



National Sustainable Agriculture Coalition

December 15, 2014

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

Docket No. FDA-2011-N-0920
RIN 0910-AG36

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

Re: Comments on the supplemental proposed rule for Current Good Manufacturing Practice and Hazard Analysis and Risk Based Preventive Controls for Human Food

On behalf of the represented member organizations¹ of the National Sustainable Agriculture Coalition (NSAC), I submit the following comments on the supplemental proposed rule for Current Good Manufacturing Practice and Hazard Analysis and Risk Based Preventive Controls for Human Food. 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,

A handwritten signature in cursive script that reads "Sophia Kruszewski".

Sophia Kruszewski, Policy Specialist
National Sustainable Agriculture Coalition

¹ Agriculture and Land-Based Training Association – Salinas, CA; Alternative Energy Resources Organization – Helena, MT; California Certified Organic Farmers – Santa Cruz, CA; California FarmLink – Santa Cruz, CA; C.A.S.A. del Llano (Communities Assuring a Sustainable Agriculture) – Hereford, TX; Catholic Rural Life – Des Moines, IA; Center for Rural Affairs – Lyons, NE; Clagett Farm/Chesapeake Bay Foundation – Upper Marlboro, MD; Community Alliance with Family Farmers – Davis, CA; Dakota Rural Action – Brookings, SD; Delta Land and Community, Inc. – Almyra, AR; Ecological Farming Association – Soquel, CA; Farmer-Veteran Coalition – Davis, CA; Fay-Penn Economic Development Council – Lemont Furnace, PA; Flats Mentor Farm – Lancaster, MA; Florida Organic Growers – Gainesville, FL; GrassWorks – New Holstein, WI; Hmong National Development, Inc. – St Paul, MN and Washington, DC; Illinois Stewardship Alliance – Springfield, IL; Institute for Agriculture and Trade Policy – Minneapolis, MN; Iowa Natural Heritage Foundation – Des Moines, IA; Izaak Walton League of America – St. Paul, MN/Gaithersburg, MD; Kansas Rural Center – Whiting, KS; The Kerr Center for Sustainable Agriculture – Poteau, OK; Land Stewardship Project – Minneapolis, MN; Michael Fields Agricultural Institute – East Troy, WI; Michigan Food & Farming Systems – MIFFS – East Lansing, MI; Michigan Organic Food and Farm Alliance – Lansing, MI; Midwest Organic and Sustainable Education Service – Spring Valley, WI; The National Center for Appropriate Technology – Butte, MT; Nebraska Sustainable Agriculture Society – Ceresco, NE; Northeast Organic Dairy Producers Alliance – Deerfield, MA; Northern Plains Sustainable Agriculture Society – LaMoure, ND; Northwest Center for Alternatives to Pesticides – Eugene, OR; Ohio Ecological Food & Farm Association – Columbus, OH; Organic Farming Research Foundation – Santa Cruz, CA; Rural Advancement Foundation International – Pittsboro, NC; Union of Concerned Scientists Food and Environment Program – Cambridge, MA; Virginia Association for Biological Farming – Lexington, VA; and Wild Farm Alliance – Watsonville, CA.

ACKNOWLEDGEMENTS

The National Sustainable Agriculture Coalition's (NSAC) comments on the supplemental proposed rule for Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food are the result extensive analysis by, discussion by, and feedback from NSAC's Food System Integrity Committee, NSAC's committee charged with working on the Food Safety Modernization Act. To develop the recommendations below, several subcommittees were formed to work in detail on specific issues.

The following individuals contributed to the drafting of these comments:

NSAC members:

Roland McReynolds, Carolina Farm Stewardship Association
Roger Noonan, New England Farmers Union
Brian Snyder, Pennsylvania Association for Sustainable Agriculture
Steve Warshawer, Wallace Center

NSAC partners:

Alli Condra, Alexandra Jordan, and Kelliann Blazek
Center for Health Law & Policy Innovation at Harvard Law School

Mindy Goldstein and Jeni Lamb
Turner Environmental Law Clinic at Emory University School of Law

NSAC staff:

Ferd Hoefner, Policy Director

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I. INTRODUCTION

The National Sustainable Agriculture Coalition (NSAC) is an alliance of over 100 grassroots organizations nationwide that collectively advocate 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 both the Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food (Preventive Controls Rule) and Animal Food (Animal Food 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;

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

- 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 farm³;
- The requirement to determine the number and types of food facilities co-located on farms, by commodity and by processing activity, to inform rulemaking⁴;
- The requirement to provide modified requirements for small and mid-sized farmers and facilities engaged primarily in selling food through direct-to-consumer supply chains⁵;
- 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 activities¹⁰;
- 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;
- 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 commodities¹⁵;

³ Food, Drug, & Cosmetic Act §§ 418(n)(3)(A) and 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).

¹³ *Id.* § 419(a)(3)(F).

¹⁴ *Id.* § 419(b)(3).

¹⁵ *Id.* § 419(a)(1)(B).

- The requirement to reduce the paperwork and information collection burden of the regulations¹⁶; 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 Preventive Controls Rule for Human Food, 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.

¹⁶ *Id.* § 419(c)(C).

¹⁷ Food Safety Modernization Act § 209(b).

II. SUMMARY OF RECOMMENDATIONS

NSAC provides full comments and recommendations in the sections 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 revisions to definitional elements that eliminate the distinction between activities done to a farm's own RACs vs. another farm's RACs.
- Clarify that activities done on RACs that do not transform or change the nature of the RAC – like packaging, labeling, and drying/dehydrating – are not considered manufacturing and processing.
- Further revise the farm definition to better reflect what farms look like and how farms operate by removing “in one general physical location” and “under one ownership” from the definition.
- Retain the changes to the definitions of “harvesting,” “packing,” and “holding,” and clarify that mixing or blending intact RACs is considered “holding” 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.
- Remove the environmental monitoring and product testing requirements from the regulations and instead put them in Level 1 guidance, with opportunity for public comment.
- Eliminate the onsite audit requirement from the proposed supplier program, and move any supplier verification program to Level 1 guidance.
- 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.
- Retain and build upon the improvements to the withdrawal and reinstatement processes.
- Define “very small business” as a business with “less than \$1,000,000 in total annual sales of human food regulated [or covered] by the Preventive Controls rule, adjusted for inflation.”
- Clarify that the sale and distribution of food through a community supported agriculture program, roadside stand, farmers market, or other direct-to-consumer platforms is included in the definition of sales direct to consumers for purposes of defining a “retail food establishment.”
- Establish an outright exemption from the Preventive Controls Rule for businesses with \$25,000 or less in annual average monetary value of food regulated [or covered] by the Preventive Controls Rule sold over a three-year period, adjusted for inflation.

