March 27, 2017

Food and Drug Administration
Division of Dockets Management (HFA-305)
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852.

Re: Docket No. FDA-2012-D-1002; NSAC Comments on the revised draft guidance for industry entitled "Questions and Answers Regarding Food Facility Registration (Seventh Edition)"

Submitted online via www.regulations.gov

On behalf of the represented members of the National Sustainable Agriculture Coalition (NSAC), I submit the following comments to Docket No. FDA-2012-D-1002: the revised draft guidance for industry entitled "Questions and Answers Regarding Food Facility Registration (Seventh Edition)." NSAC is an alliance of grassroots organizations that advocates for federal policies that support small and mid-size family farms, protect natural resources, promote vibrant rural communities, and ensure healthy food access through local and regional food system development. Many of our member organizations work directly with the family farms, food hubs, and value-added enterprises that are engaged in direct-to-consumer and intermediated markets and are building local and regional supply chains to improve the health and well-being of American families.

NSAC has actively engaged in the FSMA process throughout the legislative debates, rulemaking, and now implementation, all with an eye toward ensuring that the Food and Drug Administration (FDA) can meet its public health goals in a way that is scale- and supply-chain appropriate, so that small and mid-sized farms and businesses, including those comprising the local/regional food sector, can prepare for and adapt to a changing food safety landscape. These enterprises include diversified, sustainable, organic, and identity-preserved agricultural operations; beginning and socially disadvantaged farmers; value-added farm businesses and small-scale processors; and direct and intermediated supply chain participants. These operations need to be able to meet the new challenges FSMA brings, while continuing to supply fresh fruits and vegetables and meet the growing demand for local, organic, identity-preserved, and value-added products.

We strongly advocated for and supported the changes that FDA made to the definitions of "farm" and "retail food establishment" over the course of the rulemaking process, changes that greatly improved farmers' ability to determine which rules apply to them. And we appreciate FDA's efforts now to provide, through the guidance process, additional clarity on the fundamental issues of which operations are required to register with FDA as food facilities. This is so important because, despite the improvements made during rulemaking, the definition of "farm" is still causing significant confusion as farm enterprises attempt to determine where they fit within the definition and the broader FSMA regulatory scheme. And while this Q&A provides useful information on specific scenarios, we believe additional interpretation and clarity is needed for the entire farm definition, that go beyond this Q&A document. We made similar comments on FDA's draft guidance

110 Maryland Avenue NE, Suite 209 • Washington, DC 20002-5622
p (202) 547-5754 f (202) 547-1837 • www.sustainableagriculture.net

classifying activities that fall within the "farm" definition, and are attaching those comments here as an appendix for further reference. It is with this bigger picture context in mind that we provide the following general and specific comments and recommendations on this Draft Guidance.

I. GENERAL COMMENTS ON THE FARM DEFINITION

We appreciate FDA's work to provide additional guidance and clarity on aspects of the farm definition through the farm/facility activity classification guidance, and through this Q&A that includes questions that address a range of specific types of farm operations that are considering whether they must register with FDA or not. In particular, we believe the specific examples and Q&A format of this guidance can serve as a great resource for farmers and food businesses seeking to determine whether they must register with FDA or not. However, additional clarity is required on the remaining ambiguities around who must register based on aspects of the farm definition that are not addressed in this guidance.

In Question O.5. of this draft guidance, FDA acknowledges the residual confusion about the farm definition, particularly regarding the ownership element, stating that FDA is "considering whether future rulemaking to modify the "farm" definition is appropriate to address the issue. FDA does not intend to prioritize enforcing the registration requirement for these businesses [that would meet the secondary activities farm definition but for the majority ownership criteria]."

This statement does not provide sufficient assurance that farmers will not be pressured to register if their situation is not crystal clear. We continue to hear stories of farmers who are told by various state and federal officials (or buyers) that they must register with FDA, despite the fact that, based on their assessment, their operations satisfy the farm definition criteria. In other cases, we hear from farmers for whom ambiguities remain regarding how the farm definition applies to their operation.

