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Rockville, MD 20582

Docket No. FDA 2011-N-0921  
RIN 0910-AG35

Sent via electronic submissions on the Federal eRulemaking Portal: [www.regulations.gov](http://www.regulations.gov)

**Re: Comments on FDA Proposed Rule for the Standards for Growing, Harvesting, Packing, and Holding of Produce for Human Consumption, 78 Federal Register 3504 (January 16, 2013)**

To Whom It May Concern,

These comments on the Food and Drug Administration's (FDA) Proposed Rule for the Standards for Growing, Harvesting, Packing, and Holding of Produce for Human Consumption (Produce Safety Rule) are submitted on behalf of the Harvard Law School Food Law and Policy Clinic (FLPC).

The FLPC was established in 2010 in order to link Harvard Law students with opportunities to provide pro bono legal assistance to individuals and communities on various food policy issues. The Clinic aims to increase access to healthy foods, prevent diet-related diseases such as obesity and type 2 diabetes, and assist small and sustainable farmers and producers in participating in local food markets. As such, we are concerned that the proposed rules will disproportionately impact the types of operations we seek to serve. The rules as currently written do not adequately take into account the realities of these small- and mid-sized farmers and producers. These operators are crucial to the U.S. food system: they increase the diversity of our food system; provide additional sources of fresh fruits and vegetables for a variety of markets; and are economic drivers, often playing an integral role in rural (and increasingly urban and suburban) economies. Our work on this topic is closely connected to the work of the National Sustainable Agriculture Coalition (NSAC), and therefore, we give our support to the comments submitted by NSAC and their member organizations.

Congress stated in the legislative history of the Food Safety Modernization Act (FSMA) that one goal of FSMA is to create standard on-farm practices that will improve the safety of the nation's fresh produce supply in a way that accommodates the diversity of farming operations. The FLPC recognizes the magnitude and complexity of the task delegated to FDA and commends FDA for its efforts to write regulations that take into consideration the various sizes and types of agricultural operations across the country. There are, however, a number of places where the proposed rule can be strengthened to better accommodate the realities of small- and mid-sized diversified farming operations, particularly around the qualified exemption provisions.

The proposed rules are incredibly complex and although our comments address numerous issues, we feel more time is needed to wrestle with the complexity and to identify the nuances of the rules. Therefore, we urge FDA to issue a second proposed rule that will give the public another opportunity to comment. Other issues may arise after FDA addresses the comments to this proposed rule and thus immediately issuing a

final rule, or even an interim final rule, will not be adequate for ensuring a robust set of food safety regulations.

We have included an appendix to these comments that provides proposed modified language based on our comments.

Thank you for your consideration of the FLPC's comments and recommendations on this proposed rule.

Sincerely,



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### **Acknowledgements**

These comments were written in collaboration with Ariane Lotti, of the National Sustainable Agriculture Coalition, and are based on the contributions of and conversations with members of the National Sustainable Agriculture Coalition Food System Integrity Committee.

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## I. Comments on the Organizing Principles in the Preamble

In the Preamble to the proposed Produce Safety Rule, FDA has set out five “organizing principles” to help the FDA distinguish which activities trigger the Produce Safety Rule and which activities trigger the Preventive Controls Rule. The five organizing principles focus on a farm’s relationship to and actions involving raw agricultural commodities (RACs). It is crucial that these principles reflect and include the diversity of modern farming practices.<sup>1</sup> The five organizing principles are as follows:

- (1) The basic purpose of farms is to produce RACs and RACs are the essential products of farms.
- (2) Activities that involve RACs and that farms traditionally do for the purposes of growing their own RACs, removing them from the growing areas, and preparing them for use as a food RAC, and for packing, holding and transporting them, should all be within the definition of “farm.”
- (3) Activities should be classified in part on whether the food operated on is a RAC or a processed food, and on whether the activity transforms the RAC into a processed food.
- (4) Activities farms may perform on others’ RACs should appropriately be classified as manufacturing/processing, packing, or holding in the same manner as these activities are classified off-farm when the RACs are to be distributed into commerce.
- (5) Manufacturing/processing, packing, or holding food—whether RACs or processed foods, from any source—for on the farm should remain within the farm definition.<sup>2</sup>

In a number of ways, FDA’s organizing principles have neglected to take into account many of the realities of modern farming. These narrow principles fail to recognize the diversified nature of many farming operations; because these principles are the foundation upon which the Produce Safety Rule requirements rest, it is imperative that FDA reconsider its organizing principles and amend them to accurately reflect common farming practices.

### 1. FDA should amend the organizing principles to include the marketing and sale of RACs as integral to farm operations.

As expressed in the Produce Safety Rule Preamble’s first organizing principle for these definitions, FDA has concluded that “the basic purpose of a farm is to produce RACs.”<sup>3</sup> This purpose does not completely reflect modern farming; no food and agricultural business is serving its “basic purpose” if those RACs do not make their way to consumers. FDA omits half of a farm’s central focus—getting food to customers—and reinforces that omission explicitly in the second and fourth guiding principles.<sup>4</sup> In the second guiding principle, FDA lists traditional farm activities but excludes any mention of sales and getting the RACs to consumers.<sup>5</sup> Regarding the fourth guiding principle, FDA explains that “the essential purpose of a farm is to produce its own RACs, not to handle RACs grown on unrelated farms for distribution into commerce.”<sup>6</sup> In these principles, FDA undercuts the capacity of the Produce Safety Rule to account for the farm or farm mixed-type facility (an operation that conducts both farm and facility activities) as a market participant—a purpose that affects all farming activities from seed to sale.

We are concerned that FDA’s definitions ignore some important direct and intermediated marketing

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<sup>1</sup> 78 Fed. Reg. at 3541 (Preamble).

<sup>2</sup> 78 Fed. Reg. at 3540-3541 (Preamble).

<sup>3</sup> 78 Fed. Reg. at 3541 (Preamble).

<sup>4</sup> 78 Fed. Reg. at 3541 (Preamble).

<sup>5</sup> 78 Fed. Reg. at 3541 (Preamble).

<sup>6</sup> 78 Fed. Reg. at 3541 (Preamble).

practices used by small- and mid-sized producers. These farmers are increasingly using direct-sales and other intermediated-marketing platforms to sell their products. The organizing principles neglect to include certain activities that constitute traditional farming practices by leaving out the marketing and sales (i.e., business) element of agricultural production, focusing only on harvesting, packing, and holding.<sup>7</sup>

**Recommendation:** In the final Produce Safety Rule, FDA should amend the first organizing principle by adding language that expressly includes commerce as an integral part of a farming operation. Further, FDA should amend the second organizing principle to include delivery to customers and buyers as an integral part of a farming operation. We provide specific recommended changes to the language of the Preamble in the appendix to these comments.

## II. Comments on Coverage Provisions in Subpart A—General Provisions

### 1. FDA should clarify the Produce Safety Rule’s coverage provisions.

The Produce Safety Rule applies to “covered farms” doing “covered activities” on “covered produce.”<sup>8</sup> The proposed sections in the Produce Safety Rule dealing with coverage can be clarified to ensure farmers are able to easily understand whether, and how, the regulations apply to them.

#### *Covered Farms*

In § 112.4, FDA describes which farms are subject to the requirements of the Produce Safety Rule:

(a) Except as provided in paragraph (b) of this section, if you are a farm or farm mixed-type facility with an average annual monetary value of food (as “food” defined in § 112.3(c)) sold during the previous 3-year period of more than \$25,000 (on a rolling basis), you are a “covered farm” subject to this part. If you are a covered farm subject to this part, you must comply with all applicable requirements of this part when you conduct a covered activity on covered produce.

(b) You are not a covered farm if you satisfy the requirements in § 112.5 and we have not withdrawn your exemption in accordance with the requirements of Subpart R of this part.<sup>9</sup>

This section is confusing in two main ways. First, FDA asserts that you are not covered by the Produce Safety Rule “if you satisfy the requirements in § 112.5.”<sup>10</sup> However, farms that satisfy the requirements of § 112.5 are considered “qualified exempt farms” and are subject to modified requirements, and may have their exemption withdrawn. It is misleading to say that farms satisfying the requirements of § 112.5 are “not covered.” It is critical that FDA use terms carefully; “covered,” “non-covered,” and “covered-but-exempt” refer to very different states under the Produce Safety Rule. Farms making over \$25,000 doing covered activities to covered produce are *covered* by the Produce Safety Rule. Farms making less than \$25,000 are *not covered* (meaning not subject to any provisions under the Produce Safety Rule). Farms that are eligible for the qualified exemption are *covered-but-exempt* (because they do covered activities on covered produce, but are exempt under the Tester-Hagan amendment); these farms are still required to comply with certain requirements under the Produce Safety Rule. The Produce Safety Rule should be revised to reflect consistency in the use of terms indicating coverage.

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<sup>7</sup> 78 Fed. Reg. at 3541 (Preamble).

<sup>8</sup> 78 Fed. Reg. at 3632 (Sub. A § 112.4(a)).

<sup>9</sup> 78 Fed. Reg. at 3632 (Sub. A § 112.4).

<sup>10</sup> 78 Fed. Reg. at 3632 (Sub. A § 112.4(b)).

Second, the Produce Safety Rule purports to only cover farms or farm mixed-type facilities whose annual sales of food are over \$25,000 in the last three years.<sup>11</sup> In §112.4(b), the rule explicitly states that qualified farms (defined in § 112.5 as those that have average annual sales of less than \$500,000 and sell more than half of their sales to qualified end-users) are *not covered*.<sup>12</sup> However, the rule does not explicitly mention that farms with sales below the \$25,000 threshold are not covered by the Produce Safety Rule. Therefore, the farmer is left to infer that a farm with under \$25,000 in annual food sales over the last three years is not covered at all.<sup>13</sup> This is important because, unlike farms and farm mixed-type facilities that have a qualified exemption that can be withdrawn, if a farm is *not covered at all*, it will never be subject to the provisions of the Produce Safety Rule.<sup>14</sup> The fact that farms below the \$25,000 threshold cannot be subject to any “withdrawal” and may never be asked to come into compliance with the Produce Safety Rule is not expressly stated in the proposed rule.

