FOOD & FARMING NETWORK

Building Northwest Michigan's Agricultural Future




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5630 Fishers Lane, Rm. 1061
Rockville, MD 20582

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

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 comments on the proposed rule for Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food

To Whom It May Concern:

The Northwest Michigan Food & Farming Network appreciates the opportunity provided by the Food and Drug Administration (FDA) to submit comments on the proposed rule for Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption ("Produce Rule"); and comments on the proposed rule for Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food "Preventive Controls Rule").

The Northwest Michigan Food & Farming Network is comprised of leaders, organizations and businesses in the sectors of farming, health, economic development, land conservation, school food, retail and local food economy initiatives in a 10-county region in rural Michigan. The Network's overarching goal is that by 2020 the region's food and farming systems are more resilient and provide at least 20% of our region's food. This goal aligns with the Michigan Good Food Charter, which was developed by a broad cross section of stakeholders from throughout the state. It outlines 25 agenda priorities for the next 10 years and has been endorsed by the Michigan Commission on Agriculture and Rural Development and the Michigan Departments of Agriculture and Rural Development; Community Health; and Education. The Northwest Michigan Food & Farming Network is chaired by MSU Extension and convened by the nonprofit Michigan Land Use Institute, which catalyzed a regional local food branding initiative entitled *Taste the Local Difference* that engages nearly 300 participating farms.

As community food system leaders, we are committed to the belief that everyone deserves safe, healthy food and that small and mid-scale family farms selling into local markets with shorter supply chains are part of the solution to providing this food. These farms also are providing much needed access to healthy food for lower income families in our region and they are at the forefront of farm to school programs that are proven here and across the country to be effective in engaging children in developing healthy eating habits.

Our region's Chamber of Commerce and its Economic Development Corporation, farm and food businesses, and nonprofit organizations have made major investments over the last decade to build profitable local food markets and regional access to healthy food. We fear that the new FDA rules will reverse those gains and halt additional progress because the FDA's definition of farms and facilities are

unclear; the exemptions for small farms are confusing and often subjective; and costs that farmers will incur in order to comply with the regulations are excessive and not scaled to the appropriate level of risk. We ask that FDA, as it undertakes its important role in advancing food safety, will take the time to understand the nuances of today's modern agriculture, which is not one-size-fits-all, and make appropriate changes.

Scope of local food systems impact: In order to achieve its 20% by 2020 goal, members of the Food & Farming Network have worked strategically to build the region's local food infrastructure and support services. Small- to mid-scale farms and other businesses have made significant investments to meet the market demand and interest in buying locally grown food by our region's grocery stores, restaurants, schools, hospitals, and other institutions. Our regional Council of Governments obtained a Food Hub grant that is catalyzing a food innovation district that includes a local foods distribution company and a consortium of small to mid-scale growers that will aggregate fruits and vegetables and provide minimal processing to meet area school, restaurant and retail needs. Our regional MSU Cooperative Extension Services and Soil Conservation Service have provided crucial production training and food safety tools that are scale-appropriate and provide needed food safety without the high costs that the FDA rules threaten to impose; the Michigan Land Use Institute works with area schools on purchasing locally grown food, including eight districts in four counties that are a part of a USDA National Farm to School Grant; our regional Chamber of Commerce pledged to work only with vendors who would source at least 20% local food for its events and challenged all of its business members to do the same; the chamber's Economic Development Corporation created a 2020 bridge loan fund for local farm and food entrepreneurs in order to support innovative business ideas; and our region's direct market sector has spurred a growth of farmers markets from only a handful a decade ago to 34 public markets now, and with markets accepting SNAP payments and incentive programs like Double Up Food Bucks that benefit low income families; one major employer provides an online ordering system for its employees to order from small local farms as a wellness benefit; and dozens of Community Supported Agriculture farms provide households with weekly groceries. The products grown here include fruits, vegetables, hops for area breweries, vineyards and a growing sector of proteins. With the move in previous decades toward a more globalized and consolidated food system, the infrastructure to support small and mid-scale farms declined. From 2002-2007, though, the number of farms in Michigan *increased* from 53,315 to 56,014. Many of these new farmers are small-scale entrepreneurs seeking to create shorter supply chains through direct marketing to meet the demand for healthier, local, and more sustainably produced food. The growth in the local food market sector here also has spurred additional business investment, including a local foods distribution company, Cherry Capital Foods, which was established in 2007, employs 23 people and provides food safety assurances to customers through its own business GAP certification.

The Northwest Michigan Food & Farming Network and the region's entrepreneurial farmers recognize the critical importance of providing healthy and safe food for our nation's tables. However, we are concerned that the rules do not indicate sufficient understanding of the differing levels of risk between large national and international-scale agricultural operations and those that serve largely local markets, nor the innovations that small farms and small-farm product aggregation centers (Food Hubs) are developing that are building rural economies and access to healthy food for all of our citizens. With short supply chains in regional food markets, local health officials are able to spot, track down and stem the spread of foodborne illnesses quickly, unlike the problems that arise from large national and international processing facilities with huge flows of product that are co-mingled. A one-size-fits-all approach does not make sense and wasn't intended by Congress when it wrote the FSMA law.

Please ensure regulations are scale appropriate and allow innovation in local and regional food systems to continue. We provide comments on the proposed Produce Rule and the Proposed Preventive Controls Rule below, with these overarching goals in mind. These improvements must be made in order for the regulations to work for small and mid-scale farms, and for regional food systems to continue building

jobs and providing access to healthy food. Our comments reflect our own concerns and experiences as food systems leaders and of small and mid-scale farmers who have provided comments to the Network to forward on to you, via interviews and from meetings they have held regarding the FDA rules. Our comments also includes research and language of the National Sustainable Agriculture Coalition, of which Network convenor Michigan Land Use Institute is an active member, and which other organizations in the Network and farms in the region actively follow for its careful consideration and advocacy for regional and sustainable food systems.

Given the large number of serious problems in the proposed rules, it is our strong view that FDA should release a second, substantially revised set of proposed rules for public comment before finalizing these regulations. An interim final rule for public comment would not be satisfactory because it would trigger implementation of very flawed set of rules.

Thank you for considering our comments.

Sincerely,

Rob Sirrine, Ph.D.
Chair, Northwest Michigan Food & Farming Network
Community Food Systems Educator, MSU Extension
Affiliate, MSU Center for Regional Food Systems

Comments on Issues in the Proposed Produce Rule

I. Comments on the Overall Regulatory Framework

A. An Integrated Approach to the Produce Rule is the Correct Approach

In the proposed Produce Rule, FDA has implemented part of the requirement from the Food Safety Modernization Act (FSMA) to "minimize, as appropriate, the number of separate standards that apply to separate foods" (P.L. 111-353, § 105(a)(c)(1)(D)). Specifically, FDA has taken an "integrated approach" and has not set forth separate standards for separate foods (with the sole exception of sprouts) in the proposed Produce Rule.

The Food & Farming Network believes it is critical to take this integrated approach. Smaller-scale diversified farms in northwest Lower Michigan have in the last two years invested in their businesses to meet a gap in our region for vegetables at a scale that can serve school needs. While our region is rich in commodity fruit production, vegetable production is generally the purview of the smaller scale Community Supported Agriculture and other small to mid-scale farms. These farms typically plant a wide diversity of crops rather than the mono-cropping that is more prevalent for commodity farms. This farmer consortium of diverse-product farms investing in this school market project are operating with business models that do not include scaling up to commodity scale agriculture. Instead, they are interested in scaling up in one or two products each that they each grow well in order to meet school needs for vegetables. A "commodity specific" approach for farms would be overly burdensome and expensive and deter farms from investing in such innovative approaches to meet regional school needs and other local market opportunities with retailers and restaurants in close proximity.

As another example, here is a quote from comments that another farmer in our region is providing to FDA in his own comments. This farmer is larger in scale than those farms mentioned above, with an 80-acre diversified fruit and vegetable farm. He sells largely into local retail, restaurant and school markets, and also to some processors. This farmer also is an MSU Extension Director emeritus, very well connected to the broad range of our region's farming community from small grower to large. Here is one paragraph from his comments to you in a separate document:

"I firmly believe that we need to provide safe food to consumers and we need to avoid practices that cause health problems for the consuming public. Our farm has been food safety certified by the Michigan MAEAP Food Safety Program. We have a food safety plan but have avoided USDA GAP and other certification programs (Primus, etc.) mainly due to the cost as we are a very diversified operation and the cost to certify every crop would be extremely expensive (approximately $800 per crop per certification annually). It is my hope that once the FSMA rules are in effect, that only 1 integrated certification is needed per farm as good practices have a lot of similarity for most crops. It's more the attitude toward food safety than anything else. The important thing in my mind is for farmers to be educated on good practical and scientific practices that will produce safe food. I think education will yield better results than regulation because then the attitude will likely be right."

