



## National Sustainable Agriculture Coalition

June 8, 2015

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

Docket No. FDA– 2002–N–0323

### **Re: Comments on Proposed Rule to Amend Regulations for Food Facility Registration**

On behalf of the represented members of the National Sustainable Agriculture Coalition (NSAC),<sup>1</sup> we submit the following comments on the proposed rule to amend the regulations for food facility registration. 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.

NSAC has been actively involved in many of the proposed FSMA rules, and in this case we are particularly concerned with this proposed rule's impacts on innovative, direct-to-consumer and intermediated market platforms that are driving the growth and development of local and regional supply chains. It is critical to our nation's public health, the economic viability of small and mid-sized farms and food enterprises, and the vitality of our rural communities that new food safety regulations work to support, not stifle, innovation and diversity in our food supply. We welcome the opportunity to submit comments, and look forward to working with the Food and Drug Administration to ensure that the regulations and their implementation are successful and supportive of sustainable agriculture and food systems.

Sincerely,

Sophia Kruszewski  
Policy Specialist

Ferd Hoefner  
Policy Director

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

## I. INTRODUCTION

NSAC has been waiting for this clarification for some time, and is pleased that FDA has finally released the proposed language for review. However, there are several aspects of the proposed rule that we find concerning, and we offer the following comments and recommendations. First, we comment on the proposed modification to the definition of “retail food establishment” and the confusion presented by disregarding congressional intent and restricting the modified language to establishments located on farms. Second, we respond to the agency’s request for comment regarding the supporting definitions of roadside stand, farmers market, and community supported agriculture. Finally, we provide comments on several aspects related to requirements for food facilities that must register with FDA, particularly regarding the classification of “farm mixed-type facility” as an activity; the electronic record requirement; civil and criminal penalties for failure to register, renew, or cancel registration; and the time period to update or cancel a registration.

## II. RETAIL FOOD ESTABLISHMENT DEFINITION

### A. Context for the FSMA language directing FDA to clarify the definition of “retail food establishment”

Concerned that new food safety regulations would inadvertently harm growing local and regional markets, and the small and mid-sized farm and food enterprises that comprise them, Congress included language in FSMA directing FDA to clarify the definition of “retail food establishment.”<sup>2</sup> In particular, Congress sought to ensure that sales through off-farm direct marketing platforms like farmers markets, CSAs, and farm stores were treated the same as direct-to-consumer sales from the farm. Accordingly, Congress included language in FSMA to protect enterprises selling direct to consumer from overly burdensome and inappropriately tailored regulations:

The Secretary shall amend the definition of the term “retail food establishment” in section in 1.227(b)(11) of title 21, Code of Federal Regulations to clarify that, in determining the primary function of an establishment or a retail food establishment under such section, the sale of food products directly to consumers by such establishment and the sale of food directly to consumers by such retail food establishment include--

- (A) the sale of such food products or food directly to consumers by such establishment at a roadside stand or farmers' market where such stand or market is located other than where the food was manufactured or processed;
- (B) the sale and distribution of such food through a community supported agriculture program; and
- (C) the sale and distribution of such food at any other such direct sales platform as determined by the Secretary.<sup>3</sup>

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<sup>2</sup> Food Safety Modernization Act § 102(c).

<sup>3</sup> *Id.*

## B. The proposed changes do not adhere to the letter or spirit of FSMA

### 1. *For farms, the establishment does not need to be located on the farm to qualify as a retail food establishment.*

FDA has interpreted FSMA's mandate as only being applicable to food sold "directly to consumers from an establishment located on a farm."<sup>4</sup> We strongly disagree with this interpretation. FSMA Section 102(c) had two aims: the first was to reinforce that CSAs, farmers markets, roadside stands, and other direct-to-consumer operations that sell the majority of their food directly to consumers are not facilities, do not have to register with FDA as facilities, and are not subject to the Preventive Controls Rule. The second aim was to clarify that the location of the direct sale could not trigger the facility definition – e.g., a farm that makes jam out of their strawberries for sale at the farmers market or inclusion in their CSA would not be considered a facility if the majority of those processing sales were direct to consumer. Foundational to this clarification was the intent that the law apply equally to direct sales from farms whether the sales occur on, or off, the farm. That is, the language applies the same to a CSA whether the CSA has an off-site drop-off or an on-site pick-up.