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.

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 risk-based mandate and approach. Specifically, FDA should modify the organizing principles so that they read:

¹⁸ See NSAC’s 2013 Produce Rule comments at 30–31.

¹⁹ 79 Fed. Reg. 58538.

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 performed 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, 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.

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

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

²¹ See Appendix I, NSAC’s 2013 Preventive Controls comments, regarding Congressional intent and FDA’s broad authority to modify the farm definition to ensure that farms are not inappropriately regulated as facilities, at 25–27.

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 not 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 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

²² See Appendix I at 29–35.

²³ 79 Fed. Reg. 58438.

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 guidance²⁴ – 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.

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 the farming community, the majority of which runs 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

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/HarmonizedStandard-pre-farmgate130501.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/ProduceandPlantProducts/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.”

²⁶ See Appendix I at 30–31.

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.”).

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 operators²⁹ – 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 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.

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

³¹ 79 Fed. Reg. 58535

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 defined “you,” as “the owner, operator, or agent in charge of a facility that manufactures/processes, packs, or holds food for consumption 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

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

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).

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 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 or³⁵
 - (2) Packaging and labeling raw agricultural commodities, when these activities do not involve additional manufacturing/processing.

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

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 I at 37.

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);
- 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.

³⁷ 79 Fed. Reg. 58439.

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.

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 PRODUCT TESTING AND ENVIRONMENTAL MONITORING

FDA requests comments on the new proposed requirements for product testing and environmental monitoring. Specifically, FDA requests comments on “when and how” environmental monitoring and product testing programs are an appropriate means of implementing FSMA, and whether either activity should be included in the final rule. We believe these verification measures are not appropriate for inclusion in the rule itself, but are appropriate for guidance.

FSMA requires FDA to promulgate science- and risk-based standards for conducting a hazard analysis, documenting hazards, implementing preventive controls, and documenting the implementation of the preventive controls.⁴⁰ FDA acknowledges that product testing and environmental monitoring are verification measures, and are not themselves preventive controls.⁴¹

FDA acknowledges that “there are limitations to product testing,” but maintains that “[n]onetheless, product testing programs, when implemented appropriately based on the facility, the food, and the nature of the preventive control, could be used to verify that the preventive controls are effectively and significantly minimizing or preventing the occurrence of identified hazards.” Therefore, FDA provides what it considers a “flexible” approach to including product testing “as appropriate to the facility, the food, and the nature of the preventive control.”⁴²

We disagree that the proposed language provides sufficient flexibility. If the agency intends to provide a flexible approach to product testing and environmental monitoring, then FDA should include these verification measures in Level 1 guidance for industry, not the regulations themselves.

Level 1 guidance provides an opportunity to ensure flexibility in the verification measures selected by a particular facility. Such 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.

The inclusion of product testing as a codified requirement – and the associated paperwork and recordkeeping burden – makes it very difficult for businesses to justify a decision not to do product testing. The costs of requirements like these are disproportionately burdensome on the smallest operators, and are of particular concern for operations like food hubs that are only doing low risk packing and holding, or are doing minimal processing, but on many different types of produce from a variety of farmers.

⁴⁰ 21 U.S.C. 350g(n)(1)(A).

⁴¹ 78 Fed. Reg. 58543.

⁴² 79 Fed. Reg. 58544.

Product testing on intact RACs is not an effective way to ensure food safety; the costs to facilities are high, and the results are uninformative. But without additional explanation from the agency on what types of facilities it considers “appropriate” to implement product testing, we can only assume that such a requirement would apply to those foods that FDA considers pose a greater risk, like fresh fruits and vegetables usually consumed raw.

As we stated in our comments on the original proposed Preventive Controls rule, product-level testing of RACs would impose excessive and unnecessary costs on farms and low-risk establishments that pack and hold RACs. There is widespread recognition in the scientific community and in the produce industry that product-level testing requires massive expenditures and provides little, if any, return in terms of food safety, because it is impossible to perform enough testing to generate statistically significant results. Testing that is not statistically significant, by definition, cannot provide any reliable validation for a food safety program. Farms are, by their very nature, exposed to the environment. To impose essentially random testing requirements simultaneously exposes a farm to liability for events it cannot control – where random tests find a pathogen outlier – and contributes to a false sense of security where random testing consistently fails to uncover instances of contamination above an action level. As Dr. William Sperber, a pioneer in the development of HACCP, states, “any pathogen performance standard used in the context of [pathogen reduction or HACCP planning] ... is not science-based. At best it is a very poor and inappropriate use of statistics.”⁴³

FDA proposes to require environmental monitoring for facilities that produce ready-to-eat foods that are exposed to the environment prior to packaging, where the packaged food does not receive a kill step.⁴⁴ FDA acknowledges public comments that environmental monitoring is of limited benefit in certain circumstances,⁴⁵ but states that “[e]nvironmental monitoring programs, when implemented appropriately based on the facility, the food, and the nature of the preventive control, could be used to verify that the preventive controls are effectively and significantly minimizing or preventing the occurrence of identified hazards.”⁴⁶ To maximize flexibility, this verification measure should be in Level 1 guidance, not the rule.

