National Sustainable Agriculture Coalition

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Re: Comments on the proposed rule for Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food

On behalf of the represented member organizations[1] of the National Sustainable Agriculture Coalition (NSAC), I submit the following comments on the proposed rule for Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food. NSAC welcomes the opportunity to submit comments, and looks forward to working with the Food and Drug Administration to ensure that the regulations and their implementation are successful and supportive of sustainable agriculture and food systems.

Sincerely,

Ariane Lotti, Assistant Policy Director
National Sustainable Agriculture Coalition

[1] Agriculture and Land-Based Training Association - Salinas, CA; Alternative Energy Resources Organization - Helena, MT; California Certified Organic Farmers - Santa Cruz, CA; California FarmLink - Santa Cruz, CA; C.A.S.A. del Llano (Communities Assuring a Sustainable Agriculture) - Hereford, TX; Center for Rural Affairs - Lyons, NE; Clagett Farm/Chesapeake Bay Foundation - Upper Marlboro, MD; Community Alliance with Family Farmers - Davis, CA; Dakota Rural Action - Brookings, SD; Delta Land and Community, Inc. - Almyra, AR; Ecological Farming Association -Soquel, CA; Farmer-Veteran Coalition - Davis, CA; Fay-Penn Economic Development Council - Lemont Furnace, PA; Flats Mentor Farm - Lancaster, MA; Florida Organic Growers - Gainesville, FL; GrassWorks - New Holstein, WI; Hmong National Development, Inc. - St. Paul, MN and Washington, DC; Illinois Stewardship Alliance - Springfield, IL; Institute for Agriculture and Trade Policy - Minneapolis, MN; Iowa Natural Heritage Foundation - Des Moines, IA; Izaak Walton League of America - St. Paul, MN/Gaithersburg, MD; Kansas Rural Center - Whiting, KS; The Kerr Center for Sustainable Agriculture - Poteau, OK; Land Stewardship Project - Minneapolis, MN; Michael Fields Agricultural Institute - East Troy, WI; Michigan Food & Farming Systems (MIFFS) - East Lansing, MI; Michigan Organic Food and Farm Alliance - Lansing, MI; Midwest Organic and Sustainable Education Service - Spring Valley, WI; National Catholic Rural Life Conference - Des Moines, IA; The National Center for Appropriate Technology - Butte, MT; Nebraska Sustainable Agriculture Society - Ceresco, NE; Northeast Organic Dairy Producers Alliance -Deerfield, MA; Northern Plains Sustainable Agriculture Society - LaMoure, ND; Northwest Center for Alternatives to Pesticides - Eugene, OR; Ohio Ecological Food & Farm Association - Columbus, OH; Organic Farming Research Foundation - Santa Cruz, CA; Rural Advancement Foundation International – USA - Pittsboro, NC; Union of Concerned Scientists Food and Environment Program - Cambridge, MA; Virginia Association for Biological Farming - Lexington, VA; Wild Farm Alliance -Watsonville, CA.

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ACKNOWLEDGEMENTS

The National Sustainable Agriculture Coalition's (NSAC) comments on the proposed rule for Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food are the result of months of analysis by, discussion by, and feedback from NSAC's Food System Integrity (FSI) Committee, NSAC's committee charged with working on the Food Safety Modernization Act. To develop the recommendations below, the FSI Committee met weekly by phone and twice in person between early January when the proposed rules were released and the mid-November public comment deadline. Several subcommittees were formed to work in detail on specific issues.

The following people contributed to the drafting of these comments:

NSAC members:

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I. INTRODUCTION

The National Sustainable Agriculture Coalition (NSAC) is an alliance of grassroots organizations from across the country that advocates for federal policy reform to advance the sustainability of agriculture, food systems, natural resources, and rural communities. NSAC member organizations are leaders in the sustainable agriculture and food systems sector, and have worked with farmers and communities to pioneer practices, systems, and supply chains that support the multiple goals of sustainable agricultural systems. NSAC member groups work directly with small and mid-sized family farmers, sustainable and organic farmers, and on-farm food processors who conduct activities within the scope of the Food and Drug Administration's (FDA) proposed rules on Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption (Produce Rule) and Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food (Preventive Controls Rule).

Sustainable agricultural systems advance production, social, economic, and environmental objectives simultaneously. In the US Code of Federal Regulations, "sustainable agriculture" is defined as "an integrated system of plant and animal production practices having a site-specific application that will, over the long-term—

"(A) Satisfy human food and fiber needs;

"(B) Enhance environmental quality and the natural resource base upon which the agriculture economy depends;

"(C) Make the most efficient use of nonrenewable resources and on-farm resources and integrate, where appropriate, natural biological cycles and controls;

"(D) Sustain the economic viability of farm operations; and

"(E) Enhance the quality of life for farmers and society as a whole."[2]

Sustainable agriculture and food systems, when referenced throughout these comments, refer to practices, systems, and supply chains that advance these multiple goals.

Given the potential devastating economic impact of ill-devised food safety regulations on sustainable agriculture and on small and mid-sized family farmers and food processors, NSAC engaged heavily in the legislative process that resulted in the enactment of the Food Safety Modernization Act (FSMA). We engaged in this process with four guiding principles in mind:

1. **Everyone has a role in ensuring a safe food supply:** From the farmers and field workers to the end consumer, everyone in the food supply chain has a role in ensuring safe food.

2. **Focus on the highest risk:** Different production systems and supply chains pose inherently different risks to the safety of our food supply. There are limited government resources, and they must be focused on addressing the highest risks.

[2] 7 U.S.C. 3103(19)

3. **Regulations should be science-based:** The emotional reaction to food safety outbreaks has, at times, resulted in the knee-jerk imposition of practices that have little basis in sound scientific evidence. Overall, the totality of the science behind the role of farm practices in food safety outbreaks is grossly under-examined and requires much more investigation.

4. **One size does not fit all:** Regulations must be scale- and supply-chain appropriate to be effective; a one-size-fits-all approach will put small and mid-sized farms and processors out of business, undermining public health goals, such as increased production of, availability of, and access to healthy foods, as well as economic opportunity, equity, and job-creation goals.

The implementation of these principles throughout the legislative debates around FSMA led to the inclusion of a number of important provisions that formed the basis for the flexible, scale- and supply-chain appropriate framework set forth by Congress. These provisions include:

- The requirement to "provide sufficient flexibility to be applicable to various types of entities engaged in the production and harvesting of fruits and vegetables that are raw agricultural commodities, including small businesses and entities that sell directly to consumers, and be appropriate to the scale and diversity of the production and harvesting of such commodities"[3];
- The requirement to "provide sufficient flexibility to be practicable for all sizes and types" of businesses and facilities, including small businesses such as a small food processing facility co-located on a farm[4];
- The requirement to determine the number and types of food facilities co-located on farms, by commodity and by processing activity, to inform rulemaking[5];
- The requirement to provide modified requirements for small and mid-sized farmers and facilities engaged primarily in selling food through direct-to-consumer supply chains[6];
- The requirement to "minimize, as appropriate, the number of separate standards that apply to separate foods"[7];
- The requirement to "take into consideration, consistent with ensuring enforceable public health protection, conservation and environmental practice standards and policies established by Federal natural resource conservation, wildlife conservation, and environment agencies"[8];
- The requirement to "not include any requirements that conflict with or duplicate the requirements of the national organic program established under the Organic Foods Production Act of 1990"[9];
- The requirement to clarify through rulemaking the activities that are part of the definition of "facility" in the Federal Food, Drug, and Cosmetic Act (FD&CA) § 415, including "activities

[3] Food, Drug, & Cosmetic Act § 419(a)(3)(A)

[4] Food, Drug, & Cosmetic Act §§ 418(n)(3)(A) and 419 (c)(1)(B); We note that the use of the phrase "**such as** a small processing facility co-located on a farm" (emphasis added) does not limit the application of this regulatory discretion solely to processing facilities co-located on farms.

[5] Food, Drug, & Cosmetic Act § 418(l)(5)

[6] Food, Drug, & Cosmetic Act §§ 418(l) and 419(f)

[7] Food, Drug, & Cosmetic Act §§ 418(n)(3)(C) and 419(c)(1)(D)

[8] Food, Drug, & Cosmetic Act § 419(a)(3)(D)

[9] Food, Drug, & Cosmetic Act § 419(a)(3)(E)

that constitute on-farm packing or holding of food that is not grown, raised, or consumed on such farm or another farm under the same ownership" and "activities that constitute on-farm manufacturing or processing of food that is not consumed on that farm or on another farm under common ownership"[10];

- The requirement to exempt certain facilities or modify their requirements if they are engaged in low-risk manufacturing, processing, packing, and holding activities[11];
- The requirement to amend the definition of a "retail food establishment" to clarify that the sale of products directly to consumers through direct-to-consumer sales platforms (e.g., roadside stands, farmers' markets, community supported agriculture (CSA) programs, etc.) are considered sales directly to consumers for the purposes of defining a "retail food establishment"[12];
- The requirement to "not require a business to hire a consultant or other third party to identify, implement, certify, compliance with these procedures, processes, and practices"[13];
- Considerations for small and very small businesses, including the requirement to define "small business" and "very small business,"[14] longer compliance periods,[15] and the option to exempt or create modified requirements for small and very small businesses that produce and harvest low-risk produce commodities[16];
- The requirement to reduce the paperwork and information collection burden of the regulations[17]; and
- The establishment of a food safety training program.[18]

The correct implementation of these provisions aimed at establishing a flexible, scale- and supply-chain appropriate framework is absolutely critical to ensuring that the regulations support and advance the growth, opportunity, and success of sustainable agriculture and food systems.

NSAC welcomes the opportunity to comment on the proposed Preventive Controls Rule, and is grateful for FDA's outreach to the sustainable agriculture community during the comment period. We look forward to continuing to work with the agency to ensure the correct implementation of the law, and to make sure the regulations and their implementation are successful and supportive of the sustainable agriculture and food systems.

NSAC makes the following comments on FDA's proposed Preventive Controls Rule. We first provide a brief summary of our recommendations and then make comments on issues in the order in which they appear in the proposed Preventive Controls Rule.

[10] Food Safety Modernization Act § 103(c)
[11] Food Safety Modernization Act § 103(c)(1)(D)
[12] Food Safety Modernization Act § 102(c)
[13] Food, Drug, & Cosmetic Act § 419(c)(1)(E)
[14] Food, Drug, & Cosmetic Act § 419(a)(3)(F)
[15] Food, Drug, & Cosmetic Act § 419(b)(3)
[16] Food, Drug, & Cosmetic Act § 419(a)(1)(B)
[17] Food, Drug, & Cosmetic Act § 419(c)(C)
[18] Food Safety Modernization Act § 209(b)

II. SUMMARY OF RECOMMENDATIONS

A summary of NSAC's top recommendations on the proposed Preventive Controls Rule, in the order in which they appear in the comments below, is as follows:

- FDA must undertake the food processing sector study again so that it complies with law.
- FDA must retain but expand the list of on-farm low-risk activity/food combinations.
- FDA must significantly revise the preliminary Economic Impact Analysis to more accurately assess the costs and benefits of the rule.
- FDA must fulfill its Tribal consultation requirements.
- FDA must consider the impacts of the Preventive Controls Rule in its assessment of environmental impacts of the Produce Rule.
- FDA must release a second proposed rule for public comment before issuing a final rule.
- FDA must make clear that product from qualified facilities cannot de facto be considered "adulterated."
- FDA must revise the definition of "farm" and the supporting definitions of "facility" to reflect usual and customary activities that many farms do, and thus limiting the scope of the term "facility," consistent with FSMA.
- FDA must amend the definition of "retail food establishment" to clarify that the sale and distribution of food through a community supported agriculture program, roadside stand, farmers' market, farm store, tailgate market, internet sale, or other direct-to-consumer platforms is included in the definition of sales direct to consumers for purposes of defining a "retail food establishment," as required by the FSMA statute.
- FDA must adopt a "very small business" definition of at least $1,000,000 in sales of food regulated under the Preventive Controls Rule.
- FDA must establish an outright exemption from the Preventive Controls Rule for businesses with $25,000 or less in annual average monetary value of product covered by the Preventive Controls Rule sold over a three-year period, adjusted for inflation.
- FDA must amend the definition of "qualified facility" to calculate sales based on the average annual monetary value of food covered by the Preventive Controls Rule, not all food.
- FDA must retain the "self-certification" approach in the modified requirements, consistent with FSMA.
- FDA must completely revise the process for withdrawing an exemption to meet the requirements of FSMA and establish a clear and fair process by limiting the circumstances that would lead to a withdrawal, establishing a three-tiered withdrawal process, and establishing a mechanism for regaining the qualified status.
- FDA must work with USDA to request funding for the National Food Safety Training, Education, Extension, Outreach, and Technical Assistance Program in the Administration's budget request.
- FDA must train field staff so that they understand farming systems and can accurately and fairly enforce the law.

III. COMMENTS ON MAJOR DEFICIENCIES IN THE PROPOSED RULE AND THE NEED FOR A SECOND PROPOSED RULE

Summary

NSAC makes comments and recommendations on the deficiencies in and revisions needed to the analyses accompanying the rule. FDA has not met, or in some cases only partially met, certain legal requirements for the promulgation of the proposed rule. We make comments below on analyses that the agency must substantially revise, undertake, or advance to more accurately assess the impact of and meet the impact analysis requirements of promulgating the proposed Produce Rule. Specifically, we make comments on:

1. FDA's food processing sector study;
2. FDA's Draft Qualitative Risk Assessment of Risk of Activity/Food Combinations for Activities (Outside the Farm Definition) Conducted in a Facility Co-Located on a Farm;
3. FDA's preliminary economic impact analysis of the Preventive Controls Rule;
4. FDA's failure to meet Tribal consultation responsibilities; and
5. FDA's scoping notice on the intent to prepare an EIS.

NSAC makes comments on the need for a second proposed rule for public comment.

Comments

A. The food processing sector study is woefully inadequate and must be undertaken again to comply with the law.

FSMA requires FDA to conduct a food processing sector study to determine the size and scope of the food processing sector, including in particular the number and types of food facilities co-located on farms.[19] FSMA requires the results of the food processing sector study to inform the regulatory definitions of "small" and "very small" businesses.

The food processing sector study[20] that FDA released as part of the proposed Preventive Controls Rule is grossly inadequate and fails utterly to provide the information required by FSMA to determine the number of facilities co-located on farms and what the production, distribution, and risk profiles of those facilities are. The study acknowledges its severe data limitations and, therefore, relies primarily on the professional opinion of a small group of individuals who are not experts in on-farm or small-scale processing. Without this information, FDA cannot adequately determine the impact of the proposed Preventive Controls Rule, how many operations will be subject to the Preventive Controls Rule, and what the costs of compliance will be.

We know of no other instances of federal regulations that seek to regulate a completely indeterminate universe of regulated entities. Congress recognized this problem, and therefore charged the agency to conduct a thorough study to determine the size and scope of the universe of farms and businesses that may be subjected to regulation. Congress specifically charged the agency

[19] Food, Drug, & Cosmetic Act § 418(l)(5)

[20] US Food and Drug Admin. "Food Processing Sector Study." 2011.

with obtaining these data before issuing rules. The Food Processing Sector Study not only fails at this task, but the agency has made no indication of how it intends to rectify the situation.

NSAC submitted more complete comments on the food processing sector study as part of its comments on the Draft Qualitative Risk Assessment of Risk of Activity/Food Combinations for Activities (Outside the Farm Definition) Conducted in a Facility Co-Located on a Farm (Draft RA) on February 15, 2013 (see Appendix I for NSAC's comments submitted on the Draft RA).[21] We are hereby incorporating our comments on the food processing sector study included in the Draft RA comments into these comments on the Preventive Controls Rule, and reiterate here the essential need for an actual food processing sector study to determining the scope, impact, and costs of the Preventive Controls Rule.

Recommendation: FDA should conduct an actual food processing sector study that includes large-scale surveys of actual farm mixed-type facilities and the activities they conduct. FDA should release that study for public comment and should incorporate the findings into the Preventive Controls Rule before finalizing the Preventive Controls Rule. In conducting the revised study, FDA should consider entering into cooperative agreements with agencies and groups who work with what the rules call farm mixed-type facility operators and are able to conduct those surveys.

B. FDA needs to expand the list of on-farm low-risk activity/food combinations.

In FSMA, Congress required FDA to conduct a science-based risk analysis of on-farm packing, holding, manufacturing, and processing activities, and to consider the results of that analysis to exempt or develop modified requirements to the Preventive Controls requirement for small or very small businesses that conduct only low-risk activities.[22] NSAC submitted more complete comments on the Draft Qualitative Risk Assessment of Risk of Activity/Food Combinations for Activities (Outside the Farm Definition) Conducted in a Facility Co-Located on a Farm (Draft RA) on February 15, 2013 (see Appendix I for NSAC's comments submitted on the Draft RA).[23] We are hereby incorporating our comments on the Draft RA into these comments on the Preventive Controls Rule.

C. FDA's preliminary economic impact analysis contains many flaws and must be significantly revised to more accurately reflect the costs of the proposed standards.

Under the terms of the Regulatory Flexibility Act and Small Business Regulatory Enforcement Fairness Acts (RF/SBREFA), federal regulatory agencies are required to analyze the impact of their regulatory actions on small businesses and, where the regulatory impact is likely to significantly affect a "substantial number" of these small entities, seek less burdensome alternatives for them. Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available

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[21] National Sustainable Agriculture Coalition. "Comments on Draft Qualitative Assessment of Risk of Activity/Food Combinations for Activities (Outside the Farm Definition) Conducted in a Facility Co-Located on a Farm" (hereinafter "Draft RA Comments"). Docket # FDA-2012-N-1258, comment tracking number 1jx-83p8-w3kr.

[22] Food Safety Modernization Act § 103(c)

[23] National Sustainable Agriculture Coalition. "Comments on Draft Qualitative Assessment of Risk of Activity/Food Combinations for Activities (Outside the Farm Definition) Conducted in a Facility Co-Located on a Farm" (hereinafter "Draft RA Comments"). Docket # FDA-2012-N-1258, comment tracking number 1jx-83p8-w3kr.

regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits.

FSMA specifically requires that FDA comply with the Paperwork Reduction Act (PRA) with respect to the recordkeeping burdens created by the Preventive Controls and Produce Rules, and in particular to minimize the recordkeeping burden on small entities.[24] FSMA requires that the Preventive Controls and Produce Rules provide sufficient flexibility to be practicable for all sizes and type of facilities, including small businesses; and further requires the Produce Rule to provide sufficient flexibility for all types of entities, including small businesses and entities that sell directly to consumers, engaged in the production and harvesting of raw agricultural commodities, and be appropriate to the scale and diversity of production and harvesting of such commodities.[25]

We appreciate that FDA has acknowledged that the proposed Produce and Preventive Controls Rules will have a significant impact on a substantial number of small entities, and that it has attempted draft Economic Impact Analyses (EIAs) of both rules. Unfortunately, both those EIAs fail to achieve their statutorily required purposes, and the requirements of Executive Orders 12866 and 13563, to maximize the net benefits of proposed regulations by:

- Minimizing the full extent of those significant impacts while overstating the economic benefits of the rule, and so inadequately documenting the need for less burdensome alternatives for affected small businesses; and
- Failing to adequately respond to the significant impacts that it does identify in the EIAs by offering less burdensome alternatives.

Further, even as they understate the negative effects on small businesses, the EIAs still make plain that:

- The Produce Rule and Preventive Controls Rule do not provide sufficient flexibility to be practicable for small businesses, as required by FSMA;
- The rules are not appropriate to the scale and diversity of farms engaged in the production and harvest of raw agricultural commodities (RACs), as required by FSMA; and
- FDA has not taken sufficient steps to minimize paperwork burdens on affected small businesses, as required by FSMA and the PRA.

We first provide overarching comments on both EIAs and then make specific comments on the Preventive Controls Rule EIA.

1. The EIAs fail to document benefits of regulating small businesses.

For both the Produce Rule and Preventive Controls Rule, evidence cited in the EIAs, and backed up by independent scholars, shows that the new rules will not guarantee that produce and processed food will be free of contamination. Foodborne disease outbreaks will continue to occur. Pathogens will continue to adapt to changing conditions, including newly sanitized packing and processing operations. Entirely new pathogens will be discovered. The assumption in the EIAs is that a risk-free system is not a realistic or attainable goal. We agree that there is no such thing as a zero-risk

[24] Food, Drug, & Cosmetic Act §§ 418(n)(3)B) and 419(c)(C)

[25] Food, Drug, & Cosmetic Act §§ 418(n)(3)(A), 419(c)(B), and 419(a)(3)(A)

system. The prime question, then, is whether the regulations and their associated costs will result in a net benefit and a decrease of foodborne illness outbreaks. The EIAs fail to adequately answer this question.

The EIAs reveal that FDA does not have data that document the added benefits of the procedures it proposes: Most all of the largest produce farms have already implemented Good Agricultural Practices, and over 99 percent of food processing is already covered by or compliant with the proposed preventive controls, according to FDA. These are examples of existing models upon which the agency based its proposed regulations. Even large-scale produce farmers and processors that have pioneered adoption of food safety protocols, however, have experienced outbreaks of pathogens, revealing the evolving nature of the science of food safety and the uncertainty of the practices and procedures that actually reduce risk in the food supply.

The new rules would bring tens of thousands of smaller farms and processors into direct communication with FDA, by requiring them to register with the agency, or subjecting them to closer scrutiny and additional paperwork. This will certainly increase costs, but whether it will decrease foodborne illness outbreaks is not as clear.

2. Costs of compliance will be borne by the private sector and primarily by small businesses.

The EIAs show that small farms and processors will be subject to very substantial costs to comply with the new rules. Few, if any, of them will be able to pass along these costs to consumers, since they hold little power in the marketplace. FDA predicts that small farms and small processors may opt to close their businesses, rather than face compliance costs, and that new farm and food businesses will not enter the marketplace because of the economic burden of those rules. The rules threaten the existence of thousands of farmers and processors – those operating at the creative edge of the food industry, creating new community-based solutions and providing competition in a highly concentrated industry.

3. The loss of small businesses will have a significant impact on market structure.

The net effect of the proposed rules, by FDA's own reckoning, will be to reduce the number of small businesses competing in the food and agriculture marketplace, increase concentration in the food industry, and so increase the nation's reliance on – and vulnerability to – the national-scale food manufacturing and distribution system that has been responsible for the vast majority of foodborne illness outbreaks.

The point about small firms providing competition in a highly concentrated industry is important. The produce and food processing industries are highly concentrated markets. In a review of FSMA's economic implications, noted agricultural economists Ribera and Knutson stated the following about impacts on market competition:

> "From a market structure perspective, smaller plants represent the competitive fringe of firms that provide important elements of competition in other highly concentrated markets. Therefore, regulatory activity that adversely affects the competitive fringe also can be expected to have adverse effects on competition. As a consequence, the exit of smaller

firms not only adversely affects costs, but also affects consumer choice, including product diversity and product prices."[26]

Ribera and Knutson conclude that harming the smallest farms also reduces the competitiveness of the entire produce sector:

> "If not carefully designed, HACCP-type regulation [for farms] could result in small and very-small produce farms being limited to direct marketing where food safety regulation is exempt from FSMA regulation. In the process, an important segment of the competitive fringe of produce farms would be eliminated from commercial produce markets."[27]

Understanding the complex and critical role that small firms play within the broader industry sectors is important for fully understanding the impact of the proposed rules. It is not just the fact that there will be a loss of small firms, but that that loss will impact in a negative way the market structure of the sector and the products available and prices charged to consumers.

4. The stated benefits are necessarily highly speculative and the impact on public health is unclear.

Immense uncertainty lingers over the calculations of proposed benefits, especially given the FDA claim that over 90 percent of foodborne illnesses go undetected. Because of this uncertainty, and because of the adaptive nature of pathological organisms and contamination pathways, any calculation of disease reduction, or financial benefits that might be derived, from either the Produce or Preventive Controls Rules is necessarily highly speculative. This means that evaluating the success of the new rules will be highly speculative as well. To threaten small businesses viability and survival without effectively demonstrating actual public health benefits is contrary to the letter and intent of FSMA, as well as the RF/SBREFA and Executive Orders 12866 and 13563.

FSMA creates a legislative mandate for FDA to enhance programs to prevent foodborne illness in the US. However, that mandate exists within the larger context of FDA's responsibility to improve public health. Every year in this country, approximately 800,000 people die from complications of heart disease; more than 200,000 die from complications of diabetes; and approximately 50,000 die from colon cancer. Thirty-six percent of American adults are obese today, up from just 13 percent in 1962, and today 17 percent of children and youth are obese.[28] These and other diet-related disease epidemics drive sustained long-term increases in health care costs and human misery, including an estimated annual medical cost of $147 billion according to the CDC. Fresh produce and minimally processed foods are widely accepted by science and the public health profession as critical components of the solution to this crisis. Increasing the supply of fresh produce – which generally is nutritious when it is consumed in close temporal (and therefore geographic) proximity to where it is harvested – should be a goal that drives all FDA action with respect to the food supply.

Federal regulatory action in the food and agriculture arena occurs in the context of a long-term trend in the US of consolidation in the food and agriculture industry, loss of farmland, the increasing

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[26] Ribera, L. and R. Knutson. "The FDA's Food Safety Modernization Act and its economic implications." *Choices Magazine* 26 (2013). Page 3.

[27] Ibid. Page 4.

[28] Ogden, C. et al. "Prevalence of obesity in the United States, 2009-2010." *NCHS Data Brief* 82 (2012).

average age of our farmers, and increased dependence on food from overseas, which is very often grown in conditions that are far less conducive to the effective control of pathogens. The nascent counter-trend in this country of farmers, including new farmers, transitioning their businesses to serve the market for locally grown foods should be cultivated, not curtailed, as a means of combating the long-term epidemics of chronic diet-related disease. To promote and encourage this movement to produce more healthy food, it is critical to ensure that these farms and small businesses can grow and innovate.

Even with their flawed estimation of Produce and Preventive Controls Rules' costs to small business, the EIAs show that the rules will have the opposite effect. Indeed, by reducing the availability of fresh and minimally processed foods, and by stifling economic development opportunities in the burgeoning market for local foods, the net effect of the proposed rules potentially may result in the net costs of the rule far exceeding the net benefits they create, in violation of Executive Orders 12866 and 13563.

Recommendation: To achieve the statutory objectives of the RFA/SBREFA, FSMA, and PRA, FDA must, as part of the preparation for a set of second proposed rules for both produce standards and preventive controls, conduct a more thorough and accurate regulatory flexibility analysis so that the agency better understands the consequences of its proposed rules for small business. FDA must use that revised analysis as a basis for adopting meaningful regulatory alternatives for small businesses in a new proposed rulemaking for both the Produce and Preventive Controls Rules.

We discuss below some of the specific areas where the Preventive Controls Rule EIA does not accurately account for the true costs and benefits of the proposed rules, and where the findings of the EIAs as published reveal the need for more meaningful regulatory alternatives for small business than those in the Preventive Controls Rule.

5. The Preventive Controls Rule EIA contains significant flaws that must be addressed in order to comply with statutory requirements.