We therefore continue to strongly urge the agency to provide clarity on the ownership and location aspects of the farm definition through separate Level 1 draft guidance for public comment, and to ensure that operations solely engaged in Produce Rule activities are solely covered by the Produce Rule -- and not the Preventive Controls Rule -- throughout the implementation process. Doing so would provide farmers with appropriate resources to guide their decision-making, and would also provide clear information that can be pointed to in the event that an inspector or auditor questions their assessment of their exemption under the farm definition.

Along those lines, we also strongly recommend that all guidance information related to the farm definition be pulled out and be compiled into a single document. Having that information repeated in several guidance (the Registration Q&A, etc.) documents is fine, but it is critical that farmers – many of which are newly subject to this regulatory regime – have a simple and accessible way to find critical information related to their coverage under the new rules. For that reason, we urge the agency to consolidate all information related to the farm definition into a single farmer-friendly guidance document, and would be glad to lend our support in developing such a document.

II. SPECIFIC COMMENTS ON THE DRAFT GUIDANCE

In general, we find this draft Q&A very helpful. However, there are places where additional interpretation or explanations in plain language (rather than restatements of or citations to the regulatory text) would make the document more useful to farmers assessing whether or not their

operation is subject to FDA registration requirements. In the following sections, we provide specific feedback on specific Q&As to enhance the overall readability and usefulness of the document for farmers seeking information on registration.

B.1.1 Are farms exempt from registration?

Rather than direct readers to a later question to define "farm mixed-type facility," the term should be defined the first time it is used in Question B.1.1. In general, given the length and complexity of this document, we believe that key terms such as "retail food establishment" or "farm mixed-type facility" should be defined in plain language *each time they are used*. Moreover, to truly be useful to farm mixed-type facilities, the guidance must also make clear each time farm mixed-type facilities are referenced that only the non-farm activities of farm mixed-type facilities are subject to the regulation under the Preventive Controls Rule.

Specifically, we recommended the following changes on page 5 (deletions ~~struckthrough~~, additions underlined):

> Therefore, if your farm operation conducts activities that fall within the definition of "farm" in 21 CFR 1.227, the farm is exempt from registration. However, if your farm is a "farm mixed-type facility," you must register. ~~For a discussion of "farm mixed-type facility," please see Question B.1.5 in this document.~~ A "farm mixed-type facility" is an establishment that meets the farm definition for certain activities, but also conducts activities that fall outside the farm definition that therefore require the establishment to register its non-farm activities with FDA. If a farm mixed-type facility must register with FDA, then the Preventive Controls Rule applies to that entity; however, the activities of the farm mixed-type facility that are within the "farm" definition are not subject to the Preventive Controls Rule. Only those activities that require that farm mixed-type facility to register with FDA (i.e. manufacturing/processing) are subject to regulation under the Preventive Controls Rule.

We urge the agency to make these changes each time the guidance references farm mixed-type facilities.

B.1.3 Is a farm that grows tomatoes and sells them directly to consumers from a roadside stand located on the farm exempt from registration?

Similarly, the guidance should fully and clearly define "retail food establishment" the first time it is used in the document, as follows in the response to Question B.1.3 on page 6:

> If the primary activity of the roadside stand is selling food (including the tomatoes) directly to consumers, it is exempt as a "retail food establishment" (21 CFR 1.227). A farm can be a "retail food establishment" if the majority of its sales are direct to individual consumers, whether through roadside stands, CSAs (community supported agriculture), farmers markets, online sales platforms, or any other direct marketing platform. In calculating whether a majority of the sales are direct to consumers, sales to businesses or other retail food establishments do not count as direct sales.

B.1.7 Does placing stickers on fruit on a farm amount to "manufacturing/processing" and, therefore, require registration of the facility in which the application of the stickers occurs?

This Q&A should make it clearer that labeling is not an activity that requires a farm to register in the response to Question B.1.7, as follows:

> We consider labeling, including stickering, to be a "manufacturing/processing" activity. However, placing labels (e.g., stickers) directly on raw agricultural commodities (RACs), on boxes or other containers holding packed RACs, or on consumer packages containing RACs, is within the "farm" definition, and therefore that activity does not require a farm to register with FDA.

B.1.8 Produce grown on a farm is picked and trimmed and then sent to be packed at a packing shed that is owned by the same person that owns the farm. The packing shed is not in the same general physical location as the farm. The packaged produce is then shipped by the farmer to a distributor. Does the packing shed have to register?

