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Dec. 15, 2014
Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20582

Docket Nos. FDA-2011-N-0921, FDA-2011-N-0920 and FDA-2011-N-0922

RIN 0910-AG35, RIN 0910-AG36 and RIN 0910-AG10

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

Re: Comments on the supplemental proposed rules for:
Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption;
Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food; and
Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals

To Whom It May Concern:

The Carolina Farm Stewardship Association (CFSA) provides the following comments on the Food and Drug Administration's (FDA) supplemental proposed rules for: Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption (the Produce Rule); Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food (the Preventive Controls Rule); and Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals (the Animal Feed Rule).

CFSA is a member-based 501(c)(3) organization representing 3,000 farmers, businesses and consumers in North and South Carolina, with a mission to advocate, educated and build the systems to support a sustainable regional food system centered on organic agriculture and local food. Founded in 1979, CFSA is the oldest sustainable agriculture organization in the Southeast. Our farm and business members range from large-scale produce operations with over 1,000 acres of certified organic farmland selling through regional, national and international markets, to less-than-an-acre market gardens selling produce and livestock products through direct marketing; from the largest organic egg processors in the nation, to cottage food producers manufacturing foods under state inspection in home kitchens and shared-use commercial kitchens; from mid-scale grain and dairy farms selling in organic commodity markets, to food

hub businesses distributing local produce to high-end restaurants; from breweries that provide spent grains to farms for animal feed to family farms growing organic corn and soybeans that are milled into animal feed on-farm; from five-plus- generation farm families, to young people from urban backgrounds and second-career farmers who have transitioned from successful businesses in non-food industries. This diverse membership means that we are able to bring a wide range of farming and food experience and knowledge to bear in forming policy positions related to agriculture's potential role in human and environmental health, including food safety issues.

CFSA has been actively involved in food safety policy and training in the Carolinas and across the nation. Our Executive Director serves on the North Carolina Fresh Produce Safety Task Force, chairing its Small Farm Subcommittee; is a member of the Produce Safety Alliance and the Preventive Controls Alliance; is a co-author of the publication 'Good Agricultural Practices for Small Diversified Farms: Tips and Strategies to Reduce Risk and Pass an Audit'; and is a frequent presenter and speaker on the subject of GAPs in the context of local foods and organic farming. Our Local Produce Safety Initiative collaboration with food safety and agriculture researchers at North Carolina State University has provided training on GAPs to hundreds of farmers and cost share funding for farms to undergo USDA GAP audits. We provide consulting to food hubs in North Carolina on implementation of the USDA's Group GAP Pilot Project. We have provided extensive comment and testimony on food safety issues, including the USDA's now withdrawn proposal for a National Leafy Greens Marketing Agreement, the legislative process that led to the passage of FSMA, and the original FSMA proposed rules. We are an active member of the National Sustainable Agriculture Coalition with respect to food safety issues.

Our producer members recognize the importance of reducing food safety risks in their operations, both for the protection of their customers and for risk management purposes. For local food-focused producers in particular, due to the competitive nature of the market in local produce and foods, and because of the limited access to credit and capital available to local food producers, these producers have very limited ability to withstand the devastating effects that a foodborne illness outbreak linked to their products would have on the viability of their operations. In the typical producer's local food marketing environment, there is little question for a consumer where a contaminated product came from. The short supply-chain between the local food farm or business and ultimate consumers of her products, and the inherently limited nature of her customer base, create market incentive for protecting those customers as strong as any in the produce or food processing industries. Importantly for the assessment of the risk in short supply chains, because of the limited customer base of any one farm or local food entrepreneur in the short supply chain environment, the risk to the general public of an outbreak of food borne illness is inherently limited, in sharp contrast to the broad outbreak distribution risk posed by long supply chains stretching on a national and even international scale.

Based on that experience, CFSA members support what Congress did to include in FSMA protections for small farms and food businesses that participate in short supply chains. Those protections were intended to provide these businesses a fair chance to compete outside of the system of national and international conglomerates that characterize the long supply chain food system. Such long supply chains are characterized by capital investments to achieve hyper-efficiency and minimize labor per given food unit produced. CFSA's stakeholders have experienced the undue burden that regulators have inappropriately placed on small farms and food producers with one-size-fits-all rules developed in response to food safety problems in the long-supply-chain model. The regulations appropriate to the more mechanical processes necessary for competition at the scale required to serve national and international supply chains are

dramatically different from the appropriate food safety interventions in supply chains that don't prioritize that level of labor efficiency.

Those long-supply-chain-appropriate rules have consistently served to inappropriately increase to the capital demands and paperwork burden on small business, without providing a commensurate benefit in terms of improved public health outcomes. Arguably further increase in local food production and market opportunities would contribute a substantive improvement to the nation's health and well-being. The Centers for Disease Control (CDC) has cited industry consolidation and mass distribution as a major contributor to the emergence of food-borne disease, as centralized processing plants with larger geographic ranges increase risks of dispersed outbreaks.[1]

FSMA recognizes the health and prosperity value short supply chains contribute by providing protections for small producers from rules more appropriate for scrutiny of national and international production and distribution systems. The small business protections in the FSMA increase the ability of those short supply chain-focused producers manage pathogen risks by allowing the development of climate-, scale- and market-appropriate models for reducing illness risk while producing healthy food. FDA and other public health authorities should support these farms and food producers' efforts by providing research and resources more appropriate for the local food sector.