FDA's Economic Impact Analysis (EIA) of the proposed Preventive Controls Rule discusses different cost estimates for facilities based on three different options for the definition of "very small business":

1. Option 1: A business that has less than $250,000 in total annual sales of food, adjusted for inflation;
2. Option 2: A business that has less than $500,000 in total annual sales of food, adjusted for inflation; or
3. Option 3: A business that has less than $1,000,000 in total annual sales of food, adjusted for inflation.

In our discussion below, we reference which option we are referring to when it is necessary.

a. The benefits of the Preventive Controls Rule are speculative.

FDA acknowledges that the Preventive Controls Rule will not eliminate foodborne illness, but fails to acknowledge that there is no realistic benchmark for evaluating if it will even significantly reduce foodborne illness outbreaks. Given that more than 90 percent of foodborne illnesses purportedly

go unreported, it will be difficult to evaluate whether these provisions were ultimately effective. The estimates of both the costs and of foodborne illness and the benefits of the proposed new rule are based on very limited evidence.

For example, FDA states in the Preventive Controls Rule EIA: "We lack sufficient information to fully estimate the proposed Rule's likely benefits. Instead we attempt to estimate the total economic burden of the illnesses that could potentially be prevented by this Rule. We do not expect that all of these illnesses will be prevented; rather, we expect that the Rule would prevent some portion of them from occurring. We estimate that there are close to 1,000,000 illnesses each year that are attributable to FDA-regulated food products that would fall under the scope of this propose Rule. The monetized cost of these illnesses is estimated to be nearly $2 billion."[29]

FDA arrives at this estimate of illnesses from a very limited set of data covering foodborne illness. During the years 2003-2008, 16 outbreaks of foodborne illness (resulting in 1,655 illnesses) associated with foods that would be governed by the Preventive Controls Rule were documented over a six-year period. [30] While the importance of these illness incidents is not to be minimized, it is a very long extrapolation indeed to move from this figure to one million illnesses *per year*.[31]

If, six years into the new rule, FDA could document 32 outbreaks of foodborne illness over that six-year period, would it consider this a success by simply estimating that overall illnesses had declined, say to an estimated 750,000? Or would it cite such data as an indication that our ability to document cases of foodborne illness had improved due to a Rule that created new paths for tracing the source of future foodborne illness outbreaks? Or would the agency say that even more restrictive measures were required, since documented outbreaks had doubled? Unfortunately, any of these conclusions would be possible, based on such a small sample of foodborne illness outbreaks, and such large extrapolations to the presumed incidents of foodborne illness.

Conversely, if in a hypothetical six-year period after adoption of a final rule, only eight outbreaks of foodborne illness were documented for FDA-regulated foods, would FDA claim it had succeeded in reducing outbreaks by half, even though it would be impossible to document any reduction in the projection of one million annual illnesses occurring currently? Since FDA cannot now confirm that foodborne illness outbreaks are more likely to occur in unregulated industries than in regulated ones, how could anyone document whether this shift had occurred because of the new rule?

b. The costs of compliance clearly demonstrate the need for less burdensome alternatives.

Ribera and Knutson found that, "Complying with the regulations would be expected to impose substantial variable and fixed costs associated with the development and implementation of the required HACCP plan. As a result of the relatively high fixed costs, the average costs were projected to increase at a decreasing rate as the size of plant increased. Therefore, smaller plants would be

[29] U.S. Food and Drug Admin. "Analysis of Economic Impacts – Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food." Page 6.

[30] Ibid. Page 14

[31] Ibid. Pages 15-16

much more adversely impacted than larger plants."[32] This is borne out by FDA's own cost estimates, as discussed below.

The costs analyzed by FDA include costs associated with hazard analysis, process controls, and monitoring/verification. For the top cost items in Subpart C, under all three options, FDA estimates that no large firms hiring 500 employees or more will face additional cost burdens from the new rule. The majority of the costs associated with Subpart C compliance, according to FDA, will be borne by firms with fewer than 20 employees. Overall, FDA estimates that the average firm subject to hazard analysis and risk-based preventive controls will be required to spend $13,000 on an annualized basis; significantly, no first-year costs are detailed in this particular analysis.

The agency's calculations suggest that, under Option 1, as much as 73 percent of the costs of the new rule will be borne by very small manufacturers (those hiring fewer than 20 employees), while only 0.27 percent of the costs would be borne by very large manufacturers hiring more than 500 employees.[33] FDA's cost estimates are based on the assumption that most firms hiring over 500 employees already are covered by FDA regulation, and have food safety protocols in place.

FDA clearly understands that the proposed rule will have a negative impact on small processors: "Because facilities with less than 20 employees (both qualified and non-qualified) facilities will bear a large portion of the costs, the Agency tentatively concludes that the proposed rule will have a significant economic impact on a substantial number of small entities."[34] All told, the EIA concludes, "the regulatory costs of this proposed rule may discourage at least some new small businesses from entering the industry."[35]

Under each of the options, fully $60.8 million of the projected costs to processors of the new rule – nearly 13 percent of the total estimated costs under FDA's proposed Option 2, and the third-ranking cost on the list (after $192 million for hazard analysis and process controls and $85 million for verification and monitoring) – is simply the costs of learning about the rule.

The agency's estimates are annualized costs based on a seven percent amortization over seven years. One-time costs are far higher, and more starkly imbalanced: "We estimate that one-time costs per facility [for learning about the rule] cost for <20 employee facilities, 20-99 employee facilities, 100-499 employee facilities, and >500 employee facilities will be about $255 million, $39 million, $31 million, and $3.3 million, respectively."[36] This is a total of $328.3 million in one-time costs – 42 percent of the rule's first-year cost of $775 million under Option 1 or 48 percent under Option 3.

Certainly, learning the rule is a cost that is likely to diminish over time for existing firms, but such a steep cost simply to learn the rule suggests that the rule is too complicated. Moreover, this high cost represents a significant barrier to entry. With small firms shouldering most of the financial burden, the rule will discourage small processing firms from starting or continuing to do business.

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[32] Ribera, L. and R. Knutson. "The FDA's Food Safety Modernization Act and its economic implications." *Choices Magazine* 26 (2013). Page 2.

[33] Preventive Controls EIA Table 65a, Page 183

[34] Ibid. Page 1

[35] Ibid. Page 183

[36] Ibid. Page 118

FDA claims to have taken steps to reduce the impact on smaller processors: "The proposed rule reduces the burden on small businesses through the use of modifications and exemptions from the proposed requirements when the small businesses meet the following requirements under section 418 or 421 of the FD&C Act: for facilities engaged only in specific types of on-farm activities and involving foods that the Secretary determines to be low risk (§ 103(c)(1)(D) of FSMA)."[37] The agency continues by explaining that small businesses have more time to comply with the new rule, and finally that "very small businesses are deemed 'qualified' and therefore, qualify for the exemptions from many of the provisions of these regulations as discussed in section X.B.1 of the proposed document (§ 418(l)(1)(B) of the FD&C Act)."[38]

This imbalance of impact should be understood in context. As FDA states, "in the absence of better information, we assume that the potential for foodborne illness from facilities is equal to the facility's share of sales, because we lack data that definitively associates smaller facilities with a greater potential for outbreaks. However, we do have data that suggests smaller facilities are less likely to already be doing many of the things required by this Rule."[39] In other words, absent data that shows that larger facilities are safer than smaller, the Agency proposes to saddle smaller processors with $349 million of the costs under Option 1 that would not be borne by larger processors, because the large are presumed to be already following agency protocols.[40] It would seem that the small firms are cited as "inadequate" simply because they have not officially adopted, or reported to FDA, compliance with agency protocols.

In its analysis of the impacts on small business, the FDA overlooks the issue of one-time startup costs, and how this might disproportionately affect small processors:

> "We estimate that under Option 1 the total costs to domestic facilities in the first year, which will be the period when the industry incurs the largest cost, including both set up costs to implement the rule and the initial recurring monitoring and verification costs, will be approximately $775 million. We estimate that annually recurring costs after the first year will be $347 million. The annualized costs, which include annualized one-time set up costs and annually recurring costs will be approximately $475 million per year using a discount rate of 7 percent and discounted over 7 years. We estimate the total annualized cost to foreign facilities will be approximately $500 million. Under Option 1 the total annualized domestic and foreign cost is $975 million per year using a discount rate of 7 percent over 7 years or $843 million per year using a discount rate of 3 percent over 7 years."[41]

This calculation of expenses based on annualized costs assumes that smaller entities have the cash reserves to absorb their share of these costs in the first year, or the cash flow to allow depreciation of costs. It does a small firm very little good to know that the annualized costs of new rule are only 61 percent of the first-year costs, if the first-year costs require expenditures that the small business cannot afford to make. With average annualized costs assumed by FDA to be $13,000 per facility, this represents a significant burden on very small processors in itself. If this is only 61 percent of first-year costs, then first-year costs would total more than $21,000.

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[37] Ibid. Page 170

[38] Ibid. Pages 179-180

[39] Ibid. Page 20

[40] Ibid. Pages 9, 183

[41] Ibid. Page 5.

c. FDA displays bias in favor of large businesses.

The EIA demonstrates biases in favor of larger businesses, which underscores that FDA has insufficiently evaluated less burdensome options for small businesses to comply with the Preventive Controls Rule.

For example, review of the EIA's coverage of training programs reveals how FDA has done a poor job understanding the situation in very small firms:

> "Our Food GMP [Good Management Practices] survey included questions about types of training, duration of training, types of employees trained, and whether management conducts refresher training. The final survey report provides a complete summary of all the responses to the training questions. About nine percent of responding facilities with less than 20 employees indicated that they do not provide any food safety and sanitation training to newly hired production employees, while all responding facilities with 500 or more employees indicated that they provide training of some type."[42]

This certainly seems like an imbalance, until one looks more closely at the data presented by FDA. Agency data covering the largest firms shows that "[a]bout 60 percent of facilities with 500 or more employees provide less than one hour for training of food safety, foodborne hazards and hazard prevention." The differences between "no training," "informal training," and "less than one hour" of training may be subtle, indeed.

Note also that the FDA categories of analysis shift when smaller firms are considered. "Of those facilities that indicated that training is provided, about 33 percent of the facilities with fewer than 20 employees indicated that the principles of food safety, foodborne hazards, and the prevention of such hazards are not covered in their employee training or they spend less than one hour for training; about 61 percent of the facilities with 20 to 99 employees and the facilities with 100 to 499 employees also responded that they do not cover this topic or spend less than one hour for training. About 60 percent of facilities with 500 or more employees provide less than one hour for training of food safety, foodborne hazards and hazard prevention."

Continuing on, the report states, "In response to a similar question on personal hygiene practices, about 42 percent of facilities with less than 20 employees responded that they do not provide training for the topic or provide less than one hour of training; almost 100 percent of all other facility sizes provide at least some training in personal hygiene practices, although 53 percent provide less than one hour of training." Note that for the smaller firms, spending "less than an hour" is lumped in with "no training," while for larger firms, "less than one hour" is considered "training."

Yet the Agency's data show that when it comes to other types of training, rates in smaller firms are comparable to rates in larger firms: "Respondents to the survey were also asked whether production floor employees are trained to notice and report symptoms of illness in coworkers or themselves. About 12 percent of facilities with less than 20 employees, 13 percent of facilities with 20 to 99 employees, and 16 percent of facilities with 100 to 499 employees reported that they do not provide

[42] Ibid. Pages 127-128

training in this topic. With respect to the frequency of refresher training in food safety and sanitation for production floor employees, over 19 percent of facilities with less than 20 employees responded that they do not provide refresher training at all. About 15 percent of all facilities responded that they do not provide refresher training."[43]

Another example of FDA bias concerns responses to consumer complaints. While the EIA acknowledges that data are sparse, it nonetheless characterizes small firms as less responsive than larger firms, despite the fact that large firms often place intense obstacles in the path of consumer input – often, for example, offering consumers no phone line that is answered by an actual human being. FDA states:

> "We lack formal studies or other information that address a facility's likely response to consumer complaints. According to our expert elicitation, legitimate complaints that involve illness or foreign objects usually receive a very high priority as opposed to a quality defect in the product or a taste issue. Large and very large companies are quick to institute changes in monitoring and also often in their HACCP programs in response to a legitimate complaint. Large and very large operations also often have dedicated consumer affairs staff that focuses on the complaint and is responsible for triggering the investigative process at the local manufacturing level. It was the opinion of our experts that small and mid-sized operations often do not have any formal review process for consumer complaints. Small and some medium companies initially deal with a complaint but then move on to ongoing business with no trend analysis of complaints or formal review (Ref. 47)."

However, a small firm that responds rapidly to consumer complaints may have no need for a formal trend analysis; these may be clearly known to management who has actually addressed consumer complaints in person. Moreover, examples exist of small firms that have taken proactive steps. One case was in Asheville, North Carolina, in May, 2012, when as many as 89 people became ill from salmonella, half of which was traced back to a small tempeh manufacturer. Although the source of the infection was later determined to be a Maryland distributor that had sold a contaminated product, the small manufacturer in Asheville recalled the entire batch of potentially tainted tempeh before pathogen tests were even completed.[44]

Since FDA does not characterize the make-up of its panel of experts that offered their conjectures about business responses to complaints, it seems logical to conclude that these experts were people close to very large manufacturers, not to community-scale processors. This emphasizes the need for future regulatory oversight to include representatives from community-based firms.

d. FDA has significantly underestimated the number of farm mixed-type facilities and must make a more accurate estimate in order to accurately assess the impact of the regulations.

Because the food processing sector study discussed in section A above is so inadequate, FDA has significantly underestimated the number of farm mixed-type facilities that will be subject to both the

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[43] Ibid. Pages 127-128

[44] Burgess, J. "Asheville tempeh pulled; salmonella cases rise to 37." *Asheville Citizen-Times*. 1 May 2012; "Salmonella outbreak linked to unpasteurized tempeh sickens 60." *Huffington Post*. 8 May 2012; Lunsford, M. "Salmonella in Asheville tempeh came from outside source, says Dept. of Agriculture (updated)." *Mountain Xpress*. 4 May 2012.

Preventive Controls Rule and the Produce Rule. In the economic analysis accompanying the proposed Preventive Controls Rule, FDA estimates that 1,673 farms are also food processors counted in the number of domestic facilities impacted by the proposed Preventive Controls Rule.[45] Given FDA's proposed definitions of "farm" and supporting definitions of "facility," this estimate of operations that would be categorized as "farm mixed-type facilities" is incredibly low.

As one example of how FDA's estimates are very low, we point to USDA's National Agricultural Statistics Service (NASS) 2008 Organic Production Survey (OPS). The OPS found that 1,100 certified and exempt organic farms in the U.S. had sales from value-added organic products (approximately 7.6 percent of total certified and exempt organic farms).[46] Transforming a RAC (i.e., processing) is a feature of value-added products. If one assumes that farms that have sales from value-added products are doing value-added processing and would, therefore, be considered farm mixed-type facilities, then this number from the OPS can help inform FDA's estimate of farm mixed-type facilities.

If one applies this percentage from the OPS to farms subject to some or all of requirements of the proposed Produce Rule (covered farms (40,211) + qualified exempt farms (75,716) + exempt for commercial processing (29,972)),[47] then there would be approximately 11,088 farms that might be considered farm mixed-type facilities solely based on value-added processing activities. While there may be a greater percentage of organic farms that do value-added processing than for all farms subject to some or all of the requirements of the Produce Rule, this estimate only captures processing activities and leaves out any estimate of packing and holding activities that may trigger facility registration. This estimate also calculates the percentage solely for produce farms and not for all farms subject to the Preventive Controls Rule. Even if a direct extrapolation cannot be made, the point is that FDA has significantly underestimated the number of farm mixed-type facilities.

We discuss the need to redefine foundational terms like "farm" and supporting definitions of "facility" below to significantly shrink the universe of "farm mixed-type facilities," consistent with the intent of Congress (see comments in section V). Taking that action will shrink substantially the number of farm mixed-type facilities. Even then, however, it will remain important to have some basic and accurate idea of the size and scope of the regulated community.

D. FDA has failed to meet its Tribal consultation responsibilities.

In the proposed Preventive Controls Rule, FDA has failed to meet its Tribal consultation responsibilities. Under Executive Order (EO) 13175 issued by President Clinton, a subsequent Presidential Memorandum issued by President Obama in November 2009 reaffirming EO 13175, and the subsequent guidance from the Office of Management and Budget, federal agencies are required to consult with Tribes when they put forward two types of rules:

1. Rules with Tribal implications that have substantial direct compliance costs on Indian tribal governments; and

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[45] US Food and Drug Admin. "Analysis of Economic Impacts – Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food." January 2012. Page 47.

[46] US Dep't of Agric. "NASS Organic Production Survey." 2008. Table 3.

[47] US Food and Drug Admin. "Analysis of Economic Impacts – Standards for the Growing, Harvesting, Packing and Holding of Produce for Human Consumption." January 2012. Tables 1 and 2.

2. Rules with Tribal implications that preempt tribal law.

Consultation is important on the proposed requirements of the Preventive Controls Rule due to the high number of Tribal food and agriculture producers, and the number of Tribal-government-owned food and agriculture production systems and food businesses.

FDA has not complied with either the spirit or the letter of the two directives controlling federal agency responsibilities to Tribal government. When FDA released the proposed Preventive Controls Rule, the proposal was supposed to contain in the preamble a specific recitation describing how FDA met its responsibilities under EO 13175 and the nature of the content and context of Tribal consultation and input regarding the proposed rule. This discussion was missing altogether from the preamble and it appears that FDA has not taken the appropriate steps to meet its tribal consultation responsibilities.

Recommendation: Before issuing a final Preventive Controls Rule, FDA must meet its Tribal consultation responsibilities.

E. FDA must consider the environmental impacts of the Preventive Controls Rule.

In NSAC's comments on FDA's notice of intent to prepare an environmental analysis (EIS) before issuing the final Produce Rule, we commented that FDA must consider the impacts of the Preventive Controls Rule. Given that FDA has broadly defined the activities that result in an operation being considered a "facility," many farms will be subject to the Preventive Controls Rule. Compliance with the Preventive Controls Rule will be costly and some farms may decide to stop operating and sell their farms. The loss of farmland may result in development of that land for residential or commercial purposes. This development will likely result in impacts to wildlife habitat for threatened and endangered species, and greenhouse gas emissions from additional reliance on food sourced more than 275 miles from the point of consumption.[48]

Recommendation: In the EIS, FDA must consider the impacts of the Produce Rule, in combination with the impacts of the Preventive Controls Rule. First, even if farms do not stop operating due to the exceptional expense imposed by the Preventive Controls Rule, the additional cost of compliance associated with the Produce Rule may require some farms to shut down. FDA must consider the impacts of these additional farms shutting down. Second, FDA must consider environmental degradation imposed by the Produce Rule on top of any environmental impacts already imposed by the Preventive Controls Rule.

F. The scope and magnitude of the problems in the proposed Preventive Controls Rule requires the promulgation of a second proposed rule for public comment.

FDA's proposed Preventive Controls Rule fails to meet a substantial number of the significant requirements of FSMA. FSMA requires FDA to establish regulations that "provide sufficient flexibility to be practicable for all sizes and types of facilities, including small businesses such as a

[48] NSAC, *Scoping Notice Comments on FDA Produce Rule*, submitted in Docket No. FDA-2011-N-0921, on Nov. 15, 2013.

small food processing facility co-located on a farm"[49] and to define for the purposes of FD&CA § 418 the terms "small business" and "very small business,"[50] based on the results of a food processing sector study required to examine a number of characteristics of the food processing sector, including the "distribution of food production by type and size of operation."[51] FSMA also mandated that FDA amend the definition of "retail food establishment" to clarify that the sale of food directly to consumers includes the sale of food through community supported agriculture programs (CSAs), roadside stands, farmers' markets, and other direct-to-consumer venues.[52]

FDA has failed to implement some of the statutory requirements for the Preventive Controls Rule, has partially implemented some of these requirements, and is seeking feedback on a variety of options. We provide details on these points in the comments on the proposed requirements below, but, overall, the proposed Preventive Controls Rule is incomplete and does not adequately establish a flexible regulatory framework, particularly for value-added businesses and on-farm processors.

Additionally, in the preamble of the Preventive Controls Rule, FDA discusses certain preventive controls and verification measures that are not part of the proposed rule. Specifically, the agency discusses product testing, environmental monitoring, and a supplier approval and verification program.[53] These processes and programs were originally part of the agency's proposed rule but were removed during the inter-agency review process. Based on FDA statements made at public meetings, it is clear that FDA plans to add some, if not all, of these sections back into the rule. FDA must seek public comment on these proposals as part of a proposed rule before considering whether or not they would become part of any final rule.

When finalized, the Produce Rule and the Preventive Controls Rule will have a significant and long-lasting impact on the nature, structure, and diversity of agriculture and food systems. It is paramount that the agency fix the significant flaws in the proposed rules such that the standards work for all types and sizes of farms and operations engaged in produce production and food processing. Given the scope and magnitude of the problems in the proposed Preventive Controls Rule, the number of significant issues the agency seeks comment on, the tentative nature of many of the agency's proposals, and the flawed or incomplete analyses that accompany the rule, FDA should promulgate a second proposed rule for public comment. It is unlikely that any final rule could be considered a logical outgrowth of the proposed rule given its significant departure from Congressional directive and numerous flaws and inconsistencies. Therefore, to ensure that the agency adequately addresses the many significant problems in the proposed Preventive Controls Rule, the agency should release a second proposed rule for public comment and not an interim final rule.

Recommendation: Given the failure to meet central requirements of FSMA, FDA should release a second proposed rule for public comment that incorporates the mandates of FSMA and the recommendations in this comment before finalizing the Preventive Controls Rule. Before finalizing

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[49] Food, Drug, & Cosmetic Act § 418(n)(3)(A); We note that the use of the phrase "**such as** a small processing facility co-located on a farm" (emphasis added) does not limit the application of this regulatory discretion solely to processing facilities co-located on farms.

[50] Food, Drug, & Cosmetic Act § 418(n)(B)

[51] Food, Drug, & Cosmetic Act § 418(l)(5)

[52] Food Safety Modernization Act § 102(c)

[53] 78 Fed. Reg. at 3762-3767

a rule that includes any new preventive controls or verification measures (e.g., product testing, environmental monitoring, and supplier approval and verification), FDA must provide opportunity for meaningful public comment on the proposed additions as part of a new proposed rule.

IV. COMMENTS ON § 117.1 IN SUBPART A—GENERAL PROVISIONS

Summary

NSAC makes comments and recommendations on § 117.1 in Subpart A—General Provisions. The proposed Preventive Controls Rule must make clear that product from qualified facilities will not de facto be considered "adulterated."

Comments

A. FDA must clarify that product from qualified facilities will not de facto be considered "adulterated."

In the proposed Preventive Controls Rule, FDA does not change the definition of adulterated directly, but in § 117.1 it adds compliance with the new rules to the criteria the agency can use to determine whether food meets the conditions set forth for adulteration in the FD&CA.

Proposed § 117.1 states that:

> (a) The criteria and definitions in this part apply in determining whether a food is adulterated:
>
> (1) Within the meaning of section 402(a)(3) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342(a)(3)) in that the food has been manufactured under such conditions that it is unfit for food; or
>
> (2) Within the meaning of section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act in that the food has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health…

In the preamble, the FDA explains, "we tentatively conclude that the link between the proposed provisions and the potential for adulteration provides a basis for applying the criteria and definitions . . . in determining whether, under particular circumstances, a food is adulterated under § 402(a)(3) or (a)(4)."[54]

After FSMA, the FDA's use of compliance with preventive regulations to determine adulteration is especially significant because FSMA granted FDA mandatory recall authority for adulterated food.[55] Theoretically, then, if FDA uses a violation of the Preventive Controls Rule to determine that food is adulterated, that determination could provide the basis for a mandatory recall of that food.

The proposed rules state that the "criteria and definitions" apply in making a determination of adulteration.[56] This appears to encompass the entirety of the rules. As such, farms or facilities that violate any of the requirements in the proposed rules, including components not directly related to

[54] 78 Fed. Reg. at 3694

[55] 21 U.S.C. § 350(l) (2012)

[56] § 117.1(a)

the safety of the food (such as recordkeeping rules), could face a risk that FDA would deem their food adulterated. However, § 117.1 does say that the criteria and definitions "apply in determining" whether a food will be considered adulterated. This suggests that FDA would not automatically consider a food adulterated as a result of a violation of the proposed rules, which is an important distinction.

Similarly important, it is not clear how the exemption applicable to qualified facilities is included in the "criteria and definitions" used in making a determination of adulteration. Given that the exemption applicable to qualified facilities is within the provisions of the rule, including the definitions (it is not clear what the agency is referring to as "criteria" in this case), we assume that FDA will not just automatically assume that qualified facilities are selling adulterated food because they are by definition exempt from Subpart C of the Preventive Controls Rule. Making the assumption that product from qualified facilities is adulterated would render the exemptions meaningless and would likely lead to the collapse of Congress' vision for a flexible, scale-appropriate food safety regulatory framework.

Recommendation: In the final Preventive Controls Rule, FDA must be very clear in § 117.1 that compliance with the Preventive Controls Rule through the modified requirements for qualified facilities is not sufficient grounds for a determination of adulterated food. Said the other way, it must be abundantly clear that if a qualified facility is in compliance with the Preventive Controls Rule's modified requirements because it is a qualified facility, then its food cannot be considered adulterated solely on the fact that it is implementing modified requirements and not implementing the full set of requirements under the Preventive Controls Rule.

V. COMMENTS ON THE DEFINITION OF "FARM" AND ON THE SUPPORTING DEFINITIONS OF "FACILITY"

Summary

NSAC makes comments and recommendations on the definition of "farm" and on the supporting definitions of "facility." The proposed definitions are insufficient and flawed and must be improved so that farms are not inappropriately regulated as "facilities." We also comment on the "organizing principles," the "harvesting" definition, the failure to clarify the definition of "retail food establishment," and "farm mixed-type facilities." We provide recommended languages changes to the definitions at the end of the section.

Comments

A. FSMA supports the clarification of foundational terms but FDA has failed to adequately clarify foundational terms.

The definitions of "farm" and "facility" form the foundation of the regulatory framework in FDA's proposed Preventive Controls Rule and Produce Rule. For FDA purposes, both of those definitions have their roots in the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (BTA).[57] Congress passed BTA to "prevent, prepare for, and respond to bioterrorism and other public health emergencies" in the post-9/11 era.[58] In BTA, Congress set forth the requirement that food facilities register with FDA and in doing so, defined a "facility" as: "any factory, warehouse, or establishment (including a factory, warehouse, or establishment of an importer) that manufactures, processes, packs, or holds food."[59]

Under this requirement in BTA, the focus was on the regulated entity – facilities – and not on the non-regulated entities, such as farms. BTA did not define farms except for exclusionary purposes; the term "facility" did "not include farms; restaurants; other retail food establishments; nonprofit food establishments in which food is prepared or served directly to the consumer; or fishing vessels."[60] In promulgating the BTA regulations for registration of food facilities, FDA defined both a "facility" and a "farm."

