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Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20582

Docket Nos. FDA-2011-N-0920 (RIN 0910-AG36) and FDA-2011-N-0921 (RIN 0910-AG35)

Submitted electronically via http://www.regulations.gov

Re: Comments on the Proposed Rule for Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption and the Proposed Rule for Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food

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

To Whom It May Concern:

The Johns Hopkins Center for a Livable Future (CLF) appreciates the opportunity to provide comments on the Food and Drug Administration's (FDA) proposed rule for Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption (the Produce Rule) and the proposed rule for Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food (the Preventive Controls Rule).

The Johns Hopkins Center for a Livable Future is an academic and research center at the Bloomberg School of Public Health. The Center's mission is to promote research and to develop and communicate information about the complex interrelationships among diet, food production, environment and human health, to advance an ecological perspective in reducing threats to the health of the public and to promote policies that protect health, the global environment and the ability to sustain life for future generations.[1]

The Center has scientific, policy, and regulatory expertise in the areas of food systems and food safety, including food animal production and farming issues, as well as local and regional food systems and sustainable agriculture. Most recently, the Center issued the report, "Industrial Food Animal Production in America: Examining the Impact of the Pew Commission's Priority Recommendations" that examined many of these issues.

[1] More information about the Center can be found at http://www.jhsph.edu/clf

There are two Center priorities with particular importance for this rulemaking – minimizing the negative public health impact of animal production facility practices and supporting local and regional food systems and sustainable food production for their public health benefits. Unfortunately, FDA's proposed rules will hinder these critical goals, which will weaken produce safety. We are recommending in this comment that FDA take action to address these concerns.

First, FDA must issue a separate proposed rule that will explicitly cover the risks to produce safety from animal production facilities, particularly from animal manure contaminants migrating in environmental pathways and in manure sold or given to other farms for growing produce. This rulemaking is authorized by the Food Safety and Modernization Act (FSMA) and will be a more effective and equitable approach to control produce safety risks caused by animal production facilities.

Second, FDA must amend the Produce Rule and the Preventive Controls Rule to provide more flexibility for farms and businesses that are part of the local and regional food system and/or producing sustainably and that do not fit the current exemptions. Without this flexibility, many of these important farms will struggle to comply with the regulatory requirements. In this way, the current rules might unintentionally hinder farming and food production practices that are critical for public health. We support the similar comments of the American Public Health Association (APHA), the National Sustainable Agriculture Coalition (NSAC) and other organizations advocating for more flexibility.

Finally, FDA must amend the Produce Rule to be consistent with current federal organic standards and impose additional conditions for allowing human waste in growing produce.

We appreciate you considering our comment and would be happy to answer any questions that you might have or assist further in these efforts.

Sincerely,

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I. Introduction

A. Food Safety Modernization Act

The Food Safety Modernization Act (FSMA), which amended the Federal Food, Drug, and Cosmetic Act (FDCA), 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 419(a)(3)(B) of FDCA). These standards must apply to the produce life cycle on the farm - growing, harvesting, sorting, packing, and storing (Section 419(a)(3)(D) of FDCA). 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 419(c)(1) of FDCA). The statute mandates that FDA consider conservation and environmental practices, consistent with ensuring enforceable public health protection, in drafting the regulation (Section 419(a)(3)(D) of FDCA). The statute 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 419(b)(1) of FDCA).

B. FDA Proposed Rule for Produce Safety

FDA issued its proposed produce safety rule in the Federal Register on January 16, 2013.[1] The proposed rule would establish standards for produce farms in the growing, harvesting, packing, and holding of fruits and vegetables. The FDA also conducted a Draft Qualitative Risk Assessment upon which the standards are based.[2] The rule focuses only

on the risks caused by microbiological hazards related to produce farm practices, and excludes any risks from chemical, physical, or radiological contamination.

To address these microbiological hazard risks, the rule would establish requirements on produce farms for the following aspects of production: agricultural water; biological soil amendments; worker training and health and hygiene; domesticated and wild animals; and equipment, tools, and buildings (PR Preamble, page 3505). For agricultural water, the proposed rule would require steps for produce farms to inspect, maintain, and follow-up the water, its sources, and distribution systems (PR Preamble, page 3564-3566). The proposed rule would also establish requirements for the agricultural water quality, including specifications and testing, as well as recordkeeping (PR Preamble, page 3566-3573). For biological soil amendments, the proposed rule would require specific steps for treatment, as well as application requirements and minimum application intervals for untreated and treated biological soil amendments of animal origin (PR Preamble, page 3573-3585). The proposed rule would only allow the use of human waste for growing produce in accordance with EPA regulations (PR Preamble, page 3578).