Another policy concern that is driven by our members' experience regards the very nature of food safety programs. Standards do not ensure safety: They merely ensure that certain processes and procedures are in place. The vast majority of outbreaks of foodborne illness that occur every year originate from businesses using industry- and FDA-approved 'certified' food safety plans, including Good Agricultural Practices (GAPs), Good Manufacturing Processes (GMPs), Good Handling Practices (GHPs) and HACCP (Hazard Analysis and Critical Control Points) plans. Unfortunately, a tendency of procedure-focused food safety systems is to ignore the difference between food safety 'hazards' and 'risk.' Pathogen contamination is a theoretical possibility at every step of the food chain, from field to fork. It would be a waste of limited federal, state and private resources to attempt to police all those hazards without considering the risk of broad public health problems that each putative hazard actually presents. Risk in relation to food safety includes the potential for actual harm to occur, not the mere theoretical possibility of pathogen existence. In FSMA, Congress made its intention that FDA focus on actual risk, not potential hazards, and the burden of proof must remain on FDA to prove actual risk in a given food supply chain before imposing regulatory burdens on supply chain actors.

The experience of our members also strongly reinforces the need, recognized by Congress in FSMA, for robust training as part of a food safety system focused on prevention. FSMA authorized a competitive grants program – the National Food Safety Training, Education, Extension, Outreach, and Technical Assistance Program – to fund food safety training efforts through USDA's National Institute of Food and Agriculture (P.L. 111-353, § 209(b)). FSMA prioritized training through this program for small and mid-sized farms, beginning farmers, socially disadvantaged farmers, small processors, and small fresh fruit and vegetable merchant wholesalers. This training should integrate food safety standards and guidance with the variety of agricultural production systems, encompassing conventional, sustainable, organic and conservation and environmental practices. If final FSMA regulations are to be successfully implemented,

[1] [1] Altekruse, S. F., M. L. Cohen and D. L. Swerdlow (1997). "Emerging foodborne diseases," Emerging Infectious Diseases 3(3): 285-293.

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

Finally, our members' experience with state regulators in both Carolinas suggests that state agencies are more responsive to the needs and conditions of local businesses and economies than federal ones. The low incidence of food-borne illness from small, local sources demonstrates that state efforts are effective in protecting public health. The firsthand experience of CFSA "farm-mixed type facility" members that are currently subject to FDA inspection, and the reports of several recent incidents in which unannounced inspections of farms and "farm-mixed type facilities" by FDA personnel, reinforce this concern. Those reports from the farmers who experienced them raise serious concerns about the competence of FDA staff to be helpful partners to farms and small businesses in protecting and promoting public health. These incidents left the farmers affected fearful for their livelihoods and confused about why they had been inspected in the first place.

We appreciate FDA's efforts to address some of the key concerns identified by stakeholders in the initial proposed Produce Standards and Preventive Controls and Animal Feed rules, and are appreciative of the further opportunity to provide feedback on these supplemental proposals; and many of our comments below support the need for certain provisions of the supplemental proposed rules. We also offer extensive comments on areas of the supplementals where further changes are crucial to the economic survival of thousands of farms and local food supply chains, and the ability of those farms and food systems to contribute to improvements in public health across the nation. However, we note that there were dozens of other major problems with the original proposed rules identified in our comments and those of other food and agriculture stakeholders. FDA's response to those issues not re-opened for comment in these supplemental proposals are of equally critical importance as those covered in the supplementals.

Given the remaining serious problems in the supplemental rules; the as yet unknown FDA response to those concerns not addressed in the supplementals; and the complexity of the various FSMA regulations and the interactions among them, it is impossible to expect that final rules published in the next ten months will adequately address Congress' mandate to FDA to create a flexible, scale- and supply-chain appropriate framework for food safety risk management in the U.S. food supply. Because further comment from the regulated community will be essential to minimizing the unintended consequences of the rules and maximizing the public health benefits they are intended to furnish, we strongly urge that all seven rules be published as interim final regulations, with a minimum three year comment period. This will allow a cooperative evolution of FDA's regulatory scheme in partnership with industry, researchers, and the state regulators who will bear the brunt of implementing FSMA's regulatory mandates. Changes to regulations that would be published as soon as 2015 will unquestionably be necessary, and the interim rule process, with an appropriately extended comment period, would allow FDA to exercise its duty to implement rules while preserving flexibility to fix problems without necessitating the full-blown rule proposal process.

