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For a thriving New England

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November 15, 2013

Preventive Controls Rule
Docket No. FDA-2011-N-0920
RIN 0910-AG36
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 Preventive Controls Rule

To the U.S. Food and Drug Administration:

Thank you for the opportunity to comment on the proposed Preventive Controls Rule: "Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food."[1]

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* Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food, 78 Fed. Reg. 3646 (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).

INTRODUCTION

This comment focuses on the proposed Rule's potentially harmful impact on small- to medium-sized producers, processors, and 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, as the law requires.[3] Moreover, both the Preventive Controls Rule and the Produce Safety Rule create confusion for farmers as to when their operations are "farms," "facilities," or both. Because the proposed Preventive Controls Rule would likely force many smaller farms to shut down, it also would cause significant environmental effects that warrant conducting an environmental impact statement (EIS).

Conservation Law Foundation is concerned that, by placing a tremendous burden on the burgeoning small-scale sustainable agriculture and food sector, the proposed Rule will shift even more agricultural and food 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] Hindering the growth of sustainable agriculture and food businesses, 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 entities,[6] FDA should:

- conduct a quantitative risk assessment to determine how facility size and the complexity of distribution channels affect the risk of contaminating food covered by the Rule—and thus the risk of serious adverse health consequences—and request public comment on the assessment;
- conduct an environmental impact statement;
- change the definitions of "farm," "retail food establishment," "holding," "packing," "harvesting," "manufacturing/processing," "qualified facility," and "very small business,";
- define "farmers' market," "roadside stand," and "community supported agriculture";
- add an exclusion (similar to the Produce Safety Rule[7]) for some smaller entities;

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[2] *Id.* at 3789.
[3] *See* 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] FDA Food Safety Modernization Act, 21 U.S.C. § 350g(n)(3).
[7] *See* 78 Fed. Reg. 3632.

- amend the exemptions explicitly to exempt all farm activities from the Rule;
- amend the modified requirements for qualified facilities;
- address flaws in the due process afforded qualified facilities;
- provide a procedure for reinstating a withdrawn exemption;
- provide greater support for the delayed effective dates for small and very small farms;
- combine the list of exempt activities in subsections 117.5(h)(1) and (2) to apply to operations acting on their own and another farm's raw agricultural commodities (RACs), expand the exemptions for low-risk activities to include *all* small and very small businesses, and add pickles and salsa to the list of low-risk activities; and
- analyze the impact the Preventive Controls Rule will have on collaborative operations such as food hubs and cooperative growing operations, and exempt these collaborative operations from the Rule.

This comment details the problems with the proposed Rule and, where appropriate, offers specific textual edits. Recommended textual edits 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 also prepare an environmental impact statement. The impacts of this proposed regulatory scheme should not be underestimated. FDA must take the time needed to craft regulations that allow farms to thrive.

We appreciate the need for increased food safety in our food system. But sustaining that food system, while increasing food safety, is critical. The proposed Rule places a disproportionate burden on smaller farms and facilities and discourages them from diversifying, crucial to the economic viability of small farms with co-located facilities. It restricts consumer access to locally produced food, and risks environmental degradation by forcing a significant number of smaller farm "mixed-type facilities" to shut down. 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 SMALL ENTITIES.

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

FSMA requires FDA to "to establish science-based minimum standards for conducting a hazard analysis, documenting hazards, implementing preventive controls, and documenting the implementation of . . . preventive controls."[8] Those standards must "provide sufficient flexibility

[8] 21 U.S.C. § 350g(n)(1)(A).

to be practicable for all sizes and types of facilities, including small businesses such as a small food processing facility co-located on a farm."[9] FSMA therefore mandates that FDA base the Preventive Controls Rule in evidence and tailor the Rule to the scale and diversity of various facilities.

B. The Proposed Rule Imposes Significant Costs on Smaller Facilities and Farms, Diminishing Access to Healthier Food and Introducing Greater Risk of Contamination.

FDA estimates that a qualified facility exempt from Subpart C (Hazard Analysis and Risk-Based Preventive Controls (HARPC)) of the Rule will incur an annual cost of $1,000.[10] Estimated total annual cost under the remainder of the Rule, including Subpart B (Current Good Manufacturing Practices), per facility for small to very small businesses ranges from $13,564 to $44,069.[11] FDA estimates the proposed Produce Safety Rule will impose the following annual cost per farm based on size[12]:

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

The proposed Produce Safety Rule defines small business and very small business differently from the Preventive Controls Rule. The annual cost for a farm mixed-type facility, therefore, could range from about $19,000 to $58,000. The cost to a smaller facility not co-located on a farm is already steep. The cost to a farm with a co-located facility is substantial.

The proposed Preventive Controls Rule, when combined with the proposed Produce Safety Rule, will have a significant economic impact on a substantial number of small entities—as many as 250,000 smaller facilities and farm mixed-type facilities.[13] The proposed Preventive Controls Rule could thus detrimentally affect as high as 77 percent of *all* facilities.[14] This estimate does not even account for the facilities and farm mixed-type facilities that are just over the monetary threshold established by the proposed Rules. Farmers have stated the Rules' additional costs

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[9] *Id.* § 350g(n)(3)(A).

[10] *See* U.S. Food and Drug Administration, *Analysis of Economic Impacts*, at 7–12 (Tables 1a, 1b, and 1c).

[11] *See id.* at 82–86 (Table 19a).

[12] *See* 78 Fed. Reg. 3506.

[13] *See Analysis of Economic Impacts*, *supra* note 10, at 4; *Analysis of Economic Impacts – Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption* (hereinafter "*Analysis of Economic Impacts PSR*"), at 11, 18 (Table 1), FDA, http://www.fda.gov/downloads/Food/FoodSafety/FSMA/UCM334116.pdf (last visited Oct. 29, 2013).

[14] *See Analysis of Economic Impacts*, *supra* note 10, at 4, 7 (Table 1a).

could force them out of business.[15] The combined proposed Rules could have a detrimental economic impact on over 94 percent of all farms.[16]

Small farms add value to their operations, and remain viable businesses, by "processing" their own RACs, and by holding other farms' product, which could be raw produce or "processed" food. As drafted, the Preventive Controls Rule discourages smaller farms from diversifying in this way. Should they do so, they risk being treated as both a farm and a facility, forced to comply with both proposed Rules.

Forcing small facilities and farms to close or alter production could, in turn, have a significant impact on locally grown, processed, and distributed food. USDA estimates "107,000 farms are engaged in local food systems."[17] Defining "local" as a farm selling direct to consumers, nearly all of these farms are small or very small under the proposed Rule's definitions.[18] Farm-to-school programs (now in every state), community supported agriculture (CSA), and other consumers depend on local food. As of 2008, local food sales totaled about $4.8 billion, and today's estimates place sales at over $8 billion, a 60 percent increase in just five years.[19] The Preventive Controls Rule could seriously hamper this progress, affecting certain regions more severely, such as New England, which relies more heavily on locally grown and processed food.[20]

The Department of Health and Human Services (HHS) aims to increase the 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 United States 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.[21] To help meet HHS's goal, the proposed Rule should encourage beginning farmers and food businesses to distribute produce and minimally processed food locally. As drafted, it will have the opposite effect, imposing substantial costs on smaller operations.

