



January 4, 2010

Division of Dockets Management
HFA-305
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: "Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards of Leafy Greens; Draft Guidance," Docket # FDA-2009-D-0348.

To Whom It May Concern:

Food & Water Watch is a national nonprofit consumer advocacy organization. We appreciate the opportunity to comment on "Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards of Leafy Greens; Draft Guidance," (Docket #FDA-2009-D-0348), hereafter referred to as "the draft guidance on leafy greens."

Our comments will focus on the following issues:

- Applicability of the draft guidance on leafy greens to a variety of production systems, farm scales and supply chains
- Guidance on wildlife and wildlife habitat
- Guidance on soil amendments
- Guidance on practices to reduce the potential for the microbial contamination of leafy greens
- Guidance on recordkeeping.

1. Applicability of the draft guidance to a variety of production systems, farm scales and supply chains

Highly diversified farms

Small and mid-sized farms serve important local and regional markets, including schools and other institutions, restaurants, and grocery stores. Many also operate community supported agriculture (CSA) programs and/or sell at farmers markets or farmstands. These farms may grow as many as forty or fifty different crops and also raise livestock. They do so for a variety of reasons, including being able to supply a diverse selection of products to their buyers; providing income security by not relying on a small number of crops that can be impacted by pests, weather, or other factors; and supplying value-added on-farm activities.

For these farms, commodity-specific guidance may be inappropriate. At the very least, it will be difficult for them to implement it if the guidance for certain crops conflicts with the guidance provided for others. For example, as currently written, the draft guidance for leafy greens emphasizes the risk of wild animal intrusion, while the draft tomato guidance puts an emphasis

on the risks associated with runoff from animal operations. If producers are growing both leafy greens and tomatoes, as is common among small and mid-sized diversified farms, they will struggle to prioritize their actions in response to the different guidances. Should they install a vegetative buffer to stop runoff from cows on their neighbor's farm, or mow down vegetative buffers because they could harbor mice or birds?

We urge the Food and Drug Administration (FDA) not to go down the path of dealing with on-farm food safety by issuing distinct guidance for individual commodities. Such a commodity-specific approach misses the opportunity for a whole-farm approach to food safety and is unworkable for diversified farms that grow many different crops and will be unable to navigate different guidance for each one. We urge the agency to create whole-farm strategies for food safety and to provide guidance for specific activities that are known to be high risk, either due to the type of production, processing, or supply chain.

If the agency continues to pursue commodity-specific guidance, we offer the following recommendations on the draft guidance for leafy greens.

Recommendation: The draft guidance for leafy greens should specifically acknowledge that many farms grow multiple crops and that commodity-specific guidelines may not be appropriate for such farms. These farms can be directed to the GAPs or other general produce guidance provided by the FDA.

Recommendation: The FDA should ensure as much consistency as possible between the commodity-specific guidelines so that producers who do choose to use them are not overwhelmed by mixed messages.

Conservation-oriented and organic farms

Across the country, farms of all sizes are engaged in efforts to promote biodiversity and conserve air, water and soil resources. Some receive funding to do so through USDA conservation programs such as the Conservation Stewardship Program or the Wildlife Habitat Incentives Program. Others receive certification through the USDA's National Organic Program based in part on their success in promoting biodiversity. Some producers increase biodiversity in order to attract beneficial insects or predators that help control pest populations. Some raise livestock as well as crops to increase soil fertility, or to use the animals for weeding or pest management.

If these farms read food safety guidance that appears to either directly or indirectly discourage conservation and biodiversity practices, they may either assume that the guidelines do not apply to them or refuse to comply because implementation would conflict with important on-farm conservation efforts. Both reactions will reduce the chances that these farms will participate in a food safety program.

Recommendation: The draft guidance for leafy greens should be written so as to be consistent with conservation, organic, and environmental practice standards established by other federal agencies. More detail on this recommendation is included in sections 2, 3 and 4, below.

Farms selling direct to consumers, farms that do not co-mingle or process their products, and farms whose products are identity-preserved

The draft guidance for leafy greens treats all greens and all producers the same, regardless of the supply chain into which the products are sold. With respect to both risk and traceability, the type of supply chain has a significant impact that should be considered in the guidance.