We wish to acknowledge the collaboration of dozens of other agricultural organizations in the development of these comments. In particular CFSA relied heavily on the work of the National Sustainable Agriculture Coalition and its membership. Other organizations contributing vital information for CFSA's comments include the California Alliance for Family Farms, the National Association of State Departments of Agriculture, the New England Farmers Union, the North Carolina Department of Agriculture and

Consumer Services, multiple faculty at North Carolina State University's College of Agriculture and Life Sciences, the Pennsylvania Association for Sustainable Agriculture, the United Fresh Produce Association, the Virginia Association for Biological Farming, and the Wild Farm Alliance.

Thank you for considering these comments.

Sincerely,

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Comments on Issues in the Proposed Supplemental Animal Feed Rule

Comments on FDA's Approach to Regulating Farms, including the Definition of "Farm" and Other Supporting Definitions

CFSA 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. Absent the further changes recommended here, FDA will thwart the coordinated, targeted, non-duplicative, regulatory framework Congress sought to establish with FSMA, and will violate Congress' intentions that one operation would not be subject to multiple sets of regulations under FSMA, and that farms should continue to be exempt from the requirement to register under Bioterrorism Act.

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 comments on the 2013 proposed rules, we noted the significant flaws in FDA's foundational understanding of farms, which cast FDA's entire regulatory framework into question.[2] 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.[3]

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

[2] *See* CFSA's 2013 Preventive Controls Rule comments at 9-11.
[3] 79 Fed. Reg. 58538

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 conduct to prepare their crops and get them to markets, and so that they are consistent with FSMA's risked-based mandate and approach. Specifically, FDA should modify the organizing principles so that they read:

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

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

Foundational to FDA's proposed regulatory framework are the definitions of "farm" and "facility." When Congress passed FSMA, it was clear that the law was expanding FDA's regulatory authority over existing regulated entities (i.e. facilities) and creating authority to regulate previously non-regulated entities (i.e. farms). However, to ensure an appropriate, coordinated, and targeted regulatory framework, Congress included provisions in both §§ 418 and 419 that specify that the activities subject to the requirements of one section are not subject to the requirement of the other section.[4] 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.[5] 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

[4] Food, Drug & Cosmetic Act §§418(k) and 419(h).
[5] *See* CFSA's 2013 Preventive Controls Rule comments on the farm definition for supporting information on Congressional intent and the FDA's broad authority to modify the farm definition to ensure that farms are not inappropriately regulated as facilities, at 7–9.

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 own raw agricultural commodities (RACs) or another farm's RACs.[6] 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."[7] 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 not differentiate between activities done on a farm's own RACs and someone else's RACs in the definition of "farm," and the supporting definitions of "harvesting," "packing," and "holding."

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 – do 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.

[6] *See* CFSA's 2013 comments at 9–20.
[7] 79 Fed. Reg. 58438

While we support these 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," and merely 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 is 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.

Recommendation: The final rule should 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. Packaging and labeling and drying/dehydrating RACs are not activities that should trigger the facility definition, as long as there is no further processing done to change the nature of the RAC.

c. The term "farm" should not be defined in terms of an "establishment".

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

One of the primary purposes of definitional elements in rules is to assist the regulated community in understanding whether and to what extent the rules may affect them. For farmers, who have not historically been regulated under FDA rules, it is critical that key terms are defined in a way that is realistic and sensible. The definition that FDA ultimately codifies will be with us for generations, and we urge the agency to craft a definition that farmers now – and 50 years from now – can see themselves in. Most farmers do not refer to their businesses as "establishments." "Operation" is a much more commonly used term – notably used in existing food safety certification programs like USDA GAPs, Harmonized GAPs, LGMA, and FDA's own industry guidance[8] – and would resonate better with the farming community. Indeed, FDA's own industry guidance on microbial food safety in fresh produce uses the term "operation", demonstrating the usefulness of the term, and underscoring the critical need for consistent use of language, for the benefit of both the regulated community and the regulators.

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

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

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,[9] and FDA acknowledges this to be true.[10] We therefore urge the agency to define "farm" in a manner that reflects FDA's own awareness, 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 proposed definition and, therefore, such businesses might qualify for extended compliance periods intended for farms that qualify as small and very small businesses.[11] A definition that clearly defines a farm as including all land, parcels, and operations that comprise the farm business – and are under the effective control of one or more farm operators[12] – 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 will not result in foreign farms under common ownership as a domestic farm being considered part of that domestic farm. 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 conduct "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,[13] and – in acknowledging comments that "there is no evidence to suggest that different requirements for off-farm

[9] *See* CFSA's 2013 comments at 12–16.
[10] 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.").
[11] 79 Fed. Reg. 58440
[12] Similarly, the use of "farm operator" is much more common and clear compared to "owner." We explain this in more detail below.
[13] 79 Fed. Reg. 58438

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."[14]

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 foodborne illness risk) and distributing that produce through a shared 'off-farm' packing operation are also swept up by this inappropriate designation as facilities. Such farm operations are 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 the "alternative" preventive control for an "off-farm" packing facility is illogical and contrary to the determination FDA has made with respect to the limited foodborne illness risk that those non-covered products represent. Adopting a more sensible definition of "farm" solves this illogical outcome. In particular, removing the phrase "one general physical location" from the "farm" definition would clarify the intent that all parcels and structures are considered part of that farm operation, and provide a sensible and risk-based solution to the issue of an operation being regulated differently for doing the same activity in a different location from where RACs were harvested.

