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**Re: Comments on FDA Proposed Rule for Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food, 78 Federal Register 3646 (January 16, 2013)**

To Whom It May Concern,

These comments on the Food and Drug Administration's (FDA) Proposed Rule for the Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food (Preventive Controls 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 practices for food manufacturing and processing facilities that will improve the safety of the nation's food supply in a way that accommodates the diversity of food manufacturing and processing 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 food production 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 food production 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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### **Author & Contributors**

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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 Subpart A—General Provisions

### 1. FDA should adopt its conclusion that the Preventive Controls Rule will apply only to “facility” activities. FDA should shrink the definition of “facility” activities and expand the definitions of “farming” activities.

The proposed Preventive Controls Rule applies to facilities, which are defined in the rule as domestic or foreign facilities that are required to register under § 415 of the Federal Food, Drug, and Cosmetic Act (FDCA).<sup>1</sup> Section 415 of the FDCA defines facilities as entities “engaged in manufacturing, processing, packing, or holding food for consumption in the United States.”<sup>2</sup> The proposed Produce Safety Rule, on the other hand, applies to covered farms doing covered activities, which include growing, harvesting, packing (and packaging), and holding food.<sup>3</sup> The two rules are intended to apply distinctly to separate activities, meaning, activities triggering the Produce Safety Rule should not also trigger the Preventive Controls Rule. In some cases, a farm may be subject to both proposed rules by virtue of conducting these separate activities, for example, a farm that grows strawberries (farm activity) and then processes them into strawberry jam (facility activity). FDA calls these operations “farm mixed-type facilities.” These farm mixed-type facilities are defined in both proposed rules as “establishment[s] that engage[] in both activities that are exempt from registration under section 415 of the [FDCA] and activities that require the establishment to be registered,” or in other words, farms that do some facility activities.<sup>4</sup> Although the activities of some operations can clearly be categorized as “farm” or “facility” activities, the distinction is not always as clear. Under the proposed rules, certain activities, such as packing and holding, can be considered both farm and facility activities. Because of this, there is a chance that one operation could be subject to both the Produce Safety Rule and the Preventive Controls Rule when conducting an activity that looks more like a farm activity than a facility activity.

FDA has made the “tentative conclusion” that the Preventive Controls Rule will only apply to those activities of a farm mixed-type facility that trigger the § 415 registration regulations (i.e., those activities that are manufacturing, processing, packing, or holding in a “facility” and are not within the definition of “farming”).<sup>5</sup> The FDA should adopt this conclusion in the final rule. The Preventive Controls Rule, especially the provisions contained in Subpart C—Hazard Analysis and Risk-Based Preventive Controls (HARP-C), is tailored to the needs and challenges of manufacturing/processing activities, and is not well-suited to the agricultural activities that a farm mixed-type facility may simultaneously conduct. Likewise, a regulatory framework that makes farm mixed-type facilities comply with the Preventive Controls Rule when conducting their farm activities would be extremely burdensome. The activity-based approach taken in the proposed rule would ensure that the provisions of the Preventive Controls Rule apply only to those discrete activities that fall under the definition of “facility,” and that the rule does not have a spillover effect on a farm mixed-type facility’s agricultural activities.

As mentioned above, under the existing definitional framework, a “facility” is defined as any entity that “manufactures, processes, packs, or holds food;”<sup>6</sup> this broad definition could unnecessarily sweep in traditional agricultural activities closely linked to the business of farming and that only superficially resemble “facility” activities. Post-harvest activities like washing, labeling, packaging, and waxing are all examples of activities that can be both “farm” and “facility” activities. To help clarify the distinction between “farm” and “facility” activities, FDA added new definitions to “manufacturing/processing,”

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<sup>1</sup> 78 Fed. Reg. at 3799 (Sub. A § 117.3).

<sup>2</sup> Federal Food, Drug, & Cosmetic Act § 415, 21 U.S.C. § 350d(a)(1) (2012).

<sup>3</sup> Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption, 78 Fed. Reg. 3504, 3632 (Sub. A § 112.4(a)) (proposed Jan. 16, 2013) (to be codified at 21 C.F.R. pts. 16, 112), *available at* <http://www.gpo.gov/fdsys/pkg/FR-2013-01-16/pdf/2013-00123.pdf>.

<sup>4</sup> 78 Fed. Reg. at 3799 (Sub. A § 117.3)).

<sup>5</sup> 78 Fed. Reg. at 3677 (Preamble).

<sup>6</sup> 21 C.F.R. § 1.227(b)(2) (2012).

“packing,” “holding,” and “harvesting.”<sup>7</sup> Without these new definitions proposed in the Preventive Controls Rule, establishments that engage in these hybrid activities may be uncertain as to whether they are considered farm mixed-type facilities or pure farms. Likewise, establishments that are clearly farm mixed-type facilities may still be uncertain as to *which* of their specific activities fall under the provisions of the Preventive Controls Rule. The proposed rule’s new framework—which roots the distinction between the categories in a determination of whether the activity transforms a raw agricultural commodity (RAC) into a processed food—will help farmers determine if and how they are covered by the Preventive Controls Rule.

These new definitions are an important step in helping determine which activities trigger the Preventive Controls Rule and which trigger the Produce Safety Rule. However, the proposed rule’s new framework also distinguishes between farm and facility activities based on whether the activity is conducted on the farm’s own RACs or another farm’s RACs. Because of this, there are numerous common farming practices that will now be considered “facility” activities, and will unnecessarily subject a farm to the requirements of the Preventive Controls Rule. For example, under the proposed Preventive Controls Rule, a farm that holds the intact RACs of another farm will be considered a facility. Many farms engaged in local and regional markets hold and pack produce from other farms, oftentimes as part of collaborative farming operations. These farms should not be considered facilities based on their conducting low-risk activities on another farm’s RACs, when that same action done to their own RACs would not trigger the Preventive Controls Rule.

**Recommendation:** FDA should adopt its activity-based approach to determine whether certain activities are “farm” or “facility” activities and should ensure that only the “facility” activities will subject an operation to the Preventive Controls Rule. Further, FDA should adopt its current proposal to expand and clarify the scope of “farming” activities and accordingly shrink the definition of “facility” activities. For example, packing (including packaging) and holding of another farm’s RACs alone should not transform a farm into a farm mixed-type facility (discussed more below).

## **2. FDA should exempt packing (including packaging) and holding someone else’s RACs from the definition of facility.**

The proposed Preventive Controls Rule distinguishes between activities involving a farm’s own RACs and activities involving another farm’s RACs for purposes of triggering the Preventive Controls Rule.<sup>8</sup> Under the proposed Preventive Controls Rule, if a farm packs, packages, or holds its own RACs, it is considered a farm; but if this same farm packs, packages, or holds another farm’s RACs, it suddenly is considered a facility.<sup>9</sup> This distinction will create obstacles for collaborative farming operations and for farms incorporating other modern farming practices. For example, under the proposed expanded definition of “packing,” a farm is allowed to “pack a mix of RACs together (e.g., in a bag containing an assortment of vegetables, or a box of mixed produce for a community sponsored agriculture program farm share)”<sup>10</sup>—but only using that farm’s *own* RACs.<sup>11</sup> Similarly, a farm is allowed to store its own RACs—including using processes like fumigating or applying pesticides in preparation for storage—under the expanded definition of “holding,”<sup>12</sup> but would not be able to do this with another farm’s RACs. As a result, a farm may be completely outside the scope of the Preventive Controls Rule when handling its

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<sup>7</sup> 78 Fed. Reg. at 3799 (Sub. A § 117.3).

<sup>8</sup> See 78 Fed. Reg. at 3800–01 (Sub. A § 117.5).

<sup>9</sup> 78 Fed. Reg. at 3800-01 (Sub. A § 117.3).

<sup>10</sup> 78 Fed. Reg. at 3682 (Preamble).

<sup>11</sup> “Own RACs” in this context means “grown or raised on the same farm or another farm under the same ownership.” 78 Fed. Reg. at 3681 (Preamble).

<sup>12</sup> See 78 Fed. Reg. at 3681 (Preamble).

own RACs, but may then become a farm mixed-type facility subject to the Preventive Controls Rule (and the § 415 registration requirements) when it begins to handle another farm’s RACs in the exact same way.

This structure is problematic for operations such as community supported agriculture operations (CSAs), food hubs, buying clubs, and other cooperative growing and processing operations. These types of entities use collaboration to facilitate access to markets for small-scale farmers, making them more competitive and allowing them to provide consumers with a desired variety of products. Packing, packaging, and holding are low-risk activities (as evidenced by their inclusion in the § 117.5(g) and (h) list of exempt low-risk activities), and the simple fact that otherwise-exempt activities like packing and holding involve produce from multiple farms as a result of this collaboration should not cause these operations to be subject to the Preventive Controls Rule.

