CENTER FOR FOOD SAFETY

November 19, 2013

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20582

Dockets: **FDA-2011-N-0921** and **RIN 0910-AG35** (*Submitted online via regulations.gov)*

Comments on the Food Safety Modernization Act Produce Rule

Center for Food Safety (CFS) is a non-profit membership organization that works to protect human health and the environment by curbing the proliferation of harmful food production technologies and by promoting organic and sustainable agriculture. Our membership has rapidly grown to include over three hundred and fifty thousand people across the country that support organic food and farming, grow organic food, and regularly purchase organic products.

CFS views organic as a viable and desirable alternative to chemical-intensive and genetically modified agriculture. While our work on organic agriculture and food policy aims to support the continued growth of organic, we are committed to promoting growth with integrity. To that end we have drafted comments on FDA's proposed rule on Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption (Produce Rule) to address the major areas in the draft proposed Rule that would unfairly, and without scientific basis, impinge upon the integrity of organic production systems.

Subpart F—The Proposed Standards for Biological Soil Amendments of Animal Origin and Human Waste Violate the Requirements of FSMA

As stated on the USDA's Economic Research Service website, "consumer demand for organically produced goods has shown double-digit growth for well over a decade, providing market incentives for U.S. farmers across a broad range of products. An estimated 12,880 certified organic farms operate across the U.S.[1] Organic products are now available in nearly 3 of 4 conventional grocery stores, and enjoy substantial price premiums over conventional products."[2] Research conducted by the Organic Trade Association shows that seventy-eight percent of U.S. families buy organic food, and four in ten people stated that they were buying more organic products than the previous year.[3] Families who buy organic food at least sometimes are increasingly buying organic fruits and vegetables.[4] Organic fruits and vegetables comprise 11.6% of the total market share of the combined organic and conventionally grown markets, and that trend is projected to continue to

[1] USDA Economic Research Service. Organic Production: Overview -- Table 2. U.S. certified organic farmland acreage, livestock numbers, and farm operations. Total certified operations in 2011.
[2] USDA ERS. "Organic Agriculture Overview," Website Front Page, Available at: http://www.ers.usda.gov/topics/natural-resources-environment/organic-agriculture.aspx#.UoUv9-IRFkg.
[3] Organic Trade Association. 2011. U.S. Families' Organic Attitudes & Beliefs 2011 Tracking Study. 6.
[4] OTA. 2011. 6.

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increase.[5] This vital U.S. farm sector must be protected so it can prosper and continue to pioneer technologically advanced and sustainable agricultural production methods to feed current and future generations.

Soil fertility management serves as a core function underpinning the success of organic farming systems. The Organic Foods Production Act (OFPA) requires that organic farmers design organic system plans "to foster soil fertility, primarily through the management of the organic content of the soil through proper tillage, crop rotation, and manuring."[6] Because organic farming practices prohibit the use of synthetic fertilizers, pesticides, and sewage sludge, biologically-based fertilizers such as compost and green and animal-based manures are crucially important to the vitality of organic agriculture. They substantially contribute to the development of the healthy soils in which organic crops survive and thrive.

By making it exceedingly difficult for farmers to use biologically-based fertilizers and soil amendments, the draft rule tacitly supports expanding the use of toxic, synthetic farm inputs, many of which are known to cause adverse human health and environmental impacts. In FDA's notice of intent to prepare a draft EIS on the proposed rule the Agency acknowledges that the proposed biological soil amendment standards "are expected to result in changes in current use of treated and untreated biological soil amendments of animal origin *or potentially greater use of synthetic fertilizers"* [Emphasis added].[7] This is an unacceptable policy outcome in need of serious reconsideration and revision. Toxic, synthetic inputs can leach into air, water, and communities, creating health threats that are simply not a part of organic farming systems. In contrast to the proven manure standards required under OFPA, the proposed rule would encourage the use of chemical fertilizers that harm the natural microbial activity of soils and severely inhibit the ability of organic and other farmers to use biological fertilizers as an integral component of their soil fertility regime.