This question provides a very specific example of a packing shed assessing whether it must register. In general, we find such specific examples to be very useful. However, the question, which specifies that the packing shed is not "in the same general physical location as the farm," begs the question: what *does* count as being in the "same general physical location"? This is one of the lingering farm definition issues, like ownership, that requires further interpretation through guidance. We recommend that, in addition to developing additional guidance on the farm definition, this Q&A be modified to provide criteria that FDA relies upon to determine the meaning of "in one general physical location."

In our comments on the proposed rules, we urged FDA to remove reference to "one general physical location" in the farm definition, given the confusion that results from such a vague term, and we still support a farm 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. FDA chose not to adopt our recommended change, believing that adding "not necessarily contiguous" to the definition was sufficient.

All we know from the Preventive Controls Rule is that FDA believes "separate locations that are not in close proximity to each other should not be considered the same 'farm'" without any further indication of how "close proximity" is defined. Granted, FDA acknowledges that "even without the new phrase 'not necessarily contiguous,' some situations would be complex," but goes on to say that the agency intends "to address these types of situations with our State food safety partners."

We believe the more appropriate approach to clarifying the ambiguity in this definition is through consultation with *all* food safety partners, including the regulated industry. Level 1 guidance provides an opportunity to do so and, in our view, the most fitting and easily understandable and enforceable definition of "in one general (not necessarily contiguous) physical location" is as follows:

> *One general (not necessarily contiguous) physical location* means all of the land, parcels, and operational structures that comprise the farm business, and are under the effective control of the same farm operator(s).

B.1.22 Is a business that is not owned by farmers, and not located on a primary production farm, that collects honeycombs or honey from multiple farms, packs it (e.g., in 10-gallon containers), and sends it to a processing facility required to register?

As currently written, the response to this question does explain which aspect of the *secondary activities farm* definition this operation does not satisfy. FDA should clarify that the reason this operation is not a farm is because it does not satisfy the ownership criteria of the definition, as follows:

> Yes. The operation is a packing facility that does not meet the definition of a "secondary activities farm" (see 21 CFR 1.227) because it is not owned by farmers, and therefore is required to register.

B.1.24 If a farmer makes silage and sells that silage to another farmer for use as animal food, would the farmer be required to register?

We believe this question is valuable because we doubt many silage farmers know that they are subject to registration. However, we believe the response to this question should be modified to clarify requirements silage producers are subject to, as follows:

> Silage is a processed food made by fermenting (ensiling) green vegetation (e.g., alfalfa, clover, corn). A farm may manufacture/process food and remain within the "farm" definition, if all the food that is manufactured/processed is consumed on that farm or another farm under the same management. If the processed food is consumed on a farm under different management, then the farm manufacturing the food becomes a farm mixed-type facility and is required to register with respect to the non-farm activities of the operation, i.e. ensiling green vegetation. Therefore, in this example, the silage farmer would be required to register as a farm mixed-type facility because the farmer is selling silage to another farm under different management.
>
> However, if the farm mixed-type facility is a small or very small business (defined as having fewer than 500 employees or less than $2.5M in animal food sales, respectively), then the farm would be exempt from the majority of the Preventive Controls Rule for Animal Food, but would be subject to Good Manufacturing Practices (GMPs).

B.1.25 Does a farm that mills and bags animal food for sale have to register?

As we commented in Question B.1.1, anytime a question addresses the registration requirement for farm mixed-type facilities, we strongly urge the agency to clarify that any regulatory requirements under the Preventive Controls Rule would only apply to the activities of the farm mixed-type facility that require it to register, not any activities that fall within the *farm* definition, as follows:

> An on-farm operation that manufactures and processes food for livestock or poultry (e.g., a feed mill) does not remain within the definition of "farm" in 21 CFR 1.227 if the sale of that food is to a farm under different management, even if the raw ingredients are grown on the farm that has the feed mill. The establishment is a farm mixed-type facility and required to register. (See Question B.1.5). However, only the activities of the farm mixed-type facility that require it to register (in this case, the activities of the feed mill) are subject to subsequent regulation under the Preventive Controls Rule for Animal Food. The farming activities (in

this case, growing the raw ingredients that later are processed in the feed mill), are not subject to regulation under the Preventive Controls Rule for Animal Food.