**Recommendation:** First, FDA should modify the language in § 112.4 to clearly define which farms are “covered,” “not covered,” or “covered but exempt.” FDA should also add language to the final Produce Safety Rule that expressly states that farms with less than \$25,000 in annual sales are not covered by the Produce Safety Rule. We provide specific recommended changes to the language of Subpart A in the appendix to the comments.

#### *Covered Activities*

The Produce Safety Rule only applies to farms doing “covered activities.” Covered activity is defined in the rule as:

growing, harvesting, packing, or holding covered produce, provided that all covered produce used in covered packing or holding activities is grown, raised or consumed on that farm or another farm under the same ownership. Covered activity does not include manufacturing/processing within the meaning of this chapter.<sup>15</sup>

The rule attempts to distinguish between activities that make an operation a “farm” and subject to the Produce Safety Rule (e.g., growing, harvesting, packing, or holding covered produce), and activities that make an operation a “facility” and subject to the Preventive Controls Rule (e.g., manufacturing and processing).<sup>16</sup> However, the distinction between these categories of activities can be confusing. Certain activities that are listed as farming activities in the Produce Safety Rule, such as holding covered produce, are activities that the FDA also considers to be facility activities in certain circumstances. For example, farmers that hold their own covered produce are considered farms (because that activity is a “covered activity”); however, farmers that hold another farm’s covered produce are considered facilities, because the covered produce is not the farm’s own product.

The distinction between “farm” and “facility” activities is critical. The Produce Safety Rule defines a third category of operation, the farm mixed-type facility, which is “an establishment that engages in both activities that are exempt from registration under § 415 of the Federal Food, Drug, and Cosmetic Act (FDCA) and activities that require the establishment to be registered.”<sup>17</sup> This means that a farm mixed-

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<sup>11</sup> 78 Fed. Reg. at 3632 (Sub. A § 112.4).

<sup>12</sup> 78 Fed. Reg. at 3632 (Sub. A §§ 112.4(a), 112.5).

<sup>13</sup> 78 Fed. Reg. at 3632 (Sub. A § 112.4).

<sup>14</sup> Michelle Smith for the U.S. Food & Drug Admin., *Proposed Rules under the FDA Food Safety Modernization Act*, an FDA/NOC Webinar (2/28/2013), available at <http://instantteleseminar.com/?eventID=38205750>.

<sup>15</sup> 78 Fed. Reg. at 3630 (Sub. A § 112.3(c)).

<sup>16</sup> 78 Fed. Reg. at 3630 (Sub. A § 112.3(c)).

<sup>17</sup> The Produce Safety Rule covers the “farm” portion of a “farm mixed-type facility,” which is to say the part of a processing facility exempt from registration under FDCA § 415. 78 Fed. Reg. at 3631 (Sub. A § 112.3(c) (“Mixed-type facility”). Processing activities trigger FDCA § 415 registration, which triggers § 418 (the Preventive Controls Rule), which makes a farm a

type facility is subject to both rules (barring any exemptions). Because certain activities can be classified as both farming and manufacturing/processing (for example, washing RACs), farms and farm mixed-type facilities need to understand which activities keep their operation within the Produce Safety Rule and which activities will trigger the Preventive Controls Rule. This is significant because a farmer may think that he or she is exempt from regulatory compliance under the Produce Safety Rule, but actually be required to comply with the requirements of the Preventive Controls Rule. Farmers may not realize that they are crossing into the Preventive Controls Rule's jurisdiction because the commonality of these actions may be intrinsic to modern farming practices (e.g., holding another farm's RACs). Further, there are many common farming activities that are currently excluded from the definition of covered activity that need to be included, so as to reduce the number of ways a farm could unnecessarily be considered a facility.

The definitions of each of those covered activities (found in § 112.3) provide some guidance, but there is still a significant amount of confusion around what activities exactly will count as farming and what activities will count as manufacturing and processing.

**Recommendation:** In the final Produce Safety Rule, FDA should expand the definition of “covered activity” in § 112.3 to include as many common farming practices in the definitions of “covered activity” as possible so that farmers do not unnecessarily trigger the Preventive Controls Rule. We provide specific recommended changes to the language of Subpart A in the appendix to the comments.

#### *Covered Produce*

The Produce Safety Rule distinguishes between raw agricultural commodities that are “covered” produce, listed under § 112.1(a), and those that are “not covered” produce.<sup>18</sup> Among the foods that are not covered are foods grown by an individual for on-farm consumption and foods rarely consumed raw, listed under § 112.2(a).<sup>19</sup> There is an additional exemption for foods that are covered produce but that are subject to a processing kill-step, which “adequately reduces the presence of microorganisms of public health significance.”<sup>20</sup>

The placement of the provisions that describe covered and not covered produce in § 112.1(a) and covered-but-exempt produce subject to a kill-step in § 112.2(a), makes it confusing and difficult to determine whether something is not covered, covered, or covered-but-exempt. Separating the coverage provisions into three separate sections would clarify which types of commodities are completely outside the scope of the rule, which commodities are covered and subject to the rule, and which commodities are covered-but-exempt from most of the Produce Safety Rule's requirements.

**Recommendation:** In the final Produce Safety Rule, FDA should ensure that the provisions dealing with what food is covered and what food is not covered are clear and distinct, so as to avoid any confusion. All of the provisions dealing with what food is covered by the rule should be in one section, while all the provisions dealing with what food is not covered should be in a separate section. Specifically, FDA should move § 112.2(b)—which deals with covered produce that is eligible for an exemption based on use of a kill-step—out of the section that discusses what produce is *not* covered, and move it into § 112.1, which discusses what food *is* covered, to clearly indicate that covered produce subject to a kill-step is still covered by the Produce Safety Rule and subject to modified requirements. We provide specific recommended changes to the language of Subpart A in the appendix to the comments.

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mixed-type facility. See 78 Fed. Reg. at 3631 (Sub. A § 112.3(c)). So, only the “farm” activities of the mixed-type facility are covered by the Produce Safety Rule.

<sup>18</sup> 78 Fed. Reg. at 3629 (Sub. A § 112.1(a)).

<sup>19</sup> 78 Fed. Reg. at 3629 (Sub. A § 112.1(a)).

<sup>20</sup> 78 Fed. Reg. at 3630 (Sub. A § 112.2(b)).

## **2. FDA should only count sales of *covered produce* when determining whether a farm is under the \$25,000 average annual sales threshold.**

We commend FDA for excluding from coverage farms that have average annual sales of less than \$25,000. As FDA noted in the Preamble to the Produce Safety Rule, these operations “do not contribute significantly to the produce market and, therefore, to the volume of production that could become contaminated,” and are therefore not covered by the rule.<sup>21</sup> However, the way the rule is written now will prevent some of these very small operations from qualifying for this exclusion.

The Produce Safety Rule asserts that a farm will be covered if the farm’s average annual monetary value of *food* (as defined in § 112.3 of the Produce Safety Rule) sold over the last three years is more than \$25,000.<sup>22</sup> In § 112.3(c), “food” is defined as “food as defined in section 201(f) of the Federal Food, Drug, and Cosmetic Act and includes seeds and beans used to grow sprouts.”<sup>23</sup> Section 201(f) of the FDCA, in turn, defines “food” as “(1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article.”<sup>24</sup> The definition of *food* is very broad and may include food that is not covered by the Produce Safety Rule. This could be a problem for producers that have part of their operation growing non-covered food (such as commodity corn and soybeans, or dairy operations) and another part growing covered produce.

According to the way the Produce Safety Rule is written now, if the producer’s sale of food (both non-covered food and covered produce) exceeds \$25,000, the producer will be subject to the Produce Safety Rule even if the sales from covered produce are less than \$25,000. By changing the word “food” to “covered produce,” FDA would allow producers that may have other “food” operations not covered by the Produce Safety Rule to remain excluded from the Produce Safety Rule if their covered produce operation is small.

**Recommendation:** FDA should add language to § 112.4 that clearly states that only sales of covered produce are to be counted when calculating whether a farm is not covered due to having less than \$25,000 a year in sales. We provide specific recommended changes to the language of Subpart A in the appendix to the comments.

## **3. FDA should clarify whether farms growing non-covered produce would ever be required to come into compliance with the Produce Safety Rule.**

As discussed above, the Produce Safety Rule only applies to “covered produce.” Foods that are rarely consumed raw, listed under § 112.2(a), are not covered by the rule.<sup>25</sup> FDA’s rationale is that these vegetables will most often be cooked, thereby reducing the risk of foodborne illness.<sup>26</sup> The Produce Safety Rule does not address whether farms that grow non-covered produce can ever be required to come into compliance with the Produce Safety Rule. Are farmers who grow only non-covered foods (e.g., rarely consumed raw produce) fully outside the scope of the rule or might they be subject to a withdrawal of their “exemption” from it? For example, what if there is a foodborne illness outbreak linked to Brussels sprouts (listed as rarely consumed raw); will that farm be required to come into compliance with the Produce Safety Rule?

**Recommendation:** FDA should clarify whether farms growing non-covered produce could ever be

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<sup>21</sup> 78 Fed. Reg. at 3529 (Preamble).

<sup>22</sup> 78 Fed. Reg. at 3632 (Sub. A § 112.4).

<sup>23</sup> 78 Fed. Reg. at 3631 (Sub. A § 112.3(c)).

<sup>24</sup> Federal Food, Drug and Cosmetic Act § 201(f), 21 U.S.C. § 321(f) (2012).

<sup>25</sup> 78 Fed. Reg. at 3629 (Sub. A § 112.1(a)).

<sup>26</sup> 78 Fed. Reg. at 3524 (Preamble).

required to come into compliance with the Produce Safety Rule, if, for example, there is a foodborne illness outbreak linked to that farm. If FDA intends these farms to be entirely outside the scope of the Produce Safety Rule, FDA should make that clear in the Produce Safety Rule.