The proposed rule would establish a phase-in period for compliance depending on the produce farm's revenue from food sales (PR Preamble, page 3533). The proposed rule would extend the compliance dates for "small businesses" (between $250,000 and $500,000 in yearly food sales) by an additional year and "very small businesses" (between $25,000 and $250,000 in yearly food sales) by an additional two years.

The proposed rule would also provide exemptions from the regulatory requirements (PR Preamble, page 3505). For example, the rule would exempt produce farms from these requirements with an average annual value of food sold during the

previous three-year period of $25,000 or less. The rule would also provide a qualified exemption to produce farms if the farms have (1) food sales averaging less than $500,000 per year during the last three years and (2) the sales to qualified end-users exceed sales to others. Qualified end-users would be consumers of the food or restaurants or retail food establishments located within the same state as the produce farm or within 275 miles. This qualified exemption would apply to many community-supported agriculture (CSA) farms, you-pick operations, and farmers markets (PR Preamble, page 3550). Under the proposed regulation, these exempt farms would still be required to display identifying information (such as name and address) on the produce labeling or at the point of sale (PR Preamble, page 3550). In addition, FDA could withdraw the qualified exemption for a produce farm if necessary to "protect the public health and prevent or mitigate a foodborne illness outbreak" (PR Preamble, page 3611).

C. Summary of the Center for a Livable Future Position for the Comment

FDA's proposed rule, as written, will hinder the critical goals of minimizing the negative public health impact of animal production facility practices and supporting local and sustainable food systems for their public health benefits. FDA must take steps in this rulemaking to address these two public health areas, which will strengthen produce safety. First, FDA must issue a separate proposed rule that will explicitly cover the risks to produce safety from animal production facilities, particularly from animal manure contaminants migrating in environmental pathways and in manure sold or given to other farms for growing produce. Second, FDA must amend the current proposed rule for produce farms to provide more flexibility for local and sustainable farms that do not fit the current exemptions. Without this flexibility, many of these important farms will struggle to

comply with the regulatory requirements. In this way, the current proposed rule might unintentionally hinder these local and sustainable practices, which are critical for public health. Finally, FDA must amend the rule to be consistent with USDA Certified Organic standards and strengthen the conditions for allowing human waste in growing produce.

II. Regulating Produce Safety Risks from Animal Production Facilities

It is imperative that FDA uses this new statutory authority to address produce safety risks generated by current practices at animal production facilities, including from contamination with pathogens, chemicals, and other hazards. FDA's proposed regulation focuses only on pathogen risks at the produce farm. Sadly, this focus does not capture the origins of these risks. Manure stored at these animal production facilities contains high levels of contaminants that migrate through environmental pathways to produce grown on farms. In addition, animal production facilities sell or give this manure with contaminants to produce farms for use as fertilizer. These animal production facility practices for manure can create significant risks to the safety of produce grown on farms. These risks include contamination of produce by pathogens, including antibiotic-resistant bacteria, as well as heavy metals such as arsenic and animal drug residues. Thus, where risks to produce are generated by practices at animal production facilities, the regulation must shift "upstream" on this risk pathway to establish requirements for these animal production facilities.

This position will more effectively and efficiently target these risks to produce from animal manure at their source. Animal production facilities are in a much better position to control those risks from their practices that threaten produce grown on other farms. In addition, the practices at one animal production facility can create risks for multiple

produce farms. Importantly, this approach is also more equitable by ensuring accountability for those most responsible for creating the produce safety risks. It is fundamentally unfair that produce farms would be responsible for mitigating risks that are generated by others.

This section first explains the significant produce safety threats posed by prominent practices at animal feeding operations for the management and use of animal waste. It then describes the extensive scientific evidence demonstrating these risks, and provides the legal justification for FDA to issue a regulation under FSMA that establishes specific requirements for animal production facilities. This section then proposes an approach for a separate proposed rule to address these animal production facility risks to produce grown on farms. Finally, the section explains how this approach is more effective and fair than the current proposed rule's exclusive regulatory focus on produce farms.

A. Risks to Produce Safety from Animal Production Facilities

The common practices at animal production facilities, particularly for managing their animal waste, pose significant risks to produce grown on farms.