Recommendation: FDA should retain its "integrated approach" in the final Produce Rule and should not take a commodity-specific approach.

B. The $25,000 Gross Sales Exemption Must be Fixed to Apply Solely to Covered Produce as Provided by FSMA

When writing FSMA, Congress rejected a "one-size-fits-all" approach, and provided FDA with flexibility to ensure that the Produce Rule worked for a diversity of farming operations. Specifically, FSMA requires FDA to "provide sufficient flexibility to be applicable to various types of entities engaged in production and harvesting of fruits and vegetables that are raw agricultural commodities, including small businesses and entities that sell directly to consumers, and be appropriate to the scale and diversity of the production and harvesting of such commodities" (P.L. 111-353, § 105(a)(a)(3)(A)).

In its proposed Produce Rule, FDA proposes to exempt farms with an average annual monetary value of food sold during a previous three-year period of $25,000 or less. In the preamble to the rule, FDA tentatively concludes that "farms with $25,000 or less in sales do not contribute significantly to the produce market" and that they account for "only 1.5% of covered produce acres" (78 F.R. 3549).

The exemption for farms with $25,000 or less in gross sales is consistent with Congress' mandate to create risk-based requirements that reflect the diversity of the farming systems. The farms eligible for this exemption represent a tiny fraction of the food supply and should not be regulated under the Produce Rule. While they represent a tiny fraction of the food supply, these farms are very important for the region's tourism economy, with many small-roadside stands and u-pick operations a hallmark stop for visitors.

Instead of focusing the exemption on the gross sales of all food, however, FDA should focus the exemption on the value of covered produce. This distinction will provide some flexibility in the rule for beginning farmers, non-produce farmers who are trying to diversify their production, and family farmers who want to diversify their operations.

For example, in northwest Lower Michigan, a growing number of farms are working to supply the region with locally grown meat, eggs and milk. Another opportunity for their operations is the growing demand

for vegetables, both by households and also by our region's schools, which under new USDA rules must serve substantially more fruits and vegetables. However, if these farms devote a small portion of their operations to vegetable production and non-orchard fruits such as blueberries that schools desire but can't find in sufficient quantity regionally, they will have to include the value of the higher profit meat, eggs and milk and thus be forced to comply with the full Produce Rule and absorb its high compliance costs. This will dissuade growers from diversifying to serve a market that carries such promise for business expansion and student health. Results of the first-ever U.S. Department of Agriculture Farm to School Census reveal over $350 million dollars were re-invested into local economies. Findings from the Census also reveal that 56 percent of school districts that already have farm to school programs plan to spend even more on local purchases in the coming year. As we noted in our cover letter, eight districts in our region are participating in a USDA National Farm to School grant project with goals of making local food purchasing routine.

In addition, small growers at meetings to learn more about FDA's proposed food safety rules said that including all of the products that they produce rather than just produce could cause them so much additional expense that they would be forced to close their farmstand operations. This is true for young farmers selling into farmers markets as well, which is seen by farms in our region as an important entry-level market for beginning farmers to start building up profitable businesses. One farmer who provided comments to the Network also stated that $25,000 is not high enough: "*That isn't very much and will only limit expansion and contribute to unreported sales. This sales cap does not provide for income or profit."*

Recommendation: FDA should retain the $25,000 exemption *(or increase it)* in the final Produce Rule but should base it on the value of produce covered by the Produce Rule produced on the farm and not the value of food, as defined in § 201(f) of the Federal Food, Drug, and Cosmetic Act and referenced in § 112.3(c) of the proposed Produce Rule, sold by the farm.

C. Requiring Farm Food Safety Plans and on Farm Registration is Inconsistent with FSMA and Unreasonable

In the preamble to the proposed Produce Rule, FDA requests comment on whether the agency "should require, in a final rule, some or all covered farms to perform operational assessments and/or develop a food safety plan, and any criteria that should be employed to determine which farms should be subjected to such a requirement" (78 F.R. 3619). Additionally, FDA requests comment on whether the agency "should require, in the final rule, that covered farms, as described in proposed § 112.4(a), register with FDA" (78 F.R. 3619).

FSMA does not authorize FDA to require farms to perform operational assessments or develop food safety plans. While some farms may perform operational assessments or have food safety plans, and farms may benefit from food safety plans, requiring that all covered farms perform operational assessments or develop food safety plans is outside of the scope of FSMA. Codifying this requirement via regulation would be inconsistent with the statute and would increase costs of compliance for covered farms, would further decrease the flexibility of the regulations, and would risk applying a "one-size-fits-all" approach that Congress clearly rejected. There are several non-governmental organizations, farm groups, and private businesses that are working with farmers on appropriate food safety planning, and that work should be allowed to continue outside of the scope of federal regulations.

In our region, for example, the Grand Traverse Conservation District, an active member of the Food & Farming Network, is assisting farmers in two tandem food safety programs. The Michigan Agriculture

Environmental Assurance Program (MAEAP) helps farmers undertake voluntary management changes that will reduce the threat of groundwater contamination and improve the quality of our region's fragile watersheds.

The Michigan Safe Food Risk Assessment is a voluntary, small-farm, scale-appropriate program designed to educate producers about food safety and recognize those who use safe food management practices while protecting consumer safety. This tool is designed to educate farmers about Good Agricultural Practices, which minimize the risk of microbial contamination of fruits and vegetables. Using this tool helps growers examine their farm practices, identify any risks to food safety, and develop an action plan to minimize those risks. It examines many things including worker health and hygiene, water useage, sewage treatment, animal/wildlife/livestock exclusion, manure and municipal biosolids application, soils, field sanitation and hygiene, field harvesting and transportation, produce packing, produce traceability, pesticide and crop protection materials.

By addressing these key areas, farmers build awareness of food safety on their farm and can reduce their risk for microbial contamination. Farmers who complete the assessment with a passing score receive a certificate which can be used to demonstrate that they are implementing responsible practices to deliver safe, high quality food to their customers. As part of the larger movement to increase the resiliency of our local food systems, this tool helps ensure the safety, profitability and viability of the system. Requiring FDA registration or any extra licensing is duplicative and provides undue time and financial constraints on growers. Long-term financial viability of programs like the Michigan Food Safe Assessment will provide the best results.

FSMA does not authorize FDA to require farms to register with FDA. In the preamble, FDA fails to establish how requiring farms to register would contribute to improved food safety outcomes in produce production. Without a robust justification, and with no legal basis for requiring registration, FDA cannot and should not require farms to register.

Recommendation: FDA should not require farms to perform operational assessments or develop food safety plans in its final Produce Rule. FDA should not require farms to register with FDA in the final Produce Rule.

D. The Scope and Magnitude of Problems in the Proposed Rule Requires Promulgation of a Second Proposed Rule

FDA's proposed Produce Rule fails to meet a number of the significant requirements of FSMA. FSMA requires FDA to establish "minimum science-based standards for those types of fruits and vegetables, including specific mixes or categories of fruits or vegetables, that are raw agricultural commodities, based on known safety risks, which may include a history of foodborne illness outbreaks" (P.L. 111-353, § 105(a)(b)(1)). Additionally, FSMA requires FDA to "provide sufficient flexibility to be applicable to various types of entities engaged in production and harvesting of fruits and vegetables that are raw agricultural commodities, including small businesses and entities that sell directly to consumers, and be appropriate to the scale and diversity of the production and harvesting of such commodities" (P.L. 111-353, § 105(a)(a)(3)(A)).

The proposed produce standards are not sufficiently supported by adequate scientific evidence, and are not supported by a quantitative risk assessment, to be considered either science-based or risk-based. Additionally, a number of the standards are very prescriptive and do not provide sufficient flexibility; in fact, some of the proposed requirements would severely limit certain types of production, particularly sustainable agricultural systems, including certified organic production. We provide details on these points in the comments on the proposed standards below.

Recommendation: Given the failure to meet very central requirements of FSMA, FDA should release a second proposed rule for public comment that incorporates the mandates of FSMA and the recommendations in this comment before finalizing the Produce Rule.

II. Comments on the Proposed Standards

A. Subpart E—Standards Directed to Agricultural Water Fails to Meet the Requirements of FSMA for a Science- and Risk-Based Approach and Must be Thoroughly Revised

The proposed Subpart E—Standards Directed to Agricultural Water fails to meet the requirements of FSMA. Specifically, FSMA requires FDA to:

- Establish "minimum science-based standards for those types of fruits and vegetables, including specific mixes or categories of fruits or vegetables, that are raw agricultural commodities, based on known safety risks, which may include a history of foodborne illness outbreaks" (P.L. 111-353, § 105(a)(b)(1)); and
- "Provide sufficient flexibility to be applicable to various types of entities engaged in production and harvesting of fruits and vegetables that are raw agricultural commodities, including small businesses and entities that sell directly to consumers, and be appropriate to the scale and diversity of the production and harvesting of such commodities" (P.L. 111-353, § 105(a)(a)(3)(A)).

