National Sustainable Agriculture Coalition

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Rockville, MD 20582

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Re: Comments on the supplemental proposed rule for Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption

On behalf of the represented member organizations[1] of the National Sustainable Agriculture Coalition (NSAC), I submit the following comments on the supplemental proposed rule for Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption. NSAC welcomes the opportunity to submit comments, and looks forward to working with the Food and Drug Administration to ensure that the regulations and their implementation are successful and supportive of sustainable agriculture and food systems.

Sincerely,

Sophia Kruszewski

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National Sustainable Agriculture Coalition

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ACKNOWLEDGEMENTS

The National Sustainable Agriculture Coalition's (NSAC) comments on then supplemental proposed rule for Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption are the result of extensive analysis, discussion, feedback from NSAC's Food System Integrity (FSI) Committee, NSAC's committee charged with working on the Food Safety Modernization Act. Several subcommittees were formed to work in detail on specific issues and develop the recommendations below.

The following individuals contributed significantly to these comments:

NSAC members:

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Roger Noonan, New England Farmers Union
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I. INTRODUCTION

The National Sustainable Agriculture Coalition (NSAC) is an alliance of grassroots organizations from across the country that advocates for federal policy reform to advance the sustainability of agriculture, food systems, natural resources, and rural communities. NSAC member organizations are leaders in the sustainable agriculture and food systems sector, and have worked with farmers and communities to pioneer practices, systems, and supply chains that support the multiple goals of sustainable agricultural systems.

NSAC member groups work directly with small and mid-sized family farmers, sustainable and organic farmers, and on-farm food processors who conduct activities within the scope of the Food and Drug Administration's (FDA) proposed rules on Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption (Produce Rule) and Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food (Preventive Controls Rule).

Given the potential devastating economic impact of ill-devised food safety regulations on sustainable agriculture and on small and mid-sized family farmers and food processors, NSAC engaged heavily in the legislative process that resulted in the enactment of the Food Safety Modernization Act (FSMA). We engaged in this process with four guiding principles in mind:

1. **Everyone has a role in ensuring a safe food supply:** From the farmers and field workers to the end consumer, everyone in the food supply chain has a role in ensuring safe food.

2. **Focus on the highest risk:** Different production systems and supply chains pose inherently different risks to the safety of our food supply. There are limited government resources, and they must be focused on addressing the highest risks.

3. **Regulations should be science-based:** The emotional reaction to food safety outbreaks has, at times, resulted in the knee-jerk imposition of practices that have little basis in sound scientific evidence. Overall, the totality of the science behind the role of farm practices in food safety outbreaks is grossly under-examined and requires much more investigation.

4. **One size does not fit all:** Regulations must be scale- and supply-chain appropriate to be effective; a one-size-fits-all approach will put small and mid-sized farms and processors out of business, undermining public health goals, such as increased production of, availability of, and access to healthy foods, as well as economic opportunity, equity, and job-creation goals.

The implementation of these principles throughout the FSMA legislative debates led to the inclusion of a number of important provisions that formed the basis for the flexible, scale- and supply-chain appropriate framework set forth by Congress. These provisions include:

- The requirement to "provide sufficient flexibility to be applicable to various types of entities engaged in the 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"[2];

- The requirement to "provide sufficient flexibility to be practicable for all sizes and types" of businesses and facilities, including small businesses such as a small food processing facility co-located on a farm[3];
- The requirement to determine the number and types of food facilities co-located on farms, by commodity and by processing activity, to inform rulemaking[4];
- The requirement to provide modified requirements for small and mid-sized farmers and facilities engaged primarily in selling food through direct-to-consumer supply chains[5];
- The requirement to "minimize, as appropriate, the number of separate standards that apply to separate foods"[6];
- The requirement 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"[7];
- The requirement to "not include any requirements that conflict with or duplicate the requirements of the national organic program established under the Organic Foods Production Act of 1990"[8];
- The requirement to clarify through rulemaking the activities that are part of the definition of "facility" in the Federal Food, Drug, and Cosmetic Act (FD&CA) § 415, including "activities that constitute on-farm packing or holding of food that is not grown, raised, or consumed on such farm or another farm under the same ownership" and "activities that constitute on-farm manufacturing or processing of food that is not consumed on that farm or on another farm under common ownership"[9];
- The requirement to exempt certain facilities or modify their requirements if they are engaged in low-risk manufacturing, processing, packing, and holding activities[10];
- The requirement to amend the definition of a "retail food establishment" to clarify that the sale of products directly to consumers through direct-to-consumer sales platforms (e.g., roadside stands, farmers' markets, community supported agriculture (CSA) programs, etc.) are considered sales directly to consumers for the purposes of defining a "retail food establishment"[11];
- The requirement to "not require a business to hire a consultant or other third party to identify, implement, certify, compliance with these procedures, processes, and practices"[12];

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[2] Food, Drug, & Cosmetic Act § 419(a)(3)(A).

[3] *Id.* §§ 418(n)(3)(A), 419 (c)(1)(B); 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.

[4] *Id.*§ 418(l)(5).

[5] *Id.* §§ 418(l), 419(f).

[6] *Id.* §§ 418(n)(3)(C). 419(c)(1)(D).

[7] *Id.* § 419(a)(3)(D).

[8] *Id.* § 419(a)(3)(E).

[9] Food Safety Modernization Act § 103(c).

[10] *Id.* § 103(c)(1)(D).

[11] *Id.*§ 102(c).

[12] Food, Drug, & Cosmetic Act § 419(c)(1)(E).

- Considerations for small and very small businesses, including the requirement to define "small business" and "very small business,"[13] longer compliance periods,[14] and the option to exempt or create modified requirements for small and very small businesses that produce and harvest low-risk produce commodities[15];
- The requirement to reduce the paperwork and information collection burden of the regulations[16]; and
- The establishment of a food safety training program.[17]

Our participation in the rulemaking process has focused on ensuring both the letter and the spirit of these provisions are properly reflected in the final FSMA regulations; a flexible, scale- and supply-chain appropriate framework is absolutely critical to ensuring that the regulations support and advance the growth, opportunity, and success of sustainable agriculture and food systems.

NSAC welcomes the opportunity to comment on the supplemental proposed Produce Rule, and is grateful for FDA's outreach to the sustainable agriculture community during the comment period. We look forward to continuing to work with the agency to ensure the correct implementation of the law, and to make sure the regulations and their implementation are successful and supportive of the sustainable agriculture and food systems.

[13] *Id.* § 419(a)(3)(F).
[14] *Id.* § 419(b)(3).
[15] *Id.* § 419(a)(1)(B).
[16] *Id.* § 419(c)(C).
[17] Food Safety Modernization Act § 209(b).

II. SUMMARY OF RECOMMENDATIONS

NSAC provides full comments and recommendations on the supplemental proposed Produce Rule below. A summary of our key recommendations, in the order in which they appear, is as follows:

- Revise the 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.
- Retain the changes to the definition of "farm," and the supporting definitions of "harvesting," "packing," and "holding" to no longer differentiate between activities done on a farm's own RACs and someone else's RACs.
- Clarify that activities done on RACs that do not transform or change the nature of the RAC are not considered manufacturing/processing.
- Provide more clarity to the farm definition, particularly by removing the phrases "under one ownership" and "in one general physical location" from the farm definition.
- Retain the revisions to "harvesting," "packing," and "holding," and clarify that mixing or blending intact RACs is considered "holding," regardless of whether the RACs are the same or different.
- Any records required of farms that pack and hold RACs from other farms for traceability purposes should not exceed a one-up-one-down record of the transaction.
- Calculate all sales thresholds based on the sales of regulated product (e.g. "covered produce").
- Defer finalizing a numeric water quality standard until a full risk assessment is completed and an appropriate and scientifically sound agricultural irrigation water standard is developed.
- Move the agricultural water standard and testing frequencies to guidance, and reduce the testing frequencies significantly.
- Clarify in the preamble to the final rule that drip and trickle irrigation, including buried drip irrigation, are not direct application methods.
- Broadly define water "source" to help farmers determine how many different sample sets are required, reduce redundant testing, and share data.
- Retain the zero-day interval for properly composted manure, and eliminate the requirement to insulate compost.
- Move forward with the proposed research strategy to understand the various risks and benefits of manure use on produce fields, and ensure that the research and risk assessment is comprehensive enough to capture the range of agricultural practices, climatic conditions, and manure types used on farms across the country. Codify an interim standard that does not conflict with the National Organic Program while this process is underway.
- Move the preamble language supporting sustainable conservation practices and co-management into the codified.
- Clarify that farmers are not required to wait nine months between grazing and harvest.
- Retain and build upon the improvements to the withdrawal process, including the process to reinstate a qualified exemption.
- Clarify the role of third party audits in FSMA implementation, particularly within the context of supplier verification programs and covered farms.
- Work with USDA AMS to ensure full integration with FSMA and USDA GAPs.
- Clarify coverage of transplants or "starts" under the rule.

III. COMMENTS ON FDA'S APPROACH TO REGULATING FARMS, INCLUDING THE DEFINITION OF "FARM" AND OTHER SUPPORTING DEFINITIONS

NSAC submits the following comments on FDA's approach to regulating farms under the FSMA rules, including recommendations and comments on the organizing principles, the revised definition of "farm," and the supporting definitions of "harvesting," "packing," and "holding." The changes to these definitions in the supplemental rules are a marked improvement from the original proposed definitions. However, further significant revision is still necessary to ensure an accurate characterization of farms and farm activities, and an appropriate regulatory framework.

A. FDA's "organizing principles" are still fundamentally flawed and should be substantially revised to reflect common farming activities and levels of risk.

In the preamble to the original proposed rules, FDA described five "organizing principles" that create the framework for FDA's approach to regulating farms by attempting to explain the agency's definition of "farm." In our original on the original proposed rules, we noted the significant flaws in FDA's foundational understanding of farms, which cast FDA's entire regulatory framework into question.[18] FDA's revised approach in the supplemental rules to the issue of farms that pack and hold other farms' RACs has cleared up some concerns (resulting in the elimination of one principle) but fundamental misperceptions persist in FDA's updated organizing principles.[19]

The organizing principles continue to rest on a flawed understanding of how farming works because they assume that farms exist simply to grow their crops, and that getting those crops to market is not something that "farms" do. The reality is that a farm cannot stay in business without marketing its crops and preparing those crops for market; getting produce and agricultural products to market is an inherent part of a farm business. Additionally, the imperative to maximize the value a farm receives for its crops creates the need for value-added processing and marketing, as well as cooperative harvesting, storage, and distribution (including transportation). The agency cannot effectively move forward in finalizing regulations that cover farms when the basis for these regulations rests on a skewed and incorrect perception of why farms exist and what they do. The deletion of original organizing principle number four was necessary due to the revised approach to packing and holding others RACs, but more needs to be done to provide a solid foundation for FSMA's approach to regulating farms.

FDA must align the organizing principles and new definitional framework with the broader risk-based mandate of FSMA. The organizing principles are too narrow and neglect to include certain activities that constitute traditional farming practices by leaving out the marketing and sales (i.e., business) element of agricultural production. They also fail to incorporate the concept of risk sufficiently, which leads to the FDA to classify activities based more on distinctions about where the activities take place, the source of a food, and where the food is consumed. While those considerations may be relevant to a foodborne illness risk assessment in particular circumstances, FDA fails to directly incorporate risk into the decision process for determining how certain activities are classified under the proposed rule. This is a fundamental flaw. We elaborate on these issues in the recommendations below.

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[18] *See* Appendix II, NSAC's 2013 Produce Rule comments, at 30–31.
[19] 79 Fed. Reg. 58538.

Recommendation: FDA should revise the 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, and so that they are consistent with FSMA's risked-based mandate and approach.

Specifically, FDA should modify the organizing principles so that they read:

1. The basic purpose of farms is to produce RACs and ~~RACs are the essential products of farms~~ to prepare and deliver them for sale to end-users or other buyers.
2. Activities that involve RACs and that farms ~~traditionally have~~ perform~~ed~~ for the purposes of ~~growing~~ selling their own RACs, including growing them, ~~removing them from the growing areas~~ harvesting them, preparing them for ~~use as a food RAC~~ consumption in their raw and unprocessed state, and packing, sorting, grading, packaging, labeling, holding ~~and~~, transporting, marketing, and delivering them, should all be within the definition of "farm."
3. Even though farms traditionally also do a wide variety of activities that may be considered processing, for the purpose of these organizing principles, ~~A~~activities should be classified based ~~in part on whether the food operated on is a RAC or a processed food, and~~ on whether the activity transforms a RAC into a processed food (as defined by these rules).
4. Manufacturing/processing, packing, or holding food – whether RACs or processed foods, from any source – for consumption on the farm should remain within the farm definition.

B. FDA must ensure that the farm definition reflects reality.

Foundational to FDA's proposed regulatory framework are the definitions of "farm" and "facility." When Congress passed FSMA, it was clear that the law was expanding FDA's regulatory authority over existing regulated entities (i.e. facilities) and creating authority to regulate previously non-regulated entities (i.e. farms). However, to ensure an appropriate, coordinated, and targeted regulatory framework, Congress included provisions in both §§ 418 and 419 that specify that the activities subject to the requirements of one section are not subject to the requirement of the other section.[20] The intent behind these provisions was to ensure that one operation would not be subject to multiple sets of regulations under FSMA, and that farms would continue to be exempt from the facility registration requirement.[21] FDA's proposed definition of "farm mixed-type facility" therefore requires close scrutiny to ensure it adheres to congressional intent, which requires a broad reading of the term farm and a narrow reading of the term facility.

The revisions to the definition of "farm" and other supporting definitions in the supplemental rules are much more practical and workable for farmers. However, the overall definition of "farm" still presents an unrealistic and incomplete understanding of how most farms in America are structured, in terms of their physical, spatial, and business composition. We provide the following recommendations to improve the farm definition and ensure that coverage under the FSMA rules is appropriate and consistent with congressional intent.

[20] Food, Drug & Cosmetic Act §§418(k) and 419(h).

[21] *See* Appendix II at 27–29 (regarding congressional intent and FDA's broad authority to modify the farm definition to ensure that farms are not inappropriately regulated as facilities).

1. FDA should retain most of the proposed changes to the "farm" definition.

The proposed revisions to the farm definition and the supporting definitions of harvesting, packing, and holding are significant improvements, and – for the most part – should be retained in the final rule. Below, we offer comments and recommendations to improve upon these changes.

a. Packing and holding someone else's RACs should not make a farm or other low-risk establishment a "facility."

In our comments on the 2013 proposed rules, we provided extensive comment and recommendations on the need to revise the definitions to eliminate the distinction between activities done on a farm's own raw agricultural commodities (RACs) or another farm's RACs.[22] In the supplemental proposed Produce Rule, FDA "tentatively concur[s] with commenters who stated that packing or holding of produce presents similar reasonably foreseeable hazards regardless of whether the produce is grown and harvested on farms under the same or different ownership, and that such hazards associated with packing or holding activities would best be addressed through the standards established under the Produce Safety regulation."[23] We appreciate FDA's recognition that the hazards associated with packing and holding produce do not change based on who grew the produce.

Recommendation: The final rule should retain the changes to the definition of "farm," and the supporting definitions of "harvesting," "packing," and "holding" to no longer differentiate between activities done on a farm's own RACs and someone else's RACs.

b. Activities conducted at a farm on any RAC that do not change the nature of a RAC should not trigger the facility definition.

FDA revised the farm definition to include packaging and labeling of RACs as activities that fall within the "farm" definition, as long as there is no additional manufacturing/processing done to the RAC. We support this outcome, because labeling RACs – which are by definition single ingredient products – does not pose the same risk of foodborne illness that might be caused by a product that has been transformed from its natural or intact state or combined with other ingredients.

FDA also revised the farm definition to include drying and dehydrating of RACs without additional processing. We support the substance of this change. Any activity conducted at a farm on any RACs that does not change the nature of the RAC should not trigger registration as a facility. Requiring otherwise would be contrary to Congressional intent.

While we support this outcome, we do not agree with the logic that led to it: FDA is still defining these activities that do not change the nature of the RAC as "manufacturing/processing," but ruling them to be manufacturing and processing activities that are acceptable under the farm definition. Given that manufacturing and processing activities "change the nature of" or "transform" the RAC, it seems more appropriate to clarify that packaging and labeling and drying/dehydrating are <u>not</u> manufacturing/processing when done on intact RACs. Using the example of "washing," the agency explained that some activities can fall under multiple definitions. The agency should do the same

[22] *See* Appendix II at 33–37.
[23] 79 Fed. Reg. 58438.

with packaging and labeling and drying/dehydrating. If this cannot be done in the definitions themselves, it can and should be done both through guidance and the preamble to provide this needed clarity.

Recommendation: The final rule should, at the very least, retain the changes to the definition of "farm," to clarify that packaging and labeling and drying/dehydrating RACs are not activities that trigger the facility definition, as long as there is no further processing done to change the nature of the RAC. However, a more appropriate solution would be to clarify that activities done on RACs that do not transform or change the nature of the RAC – like packaging and labeling – are not considered manufacturing and processing.

c. The definition of "farm" should not include the term "facility."

In our comments on the original proposed rules, we recommended that FDA replace the use of the term "facility" in the definition of "farm," because farms are, by existing definition, not facilities. We appreciate that FDA has removed the term "facility" from the farm definition. However, we would encourage the agency to consider using the term "operation" rather than the term "establishment" to describe a farm.

One of the primary purposes of definitional elements in rules is to assist the regulated community in understanding whether and to what extent the rules may affect them. For farmers, who have not historically been regulated under FDA rules, it is critical that key terms are defined in a way that is realistic and sensible. The definition that FDA ultimately codifies will be with us for generations, and we urge the agency to craft a definition that farmers now – and 50 years from now – can see themselves in. Most farmers do not refer to their businesses as "establishments." "Operation" is a much more commonly used term – notably used in existing food safety certification programs like USDA GAPs, Harmonized GAPs, LGMA, and FDA's own industry guidance[24] – and would resonate better with the farming community.[25]

Recommendation: FDA should replace the use of the term "establishment" with "operation" in the definition of farm. Below, we provide the entirety of our recommended revisions to the farm definition, which we recommend FDA adopt across all applicable FSMA rules: Produce, Preventive Controls for Human Food, and Preventive Controls for Animal Food.

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[24] *See* USDA GAP & GHP Audit Program User's Guide, available at http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=stelprdc5097151; Harmonized GAP Standard, available at http://www.unitedfresh.org/assets/Harmonized Standard - pre-farm gate 130501.pdf; LGMA Commodity Specific Food Safety Guidelines for the Production and Harvest of Lettuce and Leafy Greens, available at http://www.lgma.ca.gov/wp-content/uploads/2014/09/California-LGMA-metrics-08-26-13-Final.pdf; FDA's Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables, available at http://www.fda.gov/downloads/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/ProduceandPlanProducts/UCM169112.pdf.