1. Animal Waste Practices and Contaminants

The waste from animal production facilities, which includes feces, urine, spilled feed, bedding materials, and other contents[3], 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.[4] 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.[5] By contrast, only 7.6 million tons of human waste was generated by publicly owned treatment works in the United States that year.[3] 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 or wet forms or transports the waste to local farms for fertilizer.[3]

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 can contain greater than 100 such pathogens.[7] The waste from production animals can contain parasites, viruses, and bacteria in amounts as great as one billion per gram.[7] Recent studies have confirmed this high frequency of bacteria in animal waste, including *E.coli* O157, *Salmonella* spp., and *Campylobacter* spp.[8]

The use of antibiotics in animals for non-therapeutic purposes has been a common practice at animal production facilities for decades.[9] This practice is widespread and growing. In 2011, nearly 30 million pounds of antibiotics were sold to animal production facilities for use in cattle, swine, and poultry.[10] Evidence has shown that these facilities' indiscriminate use of antibiotics in animals has contributed to the proliferation of antibiotic resistance in pathogens that can subsequently infect humans.[11] Rigorous research has demonstrated that farms that transition from routine antibiotic use to organic food animal production practices see reductions in rates of antibiotic resistance (including multidrug resistant strains) among pathogens.[12] While elimination of pathogens from animal waste is a challenging endeavor involving the hygiene of the production site and myriad other factors, the routine use of antibiotics for production purposes or for disease prevention

worsens the severity associated with pathogen risks by applying pressure to select for resistant strains. This increased resistance in pathogens in animal waste can increase the risks for food safety.

These pathogens can survive for long periods of time in animal waste. For example, researchers found that large numbers of antimicrobial-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.[13] In addition, animal manure from these facilities also can contain heavy metals, such as arsenic, [14] zinc and copper, [15] and animal drug residues, such as antibiotics,[16] that pose human health concerns.[17]

2. 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.

a. 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.[7] Microbial pathogens can move from animal waste pit or lagoon storage areas into the soil through natural seepage.[18] 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.[19] The contaminants can also leach through soils to aquifers.[7] In addition, contaminants can flow directly into surface waters from flooding of waste lagoons.[20]

One study found that surface 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.[21] 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.[16] In addition, an extensive U.S. Geologic Survey found organic wastewater contaminants in 80% of 139 streams across 30 states in 1999 and 2000.[22] 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.[23] Produce surface contamination, such as from irrigation, presents a difficult food safety challenge because later washing has limited effects in sufficiently eliminating the contaminants.[24] Second, the contaminants can be incorporated from groundwater into the produce roots.[24] 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.[25] The internalization of pathogens in a plant, such as from root uptake, poses even more risk because surface washing will not remove the contamination.[24]

b. Transmission of Animal Waste Contamination through Air Pathways

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.[26] Another study found multi-drug resistant bacteria both inside and downwind of a swine feeding operation.[27] This bacteria can then be transmitted to adjacent soil. For example, a more recent study found that methicillin-resistant *Staphylococcus aureus* (MRSA) present in pig barns moved through air pathways to deposit in soil on adjacent land.[28]

Pathogens present in animal waste 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.[29] Insects can further transmit contaminants among crops on the farm. For example, a study found that fruit flies transmitted *Escherichia coli* O157:H7 between apples grown in an orchard.[30]

c. Direct Application of Animal Waste as Fertilizer

The waste from animal production facilities is frequently sold or given to produce farms for use as fertilizer.[31] 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.[31] Studies have found that pathogens[32] and antibiotic residues[33] 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.[31] The contaminants can also flow into surface water, groundwater, and aquifers and be incorporated in produce through external (irrigation) and internal (roots) routes.[6] Unlike for human biosolids, there are no

federal treatment control requirements or pathogen limits for animal waste used as fertilizer.[11]

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.[31] 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.[7] A recent study also found that drug-resistant illnesses (community associated MRSA and skin and soft tissue infections) were higher in those individuals living closer to animal production facilities and fields with applied swine manure.[34]

d. 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.[11] 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.[35] Other studies have shown the importance of feral animals as a source of fecal contamination and vectors for spreading animal manure.[32] By all of these pathways, animal waste from animal production facilities can transport microbial and chemical hazards and thus poses a serious threat to produce safety on adjacent farms.

3. 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.[6] 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.[36] 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.[37] 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.[38] The diversity in produce and infection types, as well as the environmental risk factors, provides strong evidence of the risks to produce safety from waste from animal feeding operations.