The resulting definitions established a "broad and inclusive definition of 'facility,' and [a] relatively narrow sense of what constitutes a 'farm.'"[61] While BTA clearly exempted farms from the requirement to register as facilities, the definitions of "farm" and "facility" in the BTA regulations have created a great deal of confusion for farmers who conduct activities that fall under the arbitrary definitions of "manufacturing/processing," "packing," and "holding" contained in those regulations.[62] These confusing definitions have led to a lack of clarity around when a farm also

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[57] P.L. 107-188

[58] Public Health Security and Bioterrorism Preparedness and Response Act of 2002

[59] Public Health Security and Bioterrorism Preparedness and Response Act of 2002 § 415(b)(1)

[60] Public Health Security and Bioterrorism Preparedness and Response Act of 2002 § 415(b)(1)

[61] Russell Libby, communication to FDA, 11/6/09.

[62] The arbitrary nature of some of these distinctions and the reason for confusion that results is captured well in the following statement in the preamble to the proposed Preventive Controls Rule: "Use of an activity as an example of manufacturing/processing in current §§ 1.227(b)(6) and 1.328, or the proposed revision of that definition, does not

conducts activities that trigger the definition of a "facility" that must register with FDA and that under FSMA would become subject to the Preventive Controls Rule and increased inspection requirements.

About eight years after Congress passed BTA, Congress passed FSMA, a law with a food safety mandate that sought to regulate both "facilities" and "farms." Recognizing that FSMA was expanding FDA's regulatory authority over existing regulated entities (i.e., facilities) and creating authority to regulate previously non-regulated entities (i.e., farms), Congress in FSMA set forth a regulatory framework that was coordinated, targeted, and not duplicative, and that sought to establish greater clarity between what was a "facility" subject to preventive controls requirements in § 418 of the Federal Food, Drug, and Cosmetic Act (FD&CA) and what was a "farm" engaged in produce production regulated under FD&CA § 419. Under that framework, farms engaged in produce production would be regulated under FD&CA § 419 and food facilities would be regulated under FD&CA § 418. To emphasize that point, both §§ 418 and 419 include provisions specifying that the activities subject to the requirements of one section are not subject to the requirements of the other section.[63] The intent behind these sections was to ensure that one operation would not be subject to multiple sets of regulations under FSMA, and that farms would continue to be exempt from the requirement to register under BTA.

To further clarify the distinction between operations subject to FD&CA § 418 and those subject to § 419, Congress included in FSMA a number of provisions to clarify the definition of "facility." These provisions include the following requirements:

1. Clarifying through rulemaking the activities that are part of the definition of "facility" in FD&CA § 415, including "activities that constitute on-farm packing or holding of food that is not grown, raised, or consumed on such farm or another farm under the same ownership" and "activities that constitute on-farm manufacturing or processing of food that is not consumed on that farm or on another farm under common ownership"[64];
2. Amending the definition of a "retail food establishment" to clarify that the sale of products directly to consumers through direct-to-consumer sales platforms (e.g., roadside stands, farmers' markets, community supported agriculture (CSA) programs, etc.) are considered sales directly to consumers for the purposes of defining a "retail food establishment"[65]; and
3. Generally, "provid[ing] sufficient flexibility 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."[66]

These provisions clearly required FDA to amend existing definitions given that the universe of FDA-regulated entities under FSMA expanded to include "farms," which FDA had previously very

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represent a conclusion that the activity is always classified as manufacturing/processing under all circumstances" (78 Fed. Reg. at 3685). While we appreciate FDA's effort to clarify the definitions, it is imperative that distinctions and definitions be as clear as possible to avoid confusion in the field.

[63] Food, Drug, & Cosmetic Act §§ 418(k) and 419(h)

[64] Food Safety Modernization Act § 103(c)

[65] Food Safety Modernization Act § 102(c)

[66] Food, Drug, & Cosmetic Act § 418(n)(3)(A). We note that the use of the phrase "**such as** a small processing facility co-located on a farm" (emphasis added) does not limit the application of this regulatory discretion solely to processing facilities co-located on farms.

narrowly defined in the BTA regulations. While FSMA prohibited any changes to the term "facility" itself, it required these clarifications and allowed for changes to the supporting definitions of "facility" (i.e., "manufacturing/processing," "packing," and "holding") as well as to the "farm" definition. Nothing in FSMA prohibits FDA from amending the "farm" definition and the supporting definitions of "facility." In fact, it is clear that there is a need to adapt the definition to match the new regulatory authority over produce farms that Congress granted FDA in FSMA.

In the preamble to the proposed FSMA regulations, FDA recognizes that current definitions are vague and problematic, and that it is imperative to draw clear distinctions between "farm" activities and "facility" activities with the advent of FSMA and the associated new regulations impacting farms and facilities.[67]

Recommendation: NSAC greatly appreciates FDA's recognition of the problematic nature of existing foundational definitions and strongly agrees with the need to clarify the distinctions between farm and facility activities with the advent of FSMA, especially given the creation of the category "farm mixed-type facility" and the mandate in FSMA to clarify foundational terms. However, FDA has failed to adequately clarify foundational terms in the proposed Produce Rule and proposed Preventive Controls Rule.

B. The proposed foundational definitions applicable to both rules are insufficient and must be improved so that farms are not inappropriately regulated as "facilities."

In the preambles to the two proposed regulations, FDA lays out a new definitional framework – including organizing principles and changes to existing definitions – that includes some important steps forward to provide additional clarity and guidance for when a farm conducts activities that require it to register as a facility. However, there are still significant deficiencies and fundamental flaws in the proposed framework that must be fixed before the proposed Preventive Controls and Produce Rules are finalized to conform to FSMA. These deficiencies include:

- A flawed set of "organizational principles" that fail to incorporate the basic functions and activities that farms conduct to prepare their RACs for sale.
- The limited and flawed definition of "farm" that fails to include many of the characteristics of farms and many of the activities traditionally performed by farms, including packing (including packaging) and holding of others' RACs.
- A failure to make the "retail food establishment" clarification as mandated by law.
- An overly broad interpretation of "farm mixed-type facilities" due to deficiencies in the supporting framework and definitions.

These deficiencies create confusion among farms and food industry participants, and so limit entrepreneurship and innovation that increases consumer access to healthy, fresh produce, *because they create almost unlimited discretion for FDA to treat farms as "facilities" subject to FSMA*, despite the plain

[67] *See* 78 Fed. Reg. at 3677 ("Therefore, it is important that FDA clarify the scope of the farm definition, including the classification of manufacturing, processing, packing and holding activities relevant to that definition, and adjust it if necessary and appropriate to enhance implementation of section 418 of the FD&C Act, as well as section 415 of the FD&C Act.").

language of BTA and FSMA, and the common-sense business and marketplace understanding of those terms.

Without specific improvements, the entire regulatory framework around the interaction between the two rules will be grossly insufficient and risk significantly expanding the number of "farm mixed-type facilities," inappropriately over-regulating many farms and low-risk food businesses, and raising costs for those farms and FDA district offices alike . NSAC provides specific comments on how to improve the framework and the definitions below.

Recommendation: In the final regulations, FDA must improve the definitional framework and associated definitions to clarify the distinction between "farm" and "facility," and to reflect many of the activities that farms regularly do so that farms and other low-risk food businesses are not inappropriately regulated as facilities.

C. FDA's "organizing principles" are fundamentally flawed and should be substantially revised to reflect common farming activities and level of risk.

In the preamble of the proposed regulations, FDA describes five "organizing principles" to help understand the agency's definition of "farm."[68] The organizing principles rest on a flawed understanding of how farming works because they assume that farms exist simply to grow their crops, and that getting those crops to market is not something that "farms" do. The reality is that a farm cannot stay in business without marketing its crops and preparing those crops for market, and getting produce and agricultural products to market is an inherent part of a farm business. Additionally, the imperative to maximize the value a farm receives for its crops creates the need for value-added processing and marketing, as well as cooperative harvesting, storage, and distribution (including transportation).

FDA must align the organizing principles and new definitional framework with the broader risk-based mandate of FSMA. Establishing a risk-based regulatory framework is a core, foundational aspect of FSMA.[69] Yet in the proposed definitional framework, FDA does not incorporate the concept of risk sufficiently to be consistent with the mandate from FSMA. The classifications of activities that then result from the organizing principles is focused more on distinctions about "where the activities take place, the food used in the activities, where the food comes from, and where the food is consumed."[70] While risk may be addressed by those considerations in particular circumstances, risk is not directly part of the decision process for determining how certain activities are classified under the proposed rule. This is a fundamental flaw.

The organizing principles are too narrow and neglect to include certain activities that constitute traditional farming practices by leaving out the marketing and sales (i.e., business) element of agricultural production. They also fail to incorporate the concept of risk and make distinctions based on risk, and therefore are inconsistent with the broader risk-based mandate of FSMA. NSAC elaborates on these two issues in the comments below.

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[68] 78 Fed. Reg. at 3541 and 3680

[69] e.g., Food Safety Modernization Act §§ 105(a)(b)(1), 103(a)(n)(3)(C), 103(c)(1)(C)

[70] 78 Fed. Reg. at 3681

Recommendation: In the final regulations, FDA should revise its organizing principles to reflect the realities and range of activities that farms do to their crops to prepare those crops and get them to markets, and so that they are consistent with FSMA's risked-based mandate and approach. Specifically, FDA should modify the organizing principles so that they read (proposed new language (underlined) and language to delete (~~struck-through~~)):

1. The basic purpose of farms is to produce RACs and ~~RACs are the essential products of farms~~ to prepare and deliver them for sale to end-users or other buyers.
2. Activities that involve RACs and that farms ~~traditionally have~~ perform~~ed~~ for the purposes of ~~growing~~ selling their own RACs, including growing them, ~~removing them from the growing areas~~ harvesting them, preparing them for ~~use as a food RAC~~ consumption in their raw and unprocessed state, and packing, packaging, labeling, holding ~~and~~, transporting, marketing, and delivering them, should all be within the definition of "farm."
3. Even though farms traditionally also do a wide variety of activities that may be considered processing, for the purpose of these organizing principles, ~~A~~activities should be classified based ~~in part on whether the food operated on is a RAC or a processed food, and~~ on whether the activity transforms a RAC into a processed food (as defined by these rules).
4. ~~Activities farms may perform on others' RACs should appropriately be classified as manufacturing/processing, packing, or holding in the same manner as these activities are classified off-farm when the RACs are to be distributed into commerce.~~ Packing, holding, transporting, marketing, and delivering others' RACs, in addition to one's own RACs, should remain within the definition of "farm" because these activities do not transform those RACs into processed foods, and are well within the traditional roles that have always been performed by farms.
5. Manufacturing/processing, packing, or holding food – whether RACs or processed foods, from any source – for consumption on the farm should remain within the farm definition.

D. FDA needs to substantially revise the definition of "farm" and associated definitions to reflect the reality of farming activities.

The proposed definition of "farm" and associated definitions are significantly flawed and need to be substantially revised to include many of the activities that farms currently do. In amending the definition of "farm" in the following ways, FDA will be adjusting its definition to reflect the advent of FSMA and reality of farming. In the "farm" definition, FDA should:

1. Not include the term "facility";
2. Not limit a farm to one general location;
3. Include packing (including packaging) and holding of others' RACs;
4. Reflect common harvesting activities; and
5. Clarify that "labeling" does not trigger the "facility" definition.

NSAC details our comments on these points below.

1. The definition of "farm" should not include the term "facility."

In BTA, Congress explicitly stated that farms, restaurants, and retail food establishments were not food processing facilities that had to register with FDA. The definition of "farm" includes the term "facility" as defined in § 1.227 of 21 C.F.R., which further confuses the already-confusing distinction

between "farm" and "facility." Both the use of the term "facility" and the reference to § 1.227 of 21 C.F.R. are confusing, and invite arbitrary and capricious applications of the law.

To find an alternative to the use of the term "facility" in the definition of farm, it is instructive to look at the U.S. Department of Agriculture's (USDA) definition of "farm": "any place that sells, or normally could sell, at least $1,000 of agricultural commodities."[71] FDA could align its farm definition with the USDA definition and use "any place" rather than "facility" in the first reference. FDA should use the term "establishment" instead of "facility" in subsections (i) and (ii), which would be consistent with other definitions, such as "retail food establishment" or "mixed-type facility."

Recommendation: In the final regulations, FDA should strike the term "facility" from the "farm" definition and replace the term when it first appears with "any place" and the following uses of the term with "establishments." NSAC provides specific changes to the definitions in section H below.

2. The definition of "farm" should not be limited to "one general location."

A farm may consist of multiple parcels of land and buildings that are not in "one general location" as required by the definition. Reasons for this can be found both in traditional and in newer, innovative farming situations.

In rural areas, farm operators may frequently manage dispersed farmland parcels due to geographic and topographic conditions; local development patterns; and the fact that a single "farm" today is often composed of what used to be multiple farms, as a result of the need to achieve economic efficiencies. Farmers throughout Appalachia, for example, may cobble together multiple small sites flat enough to be suitable for agriculture in order to produce sufficient volumes of crops to establish the economic viability of their farming operations. Farms throughout the country are now made up of multiple, often non-contiguous fields, some of which are owned and many of which are share or cash rented. According to USDA, over 40 percent of farmland is rented and the average commercial farm has over 20 rental agreements.

In urban and suburban areas, farms can be even more dispersed and "parceled" by design, since such farming is opportunistic at heart, utilizing available space wherever it may be, and with locations changing often according to the whims of what are usually absentee landlords. Farms in major metropolitan areas are sometimes scattered quite broadly across the region, in part to maintain some level of production in the neighborhoods where end-users reside.

Recommendation: In the final regulations, FDA should remove the phrase "in one general location" from the "farm" definition and add a sentence that clarifies that a farm may consist of one or more contiguous or non-contiguous parcels of land (or water)[72] and may include one or more structures (e.g., outbuildings, barns, greenhouses, etc.). NSAC provides specific changes to the definitions in section H below.

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[71] U.S. Dep't of Agric. "Exploring Alternative Farm Definitions: Implications for Agricultural Statistics and Program Eligibility." Economic Research Service 2009.

[72] We include the reference to water to be consistent with the reference to "seafood" in the definition of "farm."

3. Packing (including packaging) and holding someone else's RACs should not make a farm or other low-risk establishment a "facility."

One of the most problematic areas in the definitions of "farm" and "facility" has to do with the very common practice on farms of packing or holding produce from neighboring farms to meet market demand. FDA acknowledges that the agency is proposing a "change in how FDA considers the act of placing RACs into consumer containers (1) off-farm and (2) on a farm or farm mixed-type facility with respects to others' RACs," and that "[t]his change in classification would impact a farm or farm mixed-type facility that conducts such activities if it is not currently required to register."[73] FDA states that for a farm or farm mixed-type facility, "this activity would now be classified as packaging and therefore manufacturing/processing, because the expanded definition of packing would only apply to a farm's own RACs."[74] FDA seeks comment on this issue.

NSAC provides comments on this issue in the sections immediately below, starting first with a discussion and examples of how packing and holding of others' RACs are part of farms, followed by a discussion of the low-risk nature of these activities and how the Produce Rule already proposes to regulate produce RACs. Based on those discussions and examples, NSAC then makes a recommendation that these activities should be part of the "farm" definition. We end this subsection with a brief discussion of traceability.

a. Packing and holding others' RACs are key components of farm businesses.

Packing, including packaging, and holding someone else's RACs are activities that many farms do, including as part of innovative and emerging supply chains in local and regional food systems. While FDA justifies its classification by saying that "[f]arms that conduct such activities are acting as distributors for another farm's products,"[75] the agency fails to demonstrate any increased risk of foodborne illness outbreaks arising from such packing and holding activities – activities which do not change the nature of the subject RACs. Indeed, FDA's own "Draft Qualitative Risk Assessment of Risk of Activity/Food Combinations for Activities (Outside the Farm Definition) Conducted in a Facility Co-Located on a Farm" documents that such packing, including packaging, and holding activities are low-risk with respect to RACs. Table 1 in the preamble of the proposed Produce Rule (Table 2 in the preamble of the proposed Preventive Controls Rule) documents the well-established understanding on FDA's part that packing does not change a RAC into a processed food.[76]

It has long been a practice in the produce industry to buy small amounts of produce from neighboring farms to meet market demand. The fresh market produce industry is highly volatile, and particularly subject to the effects of uncontrolled weather events. Farms must be able to meet customer needs to remain economically viable, and from time to time that may entail bringing in some amount of product from another farm. To impose preventive controls requirements on farms that conduct this time-honored practice will contravene Congress' intent that farming operations not be subject to both § 418 and § 419 of FD&CA.

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[73] 78 Fed. Reg. at 3686

[74] 78 Fed. Reg. at 3686

[75] 78 Fed. Reg. at 3686

[76] 78 Fed. Reg. at 3540 and 3679

The short supply chain marketing and distribution models described below are recent innovations that are different from traditional distribution networks because they focus on serving local and regional markets; and because they simply pack, hold, and deliver RACs, activities that FDA has recognized as low-risk and as part of the process of harvesting crops. Thus, the potential food safety risks they must mitigate are the same handling risks as individual farms, and not the risks associated with facilities where RACs and other food components are transformed into another food. To impose preventive controls requirements on these innovative new models, given that many of them are engaged only in such low-risk activities, would be inconsistent with Congress' mandate that FDA regulations provide "sufficient flexibility to be practicable" for small businesses. Indeed, based on FDA's own economic impact analysis, the cost of compliance with the Preventive Controls Rule would force many farms and groups of farms to abandon these models, which would cause a substantial negative economic impact on those farms by the loss of markets, and ultimately result in the closure of some farms and a reduction in consumers' access to healthy, fresh produce.

Here are some examples of these types of emerging farm business models that pack and hold others' RACs and inappropriately fall into the category of "facilities" under the proposed definitions:

i. Community Supported Agriculture Programs

Farms that operate community supported agriculture (CSA) programs may include RACs from a neighboring farm in a CSA box delivered directly to a consumer to augment or replace their products. It is relatively common for a CSA farm to either diversify their product offerings with RACs from a neighboring farm, or to replace their RACs with someone else's in the event of a crop failure. Farmers are also expanding CSA programs into multi-farm models where a number of farms supply products through one CSA program that delivers a box to the consumer including products from cooperating farms; each of the farms is a separate business but the marketing is done jointly. Typically, one farm hosts the CSA distribution for a multi-farm CSA, and such operations are highly likely to have fewer than 20 employees.

To subject that host farm in a multi-farm CSA, or any CSA that occasionally includes produce from more than one farm, to the Preventive Controls Rule as well as the Produce Rule would result in potentially significant compliance costs. Aggregate FSMA compliance costs to that CSA farm, judging from FDA's economic impact analyses of the two rules, could be of as much as eight percent of sales for a farm with greater than $250,000 in sales.[77] According to the USDA Census of Agriculture, the average annual earnings for farms with less than $500,000 in sales amount to just ten percent of sales; so requiring compliance with both rules could cost these farms 80 percent of their already limited earnings, which clearly does not comport with any reasonable notions of flexibility for small business.

[77] FDA's Regulatory Impact Analysis for the Preventive Controls rule estimates the average annualized cost per manufacturing facility for compliance with Subpart C Hazard Analysis and Risk-based Preventive Controls at $13,000/year. The RIA for the Produce Standards rule estimates that the average annual value of sales for a farm with between $250,000 and $500,000 in annual sales is $320,696, and that compliance with the Produce Rule will cost such farm four percent of its annual sales, or $12,828/year. The combination of FDA's estimated compliance costs for the two rules amounts almost $26,000 for such an average farm, or eight percent of sales. CSAs may qualify for the modified requirements, which would significantly reduce compliance costs, but it is not clear – because FDA has not made the clarification required in FSMA – whether sales of food through a CSA but sold off-farm would count in the definition of a retail food establishment (see comment below).

Since farms, of whatever size, that embrace CSA models do so in response to the relative benefits of such models compared to other marketing channels, it is highly likely that the effective elimination of this option for many farms would result in some of those farms going out of business. This despite the fact that the activities involved in CSA distribution are low-risk, and are effectively dealt with already by the proposed Produce Rule standards. Such outcomes would be inconsistent with Congress' risk-based framework of coordinated, targeted, and non-duplicative regulation under FSMA.

ii. Food Hubs

Food hubs[78] have also emerged as a key aspect of local and regional food supply chains, and while a wide variety of food hub types exist, they generally serve as aggregators of products from farms and to buyers. Food hubs occur both on-farm and off-farm. According to USDA, a food hub is "a business or organization that actively manages the aggregation, distribution and marketing of source-identified food products primarily from local and regional producers to strengthen their ability to satisfy wholesale, retail, and institutional demand."[79] Many hubs have evolved from an educational or social mission to bring consumers and producers together in the marketplace. While selling local foods to consumers is one function, these hubs may also seek to educate their buyers about the importance of retaining food dollars in the local economy or keeping agricultural lands in production.[80] Food hubs may use one farm as the aggregation point for the other participating farms. They are distinct from a traditional distributor because they operate short supply chains serving local or regional markets and because they typically engage solely in low-risk harvesting, packing, packaging, holding, and distribution activities on RACs.

Farmers use food hubs to aggregate products and collectively sell those products to buyers that any individual farm in the network could not supply on its own. The act of aggregating and selling collectively has a distinct advantage for farms, especially small and medium-sized farms, that otherwise might not be able to afford the space or equipment, or might not be able to produce enough product independently to secure institutional customers. Entry into local food markets can prove difficult for many farmers, particularly small and mid-sized farms, with capacity constraints and the lack of distribution systems most often being the largest hurdles to overcome.

Food hubs are part of a growing local food system that strengthens rural economies by lowering entry barriers and improving infrastructure to create and expand regional food markets. They can also create rural on- and off-farm employment, expanding opportunities for skilled workers, including youth, to remain in rural areas.[81] Food hubs tend to be driven by an ethic to pay higher prices to producers than they would receive in non-differentiated wholesale markets: a USDA Economic Research Service report that studied local food supply chains found that producers in the local food supply chain received a greater share of the retail price than they did from a mainstream

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[78] For a more in-depth discussion about food hubs, see: Michigan State University Center for Regional Food Systems and The Wallace Center at Winrock International. "Findings of the 2013 National Food Hub Survey." 2013. Available at: http://kresge.org/sites/default/files/2013-national-food-hub-survey.pdf

[79] Barham, J. et al. "Regional Food Hub Resource Guide." U.S. Dep't of Agric., Agricultural Marketing Service 2012.

[80] Matson, J. et al. "The Role of Food Hubs in Local Food Marketing." *USDA Rural Development Service Report* 73 (2013).

[81] Ibid.

food supply chain, with producers attaining net revenue per unit in local chains as much as seven times higher than the price received in mainstream chains.[82]

These benefits to small and mid-sized farms serving local food markets are threatened by the inappropriate application of preventive controls requirements on food hubs conducting only low-risk packing, packaging, storing, holding, and distribution activities. According to a 2012 USDA analysis, to be financially viable a food hub needs to achieve annual revenues of greater than $1 million, and it typically takes at least five years for a food hub establishment to achieve that level of income.[83] Numerous studies of food hubs have documented that lack of access to capital is the most common constraint for establishing and operating a food hub. With razor-thin margins in the food distribution sector generally, the financing challenges these low-risk businesses face would be compounded by the cost of compliance with Subpart C, particularly in the start-up phase, such that many of these businesses will fail, and new ones will not start. To impose preventive controls requirements on these low-risk entities would be inconsistent with Congress' mandate that FDA regulations provide "sufficient flexibility to be practicable" for small businesses.

iii. Farm Incubators

Incubator farms are unique establishments designed to build the capacity of beginning farmers to create and direct their own independent, sustainable farm businesses. A farm incubator project typically leases land at a very low rate to "incubatee" farmers that operate their farm ventures on that leased land as independent businesses. The incubator project provides shared infrastructure and equipment, and may conduct a range of low-risk harvesting, packing, and holding activities on the RACs produced by the incubatee-farmers, including especially cooperative strategies for transporting products to market. As with CSAs and food hubs, the application of Subpart C requirements to the low-risk harvesting, packing, packaging, holding, storage and distribution activities at incubator farms merely because the activities are conducted on the produce of multiple individual farms would be inconsistent with Congress' mandate that FDA regulations provide "sufficient flexibility to be practicable" for small businesses.

b. Packing (including packaging) and holding someone else's RACs are low-risk activities.

In the proposed Preventive Controls Rule, FDA has identified the packing (including packaging) and holding of someone else's RACs as low-risk activities that would result in an exemption from Subpart C of the Preventive Controls Rule if they are conducted by small and very small on-farm businesses.[84] The RACs specifically listed in § 117.5(g) as part of low-risk packing and holding include cocoa beans and coffee beans, grains, honey, intact fruits and vegetables, peanuts and tree nuts, and sugar beets. The RACs specifically listed in § 117.5(h)(2)(xviii) as part of low-risk packaging include cocoa beans; coffee beans; intact fruits and vegetables (other than modified atmosphere or vacuum packaging); grain; peanuts and tree nuts (including modified atmosphere or vacuum packaging); and sugar beets and sugarcane. While we provide our comments on FDA's list of low-risk activity/food combinations in Appendix I, it is important to note here that FDA has

[82] King, R. et al. "Comparing the Structure, Size, and Performance of Local and Mainstream Food Supply Chains." U.S. Dep't. of Agric. Economic Research Service 2010.

[83] Barham, J. et al. 2012

[84] 78 Fed. Reg. at 3801

identified packing and holding of certain others' RACs as low risk. Given that designation, packing (including packaging) and holding someone else's RACs – especially the ones listed by FDA as low-risk – should not trigger the facility definition and the additional regulatory requirements, including Subpart C, that facilities must comply with. This would also align the proposed definitional framework with the risk-based mandate of FSMA.

c. Packing (including packaging) and holding activities are part of activities covered under the Produce Rule.

Packing and holding of one's own covered produce fall within the definition of "covered activity" in the proposed Produce Rule. "Packaging" one's own RACs is part of "packing" within the "farm" definition. Logically, the same activities conducted on someone else's covered produce would be regulated in the same way, under the Produce Rule, and not under the Preventive Controls Rule. The types and degrees of risks associated with packing and holding covered RACs are essentially the same, regardless of on whose farm the RACs were grown and harvested. Subjecting the packing and holding of RACs from one's own and from a neighbor's farm to two different sets of regulations under the two different rules creates costly, unnecessary complication for the farmer and may actually compromise the efficacy with which risk is reduced.

Recommendation: In the final regulations implementing both the Produce Rule and the Preventive Controls Rule, FDA should change the definitions of "farm," "packing" (including "packaging"), "holding," and "manufacturing/processing" to align with the risk-based mandate of FSMA and the common-sense understanding and practice that the basic packing (including packaging), handling, and storing activities that farms perform, and have traditionally performed, on RACs – including on someone else's RACs – in preparing those RACs for marketing do not make a farm or other establishment a "facility" that must register with FDA and be subject to the Preventive Controls Rule. FDA should make a parallel change to the definition of "covered activity" in the Produce Rule. NSAC provides specific changes to the definitions in section H below.

d. Addressing traceability concerns

If one of the main barriers to treating the "packing" and "holding" of someone else's RACs as activities outside the definition of "manufacturing/processing" at a "facility" is the potential lack of traceability in the event of a food safety outbreak, NSAC believes there is a simple solution. To ensure that a RAC can be traced back from the low-risk entity (such as a farm) that is conducting the packing and holding activities on that RAC to the farm that supplied the RAC, FDA could require basic information from the supplying farm that identifies the immediate source of the RACs. This information could be in the form of a label, or invoice, or other document that includes information identifying the farm.

