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Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20582

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

Sent via electronic submissions on the Federal eRulemaking Portal: www.regulations.gov

Re: Comments on FDA Proposed Rule for the Standards for Growing, Harvesting, Packing, and Holding of Produce for Human Consumption, 79 Federal Register 58433 (September 29, 2014)

To Whom It May Concern,

These comments on the Food and Drug Administration's (FDA) Proposed Rule for the Standards for Growing, Harvesting, Packing, and Holding of Produce for Human Consumption (Produce Safety Rule or PSR) 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 law and 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. Our concern that the proposed rules would disproportionately impact the types of operations we seek to serve prompted us to submit recommendations during the first comment period and to again submit comments on the reproposed rules. Our work on this topic is closely connected to the work of the National Sustainable Agriculture Coalition (NSAC), and therefore, we continue to support the comments submitted by NSAC and their member organizations.

We applaud FDA for incorporating into this amended proposed rule many of the recommendations that we made during the first comment period. These revisions support small-

and midsized farmers and producers, who are crucial to the U.S. food system: they increase the diversity of our food system; provide essential sources of fresh fruits and vegetables for a variety of markets; and serve as economic drivers, often playing an integral role in rural (and increasingly urban and suburban) economies. We urge FDA to finalize the procedure for reinstatement of a qualified exemption and the provision allowing FDA to take intermediary steps before issuing an order to withdraw the qualified exemption.

We believe further revisions could more adequately take into account the realities of these small- and mid-sized farmers and facilities. In particular, we believe calculating the qualified exemption using a literal definition of "food" (rather than "covered produce") does not follow Congress' intent and is inconsistent with other FDA decisions in this area. We urge FDA to follow congressional intent and a commonsense understanding of the qualified exemption sales threshold by calculating the exemption based on sales of "covered produce." We encourage FDA to require that specific information about the reason for concern be included in both the mandatory notice of intent to withdraw a qualified exemption and the order to withdraw a qualified exemption. We have included comments and recommended modified language based on our comments.

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

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

Sincerely,

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These comments were also made possible by the research, writing, and editing of Alexandra Jordan, Harvard Law student in the Harvard Food Law and Policy Clinic.

Acknowledgements

These comments were written in consultation with Sophia Kruszewski, of the National Sustainable Agriculture Coalition.

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I. Comments on Coverage Provisions in Subpart A--General Provisions

Count only sales of *covered produce*, rather than sales of *all food*, when determining the qualified exemption sales threshold.

In determining whether a farm satisfies the criteria for a qualified exemption from the Produce Safety Rule (PSR), FDA should base the $500,000 sales threshold on sales of "covered produce" rather than on sales of "all food" sold by that farm.

The Tester-Hagan Amendment to the Food Safety Modernization Act (FSMA) created modified requirements for small farmers and facilities to protect small businesses from the economic burden of regulation.[1] Specifically, the Tester-Hagan Amendment creates modified requirements for farms where

> (A) . . . the average annual monetary value of the food sold by such farm directly to qualified end-users . . . exceeded the average annual monetary value of the food sold by such farm to all other buyers during such period; and
>
> (B) the average monetary value of all food sold during such period was less than $500,000, adjusted for inflation.[2]

In our comments to the original proposed PSR, we asked FDA to calculate the qualified exemption on sales of "covered produce" rather than sales of "all food." In the supplemental PSR, FDA addressed these comments. FDA wrote,

> [t]he criteria established in proposed § 112.5(a), including the requirement that "all food" be considered in calculating sales, are derived from section 419(f) of the FD&C Act. We, therefore, as a result of the statutory language, cannot apply the monetary value limit to covered produce sales, but instead must apply it to total of "all" food sales.[3]

We acknowledge that Congress did use the term "food" rather than "covered produce" or "produce" when establishing the qualified exemption. However, we believe that Congress did not intend for FDA interpret the term "food" literally. The purpose of the Tester-Hagan

[1] "Tester amended the new law to shield small farms and food processers from federal regulations they can't afford and don't need, while raising food safety standards for industrial-scale facilities that produce enormous amounts of food and ship it across the country." Press Release, Senator Jon Tester, Food Safety Bill Shaped by Tester Becomes Law (Jan. 4, 2011), *available at* http://www.tester.senate.gov/?p=press_release&id=2510.

[2] 21 U.S.C. § 350h(f)(1)(A)–(B) (2012).

[3] Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption, 79 Fed. Reg. 58434, 58438 (proposed Sept. 29, 2014), *available at* http://www.gpo.gov/fdsys/pkg/FR-2014-09-29/pdf/2014-22447.pdf.