**Recommendation:** In the final Preventive Controls Rule, the FDA should create an explicit exemption from the Preventive Controls Rule for farms performing “farm” activities—such as packing, packaging, and holding—on another farm’s produce as part of a collaborative farming operation.

**3. FDA should amend the definition of “retail food establishment” to ensure that sales from CSAs, farmers markets, and roadside stands qualify as sales of food products directly to consumers, for purposes of determining the primary function of an establishment.**

Under § 415 of the FDCA, only facilities are required to register with the FDA.<sup>13</sup> Retail food establishments are not considered “facilities” and thus are exempt from the registration requirements under that section<sup>14</sup> and, accordingly, from the Preventive Controls Rule. Under the Code of Federal Regulations (C.F.R.) definition of “retail food establishment,” an entity can qualify as a retail food establishment “if the annual monetary value of sales of food products directly to consumers exceeds the annual monetary value of sales of food products to all other buyers.”<sup>15</sup>

Section 102(c) of FSMA directs the FDA to clarify that sales of food through operations such as CSAs, farmers markets, and roadside stands qualify as sales of food products directly to consumers for purposes of determining whether an entity meets the retail food establishment definition.<sup>16</sup> Clarification of this definition is important for the following reasons.

Section 102(c) of FSMA makes clear that Congress intended for farms that sell more than half of their produce through CSAs, farmers markets, and roadside stands to be exempt from the Preventive Controls Rule. That provision states:

(c) Clarification of Intent

(1) Retail food establishment. 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;

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<sup>13</sup> 21 U.S.C. § 350d(c) (2012).

<sup>14</sup> 21 U.S.C. § 350d(c) (2012).

<sup>15</sup> 21 C.F.R. § 1.227(b)(11) (2012).

<sup>16</sup> Food Safety Modernization Act § 102(c) (2011).

- (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>17</sup>

Section 102(c) of FSMA makes clear that these entities should be classified as retail food establishments because more than half (if not all) of their sales are direct to consumers.<sup>18</sup> These entities do, however, engage in some manufacturing/processing, packing, and holding of food, and these activities may trigger the § 415 registration requirement if the C.F.R. does not make clear that they qualify as retail food establishments. The current definition of retail food establishment in the C.F.R. provides a non-exhaustive list of examples, including “grocery stores, convenience stores, and vending machine locations.”<sup>19</sup> FDA’s guidance document on registration requirements for small entities references roadside stands as exempt from registration in some sections, but omits these entities in enumerated lists in other sections.<sup>20</sup> Explicitly including CSAs, farmers markets, and roadside stands in the enumerated list of examples would clear up confusion.

Absent clarification, it is possible that these farms would not qualify as retail food establishments and would be considered “facilities;” thus, these farms would be required to come into compliance with the Preventive Controls Rule. This result would not only be burdensome for small farmers, it would be contrary to Congressional intent. To avoid this result, the definition of retail food establishment should include a provision stating that food sales from these operations qualify as sales directly to consumers.

**Recommendation:** FDA should modify the definition of retail food establishment in 21 C.F.R. § 1.227(b)(11) to include an express reference to CSAs, farmers markets, and roadside stands as retail food establishments. Further, FDA should add language to the definition of retail food establishment that clearly states that when calculating the sales of food that are direct to consumer, that sales of food conducted through CSAs, farmers markets, and roadside stands are to be counted. We provide specific recommended changes to the language in the appendix to the comments.

#### **4. FDA should ensure that definitions of key concepts such as “retail food establishment” and “community supported agriculture” are consistent within the Code of Federal Regulations.**

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.

As mentioned above, FDA should comply with § 102(c) of FSMA by explicitly including CSAs, farmers markets, and roadside stands in the definition of retail food establishment. FDA should then 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 Preventive Controls Rule. For instance, FDA makes changes

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<sup>17</sup> Food Safety Modernization Act § 102(c) (2011).

<sup>18</sup> Food Safety Modernization Act § 102(c) (2011).

<sup>19</sup> 21 C.F.R. § 1.227(b)(11) (2012).

<sup>20</sup> FDA’s *Guidance for Industry: What You Need to Know About Registration of Food Facilities; Small Entity Compliance Guide* lists roadside stands as an example of a retail food establishment in the category of facilities that *do not* have to register.

However, in addressing whether FSMA changed the scope of facilities required to register, the guidance document notes that “for the purposes of section 415, the term ‘facility’ does not include, in relevant part, farms, restaurants, and retail food establishments,” but does not mention CSAs or roadside stands. 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>.

to Part 1 of title 21 of the C.F.R., including for the establishment, maintenance, and availability of records that implicate the definition of retail food establishment. FDA adds new definitions to § 1.328, which sets forth definitions for the subpart addressing the establishment, maintenance, and availability of records, but does not address § 1.327, which covers who is excluded from all or part of the recordkeeping regulations.<sup>21</sup> Because confusion could result from a lack of consistency, FDA should ensure that these definitions are uniform across sections. FDA should then add the definition of CSA from 7 C.F.R § 249.2 to the Preventive Controls Rule in §117.3 (definitions) to reduce any confusion that might arise from cross-referencing another title of the C.F.R.

**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 Preventive Controls Rule. We provide specific recommended changes to the language in the appendix to the comments.

#### **5. FDA should exempt facilities that have sales of less than \$25,000 a year from the Preventive Controls Rule, as it does in the Produce Safety Rule.**

The proposed Produce Safety Rule completely exempts farms with sales less than \$25,000 from the Produce Safety Rule’s requirements, explaining that these entities “do not contribute significantly to the produce market and, therefore, to the volume of production that could become contaminated.”<sup>22</sup> Although the smallest of food processors also do not contribute significantly to the food market, the proposed Preventive Controls Rule contains no parallel provision. While there are modified requirements for very small businesses, and an extended compliance timeline for small businesses, no entity is completely exempt from the Preventive Controls Rule.

Because the food safety risk posed by these smallest of food processors, like the smallest farms, is extremely minimal, FDA should exempt these facilities from the Preventive Controls Rule. Like the smallest of farms, the smallest processors/manufacturers would remain subject to the adulteration provisions and other applicable regulations under the FDCA.<sup>23</sup>

**Recommendation:** FDA should add a provision to the final Preventive Controls Rule that clearly exempts facilities that have less than \$25,000 in average annual sales from the provisions of the Preventive Controls Rule. We provide specific recommended changes to the language in the appendix to the comments.

#### **6. FDA should apply the list of exempt low-risk activities in § 117.5(h)(2) both to farms operating on another farm’s RACs and to farms operating on their own RACs.**

The proposed Preventive Controls Rule, in § 117.5(g) and (h), exempts farm mixed-type facilities from portions of the Preventive Controls Rule if (1) the facility is a small or very small business, and (2) the only processing activities the facility performs fall within an enumerated list of on-farm, low-risk activities.<sup>24</sup> The list of exempt activities, however, is longer for farm mixed-type facilities operating on another farm’s RACs than for farm mixed-type facilities operating on their own RACs.<sup>25</sup> The difference presumably arises because, when certain activities are performed on a farm’s own RACs, those activities are considered packing, holding, or harvesting and thus fall under the umbrella of farming, which is wholly exempt from the Preventive Controls Rule.

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<sup>21</sup> 78 Fed. Reg. at 3796 (Part 1 – General Enforcement Regulations).

<sup>22</sup> 78 Fed. Reg. at 3529 (Preamble).

<sup>23</sup> 78 Fed. Reg. at 3549 (Preamble).

<sup>24</sup> 78 Fed. Reg. at 3800–01 (Sub. A § 117.5).

<sup>25</sup> 78 Fed. Reg. at 3800–01 (Sub. A § 117.5).

For example, § 117.5(h)(2)'s exemption for “shelling/hulling [another farm's] cocoa beans (i.e., winnowing), intact fruits and vegetables (e.g., dried beans and peas), and peanuts and tree nuts” is not reproduced in § 117.5(h)(1), because the shelling/hulling of one's own RACs is already a “farm” activity and, as such, already exempt from the Preventive Controls Rule. While this structure would technically allow farms operating on their own RACs to be exempt from the full list of enumerated activities under § 117.5(h)(2), the difference in the lists between § 117.5(g) and (h) may create confusion for farmers in determining if and how they are covered by the Preventive Controls Rule.

FDA can reduce this confusion, without changing the scope of the rule's coverage, by applying the longer list in § 117.5(h)(2) both to activities conducted on another farm's RACs and to activities conducted on a farm's own RACs. Because there are some differences in the way activities are described in § 117.5(h)(1) and § 117.5(h)(2), these descriptions would need to be harmonized. Table 1, included in the appendix, highlights the differences between the lists.