4. Federal Government Findings for the Risks to Food Safety from Animal Production Facilities

Other federal government agencies have reviewed the available scientific evidence and concluded that animal waste from animal production facilities poses a significant threat to human health, including from waterborne disease organisms and chemicals. For example, the EPA explained in a recent rulemaking that animal manure from these facilities contains substantial amounts of pathogens, including those resistant to antibiotics, as well as heavy metals and other substances.[39] EPA found that these pathogens in manure can be transferred to humans, such as through contaminated surface or groundwater. [39]

EPA also submitted a 2009 report to Congress that described the health of surface waters throughout the United States.[40] EPA relied on state assessments in 2004 for the health of rivers and streams, including those used for agriculture. Of the approximately 200,000 miles of streams and rivers providing water for agricultural purposes, such as for growing crops, EPA estimated that 10 percent of these waters were impaired.[40] Pathogens were the most frequent cause of impairment for all assessed streams and rivers, indicating fecal contamination.[40] In addition, EPA found that agricultural activities, such as animal production facilities, were the most common source for contamination, affecting over 94,000 miles of these streams and rivers.[40] These EPA findings are significant because they are based on widespread surface water assessments from the states and demonstrate the pathways for manure contaminants from animal production facilities through surface waters to produce crops.

The General Accounting Office (GAO) also examined in 2008 numerous studies assessing the association between animal production facilities and the quality of water and air.[41] GAO found that fifteen studies determined that manure from these facilities was associated with harmful effects to human health and the environment, including through water and air pathways.[41] These conclusions from GAO reinforce our summary of the scientific literature.

B. FDA's Draft Risk Assessment

FDA's Draft Qualitative Risk Assessment (RA) acknowledges risks to produce from animal manure, including from animal production facilities, as a significant source for these risks. The Draft RA notes three foodborne outbreaks in 2006 (for fresh spinach, lettuce, and tomatoes) resulting from animal feces contamination, including from surface water

sources and improperly stored manure (page 18). The Draft RA explains that for produce outbreaks likely caused by contaminated water, manure runoff from nearby animal feed lots were a possible source for the contamination (page 18). In one foodborne illness outbreak associated with shredded romaine lettuce, the investigation identified three animal production facilities as a possible source for the contamination (page 25). Of the 22 farm investigations conducted by FDA from 2005 to 2008 due to produce outbreaks, FDA concluded that water (3 outbreaks), soil amendments (2 outbreaks) and animals (7 outbreaks) were likely contamination sources (page 22). The Draft RA also acknowledges the findings in the EPA's 2009 report concerning surface water contamination with pathogens (page 24).

Although the Draft RA acknowledges these risks to produce from animal production facilities, the RA must incorporate the evidence provided in this comment that demonstrates the mechanisms and pathways for contamination transmission from these facilities to produce grown on farms. Most of this cited scientific literature is absent from the draft RA. This evidence provides strong scientific support for the finding of significant risks to produce generated by animal production facilities and their manure storage and handling practices. It is also important that EPA's and GAO's evaluations, described above, support these findings. The incorporation of this evidence about external animal manure threats must then shift regulatory focus to the animal production facilities themselves, which are the source of these threats.

C. Legal Justification for Regulating Animal Production Facilities that Create Produce Risks

Based on this scientific evidence, it is imperative that FDA issue a regulation under FSMA that addresses the risks to produce created by animal production facility practices.

FDA has the legal authority to issue such a regulation under the relevant statutory provisions. This position is not inconsistent with EPA laws or policies, because FSMA provides this explicit authority to FDA in the context of produce safety.

1. FSMA Provisions

The Food Safety Modernization Act, incorporated as section 419 in the Federal Food, Drug, and Cosmetic Act, provides the new authorities for FDA to regulate produce risks. Section 419(a)(1), requires FDA to "publish a notice of proposed rulemaking to establish science-based minimum standards for the safe production and harvesting of those types of fruits and vegetables … for which [FDA] has determined that such standards minimize the risk of serious adverse health consequences or death." To the extent animal waste from animal feeding operations can be incorporated in produce grown on farms, either from environmental pathways or their use as soil amendments, the proposed rule must include standards for these animal operations' waste practices to ensure the "safe production" of these fruits and vegetables.

Importantly, the statute does not limit these standards simply to produce farms. FDA admits in the proposed rule preamble that the statute does not "affirmatively identify the businesses to which the proposed rule must apply" (PR Preamble, page 3521). In limiting the proposed rule's scope to produce farms, FDA instead relies on the statute's use of the term "farm" in other provisions in Section 419 (PR Preamble, page 3521). These references, though, do not limit the rule's scope. First, the conditions in Sections 419(a) and (b) for the proposed rulemaking and final regulation do not include such "farm" references. Second, the later references to farms, such as the exempting conditions in Section 419(f), do not preclude the produce safety regulation from applying to animal

production facilities generating animal manure risks to produce. FDA also notes that section 419 of the statute does not apply to facilities subject to section 418 (PR Preamble, page 3521), but this section only applies to food manufacturers, processors, and packers, and not animal feeding operations.