Yet, contrary to congressional intent, and without any basis or justification in the statutory language, the agency's proposed change to the definition would codify that differential approach to on and off farm sales that Congress sought to avoid. This approach is as equally flawed as the agency's approach to the definition of "farm," which draws unrealistic and potentially damaging limitations around what it considers "on" and "off" farm activity.

We will again emphasize that FDA has the authority and the obligation to modify the definition of "farm" to better reflect the reality that American farms are diverse in function and form. As we noted in our comments on the supplemental proposed Preventive Controls Rule:

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.<sup>5</sup> 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.<sup>6</sup> 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

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<sup>4</sup> 80 Fed. Reg. 19259, 19183 (April 9, 2015); proposed §1.227(b)(11).

<sup>5</sup> Food, Drug & Cosmetic Act §§418(k) and 419(h).

<sup>6</sup> See Appendix I, NSAC's 2013 Preventive Controls comments, regarding Congressional intent and FDA's broad authority to modify the farm definition to ensure that farms are not inappropriately regulated as facilities, at 25–27.

definition of “farm” still presents an unrealistic and incomplete understanding of how most farms in America are structured, in terms of their physical, spatial, and business composition.

In particular, we suggested – and continue to recommend – the following definition of “farm” to ensure that coverage under the FSMA rules is appropriate and consistent with congressional intent:

*Farm* means an ~~establishment~~ operation under the effective control of one or more farm operators 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~~
    - (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.

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*Jointly controlled farm business operation* means a business that supplies raw agricultural commodities and is majority controlled by two or more farm operators.<sup>7</sup>

Just as the “off” and “on” farm distinction in the farm definition creates an unworkable result, limiting the retail food establishment clarification to on-farm establishments codifies an unrealistic view of farm form and function, and flies in the face of congressional intent.

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<sup>7</sup> We supplied detailed justifications for each of the recommended changes in our comments on the supplemental proposed Preventive Controls Rule, pages 8–15.

As opposed to the proposed rule, FDA’s most recently published guidance on food facility registration properly integrated the FSMA language regarding retail food establishments.<sup>8</sup> The guidance states:

**Q:** How did FSMA clarify the definition of “retail food establishment?”

**A:** FSMA requires FDA to amend the definition of the term “retail food establishment” in 21 CFR 1.227(b) to clarify that, in determining the primary function of an establishment or a retail food establishment, the sale of food products directly to consumers by such establishment and the sale of food directly to consumers by such retail food establishment include:

- The sale of such food products or food directly to consumers by such establishment at a roadside stand or farmers’ market where such stand or market is located other than where the food was manufactured or processed.
- The sale and distribution of such food through a community supported agriculture program; and
- The sale and distribution of such food at any other such direct sales platform as determined by FDA.<sup>9</sup>

Nowhere in this guidance is there language limiting the clarification of “retail food establishment” to on-farm locations. Given the lack of any statutory language directing or justifying such a limitation, this result is logical, and in line with statutory intent. We recommend that FDA maintain consistency with its recent guidance that so clearly implements the intent and letter of the law, and strike the unnecessarily limiting language regarding farms from the proposed amendment to section 1.227(b).

**Recommendation:** Specifically, we recommend the following changes to the proposed definition of retail food establishment:

*Retail food establishment* means an establishment that sells food products directly to consumers as its primary function. A retail food establishment may manufacture/process, pack, or hold food if the establishment’s primary function is to sell from that establishment food, including food that is manufactures/process, packs, or hold, 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 products directly to consumers exceeds the annual monetary values of sales of food products to all other buyers. Sale of food directly to consumers ~~from an establishment located on a farm~~ includes sales by that establishment directly to consumers

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Moreover, we strongly believe that the clarity FDA seeks to provide to help farmers understand whether the registration requirements apply to them can and should be found in a thoroughly and

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<sup>8</sup> Guidance for Industry: Questions and Answers Regarding Food Facility Registration (Sixth Edition), Nov. 18, 2014, <http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm331959.htm>

<sup>9</sup> *Id.* at 5.1.

