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For a thriving New England

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November 15, 2013

Produce Safety Rule
Docket No. FDA–2011–N–0921
RIN 0910-AG35
Division of Dockets Management
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852
Submitted electronically: http://www.regulations.gov

Re: Comment of Conservation Law Foundation on the U.S. Food and Drug Administration's Proposed Produce Safety Rule

To the U.S. Food and Drug Administration:

Thank you for the opportunity to comment on the proposed Produce Safety Rule: "Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption."[1] We recognize the challenge in crafting a rule that both increases food safety and supports a diverse, robust, and environmentally responsible food system. Parts of the proposed Rule effectively achieve this balance. Key areas of the proposed Rule, however, require change.

ABOUT CONSERVATION LAW FOUNDATION

Conservation Law Foundation (CLF) uses the law, science, policymaking, and the business market to find pragmatic, innovative solutions to New England's environmental problems. CLF's Farm and Food Initiative, housed within our Healthy Communities and Environmental Justice Program, works to create a robust regional food system across New England. Sustainable agriculture is vital for building resilience to climate change, conserving land, and creating a healthy, economically vibrant New England. Our Farm and Food Initiative provides legal, policy, and market-based strategies to advance sustainable agriculture at the local and regional scale. To learn more about CLF's work, please visit our website.

[1] *See* Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption, 78 Fed. Reg. 3504 (proposed Jan. 16, 2013) (to be codified at 21 C.F.R. pts. 16, 112).

INTRODUCTION

This comment focuses on the proposed Rule's potentially harmful impact on small- to medium-size farms and, as a result, the danger the Rule poses to human health and the environment. FDA acknowledges the Rule "will have a significant economic impact on a substantial number of small entities."[2] But FDA has not sufficiently minimized this impact or incorporated environmental protections in the proposed Rule, as the law requires.[3]

Conservation Law Foundation is concerned that, by placing a tremendous burden on burgeoning small-scale sustainable agriculture, the proposed Rule will shift even more agricultural production to industrial-scale operations. The industrial agriculture system consumes fossil fuel, water, and topsoil at unsustainable rates.[4] It degrades air and water quality, depletes soil fertility, and diminishes biodiversity.[5] Increased pesticide use on such large-scale farms poses human health concerns.[6] Hindering the growth of smaller, sustainable agriculture and shifting production to industrial agriculture will damage the environment, degrade human health, and decrease food safety.

Because the Food Safety Modernization Act (FSMA) requires FDA to provide flexibility to small businesses,[7] FDA should:

- conduct a quantitative risk assessment to determine how certain factors, including farm size and the complexity of distribution channels, affect the risk of contaminating produce covered by the Rule—and thus the risk of serious adverse health consequences—and request public comment on the assessment;
- raise the annual sales amount for the de minimis exclusion;
- provide greater support for the delayed effective dates for small and very small farms;
- exempt or partially exempt very small farms;
- change the definitions of "farm," "very small business," "covered activity," "harvesting," "holding," "manufacturing/processing," and "packing," and define "community supported agriculture" (CSA);

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[2] *Id.* at 3616.

[3] *See* FDA Food Safety Modernization Act, 21 U.S.C. § 350h(a)(3)(A), (D); The Regulatory Flexibility Act, 5 U.S.C. § 603.

[4] Leo Horrigan et al., *How Sustainable Agriculture Can Address the Environmental and Human Health Harms of Industrial Agriculture*, 110 Envtl. Health Perspectives 445, 445–54 (2002).

[5] *Id.* at 445.

[6] *Id.*

[7] 21 U.S.C. § 350h(a)(3).

- amend the exclusion, the qualified exemption, and the modified requirements for qualified-exempt farms;
- address flaws in the due process provided qualified-exempt farms;
- provide a procedure for reinstating a withdrawn qualified exemption;
- clarify the proposed Rule by omitting use of the second person;
- change the requirements for using biological soil amendments (BSA) to comport with the U.S. Department of Agriculture (USDA) National Organic Program;
- protect on-farm conservation practices;
- amend the numerical threshold for pathogen presence and the testing frequency of agricultural water, and do not require chemical treatment of irrigation water; and
- keep the "integrated approach" to addressing contamination risk.

This comment details the problems with the proposed Rule and, where appropriate, offers specific textual edits. Recommended textual changes are consolidated in the appendix. We urge FDA to consider these recommendations. If FDA undertakes some or all, we encourage FDA to publish a second proposed rule for public comment. FDA must take the time needed to craft regulations that allow farms to thrive.

We appreciate the need for increased safety in our food system. But sustaining that food system, while increasing food safety, is critical. The proposed Rule places a disproportionate burden on small- to medium-size farms, restricts consumer access to locally grown produce, hinders farmland conservation practices, and risks environmental degradation. Correcting these problems will protect smaller operations and the environment, while providing greater food safety.

I. THE PROPOSED PRODUCE SAFETY RULE PROVIDES INSUFFICIENT FLEXIBILITY FOR SMALLER FARMS.

A. FSMA Directs FDA To Provide Flexibility for Small Businesses.

FSMA requires FDA to "establish science-based minimum standards for the safe production and harvesting" of produce.[8] FDA must determine "that such standards minimize the risk of serious adverse health consequences or death."[9] Those standards must "be appropriate to the scale and diversity of the production and harvesting of such commodities."[10] FSMA therefore mandates

[8] *Id.* § 350h(a)(1)(A).
[9] *Id.*
[10] *Id.* § 350h(a)(3)(A).

that FDA (1) base its standards in evidence, (2) ensure that those standards actually will minimize the risk of serious adverse health consequences, and (3) tailor the standards to the scale and diversity of various farms.

B. The Proposed Rule Imposes Significant Costs on Smaller Farms, Diminishing Access to Healthier Locally Grown Produce, Harming the Environment, and Introducing Greater Risk of Produce Contamination.

The Rule defines a "very small farm" as having no more than $250,000 in total food sales per year, a "small farm" as having no more than $500,000 in total food sales per year, and a large farm as having more than $500,000 in total food sales per year. (See Part I.D.4 for recommended changes to these definitions.) FDA estimates the following annual cost per farm based on size:

	Very Small Farm	**Small Farm**	**Large Farm**	**All Domestic Farms**
Cost	$4,697	$12,972	$30,566	$459,560,000

FDA admits the data used to calculate these estimates is limited.[11] Even at these estimates, the Rule will have a significant economic impact on a substantial number of farms: roughly 62,576 small and very small farms—about 33 percent of all farms that grow produce.[12] FDA acknowledges, however, that even if farms are exempted or excluded (based on the $25,000-total-sales-or-less exclusion) under the Rule, the marketplace may require full or partial compliance.[13] Buyers usually demand that growers meet current produce safety practices, or "baseline practices."[14] After implementation of the Rule, the new standards will become that baseline. Even if a farm is exempted or excluded under the Rule, buyers might nonetheless require partial or full compliance with the Produce Safety Rule standards. The annual cost, therefore, will likely be higher than FDA estimates. Smaller farms already operate with slim profit margins.[15] Farmers have stated that this additional cost could force them out of business.[16]

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[11] 78 Fed. Reg. 3506.

[12] *Analysis of Economic Impacts – Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption* 11, 18 (Table 1), U.S. Food and Drug Admin., http://www.fda.gov/downloads/Food/FoodSafety/FSMA/UCM334116.pdf (last visited Oct. 29, 2013).

[13] *Id.* at 17–18.

[14] *Id.* at 29–30.

[15] *See, e.g.*, Ashok K. Mishra et al., *Income, Wealth, and the Economic Well-Being of Farm Households*, at 35, Economic Research Service, U.S. Dep't of Agriculture (July 2002).

[16] *See, e.g.*, Vern Grubinger, *Understanding and Commenting on the Food Safety Modernization Act Proposed Rules*, http://www.uvm.edu/vtvegandberry/factsheets/Understanding_FSMA_Rule.pdf (last visited Oct. 30, 2013) ("For example, a $5,000 annual FSMA cost for a small wholesale vegetable farm with $50,000 in sales is not appropriate or affordable. Many farms in my area gross just over

Thus, the proposed Rule could have a detrimental economic impact on at least 176,266 very small, small, and excluded farms—94 percent of all farms.[17]

Forcing small farms to close or alter production could, in turn, have a significant impact on locally grown and distributed food. USDA estimates "107,000 farms are engaged in local food systems."[18] Defining "local" as a farm selling directly to consumers, nearly all of these farms are small or very small under the proposed Rule's definitions.[19] Farm-to-school programs (now in every state), CSA, and other consumers depend on local food. As of 2008, local food sales totaled about $4.8 billion,[20] and today's estimates place sales at over $8 billion, a 60 percent increase in just five years. The proposed Rule could seriously hamper this progress, affecting certain regions more severely, such as New England, which relies more heavily on locally grown food.[21]

The Department of Health and Human Services (HHS) aims to increase consumption of fruits and vegetables by 80 percent and 37 percent respectively by 2020. Growing consumer demand for local foods has become a strong mainstream trend over the past decade, creating a structural competitive shift in the U.S. food industry. Local products now account for up to a quarter of retail fresh produce offerings. Sales are expected to continue to expand over the next five years.[22] To help meet HHS's goal, the proposed Rule should encourage beginning farmers to start small- to medium-size farms that distribute produce locally. As drafted, it will have the opposite effect, imposing substantial costs on smaller operations.