Amendment, which created the qualified exemption, was intended to protect small farms and food businesses from the heavy burden of additional regulation.

Basing the qualified exemptions on ***all*** food sold by a farm, as opposed to all ***covered*** produce sold by a farm, creates a situation in which a relatively small produce operation could face the full regulatory brunt of the PSR. Consider the following examples of how small farms could be impacted by FDA's calculation of the qualified exemption sales threshold:

- A farm that sells $500,000 worth of wheat but only $50,000 of "covered produce" subject to the PSR would be ineligible for the qualified exemption, because the total sales of food exceeds the $500,000 cap. Therefore, such farm would be disincentivized from diversifying their operation to grow more produce.
- A farm that sells $500,000 of wheat, $200,000 of covered produce, and $200,000 of processed food would be subject to the full requirements of *both* the PSR and the Preventive Controls Rule (PCR), even though the total quantity of food regulated by each rule is relatively small (and if considered separately from one another, would not be subject to either rule).[4]
- A farm that sells only $100,000 of spinach and apples at a farmers market in addition to selling $200,000 of wheat to a flour mill would be covered by the PSR, because the total sales of food to qualified end-users does not exceed the total sales of food to "other buyers."[5]

By using a literal interpretation of the term "all food" as the sales basis for the qualified exemption, we believe FDA is not following Congress' intent to provide regulatory relief for these small businesses. We believe that calculating the qualified exemption based on sales of "all food" rather than only on the food that is regulated by the PSR will cause farms and farm mixed-type facilities that should qualify for the exemption to be excluded.

In an analogous situation, FDA chose to define a qualified exemption sales threshold for animal food that goes beyond the strict statutory language and sets the threshold as just animal food covered by the rule. This indicates that FDA believes it has the authority to calculate the qualified exemption sales threshold based only on sales of the product regulated by the specific rule, as we ask FDA to do in this case.

Although FDA asserts that Congress' use of the term "food" merits a literal reading, there are internal inconsistencies in the language of FSMA where Congress uses the terms "food" and "produce" interchangeably, evidencing a lack of clear Congressional intent with regard to the

[4] This farm/facility operation would not be subject to modified requirements under the "very small business" exemption, because the total sales of "human food" exceed $1 million and total $1.1 million.
[5] *See* 21 U.S.C. § 350h(f)(1)(A) (2012).

food sales to be included in the threshold for the qualified exemption. This means that FDA should not apply a literal interpretation of the term "food," and instead should follow Congress' clear intent to protect small farms and food businesses by using only sales of "covered produce" as the basis upon which to calculate the qualified exemption sales threshold.

As described below, both the legislative intent of Congress in enacting the Tester-Hagan Amendment and FDA's interpretations in other proposed rules promulgated under FSMA suggest that the proper interpretation of the Tester-Hagen criteria is to base qualified exemptions on the sales of produce covered by the PSR, not all food sold by the farm.

1. **Counting only the sales of *covered produce* is consistent with the legislative intent of Congress in enacting the Tester-Hagan Amendment.**

There is evidence that Congress intended for the modified requirements under Tester-Hagan to apply to the types of small and mid-sized farms that would be regulated by the PSR under FDA's current interpretation of the food sales threshold. Members of the Senate, the sponsors of the Amendment, and the language of FSMA itself all indicate that exemptions in the Tester-Hagan Amendment aimed to strike a balance between ensuring food safety and protecting small businesses.

First, the congressional record indicates that several senators discussed the importance of passing a food safety bill that would be sensitive to the needs of small businesses and farmers. For example, Senator Dodd (D-CT) stated the Tester-Hagan Amendment was crucial to FSMA becoming a viable law:

> Putting this bill together required compromise. It is what we do in this Chamber every single day, and so had we not included the Tester language in this bill I think we would have had a hard time passing the legislation. The argument would have been: Well, you have included the small truck farmers who, frankly, cannot subject themselves to the kind of rules that large produce[r]s of food can, and we would have put the whole bill in jeopardy.[6]

In addition, Senator Enzi (R-WY) highlighted the importance of FSMA's provisions "providing flexibility for small and very small food processors"[7] and Senator Hatch (R-UT) underscored the "importance of promoting small businesses."[8] These statements demonstrate that the Senate incorporated the Tester-Hagan Amendment as a protection for small, local food producers.

[6] 156 CONG. REC. S8226 (daily ed. Nov. 29, 2010) (statement of Sen. Dodd).
[7] 156 CONG. REC. S7921–22 (daily ed. Nov. 17, 2010) (statement of Sen. Enzi).
[8] 156 CONG. REC. S7922 (daily ed. Nov. 17, 2010) (statement of Sen. Hatch).