Scientific research has shown that beneficial microbial activity is notably present in organically managed soils and that microbials help more readily break down harmful pathogens than do soils managed conventionally with synthetic chemicals. According to Dr. Trevor Suslow and other soil researchers, biologically active soils more effectively control the proliferation of pathogenic bacteria than less biologically diverse soils.[8] Studies have shown that *E. coli* can be killed as a result of microbial competition in soils, and that pathogen populations decline more rapidly in manure-amended soil than sterilized soil. Researchers have found that this is likely due to antagonistic interactions with indigenous soil microorganisms.[9] Microbial diversity actually contributes to solving pathogen problems in produce rather than creating them. Yet, privileging chemical-intensive soil fertility management practices over biologically-intensive ones would serve to reduce

[5] OTA. 2011. 6.; OTA. 2011. Organic Industry Survey. 20.
[6] 7 USC § 6513 (b)(1).
[7] Federal Register. 2013. Notice of Intent to Prepare an Environmental Impact Statement for the Proposed Rule, Standards for Growing, Harvesting, Packing, and Holding of Produce for Human Consumption. 78(160): 50359.
[8] See: Suslow, T.V., et al. 2003. Production Practices as Risk Factors in Microbial Food Safety of Fresh and Fresh-Cut Produce. *Comprehensive Reviews in Food Science and Food Safety*, 2(supplement): 38-77; particularly Section 2.1.2.3.
[9] Bogosian, G., Sammons, L.E., et al. 1996. Death of the *Escherichia coli* K-12 strain W3110 in soil and water. *Applied and Environmental Microbiology* 62(11): 4114-4120.; Jiang, X.P., Morgan, J., et al. 2002. Fate of *Escherichia coli* O157:H7 in manure-amended soil. *Applied and Environmental Microbiology,* 68(5): 2605-2609.

the robust soil microbial activity found in organically managed soils, curtailing a major tool available to organic farmers to combat soil pathogens. The end result would be to undermine the food safety goals that the FDA rules are intended to achieve in the first place.

Compost

Ninety-four percent of organic producers apply compost or manure as a soil fertility management practice on covered produce, according to a 2013 joint survey conducted by the Organic Trade Association (OTA) and the Washington State Department of Agriculture (WSDA).[10] The Organic Rule that governs their use clearly states that no interval is needed between the time when organic farmers apply compost and when they harvest their organic crops. That is because strict standards embedded in the Rule mandate best management practices for compost making, which ensures the elimination of pathogens before compost is ever applied to farm soils. A 45 day waiting period, as suggested in the draft produce rule, is completely unnecessary and unworkable for organic farmers. It is unclear how the agency decided upon this 45-day interval or how the literature it cites supports this conclusion. If implemented, FDA would not only force organic farmers out of compliance with NOP regulations, but it would also discourage farmers from becoming certified organic, due to the overly burdensome and completely unnecessary requirements.

According to the OTA/WSDA survey, seventy-three percent of the organic growers who use compost stated that FDA's proposed regulation would negatively impact their ability to include crop rotations and/or biological diversity in their farming operations, as mandated under the National Organic Program (NOP) standards.[11] As this survey suggests, implementation of the proposed rule would force those farmers out of compliance with OFPA or to minimally comply with the spirit, intent, and letter of the law at best. Moreover, implementation of Subpart F would also violate Congress's directive embedded in FSMA which specifically states that FDA food safety rules must not conflict with organic standards.

Requiring "insulation for compost" represents another problematic area in FDA's proposed standard. It is impractical to apply insulation to compost because doing so could result in both decreasing compost quality and unnecessarily increasing the cost of producing and applying compost. The proposed Produce Rule's preamble suggests that adequate compost curing includes proper insulation "usually consisting of around one foot thick of insulating material, e.g., hay, straw, finished compost."[12] What remains absent from this discussion is the acknowledgement that compost needs to be turned many times during the compost curing process to maintain an acceptable level of carbon dioxide and to prevent the compost from drying. This process can take up to three months before the compost is completely cured. Yet, if a one-foot-thick layer of hay or straw is adhered to compost that needs turning, it will change the carbon to nitrogen ratio of the compost. This would then require the whole pile/windrow to be re-composted and then another insulation layer would be required to be added during the curing process. Thus, the never-ending cycle of composting/insulating/turning would continue.