Locally grown food has multiple co-benefits. It provides increased access to more diverse fruits and vegetables that help prevent obesity and diet-related diseases, reduces carbon emissions by using simpler distribution channels, boosts the local economy, and keeps more jobs and wealth within communities. Farmers' markets, CSA, and roadside stands have increased dramatically across the country. Local produce from these sources provides low-income and disadvantaged communities access to fresh, healthy food.[23] This is particularly true in urban or metropolitan areas, which contain about 40 percent of all U.S. farms.[24] The proposed Rule could have a

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$500,000 in food sales, and their covered produce accounts for perhaps half of that. A ten or twenty or thirty thousand dollar hit will take a large part of their net revenues.").

[17] *Analysis of Economic Impacts*, *supra* note 12, at 11, 18 (Table 1).

[18] Renée Johnson et al., *The Role of Local Food Systems in U.S. Farm Policy*, Congressional Research Service (Mar. 12, 2013).

[19] *Id.* at 17–18.

[20] *Id.* at 1, 2, 5.

[21] *Id.* at 7, 9, 17–18.

[22] *See* Rabobank, AgFocus (Feb. 2013); Food Environment Atlas, Economic Research Service, U.S. Dep't of Agriculture, http://www.ers.usda.gov/data-products/food-environment-atlas/go-to-the-atlas.aspx#.UnDw8SiVt9R (last visited Oct. 30, 2013).

[23] *See* Molly D. Anderson, *The Case for Local and Regional Food Marketing*, Farm and Food Policy Project (May 2007); Food Environment Atlas, *supra* note 22.

[24] *See* Johnson, *supra* note 18, at 12–14.

profound effect on burgeoning, small-scale urban farms.[25] For example, in Maine, an organization works with refugee farmers in and around Portland to gain access to land, grow their own food, start small farm businesses, and help feed low-income communities. The cost of compliance with the proposed Rule would likely be too much to bear for these refugee farmers and the organization that supports them.

Food grown and distributed locally, in shorter supply chains, also reduces the risk of contamination and widespread foodborne illness outbreaks. Growing food on an industrial-scale farm and then moving it through complex supply chains multiplies the number of critical points where contamination can occur.[26] Consolidating the growing of produce on fewer, larger farms—a likely result of the proposed Rule—will not lead to greater food safety.

As drafted, the Rule may impact medium-size farms the hardest—farms with just over $500,000 in total food sales. By not qualifying for the statutory exemption, these farms will bear similar compliance costs to industrial-scale farms, but with profit margins more akin to small-scale farms. As these farms shut down, large-scale operations will fill the void, increasing environmental harm.

Sustainable agriculture benefits wildlife and water systems by increasing diversity of plants and insects—including key pollinators—reducing soil erosion, diminishing nutrient loading in rivers and streams, and reducing mortality from insecticides and herbicides.[27] Studies have shown that sourcing locally grown food—most often grown on smaller farms—produces fewer greenhouse gas emissions than sourcing food from greater distances.[28] Removing smaller farms from production will increase reliance on foods sourced more than 275 miles[29] from the point of consumption.

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[25] *See Comments on the proposed rule for Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption; and comments on the proposed rule for Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food*, Urban Farming Institute, Docket Nos. FDA-2011-N-0921 and FDA-2011-N-0920 (submitted Nov. 14, 2013).

[26] *See, e.g.*, Gardiner Harris, *U.S. Food Safety No Longer Improving*, N.Y. Times (Apr. 9, 2011), *quoting* Dr. Stephen F. Sundlof, Director of the Center for Food Safety and Applied Nutrition (CFSAN) for the U.S. Food and Drug Admin. ("As supply chains get longer and longer, there's more opportunity to introduce contaminants that have a public health effect."), *available at* http://www.nytimes.com/2009/04/10/health/policy/10food.html?_r=1&.

[27] *See, e.g.*, *Enhancing Wildlife Habitat on Farmlands*, The Ohio State University, http://ohioline.osu.edu/w-fact/0014.html (last visited Nov. 4, 2013).

[28] *See, e.g.*, Anderson, *supra* note 23; Rich Pirog et al., *Food, Fuel, and Freeways: An Iowa Perspective on How Far Food Travels, Fuel Usage, and Greenhouse Gas Emissions*, at 2 (June 2001), http://www.leopold.iastate.edu/sites/default/files/pubs-and-papers/2011-06-food-fuel-and-freeways-iowa-perspective-how-far-food-travels-fuel-usage-and-greenhouse-gas-emissions.pdf.

[29] 21 U.S.C. § 350h(f)(4)(A).

We urge FDA to re-evaluate the tremendous impact the proposed Rule will have on smaller farms. FSMA requires FDA to provide "sufficient flexibility" to small businesses. Under the Regulatory Flexibility Act, FDA must consider more options, which do exist, that allow this flexibility and will protect small farms. Before finalizing the Rule, FDA must gather more data from small- to medium-scale farmers. Protecting these growers ultimately will protect jobs, strengthen local communities, provide access to healthier food, protect the environment, and fulfill FSMA's purpose to make our food safer.

C. FDA Should Conduct a Quantitative Assessment of Risk.

FDA conducted only a qualitative assessment of risk to public health from on-farm contamination of produce,[30] admitting time did not permit a quantitative assessment of risk.[31] Though a qualitative assessment can provide an initial understanding of a problem, FDA needs to perform a quantitative assessment to develop science-based standards, grounded in evidence.[32] This quantitative risk assessment should examine how farm size and the length of a distribution chain affect the risk of contaminating produce covered by the Rule. FDA acknowledges the limitation of its qualitative assessment and thus seeks from growers data sets that will enable it to perform a quantitative study.[33] FDA must acquire more data before finalizing its rule. Without such a quantitative assessment, FDA cannot properly tailor the standards to the scale and diversity of varying production and harvesting operations and therefore cannot fulfill FSMA's mandate.

FSMA recognizes that different sizes and types of farms require different regulation. Specifically, the Act directs FDA to "provide sufficient flexibility to be applicable to various types of entities . . . including small businesses and entities that sell directly to consumers."[34] The proposed Rule provides limited flexibility through the statutorily mandated direct-to-consumer qualified exemption. But, as explained below, this flexibility is insufficient for smaller farms. Therefore, we urge FDA to conduct a quantitative risk assessment to gain the necessary data to draft a rule that provides the required flexibility for small businesses. FDA should then request public comment on the assessment.

D. The Proposed Rule Can and Must Minimize the Harmful Economic Impact on Smaller Farms.

This subsection details specific problems with the proposed Rule and, in many cases, recommends textual changes to strengthen and clarify the proposed Rule. These

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[30] *See Draft Qualitative Assessment of Risk to Public Health from On-Farm Contamination of Produce*, U.S. Food and Drug Admin., http://www.regulations.gov/contentStreamer?objectId=09000064811b4304&disposition=attachment&contentType=pdf (last visited Oct. 29, 2013).

[31] 78 Fed. Reg. 3522.

[32] *See, e.g.*, John. W. Creswell, *Research Design: Qualitative, Quantitative, and Mixed Methods Approaches*, at 4 (forthcoming 2014).

[33] *E.g.*, 78 Fed. Reg. 3618.

[34] 21 U.S.C. § 350h(a)(3)(A).

recommendations are intended to provide greater protection for small farms. Recommended additions to provisions in the proposed Produce Safety Rule are underlined. Recommended deletions are marked with ~~strikethrough~~. Omissions are indicated by ellipses (. . .). Please see the Appendix for a consolidated version of all recommended changes.

1. Raise the De Minimis Exclusion

The proposed Rule excludes from coverage farms with food sales of $25,000 or less. We commend FDA on using its discretion to follow FSMA's directive to provide flexibility to small businesses. However, FDA should strongly re-consider raising the de minimis exclusion to less than $50,000. Moreover, as explained below in Part I.D.5, the exclusion should include only "covered produce" in calculating sales, not all food sold.

FDA considered the less-than-$50,000 option in its economic analysis. Ultimately, it concluded that doing so "would represent a substantial public health impact, nearly doubling the number of preventable illnesses."[35] This "substantial impact" appears to be raising the number of foodborne illnesses by 11,000 annually. But this speculative increase is based on the assumption that small farms are just as risky as large farms.[36] This assumption is not well founded. It applies the same standards regardless of farm size, distribution channels, growing region, and farming methods. For example, this reasoning assumes that a small-scale, five-acre polyculture farm in Vermont poses the same food safety risk as a large-scale, single-crop farm in California. As noted above, longer and more complex distribution chains lead to greater risk of food contamination. FDA admits that it needs more data to understand the impact farm scale and diversity have on food safety.

In contrast, much stronger assumptions support FDA's conclusion that nearly 11,958 more small farms would be excluded from the Rule were the amount raised to $50,000.[37] This amount would free from the Rule's burdensome and costly requirements many of the small farms that provide direct-to-consumer sales.[38] A $50,000 exclusion would exclude only 2.3 percent more produce acres from coverage, still equaling a small percentage of total produce acres.[39] Excluding these additional farms would allow them to remain viable businesses and (as noted above) increase access to healthy, local foods, keep wealth in local communities, and *improve* food safety. We urge FDA to consider raising the de minimis exclusion.

2. Provide Greater Support for the Delayed Effective Dates for Small and Very Small Farms.

[35] *Analysis of Economic Impacts*, *supra* note 12, at 52–53.
[36] *Id.* at 52.
[37] *See id.*
[38] *See* Johnson, *supra* note 18, at 6.
[39] *Analysis of Economic Impacts*, *supra* note 12, at 18, 53.