The statutory conditions for the rulemaking also mandate the broader scope. First, section 419(a)(3)(A) of the statute states that the rulemaking must "provide sufficient flexibility" to apply to "various types of entities engaged in the production and harvesting of fruits and vegetables…." This flexibility extends the rule's scope to animal feeding operations (a "type of entity") that generate contaminants incorporated in produce grown on farms through environmental pathways, as well as animal manure used for fruit and vegetable production on farms. Through these well-established environmental pathways, already described in this comment, the animal feeding operations are "engaged in the production" of the produce grown on other farms within this statutory scope. In addition, when animal waste is sold or given as fertilizer from animal production facilities to produce farms, the operations are directly engaged in the produce production.

Second, section 419(a)(3)(B) of the statute also states that the proposed rule include science-based standards that cover, among other things, soil amendments and water. These important sources for contaminants can originate from animal feeding operations through fertilizer sales or environmental pathways. The standards must apply to the animal production facilities when they are the source of the soil amendments or their manure practices threaten water or land used by produce farms.

Finally, the statute's criteria for the regulations mandate the rule's application to animal production facilities. Section 419(c)(1)(A) of the statute states that the regulations

shall (i.e., must) "set forth those procedures, processes, and practices that … minimize the risk of serious adverse health consequences or death, including [those] reasonably necessary to prevent the introduction of known or reasonably foreseeable biological, chemical, and physical hazards, including hazards that occur naturally, may be unintentionally introduced, or may be intentionally introduced… into fruits and vegetables." This language mandates the promulgation of a regulation that establishes "practices" at animal production facilities that are "reasonably necessary to prevent the introduction" of contaminants (including pathogens) from animal manure that "may be unintentionally introduced" through environmental pathways or "intentionally introduced" through sales of animal manure to produce farms.

2. Consistency with EPA Authorities

FDA regulations under these FSMA provisions to control the risks to produce from animal production facilities will not conflict with EPA's regulation of such facilities. EPA's authorities are related to the environmental pathways for animal manure contaminants to flow from animal production facilities to produce farms. The Clean Water Act applies to water pathways, while the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) and Emergency Planning and Community Right to Know Act (EDPCRA) applies to air pathways.

For water pathways, EPA has authority to regulate animal production facilities under the CWA at concentrated animal feeding operations (CAFOs) that meet certain size thresholds.[39] The CWA authorizes EPA to regulate CAFOs as a "point source" under the statute and prohibits the discharge of any pollutant except in compliance with the Act. Point sources of pollutants, including CAFOs, must seek authorization for discharges

through the National Pollutant Discharge Elimination System (NPDES) permitting program.[39] NPDES permits require CAFOs to take certain steps, such as monitoring and controlling pollutants. Federal appellate court decisions, though, have restricted EPA's authority to regulate CAFOs, and require permits, to those facilities that actually discharge pollutants, such as through manure runoff.[39]

For air pathways, EPA might assert authority under CERCLA and/or EPCRA to require reporting of released substances by animal production facilities that are dangerous to human health and the environment.[9] However, EPA has decided not to require reports at this time from animal production facilities under CERCLA and EPCRA.[9]

EPA does not currently have information on the location and identity of CAFOs in the United States, which creates important challenges to identify those facilities that currently discharge pollutants and ensure compliance with the permitting requirements.[9] To address this challenge, EPA issued a proposed rule in 2011 to obtain identifying information from all CAFOs in the United States, but subsequently withdrew the rule in 2012.[42] EPA announced instead that it will rely on alternative sources, such as state records, to obtain this information.[42]

The new FSMA authorities, in section 419(a)(3)(D) of the statute, require that the rulemaking "take into consideration, consistent with ensuring enforceable public health protection, conservation and environmental practice standards and policies established by Federal natural resource conservation, wildlife conservation, and environmental agencies." A regulation under these FSMA authorities to minimize the risks to produce safety from animal production facilities will not conflict with the regulatory framework under the CWA or EPA's policies. First, where animal production facilities sell their manure to produce

farms for use as fertilizer, the EPA statutes (CWA, CERCLA, and EPCRA) are not implicated. Second, where contaminants from manure on animal production facilities threaten produce farms through water or air pathways, any regulations under FSMA to control these threats will not conflict with EPA regulations and approaches. For those facilities that discharge animal waste into the water or air that threatens produce on other farms, FDA's requirements for animal waste controls will be specific to these facilities and pathway steps responsible for the produce risks. If a facility's animal waste discharge does not threaten produce through these environmental pathways, then only EPA's permitting requirements for actual water discharges will apply.

