

January 4, 2010



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

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

Dear Food and Drug Administration:

Thank you for the opportunity for Wild Farm Alliance (WFA) to submit comments on the draft food safety guidelines:

- 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)

Targeting All Wildlife is Counterproductive

The guidances should not assume that all wildlife presence is a food safety problem. Unless this approach is modified, the FDA will likely cause unintended consequences to occur making tomatoes, melons, and leafy greens less safe. UC Davis researchers have shown that grasses and wetlands can filter up to 99% of *E. coli* pathogens. By encouraging farmers to keep wildlife off the farm, the guidances imply the removal of vegetative cover that attract wildlife. Instead of farms having functioning natural systems that filter pollutants, they could be spreading pathogens throughout foodsheds, making more people sick.

Association of Food and Drug Officials (AFDO) Guidance and Elaboration

It is much more helpful to comprehensively discuss appropriate actions that could be taken when animals are present, as is done with draft guidance put out by AFDO: "The responsible party shall assess the impact of domestic and wild animal activity on potential for pathogen contamination of produce, considering the crop characteristics, type and number of animals, pathogens of concern, nearness to the growing field, proximity to harvest, and other relevant factors." We have added one more factor to this list: conservation practices used to reduce indirect spread of pathogens. These points are further elaborated below by WFA, with our suggested changes to FDA guidances underlined:

Crop Characteristics

- If water is used to rinse or wash a harvested freshly eaten crop, such as salad mix, fresh tomatoes, or melons, it has the potential to encourage the growth and spread of pathogens, so animal presence should be assessed more closely. Additionally, bagged leafy greens can become micro-incubators and must be treated with the utmost care.

All three guidances should only apply to crops that will be rinsed or washed, not to hand-harvested and field packed lettuce, greens, melons, and tomatoes.

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- If a crop is destined to be cooked, such as bunched kale or tomatoes, then that process kills bacteria, and a less stringent set of food safety practices should apply.

The leafy green and tomato guidances should only apply to crops that will not be cooked.

Type of Animals

- Cattle are the primary reservoir of *E. coli* O157H:7 and therefore pose a significant food safety risk. Herds in feedlots and large confined dairy operations have higher percentages of this pathogen than those out on pasture, although pastured cattle are found with it too.
- Feral pigs have been found to be a significant food safety risk. Since they are non-native to North America, they did not evolve with native predators and do not use habitat to hide; rather they are attracted to sources of food and water.
- Commensal animals (including but not limited to non-field rodents and some birds) associated with human activities and contaminated areas, can be vectors of pathogens. Potential sources of contamination include use of untreated or improperly treated manure; nearby composting or manure storage areas, livestock, or poultry operations; nearby municipal wastewater or biosolids storage, treatment, or disposal areas, urban areas, and garbage dumps.
- Besides, cattle and feral pigs, the California Leafy Green Marketing Agreement includes domestic pigs, sheep, goats and deer within their term "animals of significant risk." The science does not support deer being a significant risk. In April 2009, California Department of Fish and Game and collaborators released a preliminary report stating that only 0.5% of almost 900 individual wildlife carry *E. coli* O157: H7, and that none of the 331 deer tested positive (one feral pig, two elk and one coyote did)ⁱⁱⁱ. Other studies show deer were found with 0.3, 0.6, 1.8, and 2.4% of *E. coli* O157 in Nebraska^{iv}, Southern States^v, Louisiana^{vi}, and Kansas^{vii}, respectively. In general, some types of wildlife are known to carry low levels of *E. coli* O157H:7 and *Salmonella*, but none are known to be a high risk.^{viii}

All three guidances should replace the terms "domestic animals" and "wildlife" with "animals of significant risk," using the definition of cattle, sheep, goats, and domestic and feral pigs (not including deer).

Number of Animals

- High concentrations of wildlife in the growing and harvesting environment increase risk. When there is a large number of anything with a small risk, the risk increases.

The guidances for melons and leafy greens do acknowledge this by stating: "Considering whether or not to harvest any portions of a field affected by unusually heavy wildlife activity...", but the tomato guidance should do the same.

Pathogens of Concern

- The guidance for melons has a misleading sentence and reference about the amphibian chytrid fungus (which causes Chytridiomycosis). This pathogen is not linked to any human health ailments, should be replaced as follows:

Change Melon Guidance From-

Many wildlife species (e. g., birds, insects, amphibians, and snakes) that may be present in the production environment are known to be potential carriers of human pathogens [Ref. 4 Rachowicz, J., et al., The Novel and Endemic Pathogen Hypotheses: Competing Explanations for the Origin of Emerging Infectious Diseases of Wildlife. Conservation Biology, 2005. 19(5): p. 1441-1448.]