**Recommendation:** FDA should combine into one list the currently separate lists of low-risk activities for farms that conduct those activities on their own RACs and for farms that conduct those activities on the RACs of other farms into one list. Providing one list of all exempt low-risk activities will reduce confusion among farmers. We provide specific recommended changes to the language in the appendix to the comments.

#### **7. FDA should include an explicit exemption for all farming activities from all provisions of the Preventive Controls Rule.**

Section 418(k) of the FDCA, as added by FSMA, explicitly exempts activities covered by the Produce Safety Rule from Subpart C of the Preventive Controls Rule.<sup>26</sup> The proposed Preventive Controls Rule in § 117.5(f) states “Subpart C of this part does not apply to activities of a facility that are subject to section 419 of the Federal Food, Drug, and Cosmetic Act (Standards for Produce Safety).”<sup>27</sup> However, exempting *only* those activities covered by the Produce Safety Rule, as opposed to simply *all farming* activities, may create confusion and is not mandated by the statute. There are some farming activities that are exempt from the Produce Safety Rule but that should also be exempt from the Preventive Controls Rule. Growing and harvesting grain, for example, is not covered by the Produce Safety Rule, but clearly does not fall within the “facility” activities intended to be covered by the Preventive Controls Rule. Creating an explicit exemption for only those activities covered by the Produce Safety Rule could lead to an interpretation that farming activities not covered by the Produce Safety Rule are potentially subject to the Preventive Controls Rule.

Further, the language and structure of FSMA make clear that Congress intended farming activities to be exempt from the Preventive Controls Rule. While the language of § 418(k) explicitly exempts all activities covered by the Produce Safety Rule from the Preventive Controls Rule,<sup>28</sup> the statutory structure, which creates two parallel rules to govern food safety, envisions that each rule would govern specific, separate sets of activities. Section 105 of FSMA, which underlies the Produce Safety Rule, requires creation of standards for the “safe production and harvesting of . . . fruits and vegetables.”<sup>29</sup> Section 103 of FSMA, which underlies the Preventive Controls Rule, requires evaluation of hazards affecting “food manufactured, processed, packed, or held by such facility.”<sup>30</sup> Congress chose to govern these distinct sets of activities using separate sets of regulations. It is unlikely then, that in exempting certain activities from the Produce Safety Rule, Congress envisioned that those activities would be captured by the parallel rule.

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<sup>26</sup> 21 U.S.C. § 350g(k) (2012).

<sup>27</sup> 78 Fed. Reg. at 3800 (Sub. A § 117.5(f)).

<sup>28</sup> 21 U.S.C. § 350g(k) (2012).

<sup>29</sup> Food Safety Modernization Act § 105, 21 U.S.C. § 350h(a)(1)(A) (2012).

<sup>30</sup> Food Safety Modernization Act § 103, 21 U.S.C. § 350g (2012).

The proposed Preventive Controls Rule captures this division of activities in § 117.5(k), which exempts all “farm” activities from Subpart B of the Preventive Controls Rule (by contrast Subpart C of the Preventive Controls Rule currently only exempts activities subject to the Produce Safety Rule).<sup>31</sup> Section 117.5(k) states:

Subpart B of this part does not apply to “farms” (as defined in Sec. 1.227 of this chapter), activities of “farm mixed-type facilities” (as defined in Sec. 1.227) that fall within the definition of “farm,” or the holding or transportation of one or more “raw agricultural commodities,” as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act.<sup>32</sup>

Section 117.5(k) can serve as a model for a similar exemption from Subpart C of the Preventive Controls Rule. By explicitly exempting all farming activities from the Subpart C of the Preventive Controls Rule, the FDA can ensure that it is clear with regard to the regulatory scheme governing both farming and processing, and that the final rule complies with Congress’ regulatory design.

**Recommendation:** FDA should modify § 117.5(f) to mirror § 117.5(k)’s language exempting “farms” and farm activities from coverage under the Preventive Controls Rule. We provide specific recommended changes to the language in the appendix to the comments.

## **II. Comments on the Modified Requirements for Qualified Facilities in Subpart D**

### **1. FDA should use a \$1 million or higher threshold to define very small business.**

Section 418(l) of the FDCA (§ 103 of FSMA) provides for modified requirements for “qualified facilities.”<sup>33</sup> Businesses defined as “very small businesses” categorically fall within the definition of qualified facilities (as well as businesses that have average annual sales of less than \$500,000 and sell more than half of their sales to qualified end-users).<sup>34</sup> Congress directed FDA to define the term “very small business” in regulations promulgated under FSMA.<sup>35</sup> Under § 103 of FSMA, Congress did not provide FDA with any parameters or restrictions on how to define “very small business.”<sup>36</sup> FDA, through the proposed Preventive Controls Rule, set forth three possible maximum sales thresholds for use in defining very small business—\$250,000, \$500,000, or \$1 million.<sup>37</sup> FDA is seeking comment on this issue.

FDA should adopt the \$1 million threshold, or a higher amount, such as \$5 million. FDA has the authority to define “very small business” as it sees fit; that is, the statute does not limit FDA’s ability to define “very small business.” Of the three options currently proposed, FDA should chose \$1 million, because it is the highest available. Businesses that reach \$1 million in annual sales are in most cases still quite small. A lower threshold to be a “very small business” could disadvantage small businesses that sell goods at higher prices that reflect higher input costs. Small businesses often have tight margins and \$1 million in

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<sup>31</sup> Subpart B of the Preventive Controls Rule updates the FDAs Current Good Manufacturing Practices. 78 Fed. Reg. at 3802 (Sub B §§ 117.10, 20, 35, 37, 40, 80, 93, 110).

<sup>32</sup> 78 Fed. Reg. at 3802 (Sub A § 117.5(k)).

<sup>33</sup> 78 Fed. Reg. at 3800 (Sub. A § 117.3) (“Qualified facility”); 78 Fed. Reg. at 3808 (Sub. D § 117.201) (“Modified requirements that apply to qualified facility”).

<sup>34</sup> 78 Fed. Reg. at 3800 (Sub A. § 117.5); *see also* 78 Fed. Reg. at 3702–03 (Preamble) (discussing the proposed § 117.5 exemptions in detail).

<sup>35</sup> Food Safety Modernization Act § 103(a), 21 U.S.C. § 350g(l)(1)(B) (2012).

<sup>36</sup> Food Safety Modernization Act § 103(a), 21 U.S.C. § 350g(l)(1)(B) (2012).

<sup>37</sup> 78 Fed. Reg. at 3701 (Preamble).

sales does not necessarily mean these businesses are taking in that much in profit. Further, a \$1 million or higher threshold will ensure that very small businesses are not disadvantaged in the marketplace by having to expend a disproportionately large percentage of their resources to comply with all of the Preventive Controls Rule's requirements.

**Recommendation:** FDA should adopt the \$1 million threshold (or higher) to define a "very small business" for purposes of being considered a qualified facility under the final Preventive Controls Rule.

## **2. FDA should explicitly state that businesses have the option to self-certify as qualified facilities.**

Section 117.201(a) of the proposed Preventive Controls Rule requires that qualified facilities submit documentation to the FDA demonstrating that the facility (a) meets the definitional requirements of a qualified facility,<sup>38</sup> and (b) has complied with the modified requirements for qualified facilities by either implementing an abbreviated version of the hazard analysis and risk-based preventive controls requirements (HARP-C)<sup>39</sup> or complying with state, local or other non-federal food safety laws.<sup>40</sup> The FDA has "tentatively conclude[d]" that, in lieu of submitting this documentation to FDA, it will allow qualified facilities to submit a statement that the facility meets both the definitional and compliance requirements and possesses documentation to substantiate this claim.<sup>41</sup> The final rule should adopt this proposal.

Self-certification would not only save time and money for qualified facilities, it would also reduce the paperwork burden that the agency would undertake by receiving and filing each facility's documentation. The requirement that qualified facilities keep on file the documents they rely upon for their self-certifications makes clear that this provision is a purely time-saving measure, and should allay any concerns that facilities could fabricate their qualifications. Further, the possibility of agency verification is a strong enforcement mechanism to ensure that qualified facilities maintain proper documentation, reducing the need to require these qualified facilities to expend the additional resources involved in document submission.

**Recommendation:** FDA should not require qualified facilities to submit documentation to the FDA, and should instead allow these qualified facilities to self-certify. FDA should modify the language in § 117.201(a) to explicitly allow for this self-certification. We provide specific recommended changes to the language in the appendix to the comments.