FDA's proposed agricultural water standard fails to meet the FSMA requirement for science-based standards. It adopts the Environmental Protection Agency's (EPA) recreational water standard and applies it to agricultural water. FDA acknowledges that this standard was "developed from epidemiological studies that correlated the risk of gastrointestinal illness to exposure to marine and freshwater by swimmers" (78 FR 3563). FDA is proposing to adopt this standard in the absence of other appropriate existing standards for irrigation water. There is no scientific basis developed, however, for the standard's use in produce production as an appropriate test for food pathogens.[1]

FDA does not adequately establish a risk-based approach in its proposed water standard and instead mandates testing requirements to the EPA's recreational water standard regardless of risk. FDA has not quantified the risks of using different types of water (e.g., surface or groundwater) in different parts of the country and in different farming systems, and instead assumes that the risk is significant, even though there may not be historical evidence for that conclusion. As currently proposed, FDA establishes a prescriptive standard applied to every farm that must comply with the Produce Rule standards regardless of critical factors such as risk, climate, location, farming system, and water source.

Because the standard is prescriptive and applies regardless of risk, climate, location, farming system, or water source, the standard also fails to meet the FSMA mandate to be flexible. Specifically, the standard is inflexible because it requires farmers to ensure that their water meets EPA's recreational water standard through weekly testing (surface water) and monthly testing (groundwater).

While FDA has allowed for "alternatives" for certain requirements in the water standard, the limited scope and requirements for an alternative make them untenable for farmers to use. The alternatives apply very narrowly and not to the entire standard. Additionally, the burden of proof is on the farmer to have

[1] Suslow, Trevor V. *Standards for Irrigation and Foliar Contact Water*, Produce Safety Project Issue Brief, Georgetown University, 2010.

adequate scientific data or information to show that the alternative would "provide the same level of public health protection as the applicable requirement" in the proposed standards (§ 112.12(b)). In other words, FDA is placing the burden on farmers and private entities to conduct research on public health risks generally – a task that FDA has been unable to fulfill. It is inappropriate to be placing such a significant burden on farmers and private entities and then claiming to be offering flexibility. As currently proposed, the option for alternatives would not provide true additional flexibility in the water standards.

Additionally, in FDA's 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, FDA acknowledges that the proposed water standard may lead to increased groundwater depletion because the application of the standard to surface water supplies in some regions is unworkable (78 F.R. 50359). This is a significant concern that points to the inappropriate nature of the standard and that must be addressed in the final rule.

Following is a quote from the northwest Michigan farmer leading the farmer consortium that is investing to scale up vegetable production for school needs. He was named Michigan Farmer of the Year by Michigan Food & Farming Systems, has a bachelor of science degree from Carnegie Melon University with a double major in biological sciences and economics and a minor in chemistry; and a master of science degree in plant breeding and genetics from Ohio State University. He has been a leader in area food safety, season extension, sustainable farming production practices and other trainings for beginning and small farmers. He intends to provide FDA with his own written comments, but for our purposes he said his biggest concern with many of the rules is a lack of scientific basis for them, including the testing of surface water. Yet, the financial impact of the rules will be great on farms. He said: "Complete compliance with very frequent testing would eliminate their ability to irrigate and produce quality crops."

Our MSU Extension Director emeritus farmer quoted earlier in this document, agrees: "I would think that doing water sampling once a year whether ground or surface water would be sufficient unless other risk factors are present that indicate that contamination has a probable chance of occurring. Many of us have irrigated produce crops from ponds on the farm, putting water on the harvestable part of the crop without an incident for many years…I think treating water sampling as "one size fits all" will lead to high costs with no returns."

Recommendations on Subpart E: In the final Produce Rule, FDA must take a reasonable, science- and risk-based approach to agricultural water that allows farmers to respond to specific risks in their water systems. Specifically (based on findings from the National Sustainable Agriculture Coalition):

- FDA should not include inappropriate numerical thresholds for presence of pathogens or pathogen indicators (i.e., generic *E. coli*) in water, and it should conduct sufficient research to develop an appropriate, science-based numerical standard, which might vary according to the region.
- Once sufficient research has been conducted to inform the development of an appropriate, science-based numerical standard, it is imperative that the numerical standard be included in guidance, not in the regulation itself. This allows for the standard to be updated if new research becomes available about appropriate agricultural water standards.

- FDA should not require weekly water testing; FDA should instead require farmers to collect monthly baseline information about their water systems in the first growing season and to base future actions and testing frequencies on those results.
- FDA should not increase pollution and decrease the safety of the food supply by encouraging treatment of irrigation water with chemicals.

B. Comments on Subpart F—The Proposed Standards for Biological Soil Amendments of Animal Origin and Human Waste Violate the Requirements of FSMA, Harm Conservation, and Would Put Entire Categories of Farms out of Business and Therefore Must be Thoroughly Revised

The proposed Subpart F—Standards Directed to Biological Soil Amendments of Animal Origin and Human Waste fails to meet the requirements of FSMA. Specifically, FSMA requires FDA to:

- Not "conflict with or duplicate the requirements of the national organic program established under the Organic Food Production Act of 1990…" (P.L. 111-353, § 105(a)(a)(3)(E));
- "Provide sufficient flexibility to be applicable to various types of entities engaged in production and harvesting of fruits and vegetables that are raw agricultural commodities, including small businesses and entities that sell directly to consumers, and be appropriate to the scale and diversity of the production and harvesting of such commodities" (P.L. 111-353, § 105(a)(a)(3)(A));
- Establish "minimum science-based standards for those types of fruits and vegetables, including specific mixes or categories of fruits or vegetables, that are raw agricultural commodities, based on known safety risks, which may include a history of foodborne illness outbreaks" (P.L. 111-353, § 105(a)(b)(1)); and
- "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 environment agencies" (P.L. 111-353, § 105(a)(a)(3)(D)).

The Food & Farming Network is relying on extensive findings and language below from the National Sustainable Agriculture Coalition. The comments from the leader of the vegetable farmer consortium, quoted above, apply to this section as well: a broad sense that these rules conflict with traditional ecological growing practices and are not based in appropriate science. Farmers in our region using compost, manure and other long-established organic agriculture practices said at a recent meeting that they believed strongly that "there is inadequate scientific background" for this section and it needs "more informed requirements."

FDA's proposed standard for biological soil amendments fails to meet the requirements of FSMA because the standard directly conflicts with the requirements of the national organic program established under the Organic Food Production Act of 1990. Congress was very clear in FSMA that nothing in the proposed Produce Rule should undermine organic production practices, yet FDA has ignored this mandate.

The intervals between application and harvest that FDA is proposing – specifically the nine-month interval on untreated amendments and the 45-day interval for compost – are in direct regulatory conflict with the National Organic Program (NOP) regulations. These intervals could cause a number of organic farmers to be found in non-compliance with NOP and, therefore, to risk losing their organic certification. This is exactly the situation that Congress specifically sought to avoid and prohibit when it prohibited FDA's produce standards from conflicting with the requirements of NOP (P.L. 111-353, § 105(a)(a)(3)(E)).

The proposed standard conflicts with the soil fertility and crop nutrient management practice standard of the NOP regulations (7 C.F.R. § 205.203). With respect to manure, NOP allows farms to use raw manure fertilizer if it is applied 120 days before harvest if the crop's edible portions come into contact with the soil directly, or 90 days before harvest if the edible portions do not come into contact with the soil. In the proposed Produce Rule, FDA proposes a nine-month restriction when the covered produce does not come into contact with the amendment during application, but may come into contact with an untreated biological soil amendment of animal origin, such as raw manure, after application (§ 112.56). FDA is proposing a zero-day interval if the untreated amendment does not come into contact with the covered produce during or after application. With respect to compost, NOP regulations do not set an interval between application of manure treated by a composting process that is consistent with NOP composting standards and harvest; FDA is proposing a 45-day restriction (§ 112.56), and the NOP regulations do not require insulation of compost (§ 112.54).

If FDA adopts these intervals in the final rule and does not change these intervals to align with NOP requirements, then FDA will be forcing organic farmers out of compliance with NOP regulations and actively discouraging farmers 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 U.S. Farmers need to use fertilizer to grow crops, but organic farmers are prohibited from using the synthetic-based chemicals that non-organic farmers use for fertilizer; they rely instead of biological fertilizers such as manure and compost. The nine-month interval between the application of raw manure and harvest proposed by FDA would effectively eliminate the use of manure for most organic produce farms and create additional barriers to the use of compost made with animal materials.

