August 22, 2012

Dr. Margaret A. Hamburg
Commissioner
United States Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

The opinions expressed herein are our own and do not necessarily reflect the views of The Johns Hopkins University.

RE: The Produce Safety Rulemaking for the Food Safety Modernization Act

Dear Dr. Hamburg:

We are writing to request that specific public health issues be addressed in the upcoming rulemaking to implement the mandatory produce safety provisions of the recently enacted FDA Food Safety Modernization Act (FSMA). We believe this regulation should adopt many of the agency's current recommendations for produce safety as requirements and include additional steps to assure that fruits and vegetables are safe for American consumers. In particular, we urge the FDA to use its new authority to require specific controls for produce grown near food animal production facilities and that use animal waste from these facilities as fertilizer. We recognize the regulatory authority exercised by the Environmental Protection Agency (EPA) over food animal production facilities and have included EPA in this letter to request that both agencies work together to achieve these goals. The attached memorandum provides more detailed explanation for this request and supporting scientific evidence.

As you are aware, the FSMA requires FDA to implement regulations for stricter food safety standards, including preventive controls over food facilities and mandatory produce safety standards. We appreciate the agency seeking public comments and holding public meetings to help implement numerous FSMA provisions, including the guidance for processed food hazards and preventive controls.[1] We are concerned, though, that FDA has not sought public input for the mandatory produce safety rulemaking, nor has it announced a timeframe for publishing the proposed rule. We understand that a draft proposed rule is under review by the Office of Management and Budget. We are requesting that FDA hold public meetings and open a public docket for submissions before publishing the proposed rule. We are submitting this correspondence to request that the proposed rule address specific issues, and we ask that our letter, with the attachment, be filed in a public docket for the rulemaking.

We realize the regulation and related guidance will be a significant effort. We also understand the resource constraints faced by the agency and the numerous tasks required for FSMA implementation. We would welcome the opportunity to assist the agency with these efforts, including meeting with agency officials and providing our scientific expertise on any of these issues.

[1] 76 Federal Register 99 (May 23, 2011), pp. 29767-29769.

Thanks for your consideration of this request.

Sincerely,

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I. Background

The Food Safety Modernization Act (FSMA) requires FDA to implement regulations for stricter food safety standards, including preventive controls over food facilities and mandatory produce safety standards. The FSMA produce safety provisions require the regulations to include "science-based minimum standards" to require specific farm practices for soil, hygiene, animals in growing areas, and water use, among other things (Section 105(a)(3)(B) of FSMA). These standards must apply to the produce life cycle on the farm - growing, harvesting, sorting, packing, and storing (Section 105(a)(3)(D) of FSMA). The statute requires that the farm practices be "reasonably necessary" to prevent introduction of biological, chemical, and physical hazards, including natural hazards, into fruits and vegetables that are raw agricultural commodities. (Section 105(c)(1) of FSMA). The statute mandates that FDA consider conservation and environmental practices, consistent with ensuring enforceable public health protection, in drafting the regulation (Section 105(a)(3)(D)). The FSMA requires these minimum science-based standards in the final regulation to be based on known safety risks, which may include a history of foodborne illness outbreaks (Section 105(a)(b)(1)).

II. Regulation Must Address Food Safety Threats From Animal Waste

It is imperative that FDA use this new statutory authority to address produce safety risks related to current agricultural practices. This memorandum focuses on significant produce safety threats posed by prominent agricultural practices for the management and use of animal waste.

A. Animal Waste Practices and Contaminants

The waste from animal production facilities, which includes feces, urine, spilled feed, bedding materials, and other contents[1], poses a significant threat to produce safety. Farm animal production has shifted dramatically over the past 50 years to a much more centralized, industrialized approach with large numbers of animals raised in much fewer facilities.[2] This concentration of food-producing animals has created significant challenges in animal waste disposal and management. Based on the most recent US Department of Agriculture estimate, animals from these operations produced 335 million tons of waste (dry weight) in 2005.[3] By contrast, only 7.6 million tons of human waste was generated by publicly owned treatment works in the United States that year.[4] The sheer volume of animal waste poses challenges for disposal and management. Each facility typically stores the large volume of animal waste on its site in dry ("pit") or wet ("lagoon") forms or transports the waste to local farms for fertilizer.[5]

This animal waste contains many contaminants that pose specific threats to human health. Scientific testing and analyses have identified greater than 150 microbial pathogens that can be transmitted to humans from animal waste.[6] For example, swine wastes contain greater than 100 such pathogens.[7] The waste from production animals contains parasites, viruses, and bacteria in amounts as great as one billion per gram.[8] Recent studies have confirmed this high frequency of bacteria in animal waste, including *E.coli* O157, *Salmonella* spp., and *Campylobacter* spp.[9] These pathogens can survive for long periods of time in animal waste. For example, researchers found that large numbers of anti-microbial resistant enterococci and staphylococci in poultry litter survived for at least four months when composted, a process intended to reduce or eliminate harmful microorganisms in waste.[10] In addition, animal manure from these facilities also contains heavy metals, such as arsenic,[11] zinc and copper,[12] and animal drug residues, such as antibiotics,[13] that pose human health concerns.[14]

B. Pathways for Animal Waste to Contaminate Produce on Farms

The contaminants in animal waste can move through various pathways from animal production facilities to produce grown in fields. The main pathways are described below.