## **III. Comments on the Withdrawal of an Exemption Applicable to a Qualified Facility in Subpart E**

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

However, the proposed Preventive Controls Rule's process for withdrawing an exemption from a qualified facility 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 qualified facility to come into compliance with the Preventive Controls Rule if that qualified facility is directly linked to a foodborne illness outbreak or there is a high risk to the public health from food from that

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<sup>38</sup> 78 Fed. Reg. at 3808 (Sub. D § 117.201(a)(1)).

<sup>39</sup> 78 Fed. Reg. at 3808 (Sub. D § 117.201(a)(2)(i)).

<sup>40</sup> 78 Fed. Reg. at 3808 (Sub. D § 117.201(a)(2)(ii)).

<sup>41</sup> 78 Fed. Reg. at 3769–3770 (Preamble).

qualified facility. However, the consequences of an order to withdraw are significant for these qualified facilities. It is thus imperative that the process to withdraw an exemption from a qualified facility 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 facility 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 qualified facility must come into compliance with all of the provisions of the Preventive Controls Rule, which is also costly and burdensome. It is important to provide a high threshold that would trigger an order to withdraw to make sure that qualified facilities are not unnecessarily subjected to the exemption withdrawal process.

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

Section 117.251(b) of the proposed Preventive Controls Rule states that FDA may withdraw a qualified facility's exemption:

[i]n the event of an active investigation of a foodborne illness outbreak that is directly linked to the qualified facility; or

[i]f FDA determines that it is necessary to protect the public health and prevent or mitigate a foodborne illness outbreak based on conduct or conditions associated with the qualified facility that are material to the safety of the food manufactured, processed, packed, or held at such facility.<sup>42</sup>

Many of the terms included in § 117.251 are vague and leave substantial room for discretion on the part of the FDA employee initiating an order to withdraw an exemption. Additionally, under § 117.257(c), 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>43</sup> This lack of evidentiary standard for withdrawing a qualified facility's 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 (§ 117.251(a))*

For an active investigation of a foodborne illness outbreak that may result in a withdrawal proceeding, FDA must establish that the qualified facility 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 qualified facility. 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 Facility (§ 117.251(b))*

For an order to withdraw an exemption that is based on § 117.251(b), FDA should add an evidentiary standard that requires the FDA official recommending the order to withdraw 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>42</sup> 78 Fed. Reg. at 3809 (Sub. E § 117.251).

<sup>43</sup> 78 Fed. Reg. at 3809 (Sub. E § 117.257(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 at a qualified facility sufficient to trigger the exemption withdrawal procedures. Currently, the mere requirement that the triggering conditions be “associated” with the qualified facility 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>44</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>45</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 facilities when it added the Tester-Hagan amendment to the legislation.

Second, the meaning of “material to safety” should be clarified with additional language in § 117.251(b). The final rule should ensure that not every conceivable risk to safety will be “material” enough to trigger withdrawal of a facility’s exemption. The FDA could accomplish this by explicitly stating that, for conduct or conditions to be material to food safety, there must be a reasonable probability that they will contribute to an outbreak of foodborne illness. This “reasonable probability” requirement finds support in other provisions of the FDCA<sup>46</sup> as well as in two illustrative examples that FDA itself provided in the Preamble to the Preventive Controls Rule describing the § 117.251(b) provision.<sup>47</sup> Those examples involved 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>48</sup> Incorporating the reasonable probability standard into the withdrawal process would codify the reasoning behind those examples and serve the purpose of the Preventive Controls Rule by ensuring that the agency’s actions under the rule are linked to public health outcomes.

**Recommendation:** FDA should establish evidentiary standards for withdrawing a qualified facility’s exemption. FDA should require the FDA officer recommending the withdrawal to provide evidence that shows a direct linkage to a problem in a specific qualified facility (under § 117.251(a)); FDA should also require the FDA officer recommending a withdrawal under § 117.251(b) to show credible and substantial evidence that the identified conduct or conditions merit an order to withdraw. Specifically, FDA should add language to § 117.251(b) to specify that the determination must be supported by credible and substantial evidence or information related to an individual qualified facility. We provide specific recommended changes to the language of Subpart E in the appendix to the comments.

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

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<sup>44</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>45</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>46</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”).

<sup>47</sup> 78 Fed. Reg. at 3776 (Preamble).

<sup>48</sup> See 78 Fed. Reg. at 3776 (Preamble).

Under the proposed rule, if a qualified facility is directly linked to the active investigation of a foodborne illness outbreak or if “FDA determines that it is necessary to protect the public health and prevent or mitigate a foodborne illness outbreak based on conduct or conditions associated with the qualified facility that are material to the safety of the food manufactured, processed, packed, or held at such facility,” the FDA may withdraw a qualified facility’s exemption.<sup>49</sup> Subpart E of the proposed Preventive Controls Rule appears to contemplate withdrawal of a qualified facility’s exemption as the *only* remedy for a finding of either of the triggering conditions in § 117.251. There may, however, be circumstances in which the complete withdrawal of an exemption is not needed to prevent or mitigate a foodborne illness outbreak, as outlined in § 117.251(b). More targeted measures may suffice to address certain problems, especially when the observed deficiency can be corrected with a tailored, technical solution. We therefore recommend that the FDA allow a qualified facility a chance to rectify the triggering circumstances before undertaking withdrawal proceedings.

To provide the opportunity for a more precise solution to minor violations, the final Preventive Controls Rule should include a warning letter provision that gives a qualified facility fifteen days to identify how it will remedy safety concerns, and a certain amount of time to make those changes. A warning letter provision would give FDA inspectors the ability to scale desired remedies according to the severity of food safety concerns. Indeed, a warning letter provision may encourage inspectors to address food safety conditions that cause concern but do not appear to merit the time and effort necessary to undertake the exemption withdrawal process. And it would allow businesses to correct minor, easily-remedied conduct or conditions without triggering the appeals process or full compliance, which could be burdensome to small and very small businesses.

There is precedent within FDA for using modified consequences for minor violations. The agency commonly uses warning letters to notify businesses of violations of FDA regulations.<sup>50</sup> 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>51</sup> FDA has a long history of issuing warning letters to facilities requiring those facilities to fix the identified issues. Presumably, this provision would apply to the new sections of the FDCA added by FSMA. The final Preventive Controls Rule should explicitly incorporate modified withdrawal procedures to ensure that modified procedures, such as warning letters, are recognized and used by FDA officials.

**Recommendation:** FDA should first issue a warning letter to a qualified facility before resorting to exemption withdrawal proceedings. In the warning letter, FDA should identify the conduct or conditions in question or how FDA believes the qualified facility is directly linked to an investigation of a foodborne illness outbreak, outline how the qualified facility 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 E in the appendix to the comments.

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

Given the variety of situations that may trigger a withdrawal, FDA should clarify that the withdrawal may

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<sup>49</sup> 78 Fed. Reg. at 3809 (Sub. E § 117.251).

<sup>50</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>.

<sup>51</sup> 21 U.S.C. § 336 (2012).

be a partial withdrawal of an exemption with respect to only certain subparts of the Preventive Controls Rule's requirements, and not always a total withdrawal triggering a requirement that the facility comply with all subparts of the Preventive Controls Rule's requirements. The partial withdrawal could be tailored to the facility's issues or conduct/conditions associated with the qualified facility. This way, small businesses can seek targeted solutions as needed without falling under all the substantive, costly provisions of the Preventive Controls Rule.

**Recommendation:** In the final Preventive Controls Rule, FDA should authorize the use of a partial withdrawal and modify proposed § 117.257 to include a statement that indicates whether the withdrawal order is for a partial or total withdrawal. If the withdrawal is partial, FDA should indicate with which sections of the rule the facility must comply. We provide specific recommended changes to the language of Subpart E in the appendix to the comments.

#### **4. FDA should add a new section that allows qualified facilities to regain their exempt status and that outlines the criteria and process for reinstatement.**

The proposed Preventive Controls Rule does not include a process by which a qualified facility may regain its exemption after the exemption has been withdrawn.<sup>52</sup> If a facility has eliminated the problems that led to the withdrawal, requiring the facility to fully comply with the Preventive Controls Rule would not be necessary to protect the safety of the food supply. Permanent withdrawal of a facility's exemption would, on the other hand, represent a dramatic increase in the regulatory burden for small and very small businesses. Allowing reinstatement following a food safety issue has precedent in other sections of the FDCA.<sup>53</sup> In § 415 of the FDCA, facilities that have lost their registration can regain it if safety issues are resolved and evidence does not support continuing the suspension.<sup>54</sup> The final Preventive Controls Rule should provide a similar path by which a qualified facility that has corrected the safety risk that led to the qualified exemption withdrawal, and is currently operating under safe conditions, may regain its exemption.