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[10] Washington State Department of Agriculture and Organic Trade Association. 2013. Impact of FDA's Proposed Application Intervals on Organic Fertility and Crop Rotation Requirements. 30 August to 4 October. http://www.ota.com/regulatory/foodsafety.html.

[11] WSDA and OTA. 2013.

[12] Federal Register. 2013. Proposed Rules: Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption. 78(11): 3580.

Manure

Scientific research has shown that untreated manure can easily break down in soils within a four month period, as required under OFPA. For consistency's sake, and in order to ground its regulations in science and farmers' experience, the FDA must look to the Organic Rule for guidance instead of creating new standards without any scientific basis. As the Produce Rule currently stands, it directly conflicts with established federal organic standards for manure and compost use, and would also make it impossible for organic farmers to use manure, creating an unfair and unjustifiable barrier to using a well-established source of fertilizer. This would likely result in putting untold numbers of organic farmers out of business, given their inability to properly manage soil nutrients and biodiversity.

To justify its proposed standards, FDA cites studies of *E. coli* O157 and *Salmonella* that used abnormally high rates of pathogens in the studies. Measurements of pathogen survival were taken in manure, not soil, which is not a useful measurement for drawing conclusions about pathogens in soil environments. Sterile soil was also used, which is atypical of organic farm soils that support diverse microorganisms to control pathogens. FDA cited studies of *Cryptosporidium*, *Giardia*, and *Ascaris* pathogens to justify its unreasonable manure standards, yet those pathogens are not often associated with pathogenic outbreaks in fresh produce. Clearly, FDA's use of these studies to justify long waiting intervals before a crop can be harvested is flawed. The proposed Produce Rule must be reconsidered in this regard. Here again FDA must align its manure use standards with NOP regulations by requiring the interval between the application of untreated manure and harvest to be four months long and not nine months as proposed by FDA.

In sum, the use of biological soil amendments of animal origin is a foundational practice in organic production systems. Their use is also consistent with existing and acceptable resource conservation practices. As proposed, the Produce Rule creates an unnecessary and avoidable barrier to the adoption of critical organic soil nutrient management practices that have underpinned OFPA and the organic industry. It is absolutely incumbent upon the FDA to fix these significant problems before issuing the final rule.

Subpart I —Standards Directed to Domesticated and Wild Animals are Inadequate to Support Wildlife Habitat Conservation

FDA's proposed Produce Rule has the potential to negatively impact on-farm habitat conservation measures and directly conflicts with provisions of the Organic Food Production Act (OFPA) and the accompanying National Organic Program (NOP) regulations. While the Produce Rule does not specifically advocate clearing of wildlife habitat and conservation plantings, its failure to strongly endorse these practices reinforces unfounded suspicions that conservation practices are part of the food safety problem instead of the solution. Implementing the Produce Rule as it stands could cause farmers to lose their organic certification and/or provide a disincentive for new growers to become certified organic. That is why it is imperative that FSMA regulations clearly state that extreme, earth-scraping measures are not required to improve food safety on farms and that habitat and conservation preservation measures are part and parcel of an integrated strategy to combat food-borne pathogens.

FSMA directs FDA to be proactive when it comes to conservation of wildlife habitat, but the proposed rules do not reflect that priority. On the contrary, lawmakers' intent to prevent the removal of riparian areas and habitat in the name of food safety has been undermined, as has been

the case in California when food safety purchasing agreements were introduced without explicitly supporting conservation practices. Reactions to recent food safety outbreaks often have been severe, including the complete elimination of conservation areas, as was seen after the 2006 *E. coli* 0157 outbreak linked to spinach from California's Central Coast. In this particular instance, the source of contamination was not established, but feral pigs were suspected. This led some produce buyers to stipulate that they would not buy greens harvested within certain distances of natural areas,[13] pressuring growers to remove habitat and conservation plantings in order to avoid losing production areas on the margins of their fields.