Second, the sponsors of the Amendment, Senators Jon Tester (D-MT) and Kay Hagan (D-NC), have given several justifications for reducing the federal regulatory burden on small food producers and facilities: (1) small producers and facilities can be sufficiently regulated by local and state regulations; (2) small, local producers and facilities sell directly to the consumer, which creates an incentive for producers to only sell safe food and negates the need for a federal food safety regime; and (3) the regulatory burden of FSMA would be significant for small producers and facilities and would encourage industry consolidation.[9] These strong arguments for treating small producers and facilities differently from large, industrial agricultural operations offer yet more evidence of the congressional intent behind incorporating the Tester-Hagan Amendment into FSMA. Congress intended for FDA to create different standards for differently situated and sized businesses.

Third, there are internal inconsistencies in the language of FSMA. FDA asserts that Congress' use of the term "food" merits a literal reading; however, Congress was not deliberate in choosing to use "food" or "produce" in any specific instance. In the section on standards for produce safety, the words "food" and "produce" are used interchangeably in the subsection that details notification requirements for businesses not subject to the full requirements of FSMA.[10] This suggests a lack of clear Congressional intent with regard to the food sales to be included in the threshold for the qualified exemption. FDA should not apply a literal interpretation of "food." Rather, FDA should follow Congress' clear intent to protect small farms and food businesses by using only sales of "covered produce" when calculating the qualified exemption sales threshold.

Furthermore, the legislative history of FSMA suggests that the Tester-Hagan Amendment was added late in the process. Senator Chambliss, who opposed the addition of the Tester-Hagan Amendment, explicitly stated that the Tester-Hagan Amendment was "added at the 11th hour."[11] The late inclusion of the Tester-Hagan Amendment suggests that there was no time to harmonize its language with the rest of the bill; this also supports a non-literal interpretation of the "all food" language in the Tester-Hagan Amendment. We encourage FDA to protect small farms and food businesses by reconciling these inconsistencies and calculating sales for qualified exemptions using only sales of produce covered by the PSR, rather than all food sold by the farm.

2. Counting only the sales of *covered produce* is consistent with FDA's policy decisions and interpretations in other rules proposed under FSMA.

[9] Press Release, Senator Jon Tester, Tester to Introduce "Common Sense" Amendments to Food Safety Bill (Apr. 14, 2010), *available at* http://www.tester.senate.gov/?p=press_release&id=1106. *See also* Bart Jensen & Ledyard King, *U.S. Senate Chews on Major Overhaul of Food-Safety Laws*, GREAT FALLS TRIBUNE (Sept. 18, 2010), *available at* http://www.tester.senate.gov/?p=press_release&id=35.

[10] "[W]ith respect to a ***food*** for which a food packaging label is not required . . ., [a farm that is exempt under this section shall] prominently and conspicuously display, at the point of purchase, the name and business address of the farm where the ***produce*** was grown." 21 U.S.C. § 350h(f)(2)(A)(ii) (2012) (emphasis added).

[11] 156 CONG. REC. S8225 (daily ed. Nov. 29, 2010) (statement of Sen. Chambliss).

A broad interpretation of the exemption criteria in the PSR would be more consistent with other policy decisions and interpretations FDA has made in proposed rules promulgated under FSMA, namely in the animal feed rule, the definition of "very small business" in PSR, and the exemption for farms with less than $25,000 in annual sales.

First, the Tester-Hagan exemption for facilities that average annual sales of less than $500,000 of "all food" also applies to animal food facilities, since the statute itself did not distinguish between facilities producing animal food and facilities producing human food.[12] However, FDA interpreted the statutory language of the amendment differently for the Preventive Controls Rule for Animal Feed (Animal PCR), calculating a facility's monetary value by "animal food" instead of "all food."[13] FDA maintained this original definition after asking for comments on whether a facility that sells both animal food and human food should be eligible for the qualified exemption. This suggests that both FDA and the public agreed with the logic of calculating sales for qualified exemptions by only using sales of food covered by the respective rule, rather than all food sold by the farm (or facility).

Second, the definition of very small businesses ("VSB") adopted by FDA in the PSR is determined in part based on sales of food, similar to Tester-Hagan exempt farms.[14] However, FDA modified the definition of VSB after receiving comments on the original proposed definition.[15] The revised PSR defines a VSB as a farm where "the average annual monetary value of ***produce*** . . . [sold] is no more than $250,000."[16] It appears that FDA aligned the definition of VSB with the general intent of FSMA to be sensitive to the needs of small businesses. FDA did request comments on whether the VSB monetary threshold could be applied to *covered* produce only, suggesting that FDA sees the logic in basing the modified criteria for small businesses on the sales of the types of food actually covered by the rule and recognizes Congress' intent to accommodate small and mid-sized farms.