1. Run-off and Leaching of Animal Waste Contaminants into Groundwater and Surface Waters

Many recent studies have confirmed that manure from animal production facilities can contaminate adjacent ground and surface waters with nutrient and toxin runoff, as well as various pathogens.[15] Microbial pathogens can move from animal waste pit or lagoon storage areas into the soil through natural seepage.[16] Once in the soil, these pathogens can transfer to surface water and groundwater sources. Studies have found that bacteria in animal manure applied to land can permeate soil deeply enough to penetrate groundwaters.[17] The contaminants can also leach through soils to aquifers.[18] In addition, contaminants can flow directly into surface waters from flooding of waste lagoons.[19]

One study found that surface waters and groundwaters located down gradient of a swine production facility were contaminated with significantly greater amounts of *Enterococcus* spp., *E.coli*, and fecal coliforms compared with surface water and groundwater located up gradient from the facility.[20] The study also found greater percentages of antibiotic-resistant bacteria in down-gradient surface and groundwaters, which, given the common use of groundwater as a drinking water source for rural communities, suggests an increased potential for human infection.[21] Another study found multiple classes of antibiotic compounds in swine waste storage lagoons, as well as surface and groundwater adjacent to swine and poultry facilities.[22] In addition, an extensive U.S. Geologic Survey found organic wastewater contaminants in 80% of 139 streams across 30 states in 1999 and 2000.[23] Many of the sampling sites were downstream from animal production facilities.

Once in groundwater, surface water, or aquifers, these contaminants can then be transferred to produce growing in the fields through multiple pathways. First, the contaminants can be applied to produce surfaces through irrigation sprays from water sources.[24] Produce surface contamination, such as from irrigation, presents a difficult food safety challenge because later washing has limited effects in sufficiently eliminating the contaminants.[25] Second, the contaminants can be incorporated from groundwater into the produce roots.[26] Once inside, the contaminants can expand with plant growth. For example, studies have found that *S. enterica* and *E.coli* in alfalfa and other sprouts will expand in the plant with sprouting.[27] The internalization of pathogens in a plant, such as from root uptake, poses even more risk because surface washing will not reach the contamination.[28]

2. <u>Transmission of Animal Waste Contamination through Air Pathways</u>

Animal waste stored on animal production facilities can also emit contaminants through air pathways to produce grown on local farms. For example, one study detected multi-drug resistant bacteria in the air inside of a swine feeding operation.[29] Another study found multi-drug resistant bacteria both inside and downwind of a swine feeding operation.[30] Animal waste contamination can also be transported to other locations by insects. One study found that flies carried antibiotic-resistant enterococci and staphylococci from animal waste at broiler poultry operations into surrounding communities.[31] Insects can further transmit contaminants between growing produce on the farm. For example, a study found that fruit flies transmitted *Escherichia coli* O157:H7 between apples grown in an orchard.[32]

3. Direct Application of Animal Waste as Fertilizer

The waste from animal production facilities is frequently sold to neighboring farms for use as fertilizer.[33] When this animal waste is applied directly to produce fields as fertilizer, the contaminants in the animal waste can then be transferred to the soil.[34] Studies have found that pathogens[35] and antibiotic residues[36] in soil can persist for months or in some cases even longer. The soil contaminants can then be transferred to the interior or surface of produce that is planted and grown in these fields.[37] The contaminants can also flow into surface water, groundwater, and aquifers and be incorporated in produce through external (irrigation) and internal (roots) routes.[38] Unlike human biosolids, there are no federal treatment control requirements or pathogen limits for animal waste used as fertilizer.[39] Without such requirements, animal waste used as produce fertilizer frequently remains untreated, which allows for produce contamination. Also, many farms store the purchased animal manure for several months before applying to produce fields.[40] This storage can threaten produce safety from water and air contamination similar to those threats posed by animal manure stored on adjacent animal production facilities.[41]

4. Spread of Animal Waste through Other Vectors

Waste from animal production facilities can be accidentally spread further throughout the produce farm by trucks, farm workers, and animals.[42] This transfer is not limited to physical contact between these factors and produce. One study determined that antibiotic-resistant bacteria were transmitted through the air to adjacent areas from trucks transporting chickens from production facilities.[43] Other studies have shown the importance of feral animals as a source of fecal contamination and vectors for spreading animal manure.[44] By all of these pathways, animal waste from animal production facilities poses a serious threat to produce safety on adjacent farms.