The definition of leafy greens in the draft guidance includes both raw and fresh-cut/value-added products, which travel through very different supply chains and are used in different ways by consumers. Products that are co-mingled, processed, and sold as “ready-to-eat,” such as fresh-cut bagged spinach, generally pass through more hands between farm and consumer and present different food safety risks than greens that are not processed, not sold as ready-to-eat, or are cooked before being eaten (such as kale).

In addition, products that are direct-marketed or whose identity is preserved from the farm to the consumer are inherently more traceable than products that are co-mingled. Uniform traceability requirements are both burdensome and unnecessary for participants in shorter supply chains and would not result in material improvements to food safety.

Farm-level food safety activities are important regardless of the crop, but producers’ food safety decisions do not stop there. Producers should be provided with information that will allow them to make informed decisions about how or whether to co-mingle, process or package their products. As currently written, the guidance does not provide information on the relative risks of different marketing choices or supply chains.

Recommendation: The background section of the guidance on leafy greens should provide information on the origin of leafy greens outbreaks by type of product (fresh vs. fresh-cut) as well as crop and should note that co-mingling, processing, packaging, transport and shelf-life issues will increase the risk of contamination.

Recommendation: Products that are direct-marketed or whose identity is preserved from the farm to the consumer should be uniquely addressed. Guidance on traceability should acknowledge these differences and note that traceability systems beyond one-step-forward, one-step-back are more relevant and necessary for products being sold into long supply chains.

Recommendation: The FDA should coordinate with the USDA’s National Organic Program to ensure that traceability guidelines are not duplicative or overly burdensome to organic producers.

Recommendation: The FDA should include in the comments considered for the leafy green draft guidance the transcript from the USDA’s public hearings on the proposed National Leafy Green Marketing Agreement. Seven hearings held across the country in September and October, 2009, offered a wealth of evidence about the different sectors of the leafy green industry, the different approaches to food safety used across the country, and the impact one-size-fits-all private food safety programs have had on many smaller players in the leafy green industry.

2. Guidance on wildlife and wildlife habitat

According to surveys conducted by researchers at the University of California, farmers in California have removed vegetative buffers, filter strips, and other conservation measures under pressure from produce buyers and/or auditors, who assert that the conservation measures could serve as wildlife habitat and that wildlife constitute a significant contamination risk. Producers have also installed traps and poison bait and taken other actions to broadly target wildlife that could encroach on production areas.

The science suggests that risk varies widely between animals and between regions, so one set of general guidelines on wildlife is inappropriate. The guidance fails to reflect that certain animals are more risky than others; that animals respond differently to the removal of vegetated areas around fields; that a large number of animals congregating in a production area is a greater risk than are individual animals; and that the environmental, ecological and financial costs of removing wildlife habitat often outweigh the purported food safety benefits.

Recommendation: Remove vague and general references to “wildlife” in the draft guidelines for leafy greens. The draft guidance refers broadly to “activities or conditions that may pose a risk of contamination, such as livestock, wildlife, [etc.]” and recommends that producers “minimize potential access [to production sites] by wildlife” and “minimize... wildlife activity in leafy greens fields... (e.g., reducing potential harborage and standing water, and utilizing animal repellents and attractants).” In the section on irrigation water, the draft guidelines ask producers to consider “issues such as the potential for irrigation methods to... cause pooled or standing water that attracts animals.” This vague language may encourage producers to broadly target wildlife and habitat, including ponds or other water sources, despite the fact that different animals present very different risks and must be managed differently.

*Recommendation: Provide animal-specific, region-specific guidance on wildlife, including an assessment of the likelihood that an animal will present a microbial contamination risk, so that producers can make informed management decisions. For example, wild pigs can be carriers of *E. coli* O157:H7, but in the west they do not seek native habitat for cover, so habitat destruction is not an effective deterrent. Rodents do not appear to harbor pathogenic *E. coli*; even if they did present a risk, voles can be deterred by eliminating vegetative habitat, but ground mice are attracted to open areas, so the effect of removing vegetation will be opposite on that pest.¹ A small percentage of sampled deer have been found to carry *E. coli* O157:H7 in some areas of the country,² but in other areas the risk from deer appears to be virtually nonexistent.³*

¹ University of California, Agriculture and Natural Resources Cooperative Extension. “Monterey County Crop Notes,” May-June 2008, p. 2.