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

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

Similar to our comments above, we strongly urge FDA to modify the farm definition to reflect the reality that many farming operations are not under a single ownership. Nearly forty percent of US farmland is rented from non-operating owners.[15] The percentage is generally higher for larger farms than for smaller farms, but this is a common situation across agricultural operations. With so much farmland under cash or share rent arrangements with the landowner, limiting farms to those "under one ownership" would lead to a significant number of what are objectively farms being classified as facilities solely on the basis of their ownership structure. This is a completely illogical outcome.

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

[14] 79 Fed. Reg. 58535
[15] 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

that manufactures/processes, packs, or holds food for consumption in the United States."[16] 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 Produce Rule 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.[17] 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 structure arises in the context of cooperatively owned "on-farm packinghouses." We would again note that this "on-farm" versus "off-farm" distinction is arbitrary where the operations are extensions of the farm business, and remain under majority control of one or more farm operators. We urge FDA to focus on crafting a definition that is accurate and risk-based – so that it provides a regulatory framework that ensures that farms that pack and hold covered produce without doing any additional processing that transforms the nature of the RAC are regulated as farms under the Produce Rule, not as facilities under the Preventive Controls rule, regardless of where that packing and holding takes place. We submit that, as long as the farm operators supplying the produce to be packed have at least majority control over the operation, such an operation is part of each farm. We again note that this will not result in foreign farms being considered part of a domestic farming operation, as 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, and ensure that such operations are held to appropriate US import requirements..

We appreciate FDA's that concern with respect to regulating these collaborative packing and holding operations as farms, instead of 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

[16] 78 Fed. Reg. 3796

[17] *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).

farms as well as jointly controlled farm business operations, and is one that is of necessity already practiced by these operations to ensure proper compensation of the participating operators.

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~~ or[18]

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

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

***

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

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

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

As discussed above, CFSA 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.[19] We recognize that FDA's improved definitions of packing and holding, which now include activities incidental to or necessary for the safe and effective storage or transportation of a RAC, may now address some of these activities (e.g. refrigerating, spinning). We also recognize that the list cannot be fully exhaustive. Nevertheless, in the interest of clarity, we recommend making the list as exhaustive as possible, and periodically reviewing the list to ensure that it reflects the breadth and range of practices done as part of harvesting. Under separate cover, CFSA will provide data compiled from farmers in the Carolinas documenting the widespread practice of these activities in the course of harvesting produce.

[18] 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).

[19] *See* CFSA's 2013 Preventive Controls Rule comments at 19.

***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.[20]

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.

[20] 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.[21] 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."[22] 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.

E. Farms that process animal feed solely for on-farm use should not be considered "facilities".

FDA requests comment on whether feed mills should be subject to the rules as animal food facilities.[23] FDA notes that, under the definition of "farm" as currently proposed, different business structures could result in a feed mill being considered part of the farm (and therefore exempt from the rule), or covered under the rule. For example, under a contract livestock or poultry operation – where one entity owns the feed mill and the animals, but another entity owns the establishment where the animals are raised – the farms is not "under one ownership." Therefore, the feed mill would be required to register because it is not part of the farm where the animals are raised. A fully vertically integrated operation, on the other hand, would be exempt because the same entity owns all elements of the operation. FDA asks whether

[21] *See* FSMA § 204(d)(A),(C), (E), (L). We also note that FDA has yet to propose the rule traceability and high-risk foods.
[22] FSMA § 204(d)(1)(C), (E).
[23] 79 Fed. Reg. 58482–83

fully integrated operations that include feed mills should also be required to register and comply with the Animal Food Rule and, if so, how the agency should revise the farm definition so the feed mills associated with these fully vertically integrated farming operations would not be considered part of the farm, and would be required to register.[24]

We strongly urge the agency to retain a consistent definition of "farm" across the Produce Rule and both Preventive Controls Rules. Despite congressional intent that farms not be subject to multiple rules, "farm mixed-type facilities" could be covered by all three rules. Consider the following examples, which comparable to situations facing livestock farms in the Carolinas serving the markets for local foods, and represent degrees of diversification common among farm businesses:

- Scenario 1: Farm with more than $500,000 in annual sales of food that:
    - Produces feed grains on 180 acres that are processed on-site into livestock or poultry feed that is sold off-farm;
    - Grows produce on 20 acres in a diversified rotation; and
    - Makes a number of value-added products (jam, salsa, tomato sauce, cider, bread) to sell at its farm stand.
- Scenario 2: Farm with more than $500,000 in annual sales of food that:
    - Grows animal feed grains that are processed on-site and sells all of its feed;
    - Grows a varieties of different vegetable varieties for sale through a community- supported agriculture (CSA) operation;
    - Raises chickens for on-farm consumption; and
    - Packs and sells eggs for inclusion in the CSA operation.
- Scenario 3: Farm with less than $500,000 in annual food sales that sells the majority of its food to qualified end-users and:
    - Grows, grinds, and sells poultry feed;
    - Grows, grinds, and sells grains for human consumption;
    - Grows, processes, and sells turkeys and chickens;
    - Packs and sells eggs; and
    - Grows and sells vegetables, half of which are dried or frozen.