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[15] *See, e.g.*, Vern Grubinger, *Understanding and Commenting on the Food Safety Modernization Act Proposed Rules* ("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 $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."), http://www.uvm.edu/vtvegandberry/factsheets/Understanding_FSMA_Rule.pdf (last visited Oct. 30, 2013).

[16] *See Analysis of Economic Impacts PSR*, *supra* note 13, at 11, 18 (Table 1); *Analysis of Economic Impacts*, *supra* note 10, at 4, 7 (Table 1a).

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

[18] *Id.* at 17–18.

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

[20] *Id.* at 7, 9, 17–18.

[21] *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.

Locally grown and processed food has multiple co-benefits. It provides increased access to more diverse fruits and vegetables that help prevent obesity and diet-related diseases, 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.[22] This is particularly true in urban or metropolitan areas, which contain about 40 percent of all U.S. farms.[23]

Food grown and distributed locally, in shorter supply chains, 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.[24] Consolidating the storage and processing of produce on fewer, larger farms—a likely result of the proposed Rule—will not lead to greater food safety.

We urge FDA to re-evaluate the tremendous impact the proposed Rule will have on small farms and facilities. 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 entities. Before finalizing the Rule, FDA must gather more data and input from small-scale entities. Protecting these businesses ultimately will protect jobs, strengthen local communities, provide access to healthier food, and fulfill FSMA's purpose to make our food safer.

C. FDA Should Conduct a Quantitative Risk Assessment.

FDA conducted only a qualitative assessment of risk to public health from activities that occur in a facility "co-located on a farm."[25] Though qualitative assessment can provide an initial understanding of a problem, FDA needs to perform a quantitative assessment to develop science-

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[22] Molly D. Anderson, *The Case for Local and Regional Food Marketing*, Farm and Food Policy Project (May 2007); Food Environment Atlas, *supra* note 21.

[23] *See* Johnson, *supra* note 17, at 12–14; *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).

[24] *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& (last visited Nov. 7, 2013).

[25] *See Draft Qualitative Risk Assessment for Activities (Outside the Farm Definition) Conducted in a Facility Co-Located on a Farm*, U.S. Food and Drug Admin. (Aug. 2012).

based standards, grounded in evidence.[26] This quantitative risk assessment should examine how facility size, co-location on a farm, storage of a farm's own versus another farm's raw agricultural commodities, and distribution chain length affect the risk of contaminating food. FDA should acquire more data before finalizing its rule. Without such a quantitative assessment, FDA cannot tailor the Rule's standards to the scale and diversity of varying production and processing operations, and thus cannot fulfill FSMA's mandate.

FSMA recognizes that different sizes and types of facilities require different regulation. Specifically, the Act directs FDA to "provide sufficient flexibility . . . for all sizes and types of facilities, including small businesses such as a small food processing facility co-located on a farm."[27] While FDA has provided some flexibility through the statutorily mandated exemptions, this flexibility is insufficient to allow many small entities to continue operating. 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. FDA Should Conduct an Environmental Impact Statement for the Proposed Preventive Controls Rule.

FDA has claimed a "categorical exclusion" under the National Environmental Policy Act (NEPA) for the proposed Preventive Controls Rule.[28] FDA appears to claim a categorical exclusion because it is issuing Current Good Manufacturing Practices (CGMP) and establishing standards.[29] However, if "extraordinary circumstances" exist, FDA must nonetheless conduct an environmental review.[30] A "significant effect may exist even if the Federal agency believes that on balance the effect will be beneficial."[31] True, in "many instances, a brief statement that a categorical exclusion is being invoked will suffice."[32] But "where there is substantial evidence in the record that an extraordinary circumstance might apply, an agency may act arbitrarily and capriciously by failing to explain its determination that a categorical exclusion is applicable."[33]

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

[27] 21 U.S.C. § 350g(n)(3)(A).

[28] *See* 78 Fed. Reg. 3789; 21 C.F.R. § 25.30 (stating that "[i]ssuance of CGMP regulations, HACCP regulations, establishment standards, emergency permit control regulations, GLP regulations, and issuance or denial of permits, exemptions, variances, or stays" are "categorically excluded and, therefore, ordinarily do not require the preparation of an EA or an EIS").

[29] *See* 21 C.F.R. § 25.30(j).

[30] *See* 40 C.F.R. § 1508.4; 21 C.F.R. § 25.21.

[31] 40 C.F.R. § 1508.27.

[32] *California v. Norton*, 311 F.3d 1162, 1176 (9th Cir. 2002).

[33] *Reed v. Salazar*, 744 F. Supp. 2d 98, 116 (D.D.C. 2010) (vacating the agency's rule where it insufficiently analyzed whether there were extraordinary circumstances, because substantial evidence showed such circumstances might exist).

For example, in *Sierra Club v. Bosworth*, 510 F.3d 1016 (9th Cir. 2007), the Ninth Circuit held that the U.S. Forest Service failed to assess properly the environmental significance of a categorical exclusion for certain fuel reduction projects.[34] The Forest Service "failed to consider adequately the unique characteristics of the applicable geographic areas, the degree to which effects on the quality of the environment were controversial or the risks were unknown . . . and whether there existed cumulative impacts from other related actions."[35] Unlike FDA here, the Forest Service had already analyzed some data before claiming the categorical exclusion.[36] But its evaluation was "inadequate as a cumulative impacts analysis because it offer[ed] only conclusory statements that there would be no significant impact."[37] Justification for the categorical exclusion required "some quantified or detailed information" of "high quality" and consideration of "highly controversial" aspects and uncertain risks.[38] The Forest Service failed to "analyze the incremental impact of the action when added to other past, present, and *reasonably foreseeable* future actions."[39]

Here, FDA's entire analysis in the preamble to the proposed Preventive Controls Rule is:

> FDA has determined under 21 CFR 25.30(j) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.[40]

Though FDA is issuing CGMP and standards, it is also creating a new type of controls—Hazard Analysis and Risk-Based Preventive Controls. HARPC is not listed specifically as an action qualifying for a categorical exclusion under FDA's NEPA regulations. Moreover, like in *Bosworth*, the minimal justification for the categorical exclusion for the proposed Preventive Controls Rule fails to consider the Rule's cumulative, highly controversial, and reasonably foreseeable impacts.

The proposed Rule (in combination with the Produce Safety Rule, for which FDA is conducting a full EIS) "will have a significant economic impact on a substantial number of small entities."[41] This is well documented in the record. Many small and very small farms and facilities—as defined in the proposed Rule—may be forced to shut down. Smaller farms comprise 94 percent

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[34] *Sierra Club v. Bosworth*, 510 F.3d at 1027.

[35] *Id.*

[36] *Id.* at 1028–29.