[25] Correspondingly, farmers are familiar with referring to themselves as farm "operators," which supports a more logical congruence of terminology than to refer to them as "establishers."

2. FDA should remove the reference to "one general physical location" from the farm definition.

FDA requests comment on whether the farm definition should include the phrase "one general physical location" and what, if any, impacts removing or modifying the phrase would have on other rules that already include the definition of "farm."

We strongly recommend FDA remove the reference to "one general physical location" from the farm definition. As we stated in our comments on the original proposed rules, farms may consist of multiple parcels of land and buildings that may or may not be contiguous, and this is true whether in rural, urban, or suburban settings. There are traditional as well as modern, innovative reasons for this fact,[26] and FDA acknowledges this to be true.[27] We therefore urge the agency to define "farm" in a manner that reflects this common understanding, and that resonates with farmers, the majority of which run operations comprised of multiple parcels of land. These parcels may be in separate counties or even across state lines; may be rented or leased; and may include packing or storage sheds at a distance from the fields where the crops are grown.

FDA asks how to interpret "one general physical location" for the purposes of enforcing this regulation, noting that farms in different locations could be considered different "farms" under this proposed definition and, therefore, such businesses might qualify for extended compliance periods intended for farms that qualify as small and very small businesses.[28] A definition that clearly defines a farm as including all land, parcels, and operations that comprise the farm business – and are under the effective control of one or more farm operators[29] – would avoid this potential difficulty in enforcing the rules. In general, we feel that it is better to avoid using terms in defining farms that are already difficult to discern and will only become more confusing over the years the regulations are in force. The simpler and more straightforward the definition, the more likely it will be adhered to and effectively enforced.

We also note that this modification to the definition should not result in foreign farms being considered part of a domestic farm under the same ownership. The legal practicalities of international business transactions – such as requirements in foreign jurisdictions that entities from outside that jurisdiction establish and register a business under the laws of the foreign jurisdiction in order to export from that country – prevent such an illogical and unintended outcome, ensuring that such operations are held to appropriate US import requirements.

Eliminating the "one general physical location" reference would also clarify the confusing and arbitrary distinction between "on-farm" and "off-farm" packing and holding. Under the original and supplemental proposed rules, farms that are engaged in "off-farm" packing are subject to the Preventive Controls rule, while farms that do "on-farm" packing are subject to the Produce Rule. FDA has acknowledged that the hazards are the same regardless of who grew the produce being packed and held,[30] and – in acknowledging comments that "there is no evidence to suggest that

[26] *See* Appendix II at 32–33.
[27] 79 Fed. Reg. 58440 ("We are aware that numerous produce farms own and grow crops in non-contiguous parcels of land in various geographical locations, such as in multiple States or even in more than one country.").
[28] 79 Fed. Reg. 58440.
[29] Similarly, the use of "farm operator" is much more common and clear compared to "owner." We explain this in more detail below.
[30] 79 Fed. Reg. 58438.

different requirements for off-farm establishments that pack and hold produce are needed to prevent contamination" – FDA notes that "[t]he specific steps that are necessary to ensure the safety of produce that an establishment packs and holds generally would be the same regardless of whether the establishment is on-farm or off-farm."[31]

FDA acknowledges that the hazards presented by packing and holding produce – and the necessary steps to minimize those hazards – are the same regardless of who grew it, or where it was packed, but continues to regulate them under different frameworks. This is directly contrary to congressional intent that rules be risk-based and flexible so that farms covered by the Produce Rule are not improperly subjected to the Preventive Controls rule. It is also important to note that farms harvesting non-covered produce (e.g. sweet potatoes and winter squash – produce not covered under FSMA because it is not identified as posing a significant food safety risk) and distributing that produce through a shared 'off-farm' packing operation are also swept up by this inappropriate designation as facilities. Such an operation is not subject to the Produce Rule if they are only growing and marketing non-covered produce, and so citing compliance with the Produce Rule as their 'alternative' preventive control is illogical.

Adopting a more sensible definition of "farm" solves this illogical outcome. In particular, removing the phrase "one general physical location" from the "farm" definition would clarify the intent that all parcels and structures are considered part of that farm operation, and provide a sensible and risk-based solution to the issue of an operation being regulated differently for doing the same activity in a different location from where RACs were harvested.

Recommendation: FDA should remove the phrase "in one general physical location" from the farm definition. Below, we provide full revisions to the farm definition that incorporate this recommended change.

3. FDA should remove the phrase "under one ownership" from the farm definition.

Similar to our comments above, we strongly urge FDA to modify the farm definition to reflect the reality that many farming operations are not under a single ownership. Nearly forty percent of US farmland is rented from non-operating owners.[32] The percentage is generally higher for larger farms than for smaller farms, but this is a common fact across agricultural operations. With so much farmland under cash or share rent arrangements with the landowner, limiting farms to those "under one ownership" would exclude a significant number of farms. This is a completely illogical outcome.

We encourage FDA to replace the concept of "owner" with that of a "farm operator," which we believe more accurately describes the responsible party or parties FDA is attempting to identify. In the Produce Rule, FDA defines "you" as "the person subject to some or all of the requirements under this part." In the Preventive Controls Rule, FDA has defines "you," as "the owner, operator, or agent in charge of a facility that manufactures/processes, packs, or holds food for consumption

[31] 79 Fed. Reg. 58535.
[32] 2012 U.S. Census of Agriculture, available at http://www.agcensus.usda.gov/Publications/2012/Online_Resources/Ag_Atlas_Maps/Operators/Tenure/12-M116-RGBChor-largetext.pdf.

in the United States."[33] Similar to what's reflected in the Preventive Controls Rule, the person responsible for compliance with the Produce Rule is not necessarily the owner; perhaps it is the owner of the business, but it is not necessarily the owner of the farmland. We believe FDA intends for the rules to apply to the person (or persons) with effective operational control over the farm business; this could be owners, tenants, partners, or employees. "Farm operator" is a term commonly used in the agricultural community. USDA refers to "farm operators" across grants, loans, and research programs to mean the person(s) responsible for day-to-day farm decision-making.[34] Therefore, we believe it is more appropriate to use the term "farm operator(s)," which we define below.

FDA acknowledges that farms may fall outside the single ownership designation, and asks whether to treat cooperatively owned on-farm packinghouses as under the same ownership of any or all of the growers' farms. Rather than try to shoehorn cooperative or other jointly controlled business operations into the notion of a farm being under "one ownership," we would encourage FDA to modify the definition to reflect the varied business structures common among farming operations, and regulate those jointly controlled operations as farms.

FDA's question regarding collective ownership structures is brought up under the scenario of cooperatively owned "on-farm packinghouses." We would again note that this "on-farm" versus "off-farm" distinction is arbitrary where the operations are extensions of the farm business, and remain under majority control of one or more farm operators. We urge FDA to focus on crafting a definition that is accurate and risk-based – so that it provides a regulatory framework that ensures that farms that pack and hold covered produce without doing any additional processing that transforms the nature of the RAC are regulated as farms under the Produce Rule, not as facilities under the Preventive Controls rule, regardless of where that packing and holding takes place. We submit that, as long as the farm operators supplying the produce to be packed have at least majority control over the operation, then such an operation is part of each farm. We again note that this should not result in foreign farms being considered part of a domestic farming operation.

We appreciate FDA's concern with regulating these operations as farms, not facilities, is because facility registration provides a valuable traceability tool for the agency. However, FDA is already considering in the Produce Rule whether farms that pack or hold RACs from other farms should be required to keep records of those transactions. We provide full recommendations on recordkeeping in part D below, but point out here that requiring one-up-one-down records maintained in the ordinary course of business is a sensible approach that would apply to individual farms as well as jointly controlled farm business operations.

Therefore, in response to the agency's question, we recommend that cooperative *or other jointly controlled farm businesses* be considered part of the farm of each farm operator. However, only those sales made by a farm operator through such a farmer-controlled operation should be attributed to that individual farmer when calculating farmers' sales for purposes of FSMA compliance. This is

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[33] 78 Fed. Reg. 3796.

[34] *See e.g.* USDA Economic Research Service Glossary, available at http://www.ers.usda.gov/topics/farm-economy/farm-household-well-being/glossary.aspx ("The farm operator is the person who runs the farm, making the day-to-day management decisions. The operator could be an owner, hired manager, cash tenant, share tenant, and/or a partner. If land is rented or worked on shares, the tenant or renter is the operator."); 2012 USDA Agricultural Census data reported that 54 percent of all farms reported having two operators, and 7 percent reported three operators involved in day-to-day decision making. USDA 2012 Census Highlights, Farm Demographics, ACH12-3 (May 2014).

particularly important for determining the extent of coverage to which each farmer would be subject under the Produce Rule. It would be unreasonable to attribute sales back to the individual owners beyond their proportionate contribution; otherwise individuals would rarely find the benefit to entering into such joint operations.

Take the example of ten farms that supply RACs to be packed and distributed wholesale through a food hub. The food hub only dries, packs, labels, packages and holds produce, it does not do any manufacturing or processing that changes the nature of the RACs. The food hub is a stand-alone business entity, but the ten farmers that supply the RACs to be packed and held are joint partners and collectively hold majority control over the business operation. The food hub has $2 million in sales, with each farmer making $200,000 in sales through the food hub. Separate from the food hub, one of the farmers also sells $250,000 direct to consumers through farmers markets or CSAs. Under the definition we proposed, that farmer would then be considered as having $450,000 in sales, the majority of which are sold to qualified end users for purposes of determining eligibility for the qualified exemption under the Produce Rule. This is a logical and fair outcome.

***Recommendation*:** FDA should remove the phrase "under one ownership" from the farm definition. FDA should consider cooperative or otherwise jointly controlled farm business operations as being part of each members' farm. However, only those sales made by the individual farm through the collectively controlled business should be counted when calculating individual farm sales. FDA should also replace the concept of the owner as the responsible party with "farm operator," as defined below.

***Overarching Recommendation*:** Based on all of the above, FDA should make the following changes to the farm definition:

Farm means an ~~establishment~~ operation under the effective control of one or more farm operators ~~an establishment under one ownership in one general physical location devoted to~~, the primary purpose of which is the growing and harvesting of crops, the raising of animals (including seafood) or both, including, where applicable, the sale of those agricultural products. A farm may consist of multiple contiguous or non-contiguous parcels of land, including any structures or buildings on those parcels, and including a jointly controlled farm business operation(s). The term "farm" includes ~~establishments~~ operations that, in addition to these activities:

(i) Pack or hold raw agricultural commodities;

(ii) Pack or hold processed food, provided that all processed food used in such activities is either consumed on that farm or another farm under the same ownership, or is processed food identified in paragraph (iii)(B)(1) of this definition;

(iii) Manufacture/process food, provided that:

(A) All food used in such activities is consumed on that farm or another farm under the same ownership; or

(B) Any manufacturing/processing of food that is not consumed on that farm or another farm under the same ownership consists only of:

(1) Drying/dehydrating raw agricultural commodities to create a distinct commodity, and packaging and labeling such commodities, without additional

manufacturing/processing; ~~and~~ or[35]
(2) Packaging and labeling raw agricultural commodities, when these activities do not involve additional manufacturing/processing.

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Farm operators means the persons or entities that have operational control over the farm and benefit in whole or in part from the farm's normal operation. Farm operators may be owners, tenants, partners, or employees.

***
Jointly controlled farm business operation means a business that supplies raw agricultural commodities and is majority controlled by two or more farm operators.

C. FDA should provide additional clarity to the supporting definitions of "harvesting" "holding" and "manufacturing/processing."

1. FDA should further clarify the definition of "harvesting."

As discussed above, NSAC supports FDA's revised definition of harvesting, which no longer limits harvesting activities to the farm on which RACs are grown or raised. We also support the addition of "field coring" to the list of "harvesting" activities. However, field coring is only one of several activities that are common harvesting practices and that we recommended be added to the list of harvesting activities in our original comments.[36] We recognize that FDA's improved definitions of packing and holding, which now include activities incidental to or necessary for the safe and effective storage or transportation of a RAC, may now address some of these activities (e.g. refrigerating, spinning). We also recognize that the list cannot be fully exhaustive. Nevertheless, in the interest of clarity, we recommend making the list as exhaustive as possible, and periodically reviewing the list to ensure that it reflects the breadth and range of practices done as part of harvesting

***Recommendation*:** FDA should build on the existing list of harvesting activities to also include the following activities:

- Braiding;
- Bunching;
- Cutting the edible portion of the crop from the plant;
- Hydro-cooling;
- Maintaining hydration of product;
- Refrigerating;
- Removing foliage;
- Removing free water from (e.g. spinning);

[35] We did not include detailed explanation of this recommended change because we believe it is an inadvertent error. By using "and" FDA appears to intend that farms can do (iii)(B)(1) activities as well as (iii)(B)(2) activities and still be within the farm definition. However, use of "and" implies that both (iii)(B)(1) and (2) are necessary to satisfy the definition. We do not think this is the intended (or logical) outcome, which is to provide that farms can do either (iii)(B)(1) or (iii)(B)(2) or both, and still be within the farm definition. Accordingly FDA should replace "and" with "or," and possibly include new section (iii)(B)(3): both (iii)(B)(1) and (iii)(B)(2).
[36] *See* Appendix II at 39.

- Removing or trimming roots;
- Trimming the tops of bunches of allium crops such as leeks, chives, or garlic and root crops such as carrots, beets, turnips, parsnips, etc. to prepare them for sale; and
- Trimming the lower stems of harvested herb crops such as parsley, basil, or cilantro, or the lower stems of leafy greens.

2. FDA should retain the changes to "packing" and "holding," but should further clarify the definition of "holding."

FDA's revised definitions of "packing" and "holding," which now include activities incidental to or necessary for the safe or effective transport or storage of a RAC, add significant clarity to FDA's intent regarding these definitions, and we encourage that the final definitions retain these important modifications.

FDA now includes "mixing" of RACs in the definition of "holding." We support this change, but urge FDA to clarify that mixing intact RACs, regardless of whether they are the same or different RACs, be included in the holding definition. FDA currently states that blending or mixing of the same RAC is considered holding, and that blending of processed foods is considered manufacturing/processing, but does not clarify which definition applies to the blending or mixing of different, intact RACs.[37]

This concern arises, for example, in the case of salad mixes, where several kinds of intact RACs (e.g. baby spinach, kale, and mesclun lettuce) may be mixed together. FDA has opined that this would not be considered manufacturing if there is no additional processing. This would appear the logical result; it would be inconceivable to imagine a regulatory outcome where farms are considered "farms" or "facilities" based on the combinations of *intact* RACs that they are mixing. We believe a clear solution to this issue is to categorically provide in the regulations that mixing intact RACs is included in the holding definition, regardless of whether they are the same or different RACs.
***Recommendation*:** Clarify that mixing or blending intact RACs is considered "holding," regardless of whether the RACs are the same or different.

D. FDA should not require records beyond those received and kept in the ordinary course of business.

FDA specifically requests comments on whether the agency should require farms that pack and hold produce from other farms to establish and maintain records of those transactions.

In our original comments, we suggested that FDA could address the traceability concerns associated with packing and holding RACs from other farms simply: To ensure that a RAC can be traced back from the low-risk entity (such as the farm) that is conducting the packing and holding activities on that RAC to the farm that supplied the RAC, FDA could require that receiving farms keep basic information from the supplying farm that identifies the immediate source of the RACs. This information could be in the form of a label or invoice, or other document that includes information identifying the farm that is kept in the ordinary course of business.

[37] 79 Fed. Reg. 58439.

It is important to note that FSMA does not authorize FDA to require traceability records of all covered produce farms. FSMA does authorize FDA to require maintenance of certain records for foods identified as high risk, but FSMA also restricts FDA in the types of records it can require of high-risk foods.[38] Specifically, FDA is not to require "creation and maintenance of duplicate records where the information is contained in other company records kept in the normal course of business" and cannot "prescribe specific technologies for the maintenance of records."[39] FDA should consider these statutory requirements in requiring farmers to keep records of RACs from other farms.

***Recommendation*:** If FDA decides to require farms that pack and hold RACs from other farms to maintain records for traceability purposes, those records should not exceed a one-up-one-down record of the transaction. Additionally:

- The record should be limited to those documents generated in the ordinary course of business, like a label or invoice;
- Given the highly perishable nature of covered produce, the record should not be required to be retained for more than one year; and
- FDA must accept written records, and cannot require electronic records.

[38] *See* FSMA § 204(d)(A),(C), (E), (L). We also note that FDA has yet to propose the rule traceability and high-risk foods.

[39] FSMA § 204(d)(1)(C), (E).

IV. COMMENTS ON THE SCOPE OF COVERAGE

NSAC submits the following comments and recommendations on FDA's methods for determining the scope of coverage under the supplemental proposed FSMA rules. Specifically, NSAC provides comments on the Produce Rule's *de minimis* exemption, definitions of very small and small business, and modified requirements for qualified farms; however, the underlying principles in these comments extend to coverage determinations based on sales thresholds under each FSMA rule.

A. Coverage determinations should be based on sales of covered product that each rule regulates.

FSMA directs FDA to ensure regulations that are flexible, scale-appropriate, and practical for a diversity of farming systems.[40] Specifically, Congress granted FDA significant authority to provide special considerations for small or very small businesses[41] and modified requirements for qualified entities, including very small processing facilities and small and mid-sized farmers and facilities engaged primarily in selling food through direct-to-consumer supply chains.[42] FDA's proposed and supplemental regulations respect Congress's intent to reject a one-size-fits-all approach by establishing a full exemption for farms with *de minimis* sales, special considerations for small and very small businesses, and modified requirements for farms with majority direct sales.