While it is important to provide for mechanisms to verify the effectiveness of preventive controls, FDA must consider the costs of such programs on small and very small business. For the smallest of facilities (under 20 employees), FDA estimates that the new environmental monitoring provision alone is estimated to cost \$2,891 annually.⁴⁷ The product testing provision would cost an additional \$12,000 annually just for the testing – for facilities that also have to hold products while waiting for test results, FDA estimates the total costs of testing and holding to be over \$28,000 annually.⁴⁸

These provisions impose significant added burden on facilities, and the farmers that supply them, particularly for those producing multiple crops and food products. For local food operations that source from multiple farmers, or produce multiple products, these costs will only increase,

⁴³ Sperber, William H., “HACCP and Transparency,” *Food Control* 16 (2005), 505-509.

⁴⁴ 79 Fed. Reg. 58545

⁴⁵ 79 Fed. Reg. 58544

⁴⁶ 79 Fed. Reg. 58544

⁴⁷ Preliminary Regulatory Impact Analysis, 2014 at 12.

⁴⁸ Preliminary Regulatory Impact Analysis, 2014 at 15–16.

discouraging diversification at these enterprises and discouraging entrepreneurs from entering the market to begin with.

Recommendation: To ensure a truly flexible approach to verification activities, FDA should move the environmental monitoring and product testing requirements to Level 1 guidance, with opportunity for public comment, and not include them in the final regulations. Guidance provides greater opportunity for industry innovation and stakeholder participation to determining the appropriate use of verification measures, and avoids a one-size-fits-all approach to regulations.

V. COMMENTS ON THE PROPOSED SUPPLIER PROGRAM

FDA requests comments on the proposed supplier program. Specifically, FDA is seeking comment on whether requirements for a supplier program should be included in the final Preventive Controls Rule. NSAC strongly opposes the inclusion of a supplier program in the final rule. The current 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, and particularly those farms covered by the Produce Rule. We offer the following comments and recommendations below.

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.⁴⁹ FDA may, *but is not required to*, include “supplier verification activities” as part of those preventive controls.⁵⁰ Importantly, FSMA explicitly prohibits FDA from requiring regulated entities⁵¹ to hire third parties to identify, implement, certify, or audit compliance with the rules it adopts to implement FSMA (including the Preventive Controls Rule and Produce Rule).⁵²

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.”⁵³ 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.”⁵⁴

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.⁵⁵ 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.⁵⁶

⁴⁹ 21 U.S.C. 350g(n)(1)(A).

⁵⁰ 21 U.S.C. 350g(o)(3)(G).

⁵¹ 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.

⁵² 21 U.S.C. 350g(n)(3)(D); 21 U.S.C. 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. 250g(n)(3)(C).

⁵³ Proposed 117.136; 79 Fed. Reg. 58565-67.

⁵⁴ *Id.*

⁵⁵ *Id.*

⁵⁶ *Id.*

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.⁵⁷

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 estimating the cost of this provision not on the receiving facility, but on the supplying farm or facility.⁵⁸ FDA also acknowledges that this provision will likely impose additional costs on farms, but fails to provide an estimate of those costs.⁵⁹ 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.

⁵⁷ 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, pp. 56-59.

⁵⁸ Preliminary Regulatory Impact Analysis at 19.

⁵⁹ *Id.* at 37.

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.⁶⁰

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.⁶¹ 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.⁶² 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 that the hazards are controlled.”⁶³ 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 “adequate assurance” be interpreted by FDA inspectors? What receiving facility would take that risk given this vague regulatory language, and considering

⁶⁰ 21 U.S.C. 350h(c)(1)(E).

⁶¹ 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.”).

⁶² See *Babbitt v. Sweet Home Chapter of Cmty. 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).

⁶³ Proposed 117.136(c)(2)(ii).

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,”⁶⁴ 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 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

⁶⁴ 21 U.S.C. 350g(n)(3)(A).

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.⁶⁵ 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 will not be sent to any facilities that would be required to have preventive controls before reaching consumers. The Produce Rule provides sufficient 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.

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.

⁶⁵ Proposed 117.136(c)(3), (4).

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.

VI. COMMENTS ON THE WITHDRAWAL AND REINSTATEMENT 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.⁶⁶ 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 and facilities 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."⁶⁷ 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.⁶⁸

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

⁶⁶ 21 U.S.C. §§ 350g(l) and 350h(f); under the Preventive Controls Rule, very small businesses are also qualified facilities.

⁶⁷ 79 Fed. Reg. 58553; see also 79 Fed. Reg. 58466 (Produce Rule).

⁶⁸ See, e.g. 21 U.S.C. § 336 (2013).

markets due to a draconian “one strike and you’re out” approach. If a qualified exempt business 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 or food business’ 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 business. In this case, the 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 or food business 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 facility or by initiative of the FDA District Director. Under § 117.287(a), if the withdrawal was due to conditions or conduct material to the safety of the food produced at the facility, and FDA determines the facility has resolved the problems and that continued withdrawal is not necessary to protect public health, then the FDA District Director “will, on his own initiative or at the request of the facility, reinstate the qualified exemption.” Under § 117.287 (c), if the exemption was withdrawn because an active foodborne illness investigation was directly linked to the facility, but it is determined at the conclusion of the investigation that the outbreak was not directly linked to the facility, then FDA “will reinstate” the qualified exemption. Under § 117.287 (d), if the exemption was withdrawn for a combination of § 117.251(a)(1) and (2), and FDA determines there was no direct link, then FDA will inform the business of that finding, but the business 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 § 117.287(a), if FDA determines that the problems have been resolved, FDA “will” reinstate the exemption. The use of “will” indicates that there is no discretion. Yet, the phrase continues “on his own initiative or at the request of the facility,” 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 § 117.287(a) so that it reads: “the FDA District Director ... will, on his own initiative or at the request of the facility, reinstate the qualified exemption within a reasonable period of time.”

This should also apply to requests for reinstatement under § 117.287(d). If FDA has determined that there is no direct link between a facility and a foodborne illness outbreak, and the facility requests reinstatement, then FDA must determine whether the facility has adequately addressed the conduct or conditions of concern. If FDA determines that the facility has done so, then, as § 117.287(a) states, FDA “will” reinstate. We encourage the agency to clarify that under § 117.287(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 for qualified facilities.