<sup>10</sup> We provide specific recommendations on subparts (i)–(iii) below.

thoughtfully revised definition of “farm.” Accordingly, we urge FDA to adopt our proposed changes to the “farm” definition above.

## *2. The direct marketing clarification should not be limited solely to farms.*

FDA has interpreted FSMA’s mandate as only being applicable to food sold “directly to consumers from an establishment located on a farm.”<sup>11</sup> We strongly disagree with this interpretation for an additional reason beyond that described above, which is: if you are a retail food establishment as per the definition, and you sell through a direct market channel, then it does not matter if you are a farm or not.

Congress directed FDA to make these changes in order to clarify what is and is not a “facility,” not to clarify what is or is not a “farm.” We appreciate FDA’s understanding of how this provision could apply to farms, and agree with the agency’s interpretation of how a farm mixed-type facility might avail itself of this clarification. But we caution the agency from unnecessarily limiting this language to farms. FSMA does not require this, and indeed Congress was aware of and sought to protect other types of innovative local food business models – like food hubs, buying clubs, or artisanal food entrepreneurs – from being subject to the facility registration requirement. Attempting to make this distinction between farm-based and non-farm-based establishments that deliver food to consumers through direct market channels only adds confusion and results in unfair treatment of non-farm-based businesses that make the majority of their sales direct to consumers. As detailed above, FDA’s own previously published guidance on food facility registration recognized that the language of FSMA does not limit the clarification of the RFE definition to on-farm businesses alone.

We certainly agree that farm mixed-type facilities are an important part of the universe of establishments Congress intended to protect as retail food establishments; we concur with FDA’s statement in the preamble that this clarification should “prevent” on-farm value-added operations selling primarily through local and regional markets from registering and being regulated as food facilities<sup>12</sup> and with the examples that FDA provides in the Q&A accompanying the proposed rule.<sup>13</sup> However, Congress neither implicitly intended nor explicitly directed FDA to limit this language to farms.

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<sup>11</sup> 80 Fed. Reg. 19259, 19183 (April 9, 2015); proposed §1.227(b)(11).

<sup>12</sup> *Id.* at 19165.

<sup>13</sup> FDA’s Q&A on the proposed changes to the retail food establishment language provides an example of how the retail food establishment language could apply to a farm:

**If I’m now a farm mixed-type facility, how will the proposed change to the definition of “retail food establishment,” if finalized, affect me?**

FDA uses the term “mixed-type facility” to refer to cases in which, for example, a farm grows oranges and processes them into orange juice for sale to a distributor. In that example, in which the establishment engages in both activities that are exempt from registration (the farm activities) and activities that require the establishment to be registered (the processing activities), the establishment is required to register because its processing activities are not covered by the farm definition. If, however, most of the orange juice is going to a local farmers market, the establishment could meet the proposed rule’s definition for a retail food establishment. Accordingly, the establishment would be exempt from the requirement to register under the proposed rule, if finalized. *See* Questions and Answers for Farmers on FSMA Proposed Rule for Food Facility Registration, Question 5; <http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm440992.htm>

Local and regional food entrepreneurs, producing a wide range of products from baked goods to granola to jams and jellies, are taking advantage of farmers markets and other direct marketing venues to distribute their products. In many cases, such as entrepreneurs making use of the shared-use commercial kitchens that have proliferated across the country as communities seek to harness the local food market to drive local economic growth, these local food businesses have no storefront from which to make sales. Yet the proposed limitation of the clarification at issue here to farms alone would force these businesses to register, even if 100% of their sales are direct to consumers, simply because these businesses either do not have a storefront for sales or otherwise depend on farmers market and other direct-to-consumer sales venues for the majority of their sales. Congress did not intend for this outcome.