In the initial proposed rules, FDA determined whether a farm qualified for these special considerations based in part on a calculation of <u>total</u> food sales. As we addressed in our comments on the original proposals, making threshold determinations based on total food sales severely undermined the purported "flexibility" provided by these categories. In particular, beginning farmers, non-produce farmers trying to diversify into fruits and vegetables, and family farmers with diversified operations would be discouraged from entering the market.[43]

We appreciate that FDA has revised some of the sales thresholds used to determine whether a farm or food business is considered small, very small, or exempt under the rules. Specifically, we support the change from "all food" to "all produce" for the *de minimis* exemption and the definitions of small and very small business under the Produce Rule, and the change from "all food" to "human food" in the very small business definition under the Preventive Controls Rule.[44] These changes make it somewhat clearer and easier for farmers to understand whether and to what extent the rules apply to them. However, to address questions of coverage consistently across all rules, we urge the agency to calculate all sales thresholds throughout the rules based on sales of products *actually regulated by each of the rules.*

Farms that fit FDA's definition of "mixed-type facilities" and thus are regulated under multiple rules already have a difficult task navigating the requirements of each rule. It is logical for coverage to be based on what is covered under each specific rule, rather than having a different metric for each definition. Lack of clarity and consistency across the rules on this issue will only further confuse

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[40] 21 U.S.C. §§ 350g(n)(3)(A), 350h(a)(3)(A), 350h(c)(1)(B).
[41] 21 U.S.C. §§ 350h(a)(1)(B), 350h(a)(3)(F), 350h(b)(3).
[42] *Id.* at §§ 350g(l). 350h(f).
[43] *See* Appendix II at 45–46, 53–55.
[44] We also submitting full comments on the very small business definition under the Preventive Controls rule to that docket, but underscore the importance of consistently calculating thresholds based on what is covered by each respective rule when determining coverage under all applicable FSMA rules: Produce, and both Preventive Controls Rules.

implementation and compliance for two already-confusing rules. This issue should be addressed in the final rule.

Changing the threshold in the Produce Rule from "all food" to "all produce" barely increases the scope of the *de minimis* exemption; these farms would account for less than 4% of total covered produce acres in the U.S.[45] As FDA notes, this represents a tiny fraction of the volume of produce in the marketplace that could become contaminated and, "therefore, would have little measurable public health impact."[46]

FDA states that the agency considered basing the threshold on "covered produce" but did not do so, based in part on the difficulty in determining which produce is covered or not, or in keeping track of produce sold versus produce grown for personal consumption.[47] We do not share the agency's concern that this is so difficult; we believe farmers can and would track their sales of covered versus non-covered produce, and adjust for produce consumed on the farm. Moreover, defining coverage in terms of "covered produce" versus "all produce" would likely still only cover a small fraction of the total volume of covered produce in the U.S. food supply for those farms that would qualify for the *de minimis* exemption. For small and very small businesses, they would continue to be covered by the rules, but there would just be slightly more farms that qualify for extended compliance times. This clarity and consistency would be a great benefit to farms, and would result in minimal changes to total regulatory coverage.

We also note here that the change from "all food" to "human food" in the Preventive Controls Rule's very small business definition still only exempts a tiny fraction of the total volume of processed food from coverage. According to FDA, this revised threshold would cover only a tiny percentage – less than two percent – of the food produced in the U.S.[48] For farms that might fall under the definition of "facility" and are considered "farm mixed-type facilities" under the proposed regulations, however, the threshold will have a very significant impact. We support these changes, which are fully consistent with FSMA's directive to FDA regarding considerations for small and very small businesses and farms engaged in value-added processing.[49]

Not only are these changes important for clarity and consistency of implementation, but they also encourage small and mid-sized farmers to diversify into growing and selling fresh fruits and vegetables into local and regional markets. Failure to implement this approach uniformly across both rules could stifle the development and growth of this important sector, and keep beginning farmers, non-produce farmers who are trying to diversify their operations, and family farmers who have diversified operations out of this market.

Recommendation: FDA should base coverage determinations on sales of produce or product that is regulated by each rule. Specifically, under the Produce Rule:

- FDA should exempt farms from the Produce Rule that have no more than $25,000 in gross sales of covered produce.

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[45] 79 Fed. Reg. 58437.
[46] *Id.*
[47] 79 Fed. Reg. 58437.
[48] 79 Fed. Reg. 58555.
[49] *See* 21 U.S.C §§ 350g(a)(n)(3)(A), 350h(a)(3)(A). NSAC's separate comments on the supplemental Preventive Controls Rule contain specific recommendations regarding the definition of very small business under that rule.

- FDA should define small and very small businesses as having less than $500,000 and $250,000 in sales of covered produce, respectively.

B. "Covered produce" is also the appropriate metric for farms that qualify for modified requirements under the Tester-Hagan amendment.

As discussed in the preceding section, for clarity and consistency across rules, FDA should calculate sales based on "covered produce" when determining whether a farm qualifies for modified Produce Rule requirements under the Tester-Hagan criteria for local food producers, just as FDA should for all other coverage determinations under the Produce Rule. Calculating the $500,000 threshold on sales of "all food" is inconsistent with the intent of Congress to protect small and mid-sized farmers and food businesses selling to local markets from the full weight of FSMA compliance. Congressional intent, the statutory language and structure, the agency's discretionary authority, and the public interest to ensure an abundant supply of locally sourced, healthy fruits and vegetables all support a decision to measure sales based on "covered produce" rather than "all food."

1. Congressional intent supports a broad, non-literal reading of "all food."

FDA's failure to give a more expansive reading to the Tester-Hagan amendment frustrates Congress's intent to balance improving food safety risk management with preserving small and mid-sized food producers.[50] Though FDA asserts that the text of the Tester-Hagan amendment requires the literal interpretation of "all food" in the regulations, there is a strong purposive argument that Congress intended for the modified requirements to apply to the types of small and mid-sized farms and facilities that would be subject to the full requirements if FDA maintains the currently proposed "all food" sales threshold.

As Senator Hagan said on the floor of the Senate, "farmers raising produce to sell directly to consumers at farmers markets and food co-ops face significantly different issues and pose less risk than those selling into the industrial supply chain, and should not be regulated in the same way."[51] During floor debate, many Senators spoke out in support of the protections FSMA afforded to smaller-scale operations and family farms.[52] These statements about the differences between small and mid-sized farms and large, industrial-scale food producers demonstrate why Congress would support an expansive reading of the Tester-Hagan qualified exemption, to more effectively encompass the entire class of small businesses Congress intended be eligible for modified regulatory requirements.

Senator Tester also emphasized the importance of the relationship between small producers and their customers. The personal relationship between small and mid-sized food producers and their customers creates a strong incentive for these businesses to only put safe food into commerce,

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[50] Senator Hagan said that FSMA, "with the adoption of the Tester-Hagan amendment, . . . strikes the right balance between protecting the public health from foodborne illnesses while ensuring our Nation's farmers can continue to feed America." 156 CONG. REC. S8014 (daily ed. Nov. 18, 2010). Senator Merkley stated that supported the bill because it would "improve the tracing of contaminated food," "increase inspections," *and* "protect small farms." 156 CONG. REC. S8009 (daily ed. Nov. 18, 2010).

[51] 156 CONG. REC. S8013 (daily ed. Nov. 18, 2010) (statement of Sen. Hagan).

[52] *See e.g.* 156 CONG. REC. S7921–22 (daily ed. Nov. 17, 2010) (statement of Sen. Enzi).

[52] 156 CONG. REC. S7922 (daily ed. Nov. 17, 2010) (statement of Sen. Hatch); *Id.* (statement of Sen. Hatch); *Id.* at S7929 (statement of Sen. Chambliss); 156 CONG. REC. S8009 (daily ed. Nov. 18, 2010) (statement of Sen. Merkley).

because one bad experience could crush an entire business.[53] Though large agricultural operations can experience severe fallout from a single foodborne outbreak,[54] industrial-scale agricultural businesses still have more insulation than small local producers. For example, Earthbound Farm, one of the entities responsible for the 2006 *E. coli* outbreak, not only survived the fallout from the outbreak but continues to be a profitable business.[55] The built-in incentive for small and mid-sized producers using direct marketing to sell high quality food is an effective but low-cost alternative to the full regulatory requirements of FSMA. Interpreting the Tester-Hagan amendment to cover more small and mid-sized direct market farms embodies Congress's intent to balance food safety concerns with the needs of small business.

2. FSMA's statutory language and structure show a lack of deliberateness in the use of "all food" rather than "covered produce."

FSMA's statutory language and structure also provide support for a purposive reading, rather than a strict literal interpretation, of "all food." The statutory text demonstrates that Congress was not deliberate in choosing to use "food" or "produce" in any specific instance, suggesting that FDA's strong emphasis on the use of "food" in the Tester-Hagan Amendment is misplaced. Moreover, Congress's intent for the rules to be "sufficiently flexible to be practicable"[56] and "appropriate to the scale and diversity"[57] of small businesses is clearly laid out in the statute.

The inconsistent and imprecise use of language in FSMA indicates that Congress did not carefully choose the word "food" when creating the qualified exemption criteria for the Tester-Hagan Amendment. Congress used the words *food* and *produce* interchangeably within specific sections in FSMA, indicating that Congress did not intend for very specific and different definitions to apply.

First, in the section on standards for produce safety, the words "food" and "produce" are used interchangeably in the subsection that details notification requirements for businesses not subject to the full requirements of FSMA. "[W]ith respect to a ***food*** for which a food packaging label is not required . . ., [a farm that is exempt under this section shall] prominently and conspicuously display, at the point of purchase, the name and business address of the farm where the ***produce*** was grown."[58]

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[53] *See* Editorial, *Boost Food Safety Without Burning Local Producers*, BILLINGS GAZETTE (Sept. 12, 2010, 12:10 AM); *see also* 156 CONG. REC. S8010 (daily ed. Nov. 18, 2010) (statement of Sen. Tester).

[54] The Jensen Brothers sickened at least 147 people and killed more than 30 due to their *Listeria* tainted cantaloupe. *See* Bill Marler, *Publisher's Platform: Three Years Since People Died From Cantaloupe*, FOOD SAFETY NEWS (July 22, 2014), http://www.foodsafetynews.com/2014/07/publishers-platform-three-years-since-the-primus-jensen-farms-audit/#.VIOrjNbxvyg. The brothers were sentenced to "five years probation, six months home detention, and $150,000 each in restitution fees to victims." James Andrews, *Farmers in Cantaloupe Outbreak Sentenced to Probation, House Arrest, Fines*, FOOD SAFETY NEWS (Jan. 29, 2014), *available at* http://www.foodsafetynews.com/2014/01/farmers-in-cantaloupe-listeria-outbreak-sentenced-to-probation-house-arrest-fines/#.VIPAmdbxvyg.

[55] *See* CAL. FOOD EMERGENCY RESPONSE TEAM, at 5 (detailing the entities involved in the 2006 *E. coli* outbreak). Earthbound Farm was earning about $75 million annually in 2013, *see* Mike Hornick, *Earthbound Farm may be sold*, THE PACKER (May 7, 2013), http://www.thepacker.com/fruit-vegetable-news/Earthbound-Farm-may-be-sold-206465931.html, and the company was acquired earlier this year for $600 million, *see* Angela Chen, *WhiteWave Foods Revenue Jumps on Earthbound Acquisition*, WALL ST. J. (Nov. 10, 2014), http://online.wsj.com/articles/whitewave-foods-revenue-jumps-on-earthbound-acquisition-1415624722.

[56] 21 U.S.C. § 350h(c)(1)(B).

[57] *Id.* § 350h(a)(3)(A).

[58] *Id.* § 350h(f)(2)(A)(ii) (emphasis added). Examples of produce that would require a label are tomatoes in clam shell plastic, as opposed to loose tomatoes, for which FDA does not require a package label. 78 Fed. Reg. 3504, 3550 (Jan. 16, 2013) (to be codified at 21 C.F.R. pt. 112).

This section of FSMA requires farms with a qualified exemption to give customers their name and address any time they directly market *produce that would otherwise be covered by the rule* to consumers: Though the section begins, "with respect to a *food*," the rest of the section makes it clear that this provision only applies to *produce* that is covered by the rule.[59] This is in fact how FDA has interpreted this provision because interpreting it to apply to all food, as the language suggests, would be nonsensical.[60] For example, it would not make sense if FDA were to read this section as requiring a farm with a qualified exemption to label its poultry, since poultry is a food that is regulated by the USDA, not FDA.[61]

Second, the Tester-Hagan amendment requirements for the Preventive Controls Rule are internally inconsistent. The end-user requirement[62] for qualified facilities is based on relative sales of food manufactured, processed, packed, or held at such facility (collectively "covered food"). However, the total sales requirement in the following paragraph refers to the "monetary value of all food sold by such facility."[63] If taken at face value, these requirements base the qualified exemptions on two different sets of criteria: first, the total sales of *covered food* to qualified end-users versus other purchasers; second, the total sales of *all food* sold by the facility, which are not otherwise covered by the Preventive Controls Rule. This variation in the criteria for calculating the exemption is not mirrored in the Produce Rule. This creates an irrational outcome for farms that are considered "mixed type facilities."

We understand that the revised definition of "very small business" means that farms will not need to qualify through the Tester-Hagan amendment under the Preventive Controls Rule in order to qualify for modified requirements. The main point is that these examples of inconsistent language use indicate that Congress was not deliberate in choosing every word of FSMA. When internal contradictions are apparent, FDA should give effect to the purpose of the statute rather than interpreting illogical text literally, as it did with the labeling requirements discussed above. Given that there is little to no support that Congress *deliberately* chose the words food or produce, as opposed to covered food or covered produce, FDA's strict literal interpretation of the Tester-Hagan Amendment frustrates congressional intent.

3. FDA's discretionary authority to modify "all food" extends to all rules, and should not be limited to the Preventive Controls Rule for Animal Food.

FDA's decision to narrowly interpret the exemption criteria in the Produce Rule and Preventive Controls Rule is inconsistent with other policy decisions and interpretations the agency has made in proposed rules promulgated under FSMA, namely in the Preventive Controls Rule for Animal Food. FDA created a separate regulation for facilities that process some animal food as opposed to

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[59] *See Id.*

[60] "These proposed provisions reflect our interpretation of [this section of FSMA] as applying only to food that would otherwise be covered produce but for the qualified exemption. We tentatively conclude that this interpretation is reasonable because applying these consumer notification requirements to food that would not otherwise be covered produce would mean applying requirements to food that bears no relationship to the subject of this rulemaking . . . ." 78 Fed. Reg. 3550.

[61] *See Id.*

[62] 21 U.S.C. § 350g(l)(1)(C)(ii)(I).

[63] *Id.* § 350g(l)(1)(C)(ii)(II).

facilities that solely process food for human consumption.[64] The Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals ("Animal Preventive Controls Rule") mirrors the Preventive Controls Rule for Human Food in that it also contains exemption criteria for facilities that would otherwise be covered by the rule.[65] The Tester-Hagan exemption for facilities that average annual sales of less than $500,000 of "all food" also applies to animal food facilities, since the statute itself did not distinguish between facilities producing animal food and facilities producing human food.[66] However, FDA interpreted the statutory language of the amendment differently for the Animal Preventive Controls Rule. Modified requirements apply to facilities that manufacture, process, pack, or hold animal food if:

> (1) . . . the average annual monetary value of the *animal food* manufactured, processed, packed, or held at such facility that is sold directly to qualified end-users . . . exceeded the average annual monetary value of the animal food sold by such facility to all other purchasers; and
> (2) The average annual monetary value of *all animal food* sold . . . was less than $500,000, adjusted for inflation.[67]

Clearly, FDA altered the text of the Tester-Hagan amendment to be more context-appropriate for the Animal Preventive Controls Rule. Yet, FDA fails to do the same for the Produce Rule or Preventive Controls for Human Food Rule, with illogical results. Take the not uncommon example of a farm that is staying afloat through diverse income streams. Assume a "farm mixed-type facility" annually sells $400,000 of animal feed, and – to qualified end users – $150,000 in pickles, $250,000 in pumpkins, and $200,000 in covered produce like cucumbers and tomatoes. This operation would be exempt from the Animal Preventive Controls Rule, subject to modified requirements as a very small business under the Preventive Controls Rule for Human Food, but subject to the *full extent of the Produce Rule*, despite growing only $200,000 worth of covered produce. This is an absurd result, and cannot be seen as satisfying the intent of Congress to protect smaller-scale producers engaging in direct sales.

FDA did not provide a rationale for the change in statutory language from "all food" to "all animal food," but instead simply stated in the proposed Animal Preventive Controls Rule,

> The Agency is specifying "animal food" in this definition as it intends to only include the sale of food for animals and not the sale of human food in determining whether a facility meets the requirements in those cases where a facility sells both. The Agency requests comment on whether food for animals and humans should be aggregated in determining whether a facility that sells both meets the statutory criteria of a qualified facility.[68]

FDA did not change this proposed definition of "qualified facility" after the first round of

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[64] FSMA gives FDA the authority to create modified requirements for facilities "that are solely engaged in the production of food for animals other than man." 21 U.S.C. § 350g(m). Historically, FDA has also regulated animal food separately. *See* 78 Fed. Reg. 64740–43.
[65] *See* 78 Fed. Reg. 64,824.
[66] *See* 21 U.S.C. § 350g(l)(1)(C)(ii).
[67] 78 Fed. Reg. 64,824.
[68] 78 Fed. Reg. 64,736, 64,757 (Oct. 29, 2013).

comments, which suggests that both FDA and the public saw the logic of only tallying the sales of food that is covered by the rule in the calculation of the exemption.[69]

Finally, the Animal Preventive Controls Rule requirements apply to facilities that manufacture, process, pack, or hold any animal food, even if the facility also handles human food. Though FSMA does not contain separate preventive controls guidelines for animal food processing facilities, FSMA does give FDA the authority to "exempt or modify the requirements for compliance under th[e preventive controls] section with respect to facilities that are ***solely*** engaged in the production of food for animals other than man."[70] However, as indicated by the excerpted Animal Preventive Controls Rule language above, FDA is specifically and purposely modifying requirements of compliance to exempt facilities that produce *both* human food and animal food—not "solely" animal food. FDA even justified its modification of the statutory language from "all food" to "all animal food" so as not to include human food from a facility that also produces animal food.

FDA's decision to depart from a literal reading of the statutory language and essentially expand the exemption in the Animal Preventive Controls Rule was a policy decision made by the agency to give the greatest effect to congressional intent. If FDA has the authority to make a policy decision in relation to animal food facilities that is not based in the statute, the agency can and should do the same with the Tester-Hagan qualified exemption criteria.

4. An abundant supply of fresh, healthy, locally produced food is in the public interest; the rules should not discourage farmers from diversifying into produce.

It is in the public interest to avoid discouraging farmers from diversifying into produce for local and regional supply chains, and to ensure that the promising trend of increased access to fresh, healthy fruits and vegetables continues. FDA's decision to base the qualified exemptions on ***all*** food sold by a farm or facility, as opposed to all ***covered*** food, creates a situation in which a relatively small operation could face the full regulatory brunt of the rules, which discourages farmers from diversifying into growing and selling fresh produce. Consider the following examples:

- A farm that sells $500,000 worth of grain but only $150,000 of "covered produce" through farmers markets and CSA shares would be ineligible for the qualified exemption under the Produce Rule, because the total sales of food exceeds the $500,000 cap.
- A farm that sells $500,000 in commodity crops, $300,000 of covered produce, and $300,000 of value-added product – the produce and value-added through farmers markets and CSAs – would be subject to the full requirements of *both* the Produce Rule and Preventive Controls Rule, even though the total quantity of food regulated by each rule is relatively small (and if considered separately from one another, would result in reduced compliance requirements under either rule).[71]

[69] *See* Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Control for Food for Animals, 79 Fed. Reg. 58,476, 58,509–10 (Sept. 29, 2014) (to be codified at 21 C.F.R. pt. 500) (containing no alternative definition of "qualified facility").
[70] 21 U.S.C. § 350g(m) (emphasis added).
[71] This "farm mixed-type facility" operation would not be subject to modified requirements under the "very small business" exemption, because the total sales of "human food" exceed $1 million.