C. Foodborne Outbreaks from Produce Related to Animal Waste Contamination

Numerous foodborne epidemics from produce in recent years demonstrate these public health risks. Many of these outbreaks likely resulted from fecal contamination through the above-described pathways, including some from food animal waste.[45] The *E.coli* O157:H7 outbreak in 2006 from bagged spinach was a notable example, which resulted in 205 illnesses, including 103 hospitalizations and 3 deaths. FDA's investigation found various environmental risk factors in the California spinach fields, including the proximity of irrigation wells to surface water exposed to feces from cattle and wildlife.[46] Another example involved the *Listeria monocytogenes* foodborne illness outbreak across multiple states in 2011, with at least 30 reported deaths, resulting from contaminated cantaloupe grown in Colorado. FDA's investigation found environmental risk factors, including the possibility of contamination in the field or from a cattle operation truck.[47] Another example included the multistate outbreak of *Salmonella* infections in 2005-2006 from eating raw tomatoes at restaurants, with 459 confirmed cases. FDA's investigation found environmental risk factors in a Florida grower's fields, including multiple potential animal reservoirs of *Salmonella* present in or near the drainage ditches and in animal feces.[48] The diversity in produce and infection types, as well as the environmental risk factors, provides strong evidence of the risks to produce safety from animal waste.

D. Regulation Must Adopt FDA and USDA Guidance Provisions as Requirements, With Additional Modifications and Conditions

Based on this scientific evidence, the regulation must ensure that water and soil quality controls implemented by farms protect produce from these risks posed by animal waste through various pathways, including from animal production facilities. There is currently joint FDA and USDA guidance describing good agricultural practices for fruit and vegetable safety that is an excellent foundation for immediate action. The Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables (FDA and USDA, 1998) explains steps that growers should consider to assess and minimize risks to produce.[49] In particular, the guidance recommends that growers follow good agriculture practices in ensuring the quality of agricultural water and handling of animal manure to minimize microbial hazards.

Based on our expertise and assessment of scientific research for good agricultural practices, we support most of the guidance's recommended steps for water quality and animal manure handling to manage produce contamination risks. We believe, however, that additional steps must be taken to ensure the risks from animal waste pathways described in this memorandum are adequately addressed. It is important to note that these scientific findings concerning the risks from various animal waste pathways were made after the guidance's publication. Thus, using the guidance as a foundation, we recommend the following steps be incorporated in the regulation:

1. Water Quality Protection from Animal Waste Risks

For ensuring water quality from animal waste risks, we believe the regulation should adopt the following Guide recommendations by requiring produce farms to:

- Evaluate the potential threats to their agricultural water quality, including threats emanating from animal production facilities in the region;
- Protect water sources from uncontrolled livestock on their farm or wildlife access to limit the extent of fecal contamination;
- Assess and control the risks to agricultural water quality from sources outside their farms, such as from animal production facilities where manure runoff can contaminate surface and groundwaters;
- Adopt soil and water conservation practices to help prevent polluted runoff water from contaminating agricultural water sources and produce crops;
- Minimize contact between water and edible portions of crops where water quality is unknown or cannot be controlled; and
- Conduct microbial testing for pathogens in agricultural water.

CLF also believes the regulation must require the following additional steps beyond the Guide to ensure adequate produce safety:

- Expand the above steps to include additional contaminants from animal waste, such as heavy metals and antibiotic residues in water. For example, the required water testing would go beyond examination of microbiological hazards to include these other contaminants.
- Establish mandatory concentration limits for animal waste contaminants in agricultural water.

Through all of these required measures the regulation can better ensure that the water quality for produce is sufficiently safe.

2. Soil and Fertilizer Quality Protection from Animal Waste Risks

For protecting soil and fertilizer quality from animal waste risks, we believe the regulation should adopt the following Guide recommendations by requiring produce farms to:

- Manage fecal contamination risks from animal waste stored on their land through adequate barrier and physical containment controls to minimize the risk of runoff, leaching, and wind spread;
- Implement practices to minimize the potential of recontaminating treated animal waste, such as from farm equipment use;
- Adopt adequate treatment practices for animal waste applied directly to cropland to reduce pathogen levels;
- Obtain specification sheets from animal waste suppliers with information about treatment methods for each animal waste shipment.