Similarly, § 117.287 (c) is unclear regarding the degree of discretion involved in reinstatement. In this situation, a facility essentially had an exemption withdrawn erroneously, out of the belief that an outbreak was directly linked to the facility. In this circumstance, it is appropriate – as FDA details – for reinstatement to occur without the facility’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 facility 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 food business will face if required to quickly come into compliance with the full 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 § 117.287 clarifying that a FDA District Director will reinstate a qualified exemption “within a reasonable period of time” if the Director determines that the facility has adequately resolved the issues of concern.

Specifically, for § 117.287, FDA should make the following additions:

- (a) If the FDA District Director in whose district your facility is located (or, in the case of a foreign facility, the Director of the Office of Compliance in the Center for Food Safety and Applied Nutrition (CFSAN)) determines that the facility has adequately resolved problems with the conduct and conditions that are material to the safety of the food manufactured, processed, pack, or held at the facility, 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 facility is located (or, in the case of a foreign facility, the Director of the Office of Compliance of CFSAN) will, on his own initiative or request of a facility, reinstate the 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 facility, FDA ~~will~~shall reinstate your qualified exemption under § 117.5(a) within a reasonable period of time, and FDA will notify you in writing that your exempt status has been reinstated.
- (d) If your exemption was withdrawn under § 117.251(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 facility, FDA will inform you of this finding, and you may ask FDA to reinstate your exemption under § 117.5(a), in accordance with the requirements of paragraph (b) of this section, including the requirement that – should FDA

determine that the facility has adequately resolved problems with the conduct and conditions that are material to the safety of the food produced or harvested at such facility, 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 § 117.251(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.”⁶⁹

We support this provision because intermediary steps not only allow FDA to work with facilities 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 § 117.251(b)(2) and (3), which contain actions that FDA must take before withdrawing an exemption. This includes providing notice to the facility 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 facility with the necessary due process to understand the situation at hand and meaningfully respond. The requirement that FDA consider the actions of the facility before proceeding with an order to withdraw also supports continuous improvement of food safety risk management, and saves the food business 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 § 117.251(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.⁷⁰ 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

⁶⁹ Proposed § 117.251(b)(1).

⁷⁰ 79 Fed. Reg. 58553.

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.

As proposed, the regulations require FDA to “notify the owner, operator, or agent in charge of the facility, 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 facility to respond in writing.”⁷¹ We would expect that this notification include facts specific to the facility’s situation so that the business 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 HACCP, cGMPs, and food labeling laws,⁷² and we find the degree of specificity contained in those letters to be very good. We would expect notices to farmers and food businesses 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.”⁷³ We contend that a “brief general statement” is insufficient to convey the information necessary for a food business to adequately resolve any food safety problems. If FDA will consider reinstatement based on a determination that the business has adequately addressed the source of the problem, then the order must contain facts specific enough to allow the business to address the problem and demonstrate to the agency that the problems have been resolved.

We also note that FDA warning letters under seafood HACCP, cGMPs, and other existing regulations give businesses 15 working days to respond. The withdrawal process gives 10 calendar days. Having a separate process for farmers versus farm mixed-type facilities 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 § 117.251(b)(2), and the withdrawal order in § 117.257. FDA should also standardize withdrawal notice and response procedures with existing administrative procedures. Specifically, we recommend incorporating the following revisions:

§ 117.251(b)(2) Must notify the owner, operator, or agent in charge of the facility, in writing, of circumstances that may lead FDA to withdraw the exemption, including sufficient facts specific to the situation and information about how the facility can remedy the situation, and provide an opportunity for the owner, operator, or agent in charge of the facility to respond

⁷¹ Proposed § 117.251(b)(2).

⁷² 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>.

⁷³ Proposed § 117.257(c).

in writing, within ~~40 calendar~~ 15 business days of the date of receipt of the notification, to FDA's notification;

§ 117.257(c) An explanation brief, general statement of the reasons for the order, including sufficient facts specific to the situation, information about how the facility 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).”⁷⁴ 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 or small business 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 and small businesses 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 or food business. 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 or facility 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 and Preventive Controls Rule should both provide information on the options for a farm or facility 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, in the Preventive Controls Rule, FDA should add a new section subsection to §117.257:

§ 117.257(i) A statement that the facility may request reinstatement of a withdrawn qualified exemption as provided in 117.287.”

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.

⁷⁴ 79 Fed. Reg. 58553.

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 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.”⁷⁵ 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.⁷⁶

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.”⁷⁷ 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 HACCP) are based on business or “working” days, not calendar days. We urge the agency to standardize these administrative processes across all FDA food safety rules, not just FSMA.

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

§ 117.257(d)(1) Comply with applicable requirements of this part within 120 ~~60 calendar~~ business days of the date of receipt of the order or, (2) appeal the order within ~~40 calendar~~ 15 business days of receipt of the order in accordance with the requirements of 117.264.

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.”⁷⁸ 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.⁷⁹ We strongly encourage the agency to provide a consistent timeframe across rules, and to do so consistent with existing agency procedures. 10 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

⁷⁵ 79 Fed. Reg. 58554.

⁷⁶ Proposed § 117.257(d)(1).

⁷⁷ 79 Fed. Reg. 58467.

⁷⁸ 79 Fed. Reg. 58554.

⁷⁹ Proposed § 112.201(b)(2).

notice. Furthermore, due to different mailing times throughout the country, tolling the timeline 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 and food businesses in way that ensures that they receive the order, such as by providing 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 business 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 and food businesses through delivery that includes confirmation that the appropriate person received the communication, whether it is the farm or food business 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.⁸⁰ 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 facility.⁸¹ 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 facility’s exemption if a foodborne illness outbreak is “directly linked” to a qualified facility but, without a

⁸⁰ See Appendix I at 59–65.

⁸¹ Proposed § 117.251(a)(2).

definition, there is ambiguity in how a facility may be “directly linked” to an outbreak.⁸² Because this is one of only two avenues for FDA to withdraw an exemption, and because of the significant implications for business 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 facility’s exemption and ensure that links between outbreaks and the facility 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 facility 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 facility.