FDA received several comments, after the first proposed rules were released, that calculating the qualified exemptions based on sales of "all food," as opposed to all food at issue within the specific rule, disincentivizes diversification of farm operations.[72] For relatively small businesses, the rules in their current formulation encourage farming of commodity crops at the expense of fruits and vegetables, and they encourage outsourcing food processing to large facilities as opposed to capturing additional income by processing the food on the farm to avoid the burden of full compliance with the rules. FDA has taken a step forward in looking at "produce" for the definitions discussed in Part A above, but should take the next step to measure all sales thresholds in the Produce Rule based on "covered produce."

Recommendation: FDA should calculate all sales thresholds across each rule based on the sales of the product regulated by each rule. This applies to the definitions of small and very small business in all rules, the *de minimis* exemption under the Produce Rule, and the Tester-Hagan qualified exemptions under each rule.
Specifically:

- "Covered produce" under the Produce Rule;
- "Covered human food" or "regulated human food" under the Preventive Controls Human Food Rule; and
- "Covered animal food" or "regulated animal food" under the Preventive Controls Animal Food Rule.

[72] "Some of these commenters noted that the proposed coverage of farms based on their total food sales would make it difficult for midsize farms to diversify their operations. Other commenters maintained that covering farms based on their total food sales would have an adverse impact on diversified farms that primarily raise food grains or dairy cattle (and produce dairy products) by forcing them to comply with the produce safety standards." 79 Fed. Reg. 58,437.

V. COMMENTS ON SUBPART E – STANDARDS DIRECTED TO AGRICULTURAL WATER

NSAC provides the following comments and recommendations on FDA's revised approach to setting standards for the use of water in agricultural production. We appreciate FDA's attempt to provide a more flexible, workable standard; however, the revised approach still falls short of the flexible, risk- and science-based framework that FSMA requires.

A. FDA must pursue a water quality standard that is appropriate for agricultural water.

FSMA directs FDA to establish "minimum science-based standards . . . based on known food safety risks" for raw fruits and vegetables that are raw agricultural commodities[73] 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"[74] The revised water quality standard still does not satisfy these requirements.

Although we appreciate that FDA has attempted to add flexibility into an otherwise inappropriate standard[75] by allowing for pathogen die off between irrigation and harvest, we strongly encourage the agency to take an approach to pursuing an appropriate water quality standard through research and risk assessment, just as the agency is doing with respect to the preharvest application interval for raw manure.

FDA has acknowledged that this standard was not designed to assess the hazards posed by exposure to agricultural water, and that the "routes of infection and pathogen mortality rates are different" for exposure from swimming or recreational use compared to the hazards posed by consumption of produce.[76] FDA also "acknowledges the limitations of a general requirement for agricultural water for growing using direct application that is based on a single microbial indicator and associated quantitative microbial quality threshold, in that it may not adequately account for differences in risk associated with irrigation practices used for different commodities."[77] Despite these severe limitations and the lack of science available regarding epidemiological data correlated to irrigation water, FDA continues to propose to use the EPA water quality standard.[78]

FDA maintains that it is appropriate to generalize illness rates from recreational use to agricultural use, supporting its decision in part because "there is no consensus among commenters as to other appropriate alternative criteria or methodology."[79] It is unrealistic to expect the public to provide the appropriate microbial standard given the clear lack of scientific data on the subject. FDA has a

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[73] 21 U.S.C. § 350h(b)(1).
[74] 21 U.S.C. § 350h(a)(3)(A). FDA has acknowledged that this standard was "developed from epidemiological studies that correlated the risk of gastrointestinal illness to exposure to marine and freshwater by swimmers." 78 Fed. Reg. 3563.
[75] *See* Appendix II at 61–68 for additional supporting information regarding the inappropriateness of the EPA standard.
[76] *See* 78 Fed. Reg. 3563. (["A]dverse health outcomes as a consequence of immersion while swimming in contaminated water may be different from those as a result of eating produce irrigated with contaminated water.").
[77] 79 Fed. Reg 58443.
[78] *Id.* ("The EPA analysis supporting the RWQC, while not perfect for our purposes, was developed using the necessary scientific rigor and describes illness rates due to incidental ingestion that can be generalized across different bodies of water.").
[79] 79 Fed. Reg 58443.

mandate to establish risk- and science-based standards. FDA recognizes that there are "differences in the overall expected health outcomes of a recreational water standard and an agricultural water standard" but believes that "the underlying science supporting the recreation water standard serves as an appropriate basis on which to develop standards suitable to agricultural water."[80] We do not disagree that there is science supporting the EPA's standard *as it relates to recreational water*, but if that same science is going to be used, it needs to be assessed for its relevance to the risks posed by agricultural water. These standards mark the first time that FDA will be imposing specific regulatory requirements on farms that grow covered produce – "this is the best we have" does not provide an adequate explanation to the farmers that will have to shoulder the costs associated with these requirements.

EPA notes the need for a "formal risk assessment . . . to determine an estimated disease burden for consumption of produce exposed to directly-applied agricultural water during growing."[81] If the data are absent, FDA should come up with a process for developing the science necessary to support an agricultural water standard. If a risk assessment is necessary to determine the appropriateness of applying best available science for recreational water to agricultural water, then FDA should ensure that such a risk assessment is performed. Such a process should include conducting ongoing research to develop an appropriate, flexible standard – which might vary by region, farming system, and other variables – and seeking comments and input from the public on the results and implications of the research and risk assessment before finalizing a standard.

***Recommendation*:** In the final regulations, FDA should take a risk- and science-based approach to determine an appropriate water quality standard for agricultural water, and should defer finalizing a numeric water quality standard until a full risk assessment is completed and an appropriate, scientifically-sound agricultural irrigation water standard is developed.

B. The water quality standard should be in guidance, not the regulations.

FDA requests input on how to introduce additional flexibility into the standard.[82] The allowance for die-off and the absence of a maximum generic E. coli threshold do provide flexibility for farmers to work with an otherwise ill-fitted standard. The agency has indicated that it will make tools available to help farmers understand how to work with this standard. We urge the agency to prioritize and articulate a timeline for developing these tools, including an outreach plan to help get that information into the hands of those that need it. This should extend not only to helping farmers understand how to follow the requirements of Subpart E, but also should include a plan to spur the development of affordable, on-farm water testing options.

However, to truly provide flexibility in the standard, we strongly urge the agency to include any numeric standards in guidance, not the regulations themselves. Doing so is imperative to ensuring an ongoing mechanism for updating the standard as scientific understanding advances and new data become available.

Similarly, if the agency chooses to establish a maximum generic E. coli threshold, the maximum should also be in guidance, not the regulations. As an alternative to a maximum threshold, the

[80] Reference 13, Ravaliva Memo at 8.
[81] *Id.*
[82] 79 Fed. Reg 58447.

agency could include in guidance that if you need more than "x" number of days to account for the die-off of water that significantly and exponentially exceeds the standard, then you should not be using that water in a direct application method. Doing so avoids being overly prescriptive, and reinforces a common sense approach to water use.

Recommendation: Numeric thresholds should not be codified, because codification limits the ability of the standard to be updated as the science and research evolves. Guidance provides a mechanism to allow the ongoing evaluation and updating of the standard, and is the appropriate place for any numeric thresholds.

C. FDA should significantly revise the testing regime, particularly by reducing required testing frequencies, and should move the testing regime to guidance.

FSMA requires FDA establish standards that are flexible and risk-based.[83] In the original proposed Produce Rule, FDA acknowledges that testing "frequency should reflect the risk" posed by a water source, and should be "dependent upon the results of an assessment of the risks posed by your agricultural water system."[84] In practice, however, even the agency's revised approach continues to require all farmers to adhere to a complicated and overly prescriptive testing regime that does not account for variations in critical risk factors such as climate, location, farming system, and water source. This results in a testing regime that, while an improvement from the initial proposal, still requires farmers to excessively and unnecessarily test water at significant cost, and without sufficient correlation to food safety.

For a farmer whose water is consistently below the standard, or for a farmer whose water consistently tests above the standard, the requirement to repeatedly test the water provides no additional food safety benefit. The rules fail to make the fundamental connection that the highly variable natural of many water sources – and the fact that the quality of many water sources are outside of the control of the farmer – means that this prescriptive testing regime requires farmers to shoulder the burden of a problem for which they are not directly responsible, and over which they have no control. Increasing the number of tests you require a farmer to take will not increase the safety of the food produced.

We recognize that, while the quality of the water might be out of the farmer's control, the farmer still has the responsibility to decide whether and how to use a particular water source, and that baseline testing can inform that decision. However, the twenty samples required to establish a baseline are excessive. Reducing the testing frequency – and thereby reducing the very significant burden on small farmers – is not incompatible with the goal of furthering public health outcomes. Water testing requirements must be flexible and appropriate; FDA can develop a reasonable approach to ensuring water is of sanitary quality without being overly concerned with the minutiae.

Water testing is a significant cost to farmers, and those costs fall disproportionately on small farms. These costs include not only the fees associated with shipping and testing water samples, but also lost labor. For a single-operator farm in a rural area, the farmer may have to spend three to five

[83] 21 U.S.C. §§ 350h(a)(3)(A); 350h(b)(1). FSMA also prohibits FDA from requiring the use of a third party to identify, implement, or certify compliance with the rules. 21 U.S.C. 350h(c)(1)(E). We note in our 2013 comments that the testing requirements necessarily involve the use of third party labs to test water samples. *See* Appendix II at 65–66.
[84] 78 Fed. Reg 3560.

hours, or more, in the car driving round-trip to and from a certified lab in order to have a sample tested. That is time taken away from working the farm. For farmers in more remote areas, it can be particularly difficult and expensive to access certified labs to test samples.

Labs may require samples to arrive within 24–30 hours,[85] which means expedited shipping may be required, further increasing overall costs. Each additional test that is required increases the costs to these farmers. Therefore, it is essential that testing frequencies be correlated to improving food safety outcomes. Farmers will test their water if they know that it results in producing safer food; however the number of tests and associated costs must be reasonable and affordable. For these reasons, we encouraged FDA in Part B above to support prompt development of on-farm testing options. FDA could also relax the requirement to use certified labs for water testing, and take a more flexible approach to testing frequencies.

FDA's approach to testing untreated surface water does not take into consideration critical site-specific variables in profiling surface waters. The record indicates that the 20-sample baseline is a statistical construct; it was not selected as an indicator of food safety.[86] Testing water for generic E. coli – a marker for fecal contamination – does not require statistical precision. Sampling time and location are far more important than the number of tests. The variability in water quality tests based on climatic features (e.g. temperature, storm events, diurnal cycles) along with anthropomorphic events makes routine testing impractical;[87] even multiple years' worth of tests would be inadequate given these factors. This reality demands a flexible, guidance-based approach to water testing.

A more appropriate approach, and one fully supported by EPA's approach to water testing,[88] is to include testing regimes in Level 1 guidance. Such guidance should contain guidelines for conducting the site-specific risk assessment and sanitation survey under proposed 112.42(a), and guidelines regarding testing location, depth, and time as appropriate to the way the water is used (e.g. drip vs. overhead, frost protection, irrigation practices that return off flows back to source, ponds vs. streams, etc.). If FDA must include a minimum number of tests required per year, we recommend FDA simplify the process and take advantage of existing industry best practices.

Accordingly, we recommend that FDA modify the number of samples required to establish the baseline survey for surface water. FDA is proposing to require four samples over the course of a year to establish a baseline survey for groundwater. It would be entirely reasonable for FDA to require the same for number of tests to establish the baseline survey for surface water. This would reduce the layers of complexity contained in the revised proposal, particularly for farmers using multiple water sources. Four tests – particularly drawn using guidelines for effective sample

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[85] *See e.g.* Penn State http://agsci.psu.edu/aasl/water-testing/farm-food-safety-gap-water-testing/farm-food-safety-water-sample-submission-form (30 hours); Monterey County Health Department https://www.mtyhd.org/wp-content/uploads/2014/09/Irrigation-Water-Generic-E-coli.pdf (24 hours); http://www.uvm.edu/~susagctr/whatwedo/producesafety/GAPsResources/ManualHowtoSampleIrrigation.pdf (24 hours); http://sfp.ucdavis.edu/files/146252.pdf (24 hours); http://www.olsenlab.com/submittalforms/water_submittal_complete.pdf (30 hours).

[86] *See* Reference 21, Bowers Memo.

[87] *See* Sampling and Consideration of Variability (Temporal and Spatial) For Monitoring Recreational Waters, EPA Office of Water, Dec 2010, available at http://water.epa.gov/scitech/swguidance/standards/criteria/health/recreation/upload/P12-MonRept-final_508.pdf.

[88] *See* Sampling and Consideration of Variability (Temporal and Spatial) For Monitoring Recreational Waters, EPA Office of Water, Dec 2010, available at http://water.epa.gov/scitech/swguidance/standards/criteria/health/recreation/upload/P12-MonRept-final_508.pdf.

collection (e.g. time of day, depth, and at high or low flow to get an idea of your extremes) – provide an appropriate range (that includes worst case scenarios) for farmers to use in establishing the profile of their water quality.

For annual verification, FDA should require no more tests than what is truly necessary. This could be achieved by relying on existing frequencies established under the U.S. Department of Agriculture Good Agricultural Practices (USDA GAPs) audit program:

- Municipal water: Test results are acquired from the local water authority annually or tested by the operation at least annually.
- Well water: Water is tested one time during the growing season. If fecal coliforms are present, the well is treated with a sanitizer to reduce pathogen levels and is retested. Wells are monitored to make sure casings are secure and well-maintained and that livestock and manure storage areas are excluded from the well recharge and pumping area.
- Surface water: Water is tested three times during the growing season – first at planting, second at peak use, third at or near harvest.[89]

FDA's revised approach already aligns with the USDA GAPs approach to municipal and well water. It would be reasonable for FDA to also align the surface water testing frequencies with USDA GAPs. These frequencies are already in use by many produce farmers across the country and – coupled with the proposed section 112.42(a) requirement to inspect your water source(s) at the start of and throughout the growing season[90] – three samples during the growing season would provide sufficient information for farms to understand if the character of their water source has changed enough to require changes in practices. However, we also note that USDA GAPs is only one existing approach. Harmonized GAPs do not require a specific testing frequency. Rather, these approaches determine appropriate water-testing frequencies at the farm level, based on the farmer's site-specific risk assessment and existing best practices.[91]

Consequently, we also recommend that FDA eliminate the requirement to re-establish a baseline. The requirement to re-establish the baseline assumes that farmers are not constantly responding to environmental conditions – including season, diurnal, and anthropogenic variations in water quality conditions – and imposes an arbitrary and prescriptive requirement where none is needed. More important to establishing a sound baseline are time and location (e.g. proximity to shoreline, depth, type of water body, whether the water is flowing or not, exposure to sunlight) of sampling, but these factors are too prescriptive to codify given the unique nature of each farm. They are, however, appropriate to include in guidance.

FDA understandably wants to ensure that farmers are regularly re-evaluating the quality of their water and adjusting their production practices accordingly. The agency's requests for information on scenarios that should require development of a new water quality profile using 15 new results (e.g. where the magnitude of the deviation from the existing water quality profile suggests that prior samples are no longer representative) also fall in this line of thinking. But, FDA's request for comment on whether the agency should require farms to alter practices in the current season based

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[89] *See* USDA AMS Good Agricultural Practices and Good Handling Practices, Audit Verification Program User's Guide, http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=stelprdc5097151 (April 2011) at 13.
[90] 78 Fed. Reg 3565.
[91] *See* http://www.unitedfresh.org/assets/Harmonized%20Standard%20-%20pre-farm%20gate%20130501.pdf at 14.

solely on the annual survey data under certain circumstances follows the same underlying assumption that farmers are not constantly responding to fluctuations in environmental conditions.

We are not asserting that FDA has no role in establishing guidelines to help farmers understand and work with their particular water source. However, the degree to which FDA is attempting to micro-manage this issue undermines any claims that these standards are flexible and risk-based. FDA could more appropriately address this concern by clarifying that the expectation is for farmers to continually reassess their water quality profile based on annual survey results, effectively creating a rolling baseline using annual data. Again, these specifics are much more appropriate to provide in guidance or through technical assistance than codified in the regulations.

FDA is requesting comments on whether they should "stipulate a time period beyond which data would not be appropriate to use in a water quality profile because the test results would not be expected to provide a currently representative profile of the water quality." We do not believe FDA should establish such a time period. Doing so would be logically inconsistent with the risk-based approach to understanding the individual characteristics of a particular water source. Whether the test results are still a valid representation of the water quality profile is a function of the particular water source, not an arbitrary time period. As long as the test result is still representative, then time is irrelevant.

We urge FDA not to specify the time period for which test results are still valid. Rather, FDA should clarify that growers can begin testing samples immediately, to allow the maximum possible time over which to spread out collecting samples for the baseline survey. It is not clear whether a farmer can start collecting samples immediately once the rules are finalized (if not sooner) to build up to the baseline. If that were clear, then reaching the baseline would be less onerous, particularly for those small and very small growers in the northeast where the growing season lasts only a few months.

Recommendation: FDA should significantly revise the water testing requirements. Specifically, FDA should:

(1) Move any testing frequencies to guidance, rather than the regulations;
(2) Include information in guidance on how to perform a sanitation survey/risk assessment and effective sample collection techniques, as appropriate to the unique nature of each farming operation;
(3) Use the same baseline testing frequencies for surface and groundwater (four samples over the course of a year, as close as practicable to harvest);
(4) Reduce annual testing frequencies, and model them after existing GAPs standards, which minimize the number of annual tests required, and base testing frequencies on site-specific risk assessments;
(5) Eliminate the requirement to re-establish a baseline (under either scenario – every ten years, or more frequently under other circumstances);
(6) Include references regarding when and to what extent a farmer should adjust their water quality profile and corresponding production practices in guidance, to ensure sufficient flexibility for farmers in all regions; and
(7) Not impose an arbitrary time limit on the validity of test results. Rather, FDA should clarify that farmers can start collecting samples immediately upon finalization of the rules to work toward establishing the baseline survey of samples.