[37] *Id.* at 1028 (citation omitted) ("The Forest Service does not reveal its methodology or offer any quantified results supporting its conclusory statements that there are no cumulative impacts—it argues only that through the exercise of its expertise it determined that there was no such impact. This is insufficient.").

[38] *Id.* at 1030–32.

[39] *See id.* at 1030 (citation omitted) (internal quotation marks omitted) (emphasis in original).

[40] 78 Fed Reg. 3789.

[41] *Id.* at 3646.

of all farms in the United States.[42] These farms often use agricultural practices that protect habitat and wildlife.[43] Consumers and buyers will shift from consuming produce from these smaller, often local farms,[44] to larger farms at a greater distance from the point of purchase, increasing fuel consumption and therefore greenhouse gas emissions.[45] Further, shutting down small farms will likely lead to the development of farmland, eliminating conservation measures farmers implement to protect the land. Such a development shift is an indirect effect that induces "changes in the pattern of land use," triggering the need to prepare an EIS.[46]

Farmland provides crucial habitat for wildlife and important pollinators, such as bees. A few examples of this habitat protection include: creating riparian buffer strips; allowing recently cropped lands to lie idle; planting food crops for wildlife; maintaining diverse woodlands and native grasslands; planting native wildflower crops; and using prescribed burns. The proposed Rule will significantly and directly impact a substantial number of smaller farms with co-located facilities that take these conservation measures. This will have a significant effect on key pollinators, such as bees already suffering from colony collapse,[47] if they lose vital habitat. These are cumulative impacts that present extraordinary circumstances requiring FDA to reconsider its reliance on a categorical exclusion.[48]

FDA should assess whether habitat loss will affect any threatened or endangered species.[49] Many rare, threatened, and endangered species depend on active habitat management by farmers and ranchers. According to the USDA, rangelands provide habitat for 84 percent of mammals and 74 percent of bird species found in the United States.[50] About 80 percent of threatened and endangered species rely on privately owned land for their habitat needs.[51] FDA must consult with U.S. Fish and Wildlife Service to determine what risk the proposed Rule poses to threatened and endangered species.[52] This aspect alone requires FDA to reassess the categorical exclusion.

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[42] *Analysis of Economic Impacts PSR*, *supra* note 13, at 11, 18 (Table 1).

[43] *See, e.g.*, U.S. Dep't of Agriculture, Wildlife Habitat Conservation on Private Lands.

[44] Renée Johnson et al., *The Role of Local Food Systems in U.S. Farm Policy*, at 6, Congressional Research Service (Mar. 12, 2013).

[45] *See* Molly D. Anderson, *The Case for Local and Regional Food Marketing*, at 1, 5, Farm and Food Policy Project (May 2007), *citing Greenhouse Gas Emissions from the U.S. Transportation Sector 1990–2003*, Office of Transportation and Air Quality, Environmental Protection Agency (2006).

[46] *See* 40 C.F.R. § 1508.8(b).

[47] *See* Brian Snyder, *Consider the Bees of the Field*, at 1 (Oct. 22, 2013), http://writetofarm.com/2013/10/22/consider-the-bees-of-the-field/.

[48] *See* 40 C.F.R. § 1508.7.

[49] *See* 21 C.F.R. § 25.21.

[50] *See Wildlife Habitat Conservation*, Food Alliance, http://foodalliance.org/about/principles-explained/wildlife-habitat-conservation (last visited Nov. 8, 2013).

[51] *Our Endangered Species Program and How It Works with Landowners*, at 1, U.S. Fish and Wildlife Service (July 2009), http://www.fws.gov/endangered/esa-library/pdf/landowners.pdf.

[52] *See* 16 U.S.C. §1536(a)(2).

Studies have shown that sourcing locally grown food results in fewer greenhouse gas emissions than sourcing food from greater distances.[53] Removing smaller farms from production will increase reliance on foods sourced greater than 275 miles[54] from the point of consumption. We urge FDA to study the amount of greenhouse gas emissions increase based on the number of produce acres the proposed Rule will likely remove from production. The probable increase in greenhouse gas emissions is another impact that FDA must study together with the "past, present, and reasonably foreseeable future actions" of the agricultural industry and consumers.[55]

We strongly urge FDA to reconsider the categorical exclusion. It did so with the Produce Safety Rule and is now conducting an EIS. Because both Rules work so closely together, FDA cannot adequately assess the full extent of one rule's environmental effects without also analyzing the other's effects. The controversy over the proposed Rule's detrimental impact on smaller farms and facilities is widespread, requiring FDA to reconsider the categorical exclusion. In *National Parks & Conservation Association v. Babbitt*, 241 F.3d 722 (9th Cir. 2001), 450 comments—85 percent negative—were "more than sufficient to meet the [requisite] outpouring of public protest" amounting to controversy inadequately addressed in the environmental assessment.[56] Here, FDA has already received several thousand comments and will receive many more.[57] A significant portion of these likely will express grave concern over the proposed Rule's impact on smaller farms and facilities.

E. The Proposed Rule Can and Must Minimize the Harmful Economic Impact on Small Entities.

This subsection details specific problems with the proposed Rule and, in many cases, recommends textual changes to strengthen and clarify the Rule. These recommendations are intended to provide greater protection for small farms. Recommended additions to provisions in the proposed Preventive Controls 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.

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[53] *See, e.g.*, Anderson, *supra* note 22; 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.

[54] 21 U.S.C. § 350h(f)(4)(A).

[55] 40 C.F.R. § 1508.7.

[56] *Nat'l Parks & Conservation Ass'n*, 241 F.3d at 736 (citation omitted) (internal quotation marks omitted).

[57] *See* Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food; Extension of Comment Periods, regulations.gov, http://www.regulations.gov/#!documentDetail;D=FDA-2011-N-0920-0188 (last visited Nov. 13, 2013).

1. 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. 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 both Rules.

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.[58] But in the FD&CA, the term facility specifically "does not include farms."[59] 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. Likewise, packing or holding manufactured/processed food should not transform 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 the viability of small farms. Even a minimal amount of additional paperwork will deter farms from engaging in these activities, which strengthen local food systems. Buying fresh produce or processed food in clearly labeled containers from other farms does not increase food safety risks enough to warrant forcing the buying farm to comply with the Preventative Controls Rule.[60]

At the least, the Rules should allow farms to pack or hold all food 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, i.e., manufacturing/processing, would still be subject to the Preventive Controls Rule. This

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[58] *See* 21 U.S.C. § 350d(a).
[59] *Id.* § 350d(b)(1).
[60] Grubinger, *supra* note 15, at 2.

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 (but see Part II below discussing an exception for "food hubs."), except as exempted under section 117.5.

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 **21 C.F.R. § 1.227**:

> *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. Retail Food Establishment.

The proposed definition of "retail food establishment" does not include CSA, farmers' markets, and roadside stands. FDA should adhere to its recently published statement that, in the final rule, it will consider CSAs retail food establishments.[61] FDA should change the definition to reflect this.