Change Melon Guidance To-

While wildlife species that may be present in the production environment have been shown in limited studies to be potential carriers of human pathogens, none are a significant risk. Add these references: [Stuart, Shennan, and Brown. 2006. Food Safety versus Environmental Protection on the Central Coast: Exploring the Science Behind an Apparent Conflict. Center for Agroecology and Sustainable Food Systems. University of CA, Santa Cruz. Research Brief #10; and Stuart, Diana, (2009) Constrained Choice and Ethical Dilemmas in Land Management: Environmental Quality and Food Safety in California Agriculture, Journal of Agriculture Environmental Ethics, 22:53-71.]

Nearness to the Growing Field

- If animals that pose a significant risk are near or in the field, the risk of crop contamination increases.

All three guidances should recommend that "animals of significant risk," (not including deer) be kept out of growing fields.

- If wildlife pass through a polluted area, such as a cattle feedlot, contamination potential is increased.

All three guidances should encourage increased protection where polluted areas are adjacent to the farm.

Conservation Practices Used to Reduce Indirect Spread of Pathogens

- Conservation measures provided for in the Farm Bill, such as vegetative buffer strips, grasses, and wetlands filter out contamination in overland water flows from livestock feedlots, loafing yards, pastures, and manure storage areas.
- Hedgerows and windbreaks reduce the incidence of airborne pathogens contaminating the crop.

All three guidances should encourage farmers to install conservation practices that decrease the spread of pathogens.

Specifically in the tomato guidance, the wording concerning run-off from animal operations should be modified to reflect the usage of vegetative filter strips and buffers.

In both the tomato and leaf greens guidances, the word "buffer" should be replaced with the term "vegetative buffer."

Proximity to Harvest

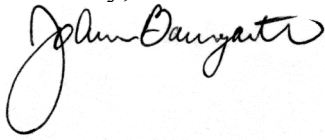
- Any part of the crop contaminated with fecal material near the time of harvest should be left in the field.

All three guidances should direct farmers not to harvest crops within 5' of feces, and to further survey the field to determine if any more fecal material is present.

Farmers will be Put in an Untenable Position

It will be impossible for farmers to comply with the current proposed guidances while also addressing other mandated practices, if the above suggested changes are not incorporated. California requires that water quality protections be used on farms, the USDA National Organic Program requires that soil, water, wildlife and wetlands be conserved, and the Endangered Species Act mandates that sensitive species present on a farm be protected. In addition, farmers benefit from natural enemy insects and pollinators that require wildlife habitat. Their pest populations decrease and yields increase when these insects are present. By making these guidelines conservation friendly, we will have a safer and more secure food system. It is imperative that these guidelines deliver a consistent message to farmers and not force the farmer to choose between irreconcilable directives from different agencies.

Sincerely,



Jo Ann Baumgartner
Director

ⁱ Tate, K. W., E. R. Atwill, J. W. Bartolome, and G. Nader. Significant *Escherichia coli* Attenuation by Vegetative Buffers on Annual Grasslands. *Journal of Environmental Quality*, 35: 795-805. 2006.

ⁱⁱ Tate, K. W., A. K. Knox, E. R. Atwill, and R. A. Dahlgreen. Management reduces *E. coli* in irrigated pasture runoff. *California Agriculture*. Vol. 61, No. 4. 2007.

ⁱⁱⁱ California Department of Fish and Game. Preliminary research results find less than one half of one percent occurrences of *E.coli* O157:H7 in wildlife in California Central Coast Counties. News Release. April 7, 2009.

^{iv} Renter, D.G., J.M. Sargeant, S.E. Hygnstorm, J.D. Hoffman, J.R. Gillespie. 2001. *Escherichia coli* O157:H7 in free-ranging deer in Nebraska. *Journal of Wildlife Diseases*, 37(4):755-760.

^v Fischer, J.R., T. Zhao, M.P. Doyle, M.R. Goldberg, C.A. Brown, C.T. Sewell, D. M. Kavenough, C.D. Bauman. 2001. Experimental and field studies of *Escherichia coli* O157:H7 in white-tailed deer. *Applied and Environmental Microbiology*, 67(3):1218- 1224.

^{vi} Dunn, J. R., J. E. Keen, D. Moreland, R. A. Thompson. 2004. Prevalence of *Escherichia coli* O157:H7 in white-tailed deer from Louisiana. *Journal of Wildlife Diseases*, 40(2):361-365.

^{vii} Sargeant, J.M., D.J. Hafer, J.R. Gillespie, R.D. Oberst, S.J. Flood. 1999. Prevalence of *Escherichia coli* O157:H7 in white-tailed deer sharing rangeland with cattle. *Journal of the American Veterinary Medical Association*, 215(6): 792-794.

^{viii} Beretti, M, and D. Stuart. Food safety and environmental quality impose conflicting demands on Central Coast growers. *California Agriculture*, Volume 62, Number 2. April–June 2008