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 facility’s exemption can cause significant financial burdens for businesses, especially for small businesses, 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 facility a condition must be. Without providing a definition, it is possible that even very attenuated connections between conditions and facilities would be sufficient for FDA to withdraw an exemption. We recommend a definition requiring that the condition is “directly and closely connected” to the facility.

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 § 117.251(a)(2):

If we determine based on credible and substantial evidence that it is necessary to protect the public health and prevent or mitigate a foodborne illness outbreak based on conduct or conditions associated with the qualified facility that are material to the safety of the food manufactured, processed, packed, or held at such facility; 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.

And we recommend the follow definitions be added to § 117.3:

(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.

(b) Necessary means that which is absolutely required, as established by credible and substantial evidence, to protect public health.

⁸² Proposed § 117.251(a)(1).

(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.

(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.

VII. COMMENTS ON THE DEFINITION OF VERY SMALL BUSINESS

NSAC supports FDA’s proposed definition of “very small business” in the supplemental proposed Preventive Controls Rule. This definition is consistent with Congress’s mandate that the FSMA rules provide flexibility for all sizes and types of businesses and facilities, including small processing facilities co-located on farms, and provide special considerations for small and very small businesses. However, we believe FDA should apply this threshold not to sales of all “human food,” but to sales of “human food covered by the Preventive Controls rule.” Below, we provide comments and recommendation on this issue.

A. FDA should retain the \$1,000,000 threshold in the final rule.

FSMA directs FDA to define “small business” and “very small business” for the purposes of the new Hazard Analysis and Risk-based Preventive Controls (HARPC) regulations, taking into consideration the results of the food processing sector study.⁸³ These definitions are important for determining the scope of coverage of the Preventive Controls Rule; a very small business can qualify for modified requirements⁸⁴ and small and very small businesses are exempt from the preventive controls requirements if they only conduct certain low-risk processing activities.⁸⁵ FSMA also directed FDA to “provide sufficient flexibility to be practicable for all sizes and types of facilities, including small businesses such as a small food processing facility co-located on a farm” when developing its HARPC regulations.⁸⁶

FDA initially proposed three options for the very small business definition. In the revised proposed rule, FDA is proposing to adopt the \$1,000,000 threshold. We support this decision, which is appropriate in light of the tiny fraction of food sales that it covers.

According to FDA, this threshold would cover only a tiny percentage – less than two percent – of the food produced in the U.S.⁸⁷ 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. Ninety-six percent of farms in the U.S. have gross sales under \$1,000,000, though they account for a minority share of total farmgate sales.⁸⁸ The percentage of all production represented by “million dollar” farms is greater with respect to fruits and vegetables (as well as dairy and livestock sectors); USDA estimates between 60 and 70 percent of these sales come from farms with over \$1 million in sales.⁸⁹ With respect to specialized vegetable and melon farms, USDA reports that eight percent of all farms accounted for 87 percent of the US vegetable crop in 2005-2007.⁹⁰ Even under the current proposed definitions, a large number of farms will still be

⁸³ 21 U.S.C. 250g(n)(1)(B).

⁸⁴ 21 U.S.C. 350g(l).

⁸⁵ 21 U.S.C. 350d(1)(D).

⁸⁶ 21 U.S.C. 250g(n)(3)(A). We note that the use of the phrase “*such as* a small processing facility co-located on a farm” does not limit the application of this regulatory discretion solely to processing facilities co-located on farms.

⁸⁷ 79 Fed. Reg. 58555.

⁸⁸ USDA Census of Agriculture, Volume 1, Chapter 1, Table 2 (2012).

⁸⁹ Hoppe, R. and D. Banker. “Structure and Finances of U.S. Farms: Family Farm Report.” U.S. Dep’t of Agric. Economic Research Service (2010).

⁹⁰ Ali, M. and G. Lucier. “Vegetable Production Concentrated on Very Large Farms.” U.S. Dep’t of Agric., Economic Research Service (2011).

considered “facilities” subject to the Preventive Controls rule, even if they do only minimal processing, or even if processing only accounts for a small percentage of their total food sales.

FDA’s decision to adopt the \$1,000,000 threshold is also appropriate in light of the two options Congress provided for facilities to qualify for modified requirements under the Preventive Controls Rule. Congress directed FDA to consider the food processing sector study in establishing the very small business definition, but otherwise did not establish parameters for the agency to use in setting this definition, leaving it largely to the agency’s discretion.

We agree with FDA that FSMA does not prevent the agency “from establishing a definition for very small businesses that would include more facilities than those that would be included under the statutory provision that considers sales to qualified end users.”⁹¹ Indeed, FDA’s authority to define “very small business” and establish modified requirements for such facilities is quite broad. The narrowly targeted provision for direct-to-consumer and direct-to-retail marketing has no particular bearing on the FSMA requirement to establish a definition for small and very small businesses as it pertains to other sections of the law. They are part of, but by no means the entirety of, the flexible, scale- and supply-chain appropriate approach that Congress established in FSMA.⁹²

Although Congress set out two options whereby facilities could qualify for modified requirements, Congress did not bind the agency to using both options. When Congress is silent on an issue, the agency may reasonably interpret its authority. In this case, choosing the \$1,000,000 threshold for very small business is entirely reasonable given that businesses this size account for such a small percentage of the food supply, and given Congress’s mandate that FDA establish flexible standards considering the effects of the rules on small and very small businesses.

Recommendation: FDA should retain the proposed \$1,000,000 threshold for the very small business definition.

B. FDA should only count foods covered by the Preventive Controls Rule against the \$1,000,000 threshold.

FDA originally proposed that the very small business definition measure “all food” in calculating the sales threshold. FDA’s revised definition calculates sales of “human food.” Establishing a threshold determination based on sales of food *actually regulated under the Preventive Controls Rule* would go even further to provide a clear, consistent process for determining coverage under the rules, particularly for those farms that may be subject to multiple rules.

Farms that are considered “farm mixed-type facilities” and subject to multiple rules already face a challenge in determining which definitions apply to which parts of their operations. Consistently calculating sales thresholds using sales of product covered under each respective rule provides clarity for regulators and the regulated community alike.