The preamble to the proposed Rule states that small businesses would have three years to comply with the Rule after its effective date and that very small business would have four years.[40] However, FSMA states that

> the regulations promulgated under this section shall apply to a small business . . . after the date that is 1 year after the effective date of the final [Produce Safety Rule] regulation and . . . the regulations promulgated under this section shall apply to a very small business . . . after the date that is 2 years after the effective date of the final [Produce Safety Rule] regulation . . . .[41]

We support FDA's decision to give small businesses three years to comply and very small businesses four years. But FDA should clarify the apparent conflict with FSMA's language. For example, FDA could state that FSMA gives it discretion to determine the precise compliance date after one and two years, respectively. In other words, the one- and two-year timeframes set the minimum time FDA must give small and very small businesses to comply, not the maximum.

3. Exempt or Partially Exempt Very Small Farms in Order To Provide Sufficient Flexibility for These Smaller Farms.

As FDA demonstrates by creating the $25,000 exclusion, the statutorily mandated direct-farm-marketing exemption is not the only means for providing flexibility to smaller farms. Currently, the only way the proposed Rule differentiates very small farms is with an extended compliance date. FDA should strongly consider an additional exemption for very small businesses—farms with no more than $250,000 in *covered produce* sales. The Produce Safety Rule is concerned with RACs, not *all food*. Sales of other types of food should not factor into whether a farm is considered a very small business. The current definition does not meet FSMA's requirement that FDA provide sufficient flexibility for small businesses that sell directly to consumers.

Given the lower risk of contamination from shorter supply chains in direct-to-consumer sales, FDA should add a qualified exemption (similar to the current one) for very small businesses whose average annual monetary value of *covered produce* sold to qualified end-users during such period exceeds the average annual monetary value of the *covered produce* sold to all other buyers during that period. Very small businesses would be subject to Subparts A, Q, and R. Although many very small businesses would likely qualify for both this and the less-than-$500,000 qualified exemption, the very-small-business exemption would be based on the value of "covered produce" rather than *all* food sold. Thus, a number of additional entities might qualify for exemption. Including only covered produce would encourage very small businesses to diversify their product offerings without risk of losing the exemption.

Alternatively, FDA should consider crafting limited compliance requirements tailored to very small businesses. Such requirements could include less burdensome recordkeeping obligations. At the least, FDA should gather additional data to assess quantitatively how farm size and supply-chain length correspond to produce contamination.

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[40] 78 Fed. Reg. 3506.
[41] 21 U.S.C. § 350h(b)(3)(A), (B).

4. Amend the Following Definitions.

i. Farm

FDA has tried to craft a definition of "farm" that distinguishes a farm's activities from a facility's activities covered under the proposed Preventive Controls Rule.[42] But the cramped definition of farm focused solely on the growing and harvesting of crops neglects a large part of a farm's business—preparing crops for distribution. Broadening the farm definition to include this important component will help clarify the Rule and serve FSMA's intention to distinguish regulations for farms—under section 419—and facilities—under section 418.

Confusion stems largely from calling a farm a "facility" in the "farm" definition. Section 415 of the Food, Drug and Cosmetic Act (FD&CA)—with which FSMA must align—requires "any facility engaged in manufacturing, processing, packing, or holding food" to register.[43] But under the FD&CA, the term facility specifically "does not include farms."[44] In the proposed Rules, FDA does not require farms to register under section 415. FDA should therefore remove the word "facility" from its definition of farm. As currently drafted, the proposed Produce Safety Rule and Preventive Controls Rule directly conflict with the FD&CA.

Additional confusion arises from both Rules attempting to distinguish "packing" and "holding" when delineating a "farm" activity from a "facility" activity. Packing or holding food, including raw agricultural commodities (RACs), as defined by the Produce Safety Rule, should not transform a "farm" into a "facility" subject to the Preventive Controls Rule, regardless of whether a farm is packing or holding its own or another farm's RACs or manufactured/processed food. A farm already holds and packs its own produce without being subject to the Preventive Controls Rule. Holding or packing another farm's produce does not introduce more points for contamination requiring regulation under the Preventive Controls Rule. A farm mixed-type facility manufacturing/processing food would already be subject to the Preventive Controls Rule. And facilities *not* co-located on a farm would still be subject to the Preventive Controls Rule if they hold or pack food. Preparing crops for distribution are essential functions of a farm and should not convert a farm into a facility. Again, defining a farm as a facility conflicts with the FD&CA.

Many farms buy and re-sell products from other farms, creating a mutually beneficial practice important for farms' viability. Even a minimal amount of additional paperwork will deter farms from engaging in those activities, which strengthen local food systems. Buying fresh produce in clearly labeled containers from other farms does not increase food safety risks enough (if at all) to warrant forcing the buying farm to comply with the Preventative Controls Rule.[45]

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[42] *See* Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food, 78 Fed. Reg. 3677 (proposed Jan. 16, 2013) (to be codified at 21 C.F.R. pts. 1, 16, 106, 110, 114, 117, 120, 123, 129, 179, and 211).

[43] *See* 21 U.S.C. § 350d(a).

[44] *Id.* § 350d(b)(1).

[45] Grubinger, *supra* note 16, at 2.

This change would allow farms to pack or hold all food (not just RACs) grown, raised, manufactured/processed, or consumed as part of a CSA without being forced to comply with the Preventive Controls Rule. CSA is a vital economic opportunity for small farms and, increasingly, is the way that many communities access fresh, local produce.

Allowing farms to pack or hold food—even manufactured/processed food—from their own farms or other farms means: Farm A could hold RACs or processed food from Farm B, without Farm A being subject to the Preventive Controls Rule. Farm B's "facility" activities—manufacturing/processing—would still be subject to the Preventive Controls Rule. This recommended change would apply only to farms or farm mixed-type facilities. Facilities *not* co-located on a farm would still be subject to the Preventive Controls Rule if they hold or pack food, except for facilities exempted under the Preventive Controls Rule.

These recommended changes would allow small farms to work together, diversify production, and expand the availability of locally grown food to their communities. The recommended textual changes are as follows under **section 112.3(c)**:

> *Farm* means an area of land, including buildings, ~~facility~~ in one general physical location devoted to the growing and harvesting of crops and preparing them for distribution into commerce, the raising of animals (including seafood), or both. Farm includes:
>
> (i) ~~Facilities that p~~Packing or holding food, including "raw agricultural commodities" (as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act), provided that all food used in such activities is grown, raised, manufactured/processed, or consumed on that farm or another farm or farms ~~under the same ownership~~; and
>
> (ii) ~~Facilities that m~~Manufacturinge/processing food, provided that all food used in such activities is consumed on that farm or another farm under the same ownership.

ii. Very Small Business

The current definition of "very small business" is a farm that sells annually no more than $250,000 in "food." Though the qualified exemption in the FSMA states that the sales counting toward that amount are sales of "food," FDA should amend the definition of very small business to count only "covered produce" sales toward the $250,000 threshold. FDA clearly has this discretion.[46] Otherwise, the Rule would require including *all* food, not just "covered produce," to determine if a farm is a very small business. As noted above, the Produce Safety Rule is concerned with RACs, not all food. The current definition fails to fulfill the intention of FSMA to provide flexibility for small businesses.

[46] *See* 21 U.S.C. § 350h(b)(3)(B).

This change would allow very small businesses to diversify their farms. The recommended textual changes are as follows under **section 112.3(b)(1)**:

> *Very small business*. For the purposes of this part, ~~your~~ a farm is a very small business if it is subject to this part and, on a rolling basis, the average annual monetary value of ~~food~~ covered produce (as defined in paragraph (c) of this section) ~~you~~ sold from that farm during the previous 3-year period is no more than $250,000.

iii. Small Business

The current definition of "small business" is a farm that sells annually no more than $500,000 in "food." For the same reasons FDA should change the definition of "very small business," FDA should amend the definition of small business to include "covered produce" sales only.

The recommended textual changes are as follows under **section 112.3(b)(2)**:

> *Small business*. For the purpose of this part, ~~your~~ a farm is a small business if it is subject to this part and, on a rolling basis, the average annual monetary value of ~~food~~ covered produce (as defined in paragraph (c) of this section) ~~you~~ sold from that farm during the previous 3-year period is no more than $500,000; and ~~your~~ that farm is not a very small business as provided in paragraph (b)(1) of this section.

iv. Community Supported Agriculture.

Collaboration with other farmers is often crucial economically for small- and very small-scale farmers whose harvest by itself may not justify an expensive trek to market. CSA offers an inexpensive, reliable way to market and sell produce. CSA provides a steady connection between constant, reliable, flexible consumers and the diverse, extremely specialized (or completely unspecialized) small-scale farming communities. This is where farming is at its most versatile, capable of implementing sustainable practices (and often incentivized to do so), and where long-term relationships justify and protect long-term investments and experimentation.