FDA's process for reinstatement of registration of food facilities serves as a logical model for reinstatement of a qualified facility's exemption under the Preventive Controls Rule. Under § 415, 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>55</sup> Under that section, if a facility's registration is withdrawn, the FDA must provide an opportunity for an informal hearing to discuss what actions are required for reinstatement of the registration.<sup>56</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."<sup>57</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 issue that led to the suspension.<sup>58</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>59</sup>

While there are differences in the ramifications of a § 415 registration withdrawal and a Preventive Controls Rule qualified exemption withdrawal, the procedures have much in common. In both cases,

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<sup>52</sup> See 78 Fed. Reg. at 3809 (Sub. E).

<sup>53</sup> 21 U.S.C. § 350d(b) (2012).

<sup>54</sup> 21 U.S.C. § 350d(b)(2) (2012).

<sup>55</sup> 21 U.S.C. § 350d(b)(1) (2012).

<sup>56</sup> 21 U.S.C. § 350d(b)(2) (2012).

<sup>57</sup> 21 U.S.C. § 350d(b)(2) (2012).

<sup>58</sup> 21 U.S.C. § 350d(b)(3)(A) (2012).

<sup>59</sup> 21 U.S.C. § 350d(b)(3)(B) (2012).

FDA has reason to believe the food produced in a facility may cause significant harm. This finding gives the agency authority to revoke the facility's registration or exemption. The consequences of both withdrawals are extremely serious. Revocation of facility's § 415 registration serves as a complete bar on sales into interstate commerce.<sup>60</sup> While qualified facilities whose exemptions are withdrawn may still sell, they must come into compliance with the full requirements of the Preventive Controls Rule. Many qualified facilities will not have the immediate cash flow necessary to come into full compliance within a short timeframe. The rule provides *non-qualified* facilities (i.e., those subject to the provisions of the Preventive Controls Rule) one to three years, depending on size, to come into compliance with the provisions of the Preventive Controls Rule.<sup>61</sup> A dramatically accelerated timeframe of sixty-days for a qualified facility that loses its exemption would be burdensome for any business, and especially onerous for small and very small businesses.

Following the § 415 model, the final Preventive Controls Rule should provide for a reinstatement process for a qualified facility's exemption. The rule should allow a facility to regain its exempt status (1) before the sixty-day compliance deadline passes, (2) after the sixty-day compliance deadline has passed, or (3) automatically at the conclusion of an investigation.

**Recommendation:** FDA should provide a process by which qualified facilities can regain their exempt status after correcting a problem. FDA should add a new provision to the final Preventive Controls 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 qualified facility to regain its qualified exempt status before the deadline to comply with the Preventive Controls Rule passes. In this situation, FDA would be required to reinstate the qualified facility's exempt status if the owner, operator, or agent in charge of the qualified facility demonstrates that the conduct or conditions that triggered the withdrawal order have been sufficiently resolved.
2. Allow a qualified facility to regain its exempt status after the deadline to comply with the Preventive Controls Rule has passed. In this situation, FDA should give the owner, operator, or agent in charge of the qualified facility an opportunity for an informal hearing during which the owner, operator, or agent in charge of the qualified facility 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 qualified facility's exemption.
3. Automatically reinstate a qualified facility's exemption if FDA concludes an active investigation of a foodborne illness outbreak and finds that the qualified facility in question was not directly linked to the foodborne illness outbreak. In this situation, FDA should provide notice to the qualified facility of the reinstatement.

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

##### **5. FDA should require the order to withdraw to contain specific information about the reason for withdrawal.**

Under § 117.257(c) of the proposed rule, an order to withdraw is required to include only “a brief, general statement of the reasons for the order, including information relevant to: (1) [a]n active investigation of a foodborne illness that is directly linked to the qualified facility; or (2) [c]onduct or conditions associated

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<sup>60</sup> 21 U.S.C. § 350d(b)(4) (2012).

<sup>61</sup> 78 Fed. Reg. at 3673–74 (Preamble).

with the qualified facility that are material to the safety of the food manufactured, processed, packed, or held at [that] facility.”<sup>62</sup> This provision raises two concerns.

First, it does not expressly require the withdrawal order to assert that withdrawal of the exemption is “necessary to protect the public health and prevent or mitigate a foodborne illness outbreak,” as required in § 117.251(b), which sets forth the conditions under which an order to withdraw may be issued.<sup>63</sup> Including this language from § 117.251(b) in § 117.257(c) is important because it requires that the FDA, in issuing an order, has linked the “material conditions” at a given facility with a public health outcome.

Second, in requiring only “a brief, general statement of the reasons for the order,” the current proposed language does not require the agency to provide specific reasons for the withdrawal order.<sup>64</sup> A lack of specificity not only hinders a facility’s ability to correct a problem, but disadvantages the facility in the appeals process, which requires the facility to respond *with particularity* to the facts and issues presented in the order.<sup>65</sup> FDA should carry the burden in providing the reasons for issuing an order to withdraw an exemption.

**Recommendation:** In the final Preventive Controls Rule, FDA should modify the language of proposed § 117.257(c) to require specific information about the reasons for the withdrawal order as well as evidence supporting the withdrawal order. Specifically, under § 117.251(a), FDA should be required to identify the direct linkage between the active foodborne illness outbreak and the qualified facility. Under § 117.251(b), FDA should be required to show measurable evidence that has been collected using generally accepted scientific standards (discussed below) indicating the presence of pathogens at the qualified facility that may pose an imminent threat to public health, identify the specific conduct or conditions that are material to the safety of the food at that qualified facility, 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 E in the appendix to the comments.

**6. FDA should require withdrawal orders to (a) state clearly that the owner, operator, or agent in charge of a qualified facility must either comply with the full requirements of the Preventive Controls Rule or appeal the order; and (b) include information about the opportunity to request an informal hearing.**

Under the proposed Preventive Controls Rule, qualified facilities have only ten days to compile and submit an appeal and request a hearing.<sup>66</sup> This short timeframe makes it imperative that qualified facility owners and operators understand their procedural rights immediately upon receipt of an order. Requiring that information on the appeals process be included within the order to withdraw an exemption will ensure that qualified facilities receiving withdrawal orders can take full advantage of the limited time allotted to appeal the order.

**Recommendation:** In the final Preventive Controls Rule, FDA should add language to § 117.257 to require that the order to withdraw an exemption include a statement that the owner, operator, or agent in charge of a qualified facility that receives the order must either comply with the requirements of the Preventive Controls 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 E in the appendix to the comments.

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<sup>62</sup> 78 Fed. Reg. at 3809 (Sub. E § 117.257(c)).

<sup>63</sup> 78 Fed. Reg. at 3809 (Sub. E § 117.251(b)).

<sup>64</sup> 78 Fed. Reg. at 3809 (Sub. E § 117.257(c)).

<sup>65</sup> 78 Fed. Reg. at 3809 (Sub. E § 117.264(a)(2)).

<sup>66</sup> 78 Fed. Reg. at 3809 (Sub. E § 117.260).

**7. FDA should deliver the order to withdraw in a way that ensures the owner, operator, or agent in charge of a qualified facility receives the order and provides confirmation of receipt of the order to withdraw the exemption. FDA should toll the ten-day time window for appeal from the date the order was received by the facility.**

Because a withdrawal order carries serious consequences for a qualified facility, and the qualified facility has only ten days to initiate an appeal,<sup>67</sup> the final Preventive Controls Rule should include precautionary measures to ensure that the facility receives notice of the order to withdraw the exemption. Requiring delivery that ensures the order is received, for example via certified mail, would not only ensure that the qualified facility receives the order but would create a record of the date of receipt. The date of receipt could then be used to begin tolling the timeframe for filing an appeal. This would ensure that qualified facility owners and operators are not penalized for any lag between the date of issuance and date of receipt.

**Recommendation:** FDA should add language to proposed § 117.254 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 Preventive Controls Rule, FDA should specify that the owner, operator, or agent in charge of the qualified facility 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 qualified facility in question, rather than from the date that the order *was issued* by FDA. We provide specific recommended changes to the language of Subpart E 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 an exemption should be withdrawn from a qualified facility, 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 qualified facility.<sup>68</sup> The proposed Preventive Controls Rule does not set forth time limits for these initial FDA actions in the process to withdraw an exemption.<sup>69</sup>

Because conditions at a facility 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 timeframe for the issuance of an order to withdraw an exemption, and another ten-day timeframe for the its approval or denial by the FDA District Director. This time limit will ensure that any action to withdraw an exemption bears a strong relation to the current conditions at a given facility. Additionally, we recommend that the FDA notify a facility within five days of a decision to approve an order to withdraw, to ensure that facility 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 consequence for a qualified facility.