FSMA makes clear that controlling produce safety threats is critical and that any consideration of relevant environmental laws and policies must be "consistent with ensuring enforceable public health protection" (section 419(a)(3)(D)). So FSMA authorizes FDA to promulgate regulations to control animal waste threats from animal feeding operations that threaten produce safety through environmental pathways or through animal waste used as fertilizer. Thus, these regulations for animal waste threats to produce can be in addition to EPA's regulation of animal production facilities for environmental threats.

D. Procedure for Rulemaking and Content of Animal Production Facility Rule

Under the Administrative Procedure Act, 5 U.S.C. §553, and the "logical outgrowth" doctrine, FDA must issue a separate proposed rule with the requirements for animal production facilities.[43] For the current proposed rule with produce farm requirements, FDA can proceed to issue the final rule after considering the comments and making

necessary changes to the provisions. It will be important for FDA to consult with EPA in the development of these animal production facility regulations.

FDA's regulation for animal production facilities should follow the principles for minimizing animal waste contamination described in the current proposed rule. First, for animal waste sold or given to produce farms, the regulation should place a greater burden on animal production facilities to minimize contamination, including harmful pathogens, in this animal waste. The regulation should require these facilities to take specific steps to minimize the contamination risks, document these steps, and certify compliance in documentation provided to produce farms. Some examples would be treatment steps and/or waiting times that are adequate to minimize these risks and any necessary testing.

Second, the regulation should require that animal production facilities take specific steps to minimize the risks for contaminants in animal waste to travel through water and air pathways and threaten produce grown on farms. These requirements should involve assessment, monitoring, and control steps to minimize the risks to produce from animal waste originating from their operations. For assessment, animal production facilities should determine whether and how their animal waste is threatening produce farms through environmental pathways by thorough inspection of storage sites and surrounding environmental pathways, including testing of water samples. For monitoring, animal production facilities should update these assessments on a periodic basis for environmental pathways. For controls, animal production facilities should implement specific steps, such as containment steps for effluents, to limit the threats to produce farms from their animal manure travelling through environmental pathways.

It will be critical for FDA to identify these animal production facilities that are subject to the regulation. First, FDA can identify these animal production facilities that threaten produce safety through each produce farm's assessment of the threats from adjacent or nearby land, which will include such facilities, required by the regulation (page 3565). In addition, FDA can require under the regulation that animal production facilities identify themselves for these purposes. This required identification would be authorized by FSMA as "reasonably necessary" under section 419(c)(1)(A) of the statute to prevent the introduction into produce of contaminants from animal manure through environmental pathways.

E. Efficiency, Effectiveness, and Equity

From both an economic and regulatory perspective, it is more efficient and effective to place the burden of minimizing produce contaminant risks from animal production facilities on those facilities themselves. These facilities are in a much better position to control those risks from their practices that threaten produce grown on other farms. In addition, the practices at one animal production facility can create risks for multiple produce farms. Produce farms would still be required under the current proposed rule, once finalized, to ensure that their own practices do not introduce new contaminant threats. But this two-part approach would ensure that produce farms are not responsible for mitigating threats from animal manure that are caused by other responsible parties, whether through land applied manure-based fertilizer or through environmental pathways. In this way the approach would be more equitable and fair.

III. Proposed Rule Requirements for Produce Farms

The Produce Rule must be amended to address additional public health concerns for local and regional food systems; sustainable food production; organic farming standards; and the use of human waste. For the purposes of this comment, CLF defines local food systems as farms and businesses serving the "qualified-end user" and "consumer" defined by FSMA in section 419(f)(4) of the statute; sustainable food production according to the USDA definition in U.S. Code Title 7, Section 3103[44], and organic farming standards as those outlined in the National Organic Program.[45]

A. Local and Regional Food Systems and Sustainable Food Production

1. Benefits to Nutritional Health and Food Safety

The redevelopment of local and regional food systems offers various health benefits. Among these benefits are the shorter time between harvest and consumption and fewer steps in the food supply chain. Farmers selling to local markets are able to offer fruit and vegetable varieties with high nutrient densities and better taste than those bred for durability and a long shelf life. Additionally, inclusion of fresh, locally sourced produce in schools through Farm to School programs results in increased consumption of fruits and vegetables, increased willingness to try new foods, and reduction in cafeteria waste.[46]

Farmers markets, mobile markets, and community-supported agriculture programs (CSAs) are providing access to fresh, healthy, affordable, and good-tasting food in thousands of urban and rural communities that otherwise lack access to healthy foods.[47] The ability of farmers to sell directly to consumers or into short supply chains is one important way that small and mid-sized producers can be financially viable. The success of these farmers —and the growth of the sector—is important to public health because these

are the producers best able to meet the food needs of limited-resource communities (because they operate at smaller scales and are able to meet lower demand that cannot be accommodated by large producers, processors and distributors), and they are creating economic opportunity in rural and urban areas desperate for growth.[48]

An important feature of short supply chains is that less time and fewer instances of handling occur between harvest and consumption. Fewer people come into contact with short-supply-chain products – limiting opportunities for contamination – and the products are distributed to fewer final consumers, all of whom are in a limited geographic area. This means that farmers can produce more delicate, and higher nutrient varieties that do not store or ship well, thus increasing the nutritional value of produce available in these areas.