² Deer were found with 0.6, 1.8, and 2.4% of *E. coli* O157 in Southern States, Louisiana, and Kansas, respectively. The higher prevalence (2.4%) was found where deer and cattle intermingle. Fischer, J., T. Zhao, M. Doyle, M. Goldberg, C. Brown, C. Sewell, D. Kavanaugh, and C. Bauman. “Experimental and field studies of *Escherichia coli* O157:H7 in white-tailed deer.” *Applied Environmental Microbiology* 67 (3) March, 2001; Dunn, J., J. Keen, D. Moreland, and T. Alex. “Prevalence of *Escherichia coli* O157:H7 in white-tailed deer from Louisiana.” *Journal of Wildlife Diseases* 40 (2), April, 2004; Sargeant, J., D. Hafer, J. Gillespie, R. Oberst, and S. Flood. “Prevalence of *Escherichia coli* O157:H7 in white-tailed deer sharing rangeland with cattle.” *Journal of the American Veterinary Medical Association* 215 (6), September, 1999.

³ California Dept. of Fish and Game News Release, “Preliminary Research Results Find Less Than One Half of One

Recommendation: Provide more explicit recognition of the risks posed by cattle, especially in feedlot operations that concentrate large amounts of waste, and provide additional guidance to producers on mitigating impacts from these operations. Cattle are by far the most common and prevalent source of E. coli 0157:H7 in the environment. Some research suggests that cattle fed grain are more likely to shed E. coli 0157:H7 in their feces than cattle fed on pasture.⁴ Many of the studies of non-ruminant wild species carrying E. coli 0157:H7 have associated the carriers with dairy or beef cattle facilities; in many cases, researchers question whether the wild species play a significant role in the persistence and spread of E. coli 0157:H7.⁵ The draft guidance on leafy greens does not make the relatively high risk of cattle clear. In fact, the list of recommended practices to reduce microbial contamination of leafy greens in the production environment does not include any guidance on livestock, instead focusing almost entirely on wild animals. This sends a message that wild animals are far more risky, when in fact the science suggests just the opposite. Producers need clear guidance on the relative risks so that they can make informed management decisions.

3. Guidance on soil amendments

The GAPs guidance includes recommendations for best management of manure and explicitly mentions that manure use can have positive food safety impacts, since beneficial soil microbes can compete with pathogens in the soil. A number of studies published in peer-reviewed journals reiterate this finding, showing that soil with a higher diversity and biomass of microbial communities has been found to suppress and reduce the longevity of E. coli 0157:H7 and other pathogens in fields.^{6,7,8}

Manure is essential to soil-building plans for many farms, especially organic farms, which cannot use many synthetic fertilizers. Organic producers are required to improve their soil organic matter under the National Organic Program rule and must comply with specific best management practices for manure use. For a farm raising crops and livestock, *not* using the

Percent Occurrences of *E. coli* 0157:H7 in Wildlife in California Central Coast Counties," Apr. 7, 2009. See also Renter, D., J. Sargeant, S. Hygnstorm, J. Hoffman, and J. Gillespie, "Escherichia coli O157:H7 in free-ranging deer in Nebraska." *Journal of Wildlife Diseases* 37 (4) October, 2001, which found *E. coli* 0157:H7 presence in 0.3% of sampled deer.

⁴ Diez-Gonzalez, F., T. R. Callaway, M. G. Kizoulis, and J. B. Russell. 1998. "Grain feeding and the dissemination of acid-resistant *Escherichia coli* from cattle." *Science* 281:1666–166. See also: Franz, E., A.D. van Diepeningen, O.J. de Vos, and A.H. van Bruggen. 2005. "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." *Appl. Environ. Microbiol.* 71:6165-6174. See also: Gilbert, R.A., N. Tomkins, J. Padmanabha, J.M. Gough, D.O. Krause, and C.S. McSweeney. 2005. "Effect of finishing diets on *Escherichia coli* populations and prevalence of enterohaemorrhagic *E. coli* virulence genes in cattle faeces." *J. Appl. Microbiol.* 99:885-894.

⁵ University of California, Agriculture and Natural Resources Cooperative Extension. "Monterey County Crop Notes," May-June 2008, p. 2.

⁶ G.S. Johannessen, G.B. Bengtsson, B.T. Heier, S. Bredholt, Y. Wasteson, and L.M. Rørvik. "Potential Uptake of *Escherichia coli* O157:H7 from Organic Manure into Crisphead Lettuce." *Appl Environ Microbiol*, 71 (5): 2221–25, May 2005.