Third, FDA proposed completely excluding from FSMA regulations of all farms with an average annual monetary value of *produce* sold less than $25,000.[17] FDA first proposed basing the exemption on annual sales of *all food*, but after receiving comments changed the calculation to *produce* sales.[18] FSMA does not include this exemption and there are no provisions that direct

[12] *See* 21 U.S.C. § 350g(l)(1)(C)(ii) (2012).
[13] Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals, 78 Fed. Reg. 64736, 64824 (Sub. A § 507.3) (Oct. 29, 2013) (to be codified at 21 CFR pts. 16, 225, 500 et al.).
[14] *See* 79 Fed. Reg. at 58475.
[15] 79 Fed. Reg. at 58470 (Sub. A § 112.3(b)(1)).
[16] 79 Fed. Reg. at 58470 (Sub. A § 112.3(b)(1)).
[17] 78 Fed. Reg. at 3632 (Sub. A § 112.4).
[18] 79 Fed. Reg. at 58471 (Sub. A § 112.4).

FDA to categorically exclude the smallest farms.[19] Creating a complete exemption for this class of small farms again suggests that FDA recognizes Congress' intent to accommodate small and mid-sized farms.

We encourage FDA to uphold the congressional intent of FSMA and protect the vitality of small businesses by adopting an interpretation of the Tester-Hagan criteria that calculates sales for qualified exemptions based on the sales of produce covered by the PSR, rather than all food sold by the farm.

Recommendation: In determining whether a farm is eligible for a qualified exemption, FDA should count sales of covered produce, rather than sales of all food.

Suggested Language:
§ 112.5 Who is eligible for a qualified exemption and associated modified requirements based on average monetary value of all food sold and direct farm marketing?
(a) You are eligible for a qualified exemption and associated modified requirements in a calendar year if:

(1) During the previous 3-year period preceding the applicable calendar year, the average annual monetary value of the covered produce ~~food~~ (as defined in § 112.3(c)) you sold directly to qualified end-users (as defined in § 112.3(c)) during such period exceeded the average annual monetary value of the covered produce ~~food~~ you sold to all other buyers during that period; and

(2) The average annual monetary value of covered produce ~~all food~~ (as defined in § 112.3(c)) you sold during the 3-year period preceding the applicable calendar year was less than $500,000, adjusted for inflation.

(b) For the purpose of determining whether the average annual monetary value of covered produce ~~all food~~ sold during the 3-year period preceding the applicable calendar year was less than $500,000, adjusted for inflation, the baseline year for calculating the adjustment for inflation is 2011.

II. Comments on the Withdrawal of Qualified Exemptions in Subpart R

1. Definitions and Evidentiary Standards

Establish an evidentiary standard for withdrawal of a qualified exemption and add definitions of "directly linked," "necessary," "associated," and "material to the safety of the food."

[19] *See* 21 U.S.C. § 350h (2012).

We encourage FDA to reconsider our earlier comments regarding the need for a "credible and substantial evidence" standard in § 112.201(a)(2) and for definitions of "directly linked," "necessary," "associated," and "material to the safety of the food" in § 112.3. These additions will help to provide better guidance for FDA in determining when it should instigate procedures for withdrawal of an exemption.

First, we believe FDA should adopt a "credible and substantial evidence" standard for withdrawal of an exemption. The proposed rules currently permit FDA to withdraw an exemption based on conditions or conduct "associated" with a qualified farm.[20] A "credible and substantial evidence" standard would provide a specific threshold that FDA must meet to begin the process of withdrawing an exemption, and it would ensure that withdrawal orders are based on evidence and not allegations.

Second, FDA should provide a definition of "directly linked." FDA may withdraw a farm's exemption if a foodborne illness outbreak is "directly linked" to a qualified farm but, without a definition, there is ambiguity in how a farm may be "directly linked" to an outbreak.[21] Because this is one of two avenues for FDA to withdraw an exemption, and because of the significant implications for farm owners that have their exemptions withdrawn, there should be clear guidance for FDA in making this determination. Defining "directly linked" will help FDA to determine when it can withdraw a qualified farm's exemption by ensuring actual proof of a link between outbreaks and farms exists and that the link is not overly attenuated. FDA surely faces immense pressure to identify the source of a foodborne illness when an outbreak occurs. Providing clear guidance on when a foodborne illness outbreak is "directly linked" to a farm will help FDA avoid responding in an overly broad way and unnecessarily withdrawing exemptions.