FDA should explicitly define CSA in the proposed Rule itself as it is defined in 7 C.F.R. § 249.2. Then, FDA should treat cooperative CSA farms like the proposed Rule treats farms under the same ownership. This will encourage small farms to work cooperatively and collaboratively, boosting farm sales and increasing local produce in the marketplace. Moreover, FDA must define CSA as a "retail food establishment" at 21 C.F.R. § 1.227 (and in the Preventive Controls Rule), so that when a farm sells through a CSA, it counts as sales to a "qualified end-user" for

purposes of the Produce Safety Rule exemption.[47] FDA should adhere to its recently published statement that, in the final rule, it will consider CSAs retail food establishments.[48]

The recommended addition is as follows under **section 112.3(c)**:

> *Community supported agriculture* means a program under which a farm or group of farms grows food for a group of shareholders (or subscribers) who pledge to buy a portion of the farm's crop(s) for that season.

v. Covered Activity.

FDA should redefine "covered activity" so that growing or harvesting "covered produce" and packing or holding food from *any* farm does not trigger the Preventive Controls Rule.[49] As noted above, packing and holding other farms' covered produce and manufactured/processed food is crucial to the business operations of small farms. Doing so should not subject farms to the Preventive Controls Rule.

Also, FDA should clarify that the Produce Safety Rule does not cover the facility activities of a farm mixed-type facility. The current definition states this implicitly. But, to eliminate ambiguity, FDA should state this explicitly.

The recommended textual changes are as follows under **section 112.3(c)**:

> *Covered activity* means growing~~,~~ or harvesting covered produce and~~,~~ packing~~,~~ or holding food, including covered produce ~~covered produce, provided that all covered produce used in covered packing or holding activities is grown, raised, or consumed on that farm or another farm under the same ownership~~. Covered activity does not include manufacturing/processing within the meaning defined in this chapter. This part does not apply to activities of a facility that are subject to part 110 of this chapter or the facility activities of a farm mixed-type facility.

vi. Harvesting; Holding; Manufacturing/Processing; and Packing.

FDA should change the definitions of "packing" and "holding" so that farms can pack or hold food, including RACs, from other farms not under the same ownership.[50] The recommended textual changes are as follows under **section 112.3(c)**:

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[47] *See Comment of Conservation Law Foundation on the U.S. Food and Drug Administration's Proposed Preventive Controls Rule*, at 12, Conservation Law Foundation, Docket No. FDA-2011-N-0920 (submitted Nov. 15, 2013).

[48] *See I Have a Farm – Does the Proposed Preventive Controls Rule Affect Me?*, U.S. Food and Drug Administration, at 3.

[49] *See* Part I.D.4.i.

[50] *See id.*

> *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 food, including raw agricultural commodities grown, ~~or~~ raised, or manufactured/processed on a ~~the same~~ farm ~~under the same ownership, but does not include activities that transform a raw agricultural commodity, as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act, into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act~~.

> *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, or manufactured/processed on a ~~the same~~ farm ~~or another farm under the same ownership~~ for storage and transport~~, but does not include activities that transform a raw agricultural commodity, as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act, into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act~~.

FDA should amend the definitions of "harvesting" to include performing this activity on farms not under the same ownership. Then, farms can gather, wash, trim outer leaves of, remove stems and husks from, sift, filter, thresh, shell, and cool RACs, and harvest, pack, or hold food and not risk becoming subject to the proposed Preventive Controls Rule.[51]

The recommended textual changes are as follows under **section 112.3(c)**:

> *Harvesting* applies to farms and farm mixed-type facilities and means activities that are traditionally performed by farms for the purpose of removing raw agricultural commodities from the place they were grown or raised and preparing them for use as food. ~~Harvesting is limited to activities performed on raw agricultural commodities on the farm on which they were grown or raised, or another farm under the same ownership.~~ Harvesting does not include activities that transform a raw agricultural commodity, as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act, into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act. Gathering, washing, trimming of outer leaves of, removing stems and husks from, sifting, filtering, threshing, shelling, and cooling raw agricultural commodities grown on a farm ~~or another farm under the same ownership~~ are examples of harvesting.

FDA should amend the definition of "manufacturing/processing" to ensure CSA will not become subject to the Preventive Controls Rule. The recommended textual changes are as follows under **section 112.3(c)**:

[51] *See id.*; Part I.D.4.iv.

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

5. Clarify Who Is and Is Not Subject to the Rule.

Under section 112.4, which explains who is subject to the Rule, FDA should exclude farms with no more than $25,000 in "*covered produce*" sales, rather than *all food* sales. "Food" is a broad term, defined under Section 201(f) of the FD&CA as "(1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article."[52] The Produce Safety Rule is concerned with contamination of RACs—covered produce. As such, the $25,000 exclusion should include only covered produce in calculating sales. These incredibly small farms would then be allowed to diversify without fear of becoming subject to the Produce Safety Rule. This small and relatively innocuous change could have a profound effect on many tiny operations, without sacrificing food safety.

Section 112.4 should use clearer language explicitly to exclude farms making $25,000 or less in covered produce sales. It also should state that a farm satisfying the requirements in section 112.5 (the qualified exemption) *is covered but exempt*. This change would clarify that farms selling less than $500,000 in food are not *excluded*, but rather *qualify for an exemption*.

The recommended textual changes are as follows under **section 112.4**:

§ 112.4 Who is and is not subject to the requirements of this part?

(a) A farm or farm mixed-type facility is a "covered farm" subject to this part if:

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

~~(b)~~ (2) ~~You~~ A farm or farm-mixed-type facility is ~~are not a~~ covered ~~farm if you satisfy~~ but exempt from the requirements of this part if ~~you~~ it ~~satisfy~~ satisfies the

[52] Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 321(f).

requirements in § 112.5 and ~~we~~FDA ~~have~~ has not withdrawn ~~your~~ the exemption in accordance with the provisions of Subpart R of this part.

(b) A farm or farm mixed-type facility is not a covered farm if the farm's average annual monetary value of covered produce (as "covered produce" is defined in § 112.3(c)) sold during the previous 3-year period was $25,000 or less (on a rolling basis).

6. Clarify Who Is Eligible for a Qualified Exemption.

Under section 112.5, FDA should ensure that the value of food sold, for determining if a farm receives the less-than-$500,000 statutory qualified exemption, is calculated using food sales from a *single farm only*. As currently drafted, the ambiguous use of the world "you" instead of "farm" could mean that the value is calculated by considering *all* farms that an owner, operator, or agent owns. But FSMA clearly mandates that the exemption apply to food sales from "[a] farm" (singular).[53] Based on the definition of "farm," this means a farm in "one general location," not multiple, non-contiguous farms under the same ownership. FDA must clarify this ambiguity.

As noted in Part I.D.3, FDA should also consider adding, under section 112.5, a qualified exemption (or partial exemption) for very small businesses.

The recommended textual changes are as follows under **section 112.5**:

§ 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~~ A farm (as defined in § 112.3(c)) is ~~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 food (as defined in § 112.3(c)) ~~you~~ such farm sold directly to qualified end-users (as defined in § 112.3(c)) during such period exceeded the average annual monetary value of the food ~~you~~ such farm sold to all other buyers during that period; and

(2) The average annual monetary value of all food (as defined in § 112.3(c)) ~~you~~ such farm 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 all food a farm sold during the 3-year period preceding the applicable calendar

[53] 21 U.S.C. § 350h(f)(1).

year was less than $500,000, adjusted for inflation, the baseline year for calculating the adjustment for inflation is 2011.

7. Clarify What Modified Requirements Apply to a Qualified-Exempt Farm.

FDA should state in the proposed Rule that a qualified-exempt farm must keep documentation to demonstrate the farm's qualified-exempt status. Rather than listing documentation requirements in the proposed Rule, we instead urge FDA to issue guidance recommending what documentation to maintain. To comply with FSMA's mandate that the rule give small businesses flexibility, the type and amount of documentation should not be overly burdensome. This would allow farms to tailor the documentation to their specific operations, providing them with increased flexibility. Still, the Rule should alert farmers that they will need to possess some documentation that proves they qualify for the exemption.

Also, FDA should add the word "labeling" to subsection 112.6(b) to eliminate ambiguity as to what modified requirement that subsection addresses.

The recommended textual changes are as follows under **section 112.6**:

§ 112.6 What modified requirements apply to ~~me~~ a farm if ~~I~~ it ~~am~~ is ~~eligible for~~ a qualified-exempt~~ion~~ farm in accordance with § 112.5?

. . .

(b) In addition, a qualified-exempt farm is subject to the following modified labeling requirements:

. . .

(c) An eligible qualified-exempt farm must also keep documentation kept in the normal course of business that demonstrates the farm's qualified-exempt status.

8. Address Flaws in the Due Process Afforded Qualified-Exempt Farms.

FDA must clarify under what circumstances it can withdraw the qualified exemption. Currently, FDA can withdraw the exemption under two circumstances: (1) when it directly links a foodborne illness outbreak to a farm; or (2) when it determines that withdrawing the exemption is necessary to protect the public health and prevent or mitigate a foodborne illness outbreak. For the latter, FDA must base the withdrawal on "conduct or conditions associated" with the farm that are "material to the safety of the food."[54]

[54] 78 Fed. Reg. 3644.

FDA should eliminate the ambiguity for withdrawing the exemption under option one by aligning it with the standard for withdrawing the exemption under option two. As written, there is ambiguity as to what a foodborne illness must be linked for FDA to withdraw the exemption. By linking it to "conduct or conditions" on the farm—like option two—FDA would clarify more precisely when it can withdraw the exemption.

Under option two, FDA should allow for a *partial withdrawal*, which it could tailor to the farm's conduct or conditions. This way, small businesses can seek targeted solutions, such as installing water purification or testing equipment, as needed, without falling under the full substantive provisions of the Produce Safety Rule, which could prove too costly for small farms. Further, FDA should require the conduct or conditions to occur *on* the farm rather than simply be *associated* with the farm. Requiring mere association leaves too much ambiguity.