The expansion of farmers markets, school, community, and home gardens, farm to school programs, and local sourcing in hospitals and other institutions has made healthy, fresh, affordable food available to many more Americans. Given that more than 100,000 Americans die each year from preventable diet-related conditions[49] and our nation spends almost $150 billion[50] annually treating health conditions related to obesity, the public health community has a clear interest in promoting improvements in food environments that are demonstrably helping Americans eat more healthfully.

2. Produce Rule Must Provide More Flexibility for Farms Using Sustainable Methods and/or that Are Part of the Local and Regional Food System

As described in section I(B), the proposed rule provides a qualified exemption from the regulatory requirements for many CSAs, you-pick operations, and farmers markets. The exemption scope is based on the exact FSMA language in section 419(f). However, the current Produce Rule language does not make these exemptions clear and many farms with sustainable practices and/or providing local and regional produce may not fit within the

exemption's scope, because their total food sales exceed $500,000 on average per year or their local food sales are less than their non-local food sales. The regulatory requirements would discourage such farms from entering (or remaining in) the local produce market, which would weaken these important food systems and diminish the above-described health gains. Therefore, the final regulation must provide more flexibility in the produce standards for farms that do not fit within the exemption threshold but are important parts of the local and regional food system.

In addition, sustainable and/or organic farms rely on animal manure sold or given to them by animal production facilities, rather than using chemical fertilizer. Because of this necessity, it is even more critical that FDA require in separate rulemaking that these animal production facilities ensure the safety of their marketed animal manure. As written, the Produce Rule would allow FDA to withdraw the exemption for an organic or sustainable farm that is currently exempt from the proposed rule's requirements because of a foodborne-illness outbreak, which would then subject the farm to all other requirements in the rule. This withdrawal would not be equitable, however, if the foodborne illness was caused by contamination of the produce from animal production facilities, either through environmental pathways or animal manure sold or given to the produce farm.

3. FSMA Supports Increased Flexibility for Local and Sustainable Produce Farms

FSMA authorizes FDA to provide more flexibility to local and sustainable produce farms in the rulemaking. In particular, section 419(a)(3)(A) mandates that the rulemaking provide "sufficient flexibility" in applying to various entities involved in produce production, including those selling directly to consumers, and be "appropriate to the scale

and diversity" of the production. Section 419(c) also mandates that the final regulation provide "sufficient flexibility to be practicable" for all sizes and types of businesses. These provisions authorize FDA to provide more flexibility and scale-appropriate regulations to farms in their adoption of produce safety practices. The exemption conditions in section 419(f) of FSMA, and adopted by the proposed rule, do not prohibit FDA from adopting this flexibility in the regulation for local and sustainable farms that do not meet the exemption conditions. In this way, these alternative standards would not conflict with the statutory exemption conditions.

B. Produce Rule Requirements for Biological Soil Amendments Must Be Consistent with National Organic Standards

FSMA makes clear in section 419(a)(3)(E) that the regulation's requirements must not conflict with the requirements of the National Organic Program (NOP) established under the Organic Foods Production Act of 1990. However, the proposed standards for biological soil amendments conflict with these NOP requirements. The draft regulations include application schedules that are not aligned with those that have been regulated and used successfully for more than a decade by certified organic farmers. For example, the proposed rule would require a minimum application interval of 9 months for untreated biological soil amendments of animal origin where produce is reasonably likely to contact soil after application (PR Preamble, pages 3581-3584). The NOP regulations, 7 CFR 205.203(c)(1) and (2), only require a minimum application interval of 120 days in these circumstances.

If FDA adopts these intervals in the final rule and does not change these intervals to align with NOP requirements, then organic farmers will be forced to change their growing methods to comply with both regulations, which likely will actively discourage them from

becoming certified organic. According to the U.S. Department of Agriculture (USDA), at of the end of 2012, there were 17,750 certified organic operations (farms and processing facilities) in the United States.[51] Organic and sustainable farming helps maintain ecosystem health and diversity. Biological diversity adds to soil health and protects our environment, and healthy soils can boost the nutrient content of food and contribute to long-term food security by ensuring land is viable for food production. A healthy country relies on diverse foods from a variety of different kinds of safe, domestic production systems.