The recommended textual changes are as follows under **21 C.F.R. § 1.227**:

> *Retail food establishment* means an establishment that sells food products directly to consumers as its primary function. A retail food establishment may manufacture/process, pack, or hold food if the establishment's primary function is to sell from that establishment food, including food that it manufactures/processes, packs, or holds, directly to consumers. A retail food establishment's primary function is to sell food directly to consumers if the annual monetary value of sales of food products directly to consumers exceeds the annual monetary value of sales of food products to all other buyers. The term "consumers" does not include businesses. A "retail food establishment" includes grocery stores, convenience stores, vending machine locations, community

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

supported agriculture (as defined in § 117.3), farmers' markets, and roadside stands.

Also, FDA should amend **21 C.F.R. § 1.327(e)(4)** as follows:

A "retail food establishment" includes grocery stores, convenience stores, vending machine locations, community supported agriculture operations, farmers' markets, and roadside stands.

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

FDA should change the definitions of "packing" and "holding" so that, as explained, farms can pack or hold food, including RACs, from other farms not under the same ownership. The recommended textual changes are as follows under **21 C.F.R. § 117.3**:

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 definition 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.

The recommended textual changes are as follows under **21 C.F.R. § 117.3**:

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 **21 C.F.R. § 117.3**:

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, <u>including as part of a community supported agriculture operation,</u> manufacturing/processing does not include activities that are part of harvesting, packing, or holding.

iv. Qualified Facility.

The "qualified facility" definition should clarify that the average annual monetary value of all food sold is determined by a single facility, not all facilities under the same ownership. A minor edit will suffice.

The recommended textual changes are as follows under **21 C.F.R. § 117.3**:

Qualified facility means (when including the sales by any subsidiary; affiliate; or subsidiaries or affiliates, collectively, of any entity of which the facility is a subsidiary or affiliate) a facility that is a very small business as defined in this part, or a facility to which both of the following apply:

(1) During the 3-year period preceding the applicable calendar year, the average annual monetary value of the food manufactured, processed, packed or held at such facility that is sold directly to qualified end-users (as defined in this part) during such period exceeded the average annual monetary value of the food sold by such facility to all other purchasers; and

(2) The average annual monetary value of all food sold <u>by such facility</u> during the 3-year period preceding the applicable calendar year was less than $500,000, adjusted for inflation.

v. Very Small Business.

We urge FDA to define a "very small business" using Option 3: selling less than $1,000,000 in sales of food *that would otherwise be covered by part 117*. According to FDA, "businesses with less than $1,000,000 in total annual sales of food produce less than two percent of all food produced in the United States."[62] As noted, the proposed Rule will significantly impact many smaller operations. Using the less-than-one-million-dollar threshold likely will not substantially impact food safety, if at all, but will allow many smaller entities to continue operating and producing healthy, locally made food.

The current definition of "very small business" also bases the sales amount on all "food" sold. Though the less-than-$500,000 exemption in the FSMA states that the sales counting toward that amount are *food* sales, FDA should amend the definition of very small business to include sales of food "that would otherwise be covered by part 117" only. FDA clearly has this discretion.[63] Otherwise, the Rule requires including *all* food, not just food part 117 means to cover, to determine if a facility is a very small business. That definition undermines the intention of the FSMA to provide flexibility for small businesses.

The recommended change would allow very small businesses to diversify their farms and facilities. The recommended textual changes are as follows under **21 C.F.R. § 117.3**:

> *Very small business* means for purposes of this part 117, a facility that has less than $1,000,000 in total annual sales of food <u>that would otherwise be covered by part 117 of this chapter</u>, adjusted for inflation.

2. Define Farmers' Market; Roadside Stand; and CSA.

As noted, the proposed definition of "retail food establishment" does not include farmers' markets, roadside stands, or CSA. FDA has stated that, in the final rule, it will ensure that retail food establishments *do* include these businesses.[64] FDA should define these terms in the proposed Rule.

The recommended textual changes are as follows under **21 C.F.R. § 1.227** (for "farmers' market" and "roadside stand") and **21 C.F.R. § 117.3** (for CSA):

> <u>*Farmers' market* means a building, structure, or place used by two or more farms, where a farm or a farm's employees or volunteers sell food directly to consumers, and at least 90 percent of the food sold by a farm was grown, raised, harvested, packed, held, or manufactured/processed by that farm.</u>

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[62] *Analysis of Economic Impact*, *supra* note 10, at 4.
[63] *See* 21 U.S.C. § 350g(i)(2).
[64] *See I Have a Farm*, *supra* note 61.

Roadside stand means a building, structure, or place where one farm sells food, grown, raised, harvested, packed, held, or manufactured/processed on that farm, directly to consumers.

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.

3. Add an Exclusion for Smaller Entities.

The proposed Produce Safety Rule has an exclusion for farms with $25,000 or less in sales. Yet FDA did not draft a similar exclusion for small facilities in the proposed Preventive Controls Rule. Protecting these facilities from regulation under the Preventive Controls Rule is just as important as protecting these farms under the Produce Safety Rule. Adding this exclusion will protect many farms with co-located facilities.

FDA should ensure the annual monetary value is only for food that would otherwise be covered under part 117. This will enable these operations to diversify by selling a combined annual monetary value of more than $25,000 of processed food and RACs.

The recommended textual changes are as follows under **21 C.F.R. § 117.5**:

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

4. Amend the Exemptions Explicitly To Exempt All Farm Activities from the Rule.

The proposed Preventive Controls Rule and Produce Safety Rule create confusion for farmers trying to determine whether their farm is a farm, a farm "mixed-type facility," or a "retail food establishment," and—once determined—trying to understand how to comply with the Rules. FDA should simplify the Rules by explicitly exempting farm activities, including (as detailed above) packing and holding, from the proposed Preventive Controls Rule. A farm that holds its own raw produce should not come under the Preventive Controls Rule for holding raw produce *and jam* from another farm, particularly when the other farm is *already* subject to the Preventive Controls Rule for "manufacturing/processing" the jam. This type of confusing and unnecessarily expensive regulation will drive smaller operations out of business. At the least, FDA should exempt very small businesses from the Rule if they pack, hold, or transport their own or other farms' RACs or food.

The recommended textual changes are as follows under **21 C.F.R. § 117.5**:

(f) ~~Subpart C of this part does not apply to activities of a facility that are subject to section 419 of the Federal Food, Drug, and Cosmetic Act (Standards for~~

~~Produce Safety).~~ Subparts B and C of this part do not apply to activities—including packing, holding, or transporting—of "farms" (as defined in section 1.227 of this chapter), farm "mixed-type facilities" (as defined in section 1.227), or community supported agriculture (as defined in section 117.3) operations.

. . .

~~(k) Subpart B of this part does not apply to "farms" (as defined in § 1.227 of this chapter), activities of "farm mixed-type facilities" (as defined in § 1.227) that fall within the definition of "farm," or the holding or transportation of one or more "raw agricultural commodities," as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act.~~

Then, FDA should amend **21 C.F.R. § 117.5(g)** as follows:

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

. . .