Because the biological soil amendment standard requirements directly conflict with NOP regulations, the proposed standard fails to provide sufficient flexibility for various types of entities engaged in produce production and specifically, for certified organic producers. Certified organic producers would be forced out of compliance with NOP regulations for the reasons described above. This is an entirely inflexible approach.

While FDA has allowed for "alternatives" for certain requirements in the soil amendment standard, the limited scope and requirements for an alternative make them untenable for farmers to use. The alternatives apply very narrowly and not to the entire standard. Additionally, the burden of proof is on the farmer to have adequate scientific data or information to show that the alternative would "provide the same level of public health protection as the applicable requirement" in the proposed standards (§ 112.12(b)). In other words, FDA is placing the burden on farmers and private entities to conduct research on public health risks generally – a task that FDA has been unable to fulfill. It is inappropriate to be placing such a significant burden on farmers and private entities and then claiming to be offering flexibility. As currently proposed, the option for alternatives would not provide true additional flexibility in the biological soil amendment standards.

Additionally, FDA's biological soil amendments standard fails to meet the FSMA requirements to be science-based. There has been very little research conducted on many of the topics related to the application waiting periods for raw manure and compost and there is not substantial evidence to make "science-based" standards. In the preamble, FDA recognizes that "pathogen survival and die-off time in soils amended with raw manure are extremely varied" and that "it is unclear in the existing literature at what point the population is low enough to minimize the potential for contamination of covered produce" (78 F.R. 3582).

For those pathogens that are more commonly associated with fresh produce, such as *E. coli* O157 and *Salmonella*, several of the references FDA cites are not applicable because abnormally high rates of pathogens were used, measurements of pathogen survival were made in manure not soil (when growers use manure, they incorporate it into soil), and sterile soil was used unlike typical soils that support diverse microorganisms antagonistic to the pathogens. In our review of the literature, we found 10 studies where *E. coli* O157, *Salmonella*, *Campylobacter*, and *Listeria* survived for fewer than 120 days (which is the NOP interval). Part of FDA's unjustified argument is based on studies that focused on pathogens such as *Cryptosporidium*, *Giardia*, and *Ascaris* (parasitic flat worms); these pathogens are not commonly associated with fresh produce outbreaks. So, even if the studies show that these pathogens usually are not present in the soil for more than a year, using these studies to justify very long waiting intervals is not appropriate because these pathogens are not commonly associated with fresh produce outbreaks. A study FDA cites that supports our stand for 120 day waiting period notes that with cycles of freezing and thawing pathogen survival is decreased significantly.

FDA chose to justify the nine-month interval between the application of manure and harvest based on too few relevant studies, and FDA needs to conduct a comprehensive review of the literature. For compost, it is not clear how the agency decided on the 45-day interval and how the literature cited supports this conclusion.

Another problematic area in the standard is around requirement insulation of compost. It is not practical to apply insulation to compost, as FDA proposes, and doing so could decrease the quality of the compost and increase the cost. In the preamble, the suggestion is made that adequate curing includes proper insulation "usually consisting of around one foot thick of insulating material, e.g., hay, straw, finished compost" (78 F.R. 3580). During the curing process, which can take up to three months, the compost may need to be turned many times because the carbon dioxide could increase to unacceptable levels, or the compost could become too dry and require water be mixed into it. If one-foot-thick layer of hay or straw is on the compost that needs turning, it will change the C:N ratio of that turned product and require the whole pile/windrow to be re-composted. If the compost is re-composted, and then another insulation layer is reapplied during the curing process, the same problem could occur where the compost needs turning, leading to an unending situation of re-composting/insulating/turning.

Finally, in FDA's 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, FDA acknowledges that the proposed biological soil amendment standard requirements as proposed "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" (78 F.R. 50359). The use biological soil amendments of animal origin is a foundational practice in sustainable production systems that aligns with existing conservation practices, and the proposed standards create a barrier to adoption of top-tier nutrient management and composting conservation standards. These are significant concerns that point to the inappropriate nature of the standard and that must be addressed in the final rule.

Recommendations on Subpart F: In the final Produce Rule, FDA must align its biological soil amendments of animal origin standards with the National Organic Program requirements and on-farm practices widely used in diversified, sustainable, and conservation-based production systems. Specifically:

- The interval between application of untreated manure and harvest should not exceed the intervals required by NOP.
- For compost, there should be no interval between application and harvest if the compost is treated consistently with NOP or similarly rigorous composting standards.

- To align with current best management practices, insulation of compost should not be required as part of an acceptable treatment process for compost.

C. The Produce Rule Fails to Comply with FSMA By Not Adequately Supporting Conservation Practices and Co-Management of Conservation, Environmental, and Public Health Considerations

FSMA directs FDA to be pro-active with respect to natural resource conservation, wildlife conservation, and environmental protection, and the proposed rule fails entirely in that regard, especially in light of recent experience. Specifically, FSMA requires FDA to:

- "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 environment agencies" (P.L. 111-353, § 105(a)(a)(3)(D));
- Not "conflict with or duplicate the requirements of the national organic program established under the Organic Food Production Act of 1990…" (P.L. 111-353, § 105(a)(a)(3)(E)); and
- "Provide sufficient flexibility to be applicable to various types of entities engaged in production and harvesting of fruits and vegetables that are raw agricultural commodities, including small businesses and entities that sell directly to consumers, and be appropriate to the scale and diversity of the production and harvesting of such commodities" (P.L. 111-353, § 105(a)(a)(3)(A)).

In the proposed animal standards, FDA does not require farmers to take any extreme measures to prohibit the presence of wild and domesticated animals in fields of covered produce, but FDA fails to protect against farmers being required to take extreme actions. Unfortunately, certain on-farm food safety certification regimes developed in response to outbreaks such as the 2006 spinach *E. coli* outbreak have created incentives for, or even forced, farmers to remove conservation practices and to actively exclude wildlife from their farms.[2] It is important to ensure against such requirements in the future and be proactive about supporting practices that benefit both food safety and conservation.

Many farmers participate in voluntary federal conservation programs such as the Conservation Stewardship Program and the Environmental Quality Incentives Program. These programs help farmers implement conservation practices and incorporate those practices into their farming systems. The final rule must ensure that there is sufficient flexibility in the standards for farmers to implement conservation practices.

FDA's proposed standard for wild animals also fails to meet the requirements of FSMA because the standard directly conflicts with the requirements of the national organic program established under the Organic Food Production Act of 1990. As mentioned above, Congress was very clear in FSMA that nothing in the proposed Produce Rule should undermine organic production practices, yet FDA has ignored this mandate.

The proposed standard conflicts with the "natural resources standard" of National Organic Program (NOP) regulations (7 C.F.R. § 205.200 and § 205.2). Organic operators must maintain or improve the natural resources (defined as soil, water, wetlands, woodlands and wildlife). It also conflicts with the "crop rotation standard" of NOP regulations (7 C.F.R. § 205.205 and § 205.2). Organic growers must provide for pest management in perennial crop systems by employing means such as alley cropping,

[2] *Farming with Food Safety and Conservation in Mind*, Wild Farm Alliance and Community Alliance with Family Farmers, 2013.

intercropping, and hedgerows to introduce biological diversity in lieu of crop rotation. Organic production is defined in NOP regulations (7 C.F.R. § 205.2) as a production system that integrates cultural, biological, and mechanical practices that foster cycling of resources, promote ecological balance, and conserve biodiversity.

If FDA does not protect the right of organic growers to use practices that co-manage for conservation and food safety, then FDA will be actively constraining growers from becoming certified organic and risk impairing the ability of existing organic growers to stay certified.

i. Produce Rule Must Incorporate Concept of Co-management and Sustainable Conservation Practices

Overall, FDA needs to more strongly support on-farm conservation practices by incorporating positive concepts and statements made in the preamble to the Produce Rule into the regulatory text itself. The preamble does not have the same force as the regulatory text, and it is important to include stronger statements about on-farm conservation in the regulatory text to ensure that the standards support the FSMA mandate to take into consideration conservation practice standards and ensure sufficient flexibility for different farming systems subject to the rule.

In the preamble, FDA includes important text on the interplay between food safety and conservation. Specifically, in the preamble FDA:

- Encourages "the application of practices that can enhance food safety, including sustainable conservation practices" (78 F.R. 3586); and
- States that the "proposed rule would not require the destruction of habitat or the clearing of farm borders" (78 F.R. 3586).