**Recommendation:** As noted above, FDA should strike the limiting language proposed in the definition of retail food establishment as follows:

*Retail food establishment* means an establishment that sells food products directly to consumers as its primary function. A retail food establishment may manufacture/process, pack, or hold food if the establishment's primary function is to sell from that establishment food, including food that is manufactures/process, packs, or hold, 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 products directly to consumers exceeds the annual monetary values of sales of food products to all other buyers. Sale of food directly to consumers ~~from an establishment located on a farm~~ includes sales by that establishment directly to consumers . . .<sup>14</sup>

### III. SUPPORTING DEFINITIONS

#### A. Roadside Stand

FDA defines "roadside stand" as a "stand situated on the side of or near a road or thoroughfare at which a farmer sells food from his or her farm directly to consumers."<sup>15</sup> Specifically, FDA requests comment on the definition of "roadside stand" and whether there should be any distance limitations contained in the definition, i.e. 275 miles.<sup>16</sup>

NSAC has consistently stated – echoing the FSMA statutory language – that food safety rules must be risk-based, and we do not support arbitrary distinctions based on, for example, geographic factors. In this instance, the determination of whether sales through a roadside stand count toward the retail sales threshold for determining if an establishment is a retail food establishment (and so not subject to the facility registration requirement), the nexus between the risk to public health and the distance between a roadside stand and the place where the food sold at that stand was grown or produced has not been established. Therefore, we do not support the imposition of an arbitrary distance within which a roadside stand must be located, unless and until FDA can justify a risk-based need for such a limitation.

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<sup>14</sup> We provide specific recommendations on subparts (i)–(iii) below.

<sup>15</sup> 80 Fed. Reg. 19183.

<sup>16</sup> *Id.* at 19165.

We have also expressed the need for consistency across rules applicable to farms and food makers. Therefore, if FDA does identify a risk-based justification for a geographic limitation on the distance between a roadside stand and the location where crops or food sold at that stand were produced, we strongly recommend the agency parallel the language in this rule with the language that is part of the qualified exemption for direct marketing farms and food businesses, and limit sales from roadside stands to those roadside stands located either within the same state or within 275 miles of the farm.

**Recommendation:** Do not impose distance limitations on sales from roadside stands for the purposes of determining the status of a business as a retail food establishment that are not risk-based. If any risk-based limitations are justified and imposed, they should be consistent with existing language in the FSMA rules: that sales include those from roadside stands within the same state, or within 275 miles.

We also note that, in the supplemental proposed Preventive Controls rule, FDA acknowledged and proposed to do away with the distinction between packing and holding your own raw agricultural commodities (RACs) or the RACs of another farm. In so doing, FDA recognized the common practice among farms to pack or hold produce from neighboring farms to meet market demand. We assume, therefore, that the language in “roadside stand” referring to selling food “directly from his or her farm” was an oversight. It is certainly a common practice for farms operating roadside stands to sell product from neighboring farms in order to offer the widest possible variety of seasonal produce, and they may also offer other value-added goods from local food businesses. We urge the agency to correct this definition to be consistent with the agency’s current thinking on the issue, as reflected in the supplemental proposed Preventive Controls rule.

**Recommendation:** Ensure consistency across definitions and approaches to assessing farm activities by removing the language in the definition of “roadside stand” that refers to food “from his or her farm.” Specifically, we recommend the following changes to the definition of roadside stand in proposed section 1.227(b)(11)(i):

. . . a stand situated on the side of or near a road or thoroughfare at which a farmer sells food ~~from his or her farm~~ directly to consumers . . .

## **B. Farmers Market**

FDA defines “farmers market” as “a location where one or more local farmers assemble to sell food from their farms directly to consumers.”<sup>17</sup> FDA requests comment on the definition of “farmers market” and, as above, requests comment on whether the definition should be limited by distance.<sup>18</sup>

We reiterate here the same points as those above regarding arbitrary geographic restrictions on the definition of “farmers market” for the purposes of determining whether sales through such markets count toward the direct-to-consumer sales threshold for defining a business as a retail food establishment. If FDA can demonstrate that such a limitation is indeed risk based, than we would recommend that the restriction maintain consistency with other language in FSMA relating to direct-market sales, and limit the inclusion of sales to farmers markets within 275 miles of the farm, or within the same state.