D. FDA should clarify that drip and trickle irrigation are not direct application methods.

The standard discussed above applies to untreated surface water used in a "direct application method." FDA has indicated that drip irrigation is not considered a "direct application method."[92] We support this decision.

However, the question has arisen regarding drip irrigation and root vegetables that are covered produce (e.g. carrots), and whether drip – particularly buried drip – irrigation in those instances is considered a direct application method. FDA has not directly responded to this question in the rules, though they have noted that the science presents "strong evidence that subsurface drip irrigation lowers the likelihood of waterborne contamination compared to furrow or overhead irrigation."[93] We recommend that FDA clarify that trickle and drip irrigation, including buried drip, are not considered "direct application methods" and therefore the requirements under subpart E do not apply when untreated surface water is used in these methods.

Recommendation: Clarify in the preamble to the final rule that drip and trickle irrigation, including buried drip irrigation, are not direct application methods.

E. FDA can do more to encourage data sharing.

FDA's revised approach to water testing provides an important clarification regarding the ability of farmers to share testing data or obtain data from third parties. However, we believe the agency could do more to support farmers who want to share test results, and support making state and federal government test results more accessible to farmers.

FDA currently does not provide a definition of water "source" or discuss in the preamble how to interpret this term. We urge FDA to clarify that the requirement to test each water source takes a broad view of the term "source," and provide guidance so farmers know whether "source" means – for example – each draw point along a river, or the river as a whole. Specifically, "source" should include any reasonable portion of a watershed where a sanitation survey identifies no reasonably foreseeable point or nonpoint source of microbial discharge between agriculture water and withdrawal points. This assumes that routine sampling is drawn from the most upstream point. This clarification would also allow farmers to more effectively take advantage of the new language that allows for data sharing.

Recommendation: To help farmers determine how many different sample sets are required, reduce redundant testing, and share data, we recommend the agency broadly define "source" as "any reasonable portion of a watershed where a sanitation survey identifies no reasonably foreseeable point or nonpoint source of microbial discharge between agricultural water and withdrawal points," and provide guidance for farmers to use in interpreting this requirement.

Recommendation: FDA should pursue a Memorandum of Understanding between FDA and EPA, and any other federal or state entity conducting water testing as appropriate, to regularly publish and make water quality testing data available to farmers.

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[92] *See* http://www.fda.gov/downloads/Food/GuidanceRegulation/UCM345226.pdf at 11.
[93] 78 Fed. Reg. 3560.

F. Recordkeeping requirements should be minimized.

Any records that FDA requires regarding the application of the 0.5 log die off rate should be limited to those records that the farmer would ordinarily keep and not require any duplicate or unnecessary records. For example, if your water does not exceed the threshold and you are not applying the log die off rate, then the only records you need are the test results. If your water exceeds the threshold, then you should record the results of the calculation (e.g. the interval, in days), the date you stopped irrigation, and the date you harvested. As with all other recordkeeping requirements, FDA must allow written records and cannot require electronic records.

Recommendation: Limit recordkeeping requirements regarding the use of the interval between irrigation and harvest to the basic information necessary to understand the calculation used and the interval applied, such as the date of last irrigation and the date of harvest.

VI. COMMENTS ON SUBPART F – STANDARDS DIRECTED TO BIOLOGICAL SOIL AMENDMENTS OF ANIMAL ORIGIN

NSAC appreciates FDA's revised approach to regulating raw manure and compost under Subpart F as laid out in the supplemental proposed rule. The original Produce Rule standards for using raw manure and compost made it effectively impossible for farmers to use manure and created barriers to the use of compost – in direct contradiction with established federal organic standards and the public interest in promoting the use of natural soil amendments instead of synthetic ones. FDA's new approach aligns with National Organic Program (NOP) standards for the use of appropriately treated compost, and defers finalizing the standard for untreated manure until it has conducted a thorough risk assessment, in partnership with USDA and stakeholders like farmers. We strongly support this revised approach and submit the following comments and recommendations.

A. FDA's decision to develop a science- and risk-based approach to regulating untreated manure is a significant improvement from the original proposal.

FDA's revised approach results from an acknowledgment of the "limited body of scientific evidence, the limitations associated with the studies we relied on, the use of a no detectable pathogen level as the basis for identifying a minimum application interval, and the need for additional research in this area."[94] FDA proposes a new approach to regulating the use of untreated manure on covered produce, and proposes to defer finalizing a minimum application interval while the agency undertakes a thorough research agenda, upon the conclusion of which FDA will propose any interval for public comment before finalization.

FDA's commitment to implementing a comprehensive research and risk assessment strategy to determine the appropriate interval(s) for the use of raw manure – and commitment to looking for ways to reduce barriers to compost – demonstrates an important step toward a risk- and science-based framework to regulating compost and manure use, and takes a systems-based approach to the issue that we strongly support. We are encouraged by FDA's stated plan to consider multiple variables in the risk assessment such as: the source and type of manure; the method of application; climatic conditions; type of commodity; and the characteristics of the soil.[95] Research areas currently proposed would address whether and how application intervals can be tailored for specific commodities, types of commodities, growing environments, and any other agro-ecological conditions.[96] We are very pleased by the agency's awareness that a single, uniform application interval may be inappropriate, and appreciate FDA's recognition that the final outcome may include multiple intervals, tailored by region or other appropriate factor.[97]

We support the comprehensive nature of this inquiry, and look forward to advising the agency on additional research needs. However, we encourage the agency to clarify its classifications of manure. Currently, FDA considers manure either "treated" or "untreated," with untreated essentially including any amendment with animal-derived components that has not been treated according FDA's specified processes. It is critical that FDA clarify where aged manure, agricultural teas, or other passive composting methods fall within the regulatory framework, and determine whether they

[94] 79 Fed. Reg. 58459
[95] 79 Fed. Reg. 58460.
[96] *Id.*
[97] *Id.*

should be covered the same or differently as "raw" manure. We would recommend that FDA answer this question as part of the overall research agenda.

We also encourage the agency to compare raw manure use in organic systems versus non-organic systems. Not all raw manure is the same. Raw manure from organically managed dairies will not have antimicrobials in it that suppresses soil microbial diversity. Organically managed animals that graze previously harvested fields will likewise leave manure that is more apt to support healthy soil processes of competition, predation and antagonism that occur with diverse microbial populations. Therefore, studies of pathogen persistence in soils should examine organic sources of manure.

We applaud FDA's commitment to working with USDA and other stakeholders to develop and implement this research strategy that FDA will use to further develop the risk assessment model. NSAC and our member organizations look forward to working with FDA and USDA to advise and participate in this process. Farmers – particularly sustainable and organic farmers – depend on natural fertilizers as their primary tool to improve the health of their plants and soil. These farmers, as well as the sustainable agriculture researchers they work with, can provide invaluable input to FDA as it undertakes this research-first strategy – to help FDA understand how farmers use natural fertilizers, to identify research gaps and resource needs, and assist the agency as it interprets the data.

However, we caution the agency against overemphasizing the use of compost over raw manure. Soil health is a critical component for assuring sustainable farming systems; it provides a broad range of environmental services, like increased water filtration, enhanced carbon sequestration, and pathogen suppression. Animal manure in particular plays a key role in ensuring sufficient nutrients and organic matter in the soil to promote high-yielding, healthy crops, and plays a particularly important role on sustainable and organic farms, as well as many more traditional farms across the country. We agree that compost can provide a lower-risk alternative to raw manure under certain circumstances, and we recognize that raw manure is used infrequently on covered produce fields. Raw and composted manure may serve different purposes in a farming system,[98] but both are critical to soil health, which in turn is essential to a safe and abundant food supply.

Recommendation: FDA should move forward with the proposed research strategy to understand the various risks and benefits of manure use on produce fields, and ensure that the research and risk assessment is comprehensive enough to capture the range of agricultural practices, climatic conditions, and manure types used on farms across the country. Specifically, FDA should:

- Engage sustainable and organic farmers, the organizations that support them, and the best experts from sustainable agriculture centers at land grant universities[99] in diverse regions of the country in this process;
- Include aged manure, agricultural teas, and other passive composting methods in risk assessment, to determine the appropriate regulatory framework for such types of soil amendments; and
- Form two advisory boards to assist in this process: one that advises the process itself and one that assists the agency in reviewing and interpreting the science. Both boards should have members representative of the diversity of American agriculture, including sustainable and

[98] *See* Appendix II at 80–82.
[99] *See e.g.* http://www.sarep.ucdavis.edu/programs/infas.

organic farmers, conservationists, and the organizations and researchers that work with them.

B. FDA should codify an interim standard for the application of raw manure to covered produce fields.

FDA acknowledges in the rules that, in deferring the standard for raw manure, the agency does not "intend to take exception to the continuation of adherence to the National Organic Program (NOP) standard."[100] Recognizing the need to ensure consumer confidence in the food supply, the good food safety record of the NOP, and FSMA's mandate that FDA regulations do not conflict with the NOP, we believe that codifying an interim standard that aligns with NOP application intervals is an appropriate and practical action.[101]

Specifically, the interim interval could require an interval of at least 90 days (or three months) between application of raw manure and harvest where the edible portion of the crop does not come in contact with the soil, and at least 120 days (or four months) in the case of crops where the edible portion does come in direct contact with the soil.

This interim interval should not substitute for FDA's science- and risk-based approach to determining appropriate standards (and we stress standards, not standard, because it is entirely possible that the risk assessment will determine that there are multiple, regionally-appropriate standards) for the application of raw manure, and we encourage the agency to complete its review in a comprehensive and efficient manner, while ensuring that all stakeholders have a clear voice in the process of conducting and interpreting the necessary research.

FDA has indicated that this process could take 5-10 years before the risk assessment is complete and a new proposal is published. Therefore, the interim standard could "sunset" after 10 years, to ensure that the research process is conducted in a timely manner, without sacrificing comprehensiveness or thoroughness.

Recommendation: FDA should codify an interim standard for the pre-harvest application interval for raw manure as follows:

- If the edible portion of the crop does not come into contact with the soil, the interval between application of untreated manure and harvest is at least 90 days (or three months).
- If the edible portion of the crop does contact the soil directly, the interval between application of untreated manure and harvest is at least 120 days (or four months).
- The interim standard should "sunset" 10 years after the final rule is published.
- Please see Appendix I for a joint statement signed by several consumer and farm organizations, including NSAC, that details areas of consensus on this issue.

C. The revised interval for the application of composted manure is proper and should be retained in the final rule. However, FDA should remove the requirement to insulate compost from the regulations.

[100] 79 Fed. Reg. 58434.

[101] We would also point out that some of the science does point to a standard close to the NOP interval as an appropriate food safety standard. *See* Appendix II at 78–79.

We strongly support the agency's revised approach to the application interval for composted manure. The zero-day interval does not conflict with NOP standards, as FSMA requires, and it contributes to the agency's newly stated goal of reducing barriers to compost.[102]

However, to align with current best management practices and the NOP, insulation of compost should not be required as part of acceptable compost treatment processes. With the exception of the insulation requirement, the Produce Rule's proposed composting practices are otherwise identical to the NOP. Not only is insulation of compost contrary to the NOP standard, but also it is impractical. Requiring insulation could both decrease the quality of the compost and increase the cost.[103]

Insulating a turned compost pile with a foot thick layer of straw is impracticable because it would be a substantial task for farms with long compost windrows to remove and reapply it. The act of turning keeps the compost active. Otherwise, carbon dioxide and moisture levels could become unacceptable. If the layer of straw was incorporated into the compost during the turning process, this would change the carbon:nitrogen ratio of the turned product and require the whole pile or windrow to be recomposted, leading to an unending situation of recomposting/insulating/turning. Insulating a static compost pile could cause the compost to become anaerobic, reducing the process' effectiveness at destroying pathogens.

Given FDA's interest in reducing barriers to compost use, FDA should remove this unnecessary and costly requirement.

Recommendation: FDA should retain the zero-day interval for properly composted manure. However, to align with best management practices and reduce barriers to the use of compost, FDA should remove the requirement to insulate compost from § 112.54(c).

D. The Produce Rule EIS must consider the impacts of the standards.

We understand that FDA intends to issue the Produce Rule draft Environmental Impact Statement (EIS) after the New Year. As we submitted in our comments on the scope of the EIS, FDA must consider the direct, indirect, and cumulative environmental impacts of the proposed standards, which include consideration of alternatives.[104] Depending upon the standard adopted, raw manure application may increase or decrease across the country. We expect a consideration of the impacts of any manure standard to be present in both the draft EIS in January, and to accompany the proposed application interval that FDA will propose at the conclusion of the risk assessment.

Recommendation: FDA must consider the impacts of the manure standard – either deferred or an interim interval – in the draft EIS. FDA must also consider the environmental impacts of the manure standard when it is re-proposed at the conclusion of the research and risk assessment process.

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[102] *See* 79 Fed. Reg. 58462 ("In recognition of the expected benefit to public health when composted manures are properly treated and handled, and to further facilitate the use of composted manure rather than raw manure. . . .").
[103] *See* Appendix II at 86–87.
[104] *See* NSAC's comments on the Produce Rule Scoping Notice (Nov. 15, 2013).

VII. COMMENTS ON SUBPART I – STANDARDS DIRECTED TO DOMESTICATED AND WILD ANIMALS

NSAC appreciates FDA's new proposed section § 112.84, which addresses some of our original concerns that the rules could undermine natural resource conservation and wildlife habitat protections on produce farms. However, we believe FDA can and should do more to support on-farm conservation efforts. Additional clarity is needed to ensure that farmers' ability to co-manage for conservation and food safety benefits is not restricted by the rule's requirements. Below, we suggest language to add to the codified, which would provide this much-needed clarity.

A. FDA has the authority to support and encourage the use of conservation practices.

Congress directed FDA to promulgate produce standards with the dual goals of improving public health and environmental health. Recognizing the interplay between the two goals, FSMA contains provisions that require 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;[105]
- Not include any requirements that conflict with or duplicate the requirements of the national organic program established under the Organic Foods Production Act of 1990;[106] and
- Provide sufficient flexibility to be applicable to various types of entities engaged in the production and harvesting of fruits and vegetables . . . and be appropriate to the scale and diversity of the production and harvesting of such commodities.[107]

FDA is tasked not only with ensuring that the rules do not conflict with the conservation and environmental practices and policies of other federal agencies, but is directed to consider these practice standards and policies in crafting its own regulations *consistent with* ensuring public health protection. Under this language, Congress clearly intended for FDA to approach environmental health proactively, consistent with FDA's proactive approach to public health.

FSMA also requires that the Produce Rule requirements do not conflict with the National Organic Program (NOP) standards. Organic production is defined in NOP regulations as a production system that integrates cultural, biological, and mechanical practices that foster cycling of resources, promote ecological balance, and conserve biodiversity.[108] Not only are conservation and wildlife habitat protections inherent to sustainable and organic farming systems, but they are required under NOP standards.

Under the NOP "natural resources standard" organic operators must maintain or improve natural resources (defined as soil, water, wetlands, woodlands and wildlife).[109] The NOP also includes a "crop rotation standard," which requires organic growers to provide for pest management in perennial crop systems by employing means such as alley cropping, intercropping, and hedgerows to

[105] 21 U.S.C. 350h(a)(3)(D).
[106] 21 U.S.C. § 350h(a)(3)(E).
[107] *Id.* § 350h(a)(3)(A).
[108] 7 C.F.R. § 205.2.
[109] 7 C.F.R. §§ 205.200, 205.2.

introduce biological diversity in lieu of crop rotation.[110] 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. To avoid this result, FDA must provide absolute clarity that co-management is allowed and encouraged under the rule.

Taking this approach is fully consistent with FDA's authority to ensure that the rules do not conflict with existing conservation practices established and supported by other federal agencies, including the NOP as described above, and the Natural Resources Conservation Service (NRCS). Many farmers participate in voluntary federal conservation programs through NRCS, such as the Conservation Stewardship Program and the Environmental Quality Incentives Program. These programs help farmers implement conservation practices, some of which help to reduce pathogens on the farm. The final rule must ensure that there is sufficient flexibility and clarity in the standards for farmers to continue using these conservation practices.

B. FDA should clarify in § 112.84 that farms can use co-management, and define co-management in the regulations.

When FDA first proposed the FSMA rules, there was great concern that the rules as written would severely undermine conservation practices and wildlife habitat protections on farms, and conflict with NOP principles of biodiversity and natural resource management. This concern is grounded in the lessons learned from certain on-farm food safety certification regimes developed in response to outbreaks such as the 2006 spinach *E. coli* outbreak, which created incentives for, or even forced, farmers to remove conservation practices and to actively exclude wildlife from their farms.[111] It is important to ensure against such requirements in the future and be proactive about supporting practices that benefit both food safety and conservation.[112]

FDA's newly proposed provision in the regulations takes an important step toward addressing these concerns. However, more can be done to clarify the intention of the new provision, and ensure that farmers continue to use sustainable practices that enhance conservation and food safety.

FDA acknowledges their support for this principle in the preamble, stating that FDA encourages "the application of practices that can enhance food safety and that are also consistent with sustainable conservation practices" as well as "the comanagement of food safety, conservation, and environmental protection."[113] We encourage FDA to move this language into the codified and proactively support conservation as Congress intended.

As currently proposed, the new provision approaches the issue in the negative, stating that the "regulation does not require covered farms to take measures to exclude animals from outdoor growing areas, or to destroy animal habitat or otherwise clear farm borders around outdoor growing areas or drainages." This issue could be addressed simply by stating the issue affirmatively. FDA could add another clause to the end of the provision that says: "farmers can use co-management of

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110 7 C.F.R. §§ 205.205, 205.2.
111 *See* Farming with Food Safety and Conservation in Mind, Wild Farm Alliance and Community Alliance with Family Farmers, 2013.
112 *See* Appendix II at 91–101.
113 79 Fed. Reg. 58464.

conservation and food safety to ensure protection of endangered species and conservation of farm boarders," and then also defining co-management in the regulations. It is critical, and well within FDA's authority, to provide absolute certainty on this issue.

FDA also acknowledges in the preamble that "…wild animals are likely to have access to production fields. The presence of animals in a production field of produce, in and of itself, is not a significant food safety risk." We recommend that FDA also place this language into the codified. Otherwise, when farmers monitor for wildlife as instructed by FDA, they may mistakenly think that all wild animals are a significant threat and want to destroy them unnecessarily.

We would also encourage the agency to acknowledge in the preamble that fostering the native soil microbial community through soil conservation practices (e.g., high organic matter inputs from cover crops, manure, and compost; reduced tillage; infrequent fumigations) generally decreases pathogen survival and reduces growth potential by promoting predation, competition, and antagonism. Moreover, vegetative conservation practices may influence fate and transport of pathogens by intercepting water and airborne pathogens, and by improving soil structure and porosity, both of which increase infiltration rates.