Third, FDA should more clearly specify when it is "necessary" to withdraw an exemption to protect the public health. We recommend defining "necessary" as "when absolutely required." The withdrawal of a farm's exemption can cause significant financial burdens for producers, especially for small producers, and the exemption should only be withdrawn when FDA is certain that it is absolutely required to protect public health.

Fourth, because FDA may withdraw an exemption based on conditions or conduct "associated" with a qualified farm,[22] FDA should define "associated" to specify how closely connected to a qualified farm a condition must be. Without providing a definition, it is possible that even very attenuated connections between conditions and farms would be sufficient for FDA to withdraw an exemption. We recommend a definition requiring that the condition is "directly and closely connected" to the farm.

[20] 79 Fed. Reg. at 58473 (Sub. R § 112.201(a)(2)).
[21] 79 Fed. Reg. at 58473 (Sub. R § 112.201(a)(1)).
[22] 79 Fed. Reg. at 58473 (Sub. R § 112.201(a)(2)).

Lastly, FDA should provide a definition of "material to the safety of the food." Without clarification, this phrase could encompass every conceivable risk to safety. A definition for "material to the safety of the food" should indicate that there must be a reasonable probability that the conduct or conditions will contribute to an outbreak of foodborne illness.

Recommendation: FDA should introduce a "credible and substantial evidence standard" and define the terms "directly linked," "necessary," "associated," and "material to the safety of the food."

Suggested Language:

§ 112.201 Under what circumstances can FDA withdraw a qualified exemption in accordance with the requirements of § 112.5?

(a) We may withdraw you qualified exemption under § 112.5:

> (2) If we determine based on credible and substantial evidence that it is necessary to protect the public health and prevent or mitigate a foodborne illness outbreak based on conduct or conditions associated with your farm that are material to the safety of the food that would otherwise be covered produce grown, harvested, packed, or held at your farm; conditions or conduct are material to the safety of food when there is reasonable probability that they will contribute to an outbreak of foodborne illness.

§ 112.3(c) What definitions apply to this part?

Associated means that which is directly and closely connected, as established by credible and substantial evidence, to a farm, farm mixed-type facility, or facility.

Directly linked means that which in a direct manner, as established by credible and substantial evidence, is immediately connected to activities on a farm, farm mixed-type facility, or facility that are under the control of the owner, operator, or agent in charge of the farm, farm mixed-type facility, or facility.

Necessary means that which is absolutely required, as established by credible and substantial evidence, to protect public health.

Material to the safety of food means traits, aspects, or characteristics of conduct actually taking place, or conditions specifically in existence on a farm or in a facility, that are directly relevant to ensuring the safety of food; that can be clearly measured; and that are identified through direct examination of the activities, conduct, and conditions of an individual farm or facility.

2. Notice of Intent to Withdraw and Possible Intermediary Steps

Finalize the revised language that allows FDA to take intermediary steps before issuing an order to withdraw an exemption.

We strongly support the provision that FDA added to § 112.201(b)(1) allowing FDA to take intermediary steps before issuing an order to withdraw an exemption. These intermediary steps include a "warning letter, recall, administrative detention, refusal of food offered for import, seizure, and injunction."[23] Because of the high cost to a farmer of a withdrawal proceeding, withdrawal of an exemption should be used as a last resort. FDA should encourage its staff to use intermediary steps as often as possible. Intermediary steps allow FDA to work with farm owners to reduce food safety risks, which will foster more understanding between FDA and the agricultural community. We strongly encourage FDA to maintain these revisions allowing FDA to take intermediary steps prior to issuance of an order in the final rule.

Finalize the revised language that requires notice prior to issuance of an order to withdraw an exemption.

We applaud FDA for adding § 112.201(b)(2) to require notice of intent to withdraw a qualified exemption to be given to the owner, operator or agent in charge of the farm before actually issuing an order to withdraw the exemption. This notice allows farmers to respond in writing to FDA's motivations for pursuing an order to withdraw the qualified exemption. Not only does this allow the farmer to take intermediary steps to proactively remedy the issue, it also may give the farmer and FDA a chance to clear up any misunderstandings before an order to withdraw is issued. This benefits both FDA, which potentially saves financial and personnel resources, and the farm owner, who potentially saves time and money on the appeals process. We encourage FDA to include this provision requiring notice prior to issuance of an order in the final rule.

Require the mandatory notice of intent to withdraw a qualified exemption under § 112.201(b)(2) to include (a) specific information about the reason for the notice of intent to withdraw and (b) how the farm can remedy the issue.