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<sup>17</sup> *Id.* at 19183.

<sup>18</sup> *Id.* at 19165.



**Recommendation:** Do not impose distance limitations on sales from farmers markets that are not risk-based. If any risk-based limitations can be justified in the context of whether a business selling product through a farmers market will be classified as a retail food establishment, and are imposed, then they should be consistent with existing language in the FSMA rules: that sales include those from farmers markets within 275 miles or within the same state.

We again note the discrepancy in the definition of farmers markets posed here with the new thinking FDA demonstrated in the supplemental proposed Preventive Controls rule, discussed above: that farms can aggregate from other farms without triggering the facility definition. Therefore, we recommend the agency strike the language in the definition of farmers market that restricts sales to those “from their farms.” FDA has accepted the common practice of farms aggregating products from other farms, and the definitions here should reflect this new thinking.

We also note that some state laws – or the markets themselves – may place requirements on whether vendors can sell food from other farms, or whether non-farm vendors can even be present at the market. However, it may not always be the farmer selling at the market. By way of example, the Farmers Market Coalition defines “farmers market” as “a public and recurring assembly of farmers or their representatives, selling directly to consumers food which they have produced themselves.”<sup>19</sup> Given the diversity of farmers markets and their operational models, we urge the agency to avoid placing unnecessary and confusing restrictions on the definition of farmers market.

It is also important to note that there are non-farmers (i.e. local artisans, bakers, jam and jelly makers, etc.) that also sell through farmers markets, and the existence of such non-farmer vendors at a farmers market should not impact the determination of whether or not a location is considered a farmers market for purposes of determining whether sales through that market count in calculating whether an operation is a retail food establishment.

Moreover, as indicated by our comments above, non-farm local food entrepreneurs (i.e. artisan bakers that obtain their ingredients from local farms but do not make the product on a farm) may also sell primarily direct to consumer through farmers markets, and if they fit the definition of retail food establishment as set forth in the Food, Drug and Cosmetic Act, without the restriction to on-farm operations as proposed, then the retail food establishment designation should also apply to such operations.

**Recommendation:** Ensure consistency across definitions and approaches to assessing farm activities by removing the language in the definition of “farmers market” that refers to food “from his or her farm.” Specifically, we recommend the following changes to the definition of farmers market in proposed section 1.227(b)(11)(i):

. . . a location where one or more local farmers assemble to sell food ~~from their farms~~ directly to consumers . . .

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<sup>19</sup> See <http://farmersmarketcoalition.org/education/qanda/>, emphasis added. We do support FDA’s acknowledgment in the preamble that the assessment of whether the farmers market would be a retail food establishment is a separate calculation, and “this analysis is not affected by the proposed amendment and is similar to how the primary function would be determined at a grocery or convenience store.”

### C. Community Supported Agriculture (CSA)

FDA defines community supported agriculture (CSA) as “a program under which a farmer or group of farmers grows food for a group of shareholders (or subscribers) who pledge to buy a portion of the farmer’s crop(s) for that season. This includes CSA programs in which a group of farmers consolidate their crops at a central location for distribution to shareholders or subscribers.”<sup>20</sup> FDA requests comment on the definition.<sup>21</sup>

In general, we support this definition, and we appreciate FDA’s acknowledgment that multiple farms may consolidate or aggregate their products at a central location for distribution through a CSA. However, we urge the agency to consistently refer to CSA activities as relating to “food” throughout the definition, rather than “crops.” Crops may be considered only vegetative products, rather than including the full range of meat, eggs, or other products that may be sold through a CSA.