Recommendation: If the agency identifies a need for traceability as a minimum requirement to justify the treatment of "packing" and "holding" of someone else's RACs as activities that do not trigger classification of the packing/holding entity as a facility subject to registration and the Preventive Controls Rule, then FDA should include in Subpart K and § 112.6 of the Produce Rule a requirement that a farm supplying RACs to another entity that will pack, hold, store, or transport those RACs, where the only processing activities conducted by the receiving entity are activities identified as low-risk in §§ 117.5(g) and 117.5(h) of the Preventive Controls Rule, provide to the farm or other establishment that receives the RACs its name and complete business address, and a

description of the RACs provided in any individual shipment. Such information requirement should not exceed documents normally kept in the ordinary course of business.

e. Consistency with FD&CA § 418(m)

NSAC notes that in § 418(m) of FD&CA, Congress specifically stated that:

> The Secretary may, by regulation, exempt or modify the requirements for compliance under this section with respect to facilities that are solely engaged in the production of food for animals other than man, the storage of raw agricultural commodities (*other than fruits and vegetables*) intended for further distribution or processing, or the storage of packaged foods that are not exposed to the environment.

However, this exclusion of *facilities solely engaged* in *storing* fruits and vegetables from the FDA's *discretionary authority* to exempt facilities from the Preventive Controls Rule does not preclude adoption of the recommendations made in this subsection D.3 of our comments with respect to the definitions of "farm," "packing" (including packaging), "holding," or "manufacturing/processing" for a number of reasons.

First, § 418(m) refers to FDA's discretion to exclude entities that are facilities from the requirements of the Preventive Controls Rule. Our recommendations above do not call for certain facilities to be exempted from the Preventive Controls Rule. Instead we call for a redefinition of terms to clarify that certain entities dealing in fruit and vegetable RACs are not facilities in the first place, consistent with Congress' intent in the BTA and FSMA, and consistent with the scientific understanding of food safety risk that FDA has acknowledged in its Aug. 2012 Qualitative Risk Analysis of the risks associated with certain food/activity combinations, which guided FDA's enumeration of low-risk activities in § 117.5(g) and (h) of the Preventive Controls Rule.

Second, our recommendations arise from the experience of farm-based and community-based fruit and vegetable RAC marketing operations that, as part of their marketing activities, pack and distribute intact RACs, in addition to holding them. We do not offer these recommendations with respect to entities that *solely* store those RACs.

Finally, we note that § 418(m) exists within a broader overall legislative framework intended by Congress to be risk-based, coordinated, targeted, and not duplicative. Congress insisted that FDA's Preventive Controls Rule provide "sufficient flexibility to be practicable" for small businesses. As discussed above, the circumstances that give rise to the recommendations made here are (1) based on the actual risks that certain traditional fruit and vegetable RAC marketing activities do, or do not, present; (2) are essential for the regulations to be practicable for small business; and (3) result in targeted coordination of regulatory enforcement activities, and the avoidance of duplicative regulation.

4. FDA needs to amend the definition of "harvesting" to reflect the reality of farming activities.

The proposed definition of "harvesting" must be amended to reflect the scope of harvesting activities, and the joint and cooperative nature of certain harvesting activities.

a. FDA needs to list additional activities under "harvesting."

In its proposed regulations, FDA has started a list of activities included in the definition of "harvesting" that do not trigger the definition of "facility" for the purposes of facility registration when done to one's own raw agricultural commodities. This list includes "[g]athering, washing, trimming of outer leaves of, removing stems and husks from, sifting, filtering, threshing, shelling, and cooling" RACs. NSAC supports the clarification of how FDA classifies these activities and urges FDA to make the list as exhaustive as possible.

Recommendation: FDA should build on its existing list of harvesting activities to also include the following activities in the definition of "harvesting":

- Braiding;
- Bunching;
- Cutting the edible portion of the crop from the plant;
- Field coring;
- Hydro-cooling;
- Maintaining hydration of product;
- Refrigerating;
- Removing foliage;
- Removing free water from (e.g., spinning) or otherwise drying for the purpose of storage and transportation;
- Removing or trimming roots;
- Trimming the tops of bunches of harvested allium crops such as leeks, chives or garlic and root crops such as carrots, beets, turnips, parsnips, to prepare them for sale; and
- Trimming the lower stems of harvested herb crops such as parsley, basil, or cilantro or the lower stems of leafy greens.[85]

FDA should periodically review the list to ensure that it reflects the breadth and range of practices done as part of harvesting.

b. FDA should not limit harvesting activities to the farm on which RACs are grown or raised.

In the proposed rules, FDA limits the definition of "harvesting" to "activities performed on raw agricultural commodities on the farm on which they were grown or raised, or another farm under the same ownership." This limit fails to account for the joint and cooperative nature of harvesting activities in certain circumstances – including the CSA, food hub, and farm incubator scenarios detailed in above – and for the low-risk nature of harvesting activities, including activities that are part of harvesting, as identified above. Given the costs of harvesting equipment and harvesting processes, farmers at times share harvesting equipment or infrastructure that would result in those

[85] A number of activities that are considered part of harvesting are captured under FDA's definitions of "packing" and "holding": sorting, culling, and grading. However, given the current distinctions between one's own RACs and someone else's RACs, some of these activities may inappropriately trigger the "facility" definition. These are low-risk activities that should not trigger the definition of "facility" on one's own RACs or when done to someone else's RACs.

harvesting activities being performed on a farm other than the farm on which they were grown or raised.

Harvesting activities do not transform crops into processed foods, and any food safety risks that are present in harvesting activities are addressed by the post-harvest components of the Produce Rule. To apply preventive controls requirements to activities that are part of harvesting merely because they take place at a different location than where the crop was grown would be unscientific; would contravene Congressional intent that farms not be regulated as facilities; would result in establishments being regulated under both § 418 and § 419, despite Congress' intent that the FSMA regulatory framework be coordinated, targeted, and not duplicative; and would fail to provide "sufficient flexibility to be practicable" for small businesses, as required by FSMA.

Recommendation: In the final regulations, FDA should not limit "harvesting" to "activities performed on raw agricultural commodities on the farm on which they were grown or raised." FDA should strike the sentence that refers to that limit in the "harvesting" definition. FDA should also clarify that harvesting activities conducted with shared or co-owned equipment are still "harvesting" even if conducted at another co-owner's farm. NSAC provides specific changes to the definitions in section H below.

5. FDA needs to clarify that "labeling" does not trigger the "facility" definition.

NSAC also urges FDA to clarify that "packing" and "packaging" of raw agricultural commodities on-farm includes affixing labels to packing and packaging containers, and that such labeling does not trigger the definition of "facility" for the purposes of facility registration. Labeling is a common activity done on farms; USDA certified organic farmers must label their products as USDA certified organic and FSMA now requires qualified exempt farms in some circumstances to label their products. Identity-preservation labeling is also an important marketing tool for many produce farmers, and facilitates efforts to both prevent and mitigate foodborne illness outbreaks.

NSAC recognizes that labeling poses a risk of foodborne illness where there is a possibility that a food product contains an allergen that is not readily apparent to the consumer through examination of the food. If an allergen is not disclosed on the label under such circumstances, injury can result to the consumer. But in the case of RACs, which are by definition single-ingredient products that the end-user cannot reasonably mistake to contain or not contain an allergen, labeling does not create a foodborne illness risk. The end-user can readily inspect a RAC or RAC package to determine if it contains tree nuts, peanuts, coconuts, soybeans, wheat, or other common food allergens.

Recommendation: In the final regulations, FDA should clarify that "packing" and "packaging" of RACs includes affixing labels to packing and packaging containers, and that such labeling does not trigger the definition of "facility" for the purposes of facility registration.

E. FDA has failed to clarify the definition of "retail food establishment" for direct marketing as required by law.

FDA has failed to implement the mandate from FSMA that requires FDA to amend the definition of "retail food establishment" to clarify that the sale of food directly to consumers includes the sale

of food through community supported agriculture programs (CSAs), roadside stands, farmers' markets, and other direct-to-consumer venues.[86]

Without this required clarification, CSAs, roadside stands, farmers' markets, and other direct-to-consumer platforms (including, but not limited to, farm stores, direct internet sales, tailgate markets, and pick-your-own operations) could be regulated like food facilities that must register with FDA and are subject to the Preventive Controls Rule. This could happen because even if the majority of the food sold by these types of operations is sold directly to consumers, the exchange of products may actually occur off-farm (e.g., CSAs routinely deliver their boxes directly to consumers at drop-off points in town, rather than at the farm). Recognizing that this distinction did not jeopardize the direct nature of the sales but that the current definition of "retail food establishment" was not conclusive on this point, Congress included this clarification in FSMA. Not making this clarification would be inappropriate and inconsistent with the statute and with the clear Congressional intent that these entities are not required to register as facilities and are not subject to the Preventive Controls Rule.

Given the importance of this clarification to the definitional framework set forth in the proposed Preventive Controls Rule, and the close interplay between this clarification and the term "facility," FDA must include this clarification in § 117.3 and other parts with revised definitions. It is not sufficient to make the clarification only in guidance[87] or outreach materials[88] because it is key component of determining coverage under FSMA regulations of direct-to-consumer farms.

Recommendation: In the final Preventive Controls Rule, FDA must clarify that the sale and distribution of food through a community supported agriculture program, roadside stand, farmers' market, farm store, tailgate market, or other direct-to-consumer platforms is included in the definition of sales direct to consumers for purposes of defining a "retail food establishment," as required by the FSMA statute. NSAC provides specific changes to the definitions in section H below.

F. FSMA supports FDA's determination that a mixed-type facility should only be subject to § 418 with respect to its activities that trigger § 415 registration.

While there are significant problems with the breadth of activities that FDA proposes to trigger facility registration (see comments above), FDA is correct in its tentative conclusion that "only those manufacturing, processing, packing, or holding activities that trigger registration under the section 415 registration regulations should be considered to be manufacturing, processing, packing, or holding of food by a facility for the purposes of section 418."[89] NSAC agrees with FDA's statement that "to conclude otherwise would mean that, for example, the farm exemption from registration would be rendered irrelevant to the coverage of section 418, except for activities on farms that will be subject to requirements under section 419 of the FD&CA."[90]

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[86] Food Safety Modernization Act § 102(c)

[87] U.S. Food and Drug Admin. "Guidance for Industry: Questions and Answers Regarding Food Facility Registration" Fifth edition, December 2012.

[88] U.S. Food and Drug Admin. FSMA Factsheet "I Have a Farm – Does the Proposed Preventive Controls Rule Affect Me?" August 2013.

[89] 78 Fed. Reg. at 3677

[90] 78 Fed. Reg. at 3677

Recommendation: In the final regulations, FDA should retain its current determination that unless an exemption from § 418 applies, a facility that is required to register under § 415 should be subject to § 418 with respect to all its activities that trigger § 415 registration regulations, but not with respect to its activities that would not trigger § 415 registration regulations.

G. FSMA requires a very narrow interpretation of "farm mixed-type facility."

In the proposed regulations, FDA proposes to codify the category of "mixed-type facilities," including "farm mixed-type facilities." Given the regulatory framework Congress established in FSMA, it is clear that Congress did not intend for one establishment or operation to be regulated under both the Preventive Controls Rule and the Produce Rule. We therefore object to the creation of the category of a "farm mixed-type facility" under the proposed rules because it violates Congressional intent in passing both FSMA and BTA.

That objection notwithstanding, to the extent that there are farm operations that carry out activities that alter the general state of RACs, any use of the term "farm mixed-type facility" as a basis for requiring a farm to register as a food facility, and be subject to the Preventive Controls Rule with respect to processing activities that alter the general state of RACs, at the very least must be construed very narrowly.

In the proposed regulations, the proposed definitions of "farm" and the supporting definitions of "facility" would greatly expand the universe of "farm mixed-type facilities" because a number of common farm activities are inappropriately categorized. To remedy these inappropriate classifications, FDA must clarify that:

- Any activity conducted at a farm on any RACs, whether grown on the farm in question or on any other farm, that does not change the nature of RAC should not trigger registration as a facility; and
- The activity/food combinations that FDA has identified as low-risk in its "Qualitative Risk Assessment Risk of Activity/Food Combinations for Activities (Outside the Farm Definition) Conducted in a Facility Co-Located on a Farm" when conducted on a farm, should not trigger a requirement for that farm to register as a facility.

The only activities occurring on a farm that should trigger registration of the establishment as a "farm-mixed type facility" should be those activities that (a) are not low risk and that (b) change the nature or alter the general state of RACs. To fail to so clarify the very limited circumstances in which a farm will be subject to registration would be contrary to Congressional intent and would result in the inappropriate over-regulation of many farms and low-risk food businesses (see comments above).

Recommendation: In the final regulation, FDA must appropriately define "farm" and supporting definitions of "facility" to support a very narrow definition of "mixed-type facility," including "farm mixed-type facility," to be consistent with Congressional intent in FSMA. Specifically, the only activities occurring on a farm that should trigger registration of the establishment as a "farm-mixed type facility" should be those activities that (a) are not low risk and that (b) change the nature of RACs.

H. Recommended language changes to definitions to § 112.3

NSAC indicates below the changes that we recommend FDA make directly in the definition section of each of the parts amended or created through the Preventive Controls Rule and the Produce Rule to incorporate our comments. We indicate proposed new language (underlined) and language to delete (~~struck-through~~).

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

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Farm means ~~a facility (as defined in § 1.227 of this chapter)~~ any place ~~in one general physical location~~ devoted to the growing and harvesting of crops, the raising of animals (including seafood) or both. A farm may consist of one or more contiguous or non-contiguous parcels of land (or areas of water) and may include one or more structures. Farm includes:

(i) ~~Facilities~~ Establishments that pack or hold food~~, provided that all food used in such activities is grown, raised, or consumed on that farm or another farm under the same ownership~~; and

(ii) ~~Facilities~~ Establishments that manufacture/process food, provided that all food used in such activities is consumed on that farm ~~or another farm under same ownership~~.

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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, braiding, bunching, cutting the edible portion of the crop from the plant, field coring, hydro-cooling, maintaining hydration of product, refrigerating, removing foliage, removing water from (e.g., spinning) or otherwise drying for the purpose of storage and transportation, removing or trimming roots, trimming the tops of bunches of allium crops, and trimming the lower stews of harvested herb crops ~~or another farm under the same ownership~~ are examples of harvesting.

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Holding means storage of food. Holding facilities include warehouses, cold storage facilities, storage silos, grain elevators, and liquid storage tanks. For farms and farm mixed-type facilities, holding also includes activities traditionally performed by farms for the safe or effective storage of raw agricultural commodities ~~grown or raised on the same farm or another 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.

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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, <u>or</u> distilling~~, labeling, or packaging~~. For farms and farm mixed-type facilities, manufacturing/processing does not include activities that are part of harvesting, packing, or holding.

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Packing means placing food into a container other than packaging the food. For farms and farm mixed-type facilities, packing also includes activities traditionally performed by farms to prepare raw agricultural commodities ~~grown or raised on the same farm or another farm under the same ownership~~ for storage and transport, 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.

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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 is manufactures/process, packs, or hold, 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 values of sales of food products to all other buyers. <u>The sales of food products directly to consumers includes the sales of such food products at roadside stands, farmers' markets, and any other direct sales platform, and through a community supported agriculture program.</u> The term "consumers" does not include businesses. A "retail food establishment" includes grocery stores, convenience stores, and vending machines locations.

VI. COMMENTS ON THE DEFINITION OF "VERY SMALL BUSINESS"

Summary

NSAC makes comments and recommendations on the definition of "very small business" in the Preventive Controls Rule. Given the requirements of FSMA, it is consistent with the law for FDA to adopt a threshold of at least $1,000,000 for the definition of "very small business" in the Preventive Controls Rule and apply it not to the sales of all food but to sales of food regulated under the Preventive Controls Rule.

Comments

A. FDA should adopt a "very small business" definition of at least $1,000,000 in covered product.

In FSMA, Congress granted FDA broad authority to provide flexibility for small and very small businesses in its strong rejection of a one-size-fits-all approach. To emphasize the importance of a flexible, scale-appropriate framework, FSMA expressly added the following overarching provisions to § 418 of Federal Food, Drug, and Cosmetic Act (FD&CA):

- The requirement to define for the purposes of FD&CA § 418 the terms "small business" and "very small business,"[91] based on the results of a food processing sector study required to examine a number of characteristics of the food processing sector, including the "distribution of food production by type and size of operation" and "the number and types of food facilities co-located on farms, including the number and proportion by commodity and by manufacturing or processing activity"[92];
- The requirement to "provide sufficient flexibility 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"[93];
- Modified requirements for qualified facilities that are either "very small business" as defined by FDA, or that meet a two-part eligibility test: have an average annual monetary value of all food sold during a previous three-year period of less than $500,000 adjusted for inflation, and sell the majority of the food directly to consumers, or to a restaurant or retail food establishment that is located in the same state as the facility or within a 275-mile radius of the facility[94]; and
- The requirement to create exemptions or modified requirements for small and very small businesses involved in certain low-risk on-farm manufacturing, processing, packing, and holding activities.[95]

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[91] Food, Drug, & Cosmetic Act § 418(n)(B)

[92] Food, Drug, & Cosmetic Act § 418(l)(5)

[93] Food, Drug, & Cosmetic Act § 418(n)(3)(A); We note that the use of the phrase "**such as** a small processing facility co-located on a farm" (emphasis added) does not limit the application of this regulatory discretion solely to processing facilities co-located on farms.

[94] Food, Drug, & Cosmetic Act § 418(l)

[95] Food Safety Modernization Act § 103(c)

Given the importance of the "very small business" definition to the success of the scale-appropriate framework that Congress set forth in FSMA, it is critical to define "very small business" so that it achieves the flexibility envisioned by Congress.

In the proposed Preventive Controls Rule, FDA has proposed three options for the definition of "very small business":

4. A business that has less than $250,000 in total annual sales of food, adjusted for inflation;
5. A business that has less than $500,000 in total annual sales of food, adjusted for inflation; or
6. A business that has less than $1,000,000 in total annual sales of food, adjusted for inflation.[96]

According to FDA's preliminary economic impact analysis, the highest threshold proposed (Option 3: $1,000,000 in total annual sales of food) would cover only a tiny percentage – less than two percent – of the food produced in the US. The impact of adopting the highest proposed threshold, or a higher threshold, would be minimal for the vast majority of facilities in the food processing sector.

For farms that might fall under the definition of "facility" and are considered "farm mixed-type facilities" under the proposed regulations, however, FDA's decision on the threshold will have a very significant impact. According to the US Department of Agriculture (USDA), farms of all types with over $1 million in sales were two percent of all farms and represented 53 percent of all sales.[97] The percentage of all production represented by "million dollar" farms is greater with respect to fruits and vegetables as well as dairy and livestock, sectors in which between 60 and 70 percent of all sales come from farms with over $1 million in sales according to USDA.[98] With respect to specialized vegetable and melon farms, USDA reports that eight percent of all farms accounted for 87 percent of the US vegetable crop in 2005-2007.[99] Given these levels of concentration, it is clear that a compelling case can be made for a very small business definition of at least $1 million with respect to farms.

Nonetheless, under the current proposed definitions, a large number of farms will be considered "facilities" subject to the Preventive Controls Rule. Yet, the HARPC requirements are designed for industrial food facilities – not for farms – and do not provide sufficient flexibility and are inappropriate for on-farm processors. Adopting at least the $1,000,000 threshold will protect the majority of farms, though a relatively small percentage of product, from HARPC requirements inappropriate to their circumstances without impacting the vast majority of the food processing sector.

The agency should in fact establish an even higher threshold, in recognition of the issues identified in our comments on FDA's preliminary economic impact analysis in section III.C, in conjunction with changes to the definitions in the Preventive Controls Rule and other provisions of the rule

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[96] Fed. Reg. at 3800

[97] Hoppe, R. and D. Banker. "Structure and Finances of U.S. Farms: Family Farm Report." U.S. Dep't of Agric. Economic Research Service (2010).

[98] Ibid.

[99] Ali, M. and G. Lucier. "Vegetable Production Concentrated on Very Large Farms." U.S. Dep't of Agric. Economic Research Service (2011).

recommended in NSAC's comments, in order to provide sufficient flexibility to be practicable for small business, as required by FSMA; to minimize paperwork burdens on affected small businesses, as required by FSMA and the PRA; and to ensure there are less burdensome regulatory alternatives for small business.

For example, food hubs represent an emerging small business model that is becoming a key aspect of local and regional food supply chains. According to USDA, a food hub is "a business or organization that actively manages the aggregation, distribution and marketing of source-identified food products primarily from local and regional producers to strengthen their ability to satisfy wholesale, retail, and institutional demand."[100] They are distinct from a traditional distributor because they operate short supply chains serving local or regional markets, and they serve small farm businesses with aggregation and distribution services, allowing those farms to aggregate products and collectively sell those products to buyers that any individual farm in the network could not supply on its own due to inability to afford the necessary capital investments or inability to produce enough product independently to secure institutional customers.

Food hubs are part of a growing local food system that strengthens rural economies by lowering entry barriers and improving infrastructure to create and expand regional food markets. Food hubs are also are key part of the Administration's emerging strategy for addressing diet-related disease prevention and healthy food access in underserved communities. Food hubs tend to be driven by an ethic to pay higher prices to producers than they would receive in non-differentiated wholesale markets: a USDA Economic Research Service report that studied local food supply chains found that producers in the local food supply chain received a greater share of the retail price than they did from a mainstream food supply chain, with producers attaining net revenue per unit in local chains as much as seven times higher than the price received in mainstream chains.[101]

According to a 2012 USDA analysis, to be financially viable a food hub needs to achieve annual revenues of greater than $1 million, and it typically take at least five years for a food hub establishment to achieve that level of income.[102] Numerous studies of food hubs have documented that lack of access to capital is the most common constraint for establishing and operating a food hub. With razor-thin margins in the food distribution sector generally, the financing challenges these low-risk businesses face would be compounded by the cost of compliance with Subpart C, particularly in the start-up phase, such that many of these businesses will fail and new ones will not start.

To impose preventive controls requirements on these entities would be inconsistent with Congress's mandate that FDA regulations provide "sufficient flexibility to be practicable" for small businesses, either for the hubs themselves or the farms that depend on them. Establishing a threshold for the definition of small business at more than $1 million in annual revenues would ensure an appropriately less burdensome regulatory alternative for these small businesses, provide sufficient flexibility for FDA's proposed rules be practicable for small business, minimize paperwork burdens on affected small businesses, and maximize the net benefits of the FSMA rules, by ensuring these establishments are not subject to onerous requirements under Subpart C of the Preventive Controls

[100] Barham, J. et al. "Regional Food Hub Resource Guide." U.S. Dep't of Agric. Agricultural Marketing Service (2012).

[101] King, R. et al. "Comparing the Structure, Size, and Performance of Local and Mainstream Food Supply Chains." U.S. Dep't of Agric. Economic Research Service (2010).

[102] Barham et al. 2012

Rule. We note with interest that in its proposed rule for Preventive Controls for Food for Animals, FDA has presented three options for defining a very small business, with possible thresholds of $500,000, $1,000,000 and $2,500,000 in sales, and we would urge the agency to consider a similar, higher option with respect to the Preventive Controls Rule in a revised proposed rule.

Additionally, the FDA's proposed $1,000,000 option refers to gross sales of "all food" and not product regulated under the Preventive Controls Rule. Nothing in FSMA restricts FDA from focusing the definition of "very small business" to products regulated under the Preventive Controls Rule instead of "food." Doing so is consistent with the fact that the Preventive Controls Rule specifically does not address animal food, and that covered produce is regulated under the Produce Rule. This is also consistent with the FSMA mandate for sufficient flexibility in the preventive controls standards. Focusing the definition of "very small business" on food regulated under the Preventive Controls Rule would provide flexibility to farms diversifying into new crops and new on-farm value-added enterprises, would help ease the compliance costs for farms and new value-added businesses, and would help focus limited FDA resources on high-risk industrial facilities.

Finally, establishing a "very small business" definition of at least $1,000,000 of food regulated under the Preventive Controls Rule would not be inconsistent with either the structure or the intent of FD&CA § 418(l) (the Tester amendment). The modified requirements set forth in § 418(l) are part of, but by no means the entirety of, the flexible, scale- and supply-chain appropriate approach that Congress established in FSMA. The provision dealing with farms that have an average annual monetary value of all food sold during a previous three-year period of less than $500,000 adjusted for inflation, and sell the majority of the food directly to consumers, or to a restaurant or retail food establishment that is located in the same state as the facility or within a 275-mile radius of the facility is a distinct and narrowly targeted provision for direct-to-consumer and direct-to-retail marketing and has no particular bearing on the FSMA requirement to establish a definition for small and very small businesses as it pertains to other sections of the law. For instance, Congress in FSMA requires a definition of very small business in the application of the requirement to create exemptions or modified requirements for small and very small businesses involved in certain low-risk on-farm manufacturing, processing, packing, and holding activities,[103] an extraordinarily important FSMA provision and one that has no direct connection to § 418(l). It would be a great disservice to these other important provisions of FSMA and contrary to Congressional intent to make the Tester amendment direct sales provision the controlling factor in establishing the definitions of very small businesses for other critical provisions of the law, all of which were included in the legislation prior to congressional agreement on the Tester amendment.

The modified requirements in § 418(l) represent one specific alternative that is mandated by FSMA for particular types of smaller businesses, and it is entirely consistent with Congress' intent to establish a threshold for "very small business" more generally that is above the $500,000 threshold in § 418(l). The threshold for the "very small business" definition for the Preventive Control Rule as a whole should be greater than $1 million, but should include an exception clause with respect to eligibility for the modified requirements under § 418(l) that establishes a lower threshold in that one specific and targeted instance, a singular instance in which Congress contemplated a lower very small business threshold for a specific application of the modified requirements section of FSMA.

[103] Food Safety Modernization Act § 103(c)

The agency has clearly shown in its preliminary economic impact analysis that the burden of complying with the proposed Preventive Controls Rule will fall on very small businesses. To comply with the directives of Congress to ensure flexibility for very small businesses, FDA must provide viable alternatives to Subpart C.

Recommendation: FDA should adopt a threshold of more than $1,000,000 for the rule as a whole, with a lower threshold in the specific application of the rule to the modified requirements provision, and apply the threshold to sales of food regulated under the Preventive Controls Rule.

VII. COMMENTS ON ESTABLISHING A $25,000 EXEMPTION

Summary

NSAC makes comments and recommendations on the need to establish an outright exemption from the Preventive Controls Rule for facilities with an average annual monetary value of covered product sold of $25,000 or less.

Comments

A. FDA should establish an outright exemption from the Preventive Controls Rule for facilities with an average annual monetary value of covered product sold of $25,000 or less.