### III. Comments on the Modified Requirements for Qualified Exempt Farms in Subpart A—General Provisions

#### 1. FDA should clarify whether operations with qualified exemptions need to keep records.

Under the proposed Produce Safety Rule, covered farms are required to keep records to show compliance with the standards set out in the proposed rule.<sup>27</sup> The rule is very clear about the types of records those covered farms are required to keep. However, FDA does not require qualified farms and farm mixed-type facilities to keep records or to submit documentation proving the operation qualifies for the exemption. There is no record-keeping, submission, qualification, or approval *process* outlined in the proposed rule,<sup>28</sup> but the Produce Safety Rule implies that certain records must be kept on file to justify an exemption *upon FDA's request*.<sup>29</sup>

In Subpart R (Withdrawal of Qualified Exemption), FDA states that when appealing an order to withdraw the qualified exemption, the owner, operator, or agent in charge of the farm must “respond with particularity to the facts and issues contained in the order, *including any documentation upon which the owner, operator, or agent in charge of the farm relies.*”<sup>30</sup> FDA does not provide any further information about what those documents need to be. If FDA is going to rely on a certain type of record/document, then FDA should list these documents in the language of the Produce Safety Rule. At the least, FDA should be explicit about its requirement to keep records that prove a farm’s qualified exempt status and be clear that it will require records to refute a withdrawal order. We discuss this issue again in the comments to Subpart R (below).

**Recommendation:** FDA should add a provision to the final Produce Safety Rule clarifying exactly what types of documents a farm with a qualified exemption should keep in case their exemption comes under question. We provide specific recommended changes to the language in the appendix to the comments.

### IV. Comments on the Withdrawal of Qualified Exemptions in Subpart R

We applaud Congress and the FDA for providing qualified exemptions for farms that participate in local and regional food systems across the United States. The Tester-Hagan Amendment was an important addition to the Food Safety Modernization Act and it is critical that the spirit and intention of Congress to exempt these farms are upheld in the regulations.

However, the proposed Produce Safety Rule’s process for withdrawing a qualified exemption from a farm currently does not consistently uphold the spirit and intention of Congress and the Tester-Hagan Amendment. We recognize that FDA should have the authority to require a farm to come into compliance with the Produce Safety Rule if that farm is directly linked to a foodborne illness outbreak or there is a high risk to the public health from produce from that farm. However, the consequences of an order to withdraw are significant for these qualified exempt farms. It is thus imperative that the process to

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<sup>27</sup> 78 Fed. Reg. at 3634 (Sub. C § 112.30) (Standards Directed to Personnel Qualifications and Training); 3636 (Sub. E § 112.50) (Standards Directed to Agricultural Water); 3637 (Sub. F § 112.60) (Standards Directed to Biological Soil Amendments of Animal Origin and Human Waste); 3640 (Sub. L § 112.140) (Standards Directed to Equipment, Tools, Buildings, and Sanitation); 3641 (Sub. M § 112.150) (Standards Directed to Sprouts); 3642 (Sub. O §§ 112.161-167) (Requirements Applying to Records That You Must Establish and Keep).

<sup>28</sup> 78 Fed. Reg. at 3551 (Preamble).

<sup>29</sup> 78 Fed. Reg. at 3551 (Preamble) (emphasis added).

<sup>30</sup> 78 Fed. Reg. at 3645 (Sub. R § 112.206(a)(2)).



withdraw an exemption from a qualified exempt farm only be used as a tool to prevent and mitigate an actual public health risk. There should be more safeguards to ensure that the process to withdraw an exemption is not abused.

Even if the qualified exempt farm does not ultimately have its exemption withdrawn, the process of countering the order to withdraw may be costly, in terms of both time and money. If an exemption is withdrawn, the farm must come into compliance with all of the provisions of the Produce Safety Rule, which is also costly and burdensome. It is important to provide a high threshold for an order to withdraw to make sure that farms are not unnecessarily subjected to the exemption withdrawal process.

### **1. Establish an evidentiary standard for a withdrawal of a qualified exemption.**

Proposed § 112.201 of the Produce Safety Rule currently states that FDA may withdraw a farm's qualified exemption:

- (a) In the event of a foodborne illness outbreak that is directly linked to your farm; or
- (b) If [FDA] determine[s] that it is necessary to protect the public health and prevent or mitigate a foodborne illness outbreak based on conduct or conditions associated with your farm that are material to the safety of the food that would otherwise be covered produce grown, harvested, packed or held at your farm.<sup>31</sup>

Many of the terms included in § 112.201 are vague and leave substantial room for discretion on the part of the FDA employee initiating an order to withdraw an exemption. Additionally, under § 112.203, FDA is not required to show evidence to support an order to withdraw an exemption, aside from a “brief, general statement of the reasons for the order.”<sup>32</sup> This lack of evidentiary standard for withdrawing a farm's qualified exemption is of significant concern and should be remedied in the final rule.

#### *Withdrawal Order Based on a Direct Linkage to an Active Foodborne Illness Investigation (§ 112.201(a))*

For an active investigation of foodborne illness outbreak that may result in a withdrawal proceeding, FDA must establish that the farm is “directly linked” to that foodborne illness outbreak. Given the importance of the term “directly linked,” FDA should clarify how outbreaks may be “directly linked” to a farm. There is a spectrum of circumstances by which outbreaks may be “linked” to farms, and without further clarification about what would be considered a direct linkage, farms that are not direct contributors to an outbreak may have their qualified exemptions inappropriately withdrawn. During a foodborne illness outbreak, there is an understandably significant level of public outcry and push for the FDA (and CDC) to identify the source of the foodborne illness outbreak and to take action to prevent the outbreak from increasing. However, this immense pressure may make it tempting for the FDA to respond to the outbreak in an overly broad way, and may cause an FDA official to assert a “direct link” when the linkage is relatively attenuated. Further, the final rule should require the FDA official issuing an order to withdraw to prove that such a direct linkage exists; this establishment of an evidence-based definition of direct linkage would be consistent with FSMA's mandate to base the proposed rules in science.

#### *Withdrawal Order Based on Conduct or Conditions Associated with the Qualified Farm (§ 112.201(b))*

For an order to withdraw an exemption that is based on § 112.201(b), FDA should add an evidentiary standard that requires the FDA official recommending the order to withdraw to show “substantial and credible evidence” that the order to withdraw is material to the safety of the food, and should clarify the meaning of “material to safety.”

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<sup>31</sup> 78 Fed. Reg. at 3644 (Sub. R § 112.201).

<sup>32</sup> 78 Fed. Reg. at 3644 (Sub. R § 112.203(c)).

First, the introduction of a “credible evidence” standard would require FDA to meet an explicit evidentiary threshold when finding that “conduct or conditions” exist on a farm sufficient to trigger the exemption withdrawal procedures. Currently, the mere requirement that the triggering conditions be “associated” with the farm means that FDA could embark on the exemption withdrawal process so long as its sources allege the necessary material risk to safety. Requiring “credible and substantial evidence” would likely improve transparency and ensure the FDA utilizes its resources in the most efficient way possible. At the same time, the standard would not deprive the FDA of the discretion that it needs to make enforcement decisions on the ground. Importantly, the FDA had previously willingly adopted the credible evidence standard in other regulatory contexts, namely, for the administrative detention of food.<sup>33</sup> However, in FSMA, Congress removed the “credible evidence or information” standard from the provision about administrative detention of food and replaced it with a “reason to believe” standard.<sup>34</sup> Although Congress changed the standard for the administrative detention of food, it does not preclude FDA from using the “credible evidence or information” standard in a different context. Further, using this standard would be more consistent with Congress’ intent to protect small farms when it added the Tester-Hagan amendment to the legislation.

Second, the meaning of “material to safety” should be clarified with additional language in § 112.201(b). The added language sets a baseline probability threshold so that not every conceivable risk to safety will be “material” enough to trigger withdrawal of an exemption. In the Preamble to the Produce Safety Rule, FDA explained that the kind of situation that would trigger an order to withdraw under § 112.201(b) would include conduct or conditions that were either “likely to lead to contamination of food” in the future or that “likely led” to the actual contamination of food in the past.<sup>35</sup> Further, adding language that requires there to be a “reasonable probability” that the conduct or conditions present a material risk to the safety of the food is echoed in other provisions of the FDCA.<sup>36</sup>

**Recommendation:** FDA should establish evidentiary standards for withdrawing a qualified exemption. FDA should require the FDA officer recommending the withdrawal to provide evidence that shows a direct linkage to a problem on a specific farm (under § 112.201(a)); FDA should also require the FDA officer recommending a withdrawal under § 112.201(b) to show credible and substantial evidence that the identified conduct or conditions merit an order to withdraw. Specifically, FDA should add language to § 112.201(b) so that it specifies that the determination must be supported by credible and substantial evidence or information related to an individual farm. We provide specific recommended changes to the language of Subpart R in the appendix to the comments.

## **2. FDA should first issue a warning letter to a qualified farm before resorting to exemption withdrawal proceedings.**

It is of significant concern that, as the Produce Safety Rule is currently written, when either of the exemption withdrawal triggering circumstances is found, withdrawal seems to be the *only* remedy contemplated by Subpart R of the Produce Safety Rule. It is possible to think of many circumstances in which the complete withdrawal of a farm’s exemption is not needed to prevent or mitigate a foodborne illness outbreak. Other, less drastic, more targeted measures may suffice to address the problem. This

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<sup>33</sup> Title 21 of the C.F.R. § 1.378 used to read: “An officer or qualified employee of FDA may order the detention of any article of food that is found during an inspection, examination, or investigation under the act *if the officer or qualified employee has credible evidence or information* indicating that the article of food presents a threat of serious adverse health consequences or death to humans or animals.” 21 C.F.R. § 1.378 (2012).

<sup>34</sup> Title 21 of the C.F.R. § 1.378 now reads: “An officer or qualified employee of FDA may order the detention of any article of food that is found during an inspection, examination, or investigation under the act if the officer or qualified employee has *reason to believe* that the article of food is adulterated or misbranded.” 21 C.F.R. § 1.378 (2012).

<sup>35</sup> See 78 Fed. Reg. at 3612 (Preamble).