CLF also believes the regulation must require the following additional steps beyond the Guide to ensure adequate produce safety:

- Expand the above steps to include additional contaminants from animal waste, such as heavy metals and antibiotic residues. In particular, the required treatment practices must be appropriate to control these other contaminants.
- Establish mandatory testing and concentration limits, for these contaminants in animal waste.

Through all of these required measures the regulation can better ensure that soil and fertilizer quality for produce is sufficiently safe.

The Guide recommends various alternative steps for animal manure applied directly to cropland as fertilizer, but we have concerns with these recommendations. First, for animal waste practices, the Guide recommends that growers consider adopting some of the practices required for municipal biosolids under EPA regulations, 40 CFR Part 503. This regulation includes biosolids testing for pathogens and chemicals, maximum contaminant limits, and management steps. We agree that these principles are critical for animal waste safety. Based on a National Academy of Sciences review of these regulations and scientific recommendations, though, we believe the specific practices in the regulation must be updated for animal waste treatment practices.[50]

It is imperative that these practices for animal waste be updated in the produce regulation and be rigorously derived evidence-based standards. We believe current risk assessment standards must be used to update these treatment standards for pathogens and chemicals in animal waste, particularly for the complex pathways described in this memorandum, including for chemical-pathogen mixes.[51] We believe that the NAS report recommendations to consider additional risk-management practices for biosolids land application are relevant also for animal waste management on produce farms, such as limitations on holding or storage practices, slope restrictions, greater distance to surface water, and soil permeability and depth to groundwater or bedrock.[52] The inclusion of such improved practices in the regulation will help ensure the safety of animal waste.

Second, the Guide states that untreated manure can be used for fertilizer if there is sufficient time between the application of manure to produce production areas and harvest. We disagree with this position because the scientific evidence described earlier shows that pathogens can survive for several months in manure,[53] as well as other contaminants in animal waste.[54] Instead, we believe that animal waste must be treated adequately in order to be used as produce fertilizer.

Third, the Guide states that passive and active treatments of animal manure can be acceptable practices to control pathogens in waste. Under the Guide, passive treatments simply involve passage of time and natural environmental factors, such as natural temperature, to reduce pathogens. The Guide also recommends composting as an active treatment alternative. For the same reasons underlying our opposition to untreated manure practices, we do not support these passive treatments or the composting approach on produce farms because of the scientific evidence that pathogens can survive for long periods of time in manure under common management practices, including composting.[55] Under the Guide, other active treatments can include pasteurization, heat drying, anaerobic digestion, alkali stabilization, aerobic digestion, or a combination of these. It is our belief that a rigorous evaluation of the literature would enable the agency to make science-based decisions regarding the effectiveness of these and other alternative treatments. We also urge the inclusion of other practices to manage additional, non-microbiological animal waste contaminants, such as heavy metals and antibiotic residues.

For all of these reasons, we have concluded that FDA must use its FSMA authority to incorporate these principles and recommended steps as requirements in the produce regulation. These requirements are even more critical because of the numerous pathogen outbreaks from produce sources that have occurred since the guidance's publication in 1998. The guidance's voluntary steps were inadequate to prevent these numerous outbreaks, and FSMA was enacted in response to these threats. In addition, as shown by this memorandum, the scientific understanding of animal waste contamination has evolved rapidly since the Guide was issued in 1998, which further supports our requested modifications. Thus, it is critical that FDA now adopt these requirements in the upcoming regulation.

III. Guidance to Assist Farmers in Implementing these Required Practices

Because produce farmers will bear the responsibility for many of these requirements, it will be important to assist farmers with implementation of these steps, particularly through guidance. The FSMA mandates outreach to farmers for this purpose (Section 103(e) of FSMA). To assist farmers in complying with the new regulatory requirements, the current produce guidance should be updated to recommend various approaches that farmers may take to control animal waste risks under the new regulatory requirements. There are many viable alternatives to current animal waste practices that can be adopted on farms today that will minimize produce contamination risks. These recommendations will be critical to provide farmers with alternative, feasible ways to comply with the new regulatory requirements and improve the safety of the nation's food supply.

IV. Conclusion

It is important that FDA incorporate in its upcoming regulation the principles and steps in the current produce guidance for addressing food safety risks, with the above-described modifications. Given the significant pathogen outbreaks from produce in recent years, it is clear that voluntary adoption of the guidance recommendations is not adequate to protect public health. In addition, the current guidance omits important risks from a broad spectrum of inputs and contaminants. It is important to note that later steps in the guidance, such as improving packaging and storage practices, are important but will not eliminate the introduction of pathogens from animal waste. Thus, more sustainable agricultural practices are needed, including good management practices for animal waste. In order to more fully protect American consumers, as intended by the passage of the FSMA, we urge FDA to take these additional steps in issuing the regulation and revised joint guidance.

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