As mentioned above, under newly added § 112.201(b)(2), FDA must issue a notice of intent to withdraw a qualified exemption. While we support the inclusion of the mandatory notice of intent to withdraw a qualified exemption, we believe further revisions to this provision would allow farm owners to better understand why they have received a notice of intent to withdraw the qualified exemption. We encourage FDA to include evidence and specific information about the reason for the notice to withdraw a qualified exemption so that farm owners know FDA's exact concerns and what they need to address in their response to the notice. It is also important that farm owners understand how they can address and rectify FDA's concerns. Therefore, it would be beneficial to include information about how they can remedy the situation in the notice of intent to withdraw a qualified exemption.

[23] 79 Fed. Reg. at 58473 (Sub. R § 112.201(b)(1)).

Recommendation: The final rule should require that the notice of intent to withdraw a qualified exemption include information about the evidence on which the order is based and information about how the farm can remedy the issue.

Suggested Language:

§ 112.201 Under what circumstances can FDA withdraw a qualified exemption in accordance with the requirements of § 112.5?

> (b)(2) Must notify the owner, operator, or agent in charge of the farm, in writing, of circumstances that may lead FDA to withdraw the exemption, <u>including facts specific to the situation and information about how the farm can remedy the situation,</u> and provide an opportunity for the owner, operator, or agent in charge of the farm to respond in writing, within 10 calendar days of the date of receipt of the notification, to FDA's notification;

3. Approval and Issuance of the Order to Withdraw a Qualified Exemption

Finalize the requirement that an order must be approved before it is issued.

The revised § 112.202(a) requires that an FDA District Director, or an FDA official senior to such Director, approve the order to withdraw an exemption before it is issued. This is an important addition that provides FDA with clear administrative procedure for issuing orders. We encourage FDA to adopt the provision requiring approval before issuance of an order to withdraw an exemption in the final rule.

Deliver the order in a way that ensures the farmer receives the order and provides confirmation of receipt of the order to withdraw an exemption.

To standardize the appeal timeline, the order to withdraw an exemption should be delivered in a manner by which delivery and receipt can be confirmed. Without a receipt of confirmation, FDA will not know whether the farm owner received the order nor will FDA know on which day it should start tolling the compliance timeline and the appeals timeline under § 112.204. If, for example, the order is delivered by certified mail with a confirmation of delivery, FDA would know when the farm owner received the order and would have a record of the date of receipt. This is important to ensure that the facility owner receives the order before the timeline for appeals has ended.

Recommendation: FDA should require that the order is issued to the farm owner in a way that ensures the farmer receives the order and provides confirmation of receipt of the order.

Suggested Language:

§ 112.202 What procedure will FDA use to withdraw an exemption?
(c) FDA must issue an order to withdraw the exemption to the owner, operator, or agent in charge of the farm in a manner by which delivery and receipt of the order can be confirmed.

4. Contents of the Order to Withdraw a Qualified Exemption

Clearly state in the order to withdraw the exemption that the owner, operator, or agent in charge of a qualified farm must either comply with subparts B through O of the Produce Safety Rule or appeal the order, and include information about the opportunity to request a hearing.

Although we applaud FDA for revising the Preventive Controls Rule so that the order to withdraw an exemption contains a statement that a facility has two options after receiving the order: comply or appeal,[24] there was no similar change made in the revised PSR. Because this would be equally helpful for farm owners to know, we encourage FDA to revise the relevant provisions in the PSR and to require that the order to withdraw an exemption clearly states farm owner's two options in the order to withdraw an exemption: either comply with subparts B through O of the PSR or appeal the order.

Because farm owners have such a short timeframe to appeal the order, it is vital that they understand their procedural rights immediately upon receiving an order to withdraw a qualified exemption. Therefore, the order to withdraw a qualified exemption should explicitly notify the farm owner that he or she has a right to an informal hearing under § 112.207 and that the informal hearing request must be submitted with the appeal within 10 calendar days of the date of receipt of the order.[25]

Recommendation: FDA should require that the order to withdraw an exemption explicitly state that the farm owner has two options: comply with subparts B through O of the PSR or appeal the order. FDA should require that the order to withdraw the exemption specify that the farm owner has the opportunity to request an informal hearing when submitting an appeal.

Suggested Language:
§ 112.203 What information must FDA include in an order to withdraw a qualified exemption?
(d) A statement that the farm must either: ~~A statement that the farm must comply with subparts B through O of this part on the date that is 60 calendar days after the date of the order.~~

(1) Comply with subparts B through O of this part on the date that is *120 calendar days after the date of receipt of the order; or

[24] 79 Fed. Reg. at 58570 (Sub. E § 117.257(d)).
[25] 78 Fed. Reg. at 3504 (Sub. R § 112.207(a)(2)).