A major concern is that third parties auditing a farm for Produce Rule compliance may not fully understand FDA's support for on-farm conservation, or don't understand the extent of practices that are supported. Farmers already report that there are wide-ranging interpretations within third party audit companies of their own internal requirements, and this would likewise occur with FDA's standards without clear explanation. The discrepancy between interpretations occurs in part because auditors are not required to have education or training in that which they audit. If co-management is defined in the rule, and practices that maintain riparian buffers and support wildlife and pollinator habitat are specifically referenced in the preamble as practices that should be encouraged, it may ease the pressure from third party auditors to find compliance deficiencies for conservation practices.

Recommendation: FDA should:

(1) Either add a subsection to § 112.84 that states: "To the maximum extent practicable, you should use co-management and sustainable conservation practices that can enhance food safety." or
(2) Clarify § 112.84 by including an affirmative statement at the end of the provision reading: "This regulation does not require covered farms to take measures to exclude animals from outdoor growing areas, or to destroy animal habitat or otherwise clear farm borders around outdoor growing areas or drainages. Rather, covered farms can use co-management of conservation and food safety to ensure the protection of endangered species and other wildlife, and the maintenance of conservation buffers, refuges, and farm borders."

Recommendation: Under either option (1) or (2) above, FDA should also define co-management in §112.3: *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 and improving biodiversity, soil, water, air, energy, and other natural resources, while also reducing pathogen hazards associated with food production.

Recommendation: Move the following language from the preamble to codified provision § 112.83: Knowing that wild animals are likely to have access to production fields, and their presence in a production field of produce, in and of itself, is not a significant food safety risk, what requirements apply regarding animal intrusion?

C. FDA should include co-management training in the Produce Rule personnel training requirements.

In our 2013 comments on the proposed rule, we included this comment. Given the need to ensure that co-management is clearly defined and understood within the context of FDA's support for practices that simultaneously reduce pathogen hazards associated with food product and achieve conservation goals, we re-emphasize this recommendation again here.

The scientific basis for on-farm food safety practices are constantly changing, and industry practices with respect to wildlife management are continually evolving. Co-management training is recognized as part of many establish curricula, including academic efforts from the Produce Safety Alliance and University of California; industry efforts like CALGMA; farmer-based organization training materials like those developed by Wild Farm Alliance and Community Alliance with Family Farmers; and federal agencies like NRCS, who – in addition to supporting conservation on farms through EQIP and CSP, will soon be publishing a technical note on co-management.

The increased support for this proactive approach across all stakeholder groups illustrates the important role that FDA plays in supporting the continuation of these practices. FSMA did not direct FDA to do so passively. Rather, FSMA directed FDA to actively support conservation and environmental health, consistent with its support for public health. The personnel training standards in the Produce Rule provide another opportunity for FDA to clearly articulate this support, by including requirements to train personnel on how conservation practices support food safety goals.

Recommendation: 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.

D. FDA should clearly state that farmers are not required to wait 9 months between grazing and harvest.

Proposed § 112.82(a) would require an "adequate waiting period between grazing and harvest for covered produce." In the original proposed Produce Rule, FDA stated in the preamble 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 the use of raw manure as a soil amendment."[114]

Given that the 9-month interval for raw manure is no longer applicable, FDA should clarify that the preamble language in the original proposed Produce Rule implying that farmers should wait nine months between grazing and harvest also no longer applies. FDA has indicated in conversation that this is the logical interpretation of this language. Given the complexity of these rules, however, we urge the agency to provide clarity at all opportunities, even when it may seem "logical."

Recommendation: FDA should state in the preamble to the supplemental rule that the 9-month interval between grazing and harvest mentioned in the 2013 rule preamble no longer applies.

[114] 78 Fed. Reg. at 3587.

VIII. COMMENTS ON SUBPART R – WITHDRAWAL OF A QUALIFIED EXEMPTION

NSAC submits the following comments and recommendations on FDA's modifications to the processes to withdraw and reinstate a qualified exemption. We appreciate FDA's revised approach, which addresses many of the concerns that arose out of the original proposal, and recommend that these revisions be retained in the final rules, with a few additional changes.

A. FDA should retain and build upon the reinstatement process.

When writing FSMA, Congress rejected a one-size-fits-all approach to regulation, and provided FDA with the flexibility to ensure that the rules work for a diversity of farms and food businesses. 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 and food businesses 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 or not more than 275 miles from that farm or facility.[115] 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 subject to modified requirements.

FDA's original process for withdrawing a farm or facility's qualified exemption raised significant due process, transparency, and fairness concerns. FDA's revised approach is a significant improvement from the original process, in particular, because it includes a process whereby farms can regain an exemption that has been withdrawn.

1. FDA is well within its authority to provide a process for reinstating a qualified exemption that has been withdrawn.

FSMA grants FDA the authority to withdraw a qualified exemption under certain circumstances. We agree with the agency that "the absence of a specific provision in section 418 of the FD&C Act for the re-instatement of an exemption that is withdrawn does not preclude [FDA] from providing for such a process."[116] FSMA did not restrict FDA's ability to allow reinstatement of a withdrawn qualified exemption. Rather, the statute is silent on the matter, giving FDA the authority to interpret the statute in a reasonable manner. FDA's decision to provide for reinstatement of a qualified exemption not only is a reasonable and appropriate interpretation of the agency's authority, but also is consistent with FDA's authority to take other courses of action before issuing a withdrawal order.[117]

Moreover, the reinstatement process provides an important protection for local food producers, and supports the agency's goal of continuous improvement. Without the opportunity for reinstatement of a withdrawn exemption, the regulatory burden and costs associated with full compliance with the rules will likely lead to direct marketers exiting the market if an exemption is withdrawn. We cannot risk losing our small business owners and produce farms working to get healthy food into local

[115] 21 U.S.C. §§ 350g(l) and 350h(f); under the Preventive Controls Rule, very small businesses are also qualified facilities.
[116] 79 Fed. Reg. 58553; 79 Fed. Reg. 58466.
[117] *See, e.g.* 21 U.S.C. § 336.

markets due to a draconian "one strike and you're out" approach. If a farm owner can show that he or she has changed practices to address the issue that resulted in the withdrawal, then reinstatement is appropriate. The reinstatement process is especially important if a farm's exemption is withdrawn on the grounds that it is directly linked to an active foodborne illness outbreak investigation, and the investigation later concludes that the foodborne illness outbreak was not actually linked to the farm. In this case, the farmer's exemption was erroneously withdrawn, and should be reinstated promptly.

Some argue that reinstatement means there is no incentive to improve your food safety practices because you can keep making people sick and then maintain your qualified exempt status. We believe the opposite to be true. The reality is that if a small-scale direct-marketing farm is implicated in a foodborne illness outbreak investigation, then their business is likely to be devastated by the harm to their reputation and loss of their customer base, such that the damage to their business will be done even before the costs of compliance with the full rules set in. FDA has criminal enforcement power to address repeat bad actors. The purpose of the withdrawal process is to provide appropriate considerations for small-scale direct marketers, and is not intended to be wielded as an unforgiving punishment.

Recommendation: FDA should retain the reinstatement process in the final rule.

2. FDA should establish a time period within which FDA will reinstate an exemption, as appropriate to the situation.

Depending on the reason why an exemption was withdrawn, reinstatement can occur at the request of the farmer or by initiative of the FDA District Director. Under § 112.213(a), if the withdrawal was due to conditions or conduct material to the safety of the food produced on the farm, and FDA determines the farm has resolved the problems and that continued withdrawal is not necessary to protect public health, then the FDA District Director "shall, on his own initiative or at the request of the farm, reinstate the qualified exemption." Under § 112.213(c), if the exemption was withdrawn because an active foodborne illness investigation was directly linked to the farm, but it is determined at the conclusion of the investigation that the outbreak was not directly linked to the farm, then FDA "will reinstate" the qualified exemption. Under 112.213(d), if the exemption was withdrawn for a combination of § 112.201(a)(1) and (2), and FDA determines there was no direct link, then FDA will inform the farmer of that finding, but the farmer must request reinstatement in writing.

We appreciate the logic behind why certain circumstances would require a different approach, but do find the variations confusing. For example, under 112.213(a), if FDA determines that the problems have been resolved, FDA "shall" reinstate the exemption. The use of "shall" indicates that there is no discretion. Yet, the phrase continues "on his own initiative or at the request of the farm," which implies some degree of discretion. We recognize that FDA must first determine that the issues have been resolved, which is a discretionary function. However, to avoid the concern that this ambiguous language would result in FDA inappropriately withholding or delaying reinstatement even after finding that the problems have been resolved, we urge the agency to add "within a reasonable amount of time" to the end of the 112.213(a) so that it reads: "the FDA District Director … shall, on his own initiative or at the request of the farm, reinstate the qualified exemption <u>within a reasonable period of time.</u>"

This should also apply to requests for reinstatement under § 112.213(d). If FDA has determined that there is no direct link between a farm and a foodborne illness outbreak, and the farmer requests

reinstatement, then FDA must determine whether the farmer has adequately addressed the conduct or conditions of concern. If FDA determines that the farmer has done so, then, as 112.213(a) states, FDA "shall" reinstate. We encourage the agency to clarify that under § 112.213(d), FDA would be expected to do so "within a reasonable period of time." This does not undermine the agency's authority to determine whether the problems have been resolved, but it does provide significant assurance of a fair and transparent process to farms that qualify for modified requirements.

Similarly, § 112.213(c) is unclear regarding the degree of discretion involved in reinstatement. In this situation, a farm essentially had an exemption withdrawn erroneously, out of the belief that an outbreak was directly linked to the farm. In this circumstance, it is appropriate – as FDA details – for reinstatement to occur without the farmer's written request. However, FDA uses the language "will" rather than "shall," which again implies discretion where none is warranted. If there was no direct link, and there were no conditions or conduct of concern, then there is nothing for the farmer to do to rectify the situation because the exemption was withdrawn in error. In such a case, FDA must restore the exemption promptly.

To provide swift and courteous reinstatement of an exemption that was erroneously withdrawn, we urge the agency to change the "will" to "shall" and reinstate the exemption immediately, if not "within a reasonable period of time." The costs that a small farmer or food business will face if required to quickly come into compliance with the full Produce or Preventive Controls Rule are significant. If an exemption was withdrawn in error, prompt reinstatement is not only fair, but also critical to keeping that operation in business.

Recommendation: FDA should add language to § 112.213 clarifying that a FDA District Director will reinstate a qualified exemption "within a reasonable period of time" if the Director determines that the farm has adequately resolved the issues of concern.
Specifically, for § 112.213, FDA should make the following additions:

(a) If the FDA District Director in whose district your farm is located (or, in the case of a foreign farm, the Director of the Office of Compliance in the Center for Food Safety and Applied Nutrition (CFSAN)) determines that the farm has adequately resolved problems with the conduct and conditions that are material to the safety of the food produced or harvested at such farm, and that continued withdrawal of the exemption is not necessary to protect the public health or prevent or mitigate a foodborne illness outbreak, the FDA District Director in whose district your farm is located (or, in the case of a foreign farm, the Director of the Office of Compliance of CFSAN) shall, on his own initiative or request of a farm, reinstate the qualified exemption within a reasonable period of time.

(c) If your qualified exemption was withdrawn under § 112.201(a)(1) and FDA later determines, after finishing the active investigation of a foodborne illness outbreak, that the outbreak is not directly linked to your farm, FDA ~~will~~ shall reinstate your qualified exemption under § 112.5 within a reasonable period of time, and FDA will notify you in writing that your exempt status has been reinstated.

(d) If your qualified exemption was withdrawn under § 112.201(a)(1) and (a)(2) and FDA later determines, after finishing the active investigation of a foodborne illness outbreak, that the outbreak is not directly linked to your farm, FDA will inform you of this finding, and you may ask FDA to reinstate your qualified exemption under § 112.5, in accordance with the requirements of paragraph (b) of this section, including the requirement that – should FDA determine that the farm has adequately resolved problems with the conduct and conditions that are material to the safety of the food produced or harvested at such farm, and that

continued withdrawal of the exemption is not necessary to protect the public health or prevent or mitigate a foodborne illness outbreak – the FDA District Director shall reinstate the qualified exemption within a reasonable period of time.

B. FDA should retain and build upon the improvements to the process for withdrawing a qualified exemption.

1. FDA should retain the changes that clarify what FDA must and may do prior to withdrawing a qualified exemption.

We strongly support the addition of §112.201(b)(1), which clarifies the steps FDA would take prior to issuing an order to withdraw an exemption. We understand that the agency views the order to withdraw as a "last resort" in terms of the tools or intermediary steps the agency has available to address food safety concerns, and we think this provision is important to convey that intent to the regulated community and regulators themselves. These intermediary steps can include a "warning letter, recall, administrative detention, refusal of food offered for import, seizure, and injunction."[118] We support this provision because intermediary steps not only allow FDA to work with farm owners to reduce food safety risks, which will foster more understanding between FDA and the agricultural community, but they also support the agency's goal of continuous improvement. We recommend FDA retain this revision in the final rules, and also include guidance and training for FDA personnel tasked with implementing this provision both on the variety of tools available to the agency, and the intention that withdrawal be used only as a last resort.

We also support the addition of §§112.201(b)(2) and (3), which contain actions that FDA must take before withdrawing an exemption. This includes providing notice to the owner, operator, or agent in charge of the farm of the circumstances that might lead FDA to withdraw the exemption; giving the owner or operator the opportunity to respond; and considering the actions taken to rectify the situation. This provides the farmer with the necessary due process to understand the situation at hand and meaningfully respond. The requirement that FDA consider the actions of the farm before proceeding with an order to withdraw also supports continuous improvement of food safety risk management on farms, and saves the farm and the agency the time and resources associated with an appeal. We recommend that FDA include these elements of the process in the final rule.

Recommendation: FDA should retain §112.201(b)(1)–(3) in the final rule.

2. FDA should provide more information in the notice of intent to withdraw and the withdrawal order itself.

FDA believes "it is appropriate to consider each situation on its individual merits" and in doing so, indicates the agency's intention that a withdrawal will be based on an individualized determination, and will not arbitrarily be applied to a class of farmers.[119] While we appreciate FDA's sentiment, if this is truly the agency's intent, then we urge the agency to make that clear in the regulations themselves, or at the very least in the preamble. This could also be done by adding more specificity to the required contents of both the notice of intent to withdraw, and the withdrawal order itself.

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[118] Proposed § 112.201(b)(1).
[119] 79 Fed. Reg. 58553.

As proposed, the regulations require FDA to "notify the owner, operator, or agent in charge of the farm, in writing, of circumstances that may lead FDA to withdraw the exemption, and provide an opportunity for the owner, operator, or agent in charge of the farm to respond in writing."[120] We would expect that this notification include facts specific to the farmer's situation so that the farmer can meaningfully understand and take steps to rectify the issue. This should not merely recite or point to the regulatory language that allows for withdrawal. We have reviewed recent warning letters sent by the agency to businesses out of compliance with seafood HAACP, cGMPs, and food labeling laws,[121] and we find the degree of specificity contained in those letters to be very good. We would expect notices to farmers regarding the intent to withdraw a qualified exemption to contain the same degree of specificity both regarding the nature of the compliance concern and the steps necessary to correct the situation.

The same applies to the withdrawal order itself. As proposed, the order is only required to contain "a brief, general statement of the reasons for the order."[122] We contend that a "brief general statement" is insufficient to convey the information necessary for a farmer to adequately resolve any food safety problems on their farm. If FDA will consider reinstatement based on a determination that the farmer has adequately addressed the source of the problem, then the order must contain facts specific enough to allow the farmer to address the problem and demonstrate to the agency that the problems have been resolved.

We also note that FDA warning letters under seafood HAACP, cGMPs, and other existing regulations give businesses 15 working days to respond. The withdrawal process gives 10 calendar days. Having a separate process for produce farmers versus seafood farmers to respond to agency communications is confusing for the farmer – particularly farmers that raise or grow food covered under multiple regulations – and for regulatory personnel that would have to adhere to separate administrative processes. For ease of implementation, we recommend that FDA standardize administrative processes across not only FSMA rules, but also across other FDA food safety regulatory schemes.

Recommendation: FDA should clarify that the decision to withdraw a qualified exemption is an individualized determination and will not be applied to a class of farmers by stating this clearly in the preamble. FDA should also include sufficient facts specific to the situation in both the required notice of intent to withdraw a qualified exemption under § 112.201(b)(2), and the withdrawal order in §112.203. FDA should also standardize withdrawal notice and response procedures with existing administrative procedures. Specifically, we recommend incorporating the following revisions:

> § 112.201(b)(2) Must notify the owner, operator, or agent in charge of the farm, in writing, of circumstances that may lead FDA to withdraw the exemption, <u>including sufficient facts specific to the situation and information about how the farm can remedy the situation,</u> and provide an opportunity for the owner, operator, or agent in charge of the farm to respond in writing, within ~~10 calendar~~ <u>15 business</u> days of the date of receipt of the notification, to FDA's notification;

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[120] Proposed § 112.201(b)(2).
[121] *See e.g.* http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2014/ucm425102.htm; http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2014/ucm424928.htm; http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2014/ucm423357.htm.
[122] Proposed § 112.203(c).

§ 112.203(c) An explanation ~~brief, general statement~~ of the reasons for the order, including sufficient facts specific to the situation, information about how the farm can remedy the situation, and information relevant to. . . .

In the Preventive Controls Rule, FDA has tentatively concluded "that it would be useful for the order to itself specify the two options that a facility has upon receipt of the order, even though the order would otherwise include this information (because the order will contain the full text of the withdrawal provisions)."[123] We strongly support this decision, and encourage the agency to do the same in Subpart R of the Produce Rule. Even though the order would contain the full text of the withdrawal provision, it is helpful to explain what that means in lay terms. A farmer receiving this notice will likely understand and respond much better to a sentence or two explaining the regulatory language than the regulatory language alone. This is a reasonable approach, and we encourage the agency to consider doing this for all communications to farmers that include regulatory text.

FDA should also include information in the order that explains how a withdrawal could be reinstated. As above, this should not just reference the regulatory language, but should explain the reinstatement process as it relates to the individual farmer. For example, if the withdrawal order is due to conditions or conduct material to food safety, then the order should also contain information stating that the farmer can request that the withdrawal be reinstated, and provide information on how to submit a written request for reinstatement to FDA, and the information that must be included in the request, so FDA can determine if the conduct or conditions have adequately been resolved.