~~However, a~~A farm that includes an operation that manufactures/processes and packs animal food (e.g., mills and bags animal food) can be within the definition of "farm" in 21 CFR 1.227 as long as all of that animal food is consumed on that farm or another farm under the same management. Because it is a farm, it is not required to register.

B.2.7 How did the Registration Final Rule amend the definition of "retail food establishment?"

We appreciate new question B.2.7, which clarifies the changes to the "retail food establishment" definition, and would recommend one small change on page 15 for additional clarity as to the requirements of the definition, as follows:

> For example, an establishment located on a farm that sells apples it grows and apple pies it manufactures directly to consumers at a farmer's market would consider those sales in determining its primary function. At the same time, if a farmer manufactures or manages the manufacturing of jellies from the apples that he grows at an off-farm location, such as an incubator kitchen, and sells those jellies directly to consumers at a farmer's market, the jelly-making operation would be a farm-operated business and may consider those sales in determining its primary function (e.g. whether the majority of its sales are direct to consumer), and therefore whether the "retail food establishment" exemption applies.

Similarly, in Question C.4.4, we recommend the agency provide the definition of a retail food establishment to the answer, or at the very least refer to the earlier Q&A that provides the definition, as follows:

> **Am I required to register if I use heat to pasteurize the honey I produce on my farm?**
>
> Under 21 CFR 1.227, heating honey for pasteurization is considered manufacturing/processing. Therefore, if you use heat to pasteurize the honey you produce on your farm, you must register unless: (1) all the honey that has undergone manufacturing/processing is consumed on your farm or another farm under the same management, or (2) your manufacturing/processing operation meets the definition of a retail food establishment. To qualify as a retail food establishment, the majority of your sales must be direct to individual consumers, not businesses; see *Q X.X.X* above for more information.

B.2.13 If I supply food directly to consumers via the Internet or mail-order, am I a retail food establishment?

Wherever possible, we urge the agency to restate definitions and interpret them into plain language for the reader, in addition to (or rather than) citing to the CFR or parts of the preamble. Having all of the information available in one central location, and translated into plain language, makes for an incredibly useful document to regulated entities. Q&A B.2.13 is one example where such additional text would be valuable, but it is by no means the only location.

A: Maybe. Facilities that sell food directly to consumers via the Internet or mail-order may be retail food establishments, provided they meet the other criteria of the "retail food establishment" definition in 21 CFR 1.227 (for more information see Comment 82 in the Interim Final Rule; 68 FR 58894 at 58914 to 58915). The other criteria to be a retail food establishment is that the majority of food sales from that establishment must be direct to individual consumers, not businesses or other retail food establishments. A retail food establishment can have some sales to businesses (retail or wholesale), but the majority (at least 50.1%) must be direct to individual consumers.

B.2.14 For purposes of the "retail food establishment" definition, can sales at produce auctions, food hubs, and buying clubs be considered sales that are directly to consumers?

This is a valuable question but, given the number of possible scenarios, there is no straightforward yes or no answer. We therefore recommend the agency break out the various scenarios and provide further clarity, as follows:

Maybe; it depends on the types of sales being made through the platform, because sales at such platforms can be to different types of entities. In some cases, sales may be to consumers. However, sales may also be to restaurants, wholesalers and other businesses. Therefore, whether these businesses qualify as "retail food establishments" depends on the breakdown of sales and the percentage that are direct to consumers compared to the percentage that are sales to restaurants, wholesalers, and others businesses.

- An establishment's direct sales to individual consumers at these platforms can be counted as sales to consumers.
- However, a direct sale to a business at these platforms cannot be counted as sales to consumers.
- Furthermore, a direct sale to a separate business that runs these platforms, rather than to specific buyers, would not be counted as sales to consumers because businesses (including businesses that run produce auctions) are not consumers (see Comments 15 and 17 in the Registration Final Rule; 81 FR 45912 at 45924).

B.2.18 I have a farm supply store that sells to both farms (i.e., businesses) and pet owners (i.e., consumers). What percentage of animal food sales to farms would require my store to register?

