referring to “Crop Protection Sprays (Pesticides),” a statement should be made about the food safety benefits of farming practices, such as certified organic practices, that preclude the need for use of pesticide sprays.

C. Soil Amendments

In the section entitled “soil amendments”, the following recommendations are made:

“FDA recommends:

- *Refraining from use of raw animal manure with any leafy greens crop.*
- *Refraining from using biosolids as a soil amendment for any leafy greens crop.*
- *Verifying that any soil amendment that does not contain animal manure has documentation (e.g., ingredient list, statement of identity, or letter of guaranty) from the producer or seller stating that it is manure free.*
- *Implementing management plans which ensure that the use of soil amendments will not pose a significant potential human pathogens hazard (e.g., timing of applications, storage location, source and quality, and transport).*
- *Verifying the time and temperature process used during the composting process to ensure that the potential of human pathogens being carried in the composted materials is reduced, controlled, or eliminated as applicable to regulatory requirements.*
- *Maximizing the time interval between the soil amendment application and time to harvest.*
- *Implementing practices that reduce, control, or eliminate likely contamination of leafy greens fields that may be in close proximity to on-farm stacking of manure.*
- *Using soil amendment application techniques that control, reduce, or eliminate the likely contamination of surface water or edible crops being grown in near-by fields.*
- *Segregating equipment used for soil amendment applications such as compost or using effective means of equipment cleaning and sanitation before subsequent use.*
- *Minimizing the proximity of wind-dispersed or aerosolized sources of contamination (e.g., water and manure piles) that may potentially contact growing leafy greens or near-by edible crops.*

⁹ See testimony of Steve Shimek, of Monterey Coastkeeper, on page 969 of the draft transcript <http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELPRDC5080509>

- *Obtaining compost from commercial suppliers that maintain temperature monitoring and turning records.*
- *Obtaining compost from commercial suppliers that have and provide documentation of written standard operating procedures (SOPs), to prevent cross-contamination of finished compost with raw materials through equipment, runoff, or wind.”*

These recommendations create a bias toward chemical-intensive agricultural practices, and ignore the food safety risks of those systems, as discussed in the studies mentioned above. In addition, this bias does not recognize the benefits of organic nutrient management practices, nor the fact that organic farmers are required to take specific responsible approaches to manure/compost and use.

Certified organic farming operations cannot use synthetic fertilizers on their soils, but must rely on animal or green manures, or nitrogen-fixing crops, to sustain and supplement the nutrients in the soil. Manure use on organic farms is tightly regulated under standards that derive from EPA guidance on the subject.

Focusing on the dangers of manure-based nutrient management systems, without looking at the soil and microbial benefits of those systems ignores the complexity of the science on this subject, and pushes farmers in a direction that may actually be more harmful to environment and to human health.

Documentation and Records; Product Tracing

Throughout the guidance, when references are made to the need for documentation and records and product traceback, language should be added to make reference to the audit trail and recordkeeping requirements with which organic farmers must already comply as part of their certification. Without a specific reference, auditors attempting to utilize the FDA guidance for food safety audits on organic farms may not be aware of the existing requirements, which could lead to unnecessary and costly duplication.

Melon Guidance

V. Production and Harvest

In the sections referring to “fungicide treatment” and “flying insect control,” language should be added about the food safety benefits of farming practices, such as certified organic practices, that preclude the need for use of synthetic pesticides in production and postharvest.

Documentation and Records; Product Tracing

Throughout the guidance, when references are made to the need for documentation and records and product traceback, language should be added to make reference to the audit trail and recordkeeping requirements with which organic farmers must already comply as part of their certification. Without a specific reference, auditors attempting to utilize the FDA guidance for food safety audits on organic farms may not be aware of the existing requirements, which could lead to unnecessary and costly duplication.

Tomato Guidance

V. Open Field Production

2. Animal Exclusion:

In the section entitled “animal exclusion” the following recommendations are made:

“FDA recommends:

- *Excluding domestic animals and livestock from tomato fields.*
- *Taking measures to minimize wildlife presence such as using barriers or other deterrents, minimizing wildlife attractants and opportunities for harborage, redirecting wildlife to non-sensitive areas, and employing other methods identified by wildlife experts.*
- *Taking measures to remove, or prevent the harvest of, any potentially contaminated tomato product if animal intrusion into a production area is detected.”*

These recommendations create the strong incentive for farmers to remove wildlife habitat, which totally ignores the documented pathogen-reduction, filtration, and natural pest control benefits of wildlife habitat buffers. To focus on the supposed dangers of wildlife habitat without:

- 1) acknowledging the conflicting research about the pathogen risk of wildlife;
- 2) recognizing the benefits of such habitat with regard to pathogen filtration from neighboring property; and,
- 3) recognizing the benefits of such habitat with regard to encouraging beneficial insects that reduce or preclude the need for the use of potentially harmful synthetic pesticides;

ignores the complexity of science on the issue, and will result in a bias toward mono-cultural, chemical intensive agricultural system, to the detriment of food safety.