Nothing in FSMA restricts FDA from focusing the definition of “very small business” to products regulated under the Preventive Controls Rule. Doing so is consistent with the fact that the Preventive Controls Rule specifically does not address animal food, and that covered produce is

⁹¹ 79 Fed. Reg. 58555.

⁹² See Appendix I at 43–47.

already regulated under the Produce Rule. FDA took this approach in the Preventive Controls Rule for Animal Food – calculating the sales threshold based on sales of animal food, the product regulated by the rule. There is no logical reason why FDA should not do the same in the Preventive Controls Rule for Human Food. This approach is consistent with the FSMA mandate to provide sufficient flexibility in the preventive controls standards. Focusing the definition of “very small business” on food regulated under the Preventive Controls Rule would provide flexibility to farms diversifying into new on-farm value-added enterprises, would help ease the compliance costs for farms and new value-added businesses, and would help focus limited FDA resources on high-risk industrial facilities.

FDA notes that, as defined, this definition only covers a “small portion of the potential risk of food borne illness.”⁹³ Applying this threshold to sales of covered food is unlikely to expand this category much beyond this small portion of the food supply.

Recommendation: FDA should define “very small business” under the Preventive Controls Rule for Human Food as a business with “less than \$1,000,000 in total annual sales of human food regulated or covered by the Preventive Controls rule, adjusted for inflation.”

⁹³ 79 Fed. Reg. 58555.

VIII. COMMENTS ON CLARIFYING THE “RETAIL FOOD ESTABLISHMENT” EXEMPTION

FSMA directed FDA to clarify that Community Supported Agriculture farms (CSAs), farmers markets, and other direct-to-consumer businesses (including, but not limited to, farm stores, direct internet sales, tailgate markets, and pick-your-own operations) are not facilities, and therefore are not subject to registration or to regulations for food facilities.⁹⁴ Without this clarification, CSAs and other farms with direct-to-consumer sales that do light processing activities or have off-farm drop off or holding sites could be subject to inappropriate, excessive regulations designed for industrial food facilities.

We recognize that FDA has said that the separate proposed rule on this issue is forthcoming, but we find it intolerable that FDA has delayed so long in completing this clear statutory directive from Congress. This simplest of all the pieces of the FSMA framework could have easily been promulgated in 2011 and, at the very least, should have been available for comment during the comment period for the original and now the supplemental proposed Preventive Controls rule. The inability to comment on the two proposals simultaneously has significantly decreased our sector’s ability to meaningfully analyze and provide recommendations on FSMA’s regulatory framework, and particularly on the impacts on local food systems.

FDA’s failure to provide clarification on this topic causes instability in the local food sector because the impacts of these rules on direct-to-consumer businesses remain unknown. We appreciate FDA’s recent revisions to the Food Facility Registration Guidance, which provide some added clarity on this topic. However, this does not take the place of the needed change to the regulatory language.

Recommendation: As required by the FSMA statute, FDA must clarify that the sale and distribution of food through a community supported agriculture program, roadside stand, farmers market, or other direct-to-consumer platforms is included in the definition of sales direct to consumers for purposes of defining a “retail food establishment.”

⁹⁴ 21 U.S.C. 350d(c).

IX. 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 emphasize several key issues that were of great concern to us in the initial round that were not included in the supplemental proposed Preventive Controls Rule: establishing a *de minimis* exemption for facilities under the Preventive Controls Rule; the estimated number of farm mixed-type facilities; and the low-risk food/activity combinations. Please refer to our 2013 comments on the Preventive Controls Rule for full comments and recommendations.

A. Comments on Establishing a \$25,000 Outright Exemption: FDA should establish an outright exemption from the Preventive Controls Rule for facilities with an average annual monetary value of covered product sold of \$25,000 or less.

When writing FSMA, Congress rejected a “one-size-fits-all” approach, and provided FDA with flexibility to ensure that the Preventive Controls Rule worked for a diversity of facilities. Specifically, in the Preventive Controls Rule, FDA requires FDA to “provide sufficient flexibility to be practicable for all sizes and types of facilities, including small businesses such as a small food processing facility co-located on a farm.”⁹⁵

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

An outright exemption for facilities that have an average annual monetary value of food regulated by the Preventive Controls Rule of \$25,000 or less would not significantly add risk to the food supply. According to FDA’s preliminary economic impact analysis, the highest threshold proposed threshold for the definition of “very small business” – \$1,000,000 in annual gross sales food – would cover only a tiny percentage – less than two percent – of the food produced in the US.⁹⁶ That same analysis says that food businesses with less than \$250,000 in annual gross sales of food represent less than one-half of one percent of all food produced in the U.S.⁹⁷ Setting an outright exemption at the \$25,000 threshold would represent an even smaller fraction of the food businesses in the US and be targeted to creating flexibility for small food processing facilities, such as those co-located on farms.

Additionally, the exemption should be based on the value of products regulated under the Preventive Controls Rule and not all food as defined in § 117.3. Nothing in FSMA restricts FDA

⁹⁵ Food, Drug, & Cosmetic Act § 418(a)(n)(3)(A).

⁹⁶ U.S. Food and Drug Admin. “Preliminary Regulatory Impact Analysis – Current Good Manufacturing Practice and Hazard Analysis and Risk-based Preventive Controls for Human Food” at 4.

⁹⁷ *Id.*

from focusing a \$25,000 outright exemption to products regulated under the Preventive Controls Rule instead of “food.” Doing so is consistent with the fact that the Preventive Controls Rule specifically does not address animal food, and that covered produce is regulated under the Produce Rule. This is also consistent with the FSMA mandate for sufficient flexibility in the preventive controls standards. Focusing the definition on regulated product instead of all food would provide some flexibility in the rule for beginning farmers, entrepreneurs trying to launch value-added food businesses, and family farmers who have diversified their operations through value-added processing.

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

B. Comments on FDA’s Estimate of the Number of Farm Mixed-Type Facilities

1. The Food Processing Sector Study is woefully inadequate and must be undertaken again to comply with the law.

FSMA requires FDA to conduct a food processing sector study to determine the size and scope of the food processing sector, including in particular the number and types of food facilities co-located on farms.⁹⁸ FSMA requires the results of the food processing sector study to inform the regulatory definitions of “small” and “very small” businesses.