When writing FSMA, Congress rejected a "one-size-fits-all" approach, and provided FDA with flexibility to ensure that the Preventive Controls Rule worked for a diversity of facilities. Specifically, in the Preventive Controls Rule, FDA requires FDA to "provide sufficient flexibility 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."[104]

While FDA has taken initial steps to implement the flexibility specifically required by FSMA for low-risk activities/food combinations (see Appendix I) and for qualified facilities (see section VII), FDA has not built in flexibility for extremely small facilities in the same way it has in the proposed Produce Rule for farms with $25,000 or less in food sales. FDA should establish an outright exemption for extremely small facilities to ensure flexibility for the smallest food processing operations. We detail the need for additional flexibility for small business in our comments on FDA's preliminary economic impact analysis in section III.C.

An outright exemption for facilities that have an average annual monetary value of food regulated by the Preventive Controls Rule of $25,000 or less would not significantly add risk to the food supply. According to FDA's preliminary economic impact analysis, the highest threshold proposed threshold for the definition of "very small business" – $1,000,000 in annual gross sales food – would cover only a tiny percentage – less than two percent – of the food produced in the US.[105] That same analysis says that food businesses with less than $250,000 in annual gross sales of food represent less than one-half of one percent of all food produced in the U.S.[106] Setting an outright exemption at the $25,000 threshold would represent an even smaller fraction of the food businesses in the US and be targeted to creating flexibility for small food processing facilities, such as those co-located on farms.

Additionally, the exemption should be based on the value of products regulated under the Preventive Controls Rule and not all food as defined in § 117.3. Nothing in FSMA restricts FDA from focusing a $25,000 outright exemption to products regulated under the Preventive Controls Rule instead of "food." Doing so is consistent with the fact that the Preventive Controls Rule specifically does not address animal food, and that covered produce is regulated under the Produce

[104] Food, Drug, & Cosmetic Act § 418(a)(n)(3)(A)

[105] U.S. Food and Drug Admin. "Preliminary Regulatory Impact Analysis – Current Good Manufacturing Practice and Hazard Analysis and Risk-based Preventive Controls for Human Food." Page 4.

[106] Ibid.

Rule. This is also consistent with the FSMA mandate for sufficient flexibility in the preventive controls standards. Focusing the definition on regulated product instead of all food would provide some flexibility in the rule for beginning farmers, entrepreneurs trying to launch value-added food businesses, and family farmers who have diversified their operations through value-added processing.

Recommendation: To ensure sufficient flexibility for a diverse array of food businesses, FDA should establish an outright exemption from the Preventive Controls Rule for businesses with $25,000 or less in annual average monetary value of product covered by the Preventive Controls Rule sold over a three-year period, adjusted for inflation.

VIII. COMMENTS ON SUBPART D—MODIFIED REQUIREMENTS

Summary

NSAC makes comments and recommendations on the modified requirements for qualified facilities set forth in Subpart D. We recommend that FDA calculate the sales based on food covered by the Preventive Controls Rule and not all food. We support the "self-certification" approach and make recommendations that support and clarify the agency's proposed modified requirements.

Comments

A. FDA's modified requirements for qualified facilities in Subpart D are generally consistent with Congressional intent but are in need of a few revisions.

When writing FSMA, Congress strongly rejected a "one-size-fits-all" approach, and provided FDA with flexibility to ensure that the Preventive Controls Rule worked for a diversity of facilities, including small and very small businesses. To emphasize the importance of a flexible, scale- and supply-chain appropriate framework, FSMA expressly added the following overarching provisions to § 418 of Federal Food, Drug, and Cosmetic Act (FD&CA):

- The requirement to define for the purposes of FD&CA § 418 the terms "small business" and "very small business,"[107] based on the results of a food processing sector study required to examine a number of characteristics of the food processing sector, including the "distribution of food production by type and size of operation"[108];
- The requirement to "provide sufficient flexibility 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"[109]; and
- The requirement to create exemptions or modified requirements for small and very small businesses involved in certain low-risk on-farm manufacturing, processing, packing, and holding activities.[110]

It was within this broader scale-appropriate framework that Congress also specified certain modified requirements for qualified facilities through FD&CA § 418(l). To be a qualified facility subject to modified requirements – instead of the full Hazard Analysis and Risk-based Preventive Controls (HARPC) requirements in § 418 – a facility must either be a "very small business" as defined by FDA (see section VI) or meet a two-part eligibility test: have an average annual monetary value of all food sold during a previous three-year period of less than $500,000 adjusted for inflation, and sell the majority of the food directly to consumers, or to a restaurant or retail food establishment that is located in the same state as the facility or within a 275-mile radius of the facility.

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[107] Food, Drug, & Cosmetic Act § 418(n)(B)

[108] Food, Drug, & Cosmetic Act § 418(l)(5)

[109] Food, Drug, & Cosmetic Act § 418(n)(3)(A); We note that the use of the phrase "**such as** a small processing facility co-located on a farm" (emphasis added) does not limit the application of this regulatory discretion solely to processing facilities co-located on farms.

[110] Food Safety Mondernization Act § 103(c)

The option for these modified requirements was the result of the inclusion of an amendment led by Senator Tester (D-MT) (the Tester amendment). The Tester amendment is a central piece of the scale- and supply-chain appropriate framework in FSMA aimed at scaling federal food safety requirements to a facility's level of risk to the food supply. The inclusion of the Tester amendment also secured the support necessary to pass FSMA; without the specific provisions allowing for specific modified requirements, the law would have floundered and it is unclear whether FSMA would have passed.

Given the centrality of the Tester amendment to the success of FSMA and the law's scale- and supply-chain appropriate framework, it is critical to ensure that the implementation of the amendment through the Preventive Controls Rule and Produce Rule upholds Congressional intent and supports robust options for qualified facilities.

In the proposed Preventive Controls Rule, FDA sets forth modified requirements for qualified facilities in Subpart D. FDA seeks comments on some of these requirements and makes tentative conclusions about others. While there are many other provisions in the Preventive Controls Rule that impact the success of the modified requirements and need significant revisions (see, e.g., section V and section IX), FDA's modified requirements for qualified facilities in Subpart D are generally consistent with Congress' intent in FSMA. There is one notable exception where we believe a change will significantly improve the option for and implementation of the modified requirements. NSAC provides comments on these points below.

Recommendation: In the final Preventive Controls Rule, FDA must maintain and strengthen the modified requirements in Subpart D.

B. FDA should amend the definition of "qualified facility" to calculate sales based on the average annual monetary value of food covered by the Preventive Controls Rule, not all food.

NSAC is aware of the statutory language in § 418(l)(1)(C)(ii)(II) stating that the "average annual monetary value of all food sold by such facility" counts in determining whether a facility meets the two-part eligibility test for the modified requirements. However, we believe that Congress granted the agency sufficient flexibility to limit "all food" in this statement to all food regulated by the Preventive Controls Rule and not to all food included regardless of whether it is regulated by the Preventive Controls Rule. Specifically, Congress required FDA to "provide sufficient flexibility 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."[111] It is precisely the small food processing facilities co-located on farms for which this change is needed. Those small processing facilities co-located on farms or processing activities undertaken on farms will inevitably, by definition, have sales from their overall farm operation that, unless the change is made, will count unfairly against the gross sales test.

FDA has identified and addressed this very problem in its recently released proposed rule on Preventive Controls for Animal Food (Animal Food Rule). In defining "qualified facility" in the Animal Food Rule, FDA specifies "animal food" instead of "all food," saying that "it intends to only include the sale of food for animals and not the sale of human food in determining whether a facility

[111] Food, Drug, & Cosmetic Act § 418(n)(3)(A)

meets the requirements in those cases where a facility sells both."[112] Implied in the agency's proposal and analysis is the fact that if the agency recognizes that if it doesn't limit the sales calculation for a qualified facility to animal food, then very few facilities will be able to meet the sales threshold and qualify for the modified requirements.

Given the broad flexibility granted to FDA through FSMA, and that the agency itself has identified and tried to address this problem in the Animal Food Rule, we believe the agency can and should make this change.

Recommendation: In the final Preventive Controls Rule, in the definition of a "qualified facility" in § 117.3, FDA should limit the average annual value of food sold during the previous three-year period to the sales of food regulated by the Preventive Controls Rule, and not "all food."

C. Self-certification is consistent with the requirements of FSMA but the regulatory text in Subpart D should be made stronger to clearly indicate that statements certifying a facility's qualified status and food safety practices are sufficient.

The crux of the modified requirements for qualified facilities is the submission of certain documentation to FDA. FSMA requires a qualified facility to submit to FDA "documentation… that the facility is a qualified facility,"[113] as well as either:

1. "documentation that demonstrates that the owner, operator, or agent in charge of the facility has identified potential hazards associated with the food being produced, is implementing preventive controls to address the hazards, and is monitoring the preventive controls to ensure that such controls are effective,"[114] or
2. "documentation (which may include licenses, inspection reports, certificates, permits, credentials, certification by an appropriate agency (such as a State department of agriculture), or other evidence of oversight), as specified by the Secretary, that the facility is in compliance with State, local, county, or other applicable non-Federal food safety law."[115]

It is in the details of the documentation submission process where the modified requirements will either work for qualified facilities or be too burdensome to be the true modified requirements envisioned by Congress as a scale-appropriate and flexible framework.

In the preamble to the Preventive Controls Rule, for the requirement to submit documentation that a facility is a qualified facility, FDA "tentatively concludes that a statement from the owner, operator, or agent in charge of a qualified facility certifying that the facility is a very small business, otherwise meets the definition of a qualified facility under proposed § 117.3, or both, would be acceptable for the purposes of satisfying the requirements that would be established in § 117.201(a)(1). We would not, for example, require that a facility submit financial information to FDA demonstrating its total sales or to [sic] the proportion of sales to qualified end users."[116]

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[112] 78 Fed. Reg. at 64757

[113] Food, Drug, & Cosmetic Act § 418(l)(2)(B)(ii)

[114] Food, Drug, & Cosmetic Act § 418(l)(2)(B)(i)(I)

[115] Food, Drug, & Cosmetic Act § 418(l)(2)(B)(i)(II)

[116] 78 Fed. Reg. at 3769

For the requirement to submit documentation either demonstrating that a facility has identified hazards, and is implementing and monitoring controls, or that shows compliance with other applicable non-Federal food safety law, FDA "tentatively concludes that a statement from the owner, operator, or agent in change of a qualified facility certifying" these actions "would be acceptable for the purposes of satisfying the requirements."[117] FDA continues, "We would not, for example, require that a facility submit documentation to FDA demonstrating the content of their hazard identification, preventive controls, or monitoring of the implementation of preventive controls; or copies of their non-Federal licenses, inspection reports, certificates, permits, credentials, or certifications."[118]

NSAC agrees with these conclusions because they are consistent with the intent of the modified requirements, and are workable for qualified facilities; we urge FDA to adopt this "self-certification" approach in the final rule. The use of the term "documentation" in FSMA rather than "records" also supports FDA's self-certification approach because FSMA did not specify that records should be submitted to FDA, simply documentation.

Even though qualified facilities would still need to keep the relevant records on hand and be ready to furnish FDA with those documents if asked,[119] a self-certification approach would significantly reduce the paperwork burden on qualified facilities, as compared to having to submit the actual documents in every instance. Indeed, the requirement that qualified facilities file away the documents they rely upon for their self-certifications (and the possibility of checks by FDA) makes it clear that this is a purely time-saving measure, and should allay any concerns of other stakeholders that qualified facilities will have free reign to fabricate their qualifications. Using a streamlined certification process for qualified facilities will allow small businesses to reduce unnecessary costs and will permit FDA to save costs that would be incurred otherwise by receiving and reviewing all of the submitted documentation.

Despite this support for a self-certification approach in the preamble, the regulatory text in Subpart D is not clear on this option. While FSMA requires the agency to provide more details about the documentation required to show that a facility is a qualified facility through guidance, this does not preclude the agency from strengthening the text in § 117.201(a) to make its self-certification approach clear.

Recommendation: In the final Preventive Controls Rule, FDA should retain the self-certification approach to the documentation that a qualified facility must submit to FDA, but FDA should strengthen § 117.201(a) so that the self-certification approach is clear. Specifically, FDA should modify § 117.201(a) so that it reads (language to add is underlined and language to delete is ~~struck-through~~):

> (a) *Documentation to be submitted.* A qualified facility must submit the following documentation (such as a statement from the owner, operator, or agent in charge of a qualified facility) to FDA:

[117] 78 Fed. Reg. at 3770

[118] 78 Fed. Reg. at 3770

[119] § 117.201(e)

D. The frequency and details of the documentation submission process are generally consistent with FSMA but need minor revisions.

1. Frequency of submission

In the proposed Preventive Controls Rule, FDA is proposing to require that documentation from qualified facilities be "[r]esubmitted at least every 2 years, or whenever there is a material change to the information."[120]

NSAC supports having facilities resubmit documentation (using the proposed self-certification approach) every two years or when there is a material change to the information; the two-year cycle is consistent with biennial registration requirements for facilities established in FSMA § 102(a)(3). However, to eliminate any confusion, we recommend removing the phrase "at least" from the text. Given that the text includes the requirement to resubmit if there is a material change, there is no need to require or imply that a qualified facility would have to submit documentation more frequently than every two years.

Recommendation: In the final Preventive Controls Rule, FDA should retain the two-year resubmission frequency in § 117.201(c)(2) but FDA should remove the phrase "at least" so that is reads (language to add is underlined and language to delete is ~~struck-through~~):

> (c) Resubmitted ~~at least~~ every 2 years, or whenever there is a material change to the information described in paragraph (a) of this section. For the purpose of this section, a material change is one that changes whether or not a facility is a "qualified facility."

2. Details of documentation submission

In the preamble, to inform the guidance required by FSMA, the agency "request[s] comment on the efficiency and practicality of submitting the required documentation using the existing mechanism for registration of food facilities, with added features to enable a facility to identify whether or not the facility is a qualified facility. A facility that does not identify itself as a qualified facility would not be prompted to provide additional information under proposed § 117.201(a)."[121]

NSAC supports the idea of using the existing mechanism for registration of food facilities for submitting the required documentation. We think this would be an efficient and practical approach.

Recommendation: For the guidance about the documentation that a facility must submit to show that it is a qualified facility, NSAC supports the idea of using the existing mechanism for registration of food facilities for submitting the required documentation. NSAC plans to provide comment on that guidance once it is available.

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[120] § 117.201(c)(2)

[121] 78 Fed. Reg. at 3770

E. There should be no question about how to interpret the option to submit documentation showing compliance with applicable non-Federal food safety law.

FDA has correctly defined the limits of FD&CA § 418(l)(2)(B)(i)(I) in § 117.201(a)(ii); in fact, the two sections are almost identical. In an abundance of caution, we make clear the following points:

1. The option to submit documentation showing compliance with applicable non-Federal food safety law does not in any way require a facility to show compliance with *all* applicable non-Federal food safety law. FSMA used the conjunction "or" instead of "and" in describing the documentation that could demonstrate compliance. Requiring a qualified facility to show compliance with *all* applicable non-Federal food safety law would be contrary to the intent of FSMA, not to mention impractical and unnecessary.

2. The option to submit documentation showing compliance with applicable non-Federal food safety law does not mean that a qualified facility must comply with the food safety laws in all of the states in which it sells a product. In addition to the fact that we are not aware of any state blocking the import of a food product into that state because a farmer in another state was not in compliance with the importing state's food safety laws, this would be in contradiction with the intent of Congress in FSMA to establish modified requirements for qualified facilities and would be simply unworkable from a practical stand point.

Recommendation: In the final Preventive Controls Rule, FDA should retain its current position, which is consistent with FSMA, and not require a qualified facility to show compliance with *all* applicable non-Federal food safety law, and not require a qualified facility to comply with the food safety laws in all of the states in which it sells a product.

F. 2011 as the baseline year for inflation is the correct year.

In the preamble, FDA "tentatively conclude[s] that because Congress provided a specific dollar amount in section 418(l)(1)(C)(ii)(II) – i.e., $500,000 – and it provided that the dollar amount should be adjusted for inflation, it is reasonable to establish the baseline year as the year that the law was enacted."[122] NSAC agrees with FDA's determination that 2011 should be the baseline year for inflation.

Recommendation: In the final Preventive Controls Rule, FDA should retain its decision to make 2011 the baseline year for inflation.

G. FDA's interpretation of "business address" is correct.

In the preamble, FDA "tentatively conclude[s] that the use of the term 'business address' in section 418(l)(7) demonstrates Congress' intent to require the facility's full address or P.O. box, to appear on labels or other required notifications when the facility has opted to not submit documentation

[122] 78 Fed. Reg. at 3769

directed to food safety practices," and FDA "seek[s] comment on this interpretation."[123] NSAC agrees with the agency's interpretation on the meaning of "business address."

Recommendation: In the final Preventive Controls Rule, FDA should retain its interpretation of "business address."

[123] 78 Fed. Reg. at 3771

IX. COMMENTS ON SUBPART E—WITHDRAWAL OF AN EXEMPTION APPLICABLE TO A QUALIFIED FACILITY

Summary

NSAC submits the following comments on Subpart E—Withdrawal of an Exemption Applicable to a Qualified Facility. NSAC finds that Subpart E is woefully inadequate and needs to be significantly rewritten to comply with FSMA. NSAC's comments on this issue include the following:

1. The circumstances that would lead to the withdrawal of a farm's qualified exempt status;
2. Establishing a three-tiered withdrawal process;
3. Establishing a mechanism for regaining qualified exempt status; and
4. Other details relevant to the process of withdrawing a qualified exemption.

We provide recommended languages changes to the definitions at the end of the section.

Comments

A. FDA's Subpart E is woefully inadequate and must be significantly rewritten to establish a clear and fair process for withdrawing a facility's qualified exemption.

In the proposed Preventive Controls Rule, FDA establishes a process for the withdrawal of an exemption applicable to a qualified facility in Subpart E. In Subpart E, FDA sets forth two circumstances under which an exemption may be withdraw: "in the event of an active investigation of a foodborne illness that is directly linked to the qualified facility; or [i]f FDA determines that it is necessary to protect the public health and prevent or mitigate a foodborne illness outbreak based on conduct or conditions associated with the qualified facility that are material to the safety of the food manufactured, processed, packed, or held at such facility."[124] Subpart E then describes the procedure to withdraw an exemption, including the issuance of an order to withdraw, the information that must be contained in the order, the actions that a facility operator must take if he or she receives an order, the option to appeal an order, and the appeals process. Subpart E includes circumstances under which an order to withdraw can be revoked. If a facility's exemption is withdrawn, the facility is required to come into compliance with all of the requirements of the Preventive Controls Rule.

In the proposed Preventive Controls Rule, FDA tentatively concludes that "it is appropriate to be transparent about the process we would use to withdraw an exemption and that we should include the process in the proposed rule."[125] While we support FDA's tentative conclusion to be transparent about the process for withdrawing an exemption, there are significant problems with proposed Subpart E, and significant changes are needed to the process to ensure that it supports the flexible regulatory framework set forth in FSMA, and that it is clear and fair for qualified facilities.

Proposed Subpart E is woefully inadequate and must be significantly revised. As it is currently proposed, Subpart E fails to satisfy Congressional intent, is extraordinarily vague, is silent on a number of important issues, and does not provide adequate protections for facility operators from

[124] § 117.251

[125] 78 Fed. Reg. at 3775

false accusations and unfounded allegations. Subpart E places the burden on the qualified facility to be familiar with the details of the preventive controls regulations, to recognize the opportunity for an appeal of an adverse action, and to provide a higher level of information and detail than FDA requires of itself in making an initial withdrawal determination. In sum, Subpart E fails to establish a fair and clear process for withdrawing a qualified facility's exempt status.

Although FSMA stipulates that qualified facilities eligible for the exemption may suffer the withdrawal of that exemption under certain circumstances, Congress provided that stipulation in the context of FSMA's comprehensive rejection of a "one-size-fits-all" approach to food safety. The modified requirements for qualified facilities are a core aspect of the flexible, scale- and supply-chain appropriate framework that Congress set forth in FSMA, and because the inappropriate denial of those protections to any individual business or class of businesses would undermine that framework, FDA's withdrawal process must avoid such inappropriate denials to the fullest extent possible.

Failure to establish a clear and fair withdrawal process would seriously weaken the exemptions for qualified facilities, and likely lead to the collapse of the flexible, scale-appropriate framework Congress intended. Congress was clear in FSMA that qualified facilities eligible for an exemption would only have to implement modified requirements and would be exempt from the majority of the Preventive Controls Rule's preventive controls requirements. FDA estimates that the proposed requirements have significant compliance costs for very small, small, and large processors.[126] Withdrawal of a qualified facility's exempt status would subject very small and small processors to unexpectedly high compliance costs that could put them out of business. Making a clear and fair process around the withdrawal of an exemption is critical to a having a robust scale- and supply-chain appropriate regulatory framework.

The importance of the exemptions to the viability of small and very small businesses cannot be stressed enough – for many of these facilities, the costs of adopting and maintaining careful, sustainable practices mean that they run their businesses with very low profit margins. The need for robust procedures at the outset to ensure that an order to withdraw is not used as a tool to intimidate or discourage qualified facility operations is critical. Further, providing strong rehabilitation procedures after FDA initiates an order to withdraw is essential to ensure that a withdrawal of an exemption will not damage these facilities disproportionately to the risk or the actual public harm that might be created by their processing activities.

Finally, several recent incidents in which an unannounced inspection by FDA personnel has left the farmer uninformed as to why s/he was subject to the inspection and fearful for his/her livelihood, also underline the importance of a clear and fair process for withdrawal of an exemption (see Appendix II). It is important to have a fair and clear process so that farmers and facility operators are protected from inspectors who may use the authority to withdraw a qualified facility's exempt status as a way to threaten the operation.

Recommendation: Proposed Subpart E fails to establish a fair and clear process for withdrawing a qualified facility's exempt status and FDA must substantially revise Subpart E in the final Preventive

[126] US Food and Drug Admin. "Analysis of Economic Impacts – Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food." Pages 7-12. http://www.fda.gov/downloads/Food/GuidanceRegulation/FSMA/UCM334116.pdf.

Controls Rule to ensure a flexible, scale- and supply-chain appropriate regulatory framework mandated by FSMA. We provide our detailed recommendations below.

B. FSMA supports a narrow interpretation of the circumstances that would lead to the withdrawal of a qualified facility's exempt status.

In FSMA, Congress stipulated that qualified facilities eligible for an exemption could have the exemption withdrawn "[i]n the event of an active investigation of a foodborne illness outbreak that is directly linked to a qualified facility subject to an exemption under this subsection, or if the Secretary determines that it is necessary to protect the public health and prevent or mitigate a foodborne illness outbreak based on conduct or conditions associated with a qualified facility that are material to the safety of the food manufactured, processed, packed, or held at such facility."[127] This creates two standards with high thresholds that FDA must meet before contemplating the withdrawal of a qualified facility's exempt status: direct linkage and necessity. These high thresholds limit FDA's authority to broadly interpret the option to withdraw a qualified facility's exemption. (See comments on the definitions of these terms in section 1 below.)

Additionally, Congress placed limits on FDA's withdrawal authority by saying that "[n]othing in this subsection shall be construed to expand or limit the inspection authority of the Secretary."[128] This expressed limit on FDA's inspection authority under this subsection further limits the scope of the withdrawal authority.

These limitations support a narrow interpretation of the circumstances that would lead to the withdrawal of a qualified facility's exempt status. While Congress set forth the framework under which a qualified facility's exempt status could be withdrawn, it is FDA's role to implement the framework by establishing a transparent and specific withdrawal process that details the circumstances that could lead to a withdrawal. As currently written, the proposed Preventive Controls Rule fails to clarify the circumstances under which FDA would withdraw a qualified facility's exemption, resulting in the possibility of broad interpretation of the circumstances and abuse of power by FDA over when a qualified facility may lose its exempt status. The proposed Subpart E is extremely vague and appears to give FDA broad authority to withdraw a qualified facility's exemption without adequate evidence of an actual harm or likely severe problem from the facility's practices. To clarify the circumstances that would lead to a withdrawal, FDA should:

1. Define and clarify key terms; and
2. Establish an evidentiary standard for a withdrawal.

We detail our recommendations on these two points below.

1. FDA must define and clarify key terms that lead to a withdrawal.

FDA does not clarify or define a number of the terms used in Subpart E that form the basis for withdrawing a qualified facility's exemption and subjecting those businesses to sudden, costly compliance requirements. FDA should define these terms so that they are clear, consistent with FSMA's science-based mandate, and protect against bias or false allegations. The definitions of

[127] Food, Drug, & Cosmetic Act § 418(l)(3)(A)

[128] Food, Drug, & Cosmetic Act § 418(l)(3)(B)

these terms should reflect the need for the withdrawal to be based on an evidentiary standard discussed in section 2 below. Specifically, these terms are:

a. "Directly linked"

The common usage of the terms "directly linked" also supports a narrow interpretation of when a qualified facility's exemption could be withdrawn. "Directly" is defined as "in a direct manner," "in immediate physical contact," or "in the manner of direct variation."[129] "Linked" is defined as "marked by linkage and especially genetic linkage" or "having or provided with links."[130] The inclusion of "directly" means that an outbreak cannot be merely "linked" to a facility but must be "directly" linked.

For an active investigation of foodborne illness outbreak that may result in a withdrawal proceeding, FDA must establish that the qualified facility is "directly linked" to that foodborne illness outbreak. Given the importance of the terms "directly linked," FDA should very specifically state in the rule that individual facilities and classes of facilities cannot be held accountable for environmental conditions that are not the result of their own processing activities and that are external to them, nor for activities occurring at other farms or facilities. This change is critical to ensure that no qualified facility will have its exemption inappropriately withdrawn due to some broad, general linkage that is not a direct link to an in-facility activity in the control of the facility operator or facility employees.

Additionally, it is consistent with FSMA's science-based mandate to establish an evidence-based definition of direct linkage.

Recommendation: In the final Preventive Controls Rule, FDA should add a definition of "directly linked" in § 117.3 to preclude the possibility that any actions by upstream or downstream actors or any other circumstances outside the control of the facility operator or facility employees – unrelated to the actual conduct and practices of the subject facility – will result in a change to that qualified facility's exempt status. There should be concrete and specific evidence required to establish a direct link between a foodborne illness outbreak and a facility. Specifically, FDA should define "directly linked" as:

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

FDA should also provide clarification through guidance for public comment of how an outbreak may be "directly linked" to a qualified facility and provide specific examples of direct linkage to an outbreak. In that guidance, FDA should clarify that individual facilities and classes of facilities cannot be held accountable for environmental conditions that are not the result of their own processing activities and that are external to them, nor for activities occurring at other facilities, and that those environmental conditions or activities at other farms or facilities cannot form the basis for the withdrawal of a qualified facility's exemption. In that guidance, FDA should provide a concrete list with examples of situations in which a facility may be directly linked to an outbreak. The list

[129] Merriam-Webster Online Dictionary: http://www.merriam-webster.com/dictionary/directly. Accessed 10/29/13.

