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Oregon Tilth, Inc. is a 501(c)(3) nonprofit organization that supports and promotes biologically sound and socially equitable agriculture through education, research, advocacy, and product certification.

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Division of Dockets Management (HFA-305)
Food and Drug Administration
5639 Fishers Lane, Room 1061
Rockville, MD 20852

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

Re: 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)

On behalf of Oregon Tilth, I am writing to provide comments on the proposed Produce Rule and Preventive Controls Rule. Thank you for the opportunity.

Oregon Tilth is a nonprofit, membership-based organization that supports and promotes biologically sound and socially equitable agriculture through education, research, advocacy and certification. The organization is accredited by the USDA to offer organic certification services in accordance with the federal National Organic Program. Oregon Tilth currently certifies over 715 farm operations throughout the United States and internationally, representing over 415,000 acres of certified organic land. We certify the majority of organic operations in Oregon.

Organic and sustainable farmers take food safety seriously. Producers have an obligation and strive to provide safe food to consumers and Oregon Tilth supports efforts to make our food safer.

As the demand for healthy organic and sustainably produced food continues to increase, farmers are increasing their acreage dedicated to organic production and other farmers are transitioning their land to organic. We are concerned that if food safety rules do not better support organic production and conservation efforts, this trend may be reversed resulting in an increase in chemical pesticides, fertilizers and other farming practices that are less safe for consumers and the environment.

According to the Food Safety Modernization Act, the produce safety rule must not duplicate or conflict with the National Organic Program (NOP) standards. We are pleased to see that the proposed rule does not require duplicative trace-back and record-keeping systems, follows an Integrated Approach, and in most cases does not conflict with or duplicate the organic standards. However, there are some problematic issues in the following areas that are described in more detail below.

1. **Manure and Compost.** The proposed standards directly conflict with the requirements of the National Organic Program (NOP), severely restrict practices of organic and sustainable farmers, and harm conservation.
2. **Conservation Practices.** While the Produce Rule recognizes the importance of conservation in the preamble, it does not adequately support conservation practices and co-management of conservation, environmental, and public health considerations in the actual text of the rule.
3. **Agricultural Water.** The proposed rule establishes costly, burdensome, and unscientific standards for irrigation water; and treatment requirements conflict with NOP requirements.
4. **Direct to Consumer Marketing.** By not clarifying that CSAs, roadside stands, farmers' markets, and other platforms are direct to consumer sales, they could be regulated like food facilities that must register with FDA and are subject to the Preventive Controls Rule.
5. **Value-Added Processing.** FDA has taken important first steps in identifying low-risk on-farm packing, holding, processing, or manufacturing activities but there are a number of other activities that should be included in those lists.
6. **Definitions.** The regulations do not clarify the definitions of "farm," "facility" and other terms to reflect the nature of agriculture.
7. **Exemptions.** The exemption rules focused on gross sales of all food, not the value of covered produce.
8. **Food Safety Training.** Without adequate training resources available for covered farms and facilities, the regulations will fall well short of the goal of improving food safety.
9. **Cost of Compliance.** The costs place an unfair burden on smaller growers. As a result of the high costs of compliance, some farmers will go out of business, fewer people will start to farm, and more farmers will have to seek off-farm jobs to keep farming.

Comments on Issues in Proposed Produce Rule

1. Manure and Compost

The proposed Standards for Biological Soil Amendments of Animal Origin and Human Waste doesn't satisfy the requirements of FSMA, severely restrict practices of organic and sustainable farmers, harm conservation, and must be revised.

The proposed Subpart F—Standards Directed to Biological Soil Amendments of Animal Origin and Human Waste fails to meet the requirements of the Food Safety Modernization Act (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)).

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 (NOP). 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 "soil fertility and crop nutrient management practice standard" of National Organic Program 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. In the proposed Produce Rule, FDA proposes a nine-month restriction (§ 112.56). 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).

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. If FDA does not change these intervals to align with NOP requirements, then FDA will be actively discouraging farmers from becoming certified organic and undermine the ability of existing organic growers to stay certified. Farmers need to use fertilizer to grow crops. Organic and many other farmers who do not use synthetic-based chemicals for fertilizer rely on 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 viable use of manure as a fertilizer for most organic produce farms and create additional barriers to the use of compost made with animal materials. This is an entirely inflexible approach.

Additionally, FDA's proposed harvest intervals related to the application of compost and untreated manure will restrict organic producers' ability to rotate crops as part of a preventative pest and disease control. The Produce Rules would thus restrict producers' ability to comply with NOP regulations which require crop rotations for this purpose (7 CFR 205.205).

A recent survey of farms certified by Oregon Tilth demonstrates the importance of these soil amendments and the potential impact of this proposed rule.