The food processing sector study⁹⁹ that FDA released as part of the proposed Preventive Controls Rule is grossly inadequate and fails utterly to provide the information required by FSMA to determine the number of facilities co-located on farms and what the production, distribution, and risk profiles of those facilities are. The study acknowledges its severe data limitations and, therefore, relies primarily on the professional opinion of a small group of individuals who are not experts in on-farm or small-scale processing. Without this information, FDA cannot adequately determine the impact of the proposed Preventive Controls Rule, how many operations will be subject to the Preventive Controls Rule, and what the costs of compliance will be.

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

NSAC submitted more complete comments on the food processing sector study as part of its comments on the Draft Qualitative Risk Assessment of Risk of Activity/Food Combinations for Activities (Outside the Farm Definition) Conducted in a Facility Co-Located on a Farm on February

⁹⁸ Food, Drug, & Cosmetic Act § 418(l)(5).

⁹⁹ US Food & Drug Admin. “Food Processing Sector Study.” 2011.

15, 2013.¹⁰⁰ We reiterate here the essential need for an actual food processing sector study to determining the scope, impact, and costs of the Preventive Controls Rule.

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

2. FDA has significantly underestimated the number of farm mixed-type facilities and must make a more accurate estimate in order to accurately assess the impact of the regulations.

Because the food processing sector study is so inadequate, FDA has significantly underestimated the number of farm mixed-type facilities that will be subject to both the Preventive Controls Rule and the Produce Rule. In the economic analysis accompanying the proposed Preventive Controls Rule, FDA estimates that 1,673 farms are also food processors counted in the number of domestic facilities impacted by the proposed Preventive Controls Rule.¹⁰¹ Given FDA's proposed definitions of "farm" and supporting definitions of "facility," this estimate of operations that would be categorized as "farm mixed-type facilities" is incredibly low.

As one example of how FDA's estimates are very low, we point to USDA's National Agricultural Statistics Service (NASS) 2008 Organic Production Survey (OPS). The OPS found that 1,100 certified and exempt organic farms in the U.S. had sales from value-added organic products (approximately 7.6 percent of total certified and exempt organic farms).¹⁰² Transforming a RAC (i.e., processing) is a feature of value-added products. If one assumes that farms that have sales from value-added products are doing value-added processing and would, therefore, be considered farm mixed-type facilities, then this number from the OPS can help inform FDA's estimate of farm mixed-type facilities.

If one applies this percentage from the OPS to farms subject to some or all of requirements of the proposed Produce Rule (covered farms (40,211) + qualified exempt farms (75,716) + exempt for commercial processing (29,972)),¹⁰³ then there would be approximately 11,088 farms that might be considered farm mixed-type facilities solely based on value-added processing activities. While there may be a greater percentage of organic farms that do value-added processing than for all farms subject to some or all of the requirements of the Produce Rule, this estimate only captures processing activities and leaves out any estimate of packing and holding activities that may trigger facility registration. This estimate also calculates the percentage solely for produce farms and not for

¹⁰⁰ National Sustainable Agriculture Coalition. "Comments on Draft Qualitative Assessment of Risk of Activity/Food Combinations for Activities (Outside the Farm Definition) Conducted in a Facility Co-Located on a Farm" (hereinafter "Draft RA Comments"). Docket # FDA-2012-N-1258, comment tracking number 1jx-83p8-w3kr.

¹⁰¹ US Food and Drug Admin. "Analysis of Economic Impacts – Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food." January 2012. Page 47.

¹⁰² US Dep't of Agric. "NASS Organic Production Survey." 2008. Table 3.

¹⁰³ US Food and Drug Admin. "Analysis of Economic Impacts – Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption." January 2012. Tables 1 and 2.

all farms subject to the Preventive Controls Rule. Even if a direct extrapolation cannot be made, the point is that FDA has significantly underestimated the number of farm mixed-type facilities.

We discuss the need to redefine foundational terms like “farm” and supporting definitions of “facility” below to significantly shrink the universe of “farm mixed-type facilities,” consistent with the intent of Congress. Taking that action will shrink substantially the number of farm mixed-type facilities. Even then, however, it will remain important to have some basic and accurate idea of the size and scope of the regulated community.

C. Comments on Proposed Exemptions for On-Farm Low-Risk Activity/Food Combinations

In the supplemental proposed Preventive Controls rule, FDA acknowledges that changes will be made to these lists, given the revised approach that no longer differentiates between activities done on a farm’s own RACs or another farm’s RACs. However, FDA does not provide the fully updated lists. Therefore, we reiterate here our comments on the proposed lists, based on the draft Qualitative Risk Assessment.

1. Comments on Clarifying Certain Low-Risk Processing Definitions

To ensure clarity and transparency for producers and efficiency for regulators, FDA should define in more detail certain activities included in the definitions of low-risk activity/food combinations. Failure to provide clarity for producers and inspectors alike will result in enforcement of perceived preventive controls requirements that are not intended in FSMA or its implementing regulations.

Examples of needed clarifications include:

a. ‘Making’

FDA needs to provide more detail about what steps are included in ‘making’ hard candy, fudge, taffy, toffee; cocoa products from roasted cocoa beans; honey; jams, jellies and preserves from acid foods (e.g., acid fruits); maple syrup; soft drinks and carbonated water; and sugar from sugarcane and sugar beets. The agency deems all of those ‘making’ processes as low risk with respect to those foods. It also identifies specific elements of the manufacturing process for those products as activities separately deemed low-risk for some of those foods, but not for others.

Recommendation: FDA should review its definition of ‘making’ with respect to all of the low-risk activity/food combinations where it appears, and spell out, in detail, the specific activities included in the term ‘making.’

For example, boiling/evaporating is part of the process of making sugar from sugarcane or beets and maple syrup from maple sap; such boiling/evaporating is separately identified as a low-risk activity with respect to maple syrup, but it is not separately identified as a low-risk process for making sugar out of sugarcane or beets.