Recommendation: The Produce Rule should include the same changes to §112.203 to mirror the changes in the Preventive Controls Rule that provide information on the options for a farm to come into compliance or appeal the order. Both rules should also include reference to the process for reinstating a qualified exemption in the order, and should include a plain language explanation of the reinstatement process in the letter itself.

- Specifically, FDA should add a new section to §112.203: "(i) A statement that the farm may request reinstatement of a withdrawn qualified exemption as provided in 112.213."

C. FDA should ensure the processes for withdrawal and reinstatement are identical across both Preventive Controls and Produce rules.

As we have alluded to above, there are areas where the Produce Rule and the Preventive Controls Rule are not identical. There is no logical reason for this. We strongly encourage FDA to make the withdrawal and reinstatement process identical across all applicable rules. This is especially important to assure a consistent process for farmers that may be subject to multiple rules as "farm mixed-type facilities." A consistent process not only benefits the regulated community, but also provides a uniform process for FDA employees, easing the administrative burden of implementation and enforcement.

1. Time to come into compliance

In the original proposed withdrawal provisions, the Preventive Controls Rule provided facilities with a 60-day compliance timeline from the date of the order. In the supplemental Preventive Controls

[123] 79 Fed. Reg. 58553.

Rule, FDA "tentatively conclude[s] that the nature of what a facility would need to do to comply with an order—i.e., comply with the full requirements for hazard analysis and risk-based preventive controls—makes the timeframes in the 2013 proposed withdrawal provisions insufficient.[124] Therefore, FDA revised the Preventive Controls Rule to increase the compliance timeline to 120 days for food facilities, and tolls the requirement to come into compliance from the date of receipt of the order.[125]

FDA is asking for comment on whether they should "amend the relevant provisions in proposed part 112 (*i.e.,* proposed §§ 112.203(d), 112.204(a), 112.205(b)), which would require compliance within 60 calendar days of the date of the order, to require that a farm comply with an order to withdraw its qualified exemption within 120 days of the date of receipt of the order."[126] We support these changes to the process in the Preventive Controls Rule, which acknowledge the burden that farmers and food businesses will face as they come into compliance with the full FSMA rules, and we encourage FDA to modify the provisions in the Produce Rule to mirror the changes in the Preventive Controls Rule. However, we again note that existing FDA regulatory schemes (like HAACP) are based on business or "working" days, not calendar days. We urge the agency to standardize these administrative processes not only across FSMA rules, but across all FDA food safety rules.

Recommendation: FDA should change the timeframe for a farm to come into compliance with the full Produce Rule to mirror the changes to the Preventive Control Rule, and should standardize all timelines to be based on "working" or "business" days. Specifically:

> § 112.204(a) Comply with applicable requirements of this part within 120 ~~60 calendar~~ business days of the date of receipt of the order or, if operations have ceased and will not resume within 120 ~~60 calendar~~ business days, before the beginning of operations in the next growing season;

2. Time to respond to correspondence from FDA

In the Preventive Controls Rule, FDA has "tentatively conclude[d] that it is appropriate to link the timeframe for compliance to the date of receipt of the order, rather than to the date the order was issued" and that "[d]oing so would be consistent with our other administrative procedures."[127] The Preventive Controls Rule applies the same method to the time within which a facility must respond to a notice.

The Produce Rule, on the other hand, is based on the date of the notification, not the date of receipt.[128] We strongly encourage the agency to provide a consistent timeframe across rules, and to do so consistent with existing agency procedures. Ten days is already an incredibly short amount of time for a busy farmer to respond to an official notice from FDA, and at the very least, the time should toll upon receipt to provide the maximum opportunity to understand and respond to the notice. Furthermore, due to different mailing times throughout the country, tolling the timeline

[124] 79 Fed. Reg. 58554.
[125] Proposed § 117.257(d)(1).
[126] 79 Fed. Reg. 58467.
[127] 79 Fed. Reg. 58554.
[128] Proposed § 112.201(b)(2).

from the date of receipt of the order standardizes the number of days a farmer has to comply, no matter where in the country he or she resides.

To ensure an accurate determination of when the time tolls, FDA should deliver all time sensitive communications to farmers in way that ensures that the farmer receives the order, and provides confirmation of receipt. FDA could do this by sending communications through certified mail with a confirmation of delivery. However, it is important to ensure that the appropriate person – whether the farm owner, operator, or agent in charge – is the recipient.

Recommendation: FDA should standardize the processes across all FDA food safety rules so that all communications are considered received on the date of receipt, not the date of the notification or order. As with existing FDA processes, the days required should be measured by business or working day, not calendar day. Moreover, FDA should ensure receipt by sending time sensitive communications to farmers through delivery that includes confirmation that the appropriate person received the communication, whether it is the farm owner, operator, or agent in charge.

D. FDA should clarify key terms.

In our 2013 comments, we urged the agency to define key terms and establish an evidentiary standard for the withdrawal process.[129] In response to our comments (and presumably the comments of others), FDA stated:

> We do not consider it necessary to define terms such as "directly linked," "necessary," "associated," or "material to the safety of food," or to introduce a standard (such as "credible evidence" or "credible and substantial evidence" that shows direct linkage to a problem on a specific farm or facility) to provide for a fair process that is neither arbitrary nor capricious. 79 Fed. Reg. 58552.

While we appreciate FDA's stated intention to provide a fair process, and a process that is neither arbitrary nor capricious, we respectfully disagree that defining key terms and establishing an evidentiary standard are unnecessary. These definitions would provide assurances to the regulated community and guidance to agency personnel tasked with enforcing these provisions.

We urge the agency to reconsider our earlier comments on this issue. Specifically, FDA should adopt a "credible and substantial evidence" standard for withdrawal of an exemption. The proposed rules currently permit FDA to withdraw the exemption based on conditions or conduct "associated" with a qualified farm.[130] A "credible and substantial evidence" standard would provide a specific threshold that FDA must meet to begin the process of withdrawing an exemption, and it would ensure that withdrawal orders are based on evidence and not allegations.

Second, FDA should provide a definition of "directly linked." FDA may withdraw a farm's exemption if a foodborne illness outbreak is "directly linked" to a qualified farm but, without a definition, there is ambiguity in how a farm may be "directly linked" to an outbreak.[131] Because this is one of only two avenues for FDA to withdraw an exemption, and because of the significant

[129] *See* Appendix II at 108–14.
[130] Proposed § 112.201(a)(2).
[131] Proposed § 112.201(a)(1).

implications for farm owners that have their exemptions withdrawn, there should be clear guidance for FDA in making this determination. Defining "directly linked" will help FDA to determine when it can withdraw a qualified farm's exemption and ensure that links between outbreaks and farms are not overly attenuated. Given the pressure on FDA to identify the source of a foodborne illness when an outbreak occurs, it is critical to clearly explain when and how a foodborne illness outbreak is "directly linked" to a farm to avoid hastily and erroneously withdrawing qualified exemptions. This should be clear in the regulations, and should also be included in guidance for public comment on how an outbreak may be directly linked to a farm.

Third, FDA should more clearly specify when it is "necessary" to withdraw an exemption to protect the public health. We recommend defining "necessary" as "when absolutely required." The withdrawal of a farm's exemption can cause significant financial burdens for producers, especially for small producers, and the exemption should only be withdrawn when FDA is certain that it is absolutely required to protect public health.

Additionally, FDA should define "associated" to specify how closely connected to a qualified farm a condition must be. Without providing a definition, it is possible that even very attenuated connections between conditions and farms would be sufficient for FDA to withdraw an exemption. We recommend a definition requiring the condition is "directly and closely connected" to the farm.

Lastly, FDA should provide a definition of "material to the safety of the food." Without clarification, this phrase could encompass every conceivable risk to safety. A definition for "material to the safety of the food" should indicate that there must be a reasonable probability that the conduct or conditions will contribute to an outbreak of foodborne illness.

Recommendations: FDA should introduce a "credible and substantial evidence standard" and define the terms "directly linked," "necessary," "associated," and "material to the safety of the food." Specifically, we recommend the following modifications to § 112.201(a)(2):

> If we determine <u>based on credible and substantial evidence</u> that it is necessary to protect the public health and prevent or mitigate a foodborne illness outbreak based on conduct or conditions associated with your farm that are material to the safety of the food that would otherwise be covered produce grown, harvested, packed, or held at your farm; <u>conditions or conduct are material to the safety of food when there is reasonable probability that they will contribute to an outbreak of foodborne illness</u>.

And we recommend the follow definitions be added to § 112.3:

> <u>(a) *Directly* linked means that which in a direct manner, as established by credible and substantial evidence, is immediately connected to activities on a farm, farm mixed-type facility, or facility that are under the control of the owner, operator, or agent in charge of the farm, farm mixed-type facility, or facility.</u>
>
> <u>(b) *Necessary* means that which is absolutely required, as established by credible and substantial evidence, to protect public health.</u>
>
> <u>(c) *Associated* means that which is directly and closely connected, as established by credible and substantial evidence, to a farm, farm mixed-type facility, or facility.</u>
>
> <u>(d) *Material to the safety of food* means traits, aspects, or characteristics of conduct actually taking place, or conditions specifically in existence on a farm or in a facility, that are directly relevant to ensuring the safety of food; that can be clearly measured; and that are identified through direct examination of the activities, conduct, and conditions of an individual farm or facility.</u>

IX. COMMENTS ON THE EFFECTS OF A REQUIRED SUPPLIER PROGRAM ON COVERED FARMS

NSAC submitted the following comments and recommendations to the docket on the supplemental proposed Preventive Controls Rule. Given our concerns regarding the effects of the proposed supplier program on small-scale farms and food businesses, including the potential for costly and duplicative burdens on covered farms, we include these comments to the Produce Rule docket as well. The successful implementation of FSMA requires an integrated approach that recognizes and considers the cumulative and indirect effects of other rules. It is critical that none of the rule be considered in isolation, particularly for those entities that may be affected by multiple rules.

NSAC strongly opposes the inclusion of a supplier program in the final Preventive Controls Rule. The onsite audit requirements of the proposed program fall flagrantly outside the agency's authority under FSMA, and the agency has not adequately considered the effects of a supplier program on food businesses that work with farms, let alone the farms themselves. We offer the following comments and recommendations below, including comments on USDA GAPs and other audit programs that are relevant to this docket as well.

A. The supplier program violates Congress' express prohibition that FDA not require domestic farms and facilities to undergo third-party audits, and must not be included in the final regulation.

FSMA directs FDA to establish standards that require food facilities to develop and follow risk-based preventive controls.[132] FDA may, *but is not required to*, include "supplier verification activities" as part of those preventive controls.[133] Importantly, FSMA explicitly prohibits FDA from requiring regulated entities[134] to hire third parties to identify, implement, certify, or audit compliance with the rules it adopts to implement FSMA (including both the Preventive Controls Rule and the Produce Rule).[135]

1. Under certain circumstances FDA expressly makes the audit requirement mandatory, in violation of the statute.

In the supplemental Preventive Controls Rule, FDA proposes to require facilities to have supplier verification activities for "raw materials and ingredients for which the receiving facility has identified a significant hazard" and when "the hazard is controlled before receipt of raw material or ingredient."[136] This means the requirement would not apply to raw materials and ingredients "for which there are no significant hazards" or where "the preventive controls at the receiving facility are adequate."[137]

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[132] 21 U.S.C. 350g(n)(1)(A).
[133] *Id.* at § 350g(o)(3)(G).
[134] Under the Produce Rule, the regulated entities to which this protection applies are "businesses" covered under the rule – e.g. covered produce farms. Under the Preventive Controls rule, the regulated entities protected by this provision are "facilities," which could include farms that are mixed-type facilities, in addition to traditional food facilities.
[135] 21 U.S.C. §§ 350g(n)(3)(D), 350h(c)(1)(E). FDA's rules must also be flexible, and minimize the number of separate standards that apply to separate foods. 21 U.S.C. 350g(n)(3)(C).
[136] Proposed § 117.136; 79 Fed. Reg. 58565–67.
[137] *Id.*

FDA proposes that the facility "can determine the appropriate verification activities for raw materials and ingredients," and can choose among several verification activities, including an onsite audit.[138] However, if there is "a reasonable probability that exposure to the hazard will result in serious adverse health consequences or death" (SAHCOD), then the receiving facility must have documentation of an onsite audit before using any raw ingredients from the supplier.[139]

FDA does not provide guidance to determine what raw materials and ingredients pose "significant hazards" or meet the higher SAHCOD threshold. In response to inquiries on this question, FDA has directed us to the agency's draft Qualitative Risk Assessment of Activity/Food Combinations for Activities (Outside the Farm Definition) Conducted in a Facility Co-Located on a Farm (QRA) for guidance as to these hazard classification levels. But this suggestion creates more questions than it answers.

The QRA identifies a wide array of low-risk activity/food combinations. The document never uses the term "significant hazard" to describe any of the activity/food combinations discussed, but it does discuss a number of activity/food combinations in terms of SAHCOD, including a chart that lists 15 activity/food combinations that are not "low-risk' because they increase or introduce a SAHCOD hazard, or are intended to minimize such hazards.[140]

Based on the information presented in the QRA, we can only assume that any of the following supplier activities would be considered a SAHCOD, and subject to mandatory onsite audits under the proposed supplier program:

- A farm or pack house that washes or hydrocools RACs sold to a facility that uses those RACs in manufacturing any food that is not subjected to a kill step at the purchasing facility, such as fresh salsas, ice cream and other frozen desserts, etc.
- A farm mixed-type facility or other facility that ferments vegetables sold to a facility that uses those fermented vegetables in any food that is not subjected to a kill step at the purchasing facility.
- A farm or facility that puts a label on packaged raw peanuts or tree nuts sold to a facility that uses those nuts in manufacturing any food, such as granola mixes, candies, etc.
- A farm or facility that puts a label on packaged fudge, hard candy, toffee, taffy or milk chocolate sold to a facility that uses those candies in manufacturing any food.

There are numerous other examples of common food activity combinations, which are conducted on farms as well as at non-farm facilities, that would trigger the mandatory onsite audit under the proposed supplier program, separate from – and in addition to – any action the farm or facility is taking to satisfy compliance with the Produce Rule or the Preventive Controls Rule.

FDA contends that this requirement for onsite audits of suppliers does not contradict FSMA's prohibition against onsite audits because FDA is not requiring an audit of the supplier, but rather is requiring the receiving facility to require the audit. This argument is disingenuous at best. FDA's Supplemental PRIA acknowledges that this is, in reality, a requirement imposed on the supplier by

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[138] *Id.*

[139] *Id.*

[140] Draft Qualitative Risk Assessment of Activity/Food Combinations for Activities (Outside the Farm Definition) Conducted in a Facility Co-Located on a Farm, table 18, at 56-59.

estimating the cost of this provision not on the receiving facility, but on the supplying farm or facility.[141] FDA also acknowledges that this provision will likely impose additional costs on farms, but fails to provide an estimate of those costs.[142] Clearly, the onsite audit requirement acts as a *de facto* audit requirement on farms and facilities, in plain contravention of Congress's express directive to the agency.

2. Principles of statutory construction prohibit the supplier program.

Canons of statutory construction demonstrate Congress did not intend for FDA to require audits of farms or facilities anywhere in the proposed rules implementing FSMA. Indeed, §350h and §350g of FSMA expressly prohibit FDA from adopting regulations that require a "farm" or a "facility" respectively to hire a third party or consultant to confirm its compliance with those regulations.[143]

While §350h addresses compliance with the Produce Rule, FDA cannot subvert FSMA's prohibition by requiring – through the revised Preventive Controls Rule – that these same farms, when acting as suppliers, undergo a third party audit. To do so runs counter to Congressional intent and would essentially read the §350h prohibition out of the statute. The same is true for §350g and supplying facilities, because it would indirectly require the supplying facility to have an audit to verify compliance with the Preventive Controls, though FDA cannot require an audit directly.

In reviewing an agency's interpretation of a statute, courts are reticent to support an agency position that would have the effect of reading a provision out of the statute or rendering it a nullity.[144] Moreover, courts tend to read provisions of a statute in concert with one another, so that actions under one section of a statute do not obviate the intent of Congress in another.[145] When a farm is both a "farm" under the Produce Rule and a "supplier" under the Preventive Controls Rule, FDA's interpretation of FSMA as allowing it to require onsite audits of "suppliers" cannot be read in concert with FSMA's clear prohibition against third party auditors under §350h. Likewise when a facility is both a "facility" and a "supplier" under the Preventive Controls Rule, an interpretation of FSMA as allowing FDA to require onsite audits of "suppliers" cannot be read in concert with FSMA's clear prohibition against third party auditors under §350g.

Thus, to impose the proposed supplier verification program is to invite legal challenges from food producers, undermining the effectiveness of the entire scheme of foodborne illness risk management Congress intended in passing FSMA.

3. The complexity and uncertainty of the supplier program requirement will stifle innovation in the marketplace and disproportionately harm small business.

FDA argues that the supplier program does not counter the letter of the law because the onsite audit requirement can be waived "if the receiving facility documents its determination that other verification activities and/or less frequent onsite auditing of the supplier provide adequate assurance

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[141] Preliminary Regulatory Impact Analysis at 19.
[142] *Id.* at 37.
[143] 21 U.S.C. 350h(c)(1)(E).
[144] *See, e.g., Moskal v. United States,* 298 U.S. 103, 109 (1990) (stating the established principle that a court should "give effect, if possible, to every clause and word of a statute.").
[145] *See Babbitt v. Sweet Home Chapter of Cmtys. For a Great Or.,* 515 U.S. 687, 717–18 (1995) (upholding the proposition that definitions should be read consistently with other provisions of a statute).

that the hazards are controlled."[146] We take no comfort in this provision, because it is implausible that, in a real world scenario, a receiving facility would read the language that first requires an onsite audit and then elect to put itself on the line by verifying that it has received "adequate assurance" from the supplier. FDA does not provide any definition in the regulation of the meaning of the term "adequate assurance." How will FDA inspectors interpret "adequate assurance"? What receiving facility would take that risk given this vague regulatory language, and considering that failure to comply with the regulations is a prohibited act? The reality is that the "alternative option" approach will be impossible for all but the largest processing facilities to adopt. In practice, the onsite audit requirement flies in the face of the letter and the spirit of the law.

Moreover, qualified exempt farms and very small facilities both could be effectively robbed of customers by the proposed supplier program, because purchasing facilities will simply stop doing business with them. To continue to purchase from such very small farms and businesses, a receiving facility would have to establish an alternative verification program for them, parallel to the program it has in place for suppliers that are subject to the full Produce and Preventive Controls Rules. Most receiving facilities will likely opt not to make that investment in parallel verification programs, particularly where the "adequacy" of such a program would be so uncertain, and opt for the simplest one, leaving very small producers out in the cold. Thus the supplier program contradicts the spirit of FSMA's mandate that FDA promulgate regulations that "provide sufficient flexibility to be practicable for all sizes and types of facilities, including small businesses,"[147] and Congress' overarching intent to establish a scale- and supply-chain appropriate regulatory framework.