Farmers in our northwest Michigan region note that conservation practices provide important benefits to their farms and to society as a whole. One farm specifically plants field and farm areas to attract wildlife and improve the health of the farm ecosystem. Wildlife plantings also reduce soil erosion which farmers note can cause unhealthful water pollution including contaminated wells from agricultural chemical run-off when farms employ excessive tillage.

Recommendations: FDA should more strongly support conservation in the final Produce Rule by incorporating statements and concepts from the preamble into the regulatory text, in the definitions, training requirements, and domesticated and wild animal standards. Specifically, FDA should:

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."

ii. Produce Rule Must Support Diversified Crop-Livestock Farming Systems and Clarify Grazing

In the preamble, FDA states that the "proposed rule would not prohibit the use of on-farm domesticated working animals" (78 F.R. 3586). This is critical because many farms that grow produce covered by the Produce Rule rely on domesticated animals, such as draft horses, to produce their crops, and many farmers graze animals in fields that are later used for produce production.

Proposed § 112.82(a) would require an "adequate grazing period between grazing and harvesting for covered produce…." FDA provides additional guidance on that waiting period in the preamble and states that the agency "would not expect it to be necessary for such time periods to exceed 9 months, which is the application interval we propose for use of raw manure as a soil amendment…" (78 F.R. 3587). In addition to the significant issues with the nine-month waiting period between the application of raw manure and harvest (see comments above), FDA should not imply that an "adequate" waiting period is nine months because there is no scientific basis for that assumption.

Grazing animals leave feces on the surface of the soil exposed to sunlight. This allows UV radiation and desiccation from the sunlight to reduce survival of pathogens. In fact, one study showed significantly more rapid die off of *E. coli* O157 when livestock wastes were left on the soil surface than when incorporated.[3] More research is needed. Additionally, under most conditions, grazing animals do not leave the same amount of feces on a field as when raw manure is applied as a soil amendment. The parallel between feces dropped during grazing and raw manure applied as a fertilizer is not strong enough to argue for a similar interval and risks confusing farmers looking for guidance on what FDA means by "adequate" in proposed § 112.82(a).

Small farmers at a recent northwest Michigan regional meeting on the FDA regulations were bothered by statements such as "adequate grazing period" or "adequate distance" related to produce separation from animals. Some farm production practices integrate "working animals" of all types in and around their crop production. These farmers say it is imperative that FDA provide clear clarification based on science as to how close and at what interval animals and crops can co-exist.

Recommendations: FDA should remove the sentence from the preamble that states that the agency "would not expect it to be necessary for such time periods to exceed 9 months, which is the application interval we propose for use of raw manure as a soil amendment…" (78 FR 3587).

[3] Hutchison, M. L., L. D. Walters, et al. (2004). "Effect of length of time before incorporation on survival of pathogenic bacteria present in livestock wastes applied to agricultural soil." Applied and Environmental Microbiology 70(9): 5111-5118.

iii. Produce Rule Should Not Establish a List of "Animals of Concern"

In the preamble, FDA tentatively concludes that "current scientific evidence on the extent to which specific animals present the greatest risk for pathogens is inadequate to develop such a list" (78 FR 3586). We agree with FDA's conclusion and do not think that such a list is required by FSMA.

Recommendation: FDA should retain its current conclusion and should not develop a list of "animals of concern."

Comments on Issues in the Proposed Preventive Controls Rule

I. The Scope and Magnitude of Problems in the Proposed Rule Requires Promulgation of a Second Proposed Rule

FDA's proposed Preventive Controls Rule fails to meet a number of significant requirements from FSMA. FSMA requires FDA to promulgate regulations that "provide sufficient flexibility to be practicable for all sizes and types of facilities, including small businesses such as a small food processing facility co-located on a farm" (P.L. 111-353, § 103(a)(a)(n)(3)(A)). This requirement underpins Congress' mandate to establish a scale- and supply-chain appropriate regulatory framework for facilities. A number of specific provisions support that framework:

- FSMA requires FDA to conduct a science-based risk analysis of on-farm packing, holding, manufacturing, and processing activities, and to consider the results of that analysis to exempt or develop modified requirements for small or very small businesses that conduct only low-risk activities (P.L. 111-353, § 103(c));
- FSMA requires FDA to define "small business" and "very small business" for the purposes of the new Hazard Analysis and Risk-based Preventive Controls (HARPC) regulations, taking into consideration the results of the food processing sector study (P.L. 111-353, § 103(a)(n)(1)(B)); and
- FSMA requires FDA to amend the definition of "retail food establishment" to clarify that the sale of food directly to consumers includes the sale of food through community supported agriculture programs (CSAs), roadside stands, and farmers' markets (P.L. 111-353, § 102(c)).

FDA has failed to implement some of the statutory requirements for the Preventive Controls Rule, has partially implemented some of these requirements, and is seeking feedback on a variety of options. We provide details on these points in the comments on the proposed requirements below, but, overall, the proposed Preventive Controls Rule is incomplete and does not adequately establish a flexible regulatory framework, particularly for value-added businesses and on-farm processors.

Recommendation: Given the failure to meet a number of the requirements in FSMA, FDA should release a second proposed rule for public comment that incorporates the mandates of FSMA and the recommendations in this comment before finalizing the Preventive Controls Rule.

II. FDA Has Failed to Clarify the Definition of "Retail Food Establishment" for Direct Marketing as Required by Law

FDA has failed to implement the mandate from FSMA that requires FDA to amend the definition of "retail food establishment" to clarify that the sale of food directly to consumers includes the sale of food through community supported agriculture programs (CSAs), roadside stands, farmers' markets, and other direct-to-consumer venues (P.L. 111-353, § 102(c)).

Without this required clarification, CSAs, roadside stands, farmers' markets, and other direct-to-consumer platforms (including, but not limited to, farm stores, direct internet sales, tailgate markets, and pick-your-own operations) could be regulated like food facilities that must register with FDA and are subject to the Preventive Controls Rule. This would be inappropriate and inconsistent with the statute and with the clear Congressional intent that these entities are not required to register and are not subject to the Preventive Controls Rule.

As the Network noted in its opening letter, our region's direct market farms have grown substantially over the last decade from a handful of farmers markets to 34 and dozens of community supported

agriculture farms. It is imperative that these important, innovative market venues and farms be recognized as retail establishments. In another example, many community supported agriculture farms provide their customers with the option to purchase a product like strawberries grown on a nearby farm and pick it up at the main CSA farm with their regular box of other fruits and vegetables. As the rules are now written, it appears that the FDA may consider this CSA not just a farm but also an aggregation "facility" like a large processing plant and therefore subject to even more rules. Customers should have this commonsense opportunity to "one-stop-shop."

To repeat from our cover letter, we recognize the need for food safety. However, supply chains are so short within regional markets that local health officials will be able to spot, track down and stem any foodborne illnesses quickly; unlike the problems that arise from large national and international food processing facilities with huge flows of product that are co-mingled. A one-size-fits-all approach does not make sense, and wasn't intended by Congress when it wrote the FSMA law.

Recommendation: FDA must clarify, as part of a revised proposed Preventive Controls Rule, that the sale and distribution of food through a community supported agriculture program, roadside stand, farmers' market, or other direct-to-consumer platforms is included in the definition of sales direct to consumers for purposes of defining a "retail food establishment," as required by the FSMA statute.

III. FDA Should Adopt a "Very Small Business" Threshold of At Least $1,000,000 in Covered Product

In FSMA, Congress required FDA to define "small business" and "very small business" for the purposes of the new Hazard Analysis and Risk-based Preventive Controls (HARPC) regulations, taking into consideration the results of the food processing sector study (P.L. 111-353, § 103(a)(n)(1)(B)). These definitions are important for determining the scope of coverage of the Preventive Controls Rule; a very small business can qualify for modified requirements (P.L. 111-353, § 103(a)(l)) and small and very small businesses are exempt from the preventive controls requirements if they only conduct certain low-risk processing activities (P.L. 111-353, § 103(c)(1)(D)).

FSMA also requires FDA to "provide sufficient flexibility to be practicable for all sizes and types of facilities, including small businesses such as a small food processing facility co-located on a farm" when developing its HARPC regulations (P.L. 111-353, § 103(a)(n)(3)(A)). We note that the use of the phrase "**such as** a small processing facility co-located on a farm" (emphasis added) does not limit the application of this regulatory discretion solely to processing facilities co-located on farms.

In the proposed Preventive Controls Rule, FDA has proposed three options for the definition of "very small business":

1. A business that has less than $250,000 in total annual sales of food, adjusted for inflation;
2. A business that has less than $500,000 in total annual sales of food, adjusted for inflation; or
3. A business that has less than $1,000,000 in total annual sales of food, adjusted for inflation.