[130] Merriam-Webster Online Dictionary: http://www.merriam-webster.com/dictionary/linked. Accessed 10/29/13.

need not be exhaustive, but it would give facility operators information about what types of direct situations would trigger a withdrawal process from FDA based on direct linkage to an outbreak.

b. "Necessary"

FDA may also withdraw an exemption if it determines that it is "necessary" to protect the public health and prevent or mitigate an outbreak based on certain conditions. Given the importance of the term "necessary," FDA should provide a definition in § 117.3. The concept of "necessary" is commonly associated with being inescapable or required.[131] In the context of the withdrawal, the latter fits more appropriately. Additionally, it is keeping with FSMA's science-based mandate to establish an evidence-based definition of necessity.

Recommendation: In the final Preventive Controls Rule, FDA should add a definition of "necessary" in § 117.3 that incorporates the need for an evidence-based determination. Specifically, FDA should define "necessary" as:

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

FDA should also provide clarification through guidance for public comment of the scope of what FDA considers "necessary" to protect the public health and prevent or mitigate a foodborne illness outbreak, and provide specific examples. In that guidance, FDA should clarify that necessity is a high standard that must be established through evidence within a specific facility. In that guidance, FDA should provide a concrete list with examples of situations that would lead to the withdrawal of an exemption based on it being necessary to protect public health or prevent or mitigate an outbreak. The list need not be exhaustive, but it would give facility operators information about what types of circumstances would trigger a withdrawal process from FDA based on it being necessary to protect the public health and prevent or mitigate a foodborne illness outbreak.

c. "Associated"

Another term that is important in determining whether a qualified facility meets the threshold for having its exempt status withdrawn under proposed § 117.251(b) is "associated." The broadly understood definitions of the verb "associate" include "to join or connect together" and incorporates the concept of combining.[132] Given the potentially broad interpretation of the term "associated," FDA should define and adopt more precise language in particular to ensure that upstream or downstream actors or any other circumstances outside the control of the facility operator or facility employees – unrelated to the actual conduct and practices of the facility in question – cannot endanger that qualified facility's exempt status.

FDA should also clarify that merely because a particular product, or a product from a particular production region, has been a vehicle for outbreak before does not establish an association sufficient to justify the withdrawal of any individual qualified facility's exemptions.

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[131] Merriam-Webster Online Dictionary: http://www.merriam-webster.com/dictionary/necessary. Accessed 10/29/13.

[132] Merriam-Webster Online Dictionary: http://www.merriam-webster.com/dictionary/associated. Accessed 10/29/13.

Recommendation: In the final Preventive Controls Rule, FDA should add a definition of "associated" in § 117.3 to prevent possible broad misinterpretation of the term "associated" to encompass undocumented linkages between qualified facilities and food safety problems. Specifically, FDA should define "associated" as:

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

FDA should also provide clarification through guidance for public comment that actions by upstream or downstream parties who are unrelated to the actual conduct and practices of the facility in question cannot be the basis for establishing an association between a qualified facility and a safety concern that would jeopardize a qualified facility's exempt status. In that guidance, FDA should clarify that associated conduct or conditions that are material to the safety of food do not apply to conduct and conditions of food production practiced by a whole class of persons, types of operations, or broad categories of food production.

d. "Material to the safety of food"

Since FDA can initiate a withdrawal proceeding solely on the basis of "conduct or conditions associated with the qualified facility that are material to the safety of the food," it is important for FDA to provide a definition of what a "material" condition is. The term "material" does not clarify what degree of connection must exist between the challenged conduct and potential food safety risks, and could be broadly interpreted.

"Materiality" is not a concept that FDA often uses in other rules and regulations, and when it is used, it is not defined.[133] Outside of FDA, there is no other federal evidentiary standard in which such a broad concept of "materiality" triggers a comparably serious administrative process. When the concept of "materiality" is invoked, it is often accompanied by illustrative examples that limit, even if by implication or inference, the kinds of conditions that qualify.[134]

In the preamble to the proposed Preventive Controls Rule, FDA suggests initial limiting bounds to the concept of "materiality" and provides two examples of when it might consider withdrawing the exemption. First, there is a case where FDA "receive[s] reports to the Reportable Food Registry under section 417 of the FD&C Act about contamination of a food, and the reports may lead us to investigate a qualified facility that manufactured, processed, packed, or held the food…[and] our investigation finds conduct or conditions associated with the facility that are material to the safety of the food (for example, conduct or conditions that likely led to the contamination of the food)."[135]

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[133] 21 C.F.R. § 17.17 (in the context of civil money penalties hearings: "[t]he presiding officer shall grant the motion if the pleadings, affidavits, and other material filed in the record, or matters officially noticed, show that there is no genuine issue as to any *material* fact and that the party is entitled to a summary decision as a matter of law." Emphasis added.).

[134] See, e.g., 20 C.F.R. § 416.1450 (listing "books, records, correspondence, papers, or other documents that are material to an issue at hearing" when describing scope of admissible evidence in a Social Security Administration hearing); see also 17 C.F.R. § 229.401 (in the context of commodity and securities exchanges, regulating the disclosure of information "material to" the ability or integrity of corporate directors and providing three distinct categories of legal proceedings of particular interest).

[135] 78 Fed. Reg. at 3776

Second, there is the case where "during a routine inspection of a qualified facility, we discover conditions and practices that are likely to lead to contamination of food that would otherwise be covered produce with microorganisms of public health significance."[136]

Both of these examples necessarily accept that the action to withdraw exemption would be based on actual, documented conduct and conditions in the facility. It clearly would violate FSMA's well-considered, flexible, scale- and supply-chain appropriate framework, set forth by Congress, to assert that conduct or conditions on a facility would negatively affect public health absent a specific finding of significant risk arising from that facility's conduct or conditions.

Both of the preamble's examples provide a very limited clarification of the evidentiary concept of "materiality." In both cases, FDA discovers conditions or practices that are "likely" to lead to "contamination." While insufficient for providing regulatory certainty for qualified facilities, a standard built around "likeliness" at least incorporates a probabilistic element, whereas the current proposed language implies that even an unlikely risk may be "material" to safety. Moreover, in other provisions of FD&CA FDA incorporates the probabilistic element through a "reasonable probability" requirement.[137] A standard built around connection to contamination also provides additional, although insufficient, clarity for facilities.

The common usage definition of the term "material" includes "having real importance or great consequences" and emphasizes a relational aspect.[138]

It is critical that FDA define and clarify the concept of materiality in the Preventive Controls Rule to establish a fair and clear process around the withdrawal of a qualified facility's exemption as part of a flexible, scale- and supply-chain appropriate regulatory framework.

Recommendations: In the final Preventive Controls Rule, FDA should add a definition of "material to the safety of food" in § 117.3 to preclude a broad interpretation of the concept of materiality. Specifically, FDA should define "material to the safety of food" as:

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

FDA should also clarify the meaning of "material to the safety of food" with additional language in § 117.251(b). This language should, at a minimum, set a baseline probability threshold so that not every conceivable risk to safety will be "material" enough to trigger a withdrawal. Specifically, FDA should modify the language in § 117.251(b) so that it specifies that conduct or conditions are material to the safety of food when there is a reasonable probability that they will contribute to an

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[136] 78 Fed. Reg. at 3776

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

[138] Merriam-Webster Online Dictionary: http://www.merriam-webster.com/dictionary/material. Accessed 10/29/13.

outbreak of foodborne illness. We provide our specific recommendations to changes needed to the language of Subpart E in section D below.

Finally, FDA should develop guidance for public comment on conduct or conditions that are material to the safety of food. In that guidance, FDA should clarify that conduct or conditions that are material to the safety of food do not apply to conduct and conditions of food production practiced by a whole class of persons, types of operations, or broad categories of food production. In that guidance, FDA should provide a concrete list with examples of conduct or conditions material to the safety of food that are likely to cause contamination. The list need not be exhaustive, but it would give facility operators information about what types of activities would trigger a withdrawal process from FDA based on conduct or conditions material to the safety of food.[139]

2. FDA must establish an evidentiary standard for a withdrawal.

In the proposed Preventive Controls Rule, FDA does not require there to be evidence to support an order to withdraw an exemption, aside from the "brief, general statement of the reasons for the order."[140] The introduction of a "credible evidence" standard would avoid arbitrary and capricious withdrawal action by requiring FDA personnel and agents to meet an explicit evidentiary threshold when finding that conduct or conditions exist on a qualified facility sufficient to trigger the exemption withdrawal procedures. Additionally, requiring an evidentiary standard for withdrawal would be consistent with FSMA's overall mandate to adopt a science-based approach in food safety regulation.

Currently, the mere requirement that the triggering conditions be associated with the qualified facility means that FDA could embark on the exemption withdrawal process based on nothing more than hearsay or an anonymous tip, so long as these sources allege the necessary material risk to safety. Requiring credible and substantial evidence would likely improve transparency and exclude the most egregious cases of false/anonymous allegations or arbitrary enforcement by FDA.

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[139] The FD&CA's provisions on adulteration and misbranding may provide some guidance for FDA in determining how to define or illustrate the types of situations FDA would consider to be conduct or conditions material to the safety of food for the purposes of withdrawing an exemption. Under the FD&CA, it is a violation of the Act if a food is adulterated or misbranded (21 U.S.C. § 331). Two sections within the FD&CA list situations in which food could be considered adulterated or misbranded. For example, a food can be considered adulterated if it contains poisonous, insanitary, etc., ingredients; if other food components have been removed, substituted, or added; if it contains color additives; if it is a confectionary containing alcohol or another nonnutritive substance; and if it is oleomargarine containing filthy, putrid, etc., matter (21 U.S.C. § 342).

The situations under which a food could be considered misbranded are even more precise; a food could be considered misbranded if it has a false or misleading label; if it is offered for sale under another name; if it is an imitation of another food; if it is in a misleading container; if the nutritional information does not meet federal labeling guidelines; if there are pesticide chemicals on raw agricultural commodities; if the food contains color additives; and, if the food fails to label a potential health threat, among other reasons (21 U.S.C. § 343).

Under each of these categories, the FD&CA provides an explanation as to how the food would become adulterated or misbranded. FDA may want to use this model to provide examples that would illustrate the kinds of conditions that could trigger a withdrawal of an exemption.

[140] § 117.257(c)

At the same time, the credible evidence standard would not deprive FDA of the discretion that it needs to make enforcement decisions on the ground.

Recommendation: In the final Preventive Controls Rule, FDA should increase the evidentiary standard for withdrawing a qualified facility's exemption, including evidence that shows direct linkage to a problem on a specific facility, and should require the FDA officer recommending the withdrawal order to show credible and substantial evidence that merits an order to withdraw. Specifically, FDA should modify the language in § 117.251(b) so that it specifies that the determination must be supported by credible and substantial evidence related to an individual facility, and never to a group or class of facilities. We provide our specific recommendations to changes needed to the language of Subpart E in section D below.

C. FDA must establish a withdrawal process that is consistent with other FDA procedures and the principles of FSMA.

When either of the triggering circumstances is found, FDA is proposing withdrawal as the *only* remedy. There are many circumstances in which the complete withdrawal of a qualified facility's exemption is not needed to prevent or mitigate a foodborne illness. Other, less drastic, more targeted measures may suffice to address the problem. This would be especially true if the observed deficiency is amenable to an easy, tailored, technical solution.

The existence of intermediary remedies would have the benefit of giving FDA inspectors the ability to scale desired remedies according to the actual severity of the food safety concern. Indeed, it may be that having only one remedy in its arsenal will actually chill FDA's ability to respond effectively to emergent food safety concerns because inspectors may not want to invest the time and effort it takes to go through the exemption withdrawal process when the problem at hand is relatively minor.

An intermediary step would also help to protect qualified facilities that are initially thought to be directly linked to an outbreak but are then found not to be after further investigation. Facts can change in the process of an active investigation, and as more information becomes available FDA may find that a facility that was initially thought to be directly linked to an outbreak no longer is because a different product or contamination pathway is implicated. Without protection from false allegations in the case of active investigations of foodborne illness, FDA must not go directly to the withdrawal order option, even for facilities that may be "directly linked" to an active investigation.

We make recommendations below for the establishment of a three-tiered process:

1. Use of a warning letter;
2. Temporary conditional withdrawal; and
3. Full withdrawal.

This three-tiered process would be consistent with the FSMA principles to establish a flexible, scale- and supply-chain appropriate framework based on prevention. As discussed above, the exemptions for qualified facilities are a core component of the scale- and supply-chain appropriate framework established by FSMA, and a withdrawal process that requires full compliance with the Preventive Controls Rule could be devastating for qualified facilities. A three-tiered approach would keep that flexibility while also addressing the identified problem.

A prevention-oriented model would also engage directly with the facility in question, offer technical assistance on how to improve food safety practices, and allow the facility to take corrective actions based on the assistance before having its exempt status fully withdrawn.

1. FDA must first issue a warning letter to a qualified facility before resorting to exemption withdrawal proceedings.

FDA already has some precedent for using modified consequences for minor violations. Under the prohibited acts and penalties subchapter in the FD&CA, the Secretary is not required "to report for prosecution . . . minor violations of this chapter whenever he believes that the public interest will be adequately served by a suitable written notice or warning."[141] This authority allows FDA to consider other courses of action before issuing a withdrawal order, such as warning letters.

Once an initial order for a withdrawal determination has been made, FDA should first issue a warning letter. On the FDA website, FDA writes that "[w]hen FDA finds that a manufacturer has significantly violated FDA regulations, FDA notifies the manufacturer. This notification is often in the form of a Warning Letter."[142] Because FDA already uses warning letters for facilities to remedy violations,[143] there seems to be no reason why warning letters could not be used in the context of qualified facilities. Warning letters could be used so that minor, easily-fixed conduct or conditions can be remedied by the affected actor without triggering the compliance or appeals process, which may be quite burdensome to small and very small businesses that must scramble to gather documentation that they were not required to keep. Generally, warning letters provide fifteen days for the affected business to reply with a plan for remedying the violations.

Recommendation: In the final Preventive Controls Rule, FDA should be required to first issue a warning letter to a qualified facility before resorting to exemption withdrawal proceedings. In the warning letter, FDA should identify the conduct or conditions in question, or how FDA believes the facility is directly linked to an active investigation of a foodborne illness outbreak, and outline how the facility can remedy the situation. FDA should give the facility 15 calendar days to identify how it will remedy the issue before issuing an order to withdraw the qualified exemption. Specifically, FDA should add a new § 117.254 that addresses what actions FDA must take before issuing an order to withdraw an exemption. The new § 117.254 should specify that before issuing an order to withdraw the exemption, FDA must first issue a warning letter to the owner, operator, or agent in charge of the facility that:

1. Identifies the material conduct or conditions in question or how the facility is directly linked to an active investigation of a foodborne illness outbreak;
2. Includes information for how the facility can remedy the situation; and

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[141] 21 U.S.C. § 336 (2013)

[142] U.S. Food and Drug Admin. *Warning Letters.*
http://www.fda.gov/Food/ComplianceEnforcement/WarningLetters/default.htm (last visited Apr. 8, 2013).

[143] U.S. Food and Drug Admin. *Inspections, Compliance, Enforcement and Criminal Investigations.*
http://www.fda.gov/iceci/enforcementactions/warningletters/default.htm; see, e.g., "Warning Letter to Culpeper Farmers' Cooperative, Inc." (May 17, 2011) at
http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2011/ucm256682.htm; "Warning Letter to Pacific Cheese Company, Inc." (Aug. 1, 2011)
http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2011/ucm288527.htm.

3. Notifies the facility that it has 15 calendar days from receipt of the warning letter to respond with a plan for remedying the problem within a suitable timeframe before an order to withdraw an exemption may be issued.

We provide our specific recommendations to changes needed to the language of Subpart E in section D below.

2. FDA must issue a temporary conditional withdrawal before resorting to full withdrawal proceedings.

If the warning letter process is not sufficient to remedy the problem, FDA should issue a temporary conditional withdrawal before resorting to full withdrawal proceedings. As with the proposed warning letter option, in the temporary conditional withdrawal FDA should identify the conduct or conditions in question, or how FDA believes the qualified facility is directly linked to an active investigation of a foodborne illness outbreak, and outline how the facility can remedy the situation.

This option would last six months and allow the facility operator to address the problem in that timeframe. The temporary conditional withdrawal would automatically expire in six months, unless it was renewed by FDA for no more than one more automatically expiring six-month period.

This option should also be targeted to the particular issue or issues in the facility that are directly linked to an outbreak investigation or are material to the safety of the food, and should not encompass other practices or activities on a facility. This type of targeted approach could be tailored to the facility's directly linked issues or to the conduct/conditions associated with the facility. This way, small businesses can seek targeted solutions as needed without falling under all the substantive, costly provisions of the Preventive Controls Rule, which could prove ruinous.

Having an intermediary step before a full withdrawal would also allow facility operators to receive technical assistance and remedy the problem. This option is especially important for facility operators relatively new to food production and marketing.

Recommendation: In the final Preventive Controls Rule, a provision should be added to the effect that if FDA finds that a warning letter is not sufficient to remedy a problem, FDA would issue a temporary conditional withdrawal that includes information about the conduct or conditions in question, or how FDA believes the facility is directly linked to an active investigation of a foodborne illness outbreak, and outline how the facility can remedy the situation. The temporary conditional withdrawal should expire in six months unless renewed by FDA for one more six-month period, and it should be targeted to a particular issue within a facility. FDA should also provide technical assistance to the facility operator. FDA should specify this in the new section § 117.254 that identifies the actions that FDA should take before issuing an order to withdraw an exemption. We provide our specific recommendations to changes needed to the language of Subpart E in section D below.

3. If, after issuing a warning letter and a temporary conditional withdrawal, FDA determines that a full withdrawal is necessary, a number of changes are needed to make the process fair and transparent.

If, after issuing a warning letter and a temporary conditional withdrawal, the problem persists, FDA

may resort to a full withdrawal proceeding. However, a number of changes are needed to the proposed process to ensure that it is fair and transparent:

a. FDA should set a timeframe within which the initial determination, the approval or denial by the FDA District Director, and the issuance of the withdrawal order take place.

In the proposed Preventive Controls Rule, FDA does not set a deadline after the initial determination before which the FDA District Director must approve or deny the order. Without a deadline, the FDA officer that makes the initial determination to issue a withdrawal order could wait an indeterminate amount of time before submitting the withdrawal order to the FDA District Director. Additionally, FDA does not specify how much time the FDA District Director can take after receiving an order to withdraw and before approving or denying the order and issuing it to the qualified facility. Because conditions in a facility might change quite quickly, FDA should have to comply with a reasonably short timeframe between the initial determination and issuing the order to withdraw.

Recommendation: In the final Preventive Controls Rule, FDA must specify a timeframe for the initial determination, the approval or denial by the FDA District Director, and the issuance of the withdrawal order. Specifically, FDA should:

1. Specify that the officer or qualified employee of FDA issuing an order to withdraw must submit the order to withdraw to the FDA District Director or official senior to such Director within ten calendar days of making that determination;
2. Specify that if a full withdrawal is necessary, that the FDA District Director (or other FDA official specified in the subsection) must approve or deny the order to withdraw within ten calendar days of making that determination;
3. Specify that, once the order to withdraw has been submitted, if action is not taken by the District Director (or other FDA official specified in the subsection) within ten calendar days, that the order to withdraw is revoked; and
4. Specify that if the District Director (or other FDA official specified in the subsection) approves the order to withdraw, that the order must be delivered to the owner, operator, or agent in charge of the qualified facility within five calendar days after the FDA District Director or official senior to such Director makes the determination to approve the order to withdraw.

We provide our specific recommendations to changes needed to the language of Subpart E in section D below.

b. FDA should send the order to withdraw through certified mail with confirmation of delivery to ensure the facility operator receives the order.

Given the important information contained with an order to withdraw and the potential significant impact of the order to withdraw on a facility's business, FDA should ensure that there is confirmation of delivery and receipt of the notice letter, such as through certified mail.

Recommendation: In the final Preventive Controls Rule, FDA must require confirmation of the

delivery and receipt of an order to withdraw by the qualified facility in question, such as through certified mail. Specifically, FDA should specify that the order to withdraw the exemption must be delivered to the owner, operator, or agent in charge of the qualified facility in a manner by which the delivery and receipt of the order can be confirmed. We provide our specific recommendations to changes needed to the language of Subpart E in section D below.

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

In order to increase the standard of proof that FDA must show before issuing an order to withdraw, FDA should modify the language in proposed § 117.257. Currently in proposed Subpart E, an order to withdraw a qualified exemption must include, in relevant part, the following information:

> (c) A brief, general statement of the reasons for the order, including information relevant to:
>
> > (1) An active investigation of a foodborne illness outbreak that is directly linked to the 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[144]

The language of proposed § 117.257(c)(2) does not match the language in proposed § 117.251(b) (setting forth the circumstances under which an order to withdraw may be issued); specifically, there is no language about the withdrawal being necessary to protect the public health or prevent or mitigate a foodborne illness outbreak. Including that additional statutory language is important because it links the "material conditions" with a public health outcome.

Including specific evidence in the withdrawal order about the problem that caused the order to withdraw will help the facility operator meet the requirements of proposed § 117.264(a)(2) in the procedure for submitting an appeal, which include "[r]espond[ing] with particularity to the facts and issues contained in the order, including any supporting documentation upon which the owner, operator or agent in charge of the facility relies." Without more specific information required in the withdrawal order, it is unreasonable to expect that a facility operator could respond adequately to the information that FDA is proposing to require during the submission of an appeal.

Additionally, it is important to include the evidence used to either directly link a facility to an active investigation of a foodborne illness outbreak or evidence of conduct or conditions material to the safety of food to help ensure against false allegations or unfounded accusations.

Recommendation: In the final Preventive Controls Rule, FDA must modify in the language in proposed § 117.257(c) (new § 112.260(c)) so that the brief, general statement of the reasons for the order include:

1. Whether the order is based on 117.251(a) or 117.251(b);
2. The evidence on which the order is based;

[144] § 117.257

3. If the order is based on 117.251(a), evidence linking the active investigation of a foodborne illness outbreak directly to the facility;
4. If the order is based on 117.251(b), measurable evidence that has been collected using generally accepted scientific standards indicating the presence of pathogens within the facility that pose an imminent threat to public health, conduct or conditions that are material to the safety of food, and a statement explaining how altering the conduct or conditions would prevent or mitigate a foodborne illness outbreak.

We provide our specific recommendations to changes needed to the language of Subpart E in section D below.

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

In proposed § 117.257, FDA does not explicitly state that the qualified facility has the option to request an informal hearing, and limits the information about the opportunity for an informal hearing included in the withdrawal to 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."[145] Without an explicit statement of a qualified facility's options, the order to withdraw is confusing and unclear about what a qualified facility's options are in the event of a withdrawal. Similarly, the timeframe for appealing the order and requesting an informal hearing is not currently included in the information required in a withdrawal order. This information should also be included in the withdrawal order.

Recommendation: In the final Preventive Controls Rule, FDA must specify in proposed § 117.257 (new § 117.260) that an order to withdraw a qualified facility's exemption must include a statement that the owner, operator, or agent in charge of the facility that receives the order must either comply with the requirements of this part or appeal the order, which includes a request for an informal hearing, within 10 calendar days. We provide our specific recommendations to changes needed to the language of Subpart E in section D below.

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

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

Recommendation: In the final Preventive Controls Rule, FDA should authorize the use of a partial withdrawal and modify proposed § 117.257 (new § 117.260) to include a statement that indicates whether the withdrawal order is for a partial or total withdrawal. If the withdrawal is partial, FDA

[145] § 117.257(f)

should indicate which sections of the rule the facility must comply with. We provide our specific recommendations to changes needed to the language of Subpart E in section D below.

f. FDA should specify that a facility operator's timeframe for taking action begins once the order is received, not when the order is issued.

In the withdrawal proceedings, FDA is proposing to have the clock start ticking in the proposed timeframes based on the date of the order, not on when the order is received. For example, FDA is proposing to require a facility operator receiving the order to "[a]ppeal the order within 10 calendar days of the date of the order."[146] Given that proposed Subpart E is silent on how the order is communicated to the qualified facility in question, it is entirely possible that the facility would receive the order more than ten days after the date of the order. We provide comment above about the need for confirmation of delivery and receipt of the order, but even in the case where FDA specifies that there must be confirmation of order delivery and receipt, it is still possible that a facility would receive the order after the ten-day timeframe, especially if the facility is located in a remote area. A far more reasonable approach would be to start a facility's timeframe for taking action once the order has been received.

Recommendation: In the final Preventive Controls Rule, throughout Subpart E as appropriate, FDA must specify the owner, operator, or agent of the facility receiving an order to withdraw must take certain actions from the date that the order *was received* by the owner, operator, or agent of the facility in question. We provide our specific recommendations to changes needed to the language of Subpart E in section D below.

g. FDA should align the timeframe for compliance with the requirements of the Preventive Controls Rule in a withdrawal order with the longer timeframes for compliance in FSMA for small and very small businesses.

As part of a flexible, scale-appropriate framework, in FSMA Congress established longer compliance timeframes for small and very small businesses. Specifically, FSMA stipulated that small businesses had six months after the effective date of the final regulation to come into compliance with the Preventive Controls Rule, and that very small businesses had eighteen months.[147] Congress established these longer timeframes in recognition of the particular regulatory burden the new regulations would have on small and very small businesses.

In the proposed Preventive Controls Rule, FDA defines a very small business based on an annual sales threshold of $250,000, $500,000, or $1,000,000, and a small business as one that employs fewer than 500 people. Depending on how FDA chooses to define a very small business, a qualified facility could necessarily fall under that definition; moreover, even if FDA adopts the lowest threshold for very small business, a qualified facility would almost certainly have fewer than 500 employees and therefore qualify as a small business.

In proposed Subpart E, FDA proposes to require a facility that receives an order to withdraw to comply with the full requirements of the Preventive Controls Rule within 60 calendar days.[148] This

[146] § 117.260(a)(2)

[147] Food Safety Modernizations Act § 103(i)(2)

[148] § 117.260(a)(1)

timeframe is inconsistent with the timeframes established in FSMA for the compliance of small and very small businesses with the final regulations. Given that the situations are parallel, and that a qualified facility that has had its exemption withdrawn would be coming into compliance with the full Preventive Controls Rule for the first time, FDA should change the timeframes in Subpart E so that they align with the timeframes in FSMA for compliance with very small and small businesses.

Recommendation: In the final Preventive Controls Rule, FDA should align the timeframes for compliance with the Preventive Controls Rule in proposed §§ 117.257(d) and 117.260(a)(1) (new §§ 117.260(e) and 117.264(a)(1)) with the timeframes in FSMA for compliance with the final regulations for small and very small businesses. Specifically, the timeframe for compliance for very small businesses should be eighteen months, and for small businesses should be six months. We provide our specific recommendations to changes needed to the language of Subpart E in section D below.

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

For qualified facility's filing a written appeal from an order to withdraw an exemption, FDA proposes to require them to "[r]espond with particularity to the facts and issues contained in the order, including any supporting documentation upon which the owner, operator or agent in charge of the facility relies."[149] Given that qualified facilities are required to submit certain documentation to FDA and keep certain records supporting that documentation, FDA should not require, for purposes of a qualified facility's appeal of a withdrawal order, records that those facilities do not have to keep to support the documentation that they must submit to FDA.