(2) Appeal the order within 10 calendar days of the receipt of the order in accordance with the requirements of § 112.206.

. . .

(f) A statement that the farm may request an informal hearing as part of the appeals process within 10 calendar days of receipt of the order and 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 § 112.208;

*Described below.

Require that the order to withdraw a qualified exemption include (a) specific information about the reason for withdrawal and (b) information about the compliance requirements.

It is important to include specific information about the reason for withdrawal in the order to withdraw a qualified exemption. Once a farm owner's qualified exemption is withdrawn, the owner must fully understand why it was withdrawn in order to address the concerns and request that FDA reinstate the exemption. As a result, FDA should require that the order to withdraw a qualified exemption include specific information about the reason for withdrawal, including the evidence on which it is based.

In addition, FDA should include detailed information about the compliance requirements in layperson's terms. Because compliance requirements are complicated, FDA needs to make sure that the information is accessible and easy to understand for farm owners. Including referrals to sources of technical assistance would also help farm owners come into compliance.

Recommendation: The final PSR should require that the order to withdraw a qualified exemption include information about the evidence on which the order is based and information about compliance requirements.

Suggested Language:

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

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

(1) Whether the order is based on § 112.201(a) or 112.201(b); ~~An active investigation of a foodborne illness outbreak that is directly linked to the farm; or~~

(2) The evidence on which the order is based; ~~Conduct or conditions associated with a qualified farm that are material to the safety of the food manufactured, processed, packed or held at such farm;~~

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

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

(A) Include measurable evidence that has been collected using generally accepted scientific standard indicating the presence of pathogens of public health significance on the farm that pose an imminent threat to public health;
(B) Identify conduct or conditions on the farm that are material to the safety of food; and
(C) Include a statement explaining how altering the conduct or conditions would prevent or mitigate a foodborne illness outbreak.

5. Timeframe for Compliance with the Produce Safety Rule

Amend the timeframe for a farm to comply with subparts B through O of the Produce Safety Rule after receiving an order from "within 60 calendar days of the date of the order" to "within 120 days of the date of receipt of the order."

In the 2013 proposed withdrawal provisions, the Preventive Controls Rule provided facilities with a 60-day compliance timeline from the date of the order. Acknowledging that the 60-day timeline was too short a window for a facility to come into compliance, FDA revised the Preventive Controls Rule to increase the compliance timeline to 120 days and toll the timeline from the date of *receipt* of the order.[26] We applaud FDA for making these changes and urge FDA to make similar amendments to the relevant provisions of the PSR for the same reasons. After receiving an order to withdraw an exemption, farm owners currently have 60 days to comply with subparts B through O of the PSR. It is unrealistic to expect farm owners to be able to come into compliance within 60 days. Furthermore, due to different mailing times throughout the country, tolling the timeline from the date of receipt of the order (rather than the day it was issued) standardizes the number of days a farmer has to comply, no matter where in the country he or she resides.

Recommendation: FDA should change the timeframe for a farm to comply with subparts B through O of the PSR to "within 120 days of the date of receipt of the order."

Suggested Language:
§ 112.204 What must I do if I receive an order to withdraw a qualified exemption applicable to my farm?
(a) Comply with applicable requirements of this part within 120 ~~60~~ calendar days of the date of receipt of the order or, if operations have ceased and will not resume within 120 ~~60~~ calendar days, before the beginning of operations in the next growing season; or

6. Appealing the Order to Withdraw a Qualified Exemption

[26] 79 Fed. Reg. at 58570 (Sub. E § 117.257(d)(1)).

Toll the window for appealing an order to 10 calendar days from the date of the receipt of the order.

Under the revised language of the Preventive Controls Rule, facility owners have within "10 calendar days of receipt of the order" to appeal the order to withdraw.[27] We commend FDA for making this change and urge FDA to revise the relevant provisions in the PSR as well. Since farm owners in different parts of the country may receive the order at different times depending on the mail carrier, tolling the timeline for appeal from the date of the receipt of the order, rather than the date of issuance, is helpful to ensure that every farm owner has the same number of days to appeal the order.

Recommendation: FDA should revise the procedure for submitting an appeal to toll the 10 calendar day window for appeals from the date of receipt of the order.

Suggested Language:
§ 112.206 Can I appeal or request a hearing on an order to withdraw a qualified exemption applicable to my farm?
(a) To appeal an order to withdraw a qualified exemption applicable to a farm under § 112.5, the owner, operator, or agent in charge of the farm must:

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

7. Reinstatement of a Withdrawn Qualified Exemption

Finalize the procedure for reinstatement of a withdrawn exemption.