The proposed Rule does not state any burden of proof. The Rule should require that FDA show materiality through *substantial evidence* to justify a withdrawal or partial withdrawal. "Substantial evidence" is sufficient evidence so that a reasonable person would find it adequate to support the withdrawal or partial withdrawal.[55]

The importance of the Produce Safety Rule exemption to the viability of small and very small businesses cannot be stressed enough—for many of these farms, the costs of careful, sustainable practices mean that they run their businesses with very low profit margins. Robust procedures are needed to ensure that the potential for a withdrawal order does not discourage small farms from continuing to operate.

The recommended textual changes are as follows under **section 112.201**:

> **§ 112.201 Under what circumstances can FDA withdraw a qualified exemption in accordance with the requirements in § 112.5?**
>
> ~~We~~ (a) The FDA may withdraw or partially withdraw ~~your~~ a farm's qualified exemption under § 112.5:
>
> ~~(a)~~ (1) In the event of an active investigation of a foodborne illness outbreak that is directly linked to ~~your~~ conduct or conditions on the farm that are material to the safety of the food that would otherwise be covered produce grown, harvested, packed, or held at the farm; or
>
> ~~(b)~~ (2) If ~~we~~ FDA determines that ~~it~~ withdrawal or partial withdrawal is necessary to protect the public health and prevent or mitigate a foodborne illness outbreak based on conduct or conditions ~~associated with your~~ on the farm that are material to the safety of the food that would otherwise be covered produce grown, harvested, packed or held at ~~your~~ the farm.
>
> (b) A withdrawal or partial withdrawal under paragraph (a)(1) or (a)(2) must be

[55] *See, e.g.*, *Consolidated Edison Co. v. N.L.R.B.*, 305 U.S. 197, 229 (1938).

supported by substantial evidence. *Substantial evidence* is sufficient evidence so that a reasonable person would find the evidence adequate to support the withdrawal or partial withdrawal.

FDA should tighten the procedure for withdrawing an exemption. Adding the language suggested below will eliminate ambiguity, strengthening due process protections for small farms.

The recommended textual changes are as follows under **section 112.202**:

§ 112.202 What procedure will FDA use to withdraw an exemption?

~~(a) If FDA determines that~~ The following procedure applies for withdrawing or partially withdrawing a qualified exemption applicable to a farm under § 112.5 ~~should be withdrawn~~:

(a) ~~If any~~ Any officer or qualified employee of FDA may ~~issue~~ submit an order to withdraw or partially withdraw the exemption to the FDA District Director or official senior to such Director within 10 calendar days of making that determination.

(b) An FDA District Director in whose district the farm is located (or, in the case of a foreign farm, the Director of the Office of Compliance in the Center for Food Safety and Applied Nutrition), or an FDA official senior to such Director, must approve or deny an order to withdraw or partially withdraw the exemption within 10 calendar days of the date the order to withdraw or partially withdraw the exemption is submitted. If no action is taken within the 10 calendar days, the order to withdraw or partially withdraw the exemption is revoked.

(c) If an FDA District Director or FDA official senior to such Director approves an order to withdraw or partially withdraw the exemption, FDA must issue an order to withdraw or partially withdraw the exemption to the owner, operator, or agent in charge of the farm.

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

(e) FDA must deliver an order by certified mail with confirmation delivery within 5 calendar days of an FDA District Director or FDA official senior to such Director approving an order.

FDA should include more detailed information in the order to withdraw a qualified exemption that it sends to a farm. It should also allow 30 days to appeal the order. Given a small farmer's schedule, 10 days does not give a farmer adequate time to appeal the order. Most importantly, FDA needs to provide a mechanism for a farm that has lost its qualified exemption to regain it. The withdrawal must notify a farm that it can seek reinstatement of the exemption after a set

time period.

The recommended textual changes are as follows under **section 112.203**:

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

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

(a) The date of the order;

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

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

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

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

(1) Whether the order is based on § 112.201(a)(1) or § 112.201(a)(2);

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

(3) If the order is based on § 112.201(a)(1), the substantial evidence linking the active investigation of a foodborne illness outbreak directly to conduct or conditions on the farm that are material to the safety of the food that would otherwise be covered produce grown, harvested, packed or held at the farm;

(4) If the order is based on § 112.201(a)(2), the substantial, measurable evidence collected using generally accepted scientific standards indicating the presence of pathogens on the farm that may pose an imminent threat to public health based on conduct or conditions on the farm that are material to the safety of the food that would otherwise be covered produce grown, harvested, packed, or held at the farm;

(5) Any other relevant information;

(d) A statement that the farm must either~~;~~:

(1) If the withdrawal is a total withdrawal of the exemption, comply with subparts B through O of this part on the date that is 60 calendar days after the date ~~of~~ the

order is received by certified mail or, if operations have ceased and will not resume within 60 calendar days, before the beginning of operations in the next growing season;

(2) If the withdrawal is a partial withdrawal of the exemption, indicate with which subparts of this Rule the farm must comply on the date that is 60 calendar days after the date the order is received by certified mail or, if operations have ceased and will not resume within 60 calendar days, before the beginning of operations in the next growing season;

(e) A statement that the owner, operator, or agent in charge of the farm may appeal the order (and request an informal hearing) within 30 calendar days of the date the order is received by certified mail;

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

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

~~(g)~~ (h) A statement that the owner, operator, or agent in charge of the farm may seek reinstatement of the qualified exemption and request an informal hearing after the time for appeal has expired or the order has been confirmed on appeal;

~~(h)~~ (i) A statement that any informal hearing on a request to reinstate the qualified exemption must be conducted as a regulatory hearing under part 16 of this chapter, with certain exceptions described in § 112.213;

(j) 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 farm is located (or for foreign farms, the same information for the Director of the Office of Compliance in the Center for Food Safety and Applied Nutrition); and

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

FDA should provide guidance on what documents a farmer can present that will refute an order to withdraw an exemption. To be clear, the burden of proof—a substantial-evidence standard—should be on FDA if it attempts to withdraw an exemption and if a farmer appeals a withdrawal order. Nonetheless, FDA should explain what documents will help refute a withdrawal, though we do not suggest adding specific language directly in the Rule. FDA should publish separate guidance on this issue.

Sections 112.204 through **112.208** and **112.211** require few changes to align them with the previous proposed edits:

§ 112.204 What actions must the owner, operator, or agent in charge of the farm take ~~must I do~~ if ~~I~~ the farm receives an order to withdraw or partially withdraw a qualified exemption ~~applicable to my farm~~?

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

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

(b) Appeal the order within ~~10~~ 30 calendar days of the date ~~of~~ the order is received by certified mail in accordance with the requirements of § 112.206.

§ 112.205 Can ~~I~~ the owner, operator, or agent in charge of the farm appeal or request a hearing on an order to withdraw a qualified exemption ~~applicable to my farm~~?

. . .

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

§ 112.206 What is the procedure for submitting an appeal?

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

(1) Submit the appeal in writing to the FDA District Director in whose district the farm is located (or in the case of a foreign farm, the Director of the Office of Compliance in the Center for Food Safety and Applied Nutrition), at the mailing address, email address, or facsimile number identified in the order within ~~10~~ 30 calendar days of the date ~~of~~ the order is received by certified mail; and

. . .

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

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

(1) May request an informal hearing; and

(2) Must submit any request for an informal hearing together with its written appeal submitted in accordance with § 112.206 within ~~10~~ 30 calendar days of the date ~~of~~ the order was received by certified mail.

(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~~ approves or denies the request for an informal hearing, a written notice of the determination will be ~~given~~ distributed by certified mail to the owner, operator, or agent in charge of the farm within 10 calendar days of receiving the request for an informal hearing. If the presiding officer denies the request, the written notice will explain~~ing~~ the reason for the denial.

§ 112.208 What requirements are applicable to an informal hearing?

. . .

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

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

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

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

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

within 2 calendar days of issuance of the report. The presiding officer will then issue the final decision.

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

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

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

. . .

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

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

(b) If the owner, operator, or agent in charge of a farm 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 § 112.208(c)(4), and must issue a final decision within 10 calendar days after the hearing is held; or

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

§ 112.211 When is an order to withdraw or partially withdraw a qualified exemption applicable to a farm revoked?

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

. . .

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

9. Provide a Procedure for Reinstating a Withdrawn Qualified Exemption.

The proposed Rule provides no way for a farm to regain its qualified-exempt status if FDA revokes it. Providing strong rehabilitation procedures after FDA initiates an order to withdraw is fundamental to ensuring that a withdrawal of an exemption will not be permanent, and therefore possibly ruinous, to these farms. If a farm is able to fix the conduct or conditions that led to withdrawal, FDA should reinstate the exemption for that farm. Forcing a farm to lose permanently its qualified exemption does not serve the FSMA's intention to provide sufficient flexibility for small businesses.

In developing a reinstatement procedure, FDA can look to the model used for facilities that have lost a similar type of certification—called registration—found in section 415 of the FD&CA.[56] Under that Act, FDA 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."[57] Under section 415, if a facility has its registration suspended, FDA "shall" provide an opportunity for an informal hearing to discuss what actions are required for reinstating the registration.[58] FDA "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."[59] After the hearing on the suspension, if FDA determines that the registration should be reinstated, the registrant must submit a "corrective action plan" that outlines how the registrant will fix the problem that led to the suspension.[60] 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.[61] FDA can use this process as a guide for determining how a farm can have a qualified exemption reinstated.