Some of the above scenarios are eligible for certain exemptions or modified requirements, but all are still subject to all three rules. Determining whether and to what extent each rule applies to farmers is already incredibly difficult and confusing. For this reason, we strongly urge FDA not to adopt a different definition for "farm" for purposes of the Animal Food rule. Changing the criteria for what FDA considers to be a farm on a rule-by-rule basis adds confusion to questions of compliance, and moves further away from a farm definition that is grounded in reality.

If a feed mill is located on a farm, and all of the feed that is processed at the mill is fed to animals raised on that farm, then that operation satisfies the farm definition and should not be regulated as a facility. If the farm dries and grinds grain to feed animals on the farm, and also sells some of the milled grain to other farms for use as feed, then it would have to register, but would not have to follow HARPC because

[24] 79 Fed. Reg. 58483.

it is doing only a low-risk activity/animal food combination as identified by FDA.

Recommendation*:* FDA should not adopt a different definition of "farm" for purposes of the Animal Food Rule. On-farm processing of animal feed for use solely on-farm should remain a "farm" activity and be exempt from facility registration requirements.

A. FDA should establish an outright exemption of at least $100,000.

FDA requests comments on whether there should be an exemption from the registration requirement for feed mills of a certain size.[25] We support this concept, as recommended in our comments on the original proposed Animal Food Rule. Specifically, we recommended that FDA establish an outright exemption for *de minimis* animal food facilities with an average monetary value during the previous three-year period of animal food sales of $100,000 or less.

FDA has taken initial steps to implement the flexibility specifically required by FSMA for low- risk activities/food combinations and for qualified facilities under both Preventive Controls Rules, but 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. We are pleased that the agency is considering establishing such an exemption. Animal food facilities with less than $100,000 in sales account for a tiny fraction of total animal food sales. FDA stated in the original proposed Animal Food Rule that businesses with less than $500,000 in total annual sales of animal food produce less than 0.003 percent of all animal food produced in the US.[26] Even setting the outright exemption at $500,000 would barely impact the number of facilities covered by the rule.

Recommendation: To ensure sufficient flexibility for a diverse array of food businesses, FDA should establish an outright exemption from the Animal Food Rule for businesses with, at the very least, $100,000 or less in annual average monetary value of animal food sold over the previous three-year period, adjusted for inflation.

[25] 79 Fed. Reg. 58483.
[26] 78 Fed. Reg. 64824–25.

Comments on the Definition of Very Small Business

CFSA supports FDA's proposed definition of "very small business" in the supplemental proposed Preventive Controls Rule for Animal Feed. 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.

A. FDA should retain the $2,500,000 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.[27] These definitions are important for determining the scope of coverage of the Preventive Controls Rule; a very small business can qualify for modified requirements[28] and small and very small businesses are exempt from the preventive controls requirements if they only conduct certain low-risk processing activities.[29] 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.[30]

FDA initially proposed three options for the very small business definition. In the revised proposed rule, FDA is proposing to adopt the $2,500,000 threshold. According to FDA, this threshold would cover only a tiny percentage – less than two percent – of the animal food produced in the U.S.[31] We support this decision, which is appropriate in light of the tiny fraction of animal food sales that it covers.

FDA's decision to adopt the $2,500,000 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 that those that would be included under the statutory provision that considers sales to qualified end users."[32] 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

[27] 21 U.S.C. 250g(n)(1)(B).
[28] 21 U.S.C. 350g(l).
[29] 21 U.S.C. 350d(1)(D).
[30] 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.
[31] 79 Fed. Reg. 58502.
[32] 79 Fed. Reg. 58502

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.[33]

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 $2,500,000 threshold for very small business in 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 $2,500,000 threshold for the very small business definition.

B. FDA should only count foods covered by the Preventive Controls Rule against the $2,500,000 threshold.

In this rule, FDA calculates the sales threshold for the very small business definition on sales of "animal food." We think establishing a threshold determination based on sales of food actually regulated under the Preventive Controls Rule for Animal Food creates a clear, consistent process for determining coverage under the rules, particularly for those farms that may be subject to multiple rules. Unlike the Produce Rule and Preventive Controls Rule for Human Food, the Animal Food gets this right.

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.