⁷ van Elsas, J.D., Hill, P., Chronakova, A., Grekova, M., et al. "Survival of genetically marked *Escherichia coli* O157:H7 in soil as affected by soil microbial community shifts." *ISME Journal* 1(3):204-14, July 2007.

⁸ Franz, E., van Diepeningen, A.D., de Vos, O.J., van Bruggen, A.H. "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." *Appl Environ Microbiol.* 71(10): 6165-74, October 2005

manure generated by the animals as fertilizer presents a disposal problem and potentially much greater food safety and environmental risks.

The wording on manure use in the draft guidance for leafy greens does not reflect the science or standards used by other agencies. Instead, the draft guidance discourages manure use altogether by outlining concerns associated with its use (“Soil amendments that contain animal manure *are of concern* because human pathogens may persist...”) without mentioning any of its potential benefits. This language alienates producers who have long recognized the advantages of using well-managed manure as a soil amendment. It also counteracts the science on the role of well-managed manure in reducing soil pathogen loads.

Finally, this guidance will send a perverse message to leafy greens buyers, who may take the guidance to its extreme in developing their own standards. Some leafy greens standards in California prohibit the use of manure, even composted manure, altogether,⁹ further tilting the balance between supply and demand for animal manure in the state.

Recommendation: In addition to laying out Best Management Practices for manure use, the draft guidance should emphasize that composted, well-managed manure can help improve soil quality by increasing microbial diversity and that beneficial organisms can compete with and reduce the presence of pathogenic organisms in the soil.

Recommendation: FDA should coordinate closely with the USDA’s National Organic Program as the agency moves forward with food safety programs. It is vital for the organic sector that FDA requirements, and their interpretation by regulators, certifiers, and buyers, not be in conflict with the organic standards.

4. Guidance on practices to reduce the potential for the microbial contamination of leafy greens

As mentioned in section 1, agricultural lands across the country are the site of efforts to mitigate water and air pollution, improve soil health, and conserve biodiversity. Significant resources have been invested in the research and dissemination of conservation practices designed to minimize the impacts of agriculture on water quality and wetlands. In California’s Central Coast, for example, waterways have repeatedly failed to meet water quality standards due to elevated levels of nutrients, sediment and pesticides. The USDA’s Natural Resources Conservation Service has offered technical and financial assistance to leafy-greens and other producers to adopt conservation measures critical to protecting water quality. They and other government entities have put millions of dollars into this work.

Research has found that food safety is enhanced by the types of management practices encouraged by state and federal conservation programs and used by organic, diversified, and conservation-oriented farmers. For example, a 2006 study from the USDA’s Agricultural Research Service found that vegetative buffers such as filter strips, constructed wetlands, and contour buffer strips can retard, retain, and metabolize pollutants. Buffers restrict pollution by

⁹ See, for example, Ocean Mist Farms, <http://www.oceanmist.com/foodsafety/safetyhandling.aspx>

reducing drift, increasing sedimentation, increasing uptake by plants, and increasing microbial activity. Vegetated ditches and constructed wetlands can process pollutants in runoff.¹⁰

Also in 2006, UC Davis researchers tested the effectiveness of vegetative buffers at filtering *E. coli* 0157:H7 in runoff from cattle operations in California. They found that even narrow buffers could filter between 95 percent and 99.99 percent of total *E. coli*. These results support the assertion that buffers are an effective method for reducing livestock inputs of waterborne *E. coli* into surface waters.¹¹ Other studies have shown that large and small-scale constructed wetlands can reduce levels of fecal coliforms, *Giardia* and other pathogens in water by up to 97 percent¹² and can reduce *Salmonella* levels by 93 to 96 percent.¹³

Maintaining and improving the natural resources of farming operations and encouraging practices that filter pollutants and improve water quality is therefore critically important to food safety. Yet many farmers face unrelenting pressure from produce buyers and auditors to eliminate conservation measures because food safety guidance either directly or indirectly encourages the removal of vegetation that could serve as wildlife habitat.

The draft guidance on leafy greens recommends that producers implement “practices that reduce, control or eliminate likely contamination of leafy greens fields that may be in close proximity to on-farm stacking of manure” and that they “[exercise] 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.” The draft guidance gives no concrete suggestions for how to do this.