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

Recommendation: FDA should not require facility operators submitting a written appeal to provide documents and records that they are not required to keep. FDA should provide in guidance for public comment additional information about the types of documentation upon which FDA will rely and the standard of review that will be applied to the records during the appeal. FDA should provide examples in guidance of situations in which an informal hearing would be granted and situations in which a hearing would be denied because the presiding officer determines that there is no "genuine and substantial issue of material fact" raised in the submitted materials.[150]

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

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[149] § 117.264(a)(2)

[150] The request for 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." 78 Fed. Reg. at 3645 (Sub. R § 112.207(b)). The officer must provide notice, "explaining the reason for the denial." 78 Fed. Reg. at 3645.

In the proposed Preventive Controls Rule, it is not clear which standards and science-based justifications FDA will use when making the final decision to approve or deny an order withdrawing an exemption.[151] Ideally, FDA would create a centralized compilation of such sources, to which appealing businesses could refer in preparing their appeals and documentation for the hearing. This set of resources also provides context for the standards of review to which a final decision may be subject.

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

j. FDA should add a new section that allows qualified facilities to regain their exempt status after correcting a problem, and outlines the criteria for such a course of action.

In the proposed Preventive Controls Rule, FDA is completely silent on the issue of how a qualified facility that has had its exemption withdrawn can regain its status as a qualified facility. As with any rehabilitation effort, there should be a "clearly identified process for farms or food processing businesses that lose an exemption to gain it back, or have it extend through several stages before anything would become permanent."[152] FDA has a history of providing opportunities for facilities to fix a problem identified by FDA prior to suspending a facility's registration or starting an enforcement action under the FD&CA (e.g., using warning letters). FDA should provide the same opportunities to qualified facilities to fix the problems leading to the order to withdraw the exemption.

In developing a process to reinstate a qualified facility's exemption, FDA can look to a model used for facilities that have lost a similar type of certification, called registration, which is found in § 415 of the FD&CA (Registration of Food Facilities).[153] Similar to the proposed Preventive Controls Rule, under the statute the Secretary may suspend the registration of a facility "if the Secretary determines that a food manufactured, processed, packed, received, or held by a facility registered under this section has a reasonable probability of causing serious adverse health consequences or death.[154] Under § 415, if a facility has its registration suspended, FDA "shall" provide an opportunity for an informal hearing to discuss what actions are required for reinstatement of the registration.[155] Further, "[t]he Secretary shall reinstate a registration if the Secretary determines, based on evidence presented, that adequate grounds do not exist to continue the suspension of the registration."[156] After the hearing on the suspension, if FDA determines that the registration should be reinstated, the registrant is required to submit a "corrective action plan" that outlines how the

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[151] A final decision to affirm or deny the withdrawal is due by the tenth calendar day after the appeal is filed, or ten calendar days from a hearing (if granted), or the decision defaults to a denial (i.e. the order to withdraw lapses, and the exemption is preserved). § 117.280(a–c)

[152] Brian Snyder of the Pennsylvania Association for Sustainable Agriculture (PASA), Comments at FDA Public Meeting in Washington, D.C., 28 February 2013.

[153] Federal Food, Drug, & Cosmetic Act § 415, 21 U.S.C. § 350d (2013)

[154] 21 U.S.C. § 350d(b)(1) (2013)

[155] 21 U.S.C. § 350d(b)(2) (2013)

[156] 21 U.S.C. § 350d(b)(2) (2013)

registrant is going to fix the problem that led to the suspension.[157] 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.[158]

The process for reinstating a facility's registration can be applied in the context of a qualified facility regaining its exemption; in both cases, FDA has reason to believe the food produced in such a facility may cause some significant harm. If FDA makes such a finding, it has the authority to withdraw a facility's registration.[159] If a facility's registration is suspended, that facility is not permitted to introduce food from that facility into commerce.[160] Under the proposed Preventive Controls Rule, if a qualified facility is directly linked to a foodborne illness outbreak or FDA finds conduct or conditions associated with the facility that are material to the safety of the food and merit action to prevent or mitigate a foodborne illness outbreak, that facility can have its exemption withdrawn. If an exemption is withdrawn, the facility becomes subject to the full requirements of the proposed Preventive Controls Rule. Given the history and likelihood of foodborne illness investigations that erroneously attribute the cause of outbreaks to certain operations and products, only to later identify a different source as having been the actual cause, it would be an arbitrary and capricious agency action to not reinstate a qualified facility's exemption when the ultimate conclusion of an investigation establishes that that facility was not in fact responsible for the investigated outbreak.

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

Recommendations: In the final Preventive Controls Rule, FDA must provide for a process to regain a qualified facility's exempt status like the process used to reinstate a facility's registration. FDA should add a new § 117.290 that details how a qualified facility can regain its exempt status. Specifically, FDA should:

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

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[157] 21 U.S.C. § 350d(b)(3)(A) (2013)

[158] 21 U.S.C. § 350d(b)(3)(B) (2013)

[159] 21 U.S.C. § 350d(b)(1) (2013)

[160] 21 U.S.C. § 350d(b)(4) (2013). "If the registration of a facility is suspended under this subsection, no person shall import or export food into the United States from such a facility, offer to import or export food into the United States from such a facility, or otherwise introduce food from such a facility into interstate or intrastate commerce in the United States." 21 U.S.C. § 350d(b)(4) (2013)

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

We provide our specific recommendations to changes needed to the language of Subpart E in section D below.

k. FDA cannot remove the option to file a motion for reconsideration or stay.

In proposed Subpart E, FDA eliminates the option for a party to "petition the Commissioner of Food and Drugs for reconsideration or a stay of the presiding officer's final decision."[161] In justifying this decision, FDA states that the circumstances that would lead to a withdrawal merit "prompt action" and that a facility has the opportunity for "judicial review in accordance with § 10.45."[162] This is not a sufficient argument for justifying the removal of the option to file a motion for reconsideration or stay.

Exemption for a qualified facility from Subpart C of the Preventive Controls Rule is not in and of itself a condition material to the safety of food; the rules themselves do not convey protection from pathogens. Rather, it is specific conduct or conditions, which may occur in a facility regardless of whether it is a qualified facility or a non-exempt facility operating in compliance with the standards in Subpart C, that give rise to a foodborne illness concern. Staying the decision as to a qualified facility's exempt status therefore would not necessarily prevent "prompt action" to address an actual foodborne illness concern on the subject facility.

There might also be the chance that the lower-level decision does not reflect the overall agency policy on a particular issue, and it is important to retain the option to file a motion for reconsideration or stay. Additionally, the cost of doing so may be less than seeking judicial review, which is important for facility operators that operate on tight margins.

Recommendation: In the final Preventive Controls Rule, FDA must allow the option for a qualified facility to file a motion for reconsideration or stay. Specifically, FDA should amend proposed § 117.270(c)(6) (new § 117.274(c)(6)) to specify that the qualified facility shall have that right. We provide our specific recommendations to changes needed to the language of Subpart E in section D below.

D. Recommended Changes to § 117.3 and to Subpart E—Withdrawal of an Exemption Applicable to a Qualified Facility

We have indicated below the changes that we recommend FDA make directly to Subpart E to incorporate our comments. We indicate proposed new language (<u>underlined</u>) and language to delete (~~struck-through~~).

Recommended Language Changes to §117.3:

[161] § 117.270(c)(6)

[162] 78 Fed. Reg. at 3779

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

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

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

***

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

***

Recommended Language Changes to Subpart E:

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

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

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

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

(b) If FDA determines based on credible and substantial evidence that it is necessary to protect the public health and prevent or mitigate a foodborne illness outbreak based on conduct or conditions associated with the qualified facility that are material to the safety of the food manufactured, processed, packed or held at such facility; conduct or conditions are material to the safety of food when there is a reasonable probability that they will contribute to an outbreak of foodborne illness.

§ 117.254 Actions must FDA take before issuing an order to withdraw an exemption.

Before issuing an order to withdraw an exemption, FDA must first:

(a) Issue a warning letter to the owner, operator, or agent in charge of the qualified facility that:

(1) Identifies:

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

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

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

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

(b) If, after taking the actions in § 117.254(a), FDA determines that the issue persists, FDA shall issue a temporary conditional withdrawal before issuing an order to withdraw under § 117.257.

(1) The temporary conditional withdrawal must identify:

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

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

(iii) Includes information about how the facility can remedy the situation; and

(iv) Notifies the facility that it has 6 months from the receipt of the temporary conditional withdrawal to remedy the issue.

(2) As part of a temporary conditional withdrawal, FDA may:

(i) Target the temporary conditional withdrawal to a particular issue within the facility that needs to be remedied; and

(ii) Provide referrals to sources of technical assistance that may assist the facility in question to remedy the issue, including through training on food safety practices.

(3) The temporary conditional withdrawal expires automatically after 6 months from the date the temporary conditional withdrawal was received.

(4) Once the first 6-month period in § 117.254(b)(3) expires, FDA may renew the temporary conditional withdrawal for one additional period that automatically expires after 6 months.

§ 117.2547 Issuance of an order to withdraw an exemption applicable to a qualified facility.

(a) If, after taking the actions in § 117.254, FDA determines that the issue persists and an exemption applicable to a qualified facility under § 117.5(a) should be withdrawn, any officer or qualified employee of FDA may ~~issue~~ submit an order to withdraw the exemption to the FDA District Director or official senior to such Director within 10 calendar days of making that determination.

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

(c) FDA must issue 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) The order to withdraw the exemption must be delivered to the owner, operator, or agent in charge of the facility within 5 calendar days after the FDA District Director or official senior to such Director makes the determination under § 117.257(c).

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

§ 117.2576 Contents of an order to withdraw an exemption applicable to a qualified facility.

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

(a) The date of the order;

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

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

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

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

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

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

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

(ii) If the order is based on 117.251(b), the order shall:

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

(B) Identify conduct or conditions within the facility that are material to the safety of food; and

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

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

(d) ~~A statement that the facility must comply with subpart C of this part on the date that is 60 calendar days after the date of the order;~~ A statement that the owner, operator, or agent in charge of the facility that receives the order must either comply with the requirements of this part (as specified in subsection (e)) or appeal the order (including the option to request an informal hearing) within 10 calendar days of the date the order was received in accordance with § 117.267.

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

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

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

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

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

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

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

~~(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 § 117.27~~0~~4;

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

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

§ 117.26~~0~~4 Compliance with, or appeal of, an order to withdraw an exemption applicable to a qualified facility.

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

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

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

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

(2) Appeal the order within 10 calendar days of the date ~~of~~ the order was received in accordance with the requirements of § 117.2~~64~~70.

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

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

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

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

§ 112.264~~7~~ Procedure for submitting an appeal.

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

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

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

(b) In a written appeal of the order withdrawing an exemption provided under § 117.5(a), the owner, operator, or agent in charge of the facility may include a written request for an informal hearing as provided in § 117.2~~67~~70.

§ 117.2~~67~~70 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 § 117.26~~4~~7 within 10 calendar days of the date ~~of~~ the order was received.

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

§ 117.27~~0~~4 Requirements applicable to an informal hearing.

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

(a) The hearing will be held within 10 calendar days after the date the appeal is filed or, if applicable, within a timeframe agreed upon in writing by the owner, operator, or agent in charge of the 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 §§ 117.2547 and 117.25760, rather than the notice under § 16.22(a) of this chapter, provides notice of opportunity for a hearing under this section and is part of the administrative record of the regulatory hearing under § 16.80(a) of this chapter.

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

(3) Section 117.2747, rather than § 16.42(a) of this chapter, describes the FDA employees who preside at hearings under this subpart.

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

(5) Section 16.80(a)(4) of this chapter does not apply to a regulatory hearing under this subpart. The presiding officer's report of the hearing and any comments on the report by the hearing participant under § 117.27004(c)(4) are part of the administrative record.

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

(7) If FDA grants a request for an informal hearing on an appeal of an order withdrawing an exemption, the hearing must be conducted as a regulatory hearing under regulation in accordance with part 16 of this chapter, except that § 16.95(b) does not apply to a hearing under this subpart. With respect to a regulatory hearing under this subpart, the administrative record of the hearing specified in §§ 16.80(a)(1), (a)(2), (a)(3), and (a)(5), and § 117.27004(c)(5) constitutes the exclusive record for the presiding officer's final decision. For purposes of judicial review under § 10.45 of this chapter, the record of the administrative proceeding consists of the record of the hearing and the presiding officer's final decision.

§ 117.2747 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.

§ 117.27780 Time frame for issuing a decision on an appeal.

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

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

(1) If FDA grants the request for a hearing and the hearing is held, the presiding officer must provide a 2 calendar day opportunity for the hearing participants to review and submit comments on the report of the hearing under § 117.27~~0~~4(c)(4), and must issue a final decision within 10 calendar days after the hearing is held; or

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

§ 117.28~~0~~4 Revocation of an order to withdraw an exemption applicable to a qualified facility.

An order to withdraw an exemption applicable to a qualified facility under § 117.5(a) is revoked if:

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

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

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

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

§ 117.284~~7~~ Final agency action.

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

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

(a) If, after an order to withdraw an exemption applicable to a qualified facility has been

issued under § 117.251(b) (and confirmed upon appeal, if applicable) and the date by which the facility is required to come into compliance with the provisions of this part has not passed as per § 117.264, the owner, operator, or agent in charge of the facility demonstrates to FDA that the conduct or conditions that triggered the withdrawal order have been sufficiently resolved, FDA shall reinstate the qualified facility's exemption status.

(b) If a facility has had its exemption withdrawn under § 117.251(b) and the date by which the facility is required to come into compliance with the provisions of this part as per § 117.264 has passed, the Secretary shall provide the owner, operator, or agent in charge of the facility an opportunity for an informal hearing, upon request of said owner, operator, or agent, to be held as soon as possible but not later than 10 business days after the request, on the reasons the facility's exemption should be reinstated.

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

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

(c) If, after an order to withdraw an exemption applicable to a qualified facility has been issued under § 117.251(a), FDA concludes the active investigation of a foodborne illness outbreak and FDA finds that the facility in question was not directly linked to the foodborne illness outbreak, the Secretary shall automatically reinstate the qualified facility's exemption and notify the facility of the reinstatement.

X. COMMENTS ON IMPLEMENTATION AND TRAINING

Summary

NSAC makes comments and recommendations on the need for funding for the National Food Safety Training, Education, Extension, Outreach, and Technical Assistance Program authorized in FSMA as part of a prevention-based approach to food safety. We also comment on the need for training of FDA field staff on the diversity of farming systems and the characteristics of farms that make them different from enclosed facilities that are not part of the natural environment.

Comments

A. Food safety training needs to be a central part of the implementation of the FSMA rules.

Recognizing the additional burdens that the new regulations would place on farmers and food facilities, and recognizing the importance of training as part of a food safety system focused on prevention, Congress created a competitive grants program in FSMA – the National Food Safety Training, Education, Extension, Outreach, and Technical Assistance Program – to fund training efforts through USDA's National Institute of Food and Agriculture.[163] FSMA prioritized training through this program for small and mid-sized farms, beginning farmers, socially disadvantaged farmers, small processors, and small fresh fruit and vegetable wholesalers. FSMA emphasized that training should integrate food safety standards and guidance with the variety of agricultural production systems, encompassing conventional, sustainable, organic, and conservation and environmental practices. Unfortunately, the Obama Administration has yet to request any funding under this important new authority, and Congress has not appropriated funds to launch the program in the absence of a budget request from USDA or FDA.

If the final regulations are to be successfully implemented, training for farmers and food processing businesses – especially the target groups listed in the paragraph above – is a critical piece that must be addressed. Without adequate training resources available for covered farms and facilities, the regulations will fall well short of the goal of improving food safety.

Recommendation: As FDA moves to finalize the proposed Produce Rule and proposed Preventive Controls Rule, the agency must prioritize working with USDA to get the training program into the Administration's budget request, and prioritize working with farmer-based organizations, such as NSAC, to help secure appropriations for the National Food Safety Training, Education, Extension, Outreach, and Technical Assistance Program.

B. FDA field staff and inspectors must be trained to understand farming systems and accurately and fairly enforce the law.

Just as important as farmer training is training for FDA field personnel, inspectors, and contractors in farming practices. Farmers have shared stories with us about FDA inspections where it was clear that the inspector had never inspected a farm before or was very unfamiliar with farming in general. We include the stories in Appendix II and reference them here to emphasize the importance of

[163] Food Safety Modernization Act § 209(b)

ensuring that field staff who are enforcing the FSMA regulations are appropriately trained and familiar with the diversity of farming systems and the characteristics of farms that make them different from enclosed facilities that are not part of the natural environment.

Lack of training and knowledge about farming systems of field staff will lead to confusion and fear among farmers, which will undermine the success of the law. Many farmers are very concerned and anxious about FDA inspections not because they have doubts about the safety of the food they are producing, but because FDA has the power to devastate their farm and food businesses yet may know little about farming.

Farmers want to produce safe food. FDA wants to ensure safe food. FDA should work collaboratively with farmers to learn about the different types of farming systems and wide range of practices that farmers implement, and to understand what practices help to minimize risks of pathogen contamination of food.

Recommendation: As FDA prepares to implement the regulations, the agency must train its field staff, personnel, and contractors in the diversity of farming systems and wide range of farming practices so that they do not treat farms like industrial facilities. FDA should work collaboratively with farmers to establish field staff training that is reflective of farming realities and works to minimize potential risks of pathogen contamination of food.

XI. APPENDIX I – NSAC COMMENTS SUBMITTED ON FDA'S DRAFT RA IN FEBRUARY 2013

February 15, 2013

Docket No. FDA-2012-N-1258

Submitted electronically via http://www.regulations.gov

Re: Comments on Draft Qualitative Risk Assessment of Risk of Activity/Food Combinations for Activities (Outside the Farm Definition) Conducted in a Facility Co-Located on a Farm

The National Sustainable Agriculture Coalition (NSAC) welcomes this opportunity to comment on the Food and Drug Administration's (FDA) Draft Qualitative Risk Assessment of Risk of Activity/Food Combinations for Activities (Outside of the Farm Definition) Conducted in a Facility Co-Located on a Farm (Draft RA). On behalf of our 40 represented member organizations[164], we provide the following comments on the Draft RA detailing the science-based risk analysis of those activity/food combinations that would be considered low risk, as required by the Food Safety Modernization Act (FSMA).

NSAC is an alliance of grassroots organizations from across the country that advocates for federal policy reform to advance the sustainability of agriculture, food systems, natural resources, and rural communities. Many NSAC member groups work directly with small and mid-sized sustainable and organic farmers and on-farm food processors who conduct activities potentially within the scope of FDA's proposed rules on Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food (preventive controls), and Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption (produce standards).

[164] Agriculture and Land-Based Training Association - Salinas, CA; Alternative Energy Resources Organization - Helena, MT; California Certified Organic Farmers - Santa Cruz, CA; California FarmLink - Santa Cruz, CA; C.A.S.A. del Llano (Communities Assuring a Sustainable Agriculture) - Hereford, TX; Center for Rural Affairs - Lyons, NE; Clagett Farm/Chesapeake Bay Foundation - Upper Marlboro, MD; Community Alliance with Family Farmers - Davis, CA; Dakota Rural Action - Brookings, SD; Delta Land and Community, Inc. - Almyra, AR; Ecological Farming Association - Soquel, CA; Farmer-Veteran Coalition - Davis, CA; Fay-Penn Economic Development Council - Lemont Furnace, PA; Flats Mentor Farm - Lancaster, MA; Florida Organic Growers - Gainesville, FL; GrassWorks - New Holstein, WI; Hmong National Development, Inc. – St. Paul, MN and Washington, DC; Illinois Stewardship Alliance - Springfield, IL; Institute for Agriculture and Trade Policy - Minneapolis, MN; Iowa Natural Heritage Foundation - Des Moines, IA; Izaak Walton League of America - St. Paul, MN/Gaithersburg, MD; Kansas Rural Center - Whiting, KS; The Kerr Center for Sustainable Agriculture - Poteau, OK; Land Stewardship Project - Minneapolis, MN; Michael Fields Agricultural Institute - East Troy, WI; Michigan Food & Farming Systems (MIFFS) - East Lansing, MI; Michigan Organic Food and Farm Alliance - Lansing, MI; Midwest Organic and Sustainable Education Service - Spring Valley, WI; National Catholic Rural Life Conference - Des Moines, IA; The National Center for Appropriate Technology - Butte, MT; Nebraska Sustainable Agriculture Society - Ceresco, NE; Northeast Organic Dairy Producers Alliance - Deerfield, MA; Northern Plains Sustainable Agriculture Society - LaMoure, ND; Northwest Center for Alternatives to Pesticides - Eugene, OR; Ohio Ecological Food & Farm Association - Columbus, OH; Organic Farming Research Foundation - Santa Cruz, CA; Rural Advancement Foundation International – USA - Pittsboro, NC; Union of Concerned Scientists Food and Environment Program - Cambridge, MA; Virginia Association for Biological Farming - Lexington, VA; Wild Farm Alliance -Watsonville, CA.

Given the potential devastating economic impact of ill-devised food safety regulations on small and mid-sized farmers and food processors, NSAC engaged heavily in the legislative process that resulted in the enactment of FSMA. We engaged in this process with four guiding principles in mind:

5. Everyone has a role in ensuring a safe food supply: From the farmers and field workers to the end consumer, everyone in the food supply chain has a role in ensuring safe food.

6. Focus on the highest risk: Different production systems and supply chains pose inherently different risks to the safety of our food supply. There are limited government resources, and they must be focused on addressing the highest risks.

7. Regulations should be science-based where possible: The emotional reaction to food safety outbreaks has, at times, resulted in the knee-jerk imposition of practices that have little basis in sound scientific evidence. Overall, the totality of the science behind the role of farm practices in food safety outbreaks is grossly under-examined and requires much more investigation.

8. One size does not fit all: Regulations must be scale-appropriate to be effective; a one-size-fits-all approach will put small and mid-sized farms and processors out of business and undermine other public health goals, such as increased production, availability, and access to healthy foods.

The implementation of these principles throughout the legislative debates around FSMA led to the inclusion of a number of important provisions, including FSMA Section 103(c)(1)(C), the provision that requires FDA to prepare the Draft RA. This section, also known as the "Sanders amendment," introduced an important directive to FDA for further analysis about the varying risks of different processing activities. Certain processing activities, including ones conducted on-farm to add value to agricultural products, are inherently low risk. These low-risk activities should not be covered by the same regulatory regime to which higher-risk processing activities are subject. This focus on regulation of higher-risk activities minimizes the regulatory burden for operations conducting low-risk activities and allows limited government resources to be focused on higher-risk situations.

Through this Draft RA, FDA has started to examine the question of varying degrees of risk posed by activities conducted on farms. This is an important step in devising and implementing an effective food safety regime that does not limit and do great harm to entire sectors of the agricultural economy. In conducting this Draft RA, the FDA has significantly improved upon initial rules promulgated in 2004 as part of the implementation of the Bioterrorism Act of 2002. We applaud the agency for that progress. It is a good first step, but there is still a very long way to go, and we look forward to working with the agency to improve the quality and accuracy of the Draft RA in its next iteration.

We provide our comments on the Draft RA below. Our comments first address the severe data, background study, and expert advice limitations in the Draft RA. Those comments are followed by comments on the farm definition, comments on the specific activity/food combinations identified as low risk, comments on two issues outside the scope of the Draft RA, and finally comments on the need for a second, revised Draft RA for additional public comment.

Sincerely,

Roland McReynolds, Executive Director
Carolina Farm Stewardship Association

Ariane Lotti, Assistant Policy Director
National Sustainable Agriculture Coalition

Ferd Hoefner, Policy Director
National Sustainable Agriculture Coalition

Brian Snyder, Executive Director
Pennsylvania Association for Sustainable Agriculture

COMMENTS ON THE DRAFT RA

I. Comments on the Data Used by FDA for the Draft RA

A. Concerns about Data Limitations

FDA has asked for comment on how to improve the data employed in the Draft RA. We concur with FDA's assessment that there are many severe limitations to the data used in the Draft RA. We also agree with FDA's assertion that there are limited or no data on food contamination or serious health consequences from hazards associated with manufacturing, processing, packing, or holding activities by small and very small farm mixed-type facilities.

In view of this lack of data, it is accurate to say the Draft RA is not data-driven but is, rather, based on professional judgment at best. In light of the lack of data, we urge FDA to view this risk assessment as an initial assessment of low risk activity/food combinations with potentially significant omissions.

- *Recommendation:* Given the significant data limitations, FDA should proceed with caution in regulating on-farm processing activities, and should make a strong presumption against regulating unless a clear, overwhelming case is otherwise made.

- *Recommendation:* Given the significant data limitations, FDA should direct funding and enforcement resources to the areas of greatest evidence-based need.

- *Recommendation:* Given the significant data limitations, FDA should allow for updates to the list of low risk activity/food combinations as new data become available, and should regularly update the list, after public notice and comment, with new information.

- *Recommendation:* FDA should take steps to ensure that the data needed are collected, and should dedicate resources and enter into cooperative agreements with agencies and organizations

able to collect, analyze, and interpret data relating to the risk of activities conducted by facilities co-located on farms and facilities that aggregate product for local and regional food markets.

B. Concerns about Reliance on a Flawed Food Sector Processing Study

The determinations of the Draft RA rely in part on the grossly inadequate Food Processing Sector Study on domestic establishments co-located on farms (the Muth study) included as Reference 32 of the preventive controls rule.

The Muth study is not an adequate, realistic assessment of its ostensible subject for two reasons. First, it relies on a commercial data source that uses 4-digit Standard Industrial Classification (SIC) codes that are severely limited in scope. The SIC codes are incomplete with respect to the businesses captured and do not capture data on farms effectively. Second, the Muth study findings are principally based on the personal opinions of a focus group purported to be an oracle on a subject that, the study finds on its own terms, is neither well documented nor understood.

A valid and useful food processing sector study on domestic establishments co-located on farms, particularly with respect to the Draft RA's charge of identifying activity/food combinations conducted on farm mixed-type facilities, should be based on large-scale surveys of actual farm mixed-type facilities, rather than undocumented opinion.

Congress intended for the food processing sector study to be completed just a few months after passage of FSMA, and well before the publication of proposed rules, so that the public could review and respond to it. FDA's failure to honor that intent severely compromises the agency's ability to abide by the even more significant Congressional intent to limit the impact of FSMA on small business.

- *Recommendation:* FDA should not base its determinations in the Draft RA on the Muth Food Processing Sector Study conducted as part of the preventive controls rule. The study contains serious flaws and should not serve as the data source for assumptions and conclusions made in the Draft RA. Instead, FDA should conduct – or should enter into cooperative agreements with agencies, organizations, and/or groups able to conduct – large-scale surveys of actual farm mixed-type facilities and the activities they conduct.

C. Limited Scope of Expert Opinions

i. Limited Geographical Scope of Expert Opinions

FDA's solicitation of expert opinions to identify potential activity/food combinations conducted by farm mixed-type facilities that are within the scope of the RA was geographically limited. In particular, investigators did not solicit input from farmers and other experts in the American Southeast or Midwest. This resulted in selection bias against food/activity combinations uniquely relevant to climate, soil, and cultural/market conditions of farm mixed-type facilities in the Southeast and Midwest.