A survey conducted in 2007 of California Central Coast produce growers show that most growers had been asked to remove conservation areas or wildlife by their purchasers, and that 15% of survey respondents were actively removing conservation areas to comply with purchaser restrictions on food safety.[14] The survey identified a strong tension between conservation efforts and food safety practices on farms, even in those instances where the food safety measures are not scientifically shown to reduce contamination. Food safety requirements were found to be implemented in various ways and were often directly at odds with conservation practices such as maintaining non-crop, vegetative buffers between fields.[15] Wildlife is also adversely affected. In response to food safety expectations and fears of not being able to sell their crops, 88.9% of growers surveyed were using some type of wildlife exclusion practice.[16]

Another study of California's Central Coast agriculture conducted by the Nature Conservancy found that in the five years following the 2006 *E. coli* 0157 outbreak, 13.3% of remaining riparian habitat was eliminated or degraded in efforts to improve food safety.[17] Figure 1 (following page) shows an example of habitat destruction on the Central Coast region of California between 2005 and 2008 in the name of food safety. Much of this destruction was likely in response to food safety audits and requirements from purchasers that may have been interpreted and implemented in different, conservation-destructive ways on each farm.[18] Should this trend continue nationwide, the environmental impacts would be grave. Thus, it is crucial that FDA stipulate in the Produce Rule itself, not just in the preamble, that clearing native habitat is not expected, required, *or recommended* in order to comply with FSMA.

[13] In one example, a survey respondent said their crops planted near trees were required to have a buffer of 100-150 feet by a processor. See: Beretti, M. and Stuart, D. 2008. Food safety and environmental quality impose conflicting demands on Central Coast growers. *California Agriculture*, 62(2): 68-73.
[14] Beretti, M. and Stuart, D. 2008.
[15] Beretti, M. and Stuart, D. 2008.
[16] Beretti, M. and Stuart, D. 2008.
[17] Gennet, S., Howard, J., Langholz, et al. 2013. Farm practices for food safety: an emerging threat to floodplain and riparian ecosystems. *Frontiers in Ecology and Environment*, 11(5): 236-242.
[18] Beretti, M. and Stuart, D. 2008.

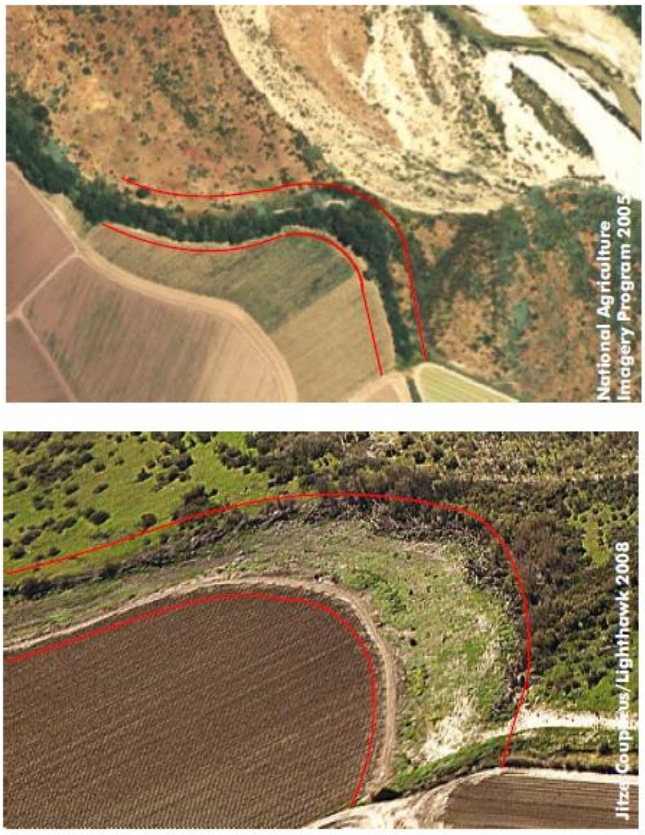

Figure 1. The red lines in the photos to the left indicate the same area at two points in time. The top photo was taken in 2005 before the 2006 E. coli 0157 spinach outbreak that catalyzed increased pressure to remove habitat. The bottom photo is from 2008, and the habitat destruction along the farm margins is clear. (Images courtesy of Wild Farm Alliance.)[19]