We challenge the premise of this question, and do not believe the registration requirement is properly applied to retail farm supply stores at all. Indeed, we contend that this interpretation of the registration requirement is new and not widely understood by farm supply stores. Moreover, this interpretation is illogical given that: (1) storage of processed animal food is a low-risk activity for which preventive controls and supplier programs are not scientifically justified, and (2) CGMPs are inapplicable to farm supply stores that do not manufacture animal feed.

There is no scientific justification for requiring these establishments to register with FDA and therefore become subject to all, or portions of, the Preventive Controls Rule for Animal Feed. We strongly urge that this issue be dealt with in separate outreach to the farm supply store community, instead of cursorily addressed in a guidance that few farm supply stores are likely to even consult. Until such outreach happens and appropriate regulations or guidance is developed informed by that

outreach, FDA should not enforce the Preventive Controls Rule for Animal Feed against farm supply stores, and should delete this Q&A from the guidance.

We further do not agree with FDA's assessment that all farms are appropriately categorized as "businesses" versus "consumers." The distinction between a "farm" and a "pet-owner" in this context is incredibly vague for a number of reasons. For example, some landowners may board animals on their property to take advantage of reduced property tax rates. Is that person a farm business, or a pet owner? Or what if a landowner has a small backyard flock of chickens on their residence and occasionally sells eggs to neighbors? Keeping track of the uses of animal feed products by their customers and the purposes of those customers' purchases will create untenable paperwork burdens for these small businesses. Therefore, if FDA must retain this Question, we urge FDA to cease categorizing all farms as "businesses" for purposes of calculating sales from a retail establishment, and to make the following changes to the response:

> To be considered a "retail food establishment" as defined in 21 CFR 1.227, the establishment's primary function must be to sell food directly to consumers. A retail food establishment's primary function is to sell food directly to consumers if the annual monetary value of sales of food directly to consumers exceeds the annual monetary value of sales of food to all other buyers (see 21 CFR 1.227). The term "consumers" does not include businesses~~, such as farms~~. Therefore, if more than 50% of a farm supply store's annual monetary value of sales of food is to consumers, such as pet owners and other individuals, then the farm supply store would meet the definition of a "retail food establishment" and would not be required to register. However, if more than 50% of a farm supply store's annual monetary value of sales of food is to other buyers that are businesses~~, such as farms~~, then the farm supply store would not meet the definition of a "retail food establishment" and would be required to register.

B.3.1 Are central kitchens that prepare food for a chain of restaurants considered to be restaurants and, therefore, exempt from registration?

We believe this is another example of new policy being created through this guidance that is novel and not well-understood by the affected industry. If central kitchens are part of the same business operation as a restaurant or retail food establishment, then they are not separate "facilities" and therefore should not be required to register with FDA, as they are already regulated by local health authorities. Such commissary kitchens are currently fully regulated by local health departments applying state-adopted Food Codes, and only exist to supply product for the "storefront" outlets of the business of which they are a part. Grocery retail food establishments as much as restaurants are adopting the model of central kitchens to produce prepared foods that are sold through consumer-facing outlets under the same ownership and management as the commissary kitchen. Indeed, some local health regulations require that food trucks have a commissary kitchen, inspected by the local health authority, as a base of operations. For these reasons, we propose the following changes:

> <u>If a</u> central kitchen <u>is under the same ownership and management as the restaurant(s) to which it is supplying prepared foods, then it is part of the restaurant and exempt from registration. Central kitchens that are independently owned and operated from the restaurants that they supply and</u> that do not sell the food they prepare directly to consumers for immediate consumption are not "restaurants," as defined in 21 CFR 1.227. Thus, they are not exempt, as restaurants, from registration.

B.6.1 Are facilities that process deer, elk, and bison required to register with FDA?

This is a very helpful question, but the response should be modified to provide clarity for the exemption from registration for facilities that are fully under USDA jurisdiction, as follows:

> Yes. Facilities that process deer, elk, and bison are required to register as a food facility with FDA because~~. D~~ deer, elk, and bison are species that are foods under FDA's jurisdiction. A facility that processes only cattle, sheep, swine, goats, horses, mules or other equines, or poultry, which are all regulated by USDA, would not be required to register with FDA. However, a ~~A~~ facility that processes deer, elk, or bison, as well as meat or poultry products under USDA jurisdiction, would not be exempt from registration because they are not regulated exclusively, throughout the entire facility, by USDA (21 CFR 1.226(g)).