<sup>36</sup> See 21 U.S.C. § 360h(e) (allowing the FDA Secretary to issue a mandatory recall of medical devices upon “find[ing] that there is a *reasonable probability* that a device intended for human use would cause serious, adverse health consequences or death”).

would be especially true if the observed deficiency is amenable to an easy, tailored, technical solution. As mentioned above, withdrawal proceedings are costly and burdensome to farms that satisfy the qualified exemption requirements. We therefore recommend that the FDA allow the farmer a chance to rectify the triggering circumstances before undertaking withdrawal proceedings. The farmer could be made aware of the circumstances via a warning letter and allowed a certain period of time to fix the issue.

The existence of intermediary remedies would have the benefit of giving FDA inspectors the ability to scale desired remedies according to the actual severity of the food safety concern. Indeed, it may be that having only one remedy in its arsenal will actually chill the FDA's ability to respond effectively to emergent food safety concerns because inspectors may not want to invest the time and effort it takes to go through the exemption withdrawal process when the problem at hand is relatively minor, or when the risk is more speculative. The text of § 112.201(b) itself sets a relatively high bar in this regard, enabling an order of withdrawal to be issued only when “withdrawal is *necessary* to protect the public health and prevent or mitigate a foodborne illness outbreak.”<sup>37</sup>

The FDA already has precedent for using modified consequences for minor violations. Under the prohibited acts and penalties subchapter in the FDCA, the Secretary is not required “to report for prosecution . . . minor violations of this chapter whenever he believes that the public interest will be adequately served by a suitable written notice or warning.”<sup>38</sup> Presumably, because this provision is part of the FDCA, it would apply to the provisions of the FDCA added by FSMA (even though it was not added by FSMA itself).

Further, on the FDA website, FDA writes that “[w]hen FDA finds that a manufacturer has significantly violated FDA regulations, FDA notifies the manufacturer. This notification is often in the form of a Warning Letter.”<sup>39</sup> Because FDA already uses warning letters for facilities to remedy violations,<sup>40</sup> there seems to be no reason why warning letters could not be used in the farm context. Warning letters could be used so that minor, easily-fixed conduct or conditions can be remedied by the owner, operator, or agent in charge of the farm without triggering the compliance or appeals process, which may be quite burdensome to small and very small businesses who must scramble to gather documentation that they were not required to keep, given their exemptions from the Produce Safety Rule.

**Recommendation:** FDA should be required to first issue a warning letter to a qualified exempt farm before resorting to exemption withdrawal proceedings. In the warning letter, FDA should identify the conduct or conditions in question, or how FDA believes the farm is directly linked to an active investigation of a foodborne illness outbreak, outline how the farm can remedy the situation, and notify the facility that it has 15 calendar days from receipt of the warning letter to respond with a plan for remedying the problem within a suitable timeframe before an order to withdraw an exemption may be issued. We provide specific recommended changes to the language of Subpart R in the appendix to the comments.

### 3. FDA should allow partial withdrawals of an exemption in certain circumstances.

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<sup>37</sup> 78 Fed. Reg. at 3644 (Sub. R § 112.201(b)) (emphasis added).

<sup>38</sup> 21 U.S.C. § 336 (2012).

<sup>39</sup> *Warning Letters*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/Food/ComplianceEnforcement/WarningLetters/default.htm> (last visited Apr. 8, 2013).

<sup>40</sup> *Inspections, Compliance, Enforcement and Criminal Investigations*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/iceci/enforcementactions/warningletters/default.htm>; *See, e.g., Warning Letter to Culpeper Farmers' Cooperative, Inc.* (May 17, 2011), U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2011/ucm256682.htm>; *Warning Letter to Pacific Cheese Company, Inc.* (Aug. 1, 2011), U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2011/ucm288527.htm>.

Under § 112.204 of the proposed Produce Safety Rule, if a qualified farm has its exemption withdrawn, the farm must come into compliance with *all* of the provisions of the Produce Safety Rule, even if the issue triggering the withdrawal process is limited to one area of the farm operation.<sup>41</sup> If the issue causing the withdrawal process is a discrete issue, it is unnecessarily burdensome to require the qualified exempt farm to come into compliance with all of the provisions of the Produce Safety Rule, especially if it might result in the farm going out of business.

The partial withdrawal could be tailored to the issues or conduct/conditions associated with the farm and identified in the order to withdraw. This way, small businesses can seek targeted solutions (such as installing water purification and testing equipment) as needed, without falling under all the substantive provisions of the Produce Safety Rule.

**Recommendation:** FDA should add a new subparagraph in current proposed § 112.203 to include a statement that indicates whether the withdrawal order is for a partial or total withdrawal of the qualified exemption. If the withdrawal is partial, FDA should indicate with which subparts of the rule the farm must comply. In order to provide some predictability in this process, FDA should provide guidance explaining under what situations it might pursue a partial order to withdraw as opposed to a total exemption withdrawal. We provide specific recommended changes to the language of Subpart R in the appendix to the comments.

#### **4. FDA should add a new section that allows qualified farms to regain their exempt status after correcting a problem and that outlines the criteria and process for such a course of action.**

The Tester-Hagan Amendment to FSMA was intended to provide small- and mid-sized diversified farm operations some relief from the numerous requirements of the Produce Safety Rule. These farms are quite small and contribute to the food supply only in local and regional markets; for them, coming into compliance with the requirements of the Produce Safety Rule after an exemption withdrawal could put them out of business. If FDA initiates a withdrawal process based on § 112.201(b) (“conduct or conditions associated with your farm that are material to the safety of the food...”), there is a high likelihood that the farm could remedy the alleged issues and continue operating in a safe manner. As discussed below, these qualified exempt farms should have the opportunity to show FDA that the identified issues have been resolved and should be able to regain their qualified exempt status. Further, if FDA initiates a withdrawal process based on an initial finding of a direct link to an active investigation of a foodborne illness outbreak, but upon conclusion of the investigation finds that the farm is not directly linked to the outbreak, those farms should have their exemption automatically reinstated.

FDA has a history of providing opportunities for facilities to fix a problem identified by the FDA prior to suspending that facility’s registration or starting an enforcement action under the FDCA (e.g., using warning letters). FDA should model the exemption reinstatement process for farms after the process used for facilities that have lost a similar type of certification (found in § 415 of the FDCA (Registration of Food Facilities)).<sup>42</sup>

Under § 415, all facilities are required to register with FDA in order to operate.<sup>43</sup> The Secretary may suspend the registration of a facility “if the Secretary determines that a food manufactured, processed, packed, received, or held by a facility registered under this section has a reasonable probability of causing serious adverse health consequences or death.”<sup>44</sup> Under § 415, if a facility has its registration suspended, FDA “shall” provide an opportunity for an informal hearing to discuss what actions are required for

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<sup>41</sup> 78 Fed. Reg. at 3645 (Sub. R § 112.204(a)).

<sup>42</sup> Federal Food, Drug, & Cosmetic Act § 415, 21 U.S.C. § 350d (2012).

<sup>43</sup> Federal Food, Drug, & Cosmetic Act § 415, 21 U.S.C. § 350d (2012).

<sup>44</sup> 21 U.S.C. § 350d(b)(1) (2012).

reinstatement of the registration.<sup>45</sup> Further, “[t]he Secretary *shall* reinstate a registration if the Secretary determines, based on evidence presented, that adequate grounds do not exist to continue the suspension of the registration (emphasis added).”<sup>46</sup> After the hearing on the suspension, if FDA determines that the registration should be reinstated, the registrant is required to submit a “corrective action plan” that outlines how the registrant is going to fix the problem that led to the suspension.<sup>47</sup> FDA can then vacate the order “upon . . . determin[ing] . . . adequate grounds do not exist to continue the suspension actions required by the order” and reinstate the facility’s registration.<sup>48</sup>

There appears to be no reason why this process cannot be applied in the context of a farm regaining its qualified exemption; in both cases, FDA has reason to believe the food produced on such a farm or facility may cause some significant harm. Under § 415, if FDA makes such a finding, it has the authority to withdraw a facility’s registration.<sup>49</sup> Under the proposed Produce Safety Rule, if FDA finds a direct link to an active foodborne illness outbreak investigation or conduct or conditions associated with the qualified exempt farm that are material to the safety of the food and necessary to prevent or mitigate a foodborne illness outbreak, FDA may initiate an order to withdraw the exemption (or issue a warning letter, as proposed above). Under § 415, if a facility’s registration is suspended, that facility is not permitted to introduce food from that facility into the stream of commerce.<sup>50</sup> Under the Produce Safety Rule, if a qualified exemption is withdrawn, the farm becomes subject to all of the provisions of the Produce Safety Rule. FDA should provide the same opportunities to farms that have a qualified exemption to fix the problems leading to the order to withdraw the exemption.

FDA should provide a process by which a farm might regain its exempt status (1) before the compliance deadline passes, (2) after the compliance deadline has passed, or (3) automatically at the conclusion of an investigation.

**Recommendation:** FDA should provide a process by which qualified farms can regain their exempt status after correcting a problem. FDA should add a new provision to the final Produce Safety Rule that expressly allows reinstatement of a qualified exemption and that outlines the criteria and process for such a course of action. Specifically, FDA should:

1. Allow a farm to regain its qualified exempt status before the deadline to comply with the Produce Safety Rule passes. In this situation, FDA would be required to reinstate the farm’s qualified exempt status if the owner, operator, or agent in charge of the farm demonstrates that the conduct or conditions that triggered the withdrawal order have been sufficiently resolved.
2. Allow a farm to regain its exempt status after the deadline to comply with the Produce Safety Rule has passed. In this situation, FDA should give the owner, operator, or agent in charge of the farm an opportunity for an informal hearing during which the owner, operator, or agent in charge of the farm can show that the conduct or conditions that triggered the withdrawal have been sufficiently resolved. If, based on this information, the Secretary determines that the evidence does not support continuing the exemption withdrawal, the Secretary shall reinstate the farm’s exemption.

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<sup>45</sup> 21 U.S.C. § 350d(b)(2) (2012).

<sup>46</sup> 21 U.S.C. § 350d(b)(2) (2012).

<sup>47</sup> 21 U.S.C. § 350d(b)(3)(A) (2012).