We applaud FDA for adding § 112.213 to establish and explain the process for reinstating a farm's qualified exemption for farms with a withdrawn exemption that later come into compliance. Without the opportunity for reinstatement of a withdrawn exemption, the regulatory burden will be too costly for many small and very small farm owners. We do not want these producers to face going out of business, as it will reduce the number and diversity of produce farms across the country. If a farm owner can show that he or she has changed practices to come into compliance with Subparts B through O of the PSR, we believe that reinstatement of the exemption is fair and maintains food safety. Furthermore, the reinstatement process is especially important if FDA withdraws a farm's exemption and an active investigation later determines that

[27] 79 Fed. Reg. at 58570 (Sub. E § 117.264(a)(1)).

the foodborne illness outbreak was not actually linked to the farm. For these reasons, we urge FDA to include this procedure for reinstatement of a farm's qualified exemption in the final rule.

Clarify that a FDA District Director will reinstate a qualified exemption under § 112.213(a) "within 10 days."

Under § 112.213, there are three pathways for reinstatement of a qualified exemption: (1) an FDA District Director can reinstate an exemption on his own initiative after determining that the farm has resolved problems with the conditions and conduct that are material to the safety of the food, (2) a farm owner can ask FDA to reinstate an exemption, or (3) FDA will reinstate a qualified exemption if it was withdrawn under § 112.201(a)(1) and FDA later determines that the outbreak is not linked to that farm.[28] The first pathway seems very discretionary, because there is no timeline for an FDA District Director to reinstate the exemption after making that determination. We suggest adding "within 10 days" to ensure that there is a timeline for FDA to reinstate a farm's exemption after the problems leading to the withdrawal have been resolved.

Recommendation: FDA should add language to § 112.213(a) clarifying that a FDA District Director will reinstate a qualified exemption "within 10 days" if the Director determines that the farm has adequately resolved problems.

Suggested Language:
§ 112.213 If my qualified exemption is withdrawn, under what circumstances would FDA reinstate my qualified exemption?
(a) If the FDA District Director in whose district your farm is located (or, in the case of a foreign farm, the Director of the Office of Compliance in the Center for Food Safety and Applied Nutrition (CFSAN)) determines that the farm has adequately resolved problems with the conduct and conditions that are material to the safety of the food produced or harvested at such farm, and that continued withdrawal of the exemption is not necessary to protect the public health or prevent or mitigate a foodborne illness outbreak, the FDA District Director in whose district your farm is located (or, in the case of a foreign farm, the Director of the Office of Compliance of CFSAN) shall, on his own initiative or request of a farm, reinstate the qualified exemption <u>within 10 days</u>.

Provide the opportunity for an informal hearing during the reinstatement of a qualified exemption.

We support the inclusion of § 112.213 to provide for the reinstatement of qualified exemptions and encourage FDA to add language to this section that provides the opportunity for an informal hearing during the reinstatement process. The rule currently only allows a farm owner to submit

[28] 79 Fed. Reg. at 58473 (Sub. R § 112.213).

a *written* request to ask for reinstatement of a qualified exemption.[29] An informal hearing would offer the farm owner and FDA representative the chance to discuss evidence and ask questions in a much more thorough way than can be achieved solely through a written request. The transcript from an informal hearing would also create a record if FDA denies reinstatement of the exemption.

Recommendation: FDA should provide farm owners with the opportunity for an informal hearing during the reinstatement process.

Suggested Language:

§ 112.213 If my qualified exemption is withdrawn, under what circumstances would FDA reinstate my qualified exemption?

(b) You may ask FDA to reinstate an exemption that has been withdrawn under the procedures of this subpart as follows:

> (1) Submit a request, in writing, to the FDA District Director in whose district your farm is located (or, in the case of a foreign farm, the Director of the Office of Compliance in CFSAN); and
>
> (2) Present data and information to demonstrate that you have adequately resolved the problems with the conditions or conduct that are material to the safety of the food manufactured, processed, packed, or held at your farm, such that continued withdrawal of the exemption is not necessary to protect public health and prevent or mitigate a foodborne illness outbreak.

(c) FDA shall provide the owner, operator, or agent in charge of the farm an opportunity for an informal hearing, upon request of said owner, operator, or agent, to be held not later than 10 business days after the request, on the reasons the farm's exemption should be reinstated.

[29] 79 Fed. Reg. at 58473 (Sub. R § 112.213(b)(1)).