We note that by defining "very small business" under the Animal Food Rule based on sales of animal food, FDA acknowledges that FSMA does not restrict the agency from doing the same in the Human Food Rule and the Produce Rule. Focusing the definition of "very small business" on animal food, the product regulated under the Animal Food Rule, provides flexibility to farms diversifying into new on-farm value-added enterprises, helps ease the compliance costs for farms and new value-added businesses, and helps focus limited FDA resources on high-risk industrial facilities. We support this decision in the Animal Food Rule, and urge FDA to carry this same logic to coverage under the Produce and Human Food Rules.

Recommendation: FDA should retain the definition of "very small business" under the Animal Food Rule as a business with "less than $2,500,000 in total annual sales of animal food, adjusted for inflation" and should carry this same logic to threshold determinations under the Human Food and Produce Rules.

[33] For additional support on this issue, *see* CFSA's 2013 Preventive Controls comments, at 23–26.

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. CFSA strongly opposes the inclusion of a supplier program in either Preventive Controls rule—Human or Animal Food. The current onsite audit requirements of the proposed program falls flagrantly outside the agency's authority under FSMA, and the agency has not adequately considered the effects of a supplier program on food businesses that work with farms, let alone the farms themselves. We offer the following comments and recommendations below.

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.[34] FDA may, *but is not required to*, include "supplier verification activities" as part of those preventive controls.[35] Importantly, FSMA explicitly prohibits FDA from requiring regulated entities[36] to hire third parties to identify, implement, certify, or audit compliance with the rules.[37]

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

In the supplemental Animal Feed 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."[38] 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."[39]

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.[40] However, if there is "a reasonable probability that exposure to the hazard will result in serious adverse health consequences or death to humans or animals" (SAHCODHA), then the receiving facility must have documentation of an onsite audit before using any raw ingredients from the supplier.[41]

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[34] 21 U.S.C. 350g(n)(1)(A).
[35] 21 U.S.C. 350g(o)(3)(G).
[36] 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" under the rule, which could include farms that are mixed-type facilities, in addition to traditional food facilities.
[37] 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).
[38] Proposed § 507.37(a)(1), (a)(2); 79 Fed. Reg. 58496.
[39] *Id*.
[40] *Id*.
[41] *Id*.

FDA contends that this requirement does not contradict the statutory 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 supplier.[42] Clearly, the onsite audit requirement acts as a *de facto* audit requirement on farms and facilities, in plain contravention of Congress's express directive to the agency.

2. Principles of statutory construction prohibit the supplier program.

Canons of statutory construction demonstrate Congress did not intend for FDA to require audits of farms or facilities anywhere in the proposed rules. Indeed, §350h and §350g 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 the regulations.[43] 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.[44] 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.[45] 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 supplier program requirement will stifle innovation in the marketplace and disproportionately harm small business.

[42] Preliminary Regulatory Impact Analysis at 87
[43] 21 U.S.C. §350h(c)(1)(E).
[44] *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.").
[45] *See Babbitt v. Sweet Home Chapter of Cmtys. For a Great Or.*, 515 U.S. 687, 717–18 (1995) (upholding the proposition that definitions should be read consistently with other provisions of a statute).

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."[46] 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 that failure to comply with the regulations is a prohibited act? Similarly, how will a receiving facility document to an inspector's satisfaction that there are no significant hazards that need to be controlled at its suppliers? The reality is that the "alternative option" approach will be impossible for all but the largest processing facilities to venture into. In practice, the onsite audit requirement flies in the face of the letter and the spirit of the law.

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 program, 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"[47], 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

[46] Proposed 507.37(c)(2)(ii).
[47] P.L. 111-353, § 103(a)(a)(n)(3)(A)

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 dialog between the parties is in the long term the most effective means for collaboration to reduce foodborne illness risk. 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 or small business 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 Animal Feed rule. 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.

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:

- Solicting/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 guidances, including public meetings, workshops, and the formation of an advisory committee including representatives from these communities;
- Holding public meetings and workshops on the draft guidances 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.[48] 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; should ensure and that local producers do not lose access to certain markets due to the costs that compliance with a supplier program would impose on receiving facilities; and should promote a culture of food safety in the food supply chain rather than encouraging dependence on audit schemes that are in fact an often flawed approach to managing foodborne illness risks. Specifically, FDA should:

- Remove the supplier program from the regulations;
- Fully analyze the economic impacts of a supplier program on farms and very small businesses;
- Develop Level 1 guidance for facilities that work with covered farms and small and very small businesses, including qualified exempt farms, *de minimis* exempt farms and facilities, and low-risk facilities, 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 and small and very small businesses to ensure that suppliers entitled to 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

[48] Proposed 507.37(c)(3), (4).

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.

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.[49] FDA acknowledges that product testing and environmental monitoring are verification measures, and are not themselves preventive controls.[50]

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."[51]

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:

- Solicting/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 guidances, including public meetings, workshops, and the formation of an advisory committee including representatives from these communities;
- Holding public meetings and workshops on the draft guidances 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 feed milling operations focused on providing feed for livestock supplied to local and regional food markets.