According to FDA's Preliminary Regulatory Impact Analysis, the highest threshold proposed (Option #3: $1,000,000 in total annual sales of food) would cover only a tiny percentage – less than two percent – of the food produced in the U.S. The impact of adopting the highest proposed threshold, or a higher threshold, would be minimal for the vast majority of facilities in the food processing sector.

For farms that might fall under the definition of "facility" and are considered "farm mixed-type facilities" under the proposed regulations, however, the impact of the decision on the threshold will have a very significant impact. Fifty-four percent of farms in the U.S. have gross sales under $1,000,000, though they

account for a minority share of the total farmgate sales. Under the current proposed definitions, a large number of farms will be considered "facilities" subject to the Preventive Controls Rule. The HARPC requirements are designed for industrial food facilities – not for farms – and do not provide sufficient flexibility and are inappropriate for on-farm processors. Adopting at least the $1,000,000 threshold will protect many farms from the inappropriate HARPC requirements without impacting the vast majority of the food processing sector.

Additionally, the FDA's proposed $1,000,000 option refers to gross sales of "all food" and not product regulated under the Preventive Controls Rule. While FSMA may require "all food" to be counted against the two-part eligibility test for farms and facilities that are eligible for modified requirements, that same restriction clearly *does not apply* to the definition of "very small business" (P.L. 111-353, § 103(a)(a)(n)(1)(B)). Focusing the definition of "very small business" on food regulated under the Preventive Controls Rule would provide flexibility to farms diversifying into new crops and new on-farm value-added enterprises, would help ease the compliance costs for farms and new value-added businesses, and would help focus limited FDA resources on high-risk industrial facilities.

Northwest Lower Michigan has numerous farms that are sharing equipment to lower costs, such as small, apple and potato washing and sorting lines. The vegetable farmer consortium mentioned earlier also is sharing in sorting, washing and minimal processing equipment for small growers to meet area school and retail needs in a newly developing food hub. This sorting and minimal processing is critical to meeting local market demands. Area schools, for example, have identified a need for fresh salad bar items because of the new USDA school food rules that require schools to serve more fruits and vegetables; and for pre-chopped carrots, floretted broccoli and other items that can be used fresh or frozen for stir fries and other hot menu items, but which are too expensive for schools to process because of labor costs. In addition, a large number of farms in the region are expanding their businesses with value-added processing. It has become an essential component for providing income year-round. Regulating these small, under $1 million businesses would neutralize this added profit value for farms.

Recommendation: FDA should adopt a threshold of at least $1,000,000 and apply it not to sales of "all food" but to sales of food regulated under the Preventive Controls Rule.

IV. Establish an Exemption for Facilities With an Average Annual Monetary Value of Covered Product of $25,000 or Less

When writing FSMA, Congress rejected a "one-size-fits-all" approach, and provided FDA with flexibility to ensure that the Preventive Controls Rule worked for a diversity of facilities. Specifically, in the Preventive Controls Rule, FDA requires FDA to "provide sufficient flexibility to be practicable for all sizes and types of facilities, including small businesses such as a small food processing facility co-located on a farm" (P.L. 111-353, § 103(a)(a)(n)(3)(A)).

While FDA has taken initial steps to implement the flexibility specifically required by FSMA for low-risk activities/food combinations (see comments below) and for qualified facilities (see comments below), FDA has not built in flexibility for extremely small facilities in the same way it has in the proposed Produce Rule for farms with $25,000 or less in food sales. FDA should establish an outright exemption for extremely small facilities to ensure flexibility for the smallest food processing operations.

An outright exemption for facilities that have an average annual monetary value of food regulated by the Preventive Controls Rule of $25,000 or less would not significantly add risk to the food supply. According to FDA's Preliminary Regulatory Impact Analysis, the highest threshold proposed threshold for the definition of "very small business" – $1,000,000 in annual gross sales food – would cover only a

tiny percentage – less than two percent – of the food produced in the U.S.[4] That same analysis says that food businesses with less than $250,000 in annual gross sales of food represent less than one-half of one percent of all food produced in the U.S.[5] Setting an outright exemption at the $25,000 threshold would represent an even smaller fraction of the food businesses in the U.S.

Additionally, the exemption should be based off of product regulated under the Preventive Controls Rule and not all food as defined in § 117.3. While FSMA may require "all food" to be counted against the two-part eligibility test for farms and facilities that are eligible for modified requirements, that same restriction clearly *does not apply* to the requirement to ensure flexibility for facilities of all sizes (P.L. 111-353, § 103(a)(a)(n)(3)(A)). Focusing the definition on regulated product instead of all food would provide some flexibility in the rule for beginning farmers, entrepreneurs trying to launch value-added food businesses, and family farmers who have diversified operations through value-added processing.

Please see comments in the preceding section about the importance of value-added processing to year-round income for small farmers. In our region, one farm that came to a farmer meeting on the FDA rules noted the difference in value for the business when it was able, for example, to process cilantro into pesto and sell the product at the farmers market. It greatly increased gross revenues and allowed a longer period of time for selling the product than if the cilantro was only sold fresh.

Recommendation: To ensure sufficient flexibility for a diverse array of food businesses, FDA should establish an outright exemption from the Preventive Controls Rule for businesses with $25,000 or less in annual average monetary value of product covered by the Preventive Controls Rule over a three-year period, adjusted for inflation.

V. FDA Needs to Expand the List of On-Farm Low-Risk Activities/Food Combinations

In FSMA, Congress required FDA to conduct a science-based risk analysis of on-farm packing, holding, manufacturing, and processing activities, and to consider the results of that analysis to exempt or develop modified requirements to the Preventive Controls requirement for small or very small businesses that conduct only low-risk activities (P.L. 111-353, § 103(c)).

FDA has partially implemented this recommendation and has taken important first steps in identifying low-risk on-farm packing, holding, processing, or manufacturing activities by developing lists of low-risk activities/food combinations in § 117.5(g) and §117.5(h) that are not subject to Subpart § 117 (Hazard Analysis and Risk-Based Preventive Controls). While the lists are extensive, they are not exhaustive, and there are a number of other low-risk activities that FDA should include in those lists.

Additionally, while we realize that FSMA requires FDA to focus on identifying low-risk on-farm activities, the fact that FDA has identified these activities/food combinations as low-risk should be grounds for exempting them regardless of whether they are conducted on farm or by a small or very small business. Regulating activities/food combinations that are low-risk is incredible regulatory overreach, a waste of scarce federal resources, and comes at a real cost to the economy. Larger farms or off-farm businesses that engage in these low-risk activity/food combinations will be forced to comply with regulations that, according to FDA, are low risk.

Finally, in the proposed Rule, FDA does not provide a mechanism for periodically updating the list of low-risk activities. It is difficult, if not impossible, to predict ahead of time what each and every possible

[4] FDA's Preliminary Regulatory Impact Analysis – Preventive Controls Rule. Page 4.
[5] Ibid.

combination of farm commodities and on-farm processing activities will be now or in the future. A mechanism for periodic updating and improvement will surely be needed.

In northwest Lower Michigan a large number of farms are involved in turning their vegetables into pickled, low-acid foods. This greatly extended the time for an income stream for one area asparagus farmer, for example, who also sells his fresh asparagus into area schools, grocery stores and restaurants in the spring. Many farms also produce their own local feed, generating oil for food, feed and fuel. Many farms have added baked goods and some producers have created value-added frozen products from fresh fruits and vegetables for farmers mrkets, CSA and institutional markets. Many of the businesses begin under the low-cost rules of Michigan's Cottage Industry Law regarding small operations, and this allows them a start-up period for their value-added products which, if successful, may lead to the farmer adding a licensed facility when the enterprise increases to large enough gross sales to justfiy the cost.

Recommendations: FDA should retain the list of low-risk activities/food combinations in § 117.5(g) and § 117.5(h) and add at least the following low-risk, value-added processing activities in the final rule:

- Acidifying, pickling, and fermenting low-acid fruits and vegetables made in compliance with existing Good Manufacturing Practices in 21 C.F.R § 113 and § 114
- Baking activities involving grain products
- Roasting grains for animal feed
- Extracting oils from seeds
- Extracting virgin olive oil
- Making molasses from sugarcane and sugar beets
- Making syrups from sorghum, rice, and malted barley

The exemption from Subpart C of § 117 based on proposed list of low-risk activities/food combinations should not be limited to on-farm activities conducted by small or very small businesses, but should be applied whenever the low-risk food/activity combination takes place, including on larger farms or off-farm businesses.

FDA should also establish a mechanism for updating the lists of low-risk activity/food combinations (§ 117.5(g) and §117.5(h)) and, as part of that mechanism, seek input from value-added processors and farmers operating mixed-type facilities, including small and very small farmers and facility operators.