Wildlife habitat preservation and restoration comprises an important aspect of pest management for organic growers. Practices such as alley cropping, intercropping, and hedgerows introduce biological diversity into farm fields and they are required under OFPA in lieu of crop rotations in organic perennial crop systems. Because FDA's proposed Produce Rule itself does not encourage sustainable conservation practices, it by default discourages many of these practices. As such, it conflicts with OFPA regulations, an issue Congress specifically stated must not be the case.[20] In contrast, OFPA regulations specifically require growers to maintain or improve natural resources and biodiversity on their farm in an ongoing basis.[21]

Habitat bordering croplands attracts beneficial insects that control pests and provide habitat for raptors and other predators as a way to control rodent populations without the use of synthetic poisons. Removing this habitat would also impact managed and native pollinators that are crucial to maintaining biodiversity and a healthy food supply. Over 4,000 species of native bees in the U.S. depend upon a wide variety of flowers and plants for both habitat and forage. Yet, the drastic declines in our nation's honey bee and native bee populations continue to threaten the vitality of our nation's agriculture and environment. Protecting managed bees, native bees and other pollinators is vital to the success of U.S. agriculture. It is estimated that one in three bites of food is

[19] Wild Farm Alliance. 2008. Environmental Destruction in the Salinas Valley: "Food Safety" Requirements to Remove Habitat Make Leafy Greens Less Safe. Available at: http://www.wildfarmalliance.org/resources/WFA%20FS%20EnvDestruct2.pdf.
[20] 7 CFR § 205.200 and §205.2
[21] 7 CFR § 205.200 and §205.2

reliant on honey bee pollination, and threats to pollinators jeopardize some of our nation's most important specialty crops. In the U.S., pollination contributes $20-30 billion in value to crop production annually.[22] Many of the nation's agricultural areas already lack sufficient habitat to support pollinators, and any policies requiring farmers to eliminate the already sparse wildlife habitat would be the nail in the coffin for countless pollinator species. Encouraging farmers to remove native habitat would adversely affect non-chemical pest control strategies, detract from natural resource conservation efforts, and be in direct conflict with OFPA.

A balance between food safety concerns and natural resource conservation can be struck by realizing the roles each play in building healthy agroecosystems. Food safety and conservation concerns can be addressed in tandem through co-management techniques that are designed for site-specific conditions.[23] For example, vegetation along streams, filterstrips, and wetlands are effective conservation practices that can help protect water supplies from pathogen-laden runoff by providing filtration. Since maintaining agricultural water quality is another focus of the Produce Rule, it would serve farmers well to maintain surface water quality to the greatest extent possible by taking advantage of the important ecosystem services that conservation practices afford. Hedgerows and native habitat strips can prevent pathogens in dust from blowing onto produce fields. Maintaining wildlife habitat to support beneficial predator populations, as mentioned above, can also play an important role in suppressing pests and contributing to food safety. CFS agrees with FDA that a national list of 'animals of concern' should not be established at this time because different animals present different food safety concerns across the country and because there is not a strong enough body of scientific evidence upon which to base a nationwide list of 'animals of concern.'