- 45% of survey respondents use untreated manure in compliance with USDA organic standards for soil fertility.
- The proposed standard restricts their ability to comply with NOP regulations which require crop rotations and for producers to maintain or increase biodiversity: 40% of survey respondents stated that a 9 month interval between the application of untreated manure and harvest would prevent them from rotating crops or introducing biological diversity.
- According to one producer, a "9 month waiting period makes no sense, I can't leave the ground fallow that long."
- The proposed compost standard also restricts the ability to comply with NOP regulations which require crop rotations and for producers to maintain or increase biodiversity as 71% of survey respondents use compost for soil fertility. According to one farmer: "This rule would require substantial changes to our use of compost in both annual & perennial situations, and would significantly reduce our flexibility in meeting our soil management objectives."

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)). 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 upon which 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 a review of the literature, 10 studies found that 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 organic standards' 120-day pre-harvest interval notes that with cycles of freezing and thawing pathogen survival are 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 requiring 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 of 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. The proposed rules are not in line with the standards used by the USDA Natural Resources Conservation Service (NRCS) which provides technical and financial assistance to producers to implement conservation practices. These are significant concerns that point to the inappropriate nature of the standard and that must be addressed in the final rule.

<u>*Recommendations*</u>: In the final produce safety regulations, FDA must align its standards for the use of manure and compost with the National Organic Program regulations. Specifically:

- The interval between application of untreated manure and harvest should not exceed the interval 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.

Diversified Crop-Livestock Farming Systems

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. 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).

Many sustainable farm operations, especially small and mid-sized ones, integrate livestock into the production of fruits and vegetables. In their multi-year rotation, for example, some producers may use a mixture of grasses and legumes. These grain crops can be used for weed control and animal feed as well as providing soil health benefits. In these operations livestock also provides an economic diversification by providing other products to market. As described above, crop rotations are required for organic farmers under the NOP. The proposed rule would dramatically limit the ability of farmers who incorporate livestock into their rotation to meet NOP requirements.

Recommendation: FDA should clarify "adequate." In order to use draft animals and integrate livestock into rotations, the period between grazing and harvesting must be significantly less than nine months to be appropriate for a farm production cycle.

2. Conservation Practices

The Produce Rule does recognize the importance of conservation in the preamble, but does not adequately support conservation practices and co-management of conservation, environmental, and public health considerations in the rule. Sustainable and organic farmers care deeply about the natural environment and are leaders in on-farm conservation practices. Conservation practices are central to organic production systems, and the NOP requires that organic farmers conserve biodiversity and protect soil, water, wetlands, woodlands, and wildlife.

FSMA directs FDA to be pro-active with respect to natural resource conservation, wildlife conservation, and environmental protection, and the proposed rule falls short 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)).

Given that farmers have been incentivized or forced to remove conservation practices and to actively exclude wildlife from their farms in response to outbreaks – including the 2006 spinach *E. coli* outbreak[1] – it is important to

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

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 conflicts with the requirements of the national organic program established under the Organic Food Production Act of 1990. The proposed standard conflicts with the "natural resources standard" of National Organic Program (NOP) regulations (7 C.F.R. § 205.200 and § 205.2), by not providing language supportive of conservation in the text of the rule (as opposed to the preamble). 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, 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 more clearly support 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.

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).

Conservation practices play an important role in decreasing food safety risks on the farm. Often with the support of USDA technical and financial assistance through the Natural Resources Conservation Service, farmers install stream-side vegetation and grassed filter strips to help keep the water supply clean by reducing the movement of pathogens, nutrients, and pesticides into streams, rivers, and lakes. Windbreaks and hedgerows reduce the amount of dust and other airborne contaminates blowing onto produce fields. These plantings also can help meet NOP buffer requirements to prevent the contamination of crops by prohibited chemicals that may be applied on adjacent land. Conservation practices also serve as wildlife habitat. That habitat can support beneficial insects that prey upon pests, raptors that serve as on-farm rodent control, or other species that are used on organic farms in place of toxic chemicals to control agricultural pests. Without explicit protection in the rules, conservation practices like native plant buffers as habitat for bees could be discouraged or forcefully removed.

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:

- Include "co-management": which should be defined as "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."
- As part of the personnel training standards, include requirements to train on-farm personnel on co-management.
- Correlate the rules with National Organic Program regulations.

3. Agricultural Water

In general, the rule establishes costly, burdensome, and unscientific standards for irrigation water – including water testing and treatment requirements.

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)).

Organic and sustainable farmers are particularly concerned about regulations related to the treatment of water. The proposed requirements to treat agricultural water with an EPA-registered antimicrobial pesticide currently conflict with national organic standards because of the limited number of antimicrobial pesticides allowed under NOP regulations. For example, while chlorine is allowed under the NOP regulations, the chlorine level restrictions which state that such substances cannot contribute to the contamination of crops, soil, or water, negate its use as an option to treat water under FSMA. Currently there are no pesticides approved under the NOP that organic farmers would be able to use to treat water. Therefore this treatment requirement conflicts with the requirements of the NOP.