5. Amend the Modified Requirements for Qualified Facilities.

FDA should allow a qualified facility to show that it is qualified for the exemption by submitting documentation or a statement from the facility owner that the facility is qualified.

The recommended textual changes are as follows under **21 C.F.R. § 117.201**:

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

. . .

6. Address Flaws in the Due Process Afforded Qualified Facilities.

FDA must clarify under what circumstances it can withdraw a qualified facility's exemption. Currently, FDA can withdraw the exemption under two circumstances: (1) when it directly links

a foodborne illness outbreak to a facility; 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 facility that are "material to the safety of the food."[65]

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" at the facility—like option two—FDA would clarify more precisely when it can withdraw the exemption. Further, FDA should require the conduct or conditions to occur *at* the facility rather than simply be *associated* with the facility. Requiring mere association leaves too much ambiguity.

The proposed Rule also does not state any burden of proof. The Rule should require that FDA show materiality through *substantial evidence* to justify a withdrawal. "Substantial evidence" is sufficient evidence so that a reasonable person would find it adequate to support the withdrawal or partial withdrawal.[66]

The importance of the Preventive Controls Rule exemption to the viability of small and very small businesses cannot be overstated—for many of these farm "mixed-type facilities," 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 entities from continuing to operate.

The recommended textual changes are as follows under **21 C.F.R. § 117.251**:

> (a) FDA may withdraw the exemption applicable to a qualified facility under § 117.5(a):
>
> ~~(a)~~ (1) In the event of an active investigation of a foodborne illness outbreak that is directly linked to conduct or conditions at the qualified facility that are material to the safety of the food manufactured, processed, packed, or held at the facility; or
>
> ~~(b)~~ (2) If FDA determines that ~~it~~ withdrawal is necessary to protect the public health and prevent or mitigate a foodborne illness outbreak based on conduct or conditions ~~associated with~~ at the qualified facility that are material to the safety of the food manufactured, processed, packed, or held at such facility.
>
> (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.

[65] 78 Fed. Reg. 3809.
[66] *See, e.g.*, *Consolidated Edison Co. v. N.L.R.B.*, 305 U.S. 197, 229 (1938).

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

The recommended textual changes are as follows under **21 C.F.R. § 117.254**:

> ~~(a) If FDA determines that~~ The following procedure applies for withdrawing an exemption applicable to a qualified facility under § 117.5(a) ~~should be withdrawn,~~:
>
> (a) ~~If any~~ Any officer or qualified employee of FDA may ~~issue~~ submit an order to withdraw the exemption to the FDA District Director or official senior to such Director within 10 calendar days of making that determination.
>
> (b) An FDA District Director in whose district the qualified facility is located (or, in the case of a foreign facility, the Director of the Office of Compliance in the Center for Food Safety and Applied Nutrition), or an FDA official senior to such Director, must approve or deny an order to withdraw the exemption within 10 calendar days of the date the order to withdraw the exemption is submitted. If no action is taken within the 10 calendar days, the order to withdraw the exemption is revoked.
>
> (c) If an FDA District Director or FDA official senior to such Director approves an order to withdraw the exemption, FDA must issue an order to withdraw the exemption to the owner, operator, or agent in charge of the facility.
>
> (d) FDA must issue an order to withdraw the exemption in writing, signed and dated by the officer or qualified employee of FDA who is issuing the order.
>
> (e) 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 the exemption that it sends to a qualified facility. FDA should include more detailed information in the order to withdraw an exemption that it sends to a facility. It should allow 30 days to appeal the order. Ten days does not give qualified facilities, particularly those co-located on a farm, adequate time to appeal the order. Most importantly, FDA needs to provide a mechanism to regain the exemption if FDA withdraws it. The withdrawal must notify a facility that it can seek reinstatement of the exemption after a set time period.

The recommended textual changes are as follows under **21 C.F.R. § 117.257**:

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

(a) The date of the order;

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

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

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

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

(1) Whether the order is based on § 117.251(a)(1) or § 117.251(a)(2);

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

(3) If the order is based on § 117.251(a)(1), the substantial evidence linking the active investigation of a foodborne illness outbreak directly to conduct or conditions at the facility that are material to the safety of the food manufactured, processed, packed, or held at such facility;

(4) If the order is based on § 117.251(a)(2), the substantial, measurable evidence collected using generally accepted scientific standards indicating the presence of pathogens at the facility that may pose an imminent threat to public health based on conduct or conditions at the facility that are material to the safety of the food manufactured, processed, packed, or held at such facility;

(5) Any other relevant information;

(d) A statement that the facility must comply with subpart C of this part on the date that is 60 calendar days after the date ~~of~~ the order is received by certified mail.

(e) A statement that the owner, operator, or agent in charge of the facility 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 418(l) of the Federal Food, Drug, and Cosmetic Act and of this subpart E;

~~(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 § 117.270;

~~(g)~~ (h) A statement that the owner, operator, or agent in charge of the facility may seek reinstatement of the 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 exemption must be conducted as a regulatory hearing under part 16 of this chapter, with certain exceptions described in § 117.286;

(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 facility is located (or, in the case of a foreign facility, the same information for the Director of the Office of Compliance in the Center for Food Safety and Applied Nutrition); and

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

FDA should provide guidance on what documents a facility 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 facility appeals a withdrawal order. Nonetheless, FDA should explain what documents will help refute a withdrawal, though we do not suggest adding specific language directly to the Rule. FDA should publish separate guidance on this issue.

The following sections, **21 C.F.R. § 117.260, 117.264, 117.267**, requires few changes to align with the previous proposed edits:

. . .

(2) Appeal the order within ~~10~~ 30 calendar days of the date of the order in accordance with the requirements of § 117.264.

. . .

. . .

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

. . .

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

(1) May request an informal hearing; and

(2) Must submit any request for an informal hearing together with its written appeal submitted in accordance with § 117.264 within ~~10~~ 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, written notice of the determination will be ~~given~~ distributed by certified mail to the owner, operator, or agent in charge of the facility 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.

7. Provide a Procedure for Reinstating a Withdrawn Exemption.

The proposed Rule provides no way for a qualified facility to regain its 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. If a facility is able to fix the conduct or conditions that led to withdrawal, FDA should reinstate the exemption for that facility. Forcing a facility to lose permanently its 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.[67] 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."[68] 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.[69] 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."[70] After a 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.[71] 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.[72] FDA can use this process as a guide for determining how a qualified facility here can have an exemption reinstated.

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[67] Federal Food, Drug, & Cosmetic Act, 21 U.S.C. § 350d.
[68] *Id.* § 350d(b)(1).
[69] *Id.* § 350d(b)(2).
[70] *Id.*
[71] *Id.* § 350d(b)(3)(A).
[72] *Id.* § 350d(b)(3)(B).