FDA should incorporate these changes into its "Draft Qualitative Risk Assessment of Risk of Activity/Food Combinations for Activities (Outside the Farm Definition) Conducted in a Facility Co-Located on a Farm" and should issue a revised Draft Risk Assessment for public comment before finalizing the Preventive Controls Rule.

VI. The Food Processing Sector Study is Woefully Inadequate and Must be Undertaken Again to Comply with the Law

FSMA requires FDA to conduct a food processing sector study to determine the size and scope of the food processing sector, including in particular the number and types of food facilities co-located on farms (P.L. 111-353, § 103(a)(l)(5)). FSMA requires the results of the food processing sector study to inform the definitions of "small" and "very small" businesses.

The food processing sector study[6] that FDA released as part of the proposed Preventive Controls Rule is grossly inadequate and fails completely to provide the information required by FSMA to determine the

[6] FDA, "Food Processing Sector Study," 2011. Reference 32 of the proposed Preventive Controls Rule.

number of facilities co-located on farms and what the production, distribution, and risk profiles of those facilities are. The study acknowledges its severe data limitations and, therefore, relies primarily on the professional opinion of a small group of individuals who are not experts in on-farm or small-scale processing. Without this information, FDA cannot adequately determine the impact of the proposed Preventive Controls Rule, how many operations will be subject to the Preventive Controls Rule, and what the costs of compliance will be.

We know of no other instances of federal regulations that seek to regulate a completely indeterminate universe of regulated entities. Congress recognized this problem, and therefore charged the agency to conduct a thorough study to determine the size and scope of the universe of farms and businesses that may be subjected to regulation. Congress specifically charged the agency with obtaining these data before issuing rules. The food processing sector not only completely fails at this task, but the agency has made no indication of how it intends to rectify the situation.

Please see comments in the two sections above to reaffirm the importance of this issue for northwest Lower Michigan farms.

Recommendation: FDA should conduct a revised, true food processing sector study that includes large-scale surveys of actual farm mixed-type facilities and the activities they conduct. FDA should release that study for public comment and should incorporate the findings into the Preventive Controls Rule before finalizing the Preventive Controls Rule. In conducting the revised study, FDA should consider entering into cooperative agreements with agencies, organizations, and/or groups able to conduct those surveys who work with farm mixed-type facility operators.

Comments on Issues in Both Rules – Proposed Produce Rule and Proposed Preventive Controls Rule

I. Foundational Definitions Applicable to Both Rules are Flawed and Must be Improved

In FSMA, Congress included a number of provisions to clarify the definitions of "farm" and "facility" from the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (BTA; P.L. 107-188). These clarifications included § 102(c) and § 103(c) discussed above (see comments above). Additionally, Congress in FSMA provided FDA with authority to provide broad flexibility in the regulations to "provide sufficient flexibility to be practicable for all sizes and types of facilities, including small businesses such as a small food processing facility co-located on a farm" (P.L. 111-353, § 103(a)(a)(n)(3)(A) and § 105(a)(a)(3)(A)). We note that the use of the phrase "**such as** a small processing facility co-located on a farm" (emphasis added) does not limit the application of this regulatory discretion solely to processing facilities co-located on farms.

These clarifications and this flexibility in FSMA are very important because the implementation of BTA and the definition of 'facility' has created a great deal of confusion for farmers who conduct on-farm activities that fall under the arbitrary definitions of "manufacturing/processing," "packing," and "holding." These confusing definitions have lead to a lack of clarity around when a farm is also considered a 'facility' that must register with FDA and is subject to the Preventive Controls Rule.

In the proposed Produce Rule and Preventive Controls Rule, FDA takes some steps forward to provide additional guidance for when a farm is also a facility that must register. However, there are still significant deficiencies in the proposed rules that must be fixed before the rules are finalized. Without specific improvements, the entire regulatory framework around the interaction between the two rules will be grossly insufficient and risk inappropriately over-regulating many farms and low-risk food businesses.

A. FDA's Organizing Principles Are Fundamentally Flawed

In the preambles of both rules, FDA describes five "organizing principles" to help understand the agency's definition of "farm." The organizing principles rest on a flawed understanding of how farming works because they assume that farms exist simply to grow crops, and that getting those crops to market is something that "farms" don't do. The reality is that a farm cannot stay in business without marketing its crops and preparing those crops for market. The imperative to maximize the value a farm receives for its crops creates the need for value-added marketing and cooperative distribution.

In northwest Lower Michigan, as in so many other parts of the country, farms are diverse operations. Farmers in our area may produce their own animal feed, on-farm fertilizer from animal and processing waste, seeds for planting, and energy to operate the farm. Farmers wash, trim, dry, and store crops at various temperatures and humidity. A successful small farm in our region will sell into many local markets for direct regional consumption, ranging from roadside stands to institutional markets. Each market is essential for that farm's overall profitability.

Recommendation: FDA should revise its organizing principles to reflect the realities and range of activities that farms do to their crops to prepare those crops and get them to markets.

B. FDA Should Not Use the Term "Facility" to Define Establishments and Properties that Are Not Facilities that Must Register with FDA

In BTA, Congress explicitly stated that farms, restaurants, and retail food establishments were not food processing facilities that had to register with FDA (P.L. 107-188, § 305). The definitions of "farm" and

"restaurant" include the term "facility," causing significant confusion. FDA must amend these definitions to clarify confusion.

Recommendation: FDA should amend the definitions of "farm" and "retail food establishment" so that they do not include the term "facility" and to further clarify that they are not facilities subject to registration under BTA nor to the FSMA Preventive Controls Rule.

C. Packing and Holding Someone Else's Fruits and Vegetables Should Not Make a Farm a "Facility"

One of the most problematic areas in the definitions of "farm" and "facility" has to do with the very common practice on farms to pack or hold small amounts of produce from neighboring farms to meet market demand. The fresh market produce industry is highly volatile, especially to the effects of uncontrolled weather events. Farms serving markets must be able to meet customer needs to remain economically viable. From time to time, it may be necessary to bring in a minimal amount of product to do that. Yet, as proposed, FDA would consider a farm that packs or holds intact fruits and vegetables a "facility" that has to register with FDA and is subject to the Preventive Controls Rule. This is unacceptable and will result in thousands of farms having to register with FDA as facilities and comply with the Preventive Controls Rule.

In northwest Lower Michigan small farmers commonly cooperate to share resources. This includes storage if one farm has excess storage capacity in any given season. As one example, in the new vegetable consortium of farmers scaling up to meet local school needs, an exemplary carrot grower who usually sells into the farmers market and CSA market has now scaled up carrot production. This scaled up production is also connected to the new food hub that is being developed in Traverse City. In this critical first two years, farms and schools are testing out product needs and values such as price points and minimal processing to find products that schools can affordably purchase and farms can profitably produce. This farmer does not have storage capacity for all of the carrots he is growing for this innovative project and until this testing phase of the school market is completed it does not make sense for him to build this storage capacity. Two other farms with storage capacity have offered to provide the storage. This simple arrangement should be encouraged, and not be discouraged by forcing a designation upon these two helpful farms as "facilities." To do so would discourage the testing and innovation needed to grow the market for these carrots, provide students with a flavorful and healthy alternative to industrially processed baby carrots (which roundly fail against the local carrots in student taste tests) and would do nothing to advance food safety.

Recommendation: FDA should change the definitions of "farm," "facility," and "manufacturing/ processing" to align with the common-sense understanding and practice that the basic packing, handling, and storing activities that farms have traditionally performed in preparing intact fruits and vegetables for marketing – including to someone else's raw agricultural commodities – do not make a farm a "facility" that must register with FDA and that is subject to the Preventive Controls Rule.

D. Establishments that Pack and Hold Intact Fruits and Vegetables Should Not be Facilities

Packing and holding of intact fruits and vegetables occurs off-farm and is a strategy used by many farmers, groups of farmers, and food businesses to more efficiently and cost-effectively aggregate product. In the proposed Preventive Controls Rule, FDA has identified packing and holding of someone else's intact fruits and vegetables on-farm as a low-risk packing of holding activity food combination (78 F.R. 3801). Given the low-risk nature of this activity, it should not trigger the 'facility' definition in other instances, such as in an off-farm establishment.

Recommendation: FDA should amend the definitions of "farm" and "facility" so that low-risk packing and holding activities of intact fruits and vegetables conducted in establishments off-farm are not "facilities" that must register with FDA and be subject to the Preventive Controls Rule.

E. FDA Needs to Include Additional Activities in "Harvesting" and "Packing" and "Packaging"

In its proposed rules, FDA has started a list of activities included in the definition of 'harvesting' that do not trigger the definition of "facility" for the purposes of facility registration when done to one's own raw agricultural commodities. We support the clarification of how FDA classifies these activities and urge FDA to make the list as exhaustive as possible.