**Recommendation:** In the final Preventive Controls Rule, FDA should modify the language of § 117.254 to include explicit timeframes by which certain actions must be taken by FDA. FDA should require the FDA officer making the initial determination that an order to withdraw is necessary to submit the order to withdraw within ten days of making that determination; FDA should also require the FDA District Director or senior official to approve or deny the order to withdraw within ten days of the inspector's submission of the order. Finally, if the order is approved, FDA should be required to issue the order to the

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<sup>67</sup> 78 Fed. Reg. at 3809 (Sub. E § 117.260).

<sup>68</sup> 78 Fed. Reg. at 3809 (Sub. E § 117.254).

<sup>69</sup> See 78 Fed. Reg. at 3809 (Sub. E § 117.254).

qualified facility within five days of the order's approval. We provide specific recommended changes to the language of Subpart E 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 facility's exemption.**

The proposed Preventive Controls Rule requires facilities to maintain certain documentation. Under Subpart C of the Preventive Controls Rule, facilities are required to keep extensive documentation of their food safety plans.<sup>70</sup> Qualified facilities, on the other hand, are only required to maintain documents that prove their status as a qualified facility (based on sales to qualified end-users), and documents that either demonstrate compliance with non-federal food safety laws or compliance with a facility's own modified food safety plan.<sup>71</sup>

For a qualified facility filing a written appeal from an order to withdraw an exemption, FDA proposes to require the owner, operator, or agent in charge of the facility 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 facility relies.”<sup>72</sup> Given that qualified facilities are required to submit certain documentation to FDA and keep certain records supporting that documentation, FDA should not require, for purposes of a qualified facility's appeal of a withdrawal order, records that those facilities do not have to keep to support the documentation that they must submit to FDA.

Additional recordkeeping requirements for qualified facilities to defend themselves against potential withdrawals of their exemptions would increase the costs of compliance that these facilities would face and directly contravene Congress' intent in establishing FSMA's flexible, scale- and supply chain-appropriate regulatory framework.

**Recommendation:** FDA should not require facility operators submitting a written appeal to provide documents and records that they are not required to keep. FDA should provide in guidance for public comment additional information about the types of documentation upon which it will rely during the appeal of an order to withdraw.

**10. FDA should indicate the standards and science-based justifications it will rely on in making its final decision to approve or deny an order withdrawing a qualified facility's exemption.**

Once an order to withdraw an exemption has been issued and approved by an FDA District Director or a more senior FDA official, the order to withdraw may be appealed.<sup>73</sup> If the owner, operator, or agent in charge of the facility chooses to appeal the order, that person must submit the appeal in writing and respond, with particularity, to the facts and issues asserted in the order to withdraw the exemption.<sup>74</sup> The written appeal and any supporting documentation submitted by the appellant is the material on which the presiding officer will make his decision to approve or deny the appeal of the order to withdraw the exemption.<sup>75</sup> However, the proposed Preventive Controls Rule does not provide any more details about on what basis the presiding officer will make his decision. The proposed rule provides details on the procedure for an informal hearing,<sup>76</sup> but if an owner, operator, or agent in charge of a qualified facility appeals without an informal hearing, the proposed rule is silent on the standards and procedure by which

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<sup>70</sup> 78 Fed. Reg. 3805-07 (Sub. C §§ 117.126-175).

<sup>71</sup> 78 Fed. Reg. at 3808 (Sub. D §117.201).

<sup>72</sup> 78 Fed. Reg. at 3809 (Sub. E § 117.264(a)(2)).

<sup>73</sup> 78 Fed. Reg. at 3809 (Sub. E §§ 117.254, 260).

<sup>74</sup> 78 Fed. Reg. at 3809 (Sub. E § 117.264(a)).

<sup>75</sup> 78 Fed. Reg. at 3810 (Sub. E § 117.277) (setting out the timeframe for issuing a decision on an appeal).

<sup>76</sup> 78 Fed. Reg. at 3809-10 (Sub. E §§ 117.264(b), 267, 270, 274).

the presiding officer will make his decision (except for the ten day timeframe for issuing the decision on the appeal).<sup>77</sup>

**Recommendation:** To ensure that qualified facilities 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 an order withdrawing a qualified facility 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.

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

Under the proposed rule, a facility 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>78</sup> To ensure that facilities have a fair opportunity to present their appeal, and that hearings are not erroneously denied, the FDA should provide guidance on the types of evidence, or lack thereof, that might justify such a decision.

**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 qualified facility appealing an order to withdraw an exemption.

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<sup>77</sup> 78 Fed. Reg. at 3810 (Sub. E § 117.277(a)).

<sup>78</sup> 78 Fed. Reg. at 3810 (Sub. E § 117.267(b)).

## **Appendix:**

# **Suggested Modified Language for the Preventive Controls Rule**

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

### **Subpart A—General Provisions**

#### **§ 117.3 Definitions**

*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.

*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 or any other type of retail food establishment, 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 or any other type of retail food establishment), 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 or any other type of retail food establishment, but does not include activities that transform a raw agricultural commodity . . . into a processed food.

#### **§ 117.5 Exemptions**

~~(f) Subpart C of this part does not apply to activities of a facility that are subject to section 419 of the Federal Food, Drug, and Cosmetic Act (Standards for Produce Safety). Subpart C of this part does not apply to “farms” (as defined in Sec. 1.227 of this chapter), activities of “farm mixed-type facilities” (as defined in Sec. 1.227) that fall within the definition of “farm,” or the holding or transporting of one or more “raw agricultural commodities,” as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act.~~

(g) Subpart C of this part does not apply to ~~on-farm~~ packing or holding of food by a small or very small business if the only packing and holding activities subject to section 418 of the Federal Food, Drug, and Cosmetic Act that the business conducts are the following low-risk packing or holding activity/food combinations ~~on food not grown, raised, or consumed on that farm mixed type facility or another farm under the same ownership~~—i.e., packing or re-packing (including weighing or conveying incidental to packing or re-packing); sorting, culling, or grading incidental to packing or storing; and storing (ambient, cold and controlled atmosphere) of:

- (1) Hard candy, fudge, taffy, and toffee;
- (2) Cocoa beans and coffee beans (raw and roasted);
- (3) Cocoa products;
- (4) Grains and grain products
- (5) Honey (raw and pasteurized);
- (6) Intact fruits and vegetables other than cocoa beans, coffee beans, peanuts, sugar beets, sugarcane, and tree nuts;
- (7) Jams, jellies, and preserves;
- (8) Maple sap for syrup and maple syrup;
- (9) Peanuts and tree nuts;
- (10) Soft drinks and carbonated water; and
- (11) Sugar beets, sugarcane, and sugar.

(h) Subpart C of this part does not apply to ~~on-farm~~ low-risk manufacturing/processing activities conducted by a small or very small business if the only manufacturing/processing activities subject to section 418 of the Federal Food, Drug, and Cosmetic Act that the business conducts are the following:

~~(1) When conducted on a farm mixed type facility's own raw agricultural commodities as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act (those grown or raised on that farm mixed type facility or another farm/farm mixed type facility under the same ownership) for distribution into commerce:~~

- ~~(i) Artificial ripening of intact fruits and vegetables;~~
- ~~(ii) Boiling/evaporation of maple sap to make maple syrup;~~
- ~~(iii) Chopping raw peanuts and raw tree nuts;~~
- ~~(iv) Coating (with coatings other than wax, oil, or resin used for the purpose of storage or transportation) intact fruits and vegetables (e.g., caramel apples) and coating raw peanuts and raw tree nuts (e.g., adding seasonings);~~
- ~~(v) Drying/dehydrating intact fruits and vegetables (without the addition of sulfites) where the drying creates a distinct commodity (e.g., drying fruits or herbs);~~
- ~~(vi) Extracting oil from grains (e.g., corn, oilseeds, soybeans)~~

~~(vii) Grinding/milling/cracking/crushing grains (e.g., making grain products such as corn meal) and raw peanuts or raw tree nuts (e.g., making ground peanuts);~~

~~(viii) Making jams, jellies, and preserves from acid foods (e.g., acid fruits);~~

~~(ix) Making sugar from sugar beets and sugarcane; and~~

~~(x) Salting raw peanuts and raw tree nuts.~~

~~(2) When conducted on food other than the farm mixed-type facility's own raw agricultural commodities for distribution into commerce: . . .~~