At the least, FDA should include in the Rule: (1) a procedure for requesting an informal hearing to reinstate the 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 exemption. The recommended additions are as follows:

§ 117.285 Procedure for requesting an informal hearing to reinstate the exemption applicable to a qualified facility.

The following procedure applies for requesting an informal hearing to reinstate the exemption applicable to a qualified facility under § 117.5(a):

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

(1) An order to withdraw the exemption has been issued under § 117.251(a)(1) or § 117.251(a)(2); and

(2)(i) The owner, operator, or agent in charge of the qualified facility has not appealed and the time under § 117.267(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 facility 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 the exemption.

(c) In the request for an informal hearing, the owner, operator, or agent in charge of such facility 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 facility 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 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.

§ 117.286 Requirements applicable to an informal hearing.

If the owner, operator, or agent in charge of the qualified facility 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 qualified facility and FDA.

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

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

(1) The order withdrawing an exemption under § 117.5(a), 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 facility, the Director of the Office of Compliance in the Center for Food Safety and Applied Nutrition) as provided in the order withdrawing an exemption.

(3) Section 117.287, 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 § 117.286(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 § 117.286(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 qualified facility's exemption under § 117.5(a) of this part if the presiding officer determines that substantial evidence demonstrates that the conduct or conditions that triggered the withdrawal order have been sufficiently resolved.

§ 117.287 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.

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

(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 § 117.286(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.

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

The preamble to the proposed Rule states that small businesses would have one year to comply with the Rule after its effective date and very small business would have two years.[73] However, FSMA states that:

[73] 78 Fed. Reg. 3674.

> the amendments made by this section shall apply to a small business . . . beginning on the date that is 6 months after the effective date of such regulations; and . . . the amendments made by this section shall apply to a very small business . . . beginning on the date that is 18 months after the effective date of such regulations.[74]

We support FDA's decision to give small businesses one year to comply and very small businesses two 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.

9. Expand the Exemptions under Section 117.5(h).

FDA should combine the list of exempt activities in subsections 117.5(h)(1) and (2) to apply to operations acting both on its own and another farm's RACs, and expand the exemptions for low-risk activities to include all small and very small businesses. FDA should also add pickles and salsa to the list of low-risk activities.

The recommended textual changes are as follows under **21 C.F.R. § 117.5(h)(1)** and **(2)**:

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

~~(1) When conducted on a farm mixed-type facility's own raw agricultural commodities as defined in section 201(r) or the Federal Food, Drug, and Cosmetic Act (those grown or raised on that farm mixed-type facility or another farm/farm mixed-type facility under the same ownership) for distribution into commerce:~~
~~(i) Artificial ripening of intact fruits and vegetables;~~
~~(ii) Boiling/evaporation of maple sap to make maple syrup;~~
~~(iii) Chopping raw peanuts and raw tree nuts;~~
~~(iv) Coating (with coatings other than wax, oil, or resin used for the purpose of storage or transportation) intact fruits and vegetables (e.g., caramel apples) and coating raw peanuts and raw tree nuts (e.g., adding seasonings);~~
~~(v) Drying/dehydrating intact fruits and vegetables (without the addition of sulfites) where the drying creates a distinct commodity (e.g., drying fruits or herbs);~~
~~(vi) Extracting oil from grains (e.g., corn, oilseeds, soybeans)~~
~~(vii) Grinding/milling/cracking/crushing grains (e.g., making grain products such as corn meal) and raw peanuts or raw tree nuts (e.g., making ground peanuts);~~
~~(viii) Making jams, jellies, and preserves from acid foods (e.g., acid fruits);~~

[74] 21 U.S.C. § 350g(i)(2)(A), (B).

~~(ix) Making sugar from sugar beets and sugarcane; and~~
~~(x) Salting raw peanuts and raw tree nuts.~~
~~(2) When conducted on food other than the farm mixed-type facility's own raw agricultural commodities for distribution into commerce:~~
(1) Artificial ripening of intact fruits and vegetables;
(2) Chopping peanuts and tree nuts;
(3) Coating (with coatings other than wax, oil, or resin used for the purpose of storage or transportation) intact fruits and vegetables (e.g., caramel apples) and coating peanuts and tree nuts (e.g., adding seasonings);
(4) Cooling intact fruits and vegetables using cold air;
(5) Drying/dehydrating (whether for storage/transport or for creating a distinct commodity) intact fruits and vegetables (without sulfiting), cocoa beans, coffee beans, grains and grain products, and peanuts and tree nuts;
(6) Extracting oils from grains (e.g., corn, oilseeds, and soybeans);
(7) Fermenting cocoa beans and coffee beans;
(8) Grinding/milling/cracking/crushing cocoa beans, coffee beans, grains (e.g., making grain products such as corn meal), and peanuts and tree nuts (e.g., making ground peanuts);
(9) Labeling (including stickering) hard candy, cocoa beans, cocoa products from roasted cocoa beans (other than milk chocolate), coffee beans, intact fruits and vegetables, grain and grain products (other than those containing wheat in a form that would not be recognized as containing wheat without a label declaration), honey, jams/jellies/preserves, maple sap, maple syrup, intact single-ingredient peanuts or tree nuts (shelled and unshelled), soft drinks and carbonated beverages, sugar beets, sugarcane, and sugar;
(10) Making hard candy, fudge, taffy, and toffee;
(11) Making cocoa products from roasted cocoa beans;
(12) Making honey;
(13) Making jams, jellies, and preserves from acid foods (e.g., acid fruits);
(14) Making maple syrup;
(15) Making soft drinks and carbonated water;
(16) Making sugar from sugar beets and sugarcane;
(17) Mixing cocoa beans, coffee beans, intact fruits and vegetables, grain and grain products, honey, maple sap and maple syrup, and peanuts and tree nuts;
(18) Packaging hard candy, fudge, taffy, toffee; cocoa beans; cocoa products; coffee beans; intact fruits and vegetables (other than modified atmosphere or vacuum packaging); grain and grain products; honey; jams, jellies and preserves; maple syrup; peanuts and tree nuts (including modified atmosphere or vacuum packaging); soft drinks and carbonated water; and sugar beets, sugarcane, and sugar;
(19) Salting peanuts and tree nuts;
(20) Shelling/hulling cocoa beans (i.e., winnowing), intact fruits and vegetables (e.g., dried beans and peas), and peanuts and tree nuts;
(21) Sifting grains and grain products;
(22) Sorting, culling, and grading (other than when incidental to packing or storage) hard candy, fudge, taffy, and toffee; cocoa beans; cocoa products; coffee

beans; intact fruits and vegetables; grain and grain products; honey; jams, jellies and preserves; maple sap; maple syrup; peanuts and tree nuts; soft drinks and carbonated water; and sugar beets, sugarcane, and sugar;
(23) Treating cocoa beans, coffee beans, intact fruits and vegetables, grain and grain products, and peanuts and tree nuts against pests (other than during growing) (e.g., fumigation);
(24) Waxing (wax, oil, or resin used for the purpose of storage or transportation) intact fruits and vegetables;
(25) Pickling raw agricultural commodities, such as cucumbers and green beans; and
(26) Making salsa.