At the least, FDA should include in the Rule: (1) a procedure for requesting an informal hearing

[56] Federal Food, Drug, & Cosmetic Act, 21 U.S.C. § 350d.
[57] *Id.* § 350d(b)(1).
[58] *Id.* § 350d(b)(2).
[59] *Id.*
[60] *Id.* § 350d(b)(3)(A).
[61] *Id.* § 350d(b)(3)(B).

to reinstate the qualified exemption; (2) the requirements that apply to such an informal hearing; (3) who will preside at the informal hearing; and (4) the timeframe for issuing a decision on reinstating the qualified exemption. The recommended additions are as follows, added as **sections 112.212** through **112.215**:

§ 112.212 If a farm's qualified exemption is withdrawn or partially withdrawn, what is the procedure for requesting an informal hearing to reinstate the qualified exemption?

The following procedure applies for requesting an informal hearing to reinstate the qualified exemption applicable to a farm under § 112.5:

(a) The owner, operator, or agent in charge of the farm may request an informal hearing to reinstate the qualified exemption at any time after:

(1) An order to withdraw the qualified exemption has been issued under § 112.201(a)(1) or § 112.201(a)(2); and

(2)(i) The owner, operator, or agent in charge of the farm has not appealed and the time under § 112.207(a)(2) for appealing the order has expired; or

(ii) The order has been confirmed on appeal.

(b) The owner, operator, or agent in charge of the farm must submit in writing a request for an informal hearing to reinstate the exemption 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 withdrawing or partially withdrawing the exemption.

(c) In the request for an informal hearing, the owner, operator, or agent in charge of such farm must present evidence demonstrating that the conduct or conditions that triggered the withdrawal order have been sufficiently resolved.

(d) 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 approves or denies the request for an informal hearing, a written notice of the determination will be distributed by certified mail to the owner, operator, or agent in charge of the farm within 10 calendar days of receiving the request for an informal hearing. If the presiding officer denies the request, the written notice will explain the reason for the denial.

(e) If the request for an informal hearing is denied, or the request for reinstatement is denied at the informal hearing, a subsequent request for an informal hearing to reinstate the qualified exemption may not be made until one

calendar year after the date the denial of the informal hearing is received by certified mail or the date the request for reinstatement at the informal hearing is denied.

§ 112.213 What requirements are applicable to an informal hearing?

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

(a) The hearing will be held within 10 calendar days after the date the request is filed or, if applicable, within a timeframe agreed upon in writing by the owner, operator, or agent in charge of the farm and FDA.

(b) The presiding officer may require that a hearing conducted under this subpart be 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 or partially withdrawing an exemption under § 112.5, rather than the notice under § 16.22(a) of this chapter, provides notice of opportunity for an informal hearing requesting reinstatement under this section and is part of the administrative record of the regulatory hearing under § 16.80(a) of this chapter.

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

(3) Section 112.214, rather than § 16.42(a) of this chapter, describes the FDA employees who preside at hearings under this subpart.

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

(5) Section 16.80(a)(4) of this chapter does not apply to a regulatory hearing under this subpart. The presiding officer's report of the hearing and any

comments on the report by the hearing participant under § 112.213(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 or partially withdrawing an exemption, the hearing must be conducted as a regulatory hearing under regulation in accordance with part 16 of this chapter, except that § 16.95(b) does not apply to a hearing under this subpart. With respect to a regulatory hearing under this subpart, the administrative record of the hearing specified in §§ 16.80(a)(1), (a)(2), (a)(3), and (a)(5), and § 112.213(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.

(d) The presiding officer shall reinstate a farm's qualified exemption under §§ 112.4(b), 112.5, and 112.6 of this part if the presiding officer determines that the evidence demonstrates that the conduct or conditions that triggered the withdrawal or partial withdrawal order have been sufficiently resolved.

§ 112.214 Who is the 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.

§ 112.215 What is the timeframe for issuing a decision on reinstating the qualified exemption?

(a) If FDA grants the request for a hearing and the hearing is held, the presiding officer must provide a 2 calendar day opportunity for the hearing participants to review and submit comments on the report of the hearing under § 112.213(c)(4), and must issue a final decision within 10 calendar days after the hearing is held.

(b) The final decision (with or without an informal hearing) of the presiding officer is considered a final Agency action under 5 U.S.C. 702.

10. Omit Use of the Second Person.

Throughout, the proposed Rule references the second person, i.e., "you." While this creates a more personable and perhaps accessible tone, it introduces ambiguity. For example, section 112.5 reads:

> (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 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 food you sold to all other buyers during that period . . . .

"You" could refer to a single farm, multiple farms, or multiple facilities. Replacing "you" with a definitive descriptor will eliminate unnecessary confusion for farmers, inspectors, and others working to implement the Rule effectively. If FDA wants to keep some uses of the second person, it should at least change all instances of "you" recommended above.

II. FDA SHOULD ENSURE THE STANDARDS FOR USING BIOLOGICAL SOIL AMENDMENTS DOES NOT CONFLICT WITH THE NATIONAL ORGANIC PROGRAM.

The proposed Rule requires a 9-month waiting period between applying untreated manure and harvesting the crop.[62] This long of a waiting period would require manure application in the fall of the year before harvest, a practice that is discouraged because it can lead to loss of nitrogen. This standard may force farmers to use chemical fertilizers over manure, threatening their USDA organic certification, and degrading water quality with increased nitrogen loading in rivers and streams.

FDA must address the likely increase in synthetic fertilizer use and manure application and, therefore, the effect on surface water. Synthetic fertilizer use leads to increased nitrogen and phosphorous runoff into watersheds.[63] Excessive nutrient loading in water systems has created hypoxic zones in streams, rivers, and the Gulf of Mexico.[64] These effects include harm to fresh fish, saltwater fish, other aquatic life, and the wildlife and human communities that depend on these species.

Both the 9-month waiting period and the 45-day waiting period, when manure is treated with a composting process, conflict with the manure management standards in the Good Agricultural Practices (GAP) and the USDA National Organic Program. FSMA mandates that FDA regulations "not include any requirements that conflict with or duplicate the requirements of the national organic program established under the Organic Foods Production Act of 1990, while providing the same level of public health protection as the requirements under guidance documents."[65] Under the National Organic Program, raw manure can be "[i]ncorporated into the

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[62] 78 Fed. Reg. 3637.

[63] *See* Nancy N. Rabalais et al., *Beyond Science into Policy: Gulf of Mexico Hypoxia and the Mississippi River*, 52 Bioscience 129, 135 (Feb. 2002).

[64] *See id.* at 129, 130.

[65] 21 U.S.C. § 350h(a)(3)(E).

soil not less than 120 days prior to the harvest of a product whose edible portion has direct contact with the soil surface or soil particles."[66] There is no specified waiting period if the manure is treated by a composting process.[67] Under the Produce Safety Rule, if raw manure is applied "[i]n a manner that does not contact covered produce during application and minimizes the potential for contact with covered produce after application," the waiting period is 9 months.[68] If manure is treated by composting and applied "[i]n a manner that minimizes the potential for contact with covered produce during and after application," the waiting period is 45 days.[69] Both of these time periods under the Rule arguably conflict—in violation of FSMA—with the National Organic Program. Though the Rule allows scientifically valid alternatives, FDA must change the Rule so as not to conflict with organic standards.

III. THE PRODUCE SAFETY RULE SHOULD PROTECT AND PROMOTE ON-FARM CONSERVATION PRACTICES.

FSMA requires FDA to take "into consideration, consistent with ensuring enforceable public health protection, conservation and environmental practice standards and policies established by Federal natural resource conservation, wildlife conservation, and environment agencies."[70] But the proposed Rule never even uses the word "conservation." FDA should incorporate language into the proposed Rule that encourages on-farm conservation practices.

Under section 112.3, FDA should consider adding a definition of "co-management": "*Co-management* means farm system management approaches that respond to site-specific conditions by integrating farm practices that promote ecological balance and public health by conserving biodiversity, soil, water, air, energy, and other natural resources, while reducing pathogen hazards associated with food production." Then, under section 112.22(a), addressing personnel training, FDA should add subsection 4: "(4) The importance of co-management of food safety and conservation, including recognizing that sustainable conservation practices can enhance food safety and taking measures to conserve wild animal habitat on the farm."

Subpart I provides standards for domesticated and wild animals. We support FDA's acknowledgement, in the preamble, that the presence of animals in a field is not, in and of itself, a significant food safety risk. Given limited scientific evidence about the risk that specific animals present, FDA is correct not to establish a list of "animals of concern" that farmers must keep from produce. Establishing such a list could erroneously support removing vital wildlife habitat in and around fields.