Recommendation: FDA should clarify that it considers making sugarcane to include boiling/evaporation, or it should separately identify boiling/evaporation as a low-risk activity with respect to sugarcane and sugar beets.

For another example, honey- and maple syrup-makers usually filter those products prior to packaging. The absence of filtration of honey and maple syrup among the low-risk food/activity combinations suggests that FDA considers filtration part of ‘making’ honey and maple syrup. But the listing of ‘filtration’ in Table 17 as a low-risk activity with respect to honey and maple syrup is inconsistent with such implied incorporation of ‘filtration’ into ‘making.’

Recommendation: FDA should remedy this confusion by detailing the activities that are part of ‘making’ these products, or by including filtration of these products in the list of low-risk activity/food combinations.

For another example, honey must be extracted from combs. Extraction of honey is listed in Table 17 as a low-risk activity with respect to honey, but is not listed in FDA’s list of low-risk activity/food combinations, creating an implication that FDA views extraction of honey as part and parcel of ‘making’ it.

Recommendation: FDA should include extraction of honey in its list of low-risk activity/food combinations.

b. ‘Chopping’ and ‘grinding/milling/cracking/crushing’ with respect to peanuts and tree nuts

To ensure producers know exactly what FDA means when it says these are low-risk activity/food combinations, FDA should detail the nut products that it expects to result from those combinations.

Recommendation: FDA should detail the nut products that result from the ‘chopping’ and ‘grinding/milling/cracking/crushing’ and peanuts and trees nuts low-risk activity/food combinations.

c. ‘Grinding/milling/cracking/crushing’ with respect to grains and grain products

Grinding/milling/cracking/crushing of grains and grain products are listed in Table 17 as low-risk activity/food combinations, but only grinding/milling/cracking/crushing of grains are included in FDA’s list of low-risk activity/food combinations. Additionally, only one of the many possible milled grain products (cornmeal) is specifically mentioned in FDA’s list of low-risk activity/food combinations.

Recommendation: FDA should provide a larger list of examples of milled grain/grain products that qualify as low risk, including wheat, oats, barley, rice, etc. That list should also specifically include sprouted grain products.

d. ‘Trimming’

‘Trimming’ is frequently included in the Draft RA along with cutting/coring/chopping/shredding/slicing/peeling as an intervention likely to introduce pathogens to fruits and vegetables. However, FDA recognizes that trimming the outer leaves of an intact fruit or vegetable is part of harvesting activities on farms or farm mixed-type facilities. Because farm mixed-type facilities may come under

FDA inspection for other processing activities, it is vital that inspectors understand that the trimming of outer leaves of RACs to ensure their marketability, along with other harvesting activities, are not processing activities covered by the preventive controls rule. This may require commodity-specific guidance for inspectors, given that harvesting and trimming activities may look different from commodity to commodity. FDA should consult with farm mixed-type facility farmers, including small and very small farmers and facility operators, in developing such guidance.

Recommendation: FDA should clarify in the Draft RA that ‘trimming of outer leaves’ of RACs is not a processing activity, and should provide further commodity-specific guidance on this issue for inspectors based on input from farm mixed-type facility farmers, including small and very small farmers and facility operators.

There are no doubt additional clarifications that FDA could make to the list of low-risk activity/food combinations in order to provide more clarity for farmers, facility operators, and inspectors.

Recommendation: FDA should provide additional clarifications to the list of low-risk activity/food combinations. In doing so, FDA should seek input from farmers operating mixed-type facilities, including small and very small farmers and facility operators.

2. Additions to the List of Low-Risk Activity/Food Combinations

There are several categories of food/activity combinations that were not designated as low-risk in the Draft RA but do pose only low risks. FDA overlooked them chiefly because of the limited scope of the inquiry into processing activities that take place on small farm mixed-type facilities. Below we provide examples of food/activity combinations that are low risk under the terms of the Draft RA. We stress that this is not an exhaustive list.

Recommendation: FDA should include the following low-risk activity/food combinations in its list of low-risk activity/food combinations:

- Making syrups from sorghum, rice, malted barley, etc. Sorghum is commonly grown in the Southeast and Midwest for the production of sorghum syrup. The manufacturing process is substantially the same as sugar from sugarcane.
- Making molasses from sugarcane and sugar beets.
- Making vinegar, including infused and flavored vinegars.
- Extracting virgin olive oil.
- Extracting oils from seeds (e.g., sunflower seeds, flax seeds, etc.).
- Roasting grains for animal feed. FDA excludes animal feed from the scope of the Draft RA, even though animal feed is ‘food’ within the meaning of the Federal Food, Drug, and Cosmetic Act (FFDCA). Small farm mixed-type facilities, particularly those focused on raising livestock or livestock feed, may roast (or extrude) grains for animal feed. By the definition of a SAHCOD, such roasting in many cases is not an intervention that could introduce or prevent/minimize a

hazard for which there is a reasonable probability that use of, or exposure to, the food will cause serious adverse health consequences or death to humans because the food is not consumed by humans. FDA should review all animal feed production activities that take place on small farm mixed-type facilities for inclusion in the list of low-risk food/activity combinations in light of the fact that such activities are not be SAHCODs.

- Some baking activities involving grain products. Many foods that are baked do, in fact, encompass “inherent controls for food-borne pathogens” in the process of arriving at the final product. For example, making some cookies with grain products requires the dough to set, which means that the flour/liquid combination has reached 195 F, well above what is needed to control pathogens.
- Low-acid fruits and vegetables manufactured in compliance with existing Good Manufacturing Practices (GMPs) under the FFDCa. It is true that acidifying, pickling, and fermenting low-acid foods are activities that significantly minimize or prevent pathogen contamination but, if poorly executed, could instead enhance pathogen growth and so present a SAHCOD. However, the FFDCa has long recognized this potential risk, and has implemented regulations governing such food/activity combinations. Therefore, to the extent a small farm mixed-type facility (or other small business) is producing acidified, pickled, or fermented low-acid fruits and vegetables in compliance with the existing status of FDA GMPs in place at the time of publication of the proposed preventive controls rule, such activity should be deemed low-risk.