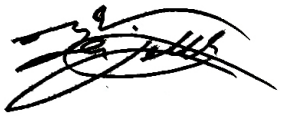
II. FDA Should Analyze the Impact the Preventive Controls Rule Will Have on Food Hubs.

FDA should analyze the impact the Preventive Controls Rule will have on collaborative agricultural operations such as food hubs and other cooperative growing operations. Small farms often depend on food hubs to aggregate product from multiple small farms. Such aggregators can then add value to the farms' produce, either by processing it into other products—such as jam—or simply storing RACs and then distributing it to wholesalers or markets more cost effectively than could small farms working alone. The proposed Rule will force food hubs to comply with costly measures, disincentivizing small- to medium-sized farms from serving as aggregators for other small farms. If these food hubs are forced out of businesses, numerous small farms might also collapse. A small number of large operations will serve as the only means for food aggregation. In turn, this could adversely affect food safety (see Part I.B). We urge FDA to exempt or partially exempt food hubs and collaborative agricultural operations from the Rule.

CONCLUSION

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

Sincerely,



Ben W. Tettlebaum
Rhodes Fellow/Attorney
Conservation Law Foundation

APPENDIX

Preventive Controls Rule
(to be codified at 21 C.F.R. pts. 1, 16, 106, 110, 114, 117, 120, 123, 129, 179, and 211)

PART 1—GENERAL ENFORCEMENT REGULATIONS

Subpart A—General Provisions

§ 1.227 What definitions apply to this subpart?

. . .

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.

Farmers' market means a building, structure, or place used by two or more farms, where a farm or a farm's employees or volunteers sell food directly to consumers, and at least 90 percent of the food sold by a farm was grown, raised, harvested, packed, held, or manufactured/processed by that farm.

. . .
Retail food establishment means an establishment that sells food products directly to consumers as its primary function. A retail food establishment may manufacture/process, pack, or hold food if the establishment's primary function is to sell from that establishment food, including food that it manufactures/processes, packs, or holds, directly to consumers. A retail food establishment's primary function is to sell food directly to consumers if the annual monetary value of sales of food products directly to consumers exceeds the annual monetary value of sales of food products to all other buyers. The term "consumers" does not include businesses. A "retail food establishment" includes grocery stores, convenience stores, vending machine locations, community supported agriculture (as defined in § 117.3), farmers' markets, and roadside stands.
. . .
Roadside stand means a building, structure, or place where one farm sells food, grown, raised, harvested, packed, held, or manufactured/processed on that farm, directly to consumers.

§ 1.327 Who is excluded from all or part of the regulations in this subpart?

. . .

(e) . . .

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

. . .

PART 117—CURRENT GOOD MANUFACTURING PRACTICE AND HAZARD ANALYSIS AND RISK– BASED PREVENTIVE CONTROLS FOR HUMAN FOOD

. . .

§ 117.3 Definitions

. . .

Subpart A—General Provisions

. . .

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.

. . .

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~~.

. . .

Qualified facility means (when including the sales by any subsidiary; affiliate; or subsidiaries or affiliates, collectively, of any entity of which the facility is a subsidiary or affiliate) a facility that is a very small business as defined in this part, or a facility to which both of the following apply:

(1) During the 3-year period preceding the applicable calendar year, the average annual monetary value of the food manufactured, processed, packed or held at such facility that is sold directly to qualified end-users (as defined in this part) during such period exceeded the average annual monetary value of the food sold by such facility to all other purchasers; and

(2) The average annual monetary value of all food sold by such facility during the 3-year period preceding the applicable calendar year was less than $500,000, adjusted for inflation.

. . .

Very small business means for purposes of this part 117, a facility that has less than $1,000,000 in total annual sales of food that would otherwise be covered by part 117 of this chapter, adjusted for inflation.

. . .

§ 117.5 Exemptions

. . .

(f) ~~Subpart C of this part does not apply to activities of a facility that are subject to section 419 of the Federal Food, Drug, and Cosmetic Act (Standards for Produce Safety).~~ Subparts B and C of this part do not apply to activities—including packing, holding, or transporting—of "farms" (as defined in section 1.227 of this chapter), farm "mixed-type facilities" (as defined in section 1.227), or community supported agriculture (as defined in section 117.3) operations.

. . .

~~(k) Subpart B of this part does not apply to "farms" (as defined in § 1.227 of this chapter), activities of "farm mixed-type facilities" (as defined in § 1.227) that fall within the definition of "farm," or the holding or transportation of one or more "raw agricultural commodities," as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act.~~

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

. . .

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

~~(1) When conducted on a farm mixed-type facility's own raw agricultural commodities as defined in section 201(r) or the Federal Food, Drug, and Cosmetic Act (those grown or raised on that farm mixed-type facility or another farm/farm mixed-type facility under the same ownership) for distribution into commerce:~~
~~(i) Artificial ripening of intact fruits and vegetables;~~
~~(ii) Boiling/evaporation of maple sap to make maple syrup;~~
~~(iii) Chopping raw peanuts and raw tree nuts;~~
~~(iv) Coating (with coatings other than wax, oil, or resin used for the purpose of storage or transportation) intact fruits and vegetables (e.g., caramel apples) and coating raw peanuts and raw tree nuts (e.g., adding seasonings);~~