It is crucial that the produce regulations acknowledge the role of conservation practices in preserving food safety and that they do not unintentionally disincentivize these techniques. FDA must be proactive in the text of the regulation, making it clear that farmers do not need to eliminate the natural environment in which they grow their crops in order to meet food safety requirements. While some of the language in the preamble is encouraging in this regard, it must be incorporated into the actual text of the regulations to ensure that it FSMA is not in any way construed as requiring habitat removal. While the practices laid out in the Produce Rule do not specifically advocate removing conservation plantings, they remain silent about the implementation of conservation practices that can also provide food safety benefits. Without specifically prohibiting or discouraging measures that curtail biological conservation and destroy wildlife habitat, in the absence of compelling reasons for doing so, the proposed rules leave open the option for buyers to create private purchasing agreements that mandate removing or discontinuing conservation measures. Since many U.S. farmers participate in USDA's Conservation Stewardship Program and the Environmental Quality Incentives Program, final regulations must be sufficiently flexible to allow farmers to implement these program requirements in areas where covered produce is grown. Otherwise, organic growers would be notably disadvantaged because they would not be able to comply with the drastic mandates of private purchasing agreements *and* OFPA, which necessitates that farmers implement biodiversity conservation practices on their farms.

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[22] EPA. 2013. "USDA and EPA Release New Report on Honey Bee Health." EPA Newsroom, May 2. http://yosemite.epa.gov/opa/admpress.nsf/0c0affede4f840bc8525781f00436213/e04602a5e7aa060685257b5f004a12d3!OpenDocument.

[23] Wild Farm Alliance and Community Alliance with Family Farmers. 2013. Farming with Food Safety and Conservation in Mind. Available at: http://wildfarmalliance.org/resources/WFACAFFFS2013.pdf.

Biodiversity Recommendations in Support of Organic

FDA can support on-farm conservation practices more definitively in its final rule by incorporating strong statements in support of biodiversity and habitat conservation into the text of the regulations. The introduction to the Produce Rule already does this by encouraging "the application of practices that can enhance food safety, including sustainable conservation practices."[24] It further states that the "proposed rule would not require the destruction of habitat or the clearing of farm borders,"[25] but this language is not detailed within the regulations themselves. If FDA does not protect the rights of organic farmers to use practices that co-manage food safety and conservation, then FDA will be constraining growers from becoming and continuing to be certified organic.

To aid FDA in addressing natural resource conservation and habitat protections in its food safety rules, CFS recommends that it incorporate statements and concepts from the preamble into the regulatory text in the definitions, training requirements, and domesticated and wild animal standards. We specifically recommend the following language additions:

1. Include in § 112.3 the following definition of "co-management": "Co-management means farm system management approaches that respond to site specific conditions by integrating cultural, biological and mechanical practices that promote ecological balance and public health by conserving biodiversity, soil, water, air, energy and other natural resources, while also reducing pathogen hazards associated with food production."

2. Include under § 112.22(a) a new subsection (4) regarding minimum requirements for training personnel who conduct a covered activity: "(4) The importance of the co-management of food safety and conservation, including recognizing that sustainable conservation practices can enhance food safety and not taking measures to destroy wild animal habitat, take endangered species or exclude all wild animals from the farm."

3. Include under § 112.83 new subsections (c) and (d) regarding animal intrusion:

> "(c) If significant wild animal intrusion, as made evident by observation of significant quantities of animals, animal excreta or crop destruction occurs:
>
> (1) You must not destroy wild animal habitat;
>
> (2) You must not clear farm borders around outdoor growing areas, ponds, or drainages;
>
> (3) You must not take an endangered species; and
>
> (4) You must focus measures on excluding only those specific animals and not all animals.
>
> (d) Whenever appropriate, use co-management and sustainable conservation practices that can enhance food safety."

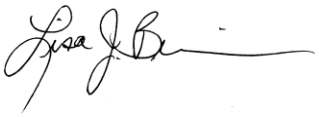
[24] Federal Register. 2013. 78(11): 3586.
[25] Federal Register. 2013. 78(11): 3586.

Conclusions

CFS supports efforts by the FDA to swiftly adopt food safety measures, as directed by Congress through the passage of FSMA. However, we caution the Agency to not institute regressive and draconian measures with respect to the spreading of compost and animal manure and with respect to natural resource conservation and habitat management. Instead, we strongly urge FDA to consult with the National Organic Program and OFPA's organic rules to determine how best to address these important soil fertility and pest management strategies so that the regulations of both agencies mutually support the continued growth of the organic sector with integrity.

Thank you for your consideration of our comments.

Respectfully submitted,



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