<sup>48</sup> 21 U.S.C. § 350d(b)(3)(B) (2012).

<sup>49</sup> 21 U.S.C. § 350d(b)(1) (2012).

<sup>50</sup> 21 U.S.C. § 350d(b)(4) (2012). “If the registration of a facility is suspended under this subsection, no person shall import or export food into the United States from such a facility, offer to import or export food into the United States from such a facility, or otherwise introduce food from such a facility into interstate or intrastate commerce in the United States.” 21 U.S.C. § 350d(b)(4) (2012).

3. Automatically reinstate a farm's qualified exemption if FDA concludes an active investigation of a foodborne illness outbreak and finds that the farm in question was not directly linked to the foodborne illness outbreak. In this situation, FDA should provide notice to the farm of the reinstatement.

We provide specific recommended changes to the language of Subpart R in the appendix to the comments.

**5. FDA should require the order to withdraw to contain specific information about the reasons causing the withdrawal order.**

Currently, in the order to withdraw a qualified exemption in § 112.203, FDA is only required to include, in relevant part, the following information:

(c) A brief, general statement of the reasons for the order, including information relevant to:

- (1) An active investigation of a foodborne illness outbreak that is directly linked to the farm; or
- (2) Conduct or conditions associated with a farm that are material to the safety of the food that would otherwise be covered produce grown, harvested, packed and held at such farm; . . .<sup>51</sup>

The language quoted above does not match the standards required to issue an order to withdraw under § 112.201(b).<sup>52</sup> Section 112.201(b) states (with the differences in italics):

[FDA] may withdraw your qualified exemption under § 112.5:

(b) If [FDA] determine[s] that it is *necessary to protect the public health and prevent or mitigate a foodborne illness outbreak* based on conduct or conditions associated with your farm that are material to the safety of the food that would otherwise be covered produce grown, harvested, packed or held at your farm.<sup>53</sup>

Specifically, in § 112.203, there is no language that the withdrawal must be necessary to protect the public health or prevent or mitigate a foodborne illness outbreak. Because initiating the exemption withdrawal process has significant consequences for these small operations, we recommend requiring a higher burden of proof to show that the withdrawal proceedings are actually necessary. This could be accomplished through additional regulatory language requiring the linking of the “material conditions” with a public health outcome in the actual order. The FDA officer issuing the withdrawal order would, therefore, be required to provide more information about the basis upon which the order is being issued, which conduct or conditions are at issue, and why the withdrawal is justified as a public health protection.

**Recommendation:** In the final Produce Safety Rule, FDA should modify the language of proposed § 112.203(c) to require specific information about the reasons for the withdrawal order as well as evidence supporting the withdrawal order. Specifically, under § 112.201(a), FDA should be required to identify the direct linkage between the active foodborne illness outbreak and the farm. Under § 112.201(b), FDA should be required to show measurable evidence that has been collected using generally accepted scientific standards indicating the presence of pathogens on the farm that may pose a specified threat to

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<sup>51</sup> 78 Fed. Reg. at 3644 (Sub. R § 112.203).

<sup>52</sup> 78 Fed. Reg. at 3644 (Sub. R § 112.201(b)).

<sup>53</sup> 78 Fed. Reg. at 3644 (Sub. R § 112.201(b)).

public health, identify the specific conduct or conditions that are material to the safety of the food on that farm, and include a statement explaining how altering the conduct or conditions would prevent or mitigate a foodborne illness outbreak. We provide specific recommended changes to the language of Subpart R in the appendix to the comments.

**6. In the withdrawal order, FDA should state clearly that the owner, operator, or agent in charge of a qualified farm must either comply with the requirements of the Produce Safety Rule or appeal the order, and include information about the opportunity to request an informal hearing.**

Only when reading Subpart R in its entirety does it become clear that an owner, operator, or agent in charge of a qualified farm has the option to either comply with the requirements of the Produce Safety Rule or appeal the order within a certain amount of time. Because this information is not clearly stated in the appropriate section of the Produce Safety Rule, there is a high probability for confusion. We recommend that the FDA include in the final Produce Safety Rule a requirement that the order to withdraw the exemption indicate the timeframe for an appeal and the opportunity to request an informal hearing. The regulations should be as clear as possible about what is required. Adding this clarifying language will help farmers understand their right to a hearing and navigate the exemption withdrawal process if necessary.

**Recommendation:** In the final Produce Safety Rule, FDA should add language to § 112.203 to require that the order to withdraw an exemption include a statement that the owner, operator, or agent in charge of the farm that receives the order must either comply with the requirements of the Produce Safety Rule or appeal the order, which includes requesting an informal hearing, within ten calendar days of the date of the order. We provide specific recommended changes to the language of Subpart R in the appendix to the comments.

**7. FDA should deliver the order to withdraw in a way that ensures the farmer receives the order and provides confirmation of receipt of the order to withdraw an exemption. FDA should toll the ten-day time window for appeal from the date the order was received by the farm.**

When an exemption withdrawal process is initiated, a series of time-sensitive activities is triggered. It is imperative that the owner, operator, or agent in charge of the farm receive the order to withdraw in a timely fashion. We believe there should be some security as to the delivery of the notice letter, for example, by using certified mail. The clock for order approval (and the clock for the appeal) should not start tolling until the letter ordering the withdrawal is received.

**Recommendation:** FDA should add language to proposed § 112.202 that requires an exemption withdrawal order to be delivered in a manner that ensures receipt of the order, such as through certified mail with a confirmation of delivery. Further, in the final Produce Safety Rule, FDA should specify that the owner, operator, or agent in charge of the farm receiving an order to withdraw must take certain actions from the date that the order *was received* by the owner, operator, or agent in charge of the farm in question, rather than the date the order *was issued* by FDA. We provide specific recommended changes to the language of Subpart R in the appendix to the comments.

**8. FDA should set a timeframe within which the initial determination to issue an order to withdraw an exemption, the approval or denial of the order by the FDA District Director, and the ultimate issuance of the withdrawal order take place.**

Once an FDA official determines that a qualified exemption should be withdrawn, that official issues an order to withdraw; the order must then be approved by an FDA District Director (or an official senior to

such Director), and then the order must be issued to the owner, operator, or agent in charge of the farm.<sup>54</sup> The proposed Produce Safety Rule does not set forth timeframes for these initial steps in the process to withdraw an exemption.

Because conditions at a farm can change quickly, it is important that any FDA action to withdraw an exemption is taken promptly upon determining that a withdrawal may be necessary. We recommend that the FDA set a ten-day time frame for the issuance of an order, and another ten-day timeframe for its approval or denial by the FDA District Director. This time limit will ensure that any action to withdraw bears a strong relation to the current conditions at a given farm. Additionally, we recommend that the FDA notify a farm within five days of a decision to issue an order to withdraw, to ensure that farm owners or operators can promptly correct the problem and/or prepare for the appeals process. This is particularly important because an order to withdraw would have serious consequences for qualified exempt farms.

**Recommendation:** In the final Produce Safety Rule, FDA should specify a timeframe for the initial determination that an order to withdraw is necessary, the approval or denial of the order by the FDA District Director, and the ultimate issuance of the withdrawal order to the owner, operator, or agent in charge of the farm. We provide specific recommended changes to the language of Subpart R in the appendix to the comments.

#### **9. FDA should rely on records kept in the normal course of business as the types of documents that will be sufficient to refute an order to withdraw a qualified exemption.**

The proposed Produce Safety Rule requires covered farms to keep specific records showing compliance with the proposed standards, and, in Subpart O, sets out general recordkeeping requirements.<sup>55</sup> Under § 112.6, the Produce Safety Rule sets out modified requirements for qualified exempt farms, which include compliance with Subpart A (general provisions), Subpart Q (compliance and enforcement), Subpart R (withdrawal of qualified exemption), and specific labeling requirements.<sup>56</sup> None of those subparts addresses recordkeeping requirements. Therefore, under the proposed Produce Safety Rule, qualified exempt farms are not required to keep the same types of records that covered farms are required to keep.

However, in the provisions addressing the withdrawal of a qualified exemption, FDA mentions it will rely on documents the farm has kept in evaluating an appeal of an order to withdraw.<sup>57</sup> Specifically, under the proposed Produce Safety Rule, a qualified exempt farm whose exemption is withdrawn has only ten days to submit a written appeal refuting claims made in the withdrawal order.<sup>58</sup> In this written appeal, farms are required to “[r]espond with particularity to the facts and issues contained in the order, including *any supporting documentation* upon which the owner, operator or agent in charge of the farm relies.”<sup>59</sup> However, as mentioned above, under the proposed Produce Safety Rule qualified exempt farms are not required to keep records showing compliance with the provisions of the Produce Safety Rule. Because these farms are not *required* to keep specific types of records, FDA should not be able to penalize a qualified exempt farm for not having the types of records FDA demands during an appeal of a withdrawal

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<sup>54</sup> 78 Fed. Reg. at 3644 (Sub. R § 112.202).

<sup>55</sup> 78 Fed. Reg. at 3634 (Sub. C § 112.30) (Standards Directed to Personnel Qualifications and Training); 3636 (Sub. E § 112.50) (Standards Directed to Agricultural Water); 3637 (Sub. F § 112.60) (Standards Directed to Biological Soil Amendments of Animal Origin and Human Waste); 3640 (Sub. L § 112.140) (Standards Directed to Equipment, Tools, Buildings, and Sanitation); 3641 (Sub. M § 112.150) (Standards Directed to Sprouts); 3642 (Sub. O §§ 112.161-167) (Requirements Applying to Records That You Must Establish and Keep).

<sup>56</sup> 78 Fed. Reg. at 3632-33 (Sub. A § 112.6)

<sup>57</sup> 78 Fed. Reg. at 3645 (Sub. R § 112.206(a)(2)).

<sup>58</sup> 78 Fed. Reg. at 3645 (Sub. R § 112.204(b)).

<sup>59</sup> 78 Fed. Reg. at 3645 (Sub. R § 112.206(a)(2)) (emphasis added).



order. Therefore, FDA should accept, for purposes of a qualified exempt farm's appeal of a withdrawal order, records farms keep in the normal course of business.