- (1) Artificial ripening of intact fruits and vegetables;
- (2) Chopping peanuts and tree nuts;
- (3) Coating (with coatings other than wax, oil, or resin used for the purpose of storage or transportation) intact fruits and vegetables (e.g., caramel apples) and coating peanuts and tree nuts (e.g., adding seasonings);
- (4) Cooling intact fruits and vegetables using cold air;
- (5) Drying/dehydrating (whether for storage/transport or for creating a distinct commodity) intact fruits and vegetables (without sulfiting), cocoa beans, coffee beans, grains and grain products, and peanuts and tree nuts;
- (6) Extracting oils from grains (e.g., corn, oilseeds, and soybeans);
- (7) Fermenting cocoa beans and coffee beans;
- (8) Grinding/milling/cracking/crushing cocoa beans, coffee beans, grains (e.g., making grain products such as corn meal), and peanuts and tree nuts (e.g., making ground peanuts);
- (9) Labeling (including stickering) hard candy, cocoa beans, cocoa products from roasted cocoa beans (other than milk chocolate), coffee beans, intact fruits and vegetables, grain and grain products (other than those containing wheat in a form that would not be recognized as containing wheat without a label declaration), honey, jams/jellies/preserves, maple sap, maple syrup, intact single-ingredient peanuts or tree nuts (shelled and unshelled), soft drinks and carbonated beverages, sugar beets, sugarcane, and sugar;
- (10) Making hard candy, fudge, taffy, and toffee;
- (11) Making cocoa products from roasted cocoa beans;
- (12) Making honey;
- (13) Making jams, jellies, and preserves from acid foods (e.g., acid fruits);
- (14) Making maple syrup;
- (15) Making soft drinks and carbonated water;
- (16) Making sugar from sugar beets and sugarcane;

- (17) Mixing cocoa beans, coffee beans, intact fruits and vegetables, grain and grain products, honey, maple sap and maple syrup, and peanuts and tree nuts;
- (18) Packaging hard candy, fudge, taffy, toffee; cocoa beans; cocoa products; coffee beans; intact fruits and vegetables (other than modified atmosphere or vacuum packaging); grain and grain products; honey; jams, jellies and preserves; maple syrup; peanuts and tree nuts (including modified atmosphere or vacuum packaging); soft drinks and carbonated water; and sugar beets, sugarcane, and sugar;
- (19) Salting peanuts and tree nuts;
- (20) Shelling/hulling cocoa beans (i.e., winnowing), intact fruits and vegetables (e.g., dried beans and peas), and peanuts and tree nuts;
- (21) Sifting grains and grain products;
- (22) Sorting, culling, and grading (other than when incidental to packing or storage) hard candy, fudge, taffy, and toffee; cocoa beans; cocoa products; coffee beans; intact fruits and vegetables; grain and grain products; honey; jams, jellies and preserves; maple sap; maple syrup; peanuts and tree nuts; soft drinks and carbonated water; and sugar beets, sugarcane, and sugar;
- (23) Treating cocoa beans, coffee beans, intact fruits and vegetables, grain and grain products, and peanuts and tree nuts against pests (other than during growing) (e.g., fumigation);
- (24) Waxing (wax, oil, or resin used for the purpose of storage or transportation) intact fruits and vegetables.

(1) A facility is not covered by this Rule if its average annual monetary value of food (as “food” defined in § 117.3) that would otherwise be covered by part 117 of this chapter sold during the previous 3-year period was \$25,000 or less (on a rolling basis).

## **Subpart D—Modified Requirements**

### **§ 117.201 Modified requirements that apply to a qualified facility.**

(a) *Documentation to be submitted.* A qualified facility must submit either the following documentation or a statement from the owner, operator, or agent in charge of a qualified facility certifying that the qualified facility meets these two requirements and has in its possession the following documentation to the FDA:

- (1) Documentation that the facility is a qualified facility as defined in § 117.3. For the purpose of determining whether a facility satisfies the definition of qualified facility, the baseline year for calculating the adjustment for inflation is 2011; and
- (2)(i) Documentation that demonstrates that the owner, operator, or agent in charge of the facility has identified the potential hazards associated with the food being produced, is implementing preventive controls to address the hazards, and is monitoring the performance of the preventive controls to ensure that such controls are effective; or

(ii) Documentation (which may include licenses, inspection reports, certificates, permits, credentials, certification by an appropriate agency (such as a State department of agriculture), or other evidence of oversight) that the facility is in compliance with State, local, county, or other applicable non-Federal food safety law, including relevant laws and regulations of foreign countries.

## **Subpart E—Withdrawal of an Exemption Applicable to a Qualified Facility**

### **§ 117.251 Circumstances that may lead FDA to withdraw an exemption applicable to a qualified facility.**

FDA may withdraw the exemption applicable to a qualified facility under § 117.5(a):

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

(b) If FDA determines 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 the qualified facility that are material to the safety of the food manufactured, processed, packed, or held at such facility; conduct or conditions are material to food safety when there is a reasonable probability that they will contribute to an outbreak of foodborne illness.

### **§ 117.252 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 qualified facility that:

(a) Identifies:

(1) If the determination is based on § 117.251(a), how the qualified facility is directly linked to an active investigation of a foodborne illness outbreak; or

(2) If the determination is based on § 117.251(b), the conduct or conditions in question;

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

(c) Notifies the qualified facility 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.

### **§ 117.254 Issuance of an order to withdraw an exemption applicable to a qualified facility.**

(a) If, after taking the actions in § 117.252, FDA determines that the issue persists and an exemption applicable to a qualified facility under § 117.5(a) 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 qualified facility is located (or, in the case of a foreign

facility, the Director of the Office of Compliance in the Center for Food Safety and Applied Nutrition), 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 the order to withdraw the exemption to the owner, operator, or agent in charge of the facility.

(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 facility within 5 calendar days after the FDA District Director or official senior to such Director makes the determination under § 117.254(b).

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

### **§ 117.257 Contents of an order to withdraw an exemption applicable to a qualified facility.**

An order to withdraw an exemption applicable to a qualified facility under § 117.5(a) must include the following information:

(a) The date of the order;

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

(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 facility; or~~

~~(2) Conduct or conditions associated with a qualified facility that are material to the safety of the food manufactured, processed, packed, or held at such facility;~~

(1) Whether the order is based on § 117.251(a) or § 117.251(b);

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

(3)(i) If the order is based on § 117.251(a), the order shall identify evidence linking the active investigation of a foodborne illness outbreak directly to the facility; or

(ii) If the order is based on § 117.251(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 within the facility that pose an imminent threat to public health;

(B) identify conduct or conditions within the facility 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 facility must comply with subpart C 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 facility that receives the order must either comply with the requirements of this part (as specified in subsection (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 § 117.264.~~

(e) A statement indicating whether the withdrawal order is for a partial or total withdrawal of the qualified facility's exemption:

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

(i) If the facility is a very small business, within 18 months of the date the order was received; or

(ii) If the facility is a small business, within 6 months of the date the order was received.

(2) If the withdrawal is total, the statement shall indicate that the facility must comply with subpart C of this part:

(i) If the facility is a very small business, within 18 months of the date the order was received; or

(ii) If the facility is a small business, within 6 months of the date the order was received.

~~(f)~~ (f) The text of section 418(l) of the Federal Food, Drug, and Cosmetic Act and of this subpart E;

~~(g)~~ (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 exceptions described in § 117.270;

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

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

#### **§ 117.260 Compliance with, or appeal of, an order to withdraw an exemption applicable to a qualified facility.**

(a) The owner, operator, or agent in charge of a qualified facility that receives an order under § 117.251 to withdraw an exemption applicable to a facility under § 117.5(a) must either:

(1) Comply with applicable requirements of this part; ~~within 60 calendar days of the date of the order; or~~

(i) If the facility is a very small business, within 18 months of the date the order was received; or

(ii) If the facility is a small business, within 6 months of the date the order was received;  
or

(2) Appeal the order within 10 calendar days of the date ~~of~~ the order was received in accordance with the requirements of § 117.264.

(b) 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.

(c) If the owner, operator, or agent in charge of the qualified facility appeals the order, and FDA confirms the order, the owner, operator, or agent in charge of the facility must comply with applicable requirements of this part: ~~within 60 calendar days of the date of the order.~~

(i) If the facility is a very small business, within 18 months of the date the order was received; or

(ii) If the facility is a small business, within 6 months of the date the order was received.

#### **§ 117.264 Procedure for submitting an appeal.**

(a) To appeal an order to withdraw an exemption applicable to a qualified facility under § 117.5(a), the owner, operator, or agent in charge of the facility must:

(1) Submit the appeal in writing to the FDA District Director in whose district the facility is located (or, in the case of a foreign facility, the Director of the Office of Compliance in the Center for Food Safety and Applied Nutrition), 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;

(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 facility relies.

(b) In a written appeal of the order withdrawing an exemption provided under § 117.5(a), the owner, operator, or agent in charge of the facility may include a written request for an informal hearing as provided in § 117.267.