FDA should, however, affirmatively support conservation practices in Subpart I. Though the proposed Rule does not require farmers to clear farm borders or destroy wildlife habitat, FDA does not explicitly prohibit these actions. FDA should strengthen the Rule by providing standards that prohibit destruction of habitat, such as native plant buffers. FDA should also

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[66] 7 C.F.R. § 205.203(c)(1)(ii).
[67] *Id.* § 205.203(c)(2).
[68] 78 Fed. Reg. 3637.
[69] *Id.*
[70] 21 U.S.C. § 350h(a)(3)(D).

include requirements to train on-farm personnel on how conservation practices support food safety goals. Native habitat is crucial for pollinators, such as bees. If farmers are pressured or required by inspectors to remove habitat, this practice would diminish biodiversity in the diet of honeybees, necessary for their survival. Separating pollinators from native habitat and cropland will ultimately cause damage to the long-term health of our crops.[71]

Conservation practices are central to organic production systems. The National Organic Program requires organic farmers to conserve biodiversity and protect soil, water, wetlands, woodlands, and wildlife. Despite FSMA's mandate that the Produce Safety Rule not conflict with National Organic Program requirements, the proposed Rule risks doing just that by not building in explicit protections for conservation practices.

IV. THE PRODUCE SAFETY RULE SHOULD CHANGE AGRICULTURAL WATER TESTING AND TREATMENT REQUIREMENTS.

Subpart E of the Produce Safety Rule contains the standards for agricultural water. The standards are costly, burdensome, and unsupported by best scientific practices. A farmer who uses water from a stream on her property to irrigate her fields would be required to take weekly water quality samples and test for generic *E. coli*, even though generic *E. coli* is not a real indicator of pathogen presence that causes foodborne illness.[72] In the event of positive test results that surpass the acceptable threshold, the farmer must immediately stop using the water and fix the problem, even if the source of the problem is not on her farm.

Many growers have few alternatives to their present source of irrigation water. The proposed Rule's stringent testing standards would likely cause these farmers to depend on groundwater if the surface waters they use fail testing.[73] Groundwater depletion is already a well-documented problem in the United States.[74] The proposed Rule's irrigation water requirements could apply severe pressure on already depleted aquifers across the United States, particularly in agricultural-heavy parts of the country.[75]

FDA must take a reasonable, risk-based approach to agricultural water that allows farmers to respond to *specific risks in their water systems*. FDA should not include unsupported numerical thresholds for presence of pathogens or pathogen indicators, i.e., generic *E. coli*, in water. Information should be included in guidance after sufficient research indicates what is an appropriate numerical standard, which might vary by region.

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[71] *See* Brian Snyder, *Consider the Bees of the Field* (Oct. 22, 2013), http://writetofarm.com/2013/10/22/consider-the-bees-of-the-field/.

[72] *See Bad Bug Book, Foodborne Pathogenic Microorganisms and Natural Toxins*, U.S. Food and Drug Admin. (Keith A. Lampel et al., eds.) (2012); Trevor V. Suslow, *Standards for Irrigation and Foliar Contact Water*, Produce Safety Project Issue Brief, Georgetown University (2010).

[73] 78 Fed. Reg. 50,359.

[74] *See generally* Leonard F. Konikow, *Groundwater Depletion in the United States (1900–2008)*, at 1, U.S. Dep't of the Interior (2013).

[75] *See id.*

The Rule should require farmers to collect monthly baseline information about their water systems in the first growing season, and base future actions and testing frequencies on those results. Importantly, the Rule should not encourage or allow chemical treatment of irrigation water.

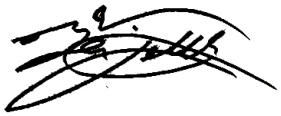
V. FDA SHOULD KEEP THE INTEGRATED APPROACH TO THE PROPOSED PRODUCE SAFETY RULE.

The proposed Produce Safety Rule acknowledges the importance of diversified farming systems by taking an "integrated approach" to the standards.[76] This method does not set separate standards for each type of commodity. Regulating based on commodity type would be detrimental to small, diversified farms. Though large-scale, industrial producers more frequently growing single crops could meet the demands of separate commodity standards, smaller farms would buckle under the requirements. We encourage FDA to maintain the integrated approach in the final rule.

CONCLUSION

Thank you for considering our comment. If you have any questions about this letter, please contact us at (207) 210-6439 x5014.

Sincerely,



Ben W. Tettlebaum
Rhodes Fellow/Attorney
Conservation Law Foundation

[76] *See* 78 Fed. Reg. 3525.

APPENDIX

Produce Safety Rule
(to be codified at 21 C.F.R. pts. 16 and 112)

PART 112—STANDARDS FOR THE GROWING, HARVESTING, PACKING, AND HOLDING OF PRODUCE FOR HUMAN CONSUMPTION

. . .

Subpart A—General Provisions

. . .

§ 112.3 What definitions apply to this part?

. . .

(b) . . .

(1) *Very small business*. For the purposes of this part, ~~your~~ a farm is a very small business if it is subject to this part and, on a rolling basis, the average annual monetary value of ~~food~~ covered produce (as defined in paragraph (c) of this section) ~~you~~ sold from that farm during the previous 3-year period is no more than $250,000.

(2) *Small business*. For the purpose of this part, ~~your~~ a farm is a small business if it is subject to this part and, on a rolling basis, the average annual monetary value of ~~food~~ covered produce (as defined in paragraph (c) of this section) ~~you~~ sold from that farm during the previous 3-year period is no more than $500,000; and ~~your~~ that farm is not a very small business as provided in paragraph (b)(1) of this section.

(c) . . .

Community supported agriculture means a program under which a farm or group of farms grows food for a group of shareholders (or subscribers) who pledge to buy a portion of the farm's crop(s) for that season.

Covered activity means growing~~,~~ or harvesting covered produce and~~,~~ packing~~,~~ or holding food, including covered produce ~~covered produce, provided that all covered produce used in covered packing or holding activities is grown, raised, or consumed on that farm or another farm under the same ownership~~. Covered activity does not include manufacturing/processing within the meaning defined in this chapter. This part does not apply to activities of a facility that are subject to part 110 of this chapter or the facility activities of a farm mixed-type facility.

. . .

Farm means an area of land, including buildings, ~~facility~~ in one general physical location devoted to the growing and harvesting of crops and preparing them for distribution into commerce, the raising of animals (including seafood), or both. Farm includes:

(i) ~~Facilities that p~~Packing or holding food, including "raw agricultural commodities" (as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act), provided that all food used in such activities is grown, raised, manufactured/processed, or consumed on that farm or another farm or farms ~~under the same ownership~~; and

(ii) ~~Facilities that m~~Manufacturinge/processing food, provided that all food used in such activities is consumed on that farm or another farm under the same ownership.

. . .

Harvesting applies to farms and farm mixed-type facilities and means activities that are traditionally performed by farms for the purpose of removing raw agricultural commodities from the place they were grown or raised and preparing them for use as food. ~~Harvesting is limited to activities performed on raw agricultural commodities on the farm on which they were grown or raised, or another farm under the same ownership.~~ Harvesting does not include activities that transform a raw agricultural commodity, as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act, into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act. Gathering, washing, trimming of outer leaves of, removing stems and husks from, sifting, filtering, threshing, shelling, and cooling raw agricultural commodities grown on a farm ~~or another farm under the same ownership~~ are examples of harvesting.

. . .

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 food, including raw agricultural commodities grown, ~~or~~ raised, or manufactured/processed on a ~~the same~~ farm ~~under the same ownership, but does not include activities that transform a raw agricultural commodity, as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act, into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act~~.

. . .

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

. . .

Packing means placing food into a container other than packaging the food. For farms and farm mixed-type facilities, packing also includes activities (which may include packaging) traditionally performed by farms to prepare raw agricultural commodities grown, ~~or~~ raised, or manufactured/processed on a ~~the same~~ farm ~~or another farm under the same ownership~~ for storage and transport~~, but does not include activities that transform a raw agricultural commodity, as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act, into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act~~.

. . .

§ 112.4 Who is and is not subject to the requirements of this part?

(a) A farm or farm mixed-type facility is a "covered farm" subject to this part if:

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

~~(b)~~ (2) ~~You~~ A farm or farm-mixed-type facility is ~~are not a~~ covered ~~farm if you satisfy~~ but exempt from the requirements of this part if ~~you~~ it ~~satisfy~~ satisfies the requirements in § 112.5 and ~~we~~FDA ~~have~~ has not withdrawn ~~your~~ the exemption in accordance with the provisions of Subpart R of this part.

(b) A farm or farm mixed-type facility is not a covered farm if the farm's average annual monetary value of covered produce (as "covered produce" is defined in § 112.3(c)) sold during the previous 3-year period was $25,000 or less (on a rolling basis).

§ 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~~ A farm (as defined in § 112.3(c)) is ~~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 food (as defined in § 112.3(c)) ~~you~~ such farm sold directly to qualified end-users (as defined in § 112.3(c)) during such period exceeded the average annual monetary value of the food ~~you~~ such farm sold to all other buyers during that period; and

(2) The average annual monetary value of all food (as defined in § 112.3(c)) ~~you~~ such farm 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 all food a farm 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.

§ 112.6 What modified requirements apply to ~~me~~ a farm if ~~I~~ it ~~am~~ is ~~eligible for~~ a qualified-exempt~~ion~~ farm in accordance with § 112.5?

. . .

(b) In addition, a qualified-exempt farm is subject to the following modified labeling requirements:

. . .

(c) An eligible qualified-exempt farm must also keep documentation kept in the normal course of business that demonstrates the farm's qualified-exempt status.