We have concerns about the large-scale use and release of chlorine and other antimicrobial pesticides into the environment that may be used to comply with the proposed microbial standards and treatment requirements. By requiring treatment without other options, FDA may in effect increase the release of antimicrobial pesticides into the environment while alternative mitigation practices may be available.

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.

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 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)). 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 standard is untenable in some regions (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.

Recommendations: FDA must take a reasonable, risk-based approach to agricultural water that allows farmers to respond to specific risks in their water systems. Specifically:

- FDA should not increase pollution and decrease the safety of the food supply by encouraging or allowing treatment of irrigation water with chemicals.
- 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.

Comments on Issues in Proposed Preventive Controls Rule

4. Direct to Consumer Marketing

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 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.

For example, CSAs frequently include products from near-by farms in weekly shares. A CSA farm may buy blueberries from another farm because it doesn't grow enough or because the CSA farm's blueberry crop failed that year. Under the current proposed regulations, including product from another farm would make that CSA a facility. This is an unnecessary burden which does not recognize and support direct to consumer farm operations.

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 "retail food establishment" as required by the FSMA statute.

5. Value-Added Processing

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 for small or very small businesses that conduct only low-risk activities (P.L. 111-353, § 103(c)). FDA has taken important first steps in identifying low-risk on-farm packing, holding, processing, or manufacturing activities by developing lists in § 117.5(g) and §117.5(h). 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. The proposed rule does not provide a mechanism for periodically updating the list of low-risk activities.

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
- 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

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.

Comments on Issues in Proposed Produce and Preventive Controls Rules

6. Definitions

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). 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)).

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 led 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.

Organizing Principles

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.

Most definitions of farming include this range of activities. For example, Oregon State Statutes (ORS 215.203) defines farming not only as "raising, harvesting, and selling crops" but also "the preparation, storage, and disposal by marketing or otherwise of the products or by-products raised on such land."

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.

Facility

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). However, the proposed definitions of "farm" and "restaurant" in the Preventive Control Rule include the term "facility," causing significant confusion.

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.

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.

Recommendations:

- 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.
- 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.
- 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.

Harvesting

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" 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. Farmers conduct a wide range of activities to their fruits and vegetables as part of harvesting.

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.

7. Exemptions

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. 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 have diversified operations.

For example, a dairy farmer who grosses $1,000,000, but has a very low net profit and is looking at options to diversify and respond to market demand for fruits and vegetables would have to comply with the full Produce Rule and absorb the high compliance costs if that farmer grows a small amount of vegetables to sell at a roadside stand during the summer.

Recommendation: FDA should retain the $25,000 exemption in the final Produce Rule but should base it on $25,000 of produce covered by the Produce Rule and not the value of food as defined in § 112.3(c). While the FSMA statute 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 in this case.

8. Food Safety Training

70% of farmers responding to a recent survey of farms certified by Oregon Tilth are currently not certified to any food safety standard. However, producers are greatly interested in training as they feel a push toward some level of food safety certification by buyers. Nearly 60% of those surveyed were interested in Oregon Tilth offering food safety training and certification as an accompaniment to organic certification.

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 yet 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 a 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.

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.

9. Cost of Compliance

A majority of farms—nearly three-quarters of farmers responding to an Oregon Tilth survey—are not certified to any food safety standards and would therefore face substantial costs of compliance. As a result of the high costs of compliance, FDA anticipates that some farmers will go out of business, fewer people will start to farm, and more farmers will have to seek off-farm jobs to keep farming. The costs place an unfair burden on smaller growers. For example, farms defined as "small" by FDA and subject to the complete Produce Rule would face nearly $13,000 in compliance costs each year, which could account for 50% or more of a produce farm's already very slim margins.

Although FDA is considering requiring food safety plans, FSMA does not authorize FDA to require farms to perform operational assessments or develop food safety plans. 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.

In a time with an aging and retiring farmer population coupled with growing consumer demand for healthy, local, organic and sustainably produced food, we cannot afford to lose existing farmers and discourage new ones. The barriers to expanding or starting a farm business are already great: scarcity of high quality farmland and high costs available land, difficulties securing farm labor, limited local processing and distribution infrastructure and more. The estimated high costs of compliance would be an excessive new barrier.

Recommendations:

- FDA must find ways to decrease the costs of compliance with the new rules, especially for small and very small farms. FDA must also base the costs on realistic assumptions about length of growing season, farm net income, and feasibility of water testing.
- 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.

A Second Proposed Rule is Needed

FDA's proposed rules fail to meet a number of the significant requirements of FSMA such as conflicts with NOP, the failure to use science-based standards, and lack of sufficient flexibility. In fact, some of the proposed requirements would severely limit certain types of production, particularly sustainable agricultural systems, including certified organic production. Due to importance of these rules, their wide-reaching potential impact and the specific issues described above, we urge FDA to publish a second round of draft rules for public comment before finalizing the Produce and Preventive Controls rules.

Thank you for the opportunity to comment.

Sincerely,

Chris Schreiner

Chris Schreiner
Executive Director, Oregon Tilth