- *Recommendation:* FDA should ensure that the final RA reflects sufficient geographic diversity by consulting with subject-matter experts – including farmers, organizations that have farm

mixed-type facility operators within their memberships, and on-farm processors that operate facilities co-located on farms – in the Southeast and Midwest.

ii. Limited Professional Scope of Expert Opinions

The investigators limited their solicitation of expert opinions solely to government agencies. They failed to reach out to actual representative businesses or organizations representing farm mixed-type facility operators. The result is the creation of significant blind spots with respect to the actual, on-the-ground activities taking place on farm mixed-type facilities. It is difficult to imagine that FDA would accept a report on processing activities taking place at large or very large businesses that did not include the input of representative businesses and trade associations. This investigation should have consulted with small and mid-sized farm owners and their organizational representatives.

To illustrate the type of information that FDA might gain by doing outreach to industry participants or organizations representing farm mixed-type facilities, we point to a survey conducted by the North Carolina Farm Bureau. That organization conducted a series of small farmer listening sessions for produce growers, held at 13 locations throughout the state in February and March, 2010, to discuss food safety issues. North Carolina is a state widely recognized for its vibrant culture of local food and food entrepreneurship. One-hundred-and-ninety farm operators completed a survey at those forums, and 85 percent of the farms represented had fewer than 40 acres in produce cultivation. Thirty-one percent of respondents performed low-risk on-farm food processing, with products including breads and cakes, shucked corn, shelled beans, dehydrated fruits and vegetables, fruit jams and jellies, molasses, vinegars, honey, sorghum syrup, maple syrup, and apple butter. This type of survey could provide insight into the activities that might be conducted by farm mixed-type facilities on foods.

The failure to undertake this outreach is of particular concern because the Draft RA is a significant step in the development of regulations. Simple good governance requires a more accurate assessment of activities that could be subject to regulatory compliance and enforcement.

- *Recommendation:* FDA should improve its approach used in the Draft RA by soliciting input from farmers, industry participants, associations, and organizations representing farm mixed-type facilities.

- *Recommendation*: Given the significant data limitations, the reliance on a flawed Food Processing Sector Study, and the limited scope of expert and professional opinion, FDA should conduct another Draft RA for public comment before finalizing the preventive controls rule.

II. Comments on the Approach Used by FDA in the Draft RA

FDA has requested comments on the approach used in the Draft RA. We believe the Draft RA reflects some significant progress with respect to normal farming activities. In particular, we believe it is reasonable and very important to exclude activity/food combinations that are always within the definition of 'farm,' as that definition is revised in FDA's proposed preventive controls and produce rules. Those revisions will merit further detailed discussion in the comments on the full rules themselves. But, for purposes of this RA, those revisions ensure that Sections 418 and 419 are practical and reasonable to implement, because they recognize that certain activities that have always

been part of harvesting and packing of a farm's own products are not, in fact, processing activities. The proposed Sections 418 and 419 acknowledge that:

- 'Harvesting' includes "Gathering, washing, trimming of outer leaves of, removing stems and husks from, sifting, filtering, threshing, shelling, and cooling" a farm's own raw agricultural commodities;

- 'Packing' includes placing a farm's own raw agricultural commodities in containers that directly contact the food and that the consumer receives; and

- 'Holding' a farm's own raw agricultural commodities includes activities traditionally performed by farms for the safe and effective storage of those commodities.

The rules promulgated in 2004 for the Bioterrorism Act of 2002 inappropriately included these traditional harvesting, packing, and holding activities on farms within its list of 'processing' activities that trigger facility registration. In so doing, those rules created an unreasonable burden on farms, and, indeed, an impossible burden on regulators, given the number of farms in the nation that could be subject to registration under said rules. The Bioterrorism Act rules imposed those burdens without identifying commensurate public health benefits. In implementing FSMA, FDA has a critical opportunity to redress this marked contradiction in previous rulemaking.

- ***Recommendation:*** FDA should continue to exclude activity/food combinations that are always within the revised definition of 'farm' in the proposed produce and preventive controls rules from the requirements of Section 103 of FSMA. Additionally, we believe that FDA should also revise the Bioterrorism Act regulations concerning registration of food facilities to reflect the updated 'farm' definition.

III. Comments on Activity/Food Combinations Identified as Low Risk

This section provides our comments in response to FDA's answer to Question #9 of the Draft RA that asks which activity/food combinations are "low risk."

A. Overall Comments on the Activity/Food Combinations Identified as Low Risk

The list of low-risk activity/food combinations that FDA has identified in the Draft RA is a solid starting point. FDA's characterization in the Draft RA that certain food/activity combinations listed are low risk and, therefore, should trigger exemption from the preventive controls rules when they take place on farm mixed-type facilities, is correct. We agree that these listed food activity/ combinations are within the scope of the RA and do not present significant threats to public health.

The fact that none of the peer reviewers of the Draft RA disputed the low-risk characterization of any of the food/activity combinations listed by FDA is strong evidence supporting those characterizations. One reviewer questioned whether FDA included a broad enough selection of potential pathogens in setting the parameters for low-risk food/activity combinations. FDA noted in response that any analysis of other potential pathogens would not have impacted the RA results. Another reviewer discussed the potential classification of certain activities that are within the 'farm' definition as provided in Sections 418 and 419. FDA noted that these activities were not within the

scope of the RA, which did not address activities within the farm definition. In neither case did the reviewer specifically call into question the low-risk classification of any food/activity combination that was within the scope of the RA.

The underlying rationales for the classification of these activities as low-risk are sound. As FDA acknowledges in the Draft RA, many activity/food combinations impose inherent controls on pathogen growth as a function of the interaction of the processing activity and the food item itself. Excluding such combinations from regulation under the preventive controls rule is the commonsense outcome intended by the plain language of FSMA.

- *Recommendation:* FDA should retain all activities/food combinations identified in the current Draft RA as being low-risk activities/food combinations.

B. Comments on Clarifying Certain Low-Risk Processing Definitions

To ensure clarity and transparency for producers and efficiency for regulators, FDA should define in more detail certain activities included in the definitions of low-risk activity/food combinations. Failure to provide clarity for producers and inspectors alike will result in enforcement of perceived preventive controls requirements that are not intended in FSMA or its implementing regulations.

Examples of needed clarifications include:

i. 'Making'

FDA needs to provide more detail about what steps are included in 'making' hard candy, fudge, taffy, toffee; cocoa products from roasted cocoa beans; honey; jams, jellies and preserves from acid foods (e.g., acid fruits); maple syrup; soft drinks and carbonated water; and sugar from sugarcane and sugar beets. The agency deems all of those 'making' processes as low risk with respect to those foods. It also identifies specific elements of the manufacturing process for those products as activities separately deemed low-risk for some of those foods, but not for others.

- *Recommendation:* FDA should review its definition of 'making' with respect to all of the low-risk activity/food combinations where it appears, and spell out, in detail, the specific activities included in the term 'making.'

For example, boiling/evaporating is part of the process of making sugar from sugarcane or beets and maple syrup from maple sap; such boiling/evaporating is separately identified as a low-risk activity with respect to maple syrup, but it is not separately identified as a low-risk process for making sugar out of sugarcane or beets.

- *Recommendation:* FDA should clarify that it considers making sugarcane to include boiling/evaporation, or it should separately identify boiling/evaporation as a low-risk activity with respect to sugarcane and sugar beets.

For another example, honey- and maple syrup-makers usually filter those products prior to packaging. The absence of filtration of honey and maple syrup among the low-risk food/activity combinations suggests that FDA considers filtration part of 'making' honey and maple syrup. But

the listing of 'filtration' in Table 17 as a low-risk activity with respect to honey and maple syrup is inconsistent with such implied incorporation of 'filtration' into 'making.'

- *Recommendation:* FDA should remedy this confusion by detailing the activities that are part of 'making' these products, or by including filtration of these products in the list of low-risk activity/food combinations.

For another example, honey must be extracted from combs. Extraction of honey is listed in Table 17 as a low-risk activity with respect to honey, but is not listed in FDA's list of low-risk activity/food combinations, creating an implication that FDA views extraction of honey as part and parcel of 'making' it.

- *Recommendation:* FDA should include extraction of honey in its list of low-risk activity/food combinations.

ii. 'Chopping' and 'grinding/milling/cracking/crushing' with respect to peanuts and tree nuts

To ensure producers know exactly what FDA means when it says these are low-risk activity/food combinations, FDA should detail the nut products that it expects to result from those combinations.

- *Recommendation:* FDA should detail the nut products that result from the 'chopping' and 'grinding/milling/cracking/crushing' and peanuts and trees nuts low-risk activity/food combinations.

iii. 'Grinding/milling/cracking/crushing' with respect to grains and grain products

Grinding/milling/cracking/crushing of grains and grain products are listed in Table 17 as low-risk activity/food combinations, but only grinding/milling/cracking/crushing of grains are included in FDA's list of low-risk activity/food combinations. Additionally, only one of the many possible milled grain products (cornmeal) is specifically mentioned in FDA's list of low-risk activity/food combinations.

- *Recommendation:* FDA should provide a larger list of examples of milled grain/grain products that qualify as low risk, including wheat, oats, barley, rice, etc. That list should also specifically include sprouted grain products.

iv. 'Mixing'

To prevent confusion about the low-risk status of 'mixing' when applied to intact fruits and vegetables, grain and grain products, peanuts, tree nuts, honey, maple sap and maple syrup, coffee beans, and cocoa beans, FDA should give examples of 'mixed' products. Examples include tree nuts and dehydrated fruits combined into a trail mix, and intact leaves of a variety of lettuces combined into a salad mix.

- ***Recommendation:*** FDA should give examples of 'mixed' products, including tree nuts and dehydrated fruits combined into a trail mix, and intact leaves of a variety of lettuces combined into a salad mix.

v. 'Trimming'

'Trimming' is frequently included in the Draft RA along with cutting/coring/chopping/shredding/slicing/peeling as an intervention likely to introduce pathogens to fruits and vegetables. However, FDA recognizes that trimming the outer leaves of an intact fruit or vegetable is part of harvesting activities on farms or farm mixed-type facilities when applied to a farm's own raw agricultural commodities (RACs). Because farm mixed-type facilities may come under FDA inspection for other processing activities, it is vital that inspectors understand that the trimming of outer leaves of RACs to ensure their marketability, along with other harvesting activities, are not processing activities covered by the preventive controls rule. This may require commodity-specific guidance for inspectors, given that harvesting and trimming activities on a farm's own RACs may look different from commodity to commodity. FDA should consult with farm mixed-type facility farmers, including small and very small farmers and facility operators, in developing such guidance.

- ***Recommendation:*** FDA should clarify in the Draft RA that 'trimming of outer leaves' of RACs is not a processing activity, and should provide further commodity-specific guidance on this issue for inspectors based on input from farm mixed-type facility farmers, including small and very small farmers and facility operators.

There are no doubt additional clarifications that FDA could make to the list of low-risk activity/food combinations in order to provide more clarity for farmers, facility operators, and inspectors.

- ***Recommendation:*** FDA should provide additional clarifications to the list of low-risk activity/food combinations. In doing so, FDA should seek input from farmers operating mixed-type facilities, including small and very small farmers and facility operators.

C. Additions to the List of Low-Risk Activity/Food Combinations

There are several categories of food/activity combinations that were not designated as low-risk in the Draft RA but do pose only low risks. FDA overlooked them chiefly because of the limited scope of the inquiry into processing activities that take place on small farm mixed-type facilities. Below we provide examples of food/activity combinations that are low risk under the terms of the Draft RA. We stress that this is not an exhaustive list.

- ***Recommendation:*** FDA should include the following low-risk activity/food combinations in its list of low-risk activity/food combinations:

    - Making syrups from sorghum, rice, malted barley, etc. Sorghum is commonly grown in the Southeast and Midwest for the production of sorghum syrup. The manufacturing process is substantially the same as sugar from sugarcane.

- Making molasses from sugarcane and sugar beets.

- Making vinegar, including infused and flavored vinegars.

- Extracting virgin olive oil.

- Extracting oils from seeds (e.g., sunflower seeds, flax seeds, etc.).

- Roasting grains for animal feed. FDA excludes animal feed from the scope of the Draft RA, even though animal feed is 'food' within the meaning of the Federal Food, Drug, and Cosmetic Act (FFDCA). Small farm mixed-type facilities, particularly those focused on raising livestock or livestock feed, may roast (or extrude) grains for animal feed. By the definition of a SAHCOD, such roasting in many cases is not an intervention that could introduce or prevent/minimize a hazard for which there is a reasonable probability that use of, or exposure to, the food will cause serious adverse health consequences or death to humans because the food is not consumed by humans. FDA should review all animal feed production activities that take place on small farm mixed-type facilities for inclusion in the list of low-risk food/activity combinations in light of the fact that such activities are not be SAHCODs.

- Some baking activities involving grain products. Many foods that are baked do, in fact, encompass "inherent controls for food-borne pathogens" in the process of arriving at the final product. For example, making some cookies with grain products requires the dough to set, which means that the flour/liquid combination has reached 195 F, well above what is needed to control pathogens.

- Low-acid fruits and vegetables manufactured in compliance with existing Good Manufacturing Practices (GMPs) under the FFDCA. It is true that acidifying, pickling, and fermenting low-acid foods are activities that significantly minimize or prevent pathogen contamination but, if poorly executed, could instead enhance pathogen growth and so present a SAHCOD. However, the FFDCA has long recognized this potential risk, and has implemented regulations governing such food/activity combinations. Therefore, to the extent a small farm mixed-type facility (or other small business) is producing acidified, pickled, or fermented low-acid fruits and vegetables in compliance with the existing status of FDA GMPs in place at the time of publication of the proposed preventive controls rule, such activity should be deemed low-risk.

IV. Comments on the Scope of the Food Types and Activity/Food Combinations Outside the Scope of the Draft RA

FDA is seeking comment on the food types and activity/food combinations considered to be outside of the scope of the Draft RA, and those FDA considers to be within the scope of the Draft RA. We provide two brief comments on this topic below.

A. Comment on Limiting the Scope to Very Small and Small Businesses Co-Located on Farms

We are acutely aware that FSMA limits the application of this risk assessment, and its removal of particular crop and activity combinations from regulation when conducted by small and very small entities. NSAC's proposal that became the basis for this provision of law did not limit its application to small and very small entities. We very reluctantly agreed to that limitation during negotiations in which the agency and several consumer interest groups weighed in heavily to add the restriction, and we did so in order to save the basic proposition as part of the final bill.

While we realize that in implementing the law, FDA must adhere to the statutory criteria, we nonetheless are compelled to point out that being forced to regulate crop-activity combinations which the Draft RA rightly points out as having little risk is incredible regulatory overreach, a waste of scarce federal resources, and comes at a real cost to the economy. Larger farms that engage in these low-risk activity/food combinations will be forced to comply with regulations that, according to the Draft RA, will have no real benefit. We believe this is foolish, and would urge FDA to urge Congress to correct this situation. Absent a specific science-based finding that the risk of specific crop-activity combinations changes based on farm size or mixed-facility scale, there is every reason for the farm sector to oppose the regulatory overreach and for taxpayer groups to oppose the waste of resources said regulations entail.

- *Recommendation:* FDA should urge Congress to correct the regulatory overreach implied by covering mid-sized and large farm mixed-type facilities that conduct activities/food combinations identified as low risk in the Draft RA. FDA should urge Congress not to specify a scale of coverage if an activity/food combination has been identified as low risk.

B. Comment on Exclusion of Animal Food and Feed

We realize that the current proposed preventive controls rule focuses on food for human consumption, and acknowledge that FDA plans to release a proposed preventive controls rule on food for animal consumption.

- *Recommendation:* In determining the scope and coverage of the preventive controls rule for animal food and feed, FDA should conduct a parallel Draft RA that identifies the low-risk activities and food combinations that would be exempt from the animal food preventive controls rule.

V. Comments on Releasing a Revised Draft RA for Comment before Finalizing the Preventive Controls Rule

Prior to issuing its final regulations on preventive controls – including the determinations on the exemption or modification of preventive controls with respect to processing activities conducted on farm mixed-type facilities – FDA should conduct further study to address the comments discussed throughout this document. It is FDA's responsibility under FSMA, and specifically the Sanders amendment, to conduct further research in consultation with farmers, organizations that have farm mixed-type facility operators within their memberships, and on-farm processors that operate facilities co-located on farms to more completely identify the full range of low-risk food/activity combinations currently taking place on farm mixed-type facilities that should be excluded from the preventive controls rule.

- *Recommendation:* Given the Draft RA's limitations, FDA should revise the Draft RA and release another Draft RA for comment before FDA finalizes the preventive controls rule. In revising the Draft RA, FDA should consult with farmers, organizations that have farm mixed-type facility operators within their memberships, and on-farm processors that operate facilities co-located on farms or in the local area.

- *Recommendation:* In addition to issuing a revised Draft RA, FDA should establish a process by which it regularly reviews the scope of data and input used to justify the assumptions in the Draft RA and used to make its low-risk activity/food combination determinations. The process should also establish mechanisms for regularly updating the list and supporting analyses in order to incorporate new data and information.

XII. APPENDIX II – FDA FARM INSPECTION STORIES

Following is a series of stories submitted by three different food producers regarding FDA inspections on their farms. The three represent very different kinds of operations, are located in three different states, and represent 108 years of total farming experience. Some of the stories are very recent, with some reflecting experiences over a few years. As far as we know, none of these reported inspections were in response to some kind of outbreak or report of people being sick. Some significant details have been redacted in order to protect their identities; farmers are often very reluctant to file complaints about inspectors, and will sometimes help to cover up inspector mistakes in order to avoid possible retribution. In general, these and other stories heard over the years from other producers suggest some common themes when it comes to FDA inspections on farms, as follows:

- Inspectors are usually courteous, though almost always find a way to slip in mention of the dire consequences they could choose to make happen.
- Inspectors seem quite often to have little or no experience with the type of operations they are inspecting, and sometimes don't even know what they're supposed to be looking for, or why they're even there.
- Inspectors seem uninformed of basic facts involving the diseases they are working to prevent, or even what other inspection protocols might require (as with the NOP).
- Supervisors of inspectors sometimes seem uniformed and confused as well, which raises questions as to how inspections are prioritized and assigned in the first place.
- Inspectors seem to enjoy their trips into the countryside, and may prolong inspections – for days even – in order perhaps to avoid some other assignment. They seem to enjoy talking to these types of farmers and will sometimes take undue advantage of the situation for that reason.
- Farmers are seeking a more cooperative relationship with their inspectors so that the process of inspection can be more constructive for both parties, and the safety of the food they produce can be improved over time.

1. Producer A

The subject farm grows in less than an acre of greenhouses and washes (only) produce in a small packing shed, employs fewer than ten full-time people and grosses less than $1 million yearly. He has farmed for 33 years, and is a certified organic producer:

Following some different inspection experiences at my farm in recent years:

- FDA Inspector spends two days inspecting greenhouse and packing shed to processed food standards. Admits to not having ever inspected or been trained to inspect a farm or packing shed.
- FDA Inspector trained only in manufacturing takes a quick tour, surmises the situation is simple and without problems then proceeds to describe personal gambling exploits, and an inspection in which he shut down an operation that cost the producer "at least a million dollars."
- FDA Inspector during the course of inspection asks for numerous documents to include in her report. Inspected farmer asks in return for a list of those documents and time to consult

with an attorney to verify the legality of the request. Inspector produces the list, then calls supervisor and asks for the list back.

- State Inspector on contract to the FDA appears with one page form, fills it out, and then spends two hours discussing his sideline business.
- FDA Inspector has only worked in the medical branch previously, never inspected a farm, insists that the greenhouse is a food processing facility. After an hour of discussion decides that maybe a greenhouse is a covered farm. At the end of the first day of inspection, inspector informs the inspected "I could close the inspection now, but I really like getting out of the office, so I'll be back tomorrow."
- FDA Inspector close to retirement has never inspected a farm previously. After one-hour discussion, and a call to supervisor, determines what exactly it is the inspected farm is producing which is different from the FDA database. All previous inspectors failed to determine this. Warns the inspected farmer that the new generation of inspectors is going to be much tougher than he is, and the farmer better beware.

Every inspector made it clear that they had the authority to "shut you down." No inspector has ever noted a reason to suspect adulteration. All inspectors were courteous.

2. Producer B

We are a family farm of 95 acres. For forty-one years we have been growing many varieties of vegetables organically (certified since 1987) on about 30 acres, and direct-marketing at farmers markets in the city.

Our last inspection was on a Tuesday, normally a very busy day for us since we send a truck to market at noon. I also had a visitor to interview me for a media project, so I was sitting down talking with him. It was late morning. I heard over our walkie-talkie that there was a visitor from FDA. Not finding me when he walked up, he happened to bump into my wife. He showed his badge and said that he needed to get some information about us. He asked to see our packing shed and fields, and gave her a list of other things he would need to have, such as our "water test results," our sales figures for the year, and a couple of other things. She wanted to be polite so she took him for a tour of the field and packing shed (20 or 30 minutes), while I was tied up with my other interview. Also while I was not present he found my field manager and asked him many questions about our spraying and pesticide usage.

As soon as I heard there was an FDA guy here I quickly finished my interview and went out to find him. When we met he showed me his badge (looked like a police thing) and gave me his card, which placed him with the FDA office seventy miles away. I was surprised to have this guy come from the federal government to my small farm and felt kind of nervous and unprepared. I said two or three times that I wished he had let us know he was coming so that I could have had the appropriate people here to answer his questions. (We do have a person on staff who is our "food safety person" but she was at a dentist appointment.) Our visitor made clear that this was an unannounced visit and that <u>it was NOT an official inspection</u>, but that if it had been it would still have been unannounced. I made the point that we were very busy and that the person who could best answer his questions was not here. He clearly expected me to show him some things and spend some time talking, even though I was constantly interrupted by my crew asking questions on the radio, etc.

So I took him in to show our well water test, which we happened to have, since we do the test annually to satisfy our H2A worker inspector (State Dept. of Labor). He looked at it quickly and then told me all kinds of things about what we are required to do, such as sanitizing our containers, sterilizing our washing equipment, testing our creek water (which we have never done), and especially, registering with the FDA, which we had not done and which the internet FDA information site says we do NOT have to do, as a farm. He asked if we irrigate from the creek (we do), if we spread manure (we do, within the NOP rules), if we have animals in our vegetable fields (of course we do, despite our constant efforts to keep them out), and several other things I can't remember. He mentioned seeing some things in our coolers that we don't grow (they are no longer there – we removed them that day). He stated clearly that he had determined that we are NOT a "processor." He mentioned that there would be new rules coming out soon that would affect us and that we needed to know that we are under his jurisdiction, and that if they did ever inspect us we would pay $225 per hour for any re-inspection that might be necessary. He had the impression that we were already registered with his office, which I denied. (We are not.)

The whole experience took about an hour of my time and maybe 30 or 40 other minutes with my wife and my field manager. It was intimidating, a big surprise, not pleasant at all. I asked him repeatedly how he had found us and why he had come seventy miles to us. He never answered the question.

3. Producer C

I farm on 165 acres (two locations), and have farmed for 34 years, organic from the beginning (certified in 1986). We are a completely diversified farm, selling grassfed beef, chickens and turkeys (processed on the farm), eggs, mixed poultry feed, edible soybeans, heirloom grains, honey, and other products. Recently I received an unannounced FDA inspection. It was conducted by a state agency inspector under FDA contract. He carried an FDA "identification" ID. I was not at the farm, so he contacted me on my cell phone.

He said he was here to conduct a "BSE" inspection. I said, "What!" He then tried to pronounce bovine spongiform encephalopathy, and I said, you mean Mad Cow Disease? He said yes. He wanted to inspect our feed. I explained that we are graziers – totally grass based – and did not feed a mixed ration to our bovines, only hay, baleage, and pasture along with free-choice minerals. He did not want to inspect forages or pastures. He said, "You produce feed here?" I said yes, we produce poultry feed, but we do not feed any to our bovines. He said he was going to have to sample our feed. I said it was certified organic and that we are prohibited from mixing animal parts into our feed, but we did add fishmeal. He said he was sampling for prohibited substances. I asked what those were, and he said he did not know, he was just working for FDA. Samples would be sent to a lab for analysis.

He spent about three hours on the farm with one of my employees and sampled our poultry feed and our minerals to complete a BSE/Mad Cow inspection. He also wanted to sample a bag of feather meal, which is only used as a soil nutrient and not for feed, and my employee refused to open the bag. He told the inspector that he could buy the bag and sample it, but we could not sell it to a customer if the bag were opened. The inspector backed off.

He then called me back to give me an "FDA interview" that took about 20 minutes on the phone.

It was about my feed and included questions about what was the total level of my sales per year, how much was out of state sales, how much was wholesale, who transported the feed, did I have "clean out" certificates to ensure there were no prohibited substances left in the transport (even though he did not know what constituted a prohibited substance), who transported the grain to the farm for the feed, were the grain or the trucks from out of state, did we have a recall system, etc…

After completing the telephone interview, I called two state officials who report directly to the head of the state agency to ask what was going on. Neither one knew anything about BSE inspections being conducted nor why a poultry feed operation was being inspected. One of them was responsible for the office that conducted the inspection.

Both promised to get back to me, which they did, but they still had no explanation for what was going on other than there was a contract with the federal level to conduct inspections for FDA. I began to wonder if this was just a way to earn money to cover the salaries for their state staff, and they did not want to investigate too deeply least it be known that a BSE inspection for cattle had been performed on a farm that produced only poultry feed. I later noted in the summary inspection report I received in the mail from the FDA district office that nowhere on the report did it ever indicate that the sampled feed was only labeled for poultry feed and was never fed to bovines.

The inspector then called back a few days later and said he could not give the interview over the phone, and I had to meet him in person and do it all over again. I have two locations and asked if I could meet him at the one where I lived. He said no, it had to be on the farm where the feed was ground. We met a few days later and he asked the identical questions all over again.

He said he was permitted to report "other suspected violations" that would warrant further FDA inspections, but he found none on my farm "right now." He showed me the space on his form that showed "No Other Violations" or something like that. The clear implication was that he could bring down on me a myriad of surprise inspections if I did not cooperate with him.

He asked me if I was "registered." I said I was registered under the State feed law, and that he should know that because he works for the State and has sampled feed here before. He said no, "not that," and asked if I was registered under the "Bioterrorism Act." I was surprised that he expected a farmer to be familiar with the registration requirements of the Bio-Terrorism Act. I said I did not think I was registered.

He said, at first, that I was probably not registered. Then he said that I probably was registered. He seemed to be thinking he would have no right to be on my farm if I were not registered. He said I should read some information he left with my employee several days ago and use it to register online.

He then asked me to sign a statement that I had received reasonable notice of the inspection – it is almost verbatim Section 305 of the Bioterrorism Act. I read it and said it contained nothing but a bunch of "weasel words," but he said I had to sign it. So I did, not wanting to antagonize an inspector who informed me that he could note other possible violations that could bring additional FDA inspections. I am not sure how I could have gotten reasonable notice, especially if this was a surprise inspection and if I was not even on the farm when the inspection occurred. But I was intimidated and so I signed it. He then left me with additional information about FSMA prepared by FDA and said I should read it.