Some of the records farms keep in the normal course of business include:

- Records about the type, amount, or dates of soil amendment applications;
- Records about the type, amount, or dates of spray applications;
- Water test results, even when such tests are not conducted as frequently as FDA requires of non-exempt farms;
- Soil test results, occasionally done either once or on an as-needed basis, but in some cases done annually;
- Timesheet of employees;
- Field schedules of what is planted where; and
- Financial statements.

Further, because qualified exempt farms are smaller and will have fewer resources with which to navigate the appeals process, the agency should provide guidance on the types of documents upon which it will rely in an appeal of a withdrawal order. Clarification of what records will be required would ensure that qualified exempt farms are fully aware of how they can submit an effective appeal.

**Recommendation:** FDA should not require farmers submitting a written appeal to provide documents that they do not keep in the normal course of business. FDA should provide guidance about the types of documentation upon which it will rely during the appeal of an order to withdraw.

#### **10. FDA should clarify what standards and science-based justifications it will rely on in making the final decision to approve or deny an order withdrawing a qualified farm or farm mixed-type facility exemption.**

To ensure that qualified exempt farms have the information necessary to submit an effective appeal, the FDA should create a centralized compilation of sources that set forth the standards and science-based justifications the agency will rely on in making a final decision to approve or deny the appeal of an order withdrawing a qualified farm's exemption. This set of sources should be made available for use by businesses when preparing their appeals and compiling documentation for their hearings. These resources would not only ensure a fairer appeals process, but would also provide context for the standards of review to which a final decision may be subject.

**Recommendation:** FDA should clarify, in guidance, which standards and science-based justifications FDA will use when making the final decision to approve or deny an order to withdraw. FDA should make these resources available so that appealing businesses can refer to them.

#### **11. FDA should provide clarification and guidance regarding the situations under which an informal hearing would be denied.**

Under the proposed rule, a qualified exempt farm whose exemption is withdrawn may be denied an informal hearing if the presiding officer determines that there is no "genuine and substantial issue of material fact" raised in the submitted materials.<sup>60</sup> FDA should provide guidance on this issue to ensure that qualified exempt farms have a fair opportunity to present their appeal with all the necessary information to support their case, and that hearings are not erroneously denied based on a lack of understanding of the standards of review.

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<sup>60</sup> 78 Fed. Reg. at 3645 (Sub. R § 112.207(b)).

**Recommendation:** FDA should provide guidance on the types of evidence, or lack thereof, that might justify a decision to deny an informal hearing to a farmer appealing an order to withdraw an exemption.

## **V. Comments on the Definition of “Retail Food Establishment”**

### **1. FDA should include community supported agriculture operations (CSAs), farmers markets, and roadside stands in the definition of “Retail Food Establishment.”**

Section 415 of the FDCA requires facilities “that are engaged in the manufacturing/processing, packing, or holding of food for consumption in the United States . . . to register with the FDA.”<sup>61</sup> This registration requirement does not apply to certain facilities, including farms, retail food establishments, restaurants, and non-profit food establishments in which food is prepared for, or served directly to, the consumer. As it is currently written, the definition of a retail food establishment could be interpreted to include other forms of direct marketing, such as CSAs, farmers markets, and roadside stands, but fact that is not expressly stated. Because CSAs, farmers markets, and roadside stands are not expressly included in the definition of retail food establishment, they could be considered facilities and would then be required to register under § 415 (and be subject to the Preventive Controls Rule).

However, in § 102(c) of FSMA, Congress directed FDA to clarify the definition of “retail food establishment” to ensure that it covers operations such as CSAs, farmers markets, and roadside stands.<sup>62</sup> The provision states:

(1) The Secretary shall amend the definition of the term “retail food establishment” in section 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>63</sup>

FDA has not yet followed Congress’ order to include CSAs, farmers markets, and roadside stands in the definition of a retail food establishment. If the definition of retail food establishment is clarified to include CSAs, roadside stands, and farmers markets (and any other direct sales platform that the Secretary decides to include), then those operations will *not* be considered facilities (and will not be subject to the Preventive Controls Rule).<sup>64</sup>

**Recommendation:** FDA should follow Congress’ directive to include CSAs, farmers markets, and roadside stands in the definition of retail food establishment. We recommend that FDA expressly list CSAs, farmers markets, and roadside stands in the definition of retail food establishment by adding clarifying language to the Code of Federal Regulations (C.F.R.), specifically 21 C.F.R. § 1.227, as well as

<sup>61</sup> Food, Drug, & Cosmetic Act § 415, 21 U.S.C. § 350d (2012). 21 C.F.R. § 1.225(a) (2012).

<sup>62</sup> Food Safety Modernization Act § 102(c), 21 U.S.C. § 350d (2012).

<sup>63</sup> Food Safety Modernization Act § 102(c), 21 U.S.C. § 350d (2012).

<sup>64</sup> 21 C.F.R. § 1.226(c) (2012) (a retail food establishment is not subject to registration requirements).

other relevant parts of the proposed rules and the C.F.R.<sup>65</sup> We provide specific recommended changes to the language in the appendix to the comments.

**2. FDA should ensure definitions of key concepts such as “retail food establishment” and “community supported agriculture” are consistent within the C.F.R.**

There are a number of places throughout the C.F.R. that reference “retail food establishment” and “community supported agriculture.” FDA should ensure that, wherever the definitions of “retail food establishment” and “community supported agriculture” are implicated in the C.F.R., these definitions accord with Congress’ intentions expressed in § 102(c) of FSMA, and are consistent across the C.F.R.

FDA is required under § 102(c) of FSMA to include CSAs, farmers markets, and roadside stands in the definition of retail food establishment. In addition to updating the definition of retail food establishment, FDA should standardize the definition of “retail food establishment” to ensure that CSAs, farmers markets, and roadside stands are included in the definition wherever it appears in the C.F.R. This is particularly important where portions of regulations are covered or changed by the proposed rules.

**Recommendation:** FDA should update the definition of retail food establishment in existing sections of the C.F.R. as well add the definition of CSA in relevant new sections added by the rules. We provide specific recommended changes to the language in the appendix to the comments.

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<sup>65</sup> U.S. FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY: WHAT YOU NEED TO KNOW ABOUT REGISTRATION OF FOOD FACILITIES; SMALL ENTITY COMPLIANCE GUIDE (Dec. 2012), *available at* <http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/FoodDefense/ucm331957.htm>.

## **Appendix:**

# **Suggested Modified Language for the Produce Safety Rule**

We have indicated below the changes that we recommend FDA make directly to the proposed Produce Safety Rule. We indicate proposed new language (underlined) and language to delete (~~in strike through~~).

### Preamble: Organizing Principles

1. The basic purpose of farms is to produce RACs and to handle them for distribution into commerce; ~~and~~ RACs are the essential products of farms.
2. Activities that involve RACs and that farms traditionally do for the purposes of growing their own RACs, removing them from the growing areas, ~~and~~ preparing them for ~~use~~ sale as a food RAC, and for packing, holding, ~~and~~ transporting, and delivering them to customers or buyers, should all be within the definition of “farm.”
3. Activities should be classified in part on whether the food operated on is a RAC or a processed food, and on whether the activity transforms the RAC into a processed food.
4. Activities farms may perform on others’ RACs should appropriately be classified as manufacturing/processing, packing, or holding in the same manner as these activities are classified off-farm when the RACs are to be distributed into commerce.
5. Manufacturing/processing, packing, or holding food—whether RACs or processed foods, from any source—for on the farm should remain within the farm definition.

### Proposed Rule

#### **Subpart A—General Provisions**

##### **§ 112.1 What food is covered by this part?**

- (a) Unless it is excluded from this part under § 112.2, food that is produce within the meaning of this part and that is a raw agricultural commodity (RAC) is covered by this part. This includes a produce RAC that is grown domestically and a produce RAC that is imported or offered for import in any State or territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico.
- (b) For the purpose of this part and subject to the exemptions and qualified exemptions therein, covered produce includes all of the following:

(1) Fruits and vegetables such as almonds, apples, apricots, aprium, asian pear, avocados, babaco, bamboo shoots, bananas, Belgian endive, blackberries, blueberries, broccoli, cabbage, cantaloupe, carambola, carrots, cauliflower, celery, cherries, citrus (such as Clementine, grapefruit, lemons, limes, mandarin, oranges, tangerines, tangors, and uniq fruit), cucumbers, curly endive, garlic, grapes, green beans, guava, herbs (such as basil, chives, cilantro, mint, oregano, and parsley), honeydew, kiwifruit, lettuce, mangos, other melons (such as canary, crenshaw and persian), mushrooms, nectarine, onions, papaya, passion fruit, peaches, pears, peas, peppers (such as bell and hot), pineapple, plums, plumcot, radish, raspberries, red currant, scallions, snow peas,

spinach, sprouts (such as alfalfa and mung bean), strawberries, summer squash (such as patty pan, yellow and zucchini), tomatoes, walnuts, watercress, and watermelon; and

(2) Mixes of intact fruits and vegetables (such as fruit baskets).

(c) Covered produce is eligible for exemption from the requirements of this part (except as noted in paragraphs (b)(1), (b)(2), and (b)(3) of this section) under the following conditions:

(1) The covered produce receives commercial processing that adequately reduces the presence of microorganisms of public health significance. Examples of commercial processing that adequately reduces the presence of microorganisms of public health significance are processing in accordance with the requirements of parts 113, 114, or 120 of this chapter, treating with a validated process to eliminate spore-forming microorganisms (such as processing to produce tomato paste or shelf-stable tomatoes), and processing such as refining or distilling produce into products such as sugar, oil, spirits, or similar products;

(2) You must establish and keep documentation with the requirements of Subpart O of this part, of the identity of the recipient of the covered produce that performs the commercial processing described in paragraph (b)(1) of this section; and

(3) The requirements of this subpart and Subpart O of this part apply to such produce.