We also urge FDA to clarify that "packing" and "packaging" of raw agricultural commodities on-farm includes affixing labels to packing and packaging containers, and that such labeling does not trigger the definition of "facility" for the purposes of facility registration.

Recommendation: FDA should build on its existing list of harvesting activities and include the following activities in the definition of "harvesting":

- In-field coring,
- Removing foliage,
- Removing roots,
- Braiding, and
- Bunching.

FDA should periodically review the list to ensure that it reflects the breadth and range of practices done as part of harvesting.

The Northwest Michigan Food & Farming Network agrees with the language in the recommendation above, provided by the National Sustainable Agriculture Coalition. However, farmers in our region came up with additional activities to be added to the list, such as "curing" crops in the field by harvesting them and then leaving them in the sun for a period to increase shelf life (such as with potatoes). In some cases farmers harvest and wash the crops in the field, such as with a carrot barrel washer, which provides a cleaner and more presentable product for market. One farmer's idea is that instead of building an all-inclusive list which will "always miss something," that FDA instead should create simple rules that apply to areas of concern instead of a long list trying to include all exclusions.

FDA should clarify that "packing" and "packaging" of raw agricultural commodity on-farm includes affixing labels to packing and packaging containers, and that such labeling does not trigger the definition of "facility" for the purposes of facility registration.

II. FDA Must Establish a Robust Regulatory Framework Around the Modified Requirements for Qualified Exempt Farms and Qualified Facilities as Mandated by Law

When writing FSMA, Congress rejected a "one-size-fits-all" approach, and provided FDA with flexibility to ensure that the Produce Rule and Preventive Controls Rule worked for a diversity of farms and facilities. A key part of the scale- and supply-chain appropriate regulatory framework includes specific provisions in FSMA requiring FDA to establish modified requirements for farms/facilities that gross under $500,000 in sales of all food in a previous three-year period (adjusted for inflation) and sell the

majority of their food directly to a consumer, or a restaurant or retail establishment that is located in the same state as the farm/facility or not more than 275 miles from that farm/facility (P.L. 111-353, § 105(a)(f) and § 103(a)(a)(l)). If a farmer or facility meets these qualifications, then instead of being subject to the entire produce standards or HARPC requirements, the farmer or facility is only subject to modified requirements.

In the proposed Produce Rule and proposed Preventive Controls Rule, FDA has failed to adequately implement a robust regulatory framework for qualified exempt farms and qualified facilities. While FDA has included the basic statutory language from FSMA, it has not created a complete regulatory framework for qualified exempt farms and qualified facilities. Many critical details remain unclear or unanswered and must be addressed in the final Produce Rule and Preventive Controls Rule to be consistent with Congressional intent to establish a flexible and appropriate regulatory frame for farms and facilities that supply direct-to-consumer markets.

Additionally, while FSMA specifies that the $500,000 threshold should apply to "all food," Congress also gave FDA flexibility to ensure that the regulations would be appropriate and practical for a diversity of farming systems (P.L. 111-353, § 103(a)(a)(n)(3)(A) and § 105(a)(a)(3)(A)). The calculation of the $500,000 based off of "all food" creates significant barriers for farmers that are diversifying into produce production or value-added production. Those farmers, because they have sales from other agricultural products – including dairy, grain crops, hay, livestock, etc. – would be subject to the full weight of the food safety regulations if they grow a small amount of fruits or vegetables, or process a small about of product through value-added processing activities. This is a significant barrier to the diversification of farming systems and to the transition of farmers into fruit and vegetable production to meet growing demand. FDA should use the authority that Congress awarded the agency in FSMA to promulgate flexible regulations that work for all sizes and types of farms and facilities to fix this issue.

As noted above in the Produce Rule, in northwest Lower Michigan, a growing number of farms are working to supply the region with locally grown meat, eggs and milk. Another opportunity for their operations is the growing demand for vegetables, both by households and also by our region's schools, which under new USDA rules must serve substantially more fruits and vegetables. However, if these farms devote a small portion of their operations to vegetable production and non-orchard fruits such as blueberries that schools desire but can't find in sufficient quantity regionally, they will have to include the value of the higher profit meat, eggs and milk and thus be forced to comply with the full Produce Rule and absorb its high compliance costs. This will dissuade growers from diversifying to serve a market that carries such promise. In addition, we have a number of growers who have large orchard operations with fruit destined for commodity processing who have grown interested in diversifying to include a small portion of their farms to CSA-type or other local market vegetable production, precisely because they see the potential of this market and realize it could be an easy addition at the edges of orchards. In this case, unlike the dairy example, all of the product is produce and yet only a small portion is for local markets and it is a similar example of diversification. We do not know the solution for this, but it shows how farms or facilities in a commodity produce growing region can quickly be dissuaded from diversifying to meet local markets because the exemptions are too strict or not clearly enough defined.

Recommendations: FDA must retain and significantly improve the regulatory framework for qualified exempt farms and qualified facilities in the final Produce Rule and the final Preventive Controls Rule. Specifically, in both the Produce Rule and the Preventive Controls Rule:

1. **FDA must retain the modified requirements for qualified exempt farms in the Produce Rule and qualified facilities in the Preventive Controls Rule.**

2. **FDA must establish a clear and fair process for withdrawing a farm or facility's "qualified exempt" or "qualified" status.** Specifically, FDA should:

    a. Increase the evidentiary standard for withdrawing an exemption, including evidence that shows direct linkage to a problem on a specific farm or facility, and should require the FDA officer recommending the withdrawal to show credible and substantial evidence that merits an order to withdraw.

    b. Define critical terms that clarify the situations under which a farm or facility's status as "qualified exempt" or "qualified," respectively, can be withdrawn. Specifically, FDA should:

        i. Define "directly linked" and "associated" to limit the possible broad interpretation of these terms and so that upstream actors, unrelated to the actual conduct and practices of the farm or facility in question, cannot endanger that farm or facility's status. There should be explicit temporal, location-based, and product- or activity-based suggestions for determining direct linkage or association.

        ii. Define "material to the safety of food" to mean measurable traits that can be clearly identified in individual cases, and never by conjecture be applied to a whole class of persons, types of operations, or broad description of food being produced.

    c. First issue a warning letter before resorting to exemption withdrawal proceedings.

    d. If a withdrawal order is warranted, submit an order to withdraw the exemption to the FDA District Director or official senior to such Director within 10 calendar days of making that determination. The FDA District Director or other senior to such Director must approve or deny the order to withdraw within 10 calendar days of when it is submitted. The order to withdraw must be delivered to the owner, operator, or agent in charge of the farm or facility within 5 calendar days after that determination.

    e. In the withdrawal order, state clearly that the owner, operator, or agent in charge of a qualified exempt farm or qualified facility must either comply with the requirements or appeal the order, and include information about the opportunity to request an informal hearing.

3. **FDA must establish a process by which qualified exempt farms or qualified facilities can regain their exempt status and outline the criteria for such a course of action.**

4. **FDA must apply the $500,000 threshold to product or product covered by the Produce Rule or Preventive Controls Rule, respectively, not to "all food."**

III. Food Safety Training Needs to be a Central Part of the Implementation of the FSMA Rules

Recognizing the additional burdens that the new regulations would place on farmers and food facilities, and recognizing the importance of training as part of a food safety system focused on prevention, Congress created a competitive grants program in FSMA – the National Food Safety Training, Education, Extension, Outreach, and Technical Assistance Program – to fund training efforts through USDA's National Institute of Food and Agriculture (P.L. 111-353, § 209(b)). FSMA prioritized training through

this program for small and mid-sized farms, beginning farmers, socially disadvantaged farmers, small processors, and small fresh fruit and vegetable merchant wholesalers. FSMA emphasized that training should integrate food safety standards and guidance with the variety of agricultural production systems, encompassing conventional, sustainable, organic, and conservation and environmental practices. Unfortunately, due to the fiscal crisis, Congress has not to date appropriated funds to launch this much-needed program.

If the final regulations are to be successfully implemented, training for farmers and food processing businesses – especially the target groups listed in the paragraph above – is critical piece that must be addressed. Without adequate training resources available for covered farms and facilities, the regulations will fall well short of the goal of improving food safety.

In northwest Lower Michigan our region's small and mid-scale farmers give high marks to the Michigan Safe Food Risk Assessment described at length above.

Recommendation: As FDA moves to finalize the proposed Produce Rule and proposed Preventive Controls, the agency must prioritize working with USDA and public sector farmer-based organizations to launch and secure funding for the National Food Safety Training, Education, Extension, Outreach, and Technical Assistance Program.