Another direct conflict that the supplier program creates with FSMA's express provisions is the fact that Congress mandates staggered compliance deadlines for small and very small businesses under the Produce and Preventive Controls Rules. To the extent a receiving facility is required to come into compliance with FSMA sooner than a current or prospective supplier, such facility is in effect creating pressure for that supplier to come into compliance on a timetable inconsistent with that intended by Congress and established in the agency's regulations. The "adequacy" of the receiving facility's verification activities becomes potentially even more problematic to demonstrate to FDA inspectors.

We are well aware that supplier audits are an increasingly common practice in the marketplace; we question whether this trend is actually effective in reducing foodborne illness risk in the supply chain. In practice, buyers usually have very little ability to assess or understand the meaning or validity of the standards underlying commonly used certification programs. In particular, private third-party audit schemes often rely on proprietary standards that may or may not reflect good science related to pathogen control, but because these third-party audit providers aggressively market their services to large buyers they have become widely adopted.

By elevating audits as the default method of supplier verification, FDA is increasing the reliance of the food industry on these opaque and potentially flawed instruments, which are by their nature only a snapshot in time and therefore not reflective of a firm's culture of food safety, even though it is accepted that such a culture is the truly necessary and effective foundation of a successful program for reducing foodborne illness risk. And by mandating the audit approach on a massive scale practically overnight, the supplier verification program requirement would result in a proliferation of

[146] Proposed § 117.136(c)(2)(ii).
[147] 21 U.S.C. §§ 350g(n)(3)(A), 350h(c)(1)(B).

new audit schemes and poorly trained third-party auditors to implement them, further diluting the effectiveness of supplier verification as a risk-reduction tool, and so potentially putting more of the food supply in jeopardy of pathogen contamination.

Ultimately the best means for supplier verification is a decision between the buyer and the seller, and one in which dialogue between the parties is, in the long term, the most effective means for collaboration to reduce foodborne illness risk. Moreover, with innovative collective programs for food safety risk management growing in popularity (and actively supported by sister federal agencies, such as the USDA's Group GAP pilot project), this provision will stifle some the most innovative approaches to reducing foodborne illness risks. FDA attempts to shoe-horn flexibility into the audit requirement, but the reality is that if this requirement is codified, it will become the default, and any farm selling to a manufacturing facility will be required to get an audit, and any facility selling to another facility will have to undergo a third-party audit in those years when it is not itself inspected by FDA under the Preventive Controls rules. This is clearly contrary to the intent of Congress, and must be addressed.

***Recommendation*:** FDA cannot include an onsite audit requirement in the supplier program, and must remove this language from the regulations.

B. FDA should not include the supplier program in the final rule, but could include it in guidance with education and training for affected entities.

The supplier program is quite concerning for the sustainable agriculture community, and for the continued growth of local and regional food systems. The costs associated with this provision, particularly the audit requirement, are significant, and the PRIA fails to capture the full impacts on farms. Not only will this provision impact farms supplying facilities with fresh fruits and vegetables, but it will significantly impact the ability of value-added businesses and food hubs to continue sourcing from smaller scale, local producers. Given the concerns that this requirement will impose duplicative, costly requirements on covered farms – in addition to the significant burden it will place on smaller facilities purchasing from local suppliers or selling to other receiving facilities – we urge FDA to remove the entire supplier program from the final rules and instead include principles of adequate supplier verification programs in Level 1 guidance.

Level 1 guidance provides an opportunity to ensure flexibility in the verification measures selected by a particular facility, and provides the opportunity to educate receiving facilities that might be purchasing raw materials from covered farms, qualified exempt farms, or exempt farms. Such a program of Level 1 guidance development should include FDA:

- Soliciting/accepting drafts of proposed guidance documents from the sustainable agriculture and local/regional food system community for FDA to consider;
- Publishing its list of possible topics for future FSMA guidance document development or revision during each year;
- Seeking input in advance from the sustainable agriculture and local/regional food system community before preparing draft guidance, including public meetings, workshops, and the formation of an advisory committee including representatives from these communities;
- Holding public meetings and workshops on the draft guidance after they are published; and
- Presenting the draft guidance to an advisory committee including representatives from the sustainable agriculture and local/regional food system community.

FDA's proposed supplier program includes specific considerations for qualified facilities, qualified exempt farms, and exempt farms. This includes annual documentation of status, and biennial assurance from the supplier regarding compliance with applicable regulations, the food safety practices it uses, and assurance that the food is not adulterated.[148] These are important considerations, but should be included in outreach and training materials through guidance so that affected entities understand the requirements associated with different types of suppliers.

Recommendation: FDA must ensure that farms covered under the Produce Rule are not subject to duplicative verification measures and costs as a result of the preventive controls rule, and that facilities continue to purchase from local producers.
Specifically, FDA should:

- Remove the supplier program from the regulations;
- Fully analyze the economic impacts of a supplier program on farms;
- Develop Level 1 guidance for facilities that work with covered farms, especially qualified exempt farms or *de minimis* exempt farms, to ensure that receiving facilities fully understand what is and is not required of those suppliers, and to ensure that such farms are not subject to duplicative and burdensome requirements under the Preventive Controls Rule that they are not otherwise subject to under the Produce Rule;
- Develop Level 1 guidance for facilities that work with covered farms, especially farms that qualify as small and very small business, to ensure that farms with have extended time to come into compliance with the Produce Rule are not inadvertently forced into compliance sooner than otherwise required through supplier verification programs; and
- Not require verification activities in circumstances in which a RAC, such as fresh produce, is not sent to any facility that would be required to have preventive controls before reaching consumers. The Produce Rule provides assurances for such activities, and the Preventive Controls Rule should not require duplicative, burdensome requirements on covered farms.

C. FDA should clarify the role of third party audits in FSMA implementation.

Given Congress's mandate that FDA not require third parties to verify or audit compliance with the rules, FDA's approach to FSMA implementation must not overemphasize the relative value of audits as a compliance tool. Third party audits are increasingly common in the marketplace, and FDA has indicated in conversation and outreach communications that they will look to audits as a means to target the agency's limited enforcement resources.

Clearly, third party audits play an important role in FSMA implementation. However, FDA must ensure that the other available tools to encourage compliance – particularly those that satisfy the new "educate before you regulate" mantra – are emphasized first. This includes management decisions, industry commitments, and creating a culture of food safety; all accomplished through training, capacity building, and technical assistance. Audits are one tool in FDA's toolbox. It is critical that the agency not increase the relative importance of audits to the level where they become dangerous for the continued existence of smaller enterprises.

[148] Proposed § 117.136(c)(3), (4).

Recommendation: FDA should clarify the relative value of third party audits over other efforts to ensure compliance with the rules, and the higher relative value of education, training, and technical assistance efforts.

D. FDA should work with USDA AMS to support the USDA GAPs program's continued success as an accessible food safety certification program for small and mid-sized farms.

We understand that FDA and USDA AMS have had conversations about working together to ensure that USDA GAPs remains a viable and attractive option for small and mid sized farms seeking market access through voluntary food safety certification programs. USDA has indicated that their goal is to ensure that a farm that passes a GAP audit would also be prepared to pass a FSMA inspection. Essentially, a USDA GAPs auditor would look at the farm and see the same things that an FDA inspector would. We support that goal, and urge FDA to do everything in its power to assist its sister agency in providing this service to small and mid-size farmers.

Recommendation: FDA should work with USDA AMS to ensure full integration between the FSMA requirements and the GAPs program, so that USDA GAPs can continue to provide farmers serving local and regional food markets with an accessible voluntary certification program.

X. COMMENTS ON REMAINING ISSUES OF CONCERN

We very much appreciate this second opportunity to submit comments on certain parts of the proposed FSMA rules. FDA has stated that the agency is still considering all of the comments on issues that were not re-proposed in the supplemental rules. NSAC submitted comprehensive comments on many issues in the rules that are not addressed in the supplemental proposals, and is pleased to know that FDA will continue reviewing and considering these comments in crafting a final rule. However, we would like to highlight a few key issues that were of great concern to us in the initial round that were not included in the supplemental rules: farm registration; routine farm inspections; farm food safety plans; alternatives; and records for qualified exempt farms.[149] We first address the issue of whether farmers growing "starts" or "transplants" for sale are covered by the Produce Rule.

A. Comments on Selling Seedlings or "Starts" for Transplanting

FDA should clarify that the Produce Rule does not cover farmers who grow and sell seedlings or "starts" for transplanting. FDA has not addressed this issue in either proposed or supplemental rule.

The Produce Rule only applies to farms that sell covered produce that are raw agricultural commodities. Produce is defined as "any fruit or vegetable" and includes mushrooms, sprouts, peanuts, tree nuts, and herbs. A vegetable is the edible part of an herbaceous plant, such that "vegetable" means the harvestable or harvested part of any plant whose fruit, fleshy fruiting bodies, seeds, roots, tubers, bulbs, stems, leaves, or flower parts <u>are used as food.</u>

We interpret this to mean that a transplant or seedling is only considered "covered produce" if it contains the edible or harvestable part of the plant *and* is used as food. Therefore, to be covered under the rule, a transplant would have to meet a two-part test: (1) does it contain the edible or harvestable part of the plant, and if so (2) is it intended for use as food? However, FDA has not stated a clear determination on this issue, but has indicated that their inquiry would stop after the first question: does the seedling contain a harvestable part of the plant? Most transplants would not satisfy part (1), because they are typically sold at a stage where they are not bearing fruit or otherwise harvestable. However, some transplants, like herbs or leafy greens, could technically be eaten in their seedling stage.

Take a farmer selling seedlings retail at a farmers market alongside other produce. If the farmer is selling eggplant, tomato, and basil starts, then under this interpretation, each one has a different status. The basil would be covered, the tomato only if there are actual fruits on the plant, and the eggplant would not be covered because eggplants are not covered produce. This introduces a level of complexity that is unmanageable for a diversified farmer. In the case of a farm that only sells seedlings, the question of coverage is unnecessarily complicated. A clearer way to address this issue is to base it on intent at time of sale, as laid out in the two part test above. If the seedling is technically edible but is being sold by a farmer whose stand clearly is selling *only* seedlings, or is being sold wholesale, then it would be unreasonable to assume that the seedling was intended as food. If the seedling is basil, for example, that is fully leafed out and sold alongside other herbs in the supermarket, then it is reasonable to assume that a purchaser could reasonably believe that the plant was intended to be eaten, and not transplanted.

[149] *See* Appendix II for full comments and recommendations.

Recommendation: FDA should clarify that the Produce Rule does not cover seedlings, unless the seedlings contain the harvestable portion of covered produce *and* a reasonable person could think the seedlings were intended to be sold as food at the time of purchase. FDA should provide guidance for producers that sell seedlings on the situations where a seedling may or may not be covered (e.g. wholesale vs. retail, the stage of maturity at sale, etc.), or where it would be advisable to include a sign or other information informing purchasers of the intended use of the seedling.

B. Comments on Farm Registration: Requiring 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 the final rule, that covered farms, as described in proposed § 112.4(a), register with FDA."[150]

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 require farms to register.

Recommendation: In the final Produce Rule, FDA should not require farms to register with FDA.

C. Comments on "Routine" Farm Inspections: FSMA does not grant FDA the authority to routinely inspect farms, and any such reference must be removed from the Produce Rule.

In the preamble discussion of the Subpart R, FDA states that it may withdraw a qualified exemption if "during a *routine inspection* of a farm to which the qualified exemption in proposed § 112.5 applies, we discover conditions and practices that are likely to lead to contamination of food that would otherwise be covered produce with microorganisms of public health significance." FSMA does not give FDA new authority to "routinely inspect" farms, especially qualified exempt farms.

FSMA requires FDA to increase the inspection of facilities, and while certain farms may have facilities that may be subject to inspection, FSMA does not give FDA new authority to routinely inspect farms, including qualified exempt farms. FSMA expressly states that, in the subsection about withdrawals of exemptions, "[n]othing in this subsection shall be construed to expand or limit the inspection authority of the Secretary." Despite these clear restrictions from FSMA, FDA is saying in the preamble to the proposed Produce Rule that it may start to routinely inspect qualified exempt farms.

Recommendation: In the final Produce Rule, FDA should not state in the preamble or elsewhere in the proposed Produce Rule that it plans to routinely inspect farms, including qualified exempt farms. No less importantly, FDA should also provide clear guidance and training to all of its staff and contracting entities, including state and local entities, that they have no such power or authority.

[150] 78 Fed. Reg. at 3619

D. Comments on Farm Food Safety Plans: Requiring farm food safety plans is inconsistent with FSMA.

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."[151]

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, 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, including many NSAC member organizations. NSAC supports appropriate food safety planning but that work should be allowed to continue outside of the scope of federal regulations.

Recommendation: In the final Produce Rule, FDA should not require farms to perform operational assessments or develop food safety plans. This work should remain outside the scope of federal regulation.

E. Comments on Alternatives in the Produce Rule: The alternatives are not practical enough to provide adequate flexibility.

As a way to provide flexibility to certain requirements in Subparts E and F, FDA proposes to allow the use of alternative practice in §112.12. While we appreciate the agency's attempt to provide some flexibility through the use of alternatives, as currently proposed the option for alternative practices would not provide the flexibility necessary to comply with the mandate from Congress to establish flexible, applicable, and practicable standards. We detail the reasons for this below and then provide a recommendation based on these points.

1. The alternatives apply to only a small subset of Produce Rule requirements.

The option to use an alternative practice applies narrowly to one requirement in Subpart E and to three requirements in Subpart F. These are all requirements that include a specific numerical standard or interval. Yet, the option for an alternative does not apply to other numerical requirements in the Produce Rule, such as the frequency of water testing requirements in § 112.45 and requirements for agricultural water in § 112.44(a). The narrow focus of the alternatives to only certain requirements in the proposed Produce Rule limits the flexibility the option is meant to provide.

[151] 78 Fed. Reg. at 3619

2. The standard for establishing an alternative practice is too high.

To establish an alternative practice, a farmer must show that there is "adequate scientific data or information to support a conclusion that the alternative would provide the same level of public health protection as the applicable requirement established in this part."[152] This requirement means that FDA is requiring the science supporting an alternative practice to address public health risks generally. This is an enormous task that research aimed at agronomic practices tailored to a specific production system, climate, or region cannot reasonably be expected to accomplish.

In point of fact, FDA itself has not been able to assess the public health risks of the standards it is proposing in the Produce Rule and has had to rely on limited data. The body of scientific literature on the role and risks of farm practices in food safety is limited at best and rapidly evolving. Neither FDA in its proposed standards nor a farmer trying to use an alternative practice would be able to show that practices provide an equivalent level of public health protection because the base level of public health protection has not been established.

3. The research required to support an alternative practice is too costly for small and mid-sized farmers.

In the preamble, FDA recognizes that more research is needed; we completely agree. There are many topics concerning on-farm practices and their role in food safety that merit scientific study and investigation. It is important for federal and other public research institutions to work directly with farmers on food safety research questions, because farmers, and especially small and mid-sized farmers and local farm groups, are not able to themselves fund the long-term research that would be required to establish alternative practices. As an organization that has long advocated for and supported investments in on-farm research and extension, NSAC strongly supports on-farm food safety research, but we are also acutely aware of the limited resources that farmers have to invest in research and support long-term research studies. It is critical to ensure that farmers are actively involved in setting the research agenda and engaged as partners in the research process, but they cannot shoulder the expense of the research needed to establish the general public health risks of farming practices.

Recommendation: In the final Produce Rule, FDA must ensure sufficient flexibility by improving the requirements in Subparts E and F and establishing practical and applicable requirements. Additionally, FDA should ensure flexibility by allowing alternatives to other requirements of the Produce Rule, such as the frequency of water testing requirements in § 112.45 and requirements for agricultural water in § 112.44(a). Finally, FDA should work with farmers and research institutions and agencies to conduct research needed to support alternative practices that are relevant and appropriate to the wide range and diversity of farming systems impacted by the Produce Rule.

F. Comments on record requirements for qualified exempt farms: It would be inconsistent with FSMA to require qualified exempt farms to establish and maintain records in accordance with subpart O.

In the preamble, FDA "request[s] comment on whether we should require farms to be able to provide adequate documentation, as needed to demonstrate the basis for the qualified exemption.

[152] Proposed § 112.12(b).

Specifically, we request comment on whether we should do this by requiring records to be established and maintained in accordance with the requirements of proposed subpart O, or if there is an alternative strategy by which we could require retention of and access to such records (such as by requiring farms only to retain records kept in the normal course of their business bearing on the criteria for the qualified exemption that they use to determine their eligibility and requiring FDA access to such records upon request)."[153]

FDA rightly notes that § 419 of FD&CA "does not explicitly require farms that meet the criteria for the qualified exemption to establish and maintain documentation of the basis for their exemption."[154] This is an important point to emphasize. The modified requirements through § 419 are less onerous than those through § 418, which require qualified facilities to submit certain documentation to FDA. The Tester amendment explicitly included documentation submission requirements for qualified facilities and explicitly excluded such requirements for qualified farms. Congress determined that the notification to consumers was sufficient for qualified farms.

NSAC recognizes that having documentation to support a qualified farm's status may be useful for FDA. However, we also note that according to FDA, the recordkeeping requirements are the fifth costliest aspect of the proposed Produce Rule.[155] The qualified exemptions were designed specifically to decrease this type of burden on small businesses and FDA must not require more than what is absolutely necessary.

To that end, NSAC does not support requiring qualified exempt farms to establish and maintain records in accordance with the requirements of subpart O. We do support the alternative that farms not be required to retain records that are not kept in the normal course of business. However, we do not support including recordkeeping or documentation requirements in the rule itself. We think the better option is for FDA to issue guidance, for public comment, that would establish guidelines for the type of documentation qualified farms should keep that supports their status. In such guidance, it is very important that the guidelines established protect a farm's privacy, especially with respect to financial records.

Recommendation: In the final Produce Rule, FDA should not require qualified exempt farms to submit documentation to FDA. FDA should not require qualified exempt farms to establish and maintain records in accordance with Subpart O. FDA should set recordkeeping guidelines for qualified exempt farms in guidance for public comment, not in the rule itself. Those guidelines should not require qualified farms to establish and maintain documents or records that are not kept in the normal course of business.

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[153] 78 Fed. Reg. at 3551.

[154] 78 Fed. Reg. at 3550.

[155] Travis Minor, presentation at FDA Public Meeting, Washington, DC.