[49] 21 U.S.C. 350g(n)(1)(A).
[50] 78 Fed. Reg. 58543
[51] 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. As we stated in our comments on the original proposed Preventive Controls rule, product-level testing of RACs would impose excessive and useless costs on farms and low-risk establishments that pack and hold RAC. 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 can't provide any reliable validation for a food safety program. Farms are by their nature exposed to the environment, and 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."[52] 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 broadly.

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.[53] All finished animal food is considered "ready to eat," therefore FDA proposes to require environmental monitoring for facilities where, prior to packaging, "contamination of an animal food with an environmental pathogen is a significant hazard."[54] While environmental testing may be appropriate in certain circumstances, the costs associated with such measures are extremely high. FDA estimates that environmental monitoring would cost $3,457 annually for testing alone (based on monthly testing).[55] That number is unchanged regardless of business size, meaning that the smallest businesses carry a disproportionately high burden of these new costs. To maximize flexibility, particularly for the smallest facilities, 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 These provisions impose significant added burden on facilities, and the farmers that supply them, particularly for those producing multiple crops and products. For local food operations that source from multiple farmers, or produce multiple products, these costs will only increase, 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

[52] Sperber, William H., "HACCP and Transparency," Food Control 16 (2005), 505-509.
[53] 79 Fed. Reg. 58545
[54] 79 Fed. Reg. 58494; 79 Fed. Reg. 58517
[55] Reference 1, Preliminary Regulatory Impact Analysis at 81

for industry innovation and stakeholder participation to determining the appropriate use of verification measures, and avoids a one-size-fits-all approach to regulations.

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Comments on the Withdrawal and Reinstatement of a Qualified Exemption

CFSA 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 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.[56] If a farm or facility meets these qualifications, then instead of being subject to the entire produce standards or HARPC requirements, the farm or facility is subject to modified requirements.

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

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

FSMA grants FDA the authority to withdraw a qualified exemption under certain circumstances. We agree with the agency that "the absence of a specific provision in section 418 of the FD&C Act for the re-instatement of an exemption that is withdrawn does not preclude [FDA] from providing for such a process."[57] 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.[58]

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 markets due

[56] 21 U.S.C. §§ 350g(l) and 350h(f); under the Preventive Controls Rule, very small businesses are also qualified facilities.
[57] 79 Fed. Reg. 58553; see also 79 Fed. Reg. 58466 (Produce Rule).
[58] *See*, *e.g.* 21 U.S.C. § 336 (2013).

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

Some argue that reinstatement means there is no incentive to improve your food safety practices because a firm can keep making people sick and then maintain its qualified exempt status. We believe the opposite to be true. The reality is that if a small-scale direct-marketing firm 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 owner or by initiative of the FDA District Director. Under § 507.85(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 farm, reinstate the qualified exemption." Under § 507.85 (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 § 507.85(d), if the exemption was withdrawn for a combination of § 507.60(a)(1) and (2), and FDA determines there was no direct link, then FDA will inform the facility of that finding, but the facility 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 § 507.85(a), if FDA determines that the problems have been resolved, FDA "shall" reinstate the exemption. The use of "shall" indicates that there is no discretion. Yet, the phrase continues "on his own initiative or at the request of the 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 § 507.85(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 <u>within a reasonable period of time."</u>

This should also apply to requests for reinstatement under § 507.85(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 § 507.85(a) states, FDA "will" reinstate. We encourage the agency to clarify that under § 507.85(d), FDA would be expected to do so "within a reasonable period of time." This does not undermine the agency's authority to determine whether the problems have been resolved, but it does provide significant assurance of a fair and transparent process to facilities that qualify for modified requirements.

Similarly, § 507.85(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 Animal Feed 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 § 507.85 clarifying that a FDA District Director will reinstate a qualified exemption "within a reasonable period of time" if the Director determines that the farm has adequately resolved the issues of concern.

Specifically, for § 507.85, 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 Division of Compliance in the Center for Veterinary Medicine) determines that the facility has adequately resolved problems with the conduct and conditions that are material to the safety of the animal food manufactured, processed, pack, or held at the facility, and that continued withdrawal of the exemption is not necessary to protect the public (human and animal) health or prevent or mitigate a foodborne illness outbreak, the FDA District Director in whose district your facility is located will, on his own initiative or request of a facility, reinstate the exemption <u>within a reasonable period of time</u>.

(b) If your qualified exemption was withdrawn under § 507.60(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~~ <u>shall</u> reinstate your qualified exemption under § 507.7(d) <u>within a reasonable period of time</u>, and FDA will notify you in writing that your exempt status has been reinstated.