Subpart R—Withdrawal of Qualified Exemption

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

~~We~~ (a) The FDA may withdraw or partially withdraw ~~your~~ a farm's qualified exemption under § 112.5:

~~(a)~~ (1) In the event of an active investigation of a foodborne illness outbreak that is directly linked to ~~your~~ conduct or conditions on the farm that are material to the safety of the food that would otherwise be covered produce grown, harvested, packed, or held at the farm; or

~~(b)~~ (2) If ~~we~~ FDA determines that ~~it~~ withdrawal or partial withdrawal is necessary to protect the public health and prevent or mitigate a foodborne illness outbreak based on conduct or conditions ~~associated with your~~ on the farm that are material to the safety of the food that would otherwise be covered produce grown, harvested, packed or held at ~~your~~ the farm.

(b) A withdrawal or partial withdrawal under paragraph (a)(1) or (a)(2) must be supported by substantial evidence. *Substantial evidence* is sufficient evidence so that a reasonable person would find the evidence adequate to support the withdrawal or partial withdrawal.

§ 112.202 What procedure will FDA use to withdraw an exemption?

~~(a) If FDA determines that~~ The following procedure applies for withdrawing or partially withdrawing a qualified exemption applicable to a farm under § 112.5 ~~should be withdrawn~~:

(a) ~~If any~~ Any officer or qualified employee of FDA may ~~issue~~ submit an order to withdraw or partially withdraw the exemption to the FDA District Director or official senior to such Director within 10 calendar days of making that determination.

(b) An FDA District Director in whose district the farm is located (or, in the case of a foreign farm, the Director of the Office of Compliance in the Center for Food Safety and Applied Nutrition), or an FDA official senior to such Director, must approve or deny an order to withdraw or partially withdraw the exemption within 10 calendar days of the date the order to withdraw or partially withdraw the exemption is submitted. If no action is taken within the 10 calendar days, the order to withdraw or partially withdraw the exemption is revoked.

(c) If an FDA District Director or FDA official senior to such Director approves an order to withdraw or partially withdraw the exemption, FDA must issue an order to withdraw or partially withdraw the exemption to the owner, operator, or agent in charge of the farm.

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

(e) FDA must deliver an order by certified mail with confirmation delivery within 5 calendar days of an FDA District Director or FDA official senior to such Director approving an order.

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

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

(a) The date of the order;

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

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

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

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

(1) Whether the order is based on § 112.201(a)(1) or § 112.201(a)(2);

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

(3) If the order is based on § 112.201(a)(1), the substantial evidence linking the active investigation of a foodborne illness outbreak directly to conduct or conditions on the farm that

are material to the safety of the food that would otherwise be covered produce grown, harvested, packed or held at the farm;

(4) If the order is based on § 112.201(a)(2), the substantial, measurable evidence collected using generally accepted scientific standards indicating the presence of pathogens on the farm that may pose an imminent threat to public health based on conduct or conditions on the farm that are material to the safety of the food that would otherwise be covered produce grown, harvested, packed, or held at the farm;

(5) Any other relevant information;

(d) A statement that the farm must either~~;~~:

(1) If the withdrawal is a total withdrawal of the exemption, comply with subparts B through O of this part on the date that is 60 calendar days after the date ~~of~~ the order is received by certified mail or, if operations have ceased and will not resume within 60 calendar days, before the beginning of operations in the next growing season;

(2) If the withdrawal is a partial withdrawal of the exemption, indicate with which subparts of this Rule the farm must comply on the date that is 60 calendar days after the date the order is received by certified mail or, if operations have ceased and will not resume within 60 calendar days, before the beginning of operations in the next growing season;

(e) A statement that the owner, operator, or agent in charge of the farm may appeal the order (and request an informal hearing) within 30 calendar days of the date the order is received by certified mail;

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

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

~~(g)~~ (h) A statement that the owner, operator, or agent in charge of the farm may seek reinstatement of the qualified exemption and request an informal hearing after the time for appeal has expired or the order has been confirmed on appeal;

~~(h)~~ (i) A statement that any informal hearing on a request to reinstate the qualified exemption must be conducted as a regulatory hearing under part 16 of this chapter, with certain exceptions described in § 112.213;

(j) 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 farm is located (or for foreign farms, the same information for the Director of the Office of Compliance in the Center for Food Safety and Applied Nutrition); and

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

§ 112.204 What actions must the owner, operator, or agent in charge of the farm take ~~must I do~~ if ~~I~~ the farm receives an order to withdraw or partially withdraw a qualified exemption ~~applicable to my farm~~?

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

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

(b) Appeal the order within ~~10~~ 30 calendar days of the date ~~of~~ the order is received by certified mail in accordance with the requirements of § 112.206.

§ 112.205 Can ~~I~~ the owner, operator, or agent in charge of the farm appeal or request a hearing on an order to withdraw a qualified exemption ~~applicable to my farm~~?

. . .

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

§ 112.206 What is the procedure for submitting an appeal?

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

(1) Submit the appeal in writing to the FDA District Director in whose district the farm is located (or in the case of a foreign farm, the Director of the Office of Compliance in the Center for Food Safety and Applied Nutrition), at the mailing address, email address, or facsimile number identified in the order within ~~10~~ 30 calendar days of the date ~~of~~ the order is received by certified mail; and

. . .

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

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

(1) May request an informal hearing; and

(2) Must submit any request for an informal hearing together with its written appeal submitted in accordance with § 112.206 within ~~10~~ 30 calendar days of the date ~~of~~ the order was received by certified mail.

(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~~ approves or denies the request for an informal hearing, a written notice of the determination will be ~~given~~ distributed by certified mail to the owner, operator, or agent in charge of the farm within 10 calendar days of receiving the request for an informal hearing. If the presiding officer denies the request, the written notice will explain~~ing~~ the reason for the denial.

§ 112.208 What requirements are applicable to an informal hearing?

. . .

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

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

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

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

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

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

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

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

. . .

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

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

(b) If the owner, operator, or agent in charge of a farm 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 § 112.208(c)(4), and must issue a final decision within 10 calendar days after the hearing is held; or

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

§ 112.211 When is an order to withdraw or partially withdraw a qualified exemption applicable to a farm revoked?

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

. . .

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

§ 112.212 If a farm's qualified exemption is withdrawn or partially withdrawn, what is the procedure for requesting an informal hearing to reinstate the qualified exemption?

The following procedure applies for requesting an informal hearing to reinstate the qualified exemption applicable to a farm under § 112.5:

(a) The owner, operator, or agent in charge of the farm may request an informal hearing to reinstate the qualified exemption at any time after:

(1) An order to withdraw the qualified exemption has been issued under § 112.201(a)(1) or § 112.201(a)(2); and

(2)(i) The owner, operator, or agent in charge of the farm has not appealed and the time under § 112.207(a)(2) for appealing the order has expired; or

(ii) The order has been confirmed on appeal.

(b) The owner, operator, or agent in charge of the farm must submit in writing a request for an informal hearing to reinstate the exemption 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 withdrawing or partially withdrawing the exemption.

(c) In the request for an informal hearing, the owner, operator, or agent in charge of such farm shall present evidence demonstrating that the conduct or conditions that triggered the withdrawal order have been sufficiently resolved.

(d) 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 approves or denies the request for an informal hearing, a written notice of the determination will be distributed by certified mail to the owner, operator, or agent in charge of the farm within 10 calendar days of receiving the request for an informal hearing. If the presiding officer denies the request, the written notice will explain the reason for the denial.

(e) If the request for an informal hearing is denied, or the request for reinstatement is denied at the informal hearing, a subsequent request for an informal hearing to reinstate the qualified exemption may not be made until one calendar year after the date the denial of the informal hearing is received by certified mail or the date the request for reinstatement at the informal hearing is denied.

§ 112.213 What requirements are applicable to an informal hearing?

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

(a) The hearing will be held within 10 calendar days after the date the request is filed or, if applicable, within a timeframe agreed upon in writing by the owner, operator, or agent in charge of the farm and FDA.

(b) The presiding officer may require that a hearing conducted under this subpart be 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 or partially withdrawing an exemption under § 112.5, rather than the notice under § 16.22(a) of this chapter, provides notice of opportunity for an informal hearing requesting reinstatement under this section and is part of the administrative record of the regulatory hearing under § 16.80(a) of this chapter.

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

(3) Section 112.214, rather than § 16.42(a) of this chapter, describes the FDA employees who preside at hearings under this subpart.

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

(5) Section 16.80(a)(4) of this chapter does not apply to a regulatory hearing under this subpart. The presiding officer's report of the hearing and any comments on the report by the hearing participant under § 112.213(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 or partially withdrawing an exemption, the hearing must be conducted as a regulatory hearing under regulation in accordance with part 16 of this chapter, except that § 16.95(b) does not apply to a hearing under this subpart. With respect to a regulatory hearing under this subpart, the administrative record of the hearing specified in §§ 16.80(a)(1), (a)(2), (a)(3), and (a)(5), and § 112.213(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.

(d) The presiding officer shall reinstate a farm's qualified exemption under §§ 112.4(b), 112.5, and 112.6 of this part if the presiding officer determines that the evidence demonstrates that the

conduct or conditions that triggered the withdrawal or partial withdrawal order have been sufficiently resolved.

§ 112.214 Who is the 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.

§ 112.215 What is the timeframe for issuing a decision on reinstating the qualified exemption?

(a) If FDA grants the request for a hearing and the hearing is held, the presiding officer must provide a 2 calendar day opportunity for the hearing participants to review and submit comments on the report of the hearing under § 112.213(c)(4), and must issue a final decision within 10 calendar days after the hearing is held.

(b) The final decision (with or without an informal hearing) of the presiding officer is considered a final Agency action under 5 U.S.C. 702.