Organic production relies on the use of natural compost and it is a foundational conservation practice in sustainable agriculture production. There are public benefits from a thriving organic production system in the United States, as there are many negative public health consequences associated with the use of chemical pesticides, herbicides, and synthetic fertilizers in food production. Although the public health consequences of pesticides in our food supply are not addressed through FSMA, the FSMA proposed regulations should not derail this important, expanding, healthy sector of our food system. Clearly, the regulations must agree with the FSMA statute and not undercut NOP requirements. Not only must, FDA ensure that the standards for biological soil amendments of animal origin do not hinder farmers' participation in the National Organic Program, the final Produce Rule must not discourage on-farm conservation practices.

As noted in section III(A)(2) for sustainable farms, because organic farmers must rely on animal manure sold or given to them by animal production facilities, FDA must require in the separate rulemaking that these animal production facilities ensure the safety of their marketed animal manure.

C. Produce Rule Must Strengthen Requirements for Use of Human Waste

The proposed rule also allows the use of human waste for growing produce in compliance with EPA's regulations for the land application of municipal biosolids, 40 CFR Part 503. This regulation includes biosolids testing for pathogens and chemicals, maximum contaminant limits, and management steps. However, we believe these requirements must be updated for human waste used in growing produce, based on a National Academy of Sciences review of these EPA regulations and scientific recommendations.[52]

It is imperative that these human waste requirements be strengthened in the Produce Rule using rigorously derived evidence-based standards, in accordance with the NAS report. We believe current risk assessment methods must be used to update these treatment standards for pathogens and chemicals in human waste, particularly for the complex pathways described in this comment, including for chemical-pathogen mixes.[52] We believe that the NAS report recommendations to consider additional risk-management practices for biosolids land application are relevant for human 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 produce grown using human waste.

Strengthening these standards for human waste used in growing produce will not conflict with EPA's regulatory requirements. Section 419(a)(3)(D) of FSMA makes clear that any consideration of environmental practice standards must be consistent with ensuring public health protection for produce safety. FDA should incorporate the NAS recommendations for human biosolids in the Produce Rule to ensure greater public health

protection through safer produce. These requirements will be in addition to the EPA regulatory requirements for land application and specific only to human waste used on produce farms.

IV. Proposed Rule Requirements for Facilities

As noted in Section III(A), there are numerous public health benefits associated with local and regional food systems. The businesses that process and transport products in the local and regional food chains are essential parts of the system. In order to protect this important infrastructure, FDA must clarify the definition of a "retail food establishment" to specify that the sale of food directly to consumers includes the sale of food through community-supported agriculture programs, roadside stands, farmers markets and other direct-to-consumer venues. Additionally, clarity around the definition of small businesses is needed so that infrastructure like "food hubs," businesses that are aggregating, processing, packing and distributing products and facilitating important redevelopment of local and regional food systems remain viable.

On-farm processing is an important piece of local and regional food system infrastructure, especially for things like farm to school since farmers can do basic chopping of produce to ensure schools—which often lack full kitchens—can use the products. To meet demand and or facilitate the ability of smaller farms to serve a larger buyer, some farmers aggregate product from various farms. Packing and holding someone else's fruits and vegetables should not make a farm a "Facility."

Additionally, some farms add value to their products by processing them on-farm or at small-scale processing facilities or kitchen incubators. These farmers and facilities are subject to local food safety laws. The FSMA statute recognizes this, but the proposed

regulations create uncertainty and confusion and establish costly requirements that will not necessarily increase food safety.

V. Conclusion

Based on the above analysis, FDA must take the following steps in this rulemaking:

(1) Initiate a separate rulemaking to propose requirements for animal production facilities to minimize the risks generated by their animal manure practices, including from environmental pathways and manure sold or given to produce farms.

(2) In the Produce Rule, provide flexibility in the regulatory requirements for local and sustainable produce farms and ensure that soil amendment standards are consistent with national organic standards.

(3) In the Produce Rule, strengthen the requirements for human biosolid application on produce farms, consistent with the NAS recommendations.

(4) In the Preventive Controls Rule, ensure businesses and farms that are part of the local and regional food system are not subject to regulations that are neither mandated nor necessary and that could threaten their viability.

Through these steps, the rulemaking will help ensure produce safety and strengthen local and regional food systems and sustainable and organic food production. By focusing on the role of animal production facilities in generating risks to produce, the rulemaking will properly shift more responsibility to the responsible actors in the food chain. This approach will be more efficient and equitable and better protect the safety of fruits and vegetables for all Americans.

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