#### **§ 117.267 Procedure for requesting an informal hearing.**

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

(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 § 117.264 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 material submitted. If the presiding officer determines that a hearing is not justified, written notice of the

determination will be given to the owner, operator, or agent in charge of the facility explaining the reason for the denial.

### **§ 117.270 Requirements applicable to an informal hearing.**

If the owner, operator, or agent in charge of the facility request 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 time frame agreed upon in writing by the owner, operator, or agent in charge of the facility and FDA.

(b) The presiding officer may require that a hearing conducted under this subpart be completed 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 §§ 117.254 and 117.257, 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 facility, 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 117.274, 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 § 117.270(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 a 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), and (a)(5), and 117.270(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.

**§ 117.274 Presiding officer for an appeal and for 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.

**§ 117.277 Time frame for issuing a decision on an appeal.**

(a) If the owner, operator, or agent in charge of a facility 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 a facility appeals the order and requests 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 § 117.270(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.

**§ 117.280 Revocation of an order to withdraw an exemption applicable to a qualified facility.**

An order to withdraw an exemption applicable to a qualified facility under § 117.5(a) 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 facility 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 facility appeals the order and requests an informal hearing, FDA denies the request for an informal hearing, and FDA does not confirm the order within the 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 facility appeals the order without requesting an informal hearing, and FDA does not confirm the order within the 10 calendar days after the appeal is filed, or issues a decision revoking the order within that time.

**§ 117.284 Final agency action.**

Confirmation of a withdrawal order by the presiding officer is considered a final agency action for

purposes of 5 U.S.C. 702.

**§ 117.285 If my exemption is withdrawn, what is the procedure for getting my exemption reinstated?**

(a) If, after an order to withdraw a qualified facility's exemption has been issued under § 117.251(b) (and confirmed upon appeal, if applicable) and the date by which the qualified facility 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 facility demonstrates to FDA that the conduct or conditions that triggered the withdrawal order have been sufficiently resolved, FDA shall reinstate the qualified facility's exemption status.

(b) If a qualified facility's exemption is withdrawn under § 117.251(b) and the date by which the qualified facility is required to come into compliance with the provisions of this part as per § 117.260(b) has passed, the Secretary shall provide the owner, operator, or agent in charge of the facility 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 qualified facility's exemption should be reinstated.

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

(2) The Secretary shall reinstate qualified facility's applicable exemption under §§ 117.5, 117.7 and 117.201 of this part if the Secretary determines, based on evidence presented, that adequate grounds do not exist to continue to withhold the qualified facility's exemption status.

(c) If, after an order to withdraw a qualified exemption has been issued under § 117.251(a), FDA concludes the active investigation of a foodborne illness outbreak and FDA finds that the facility in question was not directly linked to the foodborne illness outbreak, the Secretary shall automatically reinstate the qualified facility's exemption (without a hearing) and notify the qualified facility of the reinstatement.

## **Code of Federal Regulations**

21 C.F.R. § 1.227 What definitions apply to this subpart?<sup>79</sup>

*Retail food establishment* means an establishment that sells food products directly to consumers as its primary function. . . . A "retail food establishment" includes grocery stores, convenience stores, vending machine locations, community supported agriculture (as defined in this part), farmers markets, and roadside stands. Sales of food directly to consumers include sales of food to consumers conducted through community supported agriculture (as defined in this part), farmers markets, and roadside stands.

21 C.F.R. § 1.327 Who is excluded from all or part of the regulations in this subpart?

(e)(4) A "retail food establishment" includes grocery stores, convenience stores, vending machine locations, community supported agriculture operations, farmers markets, and roadside stands. Sales of

<sup>79</sup> Proposed change in the Preventive Controls Rule, 78 Fed. Reg. at 3795 (Part 1 – General Enforcement Regulations).

food directly to consumers include sales of food to consumers conducted through community supported agriculture (as defined in this part), farmers markets, and roadside stands.

### Table 1. Comparison of Low-Risk Manufacturing/Processing Activities

The words in **bold blue** indicate the differences between the two provisions.

§ 117.5(h)(1)	§ 117.5(h)(2)
<b>Activities covered in both provisions:</b>	
(i) Artificial ripening of intact fruits and vegetables;	(i) Artificial ripening of intact fruits and vegetables;
(ii) <b>Boiling/evaporation</b> of maple sap to make maple syrup;	(xiv) <b>Making</b> maple syrup;
(iii) Chopping <b>raw</b> peanuts and <b>raw</b> tree nuts;	(ii) Chopping peanuts and tree nuts;
(iv) Coating (with coatings other than wax, oil, or resin used for the purpose of storage or transportation) intact fruits and vegetables (e.g., caramel apples) and coating <b>raw</b> peanuts and <b>raw</b> tree nuts (e.g., adding seasonings);	(iii) Coating (with coatings other than wax, oil, or resin used for the purpose of storage or transportation) intact fruits and vegetables (e.g., caramel apples) and coating peanuts and tree nuts (e.g., adding seasonings);
(v) Drying/dehydrating intact fruits and vegetables (without the addition of sulfites) <b>where the drying creates a distinct commodity</b> (e.g., drying fruits or herbs);	(v) Drying/dehydrating ( <b>whether for storage/transport or for creating a distinct commodity</b> ) intact fruits and vegetables (without the addition of sulfites), <b>cocoa beans, coffee beans, grains and grain products, and peanuts and tree nuts</b> ;
(vi) Extracting oil from grains (e.g., corn, oilseeds, soybeans);	(vi) Extracting oils from grains (e.g., corn, oilseeds, and soybeans);
(vii) Grinding/milling/cracking/crushing grains (e.g., making grain products such as corn meal) and <b>raw</b> peanuts or <b>raw</b> tree nuts (e.g., making ground peanuts);	(viii) Grinding/milling/cracking/crushing <b>cocoa beans, coffee beans</b> , grains (e.g., making grain products such as corn meal), and peanuts and tree nuts (e.g., making ground peanuts);
(viii) Making jams, jellies and preserves from acid foods (e.g., acid fruits);	(xiii) Making jams, jellies and preserves from acid foods (e.g., acid fruits);
(ix) Making sugar from sugar beets and sugarcane; and	(xvi) Making sugar from sugar beets and sugarcane; and
(x) Salting <b>raw</b> peanuts and <b>raw</b> tree nuts.	(xix) Salting peanuts and tree nuts;
<b>Activities covered only if done to another's RACs:</b>	
	(iv) Cooling intact fruits and vegetables using cold air;
	(vii) Fermenting cocoa beans and coffee beans;
	(ix) Labeling (including stickering) hard candy, cocoa beans, cocoa products from roasted cocoa beans (other than milk chocolate), coffee beans, intact fruits and vegetables, grain and grain products (other than those containing wheat in a form that would not be recognized as containing wheat without a label declaration), honey, jams/jellies/preserves, maple sap, maple syrup, intact single-ingredient peanuts or tree nuts (shelled and unshelled), soft drinks and carbonated beverages, sugar beets, sugarcane, and sugar;

	(x) Making hard candy, fudge, taffy, and toffee;
	(xi) Making cocoa products from roasted cocoa beans;
	(xii) Making honey;
	(xv) Making soft drinks and carbonated water;
	(xvii) Mixing cocoa beans, coffee beans, intact fruits and vegetables, grain and grain products, honey, maple sap and maple syrup, and peanuts and tree nuts;
	(xviii) Packaging hard candy, fudge, taffy, toffee; cocoa beans; cocoa products; coffee beans; intact fruits and vegetables (other than modified atmosphere or vacuum packaging); grain and grain products; honey; jams, jellies and preserves; maple syrup; peanuts and tree nuts (including modified atmosphere or vacuum packaging); soft drinks and carbonated water; and sugar beets, sugarcane, and sugar;
	(xx) Shelling/hulling cocoa beans (i.e., winnowing), intact fruits and vegetables (e.g., dried beans and peas), and peanuts and tree nuts;
	(xxi) Sifting grains and grain products;
	(xxii) Sorting, culling, and grading (other than when incidental to packing or storage) hard candy, fudge, taffy, and toffee; cocoa beans; cocoa products; coffee beans; intact fruits and vegetables; grain and grain products; honey; jams, jellies and preserves; maple sap; maple syrup; peanuts and tree nuts; soft drinks and carbonated water; and sugar beets, sugarcane, and sugar;
	(xxiii) Treating cocoa beans, coffee beans, intact fruits and vegetables, grain and grain products, and peanuts and tree nuts against pests (other than during growing) (e.g., fumigation);
	(xxiv) Waxing (wax, oil, or resin used for the purpose of storage or transportation) intact fruits and vegetables.