~~(v) Drying/dehydrating intact fruits and vegetables (without the addition of sulfites) where the drying creates a distinct commodity (e.g., drying fruits or herbs);~~
~~(vi) Extracting oil from grains (e.g., corn, oilseeds, soybeans)~~
~~(vii) Grinding/milling/cracking/crushing grains (e.g., making grain products such as corn meal) and raw peanuts or raw tree nuts (e.g., making ground peanuts);~~
~~(viii) Making jams, jellies, and preserves from acid foods (e.g., acid fruits);~~
~~(ix) Making sugar from sugar beets and sugarcane; and~~
~~(x) Salting raw peanuts and raw tree nuts.~~
~~(2) When conducted on food other than the farm mixed-type facility's own raw agricultural commodities for distribution into commerce:~~
(1) Artificial ripening of intact fruits and vegetables;
(2) Chopping peanuts and tree nuts;
(3) Coating (with coatings other than wax, oil, or resin used for the purpose of storage or transportation) intact fruits and vegetables (e.g., caramel apples) and coating peanuts and tree nuts (e.g., adding seasonings);
(4) Cooling intact fruits and vegetables using cold air;
(5) Drying/dehydrating (whether for storage/transport or for creating a distinct commodity) intact fruits and vegetables (without sulfiting), cocoa beans, coffee beans, grains and grain products, and peanuts and tree nuts;
(6) Extracting oils from grains (e.g., corn, oilseeds, and soybeans);
(7) Fermenting cocoa beans and coffee beans;
(8) Grinding/milling/cracking/crushing cocoa beans, coffee beans, grains (e.g., making grain products such as corn meal), and peanuts and tree nuts (e.g., making ground peanuts);
(9) Labeling (including stickering) hard candy, cocoa beans, cocoa products from roasted cocoa beans (other than milk chocolate), coffee beans, intact fruits and vegetables, grain and grain products (other than those containing wheat in a form that would not be recognized as containing wheat without a label declaration), honey, jams/jellies/preserves, maple sap, maple syrup, intact single-ingredient peanuts or tree nuts (shelled and unshelled), soft drinks and carbonated beverages, sugar beets, sugarcane, and sugar;
(10) Making hard candy, fudge, taffy, and toffee;
(11) Making cocoa products from roasted cocoa beans;
(12) Making honey;
(13) Making jams, jellies, and preserves from acid foods (e.g., acid fruits);
(14) Making maple syrup;
(15) Making soft drinks and carbonated water;
(16) Making sugar from sugar beets and sugarcane;
(17) Mixing cocoa beans, coffee beans, intact fruits and vegetables, grain and grain products, honey, maple sap and maple syrup, and peanuts and tree nuts;
(18) Packaging hard candy, fudge, taffy, toffee; cocoa beans; cocoa products; coffee beans; intact fruits and vegetables (other than modified atmosphere or vacuum packaging); grain and grain products; honey; jams, jellies and preserves; maple syrup; peanuts and tree nuts (including modified atmosphere or vacuum packaging); soft drinks and carbonated water; and sugar beets, sugarcane, and sugar;
(19) Salting peanuts and tree nuts;
(20) Shelling/hulling cocoa beans (i.e., winnowing), intact fruits and vegetables (e.g., dried beans and peas), and peanuts and tree nuts;

(21) Sifting grains and grain products;
(22) Sorting, culling, and grading (other than when incidental to packing or storage) hard candy, fudge, taffy, and toffee; cocoa beans; cocoa products; coffee beans; intact fruits and vegetables; grain and grain products; honey; jams, jellies and preserves; maple sap; maple syrup; peanuts and tree nuts; soft drinks and carbonated water; and sugar beets, sugarcane, and sugar;
(23) Treating cocoa beans, coffee beans, intact fruits and vegetables, grain and grain products, and peanuts and tree nuts against pests (other than during growing) (e.g., fumigation);
(24) Waxing (wax, oil, or resin used for the purpose of storage or transportation) intact fruits and vegetables;
(25) Pickling raw agricultural commodities, such as cucumbers and green beans; and
(26) Making salsa.

. . .

~~(k) Subpart B of this part does not apply to "farms" (as defined in § 1.227 of this chapter), activities of "farm mixed-type facilities" (as defined in § 1.227) that fall within the definition of "farm," or the holding or transportation of one or more "raw agricultural commodities," as defined in section 201(r) of the Federal Food, Drug, and Cosmetic Act.~~
(k) A facility is not covered by this Rule if its average annual monetary value of food (as "food" is defined in § 117.3) that would otherwise be covered by part 117 of this chapter sold during the previous 3-year period was $25,000 or less (on a rolling basis).

. . .

Subpart D—Modified Requirements

§ 117.201 Modified requirements that apply to a qualified facility.

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

. . .

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

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

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

~~(a)~~ (1) In the event of an active investigation of a foodborne illness outbreak that is directly linked to conduct or conditions at the qualified facility that are material to the safety of the food manufactured, processed, packed, or held at the facility; or

~~(b)~~ (2) If FDA determines that ~~it~~ withdrawal is necessary to protect the public health and prevent or mitigate a foodborne illness outbreak based on conduct or conditions ~~associated with~~ at the qualified facility that are material to the safety of the food manufactured, processed, packed, or held at such facility.

(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.

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

~~(a) If FDA determines that~~ The following procedure applies for withdrawing an exemption applicable to a qualified facility under § 117.5(a) ~~should be withdrawn,~~:

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

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

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

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

(e) 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.

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

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

(a) The date of the order;

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

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

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

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

(1) Whether the order is based on § 117.251(a)(1) or § 117.251(a)(2);

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

(3) If the order is based on § 117.251(a)(1), the substantial evidence linking the active investigation of a foodborne illness outbreak directly to conduct or conditions at the facility that are material to the safety of the food manufactured, processed, packed, or held at such facility;

(4) If the order is based on § 117.251(a)(2), the substantial, measurable evidence collected using generally accepted scientific standards indicating the presence of pathogens at the facility that may pose an imminent threat to public health based on conduct or conditions at the facility that are material to the safety of the food manufactured, processed, packed, or held at such facility;

(5) Any other relevant information;

(d) A statement that the facility must comply with subpart C of this part on the date that is 60 calendar days after the date ~~of~~ the order is received by certified mail.

(e) A statement that the owner, operator, or agent in charge of the facility 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 418(l) of the Federal Food, Drug, and Cosmetic Act and of this subpart E;

~~(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 § 117.270;

~~(g)~~ (h) A statement that the owner, operator, or agent in charge of the facility may seek reinstatement of the 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 exemption must be conducted as a regulatory hearing under part 16 of this chapter, with certain exceptions described in § 117.286;

(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 facility is located (or, in the case of a foreign facility, the same information for the Director of the Office of Compliance in the Center for Food Safety and Applied Nutrition); and

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

. . .

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

. . .

(2) Appeal the order within ~~10~~ 30 calendar days of the date of the order in accordance with the requirements of § 117.264.

. . .

§ 117.264 Procedure for submitting an appeal.

. . .

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

. . .

§ 117.267 Procedure for requesting an informal hearing.

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

(1) May request an informal hearing; and

(2) Must submit any request for an informal hearing together with its written appeal submitted in accordance with § 117.264 within ~~10~~ 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, written notice of the determination will be ~~given~~ distributed by certified mail to the owner, operator, or agent in charge of the facility 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.

. . .

§ 117.285 Procedure for requesting an informal hearing to reinstate the exemption applicable to a qualified facility.

The following procedure applies for requesting an informal hearing to reinstate the exemption applicable to a qualified facility under § 117.5(a):

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

(1) An order to withdraw the exemption has been issued under § 117.251(a)(1) or § 117.251(a)(2); and

(2)(i) The owner, operator, or agent in charge of the qualified facility has not appealed and the time under § 117.267(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 facility 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 the exemption.

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

(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 facility 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 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.

§ 117.286 Requirements applicable to an informal hearing.

If the owner, operator, or agent in charge of the qualified facility 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 qualified facility and FDA.

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

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

(1) The order withdrawing an exemption under § 117.5(a), 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 facility, the Director of the Office of Compliance in the Center for Food Safety and Applied Nutrition) as provided in the order withdrawing an exemption.

(3) Section 117.287, 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 § 117.286(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 § 117.286(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 qualified facility's exemption under § 117.5(a) of this part if the presiding officer determines that substantial evidence demonstrates that the conduct or conditions that triggered the withdrawal order have been sufficiently resolved.

§ 117.287 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.

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

(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 § 117.286(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.