This Q&A also presents a bigger question about what compliance looks like for those facilities that fall under joint jurisdiction of FDA and USDA. We strongly urge the agency to include a question that addresses how facilities in such situations can expect to be regulated.

C.1.2 Are small food producers or hobbyists who make food out of their home and also sell the food at farmers' markets or to other consumers required to register?; C.1.3 If berries are harvested, then made into jam at a private residence for sale at markets and to retail stores, does the producer have to register the private residence as a facility?

We appreciate these questions that address home kitchen or cottage food processing. However, we believe additional clarity is needed as to how the agency defines "customary expectations for a private residence." The responses to both Question C.1.2 and C.1.3 qualify the exemption from registration for private residence kitchens to those that meet "customary expectations for private residences," but do not provide examples as to situations that do or do not. Questions C.1.1 and C.1.5 provide examples that FDA does (food made for bake sales, storing Girl Scout cookies) or does not (making maple syrup in a detached garage that has been modified and can no longer serve to park cars, or in a separate building on the property) qualify as meeting these "customary expectations." We recommend that FDA provide additional guidance on what criteria it will use in determining whether a particular home kitchen use qualifies as meeting these "customary expectations" as a separate question in this guidance, as follows:

> Q: What does FDA consider to be the "customary expectations for a private residence"?
>
> A: Customary expectations for a private residence mean that the portion of the residence used for processing or storing food has not been modified substantially such that it can no longer be used for its original residential use. Whether a private residence is subject to inspection under state or local "cottage food" laws does not affect whether the residence satisfies the customary expectations for a private residence.

C.3.4 In a lessor-lessee relationship, such as a food-producing business that rents space from a landlord, who is legally obligated to register the facility?

We are concerned that this interpretation creates potential conflicts for operators of shared-use facilities, most of whose users typically qualify as retail food establishments, which, per Question B.2.7 above, are not required to register under these circumstances. In most cases the owner/operator of shared use kitchens do not themselves produce any food, and so cannot be

responsible for conducting food production in compliance with CGMPs, preventive controls, or supplier programs. Requiring them to register puts them in the untenable position of asserting control over the users of their facilities, or of forcing their users to register, even if those users are exempt from registration as retail food establishments. This outcome would also confuse FDA's enforcement system; FDA has stated that entities that are not required to register should not register. We therefore recommend that FDA make it clear that the owner of a shared use kitchen cannot and should not require exempt businesses to register with FDA.

C.3.11 Is a stockyard or livestock market required to register?

We question the appropriateness and necessity of requiring stockyards to register, given that their "holding" activities related to live animals are governed by USDA animal welfare standards, and that no food manufacturing/processing occurs at such stockyards. We strongly urge FDA to reconsider this interpretation of the registration requirement, as it is likely to do nothing more that create duplicative regulation for these establishments without delivering any public health benefit.

I.2 What information must be submitted in a cancellation?

We have heard from several farmers that have tried to cancel their registration, based on the changes made to the farm definition that they were told they had to provide a justification or reason for their cancellation. The list in the answer to Question I.2 does not include this requirement for a justification. We request the agency include a statement in the Q&A that clarifies that a written reason or justification is not required to be included in the information submitted when cancelling a registration, and make such information clear to field staff and FURLS helpdesk as well.

I.7 If I have registered with FDA but am not required to do so, do I have to cancel the registration, or will FDA cancel the registration?

We believe this question is very important, but find that – in its current form – it raises more questions than answers, particularly for farms that were required to register under the pre-2015 farm definition and are no longer required to do so under the revised definition. Given the persistent ambiguities surrounding the farm definition, and the fact that FDA has not finalized guidance on the definition (and based on Question O.5, might even be considering a separate rulemaking on the definition), we urge the agency to include a separate question specifically focused on farms that may have registered based on misinformation or insufficient information, as follows:

> Q: If I am a farm that has registered with FDA but am no longer required to do so based on the revised farm definition, do I have to cancel my registration, or will FDA cancel the registration?
>
> A: If your operation satisfies FDA's revised definition of farm (*see Q.X.X.X*), then you are not required to register. Therefore, you should cancel your registration with FDA within 60 days of your determination that you are not required to register.