We also note that many CSAs are including food from non-farm producers in their shares. Again, taking the example of an artisan baker, a CSA may include a loaf of fresh bread made from local grains along with the weekly share of fruits and vegetables. The inclusion of food from non-farm producers should not impact whether the sales through the CSA can be counted for purposes of determining whether an operation is a retail food establishment.

**Recommendation:** Modify the definition of CSA to refer to “food” or “products” not “crops.” Specifically, we recommend the following changes to proposed section 1.227(b)(11)(ii):

CSA means a program under which a farmer or group of farmers grows food for a group of shareholders (or subscribers) who pledge to buy a portion of the farmer’s ~~crop(s)~~ food/products for that season. This includes CSA programs in which a group of farmers consolidate their ~~crops~~ food/products at a central location for distribution to shareholders or subscribers.

## IV. ADDITIONAL COMMENTS REGARDING RETAIL FOOD ESTABLISHMENTS

### A. Sales to consumers versus sales to businesses

FDA requests comment on whether the regulations should provide that sales to businesses, in addition to consumers, should be considered in determining the primary function of a retail food establishment. We appreciate the agency’s request for comment on this issue, and we believe it would certainly make sense to be consistent with the language that applies to direct sales from qualified exempt farms and facilities.

In FSMA, the retail food establishment clarification is limited to direct sales to consumers, which do not include businesses.<sup>22</sup> FDA’s request for comment on this issue is indicative of the agency’s willingness to consider modification of this language consistent with similar provisions related to farms and food businesses that primarily sell through direct markets in other portions of the FSMA rules. For example, the proposed FSMA rules for qualified exempt farms and facilities consider

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<sup>20</sup> 80 Fed. Reg. 19183.

<sup>21</sup> *Id.* at 19165.

<sup>22</sup> FSMA § 102(c)(2)(B).

sales that are direct to a “qualified end user,” defined by statute as a consumer, restaurant, or other retail food establishment that is located in the same state or within 275 miles and is purchasing the food for sale directly to consumers at the restaurant or retail food establishment. We think it would be reasonable for FDA to similarly consider sales to “qualified end users” when calculating sales for purposes of the retail food establishment. If the agency believes it has the general authority to make this change, we would certainly support them in doing so.

## **B. Sales of “food”**

As proposed, when determining the primary function of an on-farm establishment and whether it is a retail food establishment, you count the sales of “food” directly to consumers, “which would include both food that has been manufactured and processed, and food that has not ([RACs]).”<sup>23</sup> FDA requests comment on whether, “in light of the reference to ‘other than where the food was manufactured or processed’ in section 102(c)(1)(A) of FSMA or for other reasons, only the sale of processed foods off the farm should be considered in determining the primary function of an establishment located on a farm.”<sup>24</sup>

We strongly support FDA’s suggestion that only the sale of processed foods be considered in determining a business’ primary function for purposes of the classification of the operation as a retail food establishment. This interpretation is in line with both the statutory language in section 102(c)(1)(A), and the need for clarity and consistency across rules. In our comments on both the proposed and supplemental Produce and Preventive Controls rules, NSAC strongly urged the agency to base all sales thresholds used to determine a farm or food businesses’ status *only on sales of product actually covered by the respective rule*. Failure to do so not only causes confusion for farms subject to multiple rules, but also discourages diversity on farming operations. The same is true here.

Take the simple example of an apple orchard that sells \$600,000 in apples wholesale, \$50,000 in apples at a farmers market, and \$10,000 in apple pies at the farmers market. If this farm must consider sales of RACs and processed foods in determining their primary function, then they will not qualify for the retail food establishment exemption. This result frustrates the intent of the statute, which aimed to protect small and very small businesses from excessive and burdensome regulatory requirements. It also is nonsensical, given that FDA has acknowledged that the Preventive Controls Rule only applies to a farm mixed-type facility’s processing activities, not its “farm” activities. It is therefore illogical to factor in sales of RACs when assessing the portion of a value-added processing operation’s sales that are direct to consumer. Accordingly, we encourage the agency to codify this language to distinguish sales of processed foods.