(c) If your exemption was withdrawn under § 507.60(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 § 507.5(d), 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 animal food manufactured, processed, packed, or held 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 § 507.60(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."[59] 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 § 507.60(b)(2) and (3), which contain actions that FDA must take before withdrawing an exemption. This includes providing notice to the owner, operator, or agent in charge of the 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 in facilities, and saves the facility 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 § 507.60(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

[59] Proposed § 507.60(b)(1).

will not arbitrarily be applied to a class of facilities.[60] While we appreciate FDA's sentiment, if this is truly the agency's intent, then we urge the agency to make that clear in the regulations themselves, or at the very least in the preamble. This could also be done by adding more specificity to the required contents of both the notice of intent to withdraw, and the withdrawal order itself.

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."[61] We would expect that this notification include facts specific to the facility's situation so that the facility can meaningfully understand and take steps to rectify the issue. This should not merely recite or point to the regulatory language that allows for withdrawal. We have reviewed recent warning letters sent by the agency to businesses out of compliance with seafood HAACP, cGMPs, and food labeling laws,[62] and we find the degree of specificity contained in those letters to be very good. We would expect notices to facilities 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."[63] We contend that a "brief general statement" is insufficient to convey the information necessary for a facility operator to adequately resolve any food safety problems at the facility. If FDA will consider reinstatement based on a determination that the facility has adequately addressed the source of the problem, then the order must contain facts specific enough to allow the facility to address the problem and demonstrate to the agency that the problems have been resolved.

We also note that FDA warning letters under seafood HAACP, cGMPs, and other existing regulations give businesses 15 working days to respond. The withdrawal process gives 10 calendar days. Having a separate process under the Preventive Controls rule versus seafood HACCP rules to respond to agency communications is confusing for the facility 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 § 507.60(b)(2), and the withdrawal order in § 507.65. FDA should also standardize withdrawal notice and response procedures with existing administrative procedures. Specifically, we recommend incorporating the following revisions:

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[60] 79 Fed. Reg. 58553
[61] 117.251(b)(2).
[62] *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.
[63] Proposed § 507.65

§ 507.60 (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 in writing, within ~~10 calendar~~ 15 business days of the date of receipt of the notification, to FDA's notification;

§ 507.65 (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)."[64] 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 both Preventive Controls Rules should provide information on the options for a farm or facility to come into compliance or appeal the order. All 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 Animal Food Rule, FDA should add a new section to 507.65: "(i) A statement that the facility may request reinstatement of a withdrawn qualified exemption as provided in 507.85."

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

[64] 79 Fed. Reg. 58553

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

1. Time to come into compliance

In the original proposed withdrawal provisions, both Preventive Controls Rules provided facilities with a 60-day compliance timeline from the date of the order. In the supplemental Preventive Controls Rules for both Human and Animal Food, 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.[65] Therefore, FDA revised both Preventive Controls Rules 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.[66] CFSA supports this change. However, we again note that existing FDA regulatory schemes (like HAACP) are based on business or "working" days, not calendar days. We urge the agency to standardize these administrative processes not only across FSMA rules, but across all FDA food safety rules.

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

> § 507.65(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 ~~10 calendar~~ 15 business days of receipt of the order in accordance with the requirements of § 507.69.

2. Time to respond to correspondence from FDA

In the Preventive Controls Rules, 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."[67] The Preventive Controls Rules apply the same method to the time within which a facility must respond to a notice. 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.

To ensure an accurate determination of when the time tolls, FDA should deliver all time sensitive

[65] 79 Fed. Reg. 58554.
[66] § 117.257(d)(1).
[67] 79 Fed. Reg. 58554

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.[68] 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.[69] 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 definition, there is ambiguity in how a facility may be "directly linked" to an outbreak.[70] Because this is one of only two avenues for FDA to withdraw an exemption, and because of the significant implications for facility owners that have their exemptions withdrawn, there should be clear guidance for FDA in making this

[68] *See* CFSA's 2013 Preventive Controls Rule Comments, at 37-42.
[69] § 117.251(a)(2).
[70] § 117.251(a)(1).

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 facilities 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 producers, especially for small producers, and the exemption should only be withdrawn when FDA is certain that it is absolutely required to protect public health.

Additionally, FDA should define "associated" to specify how closely connected to a qualified 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 § 507.60(a)(2):

> If FDA determines <u>based on credible and substantial evidence</u> that it is necessary to protect the public health and prevent or mitigate a foodborne illness outbreak based on conduct or conditions associated with the qualified facility that are material to the safety of the food manufactured, processed, packed, or held at such facility; <u>conditions or conduct are material to the safety of food when there is reasonable probability that they will contribute to an outbreak of foodborne illness</u>.

And we recommend the follow definitions be added to § 507.3:

> <u>(a) *Directly* linked means that which in a direct manner, as established by credible and substantial evidence, is immediately connected to activities on a farm, farm mixed-type facility, or facility that are under the control of the owner, operator, or agent in charge of the farm, farm mixed-type facility, or facility.</u>
> <u>(b) *Necessary* means that which is absolutely required, as established by credible and substantial evidence, to protect public health.</u>
> <u>(c) *Associated* means that which is directly and closely connected, as established by credible and substantial evidence, to a farm, farm mixed-type facility, or facility.</u>

(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.