## **§ 112.2 What produce is not covered by this part?**

(a) The following produce is not covered by this part:

(1) (a) Produce that is rarely consumed raw, specifically the produce on the following exhaustive list—arrowhead, arrowroot, artichokes, asparagus, beets, black-eyed peas, bok choy, Brussels sprouts chick-peas, collard greens, crabapples, cranberries, eggplant, figs, ginger root, kale, kidney beans, lentils, lima beans, okra, parsnips, peanuts, pinto beans, plantains, potatoes, pumpkin, rhubarb, rutabaga, sugarbeet, sweet corn, sweet potatoes, taro, turnips, water chestnuts, winter squash (acorn and butternut squash), and yams;

(2) (b) Produce that is produced by an individual for personal consumption or produced for consumption on the farm or another farm under the same ownership; and

(3) (c) Produce that is not a raw agricultural commodity.

~~(b) Covered produce is eligible for exemption from the requirements of this part (except as noted in paragraphs (b)(1), (b)(2), and (b)(3) of this section) under the following conditions:~~

~~(1) The covered produce receives commercial processing that adequately reduces the presence of microorganisms of public health significance. Examples of commercial processing that adequately reduces the presence of microorganisms of public health significance are processing in accordance with the requirements of parts 113, 114, or 120 of this chapter, treating with a validated process to eliminate spore-forming microorganisms (such as processing to produce tomato paste or shelf-stable tomatoes), and processing such as refining or distilling produce into products such as sugar, oil, spirits, or similar products;~~

~~(2) You must establish and keep documentation with the requirements of subpart O of this part, of the identity of the recipient of the covered produce that performs the commercial processing described in paragraph (b)(1) of this section; and~~

~~(3) The requirements of this subpart and subpart Q of this part apply to such produce.~~

### § 112.3 What definitions apply to this part?

...

Community supported agriculture 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) for that season.

Covered activity means growing, harvesting, or holding covered produce, provided that all covered produce used in covered packing or holding activities is grown, raised, or consumed on that farm or another farm under the same ownership. Covered activity does not include manufacturing/processing within the meaning defined in this chapter. This part does not apply to activities of a facility or the facility activities a farm mixed-type facility.

Holding means storage of food. Holding facilities include warehouses, cold storage facilities, storage silos, grain elevators, and liquid storage tanks. For farms and farm mixed-type facilities, holding also includes activities traditionally performed by farms for the safe or effective storage of raw agricultural commodities grown or raised on the same farm under the same ownership or as part of a community supported agriculture operation, but does not include activities that transform a raw agricultural commodity . . . into a processed food.

Manufacturing/processing means making food from one or more ingredients, or synthesizing, preparing, treating, modifying or manipulating food, including food crops or ingredients. Examples of manufacturing/processing activities are cutting, peeling, trimming, washing, waxing, eviscerating, rendering, cooking, baking, freezing, cooling, pasteurizing, homogenizing, mixing, formulating, bottling, milling, grinding, extracting juice, distilling, labeling, or packaging. For farms and farm mixed-type facilities (including as part of a community supported agriculture operation), manufacturing/processing does not include activities that are part of harvesting, packing, or holding.

Packing means placing food into a container other than packaging the food. For farms and farm mixed-type facilities, packing also includes activities (which may include packaging) traditionally performed by farms to prepare raw agricultural commodities grown or raised on the same farm or another farm under the same ownership for storage and transport or as part of a community supported agriculture operation, but does not include activities that transform a raw agricultural commodity . . . into a processed food.<sup>66</sup>

### § 112.4 Who is subject to the requirements of this part?

(a) Except as provided in paragraph (b) or (c) of this section, if you are a farm or farm mixed-type facility with an average annual monetary value of ~~food~~ covered produce (as "~~food~~" covered produce defined in § 112.3(e) § 112.1 and § 112.2) sold during the previous 3-year period of more than \$25,000 (on a rolling basis), you are a "covered farm" subject to this part. If you are a covered farm subject to this part, you must comply with all applicable requirements of this part when you conduct a covered activity on covered produce.

(b) You are not a covered farm or farm mixed-type facility if your average annual monetary value of

<sup>66</sup> 78 Fed. Reg. at 3631 (Sub. A § 112.3(c)).

covered produce (as “covered produce” defined in § 112.1 and § 112.2) sold during the previous 3-year period was \$25,000 or less (on a rolling basis).

(c) You are a covered farm or farm mixed-type facility but exempt from the requirements of this part if you satisfy the requirements in § 112.5 and we have not withdrawn your exemption in accordance with the provisions of Subpart R of this part.

### **§ 112.6 What modified requirements apply to me if I am eligible for a qualified exemption in accordance with § 112.5?**

~~(a) If you are eligible for a qualified exemption in accordance with § 112.5, you are subject to the requirements of:~~

~~(1) (a) This Subpart A (General Provisions); and~~

~~(2) Subparts Q and R of this part. (b) Subpart Q (Compliance and Enforcement);~~

(c) Subpart R (Withdrawal of Qualified Exemption);

~~(b) In addition, you are subject to the following modified requirements:~~ (d) The following modified labeling requirements:

(1) When a food packaging label is required on food that would otherwise be covered produce under the Federal Food, Drug, and Cosmetic Act or its implementing regulations, you must include prominently and conspicuously on the food packaging label the name and the complete business address of the farm where the produce was grown.

(2) When a food packaging label is not required on food that would otherwise be covered produce under the Federal Food, Drug, and Cosmetic Act, you must prominently and conspicuously display, at the point of purchase, the name and complete business address of the farm where the produce was grown, on a label, poster, sign, placard, or documents delivered contemporaneously with the produce in the normal course of business, or, in the case of Internet sales, in an electronic notice.

(3) The complete business address that you must include in accordance with the requirements of paragraph ~~(b)(1) or (b)(2)~~ (d)(1) or (d)(2) of this section must include the street address or post office box, city, state, and zip code for domestic farms, and comparable full address information for foreign farms.

(e) The following modified recordkeeping requirements:

(1) Documentation kept in the normal course of business that proves the farm’s qualified exempt status.

(2) Documentation that can be used to address, with particularity, the facts and issues contained in potential withdrawal order.

### **Subpart R—Withdrawal of Qualified Exemption**

#### **§ 112.201 Under what circumstances can FDA withdraw a qualified exemption in accordance with**

## **the requirements of § 112.5?**

We may withdraw your qualified exemption under § 112.5:

(a) In the event of an active investigation of a foodborne illness outbreak that is directly linked to your farm; or

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

## **§ [new section, to be numbered] What actions must FDA take before issuing an order to withdraw an exemption?**

Before issuing an order to withdraw an exemption, FDA must first issue a warning letter to the owner, operator, or agent in charge of the farm that:

(a) Identifies:

(1) If the determination is based on § 112.201(a), how the farm is directly linked to an active investigation of a foodborne illness outbreak; or

(2) If the determination is based on § 112.201(b), the conduct or conditions in question;

(b) Includes information about how the farm can remedy the situation, including referrals to sources of technical assistance relevant to the issue(s) identified; and

(c) Notifies the farm that it has 15 calendar days from receipt of the warning letter to identify and inform FDA in writing of how it will remedy the issue.

## **§ 112.202 What procedure will FDA use to issue an order to withdraw an exemption?**

(a) If, after taking the actions in § [new section], FDA determines that the issue persists and a qualified exemption applicable to a farm under § 112.5 should be withdrawn, any officer or qualified employee of FDA may issue submit an order to withdraw the exemption to the FDA District Director or official senior to such Director within 10 calendar days of making that determination.

(b) An FDA District Director in whose district the farm is located (or, in the case of a foreign farm, the Director of the Office of Compliance in the Center for Food Safety and Applied Nutrition), or an FDA official senior to such Director, must approve or deny an order to withdraw the exemption within 10 calendar days of making that determination.

(c) FDA must issue an order to withdraw the exemption to the owner, operator, or agent in charge of the farm.

(d) FDA must issue an order to withdraw the exemption in writing, signed and dated by the officer or qualified employee of FDA who is issuing the order.



(e) The order to withdraw the exemption must be delivered to the owner, operator, or agent in charge of the farm within 5 calendar days after the FDA District Director or FDA official senior to such Director makes the determination under §112.202(b).

(f) The order to withdraw the exemption must be delivered to the owner, operator, or agent in charge of the farm in a manner by which delivery and receipt of the order can be confirmed.

### **§ 112.203 What information must FDA include in an order to withdraw a qualified exemption?**

An order to withdraw a qualified exemption applicable to a farm under § 112.5 must include the following information:

(a) The date of the order;

(b) The name, address and location of the farm;

(c) A brief, general statement of the reasons for the order, including ~~information relevant to:~~

~~(1) An active investigation of a foodborne illness outbreak that is directly linked to the farm; or~~

~~(2) Conduct or conditions associated with a farm that are material to the safety of the food that would otherwise be covered produce grown, harvested, packed and held at such farm.~~

(1) Whether the order is based on § 112.201(a) or § 112.201(b);

(2) The evidence on which the order is based;

(3)(i) If the order is based on § 112.201(a), the order shall identify evidence linking the active investigation of a foodborne illness outbreak directly to the farm.

(ii) If the order is based on § 112.201(b), the order shall:

(A) include measurable evidence that has been collected using generally accepted scientific standards indicating the presence of pathogens of public health significance on the farm that pose an imminent threat to public health;

(B) identify conduct or conditions on the farm that are material to safety of food; and

(C) include a statement explaining how altering the conduct or conditions would prevent or mitigate a foodborne illness outbreak.

(4) Any other relevant information, such as a synopsis of past warning letters and/or temporary partial withdrawals related specifically to the problem triggering the withdrawal.

~~(d) A statement that the farm must comply with subparts B through O of this part on the date that is 60 calendar days after the date of the order; A statement that the owner, operator, or agent in charge of the farm that receives the order must either comply with the requirements of this part (as specified in subparagraph (e)) or appeal the order (including the option to request an informal hearing) within 10 calendar days of the date of the order in accordance with § 112.206.~~

(e) A statement indicating whether the withdrawal order is for a partial or total withdrawal of the exemption;

(1) If the withdrawal is a partial withdrawal, the statement shall indicate with which subparts of this Rule the farm must comply:

(i) If the farm is a very small business, within 2 years of the date the order was received;  
or

(ii) If the farm is a small business, within 1 year of the date the order was received.