**Recommendation:** Modify the language regarding the “sale of food” in the last line of the retail food establishment definition, section 1.227(b)(11) to read “sale of manufactured or processed food.”

## **C. Other direct market platforms**

FDA provides a list of “other direct market platforms” and requests comment on the list. The list is non-exhaustive and includes “door-to-door sales; mail, catalog and internet order, including online

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<sup>23</sup> 80 Fed. Reg. 19166.

<sup>24</sup> *Id.*

farmers markets and online grocery delivery; religious or other organization bazaars, and State and local fairs.”<sup>25</sup> We think that this list is a good start, and would encourage the agency to keep the list non-exhaustive, given the rate at which novel, innovative direct marketing businesses are developing and adapting to consumer demand.

For instance, it is important to note that there are many innovative non-farm food businesses adapting the CSA model to their business. One example is community-supported bakeries, where bakers sell subscriptions to members that guarantee those members regular delivery of breads and other baked goods. Another is buying clubs, where consumers organize themselves to procure bulk quantities of food from local farms and food vendors and divide the products purchased among themselves. There are many similar emerging models of local, direct-to-consumer food distribution, where the ‘establishment’ in question may not even have a ‘storefront’ at their business location from which to make direct-to-consumer sales. It would be inconsistent with Congressional intent in the Bioterrorism Act and FSMA to fail to classify sales through these channels as direct-to-consumer.

It is critical to the continued growth of local and regional food markets that FDA does not inadvertently stifle innovation in these new markets by limiting FSMA’s clarification of direct market platforms only to farm businesses. Congress made it clear in FSMA that new food safety rules are to minimize the burden on small and very small businesses, and this consideration should carry over to the retail food establishment clarification as well.

**Recommendation:** Make the following changes to section 1.227(b)(11)(iii): “other such direct-to-consumer sales platforms, including, but not limited to buying clubs; non-farm community supported food distribution models; food hubs; door-to-door sales; mail, catalog and Internet order, including online farmers markets and online grocery delivery; religious or other organization bazaars; and State and local fairs.”

## V. REGISTRATION REQUIREMENTS

### A. Farm mixed-type facility activity classification

FDA is proposing changes to “improve the utility of the food facility registration database” by requiring certain additional data elements in registrations that is currently optional.<sup>26</sup> This includes the type of activity conducted at the facility, which includes a specific activity classification for “farm mixed-type facility.”<sup>27</sup> FDA notes that this classification is important to “help the agency efficiently inspect farm mixed-type facilities, [because] the expertise required to inspect such facilities may differ from the expertise required to inspect non-farm manufacturing/processing facilities.”<sup>28</sup>

We appreciate FDA’s acknowledgment of the need for specialized inspections for farm mixed-type facilities. As we have discussed with the agency on multiple occasions, on-farm FDA inspections have proven to be complicated, awkward, frustrating, and anxiety-inducing events. We appreciate FDA’s commitment to training inspectors on appropriate farm inspection protocol, but we

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<sup>25</sup> 80 Fed. Reg. 19183.

<sup>26</sup> *Id.* at 19164.

<sup>27</sup> *Id.* at 19174.

<sup>28</sup> *Id.*

recognize that the impacts of that training effort may still be years away. Meanwhile, farms continue to experience awkward and, at times, inappropriate visits from inspectors that are untrained and unable to properly inspect and provide guidance to the farmer. This is compounded by the fact that FDA has yet to fully explain how “farm mixed-type facilities” will be determined, and how FDA will proceed with implementation and compliance activities in way that follows FSMA’s mandate to avoid the duplication of regulatory burdens under the Produce and Preventive Controls Rules for these operations. Given these factors, it is critical that FDA provide a detailed implementation plan unique to farm mixed-type facilities, and conduct significant outreach and education to farms so they understand how to register, and what expectations there are regarding compliance and enforcement activities.

We also note that the agency has already identified a list of low-risk food/activity combinations, and we would encourage the agency to ensure that inspectors and others involved in determining inspection frequencies are thoroughly trained in low-risk combinations to ensure the most effective and efficient use of government resources in deploying inspectors to farm mixed-type facilities (or non-farm facilities) doing only those low-risk food/activity combinations.