We also note that the response to Question I.7 is confusing, because it answers "yes" to an either/or question. We recommend the following change:

> ~~Yes~~ In general, you are responsible for ~~must~~ canceling your registration within 60 calendar days of the reason for cancellation (see 21 CFR 1.235(a)). However, as specified in 21 CFR

1.241(c), we will cancel registrations if we independently verify that a facility is not required to register.

K.1 What are the consequences if an owner, operator, or agent in charge of a facility does not register, renew, update, or cancel the facility's registration, as required in section 415 of the FD&C Act and 21 CFR part 1, subpart H?

We believe this response should be modified to reflect FDA's position on enforcing the registration requirement against operations that are very close to meeting the secondary activities farm definition, to align with FDA's statements on the matter (for example in Question O.5) and the recent final rule extending compliance dates for those facilities (81 Fed. Reg. 57784), as follows:

> The failure of an owner, operator, or agent in charge of a facility to register its facility, renew the registration of its facility, update required registration elements of its facility's registration, or to cancel its registration in accordance with the requirements in 21 CFR part 1, subpart H is a prohibited act under section 301(dd) of the FD&C Act (21 U.S.C. 331(dd)). See 21 CFR 1.241(a). The United States can bring a civil action in Federal court to enjoin a person who commits a prohibited act. The United States also can bring a criminal action in Federal court to prosecute a person who is responsible for the commission of a prohibited act (21 CFR 1.241(a)). In addition, under section 306 of FD&C Act, FDA can seek debarment of any person who has been convicted of a felony relating to importation of food into the United States. <u>However, FDA does not intend to prioritize enforcing the registration requirement for certain facilities that would qualify as secondary activities farms except for the ownership of the facility, certain facilities that color RACs, and facilities solely engaged in the ginning of cotton.</u>
>
> If food being imported or offered for import into the United States is from a foreign facility for which registration has not been submitted, the food must be held at the port of entry and may not be delivered to the importer, owner, or consignee of the food until the foreign facility is registered. However, the food may be directed to a secure facility by FDA and/or U.S. Customs and Border Protection (CBP) (section 801(l) of the FD&C Act).

M.2 Is a registered facility responsible for ensuring that the companies with which they deal are registered?

We believe this question provides an opportunity for FDA to provide information to receiving facilities about the requirements of their suppliers. As we have raised to the agency in the past, and included in our comments on the proposed rules, we have serious concerns about both the legality of the onsite audit requirement in the final Preventive Controls Rule, and the pressure and duplicative requirements that it will place on produce farms. We therefore encourage the agency to use this opportunity to provide information to facilities regarding supplier requirements, as follows:

> There are no direct penalties for doing business with a company that is not registered. However, if a company offers food for import into the United States and the food is from a foreign manufacturing facility that is not registered, the company may be unable to complete the prior notice for the shipment (21 CFR 1.281(a)(6)), which is required to import the shipment.

For receiving facilities, if a supplier is a qualified facility or an exempt or qualified exempt farm under the Produce Rule, then an onsite audit of that supplier is not required. Rather, for qualified facilities, the receiving facility need only obtain the same attestations of the qualified facility that are required by FDA:

1. Written assurance (before approving the supplier, and annually thereafter) that the supplier satisfies the status of a qualified facility, and
2. Written assurance that the supplier is producing the raw material/ingredient in compliance with applicable FDA food safety regulation (at least every two years), including:
    - a brief description of the preventive controls that the supplier is implementing to control the applicable hazard in the food; or
    - a statement that the facility is in compliance with State, local, county, tribal, or other applicable non-Federal food safety law.

If a receiving facility has suppliers that are produce farms that are exempt or qualified exempt farms under the Produce Rule, the receiving facility must:

1. Obtain a written assurance (before approving the supplier and then annually thereafter) that the raw material/ingredient provided by the farm is not subject to the Produce Rule because the farm is exempt/qualified exempt; and
2. Obtains a written assurance (at least every two years) that the farm acknowledges that its food is subject to section 402 of the Federal Food, Drug, and Cosmetic Ac

We appreciate your consideration of these views, and look forward to continued engagement with the agency to ensure FSMA rules that can meet public health goals while supporting diverse and sustainable food and farm systems.

Sincerely,

Senior Policy Specialist
National Sustainable Agriculture Coalition