7. Tomato Production Practices

In the subsection entitled “Soil Amendments Containing Manure, Composts, and Biosolids,” the guidance states the following:

“FDA recommends:

- *Refraining from use of raw animal manure.*
- *Verifying that any soil amendment that does not contain animal manure has documentation (e.g., ingredient list, statement of identity, or letter of guaranty) from the producer or seller stating that it is manure free.*
- *Implementing management plans that ensure that the use of soil amendments does not pose a significant potential human pathogens hazard (e.g., timing of applications, storage location, source and quality, and transport).*

- *Verifying the time and temperature process used during the composting process to ensure that the potential of human pathogens being carried in the composted materials is reduced, controlled, or eliminated.*
- *Maximizing the time interval between the soil amendment application and time to harvest.*
- *Implementing practices that reduce, control, or eliminate likely contamination of tomato fields that may be in close proximity to on-farm stacking of manure.*
- *Using soil amendment application techniques that reduce, control, or eliminate the likely contamination of surface water or edible crops being grown in adjacent fields.*
- *Segregating equipment used for soil amendment applications such as compost or using effective means of equipment cleaning and sanitation before subsequent use.*
- *Minimizing the proximity of wind-dispersed or aerosolized sources of contamination (e.g., water and manure piles) that may potentially contact growing tomatoes or adjacent edible crops.*
- *Obtaining documentation from compost suppliers including composition, dates of treatment, methods utilized (e.g., time/temperature management, turning, and steps to minimize cross-contamination of finished compost by raw or in-process product), and any test results or process verification data demonstrating that any compost, manure or biosolids applied to tomato fields have been sufficiently treated to reduce pathogens that may be present.”*

As stated in our specific comments on the leafy greens guidance, the above recommendations reflect a bias toward chemical-intensive agricultural practices, while ignoring the food safety risks of those systems. Further, they ignore the benefits of organic nutrient management practices and their role in producing safe and healthful food.

Certified organic farming operations cannot use synthetic fertilizers on their soils, but must rely on animal or green manures, or nitrogen-fixing crops, to sustain and supplement the nutrients in the soil. Manure use on organic farms is tightly regulated under standards that derive from EPA guidance on the subject.

Focusing on the dangers of manure-based nutrient management systems, without looking at the soil and microbial benefits of those systems ignores the complexity of the science on this subject, and pushes farmers in a direction that may actually be more harmful to environment and to human health.

In the subsection entitled, “Crop Protection Sprays (Pesticides)”, a statement should be made about the food safety benefits of farming practices, such as certified organic practices, that preclude the need for use of pesticide sprays.

Documentation and Records; Product Tracing

Throughout the guidance, when references are made to the need for documentation and records and product traceback, language should be added to make reference to the audit trail and recordkeeping requirements with which organic farmers must already comply as part of their certification. Without a specific reference, auditors attempting to utilize the FDA guidance for food safety audits on organic farms may not be aware of the existing requirements, which could lead to unnecessary and costly duplication.

In Conclusion

The member organizations of the National Organic Coalition share a concern about food safety and a strong belief that diversified, conservation-oriented sustainable and organic farming systems with abundant wildlife habitat are highly compatible with safe food, and in fact, are part of the solution. We strongly believe that conservation and food safety goals are compatible.

However, the general recommendations laid out in the three FDA food safety guidance for leafy greens, tomatoes, and melon demonstrate a decided, though perhaps unwitting, bias in favor of conventional mono-cultural, chemical-intensive farming systems, where domesticated and wild animals are viewed only as negatives, where crop diversity is viewed as a nuisance, and where synthetic pesticides and fertilizers are an assumed necessity.

One of the most enlightening and intellectually honest statements that FDA could make to the public about produce food safety is to acknowledge the uncertainty of the science in this arena.

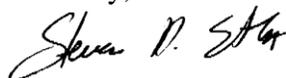
- Do the harms of manure use from a human pathogen standpoint outweigh the benefits from the standpoint of building health soils with healthy microbial action to help combat the pathogens, and to preclude the need for synthetic fertilizers that degrade the soil?
- Is wildlife truly a significant vector of pathogen contamination?
- Do the filtration and beneficial insect benefits of wildlife habitat outweigh any potential fecal contamination issue?
- Do the harms of pesticide residue exceed the benefits of pesticide use?
- Are the long-term human health threats of pesticide residue exposure of equal concern to the more immediate potential of microbial pathogens? Are the two really in conflict?
- Does it make sense, from a risk perspective, to tightly regulate individual farms, or would FDA achieve maximum risk abatement by targeting the produce processing sector?

It is unfortunate that the scientific debate on these issues is not more advanced. But the insufficiency and uncertainty must be acknowledged and remedied through greater focus and resources, not ignored in order to facilitate an immediate and demonstrable FDA action plan on food safety protocols.

The stakes in the food safety debate are quite high. To anoint conventional, chemical-intensive agricultural systems as the best avenue for production of safe food, in the face of scientific evidence to the contrary and a lack of epidemiological data in support, threatens to nullify the consumer-and-farmer driven growth in organic and sustainable farming systems.

We urge the Agency to strongly consider the general principles and specific recommendations laid out in our comments, to understand how the current guidance drafts demonstrate a bias in favor of chemical-intensive agriculture systems, and to sponsor the research necessary to help answer the gaping questions in food safety science.

Sincerely,



Steve Etka, National Organic Coalition