**Recommendation:** Develop, with stakeholder input, an implementation plan for farm mixed-type facilities. This should include outreach and education plans to help farms understand the registration process, in particular how to select the food and activity classifications are appropriate to their operation and avoid misclassification; timelines and activities for farm and inspector training; and details on how the agency will carry out compliance and enforcement activities on farm mixed-type facilities to avoid duplicative regulatory burdens on those operations, including considerations for those doing only low-risk food/activity combinations.

## **B. Electronic registration requirement**

FDA requests comments on the waiver of the electronic registration requirement.<sup>29</sup> We acknowledge that FSMA allows FDA to require all registration to be electronic, and we appreciate the agency’s sensitivity to the fact that there are individuals or entities for whom electronic registration is not an option. However, FDA states that the primary reasons for this are “conflicting religious beliefs, or no reasonable access to the internet.”<sup>30</sup> We submit that conflicting religious beliefs are not necessarily the only beliefs that lead an individual or entity to decide not to use technology; it may also be philosophical or political. Accordingly, we support the waiver requirement, but would urge the agency to avoid limiting the waiver only to those with conflicting *religious* beliefs.

**Recommendation:** Expand the waiver for electronic registration beyond “conflicting religious beliefs” to include philosophical and political beliefs.

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<sup>29</sup> *Id.* at 19167.

<sup>30</sup> *Id.* at 19177.

### C. Criminal/civil penalties for failure to renew or register on time

The proposed rule also amends existing regulations regarding the consequences of failing to register, update, or cancel a food facility registration.<sup>31</sup> These consequences include both civil and criminal penalties.<sup>32</sup> We strongly urge the agency to ensure that there is significant outreach, education, and clear information regarding the registration process prior to enforcing these new requirements.

FDA has acknowledged to us, and acknowledges in the preamble to this proposed rule, that the registration program has been problematic, particularly for farms. There are cases of farms that have involuntarily registered due to pressure from poorly-trained inspectors, the action of inspectors to register an establishment without the knowledge of its operators, or bad advice from third parties that provide misleading or inaccurate information. Such operations cannot be penalized for failure to cancel an unnecessary registration. That is just one example, but this kind of misinformation has been going on for years, and so there must be significant work done now to explain the registration process to small and very small businesses, and particularly to farms. These problems must be worked out and evidence shown that problems have been addressed before imposing civil or criminal penalties on entities newly subject to registration requirements.

We recommend the agency begin these outreach actions with respect to the registration requirements immediately, in cooperation with organizations that have the trust of farmers, and ensure sufficient outreach and education is underway before imposing any kind of penalty for failure to register, update, or cancel a registration. There must be significant clarity regarding which farms must register, both for farmers and regulators, before any penalties regarding registration are enforced.

**Recommendation:** Undertake significant outreach and education on the issue of facility registration, particularly to address the misinformation and confusion surrounding farms that must register. Refrain from imposing civil or criminal penalties for failure to register, renew, or cancel a registration – and make it clear that these provisions will not be enforced – until such outreach and education is well underway.

### D. Time period to update or cancel registration

For the same reasons as expressed in section V.C. of these comments above, we strongly oppose the requirements in the proposed § 1.234(a) and § 1.235(a) to reduce the amount of time facilities have to record changes in their status or cancel their facility registration from 60 to 30 days. With the significant amount of work that needs to be done now to explain the registration process to small and very small businesses, and particularly to farms, reducing the amount of time businesses have to make changes in their registrations would be counterproductive and damaging to small and very small businesses, without providing any commensurate benefit to public health. If anything, the time period should be increased to 90 days.

**Recommendation:** Increase the time period allowed for facilities to update (§ 1.234(a)) or cancel (§ 1.235(a)) their registrations from 60 to 90 days.

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<sup>31</sup> *Id.* at 19168.

<sup>32</sup> *Id.*