Clear guidance encouraging practices that benefit food safety and are common to organic, diversified, and conservation-oriented farms will facilitate widespread adoption of food safety measures. It will also ensure consistency among federal farm programs, result in more efficient use of taxpayer dollars, and reduce confusion for producers and consumers. Finally, it will help reduce the incidence of “super metrics” promoted by produce buyers and auditing firms that interpret FDA guidance in extreme ways. We run the risk of overriding twenty years of successful on-farm conservation and resource management efforts if federal guidance does not move in this direction—and we may also jeopardize food safety in the process.

Recommendation: The draft guidance on leafy greens should explicitly encourage and provide examples of conservation practices known to benefit food safety. These could include windbreaks and vegetative buffers around waterways, between manure storage areas and crop fields, and between livestock and crop fields to manage dust and filter runoff.

¹⁰ Dabney, S.M., Moore, M.T., and M.A. Locke. “Integrated management of in-field, edge-of-field, and after-field buffers.” *Journal of the American Water Resources Association*. 42(1): 15-24, 2006.

¹¹ Tate, K.W., Atwill, E.R., Bartolome, J.W., and G. Nader. “Significant *Escherichia coli* Attenuation by Vegetative Buffers on Annual Grasslands.” *J Environ Qual* 35:795-805 (2006)

¹² Nokes, R.L., Gerba, C.P., and M.M. Karpiscak. “Microbial water quality improvement by small scale on-site subsurface wetland treatment.” *J Environ Sci Health A Tox Hazard Subst Environ Eng*. 2003 Sep;38(9):1849-55.

¹³ Hench, K., Bissonnette, G., Sextone, A., Coleman, J., Garbutt, K. and J. Skousen, “Fate of physical, chemical, and microbial contaminants in domestic wastewater following treatment by small constructed wetlands.” *Water Research* 37:921-927, 2003.

Recommendation: The draft guidance on leafy greens should explicitly discourage practices known to be counterproductive to food safety and resource conservation, such as blanket habitat destruction or the maintenance of bare-ground buffers around production fields.

Recommendation: Ensure that the draft guidance on leafy greens is consistent with conservation and environmental practice standards established by other federal agencies and with certified organic production methods and requirements. FDA should coordinate with relevant agencies to ensure that standards and programs are not in conflict.

5. Guidance on recordkeeping

Prescriptive recordkeeping requirements can create a burden for small-scale producers, those with limited or no access to computers or the internet, and diversified farms that produce multiple types of crops for different buyers. FDA guidance on recordkeeping, written food safety plans, Standard Operating Procedures, HACCP plans, or other documentation must not be biased towards the largest, most automated operations. This is an area in which flexibility is of the utmost importance.

A key point in developing any recordkeeping system should be a consideration of what records producers are already keeping to comply with country of origin labeling, the Perishable Agricultural Commodities Act, the Bioterrorism Act of 2002, the National Organic Program, and other programs.

Recommendation: The draft guidance for leafy greens should explicitly acknowledge that records may be kept electronically or on paper. FDA should pay special attention to recordkeeping requirements that are already in place and recommend ways to make recordkeeping compatible with these existing systems, including organic certification.

Conclusion

As the FDA develops its on-farm food safety guidance, we urge the agency not to proceed in a vacuum. Work on the issue of food safety is underway in several other venues, including Congress and the USDA, and we urge FDA to consider these policy arenas, as well as industry-driven food safety programs as you proceed. It is burdensome for farms to have to track the results of multiple policy processes as well as private programs required by their buyers.

Additionally, we urge the agency to develop any guidance or regulation in a way that does not put organic, diversified, conservation-oriented, or small-scale farms at a disadvantage. To do so, regulations or guidance must have some flexibility, not discourage or penalize efforts to protect wildlife habitat and conservation practices, not conflict with organic production practices, and not promote a sterilization model of farming.

Finally, we urge the agency to re-evaluate its research agenda and prioritize research that will shed more light on the risk of wildlife as a vector for transmission of pathogens to the food supply, the impact different processing techniques have on contamination rates, and the use of alternative methods such as vegetative buffers for pathogen control.

Food & Water Watch appreciates the opportunity to comment on the FDA's draft guidance on leafy greens. Please contact Patty Lovera at (202) 683-2500 if you have questions or need more information.

Sincerely,

A handwritten signature in black ink, appearing to read "W. Hauter", with a long horizontal flourish extending to the right.

Wenonah Hauter
Executive Director