(2) If the withdrawal is total, the statement shall indicate that the farm must comply with subparts B through O of this part:

(i) If the farm is a very small business, within 2 years of the date the order was received;  
or

(ii) If the farm is a small business, within 1 year of the date the order was received.

~~(e)~~ (f) The text of section 419(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350(f)) and of this subpart;

~~(f)~~ (g) A statement that any informal hearing on an appeal of the order must be conducted as a regulatory hearing under part 16 of this chapter, with certain exemptions described in § 112.208;

~~(g)~~ (h) The mailing address, telephone number, email address, and facsimile number of the FDA District Director in whose district the farm is located (or for foreign farms, the same information for the Director of the Office of Compliance in the Center for Food Safety and Applied Nutrition); and

~~(h)~~ (i) The name and the title of the FDA representative who approved the order.

#### **§ 112.204 What must I do if I receive an order to withdraw a qualified exemption applicable to my farm?**

The owner, operator, or agent in charge of a farm that receives an order to withdraw a qualified exemption applicable to that farm under § 112.5 must either:

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

(1) If the farm is a very small business, within 2 years of the date the order was received; or

(2) If the farm is a small business, within 1 year of the date the order was received; or

~~(b) Appeal the order within 10 calendar days of the date of the order~~ was received in accordance with the requirements of § 112.206.

#### **§ 112.205 Can I appeal or request a hearing on an order to withdraw a qualified exemption applicable to my farm?**

(a) Submission of an appeal, including submission of a request for an informal hearing, will not operate to delay or stay any administrative action, including enforcement action by FDA, unless the Commissioner of Food and Drugs, as a matter of discretion, determines that delay or a stay is in the public interest.

(b) If the owner, operator, or agent in charge of the farm appeals the order, and FDA confirms the order, the owner, operator, or agent in charge of the farm must comply with the applicable requirements of this part ~~within 60 calendar days of the date of the order, or, if operation have ceased and will not resume within 60 calendar days, before the beginning of the next growing season.~~

(1) If the farm is a very small business, within 2 years of the date the order was received; or

(2) If the farm is a small business, within 1 year of the date the order was received.

### **§ 112.206 What is the procedure for submitting an appeal?**

(a) To appeal an order to withdraw a qualified exemption applicable to a farm under § 112.5, the owner, operator, or agent in charge of the farm must:

(1) Submit the appeal in writing to the FDA District Director in whose district the farm is located (or in the case of a foreign farm, the Director of the Office of Compliance in the Center for Food Safety and Applied Nutrition), at the mailing address, email address, or facsimile number identified in the order within 10 calendar days of the date ~~of~~ the order was received; and

(2) Respond with particularity to the facts and issues contained in the order, including any supporting documentation upon which the owner, operator or agent in charge of the farm relies.

(b) In a written appeal of the order withdrawing an exemption provided under § 112.5, the owner, operator, or agent in charge of the farm may include a written request for an informal hearing as provided in § 112.207.

### **§ 112.207 What is the procedure for requesting an informal hearing?**

(a) If the owner, operator, or agent in charge of the farm appeals the order, the owner, operator, or agent in charge of the farm:

(1) May request an informal hearing; and

(2) Must submit any request for an informal hearing together with its written appeal submitted in accordance with § 112.206 within 10 calendar days of the date ~~of~~ the order was received.

(b) A request for an informal hearing may be denied, in whole or in part, if the presiding officer determines that no genuine and substantial issue of material fact has been raised by the materials submitted. If the presiding officer determines that a hearing is not justified, a written notice of the determination will be given to the owner, operator, or agent in charge of the farm explaining the reason for the denial.

### **§ 112.208 What requirements are applicable to an informal hearing?**

If the owner, operator, or agent in charge of the farm requests an informal hearing, and FDA grants the request:

(a) The hearing will be held within 10 calendar days after the date the appeal is filed or, if applicable,

within a timeframe agreed upon in writing by the owner, operator, or agent in charge of the farm and FDA.

(b) The presiding officer may require that a hearing conducted under this subpart be conducted within 1 calendar day, as appropriate.

(c) FDA must conduct the hearing in accordance with part 16 of this chapter, except that:

(1) The order withdrawing an exemption under § 112.5, rather than the notice under § 16.22(a) of this chapter, provides notice of opportunity for a hearing under this section and is part of the administrative record of the regulatory hearing under § 16.80(a) of this chapter.

(2) A request for a hearing under this subpart must be addressed to the FDA District Director (or, in the case of a foreign farm, the Director of the Office of Compliance in the Center for Food Safety and Applied Nutrition) as provided in the order withdrawing an exemption.

(3) Section 112.209, rather than § 16.42(a) of this chapter, describes the FDA employees who preside at hearings under this subpart.

(4) Section 16.60(e) and (f) of this chapter does not apply to a hearing under this subpart. The presiding officer must prepare a written report of the hearing. All written material presented at the hearing will be attached to the report. The presiding officer must include as part of the report of the hearing a finding on the credibility of witnesses (other than expert witnesses) whenever credibility is a material issue, and must include a proposed decision, with a statement of reasons. The hearing participant may review and comment on the presiding officer's report within 2 calendar days of issuance of the report. The presiding officer will then issue the final decision.

(5) Section 16.80(a)(4) of this chapter does not apply to a regulatory hearing under this subpart. The presiding officer's report of the hearing and any comments on the report by the hearing participant under § 112.208(c)(4) are part of the administrative record.

(6) No party shall have the right, under § 16.119 of this chapter to petition the Commissioner of Food and Drugs for reconsideration or a stay of the presiding officer's final decision.

(7) If FDA grants a request for an informal hearing on an appeal of an order withdrawing an exemption, the hearing must be conducted as a regulatory hearing under regulation in accordance with part 16 of this chapter, except that § 16.95(b) does not apply to a hearing under this subpart. With respect to a regulatory hearing under this subpart, the administrative record of the hearing specified in §§ 16.80(a)(1), (a)(2), (a)(3), and (a)(5), and 112.208(c)(5) constitutes the exclusive record for the presiding officer's final decision. For purposes of judicial review under § 10.45 of this chapter, the record of the administrative proceeding consists of the record of the hearing and the presiding officer's final decision.

### **§ 112.209 Who is the presiding officer for an appeal and an informal hearing?**

The presiding officer for an appeal, and for an informal hearing, must be an FDA Regional Food and Drug Director or another FDA official senior to an FDA District Director.

### **§112.210 What is the timeframe for issuing a decision on an appeal?**

(a) If the owner, operator, or agent in charge of a farm appeals the order without requesting a hearing, the presiding officer must issue a written report that includes a final decision confirming or revoking the withdrawal by the 10th calendar day after the appeal is filed.

(b) If the owner, operator, or agent in charge of the farm appeals the order and request an informal hearing:

(1) If FDA grants the request for a hearing and the hearing is held, the presiding officer must provide a 2 calendar day opportunity for the hearing participants to review and submit comments on the report of the hearing under § 112.208(c)(4), and must issue a final decision within 10 calendar days after the hearing is held; or

(2) If FDA denies the request for a hearing, the presiding officer must issue a final decision on the appeal confirming or revoking the withdrawal within 10 calendar days after the date the appeal is filed.

### **§ 112.211 When is an order to withdraw a qualified exemption applicable to a farm revoked?**

An order to withdraw a qualified exemption applicable to a farm under § 112.5 is revoked if:

(a) An officer or qualified employee of FDA submits an order to withdraw, and FDA does not approve the order to withdraw within 10 calendar days after the date the order to withdraw was submitted; or

~~(a)~~ (b) The owner, operator, or agent in charge of the farm appeals the order and requests an informal hearing, FDA grants the request for an informal hearing, and the presiding officer does not confirm the order within the 10 calendar days after the hearing, or issues a decision revoking the order within that time; or

~~(b)~~ (c) The owner, operator, or agent in charge of the farm appeals the order and requests an informal hearing, FDA denies the request for an informal hearing, and FDA does not confirm the order within 10 calendar days after the appeal is filed, or issues a decision revoking the order within that time; or

~~(c)~~ (d) The owner, operator, or agent in charge of the farm appeals the order without requesting an informal hearing, and FDA does not confirm the order within 10 calendar days after the appeal is filed, or issues a decision revoking the order within that time.

~~(d)~~ (e) Confirmation of a withdrawal order by the presiding officer is considered final Agency action for purposes of 5 U.S.C. 702.

### **§ 112.212 If my qualified exemption is withdrawn, what is the procedure for getting my qualified exemption reinstated?**

(a) If, after an order to withdraw a qualified exemption has been issued under § 112.201(b) (and confirmed upon appeal, if applicable) and the date by which the farm is required to come into compliance with the provisions of this part has not passed as per § 112.205(b), the owner, operator, or agent in charge of the farm demonstrates to FDA that the conduct or conditions that triggered the withdrawal order have been sufficiently resolved, FDA shall reinstate the farm's qualified exemption status.

(b) If a farm has had its qualified exemption withdrawn under § 112.201(b) and the date by which farm is required to come into compliance with the provisions of this part as per § 112.205(b) has passed, the

Secretary shall provide the owner, operator, or agent in charge of the farm an opportunity for an informal hearing, upon request of said owner, operator, or agent, to be held as soon as possible but not later than 10 business days after the request, on the reasons the farm's qualified exemption should be reinstated.

(1) The owner, operator, or agent in charge of such farm shall present evidence demonstrating that the conduct or conditions that triggered the withdrawal order have been sufficiently resolved.

(2) The Secretary shall reinstate a farm's qualified exemption under §§ 112.4(b), 112.5, and 112.6 of this part if the Secretary determines, based on evidence presented, that adequate grounds do not exist to continue to withhold the farm's exemption status.

(c) If, after an order to withdraw a qualified exemption has been issued under § 112.201(a), FDA concludes the active investigation of a foodborne illness outbreak and FDA finds that the farm in question was not directly linked to the foodborne illness outbreak, the Secretary shall automatically reinstate the farm's qualified exemption (without a hearing) and notify the farm of the reinstatement.